

The Efficacy of a Diode Laser with Contact Cooling and Suction (TriActive™ System) in the Treatment of Cellulite

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Background

Cellulite is a major cosmetic concern for most women. According to the *American Academy of Dermatology*, “Almost all women who are not severely malnourished have cellulite”¹. Cellulite treatment has become a significant revenue source in the aesthetic market². The development of the Tri-Active™ System, a Class I (over-the-counter) device for the treatment of cellulite, expands the options for cellulite treatment.

Cellulite refers to “lumpy” deposits of fat under the skin, resulting in skin with an “orange peel” appearance, typically on the thighs, hips and buttocks. The current theory of cellulite development suggests that obstructions of vascular and lymphatic flow in the hypodermis (the layer of fat and connective tissue under the skin) cause the development of connective tissue pockets between the skin and the basement membrane. These pockets then become filled with trapped fat, resulting in the dimpled appearance of the skin [Figures 1, 2].

Various factors have been implicated in the formation of cellulite including genetics, hormonal influences, vascular health, and systemic disease, combined with lifestyle issues such as sedentary lifestyle, stress, and diet. While excessive weight contributes to the degree and appearance of cellulite, physically active women with low percent body fat are subject to cellulite as well.

Based on this hypothesis, the Tri-Active™ system [Figure 3] was developed to address the underlying components of cellulite. Tri-Active™ incorporates Class I laser diodes, localized contact cooling and rhythmic suction massage. It promotes microcirculation^{3,4}, resulting in a reduction in the appearance of cellulite

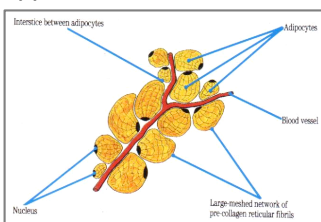


Figure 1: Normal architecture of hypodermis

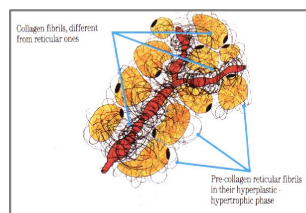


Figure 2: Development of collagen fiber “pockets”, with trapped fat



Figure 3: Tri-Active™ cellulite treatment system and handpiece, showing suction port (center) and laser diodes (periphery)

Studies have evaluated the effectiveness of the Tri-Active™ system for the treatment of cellulite⁵, proving its' utility, however the underlying contributions of laser diodes, cooling and dynamic suction massage have not been elucidated. The purpose of this study is to determine if there is a treatment benefit due to diode lasers in the Tri-Active™ system.

Methods

10 female patients, ages 18-60 years old, with moderate to severe cellulite bilaterally were enrolled in the Tri-Active™ treatment study. Participants discontinued all other cellulite treatments one month prior to study protocol. All patients were treated bi-weekly for a total of sixteen treatments. Half of the affected body areas were treated with the diode laser, contact cooling and suction operational, per the standard Tri-Active™ treatment protocol, while the contralateral side was treated with contact cooling and suction operational, but with the laser diodes off throughout the course of treatment.

Digital photographs were taken prior to treatment, at treatments nine and sixteen, and one and three months post-treatment to evaluate treatment efficacy. The

Subject Questionnaire:

<i>Percent Noticing Improvement</i>	<i>Percent Satisfied with Treatment</i>	<i>Percent Who would Continue Treatment</i>	<i>Percent who would Recommend Treatment</i>
90%	80%	80%	90%

Table 1: Response to subject questionnaire regarding perceived outcome and satisfaction following a full course of Tri-Active Treatments

photographs were evaluated by independent physician observers who were not involved with the study protocol. In addition, patients were surveyed to provide subjective evaluation of their treatment experience.

Results

90% of patients reported improvement, noting skin tighter, firmer, smoother, softer, less dimpled and buttocks lifted. 80% were satisfied with the treatments and would continue treatment. Patients found the treatment experience relaxing and noted improvement as early as the first treatment. 90% would recommend treatment. There was occasional mild bruising, but no significant side effects were reported. 70% of subjects exercised regularly during the course of treatment. 10% continued on a pre-existing diet regimen.

Independent physician observer evaluation of photos [Figure 4] found an average of 83% improvement in

Observer Evaluation:

<i>Percent Improvement Laser On</i>	<i>Percent Improvement Laser Off</i>
83%	17%

Table 2: Observer evaluation of improvement comparing treatment with and without laser component

cellulite with less dimpling, improved skin tone and smoothness, on the laser-treated side compared with an average of 17% improvement on the non-laser treated side. Improvements were maintained one month post-treatment. Limb measurements showed no correlation with improvement in the appearance of cellulite.

Conclusions

Greater improvement of cellulite occurred on the side treated with the laser operational, in addition to cooling and suction, compared to the contralateral side treated with cooling and suction only. Thus, we propose the laser component in treatment with the Tri-Active™ system improves clinical outcome. The mechanism of improvement is not well understood, requiring further study.

Treatment with the Tri-Active™ system is well tolerated without known side effects and results in improvement in the appearance of cellulite in 83% of subjects following a course of treatments. The results of treatment are maintained for at least one month following treatment. This study is ongoing to determine if the effects are longer lasting. The majority(80%) of the patients were satisfied with the results of the Tri-Active™ treatment and would recommend the Tri-Active™ procedure to others.



Figure 4: Example of treatment outcome (with laser) in moderate cellulite before (left) and one month following final treatment (right)

References:

- 1 "Dermatologists Shed Light on Treatments for Cellulite: AAD press release August 2, 2002.
- 2 The American Society of Plastic Surgery Cosmetic Surgery National Data Bank 2003 Statistics.
- 3 Stadler I, Evans R, Kolb B, et al. "In vitro effects of low-level laser irradiation at 660 nm on peripheral blood lymphocytes" *Lasers Surg Med*, 2000, 27(3) p255-61
- 4 Schindl A, Schindl M, Schindl L, et al. "Increased dermal angiogenesis after low-intensity laser therapy for a chronic radiation ulcer determined by a video measuring system" *J Am Acad Dermatol*, Mar 1999, 40(3) p481-4
- 5 Boyce S, Et. Al. "Clinical Evaluation of a Device for the Treatment of Cellulite: Tri-Active" Presented at American Academy of Cosmetic Surgery Annual Meeting, 2004