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Hi5 Protocol for the Use of Microfocused Ultrasound with Visualization

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Background: Microfocused ultrasound with visualization (MFU-V) is used for lifting and tightening of facial tissues. Standard protocols are completed in a single session. Despite excellent outcomes, we identified several barriers of entry for a significant number of patients. Therefore, we devised an individualized pan-facial protocol that is delivered as a series of short, intense treatments to address these issues.

Methods: We enrolled 12 participants with mild-to-moderate skin and fibromuscular laxity to receive one superficial and one deep pass per visit (average 280 lines). Qualitative improvements were rated by both patients and physicians at 6 or 10 months due to COVID-19 delays. Changes in the submentum and eyebrow heights were quantified.

Results: Ten patients (age range: 31–61 years) underwent an average of four MFU-V treatments. Two patients were excluded after massive weight gain. Skin and fibromuscular ptosis and overall soft tissue laxity improved in all patients. Mean brow height increased by 1.7 mm, whereas the mean submental lift was 78.7 mm^2. All patients and treating physicians rated an improvement in appearance, whereas independent physicians rated improvements in 87% of cases. Four patients self-rated as "markedly improved." Pain was rated at up to 6.2 (out of 10). Although mask-wearing was mandatory, loss of elasticity, wrinkles, and skin roughness all improved. Superficial welts (n = 5), erythema (n = 3), tenderness (n = 3), and mild bruising (n = 2) occurred, but all resolved within a few days and no severe or permanent adverse events occurred.

Conclusion: The Hi5 protocol was noninferior to standard single-session protocols and improved brow heights and submental lifting. *(Plast Reconstr Surg Glob Open 2023; 11:e5184; doi: 10.1097/GOX.0000000000005184; Published online 14 August 2023.)*

INTRODUCTION

Microfocused ultrasound (MFU) with visualization (MFU-V; Ultherapy; Ulthera, Inc., Mesa, Ariz.) is US Food and Drug Administration–cleared and effective[1] for brow lifting[2] and treating marionette lines[3] and lower face, jaw, and neck laxity.[4–10] MFU-V focuses ultrasound energy at precise depths in the superficial fascia and deep dermis, propagating friction within tissue molecules for release as heat. Discrete thermal coagulation points (TCPs) form where tissue heats up to 70°C, leaving normal tissue in between for healing.[11] Coagulation at this temperature optimizes neocollagenesis and tissue remodeling,[12,13] ultimately lifting and tightening soft tissues, and improving lines and wrinkles.[9] The MFU-V system incorporates real-time visualization for targeting at precise tissue depths to deliver MFU energy, facilitating treatment safety and reliability.[10] Treating at two depths produces superior outcomes to treating at one depth.[8] The authors have found that visualization also enables positioning of TCPs at or just superficial to the superficial musculoaponeurotic system (SMAS), and at a second layer just beneath the dermis, targeting the deep and superficial origins of the retinacula cutis ligaments. This tightens the loose, fibrous meshwork supporting adipocytes within the superficial fat pads, producing a smoother face contour and a refreshed appearance.

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MFU-V protocols are designed for a single, full-face session requiring 800–1200 lines.[14] More MFU-V lines or energy improve outcomes[15,16] but can cause pain.[17] Although MFU-V is a safe procedure, obstacles to MFU-V treatment include inadequate pain management, lengthy appointments, and a significant financial outlay for results that are not immediately visible, which influence a patient's perception of whether treatment costs were reasonable.

Pain is experienced variably between patients and treatment areas.[2] In pivotal MFU-V studies, patient-reported pain scores varied among those given pretreatment oral and/or topical agents, from 5.7 to 6.5 (on a 10-point scale) with combination medications including opiates and anxiolytics,[4] to over 7 with topical local anesthetic gels.[2,9] Intratreatment comfort can be enhanced through systemic agents or fast-acting, deep-penetrating topical analgesics,[18,19] and/or local anesthetic blocks. However, incorporating these strategies necessitates longer appointments and transportation assistance while increasing costs. Data on effective medication strategies for intraprocedural comfort are limited,[20,21] and no standardized practices exist for pain relief with energy-based procedures, including MFU-V.[18,22] A recent consensus indicated that lower MFU energy levels improve patient comfort, allowing treatment continuation.[22] The use of multiple MFU lines per area is likely to contribute to wind-up pain,[23] whereby the perception of pain intensity increases with repeated delivery of noxious stimuli above a critical rate, resulting in patients becoming more uncomfortable as the treatment progresses.

We devised the full-face and upper neck Hi5 protocol to deliver a prescribed number of MFU-V lines over multiple sessions. Treatment is customized to individual patient requirements, and is based on clinical assessments of tissue laxity, enabling MFU-V to be given as shorter procedures requiring only over-the-counter analgesics and avoiding the per-session financial outlay. This study aims to demonstrate noninferiority of the Hi5 protocol to that of single-session protocols.

Takeaways

Question: Is the Hi5 protocol for MFU-V treatment over multiple, shorter, staged sessions noninferior to that of a single-session protocol?

Findings: Our spaced-apart, staged treatment plan is noninferior to a standard, single-session treatment protocol, but multiple, shorter treatments increase patients' tolerance of high energy, avoid strong pain relief, minimize downtime, and increase affordability.

Meaning: The Hi5 pan-facial MFU-V protocol allows delivery of high-level MFU energy for positive outcomes while individualizing treatments and fulfilling patients' demands for quick procedures.

METHODS

This pilot case study enrolled 12 participants at two Australian clinics—four in New South Wales ("Sydney Participants"), and eight in Victoria ("Geelong Participants"). Ten patients (nine females, one male; age range: 31–61 years) were included in analyses, and all patients underwent an average of four treatments (range: 3–5).

Inclusion and Exclusion Criteria

Included individuals had mild-to-moderate skin and fibromuscular laxity and neck fat thickness, and sought treatments for overall soft tissue laxity. Excluded patients had medical conditions or treatments that would affect wound healing; active localized inflammatory or infective skin conditions (eg, acne); severe actinic damage; immune compromise; thin skin or severe skin laxity; bleeding disorders; pregnancy or lactation; previous facial surgery or trauma; previous biostimulant treatments (eg, dermal fillers, threads or skin tightening device) or skin resurfacing; and neuromodulator or filler treatment within 6 months of study initiation. Two patients (one per clinic) were excluded after weight gain over 15 kg associated with COVID-19 restrictions during the study. Restrictions also prevented the planned 6-month follow-up of Sydney participants who returned at 10 months, and their data were collected for evaluation of later time points. This study complied with the Declaration of Helsinki guidelines. All participants provided written informed consent.

Treatment Planning

Sessions were spaced one to several weeks apart to accommodate schedules and pay-as-you-go financing. Participants' faces and necks were individually assessed and mapped by marking with a treatment grid comprising 2.5-cm^2 boxes (Fig. 1). Each box was assessed for skin and SMAS laxity on a scale of 1 (minimal) to 5 (extreme), and with up to five red dots (each denoting five deep MFU-V lines targeting the SMAS) and up to five blue dots (each denoting five superficial MFU-V lines targeting the deep dermis). Areas of potential nerve damage were marked for superficial treatment only. The grid was photographed and served as the patient's master plan.

Treatment Protocol

Patients took paracetamol (2 g) and ibuprofen (400 mg; if not contraindicated) before arriving for treatment. (**See Video 1 [online]**, which displays the Hi5 treatment protocol.) Sydney participants were also offered Entonox (BOC Australia, North Ryde, New South Wales, Australia; 50% nitrous oxide, 50% oxygen) analgesia. For all patients, we selected the appropriate transducer postvisualization to ensure that superficial treatment reached the deep dermis or immediate subdermal level, while deep treatment reached the SMAS. We selected MFU energy levels according to the maximum energy tolerated by the patient, which varied between areas (the forehead and neck being more sensitive to high energy levels). Superficial treatments used the 10-MHz, 1.5-mm transducer with variable pressure applied to place the TCP at or just below the deep dermis. Deep SMAS treatments used an appropriate transducer for

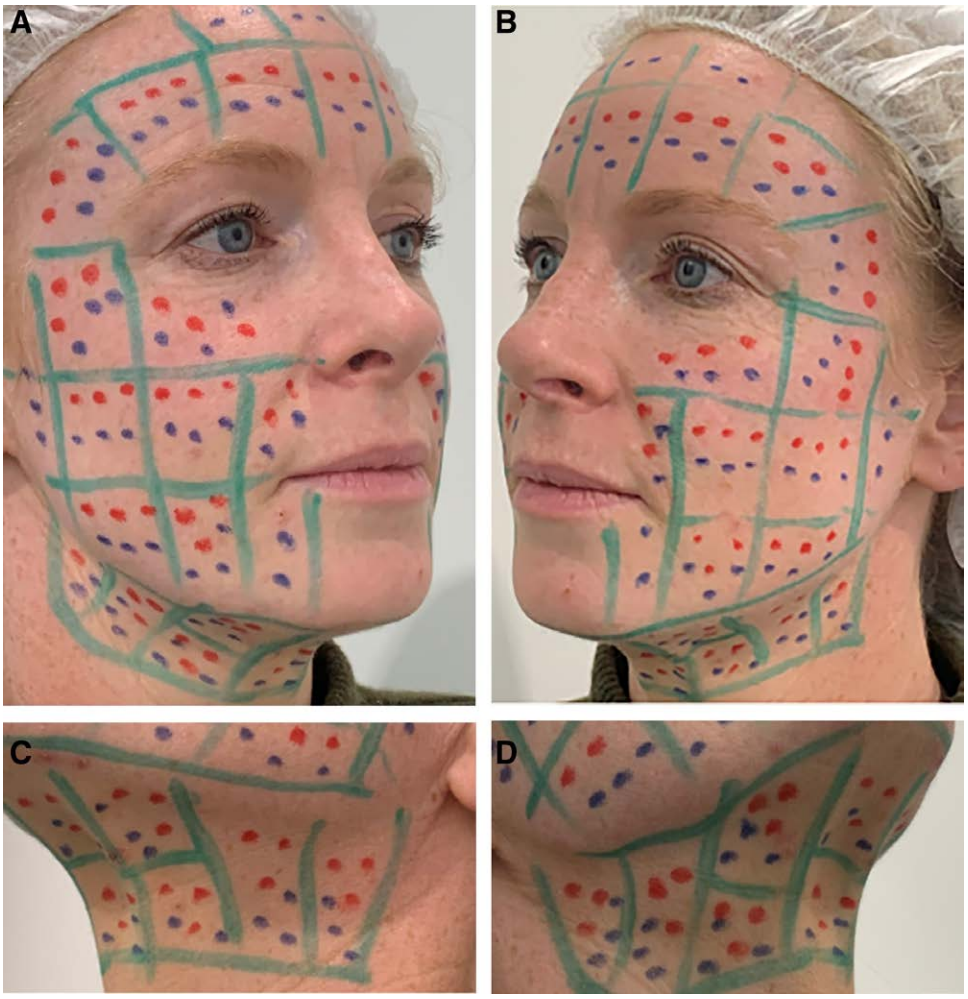

Fig. 1. Patient treatment grid. One horizontal line was marked at the lateral canthus, a second horizontal line was drawn from the alar base to the upper tragus, and a third horizontal line was marked from the oral commissure to the base of the earlobe. Vertical lines were drawn downwards from the lateral orbital rim and mid-pupillary line, as well as from 1-cm medial to the oral commissure. A-B, In a wide face, a further vertical line was drawn in the preauricular area. In the forehead, vertical lines were drawn upward from the medial end of the brow and mid-brow, and obliquely angled lines were drawn from the eyebrow tail to the border between the upper temple and hairline. A transverse line was also marked in the forehead at the junction of the superior temporal crest and hairline. C-D, The jawline was also marked. In the upper neck, vertical lines were drawn from the mandibular border to a transverse line at the level of the cricothyroid junction.

accurate targeting only after the layer was visualized. We performed one superficial pass (five lines/box) and one deep pass (five lines/box) per visit, with an average of 280 lines over the full-face and upper neck, spaced approximately 5-mm apart and vectored in the direction of the desired lifting. The number of treatment visits depended on the planned total number of passes (one deep and one superficial per visit).

Data Collection

Patients were photographed using VECTRA's H2 system and VISIA (both Canfield Scientific, Parsippany, N.J.) pretreatment and at 6 months posttreatment, to assess soft tissue lifting and skin quality changes. To prevent operator bias, an independent Getz Healthcare (Australia) employee, trained and experienced in operating the Canfield VECTRA H2 system and its camera (Canon EOS Rebel T6i, Tokyo, Japan), positioned the patients standing upright and photographed them pre- and posttreatment using the VECTRA three-dimensional (3D) H2 camera. The 3D images were visualized using the Face Sculptor software (version 7.6.0.). Within the Vectra analysis module (VAM), the baseline (pretreatment) 3D image was registered to the axis grid to establish a permanent reference to which the posttreatment image was registered, and to measure distances between fixed-point landmarks (medial and lateral canthi and the apex of the nostril). Images

were saved in two dimensions (2D). Using the open-source software, Inkscape (https://inkscape.org), scaling measurements were derived with VAM software measurements, and applied to the 2D images to calculate submental areas[6] and brow heights,[2] as described previously. Patients scored their pain (on a 10-point scale), and used the Global Aesthetic Improvement Scale (GAIS; a 5-point scale) alongside the two treating physicians and three independent physicians to evaluate aesthetic improvements between pretreatment and posttreatment photographs. Due to restrictions, Geelong participants (n = 7) were assessed at 6 months, whereas Sydney participants (n = 3) were assessed at 10 months.

Quantitative Measurements

Treatment-related changes were quantified in submental areas (adapted from Oni et al)[6] and brow heights (adapted from Alam et al).[2] Submental changes were calculated using a lateral image and an enclosed area between the lower neckline above the thyroid notch to the point where the chin joined the neck (Fig. 2). Contralateral views were used. To calculate brow height changes, a line was drawn to connect the two inner canthi. Points were drawn at the upper margin of the brow at the medial, lateral, and central points and two points were marked halfway. Digital guides were marked at intercanthal line intersections. The distance was measured between the eyebrow height and the corresponding point on the intercanthal line (Fig. 3).

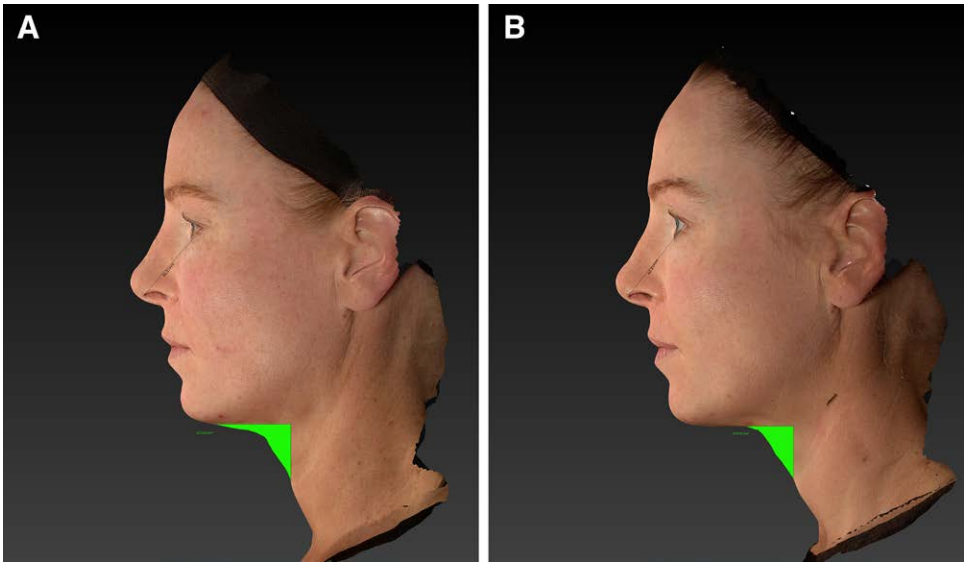

Fig. 2. Measurement of changes in submental areas. Pretreatment (A) to posttreatment (B) changes are spatially indicated in areas highlighted in green.

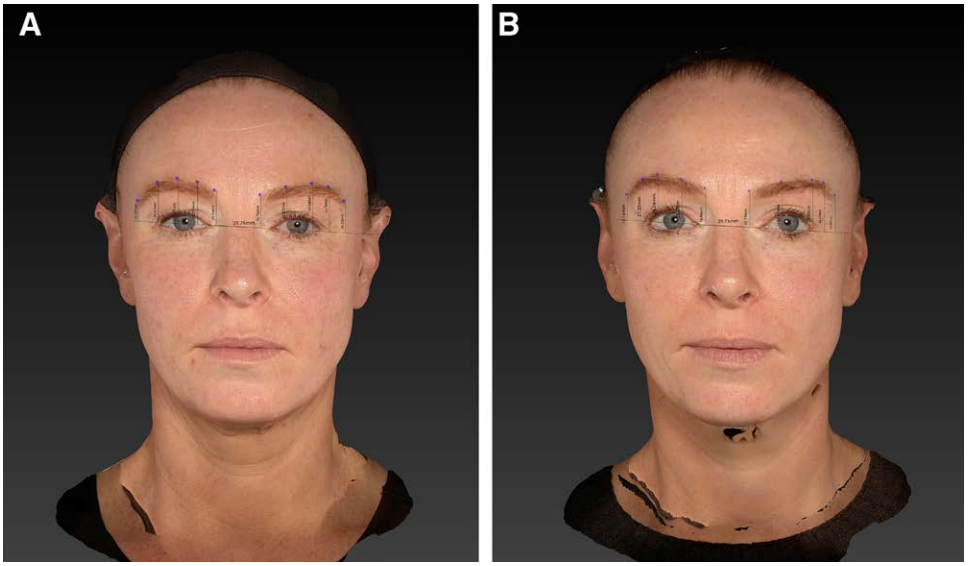

Fig. 3. Measurement of changes in brow height. Patient is shown before (A) and after (B) treatment.

Area changes and intercanthal distances were measured using Inkscape and VAM images.

Qualitative Assessments

Pretreatment and posttreatment (6 months, Geelong; 10 months, Sydney) VECTRA photographs were provided to patients and two treating and three independent physicians. Qualitative outcomes were evaluated using the GAIS. For the secondary outcome of pain control, patients rated their pain on a 10-point scale (1: minimal; 10: severe) immediately after each session, and their scores were averaged. Skin quality assessments were planned in three preselected, localized areas, with scoring of VISIA photographs according to the Scientific Assessment Scale of Skin Quality (SASSQ)[24] conducted by physicians. The SASSQ evaluates six parameters (skin elasticity, wrinkles, surface roughness, pigmentation, erythema and pore size) of skin quality using a five-point photonumeric scale (0–4).

RESULTS

VECTRA-based Quantification of Post-MFU-V Treatment-associated Changes

All patients experienced some improvement in skin and fibromuscular ptosis and overall soft tissue laxity (Figs. 4–6). Eight patients experienced an average of 1.7 mm increase in mean brow height (Fig. 5A) and 1.8 mm in maximum brow height (Fig. 5B). The mean submental lift per patient was 78.7 mm^2 (Fig. 6). Two patients (patients ID: 10 and ID: one in Fig. 5; one in Fig. 7) had levator dehiscence of the upper eyelid with

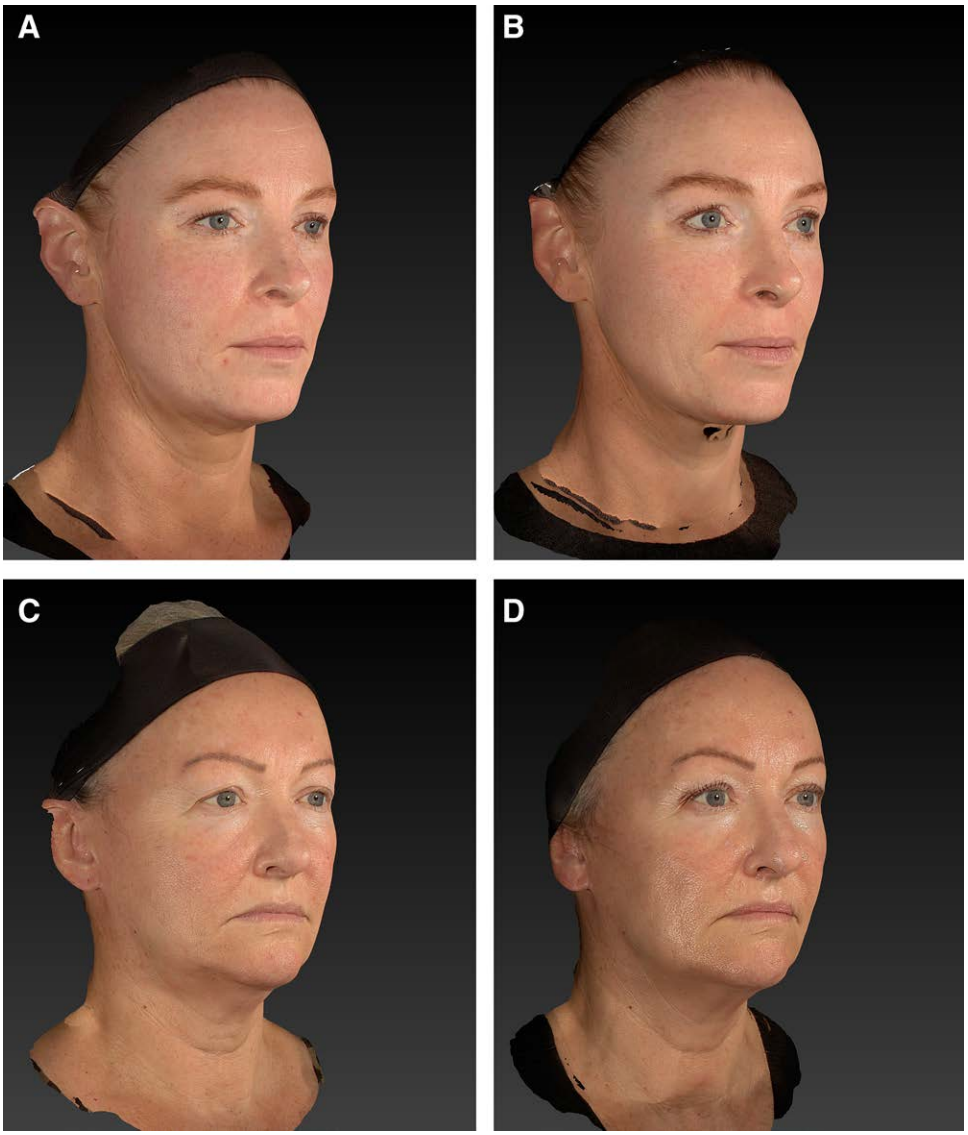

Fig. 4. Patient photographs. Patients before treatment (A, C) and after treatment (B, D) demonstrating improvements in overall soft tissue laxity and brow height.

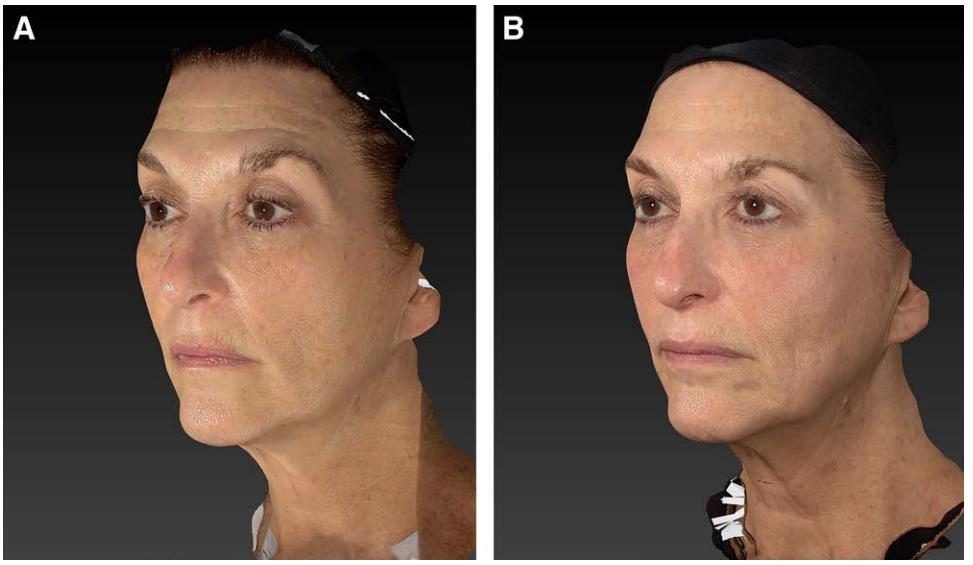

Fig 5. Pretreatment levator dehiscence of the upper eyelid and compensatory brow elevation, and post-treatment normal resting position. Improvement in mean (A) and maximum (B) brow heights (mm) pre- and posttreatment.

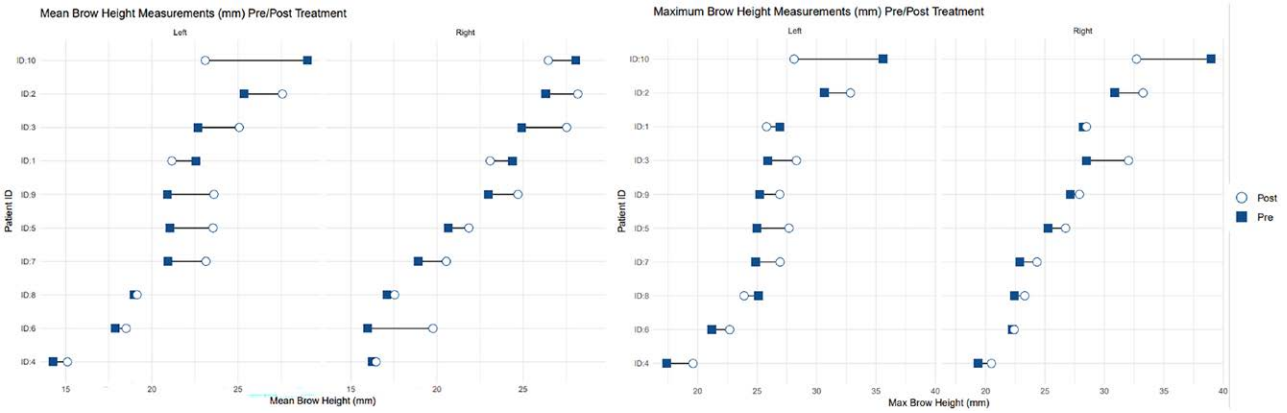

Fig 6. Improvement in submental area measurements (mm^2) pre- and posttreatment. ID, patient number.

compensatory brow elevation pretreatment, with brows returning to the normal resting position after treatment. Due to abnormally raised resting positions pretreatment, only their brow measurements were excluded.

Patient and Physician GAIS Scores

All patients agreed that their appearance improved (Fig. 8). The treating physicians reported improved appearance in all patients, whereas independent physicians scored improvements in 87% of cases. Of 10 patients, three scored their appearance as "very much improved" and four as "markedly improved."

Pain Scores and Treatment Tolerability

Pain was calculated as a mean of the range experienced, since some areas experienced more pain than others (generally the submentum and forehead at the SMAS level) which biased the score to a higher overall rating. Although treatments were conducted at an MFU intensity of 3 or 4 (out of 4), no dropouts occurred. Geelong participants received level 3 and 4 MFU, took only oral paracetamol and ibuprofen, and had a mean pain score of 5.8 (range 4.5–7.3; Table 1). Sydney participants had Entonox and level 4 treatment, with a mean pain score of 4.75 (range 2–6.25; Fig. 9; Table 1). In both clinics, patients could tolerate the short-lived pain durations in the more painful areas due to the shorter treatment sessions (15–20 minutes per session).

Skin Quality

Our study coincided with mandatory outdoor mask-wearing, which aggravated inflammatory skin conditions in four patients. Nevertheless, six skin quality parameters were assessed using the SASSQ, with an understanding that outcomes would be inferior to that in a non-pandemic setting. Although pore size, erythema, and pigmentation appeared unchanged, loss of elasticity, wrinkles, and skin roughness improved (Table 2).

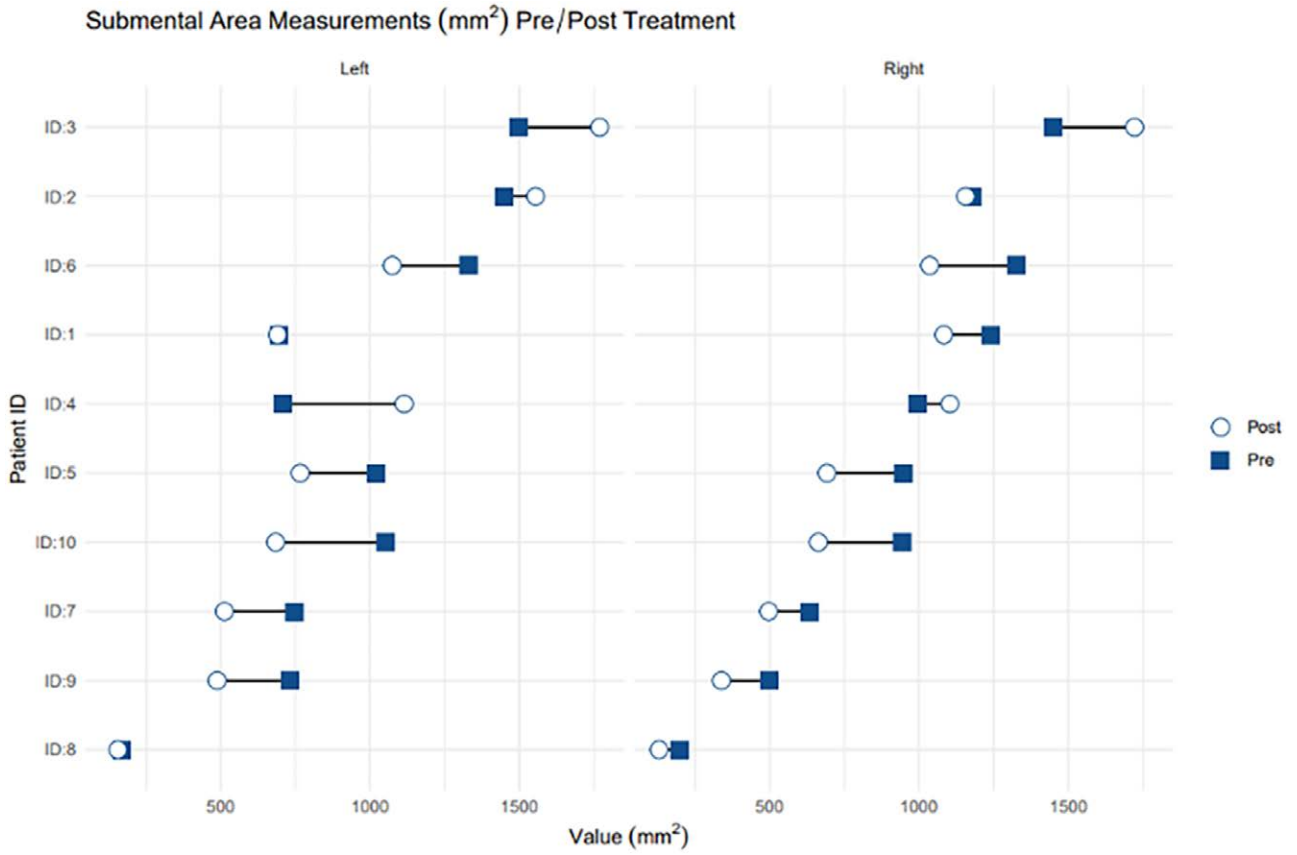

Fig. 7. Patient with levator dehiscence. Pretreatment (A) and posttreatment photographs (B) demonstrate brows returning to normal resting position.

Adverse Events

Five patients developed superficial welts after the first superficial treatment, which resolved within a few days of initiating antihistamine therapy. Three patients experienced erythema lasting a few days, three reported immediate posttreatment tenderness, and two experienced mild bruising not requiring treatment. No severe or permanent adverse events were reported.

DISCUSSION

Our pilot study showed that the Hi5 protocol produces noninferior outcomes to that of established single-treatment protocols, with outcomes not diminished by multiple sessions but achieving an average change of 1.7 mm in mean brow height and 1.8 mm in maximum brow height (Fig. 5). These results were comparable to a study,[2] wherein a single session produced an average change of 1.7 mm in mean brow height and 1.9 mm in maximum brow height. Our patients also showed an average submental lift of 78.7 mm^2 (Fig. 6) versus 45.2 mm^2 in a larger clinical study.[6]

MFU-V is a safe procedure that lifts and tightens soft tissues in the face, neck, and décolleté. Our Hi5 protocol was devised as a full-face and upper neck treatment protocol, customized to patients' requirements, and based on clinical assessments of tissue laxity. We delivered the prescribed number of treatment lines over multiple sessions. Per session, we delivered one pass of deep lines and one pass of superficial lines, spaced several millimeters apart, to the full-face and upper neck. Our patients tolerated a single pass of high energy delivered at dual depths as spaced, full-face lines, for a short duration, thus avoiding the wind-up phenomenon. Our patients also benefitted from shorter appointments, oral over-the-counter pain medications not requiring posttreatment transport assistance, and found it easier to budget for their sessions.

Visualization enhances efficacy and safety.[11] Accurate placement of TCPs to target the correct tissue layer minimizes adverse events like excess pain when approaching the periosteum, nerve damage, bruising, burns, and postinflammatory hyperpigmentation from overly superficial TCPs. Published nonclinical data from artificial tissue blocks shows the energy delivered to each tissue layer,[11] confirming the precision of the depth targeted with this device, but these findings must be correlated in vivo. Physicians should consider that MFU energy is wasted by inaccurate TCP placement into fat, muscle, or bone where neocollagenesis and tissue tightening will not occur.

Our Hi5 protocol utilizes a pan-facial and upper neck approach rather than considering facial regions individually,[25,26] and is based on the subcutaneous filling of temples having a distal lifting effect on the lower face.[27] Filling the

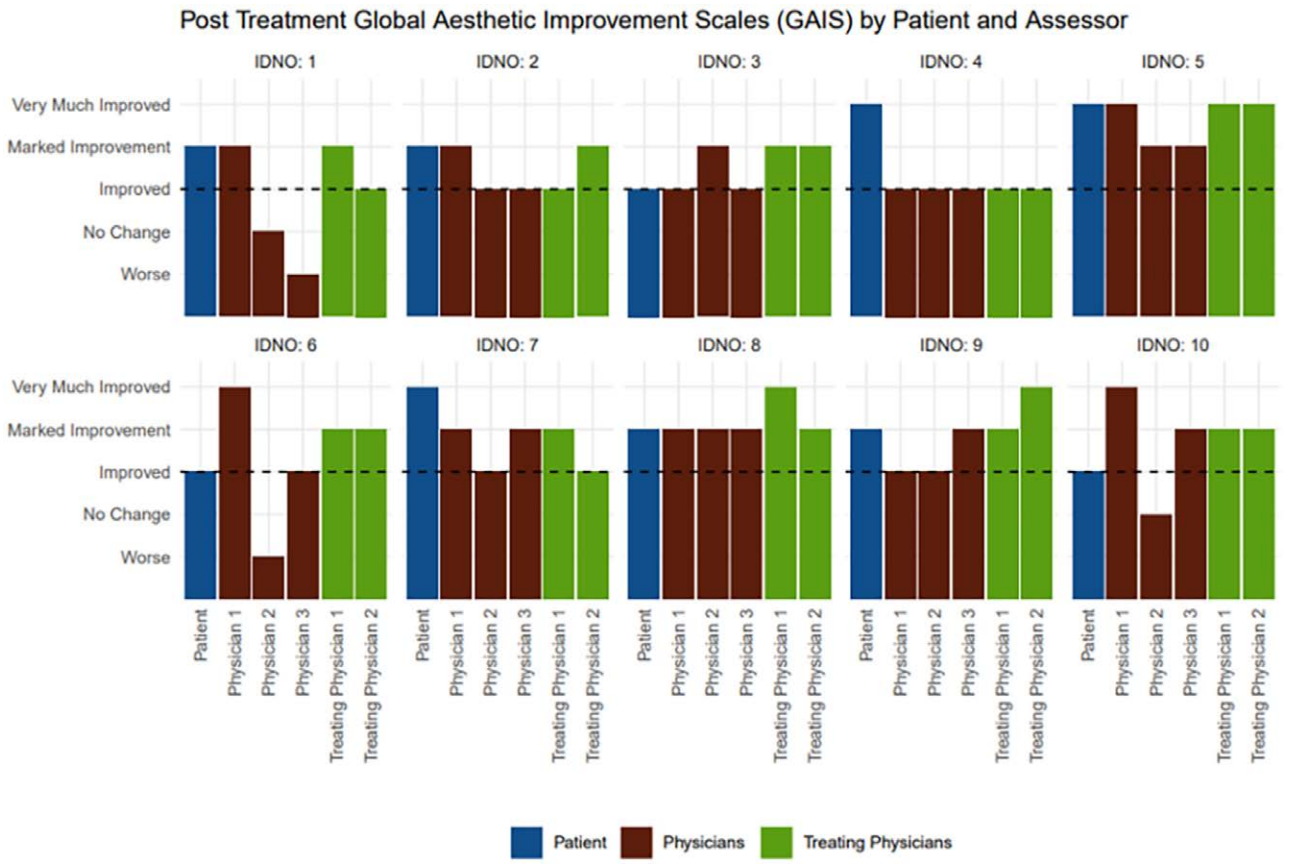

Fig. 8. Global aesthetic improvement scores by patient and assessor. IDNO, patient number.

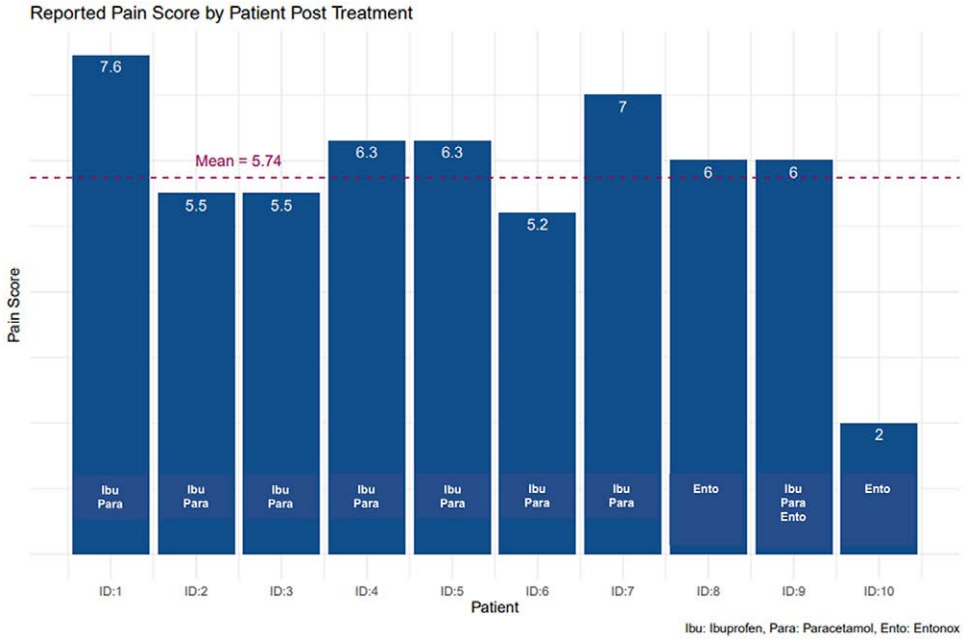

Fig. 9. Individual and average pain scores. Ento, entonox; Ibu, ibuprofen; ID, patient number; Para, paracetamol.

Table 1. Pain Score

	Pain Score (1: Minimal Pain; 10: Severe Pain)				
Patient	Session 1	Session 2	Session 3	Session 4	Average Score
A	7	7	8	0	7.3
B	6	5	5	5	5.25
C	3	6	6	0	5
D	6	6	6	0	6
E	7	5	6	0	6
F	6	4	5	3	4.5
G	7	6	7	7	6.75
H	1	1	3	3	2
I	7	6	6	6	6.25
J	6	6	6	0	6

Patients rated their pain on a 10-point scale (1: minimal pain; 10: severe pain) immediately after each treatment session. Scores were totaled and averaged.

superficial temporal fat compartments repositions the fibrous septae between layer three and the skin, resulting in the lifting affect.[26] Likewise, MFU-V tightening of the upper face SMAS and retinacula cutis may have a widespread effect because of the layered facial anatomy. We hypothesize that some of our observed "lifting effects" might be due to tightening of the retinacula cutis supporting superficial adipose tissue and producing a smoothing effect. Consequently, the face appears slimmer and more oval.

A recent consensus recommended customizing treatments,[14] but no guidelines currently exist. We propose several considerations: first, the degree of laxity in the deeper soft tissues and skin should be assessed on a five-level scale. For example, deeper tissues assessed to be level 3 laxities should be planned for three deep passes (SMAS level) while very lax skin (level 5) should be planned for five passes to the skin. On the face, each box on a drawn grid is individually assessed to reflect differences between facial areas. Secondly, the target treatment layers within the SMAS and deep dermis should be visualized on ultrasound (with any transducer) before selecting an appropriate transducer for the targeted depth, since these depths vary pan-facially. For improved accuracy, pressure on the skin is changed as needed to ensure that the line of TCPs is placed precisely at the required depth.

Two patients had raised resting brow positions pretreatment due to levator dehiscence. The incipient ptosis is compensated by subconscious raising of the brow. However, unexpectedly, both patients' brows returned to normal (lower) resting positions posttreatment, possibly due to indirect tightening of the periorbita and its connections to the levator apparatus.[28]

GAIS improvements were reported by treating physicians and all patients, whereas independent physicians saw some improvement (87% of cases versus 78% of patients) at 180 days posttreatment as previously reported.[16] The primary outcome of GAIS was noninferior when compared with reports of 50%–78% satisfaction at 6 months.[16,29]

As various factors contribute to pain, our patients' pain experience was an important evaluation. Higher energy settings improve treatment efficacy and outcomes,[9,12,30] but are associated with increased pain.[20] Wind-up with high-level MFU energy was avoided by reducing the number of treatment lines per session, with TCP lines spaced at 0.5-cm intervals and delivered by one transducer pass per depth (deep and superficial). All patients found pain to be tolerable over the short treatment duration and most patients only took over-the-counter, mild analgesics (paracetamol and ibuprofen) pretreatment. Notably, our incidence of adverse events like mild welts (which resolved quickly) were higher than that occurring with the standard Ultherapy protocol, because the Hi5 protocol targets the deep dermis using the 10–1.5 transducer.

Patients often seek non-surgical treatments for affordability and minimal downtime. Hi5 protocol treatments took an average of 20 minutes, with no extra time needed for application of local anesthetic creams, which can take up to 60 minutes to penetrate 3 mm,[31] or nerve block administration. Avoiding opiate or sedating medications avoids recovery time, allowing immediate postprocedure driving and/or return to work. Thus, the Hi5 protocol is an ideal "walk in, walk out, lunchtime procedure," and overall costs can be spaced out and budgeted for.

Interestingly, Hi5 protocol-treated patients outside this study demonstrated improved skin quality, potentially due to extracellular matrix tightening by the retinacula cutis, thus improving fat fitness and ultimately, skin metabolism, and warranting further investigation.[32–34] Unfortunately, mandated mask-wearing (indoors and outdoors) aggravated inflammatory skin conditions for study participants. Thus, skin quality improvements were not expected and conclusions from skin quality assessments were unreliable. However, the SASSQ indicated improvements in certain skin quality parameters (though not statistically significantly), which was surprising given the inflammation associated with near-constant, mask-wearing. Surgical mask-wearing dehydrates the skin and increases sebum production and pH levels, whereas friction from the mask might damage the protective barrier of the skin surface and disturb its moisture balance, leading to increased comedones and acne with papules and pustules, or aggravated rosacea.[35,36]

Our study was limited by a lack of a control and the small sample size for demonstrating that dividing treatments into multiple sessions did not compromise results. Histological studies are needed to demonstrate post-MFU-V retinacula cutis tightening and superficial adipose tissue changes. Our

Table 2. Skin Quality Improvements

	Loss of Elasticity	Wrinkles	Skin Roughness	Pigmentation	Erythema	Pore Size
Pre-treatment	2.28	1.94	2.10	1.83	1.89	1.54
Post-treatment	1.74	1.52	1.83	1.70	1.87	1.37
Average	0.54	0.42	0.27	0.13	0.02	0.17

Assessments of pore size, erythema, pigmentation, roughness, wrinkles, and loss of elasticity were made using the SASSQ.

patient photography could not capture neck and shoulder positions, which may have improved the evaluation of submental changes. Finally, the level of the patients' gaze varied between pre- and posttreatment photographs, which may exaggerate the observed brow height improvements.

CONCLUSIONS

Our Hi5 pan-facial MFU-V protocol delivered high-level MFU energy for positive outcomes, while individualizing treatments, and demonstrated the noninferiority of a spaced-apart, staged treatment plan to the standard single-session protocol. Multiple, shorter sessions enable patients to tolerate high-energy delivery and avoid strong pain relief, which in turn, fulfills their demands for quick procedures with minimal downtime, and increases their budget options.

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DISCLOSURE

Drs. Corduff and Lowe are speakers for and clinical advisors to Merz Aesthetics.

PATIENT CONSENT

The patients provided written consent for the use of their images.

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