Use of a Novel, Collaborative Non-cultured Epidermal Cell Suspension Protocol to Reduce Time and Resource Barriers for Providers

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Background

Surgical therapies are an effective method for treating stable vitiligo including the melanocyte-keratinocyte transplant procedure (MKTP), also known as non-cultured epidermal cell suspension (NCES) grafting. This technique has been established as a standard-of-care modality given its high rate of successful repigmentation with good cosmetic outcomes[1,2]. Patients with segmental vitiligo stable for more than six months have the best results with NCES grafting[2,3].

Despite its clear efficacy, access to this treatment in the United States is limited by the few centers that provide this service. There are also significant resources involved in the NCES procedure, including need for specialized equipment and reagents as well as provider and staff time. With elimination of these barriers, NCES grafting has the potential to be utilized even in busy general dermatology practices.

Objective & Hypothesis

Objective. In this pilot study, we aimed to assess the efficacy and safety of a novel NCES protocol in an initial cohort of treated patients.

Hypothesis. Our novel protocol involves "outsourcing" graft processing to a local biotechnology company, TeVido BioDevices, which we posited would lead to easier implementation and significant time and resource savings for providers without compromising quality and extent of repigmentation in patients with stable vitiligo.

Materials & Methods

Four patients with limited areas of vitiligo recalcitrant to other therapies were recruited for the novel NCES protocol as detailed below:

Graft Harvesting. A split thickness skin graft was harvested from the donor site using a Goulian Weck knife (Edward Weck & Co. Inc., Research Triangle Park, NC) or DermaBlade (Personna Medical, Division of American Safety Razor Co., Staunton, VA) and was placed in a Lactated Ringers solution.

Image 1. Syringes filled with melanocyte keratinocyte rich solution.

Creating the Cell Suspension. TeVido Bio-Devices transported the graft to their facility where they separated the epidermis from the dermis, enzymatically and mechanically released the epidermal cells, centrifuged the epidermis to create a pellet and re-suspended the epidermal cells in a 1 mL syringe with Lactated Ringers in a manner consistent with standard MKTP technique[4].

Placing and Dressing the Graft. Later that day, TeVido returned the NCES to the clinic. The patient's vitiliginous patch was abraded using a mechanical dermabrader (Robbins Instruments, Inc., Chatham, NJ) down to the dermal-epidermal junction, signified with pinpoint bleeding. The NCES solution was applied using the syringe. Vaseline, gauze, and Tegaderm were applied over the recipient area.

Post-Procedure. Patients returned for one-week, one-month, and three-month follow-up appointments. Three weeks post-procedure, patients started UVB treatment two to three times weekly at home or in the office.

Results & Discussion

Herein are the results of four patients treated with the novel NCES protocol.

#	Patient Age & Gender	Location of Vitiligo	Type of Vitiligo	Duration of Vitiligo	Date of MKTP	Repigmentation to Date
1	37 yo M	L anterior thigh	Stable segmental with leukotrichia	3 years	09/05/19	50%
2	35 yo F	R anterior shin	Minimally active nonsegmental	30+ years	10/03/19	Initially 50%, then regressed
3	34 yo M	R anterior shin	Minimally active nonsegmental	Many years	08/01/19	< 25%
4	26 yo M	R jaw	Stable segmental	17 years	10/17/19	>50%

Table 1. Characteristics and results of the first four patients treated with the novel NCES grafting protocol at Dell Medical School.

Patient 1 exhibited approximately 50% repigmentation after NCES grafting as estimated by Image J analysis. Woods lamp exam 5 months post-procedure shows evidence of continued repigmentation.

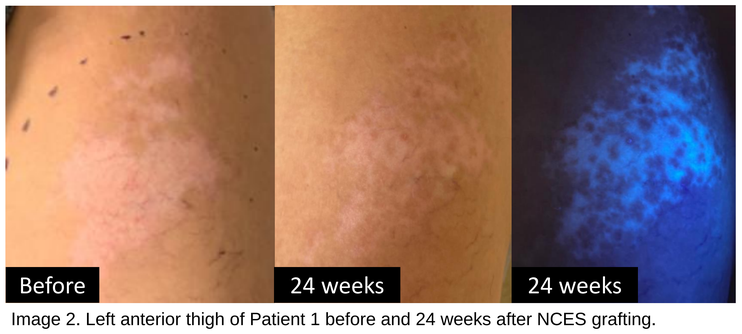

Image 2. Left anterior thigh of Patient 1 before and 24 weeks after NCES grafting.

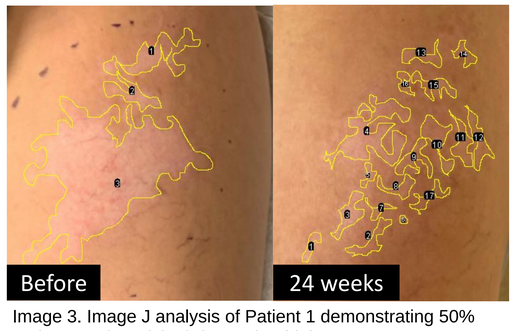

Image 3. Image J analysis of Patient 1 demonstrating 50% repigmentation of the left anterior thigh.

Patient 2 initially exhibited approximately 50% repigmentation after NCES grafting. However, she has developed new vitiliginous areas since the procedure. The repigmentation of the site has since partially regressed.

Patient 3 exhibited minimal repigmentation after NCES grafting. He had previously failed both blister grafting and mini-punch grafting, and there was evidence of vitiliginous activity elsewhere during the months post-procedure.

Patient 4 exhibited >50% repigmentation after NCES grafting. However, the repigmentation was patchy, possibly due to uneven NCES adhesion.

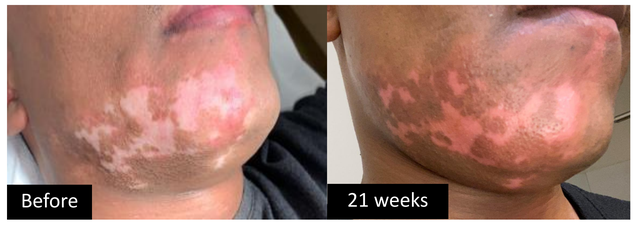

Image 4. Right jaw of Patient 4 before and 21 weeks after NCES grafting.

Limitations

- The cell suspension created was often too thin. Therefore, a Vaseline "wall" had to be used to keep the suspension on the dermabraded vitiliginous patch.
- Although two of the patients reported stability pre-procedure, they began developing new lesions post-procedure, which likely affected their results.

Conclusion

This novel NCES protocol offers time and resource savings to providers in busy clinics by "outsourcing" of specimen processing to a local biotechnology company, TeVido BioDevices. Our protocol limits provider time to two relatively brief patient visits with no staff effort required in between. Preliminary results indicate at least 50% repigmentation in 3 of 4 patients treated, although covert vitiligo activity affected the results of two patients. This procedure has the potential to make NCES grafting feasible for greater numbers of dermatologic providers and resultantly, many more vitiligo patients.

References

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Emily L. Clarke is a fourth-year medical student at Dell Medical School in Austin, Texas who is interested in dermatology. Her research interests include vitiligo and expanding access to care.

Disclosures

Ms. Clarke has no relevant disclosures. Dr. Ahmed serves as a principal investigator for a Pfizer clinical trial for vitiligo. Neither of the authors have any conflict of interest or receive compensation from TeVido BioDevices who is a collaborator in this research.

TruPigment™ is an autologous noncultured epidermal cell suspension, intended for homologous use and processed by TeVido BioDevices, Inc in an FDA registered Tissue Establishment.