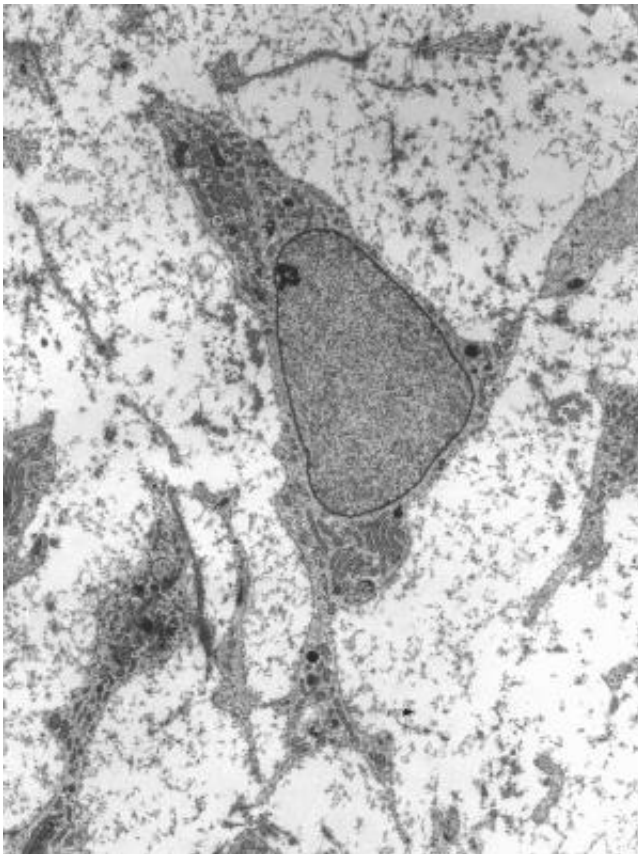


# Phase I clinical trial shows promise of adipose-derived stem cells in treating lymphedema

February 18 2021

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Mesenchymal stem cell displaying typical ultrastructural characteristics. Credit: Robert M. Hunt/Wikipedia

Can stem cells alleviate lymphedema, a chronic debilitating condition

affecting up to one in three women treated for breast cancer? Results of a phase I clinical trial released today in *STEM CELLS Translational Medicine (SCTM)* show there is a strong possibility that the answer is yes.

Lymphedema is swelling due to a build-up of fluid in [lymph nodes](#)—vessels that help rid the body of toxins, waste, and other unwanted materials- usually occurring in an arm or leg. While it can be the result of an inherited condition, its most common cause in the Western world is the removal of or damage to the lymph nodes during the course of cancer treatment. The results can be both physical (the swollen area can be stiff and/or sore and there is an increased chance of infection) and cosmetic (the skin can become leathery and scarred, and the affected limb can be grossly swollen and deformed).

Mads Gustaf Jørgensen, M.D., of the Department of Plastic Surgery, Odense University Hospital in Denmark, is corresponding author of the study whose results are detailed in *SCTM*. "Patients with [breast cancer](#)-related [lymphedema](#) (BCRL) have reduced quality of life and arm function. Current treatments are palliative only. The focus is on controlling the condition through exercise, compression garments and pumps, manual drainage, meticulous skin care, therapy and a healthy lifestyle.

"However, while treatments to improve lymphedema are lacking, [preclinical studies](#) suggest that adipose-derived regenerative cells (ADRCs) can alleviate lymphedema," he said. "We, therefore, aimed to assess whether ADRCs can alleviate lymphedema in clinical reality with long-term follow-up."

The study's primary endpoint was change in arm volume, with secondary endpoints of safety, change in lymphedema symptoms, quality of life, lymphedema-associated cellulitis and conservative treatment use.

To conduct their study, the team treated 10 BCRL patients with ADRCs—which are harvested from adult fat—and a scar-releasing lipotransfer to the axillary region. When they followed up with each patient at intervals of 1, 3, 6, 12 and 48 months post-treatment, they saw no significant decrease in BCRL volume.

"However," Dr. Jørgensen said, "self-reported upper extremity disability and arm heaviness and tension improved. Six patients reduced their use of conservative BCRL treatment. Five felt that their BCRL had improved substantially, and four of these would redo the treatment. We did not observe any cases of locoregional breast cancer recurrence."

"This has led us to conclude that axillary-delivered ADRCs and lipotransfer are safe, feasible and improved BCRL symptoms and upper extremity function. Their effectiveness was observed shortly after treatment and sustained for up to four years. Randomized controlled trials are needed to confirm the results of this study," he added.

"These results are certainly promising because the therapy appears to be safe, feasible and minimally invasive," said Anthony Atala, M.D., Editor-in-Chief of *STEM CELLS Translational Medicine* and Director of the Wake Forest Institute for Regenerative Medicine. "This study highlights the ability of these fat-derived [stem cells](#) to potentially alleviate lymphedema and cellulitis in patients. We look forward to the continuation of this research to further document clinical efficacy."

**More information:** "Adipose-derived regenerative cells and lipotransfer in alleviating breast cancer-related lymphedema: An open-label phase I trial with 4 years of follow-up," *STEM CELLS Translational Medicine (SCTM)* [DOI: 10.1002/sctm.20-0394](https://doi.org/10.1002/sctm.20-0394)

Provided by AlphaMed Press

Citation: Phase I clinical trial shows promise of adipose-derived stem cells in treating lymphedema (2021, February 18) retrieved 25 April 2024 from <https://medicalxpress.com/news/2021-02-phase-clinical-trial-adipose-derived-stem.html>

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