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

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ABSTRACT:

This open, 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 cutaneous 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 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, participants used daily sunscreen and 4% hydroquinone cream. Clinical evaluation, including photographs and patient self-assessment, indicated a significant improvement in melasma lesions without relevant adverse effects. 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 participants. This study reinforces the relevance of picosecond lasers as a minimally invasive and efficient therapeutic option for hyperpigmentation.

Keywords: Laser, picosecond, picore, melasma

INTRODUCTION:

Melasma is a pigmentation disorder that occurs mainly on the face with hyperchromic, brown or grayish spots. It is usually attributed to various factors such as: genetic predispositions, pregnancy, hormonal dysfunction and exposure to ultraviolet (UV) light. However, the pathogenesis is not yet 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]. Various Q-switch nanosecond laser systems with various wavelengths (532, 755 and 1064 nm) and pulse durations (10~100 ns) have been developed [6]; however, nanosecond pulse durations 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 injury to the surrounding skin [7].

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

METHODOLOGY:

Description of the Type/Design of the Study Conducted

Open, monocentric study, with 15 volunteers of both sexes, with dermatological lesions of Melasma who underwent 3 sessions, one every 3 weeks (21 days) with Picore Picosecond Laser applied to the Melasma lesions with the Zoom handpiece; spot size 7 mm; Blue T mode; energy 1.03 mJ/cm2; pulse 10 Hz and with 3 passes.

Procedures for Identification of the Research Subject

The research subjects participating in the study had their identity preserved and were identified by letters corresponding to the first and last initial, 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 medicines, 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 attend the Gobbato Dermatology Clinic. 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, and then a medical consultation was held to obtain clinical history, perform a physical examination and dermatological examination, and take photographs with the FACEBOXR machine.

Clinical Parameters

PHOTOGRAPHIC evaluation performed by the specialist physician (dermatologist) AND PATIENT SELF-ASSESSMENT regarding the improvement of the clinical aspects of MELASMA.

Pain Tolerability Assessment During Sessions

Clinical assessment of pain tolerability was performed with the commonly used rating scale, the Numerical Rating Scale (NRS) which consists of scores from 0 to 10, which was filled out by the patient themselves at the end of each application.

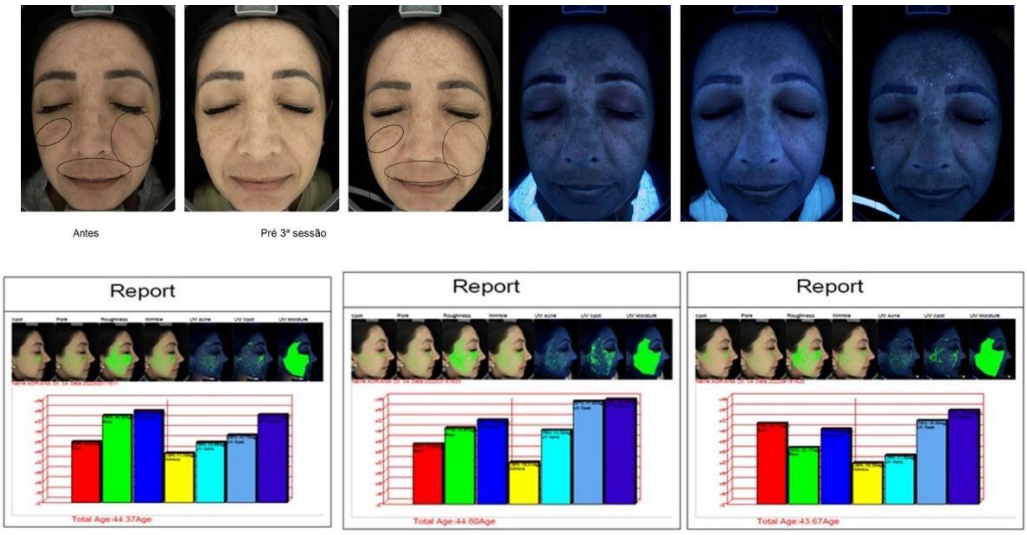
Results

Patient Self-Assessment

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

- RC130884F- Global improvement of Melasma, mainly in the malar regions, without pain and without rebound for 1 month. Extremely satisfied.
- FC010878F- Significant improvement of Melasma in the frontal region, with slight Melasma still in the malar regions. Very satisfied.
- CS111170F- Improvement of Melasma in the malar regions and nasal dorsum, but without much improvement on the forehead. Satisfied.
- BC020782F- Lightening of the malar regions and forehead, without much lightening on the upper lip. Very satisfied.
- AS261078F- Noticed 60% lightening and that the skin became softer, brighter and firmer. Reports that the treatment was satisfactory.
- CM120585F- Significant lightening of all Melasma lesions, without lightening of the solar melanosis lesion on the right malar region. Extremely satisfied.
- LB090375F- Patient noticed 90% lightening of Melasma. Extremely satisfied.
- ES100484F- Total lightening of the lesions on the upper lip, improvement of the lesions on the forehead and malar regions. Very satisfied.
- SR170573F- Noticed improvement since the last session. Satisfied.
- JM051093F- 80% improvement in the supralabial region and improvement of the malar regions. Extremely satisfied.
- RP240587F- Global lightening, however, still with light spots. Very satisfied.
- KO160476F- 80% lightening. Very satisfied.
- RM200981F- improvement of Melasma. Extremely satisfied.
- EG011277F- Significant lightening of the malar regions. Very satisfied.
- DS021092M- Lightening, however, without total lightening. Very satisfied.

Figura 02: Paciente Modelo Representativa dos 15 participantes do Estudo



Fonte: acervo pessoal.

CONCLUSION:

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

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