needed to provide further support for the medical necessity criteria in current use.

**Adipose Stem Cell Therapy for Amputation Site Soft Tissue Restoration: A Prospective, Randomized Controlled Clinical Trial**

**Presenter:** Francesco M. Egro, MBChB, MSc, MRCS

**Co-Authors:** Debra A. Bourne, MD; Danielle M. Minteer, PhD; Aaron Wyse, MD; Albert D. Donnenberg, PhD; Vera S. Donnenberg, PhD; Gretchen Haas, PhD; Rory A. Cooper, PhD; Kacey Marra, PhD; Lauren Kokai, PhD; Sydney Coleman, MD; Paul F. Pasquina, MD; J. Peter Rubin, MD, FACS

**Affiliation:** University of Pittsburgh, Pittsburgh, PA

**BACKGROUND:** Nearly 2 million people in the United States experience limb loss each year. Challenges precluding successful long-term prosthesis use include skin break down, pain, and poor fit. These challenges are often exaggerated for military service members with combat-related wounds. The aim of this Department of Defense–supported study was to assess the efficacy of standard autologous fat transfer compared to fat graft enriched with adipose-derived stem cells (ASCs) to reduce pain and improve lower extremity amputation site soft tissue volume and quality.

**METHODS:** Ten patients with pain and limited function at amputation sites were randomized to either the standard group treated with autologous fat grafting to the amputation site or the enriched group which was enriched with stromal vascular fraction, which is a concentrated source of ASCs. Outcome measures included (1) pain score (visual analog scale); (2) graft cell composition (flow cytometry); (3) volume retention assessed by computed tomography scan; and (4) quality of life questionnaires (RAND SF-Item Health Survey and satisfaction with physical appearance scale).

**RESULTS:** Study subjects were randomized (enriched: n = 3, mean age 46.4 ± 18.1; standard: n = 7, mean age 56.3 ± 13.0). All participants received treatment with no significant adverse events. Follow-up was 2 years. No significant differences (P = 0.06) were detected in graft cell viability (82.7% ± 3.6% in the enriched group and 69.9% ± 31.8% in the standard group). The composition of the harvested fat was similar between groups (enriched: 36.0% ASC, 5.9% endothelial, 1.5% pericyte, 54.8% nonhematopoietic; and standard: 28.8% ASC, 4.3% endothelial, 1.3% pericyte, 42.3% nonhematopoietic). Subjects in the enriched group experienced a significant reduction in pain, beginning at 2 months postprocedure and lasting through 24 months (P < 0.05). The standard group reported a trend toward improvement in pain scores that reached statistical significance at 3 and 6 months postoperatively (P < 0.05). The enriched group had better pain control than the standard group that reached statistical significance at 2 months postprocedure (P = 0.036). Both groups demonstrated improvement in hypersensitivity, prosthetic fit, and pain at 1 month posttreatment, lasting through 2 years. Importantly, 6 of the 10 subjects discontinued pain and/or anti-anxiety medication after fat grafting. There was no significant difference between groups in graft volume retention (P > 0.05). There was significant improvement in self-rated satisfaction with physical appearance (P = 0.007) and a trend for improvement in self-rated freedom from pain.

**CONCLUSIONS:** Fat grafting to individuals with complicated residual limbs reduces pain and hypersensitivity, while enhancing prosthetic fit and quality of life. Graft enrichment with adipose stromal cells further enhances pain relief.

**Risk Factors for Amputation Following Lower Extremity Free Tissue Transfer in a Chronic Wound Population**

**Presenter:** Peter Wirth, BA

**Co-Authors:** Jonathan A. Schwitzer, MD; Vikas S. Kotha, BS; Elliot T. Walters, MD; Karen Kim Evans, MD

**Affiliation:** Georgetown University School of Medicine, Washington, DC

**PURPOSE:** Chronic wounds of the lower extremity pose a number of challenges for management by surgeons. Nonhealing, infected, or otherwise complicated wounds may fail local wound care, often leading to amputation. Historically, there has been a debate regarding limb salvage microsurgical free tissue transfer (FTT) versus amputation. When utilized appropriately, lower extremity microsurgical FTT can lead to successful limb salvage in a majority of patients. Limb salvage, as opposed to amputation, can have a profound impact on quality of life, independence, and mortality. However, limb salvage requires costly multidisciplinary care that becomes increasingly expensive if there is flap failure, necessitating a return to