



TearRestore

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INTERVENTIONAL CLINICAL TRIAL

**THE EFFECT OF WARM COMPRESS THERAPY USING THE TEARRESTORE EYELID
WARMING MASK ON MEIBOMIAN GLAND FUNCTION**

An overview of the TearRestore Thermal Mask and
discussion of the clinical trial end points



TEARRESTORE.COM

TearRestore Contact

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TearRestore Thermal Mask

The TearRestore Thermal Mask is the first and only open-eye warm compress. The device offers dry eye sufferers consistent heat, the ability to see during treatment, and natural expression of the Meibomian Glands (blinking) throughout use. The product includes a durable soft plastic frame and specially designed reusable thermal packs.



Features

Improved Patient Outcomes

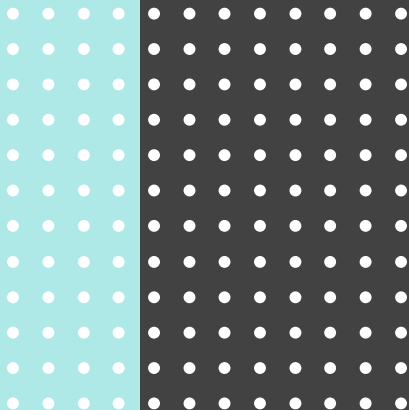
The TearRestore mask offers the unique ability to see and remain active during treatment. This feature has the ability to improve both patient compliance and overall quality of life.

Consistent Heat

TearRestore thermal packs supply therapeutic heat (>40C) for a minimum of ten minutes every use. The amount of heat is regulated by the composition of the fluid which provides consistency across patients.

Targeted Treatment

TearRestore's durable soft plastic frame utilizes anatomical norms to target the oil glands of the eyelid while avoiding the globe. This permits the user to blink throughout treatment, resulting in natural oil gland expression throughout use.



Clinical Trial: The Effect of Warm Compress Therapy Using the TearRestore Eyelid Warming Mask on Meibomian Gland Function

Summary:

The TearRestore Thermal Mask underwent a study to learn more about the effectiveness of the device on signs and symptoms of Meibomian Gland Dysfunction (MGD). MGD is a leading cause of dry eye symptoms. Warm compress treatments have been recommended as part of the standard of care by eye physicians, and are an important means in treating MGD. However, current treatment options suffer from varied temperature maintenance and poor compliance. The TearRestore mask offers patients a unique experience through providing sustained heat and the ability to see throughout the treatment, which will improve efficacy through improved compliance. If shown to be effective in altering Meibomian gland secretions at a single visit, this novel treatment could potentially offer the millions of patients suffering from MGD a more convenient and effective way to treat the condition.

Design/Interventions

Primary Intervention

Study assessments were performed before a single 10 minute session of wearing the TearRestore Mask and then study assessments were repeated after the 10 minute single session had been completed.

Optional Extension

Subjects had the option to extend use of the TearRestore Mask at home for a period of 28 to 60 days. They will use the mask for a 10 minute time period one time per day and record the use in a diary.

+90%
Tear Breakup Time

ClinicalTrials.gov Identifier: NCT04309799

Locations

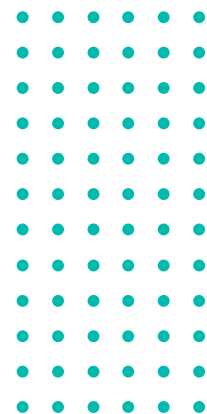
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Results

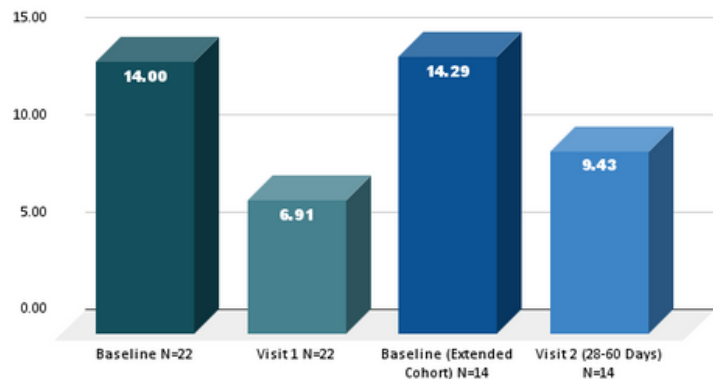
End Points

Standardized Patient Evaluation of Eye Dryness (SPEED) Questionnaire

Patient's subjective dryness was reduced by 51% after first treatment and 34% from baseline after 28-60 days

51% Reduction In Dry Eye Symptoms

Symptom Score, Mean (SPEED)



Tear Breakup Time

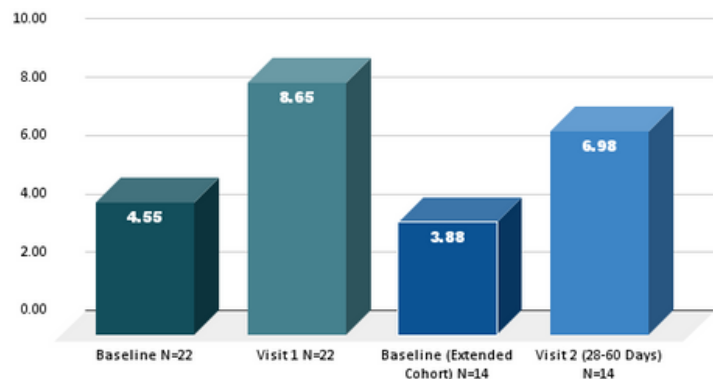
The Tear Breakup Time increased by 90% after the first treatment and 80% from baseline after 30-60 days

90% TBUT Increase

Number of Meibomian Glands Yielding Liquid Secretions

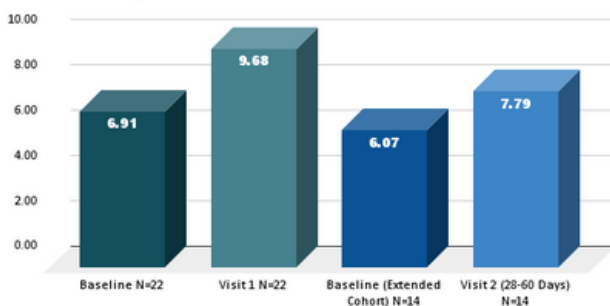
The number of Meibomian Glands yielding liquid secretions increase by 40% after initial treatment and 28% from baseline after 30-60 days

Tear Breakup Time, Mean (Sec)



40% Increase in Functional Meibomian Glands

Number of Meibomian Glands Yielding Liquid Secretions, Mean



Population/Criteria

Data was collected from a population of 22 eyes (age 18-89) of any race, gender or ethnicity, diagnosed with meibomian gland dysfunction. Additional inclusion/exclusion criteria were applied. More information can be found at ClinicalTrials.gov