Colloidal Oatmeal Therapeutic Scented Lotion and Wash Clinically Shown to Be As Well Tolerated and Gentle to Sensitive Skin As a Fragrance-Free Therapeutic Lotion and Creamy Wash

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ABSTRACT

- There is a wide range of body-moisturizing options available within the marketplace. Patients, including those with sensitive skin, tend to prefer the product experience of a scented formulation over that of a fragrance free formulation. To minimize the potential risk of skin irritation and sensitization, dermatologists typically recommend fragrance free therapeutic products to their patients. With the ability to intensely moisturize, relieve irritation and help prevent the recurrence of extra-dry skin, it is important that therapeutic body moisturizers and cleansers are not only gentle and mild, but also have an aesthetic profile patients prefer to drive compliance and deliver on these benefits.

- In order to give people with sensitive skin better options when choosing therapeutic moisturizing and cleansing products, as well as help drive patient compliance, a colloidal oatmeal moisturizer and wash formulation was developed that used two novel scents (coconut and chamomile). The ingredients used to create these scents also provided skin conditioning benefits to the formulation. This study was conducted to evaluate the tolerance of both scented body wash and lotion regimens, and compare them to a commercially available therapeutic fragrance free regimen.

- This was a single-center, randomized crossover, controlled, blinded 4-week clinical use study. Eighty-nine subjects, aged 18 to 70 years, with history of self-perceived sensitive skin were enrolled. Subjects enrolled had previous documented skin sensitivities to household or skin care products. The study consisted of two 2×2 crossover substudies, one for each scented product regimen. The fragrance free regimen consisted of a highly recommended therapeutic fragrance free wash and lotion. At baseline (Visit 1), each subject was randomly assigned to one of the two cells (coconut or chamomile) and one of the two treatment sequences within the cells (scented versus fragrance free). This study consisted of five visits over a 4-week usage period. Visits were conducted at baseline and Weeks 1, 2, 3, and 4.

- The regimens were evaluated by a dermatologist via clinical tolerance assessments including rash, redness, burning, tightness, etc. Weekly self-assessment questionnaires were completed by the subjects. Statistical analysis of the clinical assessments found that both the coconut and chamomile colloidal oatmeal therapeutic scented wash and lotion regimens were as well tolerated as the nonscented regimen. Furthermore, self-assessments showed that the sensitive-skin subjects found the scented regimens more pleasing to use when compared to the commercially available nonscented regimen. No product-related adverse skin reactions were observed with either of the scented regimens.

OBJECTIVES

- Compare the clinical tolerance of two scented colloidal oatmeal body wash and lotion regimens to a leading, commercially available fragrance free therapeutic body wash and lotion.
- Evaluate patient response to both scented and fragrance free regimens.
- Assess the coconut and chamomile colloidal oatmeal therapeutic scented regimens' ability to provide beneficial therapeutic moisturization.

STUDY DESIGN

- Single-center, randomized crossover, controlled, blinded 4-week clinical use study.
- Eighty-nine subjects, aged 18 to 70 years, with reported sensitivities to common household/ skincare products.
- Two 2×2 crossover substudies, one for each scented product regimen.
- Clinical tolerance assessments evaluated at each of the 5 visits over a 4-week usage period and through a weekly self-assessment questionnaire.

RESULTS

Figure 1. Dermatologist Grading Tolerance

Comparison between the mean grading scores for the studied clinical parameters after two weeks of using either the coconut or fragrance free regimen.

No statistically significant difference ($P > 0.05$) in tolerance between the coconut scented regimen and the fragrance free regimen.

Clinical Parameter		Week 1	Week 2
Redness	Coconut	0.05	0.02
	Fragrance Free	0.02	0.00
Itch/Burn	Coconut	0.05	0.03
	Fragrance Free	0.02	0.00
Dryness	Coconut	0.06	0.00
	Fragrance Free	0.00	0.00

Clinical Score: 0-none, 1-mild, 2-moderate, 3-severe

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Figure 2. Self-Assessment Week 2

- The self-assessment mean scores after 2 weeks of treatment for both the chamomile and coconut regimens versus a leading fragrance free regimen:
  - Scale 1-10, the higher the score, the more favorable the assessment
  - Both scented regimens were comparable to the fragrance free regimen for all parameters, and in some cases, outperformed the fragrance free regimen.

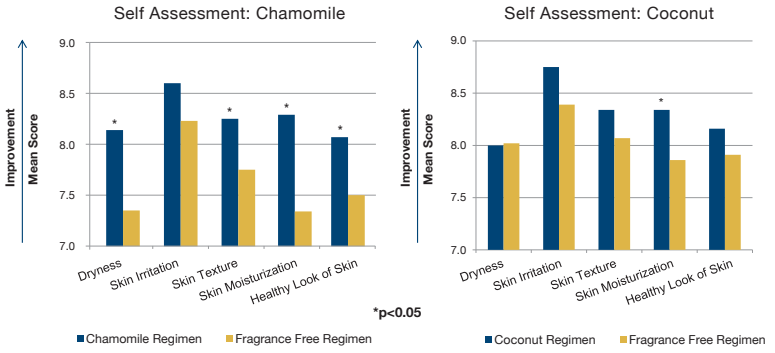
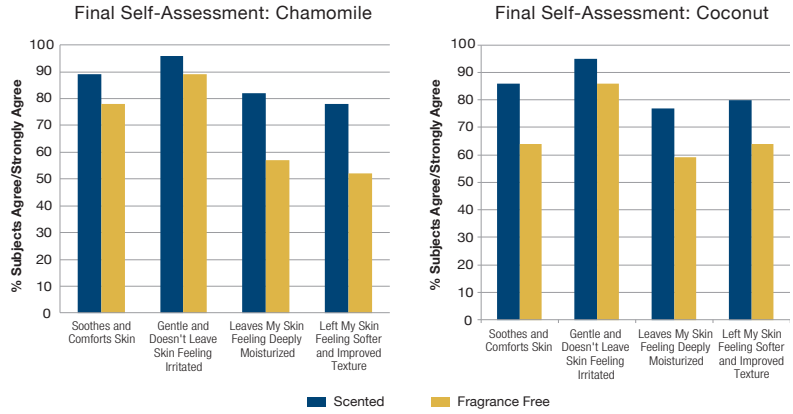


Figure 3. Final Self-Assessment

- Results of the final questionnaire given to subjects at the completion of each 4 week regimen Subject-perceived benefits to skin (after 2 weeks using the regimen)
- Subjects rated the scented regimen higher for comforting, soothing, and gentleness to the skin



CONCLUSIONS

- Statistical analysis of the clinical assessments found that both the coconut and chamomile colloidal oatmeal scented regimens were as well tolerated as a leading fragrance free therapeutic regimen (P> 0.05).
- Self-assessments of various skin health parameters revealed that subjects found the chamomile and coconut colloidal oatmeal regimens as effective, if not more effective, than the fragrance free regimen.
- Final self-assessments showed the subjects rated the gentle scented regimen higher for comforting, soothing, and gentleness to the skin when compared to a leading fragrance free therapeutic body wash and lotion regimen.
- Study demonstrated that the coconut and chamomile colloidal oatmeal therapeutic scented wash and lotion regimens provide beneficial therapeutic moisturization while maintaining a pleasant aesthetic.
- Final self-assessment questionnaires showed sensitive-skin subjects rated the scented colloidal oatmeal regimens higher for many aesthetic attributes when compared to the fragrance free competitor, which can result in improved patient compliance.

ACKNOWLEDGEMENTS

- *The authors wish to thank the participants in these studies.*
- *Writing assistance was provided by Richard Bradley Rzendzian, PharmD, of Johnson & Johnson Consumer Inc. (Skillman, NJ, USA).*
- *Editorial assistance was provided by Alex Loeb of Evidence Scientific Solutions (Philadelphia, PA, USA), and was funded by Johnson & Johnson Consumer Inc.*

CONFLICTS OF INTEREST

- *This study was supported in full by Johnson & Johnson Consumer Inc. (Skillman, NJ, USA).*
- *Judith Nebus, Heather Smith, and Neena Tierney, PhD, are employees of Johnson & Johnson Consumer Inc.*
- *Joseph Fowler, MD, is a consultant to Johnson & Johnson Consumer Inc.*

A Scented Therapeutic Moisturizer That Is Mild and Provides Skin Barrier Benefits

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ABSTRACT

- Scents are commonly thought of as potential irritants that can induce skin inflammation reactions in subjects with very dry, sensitive, or compromised skin conditions. Consequently, dermatologists often recommend the use of fragrance free therapeutic moisturizers to patients with sensitive or compromised skin, which may result in poor patient compliance. A therapeutic moisturizer containing a scent that is nonirritating to skin could provide clinicians with options to recommend to patients to improve compliance.
- A set of scents were evaluated in vitro for their inflammation or irritation potential in skin cells, and coconut and chamomile scents were found to be very mild and nonirritating. Indeed, moisturizers containing the coconut and chamomile scents were shown to be as gentle as the fragrance free moisturizer.
- Furthermore, the therapeutic moisturizers containing scents were found to induce similar levels of expression of the genes that are associated with skin barrier.
- Taken together, these results demonstrate that this scented moisturizer is as mild as a fragrance free lotion, and additionally can similarly induce the expression of multiple barrier genes involved in skin barrier function.

OBJECTIVES

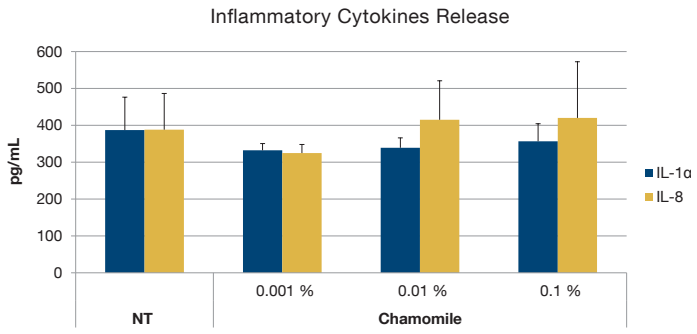
- Evaluate a set of mild scents (chamomile, coconut) for their inflammation or irritation potential using skin cells in vitro.
- Therapeutic moisturizers containing scents were further evaluated for their effect in vitro on:
  - the epidermal skin barrier, and
  - the expression of genes related to the epidermal skin barrier

STUDY DESIGN

- Human keratinocyte culture was used to evaluate the inflammatory effects of scents:
  - Interleukin (IL)-1α and IL-8 by enzyme-linked immunosorbentassay (ELISA).
- Used MatTek epidermal equivalent tissues (Ashland, MA, USA) to evaluate the effects of scented lotions on the barrier integrity, gene expression, and irritation as compared with fragrance free lotion:
  - The tissues were topically treated by 6 µL of lotion for 24 or 48 hours.
  - Measured barrier integrity by transepidermal electrical resistance (TEER), and the inflammatory cytokines IL-1α and IL-8 by ELISA.

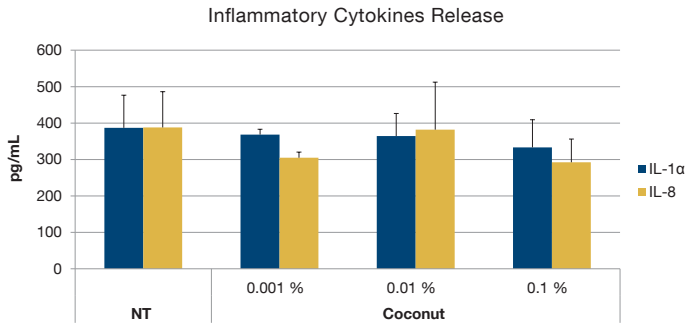
RESULTS

Figure 1a. Chamomile Did Not Induce IL-1α and IL-8 Release in Human Keratinocytes



Assessment of inflammatory cytokines, IL-1α and IL-8, released from human keratinocyte cultures showed that chamomile scent did not induce an inflammatory response at the doses tested. NT, no treatment control.

Figure 1b. Coconut Did Not Induce IL-1α and IL-8 Release in Human Keratinocytes



Assessment of inflammatory cytokines, IL-1α and IL-8, released from human keratinocyte cultures showed that coconut scent did not induce an inflammatory response at the doses tested. NT, no treatment control.

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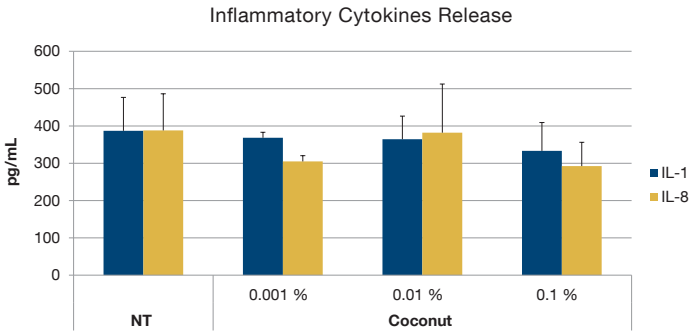
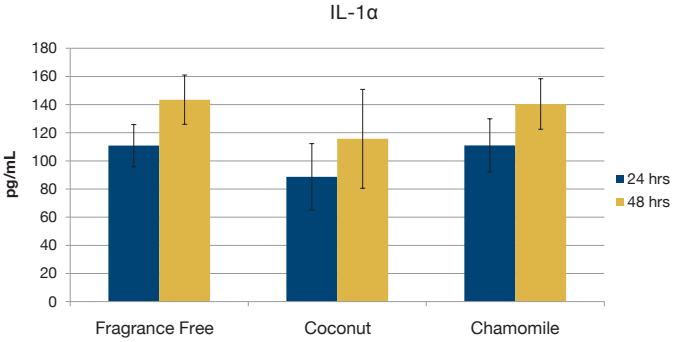
RESULTS (CONTINUED)

Figure 2a. Moisturizers Containing Scent Performed Similarly to the Fragrance Free Moisturizer on Skin Barrier in Human Epidermal Skin Equivalents



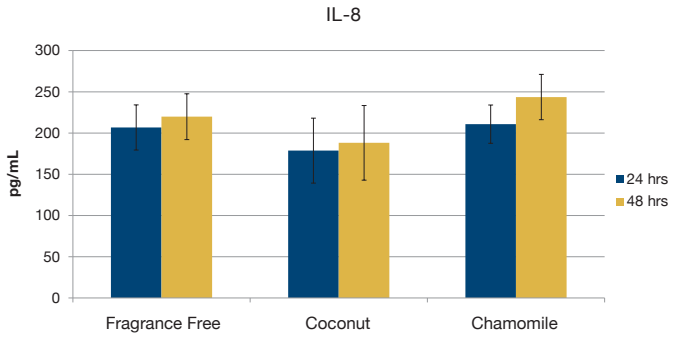
Moisturizers containing either coconut or chamomile scent caused similar TEER changes to a fragrance free moisturizer.

Figure 2b. Moisturizers Containing Scent Performed Similarly to the Fragrance Free Moisturizer by Not Increasing Inflammatory Mediator Release



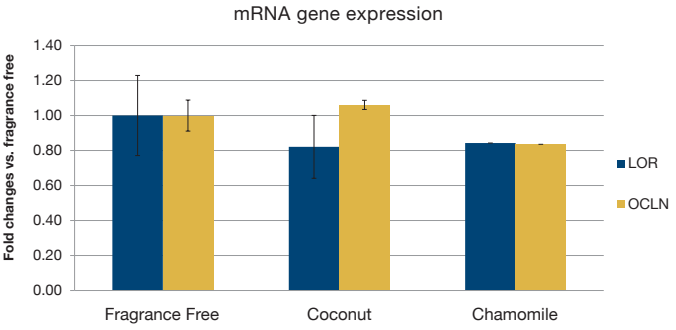
Moisturizers containing no scent, coconut scent, or chamomile scent induced similar IL-1α release from human epidermal skin equivalents after 24-or 48-hour exposure.

Figure 2c. Moisturizers Containing Scent Performed Similarly to the Fragrance Free Moisturizer by Not Increasing Inflammatory Mediator Release



Moisturizers containing no scent, coconut scent, or chamomile scent induced similar IL-8 release as a fragrance free moisturizer.

Figure 3. Moisturizers Containing Scent Performed Similarly to the Fragrance Free Moisturizer on Skin Barrier Gene Expression



Moisturizers containing either coconut or chamomile scent induced similar levels of expression of the barrier-relevant genes loricrin (LOR) and occludin (OCLN) as a fragrance free moisturizer in human epidermal skin equivalents.

CONCLUSIONS

- Coconut and chamomile scents were found to be very mild and nonirritating.
- Moisturizers containing the coconut and chamomile scents were shown to be as gentle as the fragrance free moisturizer.
- Moisturizers containing scents were found to have a similar gene expression profile to the fragrance free moisturizer for the genes related to epidermal skin barrier.
- Mild, nonirritating therapeutic moisturizers containing scents can provide clinicians with additional treatment options using scented therapeutic moisturizers, thus encouraging increased patient compliance.

DISCLOSURES

- *Michelle Garay, Wen-Hwa Li, Xinni Chen, Olha Ilnytska, Ramine Parsa, Simarna Kaur, and Michael Southall are or were employees of Johnson & Johnson Consumer Inc. when these experiments were conducted.*
- *This study was supported by Johnson & Johnson Consumer Inc., Skillman, NJ, USA.*
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