



Adipose Tissue Allograft as a Novel Adjunct Therapy for Lipodermatosclerosis and Venous Leg Ulcer Care



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INTRODUCTION

Chronic venous disease (CVD) affects an estimated 2.5–6 million individuals in the United States, with about 20% developing lipodermatosclerosis (LDS) (1). LDS is a chronic inflammatory condition characterized by subcutaneous adipose tissue degeneration, fibrosis, and skin induration, resulting from tissue hypoxia caused by the adverse effects of fibrosis on microvasculature (2). LDS significantly increases the risk of venous leg ulcer (VLU) development (3). Current treatments for LDS fail to address adipose tissue loss or avascularity, leaving patients with chronic pain and a persistent risk of VLUs, even after closure (4). This case series tested the hypothesis that human cryopreserved adipose tissue allograft (hCAT*), designed to target adipose defects, may serve as an adjunct to VLU standard of care (SOC) in patients with LDS.



METHODS

Patients with LDS and either open or newly epithelialized VLUs were selected to receive hCAT. Between July 2024 and January 2025, three patients (two male, one female) underwent hCAT implantation.

Prior treatments included SOC therapies such as advanced cellular therapies, cellular and/or tissue-based products (CTPs), and compression therapy with a reverse pressure gradient pump—specifically, a non-pneumatic compression device (NPCD) and an advanced pneumatic compression device (APCD)—as well as reverse pressure gradient stockings. Surgical intervention was performed for iliac compression when indicated.

Each patient received a local anesthetic and two subcutaneous 3.0 mL hCAT implants, administered via an 18-gauge needle into the periphery of the VLU site, approximately 2 cm from the affected area. The implants were given two months apart.

Outcomes included skin induration improvement as evidenced by palpation, suppleness to skin and subcutaneous tissue, and ulcer resolution.

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CASE 1

Patient: 44-year-old male

Condition: Ulceration on the lower leg in an area of stasis and LDS; preceded by edema and bullae

Significant Medical History: Diabetes mellitus (DM), hypertension, venous stasis, VLU, LDS

Prior Therapies: SOC, including debridement, collagen, and advanced dressings; treatment for common iliac vein compression/May-Thurner syndrome; dual-layer compression system, intermittent pneumatic compression (IPC), NPCD, and reverse pressure gradient stocking

Outcome: Ulcer resolved within 2 months after the first hCAT implant. Eight months after the first implant, the skin and subcutaneous (SC) tissue have remained supple, and the ulcer has remained epithelialized



Noted induration in peri-ulcer area and advanced LDS



Ulcer resolution with skin improvement and LDS response 2 months after 1st implant

CASE 2

Patient: 66-year-old male

Condition: Recently closed ulcer on the right lateral malleolus; advanced stasis dermatitis and LDS

Significant Medical History: Hypertension, venous insufficiency, surgical history of open reduction and internal fixation (ORIF) of the left ankle

Prior Therapies: SOC, acellular amnion CTP; treatment for common iliac vein compression/May-Thurner syndrome; dual-layer compression system, IPC, NPCD, and reverse pressure gradient pump

Outcome: The ulcer has remained closed for 6+ months, with the epidermis becoming more supple over time



Sustained ulcer epithelialization 2 months after hCAT implant



Sustained epithelialization at 6 months with more durable, robust tissue and improved peri-ulcer integrity

CASE 3

Patient: 66-year-old female

Condition: Bilateral lower leg ulcer in an area of advanced LDS, leg edema, and venous stasis; preceded by bullae

Significant Medical History: Lymphedema, venous stasis (VS), congestive heart failure (CHF), coronary artery disease (CAD), non-insulin-dependent diabetes mellitus (NIDDM), cataracts, peripheral artery disease (PAD)

Prior Therapies: SOC, including collagen, weekly debridement, and advanced dressings; treatment for common iliac vein compression/May-Thurner syndrome with bilateral stenting; IPC, APCD, and reverse pressure gradient stocking

Outcome: Ulcer on right leg completely epithelialized between first hCAT implant and 2-month follow-up (2nd implant). The right leg ulcer reduced in size. SC tissue on both legs was more supple with noticeable improvement in LDS



Right leg with LDS in peri-ulcer area



Ulcer resolution with supple SC tissue and less induration on the right leg, LDS response

CONCLUSION

hCAT shows promise as a therapeutic option for LDS patients at risk for VLUs. Patients exhibited notable improvements in skin quality, with affected areas becoming more supple and healthier in appearance. Enhanced tissue suppleness led to a better response to compression therapy for edema management after hCAT implantation. When ulcers resolved, the epithelialization was more robust and durable.

All patients have continued to demonstrate marked clinical improvements, including reduced induration, with the product remaining palpable at implantation sites (longest follow-up: 8 months). No product-related adverse events have been reported.

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