

FDA Clears PDT System for Striae, Scars

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Hypopigmented scars of chest at baseline (top) and after four treatments with UVB phototherapy system.

New York - Localized treatment with a UVB phototherapy system is a significant therapeutic advance for safe and selective cosmetic repigmentation of hypopigmented striae and scars, Macrene Alexiades-Armenakas, M.D., Ph.D., said.

The device (ReLume), a product of Lumenis Inc., in late October received FDA marketing clearance for the treatment of leukoderma. It uses a high-intensity, incoherent light source (a 2-watt mercury vapor arc lamp) that emits in the wavelength range of 290- to 320nm. The system features both an adjustable pulse width (range, 0.5 to 2 seconds) and fluence (range, 50 to 800 mJ/cm²). It can be used to treat hypopigmented striae and scars located in any anatomic region, and in patients of any skin type.

Dr. Alexiades-Armenakas, research director, Laser & Skin Surgery Center of New York, has been involved in an initial study evaluating the repigmentation phototherapy system. The protocol plans to enroll 20 patients, of whom 15 have already been treated. Data from the first seven patients treated for striae alba or hypopigmented scars resulting from acne, traumatic wounds, or surgery were presented by Dr. Alexiades-Armenakas' colleague, Leonard Bernstein, M.D., at the annual meeting of the American Society for Dermatologic Surgery.

Patients in the study underwent twice-weekly treatments for seven weeks. Physician visual assessment showed repigmentation increased over time, reaching about 60 percent to 70 percent after 10 treatments and 75 percent to 100 percent after completion of the seven-week course. Those findings were confirmed by evaluations performed by a blinded rater, and the treatment effect is also being evaluated objectively with spectrophotometry, although those data are still being collected and have yet to be analyzed.

Good Results, Not Perfect

The phototherapy was tolerated very well, with only occasional mild erythema, but there were no reports of blistering, scarring, or pain, and no post-treatment downtime. However, during three months of follow-up after phototherapy cessation, the treatment benefit dissipated, with a loss of about 50 percent of repigmentation after three months.

"To date there have been no predictably safe and effective options for improving the appearance of hypopigmented scars present in cosmetically important areas," Dr. Alexiades-Armenakas said. "This localized UVB light treatment is not a perfect solution, but it does increase the level of pigment in the treated site into the range of the surrounding skin. The improvement achieved makes an important cosmetic and psychological difference for affected patients, and I think we can look forward to additional refinements that will help us obtain even better and more long-lasting results."

"In the mean time, patients considering this option must recognize that it takes a number of treatments to achieve repigmentation and maintenance is required," she added. "Therefore, interested individuals must have the time and ability to come in for regular visits. The patients we have treated who fulfill those criteria feel it has certainly been worth the effort."



Hypopigmented scars at pretreatment (left) and after 10 treatments with UVB phototherapy system. (Photographs courtesy of Macrene Alexiades-Armenakas, M.D.)

In the study performed at the Laser and Skin Surgery Center of New York, patients first underwent minimal erythema dose (MED) testing, and the treatment was begun with a fluence equivalent to 70 percent of the MED. For subsequent treatments, the fluence was increased by increments of 20 mJ/cm² until erythema occurred.

In addition to completing collection of clinical data from the trial, Dr. Alexiades-Armenakas said biopsy studies are being done to characterize changes in melanocyte numbers and pigment levels associated with the phototherapy treatment.

"We believe the irradiation induces melanocytes to increase melanin production, and that after removal of the UVB light stimulus the cells return to their constitutive level of pigment expression. If that is the biologic response occurring, it would explain why maintenance therapy is necessary," she said.

Some patients have received further treatment to maintain repigmentation, and it appears those sessions may be scheduled on a less frequent basis compared with the original treatment protocol.

"It is unclear what regimen would be recommended for ongoing treatment as we have not formally evaluated that question, but anecdotally our patients have been returning every three to four weeks," Dr. Alexiades-Armenakas said.

Further investigations will aim to determine if it is possible to identify predictors of response and methods for improving the rate of onset and persistence of the repigmentation. In regard to those issues, Dr. Alexiades-Armenakas stated that based on the limited experience available so far, it is her clinical impression that darker-skinned patients achieve a faster and more long-lived response relative to patients with lighter skin.

"Perhaps we may be able to do a skin-type analysis and tell patients from the outset how many treatments they might need to achieve repigmentation and what maintenance schedule is likely necessary," she said.

The researchers are also examining how treatment response might be influenced by underlying pathology and if topical therapies or photosensitizers might be used as adjuvants to improve the rate of pigmentation and its durability. Although the phototherapy has not been associated with any significant adverse reactions, carcinogenesis remains a theoretical concern. The absolute long-term risks of this particular treatment are unknown, but Dr. Alexiades-Armenakas said that they are likely minimal, due in part to the very low doses of UVB light being delivered.

Calculations she has performed show that a patient would have to undergo 14 initial treatments and monthly maintenance over another 33 months to reach the same cumulative dose associated with a four-month clearing and taper course of broadband UVB treatment for psoriasis. That estimate assumes psoriasis treatment in a patient with type II or III skin receiving a total dose of 8 J and administration of a relatively high dose of 200 mJ/cm² per each repigmentation treatment session, Dr. Alexiades-Armenakas said.

She also reminded clinicians that any real risk of increased skin malignancies in psoriasis patients treated with UVB phototherapy remains to be elucidated. "Data show there is a small increased incidence of squamous cell and basal cell carcinomas in patients who have received broadband UVB treatment, but whether those tumors are a consequence of phototherapy or coincide with the increase in skin cancer rates noted in the general population remains to be established," Dr. Alexiades-Armenakas said.

As a caveat, she added that in her own practice she would not use the UVB phototherapy system to treat skin cancer scars. "Even in the absence of clear-cut data about risks associated with UVB phototherapy in patients with a history of skin cancer, I believe very strongly on a theoretical basis that it would be imprudent to treat those individuals," she said.

Dr. Alexiades-Armenakas has no financial interest in Lumenis or the ReLume phototherapy system.

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