

Important aspects of microfocused ultrasound: literature review

Summary

Introduction: Widely used in aesthetics, microfocused ultrasound is a non-invasive technique that uses high-frequency sound waves to treat deep tissues in the human body. On the face, it is often used to treat wrinkles, fine lines and sagging skin. The treatment is carried out with a specialized ultrasound device that emits sound waves at focal points of coagulation in layers of the skin, subcutaneous tissue and SMAS, heating and stimulating collagen and elastin in order to promote tissue regeneration and strengthening. It is considered safe and effective, and generally causes no discomfort and requires no recovery time. The aim of this study was to review the scientific literature on microfocused ultrasound in order to gain a more comprehensive understanding of the technical, biological and clinical aspects of this technology, including its mechanisms of action, indications, contraindications, results and possible complications.

Results: According to scientific reports, microfocused ultrasound has become the treatment of choice for mild to moderate skin laxity of the face. It is clearly an effective treatment for skin tightening and the procedure is safe and tolerable.

Conclusion: Thus, it can be concluded that microfocused ultrasound can be a safe treatment option with satisfactory clinical resolution to improve the appearance of the skin and treat a variety of aesthetic conditions.

Keywords: ultrasound therapy, rejuvenation, aesthetics

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Introduction

Skin aging is an intrinsic and inevitable process of human aging. As we age, changes occur in the structure of the skin that directly affect its appearance and normal physiological functions.¹ The face is one of the areas most exposed and susceptible to the effects of ageing, making it one of the main aesthetic concerns associated with skin ageing.² This suggests that facial ageing is influenced by a variety of endogenous and exogenous factors, such as genetics, sun exposure, pollution, smoking and other environmental factors, which are interconnected and contribute significantly to the appearance of the main signs of ageing, wrinkles, fine lines, dark spots, textural changes, sagging, facial furrows and drooping eyelids.³ Although skin aging cannot be stopped completely, it is possible to slow it down and minimize its impacts. In addition, there is a wide range of aesthetic procedures available today that can help rejuvenate the appearance of the skin.^{4,5} Among these procedures, there is a growing demand for non-invasive facial treatments, driven by a number of factors that may include the search for safer and less invasive solutions, with little or no downtime, greater affordability compared to invasive surgical procedures, and provide more natural results and without the use of needles.⁶ This significant increase in interest and demand for facial rejuvenation and harmonization treatments has stimulated studies and research to develop new treatment modalities and improve existing ones, as is the case with techniques that use microfocused ultrasound (HIFU).⁷ Microfocused ultrasound works by emitting high-frequency sound waves focused on deep, specific areas of the skin. The absorption of energy gently heats these areas without damaging the skin's surface, generating an inflammatory response that stimulates the production of new collagen and elastin fibers in the skin. Progressively, the use of microfocused ultrasound can lead to firmer, younger-looking skin with fewer wrinkles. In addition, this technique can help improve the texture and tone of the skin, giving it a brighter, healthier appearance.⁸

Microfocused ultrasound stands out from other ultrasound procedures for its ability to reach the deeper layers of the skin, including the superficial aponeurotic muscular system, also called SMAS, a layer of fibrous connective tissue that surrounds the facial muscles in the posterior region of the face, and which provides a greater facelift (Figure 1).⁹ Considering the information presented, in order to contribute to the advancement of scientific knowledge in the field of aesthetics about microfocused ultrasound, the aim of this work was to carry out a literature review in order to gain a more comprehensive understanding of the technical, biological and clinical aspects of this technology, including its mechanisms of action, indications, contraindications, results and possible complications. In addition, this review can identify gaps in current knowledge and areas that need further research to optimize the use of microfocused ultrasound in clinical practice.

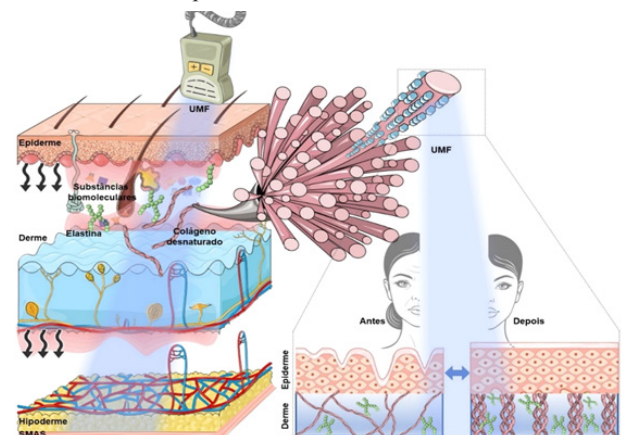


Figure 1 Schematic illustration describing the use of microfocused ultrasound for skin rejuvenation.

Methodology

A search was carried out in the Pubmed and BVS databases, using the following descriptors “Microfocused Ultrasound AND Facial rejuvenation AND Skin Laxity Treatment” with the use of corresponding terms in the national language, and the association between the terms was also carried out in order to broaden the search. The inclusion criteria adopted were: articles dated between 2018 and 2023, articles published in Portuguese and English, and which only covered articles related to the use of microfocused ultrasound in the orofacial region. Exclusion criteria: duplicate articles, works that did not present their respective abstracts on the search platform, or that did not contemplate the proposed methodology (Figure 2).

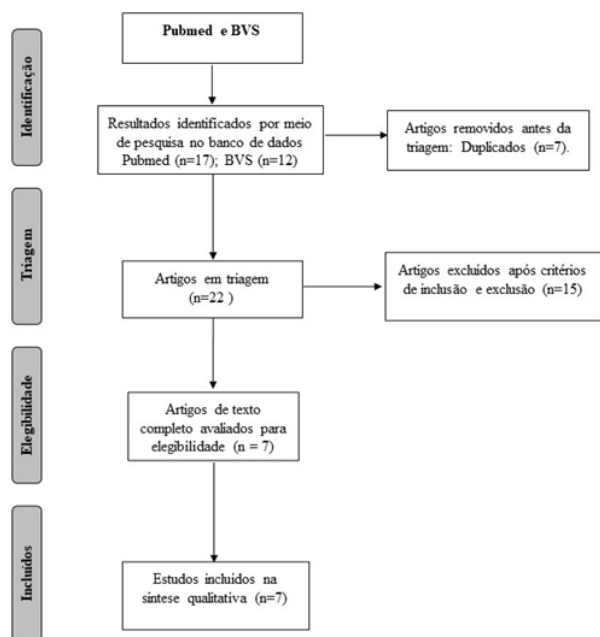


Figure 2 Flowchart of the search strategy to identify eligible studies.

Results

The search resulted in 17 scientific articles in PubMed, and 12 articles in the BVS database, removing 7 duplicates, which generated 22 articles. Applying the inclusion and exclusion criteria, a further 15 articles were removed. After refining the search, a total of 7 studies were eligible to form the basis of this literature review (Table 1). In the clinical research experience, which treated approximately 5,000 patients over 7.5 years, the authors collaborated and discussed their approaches to optimizing patient comfort and satisfaction. Included in their respective approaches are practical guidelines for selecting patients and setting expectations, as well as various research-based pharmacological and non-pharmacological approaches that can be used to maximize patient comfort.¹⁰ Clinical study with 43 subjects,

all patients completed microfocused ultrasound treatment with a 90-day follow-up. Erythema and edema were acute and transient responses. One patient complained of muscle pain in the neck region, which resolved in two weeks. Most patients rated their tolerance to the procedure as fair or good, but mentioned that treatment with the 4 MHz, 4.5 mm probe was sometimes painful. One patient requested that treatment in the neck region be stopped due to a choking sensation. There were no other serious adverse effects.¹¹ Another study included a total of 24 individuals, 23 women and 1 man, with less facial laxity. According to the results, 15 patients (62.5%) were assessed as having no change. Among 5 individuals (20.9%) who had some improvement, 4 of them (16.7%) were assessed as slightly improved and 1 individual (4.2%) was assessed as moderately improved. Four individuals (16.7%) were classified as worsening, 1 and 2 of whom were assessed at 12 and 32 months of follow-up, respectively.¹²

A systematic review was carried out to evaluate the effect of microfocused ultrasound treatment on skin tightening. The overall results showed that the treatment improved skin stiffness to varying degrees in the majority (>90%) of the patients included over the long term. The percentage of patients in the moderate improvement group increased from 36% to 52% and the mild improvement group decreased from 47% to 34% during the 90 to 180 days of follow-up. Support for this improvement is also seen in the no change category, which decreased from 25% at 3 months, to 17% at 6 months and 5% at one-year follow-ups.⁷ A recent investigation highlighted MFU-V’s high accuracy in thermal coagulation point formation at specific tissue depths and its safety profile. It also emphasized that this should be customized according to the patient’s needs, face size, skin laxity, fat distribution, skin quality and ultrasound imaging results. This way, the correct transducers and the number of lines for each tissue plane can be determined. The coagulation points of microfocused ultrasound can vary according to the model of device and the intensity used during the treatment process.¹³

Previous studies on 573 patients have shown that side effects other than pain were transient erythema with or without edema in almost all patients. More uncommon were ecchymoses/hematomas in four cases, transient dysesthesia in four cases, cheek papules in one case, skin burns in two cases, white linear striae of the neck in two cases and one case of white dermal papules on the neck. These unusual adverse effects were observed in 2% of the total number of patients treated (14 patients).⁸ Positive results have been shown to be more significant in patients with mild to moderate facial aging and those with a body mass index of 30 kg/m² or less. For elderly patients with severe skin laxity and marked platysmal bands, surgical treatment should be discussed and prioritized.¹⁴ In view of all the results presented by microfocused ultrasound treatment, a description was made of the coagulation points of the main microfocused ultrasounds released by the National Health Surveillance Agency (ANVISA): Ultraformer III, Ulthera, Herus, Reface and Ultraformer MPT, the main characteristics of which are shown in Table 2.^{6,8,11,13,17-19}

Table 1 Distribution of articles by title, reference, objective, main results and conclusion

Author	Objective	Results	Conclusion
Fabi et al. ¹¹	To share the authors' extensive experience in optimizing comfort for their patients with MFU-V.	The authors share their approaches to optimizing patient comfort during the procedure and provide an overview of the measures that can be adopted to support patient comfort and satisfaction.	They found that attention to patient comfort is directly related to satisfaction and appears to be a primary factor in patients' decision to return for further treatment.
Friedman et al. ¹²	Report on the experience with Double IFUS (Doublo™, HIRONIC Co.) in the treatment of sagging neck and lower face.	Nine patients (52.9%) reported some improvement. Erythema and edema were acute and transient responses	Ultrasound seems to be a safe modality for facial skin tightening in selected patients with minor skin laxity and no volume discrepancy.

Table 1 Continued...

Author	Objective	Results	Conclusion
Yalici-Armagan et al. ¹³	To evaluate the efficacy and safety of a new microfocused ultrasound (MFU) device in lower facial sagging.	According to the images, 5 patients (20.9%) showed improvement and 15 patients (62.5%) had no change. Four individuals (16.7%) were scored as worsening. According to the images, 11 individuals (45.9%) reported an improvement, while 9 individuals (37.5%) reported no change.	The relatively high rate of improvement observed by the patients' self-assessments compared to the researchers' assessment from the photographs suggests that we need to find new assessment methods other than photography that can reflect how the patients feel.
Khan et al. ⁷	To systematically review the efficacy of microfocused ultrasound (MFU) for facial sagging.	They showed that 92% of patients demonstrated an improvement in skin tightening and/or wrinkle reduction that continued for up to a year.	MFU treatment is effective for mild to moderate facial skin tightening.
Park et al. ¹⁴	To review the published information on the safety and efficacy of non-invasive energy devices in aesthetic skin tightening, to compare them with our experiences in Asian patients and to disseminate a consensus for optimizing microfocused ultrasound with visualization (MFU-V) in Asian patients.	We highlight the differences between devices and platforms and identify factors that require attention and caution. Due to the increase in new devices without strong clinical evidence of safety and efficacy in Asia, it is necessary to convene physicians with substantial experience in MFU-V and draw up a consensus on the selection, planning and personalization of Asian patients.	We have shown that the MFU-V satisfies this clinical imperative. In addition, the patented DeepSEE® technology allows users to non-invasively "see" through the skin to ensure treatment precision, facilitate optimal skin lifting and tightening, and increase patient comfort and safety. We therefore believe that the MFU-V is the gold standard for non-surgical lifting and skin tightening.
Contini et al. ⁸	To analyze and examine the effects and benefits of MFU treatment to improve the skin.	The results of the literature study revealed that significant improvements in the overall aesthetics of sagging of the mid and lower face can be achieved using a microfocused ultrasonic treatment plan.	Better rates of improvement have been reported by patients' self-assessment and by the assessment of clinical investigators, which sets it apart from all other skin tightening methods.
Néri et al. ¹⁵	To review the scientific literature on the use of MFU in the process of facial rejuvenation and correction of sagging skin.	MFU can be applied to the subcutaneous tissue, producing small thermal coagulation points within the middle to deep reticular layer of the dermis and subdermis. The application of heat to these discrete thermal coagulation points causes collagen neosynthesis and consequent skin tightening.	MFU has been shown to be a safe technique and is considered effective, non-invasive, well tolerated by patients and viable for medical and dental clinical practice.

Table 2 Coagulation points of the main microfocused ultrasounds released by the National Health Surveillance Agency (ANVISA), and their main characteristics

Ultrasound	Information	Depth	Number of coagulation points on the line	Scanner/Pen	Transducers
Ultraformer III	Classys Inc. (South Korea)	1.5 mm to 13 mm	10	Scanner	Micro and Macrofocused
Ulthera	Merz Aesthetics (USA)	1.5 mm to 4.5 mm	17	Scanner	Microfocused
Herus (4D)	Fismatek (Israel)	1.5 mm to 4.5 mm	10	Scanner/Pen	Microfocus and Macrofocus
ReFace	Cluederm (South Korea)	1.5 mm to 4.5 mm	10	Scanner/Pen	Micro and Macrofocused
Ultraformer MPT	Classys Inc. (South Korea)	1.5 mm to 13 mm	10	Scanner/Pen	Microfocused

Discussion

In recent years, numerous scientific investigations have focused on the use of microfocused ultrasound, which has led to a significant number of scientific articles being published on the subject. These studies have demonstrated the effectiveness of microfocused ultrasound in various areas, with great success in aesthetics. In addition, it offers more and more treatment options and improves aesthetic results.¹⁴ It is a relatively new and modern technique that is available to facial harmonization specialists. Its results are promising and its efficacy and safety have been proven in several clinical studies.⁷ Microfocused ultrasound technology specifically targets the dermis layer, adipose tissue and muscle tissue, allowing for precise and controlled treatment. This means that the heat generated by the sound waves is delivered only to the layer that needs to be treated, according to the cartridge chosen at the time, preserving the adjacent layers.¹⁶ Regarding the indications and contraindications of microfocused ultrasound. It is known that the main indication is the treatment of mild to moderate cutaneous hypotonia, characterized by a lack of skin support fibres. As such, the procedure is suitable for people who want

to improve the appearance of their facial skin, but who don't want to or can't undergo more invasive surgical procedures.¹⁶

In a scientific study aimed at optimizing patient comfort during the application of microfocused ultrasound, some findings were pointed out. They stated that microfocused ultrasound treatment (MFU-V; Ultherapy®) is best suited to patients with fine lines and mild to moderate wrinkles and should not be used on patients with severe static wrinkles. This is because the patient must have good tissue elasticity and sufficient volume, so that skin tensioning does not reveal volume deficits.¹¹ Another clinical study treated sagging of the lower third of the face and neck with ultrasound in 43 patients. Based on a global rating scale of 0 (exacerbation) to 5 (75-100% improvement), within three months, an improvement was seen in nine patients who had only mild sagging, and the rest showed no effect at all.¹² Corroborating this data, a systematic database search analyzed 16 studies to evaluate the efficacy of MFU treatment in facial skin tightening in females. They concluded that excessive skin laxity and body mass index (BMI) >30 were contraindications for MFU treatment, as the positive results decreased with increasing laxity and BMI.⁸ Of the information

previously mentioned, the articles were concerned with the indication of ultrasound in cases of mild to moderate skin laxity of the face and neck. With regard to side effects, other studies have evaluated the efficacy and safety of microfocused ultrasound (MFU) in sagging of the lower third of the face in 24 patients. The findings reported minimal pain during the treatment session. No patient reported severe pain requiring additional pain relief with analgesia or sedation and none dropped out of the study due to intolerable pain or side effects. Only one patient reported a transient burning sensation/dysesthesia on the face after the procedure which lasted approximately 6 months and another patient showed mild erythema after application. No serious adverse events were observed.¹³

Similarly, another study presented similar data and also reported moderate pain from the MFU procedure and the presence of transient erythema with or without edema. Other adverse effects were rare (2%), including dysesthesia (numbness or hypersensitivity), bruising and stinging, jaw burns, stretch marks and contact dermatitis.⁸ Few complications have been reported previously, most of which include mild and transient erythema and edema, transient paralysis of the lips and eyebrows, no serious complications. Another adverse effect is skin burns, caused by ultrasound energy being delivered too shallowly, incorrect coupling of the transducer to the skin or stacking of the energy pulses, lack of spacing between the lines, producing cumulative skin damage. This is a rare occurrence, but can lead to scars.¹⁴ Another clinical analysis mentioned unusual side effects such as ecchymoses/hematomas in four cases. They concluded that these types of complications are rare and may be underreported.¹⁴ The research cited above clearly shows that microfocused ultrasound has minimal side effects, which generally last a few days, and nerve and bone irritation is rarely observed, as the frequency of the transducer fixes the depth of penetration. This confirms the great acceptance by patients due to its high tolerance. Regarding the approach to the efficacy and safety of microfocused ultrasound, although it is considered a safe treatment, microfocused ultrasound also has its limitations.⁶

In this sense, studies have shown that this non-invasive treatment modality is based on converting the energy of ultrasound waves into heat and cavitation. The target areas are the subdermal connective tissues, such as the superficial layer of the aponeurotic muscular system, SMAS, and the deep dermal layers. In view of this, they pointed out that the effectiveness of microfocused ultrasound is directly related to several variables that can be altered during MFU therapy. This is due to the fact that different transducers can be used with different frequency and energy settings.⁷ In more detail, this review also mentioned the fact that the wavelength (MHz) determines the depth of tissue penetration. A higher frequency ultrasound has less penetration into the tissue. The energy applied, measured in joules (J), determines how much the tissue heats up and is responsible for the effect. They suggested that increasing the energy at different depths can enhance the effectiveness of the treatment.⁷ It should be noted that the distribution of thermal coagulation points in microfocused ultrasound refers to the specific areas where the ultrasound is applied to achieve the desired effects. These can vary depending on the specific device used, the aim of the treatment and the area of the body being treated. Generally, the professional in charge of the procedure will determine the distribution of the coagulation points based on the patient's individual assessment and the lifting and rejuvenation treatment goals.^{7,8}

Thermal coagulation points that hit the subcutaneous tissue do not cause lipatrophy, as the changes are considered microscopic, but the atrophy caused can lead to hardening of the skin. Repeated

coagulation points in the same place and/or high energy can cause fat necrosis.⁷ Previous research has also linked its findings to the efficacy and safety of microfocused ultrasound treatment. It emphasized that the waves are not ablative, which avoids many of the complications related to epidermal heating.¹⁴ In another investigation, the authors stated that there are a considerable number of studies in the scientific literature which have evaluated the effectiveness of microfocused ultrasound and obtained positive results for its viability in clinical practice. In addition, they emphasized that the effectiveness of the treatment also depends on the unique physical characteristics of each patient, and the adjustments to the energy and focal depth of the ultrasound used.¹⁵ The FDA has classified microfocused ultrasound as class II, i.e. intermediate risk. To minimize these risks, the energy delivery or focus needs to be spaced out, as lowering the energy levels results in less effective treatment outcomes.¹⁵ The aforementioned studies point to the satisfactory results of microfocused ultrasound and relate the effectiveness of the treatment to the difference in the model of device used, as well as the modulated parameters, and the intrinsic characteristics of each patient. The favorable assessment of researchers, qualified professionals and patients regarding the benefits of microfocused ultrasound in each region of the face is clear. Patient satisfaction with elective aesthetic procedures is an important indicator of treatment success.

Conclusion

The growing interest in preventing ageing and caring for the skin has led people to seek less invasive and safer aesthetic treatments. Technology is constantly evolving and improving, with new generations of equipment being developed to make treatment even more effective and personalized. It is important to remember that the coagulation points of microfocused ultrasound should always be adjusted by a trained and experienced professional to ensure the safety and effectiveness of the treatment. In summary, it can be concluded that microfocused ultrasound can be a safe and effective treatment option for improving the appearance of the skin and treating a variety of medical and aesthetic conditions. However, it is important that patients discuss the risks, benefits and possible side effects with qualified professionals before deciding to undergo treatment. And there is a need for long-term double-blind randomized clinical trials to confirm the safety and efficacy of HIFU.

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Conflicts of interest

The author declares there is no conflict of interest.

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