Novel Radiofrequency (RF) Device for Cellulite & Body Reshaping Therapy

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ABSTRACT

Cellulite is among the most disturbing and challenging skin disorders known in the aesthetic market. Despite multi-disciplinary physical or mechanical treatments, pharmacological agents, exercise and diet regimens, cellulite signs and symptoms remain, in most cases, unaffected. In the past decade, cellulite management has inspired a new generation of innovative medical devices promising correction of cellulite signs and symptoms. It is now evident that weakened connective tissue and diminished microcirculation play key roles in the pathophysiology of cellulite. Therefore, long term correction of cellulite is possible through modification of weakened connective tissue and improvement of microcirculation functioning. The Accent (Fig. 3; Alma Lasers, Ft. Lauderdale, Florida). is a novel radiofrequency (RF) device to treat cellulite by employing volumetric thermotherapy. The Accent has both Bipolar and Unipolar (patent pending) RF handpieces for the treatment of various body reshaping therapies and other skin imperfections. Both of these RF handpieces improve cellulite symptoms through three mechanisms: (1) Deep dermal heating/tightening - up-regulation of collagen expression (neocollagenesis and remodeling); (2) Enhancement of stagnant blood microcirculation (hyperemia by vasodilatation) and lymphatic drainage of trapped fatty deposits and toxins and; (3) thermally induced fat cell dissolution and adipocytes apoptosis.

INTRODUCTION

There are two clinically reported mechanisms that have demonstrated the ability to thermally modify the skin's connective tissue: optical energy (laser and pulsed light) and radiofrequency (RF). Although RF and lasers/light devices differ fundamentally in the way they generate heat within the tissue, both types of devices are capable of producing temperatures within the critical temperature range (65-75°C) for connective tissue shrinkage and remodeling. [1]

Light and RF can be controlled through adjustments in:

- Electromagnetic power (Watts)
- Exposure time (sec, msec)
- Method of electromagnetic energy application
- Tissue resistance and impedance (RF)
- Natural biologic chromophore (Laser) /ions or dipole molecules (RF)

Recent developments have made it possible to use radio frequency energy for non-invasive aesthetic applications. With controlled delivery of RF to the dermis, deep dermis and (when applicable) subdermal layers, RF treatment has demonstrated the ability to stimulate collagen production. This collagen production results in the softening of wrinkles (i.e. periorbital rhytides and improvement to nasolbial folds, jowls, and marionette lines). Cooling is an important ingredient when using radio frequency to help control epidermal heating (and potential for injury) as well as provide additional patient comfort. [2, 3]

NEW TECHNOLOGY

Traditionally, medicine has utilized RF in one of two configurations: Monopolar and Bipolar. Both configurations utilize a two electrode system: one for coupling 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). For lypolysis, a monopolar configuration for deep tissue (volumetric) heating is less beneficial because the current will find a path of low resistance (through blood and lymphatic vessels) where fat cells would not be directly affected. The new Accent system by Alma Lasers Ltd. (Ft. Lauderdale, Florida) 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).

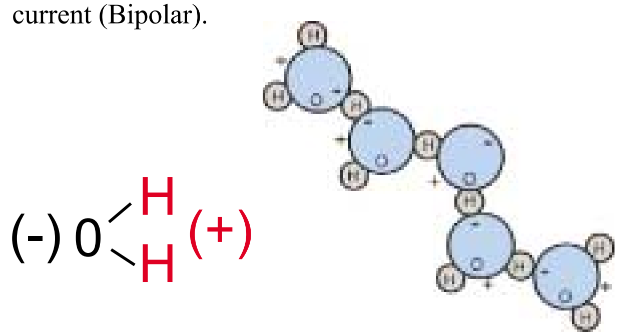

Fig. 1. Water (dipole) molecule

The Unipolar handpiece imposes its thermal effect by the interaction between the dipole movement of water molecules within the biological tissue (Fig. 2) and through the rotation and friction of water molecules. The Unipolar handpiece applies an electromagnetic field that produces heat in the area adjacent to the handpiece with a controllable depth of penetration. Figure 3 shows temperature gradient and depth of penetration following exposure to the Unipolar handpiece. It can be seen that the highest temperature achieved is located several millimeters beneath the skin (white area ~10mm depth). Consequently, aggressive cooling is not required to protect the epidermis.

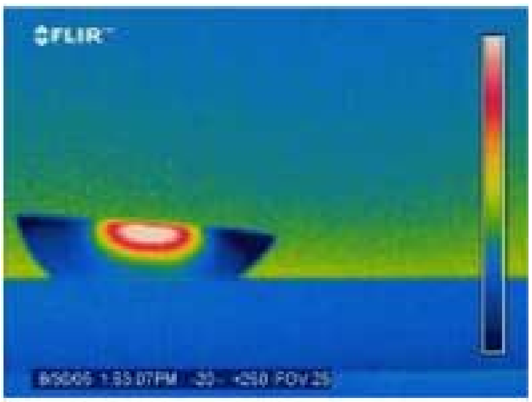

Fig. 2. Thermogram of Accent Unipolar handpiece temperature gradient and depth of penetration.

DEVICE OVERVIEW

The Accent has 2 handpieces (Bipolar and Unipolar) and an RF-generator that operates at a frequency of 40.68 MHz. The Accent Unipolar handpiece (patent pending) provides RF energy without the need or potential hazards of a ground or “return electrode”. The Accent system is the first aesthetic medical system to provide Unipolar technology for skin tightening, cellulite reduction and for subdermal fat reduction. The Accent system also includes a Bipolar handpiece to provide more superficial heating to induce tissue tightening. in places such as the forehead and neck where the dermis is thin.

Fig. 3. The Accent system

Both handpieces (Fig. 4) are used in a continuous sweeping ("paint-brush") motion while in contact with the skin. The Unipolar RF energy penetrates to a depth of up to 20 mm, heating the skin tissue and subcutaneous tissue without damage to the tissue surface. The applied RF power for the Unipolar handpiece is 100-200 Watts and 60-100 Watts for the Bipolar handpiece, dependent on the clinical application and treatment area. The Unipolar handpiece utilizes higher energy since it heats greater tissue volume as compared to the Bipolar handpiece, which heats a smaller tissue volume.

(a) (b)

Fig. 4. The Unipolar (a) and Bipolar (b) Handpieces

The Accent Unipolar handpiece consists of an RF-resonant mechanism which includes a thermo-electric coupling (TEC) cooler with pushbutton activation. There is a blue LED (visible to the operator) that illuminates when the handpiece is activated. The application technique begins with the drawing of rectangular grids on the skin (20-60 cm2 area) with a skin marker (see Figure 7). The system is adjusted to appropriate settings of RF power (Watts) and time (seconds) for the desired application. The skin temperature is monitored using a laser thermometer and recorded on the patient’s treatment form. The application technique is always a contact sweeping motion beginning with horizontal strokes followed by vertical strokes – alternating until the time expires. To prevent friction and provide a water-free environment on the surface of the skin, a light coating of treatment oil is applied on the skin just prior to treatment. Following treatment of each grid, the skin temperature is recorded and the operator then moves on to the (non-adjacent) next treatment grid. The technique is relatively fast, painless and does not interrupt the patient’s routine, as the treatment does not require lifestyle changes and is a no downtime procedure.

CELLULITE AND FAT

It is believed that the initial changes leading to cellulite formation appear to be deterioration of the dermal matrix and vasculature, particularly loss of the capillary networks, leading to excess fluid retention within the dermal and subcutaneous tissues. This loss of the capillary network is thought to be due to engorged fat cells clumping together and inhibiting venous return.[4] Cellulite is no different from an accumulation of white fat cells found in any other part of the body. Adipose tissue consists of small vesicles or "fat cells" lodged within a matrix of areolar connective tissue. These fat cells are contained in discrete clusters in the areolar of fine connective tissue. Areolar tissue is a form of connective tissue in which the investing connective tissue matrix is separated into areolae (or spaces) which open into one another and are easily permeated by fluids. Areolar tissue binds different parts of the body together. Areolar connective tissue is found beneath the skin in a continuous layer all over the body, connecting the skin (dermis) to subjacent tissues. In many parts of the body, the areolae are occupied by fat cells. The matrix and fat cells constituting adipose tissue are referred to as "depot fat".

In cellulite, fat is stored in fat cells which lie between the skin and muscle tissue. Fat cells are grouped together into large collections which are separated by fibrous strands (fibrous septae). These fibrous strands run between the muscle and the skin and function to hold the fat in place (in small compartments). The skin is tethered down by string-like tissues that pull it inward, toward the interior of the body. As fat cells expand (with weight gain), the gap between the muscle tissue and skin expands. The fibrous strands cannot stretch and can not support the skin. The tension of these septae pulls sections of fat in along with them, causing the fat cells in the subcutaneous layer to increase and stick together within the connective tissue fibers which results in the dimpling (also described as "mattress" or "cottage cheese") (Fig. 5).

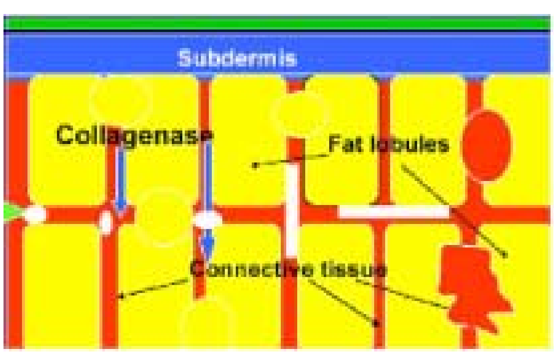

Fig. 5. The subdermal reorganization of cellulite

In vitro and in vivo studies have demonstrated that women (as compared to men) have a diffuse pattern of irregular and discontinuous connective tissue immediately below the dermis. It is believed that decreased integrity of the dermis or an increase in the compression of adipose tissue by radial oriented connective tissue septa could account for the outpouching of subcutaneous adipose tissue into the reticular dermal layer. If the connective tissue separating the dermal and adipose tissue layers is inherently weaker in affected individuals, then adipose tissue would have a tendency to extrude outward into the dermis. [5-7]

The result of the controlled thermal injury may result in tissue shrinkage (molecular contraction) followed by an inflammatory response accompanied by the migration of fibroblasts into the area creating new collagen tissue and a tightening of the skin (cellular contraction). There is also a tightening of the fibrous layer of tissue at the interface between the dermis and the subcutaneous tissue which will also serve to reduce future cellulite symptoms.

ACTION MECHANISM

The Accent provides controlled radiofrequency energy using Unipolar and Bipolar handpieces, for deep (up to 20mm) and superficial (2-4mm) penetration of RF field, respectively. The Accent RF Unipolar handpiece alleviates cellulite symptoms by means of three major mechanisms: (1) Dermal tightening of the fibrous septae due to thermal injury affecting the vasculature, which in turn initiates a cascade of inflammatory events, including fibroblastic proliferation and apparent up-regulation of collagen expression (neocollagenesis/remodeling); (2) Enhancement of local blood circulation (vasodilatation and hyperemia) and drainage of fatty deposits to the lymphatic system; and (3) fatty acid dissolution and thermal-induced fat cell apoptosis. In addition, the Bipolar handpiece promotes local dermal heating and subsequent contraction of the collagen tissue and a tightening of the skin. The deeper RF field of the Unipolar causes tightening of the fibrous layer of tissue at the interface between the dermis and the subcutaneous tissue, thus promoting reduction in cellulite symptoms. Controlled thermal injury may result in tissue shrinkage followed by an inflammatory response accompanied by the migration of fibroblasts into the area. The intentional and directed infiltration of fibroblasts to the thin layer of tissue, including the interface, may be used to reinforce its structural integrity, resulting in amelioration or elimination of the subdermal fat protrusion that causes skin bulging. 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 the dermis-epidermis interface. This newly deposited connective tissue matrix may be used to strengthen the natural fibrous layer between the dermis and subcutaneous tissue.

Adipose tissue is highly sensitive to blood flow. The thermally-induced hyperemia caused by the Unipolar RF field increases blood flow and the release of free fatty acids (FFA) to a local adipose tissue bed and may increase lipolysis stimulating catecholamines available in the local area, thus promoting release of FFA into the bloodstream. Because of the thermal trauma to the fat cells, triglycerides may be released from the fat cells (Fig. 6). These triglycerides are likely broken down into free fatty acids and glycerol by the enzyme lipoprotein lipase (LPL). The free fatty acids (water insoluble) bind to albumin and are slowly transported to the liver. Glycerol (water soluble) is transported to the liver via the interstitial fluid compartments tissue fluids and blood fluid. In addition, it has been shown that adipocyte apoptosis plays an important role in adipose tissue homeostasis and can be altered under a variety of physiological and pathological conditions such as hyperthermia.[8]

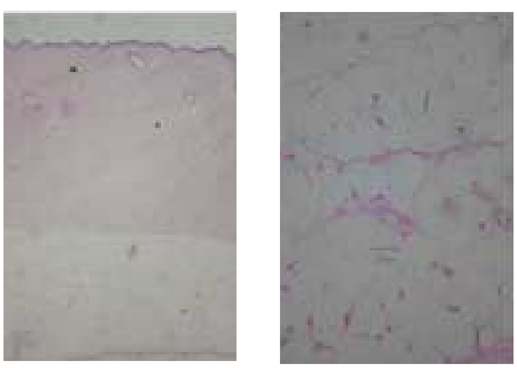

Fig. 6. Subcutaneous fat: thermal damage after Unipolar exposure @ 150 Watts (H & E)

ACCENT CELLULITE TREATMENT

After checking a patient's medical history and contraindications, the practitioner and the patient should discuss the treatment plan, expectations and desired results. The practitioner should screen the patient for skin laxity, skin quality, tone conditions and cellulite severity (Table 1). All jewelry, including necklaces, bracelets, watches, should be removed. High quality pre-and post-treatment photographs are an important step in documenting the degree of efficacy achieved during treatment. Weight (lbs or kg), thigh circumference (inches or cm), and hip-to-waist ratio should be measured using a scale and a tape measure, respectively. The intended treatment area should be marked with grids of ~ 5 x 6 cm (15 seconds exposure time) or 10 x 6 cm (30 seconds exposure time) using a surgical pen. Just before the applicator is applied to the skin, the treatment area should be lubricated with a thin layer of treatment oil to eliminate friction from the movement of the handpiece against the skin. It is advisable to periodically inspect the entire handpiece, especially the tip, to identify any damage or debris. The initial treatment parameters should be set (power - Watts and time of exposure - seconds) according to the recommended parameters. For moist 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.

Table 1. Cellulite Grading [9]

0	No dimpling smooth skin
1	Few number of small, shallow, visible dimples, sparsely located on the thighs
2	Moderate number of visible dimples (some large) on the thighs
3	Large number of visible dimples (many large) over most of the thighs
4.	Cottage cheese appearance of skin

The cooling mode of the Accent system should be set to "ON" by default (touch the applicator head to insure that the cooling is activated). During treatment, the patient should be monitored for heat sensation by employing a scale from 0 (no heat; no pain) to 5 (burning; painful). If discomfort is indicated, the parameters should be modified (reduce energy level by 10%). Before triggering a pulse, the user must assure that the treatment head's output surface is in full contact with the patient's lubricated skin. The practitioner should always apply a rubbing technique by randomly moving the applicator away from the area just exposed. It is good practice to conform to the grid borders. Epidermal temperature should be checked with a laser thermometer immediately before and after each pass. It is recommended to touch and feel the patient's skin following each pass. After reaching therapeutic threshold of ~410C (Up-slope; Phase I), multiple passes (3-5) should be applied on the treatment area (Maintenance; Phase II). In the maintenance phase, the energy level and the time of exposure should be reduced by 10-15%. During Phase I and II, homogenous erythema (hyperemia) should be visible (Fig. 7). Erythema may persist 15-30 minutes post-treatment.

Fig. 7. Endpoints: hyperemia and erythema

The patient may experience a heating sensation or pain (rare) during or just following the treatment; however, such pain should be mild and is expected to be resolved within a few minutes. There is a possibility of side effects which may include persistent erythema which will resolve normally after 24 hours. The post-treatment procedure is enhanced by having the patient rest in the office for 10 minutes. No other post-treatment actions are needed (application of aloe vera ointment is optional). The recommended treatment regimen includes (up to) six treatments spaced at 2 week intervals.

PRECLINICAL AND CLINICAL STUDIES

Ongoing preclinical and clinical studies of the Accent Unipolar and Bipolar handpieces have exhibited a high safety and efficacy profile. In a clinical study (unpublished data) using the Accent Unipolar handpiece, 18 women (ranging in age from 25- 46 years, with a cellulite severity of grade II-IV, and Fitzpatrick skin type II-V) were treated on the buttock-thigh areas twice a week for four consecutive weeks. Before and after images were taken routinely. Patients reported no change in daily activities or dietary habits. No adverse side effects or down time was noted or documented. All patients demonstrated improvement in cellulite symptoms, as seen clinically and through images taken before and after treatment. All patients reported a high satisfaction rate.

Fig. 8. Before *After 1 treatment*

Fig. 9. Before *After 2 Treatments*

Fig. 10. Before *After 3 Treatments*

Photographs courtesy of Emilia del Pino, M.D; Ramon Rosado, M.D; David Freidman, M.D; Amber Brown, M.D; and Guilherme de Almedia, M.D.

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