
DIVINE PRO

THE ULTIMATE
PLATFORM FOR
**COMPLETE SKIN
REJUVENATION**

***Alex Levenberg¹, M.D., Amikam Gershonowitz, D.V.M²,
Gali Elkin - Basudo. BSc²***

¹Physicians Center, Plastic Surgery Dept., Tel Aviv, Israel

²Pollogen Ltd., Tel Aviv, Israel

INTRODUCTION

As the population ages, common skin disorders demand greater attention. As the largest and most exposed organ of the body, the skin shows obvious and visible signs of aging. Induced by both intrinsic and extrinsic factors. Intrinsic aging is an inevitable physiological process that results in thin, dry skin, fine wrinkles, and gradual dermal atrophy, while extrinsic aging is engendered by external environmental factors such as air pollution, smoking, poor nutrition, and sun exposure, resulting in coarse wrinkles, loss of elasticity, laxity, and rough textured appearance. Long-term exposure to ultraviolet irradiation from sunlight causes premature skin aging (photoaging), characterized in part by wrinkles, altered pigmentation, and loss of skin tone.



The demand for facial rejuvenation treatments, particularly for non-invasive, non-surgical, effective, low-risk treatments with minimal pain and downtime increased in the past years. Non-invasive and minimally-invasive methods have reached an ever-growing dimension with increasing demand due to the introduction of various devices and products to the market. Multiple energy-based technologies including laser, high-intensity focused ultrasound (HIFU) and radiofrequency (RF) have evolved to meet this rising demand. RF technology, which has steadily gained popularity, achieves skin tightening by heating the dermis, and triggering a healing cascade leading to new Collagen and Elastin formation (1-4).

With understanding the needs for minimally-invasive and minimal downtime, Pollogen's Divine PRO, a multi-technology platform developed and designed to provide versatile treatment combinations, enabling practitioners to meet patients' wide range of needs with four revolutionary technologies: TriFractional, VoluDerm, TriPollar RF and DMA (Dynamic Muscle Activation); achieving smoother, tighter skin, improved facial contouring and a refreshed complexion.

TRIFRACTIONAL TECHNOLOGY

Radiofrequency (RF) skin resurfacing and pin-point ablation of the epidermal layer, inducing the natural wound healing process for skin remodeling and texture improvement.

Fractional skin resurfacing removes pin-point layers of the skin and allows the renewal and formation of healthier and better-looking skin. TriFractional technology is intended for epidermal and upper dermal remodeling which encourages production of Collagen and Elastin for a firmer a tighter skin. The smart tip design enables uniform distribution of the energy, allowing safe and effective treatment with minimal downtime and pain.



H7X7 tip

VOLUDERM TECHNOLOGY

The unique RF-assisted thermal penetration technology, using ultra-thin electrodes, allows a safe and smooth penetration of the stratum corneum, followed by a therapeutic pulse that creates micro-channels to induce controlled micro wounds, thus encouraging the generation of new collagen, elastin and hyaluronic acid.

The tip consists of a high-density array of ultra-thin electrodes (150µ) inserted uniformly and smoothly into the skin through an RF-assisted penetration-pulse mode.

The smart tip design enables uniform distribution of RF energy reducing pain and downtime.



gen100 tip

gen12

gen36

genL36

TRIPOLLAR RF TECHNOLOGY

TriPollar RF technology is an innovative, proprietary 3rd generation technology, which encourages the renewal of the skin from within. The Tripollar optimal and volumetric heating mechanism is directed at the Dermis to stimulate fibroblasts to produce collagen and elastin, while leaving the Epidermis at a comfortable temperature allowing painless and pleasant treatment. The focused Tripollar RF is clinically and histopathologically proven technology, encourages the production of collagen and elastin, resulting in tighter and smoother skin, without pain or downtime.

DMA (DYNAMIC MUSCLE ACTIVATION) TECHNOLOGY

The superficial musculo-aponeurotic system (SMAS) is a continuous, organized fibrous network connecting the facial muscles with the dermis. Due to aging, SMAS becomes less elastic, weakening the skins' support frame. Therefore, treatment of aging skin should also involve stimulation of the SMAS.

DMA is a unique and proprietary technology, applied by transcutaneous electrical muscle stimulation that causes internal muscle contraction to tone and firm the appearance of the skin.



UNIQUE AND POWERFUL SIMULTANEOUS ACTIVITY

The novel treatment of non-invasive TriPollar® RF energy combined with Dynamic Muscle Activation (DMA™) targets several layers of tissue and muscle for the treatment of wrinkles and laxity. The DMA can work separately or simultaneously with Tripollar RF during the same treatment.

The combination of the four technologies; Voluderm, TriFractional, Tripollar RF and DMA which work on three skin layers; Epidermis, Dermis and the muscle (SMAS), provides each patient with a specific and tailored treatment with best possible outcome and three dimensional skin rejuvenation.

SUPPORTING EVIDENCE

A clinical evaluation of skin texture improvement and wrinkle reduction using Fractional RF resurfacing with TriFractional H7x7 tip (Pollogen, 2019)

A recent clinical evaluation of the TriFractional H7x7 tip (Pollogen, 2019) for skin texture improvement and wrinkle reduction provide evidence of the safety and efficacy of the treatment.

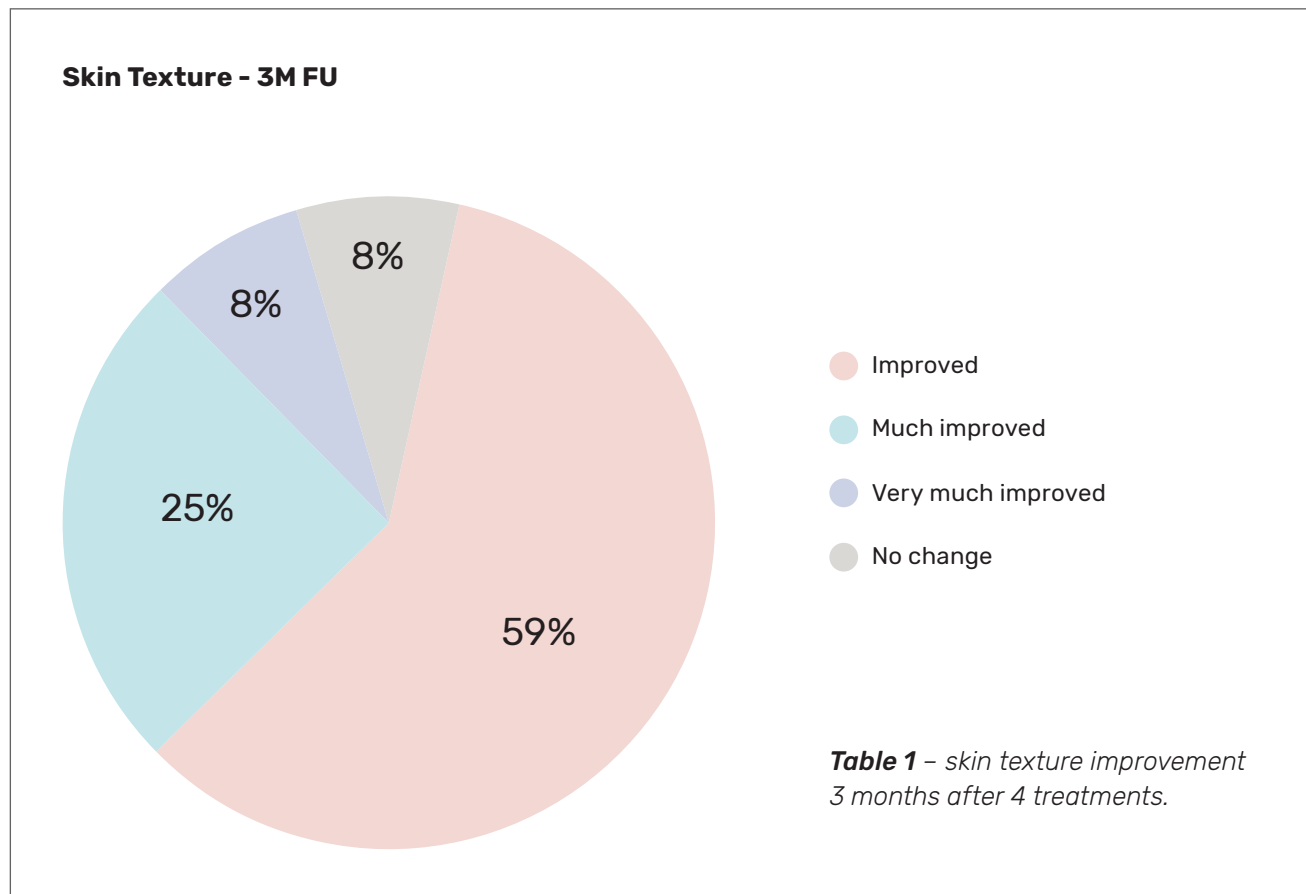
Twelve females, ages 29-60 (50±9), Fitzpatrick skin type II-IV, received four full face TriFractional treatments at 3-weeks interval. All patients returned for 1 and 3 months follow up.

Efficacy: Treatment was well tolerated; pain levels remained low throughout the study and **no topical anesthesia was required**. Improvement in brightness and wrinkles noticed by patients from the first treatment. **All patients (100%) saw overall improvement at 1 month follow up and 93% of patients saw improvement in skin texture at 3 months follow up. See additional details in table 1.** Most of the patients **(75%) reported positive self-assessment changes in all treatment areas following second treatment.** Moreover, although not specified as treatment indication, **25% reported an improvement in their acne scars as an additional benefit.**

Safety: Transient erythema and edema observed in all patients lasting for a few hours. No adverse events were reported before, through and after the treatment.

Downtime: All patients reported that they felt comfortable to go out in public one day after the treatment.

Conclusion: H7x7 TriFractional treatment found to be safe, well tolerated and effective for skin texture improvement, with minimal discomfort and downtime resulting in improved brightness, skin tightening and wrinkle reduction (Figures 1-4).



3 MONTHS AFTER 4 TREATMENTS WITH H7X7 TIP

BEFORE



AFTER



Female, 60 years old. Significant improvement in skin texture and wrinkles.

BEFORE



AFTER



Female, 28 years old. Significant improvement in skin texture.



Female, 60 years old. Significant improvement in skin texture and wrinkles.



Female, 52 years old. Significant improvement in skin texture and fine lines.

Courtesy of Pollogen In-House Clinic, Tel-Aviv, Israel

Figures 1 - 4: before and after four treatments with H7x7 fractional tip

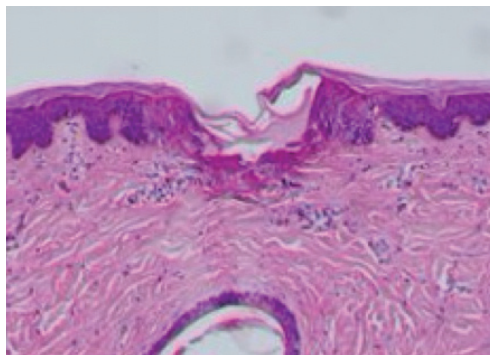
HISTOLOGICAL EVIDENCE

In-Vivo histology analysis results showed **distinct epidermal ablation and dermal coagulation**. Difference between high and low energy settings was observed in terms of the extent and rate of the healing process, with deeper dermal changes at higher energy levels, during the days post procedure. As can be seen in the Day 0 image there is a significant Epidermal removal allowing for optimal Epidermal fractional renewal while providing subtle upper dermal coagulative effect leading to dermal renewal.

Complete regeneration of the epidermis and dermis with sub-epidermal healing observed after 13 days when using low energy, and demonstrating an underlying active healing process when using high energy (**figure 5**).

Histological evidence (images courtesy of Pollogen):

DAY 0



DAY 13

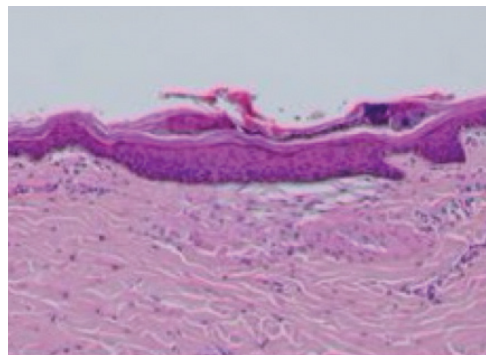


Figure 5 - demonstrating an underlying active healing process.

Skin histologies using high setting samples at day 0 (left) and day 13 (right) demonstrating healing process (H&E stain)

ADDITIONAL SUPPORTING MATERIALS

Potekaev et al. (2013) evaluated the safety and efficacy of the Tripollar RF & DMA technologies in 20 women aged 35-65 (average age 43) who received 8 weekly treatments for facial wrinkles.

Results of the quantitative measures used in this study demonstrate the safety and clinical benefit of **Tripollar RF & DMA** technologies due to their combined effects for skin rejuvenation and the treatment of facial wrinkles (5).

Efficacy: Tripollar RF & DMA technologies demonstrated significant improvement for all measured skin characteristics after 8 treatments with additional improvement at one-month follow-up.

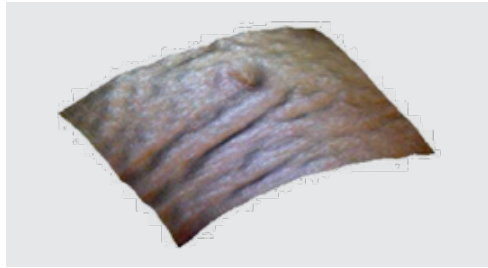
At the follow-up visit, measures demonstrated reduction in skin scaliness and roughness of over 40% and 83% increase in skin smoothness. Significant improvements were observed in skin tonus, lifting effect, reduction of sharpness of mimic and static wrinkles, and the improvement of facial skin color homogeneity. These findings were measured by non-invasive quantitative methods including 3D Visio-scanning (figure 6), micro-topography by ultrasonic derma scanning and micro-circulation of the facial skin by Laser Doppler Flowmetry (LDF).

Safety: No adverse events were detected. No negative sensations or signs of irritation were experienced during the treatment.

Downtime: Immediately after treatment, some patients reported transient erythema and slight edema that lasted several hours.

Conclusions: Tripollar RF & DMA technologies are non-invasive, effective, safe, and virtually painless treatment for reduction of wrinkles and facial skin rejuvenation.

BEFORE



1 WEEK AFTER 8 TREATMENTS



Figure 6 -
3D Visio-
scanning.

3D Imaging of "Crow's feet" wrinkle area & sectional drawing of the skin test area. Reduction in depth and length of wrinkles is observed.

Gold et al. (2019) evaluated the safety and efficacy of **VoluDerm** technology for collagen remodeling, skin volume enhancement and wrinkle reduction with 100 ultra-thin electrodes (gen100 tip). Twelve women [ages 39-58 (mean age 45.5 ± 5.2); Fitzpatrick skin types II-III; Fitzpatrick Elastosis Scale (FES) score 3-6] underwent three consecutive treatments of the entire face, including the perioral and periorbital regions at 3-week intervals.

Efficacy: Treatment was well tolerated and pain levels remained low. Improvement in skin texture, brightness and pigmentation was observed starting from the first treatment. **At one and three-month follow-ups, physician-rated FES showed statistically significant improvement of 2.67 ± 1.18 and 2.33 ± 1.03 , respectively ($P < .0001$), from baseline (4.83 ± 0.69).** According to the investigator assessment of improvement using the GAIS scale, all subjects had an improvement in skin texture and pigmentation and most of the patients (91.7%) had an improvement in skin brightness, tightness, and wrinkles (figures 7-9)

Downtime: No adverse event was reported.

Conclusion: VoluDerm technology using the novel gen100 ultra-thin electrodes tip was found to be a safe, well tolerated and effective micro-needle technology for dermal volumizing and treatment of wrinkles with minimal pain and no downtime, resulting in significantly improved skin texture, wrinkles, brightness and pigmentation (6).

Courtesy of Dr. Gold, Tennessee Clinical Research Center

Figures 7-9 - before and after three treatments with voluderm gen 100 tip

BEFORE AND AFTER 3 TREATMENTS WITH VOLUDERM GEN 100 TIP

BEFORE

AFTER



(A,B) A 49-y-old female, before treatment (A) and 3 months after the last treatment (B). Significant improvement in erythema and skin texture.



(C, D) A 38-y-old female, before treatment (C) and 1 month after the last treatment (D). Significant improvement in skin texture.



(E, F) A 44-y-old female, before treatment (E) and 1 month after the last treatment (F). Significant improvement in wrinkles, skin texture and color.

Shapiro et al. (2015) evaluated the safety and efficacy of combined **TriPollar** and **VoluDerm** technologies. The participants underwent 5 treatments; 3 treatments performed once a week and an additional 2 treatments at 2 to 3-week intervals. Some of the subjects underwent a pre-heating treatment with TriPollar RF prior to the VoluDerm treatment, as skin preparation for the VoluDerm phase of the treatment. The VoluDerm treatment parameters for each subject defined according to the treatment area and the severity of the skin condition.

Following the TriPollar RF pre-heating, either low or medium level VoluDerm parameters used at the first treatment depending on the subject's individual tolerance and skin response. Subsequently, high-level VoluDerm parameters used in following treatments according to skin tolerance.

Efficacy: the treatments demonstrated **significant dermal volume enhancement, reduction of wrinkles including naso-labial folds, perioral and periorbital lines, Improvement of skin laxity in the neck and skin texture manifested by radiant skin, smaller pores and general volume increase (figures 10 - 12).**

Downtime: No adverse events reported immediate post-procedure reactions included erythema and/or edema. Treatment was well tolerable; pain was none to minimal with no downtime.

Conclusion: Tripollar and VoluDerm technologies were found to be safe and effective technologies for dermal volumizing and treatment of wrinkles with minimal pain and no downtime (7).

Courtesy of Steven D. Shapiro M.D., Palm Beach Gardens, FL.

Figures 10-12 - before and after 1-5 treatments with Tripollar RF and Voluderm gen 36 tip.

BEFORE AND AFTER 1-5 TREATMENTS WITH TRIPOLLAR RF AND VOLUDERM GEN 36 TIP

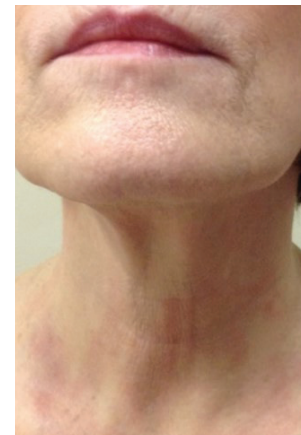
BEFORE



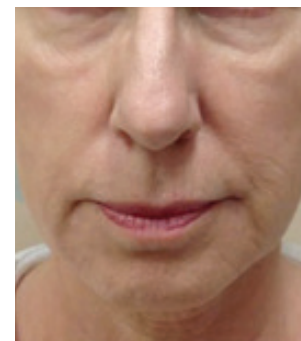
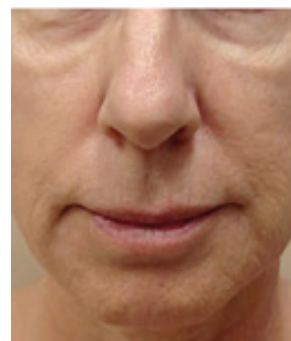
AFTER



Before and after 5 treatments. Voluderm technology (with TriPollar preheating). Improvement of skin texture, significant volumizing in cheek area along with reduction of the naso-labial folds.



Before and after 1 treatment. Voluderm technology (with TriPollar preheating). Improvement of neck skin laxity and wrinkles



Before and after 5 treatments. Voluderm technology (with TriPollar preheating). Improvement of skin texture and facial contouring.

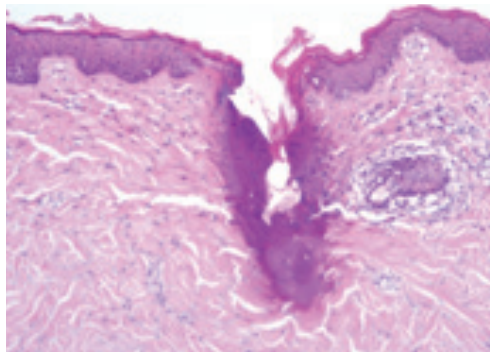
Gershonowitz et al. (2014) evaluated the safety and efficacy **VoluDerm gen 36** technology through histological evaluation of morphological changes in the target tissue. Immediate VoluDerm epidermal and dermal effects and progress of healing process, as function of time following treatment. Histology analysis of samples of 14 days demonstrated complete healing for all energy levels (Figure 13).

Results: This In-Vivo histology confirmed the safe and effective performance of the VoluDerm treatment. A fractional pattern demonstrated affected areas, surrounded by healthy tissue. Healing process proved natural dermal renewal and epidermal complete regeneration. Histology supports clinical advantages of the VoluDerm natural looking skin enhancement.

Conclusion: The major impact of VoluDerm is on the dermal layer, thus treatment is associated with less to no downtime, less patient discomfort, and less predisposition to side effects compared to other technologies in which penetration mechanism is mechanical. With VoluDerm, the visible impact on the epidermal layer is relatively minor and less prominent although the desired micro resurfacing effect is achieved. (8)

Histological evidence:

DAY 0



DAY 14

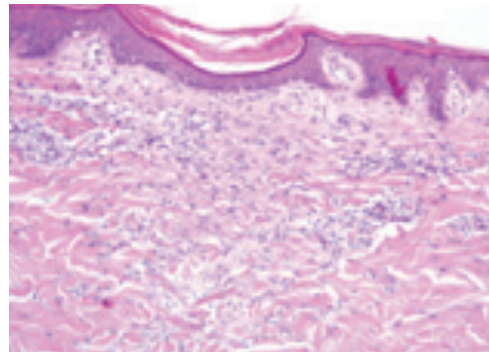


Figure 13 -
Skin histology post Voluderm gen 36 treatment

Skin histology samples after treatment with High setting, demonstrating complete healing on day 14.

BEFORE AND AFTER FROM OUR CLINICS WORLDWIDE:



Courtesy of PT Regenesi in-house clinic ,Jakarta, Indonesia

Figure 14 - *Voluderm treatment (Indonesia)*

Figure 15 - *H7x7 treatment (Indonesia)*

BEFORE AND AFTER TREATMENTS WITH TRIFRACTIONAL H7X7 TIP

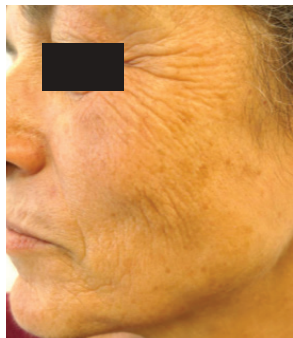
BEFORE



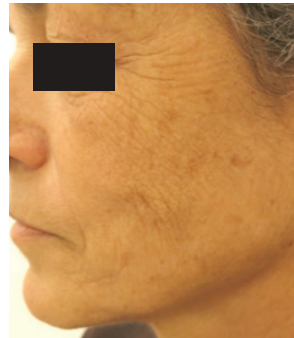
AFTER 2 H7X7 TREATMENTS



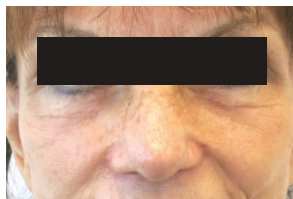
BEFORE



AFTER 5 H7X7 AND GEN100 TREATMENTS



BEFORE



AFTER 3 H7X7 TREATMENTS



Courtesy of Dr. Levenberg, Tel Aviv, Israel

Figure 15 - Trifractional treatment

SUMMARY

The Divine Pro is an aesthetic platform with four tested, validated and patented technologies TriFractional, VoluDerm, TriPollar RF and DMA. The administered treatments are proven to be safe, effective and tolerable treatments, allowing minimized patient discomfort while maximizing results. Divine Pro enables versatile treatment combinations, shown to promote skin renewal by using the body's own rejuvenation processes in order to achieve smoother, tighter skin, improved facial contouring and a refreshed complexion.

Divine Pro's revolutionary design provides treatments for patients seeking a more effective and less invasive treatment with low pain, allowing the patients to return to their routine with little to no downtime, improving their appearance and quality of life. The four clinically proven technologies enable a patient tailored and personalize treatment plan. The treatments provide immediate and long-lasting results, addressing the signs of aging by reducing wrinkles, tightening the skin and smoothening the face and the neck.

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