A randomized, controlled trial comparing skin health effects and comfort of two adult incontinence protective underwear

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Background/Purpose: It is important to confirm product use effects on skin health for products intended for prolonged skin contact. This study compared experimental and marketed reference adult incontinence protective underwear.

Methods: Randomized, single-blind (examiner), parallel study evaluating skin health effects in predominantly obese incontinent women normally using protective underwear (approximately 20% Type II Diabetes). Subjects wore experimental or marketed reference protective underwear daily, 14 consecutive days. Visual skin grading, transepidermal water loss (TEWL) assessed before, after 1 and 2 weeks of product wear. Overall assessment of comfort assessed.

Results: Of the 122 subjects (60 experimental and 62 marketed reference), 22 were diabetic and 88 were postmenopausal. Under the conditions of this study, there were no statistically significant differences in overall change from baseline for visual grading and TEWL between the experimental product and the marketed reference product for all subjects. Changes from baseline for skin erythema and skin marking were generally small for both products for all subjects as well as for both diabetics and non-diabetics. There were no serious adverse events (AEs), and no withdrawals due to AEs. Overall comfort assessments of size and fit were 'just right,' and skin comfort in the leg, waist and crotch areas were 'comfortable' or 'very comfortable' for both products.

Conclusions: In-use 14-day testing demonstrated few statistical differences between experimental product with unique odor neutralizing technology and currently marketed product for skin assessments and comfort. Both products were comfortable and well-tolerated.

Key words: diabetes – erythema – female incontinence – protective underwear – skin health – transepidermal water loss

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Urinary incontinence (UI) is the loss of bladder control (involuntary loss of urine). It is a common health problem, especially among women. Rough population prevalence estimates for females range from 5% to 69% globally. Cultural differences, willingness to report UI, and methodological differences in research are factors impacting the variation between countries. Most studies report prevalence of any UI of 25–45%, with 10% of all adult women reporting weekly leakages. The prevalence distribution between UI subtypes is more consistent, with stress incontinence range of 10–39%, mixed incontinence (both stress and urgency-related) at a range of 7.5–25%, urgency incontinence with 1–7% prevalence, and all other causes of incontinence at 0.5–1% (1). Urinary incontinence prevalence increases with age, implying UI impact will increase over the next several decades as the growing population ages. Known UI risk factors include increased body mass index, and diabetes; however, menopausal status does not appear to be an independent risk factor (1). The effects of UI on skin barrier function are well known and can cause localized incontinence-associated dermatitis (2–5).

Some women choose to manage their UI with protective garments as a lifestyle intervention. A new line of disposable options including pantiliners, pads, and protective underwear has been developed to better meet these needs. These new products contain a proprietary mixture of
functional fragrance components that quickly neutralize amines as an odor neutralizing technology (ONT) within the absorbent core. The ONT components are covered by a non-woven top sheet intended for skin contact, and a back sheet that protects undergarments from wetness. The protective underwear product provides a fitted elastic waistband which holds the core in place to provide the extra reassurance of a fitted pant for heavier urine losses.

Assessment of dermatological effects of absorbent products intended for prolonged skin contact, such as menstrual products, baby diapers, and incontinence products is important to confirm good skin compatibility, and is aimed at ensuring these products are safe for intended and foreseeable use. The toxicology/risk assessment confirms all product materials have a sufficient margin of safety and are safe for their use in the product (3). Clinical studies on finished product are typically conducted to confirm effects of product use on skin health. Thus, the present study evaluates the impact of experimental or currently marketed reference adult incontinence protective underwear on skin health in current incontinent protective underwear users during typical conditions of use over a period of 14 consecutive days. Skin complications (infections and other disorders) and slower wound healing are common in people with diabetes (6). Thus, the subject population includes diabetics (target 20%) to gain additional learning for known incontinence morbidity with increased potential for skin health issues. In addition, since vulvovaginal symptoms in this population may include irritation, burning, itching, etc. (7), postmenopausal subjects are included to understand potential skin health issues in women with estrogen loss.

Skin health is assessed primarily by visual skin grading using a standard skin erythema-grading scale (Table 1) routinely used in skin patch and product in-use tests (8–11). Additional exploratory measures include visual skin grading using a skin-marking visual scoring scale (Table 2) used with babies and incontinent adults (unpublished data), a non-invasive objective measure of skin barrier health, transepidermal water loss (TEWL) (12), and reported adverse events (AEs). We hypothesized measures of skin health would not be statistically different between the experimental and marketed reference products.

### Table 1. Skin erythema grading scale*

| Grade | Erythema/red marking scale* | Pressure marking scale |
|-------|-----------------------------|------------------------|
| 0.0   | No redness                  | No indentation         |
| 0.5   | Faint pink                  | Superficial            |
|       | (very slight indentation)   |
| 1.0   | Definite pink               | Slight indentation     |
| 1.5   | Falls between 1 and 2       | (no half grade)        |
| 2.0   | Definite red                | Moderate indentation   |
| 2.5   | Falls between 2 and 3       | (no half grade)        |
| 3.0   | Intense red                 | Deep indentation       |
| 3.5   | Falls between 3 and 4       | (no half grade)        |
| 4.0   | Very intense redness or     | Very deep indentation  |
|       | skin breaks or excoriation  |                        |

*Erythema/Red marking – redness within a pressure mark or redness in a defined pattern where there is no pressure mark. Grade should be most severe seen in the specific grading area.

### Table 2. Skin marking grading scale

| Grade | Erythema/red marking scale* | Pressure marking scale |
|-------|-----------------------------|------------------------|
| 0.0   | No redness                  | No indentation         |
| 0.5   | Faint pink                  | Superficial            |
|       | (very slight indentation)   |
| 1.0   | Definite pink               | Slight indentation     |
| 1.5   | Falls between 1 and 2       | (no half grade)        |
| 2.0   | Definite red                | Moderate indentation   |
| 2.5   | Falls between 2 and 3       | (no half grade)        |
| 3.0   | Intense red                 | Deep indentation       |
| 3.5   | Falls between 3 and 4       | (no half grade)        |
| 4.0   | Very intense redness or     | Very deep indentation  |
|       | skin breaks or excoriation  |                        |

*Pressure mark – indentation in the skin.

### Methods

The study protocol and written subject information were approved by an independent Institutional Review Board. Women from St. Petersburg, Florida and San Antonio, Texas were informed about the products, nature of the clinical investigation (including potential AEs), and provided subject written informed consent prior to study procedures. Inclusion criteria included: ambulatory, non-pregnant
female ≥18 years of age, general good health (if diabetic, most recent HbA1c score <8%), >5 urine leakage events/week, using ≥5 protective underwear ≥5 days/week, and regular menstrual cycles (as applicable). Enrollment targeted ≤15% Fitzpatrick skin Type V and VI (13), 20% Type II diabetics. Exclusion criteria included: currently using antibiotics, chemotherapeutics, antihistamines, anti-inflammatories, corticosteroids, having any skin abnormalities that could interfere with interpretation of test results, loss of bowel control >1 per month, kidney disease, current hematuria, and evidence of urinary tract or genital infection. Subjects agreed to refrain from activities that would impact testing results, such as: (1) shaving, using depilatories, or applying skin care preparations in pubic or buttocks area, (2) using tobacco, alcohol, caffeine, or having sexual intercourse 2 h before study visits, and (3) vigorous (sweat producing) exercise, swimming and sun exposure.

Eligible subjects were recruited from the general public between October 2013 and February 2014, and randomized into two groups of maximum absorbency experimental or marketed protective underwear. Groups were stratified based on self-reported number of protective underwear used per day, the presence of diabetes, and waist measure. Products were worn non-menstrually for urine leakage protection (≤24 h/day) for 14 days and subjects recorded underwear wear time, used underwear weight (using the provided balance), and leakage information on a daily diary. Visual assessments (Tables 1 and 2) and TEWL measures were taken before and after 1 and 2 weeks of product use. Assessments were completed after a 30-min acclimation by evaluators who were blinded to product assignment. One evaluator per site conducted all visual and TEWL assessments. The evaluators were qualified health professionals experienced with visual grading. In order to promote consistency, they discussed process and areas of potential discrepancy prior to the start of the study. The same TEWL instrument and operator per site were used for all subjects. A sensory (comfort) assessment was obtained at study completion, including seven attributes using a 5-point scale rating: (1) overall size, (2) waist fit, (3) leg fit; and (4) overall comfort, (5) skin comfort in the waist, (6) leg, and (7) crotch areas. Subjects were asked to report any changes in health experienced during the course of the study. AEs were recorded and reported from the first until the last study assessment as received by study subjects during site visits and/or on phone calls, or captured on study questionnaires.

Two products were tested in this study. All subjects determined eligible were randomly assigned to a product following stratification based on the self-reported amount of daily incontinence (number of protective underwear typically used per day), the presence of diabetes, and waist measurement in order to control for factors having a major impact on skin health effects. A balance and assignment program within a web-based, validated, Electronic Records/Electronic Signature-compliant platform (21 CFR Part 11) was used. This was a single-blind study. The skin grader was blinded to the identity of the test materials, and randomization was generated and maintained by a statistician independent of the project.

Statistical analysis was conducted using the intent-to-treat (ITT) population. Data were summarized with descriptive statistics and analyses were conducted using generalized linear mixed models with the product as fixed effect, and subject as random effect. Baseline scores were used as a covariate. Study site, treatment week (visit number), and diabetic status were included in the model for overall analysis. Treatment week was included for the subgroup of diabetics and non-diabetics analysis. An empirical (sandwich) variance estimator was implemented along with a small sample bias correction (14). Overall assessment of comfort was summarized by protective underwear group (i.e. frequency distributions) and compared via a Cochran–Mantel–Haenszel test. AE’s were summarized by incidence, severity, causality, and recoverability. Approximately 120 subjects were to be randomized to complete at least 50 per group. This study sample size was based on previous adult incontinence studies (unpublished data), allowing detection of average erythema change from baseline difference of 0.2 between experimental and marketed product at 0.05 alpha level with 90% power. All analyses and graphs were completed using SAS® (Cary, NC, USA), Version 9.4.
Results

Disposition, demographics, and baseline characteristics
One hundred and twenty-two subjects comprised the ITT population (Fig. 1), with 98 (80%) at the Florida site and 24 (20%) at the Texas site. The demographic and baseline characteristics were similar across both products (Table 3). The total number of products used, wear time, and weight of the used protective underwear were similar across both products (Table 4).

Adverse events
Seven AEs were reported in seven subjects. None were serious, and no withdrawals occurred due to AEs. Five AEs were definitely not related to product per principal investigator (PI): sore throat, head congestion, gastric distress, abrasion on posterior left thigh, and tension headache. Two AEs were related to product: (1) subject had perineum erythema grade of 2.0 or ‘moderate erythema’ after 1 week (PI AE severity and relationship with treatment determination: ‘mild, normal activities unaltered’; probably related to treatment); (2) subject had labia majora and perineum erythema grade 4.0 or ‘moderate-to-severe erythema and/or edema’ after 2 weeks (PI AE severity and relationship with treatment determination: ‘mild, normal activities unaltered’; possibly related to treatment). Both subjects used the marketed reference product; both AEs were resolved at follow-up.

Skin erythema
The (arithmetic) mean erythema profile was low and stable across treatment weeks for both experimental and marketed reference products and scores were lower at Week 2 than baseline (Fig. 2). Erythema average scores for all...
anatomical sites were less than 0.6 (0.5 = ‘faint, barely perceptible’), with highest scores at baseline. The lowest mean scores were observed at buttocks and mons pubis anatomical sites and the highest scores were at labia majora, labia minora, and perineum. The subjects on the experimental product had a lower baseline mean erythema score than those on the marketed reference product in four of six grading sites (buttocks, inner thighs, labia majora, and labia minora). Baseline scores were used as a covariate in analyses. Erythema change from baseline is summarized in Fig. 3. For both products, in general, overall changes were small; ranging from 0.15 to 0.02. Subgroup analyses were conducted by: treatment week, Fitzpatrick Skin type, number of protective underwear used per day, subject waist size, size of protective underwear used, study center, and the presence/absence of diabetes. Overall, there were only small differences observed across both products (ranging from 0.26 to 0.06), and the few statistically significant differences favored the experimental product. There were no statistically significant differences between the two products for presence/absence of diabetes (See Fig. 4).

**Skin marking (red marking and pressure marking)**

Overall, there were no statistically significant differences in the experimental product compared to the marketed reference product for red or pressure marking change from baseline, and

| Parameter                  | Condition                                      | Mean (standard deviation) or count (percentage) |
|----------------------------|------------------------------------------------|-----------------------------------------------|
| Age                        | Age (years)                                    | Experimental (N = 60)                         |
|                            |                                                | Marketed reference (N = 62)                   |
|                            |                                                | Overall (N = 122)                             |
| Race                       | American Indian or Alaskan Native              | 54.5 (12.95)                                  |
|                            |                                                | 57.4 (11.26)                                  |
|                            |                                                | 56.0 (12.16)                                  |
|                            | Black                                          | 1 (1.7%)                                      |
|                            |                                                | 2 (3.2%)                                      |
|                            |                                                | 3 (2.5%)                                      |
|                            | Caucasian                                      | 13 (21.7%)                                    |
|                            |                                                | 10 (16.1%)                                    |
|                            |                                                | 23 (18.9%)                                    |
|                            | Hispanic                                       | 46 (76.7%)                                    |
|                            |                                                | 50 (80.6%)                                    |
|                            |                                                | 96 (78.7%)                                    |
|                            | Non-Hispanic/non-Latino                        | 8 (13.3%)                                     |
|                            |                                                | 9 (14.5%)                                     |
|                            |                                                | 17 (13.9%)                                    |
|                            | Body mass index                                | 52 (86.7%)                                    |
|                            |                                                | 53 (85.5%)                                    |
|                            |                                                | 105 (86.1%)                                   |
|                            | Waist circumference (inches)                   | 32.9 (6.87)                                   |
|                            |                                                | 34.6 (7.12)                                   |
|                            |                                                | 33.8 (7.02)                                   |
|                            | Body mass index (kg/m²)                        | 41.3 (5.22)                                   |
|                            |                                                | 42.6 (5.46)                                   |
|                            |                                                | 42 (5.36)                                     |
|                            | Fitzpatrick skin type                          | I (very sensitive to UV/never tans)           |
|                            |                                                | 1 (1.7%)                                      |
|                            |                                                | 5 (8.1%)                                      |
|                            | II (very sensitive to UV/tans minimally)       | 14 (23.3%)                                    |
|                            |                                                | 12 (19.4%)                                    |
|                            | III (sensitive to UV)                          | 26 (43.3%)                                    |
|                            |                                                | 28 (45.2%)                                    |
|                            | IV (moderately sensitive to UV)                | 7 (11.7%)                                     |
|                            |                                                | 7 (11.3%)                                     |
|                            | V (minimally sensitive to UV)                  | 3 (5.0%)                                      |
|                            |                                                | 3 (4.8%)                                      |
|                            | VI (insensitive to UV)                         | 9 (15.0%)                                     |
|                            | Diabetic                                       | 51 (85.0%)                                    |
|                            |                                                | 49 (79.0%)                                    |
|                            |                                                | 100 (82.0%)                                   |
|                            | Postmenopausal                                 | 9 (15.0%)                                     |
|                            |                                                | 13 (21.0%)                                    |
|                            |                                                | 22 (18.0%)                                    |
|                            | Ethnic                                         | I (very sensitive to UV/never tans)           |
|                            |                                                | 1 (1.7%)                                      |
|                            | II (very sensitive to UV/tans minimally)       | 14 (23.3%)                                    |
|                            | III (sensitive to UV)                          | 26 (43.3%)                                    |
|                            | IV (moderately sensitive to UV)                | 7 (11.7%)                                     |
|                            | V (minimally sensitive to UV)                  | 3 (5.0%)                                      |
|                            | VI (insensitive to UV)                         | 9 (15.0%)                                     |
|                            | Number of incontinence pads or protective underwear used per day |
|                            | ≤2                                             | 28 (46.67%)                                   |
|                            | >2                                             | 32 (53.33%)                                   |
|                            | Diabetic                                       | 51 (85.0%)                                    |
|                            |                                                | 49 (79.0%)                                    |
|                            |                                                | 100 (82.0%)                                   |
|                            | Postmenopausal                                 | 9 (15.0%)                                     |
|                            |                                                | 13 (21.0%)                                    |
|                            |                                                | 22 (18.0%)                                    |
|                            | Ethnic                                         | I (very sensitive to UV/never tans)           |
|                            |                                                | 1 (1.7%)                                      |
|                            | II (very sensitive to UV/tans minimally)       | 14 (23.3%)                                    |
|                            | III (sensitive to UV)                          | 26 (43.3%)                                    |
|                            | IV (moderately sensitive to UV)                | 7 (11.7%)                                     |
|                            | V (minimally sensitive to UV)                  | 3 (5.0%)                                      |
|                            | VI (insensitive to UV)                         | 9 (15.0%)                                     |
|                            | Number of incontinence pads or protective underwear used per day |
|                            | ≤2                                             | 28 (46.67%)                                   |
|                            | >2                                             | 32 (53.33%)                                   |
|                            | Diabetic                                       | 51 (85.0%)                                    |
|                            |                                                | 49 (79.0%)                                    |
|                            |                                                | 100 (82.0%)                                   |
|                            | Postmenopausal                                 | 9 (15.0%)                                     |
|                            |                                                | 13 (21.0%)                                    |
|                            |                                                | 22 (18.0%)                                    |
|                            | Ethnic                                         | I (very sensitive to UV/never tans)           |
|                            |                                                | 1 (1.7%)                                      |
|                            | II (very sensitive to UV/tans minimally)       | 14 (23.3%)                                    |
|                            | III (sensitive to UV)                          | 26 (43.3%)                                    |
|                            | IV (moderately sensitive to UV)                | 7 (11.7%)                                     |
|                            | V (minimally sensitive to UV)                  | 3 (5.0%)                                      |
|                            | VI (insensitive to UV)                         | 9 (15.0%)                                     |
|                            | Number of incontinence pads or protective underwear used per day |
|                            | ≤2                                             | 28 (46.67%)                                   |
|                            | >2                                             | 32 (53.33%)                                   |

**TABLE 4. Summary of total wear time, total load, and total underwear used by week**

| Endpoint                  | Treatment Week 1 | Treatment Week 2 | P value | Treatment Week 1 | Treatment Week 2 | P value |
|---------------------------|------------------|------------------|---------|------------------|------------------|---------|
|                           | Experimental (N = 60) | Marketed reference (N = 61) |         | Experimental (N = 54) | Marketed reference (N = 56) |         |
| Number of days with pad use | 7.0 (6.0, 8.0)  | 7.0 (5.0, 10.0)  | 0.18    | 7.0 (3.0, 10.0)  | 7.0 (6.0, 8.0)  | 0.76    |
| Total wear time (hours/day) | 21.0 (9.0, 23.5) | 20.6 (3.5, 25.4) | 0.78    | 21.6 (7.6, 26.1) | 21.3 (5.0, 25.1) | 0.81    |
| Total underwear used | 14.0 (6.0, 30.0) | 14.0 (5.0, 32.0) | 0.96    | 14.0 (6.0, 28.0) | 14.0 (6.0, 32.0) | 0.56    |
| Weight of protective underwear (g) | 1196 (432.0, 5974) | 1196 (211.0, 7813) | 0.99    | 1221 (369.0, 7351) | 1217 (511.0, 7580) | 1.00    |
the only statistically significant differences in a subgroup analysis by treatment week favored the experimental product and were observed at Week 1 for the back waist ($P = 0.019$ and $P = 0.083$) for red and pressure marking, respectively.

Transepidermal water loss
Transepidermal water loss results were not normally distributed, and a non-parametric method was used to perform product comparisons. Overall, there were very small, statistically insignificant differences between the two products.

Daily diary and final comfort questionnaire
The estimated probability of body leakage (0.85 – experimental, 0.93 – marketed reference) and leakage onto clothes (0.00 – experimental, and 0.01 – marketed reference) reported from the daily diary was not statistically different between the two products. Descriptive statistics from the comfort questionnaire completed at the end of study product use demonstrated the majority of subjects rated both products as ‘just right’ with respect to overall size (82% experimental, 64% marketed reference), fit around the leg (76% experimental, 82% marketed reference), and fit around the waist (86% experimental, 68% marketed reference). The majority of subjects also rated overall comfort of the product (86% experimental, 66% marketed reference), skin comfort in the leg area (76% experimental, 73% marketed reference), and skin comfort in crotch area (71% experimental, 66% marketed reference) similarly as ‘comfortable’ or ‘very comfortable.’ The only significant difference was found for skin comfort in waist area (89% experimental, 70% marketed reference, $P = 0.01$) in favor of the experimental product.
Discussion

It is important to confirm effects of product use on skin health for products intended for prolonged skin contact. A separate paper describes the detailed overall skin compatibility evaluation and testing program for the new incontinence product line up (3). This study evaluated skin health effects and comfort during typical conditions of use in current incontinent...
protective underwear users over a 14-day time
period. The study population included a major-
ity (72%) of postmenopausal women and a sub-
population of diabetics to gain additional learn-
ing for known incontinence risk factors with
increased potential for skin health issues.
The study was sized to distinguish statistical
differences in erythema between the experimen-
tal and marketed product. A clinically meaning-
ful erythema difference is a change of 0.5 on
the visual scoring scale. Overall, there were
negligible (average scores across all anatomical
sites were less than 0.6) erythema changes
demonstrated across products. Higher mean
erythema scores were observed with both prod-
ucts at labia majora, labia minora, and per-
ineum, which is consistent with those reported
for menstrual pads (10), and appear to be more
related to areas of pressure points due to con-
tact with the product which may be influenced
by product fit and individual activity. We col-
lected information related to product comfort
and fit as discussed below; however, did not
collect information on daily activity in this
study. In addition, the control (inner thigh)
average values were either higher than or com-
parable to average test site scores across all
anatomical sites, indicating erythema changes
were not due to differences in product. Results
for erythema within a subgroup of diabetics
(n = 9 experimental, n = 13 marketed reference
product) did not demonstrate statistical differ-
ence between products. The subgroup was
small, and results were variable. Therefore,
results for the diabetic subgroup should be veri-
fied in an appropriate sized study to draw firm
conclusions.

**Exploratory outcomes**

Skin marking is cosmetic and transient in nat-
ure and correlates with product fit. Changes
from baseline between products demonstrated
improvement from baseline and no statistical
differences between products for skin marking.
One explanation for the improvement in skin
marking may be due to appropriate sizing of
the protective underwear assignment by waist
measurement within the study vs. possible
underestimation of true body measurements
and therefore tighter fit of ‘usual product’ bas-
eline protective underwear. In-use sensory
assessments demonstrated overall good fit and
skin comfort for both products with no statisti-
cal differences between the products.

Transepidermal water loss (12) is a reliable
and valid measure in children and adults. Low
TEWL rates correlate with intact skin barrier
function and high TEWL rates are indicative of
increased water loss and poor barrier function
(15–18). The overall TEWL profile was similar
between products, with no statistically signifi-
cia differences found between the two prod-
ucts. Median values were comparable between
products, higher than reported in the literature
for healthy continent women (19, 20), and con-
sistent with TEWL results reported in a small
study of incontinent adults (21). Median TEWL
values for the control site (inner thigh) were
comparable between products and higher than
values obtained for buttocks, providing evi-
dence of negligible overall product-related ery-
themata in the buttock area. Labia majora had
highest values, which is consistent with litera-
ture and indicates more compromised skin at
pressure point areas vs. product related. Limi-
tations of TEWL measure in this population
include potential confounding factors inherent
in this testing, such as: measuring a semi-
occluded anatomical site due to an overall
obese population with excessive skin folds
(skin-to-skin contact), hydrated tissue due to
sweat glands, urine leaks inherent for inconti-
nent population, and measurement proximity to
the vaginal opening. Results were skewed, with
some high values (11 of 810, 1% of assessments)
out of expected VapoMeter measurement range
(greater than 200 g/m² per hour), occurring at
labia majora for some subjects assigned a large
or extra-large product. There was no correlation
with prevalence of diabetes, or erythema scor-
ing, nor any AE reported for these high values,
and all TEWL values for ITT population were
included in the study analyses.

**Conclusion**

This study confirmed, in a real-use context dur-
ing 14-days of continued use, the skin health
effects of experimental protective underwear as
compared to a currently marketed reference
product in a population with known inconti-
nence comorbidity and increased potential for
skin health issues (majority postmenopausal,
majority obese, 18% Type II diabetics). There
were few statistical differences or trends in
statistical significance between the experimental and currently marketed reference product across all assessments. Subjective reporting of in-use sensory assessments (skin comfort and product fit) supports these results. Both products were well-tolerated by the subjects with no product-related AEs associated with the experimental product.

Compliance with Ethical Standards

Declaration of potential conflicts of interest: The study was sponsored by The Procter & Gamble Company and evaluated products developed or commercialized by the company. Mylissa Trowbridge, Baiyang Wang, Denise Gutshall, Cynthia Rodenberg, and Miranda Farage are employed by The Procter & Gamble Company.

Statement of human rights/ethical approval: All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

Author Contributions

Mylissa Trowbridge – Clinical Scientist, protocol development, manuscript writing/editing. Baiyang Wang – Statistician, protocol development, data analysis, manuscript editing. Denise Gutshall – Toxicologist, protocol development, manuscript review. Cynthia Rodenberg – Senior Statistician, protocol development. Miranda Farage – Research Fellow, protocol development/manuscript editing/review.

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