Summary of Peer-reviewed Articles for Various Clinical Indications
April 2016
Various Clinical Indications

- Atrophic acne scars and acne
- Photo-aged skin, pigmentation & hyperpigmentation
- Striae
- Leg veins, including: telangiectasias, venulectases & reticular veins
- Hair removal
Successful removal of freckles with the bipolar radiofrequency and optical energy.


STUDY DETAILS
- 30 patients (11 males, 19 females) with mean age 24.2±7.8 years (range 20–45) and Fitzpatrick skin types I–III with freckles
- 4 treatments at 3-week intervals with SR applicator, using RF energy (20-25 J/cm²) and IPL (15-20 J/cm²)
- Freckles area and severity index (FASI) scales were used by the investigator to assess improvement at 12 weeks and 1 year after final treatment.

RESULTS AT 12 WEEKS AND 1 YEAR AFTER FINAL TREATMENT
- 83% at Week 12 and 70% at Week 52 of the subjects had excellent or good improvement
- 88% at Week 12 and 76% at Week 52 of the patients reported that they were extremely or very satisfied
- Mean improvement rate (difference in mean FASI score) was 70% at 12 weeks and 66% at 12 months.
- No blistering, crusting and pigmentary changes occurred during the study.
Figure 1. A 24-year-old woman with extensive freckles

Before

1 year later showing excellent clearance
High versus moderate energy use of bipolar fractional radiofrequency in the treatment of acne scars: a split-face double-blinded randomized controlled trial pilot study

STUDY DETAILS
• 30 subjects (17 males, 13 females) with mild to moderate atrophic acne scars
• Left and right facial sides were randomly assigned for different energy (moderate energy of 60 mJ/pin or high energy of 100 mJ/pin)
• 4 bipolar fractional RF treatments at 1-month intervals
• Assessment of global acne scarring score (GASS) for each facial side (dermatologist blinded to treatment energy).

RESULTS AT 1, 3 & 6 MONTHS AFTER TREATMENT
• Mean GASS of high energy side and moderate energy side was significantly reduced at 1-, 3-, and 6-month follow-up visits (p<0.001).
• Similar rate of PIH on both sides with most cases mild to moderate in intensity and spontaneously resolved within 4 weeks.
Minimal energy eMatrix treatment combined with elure application for an expedited response in the treatment of hyperpigmentation and overall facial skin rejuvenation: A case report series.

STUDY DETAILS

• 5 Caucasian females (age range 46-76 years) with varying degrees of facial skin damage
• 3 monthly treatments: 2 passes on the entire face (excluding periorbital and perioral regions) & 3 separate passes on the periorbital and perioral regions using low energy (25 mJ/pin) bipolar fractional RF
• Topical application of a hydroquinone-free product containing lignin peroxidase (elure cream) immediately after each treatment and at home twice daily
• Assessment of global acne scarring score (GASS) for each facial side (dermatologist blinded to treatment energy).

RESULTS AT 1 MONTH AFTER EACH TREATMENT

• Noticeable improvement in skin brightness, wrinkles & skin texture after 1st treatment
• Marked reductions in erythema and fading of blemishes & solar lentigines
• Minimal, transient swelling & blistering (<1 week) in 2 patients.
Evaluation of the efficacy and safety of fractional bipolar radiofrequency with high-energy strategy for treatment of acne scars in Chinese

STUDY DETAILS
• 26 Asian patients with acne scars
• 4 monthly (85-95mj/pin) treatments with fractional bipolar RF
• Improvement and tolerance evaluated at each treatment and at the 4-week and 12-week follow-up visit.

RESULTS AT 1 and 3 MONTHS AFTER TREATMENT
• Acne score showed a **significant decrease** at 4-week and 12-week follow-up visits
• **Patient evaluation of global improvement and satisfaction increased** at the 12-week visit compared with baseline
• Side effects were limited to transient pain, erythema, dryness and low risk of PIH (less than with fractional lasers).
Clinical evaluation of the efficacy and safety of fractional bipolar radiofrequency for the treatment of moderate to severe acne scars


STUDY DETAILS

• 12 patients (Skin Type I-III) with moderate to severe acne scars
• 3–5 treatments with Sublative fractionated bipolar RF at 1-month intervals
• Evaluated clinically and photographically at each visit and 3 months after the final treatment.

RESULTS AT 3 MONTHS AFTER FINAL TREATMENT

• Very good improvement (at least one scale) after completing treatment
• 100% patient satisfaction (Global Aesthetic Improvement Scale scores) with 50% patients reporting “Very satisfied”
• Mild and transient expected erythema and minimal scab formation in the treated areas
• No adverse events.
Clinical studies of the treatment of facial atrophic acne scars and acne with a bipolar fractional radiofrequency system

STUDY DETAILS
• 23 Japanese patients with atrophic acne scars and mild to severe acne on both cheeks
• 5 fractional RF treatments at 1-month intervals
• Assessments of scar severity and the number of acne lesions and 3-D in vivo imaging analysis at 3 months after final treatment

RESULTS AT 3 MONTHS AFTER TREATMENT
• Improvement in scar volume was marked in patients with mild scars
• Moderate or > improvement in 56% of treated areas
• Significantly fewer lesions compared with baseline
• Patient assessment of treatment outcomes improved significantly
• Patient assessment of Quality of Life (QOL) improved significantly
• Significant reductions in sebum levels, skin roughness & scar depth.
Histological studies of facial acne and atrophic acne scars treated with a bipolar fractional radiofrequency system


STUDY DETAILS
• 6 subjects with atrophic acne scars and acne vulgaris
• Histological studies to compare one vs. two passes with fractional RF

RESULTS AFTER TREATMENT
• 2-pass treatment created deeper dermal thermal injury zones compared to 1-pass treatment
• Collagen was coagulated in the sebaceous glands and periangnexal structures after 2-pass treatment
• No severe side-effects were observed after treatment
• Large benefit is the preservation of adnexal structures.
Objective evaluation of the clinical efficacy of fractional radiofrequency treatment for acne scars and enlarged pores in Asian skin


STUDY DETAILS

• 31 patients (Asian skin types III and IV)
• 4 fractional RF treatments at 3-week intervals
• 2 physicians - blinded assessment of photos
• Biophysical measurements of elasticity and color
• Histological changes

RESULTS AT 3 MONTHS AFTER TREATMENT

• Significant improvements in: elasticity & melanin/erythema index
• Significant increase in collagen
• Average score of 3 (51-75%) for overall improvement
• Physician assessments showed improvement in smoothness of the scars, pore size & brightness
• 100% of patients reported satisfaction and improvement
• No pigmentation or other side effects.
Treatment of acne scars of skin types II to V by sublative fractional bipolar radiofrequency and bipolar radiofrequency combined with diode laser

STUDY DETAILS
• 20 patients (skin types II-V) with acne scars and without acne lesions
• Up to 5 Sublative fractional bipolar RF and bipolar RF combined with diode laser treatments at 4-week intervals
• Visual assessment of treatment areas at 4 and 12 weeks after treatment with Goodman Scar Scale

RESULTS AT 4 AND 12 WEEKS AFTER TREATMENT
• Scar grading was significantly reduced from baseline after 3 treatments
• **Scar grading was significantly reduced** from a median baseline score of 15 to 9.5 and 9 at the 4-week and 12-week follow-ups, respectively
• **Scar texture was significantly improved** at follow-ups
• 63% of subjects reported moderate improvement at 12 weeks
• No ulcerations, scars, infections or pigmentation changes noted.
Treatment of acne scars by fractional bipolar radiofrequency energy


STUDY DETAILS

• 10 females (skin types I-V) with mild to moderate acne scars
• 3 monthly fractional bipolar RF treatments
• Physician-assessed acne scar severity by ECCA grading scale
• Physician assessment of cosmetic appearance
• Patient satisfaction and improvement

RESULTS AT 3 MONTHS AFTER TREATMENT

• 90% of subjects showed improvement in cosmetic appearance
• Significant reduction in the median ECCA scar grading scale compared to baseline
• Subject-assessed fine lines and wrinkles, brightness, tightness, acne scar texture, pigmentation were all improved significantly
• High patient satisfaction
• Transient erythema and no lasting side effects.
There is a demand for noninvasive methods for skin tightening, wrinkle reduction & body contouring.

- Fractional bipolar RF is a newer non-ablative approach
- An array of micro-needles delivers bipolar RF energy to specific depths in tissue
- Fractionated zones of thermal damage to deep dermal collagen
- Induce wound healing, dermal remodeling and new collagen, elastin, and hyaluronic acid formation

- Achieve desired cosmetic results for wrinkle reduction, tissue tightening, and body contouring.
Electro-optical Synergy Technique
A New and Effective Nonablative Approach to Skin Aging


STUDY DETAILS
• 6 subjects (skin types III-IV) with Glogau class I to II wrinkles
• 6 sessions at 2-week intervals
• Standard photographs and skin biopsies assessed at 3 months after treatment

RESULTS AT 3 MONTHS AFTER TREATMENT
• Statistically significant increase in collagen types I, III, and VII
• Statistically significant increase in newly synthesized collagen
• Statistically significant increase in tropoelastin (new elastic fibers)
• Noticeable improvement in periorbital wrinkles, skin tightening, and texture at the end of treatment with continued improvement at 3 months.
Sublative rejuvenation - fractional bipolar RF is a newer non-ablative approach
- Minimal epidermal disruption: 5% vs. 10-70% with fractional ablative laser treatments
- Deeper coagulation in the dermis
- Healing is rapid with minimal downtime
- Appropriate for all skin types
- Improves the appearance of abdominal striae
- Unique benefit that also diminishes telangiectasia associated with acne scarring & within striae

Achieve desired cosmetic results for wrinkle reduction, tissue tightening, and body contouring.
Skin rejuvenation and wrinkle reduction using a fractional radiofrequency system


STUDY DETAILS
• 35 subjects (skin types II-IV) with mild to moderate facial wrinkles
• 3 monthly fractional bipolar RF treatments to entire face or at least 2 facial subareas
• Blinded physician assessment of skin texture and wrinkle appearance

RESULTS AT 1 MONTH AFTER TREATMENT
• 90% of subjects showed improvement in smoothness/wrinkling, 87% in skin tightness & 83% in skin brightness
• 80% of subjects were satisfied with treatment
• Only minimal discomfort (87% of patients) and No downtime
• No infections, scars, or postinflammatory pigmentary alteration
• Histologies showed complete tissue healing 2 days after treatment with denser, better organized collagen fibers.
The clinical experience and efficacy of bipolar radiofrequency with fractional photothermolysis for aged Asian skin

STUDY DETAILS
• 10 Japanese women (skin types III-IV) with photo-aged skin
• 3 fractional bipolar RF treatments every 4-6 weeks
• Physician assessment of photos for wrinkles and sagging skin
• Patient satisfaction and improvement

RESULTS AT 2 MONTHS AFTER TREATMENT
• Statistically significant improvement in average wrinkle scores for crow’s feet and lower eyelid
• 60% of the subjects showed good to excellent improvement in nasolabial sagging
• Similar improvements were observed in the subjective evaluations
• Mild erythema and edema with no PIH or other lasting side effects
• Patients were satisfied with treatment.
Safety and efficacy of fractional bipolar radiofrequency treatment in Fitzpatrick skin types V-VI


STUDY DETAILS

• 15 females (skin types V, VI) with wrinkles, texture and fine lines
• 3 monthly fractional bipolar RF treatments to full face
• 2 blinded physician assessments: Fitzpatrick Scale of Wrinkling and Elastosis (FWS) & Global Aesthetic Improvement (GAI) Scale
• Patient satisfaction and improvement

RESULTS AT 3 MONTHS AFTER TREATMENT

• 87% of subjects showed improvement in tone, texture, fine lines and wrinkle reduction (as reported by investigator #2)
• Safe treatment of Fitzpatrick skin types V & VI
• No adverse events, particularly no post inflammatory hyperpigmentation or hypopigmentation.
Combined infrared light and bipolar radiofrequency for skin tightening in Asians


STUDY DETAILS
• 19 Chinese patients (skin types III-V) with facial laxity and periorbital rhytides
• 3 treatments at 3-week intervals with combined IR and RF energies
• Blinded assessment of photos
• Patient satisfaction and improvement

RESULTS AT 3 MONTHS AFTER TREATMENT
• Statistically significant improvement in skin laxity in cheek, jowl and nasolabial area
• **89.5% of the subjects reported moderate to significant subjective improvement in skin laxity**
• Subjective improvement in skin laxity was noted in all patients after the 1\textsuperscript{st} treatment
• Transient erythema and edema with no PIH or lasting side effects.
Prospective study on combination diode laser and radiofrequency energies (ELOS) for the treatment of leg veins


STUDY DETAILS

- 25 patients (Fitzpatrick skin types I-IV)
- 35 sites (0.3-5.0 mm vessel diameters)
- Up to 3 sessions at 4- to 10-week intervals
- 80-140 J/cm² diode laser, 80-100 J/cm³ RF, 100-300 ms pulses
- Vessel clearance graded by treating and an independent physician.

RESULTS AT 1 MONTH AND 6 MONTHS AFTER TREATMENT

- ~77% of treatment sites exhibited 75-100% vessel clearance
- 90% had 50-100% vessel clearance
- Safe & effective treatment for leg veins, including telangiectasias, venulectases & reticular veins.
Hair removal using a combination radio-frequency and intense pulsed light source


STUDY DETAILS
• 69 treated patients (all Fitzpatrick skin types I-VI)
• Dark and light hair: blond, brown and black
• 1 elōs treatment to body or face
• Blinded hair counts at 3-months after treatment

RESULTS AT 3 MONTHS AFTER TREATMENT
• 43% patients achieved a >50% decrease
• Average arm results showed 65% reduction after a single treatment
• Safe treatment of all skin types, including dark skin types.
Peer-reviewed Article Conclusions about elōs Plus Treatment

- **Safe & effective** treatment option for various clinical indications:
  - Photo-aged skin & hyperpigmentation
  - Acne scars & diminishes telangiectasia
  - Skin laxity
  - Abdominal striae & improvement of telangiectasia within striae
  - Leg veins, including telangiectasias, venulectases & reticular veins
  - Hair removal

- **Safe treatment** for all skin types
- High satisfaction rate
- Little to no downtime
- Minimal & transient side effects.
- **Safe & quicker treatment** with enhanced energy treatment strategy.