

Optimizing Patient Outcomes by Customizing Treatment With Microfocused Ultrasound With Visualization: Gold Standard Consensus Guidelines from an Expert Panel

Sabrina G. Fabi MD,[a] John Joseph MD,[b] Julia Sevi MD,[c] Jeremy B. Green MD,[d] Jennifer Deaver Peterson MD[e]

[a]Goldman Fitzpatrick Butterwick Groff & Fabi, San Diego, CA
[b]Clinical Testing Center of Beverly Hills, Beverly Hills, CA
[c]Aesthetic Health, Leeds, UK
[d]Skin Associates of South Florida, Coral Gables, FL
[e]The Pearl Dermatology, Houston, TX

ABSTRACT

Background: Microfocused ultrasound with visualization (MFU-V) has emerged as a safe and reliable means for lifting and tightening lax skin. Although patients may present with similar age-related changes in the skin and connective tissue, MFU-V treatment must be customized for each patient.

Objective: The following guidelines were prepared to provide a framework for clinicians to develop a customized treatment plan based on the proper use of ultrasound imaging and key patient characteristics to achieve good clinical outcomes with MFU-V.

Methods and Materials: A panel of five expert aesthetic physicians convened to discuss recommendations on the use of MFU-V. Topics included patient factors contributing to favorable outcomes; customizing the number of treatment lines, energy settings, and treatment depths; approaches for restorative vs preventative vs maintenance treatments; and important safety considerations.

Results: Ultrasound imaging is important for selecting transducers and treatment depth and planning the number of treatment lines at each depth. Ideal outcomes are associated with higher density treatments. Treatment intervals are tailored to age, with older patients requiring more frequent treatments to maintain results. MFU-V can be applied for both preventative and restorative treatments. Managing patient expectations is essential.

Conclusion: Supported by a large body of clinical evidence, a well-characterized mechanism of action, and high patient satisfaction, MFU-V is considered by the expert panel of physicians to be a key foundation of aesthetic treatment and the gold standard for nonsurgical lifting and skin tightening.

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INTRODUCTION

The ability of microfocused ultrasound (MFU) to create discrete thermal injury zones within the facial superficial musculoaponeurotic system (SMAS) and denature collagen to induce shrinkage and tissue tightening was demonstrated more than 10 years ago.[1] Since that time, numerous clinical studies have confirmed the safety and effectiveness of this technology.[2] Coupled with ultrasound visualization, microfocused ultrasound with visualization (MFU-V; Ultherapy® System; Merz North America, Inc., Raleigh, NC) has emerged as a safe and reliable means for tightening and lifting lax skin.[3] MFU-V is currently approved for the lifting and tightening the skin of the brow, lower face, and submentum, and improving lines and wrinkles of the décolleté. MFU-V has also demonstrated beneficial effects when used together with other aesthetic treatments.[4-7]

Mechanism Of Action

The SMAS is an extracellular matrix consisting of collagen and elastin fibers[8,9] closely associated with specific facial muscles including the platysma, orbicularis oculi, occipitofrontalis, zygomatici, and levator labii superioris.[10] Since normal aging is associated with a 5% decrease in skin collagen with each passing decade,[11] decreased collagen content in the dermis and SMAS may lead to undesirable skin sagging, wrinkles, and folds.[12,13]

MFU-V is capable of heating tissue to >60°C, producing small (<1 mm^3) zones of thermal injury to a depth of up to 5mm within the mid-to-deep reticular layer of the dermis and sub-cutis while sparing overlying papillary dermal and epidermal layers.[14] The delivery of MFU-V to targeted areas in the SMAS and platysma

results in immediate contraction of denatured collagen and initiation of neocollagenesis and collagen remodeling.[1,15] This leads to clinically significant tissue lifting in the face and neck[16] and improvement of lines and wrinkles of the décolleté.[17]

Efficacy

In the United States, the MFU-V device is cleared for lifting the brow,[3,18] submental and neck tissue,[19] and improving lines and wrinkles of the décolleté.[20] It has also been cleared in the 28 countries of the European Union where it is indicated for sculpting and lifting the upper face, lower face, neck, and décolleté. Additional independent studies have shown MFU-V to be effective for treating lax skin on the knees,[21-22] thighs,[22] buttocks,[23] elbows,[24] upper arms,[22] and lower eyelids.[25]

Although MFU-V has proven efficacy for lifting and tightening lax skin on the face and neck when focused ultrasound energy is delivered at a single focal depth, the customized application of MFU-V at two focal depths may produce superior clinical results.[19] The use of MFU-V has also been shown to enhance the effectiveness of other treatments when combined for improving the appearance of atrophic acne scars,[4] stretch marks,[26] and cellulite.[27]

Safety

A unique feature of the MFU-V device is the ability to perform real-time ultrasound imaging, which ensures the device is properly coupled to the skin surface for the safe transfer of energy and permits the user to visualize planned treatment areas and to avoid treating non-target tissues, such as bone and large blood vessels (DeepSEE®; Ulthera, Inc., Mesa, AZ).[28] Use of the MFU-V system is contraindicated in patients with open wounds or lesions, severe or cystic acne, active implants, or metallic implants in the planned treatment area.

Normal effects associated with treatment include mild-to-moderate discomfort during treatment and transient post-treatment erythema and edema. Among patients enrolled in MFU-V clinical trials (*N*=769), reported adverse events included tenderness or soreness (n=12; 1.6%), welts or lines (n=9; 1.2%), and bruising (n=3; 0.4%).[29] There have been a few post-marketing reports of transient welts[30] and nerve injury[31]; however, these may be related to poor treatment technique and are not permanent.[32] MFU-V is also safe and effective for use in patients with darker skin types.[30]

As mentioned above, the use of MFU-V can enhance the effectiveness of other aesthetic treatments and several studies have demonstrated the safety of combining MFU-V with toxins and temporary, semi-permanent, and permanent fillers.[7,33] Expert consensus supports the combined use of multiple techniques for the safe and effective treatment of the aging face.[34]

Expert Opinion

Despite 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. To accomplish this, the MFU-V device utilizes a computer-driven platform that enables the user to visualize the proposed treatment with ultrasound-imaging transducers and form a customized treatment plan prior to applying MFU energy. The objective of the following consensus guidelines is to provide a framework for clinicians to develop a customized treatment plan informed by key patient characteristics and proper use of ultrasound visualization to assess skin anatomical features.

METHODS

A panel of five expert aesthetic physicians convened during the 2018 American Academy of Dermatology Annual Meeting in San Diego, CA to discuss recommendations on the use of MFU-V. Key topics for discussion included: patient factors that contributed to favorable or poor outcomes; customization of the number of treatment lines, energy settings, and treatment depths; distinguishing approaches for restorative vs preventative vs maintenance treatments; and important safety considerations.

RESULTS

Factors that Contribute to Satisfying Outcomes

It was agreed that MFU-V is currently the gold standard treatment for nonsurgical skin lifting. This conclusion is supported by the largest body of scientific and clinical data available among current noninvasive skin-lifting technologies. It was further agreed that the best clinical outcomes are achieved when the treatment plan is customized to each patient. The proper use of ultrasound imaging, which is a unique feature of MFU-V, is a key factor for customizing treatment.

MFU-V is effective for lifting tissue, treating skin laxity, and promoting collagen production for skin rejuvenation. Although MFU-V cannot treat bone loss, muscle atrophy, or shifting fat, most patients present with some combination of such underlying issues. It is therefore critical that clinicians accurately diagnose patient needs and understand what MFU-V can and cannot do.

It is also extremely important to properly manage patient expectations. Even poor candidates for facial rejuvenation can be satisfied with their results when expectations are properly managed. With proper expectations, overall patient satisfaction can approach 100%.

Factors that Contribute to Poor Outcomes

Several patient factors can lead to poor clinical outcomes, such as actinic damage and smoking.[35] The effects of oxidative dam-

TABLE 1.

MFU-V Coverage by Transducer*								
Lines	Ruler			Coverage				
	Height (mm)	Length (mm)	Total (mm)	4/4.5	7/4.5	7/3.0	10/1.5	TOTAL
240.0	100.0	25.0	2500.0	128.11%	81.99%	15.60%	10.83%	236.54%
120.0	100.0	25.0	2500.0	64.06%	41.0%	7.80%	5.42%	118.27%
60.0	100.0	25.0	2500.0	32.03%	20.5%	3.9%	2.71%	59.13%
30.0	100.0	25.0	2500.0	16.01%	10.25%	1.95%	1.35%	29.57%
25.0	100.0	25.0	2500.0	13.35%	8.54%	1.62%	1.13%	24.64%
15.0	100.0	25.0	2500.0	8.01%	5.12%	0.97%	0.68%	14.78%
10.0	100.0	25.0	2500.0	5.34%	3.42%	0.65%	0.45%	9.86%
5.0	100.0	25.0	2500.0	2.67%	1.71%	0.32%	0.23%	4.93%

*From Casabona G. Skin laxity of buttocks and lateral thigh algorithm for assessment and treatment plan. Presented: Expert Summit, Copenhagen Denmark, November 16, 2018.

age caused by smoking are associated with poor overall skin quality, which is less likely to achieve the same magnitude of response as healthy skin. To help counter this effect, some advisors provide oral nutritional supplements and vitamins, such as ascorbic acid (vitamin C) to counteract the damaging oxidative effects of smoking and maximize the beneficial effects of MFU-V.

Another factor is a high body-mass index (BMI), especially for a single MFU-V treatment. As it is challenging to lift heavy tissue of high BMI patients with MFU-V, they may be better candidates for surgical intervention. Alternatively, they may achieve desired effects with multiple MFU-V treatments. Conversely, patients with a very low BMI may have skin laxity secondary to volume depletion. In these cases, volume restoration may be considered first and MFU-V as a secondary intervention.

Other factors that contribute to poor outcomes include unrealistic expectations, as discussed above, and technical errors such as delivering MFU energy at incorrect tissue depths.

Factors to Consider Prior to Treatment

Some individuals may not be ideal candidates for MFU-V due to underlying medical comorbidities. These include individuals with connective tissue disorders, immune deficiencies, or other disorders that may affect the normal healing and tissue remodeling processes. Similarly, chronic treatment with anti-inflammatory or immunosuppressive medicines may affect how well patients heal from thermal injury.

Customized Treatment: Energy Levels and Line Counts

It was universally agreed the MFU-V energy setting should be set at the highest tolerable level, titrating down as needed for patient comfort. All participants were comfortable with providing treatment using multiple energy levels with no expectation of diminished results, provided proper treatment line density is maintained.

Participants were not comfortable with proposing an upper or lower limit on number of lines for a full-face and neck treatment. It was agreed that a range of 800-1200 lines was reasonable, recognizing that the actual number and placement of lines is based on individualized needs, including the size of the patient's face and the results of ultrasound visualization. Surface area covered by each transducer with the same number of lines are delivered in the same treatment area are provided in Table 1. Adjustments in number of lines can be made to provide the same amount of treatment coverage depending on transducer used.

Visualization should always be performed to assess the depth of the SMAS relative to more superficial layers of the skin as these depths will influence transducer selection and planned number of lines at each depth.

Treating at three depths is considered optimal, but it was acknowledged that many patients may not be good candidates for this approach because the measured depth of target tissues does not align with available transducers. To conserve the density thermal coagulation points, most experts suggested increasing the line count at two other treatment depths if one transducer is not used. Treating at a single depth is not recommended, as it is difficult to achieve the treatment density required for effectiveness without stacking too many thermal coagulation points at a single depth which may lead to adverse events.

Sequential Treatments to Optimize Outcomes

One of the meeting participants is currently performing an investigator-initiated study to assess the potential efficacy of sequential treatments performed 6 weeks apart to optimize the lifting results of MFU-V. The hypothesis behind this study is that the wound repair mechanism is still working within this time interval and performing additional treatments may capitalize on these ongoing processes. It was agreed that this was a safe approach, as prior evidence from studies that assessed the use of MFU-V for treating rosacea and acne scars used treatment in-

tervals between 14 and 45 days with safe and effective results. There was some discussion regarding whether this short-interval approach is optimal for maximizing collagen, as full remodeling and maturation requires 6-12 months; however, no consensus was reached due to lack of evidence. Additional studies are needed to investigate the histologic effects and aesthetic outcomes using shorter intervals between treatments.

Restoration vs Prevention

All participants agreed that the total number of MFU-V treatment lines would not vary if the patient was seeking significant tissue lift or preventative treatment (restoration vs rejuvenation). In either case, the best possible treatment should be offered to maximize results and ensure patient satisfaction.

The group was divided regarding the distribution of treatment lines for older patients seeking restoration vs younger patients seeking rejuvenation. One-half of the group indicated they may place more lines superficially in younger patients to stimulate collagen in those layers of the skin. The other half indicated they would treat both patient groups the same, suggesting that targeting the deeper layers of the SMAS is key for all age groups.

Maintenance

All participants agreed that 12- to 18-month treatment intervals are generally effective for MFU-V treatment maintenance with some possible adjustments for patient age. Younger patients ~30 to 45 years old and those seeking early intervention/rejuvenation may only require retreatment on the higher end of that range, possibly up to every 24 months. Older patients more than 50 years old should be retreated closer to every 12 months.

For long-term planning that involves multiple retreatments, it is important to manage "perception drift".[36] Patients need to be reminded about their original pre-treatment baseline so that they can appreciate their ongoing progress because MFU-V treatments after the initial treatment are not likely to result in a change of the same magnitude. It is important to counsel these patients that these are maintenance treatments to sustain the original result over time as much as possible.

There was some discussion about terminology and whether "maintenance" is really the best description of this process. It was noted that several other terms may resonate better with patients, including "preservation," "continuation," "regeneration," and possibly "preservation of regeneration."

Pre- and Post-Treatment Patient Imaging

It was agreed that high-quality standardized digital imaging is essential, particularly for revealing subtle changes in laxity or lifting. Quantitative analysis systems, such as those offered by Canfield, Inc., were highly recommended. Pretreatment imaging is critical from a medico-legal standpoint and for documenting any possible aesthetic issues and asymmetries.

It was also agreed that photos can be an effective patient retention tool although the group was split on the importance of reviewing pre- and post-treatment photos for establishing patient satisfaction. Some felt strongly that it is in everyone's interest to recommend that patients return after 6 months for follow-up photos. If they have an opportunity to retrospectively review and understand how they have improved, it may enhance patient satisfaction and possibly spread a positive message for the provider. Asking patients to return for post-treatment photos also allows the provider to reassess patient needs for other aesthetic concerns and provide advice regarding other potential treatments, such as fillers, toxin, or topical skincare. Integrating multiple treatment modalities can also enhance patient perception of MFU-V effectiveness and improve overall satisfaction.

Safety Recommendations

Participants were all in agreement with the following safety recommendations:

- Avoid treating the auricular area, particularly adjacent to the earlobe as facial nerves are more superficial in these areas and could be inadvertently affected at MFU-V treatment depths.
- Avoid excessive stacking of lines at one depth which can cause serious injury.
- Avoid buccal nerve injury.
- Never use lidocaine infiltration or a tumescent anesthetic prior to MFU-V because ultrasound energy is absorbed by liquids and excessive heating of liquid anesthetic boluses in the skin increases the potential for adverse events.
- MFU-V should not be performed on skin that is compromised due to disease, injury, or medical procedure because transducers are intended for multiple uses.
- For same-day combination treatments, MFU-V should be performed prior to filler or toxin injections according to published consensus recommendations for combination treatment.[34]

Comfort Management

All participants use different combinations of pretreatment medications and techniques for comfort management, but two common treatments were the use of a topical anesthetic and distraction techniques, such as cool air, a stress ball, massage, or music. One participant noted that after implementing a 100% customized treatment approach, overall patient-reported pain scores decreased and were less heterogeneous. This was likely due to more carefully targeting tissues and avoiding placing energy in potentially painful areas.

TABLE 2.

Consensus Summary
Factors that Contribute to Satisfying Outcomes
Best clinical outcomes are achieved when treatment plans are customized to the patient.
Ultrasound imaging is a key factor for customizing treatment.
It is important to properly manage patient expectations.
Factors that Contribute to Poor Outcomes
Poor skin quality from smoking and actinic damage is less likely to achieve the same response as healthy skin.
Patients with high BMI may be better candidates for surgical intervention.
Unrealistic expectations contribute to poor outcomes.
Factors to Consider Prior to Treatment
Medical comorbidities that affect the normal healing and tissue remodeling processes.
Chronic treatment with medications that affect how well patients heal from thermal injury.
Customized Treatment: Energy Levels and Line Counts
Energy settings should be set at the highest tolerable level, reducing as necessary.
A range of 800-1200 treatment lines is reasonable but dependent on patient needs.
Visualization should be performed to assess the depth of the SMAS to determine treatment plan.
Treating at three depths is optimal but not all patients are candidates for this approach due to limited skin thickness.
Sequential Treatments to Optimize Outcomes
Repeated treatments every 6 weeks is a safe approach based on studies for treating rosacea and acne scars.
Restoration vs Prevention
The number of MFU-V treatment lines should be the same for restoration and rejuvenation.
Maintenance
Treatment intervals of 12 to 18 months are generally effective for maintenance with some possible adjustments for patient age.
It is important to manage “expectation drift” from initial treatment results.
Pre- and Post-Treatment Patient Imaging
High-quality standardized digital imaging is essential for demonstrating treatment effects and also for medico-legal protection.
Safety Recommendations
Avoid excessive stacking treatment lines at one depth which can cause injury.
Lidocaine infiltration and nerve blocks are not recommended for comfort management.
For combination treatments, MFU-V should be performed prior to filler or toxin injections.
Comfort Management
Topical anesthetics.
In addition to medications, distraction techniques, such as vibratory devices, cool air, a stress ball, massage, or music may be beneficial.
Absolute Contraindications
Pregnancy.
Presence of permanent fillers.
Body dysmorphic disorder.
Patients who refuse pretreatment photos.

Absolute Contraindications

- Patients who are pregnant
- Patients with permanent fillers in or adjacent to the treatment area, particularly silicone. Participants will treat over PLLA and calcium hydroxylapatite, depending on the timing and filler location.
- Patients who demonstrate signs of body dysmorphic disorder.
- Patients who refuse to allow pretreatment photos.
- Patients predisposed to being dissatisfied with their treatment results based on a screening tool.

Participants agreed that there was no age group in which MFU-V should be considered an absolute contraindication. All patients can benefit from collagen stimulation, although older patients should be specifically counseled regarding the magnitude of results they can expect.

Tissue Targeting

Participants indicated that they often target the subcutaneous fat layer, particularly if they are trying to achieve a sculpting effect. For example, if a patient has prominent jowls, targeting the fat may reduce the volume slightly, thus improving the overall appearance of the lift. Another anecdotal observation was that MFU-V may also help to thicken the fibrous septae in the fat layer, contributing to the lifting effects. Moreover, there are small connective tissue fibers connecting the skin to the superficial fascia (SMAS/platysma), therefore energy delivered superficial to the fascia could potentially induce lifting and tightening.

Subcutaneous fat may also be targeted if a patient has a particularly deep SMAS secondary to high BMI. If the fat layer is targeted during the initial treatment, it may thin the fat layer making the deep SMAS accessible to the 4.5 mm transducer during a follow-up treatment. One participant noted that most of their patients who request MFU-V require improvement primarily in the jawline and neck areas. Therefore, they concentrate delivery of lines in this area, noting "lines of energy are a precious commodity, so I focus it where it is needed most," typically delivering 1000 lines to this area (omitting the brow/upper face areas) with excellent outcomes.

Regarding the question of whether the fascia is the best target for treatment, or perhaps that the contributions of more superficial layers of the skin are underappreciated, it was agreed that the relative contribution of skin tightening, and fascia tightening may vary according to certain patient factors and merits further investigation.

Positioning MFU-V in Clinical Practice

One participant almost never discusses the lifting ability of MFU-V, preferring to approach discussions from the biostimulation perspective, ie, stimulating collagen formation. MFU-V is used as monotherapy in only 5-10% of patients and that proportion is declining. Most patients are receiving MFU-V as an adjunct to toxins, fillers, or laser treatments. MFU-V can also be positioned as a valuable method for maintaining results of face lifts. The most satisfied patients are those with little overall cost barrier who can invest in a comprehensive treatment plan with multiple modalities. All agreed that the provider needs to educate their patients to the best of their ability, and if patients are looking for something dramatic, they should provide other options.

CONCLUSION

Supported by a large body of clinical literature, a well-characterized mechanism of action, and high reported patient satisfaction, MFU-V is considered by the expert panel of physicians to be a key foundation for aesthetic treatment and the gold standard for nonsurgical lifting and skin tightening. The consensus guidelines presented here extend the available clinical data to provide a framework for physicians to fully customize their approach to treating patients with MFU-V, leading to excellent outcomes that are integral to a patient's overall aesthetic treatment plan. These guidelines are summarized in Table 2.

DISCLOSURES

All authors are consultants for Merz North America.

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AUTHOR CORRESPONDENCE

Sabrina G. Fabi MD
E-mail:..... SFabi@gbkderm.com