Fractional High Intensity Focused Radiofrequency in the Treatment of Mild to Moderate Laxity of the Lower Face and Neck: A Pilot Study

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Background and Aims: The aging process is commonly associated with skin laxity in the lower face and neck. Conventional surgery can correct this at least to some extent, but is invasive. Fractional high-intensity focused radiofrequency delivered to the dermis with insulated microneedles has recently attracted attention in facial rejuvenation. The present pilot study was designed to assess the efficacy of HiFR for skin laxity of the lower face and neck.

Methods: Thirty-three patients (7 males, 26 females, age range 37–74 years) with mild to moderate skin laxity of the lower face/neck participated in the study. Three treatments were given at monthly intervals with protocols developed by the authors, three passes per session, at decreasing dermal depths for each pass. Histologic assessment of skin immediately after treatment was performed to identify the site and area of damage in the dermis. Clinical digital photography was taken at baseline and at 6 months after the final treatment session, based on which standardized computer measurement of improvement in the gnathion and cervicomental angles was the primary objective evaluation. A global assessment of improvement was graded by blinded assessors based on the photography. A telephone survey of patient satisfaction was performed at 12 months post-treatment.

Results: A significant post-treatment decrease in the cervicomental and gnathion angles was seen of 28.5° and 16.6°, respectively ($P < 0.0001$ for both). Histology immediately post-treatment showed a clear demarcated and roughly oval area of coagulation associated with the tip of the needle, confined to the dermis and not involving the epidermis. In the global assessment 81.8% of the patients achieved moderate or higher results, and 87% of patients were very satisfied or better. Downtime was minimal, lasting 3–4 days, and no persistent adverse events were recorded.

Conclusions: Fractional HiFR proved safe and effective in the treatment of neck laxity in a large age range of patients, including the elderly. Lasers Surg. Med. 48:461–470, 2016. © 2016 Wiley Periodicals, Inc.

Key words: skin laxity; wound healing; coagulation; collagenesis; remodeling

INTRODUCTION

As the facial skin ages, owing to both the photoaging and intrinsic aging processes, progressively deeper lines and wrinkles may appear as the extracellular matrix (ECM) fibrous components of collagen and elastin degrade and lose their resilience. With loss of fat in the mid face and loss of ECM resilience, skin laxity develops in the lower third of the face and under the relentless 10 N/kg force of gravity, unsightly pendulous folds of tissue appear at the jowls and neck, with deep horizontal wrinkling of the neck. Horizontal creases can be exacerbated or form over time by occupations or habits such as typing with a laptop on the lap or reading with a book down low, that lend oneself to constant flexing of the neck or having the chin tipped down over long periods of time.

Of all the visible signs of the aging countenance, sagging jowls and lax neck skin are among the most cosmetically troublesome to the aesthetic patient. Unfortunately, these signs are also among the most challenging to treat. Treatment of this region is desirable to truly provide a complete and visible reduction in aged appearance. In photo- and chronological aging of the skin, the appearance of skin laxity, wrinkling and lines of the skin are initially associated with the deterioration of both the epidermis and dermis, in particular the collagen and elastin fibers as the scaffolding of the extracellular matrix, and aging of the fibroblasts themselves.

Traditional conventional rhytidectomy offers an answer, but at the cost of an extremely invasive procedure, and even then this approach may not completely address the

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laxity of the skin of the neck nor does this procedure address the loss of resilience of the ECM of the skin. As an analogy, cutting and re-draping the tablecloth to fit a table does not usually get the wrinkles and creases out. Furthermore, there is only a finite number of times the procedure can be repeated, as photo- and intrinsic aging once again take their course.

Various laser procedures have been reported for facial rejuvenation. For severe facial photodamage, the gold standard is still full ablative laser resurfacing with the CO_2 or Er:YAG lasers, or a combination of these [1]. Although the results can be excellent, the immediate postoperative sequelae of unpleasant oozing and crusting inevitably occur, followed by what can often be weeks of erythema leading to prolonged patient downtime. The potential for scarring and pigmentary changes is very high through poor compliance with the wound management protocol. Although ablative resurfacing can address photodamage on the face, the neck area is contraindicated; however, because of the comparative paucity of pilosebaceous units to aid in island re-epithelialization [2,3].

To overcome these postoperative problems and potentially expand the indications of laser rejuvenation to non facial areas, such as the neck, fractionation of the laser beam into multiple microbeams was developed with both nonablative and ablative approaches, whereby the zones of microdamage were surrounded by large areas of normal dermis and epidermis which minimized downtime and hastened wound healing. Unlike the full ablative approach the fractional ablative lasers could be used on the neck, but results tended to be modest for skin laxity [4], and for nonablative lasers, skin laxity was hardly addressed at all [5].

Radiofrequency (RF)-based systems gained attention, appearing first as superficial RF where the electrodes were placed in contact with the epidermis [6]. Skin resistivity-related electrothermal damage was created as the RF energy passed through the tissue between the electrodes, creating areas of coagulation which kick-started the wound healing process with associated collagenesis and elastinogenesis, followed by remodeling, to give a renewed and rejuvenated ECM. One issue with external RF was the creation of hotspots at the level of the epidermis by the electrodes, necessitating aggressive cooling to prevent epidermal electrothermal damage [7]. The second, and more serious issue, was lack of sufficient thermal damage delivered in the mid to deep dermis, the major target in tightening lax skin. Because the thermal effect was essentially non-fractional, raising temperatures in the skin high enough to cause irreversible coagulation could generate large area wounds and risks of burn and scarring in addition to substantial discomfort. As a result, this approach was modified to achieve acceptable pain tolerance using longer exposure times and lower temperatures that achieved partial denaturation of collagen that, while not causing removal and replacement of aged collagen, was demonstrated to stimulate new collagen and elastin and achieve some benefits in the reduction of skin laxity.

More recently, microneedle electrodes were developed to deliver the RF energy directly into the dermis [8], with the later units having the shaft of the needle insulated, leaving the tip of the needle as the active electrode, limiting epidermal damage to mechanical needling and obviating the need for epidermal cooling. The sheathed configuration of the needle and exclusive tip delivery of energy may also help to bypass most pain receptors, which are localized within the first 200 μm of the skin [9]. The technology has been termed high-intensity focused radiofrequency (HiFR), since the insulated microneedles deliver high intensity energy focused around the active tips. HiFR is proposed as a unique method to rebuild a degraded ECM, as well as encouraging epidermal renewal through mechanical microneedling. By bypassing thermal injury to the epidermis and dermoepidermal junction (DEJ), the approach was designed to minimize post-treatment downtime and the risk of prolonged erythema and post-inflammatory pigmentation. These sequelae have previously limited the ability of fractional laser, and other through the surface and down heating methods, to treat darker skin types and tanned skin. A multicenter trial of 499 patients in five geographically different centers of such a system for facial wrinkles [10], where the user could alter the depth of the needles in the dermis for each pass, showed safety and good efficacy. Based on the proven efficacy on facial wrinkles, the present study was therefore designed to assess the efficacy of HiFR with insulated microneedles in the treatment of mild to moderate laxity of the lower face and neck.

SUBJECTS AND METHODS

Subjects

The study subjects comprised a total of 33 persons, (7 males, 26 females, age range 37–74 years, mean age 51.3) with mild to moderate skin laxity of the lower face and neck. All subjects, having had the concept and aims of the study explained to them, together with expected results and possible side effects, gave written informed consent to participate in the study, and to have their clinical photography used for scientific reporting purposes. The study was performed under the precepts of the World Medical Association Declaration of Helsinki (6th revision, 2008). Subject demographics are shown in Table 1.

HiFR System

The HiFR system delivered 1 MHz RF energy via a bipolar array of microneedles embodied in a single-use disposable tip (INFINI^{TM}, Lutronic Corp, Goyang, South Korea). A 1 cm^2 7×7 array of needles was used exclusively in the present study. All of the 200 μm diameter microneedles ($\sim$34 G) are gold-coated surgical stainless steel and are insulated except for the first 300 μm at the very tip comprising the active electrode. Because the shaft of the needle is insulated, no electrothermal damage is delivered to the epidermis and DEJ and epidermal cooling is not required. Epidermal damage is limited to mechanical microneedling. During each pulse the device automatically

TABLE 1. Patient Demographics and Results of Standardized Computer Measurements of the Cervicomental and Gnathion Angles (Refer to the Text for an Explanation)

Pts	Sex	Age	Ce° pre	Ce° post[a]	Ce° Diff	Ce%	Gn° pre	Gn° post[a]	Gn° Diff	Gn%
1	F	71	116	84	32	28	89	77	12	13
2	F	42	146	96	50	34	107	83	24	22
3	F	41	134	105	29	22	100	83	17	17
4	F	37	136	108	28	21	96	84	12	13
5	M	54	137	113	24	18	112	93	19	17
6	F	47	142	113	29	20	115	99	16	14
7	F	50	133	117	16	12	106	88	18	17
8	M	52	154	120	34	22	116	94	22	19
9	M	74	153	126	27	18	117	101	16	14
10	F	43	124	111	13	10	99	86	13	13
11	F	36	114	87	27	24	114	87	27	24
12	F	44	142	96	46	32	109	96	13	12
13	F	44	134	101	33	25	107	91	16	15
14	F	36	136	107	29	21	112	94	18	16
15	F	55	141	115	26	18	99	87	12	12
16	F	47	141	116	25	18	101	91	10	10
17	M	50	132	117	15	11	106	93	13	12
18	F	54	155	122	33	21	99	86	13	13
19	F	68	153	124	29	19	111	95	16	14
20	F	61	124	113	11	9	105	89	16	15
21	F	65	119	89	30	25	112	93	19	17
22	M	36	136	99	37	27	103	89	14	14
23	M	44	135	100	35	26	107	93	14	13
24	F	64	136	108	28	21	100	85	15	15
25	F	55	141	117	24	17	111	96	15	14
26	F	70	141	118	23	16	114	87	27	24
27	F	49	132	116	16	12	113	97	16	14
28	F	51	155	124	31	20	100	85	15	15
29	M	68	144	123	21	15	102	90	12	12
30	F	38	124	109	15	12	114	94	20	18
31	F	63	113	82	31	27	88	75	13	14.8
32	F	42	145	96	49	34	104	82	22	21.2
33	F	41	150	105	45	43	100	79	21	21.0
Average (SD)		51.27 (11.42)	136.9 (11.72)	108.4 (12.12)	28.5 (9.8)	21.2 (7.62)	105.7 (7.44)	89.2 (6.22)	16.6 (4.3)	15.6 (3.55)

Ce° pre: Cervicomental angle at baseline. Ce° post: Cervicomental angle at 6 month follow-up. Ce° Diff; (Ce° pre − Ce° post).
Ce%: Ce° Diff expressed as a percentage.
Gn° pre: Gnathion angle at baseline. Gn° post: Gnathion angle at 6 month follow-up. Gn° Diff: (Gn° pre—Gn° post).
Gn%: Gn° Diff expressed as a percentage.
SD: Standard deviation.
[a]Statistically significant difference ($P < 0.0001$, Student's paired t-test).

inserts the microneedle array into the skin, delivers RF energy at the designated power level and pulse duration, then automatically retracts the needles. Pulses can be delivered at well over 1 pulse/second during a treatment. The depth of needle insertion can be varied from 0.5 to 3.5 mm. The RF energy can be set from level 1 (2.5 W) to level 20 (50 W) in 2.5 W increments and pulse duration adjusted from 10 to 1,000 ms.

Treatment Protocol

All patients were treated over three sessions, with 1 month between sessions. The depth, power level and pulse duration parameters used for treatments are shown in Table 2. Topical anesthesia (7% lidocaine—7% tetracaine) was applied for 1 hour before treatment, excess cream was thoroughly removed and the face cleansed before HiFR treatment. Each session consisted of three passes at the depths noted in the above table. The first pass was delivered working laterally on the neck and jowls, the second pass delivered vertically, and the third pass again laterally delivered (see Fig. 1 as a guide). The order of directional treatment, going from lateral to vertical was not felt to be critical, at the discretion of the authors, and kept consistent throughout all treatments.

TABLE 2. HiFR Settings for Laxity of the Lower Third of the Face and Neck (Developed by MTC, Validated by GM).

Passes	Depth (mm)	Level	Exposure time (s)
		Neck	
1	1.5–2.0	8–9	220–230
2	1.0–1.5	6	160
3	0.75–1.0	6	160
		Lower third of face/submental region	
1	2.5	8–11	280–320
2	1.5	8–9	230–250
3	1	6	160

Higher end of ranges was used in thicker skin.

Note from Table 2 that the power and pulse duration time settings decreased as the needle depth became more shallow. This was to prevent any secondary thermal damage to the uncooled epidermis caused by conducted heat spreading from the areas of coagulation at the needle tips. Each shot was delivered carefully abutted to the previous shot to obtain uniform and thorough coverage without leaving any gaps. Pinpoint bleeding was controlled intra-operatively by using compression with sterile gauze dampened with saline solution. Following treatment, a cooling mask was applied over the neck and jawline and a topical antibiotic cream was subsequently applied, the patient being instructed to apply the same cream at home on the day after treatment.

Clinical Photography

Standardized digital clinical photography (Canon 5D Mark II, fixed focus, anular flash) was taken at baseline and at 6 months after the final treatment session. Care was taken to reproduce all elements of the photographs between the baseline conditions and the 6-month follow-up assessment: camera settings, distance between camera and subject (predetermined by fixed focus), lighting conditions (anular flash), angle of the head (in the Frankfurt plane—patients stared at a point on the wall to elicit an "infinity" gaze), and a plain dark-colored background. The clinical photography was used to compare baseline with the findings at the 6-month assessment for the computerized craniometry-based assessment as described below, and for the clinicians' blinded global assessment of improvement.

Assessment With the Gnathion and Cervicomental Angles

Fiducial craniometric points for standardized computerized measurements were the glabella (the most prominent or anterior point of the forehead in the midsagittal plane at the level of the superior orbital ridges); the pogonion (the most prominent or anterior point of the skin over the chin in the midsagittal plane); the menton (the lowest point of the skin on the underside of the chin); and the cervical point (where the skin of the neck meets the jaw). Figure 2 shows how these were arrived at. On photographs with the patient viewed in lateral profile and gazing straight ahead, the computer imaging program was used to draw a line from the glabella (G) to the pogonion (P), extended slightly. Another line was drawn from the cervical point (C) through the menton (M) and allowed to intersect with the G–P line. That angle was measured to provide the gnathion angle (Gn) at baseline and at the 6-month follow-up. A third line was drawn from the anterior skin of the neck up through the cervical point, transecting the M–C line. That angle was measured to give the cervicomental angle at baseline and at the 6-month assessment.

All clinical subject images were imported from the camera using Photoshop, and exported as jpeg files without post-processing. The angle measurements were calculated by author MC using Able Image Analyzer (Mu Labs Imaging Software, http://able.mulabs.com) Measurements were verified independently by author GM using Klonk Image Measurement (http://www.imagemeasurement.com). Statistical significance was calculated using SAS (Cary, NC).

Histological Verification

To verify independently the extent and location of the dermal electrothermal coagulation damage and to ensure lack of epidermal involvement by conducted heat damage, biopsies were taken under IRB approval from the skin of non-study human subjects immediately after *in vivo* HiFR treatment with a selection of the treatment parameters from Table 2. This group of subjects were informed and consenting patients about to undergo unrelated surgical excisional procedures. Immediately prior to skin excision,

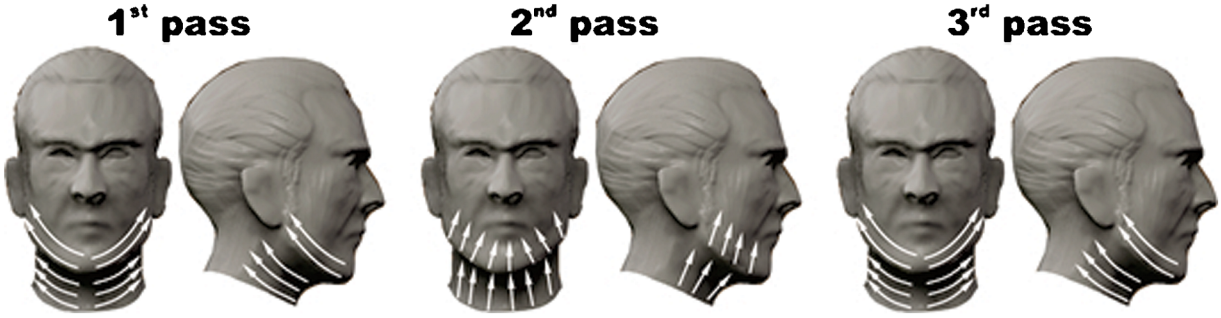

Fig. 1. The direction of the needling as it changed pass by pass.

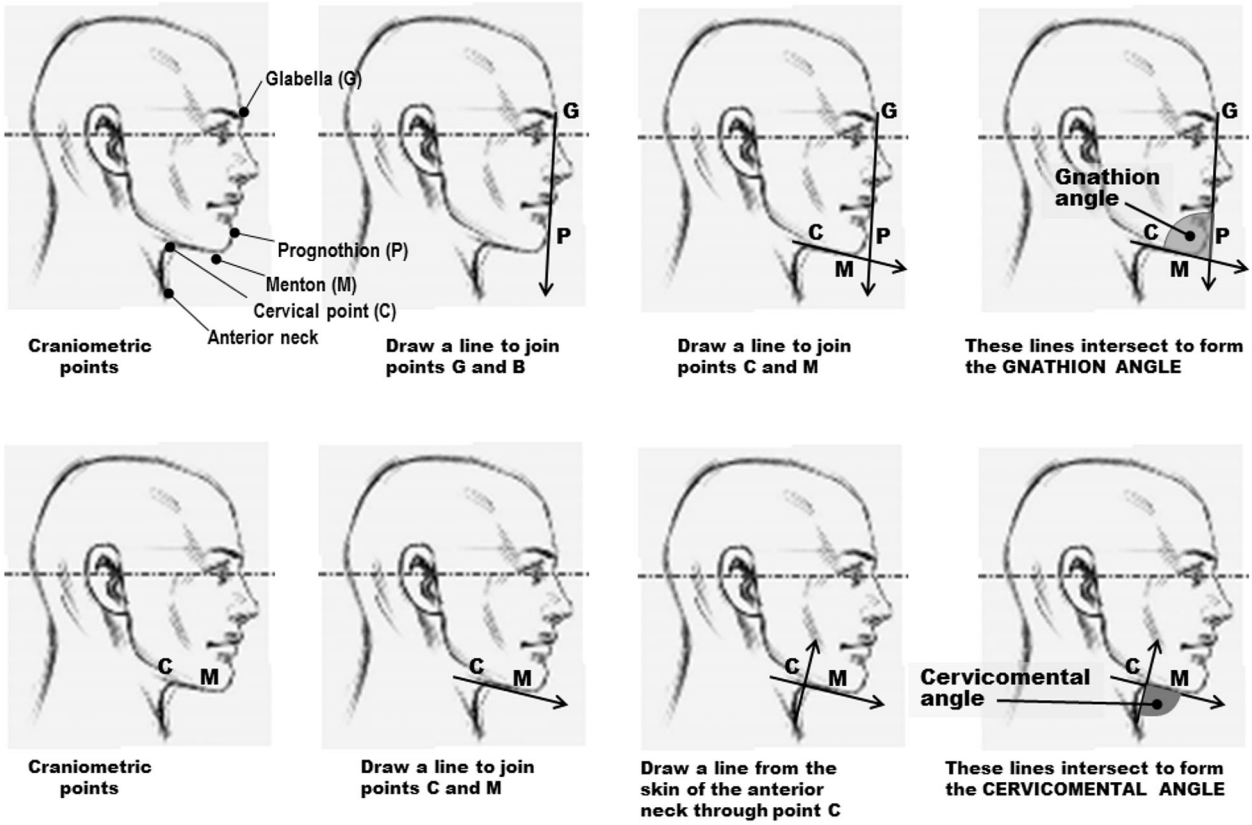

Fig. 2. Steps performed to create the gnathion and cervicomental angles from the clinical.

HiFR was performed on the preauricular skin and punch biopsies were taken straightaway. Biopsy specimens were coded, preserved in formalin and routinely processed for hematoxylin and eosin staining.

Clinician and Patient Assessments

Two complete sets of the clinical photography were prepared with the baseline and 6-month photography randomly assigned to the right or left of each slide. Furthermore, the order of the patients was randomized from the original order as seen in column 1 of Table 1 for each set. Two blinded independent dermatologists were asked first to correctly identify the baseline and 6-month views for each patient, and then to grade the improvement (if any) on a 7-point scale as follows: −1, exacerbation; 0, no change; 1, minimal improvement; 2, modest improvement; 3, moderate improvement; 4, significant improvement; and 5, impressive improvement. At approximately 12 months after treatment, a telephone survey was carried out to elicit patient satisfaction as follows: 0, extremely dissatisfied; 1, somewhat satisfied; 2, moderately satisfied; 3, very satisfied; and 4, extremely satisfied. In addition, patients were asked if they would return for another treatment if needed, and if they would recommend the treatment to their friends. It should be noted that all subjects were paying patients.

RESULTS

All 33 patients completed the treatment sessions, the 6-month follow-up and the 1-year telephone survey.

Histology

Figure 3 shows a representative example of an H&E stained specimen obtained from human skin *in vivo* immediately after HiFR treatment. The set needle depth for this specimen was 1.0 mm, the level was 10 and the exposure time was 300 ms, representing a fairly aggressive set of the HiFR parameters used in the present study. A needle track can be seen extending from the epidermis down into the dermis, culminating in a roughly oval shaped zone of well-demarcated coagulation around the location of the microneedle tip, as shown by the darker-stained eosinophilic area, surrounded by normal undamaged dermal tissue. No coagulation damage is seen at the edges of the needle track. and the coagulation zone goes nowhere near the epidermis. By compiling the area of the coagulation zones as seen in 2-dimensions in the stained specimens compared with the area of undamaged tissue, the damage zone appears similar to what is seen with fractional ablative laser treatments [11].

To account for the pattern of dermal injury, (in the HIRF scenario), heating occurs via alternating current flow much like electrocautery surgical bipolar tips. Current

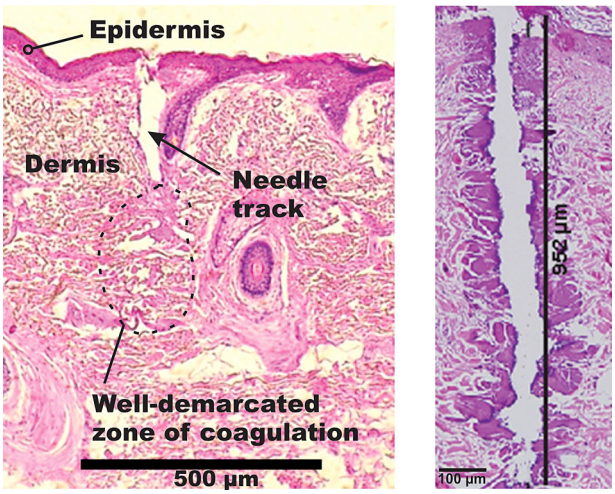

Fig. 3. (**Left**) Example of HiFR histology showing a zone of dermal coagulation with clear boundaries (dashed line), surrounded by undamaged tissue. The track caused by the insulated microneedle is seen through the epidermis down to the area of dermal coagulation, but there is no surrounding zone of secondary thermal damage to cause any potential side effects, or to slow down wound healing. (**Right**) Typical microablative zone created by a fractional CO_2 laser. The ablated tissue extends from the epidermis down into the dermis, and is surrounded for its entire length by a zone of secondary thermal damage. The coagulation zone is therefore not isolated at any specific depth in the dermis.

flow is restricted to the active 300 μm of the very tip due to non-conductive insulation surrounding the needles. Hence, there is no thermal injury except surrounding the active region of the tip. In the 7×7 array, the central 25 pins are surrounded on both sides by opposite polarity needles and current flow is symmetrical. The needles are spaced 1.4 mm apart.

For the outermost pins, since current flow decreases as a function of distance, there is still a fairly symmetrical injury pattern because the distance to the nearest opposite polarity pin is 1.4 mm (center to center) compared to the distance across the 200 μm diameter pin of ±100 μm. Therefore, even though there is slightly less current flow from the opposite side of the needle due to slightly longer distance to opposite polarity pin, the difference is relatively small and so the thermal injury pattern is reasonable symmetric. Given the tissue variation and distortion that inherently takes place during processing and the uncertainly of exactly how the histological slice actually cuts across the damage zone, it was difficult to definitively determine if the damage zones were slightly asymmetrical.

Improvement in the Craniometry Angles

Both the cervicomental and gnathion angles showed significant improvement at the 6-month assessment compared with the baseline (Fig. 4). Average improvements in the cervicomental and gnathion angles were $28.5 \pm 8.9^\circ$ (± standard deviation) and $16.6 \pm 4.3^\circ$, respectively ($P < 0.0001$ for both, Student's paired t-test, confidence interval 95%), representing an average percentage improvement of 21.2% and 15.6%, respectively, compared with the baseline findings (Table 1, Fig. 4). For the cervicomental angle, the majority of patients recorded an improvement in the range from 21° to 35°, and a range from 11° to 20° for the gnathion angle. The inserts shown in Figure 4 show the average cervicomental and gnathion angles before and after treatment and illustrate that the extent of the observed change was quite noticeable.

Post-Treatment Sequelae

All patients reported mild to moderate pain during treatment which spontaneously subsided very shortly after treatment: no patient withdrew from the study or asked for treatment to be halted because of the pain. Subject downtime consisted of 2 to 4 days of a mildly, stippled papules and erythema, arrayed in a grid-like pattern, and corresponding to the needle-tip insertion sites. Purpura was present in a only few subjects, mostly in the perioral area. Other side effects were mild edema which lasted for 12–24 hours. No other persistent adverse events were reported.

Clinical Global Assessment

The assessors correctly identified the baseline and 6-month photography in 100% of the 33 patients. There were no patients in whom the condition had got worse nor were there any patients in whom there was not at least some improvement, so improvement was noticed in all patients. The improvement was graded as minimal (i) in one patient, modest; (ii) in five patients, moderate (iii) in seven, significant; (iv) in 16 and impressive; (v) in four patients. Improvement scored at grade 3 (moderate) or higher was therefore seen in 81.8% of patients (Fig. 5).

Patient Satisfaction

From the telephone survey conducted at least 1 year after treatment, 100% of the patients were satisfied with six patients moderately satisfied, 23 patients very satisfied and four patients extremely satisfied. Over 80% of patients were very satisfied or better. A large percentage said they would come back for retreatment when necessary, and all said they would recommend the treatment to their friends (Fig. 5).

Clinical Examples

Figures 6–8 show representative examples of baseline findings *versus* the findings at 6 months after the final treatment session in three female subjects. An improvement in the cervicomental angle of 29° was achieved in all three subjects, with various degrees of tightening and lifting of the skin of the neck.

DISCUSSION

Of all the visible signs of the aging countenance, sagging jowls and lax neck skin are among the most cosmetically troublesome to the aesthetic patient. Unfortunately, these signs are also among the most challenging to treat.

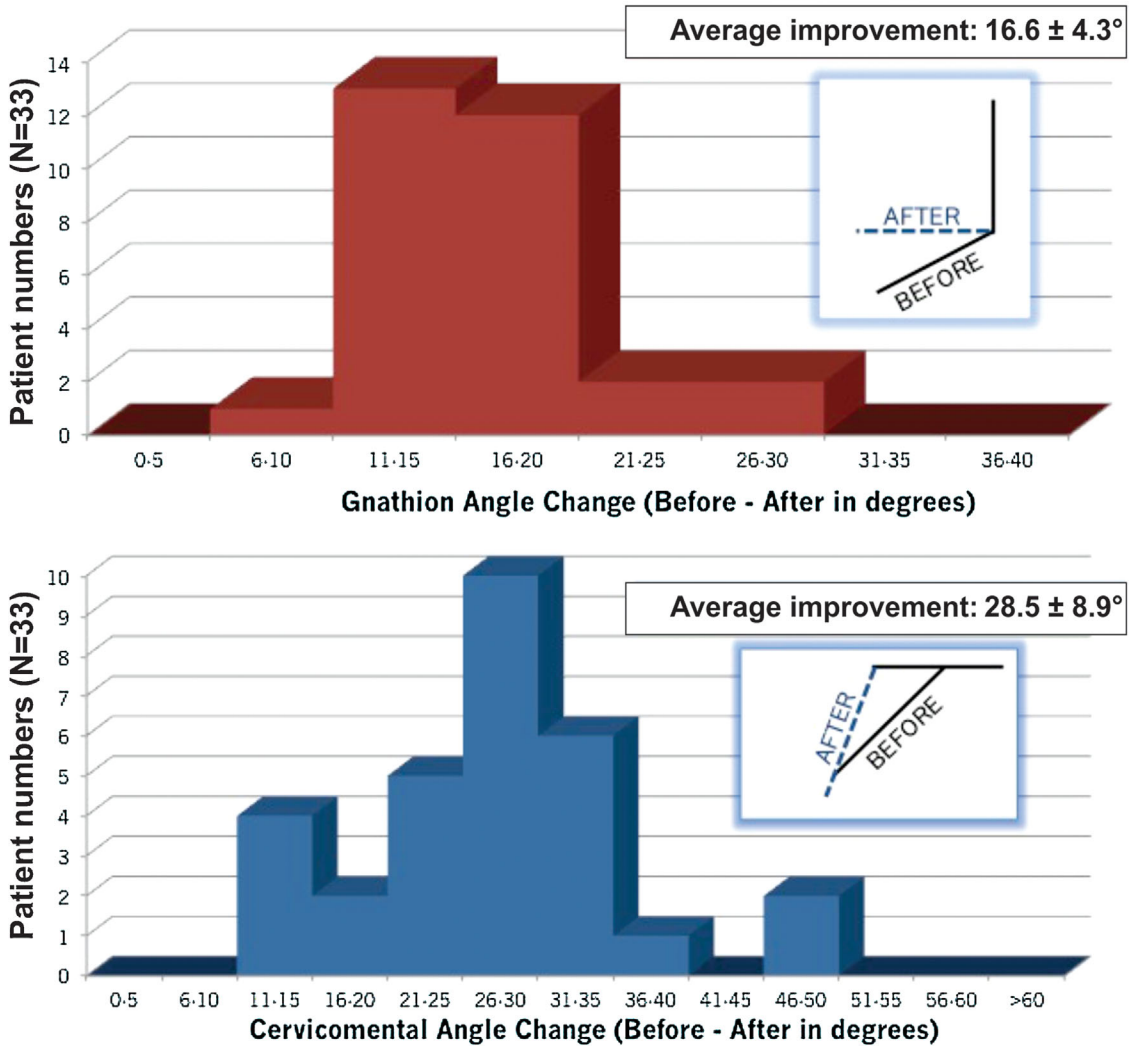

Fig. 4. The range in degrees of changes by patient numbers in the gnathion angle (**upper graph**) and the cervicomental angle (**lower graph**) illustrated.

Treatment of this region is desirable to truly provide a complete and visible reduction in aged appearance. In photo- and chronological aging of the skin, the appearance of skin laxity, wrinkling and lines of the skin are initially associated with the deterioration of both the epidermis and dermis, in particular the collagen and elastin fibers as the scaffolding of the extracellular matrix, and aging of the fibroblasts themselves. In more severe cases, there is also downward migration of the fad pads and ligamental changes. A full rhytidectomy can certainly address the majority of the problems associated with the laxity, but does not really effect any dermal ECM repair or rejuvenate the epidermis, and is moreover an extremely surgical invasive procedure. HiFR is proposed as a unique method to rebuild a degraded ECM, as well as encouraging epidermal renewal through mechanical microneedling.

Treatment of the face without addressing the neck still belies the actual chronologic age. The comparative lack of pilosebaceous units in the neck makes this anatomical zone out for treatment with full ablative laser resurfacing inherently risky and fraught with complications [2]. The introduction of nonablative fractional laser rejuvenation held some promise, but although skin texture and wrinkles responded well, laxity remained unchanged [5]. The ablative fractional laser approach gave better results, but for skin tightening were less than expected [4]. There have also been problems associated with fractional ablative laser rejuvenation including scarring and pigmentary changes [12,13]. The authors of these articles advised less aggressive treatments of the neck, especially the lower neck, even with a fractional approach.

The major difference between the microneedle-based HiFR system used in the present study and ablative or nonablative fractional lasers is the variable depth in the dermis to which energy can be delivered while sparing thermal injury to the epidermis and DEJ. Histology evaluations in this study and other published work has confirmed the fact that electrothermal coagulation is

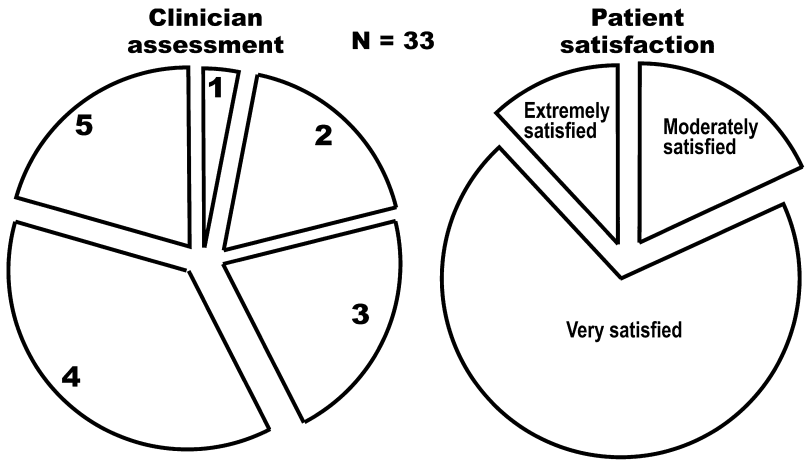

Fig. 5. Results of clinician global assessment (**left**: 1, minimal improvement; 2, modest improvement; 3, moderate improvement; 4, significant improvement; and 5, impressive improvement) and patient satisfaction (**right**).

limited to the zone around the needle tip [14]. No residual thermal damage was seen in the epidermis and dermis, such as is evident in the fractional ablative approach as an area of mild necrosis in the dermis and epidermis surrounding the microablative column (Fig. 3). The sparing of thermal injury in the epidermis and DEJ minimizes the side effects and corresponding downtime, which is considerably less than the fractional laser approaches that achieve a high degree of coverage and deep dermal depths.

The limitation of the depth at which damage can be delivered in the dermis is particularly true for bipolar surface RF where the delivery and return electrodes are in the handpiece. In that scenario, the depth of the electrothermal reaction in the tissue is physically limited to one-half of the distance between the electrodes. In monopolar RF, where the delivery electrode is in the handpiece and the return electrode is usually a large plate electrode firmly attached to the thigh or other large area of skin, the RF energy passes down through the dermis and into the subdermal layers as it seeks out the return electrode. With cooling applied to the epidermis, a pattern of graded thermal damage can be delivered into the dermis. Increasing the power can achieve a deeper coagulative effect, but the trade-off is pain. In neither of these external RF approaches is there a truly isolated area of irreversible

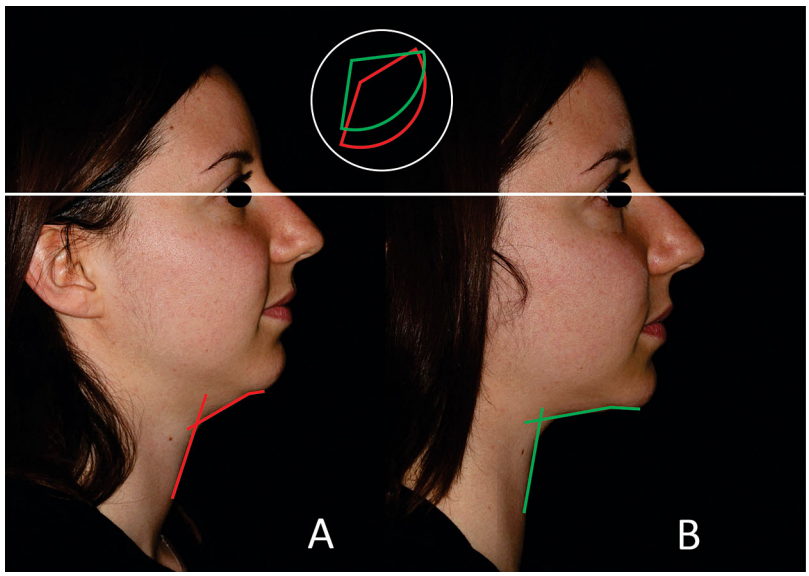

Fig. 6. 36-year-old female (Patient No. 14) at baseline (**A**) and 6 months after the final treatment (**B**). The cervicomental angles at baseline and follow-up are outlined in red and green, respectively. The improvement in the angle was 29° with significant tightening and lifting as illustrated in the inset. The patterns inside the circle graphically represent the overlying angles, going from more obtuse (red) to more acute (green).

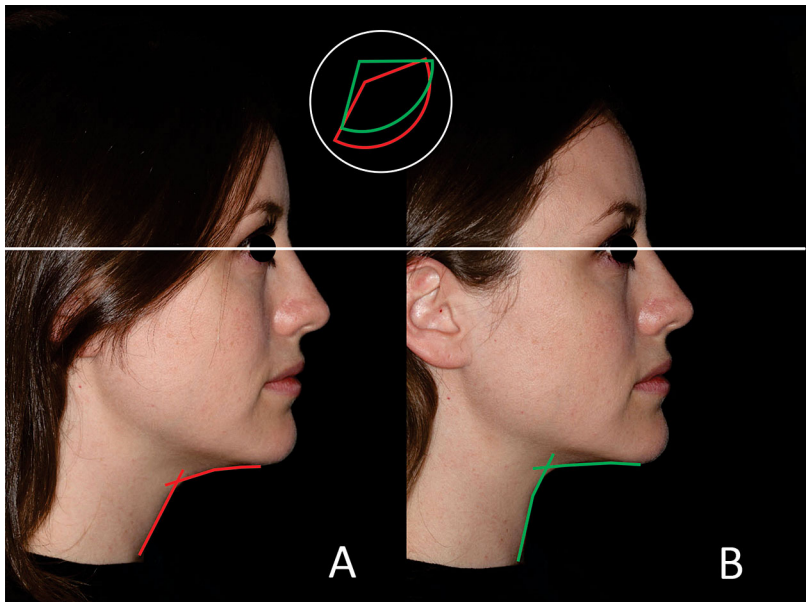

Fig. 7. A 41-year-old female (Patient No. 3) at baseline (**A**) and 6 months after the final treatment (**B**). The cervicomental angles at baseline and follow-up are outlined in red and green, respectively. The improvement in the angle was 29° with better delineation of the jawline and good lifting and tightening as illustrated in the inset. The patterns inside the circle graphically represent the overlying angles, going from more obtuse (red) to more acute (green).

coagulation in the dermis surrounded by an area of normal undamaged skin as is the case in fractional HiFR.

In comparison to partial denaturation, the body's natural healing response to coagulated tissue is to remove the damaged tissue and replace with new healthy tissue provided the zones of damage are sufficiently small. Over a series of treatments a significant percentage of the aged ECM can be replaced with new tissue. The sequelae following partial denaturation is quite different in that the natural healing response is to repair the injured tissue while stimulating some new tissue formation. This has been documented with the use of traditional external

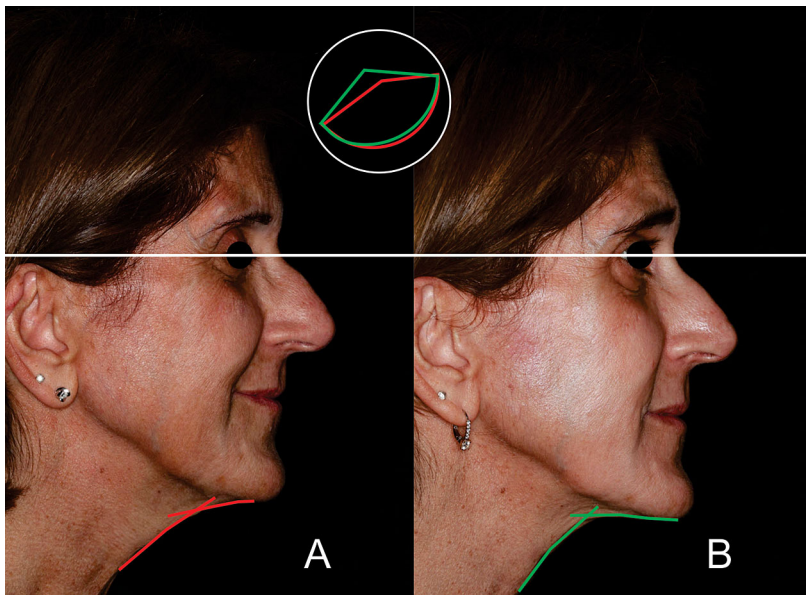

Fig. 8. A 68-year-old female (Patient No. 19) at baseline (**A**) and 6 months after the final treatment (**B**). The cervicomental angles at baseline and follow-up are outlined in red and green, respectively. The improvement in the angle was 29° with significant lifting and tightening as illustrated in the inset. Note also the overall improvement in the quality of the skin. The patterns inside the circle graphically represent the overlying angles, going from more obtuse (red) to more acute (green).

fractional RF devices [7]. Whereas over a series of treatments new ECM can be generated, the aged structural elements still remain. We hypothesize that this fundamental difference is the basis for why results following HiFR achieved lasting (so far over 1 year) patient satisfaction.

Microneedle RF treatment that produces well defined zones of coagulative damage has previously been shown to induce collagenesis and elastinogenesis with remodeling [15]. While the HiFR system used in the current study is different that used in the previous study, both devices achieve similar total amounts of injury while sparing the epidermis and thus HiFR would be expected to achieve a similar induction of remodeling. The ability to control both the density and volume of the damage [16] with multiple depth passes combined with the wound healing process triggered by the coagulated tissue is likely the best explanation for the significant efficacy in the lifting of the face and neck observed in the patients in the present study. The fact that the maximum depth of needle insertion was 2.5–3.0 mm or less means that the fractional coagulative damage treatment of the dermis was sufficient to achieve the observed significant lifting of the chin and neck skin. In addition, although mechanical microneedling of the epidermis on its own has beneficial effects on skin quality through enhancing the proliferation of skin cells [17], this approach has not been shown to induce lifting of the skin.

There is a limitation to the present study in that it was not a split-face or comparative protocol. However, statistical significance was achieved for this study population and results included objective photographic measurements of angle improvements. The authors feel this objective method is very important, in light of the difficulty in laxity studies with determining improvement by the grading of clinical photography alone. Future studies should address the split-face or comparative modality approach.

CONCLUSIONS

The results of the present study suggest that HiFR with insulated microneedling offers a powerful, safe and effective alternative to other treatment modalities for mild to moderate laxity of the lower face and neck in a large age range of patients, including the elderly. Side effects, pain, and downtime were transient and minimal. The 6-month follow-up, together with the clinical and objective assessments coupled with positive patient survey responses 1 year after treatment, suggests good latency of the results.

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