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DEVELOPMENT AND CLINICAL EVALUATION OF A STANDARDIZED MICROFOCUSED ULTRASOUND (MFU) PROTOCOL FOR FACIAL REJUVENATION USING THE VISALIFT® DEVICE

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Abstract: INTRODUCTION Facial aging involves progressive structural changes in the skin, fat compartments, SMAS, and bone framework, culminating in skin laxity, loss of contour definition, and tissue ptosis. Microfocused ultrasound (MFU) promotes precise thermal deposition in specific tissue planes, inducing immediate collagen contraction and subsequent neocollagenesis, with epidermal preservation. Despite its widespread clinical use, standardized and device-specific protocols are still limited, impacting the reproducibility and predictability of results. **Objective** To develop and clinically evaluate a standardized microfocused ultrasound protocol for facial rejuvenation using the Visalift® device, emphasizing safety, reproducibility, and objective three-dimensional evaluation. **Methods** This methodological case report describes the application of a structured MFU protocol in a 65-year-old woman patient with clinical indication for surgical neck rejuvenation and no contraindications to MFU treatment. The patient underwent three treatment sessions every 30 days using the Visalift® device. Transducers with focal depths of 4.5 mm, 3.0 mm, and 1.5 mm were applied with predefined energy parameters, with the total number of shots dynamically adjusted according to tissue response and recorded at the end of each session. Clinical outcomes were evaluated using standardized three-dimensional images with the Vectra H2 3D system. **Results** Progressive improvement in skin laxity and facial contour definition was observed throughout the treatment. Three-dimensional analysis showed homogeneous volumetric changes consistent with tissue contraction and collagen remodeling, predominantly in the lower third of the face and in the cervicofacial region. No clinically relevant adverse events were recorded. **Conclusion** The standardized MFU protocol with the Visalift® device demonstrated reproducibility, and a favorable safety profile in this case report. This structured approach can contribute as a methodological reference for MFU-based facial rejuvenation protocols. **Ethical Considerations and Consent** This case report was conducted in accordance with the ethical principles of the Declaration of Helsinki. As this is an individual clinical description, without experimental design or modification of the usual therapeutic conduct, there was no characterization of research involving human subjects under the terms of CNS Resolutions 466/2012 and 510/2016, and submission to the Research Ethics Committee was not required. Written informed consent was obtained from the patient, including specific authorization for the use and publication of clinical data and images, with a guarantee of confidentiality and anonymization.

Keywords Microfocused ultrasound, facial rejuvenation, skin laxity, collagen remodeling, standardized protocol, energy-based devices, tissue biostimulation, Visalift®

Introduction

Facial aging is a progressive and multifactorial process involving structural, functional, and biological changes in the skin and underlying support tissues. Over time, there is a reduction in the synthesis and organization of dermal collagen, fragmentation of elastic fibers, and a decrease in the thickness of the dermis, resulting in loss of elasticity and skin laxity. At the same time, the redistribution and atrophy of superficial and deep fat compartments, associated with craniofacial bone resorption, promote volumetric changes and compromise the definition of facial contours. The weakening of the superficial musculoaponeurotic system (SMAS) and retention ligaments further contributes to tissue ptosis and the characteristic configuration of facial aging (Jewell et al., 2011; Laubach et al., 2011; Alam et al., 2010; Fatemi, 2013; Sasaki & Tevez, 2021; White et al., 2007; Rieder & Narurkar, 2022; Yang et al., 2022).

Although aging is a universal phenomenon, its clinical manifestations show considerable interindividual variability, determined by intrinsic factors such as genetic predisposition and chronological aging, and by extrinsic factors, including chronic exposure to ultraviolet radiation, smoking, and environmental influences. The interaction of these elements defines the intensity and pattern of the aging process in each individual (Ruivo, 2014).

The increased demand for minimally invasive procedures, with shorter recovery times and favorable safety profiles, has driven the development of energy-based technologies in aesthetic medicine. In this context, microfocused ultrasound (MFU), also known as high-intensity focused ultrasound (HIFU), stands out for allowing the precise deposition of thermal energy in predetermined tissue planes, while preserving epidermal integrity (Jewell et al., 2011; Laubach et al., 2011; Alam et al., 2010; Fatemi, 2013; Sasaki & Tevez, 2021; Kassir et al., 2020).

The mechanism of action of MFU is based on the conversion of focused acoustic energy into heat, generating thermal coagulation points at depths typically ranging from 1.5 mm to 4.5 mm. These thermal microfoci promote immediate collagen contraction, followed by a controlled inflammatory response, neocollagenesis, and progressive remodeling of the extracellular matrix. Consequently, clinical improvement occurs gradually over the weeks following treatment (Park et al., 2020; Lee et al., 2021; Kim et al., 2024; Yang et al., 2022).

Despite its widespread use in facial rejuvenation, there is significant heterogeneity in the parameters of MFU application, including transducer selection, energy levels, number of shots, and therapeutic sequencing (Figure 1). This variability reflects the absence of standardized and specific protocols for each device, which may compromise the reproducibility of results and the predictability of clinical response.

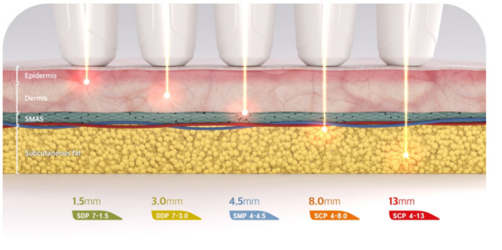

Figure 1. Illustrative diagram of the depths of action of microfocused ultrasound (MFU), demonstrating the focal deposition of thermal energy in specific planes (1.5 mm to 13 mm), including the dermis, SMAS, and subcutaneous tissue, with epidermal preservation.

In this context, the definition of reproducible protocols for energy-based devices becomes especially relevant in aesthetic dermatology practice, where predictability and safety are decisive for the quality of results.

Thus, the present methodological case report aimed to develop and clinically evaluate a structured MFU protocol specifically designed for the Visalift® device (Figure 2). The proposed protocol integrates anatomical guidance, strict control of energy parameters, and objective three-dimensional evaluation, aiming to optimize safety, reproducibility, and clinical outcomes in facial rejuvenation.

Figure 2. Visalift® microfocused ultrasound device used in treatment sessions, with digital interface and handpiece for focused energy application.

Study Methodology

Study Design

This study was designed as a methodological case report with the purpose of describing, systematizing, and clinically evaluating a standardized microfocused ultrasound (MFU) protocol applied to facial rejuvenation using the Visalift® device.

The protocol was based on established anatomical and pathophysiological principles related to facial aging, as well as the recognized biophysical mechanisms of MFU, including focused thermal deposition in specific tissue planes, immediate collagen contraction, and subsequent remodeling of the extracellular matrix.

The intervention was conducted on a single female patient, aged 65, who had previously undergone a detailed clinical evaluation, with confirmation of therapeutic eligibility and absence of contraindications for MFU treatment.

Treatment Protocol

The therapeutic protocol was structured to consist of three sequential sessions of microfocused ultrasound (MFU), performed at a standardized interval of 30 days between each application, using the Visalift® device. The interval was defined based on the physiological time required for the onset of collagen remodeling following the formation of thermal coagulation points (Jewell et al., 2011; Laubach et al., 2011; Alam et al., 2010; Fatemi, 2013; Sasaki & Tevez, 2021).

Before each session, standardized asepsis of the facial and cervical area was performed with an appropriate antiseptic solution, followed by the uniform application of water-soluble ultrasonic coupling gel to optimize acoustic energy transmission, reduce reflection losses, and ensure accurate thermal deposition in the target tissue planes.

The treatment was performed with the patient in a semi-reclined position, maintaining neutral cephalometric alignment. The application followed a previously defined anatomical map, with delimitation of the treatment areas and identification of risk zones, including the periorbital region, the path of the marginal mandibular nerve, and superficial vascular regions (White et al., 2007; Laubach et al., 2012).

The distribution of the shots was performed in a linear and vectorial manner, respecting the natural vectors of facial support and the anatomy of the superficial musculoaponeurotic system (SMAS). The spacing between thermal coagulation points was kept uniform to avoid excessive energy overlap and reduce the risk of adverse events (Rieder & Narurkar, 2022; Yen et al., 2023; Paik et al., 2023).

The energy parameters were predefined. The total number of shots was dynamically adjusted according to the observed tissue response and recorded at the end of each session. Throughout the procedure, the patient was monitored for tolerability and any clinical complications (Lee et al., 2021; Kassir et al., 2020).

Transducer Depths and Targeted Tissue Layers

In each session, transducers with focal depths of 4.5 mm (SMAS), 3.0 mm (deep dermis), and 1.5 mm (superficial dermis) were used, with energy parameters previously established for each tissue plane.

Although the depths and energy levels were defined a priori, the total number of shots was not rigidly predetermined before the start of each session. The application was conducted dynamically and individually, guided by real-time clinical assessment of the immediate tissue response, including visible signs of skin contraction, improved surface tension, and modification of the facial contour.

The distribution of shots followed previously defined anatomical vectors, respecting safety zones and facial structural limits (Figure 3). The procedure prioritized uniform energy deposition and progressive clinical response, avoiding excessive overlap of thermal coagulation points.

Figure 3. Illustrative diagram of the areas and vectors of application of microfocused ultrasound (MFU) on the face and cervical region. The linear markings indicate the standardized distribution of shots, while the "X" symbols represent anatomical risk zones where application of the device is not recommended.

The final count of the total number of shots per transducer was performed at the end of each session, allowing quantitative recording of the parameters actually applied.

This approach was adopted with the aim of integrating technical standardization (depth and energy) with therapeutic individualization based on the observed tissue response, maintaining safety and methodological consistency.

Clinical Evaluation and 3D Imaging

Clinical outcomes were evaluated using standardized three-dimensional photographic documentation using the Vectra H2 3D system (Canfield Scientific, Parsippany, NJ, USA) (De Boulle et al., 2021; Fourie et al., 2011; Weinkle et al., 2020).

Image acquisition was performed in a controlled environment, with strict standardization of lighting conditions, camera positioning, cephalometric alignment of the patient, neutral facial expression, and background isolation to ensure reproducibility and minimize confounding variables. The images were obtained at baseline (pre-treatment), 30 days after the third therapeutic session, and 180 days after the third session.

Three-dimensional volumetric analyses and standardized clinical evaluations were conducted. Colorimetric displacement maps and three-dimensional overlays were used to visualize and quantify tissue contraction and structural remodeling patterns (Suh et al., 2016; Hanke et al., 2013).

The use of standardized three-dimensional imaging contributed to a reduction in observational bias and increased analytical objectivity compared to conventional two-dimensional documentation (De Boulle et al., 2021; Fourie et al., 2011; Weinkle et al., 2020).

Results

The application of the standardized microfocused ultrasound (MFU) protocol with the Visalift® device resulted in progressive and clinically observable improvement in facial contour over the three therapeutic sessions.

A reduction in skin laxity and greater definition of facial contours were identified, especially in the lower malar, mandibular, and cervicofacial regions. These changes were more pronounced in the lower third of the face and in the cervical region. Clinical improvements were already noticeable after the first session, with progression in subsequent evaluations. Thirty days after the third session, greater definition of the cervicomentonian angle and reduction of submental laxity were observed (Figure 4 and Figure 5).

Figure 4. Right lateral view of the patient, showing the initial situation and 30 days after the end of the last treatment session.

Figure 5. Right lateral view, 45-degree position, showing the patient's initial condition and 30 days after the end of the last treatment session.

Three-dimensional volumetric analysis performed with the Vectra H2 3D system showed homogeneous changes consistent with tissue displacement and reduction of ptotic displacement vectors, particularly along the mandibular border and submental region (Figure 6).

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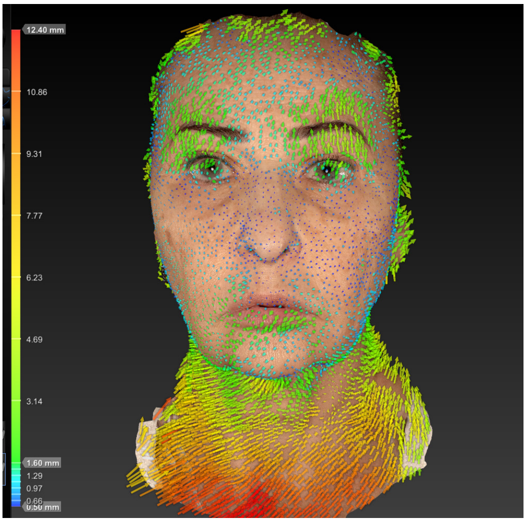

Figure 6. Colorimetric volumetric displacement map generated by the Vectra H2 3D system, illustrating the extent, lifting effect, and distribution of tissue changes observed 30 days after the end of the last treatment session.

The three-dimensional superimposition of the images—initial and thirty days after the last session—showed consistent patterns of tissue retraction (Figure 7).

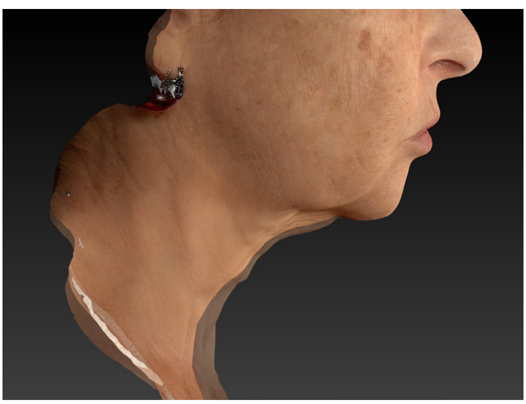

Figure 7. Overlay of right lateral images showing the patient's initial condition and 30 days after the end of the last treatment session, demonstrating the volumetric changes achieved by the procedure.

The evaluation of the skin appearance was conducted by standardized visual inspection based on the three-dimensional images obtained, without the use of specific instruments for biomechanical measurement or instrumental analysis of skin quality. Thus, observations regarding texture and surface appearance were exclusively clinical.

At the 180-day follow-up after the third session, the facial contours obtained were maintained, with no evidence of significant regression of flaccidity, suggesting maintenance of the clinical effects in the medium term (Figure 8).

Figure 8. Frontal view showing the patient's initial condition and 180 days after the last treatment session.

Throughout the follow-up period, no clinically significant adverse events were reported, including persistent pain, neurosensory changes, asymmetries, or tissue depressions.

Discussion

The findings of this methodological report are consistent with the current literature supporting the efficacy of microfocused ultrasound (MFU) in noninvasive facial rejuvenation. Immediate tissue contraction followed by progressive collagen remodeling is widely described in clinical and histological studies, especially when energy application is performed in a controlled manner and respecting anatomical references (Jewell et al., 2011; Laubach et al., 2011; Alam et al., 2010; Fatemi, 2013; Sasaki & Tevez, 2021; White et al., 2007; Fabi & Goldman, 2014; Rho et al., 2015).

The clinical improvements observed are consistent with the mechanism of thermal coagulation point formation at specific depths, triggering a controlled inflammatory response and subsequent reorganization of collagen and elastic fibers. Histological studies show that the remodeling process typically occurs between four and twelve weeks after treatment, which explains the gradual evolution of the results observed in this case (Suh et al., 2016; Park et al., 2020; Alhaddad et al., 2023).

The combined use of transducers with different focal depths (4.5 mm, 3.0 mm, and 1.5 mm) reflects a multilayer approach, allowing simultaneous action on the SMAS, deep dermis, and superficial dermis. This strategy favors a more uniform three-dimensional effect and is in line with studies that demonstrate better results when multiple tissue planes are treated (Yen et al., 2023).

The most evident response in the lower third of the face and in the mandibular region is supported by the literature, which points to greater responsiveness of these areas to MFU, possibly due to local anatomical characteristics, such as adipose compartmentalization and the presence of fibrous septa (Wu et al., 2022).

The incorporation of three-dimensional documentation with the Vectra H2 3D system represents one of the strengths of this study. Volumetric analysis contributes to greater objectivity in the evaluation of results, reducing the subjectivity inherent in traditional two-dimensional photographic documentation (De Boulle et al., 2021).

With regard to safety, the absence of clinically relevant adverse events reinforces the safety profile of MFU when energy parameters and anatomical risk areas are adequately respected. This highlights the importance of technical standardization as a tool for reducing complications (Kassir et al., 2020; Patel et al., 2023).

As a limitation, this is a single case report, without the use of specific instruments for biomechanical measurement of skin quality, which restricts the generalization of the results. Prospective studies with a larger number of patients and prolonged follow-up are necessary to validate and expand the findings presented.

Conclusion

The standardized microfocused ultrasound (MFU) protocol using the Visalift® device promoted progressive clinical improvement of facial contour and reduction of skin laxity in this case report, maintaining a favorable safety profile during follow-up. The effects were most evident in the lower third of the face and in the cervicofacial region and remained stable at the 180-day follow-up, reinforcing the clinical consistency of the protocol.

Three-dimensional documentation corroborated changes consistent with tissue contraction and structural repositioning, reinforcing the clinical applicability of the proposed approach.

Standardization of the protocol, with clear definition of depths and energy parameters, may contribute to greater predictability and consistency of results in clinical practice.

As this is a single case report, the findings should be interpreted with caution, and studies with a larger number of patients and longer follow-up are needed to confirm the results.

Conflict of Interest

The authors declare the following professional relationships: Rodrigo Blas and Ana Carolina Borba are speakers for Allergan Aesthetics (AbbVie). Isabel Garcia and Julie Bae are speakers for Pharmaesthetics. These relationships did not influence the study design, data collection, data interpretation, or the preparation of this manuscript.

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