Evaluation of Micro-Focused Ultrasound for Lifting and Tightening Neck Laxity

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ABSTRACT

Background: A novel device using micro-focused ultrasound with high-resolution ultrasound visualization (MFU-V) produces non-invasive lifting and tightening of lax skin on the face and neck when treatment is delivered at a single focal depth (Ulthera® System; Ulthera, Inc., Mesa, AZ).

Objective: The following study was performed to test the hypothesis that customized application of MFU-V at two focal depths will produce clinical results that are superior to treatment at a single focal depth.

Methods and Materials: Adult subjects (N=71) with skin laxity in the lower face and neck were enrolled; 64 met all entrance criteria and received treatment. On the basis of physical and anatomical characteristics, patients were assigned in nonrandomized fashion to one of three treatment groups to undergo treatment on the submental, submandibular, lower neck, and platysmal areas with MFU-V at single or dual depths.

Results: Among evaluable subjects (N=64), investigator-assessment and subject-self-assessment demonstrated improved aesthetic changes at 60, 90, and 180 days after treatment. Overall, subjects that received MFU-V at two focal depths to the entire treatment area achieved slightly greater aesthetic improvement than subjects receiving MFU-V at single focal depths. There were no unexpected adverse events.

Conclusion: Applying treatment with MFU-V at two focal depths may provide improved aesthetic results in some subjects.

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INTRODUCTION

A novel device integrates micro-focused ultrasound with high-resolution ultrasound visualization (MFU-V) to cause sub-dermal collagen denaturation and subsequent *de novo* collagen synthesis and remodeling.[1,2] When applied to areas of lax skin, the result is significant skin lifting and tightening.[3-7] MFU-V has been demonstrated to be safe and effective in numerous clinical trials as a noninvasive aesthetic treatment, and it is FDA-cleared to non-invasively lift tissues of the eyebrow, neck, and submentum (Ulthera® System; Ulthera, Inc., Mesa, AZ).[8]

Despite the similarities in age-related changes in the skin and connective tissue, the clinical presentation of each patient is unique, and MFU-V treatment must be customized for each patient. The MVU-V device uses six transducers that emit ultrasound energy at a range of frequencies and at multiple focal depths.[8] Each ultrasound transducer can also provide tissue imaging to a depth of 8 mm. The MFU-V device utilizes a computer-driven platform that enables the clinician to visualize the proposed treatment with ultrasound-imaging transducers and develop a treatment plan prior to applying micro-focused ultrasound energy.

Using these transducers, micro-focused ultrasound is delivered in a series of lines at discrete tissue depths, including the variable depths of the superficial muscular aponeurotic system. Thermal coagulation points are formed when ultrasound energy is focused to a point less than 1 mm^3 in size below the skin surface. At such points, 95% of the delivered ultrasound energy is converted to heat, thereby raising the local temperature to ~65°C. At this temperature, denaturation and contraction of collagen and stimulation of neocollagenesis occurs while the superficial layer of skin and other intervening tissues remain unaffected.[2] Each line of treatment consists of a row of thermal coagulation points at a single focal depth. These treatment lines are typically spaced 2-3 mm apart.

MFU-V has proven to be effective for lifting and tightening lax skin on the face and neck when focused ultrasound is delivered at a single focal depth.[3-6] The present nonrandomized, prospective study was performed to determine whether the customized application of MFU-V at two focal depths can produce improved clinical results compared to treatment at a single focal depth.

METHODS

Study Subjects

The study enrolled 71 healthy men and women that were 30 to 65 years of age and expressed interest in MFU-V for lifting and tightening of the face and neck. Subjects were required to have

skin laxity in the lower face and neck and a score of 2 to 5 on the L'Oreal Photographic Scale for ptosis on the lower face, neck, and horizontal neck folds, and a score of 3 to 5 for neck sagging. Woman of childbearing potential were required to have a negative urine pregnancy test at Visit 1 and to agree to use an acceptable method of birth control during the study.

The study excluded patents with an illness, condition or concomitant medication that could affect wound healing. Other exclusion criteria included:

- severe solar elastosis or excessive subcutaneous fat or skin laxity in the face and lower neck;
- severe or cystic acne, significant wounds, marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, or thick sebaceous skin in the intended treatment area;
- prior retinoid, microdermabrasion, or prescription glycolic acid treatments in the intended treatment area during the previous 2 weeks;
- ablative resurfacing laser treatment;
- nonablative, rejuvenative laser or light treatment during the previous 6 months;
- dermabrasion, deep facial peels, facelift, blepharoplasty, brow lift, contour threads, facial skin tightening procedure, or injectable filler of any type on the lower 2/3 of the face within the past year;
- systemic retinoids within the past 6 months or topical retinoids within the past 2 weeks;
- neurotoxins on the lower 2/3 of the face within the past 6 months for subjects assigned to Groups A and C or neurotoxin in the facial area within the past 6 months for subjects assigned to Group B (Groups A, B, and C defined below);
- presence of a metal stent or implant in the facial area to be treated;
- history of chronic drug or alcohol abuse, autoimmune disease, or smoking during the past 5 years;
- any other condition or therapy that, in the investigator's opinion, may place the subject at risk or confound the objectives of the study;
- or were pregnant, lactating, or planning to become pregnant.

Ethics

The protocol used in this study was approved by an independent institutional review board (Asentral, Inc. IRB, Newburyport, MA). Enrolled subjects provided informed consent prior to participating in any study-related activities. ClinicalTrials.gov Identifier: NCT01368874.

Treatment Device

The treatment device employs transducers capable of emitting focused ultrasound at frequencies of 4, 7 and 10 MHz at focal depths of 1.5, 3.0, and 4.5 mm, respectively (Ulthera® System; Ulthera, Inc., Mesa, AZ).[8] Transducers were also used for ultrasound imaging to visualize underlying tissue prior to treatment and to ensure adequate acoustic coupling of the transducer with the skin surface.

Treatment Procedure

Prior to the treatment visit, the investigator assessed the characteristics of each subject, including age, gender, and the subcutaneous soft tissue in the areas to be treated. On the basis of physical and anatomical characteristics, subjects were assigned in nonrandomized fashion to one of three treatment groups:

Group A. Submental and submandibular areas were treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). The lower neck was treated with one transducer (7 MHz, 3mm transducer; single depth). These subjects received 246-296 lines of treatment (Figure 1).

FIGURE 1. Submental and submandibular areas of subjects in Group A were treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth) and the lower neck was treated with one transducer (7 MHz, 3mm; single depth). These subjects received 246-296 lines of treatment.

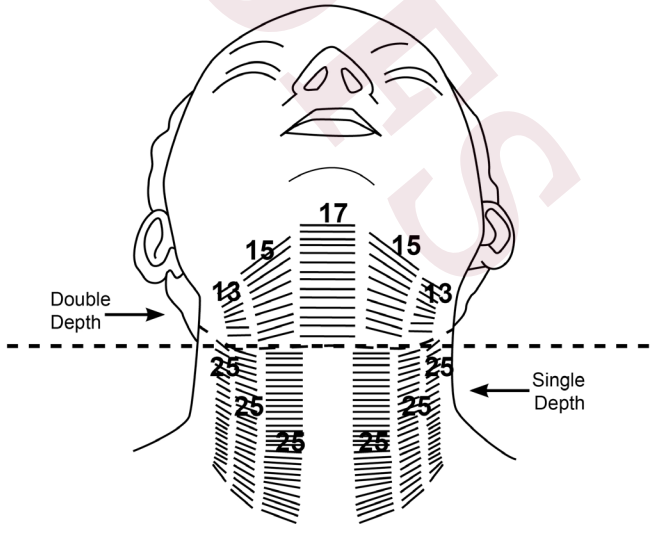
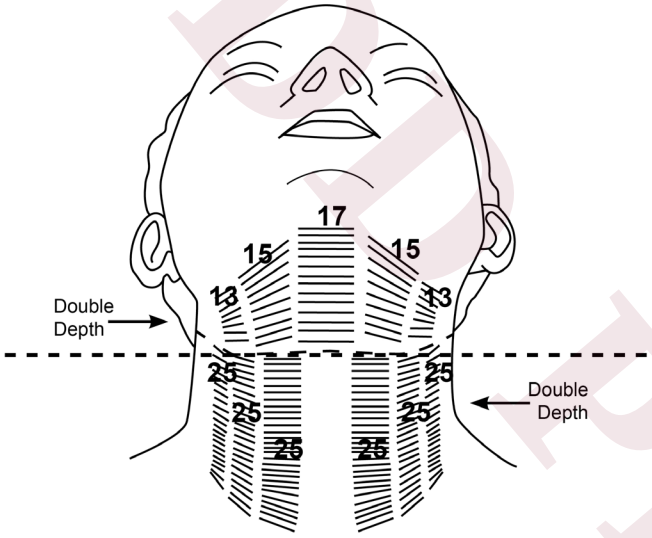


FIGURE 2. Submental and submandibular areas of subjects in Group B were treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). The lower neck was treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). The platysmal muscle above the jaw line (jowls) was treated with two transducers (4 MHz, 4.5mm and 7 MHz 3mm; single depth). These subjects received 426-526 lines of treatment.



Group B: Submental and submandibular areas were treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). The lower neck was treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). The platysmal muscle above the jaw line (jowls) was treated with two transducers (4 MHz, 4.5mm and 7 MHz 3mm; dual depth). These subjects received 426-526 lines of treatment (Figure 2).

Group C: Submental and submandibular areas were treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). The lower neck was treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). These subjects received 346-446 lines of treatment (Figure 3).

Depending on the anatomical characteristics of each subject, two or three columns of MFU-V treatment were applied to each side of the lower neck. The treatment length for each line exposure was a maximum of 25 mm, and the spacing between each treatment line was 2-3 mm.

Outcome Measures

Efficacy

Standardized 2-dimensional digital images were obtained for each subject prior to the MFU-V procedure and at the 60-, 90-, and 180-day follow-up evaluations using fixed camera and lighting conditions. Depending on study group assignment, efficacy was determined by three physician reviewers using a blinded comparison with baseline photographic images; the reviewers evaluated the improvement in overall lifting and tightening of the jowls and/or neck laxity at 90 days posttreatment. If a change was noted, the blinded reviewer was asked to choose the correct posttreatment image. The primary efficacy endpoint was proportion of treated subjects demonstrating improvement in skin laxity, horizontal neck folds, neck sagging, texture, and/or ptosis.

The secondary efficacy endpoints were improvement in overall lifting and tightening of jowl and/or neck laxity at 60, 90, and 180 days posttreatment based on Physician Global Aesthetic Improvement Scale (PGAIS) and Subject Global Aesthetic Improvement Scale (SGAIS) scores ranging from 1 (Very Much Improved) to 5 (Worse).[9] Other assessments included a Patient Satisfaction Questionnaire at 90 and 180 days posttreatment and L'Oreal Photographic Scale scores obtained at baseline and at 60, 90, and 180 days posttreatment. The L'Oreal scales include the following categories with higher grades denoting increasing severity:

- horizontal neck folds (grades 0-6),
- neck sagging (grades 0-7),
- texture (female grades 0-5; male grades 0-7),
- and ptosis (female grades 0-5; male grades 0-7).

FIGURE 3. Submental and submandibular areas of subjects in Group C were treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). The lower neck was treated with two transducers (4 MHz, 4.5mm and 7 MHz, 3mm; dual depth). These subjects received 346-446 lines of treatment.

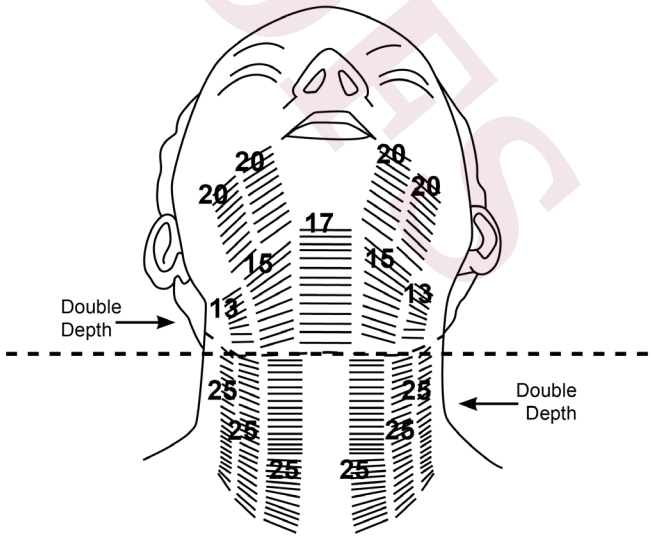


TABLE 1.

Demographic Characteristics by Treatment Group			
	Group A (N=34)	Group B (N=5)	Group C (N=25)
Mean age, y (min, max)	55.1 (43, 65)	57.4 (49, 62)	55.2 (39, 65)
Mean baseline BMI (min, max)	25.5 (19.0. 32.8)	22.5 (19.6, 23.5)	26.3 (18.5, 36.4)
Gender			
Female	32	5	24
Male	2	0	1
Race/Ethnicity			
Caucasian	32	5	19
Hispanic/Latino	2	0	5
Black/African American	0	0	1
Fitzpatrick Skin type			
I	6	0	4
II	18	5	8
III	10	0	12
IV	0	0	0
V	0	0	1

Safety and Tolerability

Each subject received a pretreatment pain medication at the discretion of the investigator. During the treatment procedure, subjects were asked to rate any discomfort they experienced using a validated 11-point numerical rating scale with 0 denoting no pain, and 10 denoting the worst possible pain. Pain scores were obtained following the treatment of each facial area and for each transducer used. The treated areas were examined by the investigator after approximately 30 minutes for signs of acute adverse effects such as erythema or edema. Subjects were queried at each follow-up visit about adverse events, and the treatment site was reexamined.

RESULTS

Among the 71 enrolled subject, six did not meet all the entrance criteria and were ineligible to participate, and one participant withdrew consent prior to completing treatment. The remaining 64 subjects were treated in Group A (n=34), Group B (n=5), and Group C (n=25). Two subjects were lost to follow-up after completing the 60-day follow-up visit, and two were lost to follow-up after completing the 90-day follow-up visit. The demographic characteristics of the enrolled subjects are provided in Table 1.

Primary Efficacy Outcomes

The data were analyzed at the 180-day follow-up evaluations before the blind was broken after removing poor-quality pre- and posttreatment images (ie, images with poor lighting, focus or positioning, which might create possible assessment bias). Of the remaining subjects (n=42), 52% were judged to be improved 90 days posttreatment, 33% were assessed as improved, but the blinded evaluator did not select the correct pretreatment image from those provided and 14% were assessed as having no change. The proportion of subjects assessed as improved with a correct posttreatment image selected were higher among subjects in Group A (single depth treatment on lower neck; 63%) compared with those in Group C (dual depth treatment on lower neck; 52%) and Group B/C (dual depth treatment on lower neck plus cheek treatment in five subjects of Group B; 46%) (Table 2).

Secondary Efficacy Outcomes

Physician Global Aesthetic Improvement Scale Scores

The proportion of subjects Group A rated as Very Much Improved on the PGIAS at 60, 90 and 180 days posttreatment was 0%, 11.5% ,and 23.3%, respectively, while the proportion of subjects showing any improvement was 63.9%, 78.7%, and 66.7%, respectively. The mean (SD) score at day 60 was 3.2 (0.7). The proportion of subjects in Group B rated as having any

TABLE 2.

Blinded Assessment by Study Group					
Assessment, n (%)	Group A (N=32)	Group B (N=5)	Group C (N=24)	Group B/C (N=29)	Overall (N=61)
Improved	17 (53)	1 (20)	11 (46)	12 (41)	29 (48)
No change	6 (19)	0 (0)	4 (17)	4 (14)	10 (16)
Improved, but incorrect pre- vs posttreatment image selected	9 (28)	4 (80)	9 (38)	13 (45)	22 (36)
Reanalyzed Data*	Group A (N=16)	Group B (N=5)	Group C (N=21)	Group B/C (N=26)	Overall (N=42)
Improved	10 (63)	1 (20)	11 (52)	12 (46)	22 (52)
No Change	2 (13)	0 (0)	4 (19)	4 (15)	6 (14)
Improved, but incorrect pre- vs posttreatment image selected	4 (25)	4 (80)	6 (29)	10 (38)	14 (33)

*These data were analyzed after 19 subjects were removed due to poor quality pre- and posttreatment images.

TABLE 3.

Patient Satisfaction Questionnaire		
Area of Improvement, n (%)[a]	Day 90 N=50	Day 180 N=43
Lines/Wrinkles/Cheek/Neck/Mouth	13 (26.0)	15 (34.9)
Less Sagging on Cheeks/Jawline	27 (54.0)	20 (46.5)
Tighter / Lifted Under Chin	31 (62.0)	29 (67.4)
Smoother Skin Texture	10 (20.0)	6 (14.0)
More Even Skin Tone	4 (8.0)	2 (4.7)

[a]Subjects could select more than one response

improvement was 74.2% and 78.1% at days 60 and 90, respectively, declining to 42.0% at day 180. The proportion of subjects in Group C rated as having any improvement on the PGAIS was 56.0% at day 60, 87.5% at day 90, and 95.8% at day 180. The proportion of subjects in combined Groups B and C (i.e., all subjects who received dual depth MFU-V treatment over all treated areas), rated by the investigator as having any improvement was 53.3% at day 60, 79.3% at day 90, and 93.1% at day 180.

Subject Global Aesthetic Improvement Scale Scores

The proportion of subjects rated Very Much Improved on the SGIAS at 60, 90 and 180 days posttreatment was 4.9%, 11.5%, and 15.0%, respectively, while the proportion of subjects showing any improvement was 67.2%, 68.9%, and 63.3%, respectively. The mean (SD) score at day 60 was 3.1 (0.8). The proportion of subjects Very Much Improved in Group A at 60, 90 and 180 days posttreatment was 9.7%, 9.4%, and 6.4%, respectively, while the proportion of subjects with any improvement was 61%, 66%, and 55%, respectively. The proportions of subjects Very Much Improved in Group C on the SGAIS at 60, 90, and 180 days posttreatment was 0%, 12.5%, and 20.8% while those with any improvement were 72.0%, 75.0%, and 79.2%, respectively. Among subjects in the combined Groups B and C (ie, all subjects who received dual depth MFU-V treatment over all treated areas), the proportion of subjects Very Much Improved on the SGAIS at 60, 90, and 180 days posttreatment was 0%, 13.8%, and 24.1%, respectively, while those with any improvement was 73.3%, 72.3%, and 72.4%, respectively.

Patient Satisfaction Questionnaire

Across all study groups, approximately 80% of subjects reported that they noticed improvement at 90 days posttreatment in the treated neck and lower neck regions (Groups A and C), and in the treated jowls, neck, and lower neck regions (Group B). At day 180, 68% of Group A subjects reported continued improvement, whereas approximately 80% of subjects in Groups C and B/C reported continued improvement.

Overall, many subjects reported improvement in "Less Sagging on Cheeks/Jawline" at days 90 and 180 (54% and 47%, respectively) and "Tighter/Lifted Under Chin" at days 90 and 180 (62% and 67%, respectively) (Table 3). The percentage of subjects reporting improvement in "Lines/Wrinkles/Cheek/Neck/Mouth" increased from 26% on day 90 to 35% on day 180. MFU-V had relatively little effect on "More Even Skin Tone."

Among the subjects in Group A, improvement in "Less Sagging on Cheeks/Jawline" and "Tighter/Lifted Under Chin" was noted at day 90 (52% for each category) (Table 4). At 180 days posttreatment,

TABLE 4.

Area of Improvement by Study Group					
GROUP A			GROUP B		
Area of Improvement, n (%)[a]	Day 90, N=25	Day 180, N=20	Area of Improvement, n (%)[a]	Day 90, N=5	Day 180, N=5
Lines/Wrinkles/Cheek/Neck/ Mouth	3 (12.0)	3 (15.0)	Lines/Wrinkles/Cheek/Neck/ Mouth	4 (80.0)	4 (80.0)
Less Sagging on Cheeks/Jawline	13 (52.0)	6 (30.0)	Less Sagging on Cheeks/Jawline	4 (80.0)	4 (80.0)
Tighter / Lifted Under Chin	13 (52.0)	13 (65.0)	Tighter / Lifted Under Chin	5 (100.0)	5 (100.0)
Smoother Skin Texture	7 (28.0)	2 (10.0)	Smoother Skin Texture	1 (20.0)	0 (0)
More Even Skin Tone	2 (8.0)	2 (10.0)	More Even Skin Tone	1 (20.0)	0 (0)
GROUP C			GROUP B/C		
Area of Improvement, n (%)[a]	Day 90, N=90	Day 180, N=18	Area of Improvement, n (%)[a]	Day 90, N=25	Day 180, N=23
Lines/Wrinkles/Cheek/Neck/ Mouth	6 (30.0)	8 (44.4)	Lines/Wrinkles/Cheek/Neck/ Mouth	10 (40.0)	12 (52.2)
Less Sagging on Cheeks/Jawline	10 (50.0)	10 (55.6)	Less Sagging on Cheeks/Jawline	14 (56.0)	14 (60.9)
Tighter / Lifted Under Chin	13 (65.0)	11 (61.1)	Tighter / Lifted Under Chin	18 (72.0)	16 (69.6)
Smoother Skin Texture	2 (10.0)	4 (22.2)	Smoother Skin Texture	3 (12.0)	4 (17.4)
More Even Skin Tone	0 (0)	0 (0)	More Even Skin Tone	2 (8.0)	0 (0)

[a]Subjects could select more than one response.

TABLE 5.

Patient Satisfaction		
Response, n (%)	Day 90, N=61	Day 180, N=60
Very satisfied	15 (24.6)	14 (23.3)
Satisfied	25 (41.0)	19 (31.7)
Dissatisfied	18 (29.5)	18 (30.0)
Very dissatisfied	3 (4.9)	7 (11.7)
Neutral[a]	0 (0)	2 (3.3)
Very satisfied or satisfied	40 (65.6)	33 (55.0)

[a]Two subjects did not answer but provided responses deemed neutral by the monitor.

the percentage reporting "Less Sagging on Cheeks/Jawline" decreased to 30%, but the percentage of subjects reporting "Tighter/Lifted Under Chin" increased to 65%. Many subjects in Group C also reported improvement in "Less Sagging on Cheeks/Jawline" and "Tighter/Lifted Under Chin" at day 90 (50% and 65%, respectively). Most improvement continued through day 180 with 56% and 61% percent of subjects reporting "Less Sagging on Cheeks/Jawline" and "Tighter/Lifted Under Chin," respectively (Table 4). Among subjects in the combined Group B/C, 40% reported "Improvement in Lines/Wrinkles/Cheek/Neck/Mouth" at day 90, with the proportion increasing to 52% at day 180. At day 90, these subjects also reported "Less Sagging on Cheeks/Jawline" (56.0%) and "Tighter/Lifted Under Chin" (72.0%) changing to 61% and 70%, respectively, at day 180.

Overall subject satisfaction is summarized in Table 5. Questionnaire responses from subjects in the single-depth Group A indicated 63% and 42% were satisfied with their results at 90 and 180 days posttreatment (Table 6). By contrast, 75% of subjects in the dual depth Group C were satisfied with their results at both 90 and 180 days post-treatment.

L'Oreal Photographic Scales

Mean investigator assessments of horizontal neck folds, neck sagging, texture, and ptosis changes using the L'Oreal Photographic Scale at baseline and at 60, 90, and 180 days posttreatment are shown in Table 7. There were approximately 1-point improvements in the horizontal neck folds and neck sagging scores from baseline to day 90 and persisted through day 180. There were no substantial changes in baseline texture or ptosis scores.

Analysis of the data according to study group revealed slightly greater improvement in neck sagging and ptosis scores in Groups C and B/C compared with Group A, which showed no improvement (Table 8). Because the study population was predominately composed of female subjects (95%), no subgroup L'Oreal Photographic Scale analyses based on gender were performed.

Safety Outcomes

Most subjects (89%) received a combination of two or three pretreatment medications including hydrocodone/acetaminophen 5/500 mg (n=38) and 10/1000 mg (n=17); ketorolac 10 mg (n=20)

TABLE 6.

Patient Satisfaction by Study Group					
GROUP A			GROUP B		
Response, n (%)	Day 90, N=31	Day 180, N=32	Response, n (%)	Day 90, N=5	Day 180, N=5
Very satisfied	7 (21.9)	4 (12.9)	Very satisfied	2 (40.0)	1 (20.0)
Satisfied	13 (40.6)	9 (29)	Satisfied	0 (0)	1 (20.0)
Dissatisfied	10 (31.3)	12 (38.7)	Dissatisfied	3 (60.0)	2 (40.0)
Very dissatisfied	2 (6.3)	4 (12.9)	Very dissatisfied	0 (0)	1 (20.0)
Neutral[a]	0 (0)	2 (6.5)	Neutral[a]	0 (0)	0 (0)
Very satisfied or satisfied	20 (62.5)	13 (41.9)	Very satisfied or satisfied	2 (40.0)	2 (40.0)
GROUP C			GROUP B/C		
Response, n (%)	Day 90, N=24	Day 180, N=24	Response, n (%)	Day 90, N=29	Day 180, N=29
Very satisfied	6 (25)	9 (37.5)	Very satisfied	8 (27.6)	10 (34.5)
Satisfied	12 (50)	9 (37.5)	Satisfied	12 41.4)	10 (34.5)
Dissatisfied	5 (20.8)	4 (16.7)	Dissatisfied	8 (27.6)	6 (20.7)
Very dissatisfied	1 (4.2)	2 (8.3)	Very dissatisfied	1 (3.7)	3 (10.3)
Neutral[a]	0 (0)	0 (0)	Neutral[a]	0 (0)	0 (0)
Very satisfied or satisfied	18 (75.0)	18 (75.0)	Very satisfied or satisfied	20 (69.0)	20 (69.0)

[a]Two subjects did not answer but wrote in responses that were deemed neutral by the monitor.

TABLE 7.

L'Oreal Photographic Scale Scores				
Mean Score (SD)	Baseline N=64	Day 60 N=61	Day 90 N=61	Day 180 N=60
Horizontal Neck Folds	3.0 (0.9)	2.3 (1.1)	2.1 (1.1)	2.3 (1.2)
Neck Sagging	3.7 (0.8)	2.8 (1.2)	2.7 (1.2)	2.7 (1.3)
Texture	2.8 (1.1)	2.4 (1.2)	2.4 (1.2)	2.5 (1.1)
Ptosis	3.2 (1.0)	2.5 (1.1)	2.5 (1.0)	2.6 (1.1)

and 60 mg (n=28); lorazepam 2 mg (n=27); alprazolam 0.5 mg (n=13), 1.0 mg (n=11), and 1.5 mg (n=4); ibuprofen 400 mg (n=1); acetaminophen 650 mg (n=1); clonazepam 1 mg (n=1); naproxen 1600 mg (n=1); and tramadol 50 mg (n=1). Mean overall pain scores for all study groups were between 4 and 6 (Table 9).

There were 17 reports of adverse events during the trial, but only two were considered treatment-related. One subject described as numbness in lower neck on the day of MFU-V treatment that resolved after 5 days; the same subject then reported throbbing pain in lower neck that persisted for 3 weeks. Both events were considered mild in severity and treated with nonsteroidal anti-inflammatory medications.

DISCUSSION

The results of this study are consistent with previous studies demonstrating that the use of MFU-V is associated with significant skin lifting and tightening of lax skin on the face and neck areas.[3-7] Although the differences between treatment groups were modest, the overall results suggest that subjects who received MFU-V at two focal depths to the entire treatment area demonstrated greater aesthetic improvement and greater satisfaction compared with subjects who received MFU-V at dual focal depths in the submental and submandibular areas but at only a single focal depth in lower neck region. Adding a dual depth of MFU-V treatment to the jowls did not improve outcome scores despite the substantially larger number of treatment lines (426-526 lines vs 246-296 lines); however, this group was limited to only five subjects.

Analyses using the PGAIS and SGAIS were conducted using photographs and live assessments. On the basis of blinded evaluation of photographs, subjects in Group A showed greater improvement compared with those in other groups; however, most subjects in Group A were treated at a different study site than those in Group C, which could have contributed to scoring variability. Most subjects demonstrated visible aesthetic improvements in both the PGAIS and SGAIS scores by day 60, which persisted at the 180-day assessment. The most striking improvements were observed in PGAIS scores among subjects in Groups B and B/C, with aesthetic improvement increasing over the 180-day study period. The aesthetic improvement was less impressive among subjects in Group A, as their improvement decreased after 60 days. Similarly, SGAIS scores were higher among subjects in Groups B and B/C compared with those in Group A.

Across all study groups, a substantial proportion of subjects noted aesthetic improvement at 90 days posttreatment in the treated neck and lower neck regions (Groups A and C), and jowls, neck, and lower neck regions (Group B). These improvements persisted throughout the study for subjects in Groups C and B/C. Overall, about half of the subjects reported improvement in "Less Sagging on Cheeks/Jawline" at days 90 and 180. The majority of subjects (65%) also indicated that they were satisfied with their 90- and/or 180-day treatment results. L'Oreal Photographic Scales analyses revealed improvements in Horizontal Neck Folds and Neck Sagging scores from baseline to day 90. The results for Neck Sagging persisted through day 180.

TABLE 8.

L'Oreal Photographic Scale by Study Group								
Mean Scores (SD)	Baseline, N=64				Day 60, N=61			
	Group A	Group B	Group C	Group B/C	Group A	Group B	Group C	Group B/C
Horizontal neck folds	3.0 (1.0)	3.8 (0.08)	2.9 (0.07)	3.1 (0.8)	2.6 (1.1)	2.0 (0.7)	1.9 (0.9)	1.9 (0.9)
Neck sagging	3.5 (0.8)	4.2 (0.4)	3.8 (0.7)	3.9 (0.7)	2.9 (1.0)	2.4 (0.9)	2.8 (1.5)	2.7 (1.4)
Texture	2.4 (1.2)	3.2 (0.8)	3.1 (0.8)	3.1 (0.8)	2.3 (1.2)	2.4 (0.5)	2.5 (1.3)	2.5 (1.2)
Ptosis	3.2 (1.0)	3.6 (0.9)	3.2 (0.9)	3.3 (0.9)	2.7 (1.1)	2.4 (0.5)	2.2 (1.2)	2.2 (1.1)
Mean Scores (SD)	Day 90, N=61				Day 180, N=60			
	Group A	Group B	Group C	Group B/C	Group A	Group B	Group C	Group B/C
Horizontal neck folds	2.6 (1.2)	2.4 (0.5)	1.5 (0.7)	1.6 (0.7)	2.7 (1.2)	2.0 (1.0)	1.7 (0.8)	1.7 (0.8)
Neck sagging	2.9 (1.1)	2.6 (1.1)	2.4 (0.3)	2.4 (1.3)	3.2 (1.2)	2.0 (0.7)	2.2 (1.4)	2.2 (1.3)
Texture	2.3 (1.2)	2.4 (0.9)	2.6 (1.2)	2.6 (1.2)	2.3 (1.2)	2.6 (1.1)	2.6 (0.9)	2.6 (0.9)
Ptosis	2.8 (0.9)	2.6 (0.9)	2.1 (1.1)	2.2 (1.1)	3.0 (1.1)	2.2 (1.1)	2.1 (0.9)	2.1 (0.9)

TABLE 9.

Mean (SD) Pain Scores				
Treatment Area	Overall (N=64)	Group A (N=34)	Group B (N=5)	Group C (N=25)
Submental	3.9 (1.6)	4.0 (1.7)	4.6 (0.9)	3.7 (1.4)
Submandibular	4.3 (1.6)	4.2 (1.8)	5.2 (1.3)	4.2 (1.2)
Lower neck	5.0 (1.7)	5.1 (2.1)	5.6 (0.5)	4.8 (1.4)
Lower face	NA	NA	3.6 (1.3)	NA

NA, not treated in that group.

The study also further demonstrated the safety of MFU-V. The MFU-V procedure was well tolerated with only two adverse events were reported in one subject which were mild in severity and resolved without sequelae.

This study had several limitations. Enrolled subjects were nearly all Fitzpatrick Skin types 1-3. Despite an effort to standardize pre- and posttreatment subject photographs, a relatively large number of images were removed from the 180-day follow-up analysis due to poor quality, reducing the planned number of subjects in each group. In addition, too few patients were considered suitable Group B treatment candidates preventing meaningful comparisons to be made. Additional research in a larger and broader subject population utilizing a randomized, controlled, blinded study design will add strength to the positive results from dual depth MFU-V treatment observed in this study.

CONCLUSION

The results of this study further demonstrate the safety and effectiveness of MFU-V for lifting and tightening lax skin in the facial and neck areas and provide a foundation for additional research to assess the beneficial aesthetic effects of dual-depth MFU-V for lifting and tightening lax skin on the face and neck.

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DISCLOSURES

AQ: PROVIDE STATEMENT LISTING ANY FINANCIAL RELATIONSHIPS WITH INDUSTRY OR POTENTIAL CONFLICT OF INTEREST.

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