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Original Article

Self-Adherent Dressing versus No Dressing after Distal Hypospadias Repair: A Randomized Clinical Trial

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Abstract:
Background: The use or type of dressing post distal penile hypospadias (DPH) repair is not well defined. Self-adherent dressing is a cohesive elastic dressing which is applied to itself and not to skin thus possibly providing secure support with less trauma at the time of removal.
Aim of the work: To evaluate the success rate and complication rates of DPH repair when using self-adherent dressing versus no dressing.
Subjects and Methods: This prospective randomized controlled trial was conducted at Cairo University Specialized Children Hospital. Fifty-four children with fresh distal penile hypospadias or a first-time distal urethrocutaneous fistula were randomly assigned to one of two groups: Group 1 (self-adherent dressing) and Group 2 (No dressing). Patients were followed postoperatively at day 1, day 5 (at catheter and dressing removal), and 3 months. Outcomes measured included wound bleeding on day 1, penile edema on day 5, signs of infection (erythema or purulent discharge) on day 5, wound dehiscence on day 5, and urethrocutaneous fistula formation by 3 months.
Results: By postoperative day 1, no cases of significant penile bleeding or hematoma were observed in either group. By day 5, penile edema was noted in 16 (29.6%) of the cohort. The frequency of edema was significantly lower in the self-adherent dressing group (4 cases, 14.8%) compared to the no-dressing group (12 cases, 44.4%) (p = 0.040). Signs of infection by day 5 were observed in 5 patients (18.5%) overall, with no statistically significant difference between both groups (p= 0.638). In the self-adherent dressing group, 2 patients (7.4%) had mild erythema (hyperemia) and none had purulent discharge; in the no-dressing group, 1 patient (3.7%) had erythema and 2 patients (7.4%) developed purulent discharge (p=0.141). All observed infections were minor and managed conservatively. No instances of wound dehiscence were found in either group by day 5. At the 3-month follow-up, urethrocutaneous fistula had occurred in 9 patients (16.7% overall): 4 patients (14.8%) in the self-adherent dressing group and 5 patients (18.5%) in the no-dressing group (p=0.71). The overall primary success rate was 85.2% self-adherent dressing versus 81.5% with no dressing (p= 0.71).
Conclusion: using a self-adherent dressing reduced early postoperative edema by 50% compared to no dressing. There was no significant difference in infection and fistula rates. Thus, using a soft self-adherent dressing may enhance the overall comfort of the patient and the appearance of the wound without necessarily jeopardizing the healing process. Cost-effectiveness and availability remain to be studied.

Keywords: distal penile hypospadias; urethrocutaneous fistula; postoperative dressing; self-adherent dressing; no dressing
Abbreviations: DPH; distal penile hypospadias; MAGPI: meatal **a**dvancement and **g**lanuloplasty; TIP: tubularized incised plate urethroplasty

Introduction

Hypospadias is one of the most common congenital anomalies in male children, characterized by an ectopic ventral urethral meatus (often with a deficient ventral foreskin and chordee). It occurs in approximately 1 in 200–300 live male births, making it a significant pediatric urological condition (*1*). Distal hypospadias repairs typically have high success rates, but complications such as urethrocutaneous fistula can still occur in a subset of cases. One of the controversial aspects of hypospadias surgery is the use of postoperative dressings. An ideal dressing is thought to reduce edema and hematoma by providing gentle, uniform compression and to protect the wound, while being easy to apply and remove without causing trauma. In theory, dressings can

act as a "hermetic seal" to immobilize the penis and prevent bleeding. On the other hand, dressings might compromise penile circulation or harbor urine and bacteria, thereby potentially increasing infection risk, and dressing removal can be painful for the child. A survey of pediatric urologists found that many surgeons favored the use of dressings primarily to decrease edema and immobilize the penis (*2*). However, more recent studies have challenged this practice and reported no significant differences in hypospadias repair outcomes with or without dressings, concluding that routine dressings may not be necessary for all cases (*3*), and the absence of a dressing did not adversely affect the success of hypospadias repair or increase complication rates (*4*). In light of such evidence, the necessity and benefit of routine dressings after hypospadias surgery remain uncertain. Indeed, a recent literature review noted there is no clear consensus or evidence favouring any particular postoperative dressing method for hypospadias. While some surgeons have adopted a minimalist approach (omitting dressings entirely in select cases), others still prefer to use dressings but have sought to improve dressing techniques. One such innovation is the use of self-adherent dressing, a flexible cohesive dressing that sticks only to itself. Unlike traditional adherent tapes or gauze wraps, the it does not adhere to the skin or surgical site, potentially reducing the risk of shearing or trauma upon removal, and some suggested that it provides sufficient pressure to minimize edema and bleeding while avoiding circulatory compromise (*5*). Because self-adherent dressing can be easily unwrapped without pulling on the skin or sutures, it may alleviate the pain and anxiety associated with dressing changes. Despite these theoretical advantages, no prior study to date has specifically compared outcomes of hypospadias repair with self-adherent dressing versus no dressing. Given the ongoing debate and the lack of evidence, we designed a study to address this gap. We aimed to evaluate the success rate and complication rates of DPH repair when using self-adherent dressing versus no dressing.

Subjects and Methods

This study was a prospective randomized case control trial conducted at the Pediatric Urology Unit of Cairo University Specialized Pediatric Hospital, Cairo University, Egypt. The study was approved by the institutional research ethics committee, and written informed consent was obtained from the guardians of all participants. The trial was carried out between November 2022 and September 2023 (after ethical approval on 9/11/2022, MS 118-2023) and adhered to CONSORT guidelines for randomized studies.

Participants

The study included male children with DPH or distal urethrocutaneous fistula presenting for first-time repair. DPH was defined as glandular, coronal, sub-coronal, or distal shaft urethral meatal positions. Distal urethrocutaneous fistula cases were those with a single fistula opening on the distal penile shaft (typically a complication of an unrecognized minor hypospadias or iatrogenic from prior circumcision) that had not been repaired before. Inclusion criteria were: boys aged 6 months to 13 years with distal hypospadias (any subtype as above) or an isolated distal fistula, who were candidates for single-stage repair. Exclusion criteria included proximal hypospadias (midshaft, proximal penile, penoscrotal, etc.), "crippled" or multi-stage hypospadias cases (those with multiple prior failed repairs), cases requiring two-stage repair, patients with bleeding diathesis or other contraindications to standard surgery, and children outside the age range (younger than 6 months or older than 13 years were not included). These criteria ensured a relatively homogeneous patient population of distal cases and avoided confounding factors associated with proximal repairs or complex re-do surgeries.

Methods

Participants were randomly assigned into two postoperative management groups using a simple randomization (1:1 allocation ratio). Randomization was done by drawing group assignment from a sealed envelope box on the day of surgery. The two groups were defined as follows:

Group 1 – underwent a standard distal hypospadias repair followed by application of a self-adherent dressing. They all applied the Coban™ (3M, USA). The dressing protocol involved placing a layer of sterile Vaseline gauze or plain gauze soaked in antibiotic ointment (e.g., gentamicin or tetracycline ointment) directly around the penis to cover the suture line. Then, an elastic self-adherent dressing wrap was gently but snugly wrapped around the penile shaft over the gauze to cover the glans penis distally and the whole penile shaft proximally. Care was taken not to stretch the dressing excessively to avoid undue tightness. The dressing was applied just to achieve a firm support. The distal end of the dressing was pressed onto itself to self-adhere

and stay in place. This dressing was left intact for 5 days postoperatively. Being of self-adherent material, as well as the care giver was instructed to ensure all-time the dressing dryness and immobilization, all assisted the dressing not to deglove the dressing. A small-caliber silicone urethral stent (feeding tube, Viomed, China) was left in the urethra and taped to the abdomen, also to be removed on postoperative day 5. Parents were instructed to keep the area dry, avoid any stools contamination as possible (by using double diaper technique passing the child penis with dressing through a hole in the inner diaper to avoid contamination with stools which will be trapped in the inner diaper). The penis was kept straightened through aforementioned stent taping to the abdomen to eschew penile back retraction into the inner diaper. This technique was applied for both toilet-trained and non- toiled trained boys to avoid any possible, even expected, contamination. Indeed, the touted double diaper technique is our center protocol in hypospadias repair and is usually associated with better outcomes compared to single diapering. The parents were also instructed to immediately report any signs of circulatory compromise (although none were expected due to the self-limited elasticity of the dressing). After dressing removal, an antibiotic ointment was prescribed to be applied twice daily over the wound site.

Group 2 –Patients in this group underwent the same standard hypospadias repair but no formal postoperative dressing was applied. At the end of surgery, a simple gauze wrap with mild pressure was applied for approximately 4 hours to aid initial hemostasis in the recovery period, then removed. After that, the surgical site was left exposed (no dressing), with only the urethral stent in place (secured to the abdomen). The penis was kept elevated on the abdomen with the same double diaper technique. Parents were instructed on general wound care (keeping the area clean, use of antibiotic ointment on the wound site twice daily) but without any dressing or wrapping. The urethral stent remained for 5 days in this group as well.

All surgeries were performed, using standard techniques. In each case, an appropriate hypospadias repair procedure was selected based on the anatomy. The Snodgrass technique (tubularized incised plate urethroplasty, TIP) was the most commonly used: this involves a midline relaxing incision in the urethral plate and tubularization over a stent to create the neourethra, with a vascularized flap coverage (*6*). For very shallow distal defects, a meatal advancement and glanuloplasty) (MAGPI) repair was used, and with suitable anatomy underwent the Mathieu flip-flap repair (*7*). Cases of isolated distal fistula underwent excision of the fistula tract and multilayer closure (essentially similar to a small hypospadias closure) (*6*). By randomization design, each surgeon utilized the same postoperative care (self-adherent dressing or none) for the patient as assigned. Surgeons were not blinded to group assignment, as the presence or absence of a dressing was evident.

Outcome Measures and Follow-Up

Patients were admitted for day surgery or overnight stay as per standard protocol. Postoperative assessments were carried out at defined intervals:

- Immediate postoperative (Day 1): The first day after surgery, each patient was examined for penile bleeding or hematoma formation. Any evidence of bleeding through the dressing (especially for Group 1) or from the wound was noted. Hematoma was assessed by palpation of the penis for any tense swelling. Pain was managed with (dose calculated for weight) appropriate analgesics for all patients.

- Early postoperative (Day 5): On postoperative day 5, patients returned for removal of the urethral stent in both groups. In Group 1, the dressing was also removed at this visit by gently unwrapping the self-adherent dressing. The wound was inspected for edema (swelling of the penile skin), signs of infection (defined as erythema beyond the incision, purulent discharge, or abscess), and wound dehiscence (partial or complete separation of the wound edges). Any noted redness or drainage was recorded, and wound swabs were taken if infection was suspected. Parents were queried about the child's comfort and any issues with the dressing or wound care at home. After removal of dressings and stents, all patients were advised to continue applying antibiotic ointment to the penis for a few more days and to allow the site to heal open to air. The need for frequent dressings were assessed for each patient in respect to the wound status, and if needed in infected cases, dressing was performed on an outpatient basis.

- Late postoperative (3 months): Patients were evaluated at 3 months after surgery to assess the primary success outcome: urethrocutaneous fistula formation or any urethral breakdown. A fistula was diagnosed if there was any abnormal urethral leakage of urine through an opening along the repair site. We also noted any other late complications such as meatal stenosis (if the child had difficulty voiding) or penile curvature. Cosmetic outcomes (appearance of the meatus and penis) were qualitatively noted but not formally scored in this study. Three months was chosen as a follow-up point by which most fistulas would have declared themselves.

The primary endpoints of the study were the rates of urethrocutaneous fistula (failure of repair) and overall success of hypospadias repair in each group. Secondary outcomes included incidence of postoperative edema, infection, wound dehiscence, and any other complications. We also compared the groups for differences in need for urgent postoperative visits or interventions (for issues like bleeding or dressing problems).

Statistical Analysis

All data were collected in a standardized form and entered into IBM SPSS Statistics (Version 28; IBM Corp., Armonk, NY, USA). Continuous variables such as age were summarized as mean ± standard deviation (SD) and median with range. Categorical variables (e.g., presence of complication, success or failure) were summarized as frequencies and percentages. Group comparisons for continuous data (such as age) were performed using the Mann–Whitney U test (a non-parametric test appropriate due to the non-normal age distribution). Categorical outcomes were compared using the Chi-square test or Fisher's exact test when expected cell counts were <5. A p-value <0.05 was considered statistically significant for all comparisons. No interim analyses were done. The sample size (54 patients) was determined by the available cases during the study period; a post-hoc power analysis for the observed difference in edema was not performed, which we acknowledge as a limitation.

Results

A total of 54 patients were enrolled and completed the study (27 in the self-adherent dressing group, 27 in the no-dressing group). The mean ± SD age at surgery was 4.19 ± 2.38 years (median 4 years, range 9 months to 11 years), with no significant age difference between the two groups (p = 0.174). The cohort included infants, toddlers, and older children, reflecting the typical age range for hypospadias repairs at our center. Most patients were from the local region; the distribution of patient residence (Cairo 22.8%, Giza 53.2%, and other governorates) was similar in both groups, and there was no statistically significant difference in demographic factors between groups. All children in both groups had no other congenital abnormalities.

Among the 46 patients with hypospadias (excluding 8 isolated fistula cases), the location of the native meatus was glanular in 4 (7.4%), coronal in 22 (40.7%), sub-coronal in 9 (16.7%), and distal penile shaft in 11 (20.4%). In addition, 8 patients (14.8% of the total sample) presented with a distal urethrocutaneous fistula without a visible hypospadias opening (these were typically cases of previously asymptomatic distal hypospadias that likely had a very distal meatus which partially ruptured to form a fistula). There was no significant difference in the distribution of lesion types between the self-adherent dressing and no-dressing groups (p = 0.99). The two groups were thus comparable in terms of hypospadias severity.

All patients underwent single-stage surgical repair. Overall, 40 (74.1%) patients received a Snodgrass TIP urethroplasty, 3 (5.6%) had a MAGPI repair, 3 (5.6%) had a Mathieu repair, and 8 (14.8%) underwent simple fistula closure. The choice of technique depended on the anatomy as indicated; notably, all fistula-only cases were treated by fistula excision and closure, while virtually all true hypospadias cases in this series were distal enough to be amenable to TIP or another single-stage repair (6, 8). The distribution of operative techniques was similar in both groups (20 patients underwent TIP urethroplasty in self-adherent dressing group versus 20 of 27 in the no-dressing group, and one in each group underwent one of the other techniques; p= 0.88). Thus, randomization achieved well-balanced groups without bias in surgical approach.

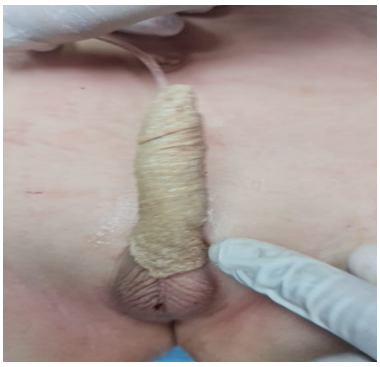

Figure 1. Self-adhesive dressing on day 1 after standard distal hypospadias repair

The same hypospadias repair technique and the same urethral stenting - after repair-Vaseline gauze was applied in 16 patients in group 1 and 14 patients in group 2, while ointment-soaked gauze was applied in 11 patients in group 1 and 13 patients in group 2 (p=0.253).

Postoperative Outcomes

All patients were followed up as planned, and no one was lost to follow-up at 3 months. The key postoperative outcomes in each group are summarized below and in Table 1.

- Bleeding and hematoma: On postoperative day 1, none of the patients in either group showed evidence of significant penile bleeding. No patient required a return to the operating room for bleeding, and there were no hematomas observed on exam. In the self-adherent group, the outer wrap showed minimal to no blood staining in all cases by the first day, indicating effective hemostasis. (Figure 1). In the no-dressing group, the immediate post-surgical compressive gauze was removed at 4 hours and there was no further bleeding noted in any patient's diaper. These findings suggest that standard surgical hemostasis was adequate in all cases, and the presence or absence of a dressing did not affect the occurrence of bleeding (both groups 0%, p= 1.0).

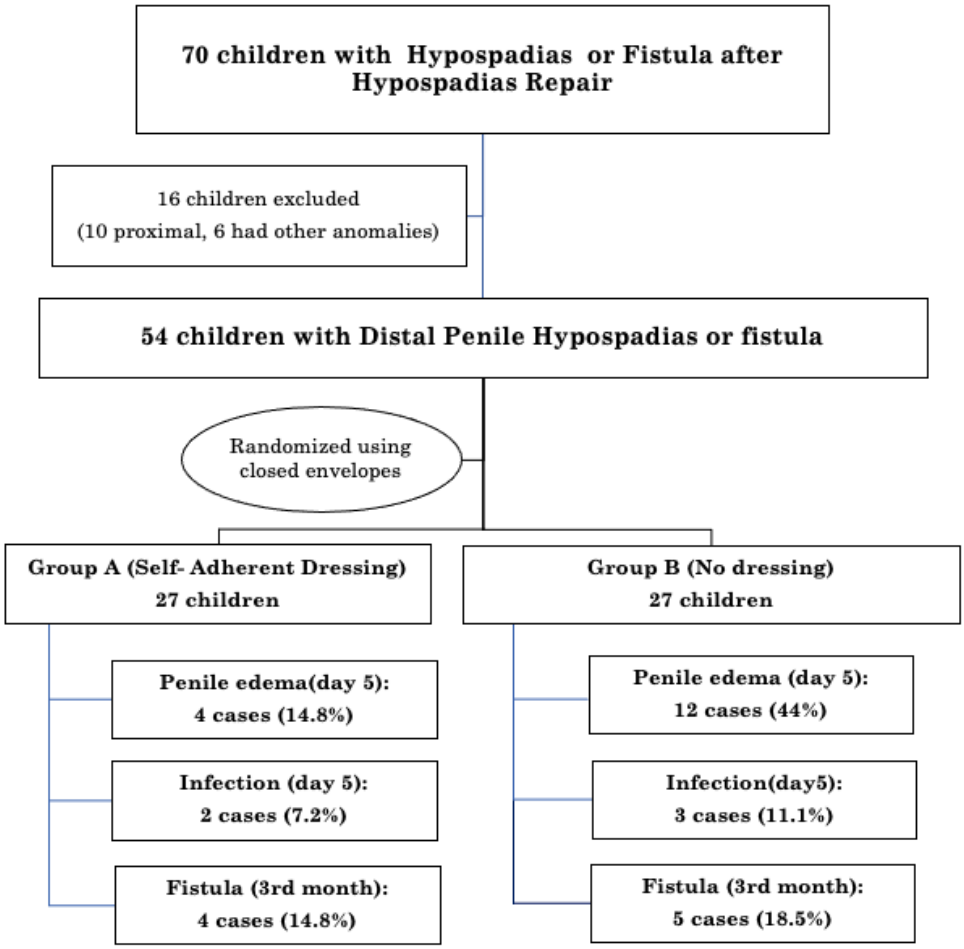

Figure 2. Consort Flow Chart of Studied Cases and Their Outcome.

- Penile Edema: By the day 5 visit (at dressing removal/stent removal), noticeable penile edema (swelling of the glans or shaft) was present in 17 patients overall (31.5%). The frequency of edema, however, differed significantly between the groups. In the self-adherent dressing group, only 4 (14.8%) out of 27 patients had appreciable edema by day 5. In contrast, in the no-dressing group, 12 (44.4%) of 27 patients developed penile edema by day 5 (p= 0.040), indicating that patients without a dressing were more than twice as likely to experience postoperative swelling as those whose penis was wrapped in self-adherent dressing. Most cases of edema were mild to moderate; the penis appeared puffy but the skin was not extremely tense. All swelling subsided in the ensuing weeks with no long-term sequelae. Nonetheless, from a clinical standpoint, reduced edema in the self-adherent dressing group made the exam and catheter removal easier and may translate to increased comfort. Figure 2 illustrates the comparative edema outcomes.
- Infection: Signs of local infection by day 5 were generally infrequent in both groups, with no statistically significant difference between them (p = 0.36). In total, 5 patients (9.3%) showed some sign suggestive of infection. In the self-adherent dressing group, 2 patients (7.4%) had mild hyperemia (redness) around the incision, while none had any purulent discharge (0%). In the no-

dressing group, 3 patients (11.1%) showed signs of infection: 1 (3.7%) with mild hyperemia and 2 (7.4%) with a small amount of purulent discharge (pus) at the incision site. Wound cultures from those with discharge grew common skin flora in one case and were sterile in another. These infections were managed with oral antibiotics and improved without further intervention, and importantly, none led to wound breakdown or fistula. The slightly higher number of infections in the no-dressing group (3 vs 2 cases) corresponded to the fact that two instances of purulent discharge occurred only in the absence of a dressing, but given the small numbers this did not reach significance. Essentially, the postoperative infection rate was low and comparable between groups. We note that the self-adherent dressing itself did not appear to predispose to infection; if anything, with fewer infections with self-adherent dressing that did not mount to statistical significance (0 pus-forming infections vs 2 in no-dressing) (p=0.141).

- Wound dehiscence: By the day 5 exam, no cases of wound dehiscence were observed in either group. All repairs appeared intact at the surface. The absence of dehiscence is consistent with the fact that any significant dehiscence in hypospadias repair usually accompanies severe infection or hematoma, which were not seen in this cohort. Thus, the use of self-adherent dressing did not result in any detectable wound edge ischemia or separation, and omission of dressing did not obviously predispose to early wound disruption in our series (both groups 0%, p= 1.0).

- Urethrocutaneous fistula formation: At the 3-month follow-up, out of 54 patients, a fistula was noted in 9 patients (16.7%). In the self-adherent dressing group, 4 patients (14.8%) developed a fistula by 3 months, whereas in the no-dressing group, 5 patients (18.5%) did so (p = 0.72), indicating that the fistula rates were similar with or without a dressing. All fistulas were small pinpoint openings along the repair; they were more frequent in those with TIP repairs (as expected, since TIP was the most common procedure) (p=0.01). None of the fistulae were large or associated with distal breakdown of the repair. There was no clear pattern suggesting that dressings (or their absence) caused these fistulae—both groups had comparable rates. The overall success rate of hypospadias closure (no fistula) was about 83% in this cohort, which is in line with general success rates for distal hypospadias primary repairs in the literature. Aside from fistulae, there were no instances of meatal stenosis, significant scarring, or other complications at 3 months in either group. The continence was not different among both groups (p=0.78).

Table 1. Postoperative outcomes of self-adherent dressing and no-dressing groups

		Self-Adherent Dressing (n = 27)		No Dressing (n = 27)		P-value †
		Mean	SD	Mean	SD	
Age in years		4.69	2.69	3.69	1.96	0.174
		Number	%	Number	%	
Continence	Continent	16	59.2	15	55.5	0.78
	incontinent	11	40.7	12	44.4	
Successful Outcome		23	85.2	22	81.5	0.71
Patients with Complications		10	37.03	17	62.9	0.056
Bleeding (Day 1)		0	0	0	0	--
Hematoma (Day 1)		0	0	0	0	--
Penile edema (Day 5)		4	14.8	12	44.4	0.040 *
Infection (Day 5)						
- Hyperemia		2	7.4	3	11.1	0.638
- Purulent discharge		0	0	2	7.4	0.141
Wound dehiscence (Day 5)		0	0	0	0	--
Fistula (3 months)		4	14.8	5	18.5	0.72

† p-value calculated using Chi-square or Fisher's exact test, as appropriate. * Indicates statistically significant difference ($p < 0.05$). 'Infection' was defined as the presence of signs of wound infection. No patient had more than one category of infection (those with purulent discharge are also included in this row based on the presence of redness). Severe infection (abscess) did not occur in any of the patients in the two groups.

- Secondary outcomes: We observed that parents of no-dressing patients tended to call the clinic slightly more often in the first few days with concerns about the exposed wound (e.g., asking if the appearance of the penis was normal without a dressing), whereas parents of self-adherent dressing patients more commonly had questions at day 5 when it was time to remove the dressing at the hospital. In terms of patient discomfort, there were no formal pain scores recorded beyond

the immediate postoperative period, but at the day 5 removal, the children in the self-adherent dressing tolerated dressing removal well, since the self-adherent dressing unwrapped easily; any mild adhesion of underlying gauze to the wound was softened with saline. In contrast, the no-dressing group did not have a removal event, but those children had been dealing with an exposed tip which sometimes caused initial discomfort with diaper contact. Overall, both strategies were well-tolerated, and all parents expressed that they would be comfortable following the same care protocol again.

Discussion

This randomized case-control trial provided evidence that both the self-adherent dressing and no dressing after DPH repair had similar short-term outcomes, but the self-adherent dressing showed an advantage in reducing early postoperative edema. In contrast, rates of infection and urethrocutaneous fistula – the most clinically significant complications– did not differ significantly between the two groups. The significantly lower edema frequency in the self-adherent dressing group (14.8% vs 44.4%) suggests that a well-applied elastic dressing can effectively mitigate postoperative swelling. Edema in the penile tissues is not merely a cosmetic concern; it can contribute to discomfort and may potentially increase tension on a healing incision. Prior studies have emphasized that excess edema and hematoma can impair wound healing by separating tissue planes, compromise perfusion, accumulate fluid in the wound (seroma/hematoma), can disturb the blood supply and inhibit proper fusion of tissue layers (*9*). Yet, the edema in our studied group was not associated with any of these complications. In practical terms, the reduced edema in the self-adherent dressing made the day 5 evaluation and catheter removal easier, and these patients possibly experienced less tenderness around the surgical site in the first few days (though pain was not formally quantified).

Notably, our trial did not find a significant difference in fistula rates between groups. This is consistent with several prior investigations that questioned the utility of dressings (*3*). Our results reinforce those findings – the key long-term outcome (fistula formation) was statistically equivalent with or without a dressing. This suggests that for distal hypospadias, the presence of a dressing is not a determining factor in whether the repair will ultimately heal successfully or break down. Surgical technique and tissue handling, along with patient factors, likely play a larger role in fistula formation than postoperative dressings.

It is worth discussing why some earlier studies actually favored no dressing (*10*). And reported observed higher complication rates (including infection and fistula) in patients who had a post-hypospadias dressing, hypothesizing that a traditional dressing could become soaked with urine and stool, creating a moist environment for bacteria and possibly impairing circulation. In our no-dressing group, we did not find a lower fistula rate than the dressing group – they were similar – but we did see that infection (particularly purulent discharge) occurred only in the no-dressing patients. We did not study the effect of personal care and diaper use on the outcome in our study, as it was beyond the scope of this study. Yet, it seems plausible that diaper use, and contamination of wound may be determining another factor irrespective of wound dressing (*4*, *5*, *9*). We did not study the long-term effects of the dressing beyond the earliest post-operative 3 months of life.

The self-adherent wrap in our protocol stayed on for 5 days, acting like a barrier. In contrast, an undressed wound was exposed to the diaper environment immediately. While no dressing means no foreign material covering the wound (and thus no risk of tape-related ischemia or bacterial colonization of dressing material), it also leaves the wound open to external soilage. We tried to mitigate that by instructing ointment application and frequent diaper changes. The net effect in our study was that infection rates were low in both groups, but it is conceivable that a properly managed dressing can reduce contamination, whereas a poorly managed one could worsen it.

The lack of objective definition and grading of edema is another confounder among studies to assess the value of dressing versus no dressing after DPH repair: (8). It seems that edema with complications as hematoma etc., the pathologic edema while the edema associated with tissue repair and sound blood perfusion is the “good” edema. None of our cases had skin blistering or ischemia in both groups. Hence, the edema might be related to other factors as rough tissue handling, surgical technique, allergy to materials used rather than the dressing or no dressing.

The self-adherent wrap did not deglove, did not adhere to tissues, did not impede blood supply and did not impede repair (*5*) while of academic interest, did not affect the short-term outcome.

Parental distress seemed less among those with dressing, yet we did not study this factor objectively as others have reported that dressing was not associated with change the level of anxiety of the parents, as the removal of the dressing posed other sorts of distress to the parents

(*11*, *12*). Hence, parental pre-operative education is necessary to relieve the child's and parent's anxiety.

The strength of this study is its prospective randomized design that does not have selection bias and confounding. Both groups were comparable in terms of patients and surgical features, thus the dressing was the only factor compared. Moreover, we used specific criteria for the outcomes and there was 100% follow-up at 3 months. Nevertheless, there are limitations. The current sample size of 54 patients is somewhat small; a bigger trial might have enabled identification of minor complications that the present study was not sufficiently powerful to detect. Furthermore, the follow-up of 3 months is fairly short; some complications for instance, urethral strictures or slight cosmetic changes may occur. One of the limitations of this study that it covered wide range of age included children who are continent and those who are still in diaper without using the same type of diapers. Another limitation is that the study was single blinded or near single blinded where the surgeons and outcome assessors were aware of group assignments, which could lead to observer bias (however, events like fistula are somewhat easy to recognize). To reduce the risk of bias, we used very specific outcomes definitions. We also had no formal scoring of the cosmetic outcome or the patient pain which might have been useful to include in future studies in order to fully compare the comfort of each approach.

From the present study, both approaches self-adherent dressing and no dressing can be considered as potential management of DPH repair. The only clear clinical benefit of the self-adherent dressing is the reduction in oedema which may result in a better immediate postoperative period. The dressing does not seem to raise the risk of infection; if anything, it may assist by keeping the area clean. On the other hand, if there are no facilities for a follow up visit or if the family is very much concerned about the management of a dressing, then not dressing the wound will simplify the care and still result in good healing. At present, the study provides evidence to support both wrapping the wound and uncovering it. The dressing is left to the personal choice of the pediatric urologist. We limited our study to distal hypospadias and distal fistula repairs. We note that these results may not be generalizable to proximal hypospadias, which is more complicated and where the role of dressings (or even extended stenting and immobilization) may differ. In proximal or more complicated cases, surgeons often apply longer duration of dressings and/or stents to avoid disrupting the repair. Investigating dressing versus no dressing in proximal hypospadias should be a separate research endeavor.

A larger multicenter cohort would establish whether our results are reproducible among more severe forms of hypospadias (proximal hypospadias repairs) and whether the role of dressings changes in this setting. Also, the use of patient pain scales and parental anxiety scales would have given a better comparison between the dressed and undressed approaches from the quality-of-life perspective.

Conclusion

This randomized case control trial provided evidence that the use of a self-adherent dressing following distal hypospadias repair was associated with lower postoperative oedema rate when compared to no dressing without affecting the healing process. The rates of infection and urethrocutaneous fistula as key indicators of surgical success were comparable between both groups. Pre-operative child and caregivers' education is necessary to explain what to expect is necessary. We suggest that postoperative care should be individualized to each child, taking into consideration the child's needs, preferences of the parent, and other factors such as resources. Comparing the effectiveness of various dressing materials (such as absorbent dressing versus non-absorbent dressing or time of dressing) may aid in enhancing the current postoperative management algorithms for pediatric hypospadias surgery.

Author Contributions

Ahmed Shoukry, Hisham Ibrahim and Mohamed Salah contributed to the study of conception and design. Material preparation, Project administration, data collection and analysis were performed by Abdallah Sadaka, Mohamed Salah and Hisham Ibrahim. The first draft of the manuscript was written by Hisham Ibrahim. All authors read and approved the final manuscript. All authors shared in the study and drafting. All authors approved the final manuscript.

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CONFLICT OF INTEREST

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

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