Early repigmentation of stable vitiligo through point-of-care melanocyte transfer using non-cultured autologous skin cell suspension

Munavalli, Girish

Dermatology, Laser & Vein Specialists of the Carolinas

Introduction: Vitiligo is an acquired depigmenting skin condition characterized by the loss of skin pigmentation, impacting 0.5% to 2% of the global population.\textsuperscript{1,2} Vitiligo presents as distinct depigmented patches resulting from autoimmune melanocyte destruction. Individuals with visual vitiligo lesions often experience negative body image, diminished self-confidence, discomfort, and overall lower quality of life (QoL).\textsuperscript{3} While there are medical treatment options available, these can be associated with poor efficacy and low medication compliance.\textsuperscript{4} Residual lesions after treatment may require surgical intervention which allows for melanocyte transplantation from an area that is pigmented to one that is lacking functional melanocytes. Through a point-of-care device, a non-cultured autologous skin cell suspension (ACSC) can be prepared using a small skin sample; the ASCS contains healthy melanocytes and is immediately applied onto skin treated with ablative laser to aid in the repigmentation of affected areas.

Objective: The objective of this study was to evaluate the one-time application of ASCS, with a 1:20 donor to treatment site expansion ratio, for the safe and effective repigmentation of stable vitiligo lesions.
**Methods:** A randomized, within-subject controlled, central observer-blinded study was conducted to compare the clinical performance of laser ablation, ASCS, and NB-UVB to NB-UVB alone for repigmentation of stable vitiligo lesions in adults. Subjects received NB-UVB phototherapy on both ASCS-treated and controlled lesions as per recommended by the Vitiligo Working Group. Repigmentation of ASCS-treated and control lesions were categorized by a Central Review Committee (CRC) of blinded dermatologists as one of the following: 0%-25%, 26%-50%, 51%-79%, or 80-100%. The primary effectiveness endpoint was defined as the proportion of lesions achieving ≥80% repigmentation for ASCS-treated versus control areas at Week 24. Early regimentation was assessed at Weeks 4 and 12 as a post hoc analysis.

**Results:** A significantly higher proportion of the ASCS-treated areas (36.0%, n = 9) compared to control-treated areas (0.0%) attained ≥80% repigmentation at Week 24 (P = 0.012). At Week 4, 30.4% (n = 7/23) of ASCS-treated areas had ≥26% repigmentation compared to 4.3% (n = 1/23) in the control areas. At Week 12, 56.5% (n = 13/23) of ASCS-treated areas had ≥26% repigmentation compared to 21.7% (n = 5/23) in the control areas. At Week 24, 64% (n = 16/25) of ASCS-treated areas had ≥26% repigmentation compared to 28% (n = 7/25) in the control areas.

**Conclusion:** A one-time treatment of ASCS, with the addition of NB-UVB, can result in excellent repigmentation results by 24 weeks, with most subjects seeing ≥26% repigmentation as early as 4 to 12 weeks.

**Keywords:** vitiligo; autologous skin cell suspension; melanocyte transfer
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References: