

## A PROSPECTIVE RANDOMIZED CLINICAL TRIAL TO EVALUATE METHODS OF POSTOPERATIVE CARE OF HYPOSPADIAS

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### ABSTRACT

**Purpose:** Hypospadias repair is a common operation performed by pediatric urologists. Perhaps the greatest variable and source of controversy of postoperative care is the surgical dressing. We hypothesized that using no dressing would achieve surgically comparable results to those traditionally achieved by a postoperative dressing and it would also simplify postoperative parent delivered home care. Accordingly we designed a prospective randomized clinical trial to compare surgical outcome and postoperative care after hypospadias repair in boys with no dressing and those who received 1 of the 2 most common types of dressing.

**Materials and Methods:** In a 12-month period 120 boys with an average age of 2.2 years underwent primary 1-stage hypospadias repair at a single center with 4 participating surgeons. Repair was performed in 60 boys with proximal and 60 with distal hypospadias on an outpatient basis. Ethics and Internal Review Board approval, and informed consent were obtained. Boys were then prospectively randomized to receive no dressing, an adhesive biomembrane dressing or a compressive wrap dressing. Comprehensive instructions on postoperative care were distributed to all families and a questionnaire was distributed to the parents at the initial followup. Surgical outcome was evaluated and questionnaire responses were analyzed. Fisher's exact test was done to test the significance of differences in surgical outcomes and questionnaire responses.

**Results:** A total of 117 boys completed the prospective randomized trial. Surgical staff withdrew 3 cases from randomized selection to place a dressing for postoperative hemostasis. We obtained 101 questionnaires for response analysis. The type or absence of the dressing did not correlate with the need for repeat procedures, urethrocutaneous fistula, or meatal stenosis or regression. Analysis revealed less narcotic use in the no dressing group and fewer telephone calls to the urology nurse, or on-call resident and/or fellow. These findings were statistically significant. In addition, there were more unscheduled visits to the urology clinic, emergency room or primary physician office by boys with than without a dressing. Furthermore, 29% of the parents were not psychologically prepared to remove the dressing and 12% were so reluctant that the dressing was removed at the urology outpatient clinic.

**Conclusions:** The surgical outcome and rate of adverse events or complications were not compromised without a postoperative dressing. An absent dressing simplified postoperative ambulatory parent delivered home care. We recommend that dressings should be omitted from routine use after hypospadias repair.

**KEY WORDS:** urethra, hypospadias, questionnaire, bandages, postoperative care

Hypospadias affects 1/300 to 400 live male births, and the correction of hypospadias is a common surgical procedure performed by pediatric urologists. Most hypospadias surgeons agree that hypospadias repair requires strict attention to detail and gentle tissue handling intraoperatively. However, postoperative care remains controversial. Perhaps the greatest variability applies to the postoperative dressing. There has been such overemphasis on the postoperative hypospadias dressing that it has become unquestioned urological folklore. In the short term the supposed benefits are improved hemostasis as well as decreased swelling, wound disruption and wound infection. In the long term dressings have been implicated in the prevention of urethrocutaneous fistula and thought to enhance the overall cosmetic result. Dressings in the past have included cotton balls immersed in saline,<sup>1</sup> an X-shaped elastic dressing,<sup>2</sup> adhesive membrane,<sup>3</sup> silicone foam<sup>4–6</sup> and transparent biomembrane dressing.<sup>7</sup> We thought that complications after hypospadias reconstruc-

tion would not be increased by an absent postoperative dressing. In addition, we postulated that the dressing is cumbersome and may add unnecessarily to the burden of postoperative care. To test our hypothesis we performed a prospective randomized surgical trial to assess objectively the clinical outcome in dressing and no dressing treatment groups in an outpatient surgical care setting. Outcome measurements included surgical results, and postoperative patient-parent comfort and satisfaction.

### PATIENTS AND METHODS

**Study design.** A prospective randomized surgical trial was designed in cooperation with surgical staff, fellow and resident physicians with operative and clinic nursing and support personnel. All boys scheduled for hypospadias repair were considered study candidates. After Institutional Review Board and Ethics Committee approval was obtained parents were approached for informed consent for the operative procedure and study protocol. A urology specialty nurse in coop-

eration with the operating surgeons guided each patient and their parents through the perioperative period. A postoperative instruction booklet was distributed to index parents before hospital discharge. Boys were then randomized, so that the urology personnel and parents were blinded to whether a dressing would be used. This information was in a coded envelope that accompanied the boy to the operating room with his hospital chart. At the end of the operation the envelope was opened by the operating room personnel and 1 of 2 or no dressing was used. The figure shows recommended postoperative hypospadias dressing care and care of the undressed penis.

Briefly, with an absent dressing after hypospadias repair a generous amount of polymixin B sulfate and bacitracin zinc in white petrolatum was placed around the incision lines and urethral meatus 3 times daily or after each diaper change in infants. Bathing twice daily in a tub was initiated on the day of surgery and continued for 7 days for 5 minutes per time. The child was placed in a diaper or underwear at all times. Care was similar in each dressing group after the dressing was fabricated and applied in the operating room. Ointment was placed on the urethral meatus 3 times daily or at each diaper change in infants. The dressings were maintained clean of particulate matter as needed by gentle cleansing. Bathing twice daily in a tub was initiated on postoperative day 3. The dressing was removed when it was soaked enough to allow easy removal by the parents. After dressing removal bathing continued for 7 days, as in the no dressing group, and ointment was placed on the incision lines and meatus 3 times daily or at each diaper change in infants.

Postoperative analgesia involved a combination of 10 to 15 mg./kg. liquid acetaminophen every 4 hours as needed with 0.5 to 1.0 mg./kg. codeine every 4 hours for acetaminophen breakthrough pain. Any evaluation by urology personnel and the reason for such an evaluation before hospital discharge or before the first scheduled followup visit was recorded. A specialized postoperative questionnaire developed by urology nurses, fellows and staff was explained and distributed to the parents of the index child on the first postoperative visit. When a urethral stent had been placed, the questionnaire was distributed when the stent was removed at the outpatient department 7 to 10 days postoperatively. In cases with no urethral stent the questionnaire was distributed at the routine 6-week followup urology clinic visit. Each questionnaire was completed by the primary caregiver (parent) and

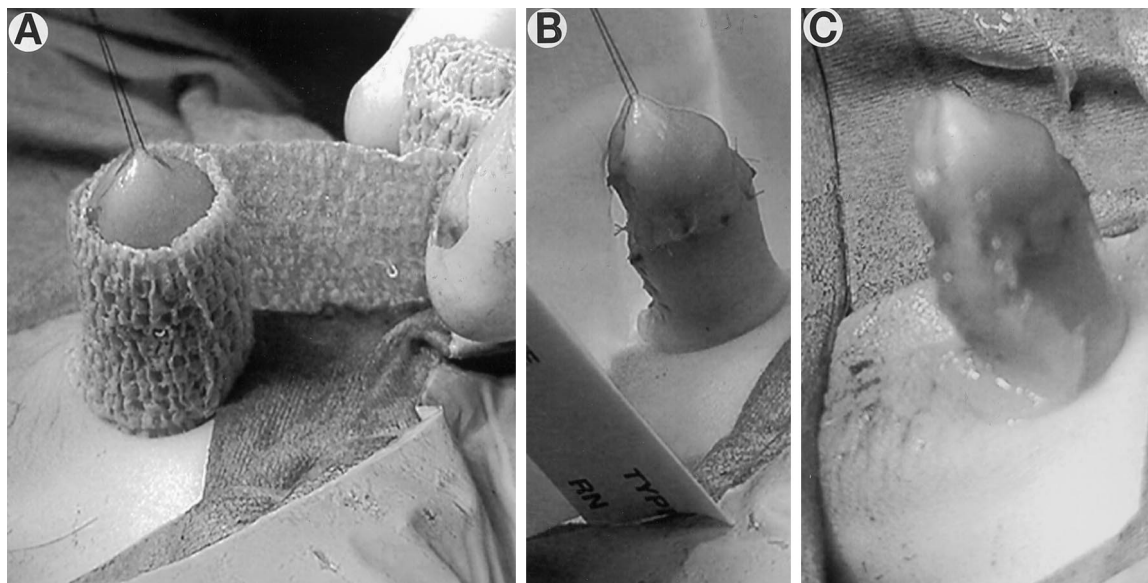
collected by the urology nursing staff at the end of the clinic visit. All parental correspondence by telephone with urology nurses, residents, fellows and staff or emergency room visits in the interim between surgery and the first visit or between visits was documented, recorded and handled in the appropriate manner.

*Patients.* During a 12-month period 120 consecutive boys with an average age of 2.2 years with distal or proximal congenital hypospadias with or without attendant chordee underwent primary 1-stage hypospadias repair. Repair was performed for distal and proximal hypospadias in 60 cases each. The type of repair was determined by 1 of the 4 operating staff surgeons (G. M., A. K., P. M. or D. B.). All operations were done on an outpatient basis. Each boy was prospectively randomized by intent-to-treat into group 1—no dressing, group 2—transparent biomembrane dressing and group 3—compressive wrap dressing. Fisher's exact statistical analysis was performed in cooperation with the department of epidemiology to determine any statistical differences between treatment groups. A monetary cost analysis was determined for each treatment group.

#### RESULTS

Of 120 patients 117 completed the prospective randomized study. Three boys were withdrawn from the randomized trial by the surgeon due to excess bleeding at the end of repair and a compressive wrap dressing was applied. A total of 16 families failed to fill out a questionnaire. Excluding the 3 boys who were withdrawn from randomization, 101 questionnaires were available for evaluation, comprising 24 cases with no, 39 with a biomembrane and 38 with a compressive wrap dressing.

*Surgical results.* Of the 117 hypospadias repairs 58 were distal and 59 were proximal. Six and 3 urethrocutaneous fistulas that developed after proximal and distal repair, respectively, were equally distributed at 3 per treatment group. Meatal stenosis developed in 5 cases, including 2 with a compressive wrap, 2 with a biomembrane and 1 with no dressing. There was meatal regression in 1 case each with a biomembrane and no dressing. A repeat procedure was required in 16 patients to close a urethrocutaneous fistula, and correct meatal stenosis and regression, including 10 and 6 who underwent proximal and distal repair, respectively. Repeat procedures were evenly distributed with 5 in the com-



A, Compressive wrap dressing. B, transparent biomembrane dressing. C, no dressing

pressive, 6 in the biomembrane and 5 in the no dressing group. Neither the specific treatment group, operating surgeon nor type of operation correlated with the need for reoperation for urethrocutaneous fistula, meatal stenosis or meatal regression.

**Questionnaire response results** (see table). No difference in pain was reported by parents in boys in the dressing and no dressing groups (see table). However, fewer boys with a compressive wrap dressing had significant pain relief with bathing. More parents of children in the compressive dressing group noticed significant pain during bathing. Regular acetaminophen administration was the same in each group. However, there was a statistically significant decrease in regular codeine use in the no dressing group.

Parents reported that the postoperative dressing fell off prematurely in 16 boys in the dressing groups and stayed on longer than recommended in 19. They also reported that dressing removal caused significant pain in 38% of the boys with a biomembrane and 82% with a compressive wrap dressing. Parents noticed a foul odor in 11 boys with dressings, which was not reported in those without a dressing. Skin irritation after dressing removal was reported in 36 boys, while only 4 without a dressing had skin irritation. Swelling was relatively constant whether or not there was a dressing. Only 40 of the 77 parents (52%) of children with a dressing removed the dressing as instructed. Of the remaining children the dressing spontaneously fell off in 28, while 9 (13%) with a dressing required an unscheduled visit to the urology clinic for dressing removal. In fact, these 9 children were among a total of 24 whose parents contacted the urology nurse or on-call resident and/or fellow with concerns about the dressing. In boys with no dressing there were only 6 telephone calls and all concerned the urethral stent. The difference in the number of telephone calls by parents about the dressing of boys with a dressing compared to no calls by the parents of boys without a dressing was statistically significant. Furthermore, the parents of 22 boys with a dressings brought the child to the family physician or pediatrician, or visited the emergency room with concerns regarding the dressing. There were only 3 such occurrences in children without a dressing and all involved the urethral stent. A total of 28 parents (36%) reported that they were not prepared for the difficulty associated with removing the dressing, although 92% thought that the postoperative instructions were helpful and sufficient.

**Cost analysis.** Cost analysis revealed that the dressing groups incurred not only the cost of the dressing, but also the cost of ointment since parents were instructed to apply the ointment to the meatus and penis after the dressing was removed. In contrast, when no dressing were used, parents incurred the cost of the ointment only. In addition, because it was difficult to quantify the additional cost of the multiple unscheduled visits to the urology clinic, emergency room or primary pediatrician office due to concern over the dressing, only a qualitative estimation was made of the additional cost that would not have been incurred if a dressing had not been used.

#### DISCUSSION

In 1981 Cromie and Bellinger categorized hypospadias dressings into the 3 categories of totally concealing, partially concealing and unconcealed dressings according to the responses received from 44 surgeons who frequently performed hypospadias repair.<sup>8</sup> The totally concealing dressing totally covers the repair and maximally immobilizes the penis. In our experience it creates a great deal of uncertainty about the status of the repair and consequently causes parent and surgeon anxiety. The partially concealing dressing, which is the most popular type, has many variations. It allows the surgeon and parents to monitor the repair, while providing some stability. The basic problems with partially concealing dressings are that they do not allow adequate hygienic cleansing of the repair and they have a propensity to fall off spontaneously and prematurely. The unconcealed dressing described by Devine and Horton<sup>8</sup> is labor intensive to apply, making it impractical for routine use.

Many "hypospadiologists" believe that the dressing has a significant bearing on the ultimate outcome of repair. They think that the dressing adds uniform support to the penis repair, while allowing ease of observation. The dressing should also be easy to apply and remain in place to enable adequate initial wound healing. Our question was not which dressing should be used, but rather whether a dressing should be used at all. In fact, if it is not necessary, could it be tested or studied in a randomized prospective manner on an outpatient surgical basis? To that end our study had certain goals. We tested whether there was any difference in surgical outcome in cohorts of boys with and without a dressing ap-

#### Parent questionnaire responses

No. pts.	No. No Dressing (%)	No. Biomembrane Dressing (%)	No. Compressive Dressing (%)
	24	39	38
<b>Pain assessment:</b>			
Did your child have pain?	21 (87.5)	31 (79.5)	36 (94.7)
Did bathing help pain?	18 (75)	30 (76.9)	20 (52.6)
Was your child comfortable when dressing removed?	Not applicable	24 (61.5)	7 (18.4)
Was your child comfortable when diaper changed?	11 (56)	17 (43.6)	22 (57.9)
Was your child comfortable during bath?	20 (83.3)	32 (82.1)	23 (60.5)
Did you give your child Tylenol regularly?	21 (87.5)	33 (84.6)	33 (86.8)
Did you give your child Codeine regularly?	18 (75)	35 (89.7)	34 (89.5)
<b>Problem assessment:</b>			
On what day after surgery did the dressing come off (day 1/2-4/5-7/greater than 8)?	Not applicable	5/17/6/7	11/21/3/2
Was the dressing easy to remove?	Not applicable	24 (61.5)	6 (15.8)
Did you notice an odor?	0 (0)	6 (15.4)	5 (13.2)
Was your child's skin red or itchy?	4 (16.7)	21 (53.9)	15 (39.5)
Was your child's penis swollen?	18 (75)	30 (76.9)	19 (52.6)
Did you remove your child's dressing?	Not applicable	18 (46.2)	22 (57.9)
Did your child's dressing fall off?	Not applicable	17 (43.6)	11 (28.9)
Did you call urology nurse about dressing?	Not applicable	9 (23.1)	15 (39.5)
Did you call urology nurse about stent?	6 (25)	4 (10.3)	9 (23.7)
Did you visit your family physician, emergency room or pediatrician?	3 (12.5)	12 (30.8)	10 (26.3)
<b>Parental anxiety assessment:</b>			
Were discharge instructions about dressing helpful?	Not applicable	35 (89.7)	36 (94.7)
Did you feel prepared to remove dressing?	Not applicable	22 (56.4)	27 (71.1)
Were you happy with results of surgery?	23 (95.8)	32 (82.1)	32 (84.2)

All responses were in the affirmative.

plied at the end of hypospadias repair. We chose 2 of the most popular types of partially concealing dressings, including the compressive wrap dressing and the Uni-Flex\* biodressing as a surrogate for the Tegaderm\* as described in 1989 by Patil and Alvarez.<sup>7</sup> Our data showed no statistically significant difference in the number of adverse events, such as bleeding, infection or edema and no difference in the incidence of urethrocutaneous fistula, meatal stenosis, meatal regression or required repeat procedures in boys with and without a dressing. Therefore, after careful review of our data we believe that surgical repair is not compromised by an absent dressing and when there is no significant postoperative bleeding, a dressing may safely be omitted from routine use after hypospadias repair.

Another goal was to determine whether an absent dressing after hypospadias repair would simplify postoperative ambulatory parent delivered home care. Although leaving a freshly closed incision uncovered is a foreign idea to some surgeons, a dressing was problematic in a significant number of parents in our study. The dressing was malodorous in some cases and caused significant discomfort during removal. The dressing was such a source of anxiety to some parents that they brought the child to the emergency room or family physician for evaluation. Some parents did not remove the dressing due to fear that they would hurt the child or damage the repair. Compared to the no dressing group there was a statistically significant greater number of telephone calls to the urology nurse, or on-call resident and/or fellow in each of the 2 dressing groups. In fact, there were no calls or unscheduled visits recorded regarding incision care in the boys without a dressing. In addition, a good portion of the parents who believed that the hospital discharge instructions were adequate were not prepared to remove the dressing at home when the time came to do so.

Our other goal was to test whether such a clinical trial could be performed in an outpatient pediatric surgical setting. By blinding the surgeon until after the surgery there was no bias in operative technique. By blinding the parents and educating them in all 3 dressing group modalities they were prepared to care for the child irrespective of the result of postoperative randomization. Parental motivation was a key to this study. By using a team approach to parental education and being available to the parents before, during and after surgery we believe that the parents were empowered and, thus, qualified to teach us about the difficulties of caring for a child after hypospadias repair done on an outpatient basis.

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#### CONCLUSIONS

This prospective randomized trial has several important findings. An absent hypospadias dressing did not compromise the outcome of reconstruction and did not increase postoperative complications, adverse events (meatal stenosis, meatal regression, infection, bleeding, edema or urethrocutaneous fistula) or the rate of reoperation. However, an absent dressing simplified postoperative ambulatory care for parents and decreased the burden on the medical-surgical staff due to the uncertainties and anxieties associated with a dressing. Cost analysis showed that the dressing is a cost in addition to that of the antibiotic ointment routinely recommended at our institution. Perhaps more important or burdensome on the medical establishment but difficult to quantify was the additional cost of unscheduled visits to the emergency room, physician office or outpatient surgical clinic. These 2 measured variables as well as the increased use of narcotics in the dressing groups were statistically significantly different in regard to whether a dressing was used. We now apply a dressing in only a minority of hypospadias repairs and when hemostasis is adequate, we recommend that a hypospadias dressing should be omitted from routine use. Furthermore, although it is often overlooked, a trial of this type is feasible and effective for reaching prescribed goals in the outpatient surgical setting, thus, contributing to the modern edict of evidence based medicine.

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