

# EndyMed 3DEEP Technology - Clinically Proven Results

EndyMed is proud of our commitment to clinically validate our claims that our 3DEEP™ technology provides superior results. Below are 4 clinical studies and one poster that were published in 2016, new additions to our extensive list of publications that prove that 3DEEP™ provides the best in RF treatments.

## **BODY CONTOURING AND SKIN TIGHTENING USING A UNIQUE NOVEL MULTISOURCE RADIOFREQUENCY ENERGY DELIVERY METHOD**

*Isabelle Rousseaux, MD • Sam Robson, MRCP*

**Objective:** The objective of this study was to examine the efficacy and safety of the latest multisource RF handpiece, specially designed for body area skin treatments. The new Shaper handpiece features six concentric electrodes, each connected to an independently controlled RF generator.

**Design and settings:** 25 patients were enrolled into the study. Patients underwent at least 5 sessions of body skin tightening and circumference reduction. The first 4 sessions were held at 1-week interval and the other 1-4 remaining sessions, at 2-weeks intervals.

**Participants:** 25 patients (23 women and 2 men).

**Measurements:** Overall change was graded by the physicians using GAIS assessment scale. Patients were asked to complete satisfaction questionnaires at the end of the treatment sessions. Images were taken prior to the treatments, before every treatment session and at the follow up visit.

**Results:** No adverse events were reported as a result of the treatment. 92% of the patients were pleased with the results and finished all the treatments sessions. 24 patients (96%) saw an improvement in body shape. 92% of the patients would recommend the treatment to others. Overall change graded by the physician by the GAIS assessment scale provided the following results:

44% of the patients had more than 75% improvement, 32% of the patients between 50% to 75% improvement, 20% of the patients had between 25% to 50% improvement and only 4% had less than 25% improvement.

**Conclusion:** Our data show that the Shaper Handpiece by Endymed Medical Ltd. provides high efficacy in skin tightening and body contouring after 5-10 painless treatments. Patient subjective questionnaires show very high satisfaction rates.

## **NON-INSULATED SMOOTH MOTION, MICRO-NEEDLES RF FRACTIONAL TREATMENT FOR WRINKLE REDUCTION AND LIFTING OF THE LOWER FACE: INTERNATIONAL STUDY**

*Michael Gold, MD, Mark Taylor, MD, Kenneth Rothaus, MD, Yohai Tanaka, MD*

**INTRODUCTION:** Skin aging occurs through both intrinsic and extrinsic processes. Fractional radiofrequency (RF) with a microneedling array is the newest form of fractional therapy to be useful in treating aging skin. The current study utilized a noninsulated fractional RF microneedling system.

**METHODS:** This multicenter clinical trial saw 49 patients complete 3 monthly treatments with the new fractional RF microneedling treatments and be followed for 3 months following their last treatment. Pain during treatment was recorded as well as overall improvement using a GAIS scale. Adverse events were also noted.

**RESULTS:** Forty-nine patients completed all of the treatments and follow-ups. Mild to moderate erythema were reported immediately after treatment which lasted up to 12 hours after the treatment. Pain, as measured on a 1-10 VAS, was noted to 4, on average. The average Fitzpatrick's wrinkle scale score at baseline was  $5.04 \pm 1.22$ , 1 month after 3 treatments  $3.829 \pm 1.69$  and 3 months after 3 treatments  $3.5 \pm 1.66$ . These results are statistically highly significant (correlated T-test,  $P < 0.001$ ). Improvement was shown in 100% of patients while 65% of patients had significant improvement (GAIS levels 3-5). Significant skin tightening and skin lifting were also observed. No unusual adverse events were noted throughout the course of the study.

**CONCLUSION:** This multicenter study showed significant wrinkle reduction, skin tightening, and lifting of the mid and lower face with the noninsulated fractional RF microneedling system. *Lasers Surg. Med.* 48:727-733, 2016. © 2016 Wiley Periodicals, Inc.

*Lasers Surg Med.* 2016 Oct;48(8):727-733. Doi: 10.1002/lsm.22546. Epub 2016 Aug 4.

## TREATMENT OF ACNE SCARS ON DARKER SKIN TYPES USING A NONINSULATED SMOOTH MOTION, ELECTRONICALLY CONTROLLED RF MICRONEEDLES TREATMENT SYSTEM

David Pudukadan, MBBS, MD

**BACKGROUND:** Noninvasive technologies for treating acne scars use radiofrequency (RF) emitting microneedles for both mechanical disruption of fibrotic strands and heat-mediated collagen remodeling.

**OBJECTIVE:** Efficacy and safety evaluation of electronically controlled noninsulated RF microneedling system on acne scars in patients with dark skin.

**METHODS:** Nineteen patients, 24 to 51 years old, skin types III to V, with acne scars were enrolled in the study. Each patient had 3 treatment sessions at monthly intervals using a multisource RF treatment platform with a microneedle RF applicator. Efficacy was evaluated by the Goodman and Barron's Global Qualitative Acne Scarring System.

**RESULTS:** No bleeding points occurred during treatments. Posttreatment erythema was observed immediately after the treatment and lasted up to 10 hours after the treatment. Improvement of at least 1 acne scar grade was noted in 11 of 19 patients (57.9%) after 1 month and in 9 of 9 patients (100%) after 3 months.

**CONCLUSION:** The tested noninsulated electronically controlled RF microneedles were found to be safe and efficient in the treatment of atrophic acne scars in skin types III to V with minimal pain or downtime.

## COMBINATION OF MICRONEEDLE RADIOFREQUENCY (RF), FRACTIONAL RF SKIN RESURFACING AND MULTI-SOURCE NON-ABLATIVE SKIN TIGHTENING FOR MINIMAL-DOWNTIME, FULL-FACE SKIN REJUVENATION.

H. Kaplan, MD, L. Kaplan

**BACKGROUND:** In the recent years, there is a growth in demand for radiofrequency (RF)-based procedures to improve skin texture, laxity and contour. The new generation of systems allow non-invasive and fractional resurfacing treatments on one platform.

**OBJECTIVE:** The aim of this study was to evaluate the safety and efficacy of a new treatment protocol using a multisource RF, combining 3 different modalities in each patient: [1] non-ablative RF skin tightening, [2] fractional skin resurfacing, and [3] microneedling RF for non-ablative coagulation and collagen remodeling.

**METHODS:** 14 subjects were enrolled in this study using EndyMed PRO™ platform. Each patient had 8 non-ablative treatments and 4 fractional treatments (fractional skin resurfacing and Intensif).

**RESULTS:** The global aesthetic score was used to evaluate improvement. All patients had improvement in skin appearance. About 43% had excellent or very good improvement above 50%, 18% had good improvement between 25 and 50%, and the rest 39% had a mild improvement of < 25%. Downtime was minimal and no adverse effect was reported.

**CONCLUSIONS:** Our data show significant improvement of skin texture, skin laxity and wrinkle reduction achieved using RF treatment platform.

*J Cosmet Laser Ther. 2016 Oct 5:1-4*

Poster presented by Dr. David Pudukadan at the 2016 EADV Congress in Vienna.

Using the ENDYMED PRO and our RF Fractional Resurfacing technology, Dr. Pudukadan's study showed significant improvement in his subjects, with minimal treatment downtime.

### SIGNIFICANT REDUCTION IN DYSCHROMIA AFTER MULTISOURCE RADIOFREQUENCY FRACTIONAL SKIN RESURFACING TREATMENTS IN SKIN TYPE V

David Pudukadan, MBBS MD, Board Certificate Dermatologist, Associate Professor Jubilee Mission Medical College, Thrissur, India.

#### Background and objectives

Facial Dyschromia are a common concern especially among women and persons of color. Dyschromia can cause psychological and emotional distress and can affect the patients' quality of life. In this preliminary study, we evaluated, for the first time, the safety and efficacy of "color blind" ablative fractional RF resurfacing for the treatment of facial dyschromias in skin type V patients.

#### Materials and Methods

Five patients, with a mean age of 33.6 years, with face and neck hyper pigmentation, were treated with ablative fractional RF resurfacing. The treatment included 3 treatment sessions with 2 weeks interval. Forehead, Cheeks and Neck areas were treated with high parameters (30msX6W). 2 weeks after 3 treatments, Melanin and color homogeneity were compared to baseline. Patients and physician satisfaction was assessed after the treatments.

#### Results

Patients experienced mild pain during the treatment and minor downtime including transient erythema that lasted a few hours. Micro crusts were visible for up to 5 days. Beneficial epidermal effects were noted as early as 1 week after the first treatment. Physician assessment of face and neck pigmentation, 2 weeks after 3 treatments, showed improvement of 70% compared to baseline. Patient satisfaction was similar (70% completely satisfied). Majority of patients would recommend this treatment to friends (65% definite yes).

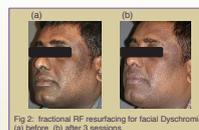


Fig 2: fractional RF resurfacing for facial Dyschromia (a) Before (b) After 3 sessions

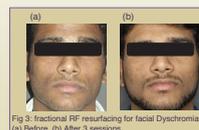


Fig 3: fractional RF resurfacing for facial Dyschromia (a) Before (b) After 3 sessions

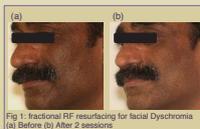


Fig 1: fractional RF resurfacing for facial Dyschromia (a) Before (b) After 2 sessions

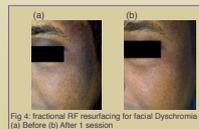


Fig 4: fractional RF resurfacing for facial Dyschromia (a) Before (b) After 1 session

#### Conclusions

This pilot study is the first evidence for a possible clinical solution to Dyschromia for dark skinned patients, using ablative fractional RF treatment. The results show significant improvement in skin condition with minimal downtime. Ablative treatments with RF technology allows removal of the micro zones of the epidermis without damaging the dermal epidermal junction. At the same time, this system provides deep volumetric heating effecting the underlying collagen and promoting neocollagenesis. Although fractional lasers are commonly used for skin resurfacing, the risks in dark skin treatments are significant. In fractional RF treatments, pain and downtime can be managed and reduced using potent numbing cream with higher concentrations of active anesthetic substances. Further studies are required to investigate the mechanism and safety of these treatments.