

CASE REPORT

## Facial skin rejuvenation by combination treatment of IPL followed by continuous and fractional radiofrequency

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### ABSTRACT

**Objective:** The objective of this study was to evaluate the safety and efficacy of combination facial treatment by 3 technologies. **Materials and methods:** Eleven patients completed the clinical trial that consisted of alternate treatments of intense pulsed light (IPL) in 3 sessions and continuous + fractional bipolar radiofrequency (RF) in 3 alternating sessions, 3 weeks apart. Follow-up visits were made at 6 and 12 weeks following the last treatment. Lesions were evaluated by photographs taken at baseline and at follow-up time points according to predetermined scales. **Results:** Results showed statistically significant improvement in wrinkling (24% after 6 weeks and 33% after 12 weeks), pigmentation (38% after 6 weeks and 62% after 12 weeks), vascular lesions (29% after 6 weeks and 67% after 12 weeks), and laxity (37% after 6 weeks and 40% after 12 weeks). **Conclusions:** Combination facial treatment by IPL, and continuous and fractional RF is safe and enables the treatment of a variety of facial lesions, taking advantage of accessible applicators for different clinical indications on the same device. Thus, comprehensive facial skin rejuvenation has become feasible.

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### KEYWORDS

Facial skin improvement;  
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### Introduction

Intense pulsed laser (IPL) treatments for skin rejuvenation, including lightening of pigmented and vascular lesions, have been extensively documented in the medical literature in the past (1–2).

Radio frequency (RF) is established as the gold standard treatment for skin tightening, whereby skin laxity and wrinkles improve (3). Non-ablative and non-invasive RF is reported to affect neo-collagenesis in the dermis (4–5) and even in the upper layer of the hypodermis (6).

Fractional ablative techniques by various lasers (7), and recently, by RF devices (8) are becoming more popular for facial skin resurfacing, as good results with minimal downtime and minor or no adverse events are recorded.

The purpose of the present study was to combine the 3 technologies and evaluate the safety and efficacy of the LUMECCA™ IPL, the FORMA™ non-invasive, non-ablative continuous bipolar RF, and the FRACTORA™ fractional ablative RF applicators of the InMode™ system.

are intended for different clinical indications. LUMECCA™ includes 2 IPL handpieces, one with the spectrum of 515–1200 nm for the treatment of light skin (I-II) and one 580–1200 nm for the treatment of darker skin (III-IV). The indications for LUMECCA™ are skin rejuvenation, including treatment of superficial pigmented and vascular lesions, as well as mild textural lesions. FORMA™ is a non-invasive continuous bipolar RF handpiece (1 MHz) that is indicated for skin tightening and wrinkle treatment. FRACTORA™ with multi-electrode 60-pin tip is an ablative fractional bipolar RF handpiece (1 MHz) that is indicated for skin resurfacing and skin rejuvenation. The technologies are selective photothermolysis for LUMECCA and bi-polar RF for FORMA and FRACTORA. Two side electrodes and a central electrode provide non-ablative skin heating and tightening by the FORMA. The FRACTORA has 2 side electrodes and 60 pointed pins that are creating fractional ablation and coagulation under the pins and sub-necrotic heating throughout the entire dermis. The InMode device is seen in Figure 1 and images of the 3 applicators used in the clinical trial are shown in Figure 2.

### Materials and methods

#### The device

This study was designed as a single-blinded, prospective study to evaluate the safety and efficacy of combination treatment of 3 applicators of InMode™ device (InMode MD Ltd., Yokneam, Israel). The applicators employ different technologies and

#### Study design

The study was designed to have 6 treatment visits and two follow-up visits. Each of the treatment visits was conducted 3 weeks apart and follow-up visits were 6 and 12 weeks following the last treatment. Three sessions with LUMECCA alternated with 3 sessions with FORMA + FRACTORA. Clear



Figure 1. InMode Device.

ultrasound gel was used for the LUMECCA and FORMA treatment, whereas for the FRACTORA, skin was topically anesthetized with EMLA 5% and completely dried before treatment with alcohol 70%.

### Patient selection

Eleven female patients aged 37–66 (mean 52) and Fitzpatrick skin type II-III completed the study. They all had photoaged facial skin with a variety of textural, pigmented, and vascular lesions. All subjects who participated in the clinical study read the protocol and signed an Informed Consent that had been approved by the Institutional Review Board or IRB and agreed to follow the treatment schedule, posttreatment care, and follow-up schedule.

Exclusion criteria included the presence of pacemaker or internal defibrillator, or any other active electrical implant anywhere in the body; Permanent implant in the treated area such

as metal plates and screws, silicone implants or superficially injected chemical substance; Current or history of skin cancer (remission of 5 years), or current condition of any other type of cancer, or premalignant moles; Severe concurrent conditions, such as cardiac disorders, epilepsy, uncontrolled hypertension, and liver or kidney diseases; Pregnancy and nursing; History of bleeding coagulopathies or use of anticoagulants in the last 2 weeks; Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications; Poorly controlled endocrine disorders, such as diabetes and thyroid dysfunction; Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash; History of cold sores (Herpes Simplex) will require a prophylactic antiviral medication when treating around the mouth and lips; History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin; Any surgery in treated area within 3 months prior to treatment; Use of medication known to induce photosensitivity, as per physician discretion; Use of isotretinoin (Accutane®) within 6 months prior to treatment; Any facial treatment that may improve skin, such as laser/IPL/RF, chemical peeling, injectable like Botox and natural fillers, dermabrasion, and harsh skin care products in the last 3 months and during the entire course of the study; Recent exposure to sunlight or artificial UV light during the study, unless appropriate protective clothing and sunscreen are used; Subjects wearing a tattoo or permanent makeup on the area to be treated; and as per the practitioner's discretion.

### Endpoint parameters

Primary safety endpoint: The study's goal to evaluate the safety of the InMode device will be established by physician's assessment of adverse events (excessive erythema and edema, localized infection, burns, change of pigmentation, or skin texture alterations). Patients will evaluate their pain according to a predetermined scale.

Primary efficacy endpoint: The study's goal to evaluate the efficacy of the InMode device will be established by change of level of wrinkles and fine lines according to Fitzpatrick scale of wrinkling and elastosis, as well as change of level of pigmentation, vascular lesions, and laxity according to predetermined scale. Assessment will be done by 2 blinded independent reviewers on random photographs.

### Assessment methods

Safety assessment was done by the investigator by recording any adverse event other than expected transient mild or moderate erythema and edema that do not require any intervention, and



Figure 2. Images of the 3 applications of InMode: LUMECCA (left), FORMA (center), and FRACTORA with 60-pin tip (right).

are desirable treatment endpoints. In addition, patients were asked to evaluate the degree of pain on a scale of 6, when 0 is no pain and 5 is intolerable pain during treatment.

Photographs were taken by Visia 6 Booth (Canfield Scientific, Fairfield, NJ, USA) before and after each treatment session and at follow-up time points. Random photographs before the first treatment session and at the follow-up time points were presented to 2 independent blinded evaluators for assessment of lesions change.

Efficacy assessment included wrinkles and fine lines assessment according to Fitzpatrick scale of wrinkling and elastosis, comprised of 3 major scores and 9 minor scores. Pigmented and vascular lesions, as well as laxity were evaluated according to predetermined scale of 5 scores: None (0) = normal;

Trace (1) = barely visible and localized; Mild (2) = somewhat visible and diffuse; Moderate (3) = visible and diffuse; and Severe (4) = extremely visible and dense. A patient treatment is considered “success” if she gains at least one score in at least one category, as established by average score of the two evaluators by comparing baseline photograph to follow-up visits.

#### **Treatment procedure and parameters**

Treatment parameters of LUMECCA IPL were matched to the subject’s skin type and sensitivity and to the lesion type (pigmented or vascular). They are the wavelength (515 or 580 nm), fluence (8–16 J/cm<sup>2</sup>), pulse width (Short or Long), cooling (Normal or Strong), and repetition rate (Single, Normal or



**Figure 3.** Facial skin before treatment (Left), 6 weeks after the last treatment (Center), and 12 weeks after the last treatment (Right). Note the improvement of wrinkles, pigments, vascular lesions, and laxity.

Table 1. Scores of facial skin pretreatment and post 6 and 12 weeks of last session for wrinkles, pigments, vascular lesions, and laxity.

Patient #	Demographics			Fitzpatrick score			Pigment score			Vascular score			Laxity score		
	Age	Skin type		Pre	Post 6 W	Post 12 W	Pre	Post 6 W	Post 12 W	Pre	Post 6 W	Post 12 W	Pre	Post 6 W	Post 12 W
1	64	2		7	6	5	3	2	1	2	2	1	3	2	2
2	37	2		4	4	3	1	1	1	1	1	1	2	1	1
3	42	3		7	4	4	3	1	1	2	0	0	3	1	1
4	58	3		8	7	6	2	1	1	2	2	1	3	2	2
5	40	3		7	5	5	2	1	1	2	1	1	3	2	1
6	54	3		7	4	4	2	1	1	1	0	0	2	1	1
7	57	2		7	5	4	2	2	0	3	2	1	2	2	2
8	52	3		7	5	5	3	1	1	2	1	1	3	1	1
9	40	3		7	5	4	3	2	1	2	2	1	3	2	2
10	58	3		7	6	5	2	2	1	2	2	1	3	3	3
11	66	3		7	6	5	3	2	1	2	2	1	3	2	2
Mean	52			6.8	5.2	4.5	2.4	1.5	0.9	1.9	1.4	0.8	2.7	1.7	1.6
%	100			100	76	67	100	62	38	100	71	43	100	63	60
SD	10			1.0	1.0	0.8	0.7	0.5	0.3	0.5	0.8	0.4	0.5	0.6	0.7
%	14.4			14.4	18.9	18.0	28.5	35.9	33.2	28.3	59.3	49.4	17.1	37.4	41.2

Fast). Test pulses preceded the parameters choice. Treatment was performed on the full face once or twice according to skin response.

Treatment parameters for the FORMA were chosen according to skin thickness and proximity of bone. They are the RF energy (38–45mJ/pin) and cut-off temperature (40–43°C). Constant movement on ultrasound gel with a complete skin contact on a limited area of one cheek or forehead was continued for 10 min after cut-off temperature is reached.

FRACTORA treatment was performed immediately following FORMA treatment after gel removal, topical anesthesia application for 30 min, its removal, and drying with alcohol 70%. Sixty-pin tip was used in a stamping technique with 30% overlap and firm pressure.

Posttreatment care included the application of a moisturizer cream to the treated area for LUMECCA and FORMA and of antibiotic ointment for 2 days until the ablated craters close. Subjects were instructed to protect the treated areas from the sunlight throughout the entire study period.

### Statistics

Statistical analysis of the score difference was performed, comparing results before treatment to those after 6 weeks and after 12 weeks after the last session. Paired *t*-test was used and level of significance was calculated (*p* values). When *P* values < 0.05, the average difference between the various categories in baseline and the 2 follow-up visits are regarded statistically significant.

### Results

Eleven female patients completed the study and 3 representative facial photographs of 3 subjects are presented in Figure 3.

Assessment of the photographs by 2 independent blinded evaluators was given randomly and comparison was made between baseline and 6- and 12-week follow-up sessions. Results for wrinkling and elastosis by Fitzpatrick scale and for pigments, vascular lesions, and laxity by scales of 5 levels, as described in “Materials and methods” are presented in Table 1.

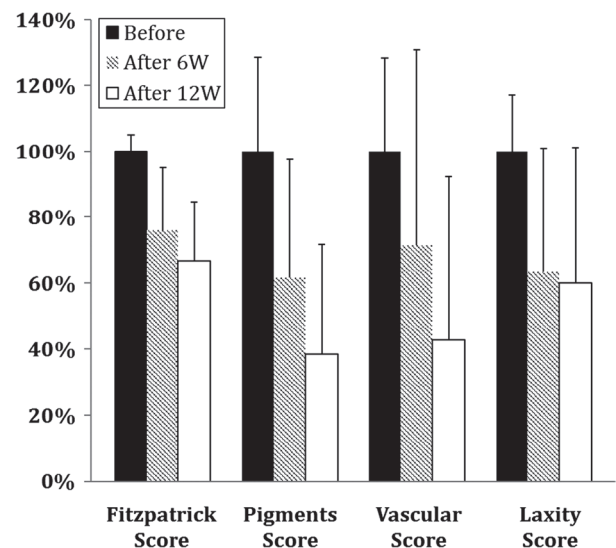


Figure 4. Lesion scores before treatment, 6 weeks and 12 weeks after the last session.

Graphic presentation of Table 1 is presented in Figure 4, when the score values of different scales are normalized to percent.

A statistical analysis by paired *t*-test demonstrated that all the results were statistically significant ( $p < 0.05$ ). All lesions improved 6 weeks after the last treatment and further improved after 12 weeks. 100% of patients showed improvement in wrinkling, 91% of patients showed improvement in pigmented and vascular lesions, and 82% had their laxity improved. Mean tested improvement after 6 and 12 weeks, respectively, was 24 and 33% for wrinkling, 38 and 62% for pigments, 29 and 57% for vascular lesions, and 37 and 40% for laxity. Statistical level of significance was the best for wrinkling ( $p = 3.8 \times 10^{-7}$ ), similar for pigments ( $p = 3.6 \times 10^{-5}$ ) and for vascular lesions ( $p = 5.3 \times 10^{-5}$ ), and last for laxity ( $p = 4.2 \times 10^{-4}$ ).

No adverse events were noted during the study. Mild erythema and edema occurred in all patients and resolved within a day of treatment with no intervention. This was an expected event of treatment endpoint. Pain level, as graded by the patients varied for each patient in the different sessions, being higher during FRACTORA treatment. Mean pain level for all patients in all sessions was  $1.9 \pm 0.6$  on a scale of 6 levels.

## Discussion

Combination treatment of 3 modalities: IPL, non-ablative continuous RF, and fractional ablative RF yields an advantage of treating simultaneously several lesions, as demonstrated in this study.

The best results were achieved for wrinkling and fine lines by the combination treatment of IPL, continuous RF, and ablative RF. Less improvement was noted for pigmented and vascular lesions and least improvement was scored for laxity, as indicated by the percent “successful” patients, the percent improvement, and the statistical level of significance. However, the differences in the degree of improvement and the statistical significance of the results of the 4 lesion types may be due to the small sample size and may not represent a substantial difference. The continuing improvement over time, with no further treatment, indicates gradual increase in skin quality, by debris removal and cellular and fibers regeneration. Pain was marginal and no adverse events were recorded.

Selective pigmentation and vascular lesions improvement is mainly due to LUMECCA IPL through selective photothermolysis (9), and partly by FRACTORA that ablates epidermal pigmentation and coagulates superficial blood capillaries (10). Non-selective improvement of skin laxity and wrinkling is also induced by both IPL and FRACTORA RF (3,5,10). However, most of the sub-necrotic effect on collagen and elastin fibers in terms of RF intensity and penetration depth is probably due to the FORMA treatment (11–13).

The ability to utilize 3 different applicators, representing 3 different technologies on the same device, is making the combined treatment accessible with no need to purchase several devices.

Therefore, we conclude that the InMode system with LUMECCA, FORMA, and FRACTORA applicators is a safe and effective device to address facial skin wrinkling, pigmentation, vascular lesions, and laxity simultaneously.

## Conclusion

The outcome of the clinical trial performed demonstrates that the combined treatment with IPL, continuous RF, and ablative RF technologies yields a safe and effective combination treatment to address a few clinical indications simultaneously. The results were all statistically significant and no safety issues were recorded.

## Declaration of interest

Dr. Gold is a consultant and speaker for Invasix. The authors alone are responsible for the content and writing of the paper.

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