Title: One-Year Safety, Efficacy, and Patient Satisfaction in a Double-Masked RCT of a New Ocular Cooling Device forChronic Ocular Surface Pain

Submitter's E-mail Address: margueritemcdmd@aol.com

Category: CORNEA

Topic: Medical and Surgical Ocular Surface

Interested in chairing a panel? Yes

Category to chair: Keratorefractive

Keywords: Chronic ocular surface pain, dry eye disease and ocular surface

Purpose: To assess long-term clinical safety, efficacy, and patient satisfaction from a double-masked, randomized, placebo-controlled study of a novel ocular surface cooling device used to treat chronic ocular surface pain (COSP).

Methods: Patients (n=20) who received a unilateral treatment with the novel ocular surface cooling device were recalled for an extended follow up visit one year after the treatment date. Clinical safety measures included corneal sensitivity,intraocular pressure, gonioscopy, and a slit lamp exam for limbal stem cell deficiency. Efficacy was evaluated using the validated chronic ocular pain questionnaire (COP-Q). Subject satisfaction was assessed using four self-narrative questions. The questions included overall satisfaction with the treatment, willingness to refer the treatment to family and friends, desire to have the fellow eye treated, and desire to have the study eye re-treated.

Results: The majority of subjects believed that the cooling treatment helped with their COSP symptoms and provided open-ended responses such as “Yes, the treatment was helpful and showed marked reduction in eye pain vs the other non-treated eye”. Furthermore, more than half the subjects would refer the treatment to their family and friends. The desire to have their fellow eye treated, as well as their study eye re-treated, was reported in most subjects. At least two of the subjects reported a continued durable effect of the treatment at one year. Clinical safety measure data and COP-Q

questionnaire results are still being analyzed and will be updated prior to the abstract deadline.

Conclusion: These results suggest that patients undergoing treatment with a novel ocular surface cooling device for chronic ocular surface pain (COSP) experience a high rate of long-term satisfaction. One-year data collection is ongoing and will be reported prior to the abstract update deadline.

AuthorsMarguerite B. McDonald, MD, FACS (Presenting Author); James Katz, MD; Alice T. Epitropoulos, MD, FACS, ABO;Preeya K. Gupta, MD; Bonnie An Henderson, MD, ABO; Anat Galor, MD, MPH

DisclosuresMarguerite B. McDonald, MD, FACS (Presenting Author): Disclosure CompleteJames Katz, MD: Disclosure IncompleteAlice T. Epitropoulos, MD, FACS, ABO: Disclosure CompletePreeya K. Gupta, MD: Disclosure CompleteBonnie An Henderson, MD, ABO: Disclosure IncompleteAnat Galor, MD, MPH: Disclosure Incomplete