INTRODUCTION

In the early stages of skin aging, fine lines and skin irregularities predominate; as it progresses, it is characterized clinically by dyschromia, volume loss, surface changes, reduced elasticity, and increased laxity. These changes are the cumulative effect of both intrinsic and extrinsic factors. Intrinsic factors, driven by cellular senescence, oxidative stress, and hormonal changes, lead to a reduction in dermal mast cells, fibroblasts, and synthesis of collagen and elastin, and are accelerated by extrinsic factors, predominately UV-photodamage, environmental pollution, gravity, and lifestyle behaviors (smoking, stress, sleep, diet, hydration).

Facial appearance influences perceptions of beauty and age, with facial wrinkles in particular viewed as a representative manifestation of skin aging. The natural contraction of facial expression muscles creates repeated
mechanical stress, causing a temporary wrinkle. UV exposure triggers an increase in the expression of elastase in dermal cells.\textsuperscript{7} The resulting solar elastosis, combined with age-related increases in collagen fiber breakdown, leads to a thinned dermis and reduced skin elasticity.\textsuperscript{6,8} These changes impair the ability of the skin to accommodate repeated mechanical stress, causing temporary wrinkles to evolve into persistent wrinkles.\textsuperscript{9}

The current spectrum of treatment options aimed at reducing the appearance of wrinkles includes topical products (vitamin A derivatives\textsuperscript{10} and chemical peels), injectables (neurotoxin, dermal fillers), and more invasive procedures such as repeated microneedling and laser resurfacing.\textsuperscript{1} Both neurotoxins\textsuperscript{11} and dermal fillers\textsuperscript{12} can contribute to rejuvenation by stimulating the production of type I collagen by dermal fibroblasts, and combination treatments are often used to optimize clinical outcomes.\textsuperscript{4} Laser resurfacing can be either ablative or nonablative and both work on the theory of selective photothermolysis. Nonablative and fractionated lasers are often preferred over traditional full-surface ablative resurfacing to meet demands for shorter healing times and improved comfort.\textsuperscript{2}

Microfocused ultrasound (MFU) therapy delivers energy to precise depths in the superficial fascia and deep dermal layers of the skin, while sparing the epidermal layers.\textsuperscript{13,14} Heating these tissues to temperatures higher than 60°C produces small thermal coagulation points,\textsuperscript{15} which results in neocollagenesis, neoelastogenesis, and tissue remodeling.\textsuperscript{16} Combining MFU with high-resolution ultrasound imaging (MFU-V, Ultherapy; Merz North America, Raleigh, NC, USA) enables direct visualization of where the MFU energy will be applied, enabling treatment to be customized to the unique needs of the patient.\textsuperscript{17} MFU-V offers the benefits of durable results and lack of downtime,\textsuperscript{14} fulfilling key attributes deemed desirable in patients seeking facial rejuvenation.\textsuperscript{17,18}

MFU-V is US Food and Drug Administration (FDA) cleared and indicated for noninvasive lifting of the skin on the brow, face, and neck, and improving lines and wrinkles of the décolleté.\textsuperscript{19} Standard protocols for a full face and neck treatment comprise the use of multiple-depth transducers with a typical range of 800–1200 lines.\textsuperscript{14} Prior research has established that multiple depth MFU-V can achieve significant lift and facial skin tightening.\textsuperscript{20} Use of other protocols, such as dual-depth treatment\textsuperscript{21,22} or vectoring of 15-30 vertical and 15-30 horizontal treatment lines each at two depths (7.0 MHz/3.0 mm, and 4.0 MHz/4.5 mm),\textsuperscript{15,22} has also been shown to further enhance its effectiveness. Significant aesthetic improvement of moderate-to-severe décolleté lines and wrinkles has been demonstrated with single treatment, multiple-depth MFU-V (120 lines 7.0 MHz/3.0 mm, and 120 lines 4.0 MHz/4.5 mm).\textsuperscript{23} Given the current mechanistic understanding of rhytid development and the mode of action of MFU-V, it is possible that a shortened MFU-V protocol comprising a single treatment with the superficial depth transducer (10.0 MHz/1.5 mm) could be effective in skin rejuvenation.

METHODS

Subject Selection

Selected subjects had expressed sufficient concern over wrinkles to seek aesthetic therapy and had static periorbital wrinkles, perioral wrinkles, or accordion lines. They had no labeled contraindications, precautions, or conditions that precluded the standard use of MFU-V,\textsuperscript{24} consented to a shortened MFU-V protocol and agreed to abstain from additional aesthetic therapies in the planned treatment areas. Subjects who had undergone any of the following treatments to relevant areas of the face within the timeframes specified were excluded—prior 6 months: any laser, needling, botulinum toxin, deep peels, microdermabrasion, threads, skin tightening; prior 12 months: dermal fillers (including biostimulant fillers) to the proposed areas. Smokers and subjects with scarring and severe elastosis were also excluded. The study protocol conformed to the ethical guidelines of the Declaration of Helsinki and all subjects provided written, informed consent and permission to publish case details.

Treatment Procedure

Before undergoing treatment, digital images of the areas to be treated were obtained for each subject using a standardized photography set up (Clinical Imaging Australia Pty Ltd, Richmond, VIC, Australia) with the subject smiling and at rest at each position under fixed camera and light conditions. Photography was repeated at 90- and 180-days post treatment using matched settings.

A thin layer of ultrasound gel was applied to the areas to be treated to visualize intradermal placement and to ensure good contact between the skin and the transducer during the procedure. No topical anesthetic was used; subjects were given access to inhaled 50% nitrous oxide/50% oxygen gas upon request.

All MFU-V treatments were performed in alignment with the Food and Drug Administration and Therapeutic Goods Administration (TGA, Australia) approved indications and usage. Following published guidelines,\textsuperscript{19} relevant areas for treatment were marked and MFU-V was administered using a single transducer at a frequency of 10 MHz, source energy 0.18\textsuperscript{25} and a focal depth of 1.5 mm. The transducer delivered ultrasound pulses to the treatment area creating thermal coagulation points in rows of 14 mm (narrow transducer) or 25 mm (standard transducer) in length, each spaced row 2–3 mm apart (Table 1).

Objectives, Outcome Measures, and Assessments

This case series examined whether a shortened MFU-V protocol could be used to achieve skin remodeling and rhytid improvement. Each case served as its own control. Outcome measures were based on a comparison of photographs from baseline and 90- and 180-days post treatment. Two clinicians, independent of the clinic, were provided with a brief overview of the procedure undertaken and a time-dated series of subject photographs. Three
images (lateral left oblique 45 degrees, frontal, and lateral right oblique 45 degrees) were provided for each subject, for each treated area at the three time points. All photographs were in the patient’s natural repose and were of sufficient resolution to support use of the zoom function up to 400%. Each clinician assessed improvement in wrinkles in each treated area from baseline to 90- and to 180-days post treatment using established rating scales (Table 2).24–26 Clinicians also rated overall aesthetic improvement at 90- and 180-days post baseline using the Physician Global Aesthetic Improvement Scale (PGAIS). In this five-point Likert scale, appearance is judged to be (1) exceptionally improved, (2) much improved, (3) improved, (4) unaltered, or (5) worsened compared with baseline.

In addition, each subject completed a Subject Global Aesthetic Improvement Scale (SGAIS) for each treated area, by comparing their 90-day photographs with baseline and then their 180-day photographs with baseline, using the same five-point rating scale as for the PGAIS. A subject satisfaction survey, using a five-point Likert scale (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree), was used to obtain subject feedback on three metrics: (1) procedure (I would have another Ultherapy treatment to the same area), (2) recommendation (I would...
recommend Ultherapy to a friend or family member), and (3) satisfaction (I am satisfied by the result from Ultherapy).

**RESULTS**

Nine women subjects, aged 38 to 64 years, contributed to the study. A total of 18 cases were available for inclusion, six in each of the three treatment areas. There was some overlap of cases between treatment areas; four subjects underwent treatment in all three areas, one subject underwent treatment in two areas and the remaining four subjects received treatment to one area only.

**Accordion Lines**

Independent assessment using the Modified Fitzpatrick Wrinkle Scale (MFWS) showed that at baseline, subjects had fine to moderate wrinkles (0.5–2.0 out of maximum score of 3.0) (Fig. 1). Both assessors noted improvement in Cases 1 to 5 at 180 days. One assessor considered Case 6 to have only very shallow wrinkles at baseline (0.5 on the MFWS scale) and noted no change in this subject over the assessment period. PGAIS scores showed that at 90-days post treatment Assessor A noted half of the cases to be unaltered and half to be improved and Assessor B noted five cases to be improved and one case to be much improved (Table 3). At 180 days post treatment Assessor A noted half of the cases to be improved, two cases to be much improved and one case (Case 3; Fig. 2) to be exceptionally improved. All subjects self-reported their accordion lines to be at 90 and 180 days, with one subject (Case 5) self-reporting being much improved at day 180 (Table 3).

**Perioral Lines**

Independent assessment using the Merz Aesthetic Lip Wrinkles at Rest Grading Scale showed that at baseline, five cases had mild wrinkles (1 out of maximum score of 4) and one case (Case 11) had severe wrinkles (3 out of maximum score of 4) (Fig. 3). Improvements in perioral wrinkles were modest, with a maximum
improvement of one point in any case at any time point; Assessor A noted improvement in 50% (3/6) of cases using the Lip Wrinkles Scale, whereas Assessor B noted improvement in five of six cases. PGAIS scores showed that at 90-days post treatment Assessor A noted two of six of the cases to be at least improved and the remaining four were assessed as unaltered, whereas Assessor B noted five of six to be improved with one subject (Case 11; Fig. 4) assessed as showing much improvement. Results were similar at day 180, with two subjects (Cases 9 and 11) recorded by Assessor B as much improved (Table 4). Two subjects self-reported their perioral lines to be unaltered at days 90 and 180 (Cases 7 and 12), four subjects rated this treatment area as improved at day 90, with two subjects (Cases 9 and 11) both indicating much improvement at day 180 (Table 4).

Periorbital Lines
Independent assessment using the Merz Aesthetic Crow’s Feet at Rest Grading Scale showed that at baseline, all six cases had at least moderate to severe wrinkles (2–4 out of maximum score of 4) (Fig. 5). Improvements

Table 3. Accordion Lines: Global Aesthetic Improvement Scores at 90 and 180 Days

| Case (Gender, Age) | PGAIS: Assessor A | 90 days | 180 days | PGAIS: Assessor B | 90 days | 180 days | SGAIS  |
|-------------------|-------------------|---------|----------|-------------------|---------|----------|--------|
| 1 (woman, 38)     | 4                 | 3       | 3        | 2                 | 3       | 3        | 3      |
| 2 (woman, 42)     | 4                 | 3       | 3        | 2                 | 3       | 3        | 3      |
| 3 (woman, 58)     | 3                 | 2       | 2        | 1                 | 3       | 3        | 3      |
| 4 (woman, 45)     | 3                 | 3       | 3        | 2                 | 3       | 3        | 3      |
| 5 (woman, 64)     | 2                 | 2       | 2        | 2                 | 3       | 3        | 3      |
| 6 (woman, 41)     | 4                 | 4       | 4        | 2                 | 3       | 3        | 3      |

PGAIS/SGAIS scoring: (1) exceptionally improved, (2) much improved, (3) improved, (4) unaltered, or (5) worsened compared with baseline.

Fig. 2. Case 3: Accordion lines. A, At baseline 0. B, At 90 days. C, At 180 days. This case was rated “much improved” by Assessor A and “exceptionally improved” by Assessor B at day 180, according to PGAIS.

Fig. 3. Clinician assessment of perioral lines using the Merz Aesthetic Lip Wrinkles Grading Scale: (A) Assessor A, (B) Assessor B. Merz Aesthetic Lip Wrinkles at Rest Grading Scale: 0 (no wrinkles) to 4 (very severe wrinkle).
in periorbital wrinkles were very good, with all cases showing some improvement and most cases showing a two-point improvement on the Crow’s Feet Scale by day 180.

PGAIS scores showed that at 90-days post treatment Assessor A noted half of the cases to be at least improved and half unaltered, whereas Assessor B noted two-thirds to be improved and one-third to be much improved (Table 5). By day 180, all cases were at least improved, with both assessors noting exceptional improvement in one-third of cases (Table 5). Both assessors noted Case 14 to have been much improved at day 90 and exceptionally improved at day 180, and Assessor B noted also noted Case 15 to be exceptionally improved at day 180 (Fig. 6). At day 90, five of six subjects self-reported at least improvement in periorbital lines; by day 180 half of the subjects had self-reported improvement and half had self-reported much improvement in this treatment area (Table 5).

Subject Satisfaction Survey

Subject satisfaction ratings were high across all three metrics for the three treatment areas (Fig. 7). Overall ratings were highest for subjects who had undergone treatment of the accordion lines: 100% (6/6) of subjects indicated they would have another treatment and

Table 4. Perioral Lines: Global Aesthetic Improvement Scores at 90 and 180 days

| Case (Gender, Age) | PGAIS: Assessor A | PGAIS: Assessor B | SGAIS |
|-------------------|------------------|------------------|-------|
|                   | 90 Days | 180 Days | 90 Days | 180 Days | 90 Days | 180 Days |
| 7 (woman, 38)     | 3       | 3       | 3       | 3       | 4       | 4       |
| 8 (woman, 42)     | 4       | 4       | 3       | 3       | 3       | 3       |
| 9 (woman, 58)     | 4       | 4       | 3       | 2       | 3       | 2       |
| 10 (woman, 45)    | 4       | 4       | 2       | 2       | 3       | 2       |
| 11 (woman, 64)    | 3       | 3       | 3       | 4       | 4       | 4       |
| 12 (woman, 56)    | 4       | 3       | 3       | 3       | 3       | 3       |

PGAIS/SGAIS scoring: (1) exceptionally improved, (2) much improved, (3) improved, (4) unaltered or (5) worsened compared with baseline.

![Fig. 4. Case 11: Perioral lines. A, At baseline 0. B, At 90 days. C, At 180 days. Assessor B rated this case “much improved” at days 90 and 180, according to PGAIS.](image)

![Fig. 5. Clinician assessment of periorbital lines using the Merz Aesthetic Crow’s Feet Grading Scale: (A) Assessor A, (B) Assessor B. Merz Aesthetic Crow’s Feet at Rest Grading Scale: 0 (no wrinkles) to 4 (severe wrinkles).](image)
they were satisfied with their results and 83% (5/6) of subjects would recommend this treatment. For periorbital and perioral treatment areas, 83% (5/6) of subjects would have another treatment in the same area and 66% (4/6) were satisfied with their results. Recommendation rates were higher for the periorbital treatment area (83% [5/6] would recommend this treatment) than for the perioral treatment area (66% [4/6] would recommend this treatment).

Safety

All subjects tolerated the MFU-V treatment well. The majority of subjects experienced mild immediate erythema to the treatment area, which settled within minutes. Less than half of subjects experienced any degree of striated linear skin patterns or wheals, which subsided within an hour and without specific treatment in all but one subject. In one subject the wheals persisted for up to 24 hours and required the application of mild topical corticosteroid before complete resolution. There was no post treatment bruising or any other significant side effects reported.

**DISCUSSION**

This case series has demonstrated the feasibility of single treatment, single depth MFU-V (10.0 MHz/1.5 mm) for superficial skin rejuvenation, with gradual improvements observed over several months. Independent clinician assessors reported visible improvements in periorbital lines (6/6 cases), accordion lines (5/6 cases) 180-days post treatment; there was some improvement but to a lesser degree in perioral lines (3/6 cases). Subjects’ self-assessments of improvement, based on SGAIS, largely mirrored those of the independent clinicians. At 180-days post treatment, all subjects reported improvement in accordion lines (83% improved, 17% much improved) and periorbital lines (50% improved, 50% much improved). However only two-thirds reported improvement in perioral lines (33% improved, 33% much improved).

**Table 5. Periorbital Lines: Global Aesthetic Improvement Scores at 90 and 180 Days**

| Case (Gender, Age) | PGAIS: Assessor A | PGAIS: Assessor B | SGAIS |
|-------------------|-------------------|-------------------|-------|
|                   | 90 Days | 180 Days | 90 Days | 180 Days | 90 Days | 180 Days |
| 13 (woman, 57)    | 2       | 1       | 3       | 2       | 3       | 2       |
| 14 (woman, 42)    | 2       | 1       | 2       | 1       | 3       | 3       |
| 15 (woman, 58)    | 3       |         | 2       | 1       | 2       | 2       |
| 16 (woman, 45)    | 4       | 3       | 3       | 2       | 3       | 2       |
| 17 (woman, 64)    | 4       | 3       | 3       | 2       | 2       | 3       |
| 18 (woman, 45)    | 4       | 3       | 3       | 4       | 3       |       |

**Fig. 6.** Case 15: Periorbital lines. A, At baseline 0. B, At 90. C, At 180 days. Assessor B rated this case as ‘much improved’ at day 90 and “exceptionally improved” at day 180.

**Fig. 7.** Subject satisfaction ratings for (A) accordion lines, (B) periorbital lines, and (C) perioral lines.
Nonsurgical lifting and skin tightening using MFU-V is supported by a large body of clinical data. A key feature is the ability to customize treatment by adjusting the energy and focal depth of the ultrasound to a patient’s unique physical characteristics. Consensus amongst clinicians is that the number of lines and use of dual or triple focal depths can be used to develop individualized protocols depending on patient expectations and requirements for restoration versus rejuvenation.

It has been suggested that stacking too many thermal coagulation points at a single depth may increase the potential for adverse events. By applying single depth MFU-V to discrete facial areas and focusing on superficial layers of the skin, the treatment was very well tolerated in this case series. Consistent with literature reports of mild post treatment sensitivity, most subjects in this case series had transient erythema, which provides an indicative signal of underlying tissue repair. However, given the limited size of this case series, further evaluation of safety with a larger patient cohort is warranted.

Prior research has demonstrated the utility of dual depth MFU-V (10.0 MHz/1.5 mm and 7.0 MHz/3.0 mm) in the periorbital area, where it has been used to tighten skin around the brows, upper and lower eyelids and festoons, reducing the need for surgical procedures. Although all skin layers are affected by aging, the facial-expression muscles are interspersed in the subcutaneous tissue. Pak et al highlight that the 10.0 MHz/1.5 mm transducer can be used to stimulate the orbicularis oculi muscle, thus providing a theoretical premise for the use of single depth MFU-V therapy for periorbital rhytid rejuvenation and supporting the positive findings in this case series.

The observation of less improvement in the perioral area, compared with the periorbital and accordion treatment areas, may be indicative of the underlying facial anatomy and other factors that influence aging in this area. For example, women have a tendency toward deeper perioral rhytids than men, attributed to smaller pilosebaceous units in the oral region and hormonal influences. In the current study, the baseline perioral wrinkle score was also in the mild category for the majority of cases, raising the possibility that MFU-V may have more of a place for the treatment of moderate to severe wrinkling.

Rejuvenation should ideally be tailored to the individual patient and need not be restricted to the use of one technique. Sufficient stimulation during the first phase (1–3 days) post-MFU, ensuring enough fibroblasts to produce collagen and elastin, is a key aspect of its mechanism of action. Other procedures that up-regulate mediators and cell-migration may be of benefit in patients for whom one MFU-V treatment may not be sufficient to induce collagen formation. Combining two procedures, MFU-V with calcium hydroxyapatite fillers, in the same treatment session has been shown to increase stimulation during this first phase, resulting in enhanced collagen production. Similarly, a multimodal approach has been demonstrated effective in neck rejuvenation, with the use of dual depth MFU-V (7.0 MHz/3.0 mm and 4.0 MHz/4.5 mm) MFU-V for laxity, neurotoxins for platysmal bands, and hyaluronic acid fillers for horizontal lines, with better results being observed in patients who were more aged at baseline. There is strong consensus for spacing multiple treatments 1–2 weeks apart, if patient-time constraints require more than one treatment at the same visit, MFU-V should be performed first, followed by injectable treatments.

Young people are adopting a prejuvenation approach, whereby they opt to use noninvasive treatments sooner to prevent signs of aging, rather than later to correct signs of aging. When considering such patients, evidence-based recommendations suggest that age-related physiological changes could be used as a guide for what to start and when. Collagen and bone volume decline both commences in the 20s. The earlier use of procedures that promote neocollagenesis and elastic fiber proliferation may therefore help to treat these underlying pathophysiological signs of aging before they become more visibly extensive. The results of the present case series support the role of single treatment, superficial MFU-V as a well-tolerated, noninvasive procedure with minimal downtime. The shortened protocol requires less time and uses fewer resources than the full protocol, making it an appealing option to consider in the prejuvenation setting. The main limitations of this study are the small number of patients treated and the lack of uniformity across photographic assessments. Formal evaluation of the protocol in a clinical trial setting with a statistically robust sample size and improved photographic standard is still needed.

**CONCLUSIONS**

MFU-V provides an established therapeutic option, which could be utilized to meet current patient demand for minimally invasive facial rejuvenation procedures. This case series demonstrates that single treatment, single depth MFU-V provides aesthetic improvements in periorbital and accordion lines, and to a lesser extent in perioral lines. All treatments were well tolerated and there was a high level of patient acceptability. The utility of MFU-V as a noninvasive therapy for superficial skin rejuvenation warrants further investigation.

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**PATIENT CONSENT**

Patients provided written consent for the use of their images.
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