

# The Efficacy and Safety of Mono-Polar Radiofrequency for Mid-Face Volume Augmentation and Face Tightening

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**BACKGROUND** Over several years, cosmetic surgeons have sought out rejuvenating effects while minimizing recovery time and the risks of postoperative infection, leading to the subsequent development of non-invasive modalities for facial rejuvenation. Non-invasive, aesthetic technologies share a common method of inducing thermal, dermal injury, and immediate, heat-induced changes in collagen structure are believed to induce tissue tightening in several clinical studies. Many studies have reported that monopolar RF is best suited for patients with early signs of aging, it is one of the most widely used noninvasive procedures for treating skin wrinkle and laxity.

**OBJECTIVE** The purpose of this study was to evaluate the safety and efficacy of pre and post-monopolar radiofrequency treatment for mid-face volume augmentation and lower face tightening.

**METHOD** Twenty-five Asian patients with mild to moderate laxity of the middle and lower face were to receive two treatments at 4-week treatment intervals. They were shown before and after treatment photographs of participants treated with a radiofrequency (RF) device. Two RF treatments were performed. The first session of the RF treatment protocol consisted of a V Tip (Treat 4.0cm<sup>2</sup>) with 600 shots applied over the full face. The second treatment session after 4-week intervals consisted of a V Tip (4.0cm<sup>2</sup>) 300shots applied mid-face, a total of two treatments. Acute clinical response and pain scores were assessed after each session. Standardized photographs, 3D Vectra photos, and reports were taken at baseline, at 4 weeks, and at 8 weeks after the second treatment. At the 4-week and 8-week post-treatment follow-up visits, a post-treatment photo was taken and assessed by both the participants and the physician. Participants also completed a self-assessment questionnaire.

**RESULT** After each treatment session, temporary anticipated adverse effects were reported. The RF treatment was well tolerated by most of the participants. The participants responded with higher scores for treatment results in all categories of the photographic analysis. The physician's photographic and 3D Vectra photo assessment demonstrated continued improvement.

**CONCLUSION** Two RF treatments yielded significantly better improvement than a single treatment in the tightening of the marionette line and nasolabial folds. Significant improvement in laxity, tightening, and volume after treatment was seen between the 4-week and 8-week follow-up visits. Skin tightening effects in the treatment areas continued to occur between 4 and 8 weeks post-procedure with extremely low adverse effects and minimal downtime.

## INTRODUCTION

Over several years, cosmetic surgeons have sought out rejuvenating effects while minimizing recovery time and the risks of postoperative infection (Carruthers et al., 2014). Also, patients have wanted less dramatic but more natural results while minimizing risk and downtime. This has led to the subsequent development of non-invasive modalities for facial rejuvenation effects, such as non-ablative laser, radiofrequency (RF), and high-intensity focused ultrasound (HIFU) (Green & Greene, 2014).

Non-invasive, aesthetic technologies share a common method of inducing thermal, and dermal injury while preserving epidermal integrity (GOLD et al., 2007). Immediate, heat-induced changes in collagen structure and long-term, dermal collagen remodeling processes are believed to induce tissue tightening in several clinical studies (Zelickson et al., 2004; Franco et al., 2009).

The use of radiofrequency in aesthetics has increased in popularity since the early 2000s. The purpose of this study was to evaluate the safety and efficacy of pre and post-mono-polar radiofrequency treatment for mid-face volume augmentation and lower face tightening.

RF energy is in the form of an electrical current that generates heat through the inherent electrical resistance of dermal and subcutaneous tissue. The generated heat produces subtle damage to collagen, and in combination with the following inflammatory cascade induced by heating, a tightening effect is realized. Through this controlled volumetric heating of the dermis, the device is especially efficacious for the treatment of moderate laxity of the lower face. The optimal candidate is a patient most commonly in the mid-thirties to mid-sixties with some sagging of the jowls but lacks the need for a surgical lifting procedure

## MECHANISM OF RADIOFREQUENCY (RF) TREATMENT

Radiofrequency (RF) has emerged as an effective treatment to achieve non-invasive skin tightening (Sadick & Makino, 2004; Rohrich, 2000; Harth & Lischinsky, 2011). Since about a decade ago, RF has been introduced as an energy source with a contact cooling system to protect the epidermis and has presented remarkable clinical results of skin tightening without epidermal damage (Seo et al., 2012; Dierickx, 2006). In contrast to light-based, non-ablative laser treatment, RF treatment delivers RF energy to the skin surface while cooling the epidermis. RF energy produces heat through a high frequency, electric current through the transducer and back to a grounding pad. The electrical current heats the deep dermis, fat and fibrous septae below the skin. RF energy is not reflected or absorbed by epidermal melanin as it passes through the skin, making it safer to use in all Fitzpatrick classification types (Beasley & Weiss, 2014).

Tissue resistance to RF energy causes heating, which causes a controlled thermal injury. According to ----, heating the dermal tissue to 42°C has been shown to trigger a wound healing cascade, leading to the formation of new collagen and elastin fibers (Hodgkinson, 2009). Treatment with higher energy levels has been shown to correlate with improved clinical results. This heating of the dermis and subcutaneous tissues is related to collagen denaturation and subsequent thickening and shorting of the collagen fibers, resulting in increased fibroblast activity and neocollagenesis with facial rejuvenating effects (Zelickson et al., 2004).

The amount of newly produced collagen seems to be dependent on the intensity of the heating of connective tissue and the time that the tissue is heated for (Franco et al., 2009). Greater improvement of laxity has also been noted in patients receiving multiple RF treatments.

## METHODS

Selected from the investigator's practice, 25 Asian patients with mild to moderate laxity of the middle and lower face were to receive 2 treatments at 4-week treatment intervals. The participants were aged 25–65 years old with Fitzpatrick skin types II and III. To participate in the study and evaluate the effects of RF treatment, the participants signed consent forms. The study conformed to the guideline of the 1975 Declaration of Helsinki. Exclusion criteria included prior cosmetic facial surgery or placement of tissue fillers, active infection, collagen disorders, immunocompromised state, electrical implants on the treatment areas, pregnancy, breastfeeding, and/or scarring in the treatment region. They were shown before and after treatment photographs of participants treated with RF. Two RF treatments were performed. A single operator using an RF device (VOLNEWMER, CLASSYS Inc., South Korea) treated all participants. The first session of the RF treatment protocol consisted of a V4cm2 treatment tip with 600 shots (energy level: 2.5~3.5: equal to the energy of Jcm2) applied over the full face. The second treatment session consisted of a V3.0cm2 treatment tip with 300 shots (energy level: 2.5~3.0: equal to the energy of Jcm2) applied mid-face. The average treatment lasted approximately 35~40 minutes and was repeated at 4-week intervals for a total of two treatments.

Prior to actual enrollment, the treating physician assessed risks, benefits, treatment discomfort and anticipated clinical results in detail. In the middle area of the face, the treatment zone extended laterally from the nasolabial folds to the preauricular area and mandibular angle; the lower face treatment area extended inferomedially from the marionette lines to the mandible. After the application of conductive fluid (VOLNEWMER coupling fluid, CLASSYS Inc., South Korea), the middle and lower face was treated in several, overlapping passes using the F3 tip. Treatment energy levels were adjusted to patient tolerance and ranged from level 2.5 to level 3.5. Acute clinical responses or adverse effects were recorded after each session by assessing edema, erythema, and blistering. Immediately post-treatment, participants rated the pain score experienced during

treatment on a scale of 0 to 4 (0, no pain; 4, severe pain). Standardized photographs were taken at baseline, at 4 weeks, and at 8 weeks after the second treatment using a 3D camera (VECTRA, CANFIELD Inc., U.S.A.). At the 4-week and 8-week post-treatment follow-up visits, a post-treatment photo was taken and assessed by both the participants and the physician. Participants completed a self-assessment questionnaire and rated improvement in facial laxity on a scale from 0 (worsened laxity) to 4 (significant improvement) by assessing standardized photographs.

## RESULTS

After each treatment session, most participants experienced mild edema and erythema as a result of thermal response on the dermal layer of the skin. Severe clinical responses such as burns, skin breakdown, or scarring were not reported (Figure 1). The mean pain rating on a numeric pain scale from 0 to 10 was 4.05 after the first treatment session and 3.75 after the second treatment session (Figure 2). On the self-assessment questionnaire, individuals reported more improvement after the second treatment (Figure 3). At 4-weeks and 8-weeks post-second treatment, the physician's photographic assessment demonstrated continued improvement (Figure 4). At 4-weeks and 8-weeks post-second treatment, the physician's 3D Vectra photo and report is demonstrated (Figure 5).

The overall aesthetic change reported by both participants and physicians was modest in most patients. But overall, the satisfaction rates of the treatment results were relatively high in most participants.

Figure 1. Adverse Effects Report

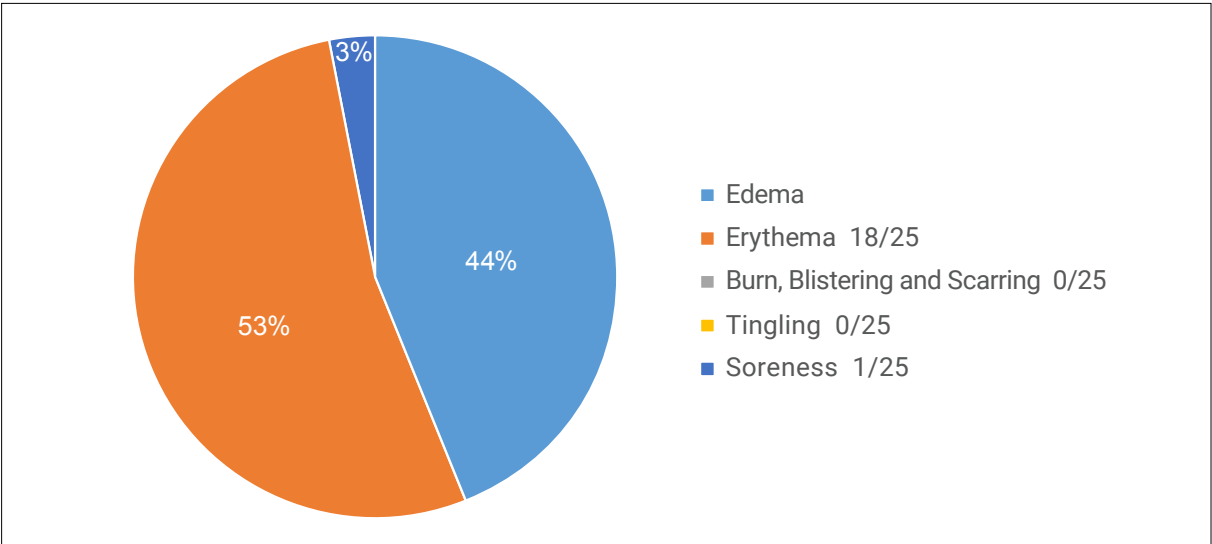


Figure 2. First Treatment: 4.05 Second Treatment: 3.75 out of 10

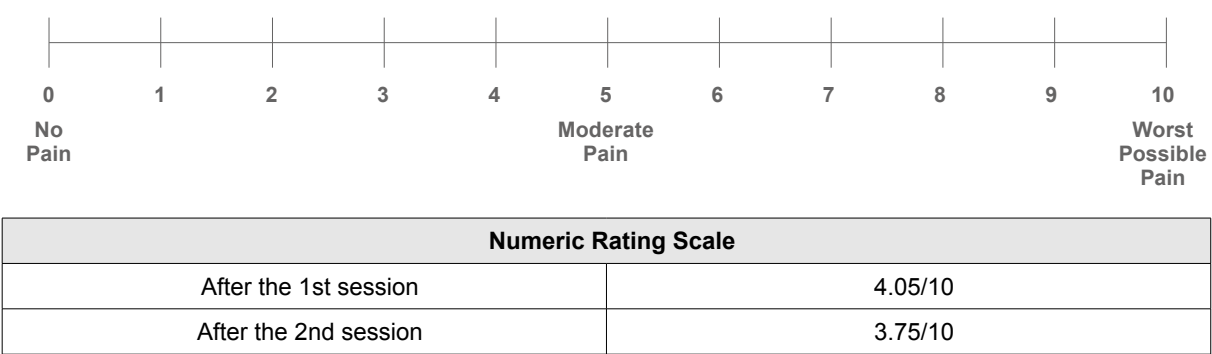


Figure 3. Self-Assessment Questionnaire

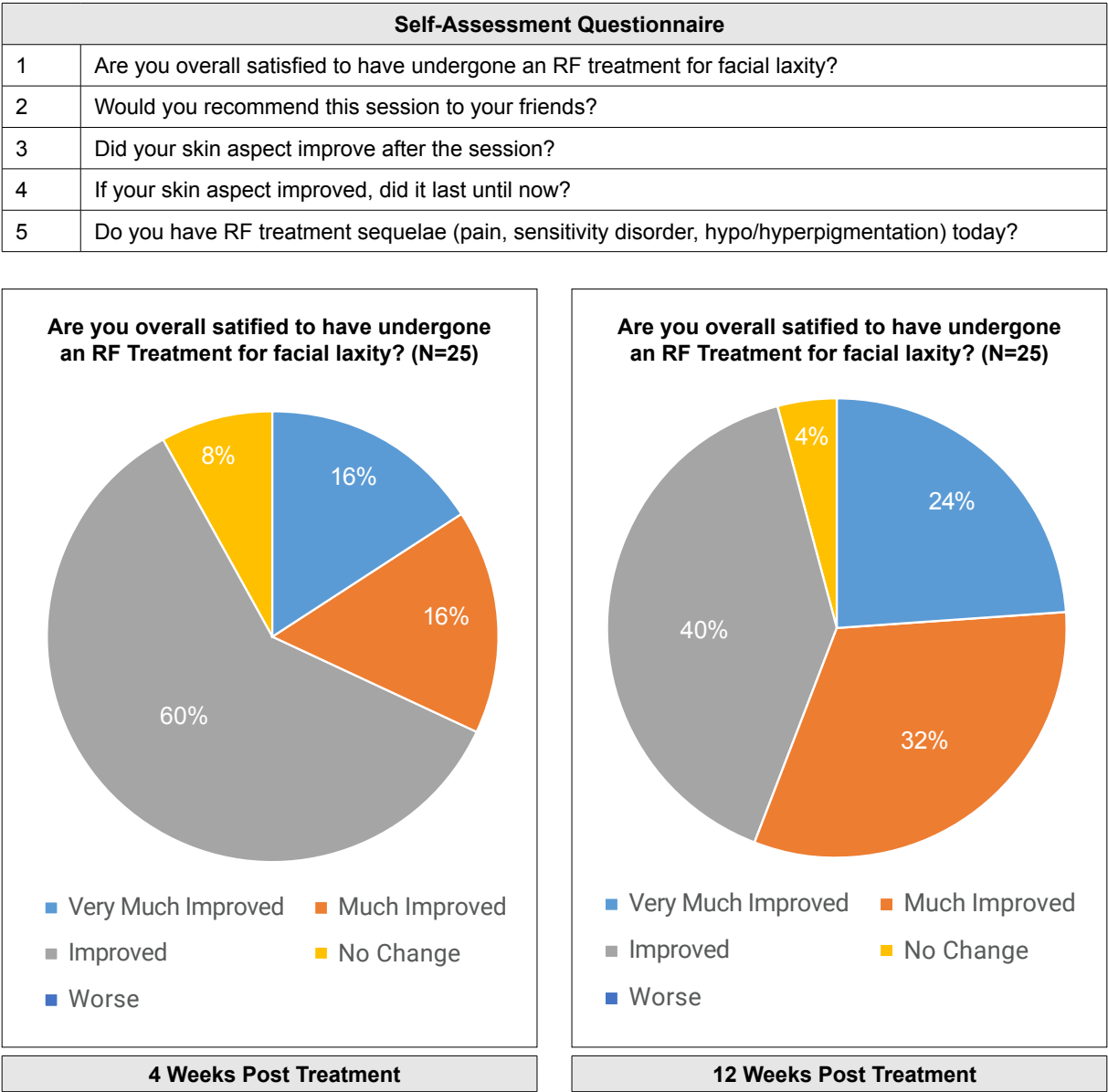
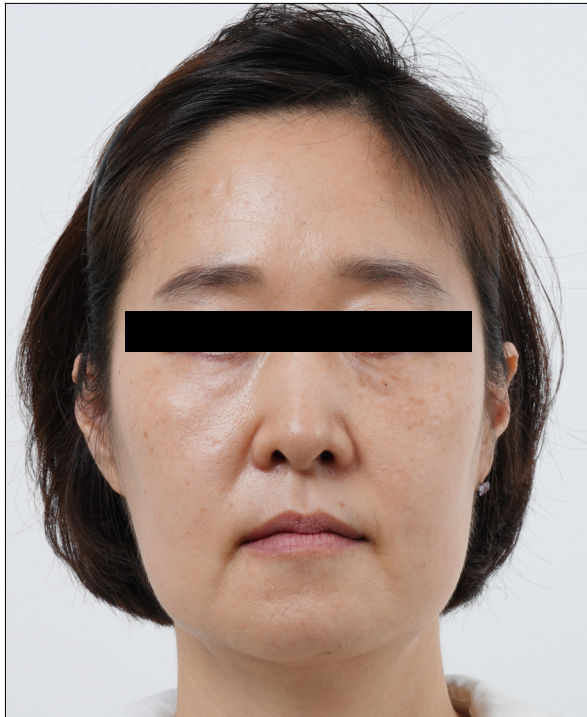
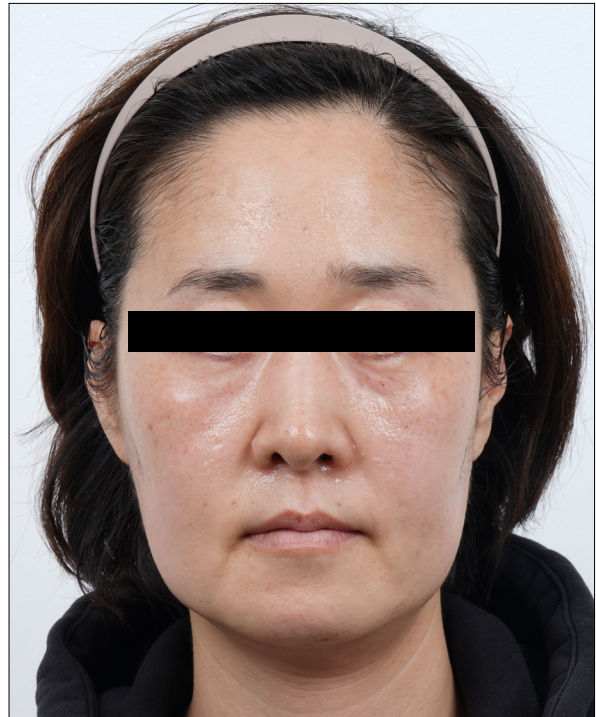


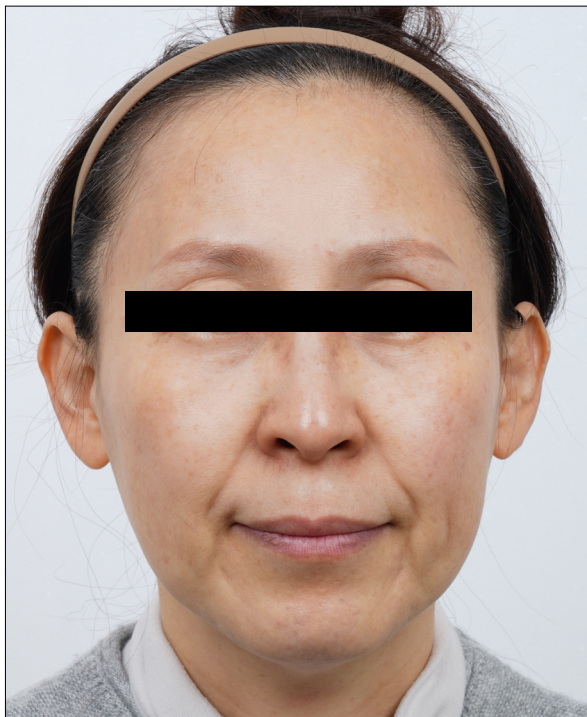
Figure 4.



**Before Treatment**



**12 Weeks Post Treatment**



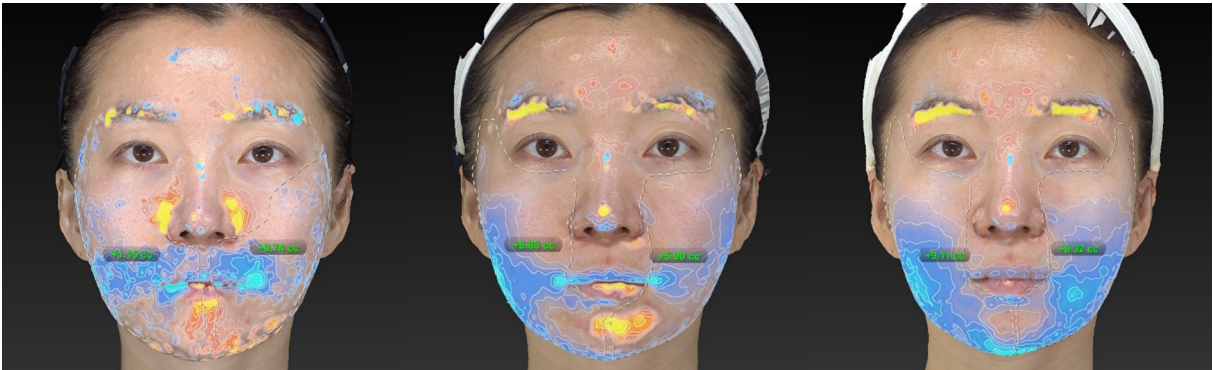
**Before Treatment**



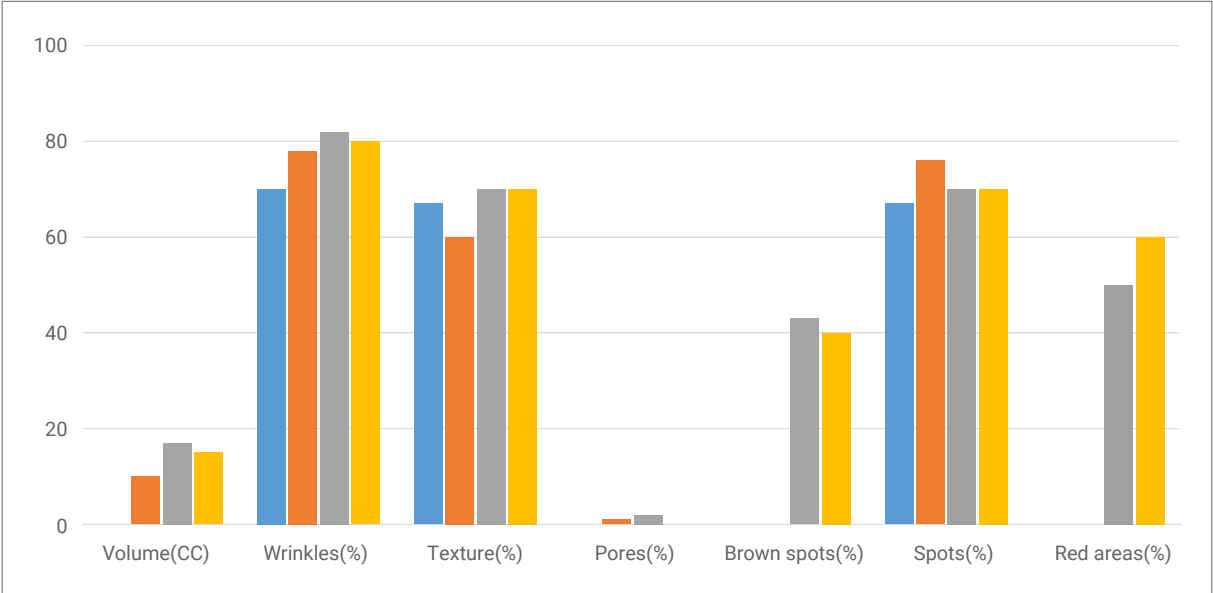
**12 Weeks Post Treatment**



Figure 5.



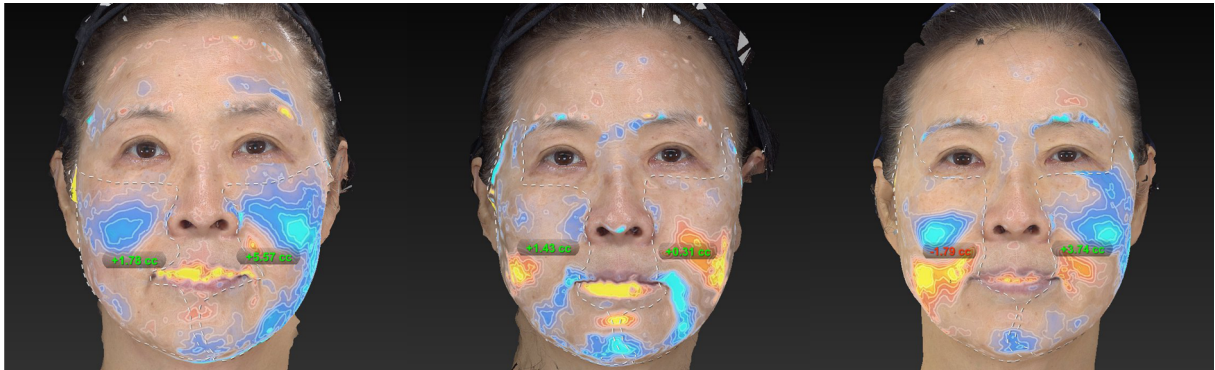
Volume Change by measurement: Left: +5.90cc/ Right: + 8.83cc



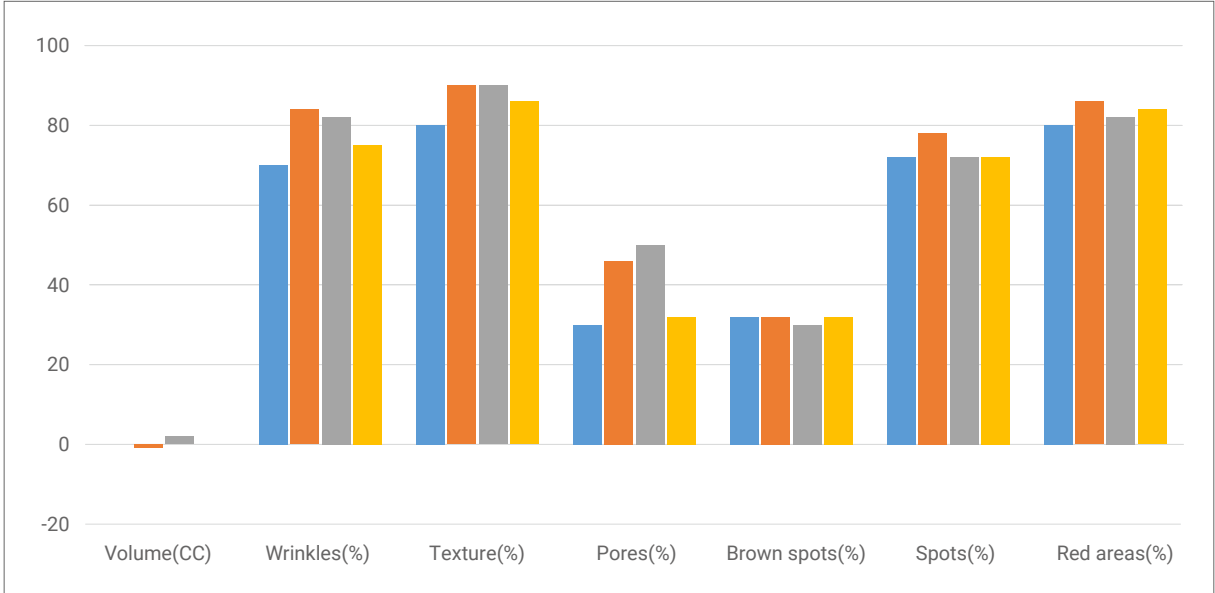
VECTRA 3D Report



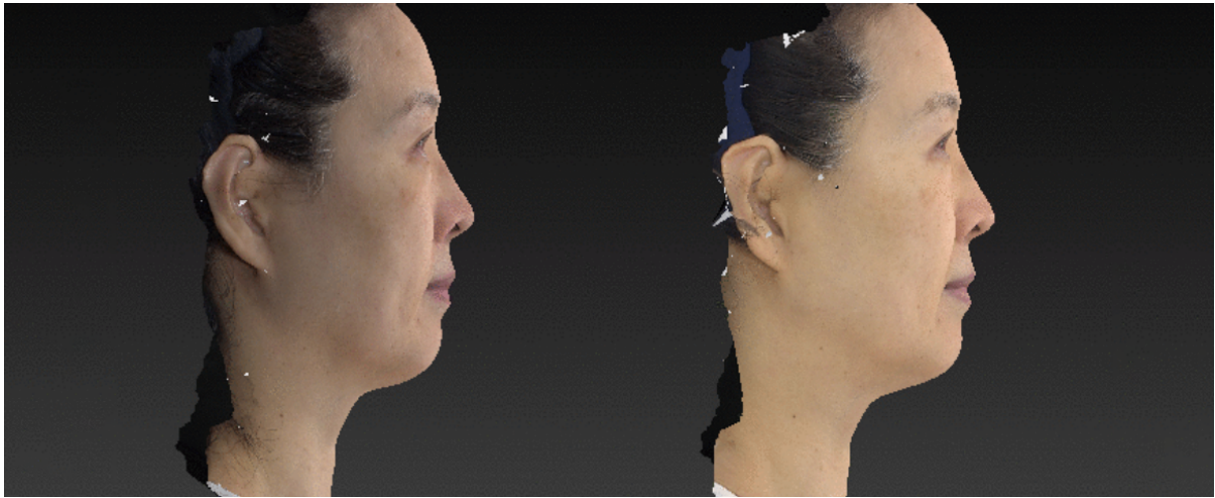
3D Rotation



Volume Change by measurement: Increase in 2.00cc



VECTRA 3D Report



3D Rotation



## **ADVERSE EFFECT**

Adverse effect rates were reported and transient edema and mild erythema were noted though those faded in a day or so. Numbness of the skin or tingling sensations, often in the distribution of the greater auricular nerve, were also reported but resolved within a week. Tissue irregularities, scarring, burning, or blistering was not reported. According to -----, tissue irregularities related to dermal layer overheating were extremely rare with an estimated rate of 0.08% in more than 161,000 cases (Sadick & Makino, 2004).

## **DISCUSSION**

Two RF treatments yielded significantly better improvement than a single treatment in the tightening of the marionette line and nasolabial folds. Significant improvement in laxity after two RF treatments was seen between the 4-week and 8-week follow-up visits. Participants' satisfaction of the clinical results was relatively high. Most of the participants tolerated the RF treatment well with minimal pain. Adverse effects were reported but they resolved on their own within a few hours. It is noted that excellent patient tolerance, consistent clinical results, and the low incidence of adverse effects clearly prove RF treatment safety and efficacy in middle and lower face tightening.

## **CONCLUSION**

This study supports several conclusions. Firstly, using an overlapping technique, two treatments of the middle and lower face with an RF device produced noticeably better results than a single treatment. Secondly, based on the clinical photography, skin tightening effects in the treatment areas continued to occur between 4 and 8 weeks' post-procedure. Finally, the RF treatment is well tolerated with extremely low adverse effects and minimal downtime.

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