

## New Treatment Holds Promise for Acne Scarring

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November 6, 2011 (Washington, DC) — A new treatment improves moderate to severe depressed acne scars, according to a study presented here at the American Society for Dermatologic Surgery 2011 Annual Meeting.

"For patients with moderate to severe distensible depressed acne scarring, this can provide an excellent option for partial and possibly complete improvement in the appearance of this type of scarring," explained Girish (Gilly) Munavalli, MD, lead clinical investigator and medical director of Dermatology, Laser, and Vein Specialists of the Carolinas, PLLC, and assistant professor of dermatology at Wake Forest University School of Medicine in Winston-Salem, North Carolina, about the azficel-T technique.

Azficel-T (*Laviv*, Fibrocell Science) uses a process in which a patient's own fibroblast cells are extracted from a small skin sample and multiplied in the Fibrocell Science lab. These collagen-producing fibroblast cells are then injected into acne-scarred areas. "Fibroblasts are the cells that generate new type I and type II collagen in the dermis of the skin. Acne scarring is fundamentally a dermal defect, and this would be correctible by this method," explained Dr. Munavalli.

"This is an off-label use of [azficel-T]. It can provide a very viable alternative to more invasive, risky methods — such as fractional ablative or traditional ablative laser resurfacing — for the improvement of acne scarring with potentially long-lasting results," said Dr. Munavalli. "Further studies are being considered for a larger-scale trial to obtain a formal [US Food and Drug Administration] indication for the treatment of acne scarring," he added.

Investigators used a multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy of azficel-T. Skin biopsies were collected from 119 patients with moderate to severe depressed acne scarring bilaterally for at least 3 years, and used for fibroblast production. Ninety-nine patients were given up to 3 injections with 2 mL of autologous fibroblasts (10 to 20 million cells/mL) on one cheek and a placebo injection (dye-free cell culture media) on the other cheek every 14 days. Treatment was given at a dose of 0.1 mL/cm<sup>2</sup> into scarred areas on the cheek, which were required to be at least 9 cm<sup>2</sup> in size.

The study's 2 prospectively defined coprimary end points were an improvement of 2 points or more on a 5-point Subject Live Acne Scarring assessment scale and a reduction in cheek acne severity of 1 point or more on a physician-assessed, validated 5-point Evaluator Live Acne Scar assessment scale. Final assessments were made 4 months after the study treatment was completed.

Patient and evaluator assessments showed a statistically significantly higher percentage of responses with azficel-T than with placebo at all but 1 assessment during the study. At the final assessment, a statistically significantly higher percentage of subjects improved with azficel-T than with placebo when rated by study investigators (58.7% vs 42.2%;  $P = .016$ ) and patients (43.1% vs 18.3%;  $P = .000011$ ).

"This is a very safe treatment with an excellent safety profile and minimal risk of scarring or pigmentary alteration of the treated skin," said Dr. Munavalli.

All reported adverse events were mild or moderate in severity, and the incidence of adverse events was comparable between azficel-T and placebo. None of the subjects reported severe adverse events, discontinued treatment, or withdrew from the study because of an adverse event. The most frequently reported adverse events were treatment area erythema (11.1% of subjects) and swelling (10.1% of subjects). Other adverse events that were possibly related to treatment included bruising, rash, irritation, nodule, pain, acne, induration, and headache.

"I was pleasantly surprised by the longevity in my subject population. Anecdotally, I have seen some of my subjects at 3 years after their last treatment with persistent improvement," said Dr. Munavalli. He noted that more research is needed, however. "How long do the results really last? We need longer official follow-up on these patients, although the anecdotal data are very promising," he explained.

Dr. Munavalli said there is another question for researchers to answer: "Can [azficel-T] cause a field effect and improve the skin texture in the entire area around the scars in addition to improving the scar itself?"

Azficel-T was first developed as a treatment for moderate to severe nasolabial fold wrinkles, also known as "smile lines," but it might have other uses. Studies are planned to look at the use of azficel-T in "fine lines and wrinkles, which are difficult to treat historically, and around the eyes and lips; another trial is being considered for the treatment of restrictive burn scars," said Dr. Munavalli.

*Dr. Munavalli reports being a clinical investigator and consultant for Fibrocell Science, and being on the speakers bureau for Medicis and Merz Pharmaceuticals.*

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