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RESEARCH ARTICLE

Efficacy of Microfocused Ultrasound Treatment on Malar Mounds in Brazilian Patients: A Prospective Study at the Professor Rubem David Azulay Dermatology Institute

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ABSTRACT

This study evaluates the efficacy and safety of the use of Micro focused Ultrasound as a treatment for Malar Mound. In addition, a specific protocol was developed to improve patients' aesthetic complaints.

Introduction: Nowadays, patients are looking for natural, less invasive and safer treatments to treat facial ageing. Malar Mound is the accumulation of edema, sagging or permanent fat in the prezygomatic region. Micro focused Ultrasound is a new and safe technology that, through heat, generates neocollagenesis, causing rejuvenation of the treated area.

Objective: To determine the level of effectiveness of using Micro focused Ultrasound in patients with Malar Mound.

Methodology: An experimental, prospective, single-center study was carried out at the Prof. Rubem Azulay Dermatology Institute between September 2024 and February 2025. The sample consisted of 13 people who underwent 5 sessions of Micro focused ultrasound every 2 weeks. High-frequency dermatological ultrasound was used to measure the soft tissues involved, and each patient completed questionnaires on satisfaction and adverse effects, as well as a photographic record before and after treatment.

Results: The result was a significant improvement in the Malar Mound in most of the patients. In the superficial musculoaponeurotic system of the medial and lateral malar region, on both the right and left sides, the results were statistically significant with a significance level of 5% ($p<0.05$). The satisfaction rate was acceptable, with 53.8% of the participants indicating that they were very satisfied. While the intensity of pain was reported as mild by 38.5% of patients and moderate by 46.2% of people. Only 3 patients reported edema, erythema or other side effects after the sessions.

Conclusions: Micro focused ultrasound proved to be effective and safe in the treatment of Malar Mound, with a high degree of patient satisfaction. A specific protocol was applied to treat the aesthetic complaint, the same one developed by the research participants. Side effects were mild and transient, reinforcing the viability of the non-surgical therapeutic alternative.

1. Introduction

Nowadays, more patients are looking for natural, less invasive treatments with a higher safety profile and fewer side effects to treat facial aging. Although aging is a physiological process and happens to everyone, it is very relevant in the physical appearance of patients, reflecting on people's self-esteem.

To understand this morphological change caused by aging, it is important to know that the zygomatic-orbital ligament plays a major role in changes to the lower eyelid and in the development of the malar mound; in other words, the formation of the malar mound is a slow, chronic process that takes years to develop. With aging, the eyelid fat pads become more edematous; this, combined with a weakened orbicularis oculi muscle and skin laxity, results in the orbital malar ligament descending onto the underlying soft tissues, creating excess skin[1,2]. The Orbito-Malar Ligament can become lax over time, that is, due to aging or the patient's own characteristics; for this reason, the Malar Mound can sometimes be observed in young people. In contrast, the Malar Septum and the Zygomaticocutaneous Ligament are much stronger and more rigid, which means that the soft tissues overlying the Orbito-Malar Ligament cause the weight of the pre-zygomatic space to be poorly supported by a resistant foundation (Malar Septum, Zygomaticocutaneous Ligament).

During aging, there is a change in the volume and position of the superficial and deep fat compartments. Folds form due to a loss of tissue, compounded by gravity and a loss of skin elasticity; furthermore, according to some studies, a slow, defective, or imbalanced lymphatic system contributes to the pathophysiology of the Malar Mound. Currently, there is little literature on the pathophysiology of the Malar Mound, and further research and new investigations on the topic are needed. Figure 1.

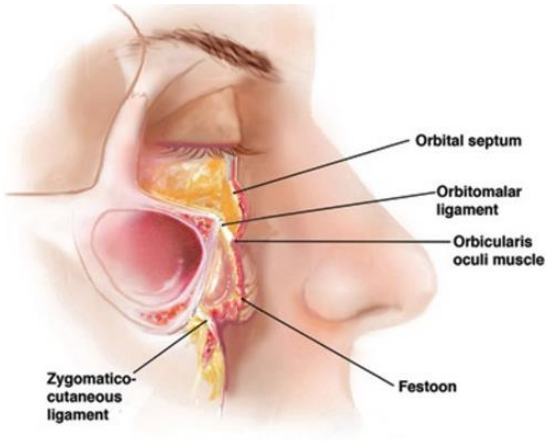


Figure 1: Sagittal section of the Malar Mound and Festoons formation[2].

In dermatology, this pathology is a therapeutic challenge for doctors, taking into account that, currently, one of the treatments offered to patients is surgery[3,4]. However, the result includes a scar that can be very unsightly and, like any medical procedure, has risks and side effects that can aggravate the patient's complaint. Thus, the aforementioned led to the development of research offering a non-invasive, safe therapeutic alternative that can be applied to all types of patients.

Micro focused Ultrasound is a new and safe technology that, through heat, generates neocollagenesis, causing a lifting effect and in case the patient has fat accumulation, it will be compacted[5,6]. An interesting fact is that the device can work in several layers of the skin, both in the subcutaneous cellular tissue and in the musculoaponeurotic system.

One of the motivations for conducting the study is to provide information, data and results that can guide and guide doctors to offer a non-surgical or invasive treatment, without recovery time, that does not interfere with activities of daily living, but that at the same time is safe, with natural results and without modifying the shape of the patients' faces.

The primary objective of the research is to determine the level of efficacy of the use of Micro focused Ultrasound in patients with Malar Mound. Other specific objectives of the research are to

determine the safety of the use of Micro focused Ultrasound in patients with Malar Mound and to elaborate a treatment protocol for Malar Mound with Micro focused.

Rejuvenation of the periorbital region is a very frequent complaint of patients, especially in the area of the junction of the lower eyelid with the zygomatic malar region, where the Malar Mound is located: sagging, edema and/or permanent fat in the prezygomatic region caused by aging, genetic predisposition and laxity of the orbitomalar ligament[7,8,9]. Figure 2.

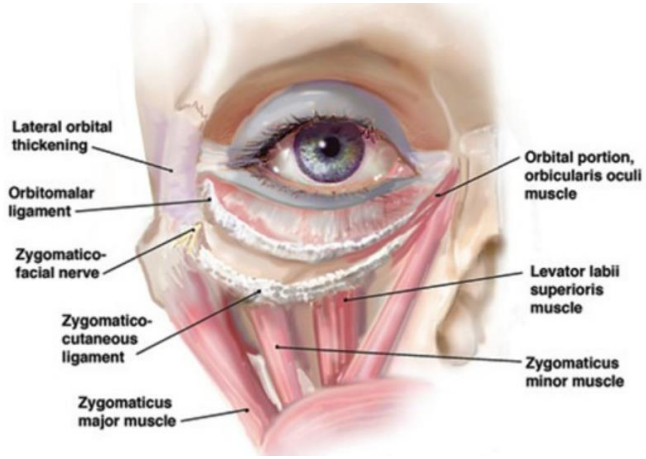


Figure 2: Anteroposterior view of the LOM, LMZ[2].

Due to its central location on the face, people report that Malar Mound interferes a lot with their self-esteem, giving the appearance of being an older, sadder and tired person. Figure 3.

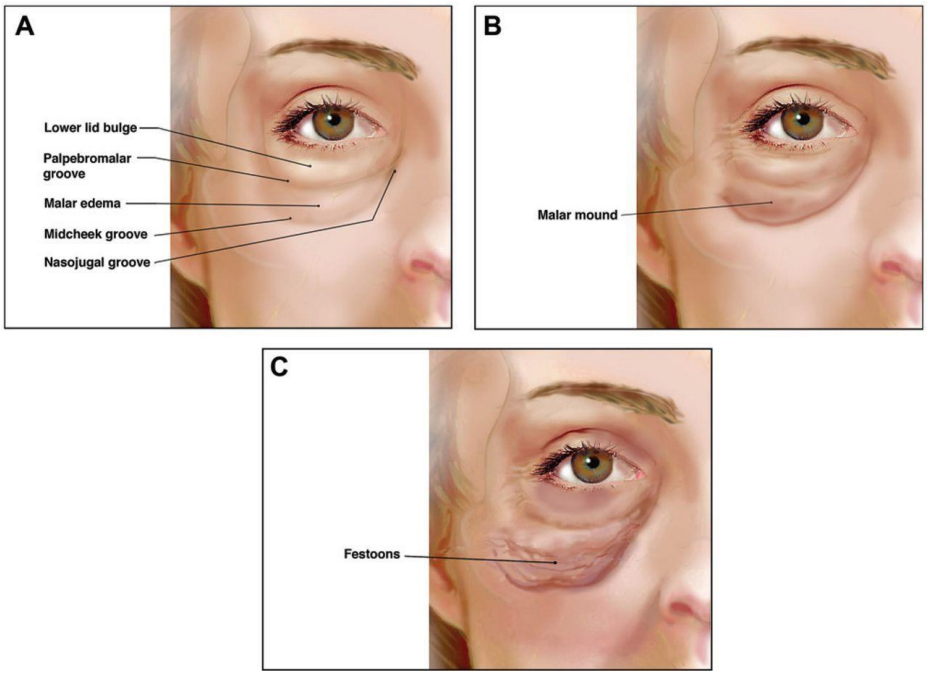


Figure 3: Malar Mound and Festoons. (A) Malar edema; (B) Malar Mound; (C) Festoons[2].

Currently, the treatment of Malar Mound is challenging, and surgery is one of the options offered to patients, which consists of excising excess fat and excess skin or performing skin muscle flaps and even facelifting, but the scar can be visible and very unsightly in most cases[9,10]. In addition, there is the risk of post-inflammatory hyperpigmentation in patients with a high phototype and the risks involved in surgery, such as poor positioning of the lower eyelid that can cause exposure of the sclera, conjunctival chemosis and, finally, even ectropion. In other words, we could worsen patient dissatisfaction.

For these reasons, our study seeks a non-surgical therapeutic alternative proposing the use of Micro focused Ultrasound, which is a non-invasive device that through heat delivers localized energy in the layers of the skin, in the subcutaneous cellular tissue and in the superficial musculoaponeurotic

system. Figure 4. The energy will denature collagen and induce neocollagenesis, which ends up producing a contraction of the tissues, resulting in a lifting (lifting effect), reduction of skin flaccidity and aesthetic improvement of the treated area[11].

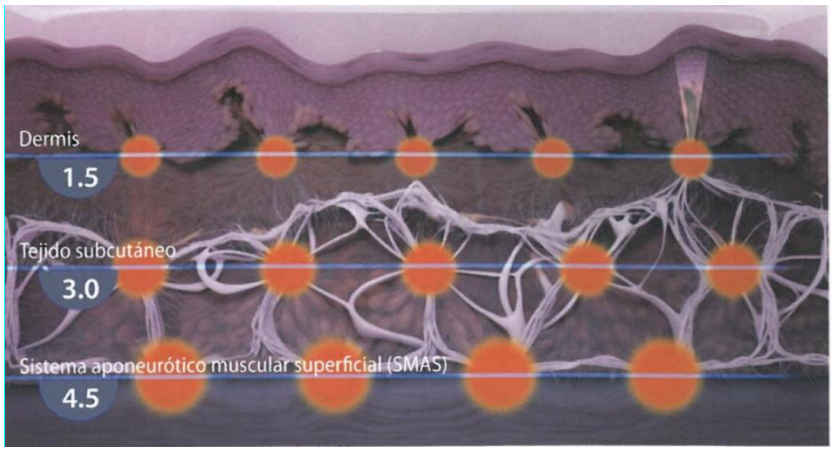


Figure 4: Depth according to the selected transducer and according to the objective to be treated[6].

Currently, there is little literature on alternative non-surgical treatments of Malar Mound and that is why with this research, in addition to fulfilling the proposed objectives, it is expected to contribute with results and knowledge that can guide and help doctors to offer the patient a different therapeutic option, which can be used safely in the vast majority of people and be used in the early stages of Malar Mound, it is also a preventive therapy.

2. Materials and Methods

At the Dermatological Institute in the city of Rio de Janeiro, during the months of September 2024 to February 2025, an Experimental, Longitudinal, Prospective and Unicentric study was developed. In the research, we will use both experimental and observational techniques.

The study was carried out with thirteen patients with the inclusion criteria:

* Patients 18 years of age or older who have provided informed consent.
* Patients of male, female or any gender diversity.
* Patients of any race, ethnicity, skin phototype.
* Patients with Malar Mound (mild, moderate, severe) unilaterally or bilaterally.
* A person with a history of autoimmune diseases under control.

Patients who met the following exclusion criteria were disregarded:

~ Patients under 18 years of age.
~ Pregnant or lactating patients.
~ Patients with cystic acne, infection or inflammation are both systemic and local.
~ People with a history of autoimmune diseases or uncontrolled collagen diseases.
~ Patients with previous aesthetic treatments, both surgical and non-surgical (botulinum toxin, permanent fillers or not), technologies (infrared energy devices including radiofrequency, ablative or non-ablative laser) in the periorbital and Malar area at least six months before the procedure.

The following instruments were used in the study:

- Clinical history of each patient, with their respective physical examination.
- High-frequency Dermatological Ultrasound (18 MHz probe), for the purpose of measuring each of the skin layers and structures before and after the study to be compared at the end of the study. The Dermatological Ultrasound was performed by the same radiologist.
- Photographic record before and at the end of the research that helps to determine the effect obtained.
- Questionnaires that were used with each patient were the satisfaction scale and another questionnaire of the effects.

The protocol that allows you to specify both the experimental and observational part is as follows:

1. Patient assessment.
2. Indication of five sessions with an interval of 15 days between each session.
3. Completion of the Informed Consent Form (ICF).
4. Completion of the Term of Authorization for the use of data and image.
5. Photographs of the patient in various positions (frontal, bilateral profile, 45 degrees bilateral). The photo will be taken 1.5 meters from the patient.

6. Perform high-frequency dermatological ultrasound of soft tissues of the periocular and bilateral zygomatic malar region.

7. Remove makeup or sunscreen and clean the periocular area and bilateral zygomatic malar region with alcoholic chlorhexidine and gauze.

8. Delimit the area to be treated with a marking pen: malar mound (prezygomatic space between the orbicularis retention ligament and the zygomatic-cutaneous ligament) and plan the number of treatment columns. (Figure 5).

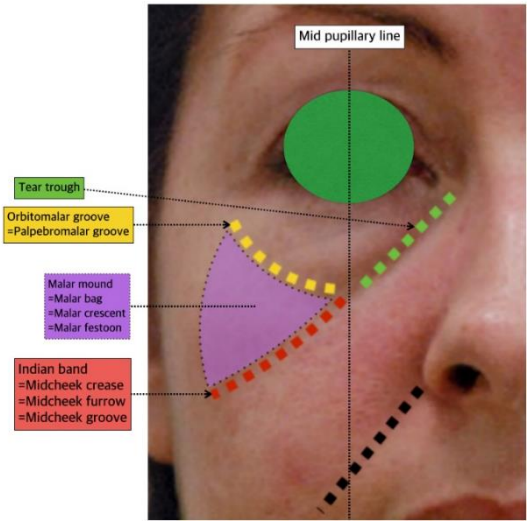


Figure 5: Marking delimiting the Malar Mound[17].

9. Apply ultrasound gel to the target site.

10. Use of Micro focused Ultrasound (Figure 6): Perform two passes with each transducer in the marking areas. The selected transducer should be placed firmly on the skin to ensure that it is evenly coupled to the surface of the skin. Ten shots will be fired at each Malar Mound with each of the transducers. The first pass is made with Microfocused ultrasound cartridge 1.5 mm – 7 MHz (energy 1-1.5 J, spacing 1.5 mm). The second pass will be with the 3 mm – 7 MHz cartridge (energy 1.1 – 1.6 J, spacing 1.5 mm), and the third pass with the cartridge 4.5 mm – 7 MHz (energy 1.7 – 2.3 J, spacing 1.5 mm). The second pass will be performed with the other pen with the pen: the first pass in an upward direction with the tip 3 mm – 4 MHz (energy 0.7 – 0.9 J) and the second pass with the tip 4.5 mm – 4 MHz (energy 1 – 1.2 J). (Figure 7.8)

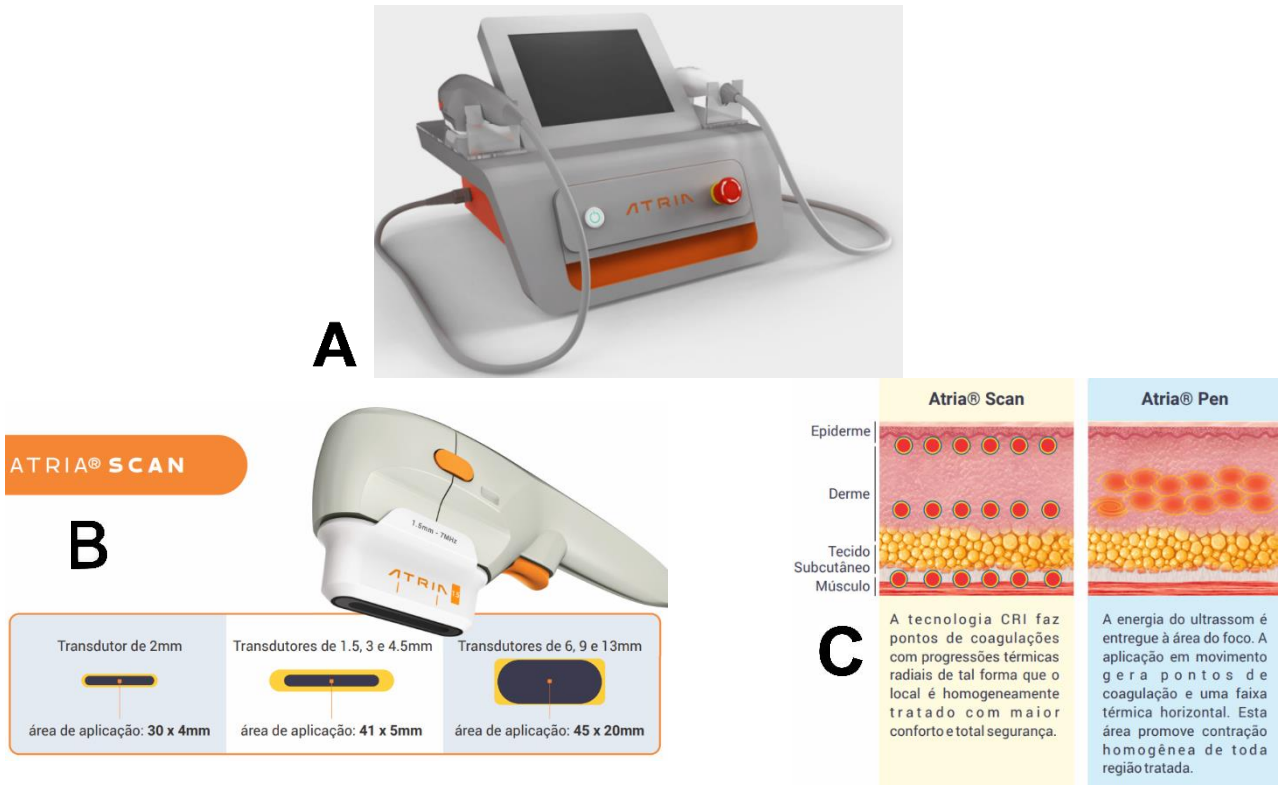
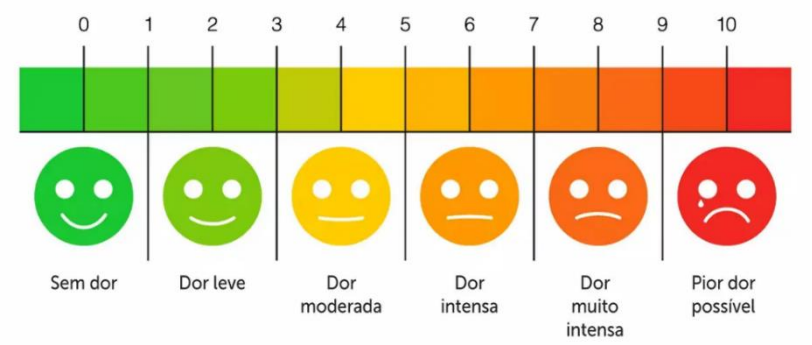


Figure 6: A: Micro focused Ultrasound. B: Different transducers of the cartridge with their respective surface area to be treated[14]. C: Differences between the mechanisms of action of cartridge and inPen[14].

11. Cleaning the gel.
12. Indication of use of FSP 50+ sunscreen daily with reapplication every four hours.
13. Return every two weeks to repeat the treatment protocol until a total of five sessions are completed.
14. At the end of the study, the patient will return 30 days after the last session: on that day the patient will be photographed again in various positions and (Frontal, bilateral profile, 45 degrees bilateral). The photo will be taken 1.5 meters from the patient. In addition, a new high-frequency Dermatological Ultrasound of soft tissues of the periocular and bilateral zygomatic malar region will be performed. Finally, the patient must complete the effects questionnaires as well as the satisfaction questionnaire to conclude with their participation. (Figures 9 and 10).

Figure 9: Customer Satisfaction Score: Mark with (X) the degree of satisfaction of the result.[15]

A: Circle the number referring to the degree of pain felt after the procedure[16].



B: Marking with (X) if during the study had any of the following effects:

▶ Erythema	☐ YES	☐ NO
▶ Edema	☐ YES	☐ NO
▶ Paresthesia or numbness	☐ YES	☐ NO
▶ Hematoma	☐ YES	☐ NO
▶ Transient nerve palsy	☐ YES	☐ NO
▶ Post-inflammatory hyperpigmentation	☐ YES	☐ NO
▶ Epidermal burns	☐ YES	☐ NO
▶ Scar formation	☐ YES	☐ NO
▶ Bubbles	☐ YES	☐ NO

Others:

Figure 10: Effects questionnaire: A:Visual Analog Scale (VAS) of Pain. B:Effects

Statistical Analysis: The analysis of information and data was performed using SPSS version 28.0. com a significance level adopted was 5% ($p<0.05$). Numerical variables were described as mean and standard deviation or median and interquartile range, and categorical variables were described as absolute and relative frequencies. The comparison of measurements before and after the intervention was made by the student's t-test for paired samples. The Microsoft Excel program was used to summarize the results with their corresponding graphs.

In the study, one of the analyses was the comparison of the measurements of the different layers that make up the Malar Mound before and after the intervention with Micro focused Ultrasound. The measures and their statistical relevance are described below.

3. Results

SAMPLE CHARACTERIZATION: In the research, the sample was composed of 13 people, 100% of the participants being female, with a mean age of 56.8 years (± 8.4 years). These data are represented and can be seen in Table 1.

Table 1 – Characterization of the sample according to age and gender.

Variables	n=13
Age (years) – mean ± SD	56.8 ± 8.4
Gender	n (%)
Women	13 (100)

DERMIS:
One of the superficial layers of the skin is the dermis, the same one that was divided into regions during the measurement of the parameters. In the dermis of the right medial malar region, its thickness before intervention was 2.3 ± 0.2 mm and after the procedure it was 2.4 ± 0.8 mm (p= 0.426). In the dermis of the right lateral malar region, the pre-intervention thickness was 1.8 ± 0.4 mm and later 2.2 ± 1.3 mm (p= 0.396). Now, on the left side, the area of the medial malar before the procedure, the thickness was 2.1 ± 0.2 mm, and then 2.3 ± 0.4 mm (p= 0.114). In the left lateral malar region, its pre-intervention thickness was 2.0 ± 0.5 mm and later 1.9 ± 0.3 mm (p= 0.389). As can be seen from the results on both the right and left sides, there is an increase in the thickness of the dermis, but it was not significant, due to the fact that the increase in the thickness of the dermis was shortly after the intervention or maybe.

SUPERFICIAL MUSCULOAPONEUROTIC SYSTEM:
Another of the parameters that were measured during the research was the superficial musculoaponeurotic system (SMAS). In this amount it was also divided into regions. Before performing the intervention, the right medial malar SMAS was 4.5 ± 2.0 mm, later the value changed from 3.3 ± 1.3 mm (p= 0.015). The right lateral malar SMAS before the procedure was 2.9 ± 0.8 mm and after the application of the technology it was 1.7 ± 1.5 mm (p= 0.031). Evaluating the contralateral side, we found that the left medial malar SMAS before the intervention had a mean of 4.4 ± 1.6 mm and after the procedure measured 3.3 ± 1.4 mm (p= 0.09). The region of the lateral malar SMAS before the use of the device was 3.2 ± 0.9 mm, after the 5 sessions the measurements evolved to 1.7 ± 0.7 mm, which was statistically significant (p= <0.001). Due to the mechanism of action of Micro focused Ultrasound, an increase in muscle tension is expected, that is, a decrease in measurements, when analyzing the data obtained from the research, a statistically significant result is evidenced in all the regions studied by corroborating the reduction of the parameters.

SUB ORBICULARIS OCULI FAT:
One of the deepest layers of the periocular and malar-zygomatic region is the Sub Orbicularis Oculi Fat (SOOF), which is also part of the pathophysiology of malar mound. The pre-intervention measurements on the right side in the medial malar region had a thickness of 7.7 ± 1.5 mm and after the procedure 8.6 ± 2.0 mm (p= 0.050), the purpose of the technology was to reduce the measurement, but when analyzing this result, which was statistically significant, it is necessary to clarify that the increase in thickness was an unexpected finding, but significant because of the large difference between the values. In the right lateral malar SOOF before the intervention, the measurement was 5.2 ± 1.3 mm, after the intervention the measurement decreased to 4.9 ± 1.2 mm (p= 0.405) mm, although having an expected decrease was not statistically significant. Analyzing the left medial malar SOOF on the opposite side before the survey, the measurement was 7.2 ± 1.6 mm, later we had a value of 7.5 ± 1.3 mm (p= 0.737), confirming a statistically non-significant result. In the left lateral malar SOOF, the same thing happened as on the right side, before the intervention the measurement was 5.1 ± 0.9 mm and after the procedure it was 4.8 ± 1.3 mm (p= 0.305), that is, even with a decrease in the parameters, they were not significant.

All data reported from the comparison of before and after the intervention can be seen in table 2.

Table 2 – Comparison of parameters before and after the intervention

Variables	Before	After	P
	Average ± SD	Average ± SD	
Right Side			
SOOF			
Malar Medial/infraorbital	7.7 ± 1.5	8.6 ± 2.0	**0,050**
Malar Lateral/zygomatic	5.2 ± 1.3	4.9 ± 1.2	0,405
SMAS			
Malar Medial/infraorbital	4.5 ± 2.0	3.3 ± 1.3	**0,015**
Malar Lateral/zygomatic	2.9 ± 0.8	1.7 ± 1.5	**0,031**
Dermis measurements:			
Medial/infraorbital malar	2.3 ± 0.2	2.4 ± 0.8	0,426
Lateral/zygomatic malar	1.8 ± 0.4	2.2 ± 1.3	0,396
Left Side			
SOOF			
Malar Medial/infraorbital	7.2 ± 1.6	7.5 ± 1.3	0,737
Malar Lateral/zygomatic	5.1 ± 0.9	4.8 ± 1.3	0,305
SMAS			
Malar Medial/infraorbital	4.4 ± 1.6	3.3 ± 1.4	**0,009**
Malar Lateral/zygomatic	3.2 ± 0.9	1.7 ± 0.7	**<0.001**
Dermis measurements:			
Medial/infraorbital malar	2.1 ± 0.2	2.3 ± 0.4	0,114
Lateral/zygomatic malar	2.0 ± 0.5	1.9 ± 0.3	0,389

SIDE EFFECTS:

After finishing the 5 sessions of Micro focused Ultrasound, each of the participants was questioned using a questionnaire to find out if they had any effect on the skin. Of the 13 patients who were part of the study, only 3 (23.1%) had some of the effects, while the remaining participants, 10 (76.9%) denied having side effects. In the literature, several possible adverse effects are described, from mild to more complex ones, but even though it is a very safe technology, the 3 patients who indicated having some effect stated that they had the following effects: erythema 1 (7.7%), edema 1 (7.7%) and another 1 (7.7%) that was reported as the appearance of pimples, fortunately the other effects such as paresthesia or numbness, bruising, transient nerve paralysis, post-inflammatory hyperpigmentation, epidermal burns, scarring or blistering have not been reported. These results can be seen in Table 3.

Table 3 – Adverse Effects

Variables	n=13
With adverse effects	**n (%)**
Yes	3 (23,1)
No	10 (76,9)
Types of adverse effects	**n (%)**
Erythema	1 (7,7)
Edema	1 (7,7)
Pimples	1 (7,7)

PAIN:

Micro focused Ultrasound is a non-invasive technology, even though some patients may experience some discomfort or pain during the procedure. Pain intensity was assessed by the Visual Analog Scale (VAS), resulting in the median degree of pain intensity being 3 with an interquartile range of 1.5 – 4, which indicates that on average the pain reported by the participants is mild, with values between 1.5 and 4. By detailing each of the VAS grades, as can be seen in Table 4, we can identify that 15.4% (2) of the patients did not report pain, 38.5% (5) of the patients reported mild pain, another 46.2% (6) of the participants reported moderate pain, and favorably none of the patients reported severe pain.

Table 4 – Visual Analog Scale (VAS) of Pain

Variables	n=13
EVA number – median (P25 – P75)	3 (1,5 – 4)
EVA Grade	**n (%)**
Pain-Free (0)	2 (15,4)
Lightweight (1 to 3)	5 (38,5)
Moderate (4 to 6)	6 (46,2)
Intense (≥ 7)	0 (0,0)

SATISFACTION:

After the 5 sessions of Micro focused Ultrasound, each patient returned 30 days later to perform the control with High Frequency Dermatological Ultrasound and filled out a questionnaire where the degree of satisfaction was evidenced. Clinically, 53.8% (7) of the participants indicated that they were very satisfied with their respective results, 15.4% (2) reported being satisfied with the treatment of malar mound, 23.1% (3) of the patients reported an indifferent result when they had no improvement or worsening of their aesthetic complaint, and finally only 7.7% (1) indicated that they felt dissatisfied with the treatment because they did not improve their malar mound. No participant reported being very dissatisfied 0%. Briefly, this information can be analyzed in table 5.

Table 5 – Degree of Satisfaction after the intervention

Variables	n=13
Degree of satisfaction	**n (%)**
Very dissatisfied	0 (0,0)
Dissatisfied	1 (7,7)
Indifferent	3 (23,1)
Satisfied	2 (15,4)
Very satisfied	7 (53,8)

4. Discussion

The research presents several points to be discussed, starting with the characterization of the sample. The sample consisted of 13 female participants, with a mean age of 56.8 years. This agrees with the literature because patients with advanced age, since the malar mound is part of the aging process, especially after the age of 40, when there is a significant decrease in collagen neoformation, accompanied by the redistribution of fat pads due to the loss of support of the facial ligaments and bone resorption.

The mechanism of action of Micro focused Ultrasound is the production of small zones of thermal coagulation, which generate an inflammatory process and, consequently, neocollagenesis. This is thanks to the 1.5mm cartridge. Regarding the dermis, although the results show an increase in the thickness of the dermis in the patients, this increase was not significant. One reason for this may be the small sample size, which suggests that more studies are needed to obtain more accurate results. Another possible reason is that collagen neoformation and dermal remodeling occur between 2 to 3 months after the procedure. In the study, the control was carried out only 1 month after the last session. It would be important, in a new study, to carry out controls with longer intervals of time. In addition, another factor that may have interfered with the result is the fact that the cartridges used for the shots have a flat surface, while the malar mound is a concave region of the face, which may have made the symmetrical distribution of the shots difficult.

Regarding the mechanism of action of Micro focused Ultrasound on the superficial musculoaponeurotic system (SMAS), the process is like that of the dermis. Micro focused Ultrasound produces micro-coagulation points, stimulating increased muscle firmness, which results in greater contraction. This is possible thanks to the 3 mm deep cartridges, which reach the SMAS. With increased firmness, the SMAS is expected to present a reduction in measurements during control dermatological ultrasonography[3]. Analyzing the SMAS data after the intervention, the parameters evaluated showed statistically significant results in the medial and lateral malar regions, bilaterally. These results are of great importance because, according to the pathophysiology of the malar mound, the ligaments involved have returned to fulfill their function, providing support to the facial structures.

The Sub Orbicularis Oculi Fat (SOOF), as the name suggests, is composed of fat and is part of the deep structures of face10. Micro focused Ultrasound,

through the 4.5 mm cartridge, reaches the adipose tissue and has no lipolysis effect, what it does is generate intense heat and through this it makes a contraction of the lobular fibrous septa. This can give an appearance of decreased fat, which is also part of the malar mound formation process. One of the findings that draws attention to the research was the behavior of the SOOF because it did not have a significant variation. The cause of these results is still unclear, but a possible explanation is that due to the repositioning of the tissues, the fat pads, which were crumbling due to aging, could have been reorganized. Another possible reason is that the parameters used did not reach the subcutaneous cellular tissue because they did not want to produce any damage to the eyeball.

High-frequency dermatological ultrasound is a useful tool in the evaluation and measurement of skin layers. However, it should be considered that this test is dependent on the operator.

In the literature, there are sufficient studies to support the safety of this technology, since it is a non-invasive procedure, with no need for recovery time, being one of the first choices in aesthetic dermatology to treat and prevent skin aging. In the study, only 3 patients (23.1%) reported side effects, while the remaining 10 patients (76.9%) reported no effects after Micro focused Ultrasound sessions. Several scientific studies have reported that, as it is a non-invasive procedure, Micro focused Ultrasound is not free of side effects, which can range from mild to more complex6. In the study, the side effects observed were erythema (1 patient), edema (1 patient) and pimples (1 patient), each accounting for 7.7%. Erythema and edema are transient, being the most frequent in literature, lasting from a few hours to 2 days. The appearance of pimples can be attributed to the occlusion of the follicular openings by the gel or to the fact that the patient does not wash her face properly after the procedure. More severe complications, such as facial paresthesia, bruising, transient facial paralysis, post-inflammatory hyperpigmentation, burns, scars, blisters, ulcers, or glaucoma, were not reported by any participant[6,13]. Fortunately, there were no serious complications in the study.

Micro focused Ultrasound, through acoustic energy that is transformed into mechanical energy and generates heat, denaturalizes collagen, favoring neocollagenesis5. This energy delivery can cause discomfort of varying intensity in patients. In the study, the Visual Analog Scale (VAS) was used to assess the degree of pain that each patient experienced during treatment. This scale includes pain levels: mild (1 to 3), moderate (4 to 6), severe (≥ 7-10), and the option to feel no pain (0). It was observed that 15.4% (2) of the participants reported no pain, 38.5% (3) reported mild pain, and 46.2% (6) reported moderate pain. No patients reported severe pain. These results suggest that the use of topical analgesia or other measures to relieve discomfort may be an interesting alternative to provide a more comfortable experience. We can also infer that the energy parameters used during the study were safe, as no patient experienced significant discomfort.

The opinion of the patients on the results obtained after the 5 sessions of Micro focused Ultrasound in the treatment of malar mound was of great importance to the researchers. Therefore, a questionnaire was applied to assess the degree of patient satisfaction with the result of the protocol, serving as a parameter to improve future investigations. The questionnaire had answer options: very dissatisfied, dissatisfied, indifferent, satisfied and very satisfied. Clinically, 7 patients (53.8%) reported being very satisfied with the results, 2 patients (15.4%) were satisfied, and 3 patients (23.1%) were indifferent, indicating that their malar mound remained the same as at the beginning, with no improvement or worsening. Only 1 patient (7.7%) reported being dissatisfied, as the malar mound did not improve. However, this patient had unrealistic expectations about the results, despite having been clearly informed about the purpose of the research. After treatment, some patients mentioned that, in addition to the improvement in the malar mound, they noticed the skin of the lower third of the face firmer, reduction of wrinkles and improvement in skin quality. These findings are not surprising, as Micro focused Ultrasound has already demonstrated beneficial cutaneous effects. What is striking is that, when treating a specific area, benefits were observed in other regions as well. For the researchers, it is gratifying to see that many patients were satisfied with the results and accepted the clinical effects well.

In the study, it was observed that, even with the improvement, some patients continue to seek more procedures to eliminate the malar mound. This leads to the reflection that the only therapeutic

alternative with immediate and definitive results would be the surgical option4, although with all the associated risks[3].

When comparing the photographs of the patients taken before and after the treatment, it was observed that, in most cases, there was a more evident improvement on one side of the face compared to the other. The patients themselves reported that one side of the face responded better to the treatment. According to the literature, this can be influenced by external factors, such as the position in which the patient sleeps. Sleeping on your side or stomach can affect blood circulation and slow lymphatic drainage, resulting in fluid retention. This factor could explain the difference in response between the sides of the face, since it is something specific to each patient and not controllable in the study. Other factors that could not be controlled during the research are the patients' lifestyle habits, which have a known impact on skin quality and response to treatment. Excessive consumption of processed foods, sugars, and fats can accelerate skin aging and make it difficult to achieve satisfactory results. Smoking, in turn, causes oxidative stress, damaging collagen and elastin fibers. These factors are relevant, as two patients who reported being indifferent or dissatisfied mentioned that they had increased their tobacco consumption and gained weight during the study period. As is well known, for treatment to have an effective response, it is essential to adopt a healthy lifestyle. This leads us to the reflection that there are external factors that cannot be controlled by researchers.

5. Conclusions

The results of the study indicate that, quantitatively, the efficacy was not statistically significant, except in the SMAS in the medial and lateral malar regions of both sides, where significant improvements were observed after the micro focused ultrasound sessions. However, clinically, through photographic records and satisfaction questionnaires, an improvement in the region of the malar mound was evidenced: of the 13 participants, 53.8% were very satisfied and 15.4% were satisfied with the results. In addition, the procedure proved to be safe and well tolerated, since no patient had serious effects; Only three reported mild effects, such as erythema, edema, and pimples. The median pain was 3 on the visual analog scale, which corresponds to mild pain. (Figure 11 and 12)

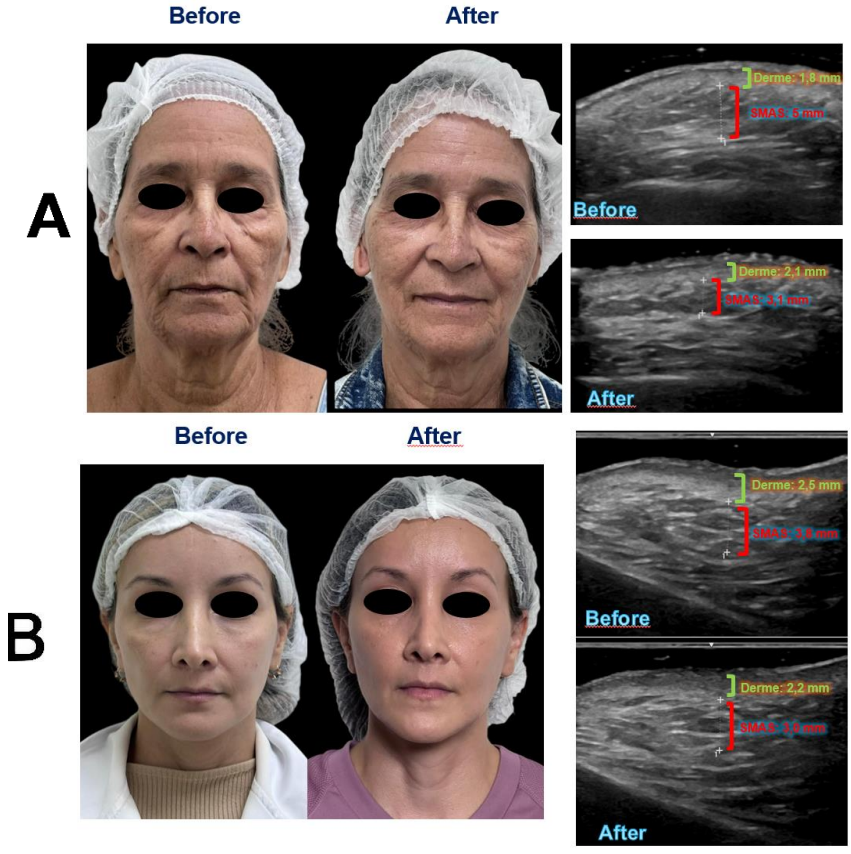


Figure 11: Patient outcomes: A: Photography before and after comparison. Before-and-after comparison following Dermatological Ultrasound. An increase in dermal thickness and a decrease in SMAS thickness are observed. B: Patient outcomes: Photography before and after comparison. Before-and-after comparison following Dermatological Ultrasound. A decrease in SMAS thickness is observed.

Concluding the analysis of the research, although the improvement in quantitative parameters such as the SMAS was statistically significant, the clinical improvement, the patient's opinion and there were no reports of side effects or prioritization of each patient's complaint, it can be said that the balance of the results are positive, which motivates the researchers to continue with future investigations and to increase the number of samples.

As it is a pioneering study, there are no previous investigations with the same number of sessions, parameters, and inclusion and exclusion criteria that can serve as a reference to compare the results. However, it is gratifying to open new avenues for future research. It is essential that further studies be carried out with larger samples to verify whether the protocol applied can be extrapolated to the general population.

6. Limitations

The main limitation of this study lies in its pioneering nature within the field under investigation, which resulted in a significant shortage of comparable literature. This lack of prior research made it difficult to contextualize the findings and limited the ability to draw robust comparisons with previous studies.

Likewise, the small number of available cases limited the statistical power of the analysis and restricted the generalizability of the results. However, this same limitation highlights the exploratory value of the work, as it opens a line of research that is still underdeveloped. We hope that in the future there will be new studies based on these results, with a larger sample size to enable the extrapolation of the use of microfocused ultrasound for the treatment of malar mound to the general population.

On the other hand, it is important to note the logistical and economic difficulties that influenced the scientific dissemination process. The time elapsed between obtaining the results and attempting publication was considerably prolonged, largely due to the lack of a budget to cover the costs associated with paywall scientific journals.

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