Treatment of Wrinkles and Skin Tightening Using Aluma™ Skin Renewal System with FACES™ (Functional Aspiration Controlled Electrothermal Stimulation) Technology

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Introduction

Resulting from a variety of intrinsic and external factors, the formation of wrinkles and skin laxity drives patients to seek treatment to restore a more youthful appearance. Non-invasive alternatives to surgical techniques are being developed that safely rejuvenate the skin by triggering shrinkage and formation of dermal collagen. One such method involves the use of radio frequency (RF) energy, based on passage of a high-frequency electromagnetic energy through the skin.

Radio Frequency — The Basics

Radio frequency current is formed when charged particles flow through a closed circuit. As the energy meets resistance in the tissue, heat is produced. The amount of heat will vary depending on the amount of current, the resistance levels in the targeted tissue and the characteristics of the electrodes.

Human tissues, including the skin, are rich in electrolytes and an array of compounds that allow current conductance with varying degrees of impedance and resulting heat formation. The amount of RF energy applied can be configured to target specific tissues. In addition, the water content of skin varies between different areas of the body, with time of day, environmental humidity, internal hydration and the use of topical moisturizing agents. Thus, the flow of RF through the skin depends on multiple factors which may not be uniform from one treatment to the next.

Radio Frequency in Medicine

RF energy has become increasingly popular for medical applications involving tissue heating in the fields of general surgery, cardiology, neurology, orthopedics, and dermatology.[1-3] Traditional RF electrosurgery is rarely reported in relation to skin resurfacing due to excessive heat generation.[4] While a relatively low-heat process ('coblation') has been adapted for ablative skin resurfacing[5], the more recent non-ablative use of RF holds promise for dermal remodeling, skin tightening and non-invasive treatment of wrinkles and fine lines.

FACES Technology

Functional Aspiration Controlled Electrothermal Stimulation (FACES) uses RF technology accompanied by vacuum-assisted positioning and folding of the skin for the treatment of wrinkles and for skin tightening. By folding the skin, the dermis is placed in a more direct alignment with the electrodes than when the electrodes are pressed onto the skin surface. A topical conductive medium and the specially designed tips enable the creation of concentrated heat in the dermis, maximizing both efficacy and safety. FACES treatment modality is available either in the Aluma Skin Renewal System *(Figure 1)* or as an add-on modality to the multi-application Lumenis One™ platform (Lumenis Inc., Santa Clara, CA).

Technical Specifications

The lightweight and ergonomically designed handpiece *(Figure 1)* is connected to an apparatus that provides adjustable vacuum (4-28 in Hg), drawing the skin between two parallel electrodes up to a predetermined depth. The bipolar electrodes are located in the pocket of a disposable tip attached to the distal end of the handpiece. The RF tips are presently available in two aperture sizes — 3x18 mm and 6x25 mm. Once the skin is properly positioned between the electrodes, a 468 kHz radio frequency current passes through the skin at a power of 2-10 watts. The duration of the pulse can be adjusted between 1-5 seconds, delivering 2-50 joules to the tissue in a single pulse. A special coupling medium is applied to the treated areas to increase RF conductivity through the stratum corneum. This allows the RF energy to pass through the epidermis causing negligible heating there while efficiently heating the targeted dermis. The tip has a proprietary design to ensure patient safety and a filter that prevents the coupling medium from entering the handpiece and system.

Figure 1: Aluma™ Skin Renewal System and Handpiece (applicable also for Lumenis One™).

Mechanism of Action

An underlying network of collagen and elastin fibers provides scaffolding for the skin and determines its degree of firmness and elasticity. Over time, this intricate fiber network loosens and unravels, altering the appearance and function of the skin. It is estimated that adult skin loses approximately 1% of its dermal collagen content on an annual basis due to increased collagen degradation and decreased collagen synthesis.[6] Aluma treatments overcome these causes of wrinkles and skin laxity.

When collagen fibers are heated, some of the cross-links are broken, causing the triple helix structure to unwind. Beyond a certain level, depending on a combination of both the maximal temperature and the exposure time, collagen fibers undergo denaturation. When the cross-links are maintained, at least partially, collagen shrinkage and thickening is achieved.[2]

Based on this principle, Aluma treatments are designed to cause shrinkage of dermal collagen using heat generated by a radio frequency current. In addition, the treatment promotes formation of new collagen via the skin's natural wound-healing response and a direct effect on the dermal cellular matrix. The extent of collagen shrinkage, fibroblast activation, fibroplasia and overall collagenesis in the different skin layers is based on a complex multivariate mechanism, which depends on temperature distribution and timing. Aluma's vacuum apparatus and tip design confine the heating to the tissue between the electrodes, allowing creation of a precise, controlled temperature per skin layer/volume. This enables shrinkage at a certain depth, followed by collagenesis at a different, preferably more superficial, layer. Mechanical stress (e.g., vacuum) has been reported to stimulate fibroblasts leading to collagenesis, possibly further increasing the effect of Aluma treatment.[7] Notably, both heat exposure and application of vacuum to the skin are also known to increase blood perfusion in the affected area, supporting the fibroblast activity and the overall rejuvenation process.

From a technical point of view, the vacuum feature of FACES on the Aluma system not only enables greater target specificity and use of low energy levels, but also keeps the skin's surface in tight contact with the electrodes, allowing proper current delivery and further contributing to both safety and efficacy.

Electrode Configuration

Two major electrode configurations are available in RF devices currently on the market — monopolar or bipolar. The two configurations differ in their derived energy field, but the resultant energy-tissue interaction is similar. In both cases, under controlled conditions, it is the tissue that becomes hot, not the electrodes.[1]

In a monopolar configuration, one electrode is active and the other (a much larger one) is placed far from the first one and serves as a grounding pad. The main advantage of monopolar delivery is the concentration of a high-power density on the electrode's surface and the relatively deep penetration of the emitted power, making this configuration more suitable for electrosurgery. However, relatively high pain levels and safety concerns may be associated with utilization of this configuration for dermatologic applications.

In a bipolar configuration, the current flows between two identical electrodes that are set a small fixed distance apart. No grounding pad is necessary. The fact that the distribution of the current in the tissue is more controlled in this setting is a major advantage over the monopolar configuration. However, in bipolar systems where the electrodes are placed flush on the skin, this configuration has the distinct disadvantage in that the depth of penetration is limited to approximately half the distance between the electrodes. This means that less energy of sufficient density reaches the deeper structures, rendering a more superficial effect regardless of the emitted energy level.[1]

The design of the Aluma tip overcomes the limitations inherent with both monopolar and flush bipolar systems and further improves the performance. The incorporation of the vacuum apparatus into the Aluma parallel bipolar electrode tip enables deeper skin layers to be reached *(Figure 2)*. Furthermore, by limiting the volume of treated tissue to only that located between the two electrodes, the required energy density can reach and affect the chosen skin layers, whether superficial or deep. This leads to effective treatments with improved safety and significantly less pain, even without anesthesia.

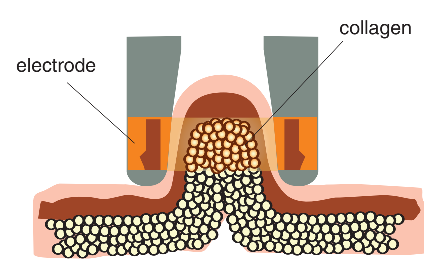

Figure 2: Skin folding and tip design target heat deep in the dermis and minimize injury to non-target tissue.

Implementation and Operation Principles

The Aluma allows the customization of treatment to patient needs, beginning with the pulse parameters—power and duration—which deliver appropriate energy to reach the visible endpoint of slight erythema immediately following each pulse. In order to reach the optimal effect, the energy level may be modified by a change of either power, time or both. Another factor that comes into play is the energy per skin layer and per volume of tissue, both of which are determined by the chosen vacuum level and the specific characteristics of the skin in the treated area. The tip aperture size, small or large, is also a factor in this equation since it enables adjustment to the characteristics, volume and dimensions of the area intended for treatment. The small tip is usually used for wrinkle treatment and the larger tip for skin tightening. The direction of the tip during treatment also contributes to the end result. For wrinkle treatment, the long axes of the tip and the wrinkle should be parallel, with the center of the wrinkle located in the middle of the tip, halfway between the two electrodes. For skin tightening, the tip should generally be placed perpendicular to the desired direction of tightening. To further increase treatment flexibility and user convenience, the tips may rotate in either direction while attached to the handpiece.

To simplify treatment, both the Aluma stand-alone system and the Lumenis One module offer the option of using sets of predetermined parameters for treatments. These may initially be the presets provided by Lumenis, but as users gain experience, additional user-programmed parameter combinations may be saved and selected.

We have demonstrated that Aluma treatments are safe and effective for all skin types. Though treatment impact is not directly related to color, skin type may be considered when choosing parameters due to other skin characteristics (e.g., darker skin tends to be thicker and sometimes coarser in certain anatomical areas).

Another aspect, related to safety, efficacy and patient comfort during treatment, involves the possibility of performing multiple passes (up to three). This enables division of high energy levels into smaller, well-tolerated doses and also allows modifying treatment parameters to distinct skin layers. Any treatment parameter may be modified between passes to achieve the desired effect per skin layer. Accordingly, the parameters may also be altered between treatment sessions, based on the visual and textural response of the treated area. The recommended treatment regimen, according to current clinical practice, includes 4-6 sessions at intervals of two to three weeks.

Clinical Trial Results

A prospective, self-controlled trial was conducted with healthy volunteers who met all eligibility criteria—42 women and 4 men were enrolled, aged 33-71 years, with a mean age 52±9 years. Patients were not pregnant, could not have any type of permanent electrical implants in their body (passive or active, e.g., pacemaker), and could not have significant skin disorders or any conditions that might alter the skin's conductivity in the treated areas (e.g., acute dryness). Patients received full face treatments at 1-2 week intervals and were followed for up to six months after the last treatment.

Using the Fitzpatrick-Goldman Classification of Wrinkling and Degree of Elastosis ('ES') for evaluation, a significant improvement in facial wrinkles was found at an early stage of the treatment course. Improvement increased gradually over the course of the trial, reaching its peak during the follow-up period *(Figure 3)*. At six months post-treatment, a mean improvement of ~2 ES units was reported, with 85% of the subjects showing improvement of at least one ES unit. The observed phenomenon is compatible with the underlying biological mechanism: rapid collagen shrinkage, followed by the relatively slow process of collagen formation, leading to the observed overall long-term effect. Over 90% of subjects expressed satisfaction with the treatment and its outcome.

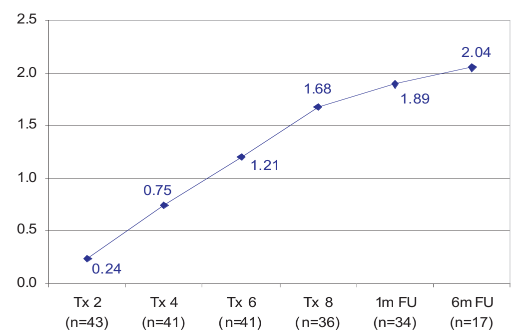

Figure 3: Elastosis Score Improvement over Course of Trial.

Each evaluation time point (e.g., 'Tx 4', '6m FU') reflects the cumulative effect achieved up until that visit; evaluations from every second treatment/follow-up are presented.

Treatments were generally painless and adverse events were rare. Most adverse events were cases of transient erythema or burn/blistering; all were mild to moderate in severity and fully resolved very quickly without hindering the treatment schedule. Almost all adverse events occurred early in our use of this device and represented a learning curve for the first investigation of this device in humans. In the early stages of the study, no preset parameters were available. The incidence of adverse events dramatically declined as we gained experience with the technology and developed presets.

Conclusion and Discussion

Vacuum-assisted positioning of the skin prior to delivery of radio frequency energy results in heat deposition deep in the dermis. Collagen contraction and subsequent regeneration lead to improvements in elastosis scores and high rates of patient satisfaction. The combination of the use of a coupling medium on the epidermis and the delivery mechanism resulted in a very low risk of adverse events and virtually no patient discomfort. This compares favorably with other radiofrequency technologies which tend to be painful and have lower rates of patient satisfaction due to unpredictability.

We have found that this procedure with its unique delivery method represents an advancement in the technology of radiofrequency treatment for wrinkles and skin laxity. Treatment is fast, virtually painless and provides consistent and predictable results. Although 8 treatments were used in the study, we agree that 4-6 treatments will be adequate to provide satisfactory patient results. Improvement continues for 3-6 months following treatment.

While this study shows wrinkle, skin texture and elastosis improvement *(Figures 4 and 5)* and high rates of patient satisfaction, there is a need for objective measurements so that we may further understand the benefits of this technology. Our research groups are addressing these needs in an ongoing study using biopsy and other objective tools to measure the effects of treatment.

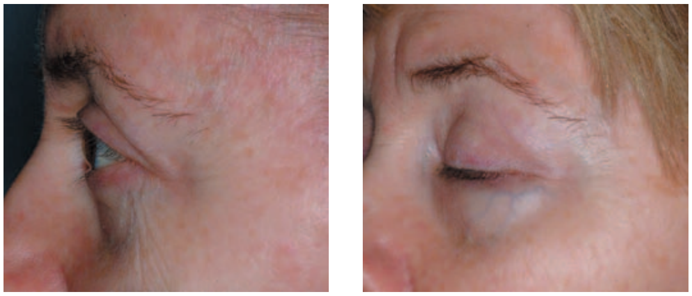

Figure 4: 56-year-old female, skin type II, before and six months after eight treatment sessions. *(photos courtesy of Michael H. Gold, MD)*

Figure 5: 56-year-old female, skin type II, before and six months after eight treatment sessions. *(photos courtesy of Mitchel P. Goldman, MD)*

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