Adverse Events after Noninvasive Radiofrequency Treatment for Cosmetic Uses

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Background and Objectives
Noninvasive skin tightening devices using radiofrequency have been used effectively in the treatment of aging skin with minimal downtime. However, studies evaluating its adverse events and complications have been limited. The objective of this study is to evaluate the adverse events associated with noninvasive skin tightening procedures using radiofrequency.

Materials and Methods
Retrospective case series of patients who presented with adverse events after radiofrequency treatment were analyzed. Adverse events and the treatments, as well as patient demographics and type of devices were identified and tabulated.

Results
Ten patients were analyzed in the study. Three patients complained of long-lasting erythema and increased skin sensitivity, while the remaining patients suffered from burn after the procedures. Nine patients were treated by non-dermatologists and one patient by dermatologists. Long lasting erythema and sensitive skin symptoms improved with topical and oral medication, while burns related to radiofrequency treatment resulted in scars and pigmentation even though they were managed with various treatment modalities.

Conclusion
Radiofrequency device is generally accepted as a safe and effective treatment modality for skin tightening. However, it may carry a risk of adverse events like burn, which may result in unacceptable scars and pigmentation. It should be carefully performed on patients and doctors should be aware of possible adverse effects.

Key words
Adverse events; Radiofrequency
INTRODUCTION

Radiofrequency (RF) devices have gained attention as a noninvasive treatment modality for cosmetic uses in the field. RF heats the deep dermis, fat, fibrous septae, and with some new delivery systems, fascia as well. The heat pocket created by RF in the dermis and subcutaneous fibrous septae results in collagen denaturation and subsequent thickening and shortening of collagen fibers. These serial biological responses stimulate new collagen synthesis in the dermis, leading to skin tightening clinically. Unlike other laser devices used for aging phenomenon, RF is not absorbed to melanocytes or hemoglobin, which is the most strong point for antiaging treatment in Asian patients who have more pigment burdens in the skin and are at high risk for developing postinflammatory hyperpigmentation.

Generally it is accepted as safe and effect treatment modality especially for skin tightening and wrinkles. However, studies evaluating its adverse events and complications have been limited. In this study, the adverse events related with RF for cosmetic uses were assessed in order to find out the safety of treatment and things to be considered during the procedures.

MATERIALS AND METHODS

We retrospectively reviewed the charts of patients who visited the laser clinic for adverse events after RF treatment from January 2013 to December 2014. Patient demographics and data were collected and the treatments on the adverse events were reviewed. Photographic documentation was done on each patient.

RESULTS

Ten cases were included and analyzed in the study. All patients were females (average age: 44.2 ± 4.7 years). Three patients complained of whole face erythema and sensitive skin after RF treatment and the rest of them presented with the first degree or second degree burn on the treated sites. Nine patients were treated by non-dermatologists; three patients by herb doctors and six patients by general doctors. One patient was treated by a dermatologist (Table 1).

The patients with persistent erythema were treated using topical soothing agents and oral antihistamines to decrease subjective symptoms and in two to 6 weeks, tingling sensation and erythema of face improved considerably.

| No | Sex/Age | RF device used | Adverse events | Doctors who performed RF treatment | Treatment modalities | Treatment outcomes |
|----|---------|----------------|----------------|-------------------------------------|---------------------|--------------------|
| 1  | F/35    | M              | Persistent erythema lasting two months | General Dr | Hexapeptide containing cream/oral ebastine | Itching sensation decreased in two weeks/erythema improved |
| 2  | F/46    | M              | Second degree burn | Herb Dr | LLLT#6/Fx#4 | Improved |
| 3  | F/41    | B              | First degree burn | Dermatologist | Topical silicon gel application for 1 month | Cleared |
| 4  | F/51    | B              | First degree burn | General Dr | LLLT#4 | Cleared |
| 5  | F/43    | M              | Second degree burn | General Dr | LLLT#4/Fx #4 | PIH |
| 6  | F/39    | M              | Persistent erythema lasting one month/sensitive skin | Herb Dr | Hexapeptide containing cream/oral ebastine | Improved |
| 7  | F/45    | M              | Second degree burn | General Dr | LLLT4 Fx#4/PDL#2 | Residual scarring |
| 8  | F/50    | M              | Second degree burn | Herb Dr | LLLT2/Fx#8 | Residual scarring |
| 9  | F/44    | M              | Facial erythema/sensitive skin | General Dr | Hexapeptide containing cream/oral ebastine | Improved |
| 10 | F/48    | M              | Second degree burn | General Dr | LLLT3/PDL#6 | Residual scarring |

Patients did not remember exactly which RF device was used for their treatment. Based on the patient’s description of the procedure, RF device was divided as monopolar or bipolar RF. Hexapeptide containing cream was used for longlasting erythema. LLLT was applied as 40 J/cm² at each treatment session (Healite II, Lutronic®, Seoul). It was performed twice a week until reepithelialization was achieved. Pulse dye laser and fractional laser settings were adjusted to the clinical condition of each patient.

M, monopolar RF device; B, bipolar RF device; Dr, doctor; LLLT, low level laser treatment; Fx, Fractional nonablative laser treatment; PDL, pulse dye laser.
with various treatment modalities including low level light, pulsed dye laser and fractional lasers, depending on the skin condition. Two patients presented with the first degree burn after bipolar RF treatment were successfully treated with topical agents and low level laser. For five patients with the second degree burn, average 10 treatment sessions were required to bring about considerable clinical outcome. Postinflammatory hyperpigmentation was found in two patients and they continued to use topical whitening agents. Three patients ended up with residual scarring even though they were vigorously treated with multiple modalities (Fig. 1).

DISCUSSION

Ruiz-Esparaza et al.¹ first reported the clinical benefit of RF on improvement of wrinkles and skin tightening back in 2003. Lots of studies have proven that RF treatment has its value for reversing skin aging phenomenon such as wrinkles and textural irregularity without serious adverse effect.²⁴⁻⁶ RF energy is not reflected or absorbed by epidermal melanin or vasculature, as it passes through the skin, making it safer to use in all skin types. Complication rates from RF have been reported extremely low especially with the newer generation technologies such as optimal epidermal cooling and vibratory tips etc. Fitzpatrick et al.⁵ evaluated the clinical safety of monopolar RF, reporting that overall second degree burn incidence was 0.36% (21 per 5,858 RF applications). Three patients had small areas of residual scarring at 6 months after the procedures. Manufacturers reported only 0.08% of tissue irregularities caused by overheating in more than 151,000 uses.⁷ Based on these previous reports, RF treatment can be accepted as safe and effective treatment modality for skin tightening which can replace invasive facial lifting surgery successfully. However, RF uses electric current on the skin and possible burn caused by electric currents should be always kept in mind during procedures.

Electric energy which is delivered in the dermis can be calculated as below⁷

\[ \text{Energy (in joules)} = I^2 \cdot R \cdot T \]

(I = current, R = impedance of the tissue, T = time of application)

Skin impedance can vary according to patients and the condition during the procedures, which means electric energy creating heating pocket in the dermis also changes and unpredictable adverse effect may happen.⁸ Harth et al.⁹ demonstrated that skin impedance varied in individuals and moreover, significant changes in impedance during the pulses also occurred. Thermal effects of RF have been proven to be beneficial in skin tightening and wrinkles. Nevertheless these effects were frequently unpredictable due to uncontrolled nature and the skin condition of treated patients.

According to this study, serious second degree burns leading to residual scarring were caused during the RF procedures, especially monopolar RF, which were performed by non-dermatologists like general doctors or herb doctors. This study may have selection bias because it was retrospective chart review and performed on the patients who visited the hospital. However, as many as five patients who suffered from second degree burn were treated by non-dermatologists and from this point of view, RF treatment is not a simple and easy modality and doctors who are well aware of the characteristics of skin and the nature of RF should do the procedures.

Burns caused by RF treatment are usually more than second degree one because they do not start from the epidermis outside, but from deep in the skin and overheating is backwardly delivered to superficial skin. The treatment takes time and even after proper care right after the adverse events, scars or postinflammatory hyperpigmentation may exist on the burn site.

**Fig. 1.** Patient No 7. She was treated using monopolar radiofrequency a week ago. She presented with facial burn on the lower face. After 6 months of multimodality treatment like low level laser, vascular laser and fractional laser, her skin lesion improved much (B). However, the burn of second degree (see arrows) left residual scarring on her face. (A) After 4 times of treatment using LLLT. (B) 6 months after treatment.
In this study, three patients complained of persistent erythema and skin sensitivity on whole face. Especially rosacea or facial telangiectasia patients are at higher risk to develop long-lasting erythema or skin sensitivity. These symptoms can be managed with proper topical care and oral antihistamines or short term oral steroid.

In conclusion, RF treatment is generally accepted as a safe and effective treatment modality for skin tightening. However, the major serious events such as burn should be kept in mind during procedures. Precise diagnosis of the skin condition of patients as well as proper epidermal cooling is a must to prevent possible serious adverse effect which can result in residual scars.

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