Informed Consent

Diamond bur Microblepharoexfoliation Combined with Intense Pulse Light and Meibomian Gland expression for Evaporative Dry Eye: A Short-term Controlled Study.

Date: May 9, 2023.

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TITLE OF STUDY

Diamond bur Microblepharoexfoliation Combined with Intense Pulse Light and Meibomian Gland expression for Evaporative Dry Eye: A Short-term Controlled Study.

PRINCIPAL INVESTIGATOR

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PURPOSE OF STUDY

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is to assess the efficacy and safety of microblepharoexfoliation (MBE) combined with intense pulse light (IPL) and meibomian gland expression (MGX) for treatment of meibomian gland dysfunction (MGD).

STUDY PROCEDURES

Participants were assigned to receive either three sessions of MBE-IPL-MGX treatment and home-based therapy (treatment group) or home-based therapy alone (control group).

MBE will be performed using the yokefellow instrument (Youke Electronic Corporation, Guangzhou, China), which contains a handpiece with a 1.80 mm diameter medical-grade diamond bur. To ensure a well-tolerated procedure, topical application of 0.1% tetracaine hydrochloride and 0.4% oxybuprocaine hydrochloride will be applied. After placing topical anesthetic, a corneal shield will be used to protect the ocular surface and a jojoba anesthetic ointment (JAO) (O´Brien Pharmacy, Kansas City, USA) containing 8% lidocaine and 25% jojoba wax were place on the lid margin. Patients will undergo MBE on the upper and lower lid margin of both eyes at 500 rpm until complete removal of accumulated biofilm debris, epithelial keratinization or capped meibomian glands. MBE will be carried out only in the first combined treatment session. Immediately after MBE, JAO will be cleaned with a cotton swab and IPL will be performed.

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IPL treatment will be carried out with Thermaeye Plus (MDS Medical Technologies SL, Barcelona, Spain). The procedure begins by applying an ultrasound gel (Carmado SL, Alicante, Spain) to the patient's periocular areas and upper eyelids. In the periocular areas, 6 light pulses were applied; 4 light pulses on the skin below the lower eyelid (with handpiece placed horizontally in the first pass and vertically in the second pass) and 2 light pulses on the canthal area (with handpiece placed vertically in first and second pass). The parameters are as follows: (1) Filter: 650 nm; (2) fluence: 9 j/cm^2; (3) pulses: 2; (4) duration: 3 ms; (5) Delay: 20 ms; and (6) Cooling: 70%. In the upper eyelids, 4 light pulses were applied; 2 light pulses in the first and second pass, respectively. The parameters are as follows: (1) Filter: 650 nm; (2) Fluence: 5 j/cm2; (3) pulses: 1; (4) duration: 3 ms and (5) Cooling: 70%. Fitzpatrick skin typing will be assessed prior to IPL treatment. Finally, the MGX will be performed on both upper and lower eyelids of each eye with a Collins forceps (Medi Instrument Inc, New York, USA). After first combined treatment session, patients were instructed to apply 0.5% dexamethasone sodium phosphate and 1% chloramphenicol topically twice a day during the first week and once a day during the second week. White Sun protection cream was recommended for the first 48 hours in the IPL treatment area.

Home-based therapy will be based on Therapearl eye mask warming compress (Bausch & Lomb, Madrid, Spain) twice a day and Eyestil synfo eyedrops (Sifi Iberica SL, Madrid, Spain) 4 times a day during the study including the follow-up period

RISKS

MBE, IPL and MGX are safe procedures, but may assess the following adverse events: eyelid margin discomfort; Eyelid margin irritation; Eyelash loss density; Cutaneous erythema; skin hyper/hypopigmentation and permanent scarring.

You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

BENEFITS

The main benefits of this treatment will be the improvements in dry eye symptoms and signs such as tear film stability, tear volume, ocular hyperemia, meibomian gland function and ocular surface staining, which will be reflected in a better quality of life.

CONFIDENTIALITY

Your responses to this informed consent will be anonymous. Please do not write any identifying information on your informed consent. Every effort will be made by the researcher to preserve your confidentiality including the following:

- Assigning code names/numbers for participants that will be used on all research notes and documents
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, Antonio Ballesteros Sánchez, please contact the Institutional Review Board at 617700530 EXT. +34.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature_____Date _____

Investigator's signature_____Date _____