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Diagnostic potential of five different biomechanical parameters to detect sclerotic cutaneous graft-versus-host disease



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Background: The current standard for assessing skin sclerosis in chronic graft-versus-host disease (cGVHD) is based on clinician assessment. The Myoton device offers quantitative measurements of 5 soft tissue properties: stiffness, relaxation time, oscillation frequency, decrement, and creep. Previous studies revealed increased skin stiffness and an ability to differentiate sclerotic from unaffected post-transplant skin. This study further evaluates the diagnostic potential of the 5 properties.

Methods: Sclerotic cGVHD patients (n = 13), post-bone marrow transplant controls (n = 10), and healthy controls (n = 14) were measured with the Myoton. Each subject was measured on 10 bilateral sites. For each of the 5 parameters, the overall value was calculated as the average over 20 measurement sites. We performed receiver operating characteristic (ROC) and area under the curve (AUC) analyses to compare the diagnostic sensitivity of these parameters.

Results: Sclerotic cGVHD patients showed significant increases ($P < .05$) in stiffness and frequency and decreases ($P < .05$) in relaxation time compared with controls. The ROC and AUC analyses revealed that the overall frequency (sensitivity: 91%; specificity: 93%; AUC: 0.92), stiffness (sensitivity: 91%; specificity: 93%; AUC: 0.92), and relaxation (sensitivity: 100%; specificity: 82%; AUC: 0.85) allow for high accuracy in the differentiation of sclerotic patients from post-BMT controls. The Pearson correlation was lowest ($R^2 = 0.651$) for stiffness versus relaxation time, suggesting that this combination provides the highest diagnostic yield.

Conclusions: Frequency, stiffness, and relaxation time of skin demonstrated high accuracy in the differentiation of sclerotic cGVHD patients from post-BMT controls. A larger study is needed to develop a multivariate predictive model.

Commercial disclosure: None identified.

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Comparing safety of blue versus red light illumination in photodynamic therapy using 10% aminolevulinic acid gel on >75-cm² treatment areas



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Background: With a growing desire by US dermatologists for field treatment of actinic keratosis (AKs) and patient compliance, photodynamic therapy (PDT) has become an important treatment modality AKs. With blue light illumination in PDT, 10% aminolevulinic-acid gel (ALA gel; Biofrontera) produces fewer local skin reactions (LSR) compared with 20% ALA solution (DUSA). However, it is unclear whether LSR in PDT with ALA gel differs with blue versus red light illumination.

Objective: This study compares LSR after blue or red light illumination in PDT with ALA gel on >75-cm² treatment areas of AKs.

Methods: This retrospective study in Texas compares the safety data in PDT sessions with blue versus red light illumination after incubation with ALA gel on >75-cm² treatment areas of AKs. Comparison of LSR with 10 J/cm² blue light (n = 103) to 37 J/cm² red light (n = 176) illumination was assessed after a specified 48-hour PDT post-care regimen (>10% zinc oxide and healing creams) every 2 hours during waking hours.

Results: No statistical difference in LSR existed between red light and blue light illumination. Irritation occurred with PDT in 4% (4/103) of blue light sessions and 5% (9/176) of red light sessions.

Limitations: This is a retrospective study.

Conclusions: This investigation finds no difference in LSR with PDT in >75-cm² treatment areas after incubation with ALA gel followed by 10 J/cm² blue light or 37 J/cm² red light illumination.

Commercial disclosure: 10% funding from Biofronteras for chart review and analysis in this investigator-initiated trial.

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Results of a large open-label safety study of daxibotulinumtoxinA for injection in glabellar lines



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Introduction: A large open-label safety study of daxibotulinumtoxinA for Injection (DAXI) assessed safety and efficacy with longer-term use and across successive glabellar lines (GL) treatment cycles.

Design: Subjects received 1-3 DAXI (40 U) GL treatments over ≤ 84 weeks and could be retreated after week 12 if back to baseline. Safety and efficacy were evaluated at least every 4 weeks, up to week 36 following treatments 1 and 2, and up to week 12 following treatment 3.

Results: 2691 subjects enrolled; of these 882 received a second treatment, and 568 received a third. No new safety signals were observed. Treatment-related adverse events (AEs) occurred in 17.8% of subjects, and were generally mild, transient, of short duration, and resolved fully. AE incidence generally decreased with successive treatment cycles. No Serious AEs were related to treatment. Eyelid ptosis occurred in 0.9% of treatments. Efficacy results were consistent with prior pivotal studies. Investigators rated over 95% of subjects as having none or mild GL at week 4 across all 3 treatment cycles. For cycles 1 and 2, it took a median of 24 weeks to lose none-or-mild status (investigator and subject) and 28 weeks to return to baseline. Results were confirmed in a cohort who received all treatments within this study.

Conclusions: SAKURA 3 establishes safety and efficacy of single and repeat DAXI treatment in a large patient population and broad selection of clinical sites. Efficacy and safety were highly consistent across treatment cycles and confirmed earlier pivotal RCT results (SAKURA-1 and SAKURA-2).

Commercial disclosure: This study was funded by Revance Therapeutics.

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Left, right, or center: Mole-ing over the location of dysplastic nevi on the human body



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Melanoma predominates on the left side of the body. While research has demonstrated a significant association between dysplastic nevi (DN) and melanoma, there are no investigations on whether DN demonstrate similar preferential lateral distribution. Here we examine the laterality and anatomic distribution of DN at a single, university center. A total of 1250 cases of biopsied DN from 2009 to 2019 were included in this study. Chi-square tests were used to evaluate DN based on gender, body site, laterality, position, and level of atypia. Analysis found no overall statistically significant laterality difference (left 49.1% vs right 50.9%, $P = .3092$). Yet, there was an increased incidence of right-sided DN specifically on the frontal trunk (right 57.1% vs left 42.9%, $P = .0466$). There was a significantly higher incidence of DN on the dorsal surface of the body (dorsal 71.7% vs ventral 28.3%, $P < .0001$), particularly in men (men 75.5% vs women 67.2% $P = .0038$). DN showed the following frequencies per body site: back 51.0%, front 18.8%, lower limbs 16.4%, upper limbs 10.1%, and head/neck 3.7%. There were significant gender differences ($P < .0001$), with a higher incidence of DN on the backs of men (men 57.9% vs women 43.3%) and on the lower limbs of women (men 10.9% vs women 22.9%). There were no site, side, or position differences based on severity of atypia. Overall, DN do not show preferential laterality, which differentiates it from melanoma. Nonetheless, DN are found at higher incidence of the backs of men and the lower limbs of women, which is similar to melanoma.

Commercial disclosure: None identified.