



# Skin Moisturisation Performance Assessment of Healthcare Hand Sanitisers



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## Abstract

Background: Hand sanitisers are used frequently by healthcare workers and are often implicated with drying skin, despite omnipresent skin care claims. Past efforts have shown the clinical laboratory skin care performance of products can be effectively used to evaluate hand cleanser performance and predict skin effects of HCW's. The primary aim is to determine the skin moisturisation performance of a broad range of European Alcohol Hand Rubs (AHR), as compared to a novel 70% ethanol foam AHR, specially formulated to enhance moisturisation.

Methods: Objective skin moisturisation assessment can be measured with standard bioengineering devices used according to European Group for Efficacy Measurements of Cosmetics (EEMCO) Guidelines. The volar forearm of subjects were pre-washed and dried for 30 minutes prior to taking baseline measurements using a corneometer. Test articles were applied (2mg/cm<sup>2</sup>) and skin moisture measurements were taken at 10 and 120 minutes following application. Changes in moisturisation relative to baseline for each product were determined using a paired t-test, and differences between products were analysed using ANOVA with post hoc analysis (P<0.05).

Results: The novel 70% ethanol foam AHR significantly increased skin hydration 10 minutes and 2 hours after application, and was superior for skin moisturisation to other AHR foams making moisturisation related claims. Other differences between test articles were observed.

Conclusions: The presence of ingredients claimed as moisturisers in an AHR formulation is not sufficient to significantly increase skin hydration. Therefore, moisturisation claims can be misleading, and should be supported with actual performance data, not based on ingredient information alone.

## Introduction

An acute moisturisation study was completed using five commercially available hand rubs by Cutest Ltd. which confirmed a preliminary acute moisturisation study conducted at GOJO Industries. The results presented are from the Cutest data set but are consistent with the GOJO data. A separate clinical trial was completed using two of the products in a multiple use scenario in intensive care units.

## Method

Acute Moisturisation Study: Subjects pre-washed their forearms with a mild, foaming handwash and allowed skin to equilibrate for 30±1 minute in a temperature (21 ± 2 °C) and humidity (45% ± 15% RH) controlled room prior to beginning study treatment. The corners of four 3 cm X 4 cm rectangles were marked on the volar forearm of each subject with a permanent marker. A Courage+Khazaka MPA9 with Corneometer CM825 probe was used to take skin capacitance readings at 30±1 minute post pre-wash to determine the baseline value. Experimental treatments including PURELL Skin Nourishing Foam, Competitor #1 (Alcohol Free Foam), Competitor #2 (Alcohol Foam), Competitor #3 (Alcohol Free Foam), Competitor #4 (Low Alcohol Foam), Untreated Skin were randomly assigned to the demarcated areas on subjects' arms. Approximately 110 minutes post pre-wash, 2 mg / cm<sup>2</sup> of test article was applied to the appropriate site and gently rubbed into the skin with a gloved finger in a clockwise motion for 15 seconds. 10 ± 1 and 120 ± 1 minutes after test article application, Corneometer readings were taken to assess skin hydration. Results were analysed using an ANOVA with multiple comparisons at an α = 0.05. This study was conducted first at GOJO Industries and further confirmed by a separate independent study conducted at Cutest Ltd.

Clinical Trial: Four intensive care units at Akron General Medical Center in Akron, Ohio participated in a four week clinical trial where 2 units were assigned to the PURELL Skin Nourishing Foam group and two units were assigned to the control group. Units designated as controls continued to use the hospital provided PURELL Foaming Alcohol Hand Rub. Test articles were blinded and placed in dispensers on the units for four weeks. Health Care Worker skin capacitance measurements were taken using a Courage+Khazaka MPA9 with Corneometer CM825 probe at baseline, 2 weeks and 4 weeks (February 11 – March 21, 2008). D-Squame skin analysis disks were used to collect skin samples from all subjects at baseline, 2 weeks and 4 weeks and analysed by CuDerm Corporation in Dallas, Texas. Self-assessment questionnaires to measure perception of skin condition were administered to subjects at baseline, 2 weeks, and 4 weeks. Results were analysed with parametric and non-parametric statistics as appropriate at an α = 0.05.

## Results

After one use, four of the five foaming Hand Rubs with did not produce average skin hydration (AU) significantly different from an untreated control at minutes 2 hours (p<0.05). PURELL Skin Nourishing Foam produced superior average skin hydration (AU) when compared to three of four other treatments at 10 minutes. Therefore, the sustained skin hydration beyond 10 minutes produced by a one time use of PURELL Skin Nourishing Foam as shown in Figure 1 was superior to the other foaming Hand Rubs tested.

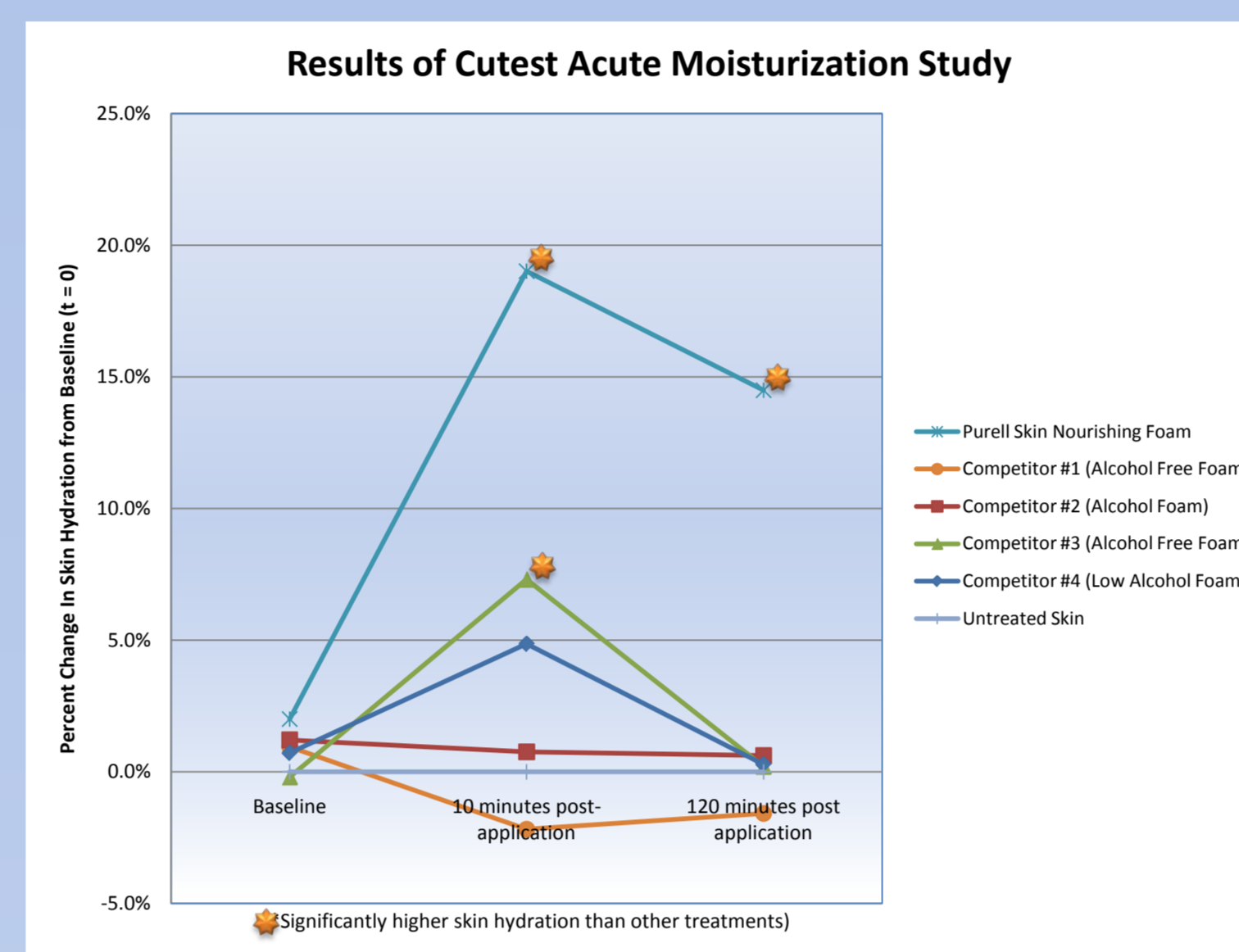


Figure 1: Comparison of Skin Hydration Performance of Various Foaming Alcohol Hand Rubs Using an Acute Moisturisation Method.

Baseline measurements demonstrate equivalent skin hydration between groups seen here below in Figure 2. After two weeks of use, the skin hydration of the treatment group significantly improved from baseline and had significantly higher skin hydration than the control group (p<0.001). After four weeks of use, the skin hydration of the treatment group significantly improved from baseline, was equivalent to the two week time point, and showed significantly higher skin hydration than the control group (p<0.037). These results demonstrate that PURELL Skin Nourishing Foam is able to improve skin moisturisation in as little as 14 days and maintain the hydration for a duration of at least one month.

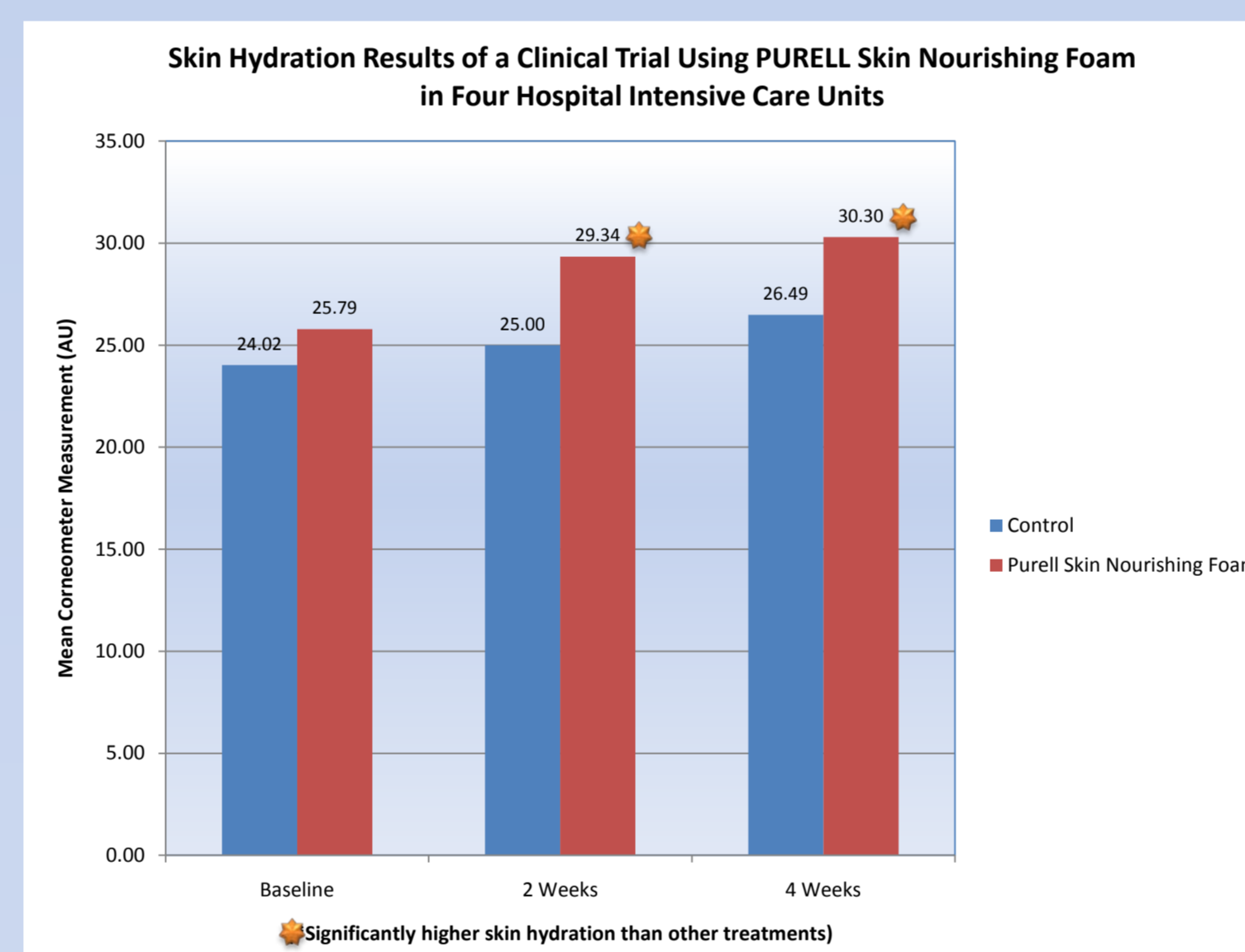


Figure 2: Skin Hydration Improvement in an Intensive Care Setting.

Desquamation index is a good overall measure of skin dryness and correlates with typical clinical grades. The change in Desquamation Index from baseline to 14 days for the PURELL Skin Nourishing Foam group was not significant (p<0.0522) seen here in Figure 3. In comparison, the change in Desquamation Index from baseline to 14 days for the Control Group indicated a significant change (p<0.0000). Similar differences were observed between baseline and 28 days for the PURELL Skin Nourishing Foam Group (p<0.0804) vs. the Control Group (p<0.0001). It is hypothesized that cold, dry, winter weather caused the control group to increase in dryness, whereas PURELL Skin Nourishing Foam was able to reduce the harsh effects of winter in the skin of healthcare workers.

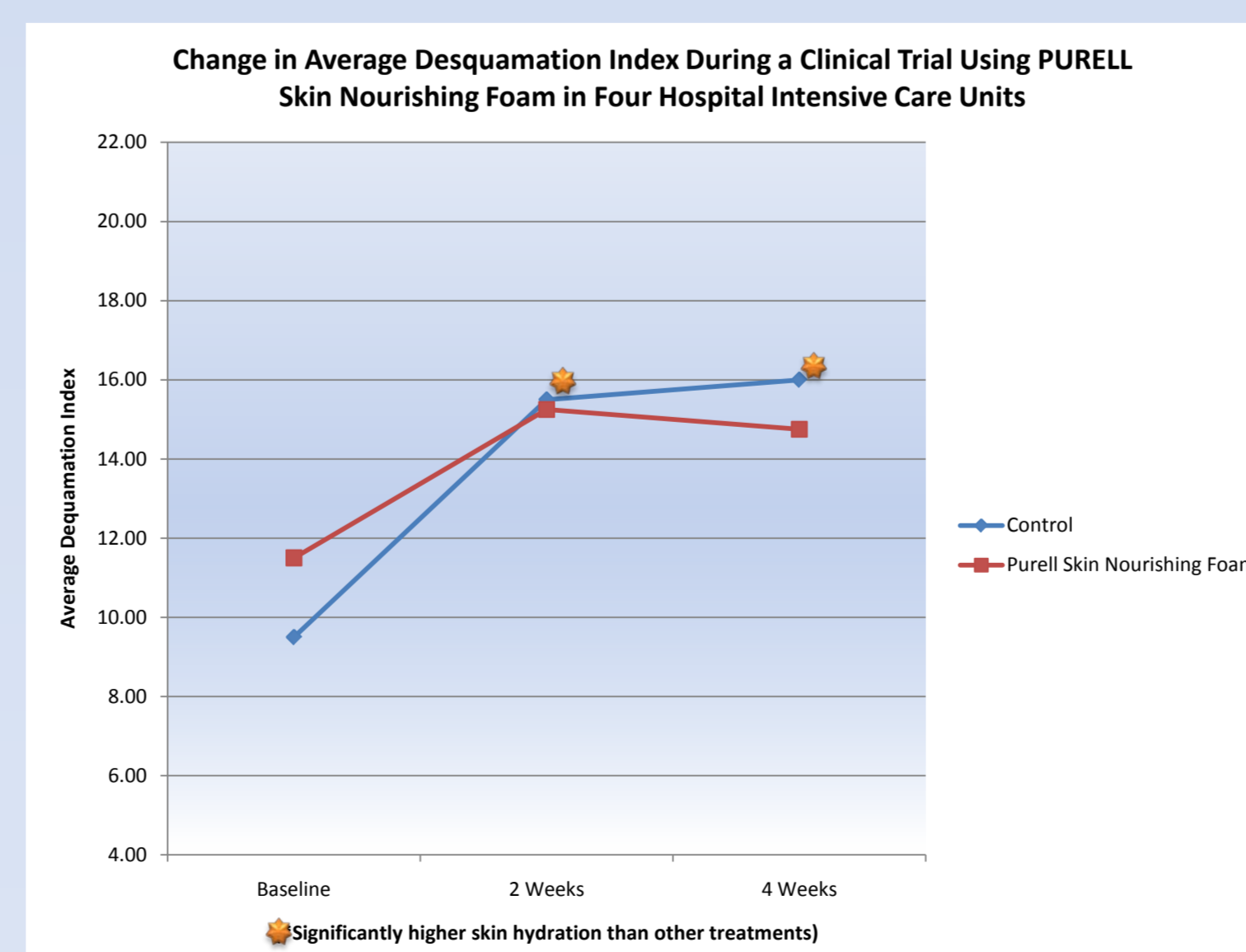


Figure 3: Change in Average Desquamation Index Over 4 Weeks.

Health care workers completed self-assessments of skin performance using a 7 point scale where ratings ranged from 0 (poor) to 7 (excellent). After 2 weeks of PURELL Skin Nourishing Foam use, subjects rated skin condition and product performance based on the following criteria as seen in Figure 4: non-drying, moisturisation, improved skin condition, softness, reduction of winter dryness and soothing. A Chi-Square Analysis revealed significant improvement from baseline in all performance parameters after 14 days of use (p<0.05). Therefore, PURELL Skin Nourishing Foam produced perceptible improvements in the skin of healthcare workers in 14 days.

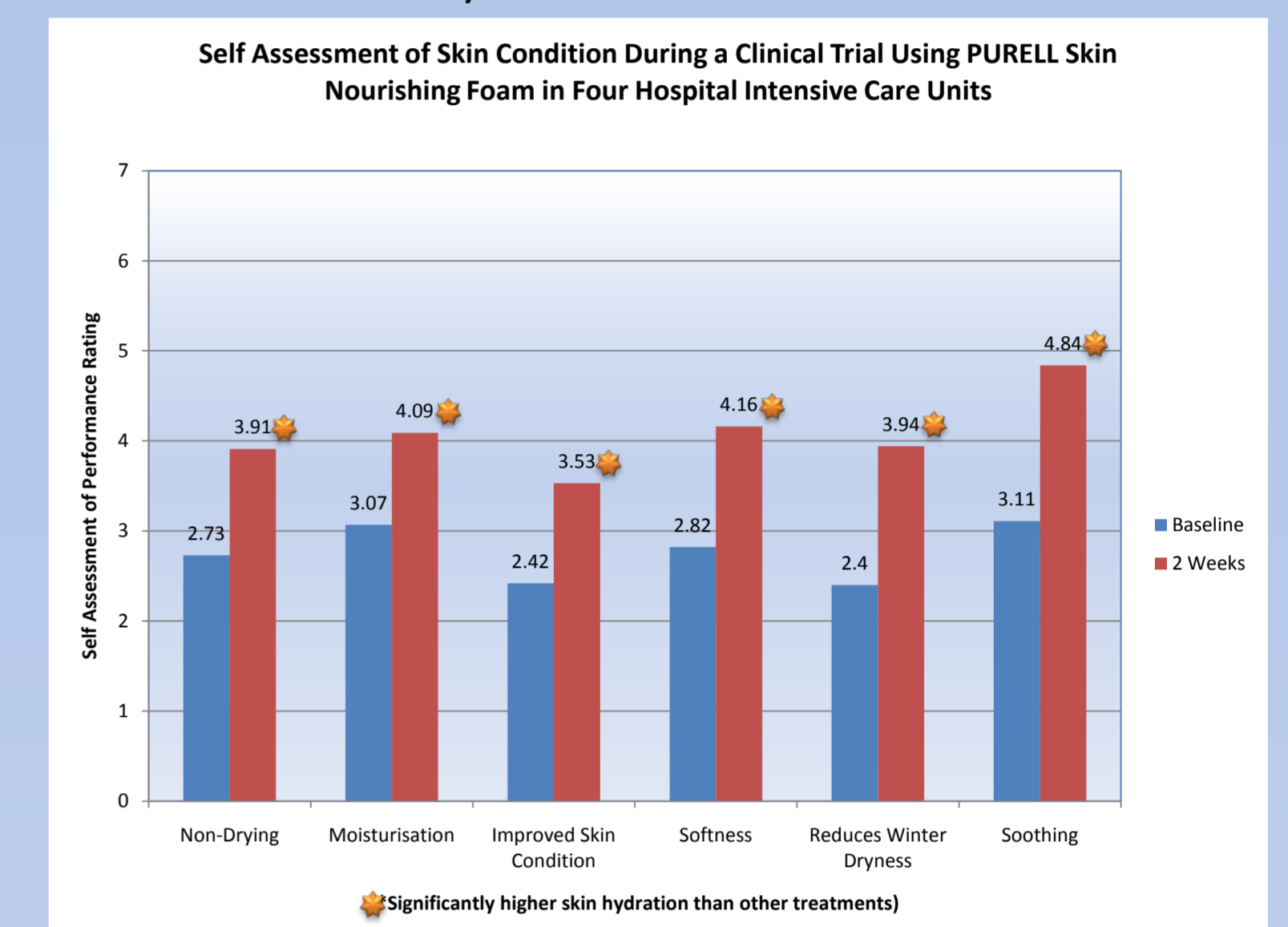


Figure 4: Subjective Assessment of Skin Health After 14 Days of Use in a Healthcare Setting.

## Conclusions

Formulation of a moisturising AHR is a significant technical challenge which is further complicated by the absence of standardised methods for substantiating moisturisation claims. As skin condition is a major factor in hand hygiene compliance, robust analysis of product skin performance beyond simple assessment of individual ingredient moisturisation data is critical to truly evaluating the skin benefit of an AHR. The results of these studies suggest:

- Criteria for substantiating AHR moisturisation claims should be established.
- The presence of moisturisers in an AHR formulation is not sufficient to improve skin condition and significantly increase skin hydration. Therefore, moisturisation claims can be misleading.
- Proper ingredient selection and formulation are imperative to providing the substantial moisturisation needed by healthcare workers.
- The moisturisation performance of PURELL Skin Nourishing Foam is superior, both immediately and over time, to other marketed AHR foams making moisturisation related claims.
- PURELL Skin Nourishing Foam's synergistic moisturizing blend improves skin condition in as little as 14 days to an extent noticeable to health care workers.

## References

1. APIC 2005, "The Impact of an Ultramild Foaming Hand Cleanser on Skin Health of Healthcare Workers – Can Laboratory Findings be Validated in a Clinical Healthcare Setting?"
2. EEMCO Guidelines is E. Berardesca; EEMCO guidance for the assessment of stratum corneum hydration: electrical methods; Skin Research and Technology; Vol 3; No 2; Pages 126-132; 1997

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