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Pilot Study for Investigating the Effect of the Bruder Eye Hydrating Compress on Contact Lens Discomfort in Contact Lens Wearers

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Background

An estimated 40.9 million people in the United States aged 18 or older wear contact lenses.[1] Though newer and healthier contact lens materials are constantly being developed, discomfort remains the top reason for contact lens discontinuation and dropout rates are estimated to be as high as 15.9% in the United States.[2] The International Workshop on Contact Lens Discomfort published in 2013 put forth dryness as a primary reason for contact lens intolerance.[3] Indeed, when a contact lens is placed on the eye, the tear film structure becomes altered resulting in a pre-lens thinned lipid layer and a post-lens thinned aqueous layer.[4] As a result of this disruption from the contact lens, the tear film tends to have an increased rate of evaporation leading to poor wetting on the surface of the contact lens and inadequate lubrication on the surface of the eye. This is further exacerbated if the patient has an already unstable lipid layer due to the presence of meibomian gland dysfunction (MGD). MGD is considered by many to be the leading cause of dry eye disease throughout the world, and is a chronic and progressive condition that can contribute to a poor quality lipid layer and lead to contact lens discomfort.[5]

Contact lens wearers often report dry eye symptoms and show signs of MGD including gland atrophy, thinned lipid layer, and increased tear film instability.[6-8] It has been shown that in many patients with intolerance to contact lenses, MGD has been observed. Therefore, treatment of MGD may support functioning of the meibomian glands and lead to improvement in patient contact lens comfort. Warm compresses are a commonly prescribed treatment method for applying localized heat to the meibomian glands to improve secretion.[9-11] With good patient compliance, warm compresses have been shown to be an adequate supplemental therapy for MGD as the heat softens meibum in glands that are obstructed allowing for secretion into the tear film. Many methods of applying heat to the eyelids for treatment of MGD exist; however, the results of the different methods can vary based on the heating method, how long the compress is applied, and whether the compress remains hot for the duration of application. Because of the sometimes seemingly ineffectiveness of the therapy due to variation in methods and no accepted standard, patient compliance for home therapy often wanes and further reduces the likelihood of successful treatment. Therefore, the purpose of this study is to assess the potential benefits of using the Bruder Moist Heat Compress, a warm compress capable of maintain heat effectively, in contact lens wearers with MGD.

Study Design & Endpoints

This will be a prospective, three-arm, randomized controlled study to evaluate the benefits of using the Bruder Moist Heat Compress in contact lens wearers who report reduced comfortable wearing time by assessing improvement in MG function and comfortable contact lens wearing time after one month of daily warm compress application. All subjects will undergo examination to determine eligibility and capture baseline status. Study endpoints will be evaluated after one month.

Thirty adults who currently wear contact lenses, who report reduced contact lens wear time will be enrolled in the study. Subjects will be randomized to either one of two treatment arms or a control arm with approximately ten subjects per group; that is, subjects will be randomized to one of the following study arms:

1) Application of Bruder Moist Heat Compress twice daily for one month (ten minute application in the morning prior to contact lens insertion and ten minute application in the evening after lens removal)
2) Application of Bruder Moist Heat Compress once daily for one month (ten minute application in the evening after lens removal)
3) Application of warm wash cloth twice daily (ten minute application each time) for one month (control group)

Subjects will be seen for three study visits over a period of four weeks according to the following visit schedule:

- Visit 1 (Screening & Randomization, Day 1)
- Visit 2 (Day 15 ± 2 days)
- Visit 3 (Final Visit, Day 29 ± 1 day)

The procedures to be performed during the visits include:

1. Questionnaires: CLDEQ long form, SPEED, OSDI
2. Medical and Ophthalmic History
3. Habitual visual acuity with contact lenses
4. Contact Lens fit assessment
5. LipiView to measure tear film thickness
6. Slit lamp examination
7. Tear film break up time
8. Corneal Staining
9. MG assessment
10. Meibography
11. Corneal Topography

Each visit will take approximately 45 minutes. Subjects will be instructed to apply the Bruder Moist Heat Compress after removal or prior to insertion of contact lenses. Subjects will heat the compress according to the instructions on the package, namely: heat for twenty-five seconds in the microwave, and depending on the microwave wattage increase by increments of five seconds to not exceed a total of thirty-five seconds. Once heated, subjects will apply the compress to closed eyelids for ten minutes. During the treatment period, subjects will complete a daily diary that captures insertion and removal time of contact lenses, as well as the time comfortable contact lens wear ends. Diaries will also be used to ensure subject compliance of application of the Bruder compress.

<u>Study Objectives</u>

Primary Objective: To show that daily application of the Bruder Moist Heat Compress in subjects with MGD who experience CL discomfort can result in an increase in comfortable contact lens wear time

Secondary Objective: To compare the efficacy of once daily application of the Bruder Moist Heat Compress versus twice daily application

Tertiary Objective: To show that the Bruder Moist Heat Compress is an effective treatment for improving meibomian gland function in symptomatic contact lens wearers

Study Endpoints

Primary: Mean change from baseline in the duration of subject-reported comfortable contact lens daily wear time (hours per day) at the week four visit

Secondary: Mean change in comfortable contact lens wear time (hours per day) in twice daily application group compared to once daily application group

Tertiary: Mean change in total meibomian gland score in treatment groups using the Bruder Moist Heat Compress compared to controls from baseline to four weeks

Inclusion Criteria:

1. 18 years or older
2. Provide informed consent and authorization to disclose protected health information
3. Have habitual contact lens corrected visual acuity in each eye of at least 20/30
4. Willing to comply with protocol
5. Wear soft daily contact lenses for total wear time of at least 4 hours a day and at least 4 days a week on average over at least a 30 day period before enrollment
6. Have a diagnosis of Contact Lens Dry Eye based on the CLDEQ results
7. Have at least a 2 hour difference between overall wear time and comfortable wear time of contact lenses
8. Assess that the contact lens fit/material/disinfection solution are acceptable and not reasons for CL discomfort

Exclusion Criteria:

1. Have any uncontrolled systemic disease that in the investigator's opinion could be expected to interfere with the study, for example, conditions associated with dry eye disease
2. Pregnant by self-report
3. Active ocular conditions: infection, allergic conjunctivitis, severe eyelid inflammation including anterior blepharitis
4. Have a clinically significant ophthalmic abnormality noted during examination or per subject history
5. Have changed the brand of contact lenses or care solutions within 30 days prior to screening or anticipates the need to change current type or brand of contact lenses or care solutions
6. Any overnight wear of contact lenses or daily disposable contact lenses
7. Require use of prescribed topical ophthalmic medications
8. Participation in a clinical trial in the past 30 days
9. Any previous refractive or corneal surgery (e.g., PRK, LASIK, radial keratotomy,etc.)
10. In the opinion of the investigator, be unwilling or unable to comply with the study protocol
11. Have temporary and/or permanent punctal plugs in either or both eyes
12. Have initiated or altered the dosage of omega-3 dietary supplements in the past 30 days

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