

Muscle stimulation for the face, a paradigm shift in facial rejuvenation

Abstract

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Background: Facial aging is a dynamic and complex process resulting from extrinsic and intrinsic factors. All layers of the facial anatomy are affected due to interrelated changes to skin, fat, muscle and bone. Despite a similar facial aging sequence, the rate of change of facial characteristics and its extent differs among individuals. In order to tailor the treatment, has a special protocol was developed targeting each tissue layer with the appropriate technology to stimulate a complete rejuvenation process.

Methods: A 3 step protocol was developed by using: First Dynamic Muscle Stimulation (DMSt) that delivers an electrical current to activate skeletal muscles and facilitate contraction. Second, TriPollar® radiofrequency (RF) produces volumetric heating of dermal and subcutaneous tissues. Third, triFX™ radiofrequency microneedles (RFMN) uses an array of microneedles that penetrate the skin and heat the deep dermis, creating zones of invisible thermal micro-wounds between areas of unaffected normal healthy skin.

This sequential treatment is repeated at weekly intervals for 4-6 treatment sessions. The triFX step is repeated every two weeks.

Results: The DMSt was previously used in a clinical study and an increase of zygomatic muscle thickness was reported. DMSt increases facial muscle tones which support the dermal structures. TriPollar® RF have shown effectiveness in improving facial skin tightness and wrinkles. Combining the two technologies (DMSt with TriPollar RF) in a sequential method was beneficial for numerous indications showing an enhanced result when combined than when each modality was evaluated alone. Adding the triFX into the treatment protocol can enhance new collagen deposition and tissue remodeling resulting in an increase of the epidermal layer volume and smoother skin texture, as shown by numerous clinical evaluations. The effects of combining all 3 technologies in a single treatment lasts for approximately 3-6 months, and may be maintained with additional session thereafter.

Conclusions: The triLift protocol provides rejuvenation treatment for all facial layers in the same treatment session, simulating a facelift without a surgical intervention and with minimal adverse effects and downtime.

Facial muscles and aging

Facial aging is a dynamic and complex process involving all layers of the facial anatomy due to interrelated changes to skin, fat, muscle and bone. It is caused by the intricate interplay of both extrinsic and intrinsic factors. Extrinsic skin aging is caused by long-term exposure to ultraviolet radiation wind, pollution, repetitive muscle movements, and various lifestyle habits such as smoking, sleep, diet and poor general health. These lead to upper dermis elastosis, destruction of its fibrillar structure, increased intercellular substance and moderate inflammatory infiltrate.^{1,2} As a result, the support and volume of dermal structures are decreased, leading to reduced skin torsion extensibility and causing wrinkling of

the overlying epidermis.³ Key intrinsic factors include gravitational effects secondary to decreased skin elasticity, volume loss in facial fat compartments, and bony and soft-tissue re-modeling through genetic and hormonal influences. In addition, repetitive mimetic muscle contractions create prolonged cutaneous changes that evolve to static and dynamic wrinkles and folds. Age-related volume loss influences muscle tone and consequently impacts bone re-modeling.⁴

Despite a similar facial aging sequence, the rate of change of facial characteristics and its extent differs among individuals.^{5,6} Rates of bone remodeling, photodamage, wrinkle development, and soft tissue redistribution varies between races and ethnicities,

and people with skin of color may have distinct pigmentation concerns. However, age-related changes in skin texture, pigment, and bone structure affect all populations.⁷

The triLift protocol is a sequenced treatment protocol using the triLift platform that targets each skin layer with the appropriate technology and energy to stimulate a rejuvenation process of that layer's cells. Specifically, dynamic in-motion electrical muscle stimulation (DMSt) is used for toning facial muscles, third generation TriPollar[®] radiofrequency (RF) is used for thickening and strengthening the dermal layer and triFX[™] radiofrequency microneedles (RFMN) are used for increasing the epidermal layer's natural volume and smoothing its texture.

Each of the technologies is discussed below together with evidence for its effectiveness and safety.



Figure 1: triLift Platform by Lumenis Be

Dynamic in-motion electric muscle stimulation (DMSt)

The triLift protocol uses dynamic in-motion electrical muscle stimulation (DMSt) to tone facial muscles. DMSt, also termed elsewhere electrical muscle stimulation (EMS), dynamic muscle activation, neuromuscular electrical stimulation, or electromyostimulation, uses an electrical current to activate skeletal muscles and facilitate contraction. The impulses generated by the device are delivered through electrodes on the skin near the muscles being stimulated. To avoid charge accumulation, which may damage the tissue, EMS devices typically deliver a pulsed biphasic current. EMS recruits muscle motor

units in a nonselective, spatially fixed, and temporally synchronous pattern, such that both slow and fast fibers are non-selectively activated at low or high force levels. Such nonselective recruitment means that all fibers, regardless of type, have the potential to be activated at relatively low intensities.⁸

EMS is commonly used in clinical settings to mimic voluntary contractions and enhance the rehabilitation of human skeletal muscles. For example, it has been shown to increase muscle strength of the quadriceps femoris and abdominal muscular strength in healthy individuals and as a post-exercise recovery tool for athletes.⁹⁻¹¹ It has also been used as a rehabilitation and preventive tool for partially or totally immobilized patients with muscle atrophy.¹²⁻¹⁶

This technology has also been used to stimulate facial muscles and to restore muscle contour, strengthening the skin's support.¹⁷ It was examined for the treatment of facial paralysis^{18,19} and Bell's palsy.²⁰ The effect of EMS technology on facial muscle tone and signs of facial aging in healthy women was evaluated in a randomized, controlled, partially blinded study. One-hundred and eight women (mean age 43.7 years, range 32-58 years) were randomized to 12 weeks of treatment with a neuromuscular electrical stimulation facial device (20 min/day, 5 days/week) or to a nonintervention control group. Participants could not alter fitness, diet or facial care routines during the study. Assessments included psychometric evaluations of facial appearance and assessor-blinded ultrasound measurements of the thickness of the zygomatic major muscle. In the neuromuscular electrical stimulation group mean zygomatic muscle thickness increased by 18.6% from baseline but not the control group. Between-group differences were significant at 6 and 12 weeks ($p=0.05$ and $p=0.0001$, respectively). In an overall evaluation, $\geq 80\%$ of neuromuscular electrical stimulation users reported improved firmness, tone and lift compared to $<5\%$ of the control group ($P<0.001$). As expected with transcutaneous electrical stimulation, transient mild erythema at the site of the electrodes occurred in all users, which resolved shortly after the end of each session. The only other adverse event was persistent fluttering of one participant's eyelid after one session, which did not recur.²¹ It was suggested that the exercise-induced increase in the zygomatic major muscle size may be linked to the shortening of the resting length of the muscle, resulting in improvements in facial tone, firmness and lift.²²

TriPollar® RF

Third-generation TriPollar® RF is used to thicken and strengthen the dermal layer. TriPollar® RF, comprises three or more electrodes that deliver radiofrequency energy into the skin at a frequency of 1 MHz and a maximum power of 50 W. This component produces volumetric heating of dermal and subcutaneous tissues through rapidly oscillating electromagnetic fields that cause movement of charged particles within the dermis and generation of heat that is proportional to the tissue's electrical resistance.²³

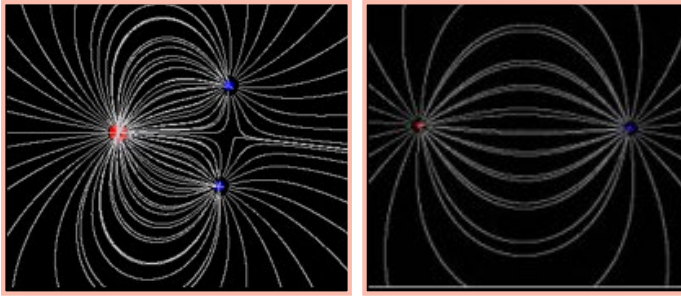


Figure 2:
Electrical field density simulation of TriPollar (left)
vs. Bipolar (right)

TriPollar® RF-based systems have shown effectiveness in improving facial skin tightness and wrinkles.²³⁻²⁶ The biological mechanism involved in skin tightening using TriPollar® RF technology included stimulation of dermal fibroblasts with increased collagen synthesis, an increase of 49% in dermal thickness, and focal thickening of collagen fibers.^{23,27} In a study that evaluated the improvement in facial wrinkles and rhytids in 37 women (mean age, 52.8 years) that received 8 weekly treatments with TriPollar® RF, improvement was observed in 94%-97% of study participants.²⁶ Levenberg reported an improvement of perioral and periorbital wrinkles in 9 women treated with RF TriPollar® technology.²⁵

In all of the studies, treatment was reported to be painless or involved minimal pain. Post-treatment transient mild-moderate erythema and/or slight edema were reported in some of the studies.²³⁻²⁶

In several studies EMS technology and TriPollar® RF were combined. In a study that included 20 women (mean age 43 years) that were treated for facial wrinkles with TriPollar® and EMS technology once a

week for 8 weeks, significant improvements in skin tonus, skin lift effect and facial skin color homogeneity were noted as well as reduced sharpness of mimic and static wrinkles. Ultrasound assessment of the skin showed significant dermal-epidermal thickening and increased dermal density.²⁴

Levenberg et al. showed that subjects who underwent facial treatments using two TriFractional treatments spaced one month apart, with two TriPollar® RF + EMS technology two weeks after each TriFractional treatment, improved acne scars, skin texture and wrinkles together with facial contouring.²⁸ In another study Eleven subjects (mean age, 43 years; Fitzpatrick skin type II-IV) with Fitzpatrick Elastosis Scale (FES) score 3-6 were treated with TriPollar® RF and EMS technology once a week for 6 weeks. At 1 and 3 months of follow-up, mean physician-rated FES statistically significantly improved from baseline by 2.27 ± 0.45 for both time points ($P < 0.0001$). At 3 months of follow-up, fine lines, wrinkles and skin tightness were improved in 81.8% of patients and were much improved in 18.2%. Pain was minimal and there was no downtime or adverse events.¹⁷

triFX Radio Frequency Microneedling

triFX™ RFMN technology uses an array of microneedles that penetrate the skin and heat the deep dermis, creating zones of invisible thermal micro-wounds between areas of unaffected normal healthy skin. The thermal effects of RF can change the shape, the length and the diameter of the collagen fibers,²⁹ cause contraction of the connective tissue,³⁰⁻³² and tissue repair response. Repeated thermal wound healing stimulates fibroblasts to enhance new collagen deposition and remodeling, resulting in further collagen tightening and an overall increase in collagen content. As debris are removed and cellular and fiber regeneration take place, a gradual increase in skin quality is observed. Assessment of changes in tissue, cells, thickness and structure of pigskin after RF application demonstrated an expanded papillary dermis due to edema and vascular congestion, followed by an accumulation of intercellular substance. Two months after the last application, an increase in the amount of collagen, elastic fibers and mucopolysaccharides was noted.^{33,34}

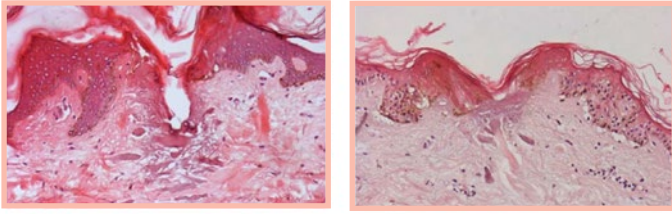


Figure 3: Ex-vivo UV aged skin histology samples at D0 (Left) and D2 in survival medium (Right). (H&E stain, magnification: x200 Left, x100 Right). Left- immediately after treatment with triFX at Low level. Micro ablation effect is visible into upper dermal layer. Right- After 2 days in survival medium. Healing process including collagen regeneration and epithelialization is demonstrated.

This technology has demonstrated effectiveness when used for treating skin resurfacing, reducing wrinkles and enhancing skin and facial appearance.³⁵ In a study that evaluated the change in skin texture and wrinkles of 12 subjects (mean age 45.5, Fitzpatrick skin types II-III) with FES score 3-6 who were treated with 3 sessions of triFX RF technology using 100 microneedles at 3-week intervals, all subjects had improved skin texture and pigmentation and in most of them (91.7%) skin brightness, tightness, and wrinkles also improved. physician-rated FES showed statistically significant improvement of 2.67 ± 1.18 and 2.33 ± 1.03 , respectively ($P < 0.0001$) from baseline to 1 and 3 months of follow-up. The treatments were well tolerated, with no downtime or adverse events.³⁶

triLift protocol

Step 1: Apply a thin layer of 87% pure medical grade glycerin. Use Applicator #2 (medium applicator) in Lift Mode to pass over the zygomaticus major and minor and the masseter for 8 minutes on each side, adjusting parameters to reach 40°C, and to visually see a contraction of these muscles.

Step 2: Use Applicator #3 (small applicator) in **TriPollar® RF** mode at 39°C to pass over the perioral and periorbital regions for up to 10 minutes each side of the face.

Step 3: Clean the area well with warm water to remove all glycerin. Thoroughly dry the skin, stretching it so as not to miss skin folds. Attach a new triFX tip (depending on the subject's condition use one of the five available triFX disposable tips). Start with low presets and increase the exposure and power each treatment session.

Perform 4-6 treatment sessions at weekly intervals. The triFX step (step 3) should be done every two weeks (i.e., at weeks 1, 3 and 6). Maintenance sessions and follow-up should be performed 3-6 months after the last treatment session, depending on the individual's baseline condition.

Conclusion

The clinical data summarized above shows that each of the triLift protocol components targets a specific facial layer: DMSt increases facial muscle tones which support the dermal structures, TriPollar® RF thickens and strengthens the dermal layer, and triFX increases the epidermal layer's natural volume and smoothes its texture. Therefore, altogether the triLift protocol provides rejuvenation treatment for all facial layers in the same treatment session, simulating a facelift without a surgical intervention and with minimal adverse effects and downtime. The effects last for approximately 3-6 months, and may be maintained with additional session thereafter.

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