

Controlled Exposure Protocol To Assess The Dry Skin Improvement Potential Of In-Shower Body Lotions

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Introduction

Assessing personal care products' potential to impact skin is an important part of the product development cycle. Because of the difficulty and high cost associated with in-use tests, the industry often relies on controlled exposure models to make these assessments. A challenge with this approach is to design controlled exposure clinical protocols that reflect expected consumer use of a product.

Recently a nontraditional product form, the in-shower body lotion, was introduced. This type of product is intended to be applied in the shower, after cleansing, and then rinsed from the skin. Because an in-shower body lotion is not a cleanser, protocols such as the forearm¹ or leg² controlled application technique that are designed to assess the skin effects of personal cleansers are not directly applicable. Similarly, because the in-shower body lotion is intended to be rinsed off after application, protocols designed to test leave-on lotions that are applied outside the shower, after the skin is toweled dry, are also not directly applicable to the in-shower body lotion.

Objective

To develop a controlled exposure protocol for in-shower body lotions that reflects consumer habits and practices and that will reliably predict in-shower body lotions' potential to improve dry skin condition.

Methods

The following are general considerations for the controlled application studies conducted with the in-shower body lotion.

Subject Population

- Healthy adult females with dry leg skin were recruited.
- The target enrollment varied between 20 and 40 subjects, depending on the study objective.

Product Dosing

- Habits and practices data for the in-shower body lotion show that consumers apply about 1µL/cm² across the various parts of their bodies. This dosage was adopted for clinical testing.
- Separate studies conducted with leave-on lotions show that 1µL/cm² is also a relevant dose for these products. This is consistent with the usage habits reported in the literature for similar types of products, e.g. sunscreens.^{3,4}

Study Design

- A randomized Latin square design was used.
- A modified procedure based on the leg controlled application technique² was followed, including a 1 week preconditioning period.
- The entire leg was washed in a controlled manner with a base cleansing product chosen on the basis of past clinical experience showing that it has minimal impact on dry skin condition under the leg wash protocol. The cleanser was rinsed from the leg.
- While the skin was still wet, the in-shower body lotion was applied with the fingers and remained on the skin for the specified period of time. The treated site was then rinsed again and patted dry. In cases where a leave-on lotion was used, the skin was patted dry after washing and rinsing. The leave-on lotion was applied with a cotted finger within 1 minute of patting the skin dry.
- Evaluations were conducted at baseline and at various times during treatment, depending on study objectives. Subjects acclimated under controlled environmental conditions for at least 30 minutes before an evaluation. The grader and instrument operators were blind to treatment identities and assignments.
- Mixed model techniques adjusting for study design parameters were used to analyze the data.

¹ J Soc Cosmet Chem 1995;46:67-76.

² Int J Cosmet Sci 1999;21:383-97.

³ Br J Dermatol 1999;140:255-8.

⁴ Photodermatol Photoimmunol Photomed 1993;9:242-4.

⁵ Dry Skin (internet). myDr; c2004 (cited 20 Oct 2004). Available from: <http://www.mydr.com.au/default.asp?article=3028>.

⁶ J Cosmet Sci 2003;54:289-300.

Results

Effect of Skin Wet Time

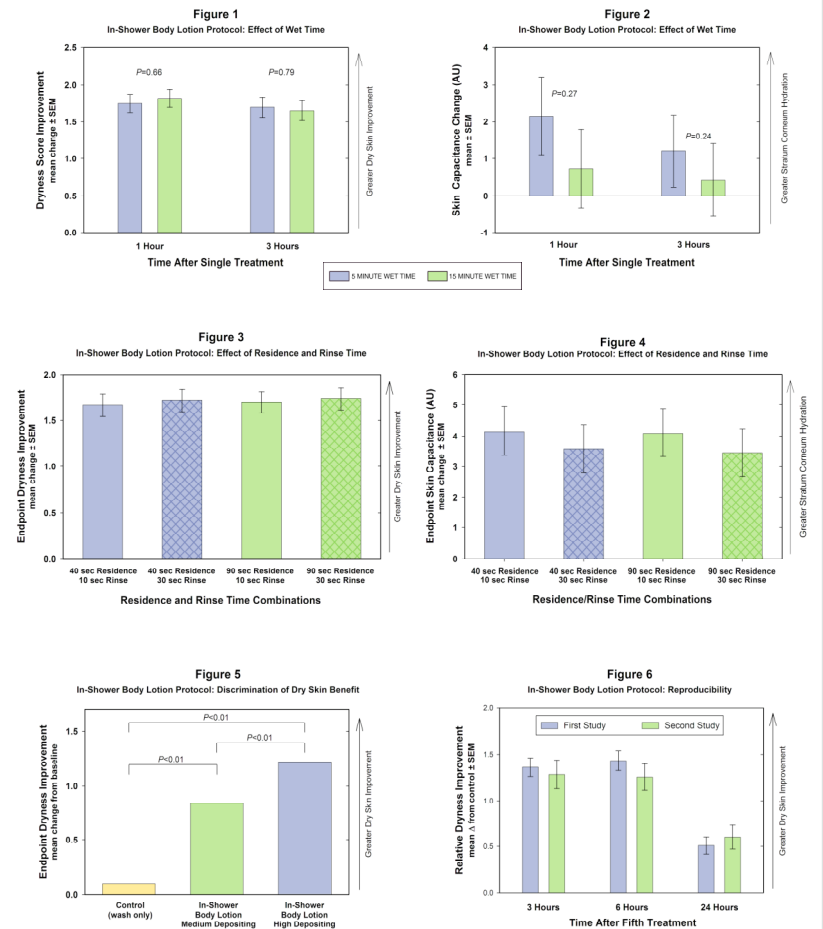
- Since the in-shower body lotion is applied after cleansing, the time spent showering and the 'wet time', prior to this application is an important protocol consideration. Identifying appropriate wet time conditions is difficult since an individual does not spend the entire time under the water stream, nor is this stream directed at a single body area for the entire shower. Habits and practices data were used to select wet times that encompass a majority of showering practices in the United States and that provide reasonable values for use in a clinical model.
- A single application pilot study was conducted to assess the impact of wet time on the dry skin improvement provided by an in-shower body lotion. Evaluations were conducted 1 hour and 3 hours after treatment (Figure 1). Wet time did not significantly impact expert dryness scores.
- The 15 minute wet time yielded lower skin capacitance readings than the 5 minute wet time (Figure 2), though this difference was not significant under the conditions of this study. This outcome appears consistent with dermatologists' recommendations to avoid excessive bathing with hot water and could reflect greater removal of lipid or natural moisturizing factor during prolonged water exposure.^{5,6} Considering the expert dryness and skin capacitance results, and to simplify study conduct, the 5 minute wet time was chosen for use in subsequent clinical work.

Effect of Residence and Rinsing Times

- The in-shower body lotion is intended to be rinsed from the skin after application. The amount of time the product remains on the skin, the residence time, and the time spent rinsing the skin are also important protocol parameters. A separate habits and practices study was conducted to determine how the in-shower lotion is used, and residence time and rinse time values bracketing the observed range of values were chosen.
- A five-day study employing a factorial design was used to assess the impact of residence time and rinse time. Skin condition was evaluated 3 hours after the final treatment. This study showed that for the conditions tested, neither residence time nor rinse time had a significant impact on expert dryness scoring (Figure 3, $P>0.57$) or on skin capacitance measurements (Figure 4, $P>0.18$). Based on this outcome, residence and rinse times of 40 seconds and 10 seconds, respectively, were chosen for use in subsequent clinical work.

Discrimination and Reproducibility

- The uniqueness of the in-shower body lotion limits the number of possible form-specific product comparisons; however, the protocol shows the dry skin benefit of in-shower body lotions relative to control and discriminates product versions that are formulated to deliver different levels of dry skin improvement (Figure 5). Results shown are for a 3 hour evaluation after 5 days of treatment.
- Results generated in two clinical studies conducted approximately one month apart using the same product demonstrate the protocol's ability to reproducibly predict an in-shower body lotion's potential to improve dry skin (Figure 6, bars of the same color represent results from a study). The results shown are after 5 days of treatment. In all cases, the in-shower body lotion provides significant dry skin improvement ($P<0.01$).



Conclusion

A controlled exposure protocol for testing in-shower body lotions was developed based on an understanding of how consumer will use this product form. Results from clinical tests demonstrate that this protocol can reliably and reproducibly predict the the dry skin improvement benefit for in-shower body lotions.