TONE: A Large, Prospective Post-Approval Study Investigating the Repigmentation of Stable Vitiligo Lesions Using a Point-of-Care Autologous Cell Harvesting Device

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INTRODUCTION

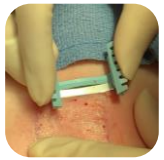
- Vitiligo is a depigmenting autoimmune skin disorder caused by loss of melanocytes, impacting 0.5% to 2% of the global population.[1-3]
- For patients with stable vitiligo, surgery allows for physical transplantation of healthy melanocytes.[1,4]
- A combination approach incorporating vitiligo surgery with pharmacotherapy may be recommended in some patients.[4]
- A point-of-care Autologous Cell Harvesting Device, FDA-approved for the repigmentation of stable vitiligo lesions, prepares autologous skin cell suspension (ASCS) to be applied onto laser-ablated lesions.[5]
- Previously reported in the randomized, within-subject controlled pivotal trial, 36% of ASCS-treated lesions achieved ≥80% repigmentation at 24 weeks post-treatment, versus 0% of control lesions.[6]
- Here, we report on TONE, a post-approval trial using this device.

OBJECTIVE

This multi-center, prospective post-approval study was conducted to evaluate repigmentation response following the application of ASCS in patients with stable vitiligo lesions in a large study population.

PROCEDURAL STEPS

1 Obtain Skin Sample

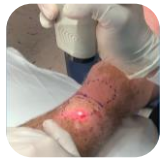


Harvest thin donor skin sample (0.015-0.02mm)

2 Prepare ASCS

Enzymatic and mechanical processing of donor skin using Device

3 Prepare Site & Apply ASCS



Prepare treatment area with epidermal laser ablation, and apply ASCS

4 Dressings & Aftercare

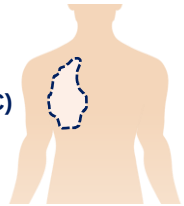
Apply dressings, protecting from moisture and trauma for 5-7 days

METHODS

Study Design

Laser ablation + ASCS **(1:20 expansion)** + NB-UVB*

Repigmentation response of treatment area at Week-24 **evaluated by blinded Central Review Committee (CRC)**



*Regimen followed recommendations from the Vitiligo Working Group[7]

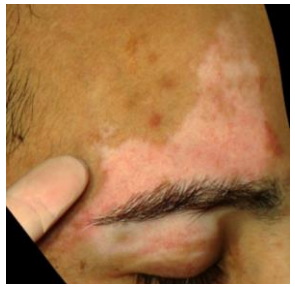
Patient Eligibility Criteria

- ≥18 years of age
- Unsatisfactory response to topicals or phototherapy (≥3-month trial)
- Depigmentation <30% body surface area
- Stable ≥12 months
- Patients with history of keloids or had lip-tip vitiligo excluded
- Concomitant therapy(ies) allowed upon agreement to maintain use for the study duration

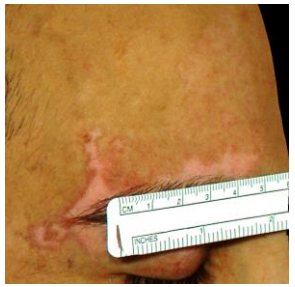
PATIENT CASE

41y.o. Male | Focal Vitiligo | Treatment area:11.6cm^2 | Fitzpatrick Skin Type IV

Pre-Treatment



Week-24 Post-Treatment



RESULTS

Patient Characteristics (N=107)	
Age, years	
Mean ± SD	46.9± 14.7
Sex, n (%)	
Male	54 (50.5)
Female	53 (49.5)
Race, n (%)	
White	73 (68.2)
Asian	16 (15.0)
Black or African American	5 (4.7)
Other	11 (10.3)
Fitzpatrick skin type, n (%)	
Type I	3 (2.8)
Type II	25 (23.4)
Type III	46 (43.0)
Type IV	21 (19.6)
Type V	10 (9.3)
Type VI	2 (1.9)
Vitiligo sub-type, n (%)	
Generalized	68 (63.6)
Focal	21 (19.6)
Segmental	18 (16.8)

- 107 patients were treated across 17 U.S. investigational sites (14 in-office, 3 hospital outpatient).
- 49% reported using concomitant therapy(ies) for their vitiligo.
- **100 patients had images evaluated by the CRC at Week-24; of those, 42% achieved ≥80% repigmentation.**
- No serious or severe device-related adverse events were reported.

CONCLUSION

- These results are consistent with those reported in the pivotal randomized controlled trial.[6]
- This study provides further evidence of the safety and effectiveness of ASCS for the repigmentation of stable vitiligo lesions, as demonstrated in a large patient population.
- A diverse population was represented with an even distribution of male and female patients, inclusion of various vitiligo sub-types, representation of all Fitzpatrick skin types I-VI, and incorporation of concomitant therapies into the protocol.
- This diversity among subjects is in-line with reported vitiligo patient population data,[3,4] indicating potential for generalizability of study findings in practical real-world applications.

References: 1. Bergqvist C, Ezzedine K. Dermatol. 2020;236(6):571-592. **2.** Daniel B, et al. Australas J Dermatol. 2015;56(2):85-92. **3.** Bibeau K, et al. J Eur Acad Dermatol Venereol. 2022;36(10):1831-1844. **4.** Mastacouris N, et al. Dermatol. 2023;159(9):986-990. **5.** US FDA, AVRL0102 approval letter, June 16, 2023. Retrieved July 11, 2024. **6.** Hamzavi IH, et al. J Am Acad Dermatol. 2024 Aug 23:S0190-9622(24)02713-0. **7.** Mohammad TF, et al. J Am Acad Dermatol. 2017;76(5):879-888.

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