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The Efficacy and Safety of Radiofrequency Microneedling Versus a Nonablative Fractional 1,550-nm Erbium:Glass Laser for the Rejuvenation of the Neck

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BACKGROUND Radiofrequency microneedling (RFMN) and nonablative fractional 1,550-nm erbium:glass lasers (NAFLs) have been reported to be used with success in neck rejuvenation. There are no head-to-head trials to compare these modalities.

OBJECTIVE The purpose of the study was to compare the efficacy and safety of radiofrequency microneedling and nonablative fractional 1,550-nm erbium:glass lasers for the rejuvenation of the neck.

METHODS This was a single-center, randomized, investigator-blinded clinical trial. A total of 21 subjects were randomized into 2 groups, NAFL and RFMN; subjects received 3 treatments 4 weeks apart and were followed up 12 weeks after last treatment.

RESULTS Subjects in NAFL and RFMN groups showed 42.1% and 8.6% improvement in the Fitzpatrick–Goldman Wrinkling Score, respectively, 41.3% and 16.3% improvement in the elastosis score, respectively. Subjects in the NAFL 1,550-nm erbium:glass group showed significantly better blinded investigator Fitzpatrick–Goldman Wrinkling and Elastosis scores; subjects in the RFMN groups showed a more significant reduction in the Horizontal Neck Wrinkle Severity Score. There was a trend for higher patient satisfaction with the NAFL.

CONCLUSION This study showed that both treatments resulted in significant improvement in wrinkling and elastosis scores; the NAFL treatment was associated with significantly better blinded investigator Fitzpatrick–Goldman Wrinkling and Elastosis scores and better subject satisfaction.

Neck rejuvenation is a common presenting concern from patients seeking aesthetic treatments.[1] Patients often seek improvement in texture, wrinkling, and laxity of the neck area.[1] Treatment of neck skin needs to take into account the unique anatomical features of this region, including generally thinner skin, greater laxity, and fewer pilosebaceous units, resulting in slower healing and a necessity for increased caution.[2–5]

Although a traditional surgical neck lift can have excellent results, it can leave behind unsightly scars and it does not address major contributing factors such as photodamage and intrinsic aging.[6] Aged skin demonstrates fragmented dermal collagen that leads to fibroblast dysregulation and a decrease in the production of new collagen.[7] This decrease in collagen is seen clinically as rhytides and laxity. Several nonsurgical modalities have been developed that stimulate collagen remodeling and neocollagenesis. Radiofrequency microneedling (RFMN) is a minimally invasive treatment that creates perforations in the epidermis and delivers radiofrequency-generated thermal energy (RF) into the underlying dermis to stimulate neocollagenesis.[8] The mechanical effects of microneedles on the skin promote secretion of growth factors to stimulate migration and proliferation of adjacent keratinocytes and fibroblast for skin remodeling.[8]

The introduction of fractional photothermolysis (FP) in 2004 represents a landmark development in modern laser technology.[9] Fractional photothermolysis generates an array of microscopic areas of thermal injury in the skin. These zones of thermal injury induce focal dermal wounds while sparing the surrounding tissue.[9] This allows for fast healing, minimal adverse events, and minimal down time.[10] Nonablative fractional lasers use midinfrared wavelengths and target water as a chromophore; in this laser technology, the laser penetrates deep into the midreticular dermis to induce neocollagenesis and remodeling. The major advantage is the preservation of an intact epidermis with minimal disruption of the dermal–epidermal junction (DEJ), which translates to shorter and milder adverse effects.[11] The

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fractional 1,550-nm erbium laser system (Fraxel re:store laser system, Solta Medical, Inc., Bothell, WA) was cleared by the FDA in 2005 for general skin resurfacing. A recent consensus group on the role of second-generation 1,550-nm erbium-doped lasers in laser surgery recommended 8 passes with fluences of 10 to 40 mJ, corresponding to a depth of 555 to 1,120 mm when treating the skin of the neck.[12,13] Fitzpatrick skin Types I to III should be treated using a treatment level of 7 to 11, whereas a treatment level of 4 to 7 is advised in skin Types IV to VI.

Few studies have been published regarding RFMN and nonablative fractional laser (NAFL) on the neck for rejuvenation.[1,13,14] In addition, there are no head-to-head trials of these 2 modalities. This study directly compares RFMN to NAFL for skin restoration on the neck.

Materials and Methods

This was a single-center, prospective, randomized, investigator-blinded, open-label, institutional review board–approved clinical trial that was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization.

After obtaining informed consent, 21 subjects aged 18 to 65 years with a mild to moderate amount of neck wrinkling and laxity, per the Fitzpatrick–Goldman Classification of Wrinkling and Degree of Elastosis Scale, were enrolled in the study.

Subjects were excluded if they were pregnant or breastfeeding; had an energy-based device treatment of the neck area within the previous 6 months; had an injectable soft tissue filler in the treatment area within the previous 12 months; had injectable neuromodulator treatment in the area within the previous 6 months; had a facial peel or microdermabrasion within the previous 4 weeks; used topical retinoids, hydroquinone, imiquimod, ingenol mebutate, concentrated hydrogen peroxide, or diclofenac to the neck within the previous 2 weeks; subjects on systemic or topical steroids; and those who had a skin condition involving the neck area that would interfere with the assessments for this study.

Intervention

A total of 21 female subjects were randomized into 2 groups: the NAFL 1,550-nm erbium:glass (Figure 1) and the RFMN group (Figure 2). Subjects in both groups received 3 treatments 4 weeks apart. Before each treatment, the neck was cleansed with isopropyl alcohol, a thin layer of compounded 23% lidocaine and 7% tetracaine was applied for 60 minutes to the treatment area. Immediately before treatment, the anesthetic was wiped off and the neck was cleansed again with isopropyl alcohol. The nonablative fractional 1,550-nm erbium:glass laser group was treated with 8 passes using a fluence of 25 to 35 mJ and a treatment Level 6 and 7 (17%, 23% coverage), and an average of 2.5 kJ. The RFMN group was treated with 3 passes using the INTRAcel device (Jeisys, South Korea) at depths 1.5 mm, 0.8 mm, and 0.5 mm, at a treatment Level 5, on a bipolar setting. Of the note, the device contains 49 insulated microneedles per cm^2. Dynamic cooling was applied during both treatments. A gentle moisturizer (Vanicream) was applied immediately after treatment in both groups. Patients were instructed to use a gentle cleanser (Cetaphil Gentle Skin Cleanser), apply a physical sunscreen with SPF 30 or greater, and a gentle moisturizer after treatments. Subjects were followed up at 4 weeks (Day 90) and 12 weeks (Day 150) after the third treatment.

Subjects were assessed using the Fitzpatrick–Goldman Classification of Wrinkling and Degree of Elastosis Scale. A blinded investigator assessed percent improvement of wrinkles at Day 90 and Day 150. Investigators assessed side effects and a Global Aesthetic Improvement Scale (1 = much improved, 2 = improves, 3 = no change, 4 = worse, and 5 = much worse) and subject satisfaction (1 = extremely satisfied, 2 = satisfied, 3 = slightly satisfied, 4 = slightly dissatisfied, 5 = dissatisfied, and 6 = extremely dissatisfied) at each visit after the first treatment. Furthermore, Horizontal Neck Wrinkle Severity Scores were assessed at each visit using a 5-grade scale (0 = absent to minimal, 1 = mild, 2 = moderate, 3 = severe, and 4 = very severe). Standardized 2D and Vectra 3D digital photography (Canfield Scientific in Parsippany, NJ) were performed at each visit.

Statistical Analyses

All statistical tests were 2-sided and interpreted at a 5% significance level. Descriptive statistics (i.e., mean, SD, etc.) were provided for all continuous variables and frequencies for all categorical variables. To track changes for individual variables across all relevant visits, single-factor analysis of variance tests were used, whereas comparisons between 2 individual visits were performed using 2-sample t-tests assuming equal variance. A p-value <0.05 was considered clinically significant.

Results

Of the 21 female subjects enrolled in the trial, 2 subjects were lost to follow-up (1 in the NAFL group and 1 in the RFMN group), mean age was 49.7 ($\pm$7.4; age range 37–60) years. One subject was of Fitzpatrick skin Type I, 15 subjects were of Fitzpatrick skin Type II, 4 subjects were of Fitzpatrick skin Type III, and 1 subject was of Fitzpatrick skin Type IV.

Subjects in the NAFL group and the RFMN group showed 42.1% and 8.6% improvement in the blinded investigator-assessed Fitzpatrick–Goldman Wrinkling Score, respectively. Similarly, subjects in the NAFL group and the RFMN group showed a significant improvement in the blinded investigator-assessed Fitzpatrick–Goldman Elastosis Score, corresponding to 41.3% and 16.3%, respectively (See **Supplemental Digital Content**, Table S1, http://links.lww.com/DSS/B93).

At Day 150, subjects in the NAFL group showed significantly better blinded investigator Fitzpatrick–Goldman Wrinkling scores when compared with the RFMN group (scores of 1.00 $\pm$ 0 and 1.63 $\pm$ 0.52, respectively; $p < .01$) (Figure 3). Similarly, the NAFL group showed significantly better blinded investigator Fitzpatrick–Goldman Elastosis

Figure 1. Frontal (A) and oblique (B) views of a subject who received nonablative 1,550-nm erbium:glass laser treatment to the neck at baseline, Day 90, and Day 150.

scores when compared with the RFMN group (scores of 2.40 ± 0.69 and 3.63 ± 1.51, respectively; $p = .03$ and 0.04) (Figure 4).

Although both the NAFL and RFMN groups resulted in reduction of the Horizontal Neck Wrinkle Severity Score (28% and 38%, respectively), only subjects in the RFMN-treated group showed a statistically significant decrease in the score ($p = .02$) from screening to Day 150.

At Day 60, subjects treated with NAFL showed significantly higher blinded investigator-assessed Global Aesthetic Improvement Scale Scores (GAISs) ($p = .03$). According to the investigator GAIS assessed at Day 150, 44% of subjects in the NAFL group were found to have 26% to 50% improvement and 29% of subjects in the RFMN group were found to have 26% to 50% improvement (Figure 5).

For adverse events, RFMN showed significantly higher scores in contour regularity (assessed immediately after treatment) at Days 30 and 60 only ($p < .01$) and erythema (assessed immediately after treatment) at days 1, 30, and 60

Figure 2. Frontal (A) and oblique (B) views of a subject who received radiofrequency microneedling treatment to the neck at baseline, Day 90, and Day 150.

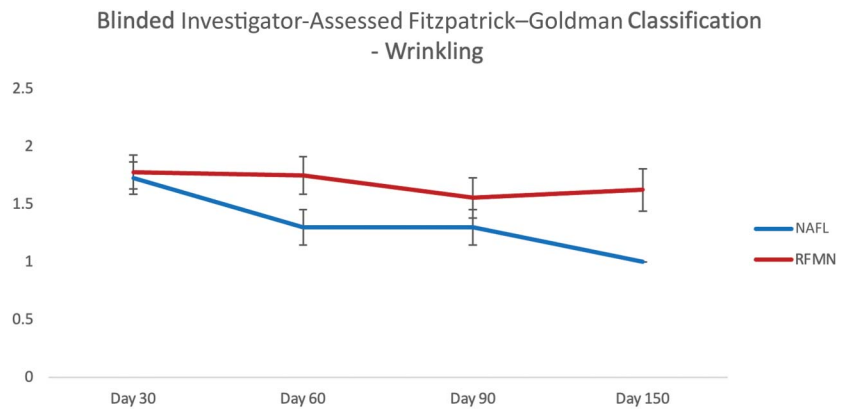

Figure 3. Blinded investigator-assessed Fitzpatrick–Goldman Wrinkling Score for nonablative 1,550-nm erbium:glass laser and radiofrequency microneedling treatment groups.

($p < .01$, $p < .01$, and $p = .02$, respectively). Side effects were short lasting and self-limited. No adverse effects were reported at Days 90 or 150.

Patient satisfaction was high for both groups; there was a trend for higher patient satisfaction with NAFL (4.2/5) than RFMN (3.5/5).

Discussion

There are a wide variety of cosmetic procedures available for rejuvenation of the neck.[15] Two commonly used modalities in rejuvenation of the neck region are NAFL and RFMN. This is the first clinical trial to compare the 2 modalities for rejuvenation of the neck area.

We found that subjects in the NAFL group had significantly better blinded investigator Fitzpatrick–Goldman Wrinkling and Elastosis scores and better subject satisfaction when compared with the RFMN group at Day 150. However, when Horizontal Neck Wrinkle Severity Scores were assessed, RFMN resulted in a significant decrease corresponding to 38% versus 28% in the NAFL group.

In this study, the NAFL group had 42.1% and 41.3% improvement in the Fitzpatrick–Goldman Wrinkling and Elastosis scores, respectively. Few previous studies that investigated NAFLs have found comparable results. Wanner and colleagues [16] conducted a study investigating the Nonablative fractional laser (1,550-nm erbium:glass) for the treatment of facial and nonfacial cutaneous photodamage in 20 subjects with 3 treatments at 3- to 4-week interval. A 51% to 75% improvement was achieved in 55% of patient treated on the neck and chest area at 9-month follow-up. Bencini and colleagues [13] performed a prospective study for neck resurfacing using a 1,540-nm erbium:glass laser in 18 women with aged neck skin. Subjects received 6 treatments at 4-week interval and had significant improvement of 31.7% of wrinkles but not laxity.

In this study, the RFMN group had 8.6% and 16.3% improvement in the Fitzpatrick–Goldman Wrinkling and Elastosis scores, respectively. Few previous studies investigated the use of RFMN in the treatment of neck laxity.[17–20] One international multicenter study from the United States and Japan investigated use of a RFMN device containing 25 noninsulated microneedle electrodes to the face and neck area in 49 patients who received 3 monthly treatments.[17] The neck area was treated with depths of 1.3 to 2.5 mm. Improvement in Fitzpatrick–Goldman Wrinkling

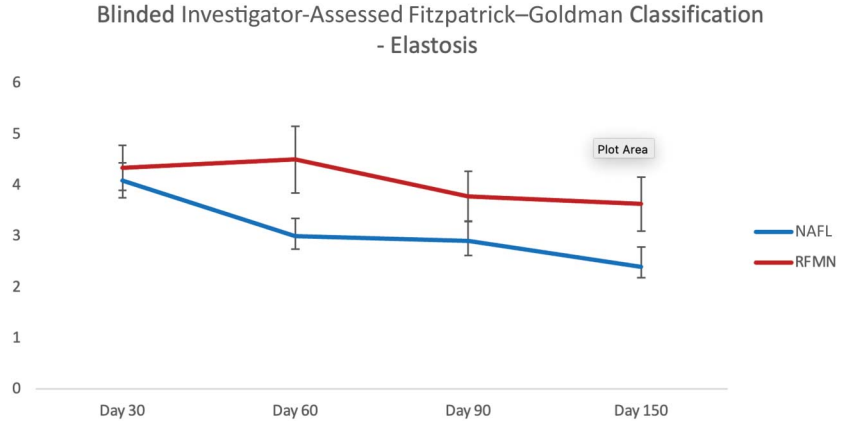

Figure 4. Blinded investigator-assessed Fitzpatrick–Goldman Elastosis Score for nonablative 1,550-nm erbium:glass laser and radiofrequency microneedling treatment groups.

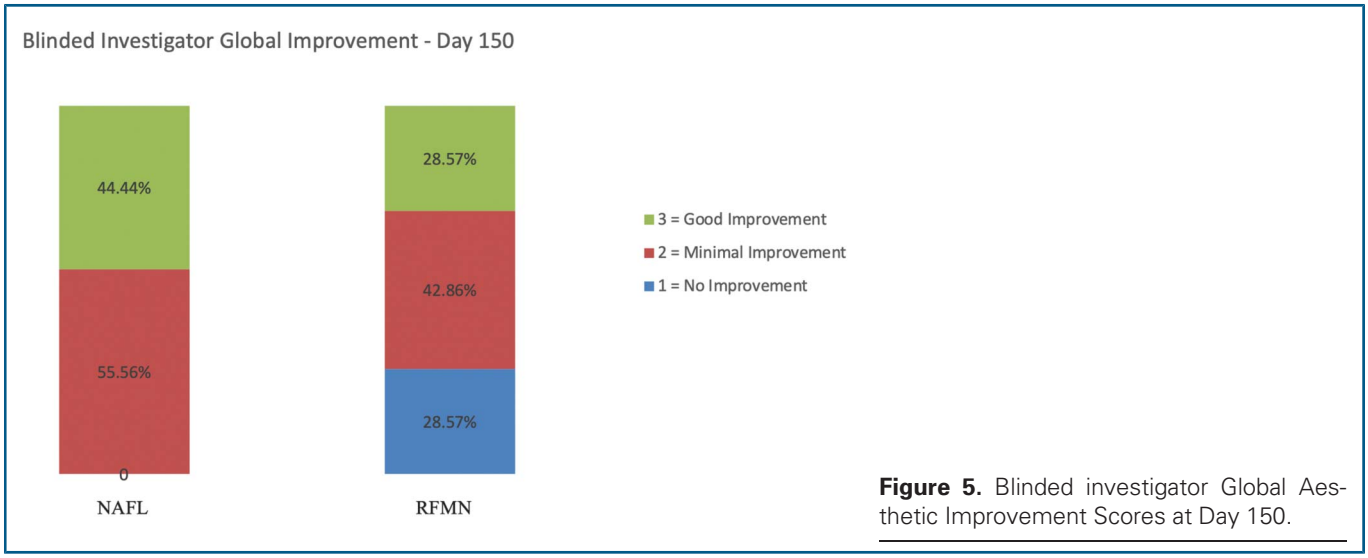

Figure 5. Blinded investigator Global Aesthetic Improvement Scores at Day 150.

and Elastosis Scales was seen in 100% of the patients; 65% of patients had significant improvement in GAIS scores. One study that compared 3 monthly sessions of RFMN versus NAFL (1,550-nm erbium:glass) for treatment of atrophic facial acne scars found results comparable to this study.[21] The authors included 20 subjects in each group and found more improvement of scar severity in the NAFL groups (25%) than the RFMN group (18.6%).

Fisher and colleagues[22] investigated short-term adverse events associated with the second-generation 1,550-nm erbium-doped fractionated laser to treat photoaging of the face, neck, chest, and hands. Side effects were transient and limited to edema, erythema, dryness, pruritus, bronzing, and acneiform eruption. A larger study by Graber and colleagues[23] compiled adverse event rates in 961 patients with Fitzpatrick skin Types I to V undergoing treatments with a 1,550-nm fractionated erbium-doped laser to the face, neck, chest, and hands for rejuvenation of sun-damaged skin. The overall adverse event rate for all sites was 7.6%, including erosions, herpetic reactivation, secondary bacterial impetiginization, edema lasting longer than 48 hours, and acneiform eruptions. Post inflammatory hyperpigmentation (PIH) occurred in 0.73% of subject and was seen in skin Types II to V. One study investigating RFMN reported 2 incidences of punctate atrophy.[20] Most studies reported side effects limited to transient erythema and edema.[17,18]

Limitations to this study included small sample size, the COVID-19 quarantine restrictions causing some visits to be conducted out of window, and short follow-up time. Clinical efficacy was observed at 150 days; however, longer follow-up can be helpful to assess longer-term efficacy. Additional treatments could further improve efficacy. Furthermore, an evaluation of specimens in the treatment areas can help delineate the histological changes seen when treatments are combined. Future studies are needed to follow patients up for a longer period, to optimize settings used, and to assess for the amount of collagen that is produced through histology or ultrasound examination.

In conclusion, this is the first clinical trial to date to compare efficacy and safety of nonablative 1,550-nm erbium:glass laser and radiofrequency microneedling in rejuvenation of the neck. This study showed that both treatments resulted in significant improvement in wrinkling and elastosis scores; the NAFL treatment was associated with significantly better blinded investigator Fitzpatrick–Goldman Wrinkling and Elastosis scores and better subject satisfaction when compared with RFMN at Day 150. The RFMN group showed more significant improvement of the Horizontal Neck Wrinkle Severity Scores. There was slightly less downtime for the NAFL group than the RFMN group, but both lasers were well-tolerated.

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