The Wipe: A Carrier of Skin Benefits

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Abstract
The authors review the functions, history and benefits of wet wipes, and discuss clinical methods of assessing benefits from using wipes to cleanse infant skin and apply

Wet wipes in the personal-care area are a relatively new and quickly developing product category. In this article we review the functions, history and benefits of wet wipes. We also describe methods of assessing clinical benefit in two areas: gentle infant skin cleaning and sunscreen efficacy.

What Is a Wipe?

A wet wipe for personal-care use is typically constructed from a substrate material, a lotion and a container. Figure 1 demonstrates these different parts of a wipe along with their key functions. Both the substrate and lotion have changed since wet wipes were introduced more than 30 years ago. (See sidebar.)

Modern substrate materials are often combinations of many fiber types, including synthetic (e.g. polyolefin), viscose, cotton and cellulose, chosen to achieve desired tactile properties. Fibers are formed into strong, tear-resistant wipe substrates using a variety of technologies for non-woven materials. Chemical binder materials are sometimes included to add strength.

Wipes are generally moistened with lotions composed of water plus various combinations of cleaning compounds, surfactants, preservatives, fragrances and other active ingredients. Lotions range from simple solutions to more complex emulsion chemistries.

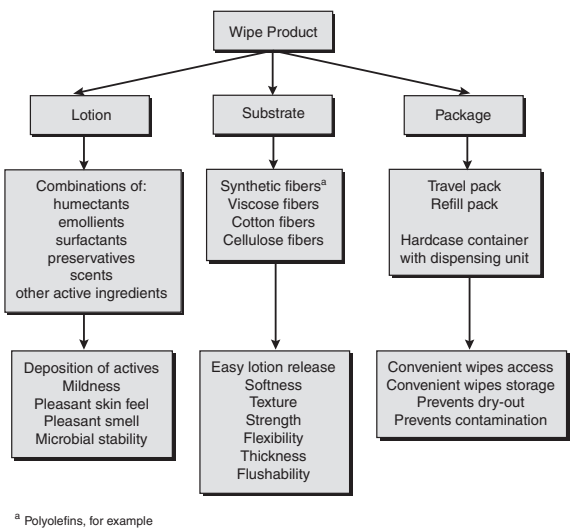

Figure 1. A wipe product and its functions

Wet wipes are usually stacked and contained in either a flexible, resealable plastic wrapping or rigid container, both of which are moisture impervious. Important functions of the package include providing a convenient dispensing unit and protecting the wipes from dirt and microbial contamination during use. Some newer containers feature wipes folded and stacked in a "pop-up" arrangement, where wipes are exposed to and removed by a user one at a time.

Benefits of Wet Wipes

Wet wipe products were initially designed as a convenient means of cleaning skin when soap and water were not available. Occasional, out-of-home use was, therefore, a primary target for product development and marketing. Baby wipes were the first products to evolve beyond this position, becoming an important, disposable tool for skin cleaning at every diaper change.

With baby care leading the way, wet wipes are being developed to deliver a much greater range of skin benefits to a far broader base of consumers. Figure 2 shows an example of the numerous benefits deliverable from wipes, including skin cleaning, skin moisturization, protection from soil and irritants, and delivery of active ingredients such as vitamins and UV filters. In today's market, products such as baby wipes, make-up removal/facial cleansing wipes, sun protection wipes and

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moist toilet paper wipes offer all of these benefits for the skin.

As wipes have evolved to deliver more advanced skin benefits, new measurement techniques have also been developed to assess product performance. We'll describe two of those techniques. One technique evaluates performance of wipes used to clean diapered skin. The other assesses performance of wipes used to apply sunscreen on infants.

History of the Wipe

Baby wipes: Disposable baby wipes have been used to clean the diapered skin area of infants for more than 30 years. The first wet wipe substrates were made from carded rayon fibers, held together by adhesive binders. These wipes were strong, but thin. They had a quite rough surface texture.

In the mid 1970s, air-laid nonwoven substrates were developed. These wipes, made from wood pulp, polyester and adhesive binders, were much thicker and softer than their predecessors. Further modifications to air-laid nonwoven materials in the 1980s involved the use of different processed fibers, such as rayon, and varying fiber blends to optimize performance.

Since the early 1990s, two new substrate-forming technologies have been increasingly used in wet wipe applications. The first is thermobonded, where heat-treatment is used to hold wood pulp and various synthetic fibers together. The second is hydroentangled, where a substrate is given strength by entwining individual fibers with high-pressure jets of water. For both thermobonded and hydroentangled substrates, design advantages include wide fiber choices and elimination of chemical adhesive binders. High quality, premium wet wipe products use these most recent thermobonded and hydroentangled substrate innovations to deliver very soft, low abrasion, cloth-like wipes for many baby-care, beauty-care and household cleaning applications.

Lotions: Lotions used in wet wipes have also evolved over the years from simple aqueous cleaning solutions to more complex systems delivering sophisticated cleaning, beauty and even health benefits.

The very first baby wipes consisted mainly of water and ethanol or isopropanol. Due to the irritation potential of short-chain alcohols, most wipes manufacturers abandoned their use in the late 1970s. Since then, preservatives, mild surfactants, emollients, humectants, fragrances and even skin protectants have been added to lotions, allowing wet wipes to deliver in-use and sensory benefits far beyond convenient moist cleansing. Water is still an important base lotion ingredient for wet wipes, but more complex oil-in-water emulsion formulas are now commonplace as wipes deliver an expanding range of hydrophilic and lipophilic ingredient chemistries.

Cleaning Diapered Skin

One of the most important recent innovation trends in the baby wipes context is a shift from merely cleaning convenience to the delivery of skin-care benefits to the diapered area. One example of this more advanced focus on skin-care benefits is Pampers Rash Care wipes. This product contains allantoin, an ingredient recognized by the US Food and Drug Administration (FDA) Diaper Rash Protectant Monograph[1] as suitable to treat and prevent diaper rash. It is regulated in the US as an over-the-counter medication and recommended for dermatitis or otherwise damaged skin in the diapered area.

Introduction of such a baby wipe product for use on damaged skin required strong supporting data demonstrating product safety and mildness. This was necessary to dispel commonly held views that disposable wipes could actually be harsh or damaging to skin. Despite the rapid improvements of wipe substrates and lotions in recent years, recollection of earlier products with rough substrates and alcohol-containing lotions made consumers and health-care professionals skeptical about actually delivering skin-care benefits from a wipe.

Therefore, a clinical study was carried out to evaluate the mildness of skin cleansing with Pampers Baby Fresh wipes versus cleansing with a washcloth and water.[2] A washcloth-and-water regimen was chosen as a control since it is often recommended to parents by health-care professionals as a "gold standard" for gentle, non-irritating skin cleansing. The design and results of this in-use clinical study for mildness are described here.

Usage protocol: The two-week clinical in-use study enrolled 90 healthy children. The children were approximately 15 months old, weighed 16-28 pounds and routinely wore disposable diapers.

In the first week of the study, the children were cleaned as usual by their parents at diaper changes, but the use of any skin-care products (such as creams, ointments and powders) was suspended in the diapered area. This was a standardization period to equalize skin condition as much as possible.

Beginning in the second week of the study, one half of the infants were randomly assigned to use the Pampers Baby Fresh wipes, while

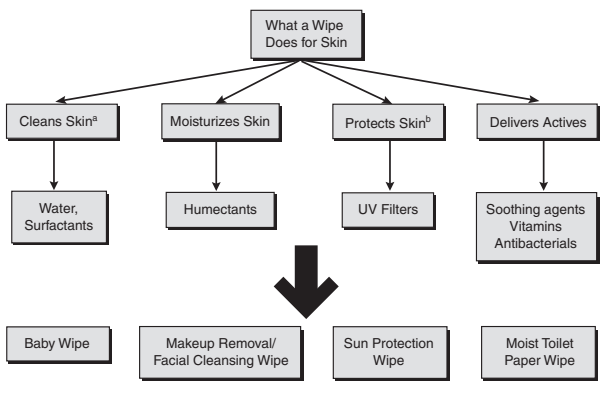

Figure 2. What wipes can do for skin

the remaining half were assigned to use water and a cotton wash cloth for cleaning at every diaper change during the next seven days. Throughout the test period, all children continued to avoid the use of creams, ointments and powders in the diapered area.

Measurement techniques: Over the course of the study, skin erythema grading and basal transepidermal water loss (TEWL) rates were measured in the diapered area as indicators of general skin health.

Skin erythema was evaluated in the genital and perianal regions prior to the beginning of test product placement, then again in the same areas after 1, 6 and 7 days of test product use. The evaluations were carried out by a single trained skin grader, who scored according to a 0-3 severity range with half-point increments.[3]

TEWL rates were measured in the buttock and genital regions prior to the beginning of test product placement and after the completion of the 7-day usage period. The TEWL parameter measured here is the currently accepted standard to determine skin barrier function.[4]

Table 1. Basal TEWL rates (g/m²/hr) among infants following diaper removal and cleaning using disposable baby wipes (DBW) or cotton washcloth + water (CWW) on Day 1 (baseline) and Day 8 (post-treatment). The data shown are the mean ±SEM of 41 children. (Reprinted with permission from Ref 2)

		TEWL rates (g/m²/hr)			
		15 min after cleaning		30 min after cleaning	
Site	Study Day	DBW	CWW	DBW	CWW
Buttocks	1	7.1 ± 0.53	8.1 ± 0.63	8.2 ± 0.91	7.9 ± 0.63
Buttocks	8	7.2 ± 0.75	8.0 ± 0.79	7.8 ± 0.73	7.2 ± 0.50
Pubis	1	11.7 ± 1.49	10.4 ± 1.03	10.8 ± 1.23	10.2 ± 0.89
Pubis	8	9.9 ± 0.54	10.5 ± 0.98	10.1 ± 0.62	9.7 ± 0.78

Results: Skin erythema grading results (Figure 3) showed that in the genital region the two treatments produced comparable levels of irritation. In the perianal region, where wiping is often more vigorous after bowel movements, a statistically significant reduction in erythema level was found for wipes users versus users of the washcloth-and-water regimen. This data demonstrated that wipes were not only equal in gentle cleaning performance to the "gold standard" of water and washcloth, but superior in a key region of diapered skin. TEWL results (Table 1) confirmed that neither wipes nor water-and-washcloth usage had a negative impact on skin barrier integrity measured after 15 and 30 min.

Taken together, these findings demonstrate that use of Pampers Baby Fresh wipes delivers equal or improved skin condition in the diapered area, compared to cleaning with washcloth and water.

The clinical study reviewed here for Pampers Baby Fresh wipes is just one example of the performance assessment techniques needed as wet wipes move up from a basic cleaning function to delivery of higher-order consumer benefits such as mildness on delicate skin. Such reassuring data is especially valuable in the baby context, but also useful for new adult wipe applications

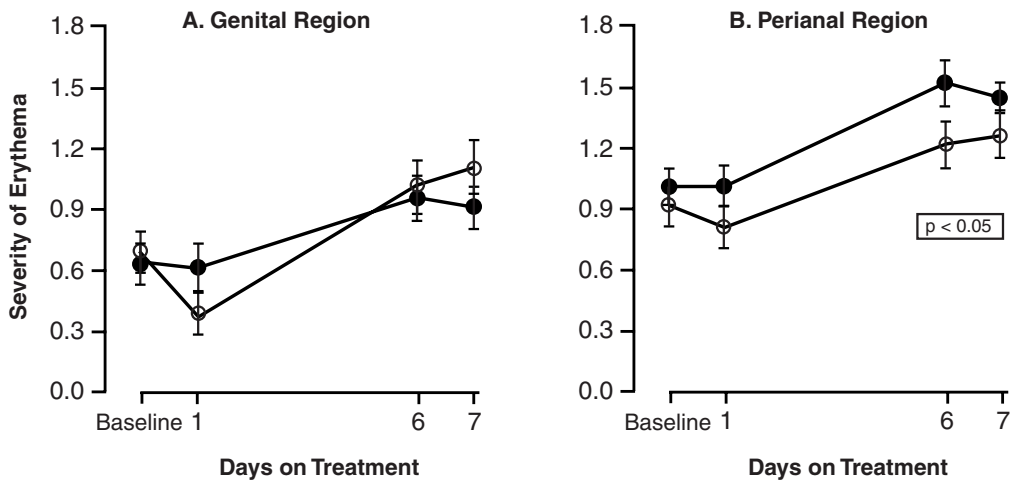

Figure 3. Severity profile of skin erythema after 1, 6 and 7 days of using cotton washcloth and water (closed circles) or disposable baby wipes (open circles) at each diaper change. The data shown are the mean of 41 children. The "p" value shown reflects a statistically significant difference between the two treatments, as determined by repeated measures ANOVA. (Adapted with permission from Ref 2)

such as make-up removal towelettes or facial cleansing cloths.

Applying Sunscreen on Infants

The conventional means of sunscreen application involves a fairly messy procedure of squeezing lotion from a bottle and spreading it by hand over the skin areas requiring UV protection. This experience can be inconvenient for adults, but an absolute struggle when adults have to apply sunscreen to children.

The more convenient alternative idea of using a wipe to deliver sunscreen lotion is especially attractive for parents of babies and young children. These parents frequently face a child unwilling to remain still for the application process. Application to delicate, contoured areas around the nose, eyes and ears can be especially challenging. A sunscreen wipe makes sun protection much more comfortable for parents and children, assuming that the wipe delivers the same level of protection as lotion applied from a bottle.

In order to assess the efficacy of a sunscreen wipe compared to lotion applied from a bottle, we formulated a high-SPF sunscreen lotion that could be applied by hand or from a wipe. The UV sunscreen actives used in the formulation were TiO_2, ZnO and octylmethoxycinnamate. Then in a clinical study, run under "real world" sun exposure conditions, we compared the sunburn protection efficacy between hand application of the lotion from a bottle (control condition) and application using a wipe impregnated with the lotion (test condition). Because the lotion was the same in each case, the only difference between the test and control conditions was the mode of sunscreen delivery to the child's skin.

Usage protocol: The clinical study was conducted in March 2001 in Buenos Aires, Argentina. A total of 61 children aged 18-48 months were enrolled. Clinical skin grading of the children was conducted by a team of three board-certified pediatric dermatologists.

The tested products were sunscreen wipes and a bottled sunscreen lotion, both with the same actives in the formulation mentioned above yielding an SPF value of 24 (water resistant) and 32 (static) as determined by the US FDA SPF methodology.[5,6] As distributed to study participants, both the wipes and lotion products were labeled as having a water-resistant SPF of 20.

The sun exposure period of the study began at 10:15 a.m. and ended at 5:15 p.m. local time on March 17, 2001. The study design was a single-blind, randomized, within-subject comparison, in which the dermatologists conducting skin evaluations were blinded as to the treatment assignments of each child. To enable a within-subject controlled efficacy comparison of the two modes of sunscreen application, we used a "split-body" design: each parent applied the bottled lotion by hand to one lateral half of the child and used the wipe on the contralateral half. Parents were not given instructions as to the amount of sunscreen lotion or wipes to use. They were simply told to apply each product as they normally would to ensure adequate protection for their child.

Following sunscreen application, each child received seven hours of exposure to ambient sunlight conditions in a setting that included a pool and open green areas for play and other recreational activities. During the period of sun exposure, the children had no restrictions imposed on their behavior and were free to access sunny or shaded areas entirely at their discretion. Parents were free to reapply sunscreen to their child as often as they deemed appropriate, with the only provision being that if

Table 2. Number of children who showed one of three grades of erythema severity at selected anatomical sites on the day following six hours of sun exposure while wearing sunscreen applied from either a wipe or a bottled lotion. (These data are irrespective of the extension, or area, covered by each individual reaction.)

	Number of children at each erythema severity grade					
	Grade 0		Grade 1		Grade 2	
Anatomical Site	Lotion	Wipes	Lotion	Wipes	Lotion	Wipes
Face	51	51	5	5	5	5
Ear	60	60	1	1	0	0
Neck	60	60	0	0	1	1
Shoulders	55	54	2	3	4	4
Back	59	59	0	0	2	2
Chest	58	59	3	2	0	0
Arm	60	59	0	1	1	1
Leg	59	59	1	1	1	1
Totals*	462	461	12	13	14	14
Percentages*	94.7	94.5	2.5	2.7	2.9	2.9

* Based on total number of observations at each severity level over all 8 anatomical sites examined.

re-application were to be done it should be both to the lotion side and wipe side of the child's body.

Measurement techniques: During the course of the sun exposure period, the intensity of UVB radiation in Minimal Erythe-matous Doses/hour (MED/hr) and the cumulative UVB exposure were measured.[a]

The skin condition of each subject was assessed during three visits. During the initial Visit 1, skin grading was carried out to document baseline condition before sun exposure. During Visit 2, at the completion of the six-hour sun exposure period, skin grading was again carried out to assess changes in skin condition. At the conclusion of Visit 2, parents were instructed to avoid any further sun exposure to their children until completion of Visit 3, the following day. The efficacy of each mode of sunscreen application was determined on the basis of erythema observations conducted by study dermatologists at Visit 3, which took place 18-24 hrs after the initiation of the period of sun exposure the previous day.

Results: 70% of subjects were in the sun between 3.5 and 5.0 hrs. The ambient conditions that prevailed during UV exposure were optimal to challenge the sunburn protection efficacy of the sunscreen test product.

Overall, the incidence of erythema observed on Visit 3 was low and no child received an erythema grade higher than 2, corresponding to a slight sunburn with no more than light red skin coloration. Table 2 lists the frequency of erythema reactions and the associated severity grade at each of the eight anatomical sites examined. As noted in the table, the highest frequency of erythema reactions was seen in the face, followed, in descending order by the shoulders, chest and back. The ears, neck, arms and legs showed very few instances of sunburn. Importantly, the frequency of sunburn responses was statistically the same, whether the lotion was applied by hand or with the wipes.

Moreover, when considered across all sites (final two rows in Table 2), it is readily apparent that the overall numbers of erythema reactions with either grade 1 or 2 severity were essentially the same for sites treated with the wipes compared to the hand-applied lotion. The data in Table 2 show that out of a total number of 976 evaluations (8 anatomical sites x 2 lateral halves/evaluation x 61 subjects), only 53 erythematous responses were observed. Of these, 41% were grade 1 (barely

[a] *Model 5D meter and 20 mm UVB detector from the Solar Light Co., Philadelphia, Pennsylvania,*

Table 3. Number of anatomical sites that showed Grade 1 or Grade 2 erythema severity on the day after children were exposed to six hours of sun while wearing sunscreen applied from either a wipe or a bottled lotion. The data were compiled across 8 anatomical sites and are grouped here according to the percentage of the site's surface area covered by the erythema.

	Number of erythematous anatomical sites, grouped according to percent of the site involved in the erythema reaction							
	<2%		2-10%		11-50%		>50%	
	Site involvement		Site involvement		Site involvement		Site involvement	
Erythema Grade	Lotion	Wipes	Lotion	Wipes	Lotion	Wipes	Lotion	Wipes
Grade 1	2	3	6	9	1	1	0	0
Grade 2	1	0	9	7	3	3	4	4
Totals	3	3	15	16	4	4	4	4
Percentages*	0.6%	0.6%	3.1%	3.3%	0.8%	0.8%	0.8%	0.8%

* Percentages are expressed on the basis of the 488 observations done for each treatment condition.

perceptible pink coloration of the skin) and 59% were grade 2 (slight burn; light red skin coloration). On a by-treatment basis, 26 occurred in the hand-applied lotion group (26/488; 5.3%) and 27 in the wipes group (27/488; 5.5 %), yielding no difference in frequency or severity of erythema between the two treatment conditions.

Table 3 summarizes the erythema results in terms of the area of coverage of each reaction. Area of coverage is related to the surface area of each anatomical site. The data were compiled across the eight anatomical sites examined. As can be seen in the table, out of a total of 53 erythema reactions recorded, 37 of the reactions (70%) involved no more than 10% of the area evaluated, with the remaining 16 reactions (30%) equally divided between those covering 11-50% of the area and those covering more than 50% of the area. Again in this instance, the results clearly demonstrate that in terms of sunburn protection, the wipe application performed as effectively as hand application of the lotion.

Upon completion of the detailed site-by-site skin evaluation of each child, the attending dermatologist was asked whether one half or the other half of the child had been better protected from sunburn. These dermatologists preferred the wipe in 3 cases (5%), the hand-applied lotion in 1 case (2%), and had no preference in the remaining 57 cases (93%); the p-value was 0.625. Thus, the attending dermatologists detected no difference in terms of sunburn protection afforded by the two tested modes of sunscreen application.

Considered in the aggregate, the results obtained both in terms of severity of erythema and surface area of the reactions provides convincing evidence that comparable sunburn protection was achieved by either mode of sunscreen application. Importantly, no instances at all of moderate or severe sunburn were observed among any of the children in this study.

The significant UV challenge accumulated during the course of the study provides a robust indication that the sunscreen formulation tested, whether delivered by hand application of lotion or via the disposable wipe, is highly effective in terms of sunburn protection. Furthermore, the observation that most of the instances of erythema affected small surface areas within the various anatomical sites demonstrates that there was no generalized failure of efficacy of the sunscreen underlying these reactions, but rather that the reactions probably arose due to defective application or rub-off of the product. Lastly, considering that children spent significant amounts of time in the pool, the outcome of the study also demonstrates that the product offers good water resistance and substantivity.

Conclusion

The clinical studies described here were designed to evaluate wipes delivering two advanced skin benefits: mild-as-water skin cleaning in the diapered area and high-SPF sun protection. The studies were conducted under "real-world" conditions for two reasons primarily: first, to determine whether use of the wipe would in any way detract from the level of benefits that parents can deliver to their children using their traditional "gold standard" practices for the same activity; second, to verify that the wipes products would effectively withstand the normal challenges such a product would face over the course of a typical usage period in a home environment. Under these demanding conditions, these studies on children yielded convincing evidence that disposable wipes were as effective as traditional methods for skin cleansing and sunscreen application. In each case, parents could achieve this level of effectiveness with minimal product use instructions, no different than those they would receive from reading the package label.

As the convenience and comfortable usage benefits of wet wipes are applied to more advanced cosmetic and even drug-level products for both children and adults, such stringent assessment of in-use efficacy will continue to be critical. Designed properly, a wet wipe can be an excellent means of applying nearly any traditional cosmetic product without the mess of jars, tubes or spray canisters. The key to sustained success is demonstrating that a disposable wipe product not only provides convenience, but delivers a desired benefit with at least equal, and preferably better, performance than the relevant "gold standard" in any given product area.

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