Evaluation of Safety and Efficacy of the TriPollar Technology for Treatment of Wrinkles

Steven D. Shapiro, MD,[1*] Yoav Eros, MD,[2] Yoav Abrahami, MD,[2] and Amos Leviav, MD[2]
[1]*Gardens Dermatology, Cosmetic Surgery Center, Palm Beach Gardens, Florida*
[2]*Plastic Surgery Department, Kaplan Hospital, Rehovot, Israel*

Introduction: Patient demand for non-surgical, non-invasive, and no-downtime wrinkle reduction treatment procedures has grown dramatically over the past decade as new treatments and technologies have been introduced. This study was performed in order to evaluate the safety and efficacy of the TriPollar radiofrequency (RF) technology and intended for wrinkle reduction treatment.
Methods: Thirty-seven Subjects were recruited in two sites and were treated for the reduction of facial wrinkles and rhytides and followed for 3 months after the last treatment. The safety of using the TriPollar system was established by the physicians' assessments and observations of adverse events after each treatment. To evaluate treatment efficacy, pre- and post-treatment photos were assessed using a blinded evaluation by two uninvolved physicians.
Results: No unexpected adverse side effects were detected or reported. All subjects participating in the study reported no pain or mild pain during the treatments. The photographic analysis of pre- and post-treatment by the two blinded physicians revealed improvement (downgrade of at least 1 score according to the Fitzpatrick scale) in 94% (according to first reviewer) and 97% (according to second reviewer) of study subjects. All patients (100%) were satisfied from treatment results to a different extent.
Conclusions: The results of this study clearly indicate that the TriPollar system offers a non-invasive, effective, safe and virtually painless wrinkle and rhytides reduction treatment. Lasers Surg. Med. 44:453–458, 2012.
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Key words: TriPollar; radiofrequency; wrinkle reduction; anti-aging; skin tightening; collagen remodeling; Apollo

INTRODUCTION

Non-invasive, energy-based, aesthetic treatments are becoming increasingly popular among female and male patients of all ages. Different technologies are presently available for treating aging skin including laser, therapeutic ultrasound, Light Emitting Diode (LED) and intense pulsed light (IPL) technologies. However, radiofrequency (RF) has emerged as the most effective and versatile modality for the broadest range of facial and body treatments, including non-invasive wrinkle treatment [1–4].

RF energy is a form of electromagnetic energy. When applied to skin tissue, rapidly oscillating electromagnetic fields cause movement of charged particles within the tissue resulting in heat generation proportional to the tissue's electrical resistance. Heating of the dermal layer can lead to shrinkage of collagen fibrils, and in addition, can induce activation of fibroblasts for production of new collagen fibers. The resultant effect is tissue remodeling and tightening which leads to improvement of wrinkles over time [5,6].

The TriPollar technology uses three or more electrodes designed to deliver RF current into the skin, inducing a focused high density power field between the poles while using low power consumption. The high density power field in the treatment area results in heat generation in the dermal and subcutaneous layers. A few studies demonstrating the effect of the TriPollar technology for various treatments such as skin tightening, cellulite and circumference reduction, including clinical and histological evidence, were previously published [7–11]. Selective and focused electro-heating of the skin is intended to stimulate collagen remodeling in the dermal layer enabling a non-invasive wrinkle treatment.

The current study was designed to evaluate the efficacy and safety of the TriPollar system for treatment of facial wrinkles and rhytides. Clinical evidence is provided demonstrating treatment safety and treatment efficacy results.

MATERIALS AND METHODS

The study was conducted in two centers: in the USA at the Gardens Dermatology and Cosmetic Surgery Center in Florida and in Israel at the Kaplan Hospital, Plastic Surgery Department. The study was approved by the Essex IRB committee in the USA and the Helsinki committee of Kaplan Hospital.

A total of 37 female subjects, ages 36–65 years (average 52.8 ± 7.69), were enrolled in the study after meeting

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*Corresponding to: Steven D. Shapiro, MD, Gardens Dermatology, 11030 RCA Center Drive, Suite 3015, Palm Beach Gardens, FL 33410. E-mail: sdshaps@aol.com
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all inclusion/exclusion criteria and providing a signed Informed Consent Form. Exclusion criteria included pregnancy, any implantable electronic device that could be disrupted by RF energy, any active dermatological or collagen vascular disorder, history of cancer, prolonged intake of medications that could affect healing, tendency of keloid scarring and specific aesthetic treatments in the treated area prior to the study.

The subject's facial wrinkles were classified by the investigators according to Fitzpatrick Wrinkle Scale [12] (Table 1). All 37 subjects were treated for face wrinkles and rhytides. Subjects received 8 weekly treatments. In addition, subjects were scheduled for two follow-up visits at 1 and 3 months following their last treatment.

Prior to the RF treatment, the treated areas were assessed visually and photographed in a standardized method using high-resolution digital photography in order to allow comparison and assessment of improvement of wrinkle appearance following treatment. Photographs were taken prior to the first treatment, at 1-month and 3-month follow-up visits.

The Apollo System is an RF system, based on TriPollar technology, that was used in this study. This TriPollar system emits RF current at a frequency of 1 MHz and a maximum power of 50 W. Three different applicators may be attached for treatment. The large applicator was used for pre-heating of the cheeks, the medium sized applicator for overall facial areas and the small applicator was used for small facial treatment areas, such as the perioral and periorbital zones.

Prior to each treatment the face was cleansed and then lubricated with medical grade glycerin. Subjects were provided with a "patient-controlled manual switch," a unique feature of the TriPollar system which enables patients to stop the treatment should they experience some discomfort. Applicators were applied with full contact. Continuous circular or elliptical movements were performed, with slight pressure. A non-contact, infrared thermometer (ThermoFocus, TechniMed Srl, Varese, Italy) was used to maintain an external skin temperature of 40–45°C according to the recommended exposure time.

Immediately after the treatment the treated area was visually assessed for immediate skin responses such as edema and erythema. In addition, patients were asked to rate pain level which they felt during the treatment by using Visual Analogue Scale for pain (VAS scale).

The study's efficacy endpoint was determined by comparing the Fitzpatrick Wrinkle scores of pre-treatment photographs (baseline) to photographs taken during the last follow-up visit at 3 months after the last treatment. The photos of the subjects were presented to the two uninvolved physicians (blinded evaluators) in a random manner and the evaluators were requested to grade each photo using the Fitzpatrick wrinkle scale. Any improvement of at least one score (downgrade score) at follow-up visit, relatively to pre-treatment (baseline) wrinkle score, was considered a success.

The safety of the procedure was evaluated by monitoring the occurrence of potential procedure related side effects such as excessive erythema, edema, and damage to natural skin texture or pain.

In addition to the efficacy evaluation by the blinded evaluators, each principle investigator (PI) at his site scored the Fitzpatrick degree of wrinkles and elastosis. The PI scoring was based on direct observation of subjects' facial skin, before the first treatment (at base line) and again at the 3-month follow-up visit.

To evaluate the subjects' satisfaction from the treatment and its results, each subject filled in a questionnaire after the treatments.

RESULTS

Since no statistically significant differences were found between the results obtained from the two study sites, the results of all 37 patients that participated in the study course and received the full course of eight treatments, are reported as one group. This finding reflects the simple, reliable, and user-independent nature of this device.

Almost all participants (92%) completed the study course—8 treatments and 3-month follow-ups (3 participants out of 37 were lost to follow-up due to personal and life style reasons that were not related to the study). The reports of treatment information and subjects' feedback for the purpose of reviewing the safety of the TriPollar system were obtained from all 37 subjects as all subjects completed the 8 treatment sessions.

The final evaluation of the efficacy of the TriPollar for treatment of wrinkles and rhytides was performed by 2 blinded evaluators using the photographs of the 34 subjects who completed the full study protocol (including the 3-month follow-up) and excluded the 3 subjects lost to follow-up.

TABLE 1. Fitzpatrick Wrinkle Scale

	Fitzpatrick Wrinkle and Elastosis Scale		
Class	Wrinkling	Score	
I	Fine wrinkles	1–3	Mild: fine texture changes with subtly accentuated skin lines
II	Fine to moderate depth wrinkles, moderate number of lines	4–6	Moderate: distinct popular elastosis (individual papules with yellow translucency under direct lighting) and dyschromia
III	Fine to deep wrinkles, numerous lines with or without redundant skin folds	7–9	Severe: multipapular and confluent elastosis (thickened, yellow and pallid) approaching or consistent with cutis rhomboidalis

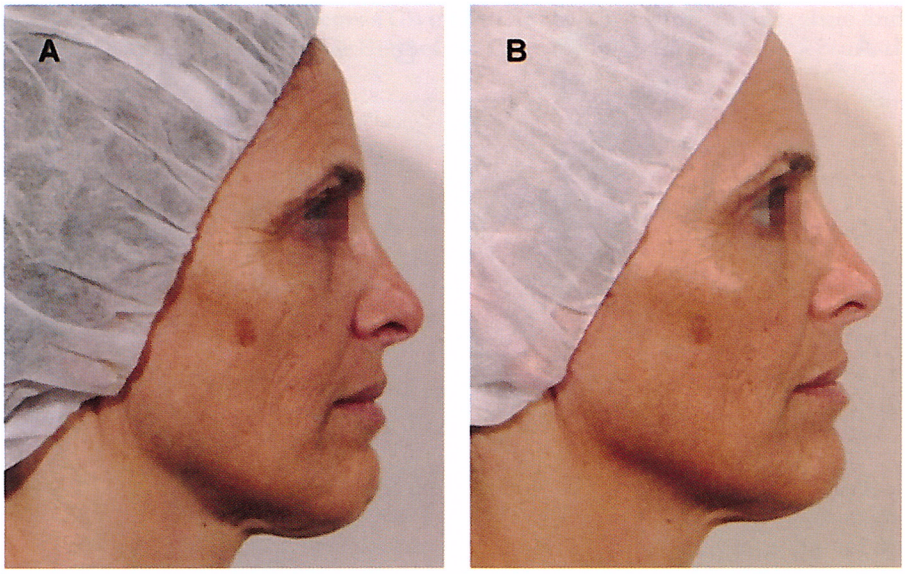

Fig. 1. A 51-year-old female. **A**: Before treatment initiation; (**B**) 3-month follow-up visit.

Treatment Safety

No unexpected adverse side effects were detected or reported. In all patients (n = 37), post-treatment mild to moderate erythema was detected. However, as this phenomenon is transient and expected as a result of the RF technology, it is not considered an adverse effect. The erythema resolved spontaneously within 30–60 minutes. None of study subjects experienced burns, skin breakdown, or scarring. All 37 subjects who underwent all eight treatments reported no pain or mild pain during the treatment. None of the subjects reported moderate or severe pain during the study. None of the subjects needed any analgesic or other pain medication during the treatments.

Treatment Efficacy

An objective evaluation of the treatment efficacy was obtained by two blinded evaluators, physicians experienced with the Fitzpatrick Wrinkle and Elastosis Scale who scored photos of the last follow-up visit and baseline photos. Success criterion for each subject was defined as a reduction of at least one score of skin wrinkle and elastosis.

The following sets of before (left) and after—at 3-month follow-up visits (right) photographs (Figs. 1–4) illustrate

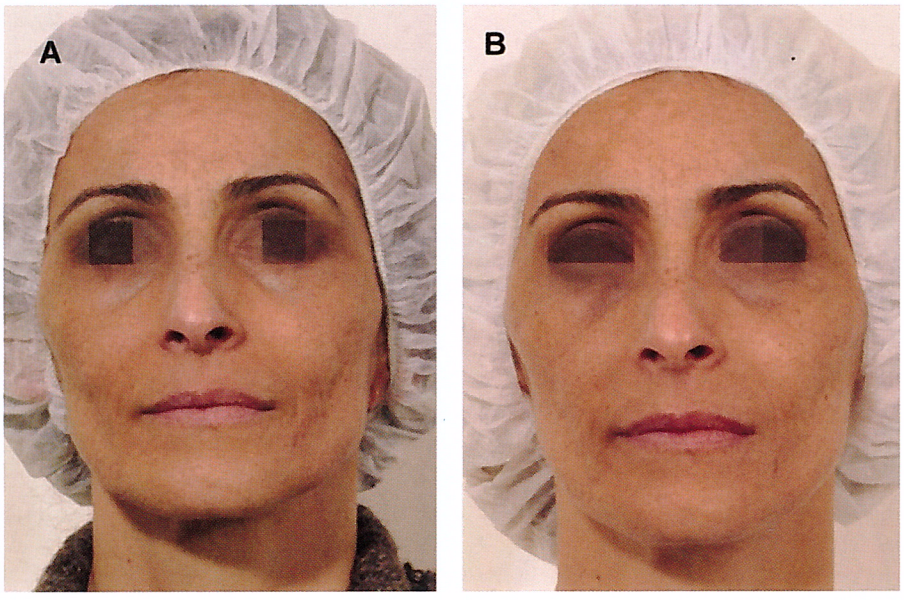

Fig. 2. A 42-year-old female. **A**: Before treatment initiation; (**B**) at 3-month follow-up visit.

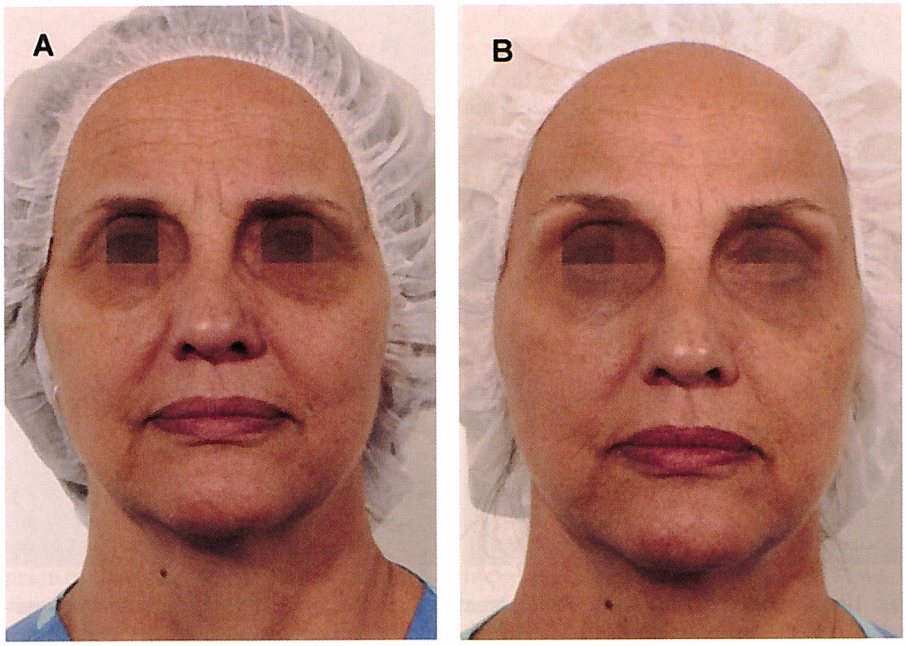

Fig. 3. A 59-year-old female. **A**: Before treatment initiation; (**B**) at 3-month follow-up visit.

the significant beneficial effect achieved by the TriPollar system.

Analysis of the blinded evaluation results revealed improvement (downgrade of at least 1 score of the Fitzpatrick scale) in 94% (according to first reviewer) and 97% (according to second reviewer) of study subjects. Statistical comparison (using paired *t*-test) was conducted among the pre-treatment Fitzpatrick score (baseline) to 3 months follow-up for each reviewer. Statistical analysis was conducted using SAS software (version 9.1). Score differences were found to be statistically significant when comparing baseline score to the scores obtained at

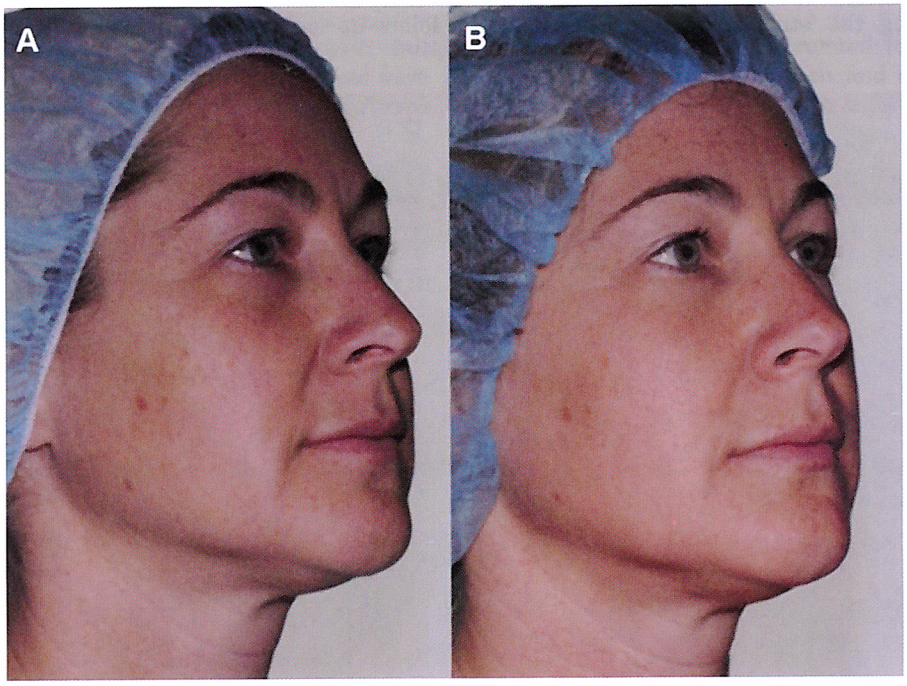

Fig. 4. A 41-year-old female. **A**: Before treatment initiation; (**B**) at 3-month follow-up visit.

TABLE 2. Averages (±STDV) of Fitzpatrick Scores Given by the Two Reviewers at Baseline and 3-Month Follow-Up (Following Eight Treatments), Grade Reduction Comparing to Baseline, and Statistical Results of Comparison

	Average Wrinkle Score					
	1st Reviewer			2nd Reviewer		
Score time	Average score	Grade reduction (comparing to baseline)	Statistical (t-test) results of the comparison	Average Score	Grade reduction (comparing to baseline)	Statistical (t-test) results of the comparison
Baseline	4.65 (±1.04)	—	—	4.79 (±1.15)	—	—
3 months follow-up	3.24 (±1.07)	1.41 (±0.74)	$P < 0.001$	3.50 (±1.02)	1.29 (±0.52)	$P < 0.001$

3-month follow-up ($P < 0.001$) for both reviewers, indicating treatment efficacy. Table 2 and Figure 5 represent averages (±STDV) of Fitzpatrick scores given by the two reviewers at baseline and at 3 months follow-up.

The study results indicate that the treatments have initiated a process of collagen remodeling that continues after the treatments sessions have been completed.

The principle investigators, each at their site, also scored the Fitzpatrick degree of wrinkles and elastosis based on direct observation of subjects' facial skin, before the first treatment (at base line) and again at the 3-month follow-up visit.

In addition to the efficacy evaluation by the blinded evaluators, the efficacy of the treatment was also demonstrated through a comparison of the average Fitzpatrick score of the subjects, as determined by the principle investigators through observation of the subjects' facial skin at baseline visit and at the 3-month follow-up visit. Analysis of scores given by the principle investigator's demonstrated an average Fitzpatrick score value reduction of 2.42 (±0.72) as determined by the principle investigators in one site and Fitzpatrick score value reduction of 1.55 (±0.69 in the second site). These results further supported the TriPollar treatment efficacy outcome.

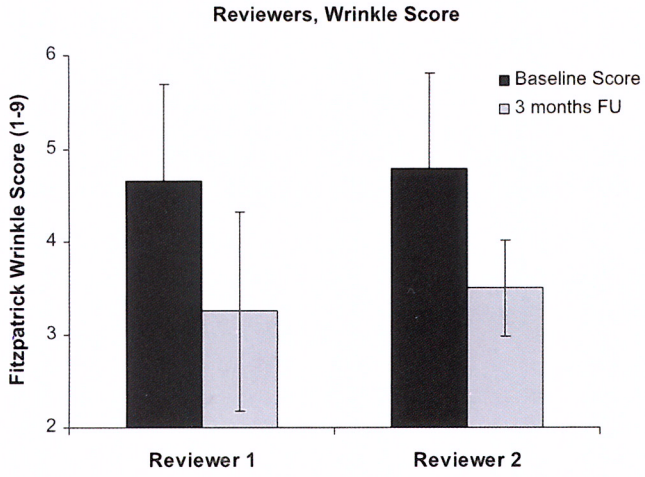

Fig. 5. Averages (±STDV) of Fitzpatrick scores given by the two reviewers at baseline and 3-month follow-up (following last treatment).

Analysis of subjects' questionnaires indicated that all patients were satisfied from treatment results to different extents; 89% reported that the treatment met their expectation or met their expectation to some extent, and 11% reported that the treatment met their expectation to a lower extent.

DISCUSSION

The clinical results of non-ablative RF anti-wrinkle and rhytides effects were previously reported in the periorbital area [13]. In this multicenter study, Fitzpatrick and his colleagues demonstrated clinical improvement in periorbital rhytides in 80% of subjects. In contrast, in 24 patients who underwent a single RF treatment for improvement of the upper third of the face, only 36% of the patient's self-assessment demonstrated improvement [14]. Another study, published recently, demonstrated the efficacy of RF based system with real-time impedance measurement for the treatment facial skin [15].

In the current study, 37 subjects were treated for facial wrinkle reduction. Thirty-four out of the treated subjects completed the full protocol and were followed for 3 months after the last treatment. In order to evaluate treatment efficacy, pre- and post-treatment photos were introduced to two uninvolved physicians for blinded evaluation.

The data reported in this study demonstrates that the TriPollar system offers a safe and effective non-invasive method to improve the appearance of age-related rhytides and wrinkles.

According to the blinded reviewers, 94% and 97% of study participants have shown downgrade of at least 1 score according to the Fitzpatrick scale.

In a similar device, it has been reported that the use of a RF device was associated with significant pain, and in a small but significant number of cases subcutaneous fat atrophy developed [1,16]. No subcutaneous fat atrophy was noted in this study. All 37 patients participating in the study reported no pain or mild pain during treatments, although the procedure was performed without using any anesthetic agents. Furthermore, no patients considered the procedure intolerable at any session and

never required use of the "patient controlled manual switch."

The results of this study clearly indicate that the TriPollar RF system offers a non-invasive, effective, safe and virtually painless wrinkle and rhytides reduction treatment.

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