# Novel Unipolar and Bipolar Radiofrequency (RF) Device for the Treatment of Facial Rhytids

*David J. Friedman, M.D., LaseOhr Dermatology Cosmetic Laser Institute, Jerusalem, Israel*

## ABSTRACT

The appearance of age-related skin is a major cosmetic and aesthetic concern in our society. Recently, radiofrequency (RF) technology has been adapted for non-ablative use for the treatment of age-related skin abnormalities. The Accent system is a novel radiofrequency (RF) device employing two distinct technologies via treatment applicators - Unipolar and Bipolar RF handpieces - on one platform. Based on a clinical study with 16 patients (29-66 years-old), four to six treatments with the Unipolar and/or Bipolar handpieces has yielded subjective and objective cosmetic improvement in the appearance of rhytids and lax facial skin in middle-aged women. These radiofrequency technologies are a safe and effective method for the treatment of lax facial skin. The ease of use, patient tolerance of the treatment due to no need for anesthesia, the lack of downtime, and the low risk of epidermal injury make RF non-ablative treatment a safe, effective and elegant therapeutic modality for the cosmetic correction of age-related skin irregularities, such as rhytids and lax skin.

## INTRODUCTION

The appearance of age-related skin is a major cosmetic and aesthetic concern with many schools of treatment. While proven effective for the treatment of aged skin, dermabrasion, chemical peels and laser resurfacing have waned significantly in popularity because of substantial post-treatment "downtime" and a prolonged recovery period, due to epidermal injury. Based on abundant histopathological evidence citing the clinical improvement of rhytids and skin laxity, dermal collagen remodeling using non-ablative, thermally induced techniques can improve the clinical manifestations of photo-aging, including facial rhytids, texture and tone. The potential risks associated with ablative laser therapy have paved the way for the development of novel non-ablative RF technologies for the aesthetic market.[1]

Recent developments have made it possible to use radiofrequency (RF) for non-invasive aesthetic applications. With controlled delivery of RF to the dermis, deep dermis and (when applicable) sub-dermal layers, RF has demonstrated the ability to stimulate collagen production resulting in a reduction of facial rhytids and improvement to nasolabial folds, jowls, and Marionette lines. In addition, subcutaneous tissue tightening for lax skin has been observed.

The Accent system (Alma Lasers Ltd., Caesarea, Israel) (Fig. 3) is a new generation of thermotherapy devices employing RF technology for non-ablative treatment of facial age-related skin irregularities and lax skin. Traditionally, invasive medicine has utilized RF in one of two configurations: Monopolar (for deep penetrating heat) and Bipolar (for superficial heating). Both technologies utilize a two electrode system: one for the emission of the RF energy and the other to serve as a return electrode for RF current. The mechanism responsible for RF heating of biological tissue is through the resistance of conductive current flow (tissue dependent).[2]

The Accent system, in contrast, employs two mechanisms of RF-induced heating of biological tissues: (1) rotational movement of water (dipole) molecules in the alternating electromagnetic fields (Unipolar) and; (2) tissue resistance to RF conductive current (Bipolar).

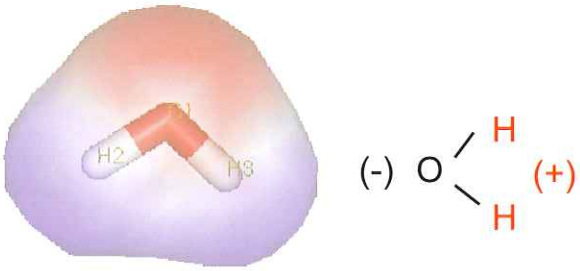



*Fig. 1. Water as a dipole molecule*

The Unipolar handpiece achieves its thermal effect by the interaction between the dipolar movement of water molecules within biological tissue (Fig. 1) and by the rotation and friction of water molecules.

The Unipolar handpiece emits an electromagnetic field that produces heat in the area adjacent to the handpiece with a predictable depth of penetration. The temperature gradient and depth of penetration following treatment with the Unipolar handpiece is shown in Fig. 2. Note that the highest temperature achieved is located several millimeters beneath the skin (the white area). Consequently, aggressive cooling is not required to protect the epidermis.

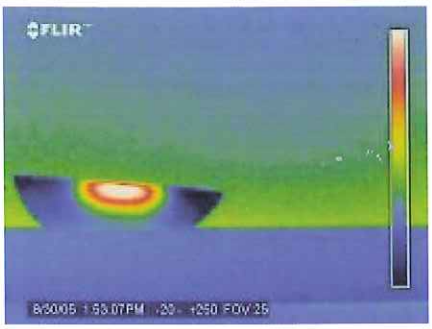



*Fig. 2. Thermogram of Accent Unipolar RF temperature gradient and depth of penetration.*

## DEVICE OVERVIEW

The Accent system has two radiofrequency handpieces, Bipolar and Unipolar, and an RF-generator that operates at a frequency of 40.68 MHz. The system has an intuitive software interface, and can be separated into two sections for easy transport between different locations.


*Unipolar*


*Bipolar*

*Fig. 3. Accent radiofrequency system*

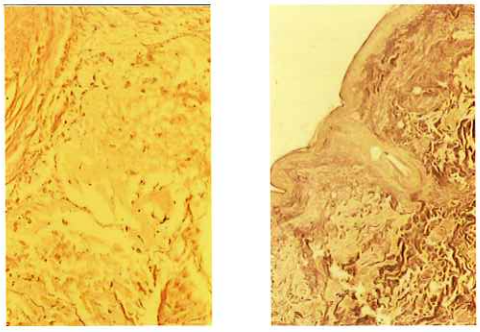
During treatment both handpieces (Fig. 3) are used in a continuous circular motion while in constant contact with the skin. The Unipolar RF energy penetrates to a depth of up to ~10mm, without damage to the skin's surface. The maximal applied RF-power for the Unipolar handpiece is 220 Watts and 100 Watts for the Bipolar handpiece; the RF-power used is dependent on the clinical application and treatment area. The Unipolar handpiece utilizes higher energy since it heats a greater tissue volume compared to the Bipolar handpiece.

Both the Unipolar and the Bipolar handpieces consist of an RF-resonant mechanism which includes a thermo-electric coupling (TEC) cooler and pushbutton activation. There is a blue LED (visible to the operator) that illuminates when the handpiece is activated.

## BIPOLAR AND UNIPOLAR RADIOFREQUENCY TECHNOLOGY

The Accent RF Unipolar and Bipolar handpieces can be used to tighten lax skin and correct fine lines and wrinkles by means of two major thermal mechanisms: (1) heat disrupts hydrogen bonds, altering the molecular structure of the triple helix collagen molecule and resulting in collagen contraction; and (2) micro-thermal injury-induced fibroblastic proliferation and apparent up-regulation of collagen expression (neocollagenesis /remodeling) leading to a thicker dermis.[3-5]

The skin's sub-dermal layer and the underlying collagen-containing tissue are heated without substantially modifying the melanocytes and other epithelial cells in the epidermis. The result is a contraction of the collagen tissue and a tightening of the skin. Controlled thermal injury may result in tissue shrinkage followed by an inflammatory response accompanied by the migration of fibroblasts into the area. The area is reinforced with additional connective tissue deposits as part of the tissue repair and healing phase. This phase is followed by a period of maturation of the newly deposited connective tissue, thereby resulting in contracture and tightening of the injured tissues and the tissue overlying dermis-epidermis interface. This newly deposited connective tissue matrix may be used to strengthen the old skin.



(a) (b)

*Fig. 4. Histopathologies of a tissue taken before (a) and three months after (b) 8 treatments with the Accent Bipolar handpiece. Increased dermal collagen density and collagen realignment are apparent after treatment.*
*(Courtesy of Prof. S. Pugliese, Rome, Italy)*

## FACIAL TREATMENT STRATEGY

The anatomical landmarks for treatment with the Unipolar and Bipolar handpieces are shown in Fig. 5. The typical treatment energy values used for treatment with the Unipolar are between 80-140 Watts and with the Bipolar are between 40-80 Watts. These values may reflect variations in skin thickness (thick, thin, medium), skin firmness (firm vs. lax), skin fragility (tough vs. fragile), and skin oiliness (oily, normal, dry).

### Unipolar

- Bilateral cheeks
- Forehead, exclusively over the frontalis muscle
- Underside of chin / neck
- Jowls and double chin

### Bipolar

- Thin tissue
- Bonier areas
- Periorbital, malar prominence, sides of nasal bridge

*Fig. 5. Treatment landmarks and movement directions for Unipolar and Bipolar handpieces.*

## ACCENT - RHYTID TREATMENT

The cooling mode should always be set to "ON" (it is recommended to touch the handpiece tip to insure that it is cold). The applicator must be in contact with the lubricated skin and in-motion, before the handpiece is triggered. The application technique begins with the drawing of rectangular grids on the skin (a 20-30 square centimeter area) with a skin marker. On the face it is advisable to use a 20 second exposure time for each pass. Before the actual therapeutic phase, the system is adjusted to the settings of RF power (Watts) and time (seconds) that will cause an increase in epidermal temperature from baseline to ~39 °C for the desired application. The skin temperature is monitored using a laser thermometer (Fig. 6). The application technique is always a contact circular motion beginning with smaller circles that expand outward before looping to another area and repeating the technique - until the time set expires. To prevent friction and provide a water-free environment on the surface of the skin, a light coating of baby oil is applied to the skin just prior to treatment.

The initial treatment parameters should be set (power and time of exposure) according to the suggested safe-start parameters. For moisturized skin or sensitive skin types, power should be reduced by 10-20 Watts. For oily skin, acne, sagging skin or aging skin, the power should be raised by 10 Watts.


*Fig. 6. Laser thermometer for monitoring skin temperature.*

After reaching the therapeutic threshold of ~40°C (Non-therapeutic: Phase I), multiple passes (3-4) should be applied on the treatment area (Therapeutic: Phase II). In Phase II, the energy level and the time of exposure should be down-titrated (10-15%). During Phase I and II, homogenous erythema (hyperemia) should be visible. Erythema may persist 15-30 minutes post-treatment. Post-treatment Aloe Vera on the treatment area is recommended.

The patient may experience a heating sensation or discomfort (uncommon) during or just following the treatment, in correlation to the energy level and exposure time. However, this heat sensation is transient. Adverse side effects may include erythema (which may be present in the treated area and will likely disappear within 1-2 hours) or skin burn (rare; which may occur if the operator did not follow instructions, i.e., used an energy level that was too high or kept the handpiece stationary).

The post-treatment procedure involves gently cleaning and drying the oil from the skin surface and having the patient rest for 10 minutes in the office. No other post-treatment actions are needed (the application of Aloe Vera is recommended). The recommended treatment regimen includes up to six treatments spaced at 2 weeks interval.

## CLINICAL STUDY

Between November 2004 - May 2005, sixteen study patients were treated for age-related skin irregularities in the facial area at LaseOhr Clinic in Jerusalem, Israel. All patients were women (age range 29-66). All patients were in good health and had had no facial procedure at least 6 months prior to enrollment. Patients received between 2 – 6 (average 4.3±1.3) treatments, spaced every 2-3 weeks and returned for a follow-up visit 1 month after the last treatment. Patients were treated in the following areas: forehead (n=9), cheeks (n=16), jowl lines (n=14), periorbital (n=7), marionette line (n=3), nasolabial folds (n=10).

The treatments were performed without any anesthesia. During the treatment both handpieces were used with active cooling. During the treatment, a discomfort score was used (0=cold; 5=extremely hot). In order to document treatment efficacy, standard photographs were taken (frontal view) before and after each treatment using a digital camera (Nikon, Coolpix 4300 Japan). As expected, all patients experienced mild-moderate erythema immediately after the treatment which was visible after the 2nd pass and resolved within 1-2 hours post treatment. The average energy levels was 120±20 Watts and 60±13 Watts for the Unipolar and Bipolar handpiece, respectively.

## Accent Study – Patient Satisfaction Scores

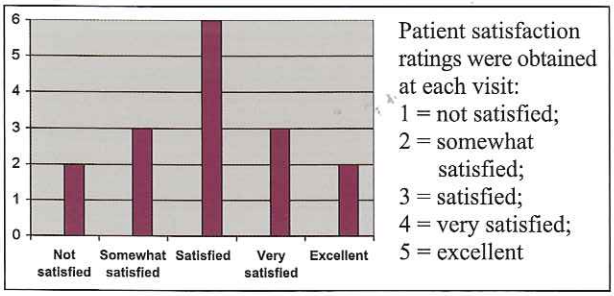



*Fig. 7. 70% of patients in the facial rhytids study were satisfied with the Accent treatment for facial rhytids.*

## Accent Study – Improvement Scores

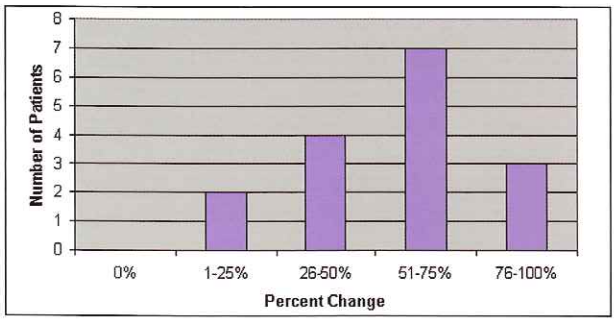



*Fig. 8. One month after last treatment the improvement score for 3 patients (19%) was marked improvement, 7 patients (44%) scored significant improvement, 4 patients (25%) scored moderate improvement, and mild improvement was scored in 2 patients (12%).*

Improvement was scored as 0% = no improvement; 1%-25% = mild improvement; 26-50% = moderate improvement; 51-75% = significant improvement and 76%-100% = marked improvement.

When the study population was divided into two age groups, the younger group (29-45 years old; n=6) reported statistically significant ($p<0.01$) higher satisfaction scores of 3.7±0.7 when compared to older group (>46 years old; n=10) which had a satisfaction score of 2.6±0.8. Photographic analysis of pre-and post-treatment digital images showed visible improvement in 11 of the 16 cases (69%) as evaluated by the treated physician. No adverse side effects were reported.

## CONCLUSION

The clinical findings of this study suggest that the Accent system can induce skin tightening and remodeling via volumetric (Unipolar) and superficial (Bipolar) thermal respectively, without causing any damage to the epidermis. While in some patients, acute tightening was noted, a phenomena consistent with collagen structural changes, the slower and more subtle tightening effects noted over one month post-treatment suggest a mechanism related to wound healing such as collagenase, type I collagen and platelet derived growth factor with the end result of dermal remodeling.

## CLINICAL EVIDENCE

(a) (b)

*Fig. 7. Peri-orbital wrinkles: before (a) and 1 month after (b) four treatments.*

(a) (b)

*Fig. 8. Cheek laxity: before (a) and 1 month after (b) four treatments.*
*Photographs courtesy of David J. Friedman, M.D.*

## REFERENCES


1. *Kim KH, Geronemus RG. Non-ablative laser and light therapies for skin rejuvenation. Arch Facial Plast Surg. 2004 Nov-Dec; 6(6): 398-409.*
2. *Sadick NS, Makino Y. Selective electro-thermolysis in aesthetic medicine: a review. Lasers Surg Med. 2004; 34(2):91-7.*
3. *Arnoczky SP, Aksan A. Thermal modification of connective tissues: basic science considerations and clinical implications. J Am Acad Orthop Surg. 2000 Sep-Oct; 8(5):305-13.*
4. *Abraham MT and Ross VE. Current concepts in non-ablative radiofrequency rejuvenation of the lower face and neck. Face Plast Surg 2005; 21(1); 65-73.*
5. *Fritz M, Counters JT, Zelickson B. Radiofrequency treatment for middle and lower face laxity. Arch Facial Plast Surg 2004;6:370-373.*



Alma Lasers™
Wellbeing Through Technology

**United States**
485 Half Day Road # 100
Buffalo Grove
IL 60089
Tel: 224-377-2000
Fax: 224-377-2050
contact@almalasers.com

**Headquarters**
14 Halamish St., P.O.B 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: 972-4-627-5357
Fax: 972-4-627-5368
info@almalasers.com

www.almalasers.com