



A retrospective study of neck rejuvenation using a noninsulated microneedle radiofrequency in Chinese subjects

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Received: 12 May 2020 / Accepted: 23 October 2020
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Abstract

Large-scale long-term retrospective study of noninsulated microneedle radiofrequency treatment on neck rejuvenation is lacking. We conducted a 3-year retrospective observation of subjects treated with noninsulated microneedle radiofrequency (NIMNRF) for neck rejuvenation in Chinese subjects. Of all subjects, 28 subjects (28.6%) received only 1 session of treatment. About 50% subjects achieved $\geq 50\%$ improvement, and average improvements were 37.0% at 3 months follow-up (M3) and 41.6% at 6 months follow-up (M6). Seventy subjects (71.4%) accepted 3 sessions of treatments. The neck aging scores were 3.57 ± 1.28 at baseline, and significantly decreased to 1.10 ± 0.84 at M3 ($p < 0.05$), 1.04 ± 0.86 ($p < 0.05$) at M6, separately. The average improvements were 73.3% at M3 and 75.1% at M6. It showed a trend of better efficacy with the increasing number of sessions ($p < 0.05$). Among of 6 subjects who was followed up for 1 year, 5 subjects who received 3 sessions of treatment achieved about 70% improvement after final session, and another 1 subject who received 1 session remained the improvement up to 40%. The results demonstrate NIMNRF treatment has significant and long-lasting effect on neck laxity and wrinkle reduction with minimal discomfort and downtime.

Keywords NIMNRF · Neck rejuvenation

Introduction

Skin aging presents coarse rhytides, sallowness, roughness, loss of burnish and resiliency, abnormal pigmentation, and telangiectasias. Histology characterizes mainly atrophic or hyperplastic epidermis, in dermis fragmented collagen and dysfunctional glycosaminoglycans and proteoglycans [1–4]. Genetics, dysregulation of the extrinsic and environment such as ultraviolet irradiation, air pollution, toxic detergent, and improper use of cosmetics may be related to skin aging [5, 6]. Regardless of age and skin type, the demand for

esthetic nonsurgical treatment to keep skin rejuvenation is increasing.

Esthetic improvement of aging neck becomes one of the most challenging aspects. Pharmacotherapy and intense-pulsed light (IPL) therapies are commonly applied for skin rejuvenation treating without scarring, whereas insufficient for tightening skin. Several other nonsurgery methods have been recommended, such as deep chemical peeling, ablative or nonablative laser resurfacing, radiofrequency (RF), intense focused ultrasound, and botulinus toxin A injection, either single or in combination [7–9]. However, these methods possess some extent of limitations, including unobvious efficacy, unacceptable pain, and downtime. For example, although deep chemical peels and ablative lasers are helpful, these procedures present considerable pain and downtime [10, 11]. Nonablative laser exerts limited effect on tightening, and nonablative photoelectromagnetic devices have slight effect on relieving rhytides [12]. The effect of botulinus toxin A injection merely lasts for several months and the treatment needs to be repeated periodically to keep the results [13]. Thus, more appropriate therapies or combination therapies are needed to be explored.

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In recent years, radio frequency (RF) systems have become popular in skin aging with less recovery time and complications while approaching clinical efficacies [14]. The earliest RF devices were monopolar and bipolar, and they were applied for improving skin wrinkles and laxity. However, due to severe pain, relatively high risk of burn or superficial effect, they were not delightfully accepted by some beauty seekers [15–17]. Afterwards, the constant diversification and refinement of RF devices have improved their applications in esthetic treatments. Recently, techniques of microneedling in combination with RF were developed to enable deeper penetration and specific tissue targeting.

In this study, we used a noninsulated microneedle radiofrequency (NIMNRF) system for neck skin tightening and wrinkle alleviation. An array of 25 gold-plated microdiameter needles are inserted into the skin by an electronic-controlled stepping motor, pulse by pulse, which makes the insertion smoothly with less discomfort. The noninsulated technology can heat both papillary and reticular dermis, inducing new collagen production in these areas. The epidermis maintains intact as its high impedance and ensures heat energy emitting at the tip of the electrode [18]. The NIMNRF achieves cylindrical microzones of coagulation in the papillary and reticular dermis with less heat to the epidermis. It delivers energy in a small pattern and supplies a continuous distribution of power, with minimal or no bleeding.

In recent years, various RF devices have been used in face rejuvenation [19]. However, the record about NIMNRF on neck aging is lacking. Herein, we conducted a 3-year retrospective observation of the subjects treating with NIMNRF for neck rejuvenation. We expect to provide an alternative treatment choice of neck aging.

Materials

Subjects

A total of 98 female subjects (aged 20–74 years, Fitzpatrick skin types of III–V) were treated in the laser center of Guangzhou Mylike medical cosmetic hospital, from 2017 to 2019. All the subjects signed written informed consents. Subjects who were taking any medical or hormonal medications, losing weight, under esthetic treatment within 3 months, or having coagulopathy were excluded. All the information of each subject containing general situations, treatment regimens and parameters, neck aging scores, satisfaction degree, and adverse events were imported to a predesigned form.

Devices and topical agents

All the subjects were treated with noninsulated microneedle radiofrequency (NIMNRF) (Intensif Handpiece, EndyMed

Medical, Caesarea, Israel). Each patient received 1–3 sessions of treatment at 3-month interval. The Intensif Handpiece of NIMNRF uses a sterile treatment tip with 25 noninsulated, gold-plated microneedles electrodes. The electrode can create maximum diameter of 300- μ m treatment field at the base that gradually tapers to a sharp edge, and penetrate up to 5.0 mm in digitally controlled increments of 0.1 mm. Pulse duration (50–200 ms with increments of 30 ms) and power (0–25 W with increments of 1 W) can be adjusted. After cleaning up with neutral cleanser, topical anesthetic (5% compound lidocaine cream, Tongfang Pharmaceutical Group Co., Ltd.) was applied to the neck skin for 1 h. The neck skin was treated with one pass, with pulse duration of 80–100 ms at 12–14 W and penetration depth of 1.8–2.5 mm. The energy was emitted only after the needles reached their desired preset depth in a stamping model.

Immediately after NIMNRF, the Neck Wrinkle Removing Set (EVE CHARM, Yuanxiang Biotechnology Co., Ltd., Guangzhou, China) was topically applied to the local skin. The components of the set contain oligopeptide-3, oligopeptide-1, soybean polypeptide, mannitol, and ultrapure water. Then the Active Protein Cristal Mask (EVE CHARM, Yuanxiang Biotechnology Co., Ltd., Guangzhou, China) was covered to the neck skin for 20–30 min and continued for 1 week at home. The mask contains glycyrrhiza glabra root extract, sodium alginate/carrageenan sodium, glycerin, propylene glycol, hydroxybenzyl ester, and water. The moisturizer and broad-spectrum sunscreen were applied daily.

Efficacy evaluation

Standardized digital photographs were taken before each session, 3 months after final session (M3) and M6 for assessing clinical improvement. The evaluation was performed based on previous classification of neck aging [20] and two of the four categories were chosen in our study. The points of 0 to 3 points were assigned to each category, i.e., skin laxity and horizontal neck lines. For skin laxity, score 0 = no, score 1 = mild, score 2 = moderate, and score 3 = severe. For horizontal neck lines, score 0 = subtle, score 1 = mild, score 2 = moderate, and score 3 = deep. The degrees of neck aging were graded on total scores of 0 to 6 points. The improvement of neck aging was reflected by decreasing rate (%), which was calculated by the difference total score (pretreatment minus post-treatment) divided by pretreatment total score. Evaluation was conducted by two independent blinded evaluators (Bihuan Xiao, Yan Sun) who were not involved in treatment. Consensus was reached through discussion or consultation with a third dermatologist (Yan Wu) when there were discrepancies between the two dermatologists.

The satisfaction degrees were rated as “very satisfied”, “moderate satisfied”, “fairly satisfied”, and “not satisfied” by the subjects themselves.

Adverse events

The potential adverse events including pain, burning, erythema, swelling, pigmentation, and scarring were recorded in the form.

Statistical analysis

Data were analyzed using SPSS (version 20.0, SPSS Inc., Chicago, IL). Paired *t* test and Kruskal–Wallis test were used for comparison analyses. A *p* value below 0.05 was set as statistically significant.

Results

Subject demographics

Ninety-eight subjects with various degrees of neck aging were enrolled in this study. These subjects were divided into five age groups, i.e., 25–30, 31–40, 41–50, 51–60, and over 60 years old, containing 8, 31, 33, 19, and 7 cases, respectively.

Treatment regimens and efficacy evaluation (Table 1)

Of all subjects, 28 subjects (28.6%) received only 1 session of treatment owing to the economic reason. The neck aging score was 3.61 ± 1.62 at baseline, and significantly decreased to 2.50 ± 1.50 at M3 (SMD = 1.11, 95%CI: 0.91 to 1.30, $p < 0.05$) and to 2.43 ± 1.55 at M6 (SMD = 1.18, 95%CI: 0.99 to 1.36, $p < 0.05$). Various degrees of improvements were noted in more than 90% of the subjects, and about 50% subjects had 50% or greater improvement. The average improvements were 37.0% at M3 and 41.6% at M6. No significant difference was observed between M3 and M6 (SMD = 0.07, 95%CI: -0.03 to 0.17, $p > 0.05$). Figure 1 showed the representative photographs of one subject who received 1 session of NIMNRF treatment.

Seventy subjects (71.4%) accepted 3 sessions of treatments. The neck aging score was 3.57 ± 1.28 at baseline. Comparing to the baseline, it significantly decreased to 2.45 ± 1.37 after 1 session (SMD = 1.13, 95%CI: 1.04 to 1.22, $p < 0.05$) and to 1.80 ± 1.30 after 2 sessions (SMD = 1.77, 95%CI: 1.62 to 1.92, $p < 0.05$). The scores continuously decreased to 1.10 ± 0.84 at M3 (SMD = 2.47, 95%CI: 2.29 to 2.65, $p < 0.05$) and to 1.04 ± 0.86 at M6 (SMD = 2.53, 95%CI: 2.34 to 2.72, $p < 0.05$). Improvements were noted in all subjects, and 75% or greater improvements were showed in 55.7% subjects at M3 and 60% subjects at M6. The average improvements were 73.3% at M3 and 75.1% at M6. No significant difference was observed between M3 and M6 (SMD = 0.06, 95%CI: -0.04 to 0.16, $p > 0.05$). It showed a

trend of better efficacy with the increasing number of sessions ($H = 100.3$, $p < 0.05$). Figure 2 showed the representative photographs of one subject who received 3 sessions of NIMNRF treatments.

The subjects who received 3 sessions had better results than those who received 1 session (SMD = 1.35, 95%CI: 1.15 to 1.55, $p < 0.05$). Six subjects were followed up for 1 year. Among of them, 5 subjects received 3 sessions of treatment and the improvement was about 70% (Fig. 2c), and another 1 subject received 1 session and the improvement was 40% (Fig. 1c).

For subjects who received only 1 session, a half subjects reported moderate satisfied, and the remaining subjects were fairly satisfied. After 2 sessions of treatment, 30% subjects were very satisfied, 40% were moderate satisfied, and 30% were fairly satisfied. For subjects who received 3 sessions, the subject's satisfactions were reported as very satisfied in 80% subjects and moderate satisfied in 20% subjects.

Evaluation of adverse events

All the subjects developed erythema which was disappeared within 48 h, and small scabs which desquamated 7–10 days after treatment. Almost all subjects reported 3 to 4 points of pain scores (potential ranges 0 to 10). Overall, treatment was well tolerated. No other adverse events, such as burning, prolonged erythema, swelling, or pigmentation were observed.

Discussion

Demand for noninvasive minimal-downtime skin rejuvenation treatment is increasing for most potential subjects. In order to balance the downtime, discomfort, efficacy, and safety, NIMNRF was introduced. Previous studies have demonstrated the efficacy of NIMNRF as a single modality or in combination with other modalities. Harth et al. [21] treated twenty subjects with acne scars through NIMNRF treatments, and 25% of subjects experienced more than 50% improvement. Haim Kaplan et al. [10] treated fourteen subjects on cheeks, neck, and submental area with fractional NIMNRF combined with nonablative multisource RF and multisource fractional skin resurfacing, and the result showed that about 43% of subjects achieved above 50% improvement.

Neck laxity and wrinkles are mainly the results of photoaging and intrinsic age-related neck degeneration. Various methods had been attempted for neck rejuvenation. Tierney et al. [22] treated 10 subjects by using fractional CO₂ resurfacing for 1-to-3 treatment sessions at 6- to 8-week intervals, achieving 59.3% improvement at 2 months posttreatment. Lee et al. [13] treated 20 subjects with horizontal neck

Table 1 Patient's neck aging scores and improvement rates after one or three treatment sessions of noninsulated microneedle radiofrequency

	Age groups (years)				
	25–30	31–40	41–50	51–60	>60
1 session	3 (10.7%)	7 (25%)	9 (32.1%)	7 (25%)	2 (7.1%)
Scores (<i>n</i> (%))					
M0	3 (3.0%)	15 (14.9%)	36 (35.6%)	35 (34.7%)	12 (11.9%)
M3	1 (1.4%)	9 (12.9%)	23 (32.9%)	27 (38.6%)	10 (14.3%)
M6	0	9 (13.2%)	22 (32.4%)	27 (39.7%)	10 (14.7%)
M3 vs. M0	–	–	*	–	–
M6 vs. M0	–	–	*	–	–
M3 vs. M6	–	–	ns	–	–
Improvement (%)					
M3	66.7	45.1	30.5	20.8	16.7
M6	100.0	45.1	38.9	20.8	16.7
3 sessions	5 (7.1%)	24 (34.3%)	24 (34.3%)	12 (17.1%)	5 (7.1%)
Scores (<i>n</i> (%))					
M0	5 (2%)	63 (25.2%)	96 (38.4%)	58 (23.2%)	28 (11.2%)
M3	0	14 (18.2%)	26 (33.8%)	24 (31.2%)	13 (16.9%)
M6	0	10 (13.7%)	27 (37.0%)	23 (31.5%)	13 (17.8%)
M3 vs. M0	–	*	*	*	–
M6 vs. M0	–	*	*	*	–
M3 vs. M6	–	ns	ns	ns	–
Improvement (%)					
M3	100.0	80.0	73.0	57.9	54.0
M6	100.0	85.5	71.8	59.6	54.0

M0, baseline; M3, 3 months after final session; M6, 6 months after final session. –represents no statistical analysis as sample size small; *represents $p < 0.05$; ns represents no statistical difference

lines by botulinum toxin A injection with 1–2 U per site (total dose 15–30 U), and achieved more than 50% improvement at 16 weeks follow-up. Michael et al. [23] utilized a fractional NIMNRF system for 49 patients with 3 treatments at 1 month interval on face/neck, noted all patients showed improvement while 65% of patients had significant improvement. In the present study, we firstly reported a large-scale long-term observation of NIMNRF treatment on neck rejuvenation retrospectively. Of 28 subjects who received only one session of treatment, the average improvements were 37.0% and about 50% subjects achieved $\geq 50\%$ improvement, at 3 months follow-up. The results suggested that NIMNRF was highly efficacious. The improvement maintained the same level 6 months

after the treatment, indicating a lasting effect of the NIMNRF. Of 70 subjects who accepted 3 sessions, the average improvements were above 70.0%, and 55.7% subjects experienced $\geq 75\%$ improvement at 3 months after the third session. It showed a trend of better efficacy with the increasing number of sessions from 1 to 3, and the efficacy maintained at a high level 6 months after the final treatment. The subjects were rather satisfactory with NIMNRF treatment, especially 3 sessions. Herein, based on our clinical experience, we used higher energies and longer interval (3 months) of each session in contrast to previous modalities of NIMNRF. The modified protocol produced relatively long-term efficacy and thus reduced the subject's economic burden.



Fig. 1 The representative series photographs of a 52-year-old woman with neck aging treating with noninsulated microneedle radiofrequency. **a** Baseline, **b** 3 months after 1 treatment session, **c** 1 year after 1 treatment session

Fig. 2 The representative series photographs of a 74-year-old woman with neck aging treating with noninsulated microneedle radiofrequency. **a** Baseline, **b** 3 months after 3 treatment sessions, **c** 1 year after 3 treatment sessions



A study where 17 patients treated with advanced 4-MHz monopolar RF for 6 sessions for face and neck laxity, showed improvement were maintained in 50% of the subjects at the 1 year follow-up [24]. Yasemin et al. [11] reported the clinical outcome of 20 patients treated with fractional CO₂ resurfacing for 1 session was effective at 1 month, but to a lesser degree at 1 year follow-up. In our study, significant neck rejuvenation was retained even up to 1 year. Among of 6 subjects who was followed up for 1 year, 5 subjects who received 3 sessions of treatment achieved about 70% improvement after final session, and another 1 subject who received 1 session remained the improvement up to 40%. The long-term efficacy of our NIMNRF should be verified in more subjects in future.

Previous reports showed that patients treated with fractional CO₂ laser showed adverse events containing erythema (up to 14 days), edema (up to 3 days), epidermal bronzing, crusting, and infection [11]. Postinflammatory hyperpigmentation occurred in up to 25% patients with Fitzpatrick skin types III and IV [11]. Concerning of injection for neck lines, the common adverse actions were skin irregularity, injection marks, bruises, accentuation of neck lines, erythema, and swelling [12, 13]. By using our NIMNRF in combination of postoperative products including Neck Wrinkle Removing Set and Active Protein Cristal Mask, the adverse events were rather less. Slight erythema (within 48 h) and small scabs (7–10 days) were seen commonly but quickly resolved. Based on these, we noted that NIMNRF treatment is tolerated with slight adverse effects and low downtime.

In conclusion, the results demonstrate NIMNRF treatment has significant effect on neck laxity and wrinkle reduction with minimal discomfort and downtime. Furthermore, it is important to receive continuous sessions to maintain the obtained efficacy.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study was performed in accordance with the International Conference of Harmonization (ICH) Good Clinical Practice (GCP) guidelines and the Declaration of Helsinki.

Informed consent Informed consent was obtained from all individual participants included in the study.

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