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NATIONAL ASSOCIATION DIRECTORS OF NURSING ADMINISTRATION/LONG TERM CARE

Use of Advanced Skin Bioengineering Instrumentation to Evaluate Skin Lotion Performance In A Long Term Care Environment

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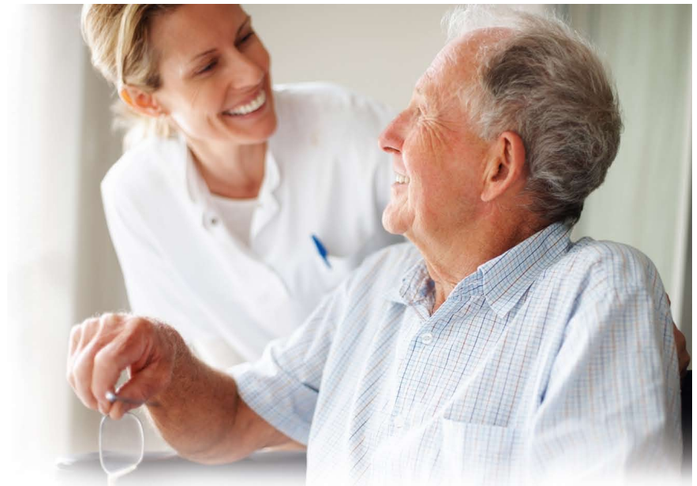

Introduction

Several changes in skin can be observed in adults over 65 years of age which result in a reduction in epidermal thickness, a general breakdown at the epidermal-dermal junction, and slower turnover of the epidermis[1,2] to as long as 31 days in contrast to 14 days for an 18 year old. These physical characteristics contribute to an increased susceptibility to damage including, drying, cracking, and skin tears of which the treatment and prevention are key challenges facing Directors of Nursing and Long Term Care facilities. Skin tears occur in excess of 1.5 million times per year affecting 14 to 24% of institutionalized adults[3]. It has been shown that increased skin elasticity[3] and improved moisturization[9] reduces the likelihood for skin tears[10]. However, subjective analyses of skin care products in limited use settings do not adequately assess the true performance of the products. In addition, objective analysis of products using methods designed for cosmetic analysis do not adequately address the needs and skin conditions associated with characteristics of skin in the aging population. This study monitors specific skin conditions of an aging population as observed in a Long Term Care environment and utilizes advanced noninvasive skin bioengineering instrumentation to objectively measure the effects of a skin care product which impact these conditions.

Two Long Term Care facilities: The Pines Lakeside Therapy Center in Canton, Ohio, and St. Luke Lutheran Community Portage Lakes in Akron, Ohio, participated in a four week clinical trial. The Pines Lakeside Therapy Center is operated by Atrium Living Centers and located in Canton, Ohio. The facility is a 60 bed Medicare and Medicaid certified nursing facility that offers Skilled Nursing, Rehabilitation and Intermediate care, as well as, Respite and Hospice care. St. Luke Lutheran Community Portage Lakes in Akron, Ohio, is a 56-bed facility and is Medicare and Medicaid facility offering Intermediate Nursing Care, Rehabilitation Services, Respite Care, Wound Care Specialists and Hospice Care amongst other services.

Problem, Hypothesis, Objective and Program Description

Measuring stratum corneum capacitance as an indicator of skin hydration has been the standard for non invasive skin measurement for decades[8]. However this does not fully address conditions that are truly relevant for an aging population. Skin elasticity as it relates to skin tearing is a key area of concern for the aging population and the care givers that interact with them[4]. Unfortunately, the accepted skin bioengineering techniques available to measure skin elasticity, such as suction and torsion devices, are too aggressive for the aging population as they may pose a risk of skin tears during the measurement process. After a thorough review of available devices, the Goodyer Linear Skin Rheometer (LSR)[6,7] was selected because it offered a unique solution to provide non invasive measurement of stratum corneum plasticization and elasticity. The LSR was used in conjunction with traditional skin bioengineering instrumentation to evaluate the performance of a lotion as it relates specifically to characteristics of aging skin.

Method

Thirty-two facility residents (17 and 15 respectively) were identified and treatment areas were marked consisting of two 4 cm^2 areas on the outside of each lower leg in the area of the calf muscle. This resulted in an effective sample size for the study consisting of 32 residents, with two each unique control/intervention sites equaling n = 64. For a period of seven days prior to baseline skin measures, participants ceased application of all lotion products to the treatment areas to facilitate a washout period and achieve a baseline skin condition. Bathing and other hygiene practices were not stopped during the study duration. At the conclusion of the washout period, baseline skin measurements described below were conducted prior to treatment with the lotion intervention. For the duration of the 21 day study, a lotion intervention was applied to only one of the two treatment areas per leg in

Nurse applying skin lotion to a resident's leg.

a predetermined random assignment both in the morning and evening by trained facility staff. One treatment control area per leg remained as untreated skin for the duration of the study. Subsequent skin measures were conducted following 10 days of lotion intervention and after 21 days of lotion intervention. Non-invasive skin measurements including stratum corneum hydration measures using the Courage+Khazaka Corneometer CM825[7], and dynamic spring rate of skin using the Goodyer Linear Skin Rheometer (LSR)[5,6] were conducted at all time points. Dynamic Spring Rate (DSR) in grams per millimeter were measured and is an inversely proportional indicator of skin elasticity. Skin measures were conducted on both the untreated control site and the intervention site of all participants. Statistical analysis was conducted with SPSS V16 using the Paired-Sample Student's t-Test algorithm to evaluate the skin measures comparisons of intervention vs. control at baseline T=0, T=10 days and T=21 days. A 95% confidence level for statistical significance ($P < 0.05$) was targeted to indicate valid difference between intervention and control.

Results & Discussion

Figure 1 shows the seven day washout period prior to baseline skin measures indicated no initial statistical difference in DSR measured between the intervention sites and control sites with a -1.553 g/mm difference (n = 32, p = 0.127). After the baseline measures and following 10 days of twice daily lotion intervention treatments, the difference at the 10 day measures indicates a statistically relevant improvement 3.155 g/mm in DSR over the control (n = 32, P = 0.009). The improvement in DSR continues through 21 days lotion application as shown by a 4.806 g/mm improvement (n = 18, P = 0.007). Note that the 21 day results at one of the facilities were not included due to the environmental conditions (temperature and humidity) at the facility being significantly outside the operation parameters of the DSR and moisturization instrumentation.

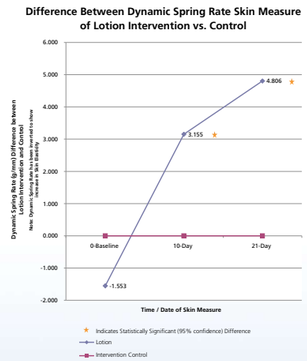

Figure 1: Comparison of a Lotion Intervention vs. Untreated Skin Control Impact on Dynamic Spring Rate Over Three Weeks of Treatment

Similar improvements to stratum corneum hydration are shown in **Figure 2**. Following the seven day washout period, initial difference in baseline stratum corneum hydration measures between the lotion intervention site and the control site show -0.828 AU (Arbitrary Units) or no statistical difference (n = 64, p = 0.341). After baseline measures and the first 10 days of twice daily lotion applications, the lotion intervention shows a 5.135 AU statistically significant improvement in stratum corneum hydration (n = 64, P = 0.000). Similar to the improvement in stratum corneum elasticity, the stratum corneum hydration also shows continued improvement through 21 days of lotion intervention shown by a 7.292 AU difference in stratum corneum hydration over the control (n = 32, P = 0.000).

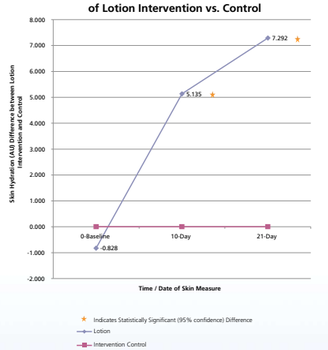

Figure 2: Comparison of a Lotion Intervention vs. Untreated Skin Control Impact on Skin Hydration Over Three Weeks of Treatment

Conclusion

Non invasive skin bioengineering instrumentation such as the Goodyer LSR (Linear Skin Rheometer) is a statistically validated mechanism for measuring specifically the change in stratum corneum plasticization and elasticity. The technique utilized by this instrument is effective at obtaining these measures without adversely impacting the fragile skin characteristic of this aging demographic. Moreover, the skin elasticity results of the LSR correlate with the statistically relevant skin hydration measures associated with the lotion intervention. In summary, the results of this study suggest:

1. Changes in skin biomechanics associated with fragile skin characteristic of aging skin can be directly measured.
2. Methodologies exist to obtain both a statistically valid objective measures of both stratum corneum elasticity and skin hydration directly from an aging skin population sample.
3. The methodology used in this study validates the theory that increasing stratum corneum hydration correlates directly to an increase in stratum corneum elasticity.
4. This study has shown that a lotion intervention statistically improves stratum corneum elasticity and moisturization resulting in better overall skin performance in 21 days.
5. A properly formulated lotion intervention is an effective mechanism to increase both stratum corneum hydration and stratum corneum elasticity of aging skin.
6. Further clinical testing is recommended to assess the full impact of this intervention and the actual rate of skin tears at a long term care facility.

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