

ORIGINAL ARTICLE

Improving newborn skin health: Effects of diaper care regimens on skin pH and erythema

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Abstract

Background/Objective: Newborn infant skin is functional but immature, and diapering products can play a significant role in infant diapered skin health. Previous work demonstrated a regimen consisting of a diaper with an emollient and apertures on the inner liner (topsheet) with an acidic, pH-buffered wipe (Regimen A) lowered newborn skin pH and reduced the enzymatic activity on skin post-stool cleaning versus a regimen without these features (Regimen B). This study extends these findings to determine the impact of Regimen A on diaper area erythema severity over a 2-week use period.

Methods: This IRB-approved, blinded, randomized, crossover study enrolled newborn infants >7 days and ≤8 weeks. Participants exclusively used two unique diaper and wipe combinations, Regimen A and Regimen B (non-emollient, non-aperture containing topsheet and wipe with limited buffering capacity), each for 14 days and preceded by a 3-day washout regimen.

Results: Diapered skin pH was reduced during Regimen A use to values similar to that of a non-diapered control site (chest), while use of Regimen B was associated with a more alkaline skin pH. Regimen A resulted in significantly fewer severe erythema episodes. At the site of highest erythema, the perianal space, the average erythema score was significantly lower and more newborns were free of erythema while using Regimen A vs. Regimen B ($P < .05$).

Conclusions: These findings demonstrate that diapering products can have a significant impact on newborn skin. They reinforce the need to support the physiological normalization of skin pH and protection from skin irritation and damage.

KEYWORDS

diaper dermatitis, diaper skin, erythema, neonatal skin, skin pH

1 | INTRODUCTION

Newborn infants depend upon a robust innate immune system, provided by the epidermis, particularly the stratum corneum, providing a physical barrier and antimicrobial protection as they adapt to the dry, cool, non-sterile environment *ex utero*. To this end, skin integrity is critical but iatrogenic skin injuries are commonplace, particularly in the neonatal intensive care unit (NICU) where skin is underdeveloped, making infants susceptible to sepsis.^{1,2} Skin health is particularly important in the diapered area as erythema was noted in 70% of full-term babies within the first week of life,³ 25% during the first postnatal month, and the incidence of perianal diaper dermatitis (DD) was reported as 28% in non-neonatal abstinence syndrome (NAS) infants and 86% of NAS patients.⁴

Disruption of the skin and the resulting inflammation of DD is due to several factors including overhydration, irritant exposure (urine, feces), friction, medications, and underlying medical illness.^{5,6} Excess skin hydration may cause maceration, lipid structure disruption, and corneodesmosome degradation. Damaged skin is more susceptible to penetration by irritants and microbes resulting in the appearance of bacteria clusters and inflammatory cells in the epidermis and ultimately the dermis.⁷

An important consideration in reducing skin irritation are innovative diaper care products which can mitigate key causes of DD development.⁸ Recommendations to prevent diaper dermatitis from pediatric and neonatal professionals include the use of superabsorbent diapers, frequent diaper changes, good skin hygiene using appropriately formulated wipes, and prophylactic use of emollient to protect the skin from external irritants like bacteria, viruses, fungi, and allergens.⁹ Superabsorbent diapers trap urine and stool to prevent overhydration while sequestering stool away from skin. Emollients can provide a protective layer similar to that imparted by vernix to the fetus during late gestation.¹⁰ Disposable baby wipes effectively clean the skin by removing fecal material and may be engineered to deliver solutions which can positively impact skin physiology, including skin pH.

In newborns, we recently showed that a product regimen consisting of a specially designed disposable diaper with an apertured, petrolatum-based emollient on the inner liner (topsheet) with an acidic, pH-buffered wipe normalized diapered skin pH and reduced residual fecal enzyme activity on skin post-stool cleaning in just three days of use (Regimen A) when compared to a diaper without an emollient or apertured topsheet and a wipe with limited pH buffering capacity (Regimen B).¹¹ In the current investigation, two product regimens with the above-mentioned product features were compared in a randomized, blinded, complete crossover study in which diapered skin erythema was assessed after 2 weeks of use for each regimen. We hypothesized that Regimen A would help mitigate the exposure of the diapered skin to urine and fecal irritants and result in less erythema when compared with Regimen B.

2 | MATERIALS & METHODS

2.1 | Subjects

Infants >7 days of age but ≤8 weeks of age and approximately <14 lb/6.4 kg were recruited and measures collected by an independent clinical research facility. The study was conducted in compliance with ICH E6 (R2) Good Clinical Practices (GCPs), including independent ethics committee (IRB) review. Subjects' parents/legal guardians provided written informed consent. Infants were included if parents were willing to use the supplied products, maintain their current diet, and avoid the use of lotions, creams, oils, powders, and other skin products in or near the diaper area. Infants were excluded if they were deemed to be in poor health by parents/legal guardians or had a diagnosis of psoriasis, ichthyosis, chicken pox, any serious, chronic medical condition such as cancer, epidermolysis bullosa, and/or organ failure or using oral or topical medications for a chronic, serious medical condition, or skin condition or taking antibiotics. Infants with baseline erythema scores of ≥2.0 were excluded. Subjects were randomized to Regimen A or B at enrollment based on gender and diet and stratified by the initial perianal DD score (stratified by scores of 0-0.5, 1.0, or 1.5). Subjects were then randomly assigned to 1 of 2 sequences: Regimen A followed by Regimen B or Regimen B followed by Regimen A.

2.2 | Design and treatments

The study was a randomized, investigator- and analysis-blinded, 14-day in-use, two-test regimen crossover-design study. Each 14-day regimen use period was preceded by a 3-day washout period. Infants were assessed at enrollment, after each washout period and at days 7 and 14 of the test regimen periods (Figure S1).

Washout products consisted of a disposable diaper without apertures or emollient on the inner liner (Honest^{®12}) and a non-pH-buffered wipe with near-neutral pH (WaterWipes^{®13}). Test products included: Regimen A, a disposable diaper with apertures (openings) and emollient on the inner liner (topsheet) with an acidic, sodium citrate, and citric acid pH-buffered wipe (Pampers[®] Swaddlers[™] diaper + Pampers[®] Sensitive[™] wipe); Regimen B, a disposable diaper without apertures or emollient on inner liner and a wipe with limited buffering capacity (Huggies Little Snugglers[®] diapers & Huggies Natural Care[®] wipes¹⁴). pH buffering capacity was determined by acid-base titration.

2.2.1 | Skin pH measurements

Diaper skin pH was measured on each infant's chest, perianal, and suprapubic site of the genital area using a Hanna Instruments[™] model 99181 pH meter (Nusfalau, Romania), calibrated daily at pH

4 and 7, and before each measurement session. Following the first measurement, the caregiver cleansed the infant's diaper area with the assigned test wipe, as they normally would, and pH measurements were taken again at the perianal and genital areas at time 0 (immediately after cleaning) and 15 minutes later.

2.3 | Erythema assessment

Erythema was scored in a blinded manner by a trained grader using a validated seven-point, 0-3 scale (0.5 increments). Graders were required to show proficiency via a rigorous training process as previously described.¹⁵ The scoring is based on the intensity of redness and area of coverage (eg, score of "0" being "Skin is clear" and "3" being "very intense redness in a large area (>10% coverage).") At each examination, the infants were examined at four distinct regions in the diaper area (genital, intertriginous, perianal, and buttocks).

2.4 | Statistics

All data analyses were conducted in a blinded fashion. The severity of erythema scores and skin pH values were analyzed using a repeated measures model for crossover data that included fixed effects for treatment, visit and treatment by visit interaction along with a random subject effect. All testing was 2-sided at $\alpha = 0.05$. Statistical analyses were performed on data collected from infants who completed both treatment periods ($n = 80$). The sample size was based on a previous study and afforded at least 80% power to detect a 0.15 difference in skin pH and 0.18 difference in erythema between the 2 product regimens.¹⁶

3 | RESULTS

3.1 | Demographics

Ninety-five infants were randomized to treatment with 80 completing the study and are included in the analyses. The average age of infants was 5.5 weeks (Table 1). The demographic profiles were similar regardless of the order of regimen use. 15 subjects did not complete the study: 8 withdrew voluntarily, 4 were dropped for missed visits, and 3 withdrew due to an adverse event.

3.2 | Adverse events

There were a total of 12 adverse events during the study and none were serious (Table 2). The adverse events included common cold/allergy symptoms ($n = 5$), scrape or wound in the diaper area ($n = 2$), thrush ($n = 2$), diaper rash due to protein allergy to milk ($n = 1$),

TABLE 1 Demographics

Demographics (per protocol population)		
Measures	Treatment sequence	
	Regimen A/B ($n = 39$)	Regimen B/A ($n = 41$)
Sex		
Girls	16 (41.0%)	16 (39.0%)
Boys	23 (59.0%)	25 (61.0%)
Ethnicity		
Hispanic/Latino	4 (10.3%)	0 (0%)
Non-Hispanic/non-latino	35 (89.7%)	41 (100%)
Race		
Black or African American	9 (23.1%)	13 (31.7%)
Multiracial	7 (17.9%)	5 (12.2%)
White/Caucasian	23 (59.0%)	23 (56.1%)
Fitzpatrick Score		
I	0 (0%)	1 (2.4%)
II	3 (7.7%)	7 (17.1%)
III	21 (53.8%)	13 (31.7%)
IV	9 (23.1%)	12 (29.3%)
V	4 (10.3%)	7 (17.1%)
VI	2 (5.1%)	1 (2.4%)
Diet at start of period 1 regimen use		
Breast milk only	16 (41.0%)	16 (39.0%)
Formula only	15 (38.5%)	17 (41.5%)
Mix of breast milk/formula	8 (20.5%)	8 (19.5%)
Diet at start of period 2 regimen use		
Breast milk only	19 (48.7%)	15 (36.6%)
Formula only	16 (41.0%)	20 (48.8%)
Mix of breast milk/formula	4 (10.3%)	6 (14.6%)
Age in Wk (Age in d)		
Mean	5.9 (41)	5.1 (36)
Median	6.0	5.0
Min-Max	2.0-8.0	2.0-8.0
Height cm (in)		
Mean	54.4 (21.4)	53.3 (21.0)
Median	54.1 (21.3)	53.3 (21.0)
Min-Max	19.0-25.5	17.8-23.5
Weight at enrollment in kg (lbs)		
Mean	4.28 (9.44)	4.23 (9.32)
Median	4.15 (9.14)	4.13 (9.11)
Min-Max	6.08-13.15	5.15-12.09

diaper rash during transition from breast milk to formula with multiple stoolings ($n = 1$), and mark on the neck ($n = 1$). None of the adverse events were considered product related by the Principal Investigator.

3.3 | Skin pH

Skin pH after each 3-day washout period was 6.01 ± 0.04 at the perianal site and 5.94 ± 0.04 at the genital site. During Regimen B use, perianal skin pH (5.28 ± 0.05) was significantly higher than during Regimen A use (4.94 ± 0.05) and chest pH (5.03 ± 0.04 ; $P < .001$, Figure S2). Similar results were obtained at the genital region with skin pH for Regimen A (5.08 ± 0.05) comparable to chest pH, and both sites were significantly lower than Regimen B (5.48 ± 0.05 , $P < .05$). The sequence of product use did not impact results.

After use of the washout regimen (3 days), Regimen A or Regimen B (14 days), there was a significant difference in skin pH between the three groups at the perianal site and after use of the baby wipe (Figure 1). Caregivers were asked to cleanse the diaper area using the assigned wipe, and skin pH was measured immediately and 15 minutes after wiping. After cleansing, the perianal site skin pH was significantly lower for Regimen A vs Regimen B and the effect was maintained up to 15 minutes post-wiping ($P < .05$) (Figure 1). The impact of wiping on genital pH was similar to perianal results (data not shown).

Adverse event	Product at first occurrence	Action
Mark on neck	RA	None
Diaper rash ^a	WO	Withdrawn
Diaper rash ^b	RA	Withdrawn
Scrape on penis	WO	None
Thrush	WO	None
Thrush	RA	None
URTI	RA	None
URTI	RB	None
URTI	WO	None
URTI	RA	None
URTI	RB	None
Wound in diaper area (MRSA negative)	RB	Withdrawn

TABLE 2 Adverse events

Note: No adverse events were considered by the Principal Investigator to be product related. Abbreviations: RA, Regimen A; RB, Regimen B; URTI, upper respiratory tract infection; WO, washout.

^aDue to transition from breast milk to formula, multiple stoolings.

^bDue to physician-diagnosed milk protein allergy.

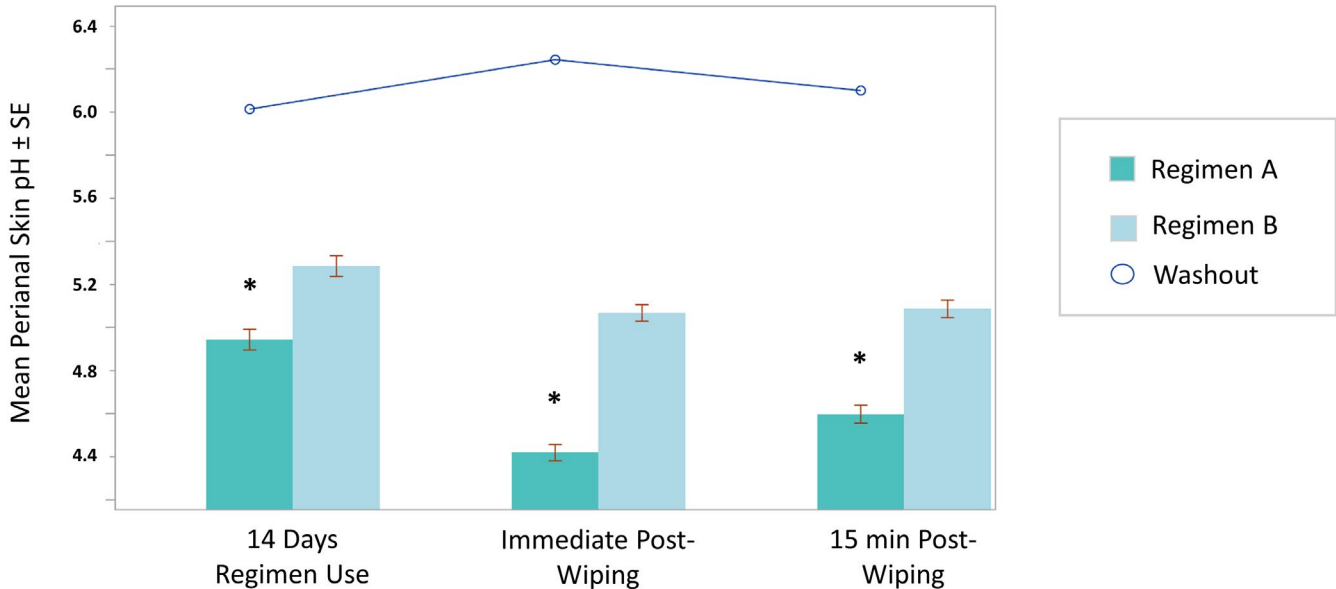


FIGURE 1 Comparison of perianal skin pH after 2 wk of product use and immediately and 15 min post wipe use. Skin pH at the perianal region was significantly lower for Regimen A vs. Regimen B after 2 wk of use. Skin pH was further lowered immediate post-wiping and remained lower 15 min afterward. The pH values for Regimen A and B were lower than during washout product use. (* $P < .05$ vs Regimen B)

3.4 | Skin erythema

During the study, more than 28% of infants experienced moderate-to-severe erythema (scores ≥ 2.0). The perianal site was the site of highest erythema followed by the intertriginous, genital, and buttocks. After the washout period, perianal erythema scores were 1.14 ± 0.05 . After use of Regimen A, 52% of infants experienced a reduction in perianal erythema scores (average score: 1.01 ± 0.04), while significantly fewer infants experienced a reduction (35%) on Regimen B (average score: 1.12 ± 0.04 ; Figure 2A, $P < .05$). A similar improvement in erythema was observed post-washout in the intertriginous region (Regimen A: 43%; Regimen B: 24%; Figure 2B, $P < .05$).

The percent of infants who experienced perianal erythema scores of "0" during the study significantly favored Regimen A vs B (17% vs. 6%, respectively, $P < .05$), and similarly for those infants who experienced no/slight erythema (scores of "0-0.5," 35% vs. 16%, $P < .05$; Figure 3A).

There was a 50% reduction in the number of more severe erythema events (scores ≥ 2) at any diaper region while infants followed Regimen A vs. Regimen B (Figure 3B, $P < .05$).

The impact of diet on the study results was also evaluated using a repeated measures model with effects for treatment, diet, and visit. Formula-fed babies had significantly higher skin pH at all diaper area

locations and higher erythema scores at the intertriginous location. The effect of diet on treatment was not significant for either skin pH or erythema, suggesting diet did not impact the treatment effect observed between the regimens.

4 | DISCUSSION

This investigation demonstrated that diapers and wipes, when used together, can substantially impact skin integrity. These findings are particularly important given very little data exist in newborns whose skin is still maturing. The results support the hypothesis, namely that a diaper with an apertured topsheet and emollient, paired with an acidic, pH-buffered wipe (Regimen A) provided lower skin pH before and after cleaning and decreased skin erythema. The benefits of Regimen A were demonstrated versus both Regimen B and the washout regimen, neither of which contained the key features of Regimen A. These results emphasize the importance of diaper care products in maintaining skin integrity. They indicate that a multifaceted approach is necessary to address the various factors that can lead to skin breakdown.

These results demonstrate the effects of Regimen A on a clinically relevant outcome, namely skin compromise measured by visible erythema, relative to Regimen B. The finding extends our previous results using a similar diaper and wipe combination where skin pH

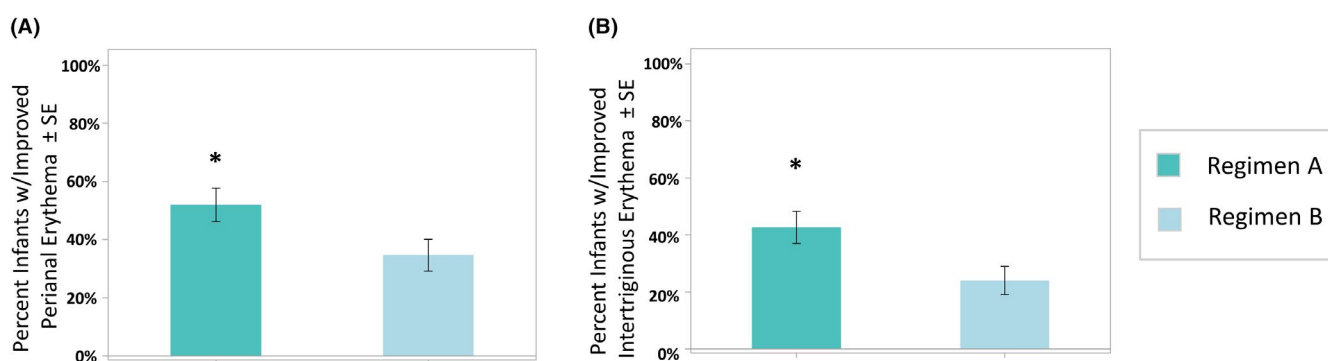


FIGURE 2 Erythema improvement after 2 wk of regimen use. Percent of infants showing improvement (lowering) in erythema scores at the perianal site A, and intertriginous site B

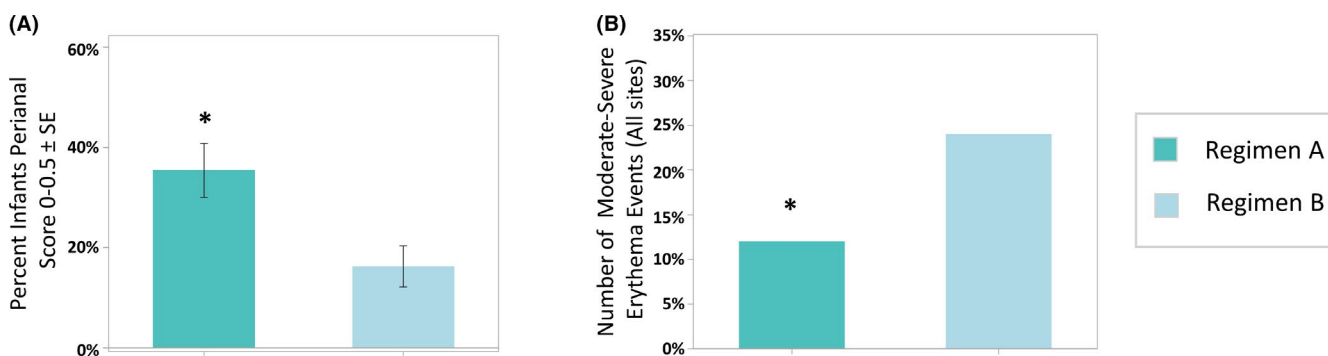


FIGURE 3 A, Percent of infants who exhibited perianal erythema scores of 0 or 0.5. B, Number of more severe erythema events during 2-week regimen use. The number of more severe erythema events (≥ 2.0) scored in the diapered area were significantly lower, while infants used Regimen A. (* $P < .05$ vs Regimen B, Washout)

was lowered and residual enzyme (proteases) activity on skin was reduced post-stool cleaning.¹¹ Overall, Regimen A use was associated with a shift away from more severe erythema, with 2-3 times as many infants on this regimen experiencing little or no erythema for the entire study compared to Regimen B. These findings are consistent with previous reports, namely that skin barrier recovery from damage (via tape stripping) was more rapid when skin sites were exposed to an acidic (pH = 5.5) HEPES solution (isotonic N-2-hydroxyethylpiperazine-N-2-ethanesulfonic acid) compared to a near-neutral pH HEPES solution (pH = 7.4).¹⁷

The diapered area is consistently exposed to irritants, for example, urine and feces, and their presence contributes to the elevated pH typically observed for diapered skin compared to non-diapered skin (eg chest).¹⁸ Many fecal enzymes (eg proteases and lipases) are maximally active at neutral or slightly alkaline pH, but have reduced activity at acidic pH. The lower skin pH and reduced residual enzyme activity observed with Regimen A¹¹ are likely key contributors to the significant reduction in skin erythema. This underscores the necessity of maintaining a sufficiently acidic pH in the diapered area to control enzyme activity and ameliorate insults to the skin, especially in the perianal region where feces and urine/feces mixtures reside. The transfer of an emollient from the diaper to the infant's skin is also likely important in providing a thin barrier to repel irritants.

During the study, Regimen A use was associated with almost 3x more infants with no erythema versus Regimen B, but also 50% fewer more severe erythema events. Visually, moderate erythema events are characterized by definite redness or very intense skin redness covering up to 50% of the anatomical site. These events, particularly in the NICU environment, alarm parents and health-care professionals as diapered skin compromise undermines baby's health (causing pain and discomfort), negatively influence parent perception (eg, reduced satisfaction with quality of health care), and may disrupt sleep. Severe erythema may increase expenditure of healthcare resources by requiring a physician visit.¹⁹ Further, skin erythema is difficult to treat and more severe erythema events trigger aggressive skin care protocols, including multiple topical barrier products or even the need for pharmacological intervention.²⁰ This is particularly significant in hospital settings (NICU) as it was reported that 53% of these infants received two or more skin care products.⁴ Products with features found in Regimen A could potentially reduce the downstream effects of skin barrier breakdown and need for additional topical or systemic therapy.

The evaluation of a diaper care system introduces a difficulty in discerning the impact of each component. The individual components all likely contribute. Previous work has shown that a disposable diaper with an emollient on the inner liner reduced diaper dermatitis²¹ and a diaper with an apertured topsheet reduced the amount of residual fecal material on skin,²² likely reducing irritation in the perianal area, versus a non-emollient diaper. Likewise, an acidic, pH-buffered wipe reduced diapered skin pH in older babies²³ and a separate study showed lower diapered skin pH improved skin barrier function and reduced perianal erythema in both premature and full-term infants.¹⁶ Differences in infant

demographics, diet, topical product usage, medications, and parental habits each can impact diapered skin breakdown. However, the crossover design allowed infants to use both products within a 5-week period, minimizing the impact of these factors. Alternative study designs would allow discernment of each attribute (eg, high liquid absorbency, emollient transfer from a diaper, acidic pH-buffered wipe) and whether the products work in an additive or even synergistic manner to lessen the negative impacts of urine and feces on delicate newborn skin.

In conclusion, these results provide compelling evidence that diapering products can impart clinically meaningful skin benefits and should be considered by decision makers, parents, and medical professionals to optimize skin health in the diapered area.

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CONFLICT OF INTEREST

Jennifer Gustin, Lisa Bohman, Gina Fadayel, Maria Mitchell and Andrew Carr are employees of The Procter and Gamble Company. Julie Ogle is a retired employee of Procter & Gamble.

AUTHOR CONTRIBUTIONS

All authors contributed to the study design, data collection, data analyses, data interpretation and/or assembly of the manuscript. We would like to thank Lisa Bowman for her efforts and expertise in data management on this study.

ETHICAL STATEMENT

This research complies with the guidelines for human studies, is IRB-approved, and is ethically in accordance with the World Medical Association Declaration of Helsinki.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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