OPEN, MONOCENTRIC CLINICAL TRIAL TO EVALUATE THE SAFETY AND EFFICACY OF A LASER DEVICE (PICORE-BLUECORE) FOR PATIENTS WITH MELASMA

Matheus Vieira Giovanuci[1]
Rodrigo Alvaro Brandão Lopes Martins[2]
Alberto Souza de Sá Filho[3]
Patrícia Sardinha Leonardo[4]

SUMMARY

This open-label, monocentric clinical trial aimed to evaluate the safety and efficacy of a Picore-Bluecore laser device in the treatment of patients with melasma. Melasma is a common skin hyperpigmentation disorder, whose causes include genetic predisposition, exposure to ultraviolet light, and hormonal changes. Fifteen volunteers, of both sexes, participated in the study and underwent three laser sessions, with intervals of 21 days between them. The sessions used the Zoom handpiece, Blue T mode, with an energy of 1.03 mJ/cm² and a pulse of 10 Hz, applied in three passes on the melasma lesions. In addition to laser treatment, the participants used daily sunscreen and a 4% hydroquinone cream. The clinical evaluation, including photographs and patient self-assessment, indicated a significant improvement in melasma lesions without relevant adverse effects. The tolerability to the treatment was high, with a low level of pain reported by the patients. The results demonstrate that the use of the Picore-Bluecore laser is safe and effective for the treatment of melasma, with a high satisfaction rate among the participants. This study reinforces the relevance of picosecond lasers as a minimally invasive and efficient therapeutic option for hyperpigmentation.

Keywords: Laser; picosecond; picore; melasma.

1,2,3,4 E-mail contato: matheusvieiragiovanuci@gmail.com - Evangelical University of Goiás – UniEVANGÉLICA

Introduction

Melasma is a pigmentary disorder that primarily occurs on the face with hyperchromic, brown, or grayish spots. Generally attributed to various factors such as: genetic predispositions, pregnancy, hormonal dysfunction, and exposure to ultraviolet (UV) light. However, the pathogenesis is still not fully understood [1–3]. Epidemiologically, it can occur in all races, more frequently in those with darker skin [2]. There are several therapeutic methods including peels, medications, radiofrequency, and laser treatment [1]. The use of high-power laser is a treatment alternative through the physical fragmentation of skin pigments. [4,5]. Several nanosecond Q-switch laser systems with various wavelengths (532, 755, and 1064 nm) and pulse durations (10∼100 ns) have been developed [6]. however, the durations of nanosecond pulses are often longer than the thermal relaxation times (10∼30 ns) of Melasma pigments, leading to partial thermal decomposition of the pigments and unfavorable thermal damage to the surrounding skin [7].

Picosecond laser systems were developed to improve the clinical outcomes of pigmented skin treatment [8]. These devices feature ultra-short pulse durations, inducing high temperature and high pressure through multiphotonic ionization in the skin, which is called laser-induced optical breakdown [9], thus they can be more beneficial for achieving the fragmentation and complete thermal decomposition of small pigments through combined mechanisms (photomechanical and photothermal). Thus, the treatment of pigmented skin with picosecond lasers involves creating uniform vacuoles in the epidermal and dermal layers through laser-induced plasma, thereby ablating small target pigments with minimal thermal damage to the adjacent tissue [11]. The objective of the present study was to evaluate the safety of the Picosecond Picore Laser when applied to Melasma lesions at conventional protocol doses over three sessions, one every 21 days.

Methodology

Description of the Type/Design of the Study Conducted

Open-label, monocentric study with 15 volunteers of both sexes, with dermatological lesions of Melasma who underwent 3 sessions, one every 3 weeks (21 days) with

Picosecond Picore Laser applied to the Melasma lesions with the Zoom Tip; spot size 7 mm; Blue T mode; energy 1.03 mJ/cm²; pulse 10 Hz and with 3 passes.

Procedures for Identifying the Research Subject

The research subjects participating in the study had their identities preserved and were identified by letters corresponding to the first and last initials, followed by the date of birth and sex (M or F). All research subjects in the study were informed that they should report the use of any medication and/or treatment, including those sold without a prescription, as well as herbal remedies, that they are ingesting or applying to the skin regularly or even occasionally.

Recruitment

The research subjects were recruited from the population of patients who spontaneously attended the Gobbato Dermatology Clinic. The patients who presented lesions compatible with the diagnosis of cutaneous Melasma, and who met the other inclusion/exclusion criteria, were invited to participate in the study. After all doubts were clarified, all participants signed the Free and Informed Consent Form (FICF) before any procedure was performed. Subsequently, a medical consultation was conducted to obtain the medical history, perform a physical examination, and a dermatological examination, followed by photography using the FACEBOXR machine.

Clinical Parameters

Photographic evaluation conducted by the specialist doctor (dermatologist) AND SELF-EVALUATION OF THE PATIENT regarding the improvement of clinical aspects of MELASMA.

Evaluation of pain tolerance during the sessions

Clinical assessment of pain tolerance was conducted using the commonly used scale table, the numerical rating scale (NRS), which consists of scores from 0 to 10, filled out by the patient themselves at the end of each application.

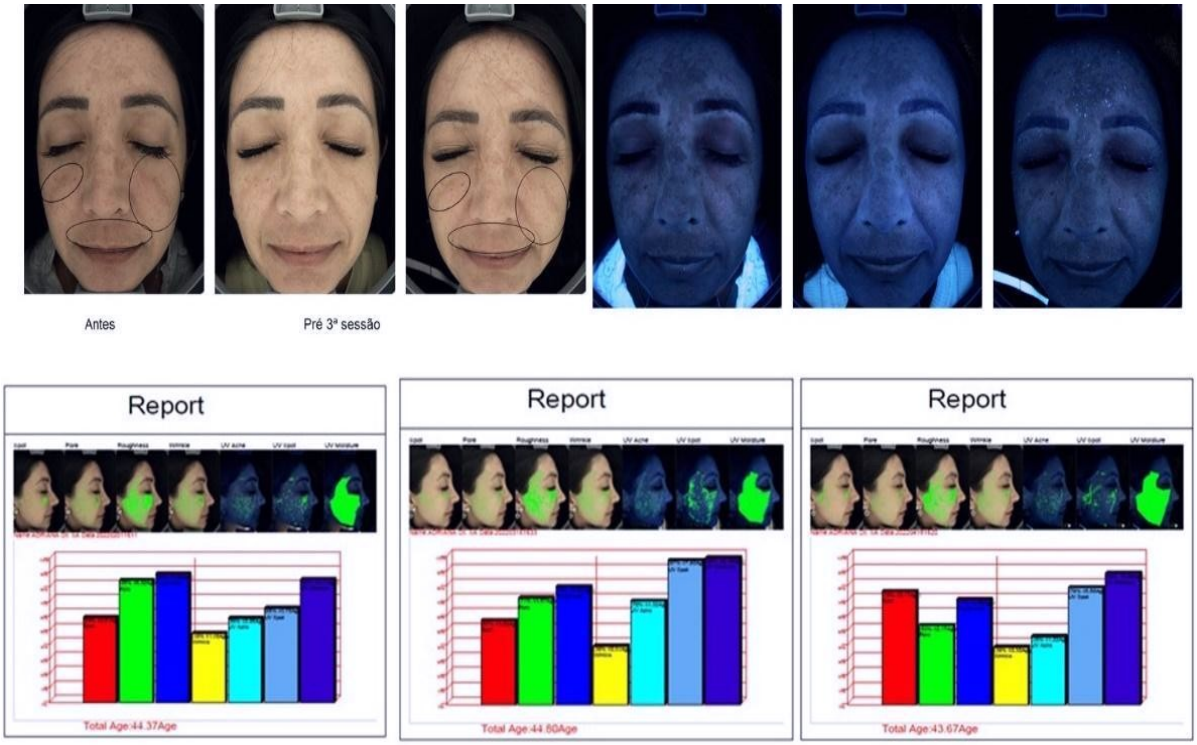
Results

Patient Self-Assessment

Reports from Patients at the Final Visit (+-3 weeks after the last session)

- RC130884F - Overall improvement of Melasma, especially in the malar regions, without pain and without rebound for 1 month. Extremely satisfied.
- FC010878F-Significant improvement of frontal region Melasma, with slight Melasma still in the malar regions. Very satisfied.
- CS111170F-Improvement of Melasma in the malar regions and nasal dorsum, but with little improvement on the forehead. Satisfied.
- BC020782F-Lightening of the malar and forehead regions, with little lightening on the mustache. Very satisfied.
- AS261078F-Noticed a 60% lightening and that the skin became softer, brighter, and firmer. He states that the treatment was satisfactory.
- CM120585F-Significant lightening of all Melasma lesions, with no lightening of the solar melanosis lesion on the right malar region. Extremely satisfied.
- LB090375F-Patient noticed a 90% lightening of Melasma. Extremely satisfied.
- ES100484F - Complete lightening of the lesions on the mustache area, improvement of the lesions on the forehead and cheekbones. Very satisfied.
- SR170573F-Noticed improvement since the last session. Satisfied.
- JM051093F-80% improvement in the supralabial region and improvement in the malar regions. Extremely satisfied.
- RP240587F-Global whitening, however, still with light spots. Very satisfied.
- KO160476F-Whitening of 80%. Very satisfied.
- RM200981F-improvement of Melasma. Extremely satisfied.
- EG011277F-Important whitening of the malar regions. Very satisfied.
- DS021092M-Whitening, however, without total whitening. Very satisfied.

Figure 02: Patient Representative Model of the 15 Study Participants



Source: personal collection.

Conclusion

We concluded that the Nd-Yag 532-1064nm Picosecond Picore laser from Bluecore is safe and effective according to the evaluation of patients/participants in the treatment of facial Melasma using the Zoom handpiece; in Blue T mode with a 7mm spot size; with an energy of 1.03 mJ/cm2; a pulse of 10 Hz, with 3 passes on the Melasma lesions, with discomfort pain very close to zero (0.71), with a satisfaction level ranging from medium to high and without adverse effects.

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