A Novel Non-Invasive System For Skin Tightening
And Cellulite Reduction Using The Innovative
TriPolar™ RF Technology

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ABSTRACT: Cellulite is one of the most disturbing and challenging skin disorders affecting the lives of more than 80% of women worldwide. Current treatments consist of: Liposuction, deep mechanical massage, applying pharmacological agents, exercise and diet regimens. Any of these treatments can reduce the signs of cellulite and its symptoms to some extent and only temporarily. It is now evident that weakened connective tissue, enlarged fat cells, and diminished micro-circulation, play key roles in the patho-physiology of cellulite. Therefore, long term correction of cellulite is possible through the modification of weakened connective tissue, reducing fat cell size and improve the overall function of micro-circulation.

Regen™, from Pollogen™ Ltd., is an innovative system for the treatment of cellulite and skin tightening using TriPolar™ RF technology. The combined effect of uni-polar RF and bi-polar RF is a unique feature of this technology and provides simultaneous deep and shallow dermal heating/tightening. Treatment results include: reduction in size of fat cell size, enhancement of micro-circulation, enhancement of lymphatic drainage and controlled inflammation. The cosmetic effect is an immediate visible reduction of cellulite and skin tightening.

INTRODUCTION: Wrinkles and cellulite are common aesthetic problems affecting the lives of more than 80% of women worldwide. It might be considered a "cosmetic" matter, but managing the appearance of cellulite or removing wrinkles can go beyond being a simple "cosmetic" problem. Many cultures have an aesthetic "ideal". So for most individuals, having cellulite or sagging skin that exceeds this arbitrary standard can cause real or perceived problems associated with their social acceptance.

It is well established that individuals are able to lose large amounts of weight by gradually reducing the volume of stored fat at the individual fat cell level (by as much as several orders of magnitude i.e. 100 to 1,000 times) by the process of lipolysis. The aesthetic problem for most individuals who achieve modest or even significant degrees of weight loss, is that the adipose tissue volume reduction is often not lost from the specific anatomical sites they desire (e.g. tummy, buttock, thigh), but occurs rather unpredictably from all anatomical areas. Over the past several years, non-invasive professional systems and technologies for body re-shaping become popular modalities for re-contour the body from a desired anatomical area.

Aesthetic non-invasive treatments using controlled radio-frequency energy source have recently become one of the most exciting modalities. Historically, the primary use of RF energy source was for medical problems in the treatment of cancer or oncology. Electro-medical methods and apparatus have been used in the past for various surgical and therapeutic procedures.

Modern RF systems for aesthetic treatments use an RF source in one of the two configurations: Bi-Polar and Uni-Polar. For heating the adipose tissue, a Uni-polar configuration is less beneficial since the electrical current will find the way with less electrical resistance to flow in the body (i.e. blood and lymphatic vessels). In a Bi-polar configuration the depth of penetration under the skin is determined by the distance between electrodes thus for a given system the depth of penetration is constant and can’t be changed for various body areas or different skin conditions. Moreover, most of these systems must use a cooling system in order to prevent epidermal overheating (and potential for burn injury) thus reducing the efficacy of the treatment and achieving moderate aesthetic results.
This article describes a new novel system for treatments of cellulite and skin tightening using TriPolar™ technology for simultaneously heating deep and shallow layers of the skin without the need for active cooling, thus providing one officious system for treatment of different aesthetic problems on all areas of the body.

CELLULITE AND ADIPOSE TISSUE: Recent studies show that the initial changes leading to formation of cellulite is due to the deterioration of the dermal micro-vascular system, leading to excess body fluid retention within the dermal and subcutaneous skin layers. This loss of capillary network in the skin is thought to be due to enlarged fat cells clumping together in the dermis and inhibiting venous return. Fat cells in cellulite are not different from those in the adipose tissue covering the entire body.

Adipose tissue “fat” is created by aggregations of fat cells containing stored fat in the form of single droplets of triacylglycerol. Fat tissue is composed of clusters of fat cells ranging in size from small fat cells to large mature fat cells. Typically they have spherical shape. A single fat cell is 95% fat by volume. The cell nucleus is displaced to one side by the accumulated lipid and the cytoplasm is reduced to a thin rim. Each individual fat cell has large numbers of hormone and other receptors in the cell wall.

Each fat cell is surrounded by delicate reticular fibers. In the angular spaces between the cells are capillaries and nerve supplies that form a loose plexus throughout the tissue. Adipose tissue is subdivided into small lobules by connective tissue septa. This compartmentalization, visible with the naked eye, is most obvious in regions where the fat is subjected to pressure and has a cushioning or shock-absorbing effect. In other regions, the connective tissue septa are thinner and the lobular organization of the tissue is less apparent.

Adipose tissue is distributed in the subcutaneous layer of the skin and exhibits regional differences influenced by genes, age, sex, activity levels and eating habits. Adipose tissue collectively constitutes a large diffuse “organ” that is metabolically very active; it is primarily engaged in the uptake and release of lipid or fat. As a result of release, the caloric content of the lipid stored in the fat can be made available as energy to cells in other parts of the body. At body temperature, the lipid in fat cell is present as liquid oil. It consists of triacylglycerol, each made up of three molecules of fatty acid esterified to glycerol.

Infants and young children have a continuous subcutaneous layer of fat. As the young child grows the fat layer thins out in some regions of the body but persists and grows thicker in certain sites of predilection. These sites differ between sexes and are largely responsible for the characteristic contour differences in male and female body form.

The diversity of human shape or contours seen in differing individual bodily fat accumulations depends on a complex combination of factors such as, age, sex, lifestyle, genetic and hormonal influences.

The process of cellulite formation from the normal skin can be divided schematically into 4 phases:

PHASE ONE: The overlying skin begins to bulge as excess fat is stored in the subcutaneous fat cells.

PHASE TWO: Accumulating fatty deposits compress the circulation to create congestion. As congestion increases, fluid and sugars leak out of the vessels to form complex sugar chains that draw even more fluid out of the vasculature.

PHASE THREE: Fat cells begin to organize within fibrous nets to become fatty lobules. These fatty lobules invade the skin’s dermis to create more skin dimpling.

PHASE FOUR: Cellulite formation is promoted by the proliferation and contraction of fibrous tissue between fatty lobules combined with the continued growth and organization of fatty lobule groups.

BIOCHEMISTRY: Lipolysis is the physiological mechanism by which adipose tissues “mobilize” or release the stored fat to make it available as energy for metabolic activities. Free Fatty Acids
(FFA) are the specific molecular energy substrate of lipolysis, and are used by many body tissues as an alternate energy substrate to glucose. Muscles in particular utilize very large amounts of FFA in a regular fashion. Muscles throughout the body have an enormous capacity to utilize FFA released by the lipolytic process. Research has firmly established that hormones, specifically catecholamines (epinephrine and non-epinephrine), are the principal naturally occurring lipolytic hormones that initiate human lipolytic processes via fat cell adrenergic receptors.

Like any chemical reaction all enzyme-mediated biological reaction rates, including those of adipose tissue (lipolysis), are temperature sensitive. Increasing the temperature of the fat cells by 10°C increases the lipolytic process rate by factor of 2 (i.e. increasing the rate of liquid fat release). Increasing the temperature of fat cells above 43°C results in protein denaturation and irreversible damage to the fat cell. Thus creating the effect of selective heating of fat cells simultaneously in the dermis and subcutaneous fat layer is desirable for cellulite reduction.

SELECTIVE ELECTRO-HEATING USING TriPolar TECHNOLOGY: The wavelengths associated with RF in the frequency range 1-100MHz are considerably longer than the dimensions of parts of the human body. For example, at 1MHz the wavelength in free space is approximately 300m. With a dielectric constant in tissue as high as 100, this would correspond to a wavelength in tissue of 30m. Thus the electric field (E) and magnetic field (B) of the RF wave close to the applicator can be considered to be stationary. For conduction heating the quasi-static B field is the major contributor to the heating process by its associated induced high-frequency current, while in capacitive heating the E field is dominate and the heating process is discussed in terms of displacement current. For selective electro-heating of fat capacitive heating is better than inductive heating due to the large electrical resistance of fat cells (roughly 2000 Ohm-cm for fat, 600 Ohm-cm for skin and 400 Ohm-cm for viscera).

For an idealized model of capacitive heating of the skin, a pair of electrodes are placed on the sides of the ideal sample consisting of the first layer of skin, then a layer of fat, followed by a layer of muscle, a RF power source drives high-frequency electrical current through those layers. The region between the electrodes consists of non-magnetic dielectrics layers. According to Maxwell equations the total current must be continuous at layer boundaries, thus, layers with higher electrical resistance produce more heat than layers with less electrical resistance. For example heat generated per unit volume in the subcutaneous fat layer would be up to 5 times higher than that generated in the dermis.

Fig. 1: TriPolar selective electro-heating: Ex-Vivo verification

A TriPolar applicator connected to a RF source operating at frequency of 1MHz was placed on a piece of pig meat having long slices of fat. The electrical current is traveling between the 3 electrodes and must pass the fat layer in between. Since fat has much more electrical resistance, it heats up much more and noticeable fat burn is seen while the surrounding tissue is intact.

SYSTEM OVERVIEW: The Regen system has 2 applicators: one for large area treatment such as the tummy, buttocks and thighs and one for small area treatment such as face, neck and arms. Both applicators are using TriPolar technology (patent pending) for administration of RF power under the skin. Regen is the only aesthetic medical system operating in a TriPolar mode for treatment of cellulite, sub-dermal fat reduction and skin tightening.
After rubbing the skin with neutral massage oil the applicator are used in a continuous sweeping movement on the skin for simultaneously heating the subcutaneous fat layer and fat cells in the dermis. The applied RF power is up to 16J/cm³ in the frequency range of 1MHz.

**REGEN CLINICAL PROTOCOL:** On going clinical studies of the Regen have demonstrated high safety and efficacy. Most of the patients see immediate visible results after the first treatment session. Proper clinical protocols were followed during treatment as set out in the Regen user manual.

**REGEN TREATMENT:**
Treatment with the Regen system is simple and straight-forward… Treatment begins with clean, dry skin and then lubrication of the treatment area with natural massage oil. Maneuver the client into a comfortable position for treatment. Then set the appropriate treatment parameters for the specified treatment area. Position applicator on the client’s skin and begin.

The applicator should be applied with a small amount of pressure and a rubbing/massaging technique (linear, circular, figure 8, e.t., depending on the area). Throughout treatment, heat sensation is monitored verbally & regularly. In addition, a physical check of the client’s skin temperature should be done periodically throughout treatment by touching and feeling skin with fingers. Three quarters of the way through the treatment to completion, the skin should become a dark rosy color and be warm to the touch.

Shortly after commencing treatment, a noticeable tightening of the skin can be seen. Visible results can be seen upon completion of the treatment. Wherein, these results are recorded via post-treatment pictures of the area treated.

**TREATMENT REGIMEN:** Treatments shall be applied once a week for a period of time of 6-8 weeks.