
TriPollar™ RF Non-Surgical Face Lift & Skin Tightening – Long Term Results

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ABSTRACT:

Background *It has been well established that TriPollar RF treatments depict immediate visible results. The question of long term collagen remodeling and maintaining the clinical results have been addressed in this study by way of thorough analysis.*

Objective *This study aims to determine the long term clinical efficacy and safety of the non-ablative regen™ system, employing TriPollar RF technology, in the treatment of skin tightening and circumference reduction of facial, neck and abdominal skin.*

Method *Subjects enrolled in the study were healthy female patients between the ages of 18-65 with lax and excess fatty facial, neck and abdominal skin were recruited for the study. Using the regen™ system, the subjects (patients) underwent a regimen of 8 TriPollar RF treatments at weekly intervals. Throughout the study, before and after each treatment, the patient's progress was photographically documented. Treatments continued until a full treatment course was concluded and expectations were met. These results were evaluated during a final clinical assessment 6 months after the last treatment, which included patient self-assessment as well.*

Results *Immediate visible results were noticed from the first treatment. The patient's results, observed gradually over the full course of treatment, revealed a significant circumference reduction and observable lifting of sagging skin. Further, these clinical results improved 6 months after last treatment due to collagen remodeling. The patient's self-assessment after the full course of the treatment was "excellent". No adverse side effects during or after any of the treatments. Further, throughout the study none of the patients experienced any need for downtime following any of the treatments.*

Conclusions *This clinical study concluded a very good overall improvement in skin laxity and circumference reduction with absolutely no downtime for any patients. The TriPollar RF treatments are safe and effective for non-surgical face lifting, skin tightening and circumference reduction on all skin types. Long term results are excellent.*

INTRODUCTION

Sagging skin in abdominal area after pregnancy or weight loss is a severe cosmetic problem as well as laxity of facial skin of patients as they age. Although dramatic clinical improvement can be achieved in facial areas with surgical lifting procedures, the treatment of lax skin in the abdomen is much more complicated.

Ablative laser skin resurfacing is a well-accepted treatment modality for facial rejuvenation because of its ability to improve, as expected, the appearance of photo-induced wrinkles. However, patients may be hesitant to pursue this treatment option because of the extended post-operative recovery period and the inherent risks of the procedure, as well as the limitation of patients able to achieve good results due to skin type.

Therefore, the development of a truly non-invasive, skin color independent, deep tissue tightening on sagging facial and abdominal skin continues to interest cosmetic surgeons and the public alike.

Recently, a novel system (regen™ powered by TriPollar™ RF technology, manufactured by Pollogen™ Ltd.) was developed to deliver the effects of Radio Frequency (RF) energies in a non-ablative treatment for all skin types. This unique system which employs a 3rd generation RF technology is based entirely on a different method than previous generation RF systems, heating simultaneously superficial and deep skin layers by delivering very focused RF current into the skin.

RF energy for medical procedures has been used for many years. When applied to tissues between two electrodes the RF current generates heat through resistance of the dermis and subcutaneous tissue. This source of heat has been extensively used in surgery for

hemostasis and tissue ablation (electro-surgery), but more recently it has been applied as a means of shrinking redundant or lax connective tissues through the mechanism of collagen denaturation. Collagen molecules are produced by fibroblasts which synthesize three polypeptide chains that wrap around one another in a triple helix. The phenomenon of thermal shrinkage of collagen begins with denaturation of the triple helix of the collagen molecule. When collagen is heated, the heat-labile intra-molecular cross-links are broken, and the protein undergoes a transition from a highly organized crystalline structure to a random, gel-like state (denaturation). Collagen shrinkage occurs through the cumulative effect of the “unwinding” of the triple helix, due to the destruction of the heat-labile intra-molecular cross-links, and the residual tension of the heat-stable intermolecular cross-links (Ref 1). Heated fibroblasts are also implicated in new collagen formation and subsequent tissue remodeling which can also contribute to the final cosmetic result. The precise heat-induced behavior of connective tissues and the extent of tissue shrinkage are dependent on several factors which includes the maximum temperature reached, exposure time, tissue hydration and tissue age.

RF energy can be applied to tissue between two points on the tip of a probe (bi-polar – 2nd generation RF technology) or between a single electrode tip and a grounding plate (mono-polar – 1st generation RF technology). Less electrical current is required with a bi-polar device than with a mono-polar device to achieve the same effect, because the current passes through a much smaller volume of tissue. With a mono-polar RF device the penetration depth can be estimated as half the electrode size while for a bi-polar RF device the penetration depth of electrical current can be estimated as half the distance between the electrodes (Ref 2).

The regen™ system is a RF device which uses a multiple-electrode, TriPollar™ configuration (see Fig 1). The TriPollar™ design, a 3rd generation RF technology, is based on 3 or more electrodes to deliver the focused RF current into the skin tissue (see Fig. 2).

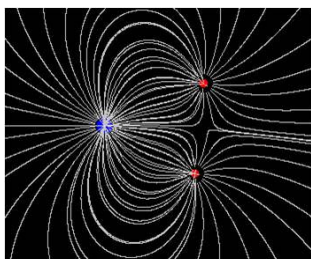


Fig. 1: TriPollar 3 electrode configuration.

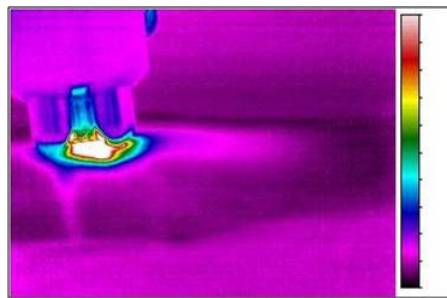


Fig. 2: An infrared picture demonstrating the application of TriPollar energy onto a piece of pork skin shows that the generated heat is focused between the three electrodes.

The depth of heat penetration is approximately the average distance between the 3 electrodes and simultaneously heats the dermal and subcutaneous layers (see Fig. 3).

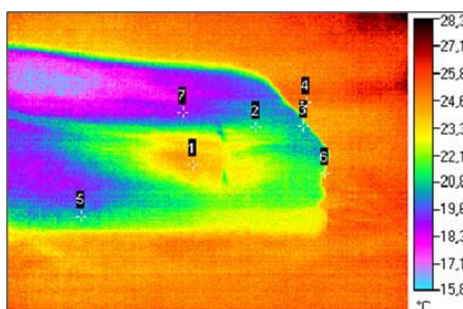


Fig. 3: An infrared picture demonstrating the application of the TriPollar energy penetrating the pork skin shows heating of superficial and subcutaneous skin layers down to a depth of approximately 20mm.

Due to its design, no active cooling of the electrodes or the skin is required. The regen™ system delivers RF energy at a frequency of 1 MHz and a maximum power of 30 Watts. Two applicators are available for body and face treatments (see Fig. 4 & 5).



Fig. 4: TriPollar applicator for facial treatments.



Fig. 5: TriPollar applicator for body treatments.

The system is indicated for the treatment of skin laxity, improvement of skin texture, treatment of cellulite, body contouring and localized fat reduction with immediate visible results on all skin types without pain.

MATERIALS AND METHODS

The safety and efficacy of the regen™ system, based on TriPollar RF technology, for treatment of skin laxity was evaluated at the D'estetica Aesthetic and Plastic Surgery Clinic in Bursa, Turkey.

All patients underwent 8 weekly treatment sessions and results were evaluated both quantitatively by measuring circumference and qualitatively through photography and patient satisfaction questionnaire. Healthy female patients between the ages of 18-65 were enrolled in the study. Exclusion criteria includes; pregnancy, any implantable electronic device that could be disrupted by RF energy and any active dermatological or collagen-vascular disorder. Patients completed a medical history form and signed an informed consent form prior to commencement of study.

Prior to treatment all jewelry; necklaces, bracelets, watches, rings, etc. must be removed. The treatment area is then cleaned with soap and water and dried completely. Pretreatment photographs are taken and circumferences at specific reference points are measured. The treatment area is then lubricated with oil. The TriPollar™ applicator suitable for the treatment area is then positioned on the skin and the Foot Switch is pressed to begin treatment. During treatment the applicator is applied with slight pressure and maneuvered in linear or circular massaging movements, depending on the area. Real-time treatment effects are monitored by both the patient and operator. The operator constantly monitors skin tightness, warmth and erythema, while periodically measuring skin temperature using a non-contact IR thermometer. Shortly after commencing treatment there will be a noticeable tightening of the skin. Additionally, approximately three quarters of the way through the treatment, erythema should be visible and the skin should be warm to the touch. Measured skin temperature should not exceed 42°C.

LONG TERM TYPICAL RESULTS

42 patients between nineteen and fifty four years old underwent TriPollar™ body and facial

treatments. All patients achieved excellent clinical results without adverse side effects.

Abdomen Treatment: A 33 years old women, 10 months after pregnancy, with lax skin in the abdomen area underwent 8 TriPollar™ treatment sessions on a weekly basis for the reduction of circumference and skin tightening (see Figs. 6-7). With each treatment session there was a gradual decrease in lax skin. Since the initial condition was very severe, this patient had an additional 8 treatments [on a weekly basis] after a one month interval following the preliminary treatment course. The patient's self-assessment of the results was graded "excellent". The only side effect noted was erythema which resolved 1-2 hours after each treatment.



Fig 6: Before TriPollar treatment.



Fig 7: 6 months after TriPollar treatment.

Face Treatment: A 34 years old woman with lax skin, double chin and mild fat in the neck area underwent 8 TriPollar™ treatment sessions on her face, chin and neck for skin tightening and wrinkle removal (see Fig. 8-9). No side effects apart from transient erythema were noted.



Fig 8: Before TriPollar treatment.



Fig 9: 6 months after TriPollar treatments.

shown to be maintained for the long term in addition to immediate visible results.

REFERENCES

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SUMMARY

The regen TriPollar™ device is a multi-polar RF system which can safely and effectively be used for skin tightening and circumference reduction on all skin types, particularly on the body and facial areas, as well as for the treatment of cellulite, reduction of localized fat, skin laxity and facial wrinkles. Application of this treatment modality is simple, non-invasive and extremely safe on all skin types. Qualitative as well as quantitative results have been documented and the outcome that transpired from this study were

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