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Disposable diapers: effective and safe

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March 2000

Dear Colleague:

Parents who can remember the old days of diaper pails and laundry services can certainly appreciate the convenience of the modern disposable diaper as they observe its use in their grandchildren. 21st-century parents may also appreciate the practical benefits of this familiar product, but probably few if any are aware of the extensive technology behind it. Even many physicians may not fully comprehend the advances in diaper development over the past decade and their impact on the health of babies.

In this special supplement, three pediatric dermatologists and a practicing pediatrician share their experience and expertise on modern diaper technology. In a roundtable discussion led by Mary Spraker, MD, Associate Professor of Dermatology and Pediatrics at Emory University School of Medicine, they elucidate its role in preventing dermatitis, reducing disease transmission, and promoting skin health in infants. Safety issues, testing of the superabsorbent core material, and environmental impact are also addressed.

We hope you'll find this supplement not only interesting and informative but useful in advising your patients on the important matter of infant hygiene. We would welcome your suggestions and comments.

Julia A. McMillan

Julia A. McMillan, MD
Editor-in-Chief
Contemporary Pediatrics

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Disposable diapers: Effective and safe

Spraker: In this roundtable discussion, we're going to focus on the disposable diaper and the impact it's had on health and society since it was introduced almost four decades ago. As pediatric dermatologists, we're expected to help pediatricians understand rashes in children, so diaper dermatitis is an important issue for us. Because general pediatricians are usually on the front lines taking care of this problem, we'll be joined by Dr. Andrew Schuman, a general pediatrician in Manchester, New Hampshire, who has been in practice for about 20 years. Also with us is Dr. James Leyden, who started the pediatric dermatology program at Children's Hospital in Philadelphia in 1970. He is the author of several seminal articles on the pathophysiology of diaper rash in the 1970s and 1980s, one of which debunked "the ammonia theory." Also on the panel is Dr. Bernice Krafchik, a professor of medicine and pediatrics at the University of Toronto, who is based at the Hospital for Sick Children. Lastly, Dr. Glenn Sipes, professor and head of the department of pharmacology at the University of Arizona, has reviewed the toxicologic information presented here.

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Clinical impact of disposable diapers

To start, I think we can agree that disposable diapers have revolutionized the way parents diaper their children. Disposable diapers are certainly convenient, thereby simplifying the lives of their caretakers. They've also become more comfortable for the infant to wear in that the newer versions are less bulky and less tightly cuffed around the legs.

Krafchik: From a clinical standpoint, perhaps the most important impact of disposable diapers has been the decrease in the number of cases of diaper dermatitis that we see. Much of this change is due to the superabsorbent material that's been added to the inner core of the diaper. This material absorbs urine to form a gel that will not release the moisture from the diaper back to the skin. The ability of the superabsorbent material to reduce skin wetness and therefore reduce the incidence and severity of diaper dermatitis has been documented in several clinical studies.[1–5]

Spraker: I concur that we dermatologists don't see as much diaper dermatitis as we did a few years ago, perhaps because it's being treated more effectively with first-line therapy by pediatricians.

Dr. Schuman, as a general pediatrician, what's your impression of diaper dermatitis incidence now?

Schuman: On behalf of my pediatrician colleagues, I appreciate the compliment that we're doing a better job than we used to do. But the reality is that I definitely am seeing much less irritant diaper dermatitis—and possibly less *Candida*—now than I did a few years ago, and I see 30 to 40 patients a day, many of them in diapers.

Krafchik: Dermatitis caused by detergents and soaps is also rare today, and we're not seeing Jacquet's erosive diaper dermatitis now as we used to in the 1970s and before.

Schuman: I agree that the change is related to the superabsorbent material added to the diaper core in the mid-1980s. It's important to remember that the ability of the superabsorbent material to absorb urine has been regularly improved since then. I see virtually no cloth diapers in my practice now, and it's normal to see only one case of diaper rash per week compared with many per day only 2 or 3 years ago.

Leyden: I would agree that diaper rashes of what I like to call the friction-induced or irritant variety are significantly reduced today in terms of both number and severity. But I'm not sure that the incidence or the prevalence of *Candida albicans*-induced diaper rash, particularly in children given amoxicillin for middle ear infections, has been influenced yet.

Spraker: Dr. Schuman, has there been any change in your practice with respect to antibiotic choice for middle ear infections?

Schuman: Yes. I'm quite sensitive to the claim that general practitioners and pediatricians have been overprescribing antibiotics for a long time, so I've been trying to prescribe them less. The thinking now is that in some situations you may not need to use antibiotics. There have been studies showing that middle ear infections can resolve by themselves.[6] However, I'm not sure what role that plays in the reduced incidence of diaper rash.

Leyden: But if you see a child with a middle ear infection and you decide you're going to prescribe an antibiotic, which would you use?

Schuman: Usually my first-line choice is amoxicillin, but at a higher dose than what was recommended previously.

Leyden: That's my point. Ampicillin and amoxicillin—which is ampicillin with a side chain—are

Diaper evolution

Time	Product	Absorbent	Outer cover
Preindustrial era	"Primitive" diaper	Grass, moss, leaves Linen or cotton "buttock clothes"	Animal skins Swaddling bands (linen or wool)
Late 1800s	Early diaper	Linen or cotton	Knitted wool
1880	Safety pin		
1930s–1960s	Commercial laundering services		
1940s	Modern cloth diaper	Cotton	Rubber pant
1950s	Modern cloth diaper	Cotton	Plastic pant
1961	Disposable diaper	Cellulose	Plastic
Mid-1980s	Disposable diaper	Superabsorbent material	Plastic
Late 1990s	Disposable diaper	Superabsorbent material	Breathable cover

Diapers: History and development

Cultural differences in diapering go back to ancient times. In most primitive societies, diapers weren't worn at all, and that is still true today in many warmer countries. In China, the mother anticipates her infant's bowel movements and holds the infant over a convenient receptacle or over the ground.

In other societies, a diaper equivalent was used. In some Native American tribes, mothers packed grass under a diaper cover made of rabbit skin; Innuits placed moss under sealskin. Infants have been "wrapped in swaddling bands" in many European societies since antiquity. Swaddling bands were strips of linen or wool 3 to 6 inches wide and 2 to 20 feet long that were wrapped tightly around each limb and then crosswise around the body. The groin area was left unwrapped so that absorbent "buttock clothes" of flannel or linen could be tucked underneath.

In Europe, it wasn't until the Industrial Revolution from 1820 onwards that the working people started taking pains to contain their infants' waste more carefully, having acquired sufficient wealth to buy household furniture and the need to protect it. By the late 1800s, infants in Europe and North America were wearing the progenitor of the modern diaper. A square or rectangle of linen, cotton flannel, or stockinet was folded into a triangular shape and held in place with a safety pin, which was introduced in the US in 1880 and replaced the hatpin. The absorbent cloth layer was covered by a "soaker" or "pilch" of tightly knitted wool to improve containment, and the infant was then placed on an absorbent quilt pad.

In the 1930s, commercial diaper laundering services appeared. The rubber pant was introduced as the outer diaper cover in the 1940s. It was popular for obvious reasons: it contained well and kept the outside of the diaper area dry. This allowed mothers to take their infants out of the house more easily, thereby liberating them to be "modern" women. In the 1950s, the plastic pant replaced the rubber pant. With the advent of the rubber and plastic pant, diapered skin was "sealed" for the first time.

Both home laundering and diaper services were used well into the 1960s. The disposable diaper revolution began in the United States in 1961 when Pampers were first introduced. In Europe, early forms of tissue-based disposable underpads and diaper inserts were made available as early as in the late 1930s in Sweden, followed by products using defibered wood pulp in the 1950s. In the mid-1980s a superabsorbent core was added, and since then there have been numerous refinements in diaper composition. Now disposable diapers are much thinner and have more efficient fasteners. They are more comfortable and convenient for infants and young children to wear. In addition to these benefits, there has been a marked reduction in skin irritation and spread of infectious disease.

—Bernice Krafchik, MB, ChB

particularly adept at selecting out *Candida* and allowing it to overgrow in the gastrointestinal tract.

Spraker: Is that more true for ampicillin and amoxicillin than it is for the cephalosporins, which are more commonly used in treating middle ear infections than they were 10 years ago?

Leyden: Yes. And if there has been a general change in prescribing, that could have an effect on the incidence of *Candida* dermatitis.

Spraker: Dr. Leyden, do you know why ampicillin and its derivatives would be more likely to promote *Candida* selection?

Leyden: I don't know the reason, but I know that it happens. I was involved in studies in the late 1960s on the effect of antibiotics on the gastrointestinal flora. We were particularly interested in how fast the flora became resistant and what ecologic changes would occur as a result. It was quite clear at that time that ampicillin had the greatest effect, with tetracycline second. There was less resistance to erythromycin and the sulfonamides. We did a similar prospective study at Children's Hospital in Philadelphia.[7] Most of those children were being given ampicillin, and it clearly changed the flora to allow overgrowth of *Candida*, if any was present initially.

Spraker: Why don't more babies get *Candida* diaper dermatitis? A large proportion of infants have gastrointestinal colonization of *Candida*.

Leyden: Actually, a large number of infants have low numbers of *Candida* in their stool. The use of selective media is required to demonstrate this colonization. However, if *Candida* is present, its growth increases dramatically when the baby is given ampicillin or amoxicillin.

I think we can agree that disposable diapers have revolutionized the way parents diaper their children and that the clinical benefits have likely been a key reason.

Mary Spraker, MD

Many other investigators have concluded that *Candida* is a secondary rather than a primary factor. I disagree, as do others who have studied *Candida*. Part of the problem is that when you see a child with a severe rash and you suspect *Candida*, often it is difficult to demonstrate its presence on inflamed skin. If you inoculate *C albicans* onto your forearm and occlude it with a dressing, in 24 to 48 hours you'll have a papulopustular eruption that will become increasingly inflamed. But if you then remove the dressing for a brief period and look at that site the next day, you won't be able to find *Candida* even though the area will still be inflamed.

We tested that. We took infants who had *Candida* in satellite pustules but not in the highly inflamed areas of a severe diaper rash. We asked the parents to keep these babies out of diapers for 2 days. When they came back 2 days later, the whole diaper area was fiery red, and we were unable to culture *Candida* anywhere unless we did a rectal swab. Yet 2 days earlier we had been able to grow the organism from skin samples. So the ability to grow *Candida* depends on when you come in on the sequence of events.

Schuman: Would you therefore advise treating an irritant dermatitis routinely with an antifungal?

Leyden: I don't see much irritant diaper rash, though general pediatricians do. The majority of cases I see as a specialist are of the more severe variety, and I suspect *Candida* in that setting. My approach for these severe cases is to give the infants an oral antifungal such as nystatin to eliminate the gastrointestinal reservoir and to treat the skin with a topical antifungal and topical low-strength corticosteroid. Not everyone agrees with me.

Krafchik: A group in Montreal studied this question and concluded that using an oral antifungal made no difference in the outcome of treating infants with a candidal diaper dermatitis.[8] They concluded that after 2 to 3 weeks, infants treated orally with nystatin and topically with antifungal creams had the same result as those who received just topical treatment.

Leyden: If you look at the end of 3 weeks and the child's no longer on antibiotics and the gastrointestinal flora is adjusting, that's true. But if you look after just one week, there's a big difference.

Krafchik: You've written about adding hydrocortisone topically.

Leyden: Yes, to treat the inflammatory response.[9]

Krafchik: Did you do a comparative study? Do you really feel that it makes a difference?

Leyden: Yes, absolutely. We set up an experimental system in which multiple sites were inoculated with the same number of yeasts and occluded in the same way. In these volunteers, who were inoculated with *C albicans* on several sites on each forearm, we were able to compare the effects of various treatments. The addition of a low-strength steroid significantly reduced the degree of inflammation compared with that of an antifungal agent used alone.

Krafchik: I think we can summarize by saying that several studies have documented an overall decrease in diaper dermatitis and that this has also been seen in clinical practice. As Dr. Schuman suggested, I think that decrease has to be related to the superabsorbent material.

Schuman: Yes, and I think we'll continue to see improvements. The amount of superabsorbent material in diapers has been increased and the amount of cellulose has decreased. That has improved the diaper's ability to draw moisture away from the skin. Other components have also been added to help keep skin dry—for example, acquisition layers that hold the urine and wick it through faster and more evenly to the superabsorbent material. They help prevent the "re-wet" phenomenon that used to occur when a child would sit on the diaper and push the moisture back through to the inner layer. We'll be talking more about this later.

The important thing is that parents can feel reassured that these technologies, especially superabsorbent material, improve skin health and hygiene and that they have undergone rigorous testing to ensure their safety.

James Leyden, MD

I've also noticed that there's less chafing because of improvements in the fasteners. That's significant, because if there's skin breakdown or irritation around the fasteners, often what follows is a full-blown rash.

Disposable diapers have also had a positive impact with respect to transmission of infection. Studies have been done on the spread of fecal material from one child to another, to a day-care worker, and to inanimate surfaces. These studies show that there's much less transmission of potentially infectious agents when disposables are used.[10] That's a very important contribution.

Causes and types of diaper dermatitis

Spraker: Now let's talk a little about the etiology of simple non-*Candida* diaper dermatitis. For years everyone was taught that ammonia was the cause. Dr. Leyden, you're the person who discredited the ammonia theory. Can you tell us how and why you did that?

Leyden: In the mid-1970s we were seeing lots of diaper rash at Children's Hospital in Philadelphia. I became convinced that there were two clinical variants. There was a severe type that I suspected was caused mainly by *C albicans*, and there was a more common type in which frictional forces seemed to be playing the major role. But, as you noted, the reigning theory in the literature then was that ammonia was the cause. When I looked for the source of that theory, I found it was traceable to one study done by Cooke in 1921.[11]

Krafchik: She claimed the offending organism was *Bacillus ammoniagenase*. This has now been shown to be a *Proteus* organism.

Leyden: Yes. On the basis of one experiment, Dr. Cooke concluded that bacteria were breaking down or releasing ammonia from urea and that the ammonia caused the diaper dermatitis. In fact, children with and without diaper rash do harbor many organisms that can liberate ammonia from urea. We did studies of children with and without various forms of diaper rash and noted what kinds of organisms were present. We showed that if you measured the ammonia present in urine at the first diaper change in the morning, you couldn't show any difference in the concentration or amount of ammonia that was produced.[12]

We tried exposing scarified skin to urine with and without urease and at various pH levels. When we put ammonia on scarified skin, we saw only slight inflammation. We concluded that ammonia or urine itself was not the major cause of diaper dermatitis. The hypothesis we generated at that point was that the majority of diaper rash cases—other than the more severe ones involving *C albicans*—were due to frictional forces on wet skin rather than to ammonia. There had been studies suggesting that wet skin was more vulnerable to friction; we did similar experiments and got similar results. Berg and coworkers subsequently confirmed our results.[13]

Krafchik: I may be old-fashioned, but I still suspect ammonia makes the rash worse, despite your findings. When we used to see babies with diaper dermatitis, we could always smell the ammonia.

Perhaps the most important impact of disposable diapers has been the decrease in the number of cases of diaper dermatitis that we see. Much of this change is due to the superabsorbent material added to the inner core of the diaper.

Bernice Krafchik, MB, ChB

Leyden: The nose is a tremendous detector. For some substances it beats gas chromatography-mass spectrometry. But the most we could show was that if you compromised the skin by scarification, you could get only a bit more erythema with ammonia exposure. It just wasn't a significant factor.

Schuman: Yet we used to be advised to add vinegar to the wash water when we washed cloth diapers—to lower the pH and counteract the ammonia.

Leyden: That's right. But probably if anything was important about washing cloth diapers, it was that they needed to be rinsed thoroughly so that there was no residual detergent on the surface that would then get onto the infant's skin and irritate it. In the cloth diaper era, that probably was very common.

Spraker: But weren't there other contributing factors? You mentioned pH, for example.

Leyden: There was general agreement back then that keeping urine acidified seemed to reduce irritation. As a result, cranberry juice and various ointments were rubbed on the skin to keep it more acidic. Buckingham and coworkers later demonstrated that, especially at an alkaline pH, a variety of proteases found in feces were capable of inducing irritation in a variety of experimental systems.[14] So the pH of the urine with its effect on fecal proteases was recognized as another factor in the pathophysiology of diaper dermatitis.

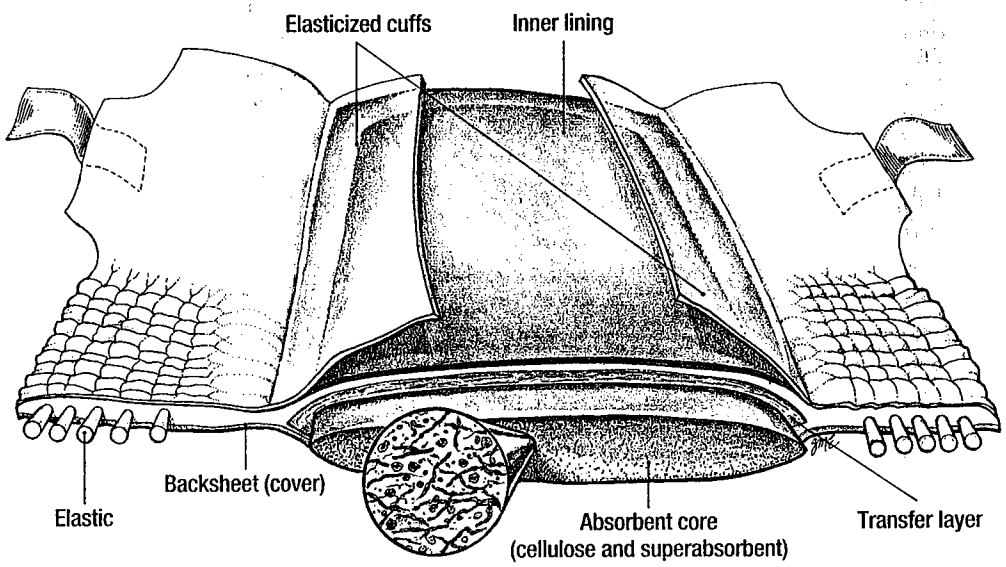
Still another factor that has not been well studied is the possible role of miliaria—failure to deliver sweat effectively to the skin surface. We demonstrated that, under occlusive dressings, plugs can develop in the acral portion of the sweat ducts and that certain organisms, particularly staphylococci, produce an extracellular polysaccharide-like substance that might be responsible.[15]

Spraker: The mildest diaper dermatitis we see takes the form of small erythematous macules or papules.

Leyden: I think that's miliaria—prickly heat.

Figure 1

Anatomy of a disposable diaper



The modern disposable diaper contains multiple layers of material, depending on the manufacturer's design, but has four basic zones of functionality. The inner layer or layers in contact with the infant's skin are made of polypropylene, a synthetic material that remains relatively dry while allowing liquid to pass through to the middle or transfer zone. The material in the transfer zone facilitates movement of the liquid away from the genital area to avoid "pooling." Moisture is then "wicked" to the superabsorbent gel material in the diaper core, which is able to absorb more than 80 times its weight of liquid. The fourth or outer layer, made of soft, textured, cloth-like polypropylene, prevents moisture from leaking through to the outer clothes or crib but is porous enough to allow humidity to escape.

Spraker: And it goes away without any specific treatment.

Krafchik: These explanations sound very plausible. But all babies experience wetness and presumably friction. So why do some get dermatitis while the others don't?

Leyden: One reason is that the stratum corneum varies a lot from one baby to another. We and others have shown that if you hydrate skin repeatedly and apply a standardized frictional force, after a certain amount of time the skin will begin to get red and eventually break down.[16] The time needed to produce that effect varies greatly from one baby to another, because the stratum corneum varies enormously in thickness and integrity.

Before superabsorbent disposable diapers were available, the skin of babies was repeatedly hydrated and essentially encased in the equivalent of a plastic bag. The diaper area was extremely humid, and the skin remained moist. The problem would vary according to the chubbiness of the baby, how much the baby was moving, and whether the caregiver was washing it too frequently or too abrasively. Hydrated skin is more easily abraded. That's why one licks a finger to turn pages—the skin moisture increases friction. All of those factors contribute to making the baby's skin redden and on occasion become severely inflamed.

Spraker: What about other factors contributing to dermatitis—or to its

decrease? What else besides the use of disposable diapers could explain the drop in incidence?

Schuman: Some studies have shown an association between breastfeeding and the incidence of diaper dermatitis, probably through some immunologic effect.

Leyden: Breastfeeding may alter the pH of the infant's feces to make them more acidic, and that could reduce the risk of dermatitis.

Spraker: So, in addition to the use of antibiotics, which encourages the growth of *Candida*, other secondary factors that can cause diaper dermatitis are frequency of changing, especially if there's a delay after fecal soiling, and breastfeeding—or rather lack of breastfeeding. What about diarrhea?

Leyden: Diarrhea certainly is not good. That would create another initiating factor.

Spraker: And the diarrhea associated with an illness may be different from normal stools. It may have a different pH and enzymatic activity.

Disposable diapers: Layer by layer

We've talked about the superabsorbent core. Let's focus now on diaper design and how the different components work [Figure 1]. From the standpoint of pure technology, these products are amazingly intricate and from the standpoint of safety, as we'll discuss later, they have undergone extensive testing [Tables 1 to 4]. Dr. Krafchik, can you talk about the inner layer—the layer that's closest to the infant's skin?

Studies have been done on the spread of fecal material from one child to another, to a day-care worker, and to inanimate surfaces. They show there's much less transmission of potentially infectious agents when disposables are used.

Andrew Schuman, MD

Krafchik: Yes. It's intriguing how many qualities that material has to fulfill. First, since it's the layer closest to the baby's skin, it has to be very smooth and soft. That's crucial for reducing friction. The inner lining also has to have wicking capability, so that the urine can pass quickly through to the center absorbent core. The inner layer itself stays dry and thus lessens hydration of the infant's skin.

Spraker: What is the inner liner made of?

Krafchik: The makers of the leading brands use polypropylene in the layer that is in contact with the skin.

Spraker: That's the material used in winter underwear for skiers and runners. It stays relatively dry while passing moisture through so that outdoor exercisers don't get as chilled. In the diaper, it also stays dry while wicking the moisture through.

Krafchik: That's correct.

Spraker: What's the next layer?

Krafchik: The urine goes rapidly through the soft inner layer and next encounters a transfer layer that temporarily holds the urine and moves it toward the superabsorbent core. The transfer material has been designed to be able to move the liquid uphill—in a child who's standing, for example—before it meets the available combination of fluff and superabsorbent material in the next layer. The transfer material allows the liquid to be distributed along the entire surface of the diaper rather than collect in a pool where it would first hit the diaper. It carries liquid away from that loaded area quickly so that the entire diaper is utilized for absorption. Then the superabsorbent material below grabs it and holds it.

Leyden: The original concept was, "Let's make the skin less wet." When the technology of the superabsorbent material came along, someone said, "Let's put it in diapers. Maybe that will make the skin less wet." And it worked. Then it became apparent that a lot of the urine was not getting to the superabsorbent gel inside. So the industry developed ways to channel or attract more liquid into the superabsorbent gel. Each new step con-

TABLE 1

Dermal allergy, irritation, and clinical tests

Type of test	No. studies	Results
Dermal allergy tests All tests were performed with dry particles and wet gel beads of superabsorbent.	67 (41 human)	No allergic effects
Guinea pig sensitization Material was tested for potential to induce an allergic sensitization reaction, usually by application to shaved skin topically or intradermally once per week (6 hours) for 3 weeks. After a rest period of 2 to 3 weeks, material was reapplied to a virgin site.		
Human repeat insult patch (RIPT) Material was tested for potential to induce an allergic sensitization reaction, usually after skin exposure for 9 to 21 days over 3 weeks, followed by a rest period of 1 to 2 weeks and reapplication of the material to the same and a virgin skin site.		
Dermal/mucous membrane irritation tests All tests were performed with dry particles and wet gel beads of superabsorbent.	184 (59 human)	Not irritating to skin or mucous membranes
Examples:		
Skin irritation tests; eye irritation tests; vaginal/penile irritation tests Material was applied to laboratory animal tissues, usually for up to 5 days. Behavior of animals was observed. Tissues were then graded for redness and swelling or other signs of irritation.		
Cumulative irritation tests in humans Panelists wore patches of the material for 21 days, usually on the back. A new patch was applied every day. Each morning the skin was graded for redness and swelling. This test assesses a material's ability to cause skin irritation that may not be evident until 2 to 3 weeks of continuous contact.		
Human scarified skin tests Material was applied for 3 days on skin where the stratum corneum had been breached.		
Clinical studies of human infants More than 200 infants wore superabsorbent diapers for 2 months and were observed weekly for skin irritation.	20+	No adverse effects noted. Reductions in the incidence and severity of diaper dermatitis were seen with superabsorbent diapers vs. non-superabsorbent diapers.

tributed to keeping the skin less wet. And that's why the incidence of diaper rash has been going down.

Spraker: In fact, the modern diaper has multiple layers and three to four zones of functionality, which underscores how complex these apparently simple products are. They're really very "high tech" devices.

Krafchik: In addition to these layers, there's also a special elasticized cuff to prevent leakage down the legs. It's generally made of the same material as the inner lining.

Spraker: The addition of this elasticized cuff in 1995 enhanced the leakage prevention properties of the diaper.

Now let's move on to the core. Dr. Schuman, can you tell us about that?

Schuman: The core is not homogeneous as you move away from the center. It varies in the amount of cellulose and the amount of superabsorbent material in particular places. About 10 years ago, the industry tried gender-specific diapers. The idea was to put most of the superabsorbent in a target zone, so there was more absorbent material in the crotch of the female diapers and more in the front of the male diaper. Now they've moved away from gender-specific diapers, but there is still more material at both primary urine entry points; that is, there is extra material where the urine's going to be, whether the baby is male or female.

Spraker: So there are two areas that are maximally loaded with superabsorbent material, but the material is also well dispersed, to utilize the other areas of the diaper for absorption and retention.

Dr. Leyden, would you finish our discussion of components by describing the outermost layer or "zone"?

Leyden: One of the trends in diaper technology is to make the outermost layer more and more vapor permeable so that it's less humid inside the diaper and the skin surface is therefore less wet.

Spraker: The outer layer or cover in the better grades of disposable diapers no longer feels like plastic. It feels like fabric.

Leyden: Yes. It's polypropylene and feels like cloth. It's still "plastic," but it's very soft, texturized plastic, and it's becoming more porous than the earlier covers in an attempt to reduce the humidity in the diaper area.

Schuman: From the practicing pediatrician's standpoint, there had been one minor drawback to the superabsorbent diapers. Before superabsorbents, we were able to extract urine quite easily from diaper material. That's more difficult to do with the superabsorbents. That's why in hospitals most NICUs still use diapers that don't have superabsorbent material. However, there have been two recent studies in which urinalysis and urine cultures were performed on extracted core material and were shown to be accurate.[17,18] That's encouraging, because using urine bags is much less convenient. It would be very helpful if we could just send the lab a wet superabsorbent diaper and say, "Test it."

Making diapers sound and safe

Spraker: Now let's talk about the important issue of safety. We've dis-

TABLE 2

Dermal absorption tests

Type of test	No. studies	Results
Acute dermal toxicity study Material was applied to the skin of laboratory animals for 24 hours at 2 g/kg of body weight, and behavior was observed for 14 days. The animals were then checked for signs of toxic effects on internal organs.	22	No effects noted
Subchronic dermal toxicity study Material was applied daily to the skin of laboratory animals for up to 30 days to determine whether it causes skin irritation or is absorbed through the skin to cause toxic effects on internal organs.	16	No effects noted

TABLE 3

Genotoxicity and development tests

Type of test	No. studies	Results
Genotoxicity/mutagenicity tests These tests were done to determine whether the material reacts with DNA or causes chromosomal aberrations or changes in chromosome number. ***Examples:*** **Ames test (*Salmonella typhimurium*) with and without metabolic activation** **TK+ mouse lymphoma test** **Rat in vivo cytogenetics** **Unscheduled DNA synthesis in rat hepatocytes** **Acute bone marrow cytogenetics in the rat** **Mouse micronucleus test**	55	Does not affect DNA
Developmental tests These tests were done to determine whether a material can induce birth defects in the offspring of pregnant laboratory animals after inhalation or oral administration of the material.	4	No effects seen

TABLE 4

Ingestion studies

Type of test	No. studies	Results
Acute oral toxicity study Superabsorbent material was administered orally as a single dose to laboratory animals at 5 g/kg of body weight. Animals were observed for behavior for 14 days and then checked for signs of toxic effects on internal organs. No animals died.	27	No effects noted*
Subchronic oral toxicity study These tests were designed to look for adverse systemic effects in laboratory animals fed measured amounts of superabsorbent over a period of 2 to 90 days. The tests were done to ensure there would be no ill effects if an infant accidentally were to ingest the superabsorbent by mouth.	24	No effects noted

*In all cases, the rat oral LD_{50} was greater than 5 g/kg of body weight and therefore "nonhazardous," according to the criteria established by the Federal Hazardous Substances Act (16CFR1500.3).

cussed how the superabsorbent in disposable diapers has helped reduce the problems of dermatitis and leakage so that disposable diapers are more convenient for parents, but is the superabsorbent material safe for babies and caretakers exposed to it? Could there be skin irritation or allergic reactions or even inhalation problems related to this material? And what would happen if a child should eat some of the core material?

We need to bear in mind that the average child wears 4,000 to 5,000 diapers before being toilet trained. Those diapers are in contact with areas that have extremely thin skin—particularly the genitals—so it's essential they be safe and nonirritating.

Dr. Leyden, you've been involved in some of the safety studies.

Leyden: According to hundreds of studies that have been done by various investigators as well as the manufacturers themselves, the materials that constitute disposable diapers appear to be very safe. In fact, more than 400 studies were performed specifically on the superabsorbent material. This is comparable to the number of studies the FDA requires to approve a new drug and far more than it requires to approve a medical device.

In addition, there have been many studies of effects on animal and human skin [Tables 1 and 2]. I've been involved in some of them, looking at the irritation potential as well as the true allergic potential of superabsorbent material. Again, no harmful effect has been demonstrated. That is despite applying the superabsorbent in both wet and dry forms to skin—both intact skin and skin where the stratum corneum has been breached by scarification as I described earlier. The diaper manufacturers do occasionally receive consumer inquiries on superabsorbent gel beads that sometimes escape from the diaper and appear on the skin. A large number of human studies have shown that these gel beads are safe for skin contact and cause no harm.

Finally, there have also been many tests both in animals and in humans on the superabsorbent material's ability to induce immunologic reactivity, and again no harmful effect has been observed. These results correlate with the experience of parents and their doctors that disposable diapers do not cause irritation or true allergic sensitization.

Spraker: How about mutagenicity or genotoxicity tests? That would refer to chemical effects that might induce changes in germ cells, possibly leading to genetic diseases, and in somatic cells, possibly leading to carcinogenesis. This would include DNA damage in one or a few DNA pairs, or mutations in the genes themselves, such as breakage, rearrangements, or changes in number.

Leyden: Those possibilities have been assessed in more than 50 independent studies [Table 3].[19] No mutagenic or genotoxic effects were seen. If any had been seen, the manufacturers would not have proceeded

with development and incorporation of superabsorbent material into these products.

Spraker: Dr. Schuman, can you comment succinctly on ingestion and inhalation?

Schuman: Yes. Again, many studies have shown that the ingestion of superabsorbent material is not harmful [Table 4]. So we don't need to worry about this material because it's been well demonstrated to be perfectly safe, even if accidentally ingested.

Spraker: But since the superabsorbent material absorbs water and swells, wouldn't it swell in the intestine if a child swallowed some of the gel material?

Schuman: The polymer particles in the diaper do swell. The particles in this material are 400 to 800 microns in diameter when dry, about the size of common table salt. They swell to three to four times that size when wet. But they don't stick together to form a mass. Studies done with animals showed the gel beads pass right through the gastrointestinal tract like little discrete beebees.

In addition, oral feeding studies for toxicologic assessment were done with rats in which superabsorbent material was added to their food in a dose of 3 grams per kilogram of body weight per day for 93 days.[20] That would be the equivalent of a child consuming an entire diaper every day. The only effect was some softening of the feces.

Spraker: What about possible exposure by inhalation to babies or their caretakers from using disposable diapers?

There have been many studies of effects on animal and human skin.... No harmful effect has been demonstrated, despite applying superabsorbent material in both wet and dry forms to both intact skin and skin whose stratum corneum has been breached by scarification.

James Leyden, MD

Schuman: That was also looked at in simulated diaper-changing studies. In several separately conducted studies, technicians changed 1,000 diapers on baby mannikins in 8 hours while the air quality was evaluated. Even under these highly exaggerated conditions, no breathable particles were found in the air.

Spraker: Dr. Krafchik, can you comment on the impact of disposable diapers on the environment?

Krafchik: As far as public safety is concerned, I think it's been shown that disposable diapers don't have any harmful effect. No toxicity has been demonstrated in the landfill sites where they're disposed of.[21–23] The manufacturers have been quite sensitive to environmental issues because of the early public concern about nonbiodegradable waste.

Spraker: In the past there has been concern about the sheer bulk of the diaper material going into landfill.

Krafchik: Numerous life cycle assessments were done in the 1980s and showed that disposable diapers did have an environmental impact but that alternative products also had comparable environmental impacts. If you use cloth, for instance, you have to use hot water, strong detergents, and energy for drying, thus depleting natural resources.

Today, since there's less bulk to diapers and less packaging, there's less material needing disposal. But manufacturers continue to work at reducing raw material usage and at making the manufacturing process less energy intensive.

Spraker: What about the possibility of recycling some of the materials?

Krafchik: In the late 1980s and early 1990s, there was some effort on the part of the manufacturers to recycle materials, but ultimately this was not feasible financially. Today, most solid waste in the US goes into landfill, including diapers, which have been estimated to be about 1% of the total landfill volume.

The superabsorbent material, however, actually has other uses. It could be recycled for horticultural applications, for example.

Spraker: Such as water trappers to add to your potted plants so that you don't have to water them as often?

Krafchik: Yes, because the material holds water and gradually releases it. There are studies that have shown there's no toxicity to soil organisms and that the material doesn't migrate into the ground water. It would be perfectly safe for the superabsorbent polymer to be present in soil and compost.[24] However, superabsorbent contaminated by feces would have to be sterilized first.

Schuman: Are there any other components of disposables that could be recycled?

Krafchik: You could recycle the plastic components, but it takes time and energy to separate, collect, and recycle them.

Schuman: So therefore it would not be cost effective. However, diapers could be considered as a potential power source. Plastic is derived from a fossil fuel, so you should be able to recover energy from it. But waste-to-energy incinerators haven't taken hold in the US because of the "not in my backyard" syndrome. That's done mostly in countries such as Japan, where they have no place to put solid waste. It can be done if the culture or society deems it necessary.[25]

Spraker: What about somehow making the diaper dissolvable so that it could go through the plumbing? That's where other fecal waste goes to get processed.

As far as public safety is concerned, I think it's been shown that disposable diapers don't have any harmful effect. No toxicity has been demonstrated in the landfill sites where they're disposed of.

Bernice Krafchik, MB, ChB

Schuman: The technology is not available yet to give us a good flushable top sheet and liner. The problem is that you would want it to disintegrate when it hits the water in the toilet but you wouldn't want it to disintegrate when urine hits it. In addition, diapers need to have a good shelf life. In some places diapers can be on the shelf for a year, enough to be affected by high humidity.

Spraker: So, to summarize, one of the other major concerns of the public is the environmental impact of disposable diapers. Studies have shown that any negative environmental impact they might have is comparable to that of the alternative diapering methods. Importantly, manufacturers have been working to reduce this impact by making diapers that use less material yet perform better.

Routine skin care and treatment of diaper dermatitis

The final areas we need to address are proper changing techniques and treatment of diaper dermatitis if it should occur. Dr. Krafchik, could you begin by describing your approach to the daily care of normal infant skin?

Krafchik: In general, babies handle diapers extremely well. Some people prefer to use an emollient like petrolatum on the skin. I don't think that is needed unless there is diaper dermatitis. My advice is to dampen a washcloth, gently wash the area, and then pat it dry during changing. When putting on the new diaper, you can either leave that area dry or apply a small amount of petrolatum.

Leyden: I agree that most babies do very well without special treatment. There's a general tendency for mothers and their doctors to think that infant skin is more vulnerable, but there's a lot of evidence to the contrary. In the absence of eczema, psoriasis, or a chronic rash, the skin of infants is actually quite hardy. In fact, you might say, "It's healthier because it's newer."

Krafchik: That's right. It's quite resistant naturally.

Leyden: It's quite capable of taking care of itself. So gentle cleansing is all you need. The technology of cleansing materials has also changed over the past 15 years. Detergents have become much more skin friendly, and infant wipes are milder as well.

Spraker: Dr. Leyden, do you think the diaper area needs to be washed after every change as Dr. Krafchik suggested? There have been studies showing that urine is not irritating, which would imply there's no need to wash the diaper area unless there's fecal soiling.

Leyden: I don't think you have to. But if you would like to, there are materials available now that allow you to do so without causing harm.

Schuman: How do you dermatologists feel about the propylene glycol that's included in some but not all of these cleansing products?

Leyden: Propylene glycol is innocuous until you get up to certain concentrations. It has to be around 10% before you can begin to show an irritant potential, and that's with exaggerated exposure. If it's in the 30% range, then it can definitely cause irritation.

Spraker: What about powders? My view is that they're not necessary because the inner layer of a disposable diaper is so smooth that the powder doesn't help reduce friction.

Leyden: That's right, but if you want to use a powder, cornstarch is preferable.

Many studies have shown that the ingestion of superabsorbent material is not harmful. So we don't need to worry about this material because it's been well demonstrated to be perfectly safe, even if accidentally ingested.

Andrew Schuman, MD

Schuman: Yes. It used to be thought that cornstarch would encourage the growth of *Candida*, but that's been disproven.[16]

Krafchik: I prefer not to use powder because it can mix with urine to become pasty and irritating.

Leyden: That's true for most powders, but not cornstarch. I once did a one-year project for the Army, which had an interest in friction. We looked at different powders and different ways of inducing friction, and we found that talcum powder intensified frictional forces on wet skin but that cornstarch reduced friction. Later I ran across an article in the lay press about long-distance bicycle riders who had found empirically that the best way to prevent erosions and irritations on their buttocks was to use cornstarch. Also, talc is dangerous. If accidentally aspirated by the infant it can cause pneumonitis.

Krafchik: Zinc is another ingredient used on skin, and some people think it has healing qualities. I've always thought of zinc oxide as an emollient. Does zinc have any medicinal qualities? Does it help in cases of dermatitis?

Leyden: It's difficult to study wound healing because there are so many variables that can't be controlled. But zinc is an interesting material that is found in a lot of systems and that has many possible effects. Probably zinc oxide has worked because it was a little more protective than petrolatum. It has antimicrobial effects at high enough concentrations.

Spraker: Dr. Schuman, as a pediatrician, how do you approach treating acute diaper dermatitis?

Schuman: The treatment varies with the appearance of the rash and the perceived cause. Irritant dermatitis is the most common variety I see, and one can argue that with mild cases you don't necessarily have to treat. Usually only a barrier paste or ointment or a mild steroid such as hydrocortisone is indicated. For *Candida* dermatitis, I prescribe a topical antifungal. Appropriate cleansing is also important when feces are present. And it's important

that the diaper be changed as soon as possible after fecal soiling.

We need to keep in mind that there are kinds of dermatitis associated with eczema, zinc deficiency, and other causes. So redness in the diaper area may not be just an irritant or *Candida* dermatitis.

Making a good thing better

Spraker: I'd like to conclude by touching briefly on the future of diapers. The diaper industry has created a wonderful product that has impressive technology behind it. A tremendous amount of research has gone into developing it, and it's working. We've all said that it's made a difference in the health and quality of life of families. But there are still opportunities.

A flushable, biodegradable diaper is certainly one of them. And we still are seeing children who have diaper dermatitis due to diarrhea or abnormal stooling patterns. Is there something that can be done to change how the diaper interacts with stool? And, of course, decreasing diaper cost further is always a goal.

Leyden: Yes. I think diaper manufacturers will continue to improve the technology of diapers with the goal of eliminating diaper rash. The important thing is that parents can feel reassured that these technologies improve skin health and hygiene and that they have undergone rigorous testing to ensure their safety.

Studies have shown that any negative impact disposable diapers might have is comparable to that of the alternative diapering methods. Importantly, manufacturers have been working to reduce this impact by making diapers that use less material yet perform better.

Mary Spraker, MD

Spraker: Thank you all for sharing your expertise and your experience with us. □

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