Evaluation of pain level during microfocused ultrasound treatment in the lower eyelid and lateral eye region: an observational study

Avaliação do nível de dor durante o tratamento com ultrassom microfocado na pálpebra inferior e na região lateral do olho: um estudo observacional

Evaluación del nivel de dolor durante el tratamiento con ultrasonidos microfocalizados en el párpado inferior y la región ocular lateral: un estudio observacional

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ABSTRACT
Microfocused ultrasound is a non-invasive technology widely used for its ability to stimulate collagen production, generate fat lipolysis and provide lifting. Despite its benefits, many patients avoid the procedure due to the associated pain and discomfort. The aim of this study was to quantitatively evaluate the pain perceived during the application of HIPRO microfocused ultrasound to the lower eyelids and sides of the eyes, using the numerical pain scale (NRS). The sample consisted of 10 individuals aged between 30 and 50. The methodology included the application of HIPRO at a frequency of 10Hz and a depth of 1.5mm, with 900 shots per treated area. Pain was measured after 450 and 900 shots. The results showed that the majority of patients rated their pain as mild or non-existent, with an average score of 1.175 out of 10 on the NRS. The variability in pain perception reinforces the importance of personalized approaches. Compared to other devices, HIPRO proved to be an effective and relatively comfortable alternative, especially for pain-sensitive patients. It is concluded that HIPRO microfocused ultrasound is a safe and effective option for facial rejuvenation, with a manageable discomfort profile and good clinical results.

Keywords: microfocused ultrasound, HIFU, pain measurement, pain.

RESUMO
O ultrassom microfocado é uma tecnologia não invasiva amplamente utilizada por sua capacidade de estimular a produção de colágeno, gerar lipólise de gordura e proporcionar lifting. Apesar de seus benefícios, muitos pacientes evitam o procedimento devido à dor e ao desconforto associados. O objetivo deste estudo foi avaliar quantitativamente a dor percebida durante a aplicação do ultrassom microfocado HIPRO nas pálpebras inferiores e nas laterais dos olhos, usando a escala numérica de dor (NRS). A amostra foi composta por 10 indivíduos com idade entre 30 e 50 anos. A metodologia incluiu a aplicação do HIPRO em uma frequência de 10 Hz e uma profundidade de 1,5 mm, com 900 disparos por área tratada. A dor foi medida após 450 e 900 disparos. Os resultados mostraram que a maioria dos pacientes classificou sua dor como leve ou inexistente, com uma pontuação média de 1,175 de 10 na NRS. A variabilidade na percepção da dor reforça a importância de abordagens personalizadas. Em comparação com outros dispositivos, o HIPRO demonstrou ser uma alternativa eficaz e relativamente confortável, especialmente para pacientes sensíveis à dor. Conclui-se que o ultrassom microfocado HIPRO é uma opção segura e eficaz para o rejuvenecimento facial, com um perfil de desconforto controlável e bons resultados clínicos.


RESUMEN
Los ultrasonidos microfocalizados son una tecnología no invasiva ampliamente utilizada por su capacidad para estimular la producción de colágeno, generar lipólisis grasa y proporcionar lifting. A pesar de sus beneficios, muchos pacientes evitan el procedimiento debido al dolor y las molestias asociadas. El objetivo de este estudio fue evaluar cuantitativamente el dolor percibido durante la aplicación de ultrasonido microfocalizado HIPRO en los párpados inferiores y los lados de los ojos, utilizando la escala numérica de dolor (NRS). La muestra consistió en 10 individuos con edades comprendidas entre 30 y 50 años. La metodología incluyó la aplicación de HIPRO a una frecuencia de 10 Hz y una profundidad de 1,5 mm, con 900 disparos por zona tratada. El dolor se midió después de 450 y 900 disparos. Los resultados mostraron que la mayoría
de los pacientes calificaron su dolor de leve o inexistente, con una puntuación media de 1,175 sobre 10 en el NRS. La variabilidad en la percepción del dolor refuerza la importancia de los enfoques personalizados. En comparación con otros dispositivos, HIPRO demostró ser una alternativa eficaz y relativamente cómoda, especialmente para los pacientes sensibles al dolor. Se concluye que el ultrasonido microfocalizado HIPRO es una opción segura y eficaz para el rejuvenecimiento facial, con un perfil de molestias manejable y buenos resultados clínicos.

**Palabras clave:** ultrasonido microfocalizado, HIFU, medición del dolor, dolor.

1 INTRODUCTION

Microfocused ultrasound is a non-invasive technology that is widely used because of its ability to stimulate collagen production, generate fat lipolysis and provide lifting. This technology uses high-intensity focused ultrasound (HIFU) waves to target specific layers of the skin, enabling non-invasive treatments with significant results (Tran et al., 2022). Its mechanism of action is through microfocused ultrasound waves, which lead to a molecular vibration that generates heat, creating well-defined thermal microlesions of around 1 to 3mm, with predetermined depths, and the adjacent tissue remains intact. Afterwards, the process results in the contraction and denaturation of collagen which induces neocollagenesis, contributing to the improvement of expression lines (Gutowski et al., 2016; Contini et al., 2023). However, despite its notable benefits, many people are afraid to use this technology due to the pain and discomfort during the procedure, thus limiting its effective application (Gutowski et al., 2016).

The current definition of pain, dated 1979 and recommended by the Taxonomy Subcommittee and adopted by the Council of the International Association for the Study of Pain (IASP), defines pain as "an unpleasant sensory and emotional experience associated with an actual or potential tissue injury, or described in terms of such an injury", being a subjective experience of each individual, influenced to varying degrees by biological, psychological and social factors, being based on people's life experiences, and through their experiences they learn the concept of pain and its applications. (Raja et al., 2021).

One of the most widely used assessment tools for measuring acute pain in clinical and research environments are the numerical rating scales (NRS), verbal rating scales (VRS) and visual analog scales (VAS) (Karcigolu et al., 2018). Among them, the numerical rating scale (NRS) allows the degree of pain to be quantified numerically, and is made up of numbers from
0 to 10, where 0 represents no pain, 1 to 3, mild pain, 4 to 6, moderate pain and from 7 to 10 severe pain (Andrade et al., 2006).

When applying HIFU, it is crucial to take into account the patient's comfort and well-being during the procedure. Many patients report pain and discomfort during the application, making the evaluation of these parameters essential to ensure greater patient satisfaction and comfort. In this context, the study of pain assessment techniques becomes necessary, even though pain is subjective and individual to each person. Pain scales have emerged as important tools in this process, allowing patients to measure pain intensity on numerical or descriptive scales, making it easier to quantify the pain reported at the end of the procedure.

In view of this, this study seeks to use the NRS scale to quantitatively assess patient pain when performing HIPRO high-intensity microfocused ultrasound and thus determine the average level of pain perceived by individuals undergoing treatment in the lower eyelid and lateral eye region, by applying pain assessment scales with this equipment.

2 METHODOLOGY

The sample consisted of 10 individuals. To take part in the study, the subjects had to meet the following inclusion criteria: be aged between 30 and 50, have preserved sensitivity, agree to take part in the study and sign the informed consent form; have expression lines or sagging in the lower eyelid and lateral eye area, self-report (according to a health declaration): have no contraindications to microfocused ultrasound. Individuals with fillers and Botox in the treated area were excluded.

2.1 PROCEDURES

For individuals who met the inclusion criteria, a facial assessment was carried out using the MEICET® Skin Analysis System, a multispectral image analysis technology to quantify expression lines, and on the same day Microfocused Ultrasound was applied, HIPRO®, with a frequency of 10Hz, a depth of 1.5mm and 0.4 joules of energy, was applied to the lower eyelid and side of the eyes, with 900 shots in this region, applied in an upward motion, starting with the transducer in the infraorbital region and directed towards the temple. After every 450 shots, a
numeric pain rating scale (NRS) will be applied, where the volunteer will have to verbally answer the level of their pain from 0 to 10, where 0 is no pain and 10 is the worst pain possible.

3 RESULT

The initial sample consisted of 12 volunteers, however, two individuals were excluded due to non-attendance on the day of collection. As a result, the final sample consisted of 10 volunteers.

Table 1 shows the data characterizing the sample. It can be seen that the majority of the individuals were female, with an average age of 40.33.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Data Presented by Number or Mean Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (M/F)</td>
<td>10 (2/8)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>40.33 ± 6.35</td>
</tr>
</tbody>
</table>

Analysis of the pain visual analog scale (NRS) showed that patients found the treatment comfortable, with the average score for all patients totaling 1.175 (none or mild discomfort) out of 10, with a standard deviation of 0.77. 40% of volunteers reported local tingling and discomfort over the bony prominence of the zygomatic bone during application. No adverse events were observed during application.

In the observation of each phase, taking into account that NRS¹ was collected at 450 shots and NRS² at 900 shots on each side. Table 2 shows the distribution of NRS¹ values on the right and left sides. The NRS¹ showed that 60% of the volunteers classified their pain level as 1 (moderately mild pain) on the NRS scale, 20% reported 0 pain (no pain), 15% reported 2 pain (mild pain) and only 5% reported 3 pain (moderate pain).
Table 2 – Continuous variable frequency distribution

<table>
<thead>
<tr>
<th>NRS¹</th>
<th>Absolute Frequency (Fi)</th>
<th>Relative Frequency (Fri)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 1</td>
<td>4</td>
<td>0.2</td>
<td>20%</td>
</tr>
<tr>
<td>1 - 2</td>
<td>12</td>
<td>0.6</td>
<td>60%</td>
</tr>
<tr>
<td>2 - 3</td>
<td>3</td>
<td>0.15</td>
<td>15%</td>
</tr>
<tr>
<td>3 - 4</td>
<td>1</td>
<td>0.05</td>
<td>5%</td>
</tr>
<tr>
<td>4 - 10</td>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>1</td>
<td>100%</td>
</tr>
</tbody>
</table>

Source: Prepared by the authors

Table 3 presents the distributions of NRS² values on the right and left sides. In the NRS², it was observed that 40% of the volunteers classified their pain level as 1 (moderately mild pain) on the NRS scale, 20% reported pain 0 (no pain), 30% reported pain 2 (slight pain) and only 10% reported pain 3 (moderate pain), no value higher than 3 was reported.

<table>
<thead>
<tr>
<th>NRS²</th>
<th>Absolute Frequency (Fi)</th>
<th>Relative Frequency (Fri)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 1</td>
<td>4</td>
<td>0.2</td>
<td>20%</td>
</tr>
<tr>
<td>1 - 2</td>
<td>12</td>
<td>0.6</td>
<td>60%</td>
</tr>
<tr>
<td>2 - 3</td>
<td>3</td>
<td>0.15</td>
<td>15%</td>
</tr>
<tr>
<td>3 - 4</td>
<td>1</td>
<td>0.05</td>
<td>5%</td>
</tr>
<tr>
<td>4 - 10</td>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>1</td>
<td>100%</td>
</tr>
</tbody>
</table>

Source: Prepared by the authors

Diagram 1 shows a comparison between the NRS¹ and NRS² pain levels. It can be seen that the level of pain reported by patients has increased significantly compared to the NRS¹. Specifically, the percentage of pain reports at level 2 increased from 15% to 30%, and at level 3, it increased from 5% to 10%. These changes indicate a worsening of the pain experienced by patients after the shots, suggesting that the procedure had a considerable impact on increasing the intensity of the pain reported. In addition, levels 0 and 1 also showed variations, with 20% of patients reporting pain at level 0 in both situations, and a decrease from 60% to 40% at level 1. These data underline the importance of monitoring and managing pain during and after procedures that can induce significant discomfort in patients.
Diagram 1 - Comparison between NRS¹ and NRS²

Source: Prepared by the authors

4 DISCUSSION

The variation in pain intensity reported during the application of microfocused ultrasound seems to be influenced by several individual factors, such as pain sensitivity, the treatment area and the patient's previous experience with aesthetic procedures. In addition, measuring patients' pain provides valuable feedback on the degree of discomfort associated with the application of microfocused ultrasound, allowing techniques to be adjusted to improve the patient experience.

In scientific circles, the effectiveness of high-intensity microfocused ultrasound (HIFU) in improving sagging and the appearance of the skin is widely recognized. This effect is the result of the contraction and denaturation of collagen, which induces neocollagenesis, an essential process for skin renewal and firmness. Previous studies, such as those by Gutowski et al. (2016) and Contini et al. (2023), confirm these benefits, highlighting the safety and effectiveness of HIFU in different aesthetic contexts.

Compared to other equipment, HIPRO, applied in movement, appears to be more comfortable for patients. It was observed that, after many shots, the report of pain increased, which can be attributed to the continuous contact of the handle with the skin, causing friction and, consequently, increased sensitivity in the treated region. This aspect should be considered when planning treatment sessions, possibly implementing breaks or cooling techniques to minimize discomfort.

The results of this study show that the majority of patients classified their pain as mild or nonexistent, with an average pain score of 1.175 on the NRS scale. This data is significant, as it
suggests that HIPRO may be a viable option for sensitive patients or those with low pain tolerance. Furthermore, no adverse events were observed, reinforcing the safety of the procedure.

The increase in pain reported throughout the shots can be explained by the gradual sensitization of the treated area. Factors such as the pressure applied, the speed of movement and the temperature of the handle can contribute to this sensitization. Therefore, future research could focus on optimizing these parameters to further reduce patient discomfort.

The use of HIPRO shows promise, not only due to the positive clinical results, but also due to the relative comfort during the procedure. This study contributes to the existing literature by demonstrating that pain, although present, is generally manageable and that the patient experience can be improved with technical adjustments.

Finally, the implementation of pain scales such as the NRS allows for an objective and standardized assessment of patient discomfort, facilitating comparisons between different studies and technologies. This study reinforces the importance of considering the patient’s well-being in aesthetic treatments, pointing out HIPRO as an effective and relatively comfortable tool for facial rejuvenation.

5 CONCLUSION

The results of this study indicate that high-intensity microfocused ultrasound (HIFU), specifically HIPRO, is effective and relatively comfortable for treating sagging and expression lines in the region of the lower eyelids and sides of the eyes. Most patients reported mild or no pain, with an average numerical rating scale (NRS) score of 1.175. Although discomfort increased with the number of shots, pain levels remained low and without significant adverse events, reinforcing the safety of the procedure. The variability in pain perception highlights the importance of a personalized approach, and the use of the NRS proved valuable for quantifying pain. Compared to other devices, HIPRO presents itself as a promising alternative, especially for pain-sensitive patients, offering effective results with manageable discomfort.
REFERENCES


