

LASER AND COSMETIC NEWS

LASER AND LIGHT-BASED TREATMENT OF CELLULITE

Macrene Alexiades-Armenakas MD PhD

Assistant Clinical Professor, Yale University School of Medicine, New Haven, CT; Private Practice, Dermatology and Laser Surgery, New York, NY

Laser and Cosmetic News covers the latest advances in laser surgery, light technology, phototherapy, and cosmetic surgery. New and emerging therapies, noteworthy publications, and exciting meeting developments will be highlighted. Controversies and opinions about the future in this field will be addressed. The aim of this column is to keep you abreast of the cutting edge in laser and cosmetic surgery.

Cellulite is an extremely prevalent condition affecting up to 90% of adult women for which acceptable treatment options have been lacking.¹ Genetic, hormonal, and vascular factors have been implicated etiologies, while the condition manifests as herniations of the subcutaneous fat into the dermis. Thus, inducing fibrosis at the dermosubcutaneous junction and increasing vascular or lymphatic circulation may be potential therapeutic options to improve the appearance of the condition.

To date, 2 laser and light based technologies have been FDA approved for the treatment of cellulite: Syneron VelasMOOTH and the Cynosure TriActive. The VelasMOOTH delivers broad-spectrum infrared light (700-2,000 nm) emitted at 20 watts or J/sec with a 5-mm depth of optical heating. This device also includes mechanical rollers and a 750-mm Hg negative pressure vacuum. Clinical studies demonstrated decreases in thigh circumference and clinical improvement one month after 8 twice-weekly treatments.² The TriActive employs massage and diode laser at 810 nm. In clinical trials, visible improvement was appreciated after 12 twice-weekly treatments.³

In addition, the Synergie AMS is FDA approved for the treatment of cellulite, but employs massage alone. The massage and suction features have been hypothesized to function by increasing vascular and lymphatic drainage, though this mechanism has yet to be proven. The laser and light is hypothesized to cause contracture and increases in deep dermal collagen, resulting in skin tightening and theoretically providing a stronger dermosubcuticular junction barrier to herniation.

Radiofrequency (RF) wavelengths were first employed to increase penetration depth and target skin laxity for the face and neck, but have been expanded for the application to body sites as well. These devices have been shown to heat the dermis and potentially the subdermal tissues, resulting in clinical findings of skin tightening by the proven histological effect of contracture of collagen and neocollagenesis.⁴ The first device in this area was a monopolar RF device Thermacool, which received FDA approval for off-face wrinkle reduction in January 2006. Newer bipolar and monopolar RF devices have since been developed to

increase efficacy and minimize discomfort, as well as to increase penetration depth and target body tissues. Clinical trials have been completed and FDA approval is pending for the Alma Accent, both for the treatment of cellulite as well as for skin tightening and rhytide reduction (Alexiades-Armenakas, unpublished data, 2006). The Accent system contains both bipolar and unipolar technologies in one device and generates 40.84 MHz of RF energy. In the unipolar mode, which was employed for the cellulite trials, RF was applied from a single electrode tip without a grounding plate and delivered to a penetration depth of up to 20 mm. In the bipolar mode, the energy is applied between 2 points on the tip of the probe to a penetration depth of 2 to 6 mm. The Accent trial was a randomized, split-design, blinded trial that eliminated the limitations of earlier studies which lacked contralateral controls. The main mechanisms by which RF wavelengths are thought to work are collagen contracture and fibrocollagenesis at the dermosubcuticular junction; less likely, lipolysis in the superficial subcutaneous fat may be postulated.

Ultrasound technologies are currently being developed for cutaneous use to induce volumetric heating and potential lipolysis, and for the treatment of cellulite. One such ultrasound device has been developed by Cutera. A randomized, split-design, controlled FDA clinical trial is currently underway to assess this device for the treatment of cellulite on the buttocks and thighs. Another ultrasound technology, Ultrashape, has been tested in a bilateral treatment design of 137 patients where a decrease in thigh circumference was recently reported.⁵ FDA approval is pending for these devices.

In summary, the treatment of cellulite with laser and light based devices is a rapidly emerging area in dermatology and laser surgery. These devices currently include near infrared, RF, and ultrasound wavelengths, with or without concomitant suction or massage. Other wavelengths are also being investigated, such as the IllumiMed PhotoActiv, a light emitting diode, which is also yet to be FDA cleared for cellulite treatment. While FDA approval may be obtained or pending for such devices, well-designed trials and long-term follow-up of published studies will be important in order to assess the efficacy of any reported results.

References

1. Alster TS, Tehrani M. Treatment of cellulite with optical devices: an overview with practical considerations. *Lasers Surg Med.* 2006; 38:727-730.
2. Alster TS, Tanzi EL. Cellulite treatment using a novel combination radiofrequency, infrared light and mechanical tissue manipulation device. *J Cosmetic Laser Ther.* 2005;7:81-85.
3. Boyce S, Pabby A, Chuchaltkaren P, Brazzini B, Goldman MP. Clinical evaluation of a device for the treatment of cellulite: Triactive. *Am J Cosmetic Surg.* 2005;22:233-237.
4. Alexiades-Armenakas MR. Laser skin tightening: non-surgical alternative to the face lift. *J Drugs Dermatol.* 2006;5:295-296.
5. Grossman K. Results of a multi-center controlled study on Ultrashape. Annual Meeting of the American Society for Dermatologic Surgery, October 30, 2006, San Francisco, CA.

BRIEF SUMMARY OF PRESCRIBING INFORMATION



For Topical Dermatological Use Only

Rx only

Indication For Use

MimyX Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. MimyX Cream helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Contraindications

MimyX Cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

Warnings

In radiation therapy, MimyX Cream may be applied as indicated by the treating Radiation Oncologist. Do not apply 4 hours prior to a radiation session.

Precautions and Observations

- MimyX Cream is for external use only.
- MimyX Cream does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- If clinical signs of infection are present, appropriate treatment should be initiated; use of MimyX Cream may be continued during the anti-infective therapy.
- If the condition does not improve within 10 – 14 days, consult a physician.
- Keep this and other similar products out of the reach of children.
- MimyX Cream may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

HOW SUPPLIED

MimyX™ Cream is available in a 70 gram tube, NDC 0145-4200-01. Store at 15°C to 30°C (59°F to 86°F). Do not freeze.

Stiefel Laboratories, Inc.
 Coral Gables, FL 33134

826801-0905

Rx only - Prescription Medical Device: Federal Law restricts this device to sale by or on the order of a physician.

REFERENCES: 1. Del Rosso JQ, Bikowski J, Hawkes S, Sanglay L. Use of a palmitoylethanolamide-containing non-steroidal cream for the treatment of atopic dermatitis: impact on the duration of and time between flares. Presented at: 2006 Meeting of the American Academy of Dermatology; July 2006; San Diego, Calif. Poster 505. 2. Data on file. [TTF clinical results and protocol], August C. Stiefel Research Institute, Inc.

MimyX is a registered trademark of Stiefel Laboratories, Inc., and Research in Dermatology is also a trademark of Stiefel Laboratories, Inc.

