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**AN EX VIVO STUDY OF THE REGEN™ TRIPOLLAR
RF DEVICE USING AN EXPERIMENTAL HUMAN
SKIN MODEL**

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Abstract:

The aim of this ex vivo study was to test the anti-cellulite and skin tightening effects of a TriPollar radiofrequency technology (regen™) on ex-vivo human skin samples harvested from abdominoplasty surgery and maintained in survival conditions. Single treatment at 25 Watts was applied.

Radiofrequency selectively heats fat cells to increase metabolism and secretion of liquid fat. A significant increase of glycerol released by the skin was found, indicating lipolysis. Additional findings included vasoconstriction of the capillaries and improvement of collagen fibers which leads to tightening of the skin.

Introduction:

Cellulite is linked to a particular configuration of the female adipose tissue. Histologically, cellulite corresponds to a modification of the subcutaneous (hypodermic) connective tissue with adipocitary hyperplasia constituted of adipose tissue rich in adipocytes, vasodilatation with venous or lymphatic stasis and exudative phenomena. The accumulation of adipose tissue takes place inside the adipocytes starting with triglycerides and sugars. Inside the adipocytes, the lipolytic function translates into triglyceride hydrolysis by the triglyceride lipase; the released glycerol will reflect the intensity of the lipolysis.

regen™, with TriPollar™ technology by Pollogen™ Ltd, is an innovative system to treat cellulite and tighten the skin. The combined effect of multiple, modulated, bipolar radio frequencies is a unique feature of this technology, resulting in simultaneous superficial and deep dermal heating. The anti-cellulite and skin tightening effects of the regen™ TriPollar™ device is the result of three separate mechanisms induced by the treatment- lipolysis, drainage and collagenesis.

We evaluated these effects using an ex-vivo human skin model. Eight human skin samples were obtained during abdominoplasty surgery. Each skin sample was placed on a porous membrane and positioned in a culture well which was kept in a sterilizer at 37°C. The culture medium, provided by GREDECO research, was placed at the bottom of the well.

A single treatment session was performed on the skin samples with the regen™ TriPollar device using the regular clinical protocol (skin temperature control, 10 minutes at 25 Watts). A group of samples was used as a control.

Treatment efficacy determination was based on analyzing three separate histological mechanisms:

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- a. Analysis of lipolysis by glycerol dosage
- b. Analysis of the draining effect by quantification of the percentage of dilated blood vessels and capillary lumen area. This was performed using a capillary dilatation model by means of a neuromediator: substance P.
- c. Anti-aging effect: A biochemical dosage of collagen synthesis and a morphometric quantification of collagen bundles were performed using a skin aging model by UV A and B.

Treatment safety was evaluated by estimating skin tolerance through analysis of epithelial skin cells viability and evaluation of mitochondrial dehydrogenases.

Results:

A) EVALUATION OF THE LIPOLYTIC EFFECT.

We observed a statistically significant increase in skin lipolysis following a single treatment session with the regen™ TriPollar device. Glycerol level increased to 2068nM/g hypodermal versus 514 for untreated skin ($p = 0.007$).

The histological aspect of adipocytes in the hypodermis after the treatment demonstrated modifications in the shape (inhomogeneity: elongated, irregular) of the membrane (withered aspect, sometimes with the partial rupture of the cell wall).

The histological analysis also allowed verification of the absence of tissue necrosis or carbonization of the hypodermis after treatment.

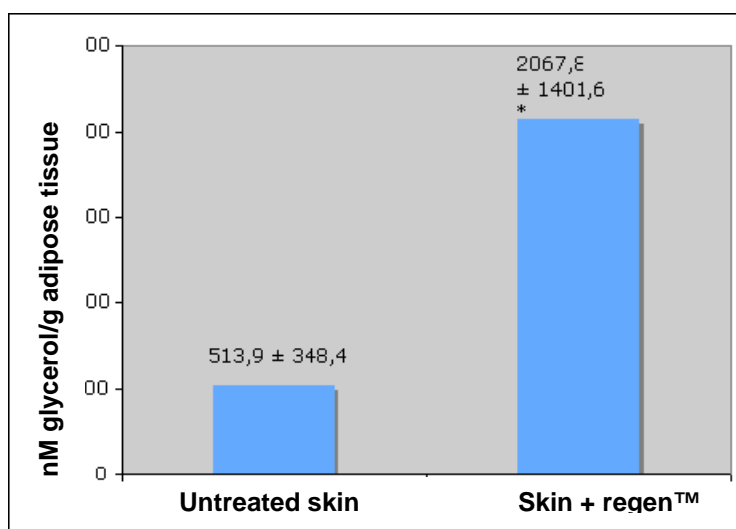


Figure 1: Glycerol dosage from total skin including hypodermis (nM/g of adipose tissue)

B) EVALUATION OF THE DRAINAGE EFFECT

After one session with the regen™ TriPollar device, a draining effect was observed with a statistically significant reduction in the percentage of dilated capillaries of 66.9% ($p=0.0056$) vs. 84.3% for control skin stimulated by substance P. In addition, a statistically significant reduction of the surface area occupied by the blood vessels is observed, $108.2\mu\text{m}^2$ vs. $183.8\mu\text{m}^2$ for control skin ($p=0.0095$).

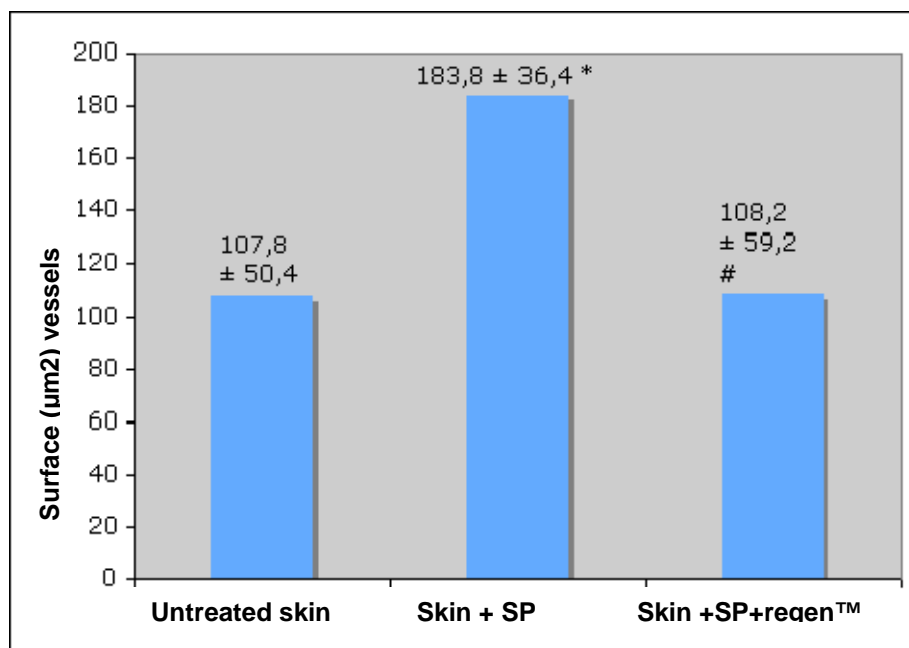


Figure 2: Morphometric analysis of the surface occupied by capillary lumen (μm^2)

C) EVALUATION OF THE COLLAGENESIS EFFECT

After treatment with the regen™ TriPollar device, a statistically significant collagen repair was observed in 76.7% of the superficial dermis vs. 67.6% for control skin ($p=0.02$), and in 78.5% of the mid dermis vs. 71.3% for control skin ($p=0.024$).

Treatment with the regen™ TriPollar leads to increase in collagen synthesis with a level of 49.5 $\mu\text{g}/\text{mg}$ in treated skin vs. 38.4 for control skin.

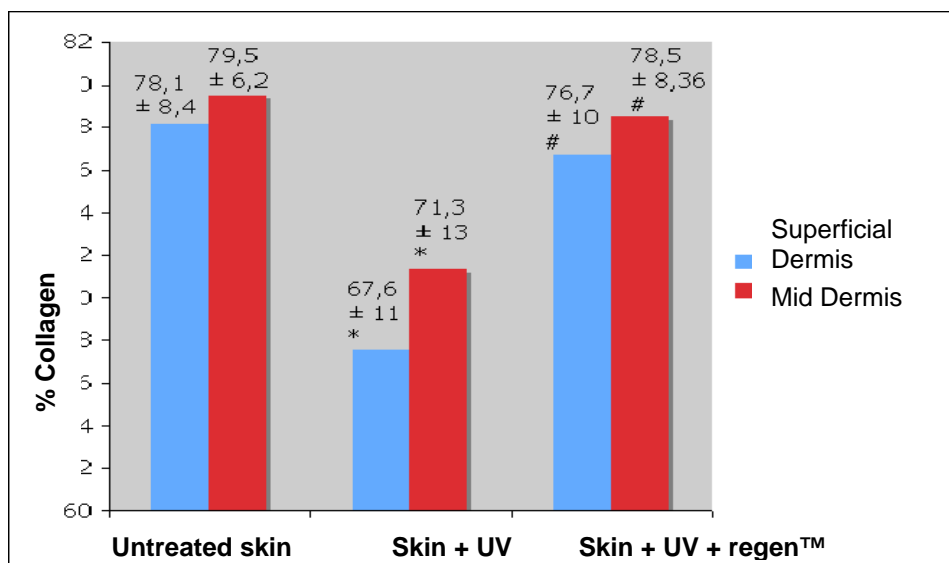


Figure 3: Histological collagen analysis (surface percentage inside the dermis)

D) EVALUATION OF SKIN TOLERANCE

Skin tolerance was excellent after treatment with the regen™ TriPollar device, with a viability rate in treated skin of 96.2% vs. 100% for control skin.

Conclusions

We observed lipolytic activity in our ex-vivo human skin model by means of the regen™ TriPollar device and measured a statistically significant increase in the amount of glycerol released by adipose tissue.

The drainage activity of the regen™ TriPollar device was also observed in our experimental model of vascular dilatation by neuromediators on ex-vivo human skin, demonstrating statistically significant vasoconstriction of the dermal capillaries.

Collagenesis was observed following treatment with the regen™ TriPollar device with a statistically significant repair of altered collagen in skin that was experimentally aged using UV radiation, with a tendency towards increasing collagen synthesis.

Skin tolerance was excellent after treatment with the regen™ TriPollar Radio Frequency device, with cell viability in the epidermis close to that of control skin.

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