An Objective Evaluation on the Effects of Non-Ablative Skin Tightening with a Broadband Infrared Light Device

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Presented at the 26th Annual Meeting of the American Society of Laser Medicine and Surgery in Boston, MA April 2006

Objective

The purpose of this study was to objectively evaluate the efficacy and safety of a treatment for skin laxity using the Titan™ broadband infrared device (Cutera Inc. Brisbane, CA).

Patients

A sample of 21 Asian female patients between the ages 31-59 years old (mean: 46.8) with Fitzpatrick skin types III and IV participated in the study. These patients all demonstrated significant signs of skin laxity and skin irregularity. They received no prior light based treatments or other medications.

Material and Method

All subjects were treated with the Titan handpiece emitting 1100-1800 nm infrared light with a 10 X 15 mm spot size. Each subject received three treatments on the forehead and cheeks at fluences ranging from 32-38 J/cm^2 at three week intervals. The skin surface was cooled to 20º C using the integrated chilled sapphire tip and a chilled colorless gel. No anesthesia was used in order to evaluate pain perception versus visible improvement.

Quantitative measurements of nasolabial fold depth at pre and post treatment were performed using the PRIMOS® system (GFM, Germany). PRIMOS is used for accurate and direct acquisition of skin surface measurements and allows full examination of skin parameters e.g. roughness, volume of wrinkles or scars or their geometrical dimensions. The 3D software can quantitatively track changes in the skin over time.

Pictures were taken using the PRIMOS technology before treatment and one and three months after the third treatment. Photos were matched and selected using the "matching" feature in order to compare and analyze the same areas only. Improvement rates were calculated using analyzed data and also evaluated statistically.

In addition, both the patient and the physician evaluated the improvement in skin tightening three months after the third treatment by answering questions regarding progress on their skin condition.

Results

Analysis of 3-Dimensional images in skin laxity and Nasolabial fold depth

Of the 21 cases receiving treatment, 15 cases post one month and 12 cases post three months were analyzed.

Improvements in nasolabial fold depths showed statistical significance between pre and post one month of treatment and between pre and post three months of treatment (paired t-test $p<0.01$).

Of the 15 cases analyzed at one month, 93% showed reduction in nasolabial fold depth (14/15).

Of the 12 cases analyzed at three months, 75% showed reduction in nasolabial fold depth (9/12).

The percent of improvement ranges from -10.21% to 30.18% (mean: 10.67%) at one month, and -1.287% to 24.37% (mean: 10.42%) at three months.

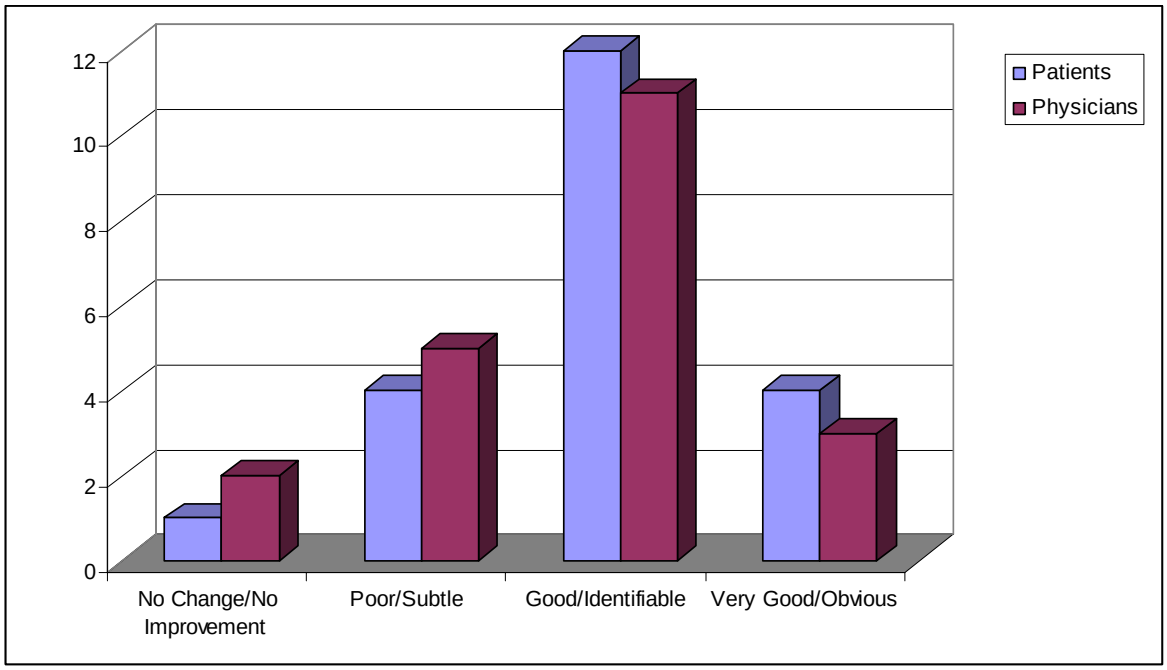
Analysis of patient and physician evaluations
Using the following scale the patients and the two physicians were asked to evaluate their level of improvement in skin tightening:

Patients	**Physicians**
A = Very Good	A = Obvious
B = Good	B = Identifiable
C = Poor	C = Subtle
D = No Change	D = No Improvement

As demonstrated from the graph, patient evaluations of their improvement fared better than their physicians' perception. Over 75% (16/21) of the patients rated their skin improvement as good to very good.

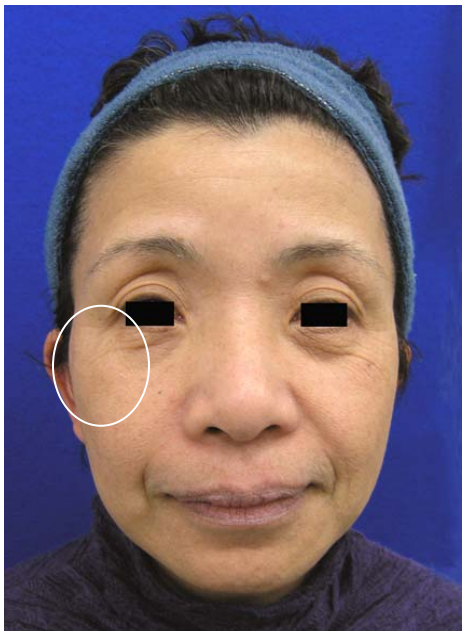
Analysis of patient evaluation of pain perception versus improvement
Patients were asked to evaluate the level of discomfort from the Titan procedure relative to the improvement in their skin. The average treatment consisted of 103 shots from the Titan handpiece.

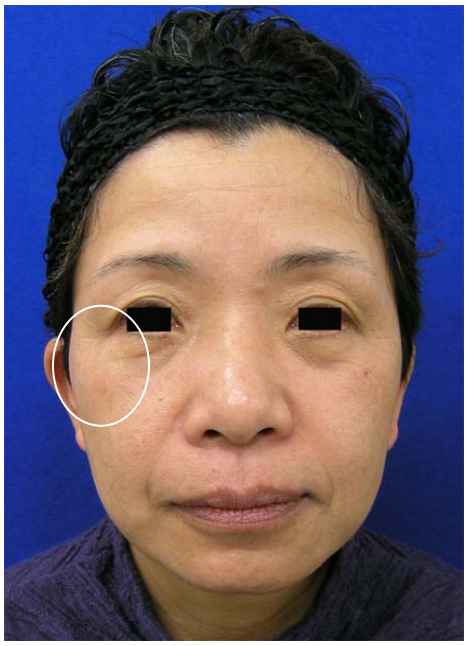
Over 90% (19/21) perceived the gain in improvement in their skin exceeded the level of discomfort of the procedure. Less than 10% (2/21) stated that the level of discomfort exceeded the gain in improvement from the procedure.

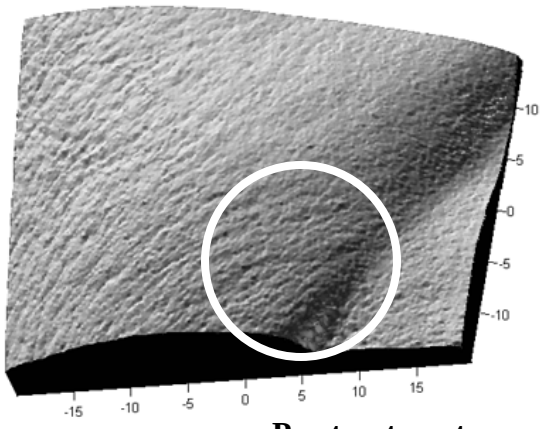


Results of patient and physician questionnaire on level of improvement in skin tightening.

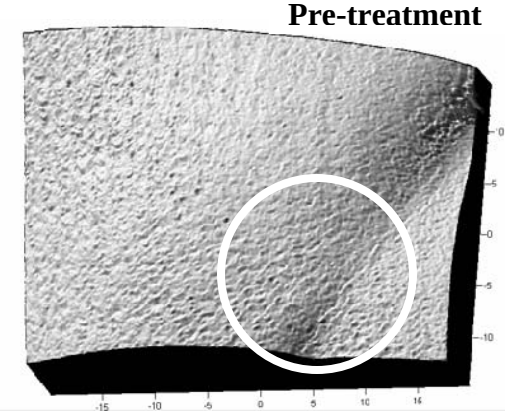
Example #1
Before (left) and after photo of a 52 year old Asian female. After photo taken after third Titan treatment.







Pre-treatment



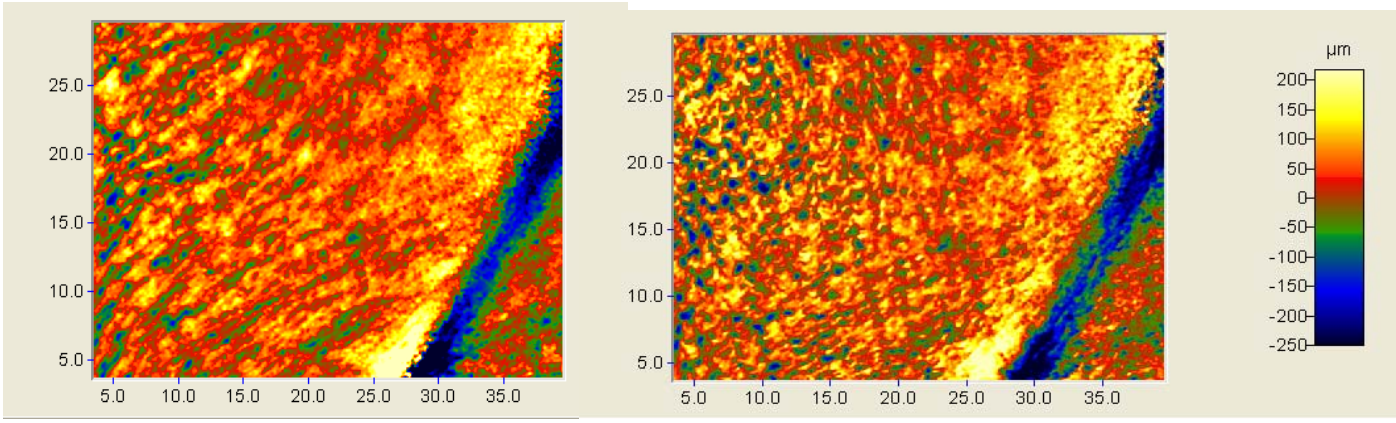
Post-treatment

The photos on the left are close ups of Patient #1 using the PRIMOS 3D software before and after the Titan procedure.

Using designated points on the skin surface, the PRIMOS software was able to perform a quantitative comparison pre and post treatment.

Patient #1 showed the most improvement with a 30.18% reduction of nasolabial fold depth

- pre 130.60 mm
- post 82.63 mm



Pre-treatment **Post-treatment**

Skin tightening is clearly evident by examining the pre and post treatment shape of the skin pores. The right photo is the 3D image after the third Titan procedure. The pre treatment skin pores (left) appear to be oval in shape due to skin laxity, whereas, the post treatment skin pores are more circular in shape.

Discussion

In this study, no topical anesthetic was used in order to evaluate whether the Titan procedure could easily be routinely performed. It was found that the Titan was easily tolerated with parameters ranging from 32-38 J/cm2 on the patients. Increasing the number of passes will increase treatment efficacy but will also require additional time for multiple passes.

The data clearly shows improvement in the reduction of skin laxity. The Titan is successful in delivering sufficient heat to its intended target depth of 1-2 mm below the surface of the skin. Furthermore, the heat delivered is sufficiently absorbed by the water inherent in the extra-cellular matrix as is evident by the stimulation of new cell growth.(2)

References

1. *Friedman PM et. al: 3D In-vivo Optical Skin Imaging for Topographical Quantitative Assessment of Non-ablative Laser Technology. Dermatology Surgery 2002,28,199-204*

2. *Zelickson B et al.: Ultrastructural Effects of Titan Infrared Handpiece on Forehead and Abdominal skin. Published by Cutera, Inc. April, 2005*