

# Non-invasive, Non-ablative Wrinkle Reduction and Skin Tightening Using High-frequency Electricity with Vacuum

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## INTRODUCTION

A multi-center study to evaluate the safety and efficacy of a bipolar RF with vacuum device for wrinkle reduction and skin tightening was initiated during May/June 2005 at the four clinical facilities of Drs. Michael H. Gold, Mitchel P. Goldman, Brian Zelickson, and Jaggi Rao. This report presents the interim results obtained at two sites (Drs. Gold and Goldman) until November 2006, the use of 3-dimensional micropopographical images to show wrinkle reduction after treatment with the bipolar RF with vacuum device, and the ultrastructural changes in postauricular skin after treatment with the bipolar RF with vacuum device (Dr. David Kist, Dr. Zelickson, Jeff Counters, Dr. Goldman, Dr. Gold, and Dr. David Mehregan).

## INTERIM ANALYSIS REPORT

Fifty-six patients aged 51.1 ± 8.0 years (mean ± SD) enrolled in the study. Patients received 8 treatments with the bipolar radiofrequency (RF) with vacuum at 2-week intervals. Results were evaluated after each treatment and at 4 and 6 months after the final treatment. The face, chin, neck, and abdomen were eligible for treatment of skin laxity, whereas only the face was eligible for the treatment of wrinkles. Patients could undergo treatment of both wrinkles and skin laxity only if the two conditions were present at different anatomical areas. A maximum of three areas were treated in each patient. This study conforms to IRB regulations and informed consent was obtained from all patients.

Evaluation measurements and timelines are listed in Table 1.

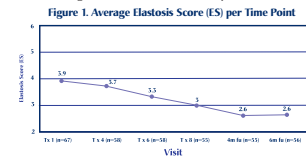
Table 1. Evaluation tools

Measurement	Evaluator	Time of Evaluation
ES*	Investigator	Pre-Tx1, 4, 6, 8, FU visits
Visual Analogue Scale†	Investigator, patient	Pre-Tx4, 6, 8, FU visits
Patient satisfaction level‡	Patient	Pre-Tx4, 6, 8, FU visits
Pain level§	Patient	Post-T1-8

\*Scale 1-9 defined in reduction criteria.  
 †Scale 0-10: 0=no improvement, 10=complete improvement.  
 ‡5-point scale: extremely satisfied, very satisfied, satisfied, slightly satisfied, not satisfied.  
 §5-point pain scale: 1=none, 2=slight, 3=moderate, 4=severe, 5=intolerable.  
 ¶5-Fitzpatrick Classification of Wrinkling and Degree of Elasticity. Pre-treatment, FU= follow up (1st and 6th mo).

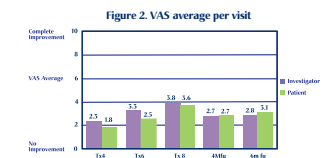
## RESULTS

The average investigator-assessed Fitzpatrick Elastosis Scores (ES) for wrinkle reduction at all time points are shown in Figure 1 (1 = excellent, 9 = poor skin elasticity).

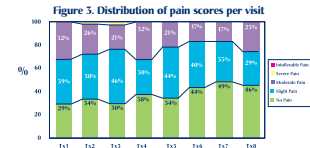


The average ES decreases from 3.9 at baseline to 2.6 at the four and six-month follow-up visits. The ES reduction at 4 months was significant ( $p < 0.05$ , t-test for paired data) compared to the baseline and to the preceding treatment and remained stable at six months.

Improvement based on the Visual Analog Scale (VAS) (0 = no improvement, 10 = complete improvement) was evaluated by both clinicians and patients before the fourth, sixth and eighth treatments and at four- and six-month follow-up visits. Results are shown in Figure 2.

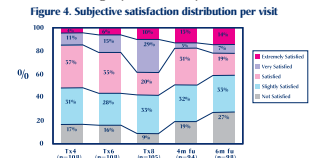


Patient VAS evaluations increased up to the eighth treatment from an average improvement level of 1.8 (on a scale of 0-10) at the fourth visit to 2.5 at the sixth visit and 3.6 at the eighth visit. The four and six-month follow-up scores were 2.7 and 3.1, a slight decrease from the peak at the eighth treatment. In comparison to the fourth visit (the first VAS evaluation), improvement was statistically significant ( $p < 0.05$ , t-test for paired data). Investigator-assessment trends were similar.



Patients also ranked their general level of pain after each treatment, using a 5-point scale (1 = none, 2 = slight, 3 = moderate, 4 = severe, and 5 = intolerable pain). The results are shown in Figure 3. No patient reported intolerable pain; most reported no pain or slight pain. Up to the fifth treatment, levels of pain were quite stable ( $p > 0.05$ , t-test for paired data). From the sixth treatment upward, a decrease in reported discomfort was observed when compared to the baseline values.

Patient satisfaction was recorded at the fourth, sixth, and eighth treatment visits as well as at the four- and six-month follow-up visits. Patients ranked satisfaction on a 5-point scale: 1 = not satisfied, 2 = slightly satisfied, 3 = satisfied, 4 = very satisfied, and 5 = extremely satisfied. Most patients reported some degree of satisfaction with the treatment (slightly to extremely satisfied).



Forty-five adverse events (52%) were recorded in 871 treatment sessions. Twenty-eight were unrelated to the study procedure. Only one adverse event was serious (bowel obstruction) but unrelated to the device. The 17 device-related cases are listed in Table 2. Thirty nine (59) cases were reported at one site (M.H.G.) and six at the second site (M.P.G.).

Patients completely recovered from all adverse events at the time of this analysis.

Anatomical Area	No. of Treated Areas	Percentage of Total
Wrinkle reduction	35	30
Periorbital	25	22
Perioral	6	5
Glabella	1	1
Forehead	1	1
Skin tightening	18	16
Neck	12	10
Forearm	8	7
Chin	5	4
Nasolabial folds	5	4
Abdomen	5	4

Adverse events included burn/blistering (n=12 events, mild to moderate), ecchymosis (n=1, mild), purpura (n=1, mild), pain (n=1, moderate), bruising (n=1, mild), and stomach cramps (n=1, moderate). Patients completely recovered from all adverse events at the time of this analysis.

Because patients could have more than one area treated, there were 115 treated areas in 56 patients. Table 2 shows the location of all total treatments (n=115).

Eight patients (~14%) accounting for 17 treatment areas (~15%) dropped out before completion of the study (4 withdrew consent, 3 were lost to follow-up, 1 had stomach cramps).

The reduction of average ES score from 3.9 to 2.6, which persisted for six months, shows the efficacy of the device and suggests that treatment benefits can be expected to last at least that long. VAS evaluations of both investigators and patients significantly increased throughout the treatment period and decreased slightly at the four and six months follow-up visits.

No correlation was found between the satisfaction levels and the pain/discomfort levels ( $r = 0.04$ ), partly because of the low variance of the pain evaluation results. In contrast, high positive correlations were found between the patients' VAS evaluations and their satisfaction levels ( $r = 0.7$ ). This strongly suggests that in this study, patient satisfaction is an outcome of how much improvement patients feel was achieved.

## CONCLUSIONS

Treatment with the bipolar RF with vacuum device is safe and effective for skin tightening and wrinkle reduction. No serious device-related adverse events have occurred. Treatment benefits can be expected to persist for six months or more.

## CASE STUDY WITH MICROTOPOGRAPHICAL PHOTOGRAPHS

A 65-year-old Caucasian woman sought wrinkle reduction in the left periorbital area. The patient received eight treatments according to the protocol of the interim analysis report. Three-dimensional images of the left periorbital areas were taken at baseline (Tx1), just before the fourth treatment (Tx4), and just before the sixth treatment (Tx6). The images in Figure 4 show the increased smoothness of the skin surface and increased shallowness of the wrinkles with continued treatment with the bipolar RF with vacuum device.

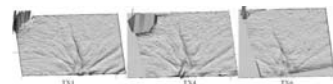


Figure 4. Three-dimensional micropopographical images of skin and wrinkles before and after successive treatments with the bipolar radiofrequency with vacuum device.

## ULTRASTRUCTURAL CHANGES

The bipolar RF with vacuum device may cause shrinkage of dermal collagen and promote formation of new collagen. In vivo post-auricular skin was treated with the bipolar RF with vacuum device (6 x 25-mm spot, 8-10 J/cm<sup>2</sup> fluence, 2-2.5 seconds). Punch biopsies of the treatment and control areas were obtained 4 months after treatment. Specimens were examined at 1 to 2-mm levels by transmission electron microscopy after hematoxylin and eosin (H&E) staining (Figure 5) and after elastic staining (Figure 6) to evaluate morphologic alterations of collagen fibrils in treated areas compared to the control area. The treated sample showed denatured collagen aggregates at the 0-1 and 1-2 mm levels with similar frequency. These immediate findings decreased to very rare denatured collagen aggregates at 4 months after treatment. RF accompanied by suction gave rise to ultrastructural changes similar to those observed with other non-invasive tightening devices.

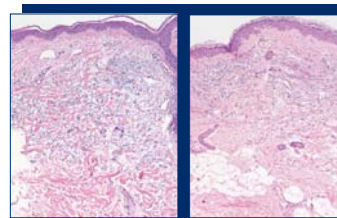


Figure 5. Photomicrograph of biopsy specimen of post-auricular skin after hematoxylin and eosin staining (a) before treatment and (b) four months after treatment with the bipolar radiofrequency with vacuum device.

Courtesy of Brian D. Zelickson, MD.

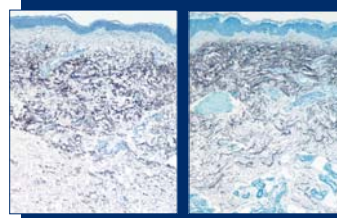


Figure 6. Photomicrograph of biopsy specimen of post-auricular skin after elastic staining (a) before treatment and (b) four months after treatment with the bipolar radiofrequency with vacuum device.

Courtesy of Brian D. Zelickson, MD.

## REFERENCES

1. Elsnor P. Skin Elasticity. In: Berardesca E, Elsnor P, Wilhelm K-P, Maibach HI, eds. *Bioengineering of the Skin: Methods and Instrumentation*. Boca Raton, Fla: CRC Press; 1995: 53-58.

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