Assessment of the Mobile Delivery of Infrared Light (1100-1800 nm) for the Treatment of Facial and Neck Skin Laxity

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ABSTRACT

Background: Previous studies have shown that although infrared light and radiofrequency delivered by stationary application is safe and effective for the treatment of rhytides, a mobile delivery of radiofrequency energy can render the treatment as painless. In addition, few studies have defined and assessed efficacy of these infrared treatments in treating laxity by quantitative grading.
Objective: This prospective study assesses the safety, efficacy, and pain profile of the application of infrared light with a mobile delivery method for the treatment of facial and neck skin laxity as assessed by a tested, quantitative grading scale.
Methods: In this study, 22 female subjects (aged 40-75 years; Caucasian and Asian ancestry) with a clinically observable excess of laxity (minimum grade 2 out of 4) on the face received 1 to 3 treatments with incoherent infrared (1100-1800 nm) light at 2-week to 4-week intervals. Each light pulse was administered in a mobile continuous fashion within a localized area measuring approximately 1 handpiece tip-width laterally and vertically. A series of 4 to 5 pulses were administered across small grid areas, followed by 6 to 8 passes to each grid area, totaling approximately 300 to 450 pulses per treatment. Each mobile pulse was delivered at fluences of 45 to 46 J/cm^2 to the face, 45 J/cm^2 to the mandible, and 44 J/cm^2 to the neck. Clinical results were evaluated employing a comprehensive 4-point grading scale from photographs at baseline, and the 1-month and 3-month follow-up visits after the final treatment. Pain ratings were evaluated by visual analog scale (VAS) gradings and patient questionnaire immediately following treatment.
Results: All subjects completed and responded to treatment. The mean treatment number was 2.1 (+/-0.9) and the mean follow-up interval was 1.9 (+/-1) months. The quantitative evaluations demonstrated: a mean baseline laxity grade of 2.9 +/-0.5 and mean post-treatment laxity grade of 2.5 +/-0.6; and a mean difference in prelaxity grades versus postlaxity grades of 0.4 +/-0.3 (95% CI; 0.2540-0.5415). The data demonstrated a statistically significant difference between before and after measurements (P<.0001) and a mean percent improvement in laxity grading scores of 14.1 +/-11.3%. The treatment discomfort was rated as a mean of 0.7 (+/-0.6) on a VAS grading scale (0 to 10). By patient questionnaire, sensation during the treatment was rated as painless by 100% of patients and rare (<5) transient moments of heat-related pain sensation were reported by 18% of patients. None of patients reported the procedure as painful or as sensing frequent (>5) or persistent heat-related pain sensation during the treatment. Other side effects included minimal erythema which resolved within 1 to 3 hours. No crusting, dyspigmentation, or scarring was observed.
Conclusion: This prospective clinical study with quantitative grading of laxity and VAS pain scores demonstrated that mobile delivery of infrared light appears to be safe, clinically effective, and painless in reducing facial and neck laxity. The mobile infrared light delivery allowed for delivery of approximately 30% higher fluence dosages and increased passes to each pulse area. The clinically observable and quantified decreases in skin laxity following treatment were statistically significant.

INTRODUCTION

Skin tightening is a term often used to describe the treatment of skin laxity by laser and light energy-based procedures, most notably radiofrequency and infrared wavelengths.[1] Skin laxity on the face is manifested by progressive loss of skin elasticity, loosening of connective tissue framework, deepening and redundancy of skin folds, and progressive prominence of submandibular and submental tissues. Intrinsic genetic factors and extrinsic factors, such as photoaging, contribute to skin laxity, as demonstrated by genetic skin disease research as well as histopathologic findings of photoaged skin, respectively.[2-4]

While no device has yet to receive approval from the Federal Drug Administration (FDA) for treatment of skin laxity, it has become evident in the laser and light field that devices inducing volumetric heating, such as radiofrequency or infrared wavelengths, treat this condition with a process conventionally referred to as skin tightening.[1,2] Since its inception with the approval of the monopolar radiofrequency device Thermage® (Solta Medical, Hayward, Calif.) in 2002 for the treatment of rhytides, volumetric heating has progressed with the development of further generations of radiofrequency devices, and more recently, the application of infrared wavelengths.[2,5] Combination bipolar radiofrequency and infrared laser or intense pulsed light were FDA-approved for wrinkle reduction in 2006.[6] This was followed by the development of a combination unipolar and bipolar radiofrequency device, which was FDA-approved for rhytide reduction on-face and off-face

TABLE 1.

Quantitative grading and classification system of laxity, rhytides and photoaging[6]

Grade		Rhytides	Laxity	Elastosis	Dyschromia	Erythema/ Telangiectasia	Keratoses	Texture
0	none	none	none	none	none	none	none	none
1	mild	wrinkles in motion, few, superficial	localized to NL folds	early, minimal yellow hue	few (1-3) discrete small (<5 mm) lentigines	pink E or few T, localized to single site	few	subtle irregularity
1.5	mild	wrinkles in motion, multiple, superficial	localized, NL and early ML folds	yellow hue or early, localized PO EB	several (3-6), discrete small lentigines	pink E or severalT localized 2 sites	several	mild irregularity in few areas
2	moderate	wrinkles at rest, few, localized, superficial	localized, NL/ML folds, early jowels, early submental SM	yellow hue, localized PO EB	multiple (7-10), small lentigines	red E or multiple T localized to 2 sites	multiple, small	rough in few, localized sites
2.5	moderate	wrinkles at rest, multiple, localized, superficial	localized, prominent NL/ML folds, jowels and SM	yellow hue, PO and malar EB	multiple, small and few large lentigines	red E or multiple T, localized to 3 sites	multiple, large	rough in several, localized areas
3	advanced	wrinkles at rest, multiple, forehead, periorbital and perioral sites, superficial	prominent NL/ML folds, jowels and SM, early neck strands	yellow hue, EB involving PO, malar and other sites	many (10-20) small and large lentigines	violaceous E or manyT, multiple sites	many	rough in multiple, localized sites
3.5	advanced	wrinkles at rest, multiple, generalized, superficial; few, deep	deep NL/ML folds, prominent jowels and SM, prominent neck strands	deep yellow hue, extensive EB with little uninvolved skin	Numerous (>20) or multiple large with little uninvolved skin	Violaceous E, numerousT little uninvolved skin	little uninvolved skin	mostly rough, little uninvolved skin
4	severe	wrinkles throughout, numerous, extensively distributed, deep	marked NL/ML folds, jowels and SM, neck redundancy and strands	deep yellow hue, EB throughout, comedones	numerous, extensive, no uninvolved skin	deep, violaceous E, numerousT throughout	no uninvolved skin	rough throughout

NL= nasolabial, ML= melolabial, SM= submandibular, PO= periorbital, EB= elastotic beads, E= erythema, T= telangiectasia.

in 2007.[7] Infrared wavelengths were subsequently developed for volumetric heating with the introduction of the 1100-nm to 1800-nm infrared light device (Titan®; Cutera, Brisbane, Calif.), which was FDA-approved for deep dermal heating in 2006.[8] A variable-depth targeting infrared laser (1310 nm) has been studied for skin tightening.[9] Thus, radiofrequency and infrared wavelengths have been employed for the treatment of skin laxity, though until now confined by FDA approval to the treatment of rhytides and/or deep dermal heating.

Skin tightening technologies are evolving rapidly towards greater efficacy, faster treatment times, and minimization of pain and side effects, with an objective to demonstrate efficacy in the treatment of skin laxity. Recently, a mobile protocol was developed for a radiofrequency device, which was shown to render the treatment painless.[7] In the current study, a similar mobile protocol was introduced for the infrared technology (1100-1800 nm) and quantitatively assessed by a tested laxity grading scale.

METHODS

Patient Selection

Twenty-two female subjects (aged 40-75 years) were enrolled. Inclusion criteria included subject aged 18 to 75 years with clinically observable excess of rhytides and laxity (minimum grade 2 out of 4) on the quantitative grading scale (Table 1) for the face and neck. Exclusion criteria included pregnancy or lactation; rheumatologic or connective tissue diseases (eg, fibromyalgia rheumatica), lupus erythematosus, scleroderma, dermatomyositis, or other autoimmune skin disease, and diseases of the thyroid or parathyroid.

Protocol

Patient Preparation

Managing patient expectations at the outset is advised. Patients who are the best candidates for skin tightening are those who have ruled out plastic surgery for the interim. Patients included for treatment in this study were cautioned: In the vast majority of cases, a minimum of 3 treatments is required to achieve significant tightening (though some patients opt to pursue as many as 5 treatment sessions) and results are first observed 2 weeks after the first treatment and progressively improve with 3 to 6 of months follow-up or more. No topical anesthetic was needed for the procedure. A thin 1-mm layer of aqueous ultrasound gel was applied. The typical treatment areas included the lower face and neck, excluding the thyroid region (Figure 1).

Treatment Intervals

Each patient received 3 treatments with incoherent infrared (1100-1800 nm) light at 2-week to 4-week intervals.

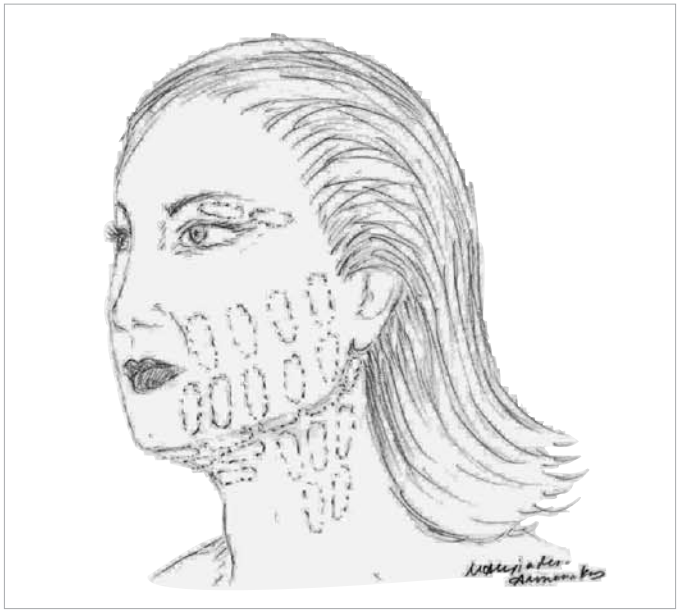

FIGURE 1. Illustration demonstrating placement of each mobile pulse. The shape of each **oval** indicates the orientation of the handpiece. The pulses were administered in a linear fashion along the jawline, along the upper neck, and in the submental area as shown. The precise groupings of pulses included: the lower cheek, mid cheek to upper cheek, mandible, upper lateral neck, submandibular, and submental areas. The passes were administered in succession to each grouping of 4 to 5 pulses before commencing in a new area. A minimum of 4, but preferably 7 to 8 passes along each segment each covering an area of approximately 1.5 cm^2 were administered. One to 2 adjacent pulses were administered in 4 to 5 passes to each brow extending to the lateral periorbital region.

Mobile Pulse Application

Each light pulse was administered in a mobile continuous fashion within a localized area measuring approximately 1 handpiece width laterally and vertically. The handpiece was moved with the initiation of each pulse, making oval/circular movements extending approximately 1 width laterally to the handpiece tip and 1 length of the handpiece tip vertically. The pulses were delivered in linear succession in small groups of 4 to 5 pulses with 6 to 8 passes were administered to each pulse group before moving to a new area. The total number of pulses was approximately 300 to 450 pulses per treatment. The pulses should be administered in a linear fashion along the jawline, along the upper neck and in the submental area as shown in Figure 1. The precise segments or grid areas included: the lower cheek, mid cheek to upper cheek, mandible, upper lateral neck, submandibular, and submental areas (Figure 1). The passes were administered in succession to each linear area before commencing in a new area. A minimum of 4, but preferably 7 to 8 passes along each segment each covering an area of approximately 1.5cm^2 were administered. One to 2 adjacent pulses were administered in 4 to 5 passes to each brow extending to the lateral periorbital region (Figure 1).

Dose/Fluence

Precooling, parallel cooling, and postcooling of the epidermis is applied to under 40°C through continuous contact with a sapphire tip. Each mobile pulse was delivered at a fluence of 46 J/cm^2 to the face, 45 J/cm^2 to the mandible, and 44 J/cm^2 to the neck. The fluence was commenced at 46 J/cm^2 for the mobile protocol to the face; 45 J/cm^2 to the mandible; and 44 J/cm^2 to the neck. If the patient sensed momentary transient discomfort, the fluence was titrated down by 1 J/cm^2 for a final target range of 44 to 46 J/cm^2 on the face and 42 to 44 J/cm^2 for neck. For superior periorbital regions, the mobile technique was initiated at fluences ranging from 26 to 30 J/cm^2. One to 2 adjacent pulses may be administered in 4 to 5 passes to each brow extending to the lateral periorbital region (Figure 1).

Clinical Evaluations

Clinical results were evaluated employing a comprehensive 4-point grading scale from photographs at baseline, and 1-month, 3-month, and 6-month follow-up visits after the final treatment.

Pain Evaluations

Pain ratings were evaluated by visual analog scale (VAS) gradings and patient questionnaire immediately following treatment.

Postoperative Care

Postoperative erythema resolved within minutes to hours and no postoperative care was needed.

RESULTS

Clinical Finding

Twenty-two female patients were enrolled, aged 40 to 75 years. Nineteen patient were of Caucasian ancestry and 3 were of Asian ancestry. All subjects completed and responded to treatment. Baseline and follow-up photography at each visit is critical and often improvements in facial skin laxity are best assessed by profile photo views. Photographic examples of laxity reduction in patients during the follow-up interval are shown in Figures 2 and 3.

Quantitative Assessments

All subjects completed and responded to treatment. The mean treatment number was 2.1 (+/-0.9) and mean follow-up interval was 1.9 (+/-1) months. The quantitative evaluations demonstrated: a mean baseline laxity grade of 2.9+/-0.5 and mean posttreatment laxity grade of 2.5+/-0.6; a mean difference in prelaxity grades versus postlaxity grades of 0.4+/-0.3 (95% CI; 0.2540-0.5415) and a mean percent improvement in laxity grading scores of 14.1+/-11.3%. Paired *t* test comparison demonstrated that the difference between the laxity grading scores prior to and posttreatment were statistically significant with a *P* value <.0001.

Pain Evaluations

The treatment discomfort was rated as a mean of 0.7 (+/-0.6) on a VAS grading scale (0 to 10). By patient questionnaire asking patient to rate the procedure as painless, mildly painful, moderately painful, or painful, sensation during the treatment was rated as painless by 100% of patients. In a separate question asking patients whether they sensed rare (<5) transient moments of heat-related pain versus frequent (>5) moments of heat-related pain versus persistent heat-related pain during the procedure, 18% (4 of 22) of patients reported only rare transient moments of heat-related pain during the course of the procedure. None of patients reported the procedure as painful or as sensing frequent or persistent heat-related pain sensation during the treatment.

Safety

Other side effects included minimal erythema which resolved within 1 to 3 hours. No crusting, dyspigmentation, or scarring was observed.

DISCUSSION

Skin laxity, manifested by progressive loss of skin elasticity, loosening of connective tissue framework, deepening and redundancy of skin folds, and progressive prominence of submandibular and submental tissues, is caused by a combination of intrinsic genetic factors and extrinsic factors, such as photoaging.[2-4] Intrinsic genetic factors influence skin laxity, such as in cases of

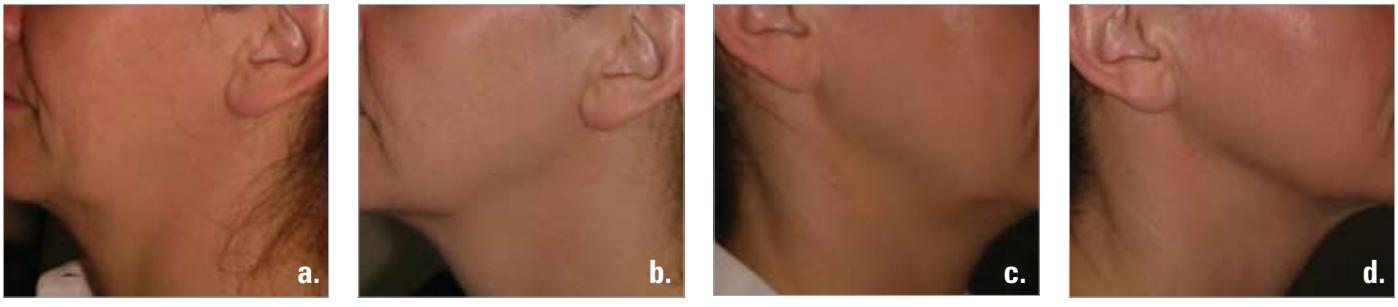

FIGURE 2. Patient prior to **(a, c)** and posttreatment **(b, d),** following 3 serial mobile delivery treatments with infrared (1100-1800 nm) light at 3-month follow-up with clinically evident reduction in skin laxity in the lower face and neck.

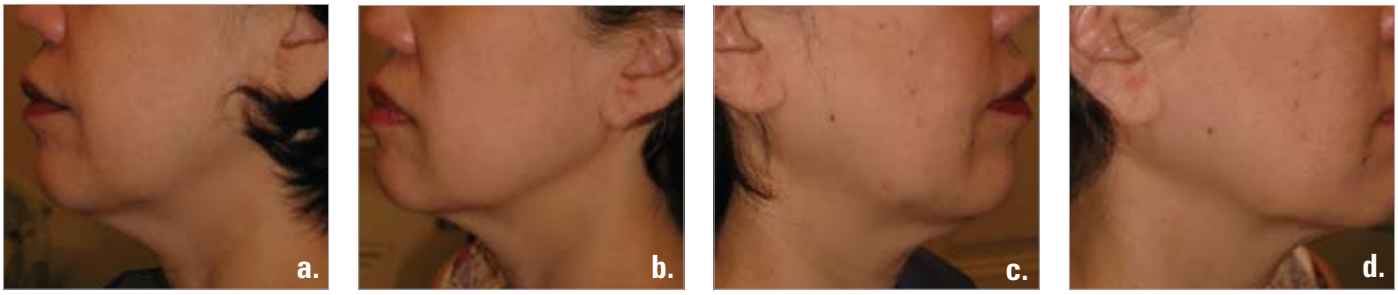

FIGURE 3. Patient pretreatment **(a, c)** and posttreatment **(b, d)**, following 2 serial mobile delivery treatments with infrared (1100-1800 nm) light at 1 month follow-up. Reduction of laxity of the lower face and neck are clinically evident.

cutis laxa, a genetic disease caused by mutations in elastin and fibulin genes, and of progeria or premature aging syndromes caused by mutations affecting telomere shortening, laminins, and DNA repair.[10-12] It is possible that progressive skin laxity during aging is due to polymorphisms or acquired mutations in these candidate genes or due to external factors affecting the corresponding proteins they encode. Photoaging is an extrinsic cause of skin laxity, resulting in solar elastosis and the corresponding loss of skin elasticity. Molecular biological findings support such an etiology: disorders of elastin degradation, such as floppy eyelid syndrome are characterized by excessive elastin degradation resulting in extreme skin laxity of the eyelids.[13]Thus, a combination of genetic and external factors likely contributes to the progressive skin laxity observed with aging.

The targeting of skin laxity through skin tightening technologies has yet to be acknowledged as a distinct application by the FDA, however laxity grading scale used here has been tested in prior and current studies of radiofrequency and infrared treatments.[6,7,9] In the current study, quantitative analysis of clinical results using this laxity grading scale demonstrated statistically significant improvements in laxity grades following treatment with infrared (1100-1800 nm) light. Quantitative analysis of laxity grading demonstrated a mean pretreatment score of 2.9+/-0.5, mean posttreatment score of 2.5+/-0.6, and mean difference in prelaxity grades versus postlaxity grades of 0.4+/-0.3 (95% CI; 0.2540-0.5415). These data demonstrated a statistically significant difference between before and after measurements (P<.0001) (Table 2). The mean percent improvement in laxity grading scores was 14.1%+/-11.3% following a mean of 1.9 serial treatments. A prior study of combination bipolar radiofrequency with intense pulsed light and diode (900 nm) laser assessed with the same quantitative grading scale demonstrated a mean percent improvement in laxity grading scores of 9.9% (95% CI; 6.6-13.2).[6] In a randomized, split-face study with blinded evaluations comparing serial unipolar versus bipolar radiofrequency treatments demonstrated mean percent improvements in laxity scores of 4.6+/-4.8% and 7.3+/-3.5%, respectively, though the data were not statistically significant.[7] A variable-depth targeting infrared (1310 nm) laser treatment was also assessed for the treatment of skin laxity using the same quantitative grading scale, and demonstrated a mean percent improvement in laxity scores of 7.9% (95% CI; 3.6-12.3).[9] Thus, the quantitative laxity grading scale employed here has been tested previously, and the current study has demonstrated efficacy of this infrared device in treating skin laxity following an average of roughly 2 treatments and a mean of 2 months follow-up with statistically significant results. This translates from a practical standpoint into a treatment which yields clinically evident improvements in skin laxity within a short time period and after few treatments which is desirable for patient satisfaction.

Mobile delivery was initially introduced for radiofrequency energy and here is used to administered infrared light, which eliminated the need for anesthesia, allowed for higher fluences dosages and rendered the treatment painless. The novel mobile delivery protocol allowed for approximately 30% higher fluences and an increased pass number to be delivered due to

TABLE 2.

Comparison of laxity grading scores pretreatment and posttreatment with infrared light using mobile delivery (N=22)

Laxity	Mean	SD	SEM
Pretreatment	2.875	.539	.115
Posttreatment*	2.477	.597	.127
Difference	.3977† (P<.0001)	.3242	.0691

*The posttreatment values represent the laxity grading scores at a mean follow-up interval of 1.9 (range: 1-3) months following a mean of 2.1 (range: 1-3) treatments.
†95% CI for mean difference (0.2540-0.5415).

markedly increased patient tolerance to the procedure. The pain assessments including VAS pain scores and questionnaires demonstrated that the vast majority of patients considered the procedure painless with a small minority describing transient momentary heat sensation which rapidly dissipated as the pulse proceeded to postcooling. Although vesiculation and blistering have been infrequent complications of the stationary technique of infrared light delivery with the current device; in contrast, no adverse events were observed using this mobile protocol. Given that the continuous mobility allows for the continual cooling of pain sensory fibers at the dermoepidermal junction (DEJ) and the DEJ itself, as discussed in prior work, it is likely that this mobile protocol increases the safety of the procedure by minimizing the risk of epidermal and DEJ thermal burns. In addition, mobile delivery did not appear to compromise clinical efficacy. In contrast, the efficacy rates shown in the current study for mobile delivery of infrared light are at least comparable to prior findings employing the stationary technique (Figures 2 and 3, Table 2).[8] Comparative studies will be needed to determine whether the higher fluences and pass numbers delivered with the mobile protocol augment efficacy when compared to the stationary approach.

Recently, such a mobile technique was shown to render the delivery of radiofrequency energy, historically known as a painful procedure, as painless and free of complications, while not compromising clinical efficacy.[7] The negation of heat-pain sensation through mobile energy delivery was theorized by the author to be due to the innervations patterns and properties of the heat sensory afferents in the skin. As discussed when this technique was first developed, the continuous movement of the energy deposition allows for heat-related pain afferent to continually cool with their lower thermal relaxation times (TRTs), while at the same time depositing thermal energy into the large targets within the dermis, namely collagen bundles, with their relatively long TRTs.[7] The peak temperatures necessary for thermal denaturation of collagen are thereby achieved in the dermis, whereas the temperatures at the DEJ remain below the 40° to 42° C threshold for firing of heat-related pain afferents.[7] Thus, with this mobile approach neocollagenesis is effectively triggered in the dermis, whereas pain sensors and structures at the DEJ are allowed to cool, making for a safer, effective and painless treatment.

CONCLUSION

This prospective study with quantitative clinical grading and VAS pain scores demonstrated that mobile delivery of infrared light appears to be a safe, clinically effective, and painless treatment of skin laxity. Quantitative assessments of facial and neck skin laxity grading demonstrated mean percent improvement of 14.1 +/- 11.3% following a mean of 1.9 treatments, a statistically significant difference between before and after measurements (P<.0001). This mobile infrared light delivery was shown to allow for 30% higher fluences and increased passes, while rendering the application painless and free of complications, with a small fraction of patients reporting rare momentary, transient heat-related pain sensation. Further study will be required to determine whether the painless mobile protocol which allows for higher fluence delivery also results in an augmentation in clinical efficacy.

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