PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL INTRALESIONAL FRACTIONAL RADIOFREQUENCY DEVICE FOR DEEP DERMAL HEATING OF FACIAL SKIN

Nark-Kyoung Rho, Jeong-Yeop Lee, Soohong Kim, Kyung-Ae Jang, Seok-Beom Park

PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL INTRALESIONAL FRACTIONAL RADIOFREQUENCY DEVICE FOR DEEP DERMAL HEATING OF FACIAL SKIN

Nark-Kyoung Rho, Jeong-Yeop Lee, Soohong Kim, Kyung-Ae Jang, Seok-Beom Park

Leaders Aesthetic Laser & Cosmetic Surgery Center, Seoul, Korea

Summary

Background and Objectives

- To evaluate the clinical efficacy and safety of a novel intralesional fractional radiofrequency device for deep dermal heating.

Study Design and Methods

- The device used for the study:

  -Equipped with a treatment tip of 25 non-insulated radiofrequency insertion needles in 1 square centimeter.
  - The range of needle penetration depth was from 0.5 mm to 3.5 mm in 0.1 mm increment.

- Histologic study using animal skin was performed before clinical trial.

- Study population: 30 Korean patients
- Standard protocol (varies depending on the treatment area)
  -a full-face treatment
  - a vertical insertion of the RF needles
  - 0.8-3.0 mm of penetration depth
  - 7-9 level of RF energy (arbitrary scale)
  - 100-200 milliseconds of pulse duration,.

- Before treatment, topical anesthetic cream was applied for 30 minutes.

- Patients were evaluated 1 day, 7 days and 1 month, and 2 months after the procedure.

Results

- The treatment was well-tolerated in all subjects.

- Immediate posttreatment erythema and edema were evident in all subjects; however, these resolved spontaneously within an hour.

- Barely noticeable microcrusts in a fractional pattern, mainly on the lateral cheek area, developed 1-2 days after treatment and spontaneously resolved after 7-8 days.

- Clinical improvement at the 1 month follow-up::

  - Skin tone and pigmentation (93%)
  - Prominent facial pores (87%)
  - Fine winkles (77%)
  - Midface laxity (70%)
  - Mentolabial folds (63%)
  - Nasolabial folds (57%)

- After 3 months, mild improvement of acne scarring was noticed in some subjects.

- Interestingly, facial flushing and rosacea improved in 3 subjects.

- No serious side effects were noticed.

Conclusion

- Intralesional deep dermal heating by fractional radiofrequency was found to be effective and safe treatment for the facial rejuvenation in Koreans.

References

1. Hantash BM, Renton B, Berkowitz RL, Stridde BC, Newman J. Pilot clinical study of a novel minimally invasive bipolar microneedle radiofrequency device. Lasers Surg Med. 2009;41:87-95.

2. Berube D, Renton B, Hantash BM. A predictive model of minimally invasive bipolar fractional radiofrequency skin treatment. Lasers Surg Med. 2009;41:473-8.

3. Alexiades-Armenakas M, Rosenberg D, Renton B, Dover J, Arndt K. Blinded, randomized, quantitative grading comparison of minimally invasive, fractional radiofrequency and surgical face-lift to treat skin laxity. Arch Dermatol. 2010;146:396-405.

4. American Society for Laser Medicine and Surgery 30th Annual Conference Phoenix, Arizona, April 16-April 18, 2010 (abstracts)

Disclosure

No significant interest with commercial supporters.

PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL INTRALESIONAL FRACTIONAL RADIOFREQUENCY DEVICE FOR DEEP DERMAL HEATING OF FACIAL SKIN

Nark-Kyoung Rho, Jeong-Yeop Lee, Soohong Kim, Kyung-Ae Jang, Seok-Beom Park

PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL INTRALESIONAL FRACTIONAL RADIOFREQUENCY DEVICE FOR DEEP DERMAL HEATING OF FACIAL SKIN

Nark-Kyoung Rho, Jeong-Yeop Lee, Soohong Kim, Kyung-Ae Jang, Seok-Beom Park

Leaders Aesthetic Laser & Cosmetic Surgery Center, Seoul, Korea

Background and Objectives

Limitations of the current fractional laser resurfacing devices

- Downtome (erythema, swelling, pain, PIH)
- Limited penetration depth

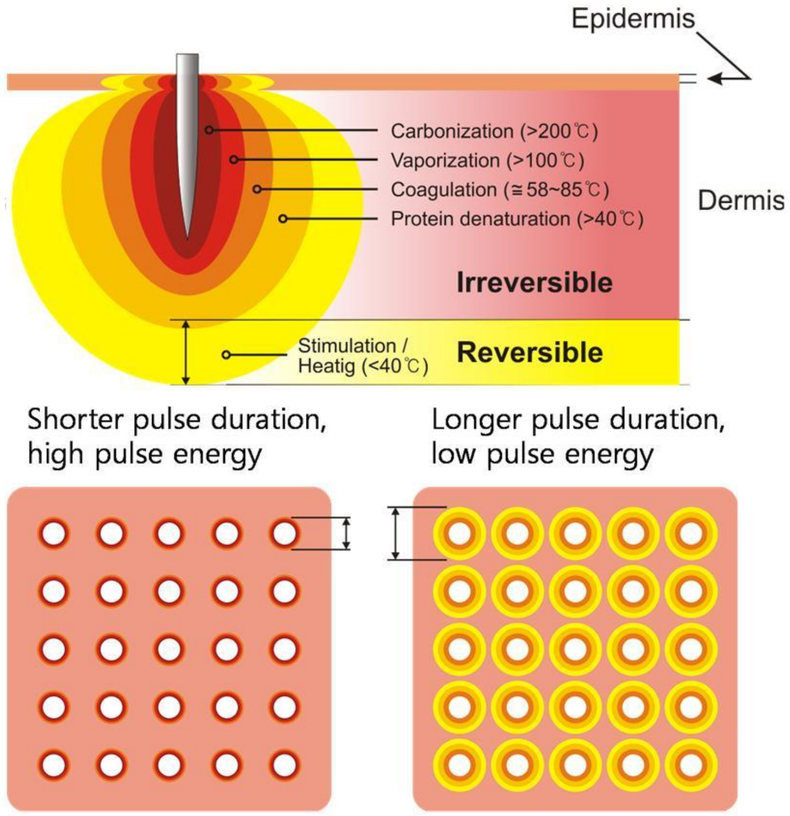
Fractional devices other than lasers

- Fractional ultrasound
  - Ulthera™ (Ulthera Inc.)
- Noninvasive:bipolar RF
  -eMatrxi (SublativeRF)™ (Syneron, Israel)
- Minimally invasive (intralesional) RF
  - Intracel™ (Jeisys, Korea)
  - ScarLet™ (VIOL medical, Korea)
  - ePrime(Miratone)™ (Syneron, Israel)

Advantages of minimally invasive, intralesional RF resurfacing

- Deeper penetration depth (up to 3 mm)
  - Improved clinical efficacy
  - Newer indications (skin laxity, seborrhea, acne, etc.)
- Minimal epidermal damage

→ less downtime, minimal complication



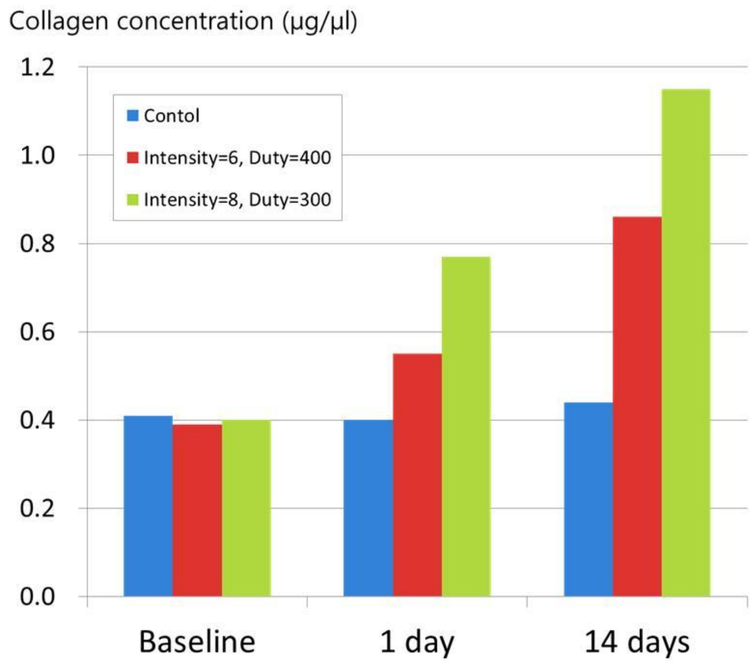
Illustrated mechanism of action of a novel minimally invasive, intralesional unipolar radiofrequency device (Scarlet™, VIOL, Korea)

Rationale of the treatment

- RF thermal injury of deeper dermis induces wound healing process leading to dermal remodeling and the generation of new collagen and extracellular matrix.
- Too vigorous wound healing may lead to the unwanted effects, e.g. prolonged erythema or scarring, thus fractional delivery of RF energy is required

Animal study

- Various combinations of RF "Intensity" (pulse energy) and "Duty" (pulse duration) were applied on the mouse back skin.
- Under the same fluence condition, pulse energy level of 6-8 and pulse duration of 200-400 μs was the most effective parameter for neocollagenesis.



Study Objectives

- The aim of the study was to evaluate the clinical efficacy and safety of a novel intralesional fractional radiofrequency device for deep dermal heating on Korean subjects.

PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL INTRALESIONAL FRACTIONAL RADIOFREQUENCY DEVICE FOR DEEP DERMAL HEATING OF FACIAL SKIN

Nark-Kyoung Rho, Jeong-Yeop Lee, Soohong Kim, Kyung-Ae Jang, Seok-Beom Park

PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL INTRALESIONAL FRACTIONAL RADIOFREQUENCY DEVICE FOR DEEP DERMAL HEATING OF FACIAL SKIN

Nark-Kyoung Rho, Jeong-Yeop Lee, Soohong Kim, Kyung-Ae Jang, Seok-Beom Park

Leaders Aesthetic Laser & Cosmetic Surgery Center, Seoul, Korea

Study Design and Methods

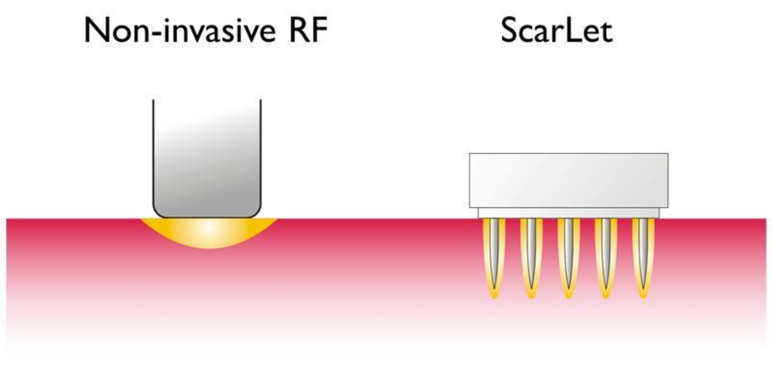
Overview

- Between July 2010 and October 2010, a single-center, non-blinded, prospective clinical trial involving 30 Korean patients was conducted using a novel minimally invasive RF device.

RF System Used (ScarLet™)

- Manufactured by VIOL Medical, Inc., Korea
- A minimally invasive, intralesional RF system

Specifications	
NEEDLE DEPTH	0.5 mm - 3.5 mm (increment: 0.1 mm)
RF CONDUCTION TIME	100 ms ~ 800 ms (increment: 100msec)
RF OUTPUT	1.5 ~ 200 V
RF ENERGY FIELD WIDTH	82 mm^2 at 1 mm depth
RF FREQUENCY	2 MHz
ELECTRODE NO.	25 pins per stamp
STAMP SIZE	1 cm^2



Non-invasive vs. minimally invasive RF devices (comparison of RF energy fields)

Treatment Protocol

Skin preparation & topical anesthesia

- Skin preparation with gentle cleanser to remove debris and makeup.
- A cream containing mixture of lidocaine 2.5% and prilocaine 2.5% was applied under occlusion for 30 minutes.

RF treatment

- Facial/neck skin was wipe-dried (no gel)
- Pulse energy levels ("Intensity") ranging from 6 to 8, pulse duration ("On Time") of 100-200 μs, and the penetration depths of 0.8-3.0 mm were applied according to the treatment regions.
- Icepack cooling and LED irradiation was applied to all patients immediately after treatment.
- All patients received follow-up 1 day, 7 days, 4 and 8 weeks after treatment for photographic documentation objective and subjective clinical evaluation, and side effect check up.

Area	Penetration depth (mm)	Intensity level	Pulse duration (μsec)
• Forehead • Upper eyelids • Lower eyelids	0.8-1.0	7	100
• Temples • Periorbital area • Nose (dorsum)	1.5	7	200
• Malar • Nose (alar parts)	2.0	7	200
• Buccal area • Chin • Submental area	3.0	8	200

- Outcome measures include:
  - Skin tone and texture
  - Prominent pores
  - Face and neck laxity
  - Seborrhea and acne
  - Telangiectasia

- Side effects evaluated includes: prolonged pain/edema/erythema, petechiae, pigmentary alterations, paresthesia, acneiform eruption, severe dryness, dermatitis, etc.

Handpiece tip with 25 pins/stamp

System used in the study

Control panel

PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL INTRALESIONAL FRACTIONAL RADIOFREQUENCY DEVICE FOR DEEP DERMAL HEATING OF FACIAL SKIN

Nark-Kyoung Rho, Jeong-Yeop Lee, Soohong Kim, Kyung-Ae Jang, Seok-Beom Park

PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL INTRALESIONAL FRACTIONAL RADIOFREQUENCY DEVICE FOR DEEP DERMAL HEATING OF FACIAL SKIN

Nark-Kyoung Rho, Jeong-Yeop Lee, Soohong Kim, Kyung-Ae Jang, Seok-Beom Park

Leaders Aesthetic Laser & Cosmetic Surgery Center, Seoul, Korea

Results and Conclusion

Results

Demographic data (n=30)

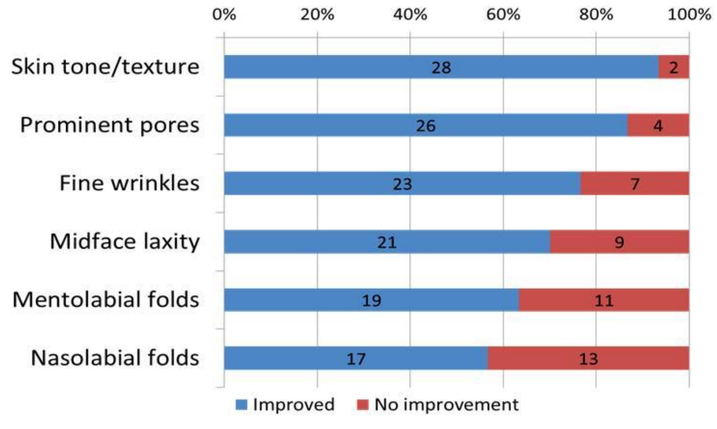
- Gender: 21 females and 9 males
- Age: 22~51 years (mean 36.3)
- Skin phototype III~IV
- Primary concerns: prominent pores, fine wrinkles, irregular skin tone, mild-moderate skin laxity, acne scarring
- Other concerns: active acne, rosacea and/or facial flushing

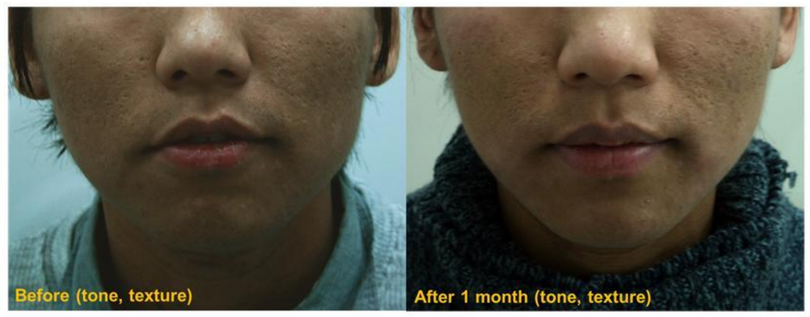
Treatment pain, erythema, edema, crusting

- Intraoperative pain
  - Well-tolerated by topical anesthetic cream
  - Most painful sites: near sensory nerve openings (supraorbital and infraorbital) and alar groove
  - Use of forced cold air was very helpful to distract the treatment pain
- Postoperative erythema and edema
  - Observed in all subjects immediately after treatment
  - Edema: resolved spontaneously after 2-3 hours
  - Erythema: tended to resolve within 24 hours (very rapid)
- Microcrusts
  - Observed in all subjects
  - Develop 2 days after treatments
  - Barely noticeable; may be prominent in the lateral cheek area
  - Spontaneously resolve within 10 days

Pre-, immediately after, 2 & 7days after treatment

Clinical improvement





Improved skin tone and texture. Lower face contour looks better. However, no significant acne scarring is noticed.

Interestingly, rosacea improved in 3 subjects.

Conclusion

- Intralesional deep dermal heating by fractional radiofrequency was found to be effective and safe for the facial rejuvenation in Koreans.
- Under conservative settings, this devices can be safely and effectively used for skin tone, texture, fine wrinkles and facial pores.
- To achieve significant scar remodeling and face lifting effect, more aggressive parameters and/or repeated treatment sessions may be required.
- Improvement of rosacea is interesting; further studies are required.