



A SUPPLEMENT TO *Pediatric News*[®]

CLINICAL POSTER HIGHLIGHTS

Protecting the Infant Skin Barrier:

ADVANCES AND INSIGHTS

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INTRODUCTION

Protecting the Infant Skin Barrier: Advances and Insights

By Professor Michael J. Cork, BSc, PhD, MB B Chir, FRCP
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The skin barrier, located in the upper part of the stratum corneum, protects the skin from the penetration of irritants and allergens and the loss of water from the viable epidermis.¹ It had previously been thought that a healthy, full-term neonate would have a similar skin barrier structure and func-

tion as that seen in adult skin. However, the combination of more-sophisticated skin barrier assessment techniques, such as closed chamber transepidermal water loss (TEWL) and Raman confocal microscopy, has shown that a baby's skin is completely different from that of an older child or adult.^{2,3} The stratum corneum in a term neonate has fewer layers and smaller corneocytes than does an adult stratum corneum.² This means that the skin barrier reserve in a term neonate's skin is much less than that in adult skin, making it much more vulnerable to the penetration of irritants and allergens and the loss of water.¹

Chu et al⁴ evaluated skin physiology in infants and adults from the United States, India, and China. They measured TEWL and high-frequency conductance on the dorsal forearm and upper inner arm and discovered that both parameters are high in infant skin, when compared to adult skin. There was a gradual decline in TEWL, which continued through 4 years of age, before the skin's water-handling properties reached the levels seen in adult skin. The same differences in skin barrier function were found in infants from the United States, India, and China. The data in this poster are therefore consistent with the large study performed by Nikolovski et al.² These observations give us a new insight into why skin diseases that arise as a result of a defective skin barrier, such as atopic dermatitis, start in the first year of life when the skin barrier is normally "defective" relative to that of an older child.

The environment on the surface of the skin interacts with the defective skin barrier in a neonate, leading to further thinning of the barrier, irritant and allergen penetration, and inflammation. This is the most important event in the development of atopic dermatitis and diaper dermatitis. Stamatias et al⁵ demonstrated that the pH and TEWL of infant skin under the diaper in areas with no clinical dermatitis were higher than skin on the thigh. Urine breaks down to produce ammonia, which raises the skin pH. Feces contain proteases that break down the skin barrier. The activity of proteases is enhanced at higher pH. This illustrates why it is essential to effectively cleanse the diaper area to remove feces and urine while reducing the pH of the skin surface in order to prevent napkin dermatitis.

Designing the optimal cleanser for a neonate's skin

Cleansers contain surfactants that are essential to solubilize fat-soluble substances, including feces, saliva, and foods. All of these substances can damage the skin barrier and so must be removed. However, because the skin barrier is defective in a neonate's skin relative to that of an adult's skin, the surfactants must be the mildest possible, so that they do not damage it.

A review of cleansers over the centuries points to rapid advances in the 1940s and 1950s with the development of the first synthetic amphoteric surfactant, the first reduced-pH glycerin soap, the introduction of Syndet (synthetic detergents), and the first ethoxylated sorbitan laurate.⁶

Complexing surfactants together to produce large micelles results in much milder products than do the small micelles of single surfactants. This is because the small micelles can penetrate easily into the skin barrier, leading to skin barrier damage and inflammation. In contrast, the large complex surfactant micelles do not penetrate the skin barrier and as a result do not damage it. Recently developed hydrophobically modified polymers may hold the key to even milder yet effective cleansing agents.⁶

A recent study demonstrated that an infant skin care product containing large-micelle surfactant complexes does not damage the maturing skin barrier of healthy newborns.

Introduction (continued)

Investigators from Charité-Universitätsmedizin Berlin in Germany conducted a prospective, randomized controlled trial that compared a wash gel alone, a wash gel with an after-bath emollient cream, and a clear water bath over an 8 week period.⁷ Skin barrier function was measured using TEWL, stratum corneum hydration (SCH), skin pH, and sebum analysis. The wash gel alone and water alone had similar effects on all of the skin barrier measurements. The combination of the wash gel and an emollient cream was shown to reduce TEWL and increase SCH, compared to bathing with water alone.

The safety of products used on a baby's skin

Any product containing water such as a cream or wash product will become rapidly contaminated with bacteria and fungi from the air and the user's skin during use. Regulators such as the US Food and Drug Administration (FDA) have provided guidance on the safety of effective preservative systems for use in topical products and may remove from market any product that is inadequately preserved.

The hazards of topical creams that do not contain preservatives was illustrated by the case reported by Sultan et al.⁸ A 2-year-old child with atopic dermatitis developed multiple abscesses and impetiginized eczematous lesions that were not controlled despite repeated courses of intravenous antibiotics. The source of the recurrent infections was found to be a preservative-free cream that the parents had obtained from an unlicensed manufacturer. Culture of this cream revealed 10 million *Staphylococcus aureus* cells per mL. Once the *bacterially contaminated, unpreserved cream* was discontinued, the child's infections rapidly resolved. This was far from an isolated incident and illustrates the importance of using adequately preserved products including those containing effective, safe preservative systems.

Effective preservation of topical products is essential for both infant and adult skin. The normal human biome is important for protecting the skin against colonization by pathogenic bacteria. Further evidence to support the belief that infant skin is significantly different from adult skin can be gleaned from another poster presented by Capone et al⁹ at the 2010 International Pediatrics Association (IPA) meeting in South

Africa. When skin swabs from 31 infants (1–12 months of age) were cultured, Firmicutes were found to predominate, which is in contrast to adult skin, which is predominated by Actinobacteria. In this study, the infant biome was shown to evolve over time, at least through the first year of life and likely longer, and microbial diversity increased with age.

Melanin pigmentation in infants and the importance of effective, safe sun protection

Mack et al¹⁰ investigated seasonal changes in facultative skin pigmentation among infants exposed to ultraviolet (UV) radiation. This study looked at infants during their first summer of life and found that facultative pigmentation increased substantially from May through September 2006 (New Jersey, USA). Similar results were observed in a second group of infants in their second summer. Both sets of infants experienced increases in apparent melanin concentration comparable in magnitude to that seen in their mothers. This poster demonstrated the low levels of melanin in infants at birth and their vulnerability to the damaging effects of UV radiation. This highlights the importance of sun protection for the neonate, which should involve advice regarding sun avoidance, including not putting an infant in direct sunlight. This should be combined with education on avoiding peak hours, using clothing and hats, and the proper use of sunscreens; how much to use, how often to use and how to correctly apply.

A poster by Bonner et al¹¹ highlighted the importance of infant sunscreen products that are specially formulated for babies' skin and are mild to their eyes. They should provide effective UV protection against critical wavelengths of both UVA and UVB rays. An ideal sunscreen for babies should achieve a sun protection factor (SPF) to protection factor UVA (PFA) ratio of at least 3:1, remain physically stable, and have a safe, effective preservative system to maintain the product free from bacteria and fungi. It is important that the sunscreen is easy to apply uniformly on the skin to offer effective sun protection over all of the skin. Bonner et al tested 17 sunscreen products, and only half of them met criteria for eye mildness. More than a third did not meet the minimum 3:1 SPF:PFA ratio recommended by experts. Of equal concern were the poor findings on antimicrobial robustness

and physical stability at various temperatures. Findings from this study also showed potential advantages of a novel, lamellar and spherulitelike formulation to achieve all criteria at an acceptable cost.

The inorganic UV radiation filters zinc oxide (ZnO) and titanium dioxide (TiO₂) are used in infant sunscreen products because they are inert and unlikely to cause cutaneous irritation. Several studies in adults have demonstrated that ZnO and TiO₂ do not penetrate through the stratum corneum.¹² It was important to repeat these studies in baby's skin because of its thinner stratum corneum. Stamatias et al¹³ applied a single application of an SPF 40 sunscreen on the skin of 10 infants between the ages of 6 and 11 months. Confocal laser scanning microscopy (CLSM) images showed that particles of ZnO and TiO₂ concentrated on the top of the stratum corneum and at the microrelief lines in both adults and infants after a single application. Raman focal spectroscopy (RCM) did not show penetration of the particles beyond the stratum corneum of adults or infants. The data presented here are some of the first to demonstrate that following topical application, particles of ZnO and TiO₂ were

not detectable in layers of the skin deeper than the stratum corneum in infants. By both methods, TiO₂ and ZnO particles in the sunscreen formulation do not appear to penetrate deeper than the first few layers of the stratum corneum in both infant and adult subjects. As in adults, statistically significant particle concentrations were not observed in the stratum granulosum of infants. These findings add to the weight of evidence reconfirming the safety of ZnO and TiO₂ for use in sunscreen products.

The posters in this supplement give an insight into some of the advances in our understanding of the structure and function of infants' skin and how we should treat their skin. The skin of an infant is different from adult skin. This includes a thinner skin barrier, less melanin pigmentation, and a developing biome. This makes the infant's skin more vulnerable to the effects of numerous environmental factors, including harsh surfactants, urine, feces, and UV radiation. Advances in skin formulation technology have led to products that are designed to enhance rather than damage the skin of an infant. The first clinical trials are demonstrating the beneficial effects of these products on the skin of neonates.

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10. Mack M et al. Development of Solar UVR-related pigmentation begins as early as the first summer of life. Poster presented at: 26th International Pediatric Association Congress of Pediatrics 2010; August 4-9, 2010; Johannesburg, South Africa.
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Micronized Sunscreen Particles Were Not Shown to Penetrate Beyond the Stratum Corneum in Adults or Children

Authors:

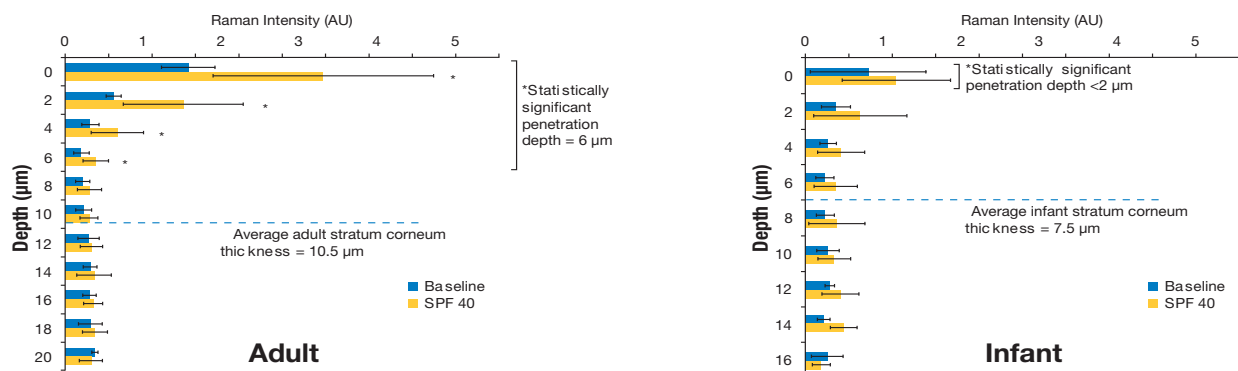
G.N. Stamatas, Johnson & Johnson Consumer France, Issy-les-Moulineaux, France; M.C. Mack, Johnson & Johnson Consumer Companies, Inc., Skillman, NJ; P. Horowitz, Discovery Pediatrics, Valencia, CA, USA

This research team recruited 10 infants and 12 adults to measure the absorption of zinc oxide (ZnO) and titanium dioxide (TiO₂) on the skin after a single application. A sunscreen containing 5% ZnO and 12.17% TiO₂ was spread over a 3-cm by 3-cm site on the forearm and allowed to remain in contact with the skin for 30 minutes with residual product then being removed, and a confocal laser scanning microscope (CLSM) was used to capture images of the stratum corneum and epidermis. A Raman confocal spectroscopy was also used to evaluate these same areas of the skin.

CLSM images showed that micronized ZnO and TiO₂ particles concentrated on the top of the stratum corneum and at the microrelief lines in both adults and infants after a single application of the sunscreen (Figure). Similarly, microspectroscopy was not able to show particle penetration beyond the stratum corneum in either adults or infants. There was no evidence that any of the particles reached into the stratum granulosum.

This study found that the particles did not appear to penetrate the skin beyond the first layers of the stratum corneum; this finding provides additional evidence to confirm what several others have found; namely, that physical particulate sunscreen filters such as ZnO and TiO₂ do not penetrate into the viable epidermis. Particulate sunscreens are also inert and, therefore, may be preferable to other sunblocks, commonly referred to as “chemical” sunblocks, for sensitive skin such as that of a baby.

Figure. Penetration Profiles of TiO₂ and ZnO in the Epidermis Can Be Quantified by Integrating the Area Over 400 to 500 cm⁻¹ in Curves Generated From Raman Spectra



TiO₂ and ZnO do not appear to penetrate below the stratum corneum in adults, which averages 10.5 µm in thickness. Similarly, TiO₂ and ZnO do not penetrate below the stratum corneum in infants, which has an average thickness of 7.5 µm. These results suggest that sunscreens that contain mineral-based pigments (TiO₂ and ZnO) do not penetrate beyond the stratum corneum in adults or infants.

Courtesy of Johnson & Johnson Consumer Products Company. Used with permission.

Commentary From Professor Cork

These data add to the body of literature that reasserts the safety of nonabsorbable sunscreens containing ingredients such as ZnO and TiO₂. Ultraviolet (UV) protection should begin early and continue throughout childhood with techniques and sunscreens designed and tested for children.

In our clinic, we recommend sunscreens with ZnO and TiO₂ for several reasons. Besides their long history of safe use, both filters absorb as well as scatter and block UV radiation while protecting against critical wavelengths of UVA and UVB. ZnO and TiO₂ also provide immediate protection, so there is no need to wait 30 minutes before they take effect. They are also photostable and do not penetrate beyond the upper layers of the stratum corneum.

Reference: Stamatas GN, Mack MC, Horowitz P. Micronized sunscreen particles were not shown to penetrate beyond the stratum corneum in adults or children. Poster presented at: 26th International Pediatric Association Congress of Pediatrics 2010; August 4-9, 2010; Johannesburg, South Africa.

Cross-Cultural Differences in Infant and Toddler Sleep

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The purpose of this large-scale, cross-cultural survey was to compare sleep patterns and problems among infants and toddlers up to 3 years of age. The researchers asked the parents of more than 29,000 children from 17 countries—including Australia, Canada, China, Hong Kong, India, Indonesia, South Korea, Japan, Malaysia, New Zealand, Philippines, Singapore, Taiwan, Thailand, United Kingdom, United States, and Vietnam—to participate in an online survey using the validated Brief Infant Sleep Questionnaire. Their findings indicate significant differences between children from predominantly Caucasian countries and predominantly Asian countries/regions. For instance, children's bedtimes varied widely, with New

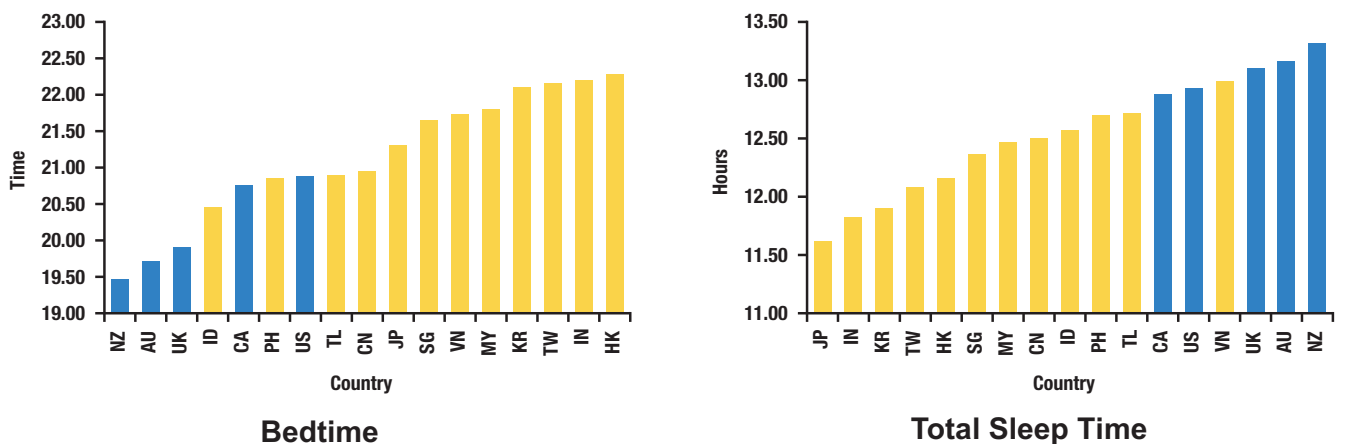
Zealand parents putting infants and toddlers to sleep at 7:27 PM on average versus 10:17 PM in Hong Kong. Similarly, total sleep time varied, with Japanese children sleeping an average of 11.6 hours, compared to 13.3 hours in New Zealand (Figure). Data on parent-perceived sleep problems were not as clearly divided between Caucasian and Asian countries, however. Vietnam, Japan, and Thailand study participants reported the fewest sleeping problems, compared to study participants from Hong Kong, Taiwan, and China, who reported the most. Study participants from Great Britain, United States, Canada, Australia, and New Zealand were near the middle of the frequency range.

The survey also found significant differences in room sharing and bed sharing among countries. Parents in Caucasian-dominant countries were far less likely to report that their children either shared their bed or their room. In Canada, for instance, 15.1% of study participants reported room sharing versus 94.5% study participants in Thailand.

In summary, in Caucasian countries, young children obtained more sleep, had later bedtimes, and were less likely to share a room, when compared to their Asian counterparts.

Figure. Bedtimes and Total Sleep Times

Significant variability in bedtimes were found, ranging from 19:27 (NZ) to 22:17 (HK); $P < 0.001$.
Variability in total sleep time was also found, ranging from 11.6 (JN) to 13.3 (NZ) hours; $P < 0.001$.



Courtesy of Johnson & Johnson Consumer Products Company.
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Cross-Cultural Differences in Infant and Toddler Sleep (continued)

The results from this study form what is currently the largest cross-cultural database of sleep patterns and problems in infants and toddlers (0–36 months). Further studies are

required to more completely understand the implications, if any, that these interesting differences in sleep patterns may have, particularly relating to children's health.

Commentary From Ms Vernon

This study found a link between parents and infants sharing a room or a bed and the amount of sleep that the infants obtain. In Caucasian-predominant countries, where young children are less likely to be sharing a room or bed, children seem to have fewer sleeping problems.

Overall, these study results indicate substantial cross-cultural differences in sleep patterns in young children. In this study, infants and toddlers in predominantly Asian countries obtain less overall sleep, have later bedtimes, are more likely to room share, and are perceived to have more sleep problems than are young children in predominantly Caucasian countries. In contrast, minimal differences were found in daytime sleep (naps). In addition, between 25% and 50% of parents across these parts of the world perceive that their child has a sleep problem, an area that clearly needs to be addressed by health care practitioners worldwide.

Furthermore, clinicians in the field of pediatric sleep should develop a culture-sensitive perception and intervention approach. These results provide a cultural perspective that can serve clinicians to be aware of the normative parenting practice of room sharing in predominantly Asian countries that may also be related to practices or beliefs held by immigrants from these countries. It also suggests that complaints about young children's sleep could be highly dependent on cultural expectations and norms and should be assessed individually on the basis of the actual sleep difficulties of the child. Finally, further studies are needed to understand the basis for and the impact of these striking differences, as well as to expand our study of infant and toddler sleep to other areas of the world (eg, Latin America, Europe, and Africa).

Development of Solar UVR-Related Pigmentation Begins as Early as the First Summer of Life

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Seasonal changes in pigmentation and the accompanying photodamage have been well documented in adults exposed to ultraviolet radiation (UVR), and the apparent effects of UVR-induced erythema and pigmentation have been used to gauge the amount of UVR exposure in this population. This phenomenon has been less well documented in infants, and unique differences in infant skin, especially its lack of facultative pigmentation in exposed sites, may make it particularly vulnerable to UVR exposure.

The purpose of this preliminary study was to determine what kind of seasonal changes in skin pigmentation occur in Caucasian infants and adults exposed to solar UVR. The investigators recruited (a) 7 infants during their first summer who were between 6 and 12 months of age at the start of the study, (b) 8 infants during their second summer who were between 16 and 24 months of age at the start of the study, and (c) 11 of the infants' biological mothers (30–40 years of age). Skin measurements were taken in May 2006 (pre-summer assessment), September 2006 (summer assessment),

January 2007 (post-summer assessment), and April 2007 (pre-summer assessment). Mothers were instructed to follow their normal skin care routine for themselves and their babies.

Facultative pigmentation before the infants' first summer, as measured by apparent concentration of melanin, was negligible, but increased significantly from May 2006 to September 2006 ($P < 0.05$) (Figure). Likewise, among infants assessed during their second summer, facultative pigmentation increased significantly from May to September 2006 ($P < 0.05$). In fact, the increases in facultative pigmentation after the summer months in both groups of infants were similar in magnitude to those seen in their mothers.

Consistent with this facultative pigmentation data, skin color (as measured by a Chroma Meter CR-300) was darker and more yellow-toned after summer in all three age groups. In aggregate, the data suggest that as early as the first summer of life, infants experience significant exposure to UVR and its associated risk of photodamage.

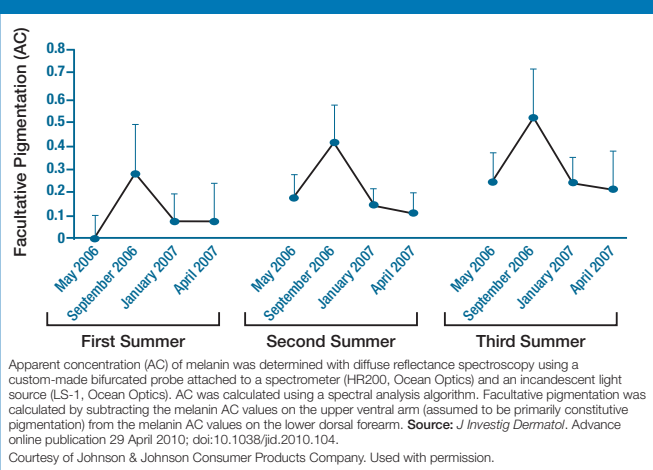
Commentary From Professor Cork

The fact that facultative pigmentation in these infants was similar to that seen in their mothers indicates that babies are getting a lot of sun exposure. The concern is that from birth their skin contains little melanin and is very vulnerable because it is much thinner than adult skin—making it quite susceptible to photodamage.

The take-home message here is that parents are not really being careful enough in terms of providing sunscreen protection. It is important to provide UV protection from birth on.

The best products contain zinc oxide and titanium dioxide, the most effective UVR filters for children's sensitive skin. In addition to protecting babies and young children from direct sun and peak daylight hours using clothing and hats, using a baby-appropriate sunscreen that is applied regularly and in sufficient quantity is recommended. Some regulatory agencies, like the US Food and Drug Administration, require parents to check with their doctor before using a sunscreen on babies younger than 3 months. In my practice, we recommend use of a sunscreen with a sun protection factor of 30 or greater from very early on.

Figure. Seasonal Facultative Pigmentation Changes Are Similar in Infants and Adults



Reference: Mack MC, Tierney NK, Ruvolo E Jr, Stamatias GN, Martin KM, Kollias N. Development of solar UVR-related pigmentation begins as early as the first summer of life. Poster presented at the 26th International Pediatric Association Congress of Pediatrics 2010; August 4-9, 2010; Johannesburg, South Africa.

Efficacy of an Internet-Based Intervention for Infant and Toddler Sleep

Authors:

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Although behaviorally based interventions can be quite effective in treating sleep disturbances—a problem that affects up to 30% of infants and toddlers—most treatment plans require personal contact with a health professional. The purpose of this study was to determine the efficacy of an Internet-based intervention for infant and toddler sleep, which, if successful, might allow wider access to effective therapy. Investigators undertook a controlled, randomized 3-week study involving 264 mothers of children (6–36 months of age) with common sleep disturbances.

A control group was assigned to follow their usual bedtime routine for the duration of the study. The two experimental groups followed recommendations accessed through an online Customized Sleep Profile (CSP) for their child's sleep after a 1-week baseline (usual bedtime routine). This entailed customized behavioral recommendations, including the practice of allowing the child to fall asleep independently. The second experimental group completed the CSP and was additionally provided with a specific bedtime routine of a bath, lotion, and quiet activities. To measure the effects of the three protocols, mothers completed the Brief Infant Sleep Questionnaire, the Pittsburgh Sleep Quality Index, and the Profile of Mood States™.

Children in the two experimental groups showed significant improvements in all problematic sleep behaviors, including improved sleep latency, 25.3 versus 14.4 minutes,

which translated into a 43% decrease from baseline after 2 weeks. Similarly, the number of night wakings diminished from 1.8 to 1.0 (44% decline), and sleep continuity improved by 36% ($P < 0.001$). The researchers also reported significant improvements in maternal sleep and mood ($P < 0.001$). There were only minor improvements seen in the control group, primarily for sleep continuity and parental perception of a sleep problem. This is likely the result of increased awareness and parental monitoring of the child's sleep. These results suggest that sleep disturbances in young children do respond to online interventions, and these benefits seem to extend to their parents as well.

Commentary From Ms Vernon

When a parent is in the pediatrician's office, there is often a lot of commotion—the baby may be crying, there may be another toddler in the room—so a mother may find it difficult to absorb educational information about good sleep hygiene. One of the advantages of an Internet program like this is that it allows parents to take in information at their own pace in a quiet, low-stress environment.

The other advantage of an online program is that it may foster more open, honest responses. Sometimes in an office setting, parents are hesitant to admit certain behavioral problems, so we often hear, “Oh, my baby sleeps fine,” from a mother and then hear the real truth somewhere down the line from another family member. Parents may be more willing to honestly discuss such problems during an anonymous online assessment.

Of course, I would hope that families who are being evaluated with this kind of Internet program are also receiving routine pediatric care in person as well.

Impaired Skin Barrier Function in Mild and Moderate Diaper Dermatitis

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This was a controlled prospective study in which 16 infants with mild to moderate diaper dermatitis were compared to 20 infants without any clinical skin symptoms; all 36 infants were between 3 and 24 months of age.

Using noninvasive bioinstrumentation, investigators evaluated (1) a section of each infant's upper thigh that was outside the diaper to serve as a control, (2) a nonirritated section of the buttock inside the diaper as a second control, and (3) a section of skin affected by the rash among the infants with dermatitis.

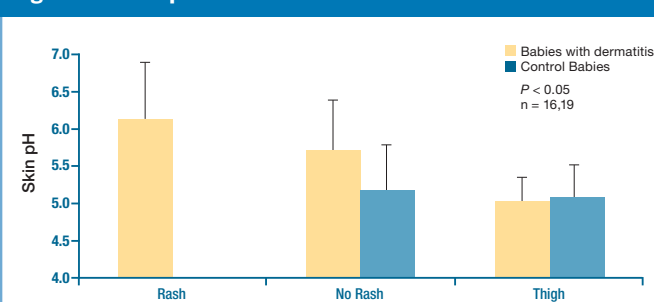
Researchers assessed four parameters:

- Transepidermal water loss (TEWL)
- Skin moisture level, as indicated by skin conductance
- Skin pH
- Skin erythema by means of diffuse reflectance spectroscopy.

Skin testing revealed that concentration of oxyhemoglobin—a biomarker for erythema—was significantly higher on the dermatitis site, when compared to both the nonirritated skin outside the diaper and the unaffected skin under it ($P < 0.05$). Similarly, TEWL and moisture, as measured by skin conductance, were higher in the rash areas, when compared to the two control sites ($P < 0.05$) (Figure). And, finally, the bioassessment indicated that among babies with diaper dermatitis, skin pH was significantly more alkaline in both diapered areas (the rash site and control skin) ($P < 0.05$). The findings suggest that covering an infant's skin, in and of itself, can disturb the skin's barrier function.

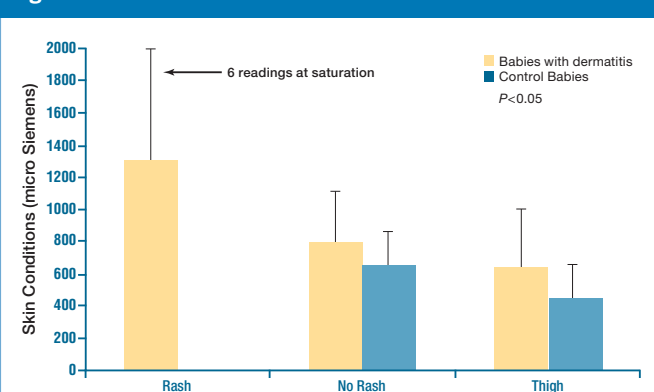
Additionally, the skin's natural protective acid mantle can be perturbed under the diaper, even in the absence of rash.

Figure 1. Skin pH



Courtesy of Johnson & Johnson Consumer Products Company. Used with permission.

Figure 2. Skin Conductance



Courtesy of Johnson & Johnson Consumer Products Company. Used with permission.

Commentary From Ms Vernon

What is important to highlight in this study is the fact that the skin of children with dermatitis was significantly more alkaline under the diaper, even in those areas that had not developed a rash. An alteration in the pH of the skin can compromise the protective barrier against bacterial infection.

Comparison of Infant Skin Development in New Jersey, Mumbai, and Beijing

Authors:

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The goals of this international study were to evaluate the differences between adult and infant skin and to determine if there are differences in the way an infant's skin develops and reacts to environmental factors in various regions of the world. With these aims in mind, researchers measured transepidermal water loss (TEWL), conductance, skin color, and apparent melanin concentration in infants in New Jersey, USA; Mumbai, India; and Beijing, China. Facial imaging measurements were also made with visual, cross-polarized, and ultraviolet (UV) fluorescence modalities.

The study found that there were similarities in the development of infant skin water-handling properties in all three regions; likewise, there were similarities in skin color and chromophore changes with exposure. TEWL and conductance were high in infant skin and decreased with barrier development as the children grew older and their skin matured. Exposure to the environment apparently accelerated this barrier development; apparent melanin content increased

and their skin darkened and appeared more yellow with exposure. From these findings, it appears that an infant's skin development continues through 4 years of age before the skin's water-handling properties become indistinguishable from that found in adults.

Evaluations on Chinese infants revealed significant differences in their skin. Facial images obtained in the winter in Beijing show marked differences from those obtained in the other locations, with pronounced facial erythema on the cheeks and chin in more than 75% of the children in this study. In some cases, the redness was accompanied by scaling. The erythema and scaling observed in the images correlated well with the dermatologists' visual assessment. Dermatologist assessment indicated that 68% of the infants in this study exhibited facial erythema, and 50% of the infants in this study had facial dryness. The pronounced redness seen in Chinese children was not observed in New Jersey infants despite the fact that both groups were assessed during the winter. The researchers speculated that the cold, dry winter in Beijing and certain seasonal and regional skin care regimens may have contributed to the differences.

In summary, the researchers concluded that (1) infant skin undergoes a development period that lasts for years, not months, before its water-handling properties and skin color become indistinguishable from those of adult skin and that these changes are independent of region, and (2) exposure to environmental elements has significant effects on the development of infant skin.

Survey of Bacterial Diversity on Infant Skin Over the First Year of Life

Authors:

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Whereas, the importance of the human skin biome is just beginning to be appreciated for adults, little is known about the infant skin biome. To determine microbiological differences and/or similarities between infant and adult skin, a research team took skin swabs from the arm, forehead, and buttocks of 31 infants, dividing them into three age groups: 1 to 3, 4 to 6, and 7 to 12 months (Figure). DNA analysis of more than 800 species revealed that Firmicutes predominated in infants, compared to Actinobacteria in adults.

The researchers also discovered differences in infant flora by body site, with streptococci, staphylococci, and propionibacteria being most prevalent on the forehead; streptococci, staphylococci, and corynebacteria being most prevalent on the

arms; and clostridia, streptococci, and ruminococci being most prevalent on the buttocks.

This research makes it clear that (1) infant flora are site specific, (2) the infant biome continues to develop over time, at least through the first year of life, and (3) the diversity of species on an infant's skin increases with age.

Commentary From Professor Cork

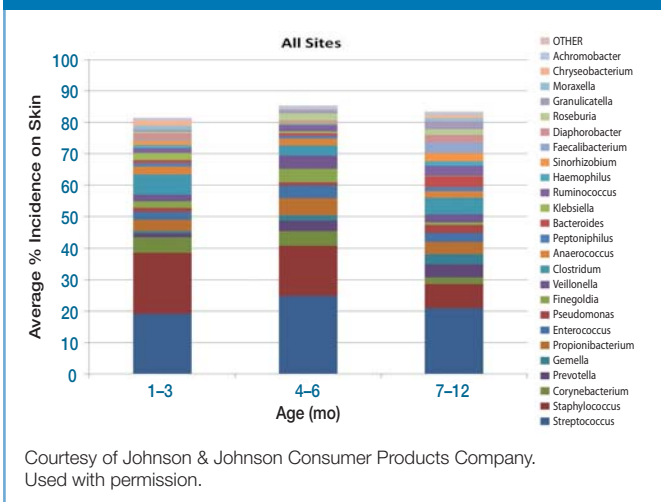
The poster by Chu and associates offers strong evidence of the differences between infant and adult skin, and these differences are pretty universal regardless of region. It also underscores the fact that environmental exposure results in additional changes to the skin and these changes may differ by region.

In addition to the structural and compositional differences between infant skin and adult skin reported in other studies and the functional differences reported in the poster by Chu et al, the poster by Capone et al documents differences in the infant biome. Interestingly, Firmicutes dominate on infant skin; whereas, Actinobacteria are more prevalent in adults. It is also interesting to note that the infant biome continues to develop through at least the first year of life.

Also of value in this investigation is the documentation of Firmicutes as the normal flora in young children. Maintaining this normal flora is essential to protecting an infant's skin and preventing the overgrowth of pathologic microbes. Similarly, this finding may prove valuable for future testing approaches of cleansing agents because it could provide a benchmark to use when gauging a product's potential to harm the skin or keep it healthy.

The presence of clostridia on the infants' buttocks is also worth noting and highlights the importance of good skin hygiene. The posters by Walters et al and Bartels et al (also reviewed in this supplement) point to the need for a hygiene program that includes more than plain water.

Figure. Species Diversity Changes Over the First Year of Life; Low-Predominance Genera Increase in Abundance With Age



Technological Advances in Cleansers for Infants: A Historical Review and Look Towards the Future

Authors:

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This historical review of infant cleanser technology began with the first recorded manufacture of soap in ancient Babylon; the ancients combined animal fats with lye to create an effective but relatively harsh cleanser that eventually gave way in the late 19th century to higher-quality cleansers. The 1900s saw the introduction of Ivory, Palmolive, and Lever soaps. Technical advances in synthetic chemistry during World Wars I and II led to rapid innovations in the 1940s and 1950s, including the introduction of the first synthetic amphoteric surfactant (General Mills); the first glycerin bar soap (Neutrogena), which reduced pH; the development

of Syndet, a synthetic detergent that further reduced pH (Unilever and Dove); and, finally, the introduction of the first ethoxylated sorbitan laurate (Polysorbate 20).

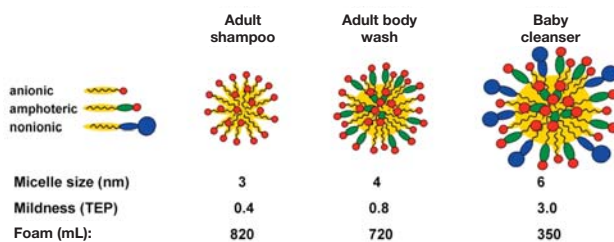
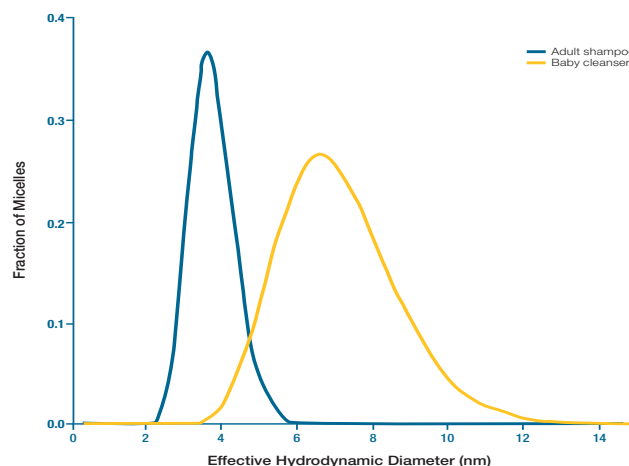
The development and consumer acceptance of liquid surfactant-based cleansers (vs soap bars) allowed for a further redefinition of mild cleansing and pH neutral systems. Advances in surfactant blending were also used to balance the competing objectives of cleansing efficacy and mildness. In spite of these advances, today's clinically proven mild cleansers are still limited in the level of mildness that they can achieve, especially for delicate infant skin. Newer hydrophobically modified polymers show promise in improving surfactant-skin interactions and may offer a new level of mildness for infants.

The **Figure** below demonstrates the importance of user age in designing a mild cleanser.

Figure. Importance of User Age in Designing a Mild Cleanser

The current state of the art in skin mildness for infant cleansing involves blending multiple surfactants to create a less aggressive surfactant system that provides:

- Reduced skin irritation
- Reduced eye irritation
- Less stinging
- Infant cleansing properties (including mildness, foaming, and cleansing) are determined by the size of the mixed micelles that are formed
- The micelle sizes (determined by dynamic light scattering) of a typical adult shampoo and baby cleanser are illustrated on the right:
 - Micelles of adult shampoos are smaller than those of a typical baby cleanser
 - Smaller micelle size in adult shampoos results in differences in cleanser performance and skin mildness



TEP = Trausepithelial Permeability Assay.
Courtesy of Johnson & Johnson Consumer Products Company.
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Commentary From Ms Vernon

A review such as this one emphasizes the need for specially formulated, mild cleansers for babies. Because we see so many young children with contact dermatitis in our practice, we also recommend fragrance-free, color-free products for those patients. Many manufacturers now offer alternative product choices for these patients and clinicians who recommend them.

This historical review also shows the gradual move away from harsh soaps, which strip the skin of its natural oils and can alter the skin's pH. A pH shift would compromise the skin's protective barrier against microbial invasion, increasing the threat of infection.

A gentle, pH-balanced cleanser, on the other hand, should be nondrying, or hydrating, for an infant's skin. We spend a lot of time in our practice encouraging parents to use gentle, moisturizing cleansers and to avoid the tendency to reach for the bar of soap. That is especially important in our area of the United States (Colorado) because the climate is already so dry.

Baby Sun Protection Products: A Competitive Assessment of Eye Mildness, SPF-PFA Ratio, Stability, and Antimicrobial Robustness

Authors:

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This study evaluated 17 commercially available sunscreen products to determine how well they met specific criteria for an ideal baby sunscreen. Criteria used included whether the product was specifically formulated for this age group and mild to the eyes, whether the product met the preferred ratio 3:1 for SPF:PFA (Sun Protection Factor, UVB protection measure; Protection Factor A, UVA protection measure), and an assessment of antimicrobial robustness (product safety), physical stability, whitening potential (aesthetics) on the skin, and overall cost to the consumer. In addition, a novel (lamellar/spherulitelike) inorganic sunscreen formulation was compared to two traditional inorganic sunscreen emulsions of comparable SPF level to determine their spreadability on infant skin. Although inorganic sunscreens such as zinc oxide (ZnO) and/or titanium dioxide (TiO₂) provide

effective UV radiation (UVR) protection, in traditional emulsions these particles can group and bunch together, resulting in uneven, nonuniform coverage. This can be a disadvantage for a product that should ideally be distributed evenly over the skin surface to provide effective UVR protection.

Of the 17 products, investigators found that 71% (12 products) failed to meet stability requirements, and 4 of these products also failed antimicrobial testing (Table). One other product (I) failed to meet antimicrobial testing, although it passed on stability. Thirty-five percent (6 products) did not meet the SPF:PFA ratio of 3:1 or better; 29% (5 products) caused unacceptable whitening on the skin (High). One product had an unacceptably high cost per ounce (\$20.00 US).

Only three sunscreens (L, M, and Q) successfully met the criteria for eye mildness, antimicrobial robustness, and stability. These three sunscreens also had an SPF:PFA ratio of 3:1 or better. L and M were traditional, emulsion, droplet-structured formulations. Q was a novel, lamellar/spherulite-

Table. Assessment of Sunscreens for Baby

Product	Tear-Free Claim	Meets No More Tears Criteria	Meets 3:1 SPF:PFA Ratio in vivo	Passes Antimicrobial Testing	Whitening Properties	Stable	Cost (\$/oz)
A (SPF 50)	Yes	x	x	x	Low	x	1.12
B (SPF 50)	No	x	x	✓	High	x	9.38
C (SPF 30+)	Yes	✓	✓	x	High	x	5.22
D (SPF 50)	No	x	x	✓	Medium	x	20.00
E (SPF 50)	No	x	x	✓	Low	x	1.31
F (SPF 50)	No	x	x	✓	Low	x	1.08
G (SPF 30+)	No	x	✓	✓	High	✓	2.25
H (SPF 30)	No	x	✓	x	Medium	x	4.37
I (SPF 30)	No	✓	✓	x	Low	✓	5.65
J (SPF 30)	No	✓	✓	✓	Medium	x	3.78
K (SPF 35)	No	✓	✓	✓	Low	x	5.65
L (SPF 30+)	No	✓	✓	✓	High	✓	1.84
M (SPF 30)	No	✓	✓	✓	Medium	✓	6.04
N (SPF 18)	No	x	x	x	High	x	4.00
O (SPF 18)	No	✓	✓	✓	Low	x	7.81
P (SPF 22)	No	✓	✓	✓	Low	x	5.65
Q (SPF 40)	Yes	✓	✓	✓	Medium	✓	2.40

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like structured formulation. L had high whitening properties on skin and also contained ingredients that are viewed as inappropriate for use on babies. M met all criteria, but had a 2.5 times higher cost per ounce than Q.

The spreadability component of the study compared a novel, lamellar/spherulite-like structured formulation (brand 1) to two marketed products (brand 2, brand 3) of comparable SPF level that used traditional emulsion droplet formulations. To compare spreadability, the three products were applied to a skin-like substrate (VITRO-Skin, IMS, Inc, Portland, ME), and a scanning electron microscope was used to evaluate how uniformly the ZnO and TiO₂ were distributed. The novel lamellar inorganic sunscreen formula was most evenly distributed over the substrate, suggesting that it would provide the best

protection against UVA and UVB radiation. In contrast, the two traditional inorganic sunscreens did not spread uniformly on the skin, which could be associated with providing inferior protection from harmful UVR.

In the final analysis, only one sunscreen (Q) was specially formulated for babies and met all of the criteria of an ideal sunscreen, including eye mildness, antimicrobial robustness, stability, SPF:PFA ratio, and acceptable aesthetics (skin whitening), and was available at a mass market price (\$2.40 US/oz). Additionally, sunscreen Q, which was similar to the tested novel formulation brand 1 (except for higher SPF level), is expected to have similarly improved spreadability relative to traditional, emulsion-based inorganic sunscreens, suggesting better UVR protection.

Commentary From Ms Vernon

This study emphasizes several of the most important characteristics of an effective infant sunscreen. Safety is probably the top priority for such products. If I am going to convince a mother to apply a sunscreen to her infant's skin, she needs to know that it is safe, and studies such as this one provide that kind of convincing evidence. Three of the products analyzed met three important safety standards: being mild, having adequate antimicrobial properties, and having an ideal SPF:PFA ratio. Equally important was the fact that these products were physically stable.

Given the growing incidence of skin cancer in all age groups, it is hard to overemphasize the need to protect even our youngest patients from the damaging effects of the sun. No doubt that is why the US Food and Drug Administration recommends that babies younger than 6 months be kept out of direct sunlight and that sun exposure be limited during peak hours for all ages. Additionally, recommendations are made by the American Academy of Pediatrics and the American Academy of Dermatology for using clothing, hats, and sunglasses and that appropriate sunscreens be used on exposed areas of the skin. In our practice, we encourage the use of appropriate sunscreens even earlier than 6 months of age.

The study also addressed the issue of product spreadability, which is a huge issue for two reasons: (1) patients will not use a product if it does not spread evenly, and (2) if the product does not cover the entire surface of the skin, the patient only gets partial UVR protection.

A Case of Life-Threatening Infections Due to Preservative Absence in a Topical Cream and Audit Demonstrating Magnitude of the Problem

Authors:

A. Sultan, J. Carr, Sheffield Children's Hospital NHS Trust, Sheffield, UK; S. Danby, The University of Sheffield, Sheffield, UK; M. Akram, A. Messenger, P. Fenton, M. Moustafa, The University of Sheffield; Sheffield Children's Hospital NHS Trust; M. Cork, Sheffield Children's Hospital NHS Trust; The Royal Hallamshire Hospital, Sheffield, UK.

This case report and product analysis initially discusses the case of a 2-year-old patient with atopic dermatitis (AD) who had multiple abscesses, impetiginized eczematous lesions, and staphylococcal septicemia that did not respond to intravenous antibiotics. At the time of his last hospital admission, a jar of an emollient cream that the parents had obtained over the counter and used without the knowledge of the clinical team was noticed next to the child's bed. The cream smelled unpleasant and was discolored. It was, therefore, sent for bacterial culture, which demonstrated high concentrations of *Staphylococcus aureus* (10^7 colony-forming units per mL). When the contaminated cream was discontinued, the patient's lesions rapidly disappeared. Further investigation revealed that the cream contained no preservatives.

The case prompted investigators to ask other parents to bring in emollients that they were currently using on their children. Their microbiological analysis of 125 samples revealed that nearly half (49.6%) were contaminated with bacteria (Table). About one of four samples contained *S aureus*, nearly 1% contained methicillin-resistant *S aureus*, 2.4% had group A *Streptococcus*, and 6.4% had other bacteria, including *Enterococcus* and nongroup A *Streptococcus*. (The remaining 16% of these samples contained normal skin flora.) The investigators believe that some of these products were the probable cause of recurrent exacerbations of their patients' AD.

This investigation of patients' emollient creams also linked several preservative-free products that were found to be contaminated with *S aureus* with serious skin infections, and their follow-up audit of the 125 samples also found that even some creams with approved preservatives were contaminated. With these results in mind, the investigators recommend several precautions for their patients with AD:

- Always wash one's hands before using creams
- Use only products with approved (by regulatory authorities) preservatives
- If the cream is dispensed in a pump or tube, avoid contact with the nozzle and wipe it after each use
- Refrigerate open containers of unpreserved products such as ointments

Table. Summary of Bacterial Growth From Cultures Taken From Emollient Samples (N=125). Data Are Presented as Percentage of the Number of Tested

No growth	50.4%
<i>S. aureus</i>	24.0%
MRSA	0.8%
Group A <i>streptococcus</i>	2.4%
Other bacteria	6.4%
Skin flora	16.0%

Commentary From Ms Vernon

Professor Cork's study raises some important issues for pediatric practitioners. In our practice in Denver, Colorado, we encounter many parents who use preservative-free creams. In fact, because we see so many patients with contact dermatitis, we have been encouraging parents to use paraben-free products, avoid organic products, and use products with fewer preservatives to reduce the risk of allergic reactions to these additives. But this new research makes it clear that preservatives serve an important purpose by preventing the buildup of pathologic microbes. In fact, the study suggests that such preservatives offer more advantages than disadvantages.

This investigation should also encourage clinicians who are caring for a patient who is not responding to a standard treatment regimen to explore the possibility that the patient is having an adverse reaction to an inadequately preserved cream. In such a situation, the best course of action would be to recommend to parents that they discontinue applying the potentially offending product and buy a new cream containing an approved preservative.

The study should also change the way we practice in general. It gives us good reason to routinely ask patients about the kinds of over-the-counter creams that they are using during our initial assessment.

Effect of Standardized Skin Care Regimens on Neonatal Skin Barrier Function in Different Body Areas

Authors:

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A prospective, randomized study was conducted to evaluate the epidermal barrier function of healthy neonates and to assess the effects of several twice-weekly bathing regimens on skin integrity. With these goals in mind, clinicians at Charité-Universitätsmedizin Berlin, Berlin, Germany, studied 64 full-term neonates who were younger than 48 hours when entering the trial. Sixteen newborns were assigned to one of four groups. Until day 7 of their lives, all 64 infants were bathed three times with a cotton washcloth moistened with water. Then group 1 received twice-weekly baths from day 7 until 8 weeks of life with a wash gel (WG); the second group was bathed with clear water and had a topical cream applied afterward (C); the third group was bathed with wash gel followed by the topical cream (WG + C); and the fourth group served as a control, being bathed in only clear water (B).

To evaluate neonates' skin barrier, transepidermal water loss (TEWL), stratum corneum hydration (SCH), skin pH, and sebum were measured on day 4 and weeks 2, 4, and 8 after birth in all groups, at four skin locations: uncovered frontal skin and mostly covered abdomen, upper leg, and buttocks. The researchers also used a neonatal skin condition score (NSCS) that measured skin dryness, erythema, and excoriation. And, finally, they documented microbial colonization by bacterial and *Candida* swabs of the umbilical region at day 2 and week 4.

After 8 weeks, the investigation found that median TEWL was significantly lower on the frontal skin, abdomen, and upper leg—but not the buttocks—in infants who were bathed with the baby wash gel and subsequent cream (WG+C) than in those in the water-only control group (B)

($P < 0.0001$). Among infants who received only the cream and water (C), TEWL was significantly lower in all four skin sites analyzed than in water only-control group ($P < 0.0001$).

The data on stratum corneum hydration revealed greater hydration on the front and abdomen in the WG+C and C groups than in the water-only control group. Also important to note was the significantly lower skin pH in the wash gel group (WG) at all four skin sites after 8 weeks than in the water-only control group ($P < 0.0001$). None of the regimens influenced *Candida* or bacterial colonization or the frequency of diaper dermatitis in this population.

In summary, the use of wash gel and cream did not negatively affect the skin barrier overall (it had a positive effect), as measured by TEWL and SCH, and in the words of the researchers: “Our data show that the added baby wash gel or additional application of cream did not harm the acidification process of the epidermal barrier during the first 8 weeks of life.”

Commentary From Professor Cork

This was one of the first studies to compare mild infant wash products ± an emollient cream to plain water, demonstrating that these products do not harm the skin pH or adversely affect other skin barrier properties such as TEWL or SCH. The combination of the mild wash product and emollient cream led to improvements in skin barrier function compared to water alone. Such cleansers are a complex of very mild surfactants, which are much safer for a baby's skin than are many of the harsher products containing sodium lauryl sulfate.

Water alone may damage an infant's skin because its pH is too high. This leads to enhanced protease activity and skin barrier breakdown. A very mild cleansing agent with a skin-appropriate pH is more appropriate for use on a baby's skin.