The use of microneedle fractional radiofrequency system in wrinkle reduction and skin tightening

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Introduction

Wrinkles and fine lines are symptoms of skin aging.

- Due to epidermal atrophy and degeneration of dermal collagen and elastic fibers

Treatments for wrinkle reduction

- Surgical reconstruction
  - Face lifting
- Non-surgical wrinkle reduction
  - Chemical peeling
  - Dermabrasion
  - Laser treatment
    Ablative laser
    Non-ablative laser
  - Radiofrequency (RF) device

Radiofrequency (RF) device

- Non-invasive, non-laser-based energy delivery
- Exploits the healing power of the healthy tissue reserve surrounding the zones of treatment
- Dynamic remodeling of collagen and elastin

Laubach HJ et al. Lasers Surg Med 2006;38:142-9.

Bipolar RF with microneedle electrode assembly

- Controlled radiofrequency thermal zones (RFTZ) are deposited in the dermis.
- Fractional radiofrequency (FRF) system
  -Capable of achieving fractional and contiguous treatment patterns
  -Spares the epidermis and key adnexal structures

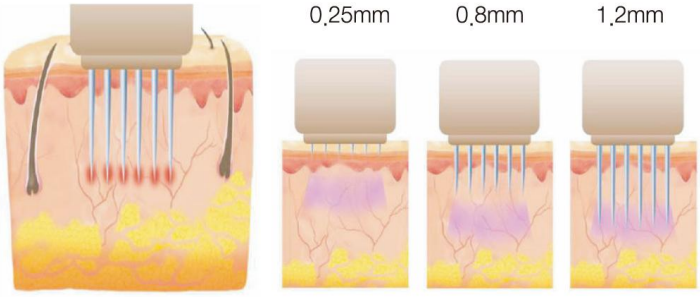
Basil M et al. Lasers Surg Med 2009;41:1-9.

Possible indications for fractional radiofrequency (FRF) and microneedle radiofrequency (MRF) system

- Simple skin rejuvenation
- Skin tightening
- Improving skin laxity and textures
- Wrinkle reduction
- Acne treatment

Fractional MRF device

- Scarlet®, VIOL Corporation, Seongnam, Korea
- Combination of RF and microneedle therapy system (MTS)
- Adjustable fluence (maximum of 185 J/cm2)
- A depth control (0.5 mm - 3.5 mm) with interval of 0.1 mm
- Tighten wrinkles, correct skin laxity and texture in aged skin



Objective

To assess the safety and efficacy of MRF surgical and stimulating unit (Scarlet®) in the treatment of Korean patients concerning wrinkles

Methods

Fractional MRF device

- Scarlet®, VIOL Corporation, Seongnam, Korea
- Topical anesthetic cream (EMLA, AstraZeneca, Sweden) was applied 30 minutes before the treatment

Standard treatment protocol

- Penetration depth: 0.8~3.5mm
  - Forehead: 1.5~1.8mm
  - Cheek: 2.5~3.0mm
  - Periorbital: 0.8~1.2mm
- Intensity level: 7~9
- Conduction time: 200 ms
- 1~3 treatment
- Patients were evaluated before and 4 weeks after final treatment.

Study population (n=32)

- Gender: 29 female, 3 male
- Age: mean 54.5 (Range: 27-77)
- Skin phototype: III~IV

Subjective evaluations

Patients' overall satisfaction	
4	Extremely satisfied
3	Very satisfied
2	Satisfied
1	Acceptable
0	Unsatisfied

Objective evaluations

- Photographs
  - Baseline and four weeks after treatment
- Objective clinical assessments
  - Performed by two blinded dermatologists

Global Improvement Scale Score		
4	〉75%	Near total improvement
3	51-75%	Marked improvement
2	26-50%	Moderate improvement
1	0-25%	Minimal improvement or steady state
0		Worsened

Objective clinical assessments

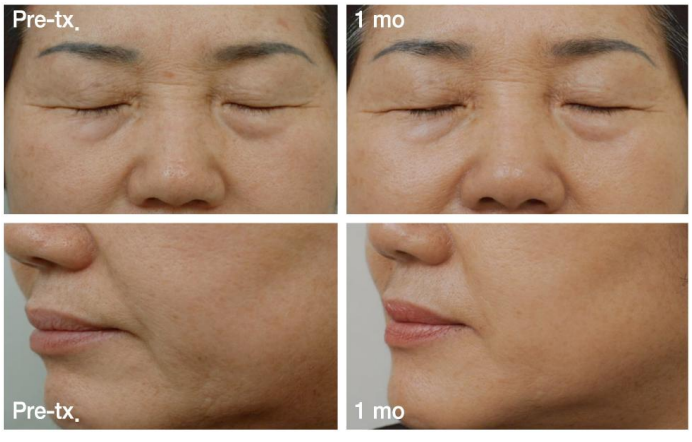
- Cutometer (Courage-Khazaka, KÖln, Germany)
- Corneometer (Courage-Khazaka, KÖln, Germany)
- Mexameter (Courage-Khazaka, KÖln, Germany)

Statistical Analysis

- Wilcoxon signed-rank test
- Statistical Package for the Social Sciences version 18.0 (SPSS Inc., Chicago, IL)

Results

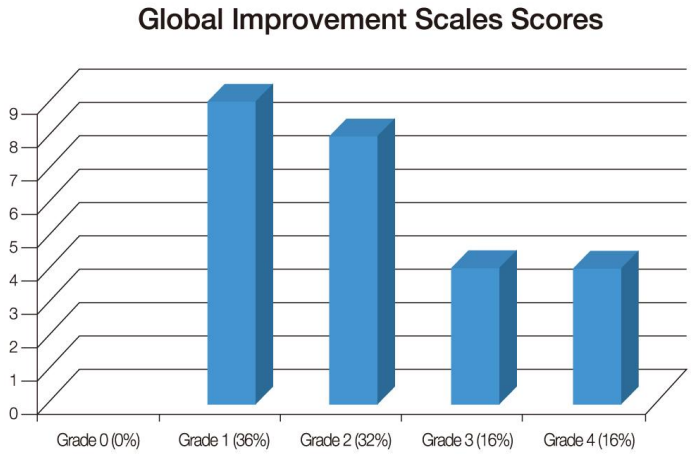
Case 1, F/64



Case 2, F/55

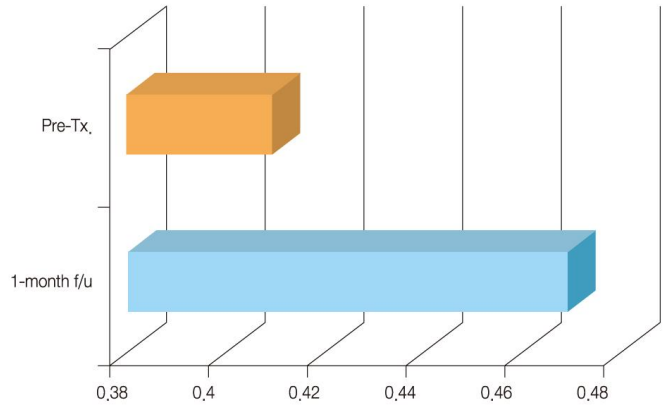
Objective clinical assessments

■ The mean grade of clinical improvement was 2.12 ± 0.27



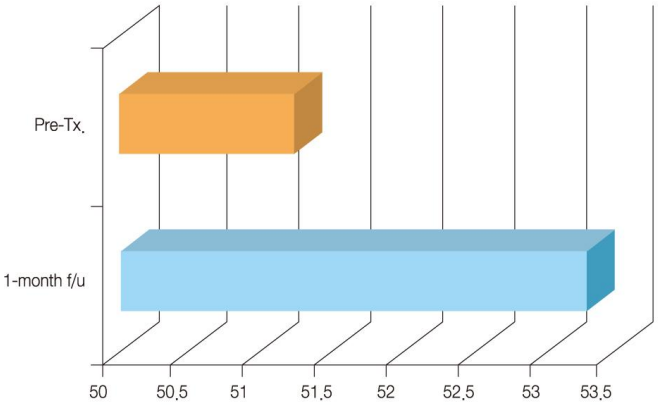
Grades of clinical improvement assessed by comparison of photos taken before a nd at the 1-mo. f/u with MRF surgical and stimulating unit (Scarlet®)

Cutometer



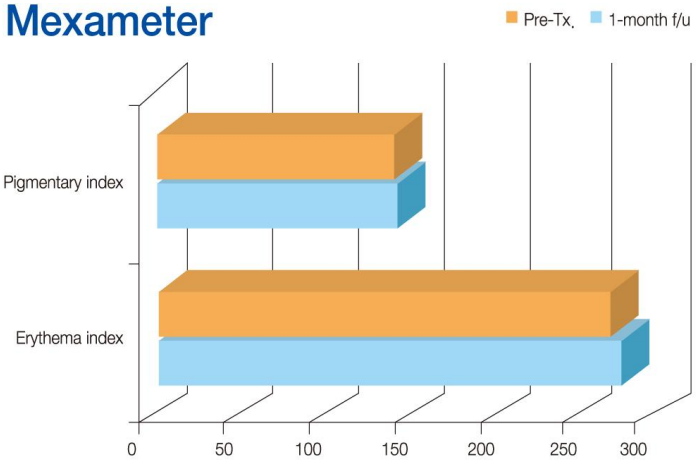
An increase in the measurement of the Cutometer from 0.41 to 0.47 (P〈0.05) was observed.

Corneometer



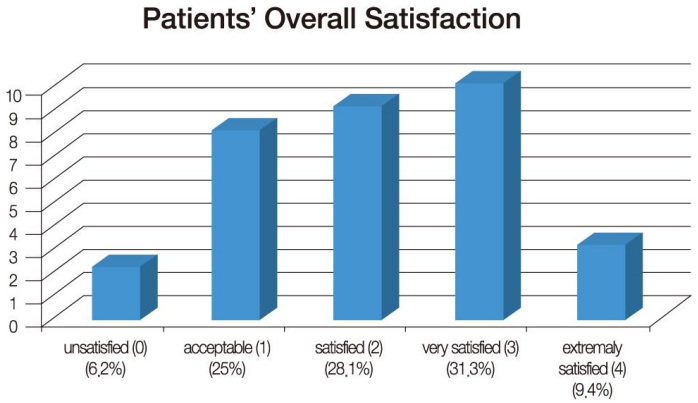
An increase in the measurement of the Corneometer from 51.3 to 53.3 (P〉0.05) was observed.

Mexameter



Increases in the measurements of the pigmentary and erythema indexes of the Mexameter from 118.7 to 121.5 and 270.1 to 276.8, respectively (P〉0.05) was observed.

Subjective clinical assessment



Grades of clinical improvement assessed by comparison of photos taken before and at the 1-mo. f/u with MRF surgical and stimulating unit (Scarlet®)

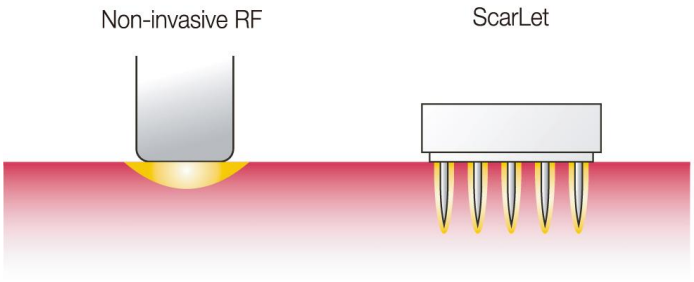
Side effects

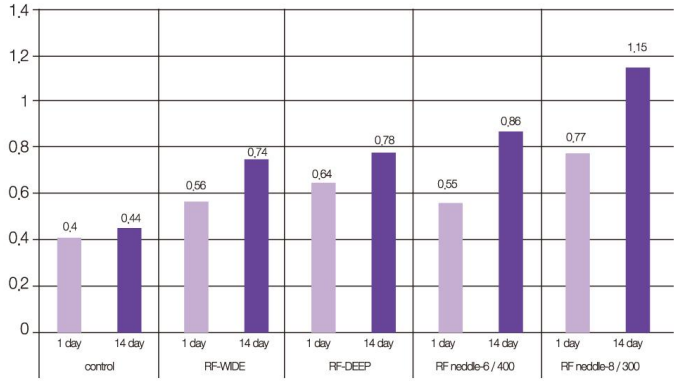
- During therapy
  - Pain - well tolerated by all patients (100%)
- Post-therapy
  - Edema/erythema
    observed in all patients (100%),
    resolved spontaneously within 3-5 days
  - Minimal bleeding episodes
    observed during and after the treatment in some patients
    resolved spontaneously within hours
- Transient hyperpigmentation (n=1, 3.1%)
- Transient edema, microneedle insertion area (n=1, 3.1%)

Discussion

- Compared to the conventional RF units, MRF surgical and stimulating unit brings longer treatment effect duration, by achieving more total increase in collagen-neogenesis.

Basil M. Hantash, et al. Lasers Surg Med 2009;41:87-95.





- Both elastin and collagen can be regenerated post-FRF using a bipolar microneedle delivery system.
  - Active dermal remodeling after MRF
  - Neoelastogenesis together with collagen reproduction

Basil M et al. Lasers Surg Med 2009;41:1-9.

- Fractional MRF has many advantages in dermatologic treatment due to its short downtime and possible aid to the absorption of other dermatologic drugs.

Laubach HJ et al. Lasers Surg Med 2006;38:142-9.

- Notably short duration of post-therapy edema and erythema is the strong point of MRF, compared to the conventional laser treatment and ordinary FRF.

Shlomit Halachmi et al. J Cos and Laser Ther 2010;12:208-12.

- In our study, post-therapy edema and erythema lasted for only 3-5 days → significantly reduced downtime compared to ablative fractional laser (average of 1 week)

Karsai S et al. Lasers Surg Med. 2010 Feb;42(2):160-7.

- More clinical evidences accompanying proper animal studies to set the optimal treatment guidelines are required.
  - To set the intensity, duty and depth for various anatomic areas
  - To assess its effect of significant scar remodeling and face lifting

Basil M. Hantash, et al. Lasers Surg Med 2009;41:1-9.

Summary

- 64% of patients showed more than moderate improvement.
- 65.6% of patients were more than satisfied.
- Post-therapy edema and erythema lasted for only 3-5 days
- Data from the cutometer, mexameter, and corneometer measurements indicated improvement in tone, skin tightening, elasticity

Conclusion

Therefore, fractional MRF can be an effective and safe treatment option for wrinkles and for the improvement of skin tone, laxity and texture.

Long-term follow-up with a larger patient population is necessary.