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ORIGINAL ARTICLE

# Biocompatible dressing for pediatric hypospadias repair

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## Abstract

**Purpose** The search for an ideal Hypospadias repair dressing continues. We aimed to develop a hypoallergenic optimized biocompatible dressing (BD).

**Method** BD with a multi-layered structure of hydrophilic treated Polypropylene with three-layered technologies; Absorbent-spunlaced hydroentangled polyester/viscose blend, outer Polypropylene, Polyester, Acrylic, and Spandex, with super Absorbent Polymer and Acrylic adhesive. Wistar rat abdominal wound model was divided into two groups: control (normal gauze dressing with adhesive) and Study (BD). The physical properties and wound characteristics were compared.

**Results** Average mass: thickness of BD was $626.7 \pm 5.6$ g $m^{-2}$: $2.6 \pm 0.015$ mm. Absorption was $1425.2 \pm 127.6\%$. Percentage desorption of solution A from dressings at 24:40 h was $1249 \pm 150\%$:$1417 \pm 230\%$. BD was hydrophilic with no particles/residue after immersion and pH neutral. The average air permeability was $11.6 \pm 1.6$ $cm^3/cm^2$/sec. The tensile force was 200N–220N with an extension on the breaking point at 24 mm. BD was superior for ease of removability on Day 6 ($p = 0.012$) and sticking quality ($p = 0.036$), absorption ($p = 0.036$), ease of removability($p = 0.036$), and sustenance ($p = 0.030$) on Day 10. BD dressing demonstrated better wound healing ($p = 0.015$) and decreased redness ($p = 0.002$) on Day 10. Histopathological healing was better with BD on Day 14($p = 0.025$) and Day 20 ($p = 0.034$).

**Conclusion** BD demonstrated better desirable physical and wound healing qualities with less inflammation compared with control normal dressing.

**Keywords** Hypospadias repair · Wound dressing · Healing · Biocompatible

## Introduction

Hypospadias repair is usually done from 6 months to 3 years before the child goes to school. A tube is placed to hold the new shape of the urethra and is removed after 7–10 days of surgery. After surgery, there is significant swelling in most cases, and proper care must be taken to prevent infection and allow the incision to heal. The application of a wound dressing or a bandage is a critical step in preventing infections and promoting rapid healing post-operatively. The design of dressing for use in hypospadias repair is challenging due to complex contours, and most dressings come out of the shaft of the penis, thus requiring additional bandages or medical tapes to hold the dressing in place. Moreover, the design of the dressing should allow the tip of the penis to be observed without removing the complete dressing. An ideal dressing should be non-sticky, hypoallergenic, absorb and retain the exudate, prevent infection, and maintain a moist healing environment. Currently, multiple dressings are being used, complicating the effective management of the patient post-operatively. Thus, there is a need for a single-piece dressing with various components designed especially for hypospadias repair, offering comfort to patients and healthcare providers and rapid incision healing. Management of pediatric

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patients post-operatively is challenging due to their inability to express the reason for discomfort.

## Purpose

The choice of wound dressings depends on the availability, climate, affordability or the personal choice/experience of the surgeon. Various types of dressings like Peha Haft®, Mepilex®, Tegaderm® and Allevyn® adhesive dressing have been used after hypospadias repair [1–4]. However, there is no dressing designed specifically for hypospadias repair in pediatric patients keeping in mind their requirements. We thus aimed to develop a hypoallergenic optimized biocompatible dressing (BD).

## Method

A biocompatible dressing (BD) was developed with multilayered structure as below.

a) *Wound contact layer* was composed of a hydrophilic treated-Polypropylene with three-layered technology (Spun-bond, Spun-bond, Spun-bond-SSS) from KTEX Nonwovens, Gujarat, India.
b) *Absorbent layer* was composed of spunlaced hydroentangled polyester/viscose blend.
c) *Outer support fabric* was composed of spandex, polypropylene, polyester, and acrylic. The acrylic adhesive used for joining all layers was ESTERBOND PS 150 from Ester Chemicals, Mumbai, and the super absorbent polymer (SAP, sodium polyacrylate) was from Acuro Organics, India.

### Fabrication of biocompatible wound dressing

#### Treatment of the absorbent layer fabric with Nano silver formulation

The commercially available aqueous Nano silver formulation (N9 Pure silver, Resil Chemicals) was applied to the non-woven absorbent layer fabric at concentrations of 50 and 100 ppm and subsequently dried.

#### Modification of SAP with glycerin

A method described by Kim et al. was used to modify SAP with glycerin [5].

#### Assembly of the absorbent layer

The SAP modified with glycerin was sandwiched between two Nano silver-treated non-woven polyester and viscose fabrics to create the absorbent layer for the wound dressing. Screen printing was used to apply acrylic-based adhesive on two Nano silver-treated fabrics. 300 mg of glycerin-modified SAP was evenly spread on the adhesive-coated side of one of the fabrics (fabric 1). The wound contact layer (Hydrophilic treated polypropylene) was pressed on the other adhesive-coated fabric using the padder at 2.5 bar pressure (fabric 2). The non-adhesive side of fabric 2 was then pressed with the modified SAP containing side of fabric 1 using the padder, and the assembly was left for 24 h and then sealed by ultrasonically welding.

#### Assembly of the composite dressing:

Screen printing (fabric of mesh count 110) was used to apply acrylic adhesive to the outer fabric. The adhesive coated outer fabric was then dried at 90 °C (air temperature). The assembled absorbent layer was applied on outer fabric by rolling with the padder at 2.5 bar pressure and a 2 m/min speed. The composite dressing was sterilized using ultraviolet radiation and packaged in a self-seal sterilization bag (Oro®, Reach Global India Pvt. Ltd.) after keeping at room temperature for 24 h.

### Characterization of the dressing material

The mass, thickness, absorbency, rate of dehydration, characteristics for dispersion, air permeability, pH, and moisture vapor transmission rate (MVTR) of the composite dressing were assessed as per corresponding standards. The samples were conditioned for 48 h at 65% relative humidity and 37 °C temperature before evaluation.

#### Dressing mass and thickness

BS EN 12127:1998 and BS EN ISO 9073-2:1997 were used to determine the mass ($g/m^2$) and thickness (mm) of the specimen [6, 7]. The thickness was measured using an ATLAS K094 digital thickness gage that runs at $1.96 \times 10^{-3}$ $N/mm^2$ of pressure.

#### Absorbency of wound dressing

BS EN 13726-1:2002 was used to evaluate the absorbency of wound dressings [8]. Dressing specimens of 5 cm × 5 cm were tested using Test Solution A (2.298 g sodium chloride and 0.368 g calcium chloride dihydrate in 1 L of deionized water).

The percent absorption was calculated using the equation $\text{Absorption}\,\% = \frac{A-B}{B} \times 100$.

Where; $B$ was specimen mass before testing and $A$ was specimen mass after testing.

#### Dehydration rate of dressing

The difference in mass between moist specimens and dry specimens was used to calculate the dehydration behavior. The specimens were conditioned for 24 h at 37 °C in an incubator before testing. The mass of specimens was determined after submerging them in an excess volume (40 times mass equivalent) of the test solution A at 37 ± 1 °C for 30 min (W). The specimens were then suspended to drain. After draining, they were weighed and kept in an incubator for 24 h and 40 h at 37 ± 1 °C (D). The dehydration was calculated according to equation $\text{Dehydration}\,\% = (W - D)/D_0 \times 100$.

where; $W$ was the wet mass of specimen and $D$ was the dry mass of specimen at 24 and 40 h, $D_0$ is the conditioned dry mass of specimen before wetting.

#### Rate of absorption

Solution A was dropped onto the specimens on the wound contact layer side to assess the absorption rate. The droplets were given time to get fully absorbed, and the amount of time taken was measured in seconds. Twenty drops were dropped onto different areas of each specimen, and the mean absorption time was calculated.

#### Dispersion characteristic of dressing

Dispersion characteristics of the dressings were determined under BS EN 13726-2:2001. For this testing, 5 cm × 5 cm dressing specimens were prepared and placed in a separate 250 ml conical flask, 50 ± 1 ml of solution A was added along the side of the flask. For 60 s, the flasks were rotated.

#### Wound dressing pH determination

The dressing specimens were conditioned at room temperature for 24 h after being suspended in deionized water at a ratio of 1:100 (w/v). The pH was measured and two measurements are made; after three hours and after twenty-four hours.

#### Air permeability measurement

Air permeability was assessed as per the ASTM D737-96 standard on an Air Permeability Master i8, Paramount, at a pressure of 125 Pa [9].

#### Tensile strength evaluation

The tensile strength was evaluated using Tinius Olsen H5KS at a maximum load of 5 kN and a speed of 200 mm/min for the dressing with dimensions 5 cm × 5 cm.

#### Moisture vapor transmission rate (MVTR) testing

According to BS EN 13726-2: 2002, MVTR was measured [8]. A container with an inner diameter of 35.7 mm and 20 ml of deionized water was used to hold the 40 mm-diameter dressing specimens. The weights of the test container after 6, 12, 18, and 24 h were calculated by the equation $\text{MVTR} = W_1 - W_2(\text{gram})/\text{Area}(\text{m}^2)$; $W_1$ was the initial weight of container; $W_2$ was the weight at different times and Area was area of the sample ($\text{m}^2$).

## Animal experiment

The study was approved by the Animal Ethics Committee [213/IAEC-I/2019 dated 23 Dec, 2019]. 24 male adult rats, each 8 weeks old, weighing between 150 and 200 g were studied in the animal house facility with a constant temperature of 25 °C and relative humidity of 60%. The rats were fed standard laboratory food and water and the study was carried out as per animal studies regulations.

The rats were anesthetized with intraperitoneal ketamine at a dose of 50 mg/kg. A transverse skin-deep wound was made on the abdomen of rats without opening the muscles or peritoneum. The wound was then closed with interrupted nonabsorbable sutures. The rats were divided into two groups alternatively. Group A was dressed with the biocompatible dressing (BD) dressing, while Group B was dressed with Normal dressing (ND) comprising of normal gauze piece dressing with adhesive. The lateral adhesive parts were not included in the design of the dressing for the rat experiments. The outcome of the dressing was assessed on days 6 and 10 for sticking quality, absorption, ease of removability and sustenance in six rats each with each dressing. The wound was assessed in 6 rats each on Days 6 and 10 for healing, redness, edema, bleeding, infection and dehiscence. These parameters were compared between the two groups.

**Table 1** Histological grading criteria for healing adapted from Shafer criteria [10]

| | Grade 1 (very light healing) | Grade 2 (moderate healing) | Grade 3 (advanced healing) | Grade 4 (well–organized) |
|---|---|---|---|---|
| Collagen content | Low | Moderate | Abundant collagen, | Fibrous connective tissue |
| Capillaries | Scarce vascularity or low number | Moderate number | Abundance of capillaries | Normal number of capillaries |
| Granulation tissue | Absent | Onset of granulation tissue | Well-organized granulation tissue | Absence of granulation tissue |
| Pus formation | Abscess formation | Nil | Nil | Nil |
| Epithelium | Necrotic epithelium | Epithelial proliferation in the margin of ulcer | Continuation of epithelialization | Complete epithelialization |

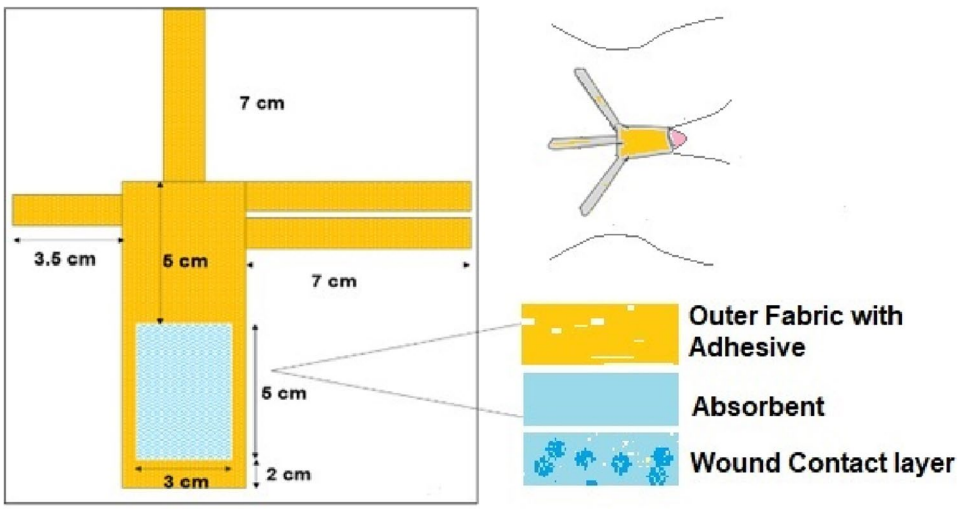


**Fig. 1** Dimension and assembly of the biocompatible dressing for Hypospadias repair

Three each in each group of these rats were anaesthetized and the wound was excised for histopathology on Day 6. Further wounds were excised on Days 10, 14 and 20 for 3 rats each.

Histological evaluation after Hematoxylin and Eosin staining was done. Two tissues were found to be autolyzed on examination and the experiment was repeated for these two rats. Histological grading criteria for healing was done according to Shafer criteria that has been adapted into a Tabular form (Table1) for easy understanding [10, 11]. Statistical testing was done using Wilcoxon Sign ranked test.

## Results

The dressing consisted of a working area of 3 cm × 5 cm {blue rectangle in Fig. 1} which contained the wound contact layer and the absorbent layer (Fig. 1). It was the only area that came in contact with the wound. The other areas of the dressing were for support of the dressing. The shape of the dressing was designed in a manner to be a composite one piece without the need for supplementary tapes as shown in Fig. 1. Three anchoring strips were designed as limbs within the dressing to fix the dressing to the lower abdomen. Two anchoring limbs were kept longer to adjust the position on the lower abdomen.

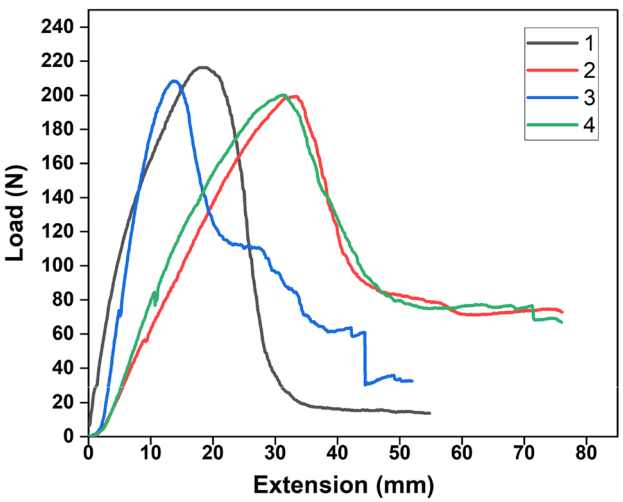


**Fig. 2** The load value for (1, 2, 3, 4) identical samples was between 185 and 220N

## Physical properties

The average mass of the dressings was 626.74 ± 5.63 $gm^{-2}$. The mean value of the thickness of the dressings was 2.60 ± 0.015 mm. The average absorption percentage of solution A by the dressing was 1425.17 ± 127.56% of the mass of the dressing. After 24 h, the percent loss of solution A from the dressings was 1249 + 150%, and at 40 h, it was 1417 + 230% (Fig. 2). Twenty drops were applied with a dropper to various locations of the dressing, and the hydrophilic nature of the dressing was confirmed by the mean computed time it took for the drops to get completely absorbed, which was 1 s.

After soaking the dressing in solution A for 60 s, there were no visible particles or residue and the dispersion was transparent. The initial pH of the solution after immersing the dressing in deionized water was 6.46. The pH value was 6.52 after 3 h, and after 24 h, it was 6.10. There was no significant change in the solution's pH after introducing the dressing, and the pH was near neutral.

The average value for air permeability was about 11.58 ± 1.59 $cm^3/cm^2$/sec. Air permeability plays an important role in oxygen transfers and allows better wound healing. The value of the load at break was between 200 and 220 N with an extension on the breaking point is 24 ± 9.5 mm (Fig. 3).

### Moisture vapor transmission rate (MVTR) testing

An ideal dressing should control the evaporation water loss from a wound at an optimal range of 700–1200 $gm/m^2$/day for normal skin and 800–1300 $gm/m^2$/day for wounds. The water vapor permeability of a wound dressing prevents excessive dehydration and build-up of exudate. The experiments show the MVTR value for the composite dressing was 1910 ± 297 $gm/m^2$/day and the percentage evaporation to the initial value of 20 ml was about 12–16 percent per day. This was the recommended range for injured wounds or surgical wounds. The MVTR measurements were also taken at 6, 12 and 18 h to ascertain the linearity in MVTR. The MVTR was 344 $gm/m^2$ at 6 h; 844 $gm/m^2$ at 12 h and 1375 $gm/m^2$ at 18 h, showing an increasing behavior.

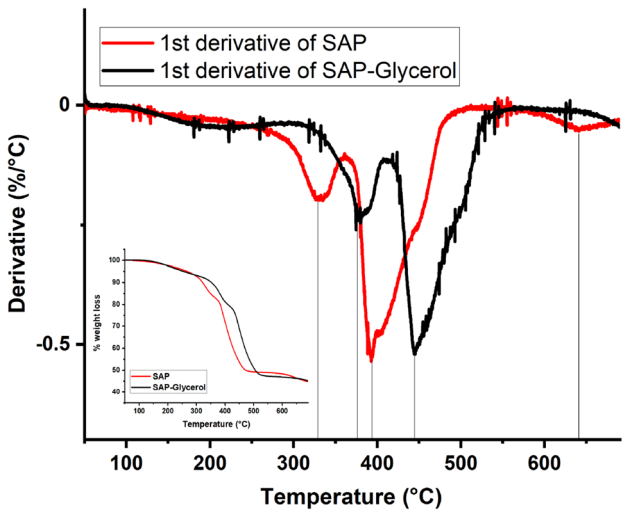


**Fig. 3** TGA thermogram of SAP and Modified SAP-G with 5% Glycerine

### Resistance Of Wound Dressing to Penetration by Odor.

In general, an unpleasant wound odor is considered as a sign of poor hygiene. The test's goal was to assess the wound dressing's resistance to odor penetration. The ISO 17299-3 method was used to test the samples. A conical flask's base was covered with a bandage approximately 10 cm × 5 cm in size, and triethylamine was carefully added to the flask wall without contacting the fabric. Triethylamine was introduced, and the flask was instantaneously sealed with parafilm. A flask without the dressing served as control. Both flasks were maintained in an incubator for two hours at a temperature of 28 °C. A syringe was used to collect the free triethylamine fumes after two hours for GC-MS analysis. The following equation was used to compute the odor reduction rate (ORR):

$$ORR(\%) : \frac{Sb - Sm}{Sb} \times 100$$

Where; ORR was the percent odor reduction rate;

Sm was the average peak area of the MS of the testing gas with a specimen;

Sb was the average peak area of the MS spectrum of the testing gas without a specimen.

The dressing had an odor reduction rate of 98.76% and a standard deviation of 0.311. This value demonstrates the wound dressing's superior absorption capacity as well as resistance to odor penetration.

### Thermogravimetric analysis (TGA).

Figure 3 displays the TGA curves of SAP and modified SAP (5 weight percent glycerol). These samples exhibited a comparable loss in the 80–260 °C range, which corresponded to physically and chemically adsorbed water loss in the samples. The considerable weight loss in SAP began at around 330 °C, whereas it began at around 380 °C in modified SAP that contained 5 wt% glycerol. The SAP and the modified SAP exhibited the greatest weight loss at 395 °C and 445 °C following initial disintegration. The modified SAP had increased thermal stability with temperature shift toward the higher side. This could be explained by the crosslinking

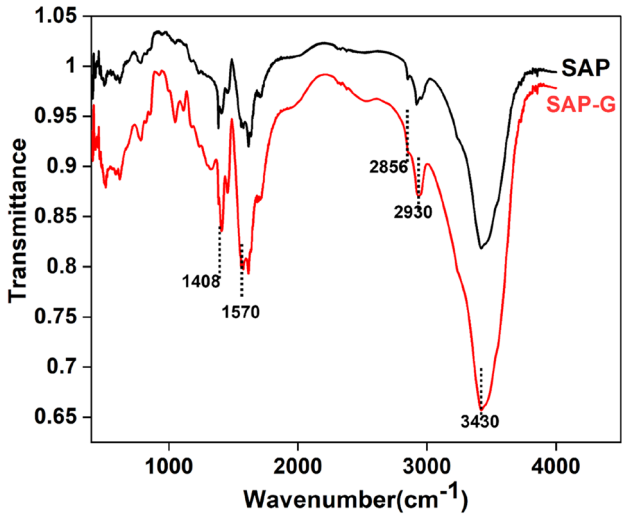


**Fig. 4** Fourier transforms infrared spectroscopy (FTIR) spectra: SAP and modified SAP (SAP-G)

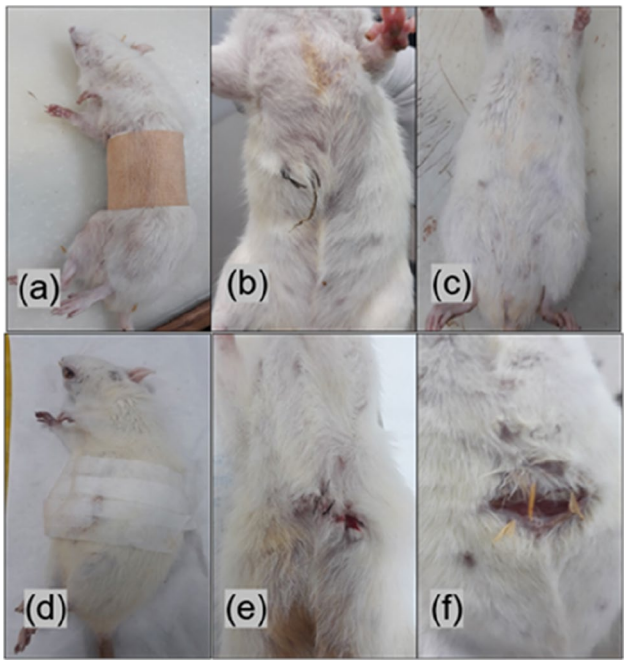


**Fig. 5** **a**–**c** Biocompatible dressing; applied on the wound; wound on Day 6; wound on Day 10. **d**–**f** Normal dressing; applied on the wound; wound on Day 6; wound on Day 10

between the SAP molecules and the glycerol particles, which enhanced temperature stability.

Fourier transformed Infrared spectroscopy (FTIR) Analysis (Fig. 4).

FTIR spectroscopy was used to identify the functional groups in the native SAP and the modified SAP. The spectrum of SAP and the SAP-Glycerol polymer is depicted in Fig. 5. At 3430 $cm^{-1}$, the stretching vibration of –OH increased on modification with glycerol. The band at 2930 $cm^{-1}$ and 2856 $cm^{-1}$ were attributed to C–H stretching vibrations of the acrylic acid of sodium polyacrylate. In polyacrylate, another bending vibration of the carboxyl group, –COO–, was seen at 1570 $cm^{-1}$ and 1408 $cm^{-1}$.

## RAT experiment results

Tables 2 and 3 depict the results of the physical properties of the dressing on Days 6 and 10. BD was superior in terms of sticking quality, absorption, ease of removability, and sustenance in six rats. On applying the Fischer's exact test, the difference was statistically significant for ease of removability on Day 6 ($p=0.012$) and sticking quality ($p=0.036$), absorption ($p=0.036$), ease of removability ($p=0.036$), and sustenance ($p=0.030$) on Day 10.

Table 4 depicts the comparison of the physical appearance of wound healing to the normal eye. Figure 5 shows the wounds in the rats and the two dressings. The wound was assessed for healing, redness, edema, bleeding, infection and dehiscence. On applying the Fischer's exact test, the difference was statistically significant for wound healing ($p=0.015$) and redness ($p=0.002$) on Day 10.

Table 5 outlines the values of grading on days 6,10, 14, and 20 in each of the 3 rats in each group. The histopathology was studied in detail. The normal skin biopsy of the rat was also examined (Fig. 6). For grading, the Shaffer criteria was adapted in a tabular form (Table 1). Figure 7 shows the various gradings of wound healing Grade I–IV in the rats.

Histopathology grading for Healing was better with BD on day 6 (3 vs 1.7), 10 (3 vs 2), 14 (4 vs 3), 20 (4 vs 1.3). Applying the two-sample Wilcoxon rank-sum test, the difference was significant on Day 14($p=0.025$) and Day 20 ($p=0.034$).

Figure 8 depicts the comparative histopathology in the rats. BD dressing had better desirable quality and demonstrated better wound healing with fewer signs of inflammation compared with the control normal dressing.

## Discussion

The results of hypospadias repair depend on many factors of which dressing is also an important component. Numerous studies have evaluated the post-operative care following hypospadias repair with attention to the dressing [12]. Some have even compared the presence of a dressing versus no dressing [13–16]. The ideal post-operative dressing requires proper covering of the phallus all around to prevent lymphatic congestion and edema while allowing inspection of the glans for any vascular compromise. Most surgeons adopt the method of dressing that suits them over hits and trials. Post hypospadias repair, what is needed is a unique dressing

**Table 2** Comparison of the physical properties of the dressing

| (Mean score 1–5) | B Dressing day 6 (n-6) | N Dressing day 6 (n-3) | B Dressing day 10 (n-6) | N Dressing day 10 (n-2) |
|---|---|---|---|---|
| Sticking quality | 4 | 4 | 5 | 2 |
| *P* value | 1.000 | | 0.036 | |
| Absorption | 4 | 3 | 5 | 3 |
| *P* value | 0.786 | | 0.036 | |
| Ease of removability | 5 | 3 | 5 | 2 (hair was coming out) |
| *P* value | 0.012 | | 0.036 | |

**Table 3** Comparison of the sustenance of the dressing

| | B Dressing day 6 (n-6) | N Dressing day 6 (n-6) | B Dressing day 10 (n-6) | N Dressing day 10 (n-6) |
|---|---|---|---|---|
| Number in which present | 6 | 3 | 6 | |
| 1-sided Fisher's exact *P* value | 0.091 | | 0.03 | 2 |

assembly with multipurpose qualities like rapid absorbent of exudate, no allergic symptoms, rapid healing, ease of passage of catheter in the center of the dressing, and proper placement of the dressing with comfort to the patient and the caregiver.

A biocompatible dressing for Hypospadias repair has been developed. Its characteristics have been studied in detail. The biocompatible hypospadias dressing consists of a wound contact layer that is hydrophilic treated polypropylene. Polypropylene offers the advantage of being an inert material and is hypoallergenic, the use of hydrophilic treated-polypropylene allows the wound exudate to pass quickly to the absorbent layer as compared to normal polypropylene which is hydrophobic; thus, preventing any leakage of exudate build-up. The absorbent layer consists of a blend of polyester and viscose, which offers quick vertical wicking of the exudate and spreading of exudate to be adsorbed by the super absorbent polymer, which is modified to maintain a moist environment and glycerol has been shown to promote healing of the wound. The top layer or outer fabric is an important structure holding all the components of the dressing together while providing comfort to both the caregiver and the patient. The top layer or outer fabric is stretchable and strong and offers a better advantage as compared with cotton or polyester alone. It also allows the application of pressure to the wound.

A lower thickness is required for long adherence of bandage on the wound part that is not affected by gravity. We have compared our Hypospadias bandage with other market products and found similarity as well. In terms of thickness, the Hypospadias bandage (**BD**) had a lower thickness of $2.60 \pm 0.015$ mm, while other bandages had more

**Table 4** Comparison of the physical appearance of the wound

| (Mean score 1–5) | B Dressing day 6 (n-6) | N Dressing day 6 (n-6) | B Dressing day 10 (n-6) | N Dressing day 10 (n-6) |
|---|---|---|---|---|
| Wound Healing | 4 | 3 | 5 | 3 |
| *P* value | 0.844 | | 0.015 | |
| Redness | 1 | 3 | 0 | 3 |
| *P* value | 0.061 | | 0.002 | |
| Edema | 1 | 3 | 0 | 2 |
| *P* value | 0.104 | | 0.182 | |
| Bleeding | 0 | 1 | 0 | 1 |
| *P* value | 0.455 | | 0.0455 | |
| Infection | 0 | 1 | 0 | 2 |
| *P* value | 0.455 | | 0.061 | |
| Dehiscence | 0 | 1 | 0 | 2 |
| *P* value | 0.455 | | 0.061 | |

**Table 5** Comparison of the histopathology grading

| DAY | TEST (BD) | CONTROL(ND) | *P* value |
|---|---|---|---|
| DAY 6 (n-3) | 3 | 2 | 0.105 |
| | 4 | 1 | |
| | 2 | 2 | |
| Mean Grade | 3 | 1.7 | Not significant |
| DAY 10 (n-3) | 4 | 2 | 0.121 |
| | 3 | 2 | |
| | 2 | 2 | |
| Mean Grade | 3 | 2 | Not significant |
| DAY 14 (n-3) | 4 | 3 | 0.025 |
| | 4 | 3 | |
| | 4 | 3 | |
| Mean Grade | 4 | 3 | Significant |
| DAY 20 (n-3) | 4 | 1 | 0.034 |
| | 4 | 2 | |
| | 4 | 1 | |
| Mean Grade | 4 | 1.3 | Significant |

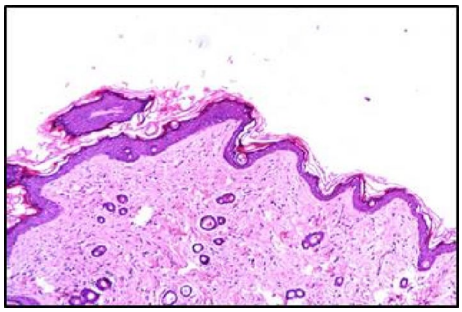

**Fig. 6** Micrograph showing Normal skin (H&E 10x)

thickness, like Medi foam N had a thickness of 5.14 mm, Alleyne (Smith & Nephew Co., 6.16 mm), Baitain (Coloplast, 4.43 mm) and Mepilex (Molnlycke Health care, 5.29 mm). In the MVTR study, BD showed a significant gain compared with other bandages as it has a value of 1910 gm/$m^2$/day while the other bandages like Medi foam N (811 gm/$m^2$/day), Alleyne (641 gm/$m^2$/day), Baitain (898 gm/$m^2$/day), Mepilex (914 gm/$m^2$/day) have a lower value. The higher MVTR represents the porosity value of dressing, and the higher value of MVTR contributes to rapid healing [17].

On evaluation of the absorption and fluid retention, the BD dressing showed higher value in comparison to other dressings. BD dressing showed 1.43 gm/$cm^2$ as absorption value with a retention value of 0.22 gm/$cm^2$, while other dressings like Medi foam N had 1.25 gm/$cm^2$ absorption and 0.47 gm/$cm^2$ as retention, Alleyne (0.73 gm/$cm^2$ absorption and 0.15 gm/$cm^2$ retention value), Baitain (0.71 gm/$cm^2$ absorption and 0.14 gm/$cm^2$ as retention value), Mepilex (0.84 gm/$cm^2$ absorption and 0.06 gm/$cm^2$ as retention value).

On comparison of tensile strength, BD dressing had a significantly higher break load value compared with different composite dressings. When compared with carboxy methyl cellulose (CMC) composite dressing and Alginate dressing, BD dressing had a load at break value in the 200–220 N range with an extension at a break of 24 mm, while CMC composite dressing had a value in the range of 55 N and extension of 3 mm, and alginate dressing had a value less than 10 N with breaking extension of 8 mm [18].

The odor reduction rate of the BD was about 98% that was an added advantage of the dressing.

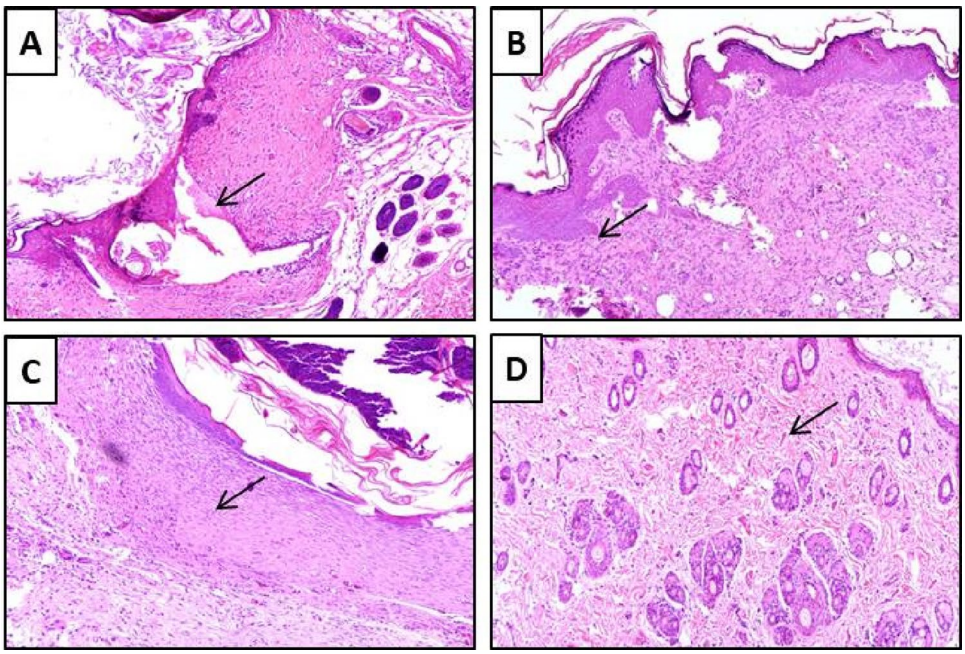


**Fig. 7** Shafer healing criteria for Histological grading. Micrographs (H&E 10x) showing **A** Grade1 healing; Irregular necrotic epithelium with collection of exudative fluid and abscess formation (Arrow) in the dermis. **B** Grade 2 healing; Epithelial proliferation (Arrow) in the margin of ulcer with onset of granulation tissue and moderate collagen content in the dermis. **C** Grade 3 healing; Continuation of epithelialization with well-organized granulation tissue (Arrow) and abundant collagen content in the dermis. **D** Grade 4 healing; Complete epithelialization with abundant fibrous connective tissue and increase of hair follicles in the dermis

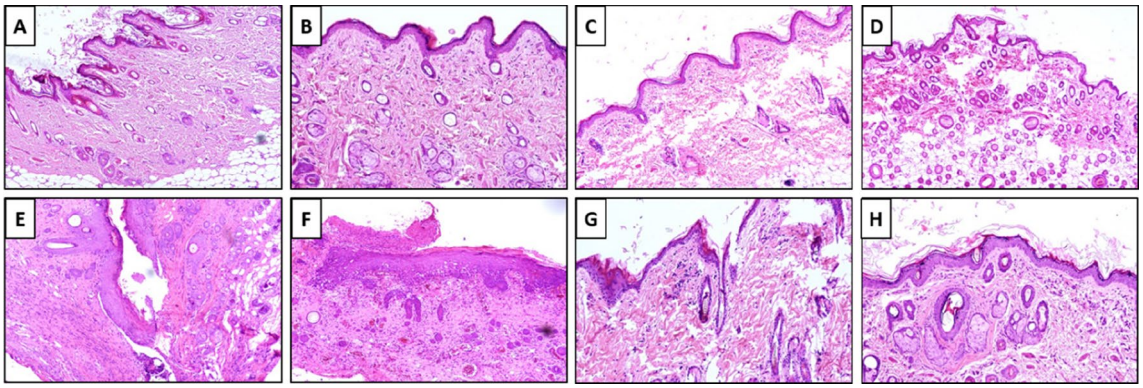


**Fig. 8** Micrographs showing histomorphological features at Day 6, 10, 14 and 20 respectively. **A–D** Biocompatible dressing showing Grade 4 healing in all A–D; Complete epithelialization of epidermis with abundant collagen fibers, marked increase of hair follicles, absence of microabscess formation and granulation tissue in the dermis (H&E 10x). **E–H**) Normal dressing; Incomplete epithelialization with ulceration of epithelium, presence of abundant inflammatory infiltrates, microabscess (Grade1-E), granulation tissue formation (Grade2-F), scant to moderate amount of collagen fibers(Grade3-G) and exudative fluid collection (Grade3-H) in the dermis (H&E 10x)

The average mass of the dressings was $626.74 \pm 5.63$ g $m^{-2}$. The mean value of the thickness of the dressings was $2.60 \pm 0.015$ mm. The average absorption by the dressing was $1425.17 \pm 127.56\%$ of the mass of the dressing. The hydrophilic nature of the dressing was demonstrated. The dispersion was clear, and no particles/residue could be seen after immersing the dressing in solution A for 60 s. The initial pH of the solution was 6.46. The next measurement was 6.52 after 3 h and after 24 h, it was 6.10. There was no change in the pH of the solution after the introduction of the dressing and the pH was near neutral. The average value for air permeability was about $11.58 \pm 1.59$ $cm^3/cm^2/sec$.

The crosslinking of SAP by glycerin for maximum water retention was carried out for super absorbency of the bandage. This crosslinking resulted in enhancing the thermal stability of superabsorbent material. The FTIR analysis showed the enhanced –OH stretching which was due to glycerin modification. Additionally, other physical properties had a higher value as compared to the standard values as shown in Table 6.

The dressing has been used in Wistar rat model of wound and found be useful with better healing and less signs of inflammation compared with the control normal dressing (Fig. 5).

BD was superior in sticking quality (4.5 vs 3), absorption (4.5 vs 3), ease of removability (5 vs 2.5), and sustenance (5 vs 2.5) in six rats combining results on days 6 and 10. The wound was assessed for healing (4.5 vs 3), redness (0.5 vs 3), edema (0.5 vs 3), bleeding (0 vs 1), infection (0 vs 1.5) and dehiscence (0 vs 1.5).

The histopathology was studied in detail. The normal skin biopsy of the rat was also examined (Fig. 6). For grading, we adapted the Shaffer criteria in a tabular form (Table 1) Fig. 7 shows the various gradings of wound healing Grade I–IV in the rats.

Histopathology grading for Healing was better with BD on day 6(3 vs 1.7), 10(3 vs 2), 14(4 vs 3), 20(4 vs 1.3).

**Table 6** Observed values of physical properties of wound dressing as per standard value

| S.No | Property | Standard value | Observed values |
|---|---|---|---|
| 1 | Absorbency of Wound Dressing (%) | As per requirement | $1425.17 \pm 127.56\%$ |
| 2 | Dehydration Rate of Dressing (%) | Depends on absorptions | $1249 \pm 150\%$ (24 h)<br>$1417 \pm 230\%$ (40 h) |
| 3 | Rate of surface Absorption (Sec) | 1–2 | 1 s |
| 4 | Air Permeability ($cm^3/cm^2/sec$) | Not available | $11.58 \pm 1.59$ $cm^3/cm^2/sec$ |
| 5 | Load at break (N) | 180 as per skin | 200–220 N |
| 6 | Moisture vapor transmission rate (MVTR) ($gm/m^2$) | 1000 for 24 h | $1910 \pm 297$ $g/m^2$ |
| 7 | Odor Reduction Rate (%) | Above 90% | $98.76 \pm 0.311\%$ |

BD demonstrated better desirable physical and wound healing qualities with less inflammation compared with control normal dressing.

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**Author contributions** SS, JR and VA wrote the main manuscript text and reviewed the literature. VA and B helped in data collection. SS, AKA and MJ designed the protocol and applied for the funding. SS and VA designed the dressing shape and format. SS did the animal experiments. B assisted in animal work and wound sample collections. JR, VA and HSJ prepared the dressing under supervision of AKA and MJ. JR, VA, HSJ, AKA and MJ studied the characteristics of the dressing. SS, HJ and AS modified the Shafer grading in Tabular format. HJ and AS studied the histology of the wounds in a blinded manner. SS and AS analysed the results after unblinding. ADU did the statistical analysis. All authors critically reviewed and approved the final manuscript

**Data availability** The authors confirm that the data supporting the findings of this study are available within the article.

## Declarations

**Competing interests** The authors declare no competing interests.

## References

1. Gangopadhyay AN, Sharma S (2005) Peha-haft bandage as a new dressing for pediatric hypospadias repair. Indian J Plast Surg 38:162–164
2. Narci A, Embleton DB, Boyaci EÖ et al (2011) A practical offer for hypospadias dressing: Allevyn. Afr J Paediatr Surg 8:272–274
3. Méndez-Gallart R, García-Palacios M, Rodríguez-Barca P, Estévez-Martínez E, Carril AL, Bautista-Casasnovas A (2017) A simple dressing for hypospadias surgery in children. Can Urol Assoc J 11(1–2):E58–E59
4. De Sy WA, Oosterlinck W (1982) Silicone foam elastomer: a significant improvement in postoperative penile dressing. J Urol 28:39–44
5. Kim YJ, Hong SJ, Shin WS et al (2019) Preparation of biodegradable superabsorbent polymer & measurements of changes in absorption properties depending on the type of surface cross-linker. Polymer Adv Tech 31:273–283
6. BS EN 12127:1998 Textiles. Fabrics. Determination of mass per unit area using small samples.
7. BS EN ISO 9073–2:1997. Textiles. Test methods for nonwovens, determination of thickness.
8. BS En 13726, 2002 Testing methods for primary wound dressings British Standard ICS 11 120 20
9. ASTM D737–96 Standard Test Method for Air Permeability of Textile Fabrics
10. Shafer W, Hine M, levy B (1983) A textbook of oral pathology, 4th edn. Saunders, Philadelphia, pp 594–614
11. Deyhimi P, Khademi H, Birang R, Akhoondzadeh M (2016) Histological evaluation of wound healing process after photodynamic therapy of rat oral mucosal ulcer. J Dent (Shiraz) 17(1):43–48
12. McLorie G, Joyner B, Herz D et al (2001) A prospective, randomized clinical trial to evaluate methods of postoperative care of hypospadias. J Urol 165:1669–1672
13. Van Savage JG, Palanca LG, Slaughenhoupt BL (2000) A prospective randomized trial of dressing versus no dressings for hypospadias repair. J Urol 164:981–983
14. Karakaya AE, Güler AG, Doğan AB (2021) Dressing or not after tubularized incised plate urethroplasty. Urol Int 105:1029–1033
15. Hadidi A (2004) Dressing vs no dressing. In: Hadidi AT, Azmy AF (eds) Hypospadias surgery. Springer, Berlin, pp 271–272
16. Van Savage JG, Palanca LG, Slaughenhoupt BL (2000) A prospective, randomized trial of dressing vs. no dressings for hypospadias repair. J Urol 164:981–983
17. Lee SM, Park K, Kim YS, Kim HJ, Moon H, Mueller S, Jeong YIL (2016) Physical, morphological, and wound healing properties of a polyurethane foam-film dressing. Biomater Res. https://doi.org/10.1186/s40824-016-0063-5
18. Uzun M, Anand SC, ShahT. (2013) Study of the pH and physical performance characteristics of silver-treated absorbent wound dressings. J Ind Text 42(3):231–243