# Clinical Results of Full Face Treatments with the VIVACE Micro-Needle System

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## Background

Safe and effective wrinkle (rhytide) treatments can be accomplished with micro-needing and RF energy. By electronically controlling the depth of the mico-needles and RF energy, the dermis can be treated for wrinkles with minimized damage to the epidermis.

## Study Design and Methods

To test the efficacy of this mode of treatment for moderate wrinkles on peri-orbital and peri-oral regions, 35 participants of diverse demographics and Fitzpatrick Scale classifications were selected to participate in a clinically controlled study. Clinical analysis of the treatment zones were conducted with a recognized and validated scale for demonstrating wrinkle improvement. Participants in the study had treatments 7-10 days apart for three treatments. They were photographed at 30 days, 60 days, and 90 days post treatment. 31 out of 35 of the participants completed all three sessions and are included in the final study analysis.

### *Patients*

31 healthy patients (female = 30; male = 1) aged 30 – 67 years with perioribital wrinkles with scores of 1 -8 on the Fitzpatrick grading scale (table 1) were included in the study. Patients with a history of facial injection with silicone, collagen, or a synthetic material placed in the intended treatment area, bleeding disorder, hypertrophic scar, keloid formation in prior 6 months, or lidocaine hypersensitivity were excluded from the study. Patients with mental disorders, metal materials in body, severe hypertension, cardiovascular and cerebrovascular disease were also excluded from the study. All patients were informed of the purpose of the study and written consent was obtained before treatment.

### *Demographics*

Of the 31 patients enrolled, 31 completed the three cycles of treatment. However, 3 patients did not show up for their 90 day post treatment follow-up. The mean age was 49 ± 0.00 year with a range of 30 – 67 years. Two subjects withdrew from the study. Reasons identified for withdrawal were determined not to be device related. Three subjects missed the 90 day post treatment follow up (subjects traveled or moved out of state and never returned):

TAG-2 :Subject traveled and never returned for the 90-day post treatment follow up. No photographic image was taken. The study center was informed by the subject that about travel plans but the subject never returned. All attempts were made to contact the subject without success.

TAG-29 : Subject moved out of state (New Mexico) and did not return for the 90-day post treatment follow up. No photographic image was taken. All attempts were made to contact the subject without success. No additional information is available regarding the subject.

TAG-30 : Subject moved out of state (New Mexico) and did not return for the 90-day post treatment follow up. No photographic image was taken. All attempts were made to contact the subject without success. No additional information is available regarding the subject.

| Clinical variables | Number of Patients |
|---|---|
| **Total enrolled** | 31 |
| **Completed treatments cycles** | 31 (100%) |
| **Completed 90 day follow up** | 28 (90.32%) |
| **Age, years** | |
| **Mean ± SD** | 49 ± 0.00 |
| **Range** | 30 – 67 |
| **Gender** | |
| **Female** | 30 (96.33%) |
| **Male** | 1 (3.33%) |
| **Fitzpatrick skin type** | |
| **I** | 1 (3.22%) |
| **II** | 4 (12.90%) |
| **III** | 17 (54.84%) |
| **IV** | 7 (22.58%) |
| **V** | 2 (6.45%) |
| **VI** | 0 |
| **VII** | 0 |
| **VIII** | 0 |
| **IX** | 0 |

Table 1: Patient demographics and study distribution

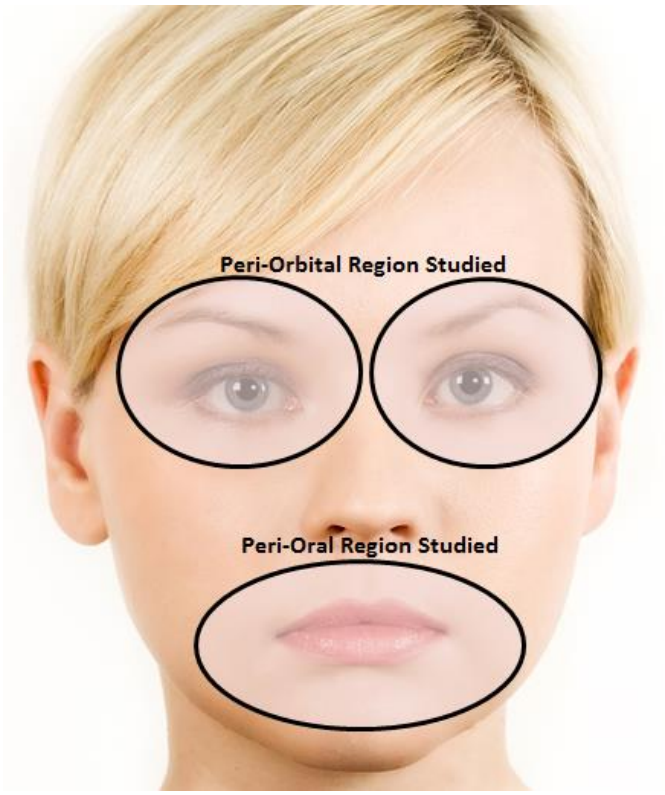
| | Fitzpatrick Skin Type | | | | |
|---|---|---|---|---|---|
| Gender | I | II | III | IV | V |
| Female | 1 | 4 | 16 | 7 | 2 |
| Male | 0 | 0 | 1 | 0 | 0 |

Table 2: Fitzpatrick Skin Type by gender

The treatment procedure were performed as follows:

- Thorough washing and drying of the face – it is important that patient not wear any kind of make-up including:
  - Lipstick
  - Eyeliner
  - Mascara
- Topical application of anesthetic cream for about 15-30 minutes
- Anesthetic cream is to be carefully cleaned from the face
- Treatment will consist of 2 to 3 passes at the targeted area at the chosen power level and exposure time over a period of 15-30 minutes.

During each treatment, three passes of the VIVACE were completed including one full face and 2 more focused passes on the peri-orbital and peri-oral regions.




For uniformity, the power level, needle depth, time (ms), and shot (pass) remained the same for all treatments through the course of the study ( see Table 3 ).

| | 1st Full face | 2nd Peri-Oral | 3rd Peri-Orbital |
|---|---|---|---|
| Power Level | 3 to 8 | 3 to 8 | 3 to 7 |
| Needle Depth (mm) | 1.0 to 1.5 | 1.3 to 2.0 | 0.6 to 1.2 |
| Time Duration (ms) | 300 to 600 | 300 to 700 | 300 to 600 |
| Shot(s) | 300 to 500 | 300 to 700 | 300 to 600 |

Table 3: applied treatment parameters

Each articipant received three different treatments and evaluations to determine their Fitzpatrick Wrinkle Severity Scale (FWSS) score change, if any. This scale is divided into two components. The first allows classification of wrinkle severity into mild, moderate, or severe scores. The second component subdivides these three scores into subsets based on a 1-9 elastosis damage scale assessment.

Particpants of the study were chosen from a diverse patient population in New Mexico where their routine treatments and measurements were conducted. All personally idenfiing information and demographics was removed from the patient data before being evaluated. The partipants were assigned the identifiers TAG-1, TAG-2, etc. for evaluation purposes. The participants were blindly and independently evaluated by three board certififed plastic surgens. The surgeons scored each of the three evaluations of the peri-orbital and peri-oral wrinkle enhancement based on wrinkle severity.

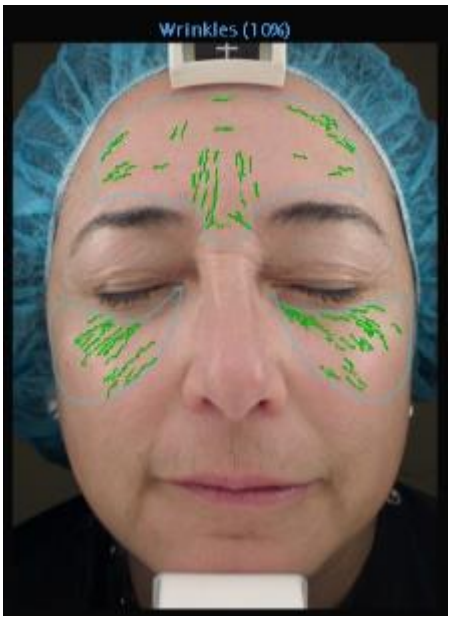
Successful treatment of the patient is defined as an improvement of at least one on the FWSS as determined by three cosmetic surgeon blinded evaluators, with the evaluation occurring at a minimum of three months after the last treatment.

**Clinical Anaylis and Photography Details**

Photographs were taken by the same individual and in the same location, position, etc. to ensure consistency. Patients were not permitted to wear makeup, jewelry, and not to have facial expression.

Pictures were blind, in that no names or other personal identifiers were visible. The patient identifier key was not available to the evaluators.

In addition to photographs, wrinkle analysis was also studied with VISIA from Canfield. VISIA's multi-point positioning system and live image overlay of patient images documented wrinkle changes with the VIVACE. The VISIA captured and automatically analyzes left, right and frontal facial views. IntelliFlash® , cross-polarized and UV lighting are used to record and measure surface and subsurface skin conditions. UV photography provides the most complete data set available for sun damage assessment and analysis, including UV fluorescence imaging to reveal porphyrins.




Example of Wrinkle Image
from VISIA in Study

**Device Description**

The VIVACE is an aesthetic device that uses Micro-needle electrodes to deliver 1 Mhz precise RF energy directly into the dermis of the skin. The thermal injury induces the production of new collagen and elastin. It is designed to provide minimally invasive dermal volumetric rejuvenation with little discomfort or downtime. It uses a touch screen LED screen to monitor and conduct patients' treatments. Various parameters can be modified and saved into stored programs on the device's memory if desired. Red & Blue Light emitting diode (LED) light help improve tone, color, and texture of the skin. The treatment cartridges are the only disposables of the machine making contamination unlikely. The device is intended for skin tightening & winkle improvement of the peri-oral and peri-orbital regions.

**Technical Specifications**

Model Name: VIVACE
Power Input: 100/230 VAC
Output Mode: Radio Frequency
Dimensions: 375(W) x 1210(H) x 335(L) mm
Weight: 20kg
Output Power Control: PWM
Display: 10.4 inch touch screen

**Results**

The study had 35 participants with 31 subjects completing all three sessions and are included in the final study analysis.

Among 31 subjects, 3 subjects didn't show up for 90 day follow-up photos. Total 28 sunjects were availabe for all 3 time assessments- 30 days, 60 days and 90 days.

**Table 1. Fitzpatrick Wrinkle Assessment Scale[19]**

| Class | Wrinkling | Score | Degree of Elastosis |
|---|---|---|---|
| I | Fine wrinkles | 1-3 | Mild (fine textural changes with subtly accentuated skin lines) |
| II | Fine to moderate-depth wrinkles, moderate number of lines | 4-6 | Moderate (distinct papular elastosis [individual papules with yellow translucency under direct lighting] and dyschromia) |
| III | Fine to deep wrinkles, numerous lines with or without redundant skin folds | 7-9 | Severe (multipapular and confluent elastosis [thickened yellow and pallid] approaching or consistent with cutis rhomboidalis) |

The elastosis degrees of the Fitzpatrick Wrinkle Assessment Scales were enhanced for 19 subjects of 28 subjects (67.8 %). over 1.0 enhancement ( 14/28 subjects, 50 %), over 0 to 0.9 enhancement ( 5/28 subjects, 17.8 %) and no enhancement of 0 ~ under 0 (9/28 subjects, 32.2 %).

| ID | Wrinkle Score (Baseline) | Average -30 | Average -60 | Average -90 | Total Change (Total Difference from Baseline -Average 90 day) |
|---|---|---|---|---|---|
| TAG-1 | II, 4 | 3.7 | 3 | 3 | 1 |
| TAG-2 | III, 7 | 7.3 | 5.3 | no show | N/A |
| TAG-3 | I, 2 | 2 | 2 | 1.3 | 0.7 |
| TAG-4 | II, 6 | 6 | 4.7 | 3.7 | 2.3 |
| TAG-6 | III, 7 | 6 | 5.3 | 4.7 | 2.3 |
| TAG-7 | I, 1 | 1.7 | 1.3 | 1.3 | -0.3 |
| TAG-8 | I, 1 | 2 | 2 | 2 | -1 |
| TAG-9 | I, 3 | 4 | 2 | 2 | 1 |
| TAG-10 | I, 1 | 1.7 | 1.7 | 1.3 | -0.3 |
| TAG-11 | II, 4 | 5.3 | 4 | 4 | 0 |
| TAG-12 | II, 6 | 5.7 | 5.3 | 3.3 | 2.7 |
| TAG-13 | II, 4 | 4 | 3.3 | 3.3 | 0.7 |
| TAG-15 | I, 1 | 2.3 | 2 | 1.7 | -0.7 |
| TAG-16 | I, 1 | 2.3 | 2 | 1.7 | -0.7 |

| | | | | | |
|---|---|---|---|---|---|
| TAG-17 | I, 1 | 2.7 | 2.3 | 2.3 | 0.3 |
| TAG-18 | II, 5 | 2.3 | 3 | 2.7 | 2.3 |
| TAG-19 | III, 9 | 7 | 6.3 | 4.7 | 4.3 |
| TAG-20 | III, 7 | 6.3 | 5.7 | 5.7 | 1.3 |
| TAG-21 | III, 7 | 6.7 | 6.3 | 6 | 1 |
| TAG-22 | III, 7 | 7.3 | 7 | 6 | 1 |
| TAG-23 | II, 6 | 6.3 | 6 | 5 | 1 |
| TAG-24 | II, 5 | 5.3 | 4.7 | 4.7 | 0.3 |
| TAG-25 | III, 8 | 7.3 | 7 | 6.7 | 1.3 |
| TAG-26 | I, 2 | 2.3 | 2.3 | 2 | 0 |
| TAG-27 | III, 8 | 7.3 | 6.3 | 5.3 | 2.7 |
| TAG-28 | III, 7 | 7 | 7 | 7 | 0 |
| TAG-29 | II, 5 | 5.7 | 5.7 | 5.3 | -0.3 |
| TAG-30 | II, 5 | 5.3 | 5.3 | no show | N/A |
| TAG-31 | II, 6 | 5.7 | 5.7 | no show | N/A |
| TAG-33 | III, 7 | 6.7 | 6 | 5 | 2 |
| TAG-35 | III,7 | 7 | 6.3 | 6.7 | 0.3 |
| | | | | | 0.91 At Average |

Table 4. Elastosis enhancement : 19 subjects of 28 subjects (67.8 %) were enhanced for elastosis.

- over 1.0 ( 14/28 subjects, 50 %), - over 0 to 0.9 ( 5/28 subjects, 17.8 %) - 0 ~ under 0 (9/28 subjects, 32.2 %)

Among 3 blind evaluators, 2 of 3 doctors assessed the wrinkle class enhancement of baseline to 90 day wrinkles at classs III-> class II (8/28 subjects, 28.6 %), class II-> class I (7/28 subjects, 25%) and no change (13/28 subjects, 46.4 %).

| **ID** | **Wrinkle Score (Baseline)** | **Gitt Score-90** | **Bell Score-90** | **Lussier Score-90** | Remarks(2/3 doctors) |
|---|---|---|---|---|---|
| TAG-1 | II, 4 | I | I | I | II->I |
| TAG-2 | III, 7 | | | | |
| TAG-3 | I, 2 | I | I | I | no change |
| TAG-4 | II, 6 | I | I | II | II->I |
| TAG-6 | III, 7 | II | II | II | III->II |
| TAG-7 | I, 1 | I | I | I | no change |
| TAG-8 | I, 1 | I | I | II | no change |
| TAG-9 | I, 3 | I | I | II | no change |
| TAG-10 | I, 1 | I | I | I | no change |
| TAG-11 | II, 4 | I | I | II | II->I |

| | | | | | |
|---|---|---|---|---|---|
| TAG-12 | II, 6 | I | I | II | II->.I |
| TAG-13 | II, 4 | I | I | II | II->I |
| TAG-15 | I, 1 | II | I | I | no change |
| TAG-16 | I, 1 | I | I | I | no change |
| TAG-17 | I, 1 | I | I | I | no change |
| TAG-18 | II, 5 | I | I | II | II->I |
| TAG-19 | III, 9 | II | II | II | III->II |
| TAG-20 | III, 7 | II | II | III | III->II |
| TAG-21 | III, 7 | II | II | III | III->II |
| TAG-22 | III, 7 | II | II | III | III->II |
| TAG-23 | II, 6 | II | II | I | no change |
| TAG-24 | II, 5 | I | I | I | II->I |
| TAG-25 | III, 8 | III | II | II | III->II |
| TAG-26 | I, 2 | I | I | I | no change |
| TAG-27 | III, 8 | II | II | II | III->II |
| TAG-28 | III, 7 | III | III | III | no change |
| TAG-29 | II, 5 | II | II | II | no change |
| TAG-30 | II, 5 | | | | |
| TAG-31 | II, 6 | | | | |
| TAG-33 | III, 7 | II | II | II | III->II |
| TAG-35 | III,7 | III | III | II | no change |

Table 5. Wrinkle class enhancement : III->II (8/28 subjects, 28.6 %), II->I (7/28 subjects, 25%), No change (13/28 subects, 46.4% )

The vast majority had a clinically significant improvement in their Fitzpatrick Wrinkle Severity Scale of the peri-oral and peri-orbital regions.

## Adverse Events

The data described below is a presentation of adverse reactions information identified from the clinical study:

- - Sensitivity
- - Light to severe erythema
- - Slight to very minor edema
- - Visible track marks
- - Slight pinpoint

Patient Number

- - Some peeling

| AE type | Treatment 1 | | Treatment 2 | | Treatment 3 | | Total | |
|---|---|---|---|---|---|---|---|---|
| | # pts | Rate | # pts | Rate | # pts | Rate | # pts | Rate |
| Erythema | 14/31 | 45.16% | 9/31 | 29.03% | 1/31 | 3.22% | 24/31 | 77.42% |
| Visible Track Marks | 3/31 | 9.68% | 2/31 | 6.45% | 1/31 | 3.22% | 6/31 | 19.35% |
| Edema | 3/31 | 9.68% | 2/31 | 6.45% | 0/31 | 0% | 5/31 | 16.13% |
| Sensitivity | 1/31 | 3.22% | 1/31 | 3.22% | 0/31 | 0% | 2/31 | 6.45% |
| Slight Pinpoint | 1/31 | 3.22% | 0/31 | 0% | 0/31 | 0% | 1/31 | 3.22% |
| Some Peeling | 0/31 | 0% | 1/31 | 3.22% | 0/31 | 0% | 1/31 | 3.22% |

Table 1: Comparison of rate after each treatment cycle

*Erythema*
Almost half of the patients experienced some level of superficial reddening of the skin (erythema). However, this event decreased with each following treatment. During the second, erythema was experienced by 9 patients and by only 1 patient after the third and final treatment. A decrease of 93% in cases of erythema.

*Edema*
Three subjects experienced very minor to slight edema in the first treatment with the subject device. The trend decreases in the second treatment with only two patients experience what was described as "immediate to slight edema". There were no reports of edema after the third treatment.

*Visible Track Marks*
A total of six patients experienced visible track marks from use of the Vivace device after treatment. The event occurred in 3 subjects after the first treatment, 2 after the second treatment and 1 after the third treatment. No patient experienced the same event in more than one treatment. The number of cases decreased by a third with each treatment.

*Sensitivity*
A total of two subjects experienced sensitivity during treatment sessions of the study. The first subject (TAG-1) reported sensitivity (left side slight sensitivity) after the first treatment. Only patient to report sensitivity during the first round of treatment among all 31 patients. Patient TAG-1 did not experience or report any other AE through the remainder of the study. A second patient (TAG-2) experienced sensitivity around the eyes and hairline. No other patient experienced or reported sensitivity throughout the study. It was determined that the reaction the first subject (TAG-1) experienced was not related to the device, it was determined that sensitivity around the eyes and hairline experienced by the second subject (TAG-2) was related to the study device.

*Discussion*

Adverse Events that occurred in greater than 5% of the subjects were Erythema (77.42%), Edema (19.35%), Edema (16.13%), and Sensitivity (6.45%). Of the 31 patients enrolled in the study, 100% completed the study (Table 1). Adverse event cases significantly decreased with each re-treatment phase for almost all AE type. Overall adverse event rates were highest at the first treatment cycle, decreasing by a third after the second treatment and with virtually little to no AE reported after the third and final treatment (from 70.97% at Tx1 down to 6.45% at Tx3). Across treatments, each AE consistently decreased after the first, second and third (final) treatment for almost every AE. This suggests patients seem to be more tolerant with each consecutive treatment to MFR therapy by the Vivace device.

**Conclusions**

It is clear that the Fitzpatrick wrinkle scale and Elastosis scores trended to improvement over the 90 days after treatment. These scores show improvement in rhytids and in solar elastosis. The independent reviewers findings are in line with previous impressions. In conclusion, a series of three VIVACE treatments appears to have positive effects on human periorbital and premolar facial skin rhytids and photo damage.

All studied parameters suggest a favorable treatment profile of the VIVACE device to reduce wrinkles in the peri-orbital and peri-oral regions. The device showed moderate, but positive improvement in wrinkle severity and elastosis damage.

In addition, to wrinkle improvement, subjects reported a myriad of other improvements as a result of the VIVACE treatments. During brief but thorough exit interviews, subjects credited the VIVACE with improvements of skin tone, sun damage reduction, scar reduction, and acne vulgaris. Future studies may justify an expansion of the range of treatments currently allotted to the device.

**About the Evaluators**

The plastic surgeons that evualated the data in this study were three board certified plastic surgeons: Steven Gitt, MD, FACS, Martin Bell, MD, JD, FACS, and Marc Lussier, MD. Steven Gitt, MD, FACS was the designated medical expert and investigator in this study. The partipants of the study were chosen and treated at New Mexico Facial Platics in New Mexico conducted by Board Certified Plastic Surgeon Farhan Taghizadeh, MD. Steven Gitt, MD, FACS and Martin Bell, MD, FACS conducted their research at North Valley Plastic Surgery, a multi-surgeon cosmetic surgery center and med spa in Phoenix, Arizona, U.S.A. Board Certified Plastic Surgeon Marc Lussier, MD conducted his research anaylais at Town Center Plastic Surgey in Valencia, CA.

**More Information on Doctors Involved in this Study**

Steven Gitt, MD, FACS**:** **http://www.nvpsaz.com/about-nvps/our-doctors/dr-gitt/**

Marc Lussier, MD**:** **http://www.lussiermd.com/plastic-surgeon-valencia-santa-clarita-ca/**

Martin Bell, MD, JD, FACS**:** **http://www.nvpsaz.com/about-nvps/our-doctors/dr-bell/**

Farhan Taghizadeh, MD**:** **http://www.nmface.com/meet-dr-t/**