



US DEPARTMENT OF DEFENSE

BLAST INJURY RESEARCH PROGRAM COORDINATING OFFICE

Transplants and Grafts

Tolerization of Vascularized Composite Allografts with Adipose Stromal Vascular Fraction Cells

Researchers at the Jewish Hospital and St. Mary's Healthcare and the Christine M. Kleinert Institute and University of Louisville, in the Louisville Vascularized Composite Allografts Program (Louisville, Kentucky), are conducting a clinical trial to explore the potential for a cell-based therapy to help control the immune system's response to a hand transplant. The goal of this study is to lessen or eliminate the need for immune-suppressant drugs. The stromal vascular fraction (SVF) of fat tissue removed from the patient by liposuction is a source of stem cells and white blood cells that have been shown to promote healing and reduce immune activation. Patients are offered the option to receive SVF as part of their immune regulation regimen. Treatment with SVF cells is being tested in conjunction with a standard immunosuppressive drug regimen in both previously transplanted patients who experience a rejection episode, as well as in new transplant recipients who will receive SVF concurrently with their hand transplant. To date, one patient from each category has been treated, both with promising results.

One patient was enrolled after experiencing a rejection episode that involved swelling and a rash 15-years post-transplant. His own fat tissue was harvested and processed to extract the SVF, and those cells were injected into the graft within hours. The rash and swelling improved within 24 hours, and the patient avoided the need for an increased immune suppressing drug regimen. The second patient (HTx-10) received SVF cells at the same time she received a double hand transplant. Remarkably, at more than one-year post-transplant, this patient remains rejection-free, even though rejection episodes in hand transplant patients are common occurrences by three months post-transplant (*Jones et al. 2017, Stivers et al. 2017*; Figure 1). Both patients are on standard immunosuppression drugs, but the bilateral hand recipient has maintained her rejection free status on lower than normal tacrolimus trough levels of 3-4 ng/ML. This data suggests that perhaps someday these drugs can be routinely reduced or eliminated altogether after Composite Tissue Allograft.

This project explores the potential for a safe, easily available cell-based therapy to modulate the immune response post-transplant and eliminate the need for lifelong immunosuppression.

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FIGURE 1: Bilateral Hand Recipient HTx-10 and photo of hands at 15 months post-transplant (Figure used with permission from the authors)

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