Ceramide-Containing Regimen Provides Superior Tolerance To Isotretinoin-Induced Side Effects And Skin Barrier Function

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INTRODUCTION

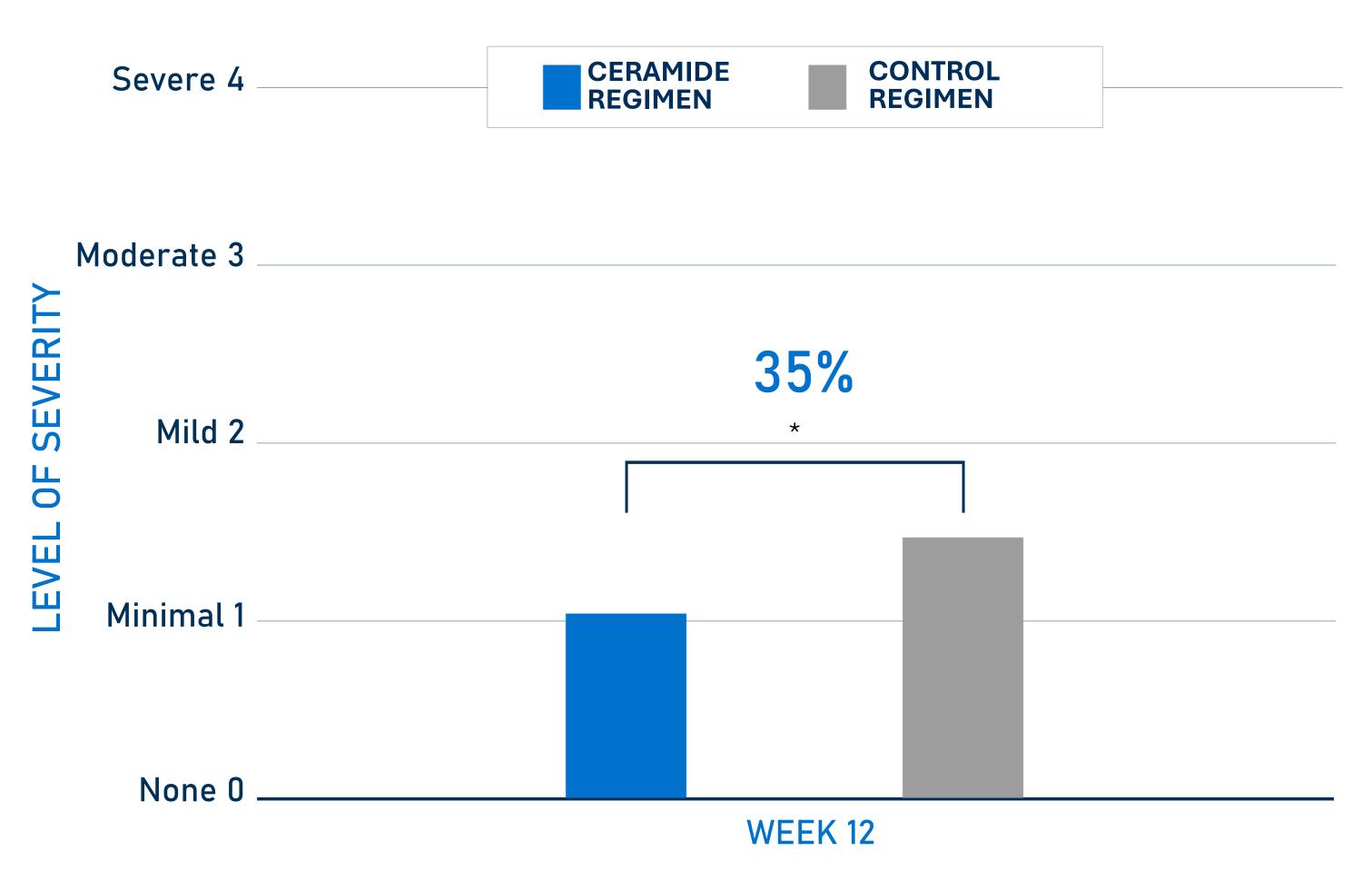
Acne-prone skin is associated with reduced ceramides, elevated transepidermal water loss (TEWL), and skin barrier disruption. As acne becomes more severe, there is an increase in TEWL and significantly reduced free sphingosines and free ceramides. Acne medications compromises skin barrier integrity and lead to side effect and quality of life consequences that results in treatment discontinuation. Oral isotretinoin is the treatment of choice for patients with severe acne and treatment-resistant moderate acne. Isotretinoin-induced side effects related to dryness are regimen including cleansers and moisturizers supports the skin barrier and isotretinoin-induced side effects.

METHODS

This 12-week study was a single-center, double-blind, randomized clinical trial recruited 126 subjects (aged 13-35 years, isotretinoin-naive) with moderate-to-severe acne (IGA scale, 3-4), in Brazil. All subjects received oral isotretinoin (0.5 mg/kg/day). Participants were randomized to adjunctively receive either a ceramide-containing skincare regimen or control skincare regimen. Both groups followed a standardized daily regimen: facial cleanser (2x/daily), facial sunscreen (morning, reapplied as needed), facial cream (night). Assessments included subjective and clinical evaluation of dryness, scaling, erythema, burning, itching, and tightness in addition to overall appearance, skin tone, skin hydration (Corneometer), and Transepidermal Water Loss (TEWL; Tewameter™ 300). Assessments were at baseline, week 4, 8, and 12.

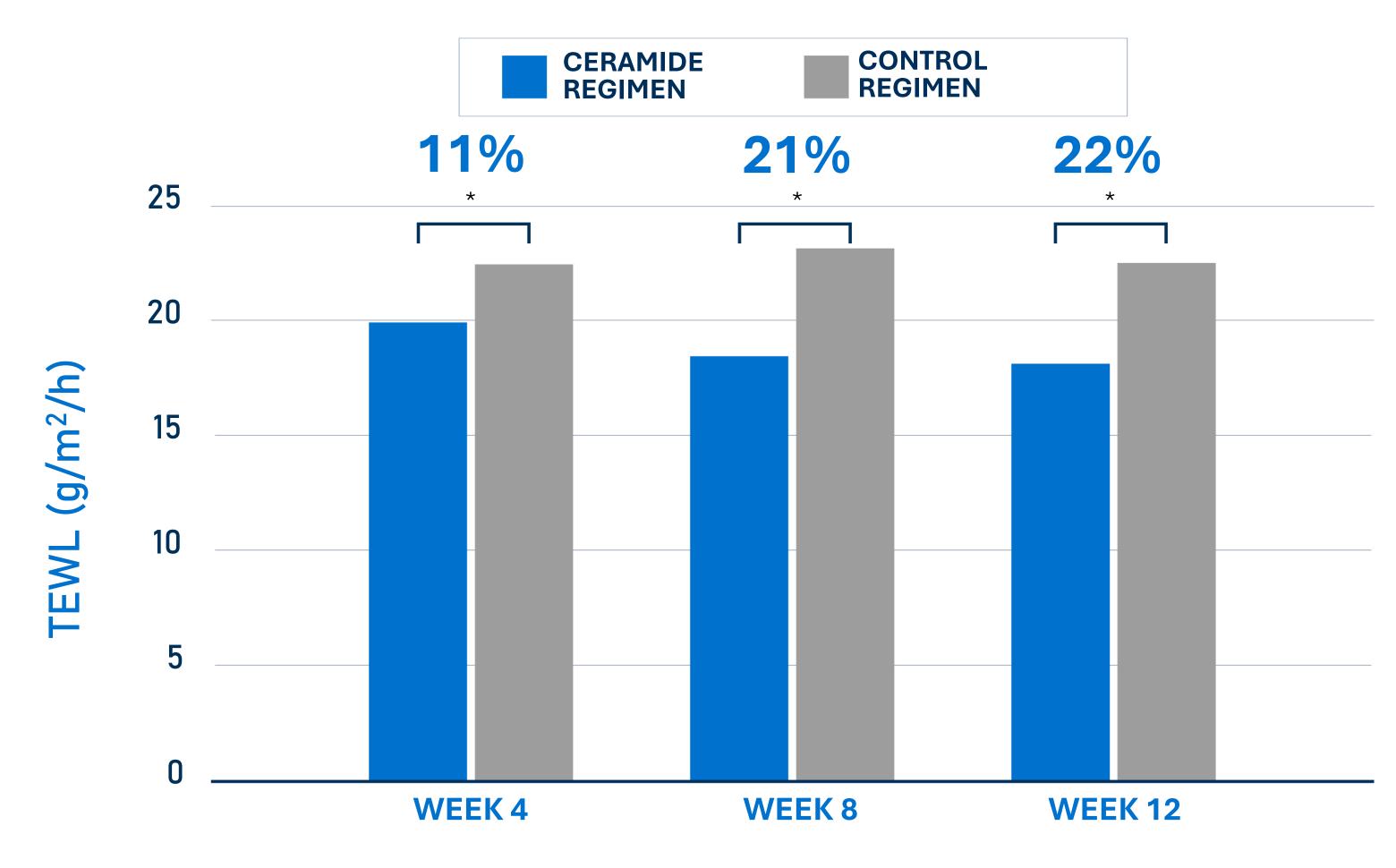
RESULTS

Fig 1. Change in Dryness Severity vs. Control



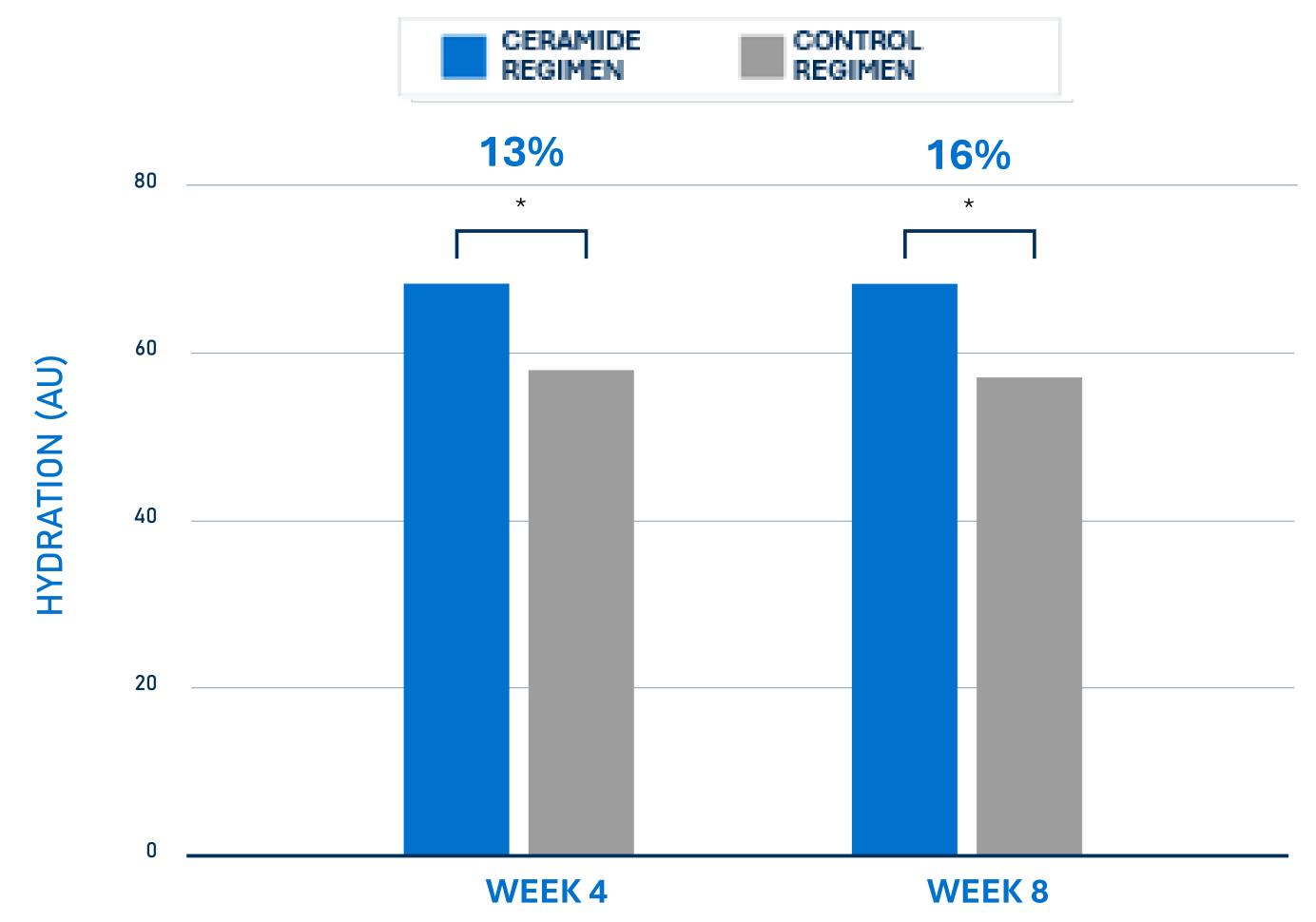
*P <0.05. Statistically significant difference.

Fig 2. Change in TEWL vs. Control



*P <0.05. Statistically significant difference.

Fig 3. Change In Hydration vs. Control



*P <0.01. Statistically significant difference between regimens.

- The ceramide-containing regimen also resulted in:
 - Significant improvement in TEWL at week 8 and week 12 vs. baseline (-6% and -9%, respectively)(*P*<0.05)
 - Significant reduction in subject-assessed scaling and tightness at week 4 vs. control (-45% and -96%, respectively)(*P*<0.01)
 - Significant improvement in dermatologist-assessed overall skin quality, skin tone evenness, skin texture, and post-inflammatory hyperpigmentation at week 12 (-22%, +25%, -27%, -22%, respectively) (*P*<0.01)
 - **High patient satisfaction and tolerance** with 96% of patients agreeing the regimen felt hydrating and resulted in skin feeling comfortable and clean and 90% of patients agreeing they would continue regimen use

CONCLUSION

When using isotretinoin, a ceramide-containing skin care regimen was associated with significantly isotretinoin-associated side effects including objective dryness, subjective tightness, and subjective scaling compared with a control regimen. A ceramide-containing regimen provided superior skin barrier support compared with the control regimen, and significantly increased hydration and reduced TEWL compared with baseline despite isotretinoin-induced dryness, indicating a stronger skin barrier compared with baseline.