avita medical
transforming lives

RECELL® System

Clinical Studies Exploring the Potential to Treat Vitiligo

VITILIGO FACT SHEET
Updated January 2021

WHAT IS VITILIGO?

Vitiligo is a disease that attacks pigment-producing cells, called melanocytes, resulting in their destruction or malfunction. The result is a loss of pigmentation in patches of skin. This loss of skin color can occur anywhere on the body and may be more noticeable in those with darker skin tones.

Vitiligo has been associated with autoimmune disease, a family history with the disease, and other triggers, such as stress, severe sunburn or skin trauma.

HOW MANY PEOPLE LIVE WITH VITILIGO?

Vitiligo affects up to 2% of the population worldwide[I], including an estimated 3-6.5 million Americans.[II] Vitiligo has a comparable market size and psychosocial impact to other major dermatology diseases including psoriasis (thick, scaly skin) and atopic dermatitis (red, cracked skin).[III,IV,V] Like these diseases, those living with vitiligo may suffer from poor body image along with low self-esteem, leading to an impaired quality of life.[VI]

HOW IS VITILIGO TREATED?

There is currently no cure for vitiligo, no FDA-approved repigmenting treatments, nor a universally accepted method for limiting the spread of the disease. Although many treatments are being used for the management of vitiligo (such as photo and laser therapy as well as topical steroids), their effectiveness for repigmentation is limited.[VII]

Globally, more than 1,000 patients with stable vitiligo have been treated with the RECELL® System to repigment depigmented skin lesions with 8 resulting peer-reviewed publications.

The RECELL® System is approved by the U.S. Food and Drug Administration (FDA) for the treatment of acute thermal burns in patients 18 years and older. Please see Important Safety Information and Instructions for Use on next page.

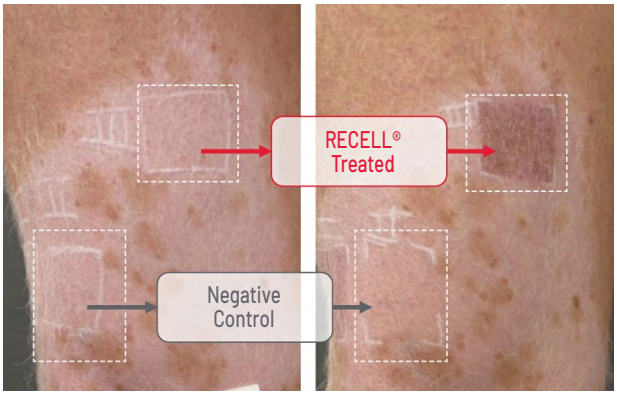

Image 1: Researchers conducted a randomized controlled pilot study utilizing Spray-On Skin™ Cells for the treatment of stable vitiligo and piebaldism patients.

This image shows the treatment and control sites before and 6 months after treatment.[VIII]

RECELL® SYSTEM CLINICAL STUDIES EXPLORING THE POTENTIAL TO TREAT VITILIGO

Following the U.S. Food and Drug Administration Investigational Device Exemption approval, a pivotal study (NCT04271501 on clinicaltrials.gov) began in September 2020 to assess the safety and effectiveness of the RECELL® System to repigment skin in patients who have vitiligo that has been stable for at least one year. The multi-center study will assess the treatment of depigmented vitiligo lesions at 24 weeks in patients whose vitiligo is stable, meaning they have not had any new vitiligo lesions or increase in size of existing lesions for at least one year.

Clinicians will obtain a small amount of the study participant's own healthy skin at the point of care to prepare a suspension of Spray-On Skin™ Cells using the RECELL® System. The solution contains keratinocytes (which process the melanin to achieve skin pigmentation and photoprotection[IX]), melanocytes (pigment-producing cells responsible for the transfer of melanin to neighboring keratinocytes[VII,X]), and fibroblasts (provide signaling factors, which promote melanocyte growth, differentiation, migration and survival[XI]) from the healthy skin sample. Spray-On Skin™ Cells are then applied to the vitiligo lesion. This animated video illustrates how the RECELL® System may work to restore pigmentation to a vitiligo patch.

Additional long-term safety and effectiveness data, including sustained repigmentation of the vitiligo lesion, will be collected over the course of the study.

In parallel with the clinical study, AVITA Medical is also partnering with a leading academic institution on a complementary, scientifically-focused feasibility study.

[I] Picardo et al. Vitiligo. Nature Reviews Disease Primers. 2015.
[II] John Harris, MD, PhD – Presentation as part of Incyte Corporate presentation. (Harris, UMass, is a global leader in Vitiligo; AVITA collaborator). https://investor.incyte.com/static-files/01f77a1c-6351-4348-adc2-597e2bc1f42eSERT
[III] National Psoriasis Foundation – Statistics, https://www.psoriasis.org/psoriasis-statistics/ Accessed 10/5/2020
[IV] The burden of vitiligo: Patient characteristics associated with quality of life. Homan, et al. JAAD. 2009
[V] Comparison of the Psychological Impacts of Asymptomatic and Symptomatic Cutaneous Diseases: Vitiligo and Atopic Dermatitis. Noh, et al. Annals of Derm. 2013
[VI] Willingness-to-pay and quality of life in patients with vitiligo. Radtke, et al. BJD. 2009
[VII] Vitiligo Research Foundation – Treatment Guidelines. https://vrfoundation.org/treatment_guidelines Accessed 10/5/2020
[VIII] Autologous cell suspension transplantation using a cell extraction device in segmental vitiligo and piebaldism patients: A randomized controlled pilot study. Koman, et al. JAAD 2015
[IX] Moreiras H et al. Melanin processing by keratinocytes: A non-microbial type of host-pathogen interaction? Traffic. 2019;20:301-304
[X] Hirobe T. Keratinocytes regulate the function of melanocytes. Dermatol Sin. 2014;32(4):200-204
[XI] Bastonini E et al. Involvement of non-melanocytic skin cells in vitiligo. Experimental Dermatology. 2019;28:667-673.

Important Safety Information

INDICATIONS FOR USE: The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL® device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous RES® Regenerative Epidermal Suspension for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds.

CONTRAINDICATIONS: RECELL® is contraindicated for the treatment of wounds clinically diagnosed as infected or with necrotic tissue present in the wound bed. RECELL® is contraindicated for the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate solution (Hartmann's Solution). The skin sample collection procedure specified for use of RECELL® should not be used with patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

WARNINGS: Autologous use only. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL® is provided sterile and is intended for single-use. Do not use RECELL® or device components if packaging is damaged, there are signs of tampering or date of use is beyond the stated expiration date. Choose a skin sample donor site that shows no evidence of surrounding cellulitis or infection. The skin sample should be processed immediately after harvesting. If a skin sample is harvested and processed according to these instructions, it should require between 15 and 30 minutes of contact with the Enzyme. Contact in excess of 60 minutes is not recommended. RECELL® Enzyme is animal derived and manufactured under strict controls to minimize risk of contamination, freedom from infectious agents cannot be guaranteed.

PRECAUTIONS: RECELL® is not intended to be used alone (i.e., without meshed autograft) for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL® used alone (i.e., without meshed autograft) have not been established for treatment of partial-thickness burn wounds: on the hands and articulated joints, >320 cm2, in patients with wounds totaling >20% Total Body Surface Area (TBSA). The safety and effectiveness of RECELL® plus autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulated joints, in patients with wounds totaling >50% Total Body Surface Area (TBSA).

SPECIAL PATIENT POPULATIONS: The safety and effectiveness of RECELL® have not been established for treatment of acute thermal partial-thickness or full-thickness burn wounds in pediatric patients younger than 18 years of age.

For complete Important Safety Information, refer to Instructions For Use, available at RECELLSystem.com

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PUBLISHED RECELL® SYSTEM VITILIGO STUDIES

Liu et al. The clinical efficacy of treatment using the autologous non-cultured epidermal cell suspension technique for stable vitiligo in 41 patients. J Dermatolog Treat, 2019.

41 adults and children with stable vitiligo (1-10 years). RECELL® cell suspension was applied to treatment area using an expansion ratio of 1:5-1:10. After 6-9 months, 80.5% of the patients showed good response; among these patients, 17.1% (7/41) showed complete or almost complete repigmentation. All 4 children showed very good response (more than 76% repigmentation).

Ren et al. The use of noncultured regenerative epithelial suspension for improving skin color and scars: A report of 8 cases and review of the literature.
J of Cosmet Derm, 2019.

Two vitiligo patients were treated with RECELL® in a 1:20-1:30 expansion post-dermabrasion, obtaining >70 and >90% re-pigmentation.

Komen et al. Autologous cell suspension transplantation using a cell extraction device in segmental vitiligo and piebaldism patients: a randomized controlled pilot study. J of the American Academy of Dermatology, 2017.

10 subjects (5 with stable vitiligo; 5 with piebaldism) received one patch treated with RECELL® in a within-patient controlled pilot study, after CO2 laser ablation. Sixty percent of sites treated with RECELL® showed >75% repigmentation; repigmentation assessed as good or excellent by 70% of the patients, vs 0% in the control.

Lommerts et al. Autologous cell suspension grafting in segmental vitiligo and piebaldism: a randomized controlled trial comparing full surface and fractional CO2 laser recipient-site preparations. Br J of Derm, 2017.

10 patients with vitiligo (n = 3) and piebaldism (n = 7) received different laser preparations prior to RECELL® treatment. Full surface ablation lead to repigmentation (median 68.7% & 58.3% with 2 settings), but no repigmentation after fractional ablation

Komen et al. Observations on CO2 laser preparation of recipient site for noncultured cell suspension transplantation in vitiligo. J Cutan Aesth Surg, 2016.

Two patients with stable vitiligo were treated with less invasive CO2 laser treatment and achieved 90% & 75% repigmentation.

Cervelli et al. Treatment of Stable Vitiligo hands by RECELL® system: a preliminary report. Eur Rev Med Pharm Sci. 2010.

A 30-year old male with 7 year history of stable vitiligo of the hands was treated with RECELL®, yielding excellent repigmentation

Cervelli et al. Treatment of stable vitiligo by RECELL® system. Acta Dermatovenerol Croat, 2009.

Reported results for 15 patients with vitiligo treated with RECELL®. In this series: 75% repigmentation was achieved in 12 patients (80%) and 25%-50% repigmentation in three (20%) patients. Excellent color match was present in ten (66.6%) and good in five (33.3%) cases compared to normally pigmented areas. Time to repigmentation was 3 weeks in 6 (40%) and 5 weeks in 9 (60%) patients; 10 (66.6%) patients were very satisfied and 5 (33.3%) were satisfied with outcomes. No reported complications.

Mulekar et al. Treatment of vitiligo lesions by RECELL® vs. conventional melanocyte-keratinocyte transplantation: a pilot study. Br J Dermatol, 2008.

Vitiligo lesions were treated using RECELL® and melanocyte-keratinocyte transplantation (MKTP), in five patients. Authors concluded that repigmentation was comparable for both techniques used. Of the 5 lesions treated with RECELL® 2 lesions showed 100%, one 65% and one 40% repigmentation; one lesion failed to repigment due to unstable disease.

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