Novel Blink-Assisted Meibomian Gland Procedure for Safe & Effective Treatment of Dry Eye: A Prospective, Masked, Multicenter Trial (CHEETAH)

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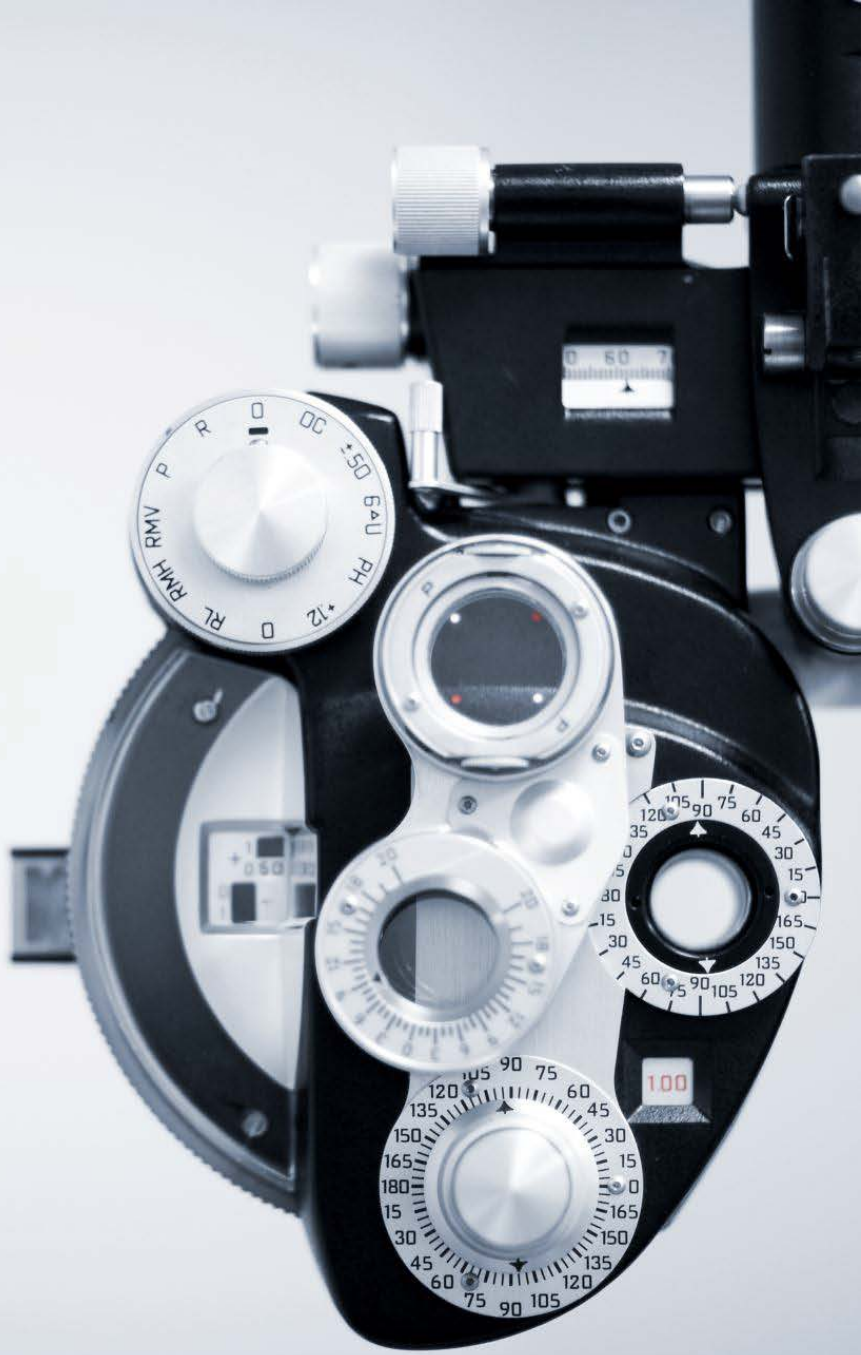

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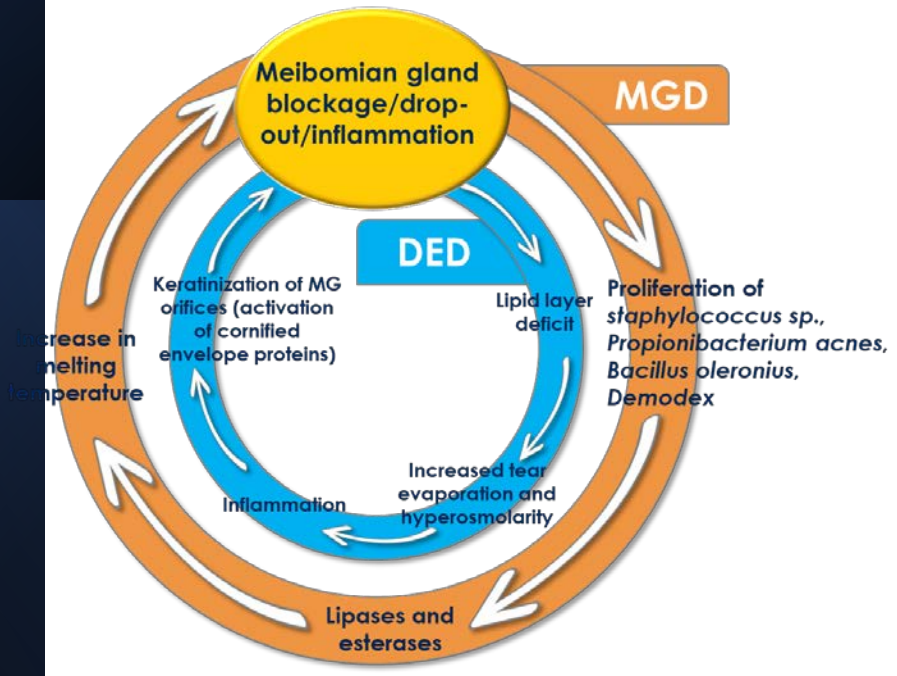
Background

Dry eye disease is prevalent

- 40 million patients suffer from dry eye
- 86% have some component of meibomian gland dysfunction (MGD); it is imperative that MGD is treated efficiently



Lipids from meibomian glands necessary for ocular surface health and integrity

Blocked meibomian glands lead to gland dilation, atrophy, low secretion, gland dropout and compromised tear film

Meibomian gland health is integral to a healthy tearfilm

CHEETAH Study Overview

- **Study overview:**
  - ✓ Prospective,
  - ✓ Single-arm,
  - ✓ Exploratory study

- **Objective**: To evaluate the safety and effectiveness of a single TearCare® procedure to treat the **signs and symptoms of dry eye disease** in adult patients.

- **Study visits**: Baseline, Treatment, Day 1, Week 1, Month 1

- **Sample size:** Both eyes of total 30 subjects were enrolled and treated at 3 sites in US (KY, IL, CA)

Key Endpoints

Effectiveness Endpoints

- Tear Break-Up Time (Primary endpoint)
- Corneal & conjunctival staining
- Meibomian Gland Secretion Score
- Symptoms (OSDI)

Safety endpoints

- Adverse events
- Best spectacle-corrected visual acuity (Snellen)

- Effectiveness was assessed at 1 month as mean change from baseline to 1 month in endpoints
- Safety was assessed using safety events reported in both cohorts

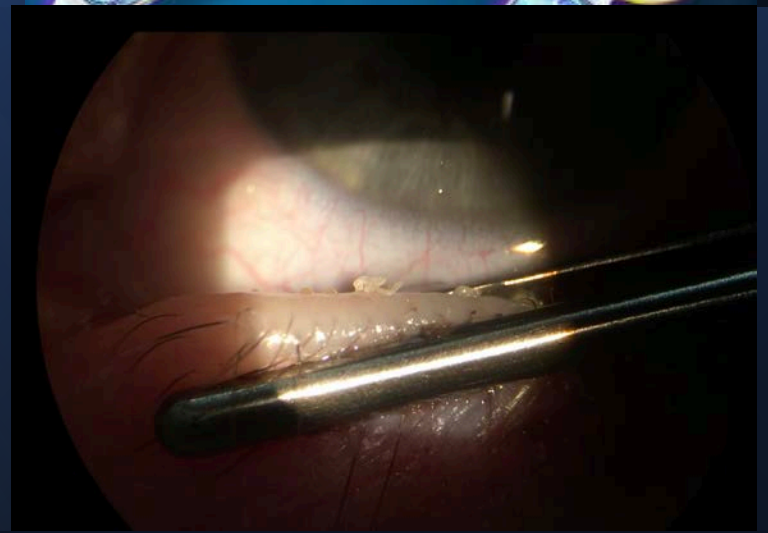
Subject eligibility Key inclusion/ exclusion

Key inclusion criteria

- Dry eye symptoms within the past 3 months
- Artificial tears used regularly over the past month
- OSDI Score of 23-79
- TBUT of ≤7 seconds in both eyes
- Meibomian Gland Secretion Score ≤12 OU
    - At least 15 expressible glands in lower lid

Key exclusion criteria

- Use of Restasis or Xiidra within 60 days, antihistamines within 10 days, systemic meds known to cause DE within 30 days, Accutane, or antibiotics IPL or LF within 12 months
- MG expression with 6 months, Blephex/debridement within 3 months, Punctal occlusion within 30 days, TrueTear within 2 wks
- History of oculoplastic, or other lid surgeries/permanent eye liner, or a history of radial keratomy
- Contact lens wear within 2 wks
- Active or recurring eye infection, eyelid & ocular surface ailments Systemic diseases causing Dry Eye, Ocular trauma within 3 months



TearCare Procedure

Meibum melting session: 15 minutes

1. The SmartLids were affixed to the external surface of the upper & lower eyelids of both eyes along the lid margins of each enrolled subject.

2. The custom, flexible, & wearable design of the SmartLids facilitates consistent conformance of the devices to the tarsal plate to enable precise targeted delivery of optimal thermal therapy to the meibomian glands while allowing the patients to maintain normal blinking

3. The SmartLids were connected to a SmartHub controller which gradually increased the temperature of SmartLids until the maximum, & therapeutically optimal temperature of 45°C, is reached & maintained through constant communication (240× per second) between the SmartHub & the SmartLids

Meibomian gland evacuation:

After the meibum-melting session, the investigator individually evacuated each meibomian gland in all four eyelids using the TearCare Clearance Assistance under direct visualization.

Endpoint Assessment

- Following the TearCare procedure, subjects were assessed for the primary and secondary effectiveness endpoints by an independent assessor. To reduce potential bias in subjective endpoint assessments, the investigator performing the TearCare procedure did not perform the endpoint assessments.

- Effectiveness was assessed as mean change from baseline in Tear Break-Up Time (TBUT), Ocular Surface Disease Index(OSDI), total Meibomian Gland Secretion Score (MGSS), & corneal/conjunctival staining. Adverse events (AE) and changes in visual acuity were used to assess safety.

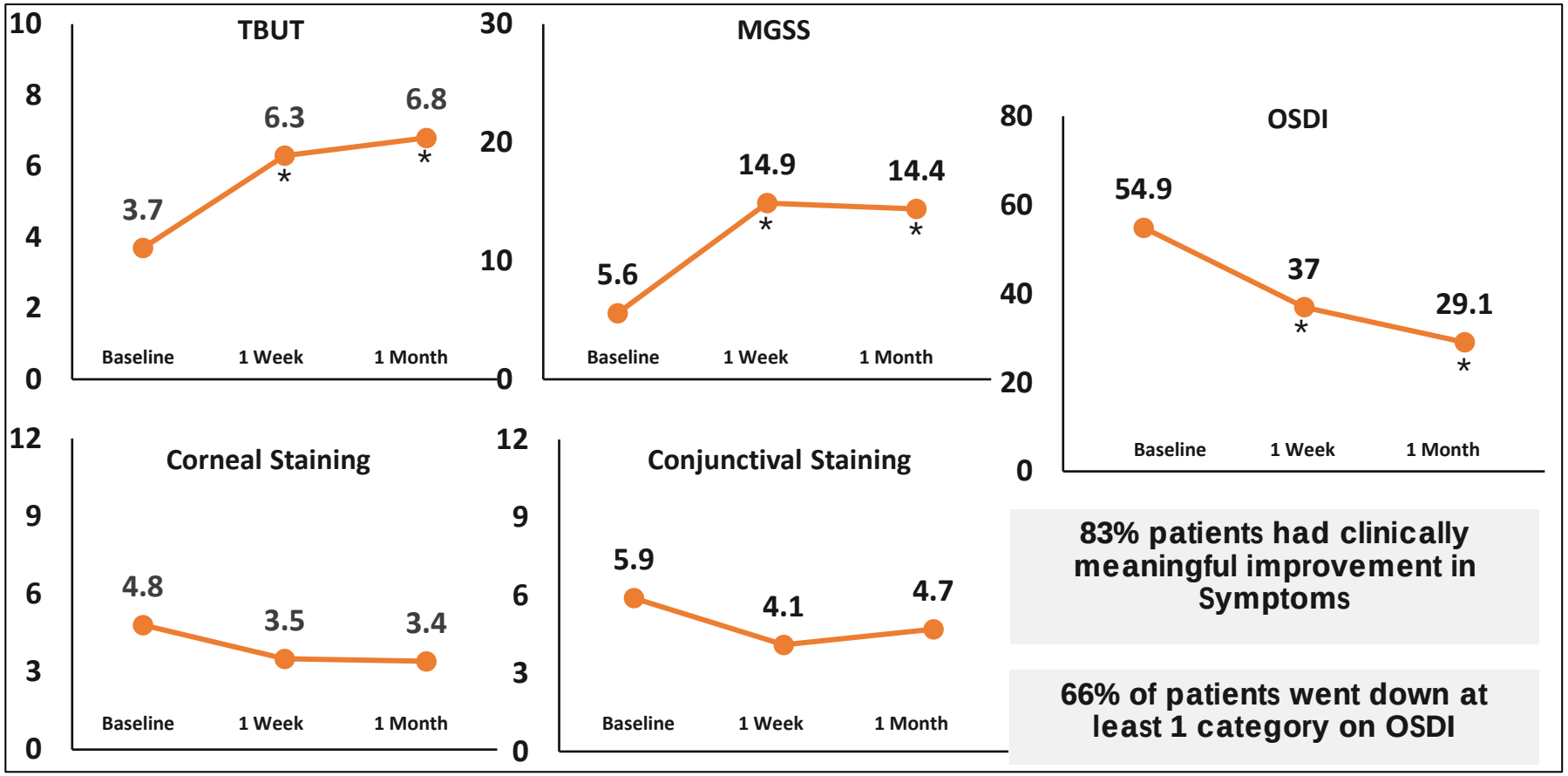
Statistical Plan

- All subjects who have at least one follow-up visit and have no major protocol deviations were included in analysis
- Outcomes measured on a per-eye basis included data from both eyes
  - ✓ Least squares means were estimated for change-from-baseline using a linear mixed-effects model to adjust within-person correlation between eyes
- Statistical significance was evaluated using paired T-test to compare 1 month outcomes with baseline measurements

Subject Characteristics

N = 30 (60.6 ± 12.4 yrs old; 76% Females	
TBUT (seconds)	3.7 (1.1)
OSDI Score	54.9 (20.2)
Meibomian Gland Score	5.6 (4.0)
Corneal Staining Score	4.8 (2.5)
Conjunctival Staining Score	5.9 (3.2)
Contact Lens Use	28 (96.5%)
History of Eyelid Surgery	3 (10%)
History of Dry Eye Rx	
Debridement	2 (7%)
Restasis	4 (14%)
Xiidra	2 (7%)
Punctal Plugs	7 (24%)
Hours of Screen Use	4.3 (3.0)

Effectiveness Endpoints



83% patients had clinically meaningful improvement in Symptoms

66% of patients went down at least 1 category on OSDI

The baseline TBUT of 3.7±1.1 seconds was improved by 2.6±1.6 (70%) seconds at 1-week & by 3.1±2.2 (84%) seconds at 1-month ($p < 0.0001$).

The baseline MGSS of 5.6±4.0 improved by 9.3±4.0 at 1-week & 8.8±5.8 at 1-month ($p < 0.0001$).

Mean baseline OSDI of 54.9±20.2 improved significantly by 17.9±20.9 (33%) at 1-week & 25.8±24.3 (47%) at 1-month ($p < 0.001$).

Safety Endpoints

The safety of the TearCare procedure was assessed by evaluating the following measures over time:

- Device-related adverse events
- Snellen BSCVA

No device-related adverse events or significant changes in visual acuity were observed.

Conclusions

A single TearCare procedure resulted in significant improvements in both the signs & symptoms of DED for ***100% of the subjects*** within 1 week of the treatment.

This study provided strong indications of safety and efficacy and demonstrated ***clinically significant improvements*** in all signs and symptoms of DED with no device-related adverse events or significant changes in visual acuity.

Interestingly, more than half the (n = 15; 52%) subjects had history of use of DED therapeutics; prescription drops being most common. Moderate to severe stage of DED at the time of enrollment, suggest failure to achieve relief with existing Rx. These subjects showed the same level of improvement in signs & symptoms of DED ***pointing to the potential of TearCare to successfully treat cases where alternative DED treatments, such as prescription therapeutics, fail.***

The results of this study suggest, TearCare system successfully achieved ***optimized trans-tarsal heat transfer directly into the meibomian glands*** at the inner eyelid, leveraged the patient's natural blink mechanism for natural gland priming and meibum flow, and facilitated the effective, lid-by-lid, manual gland evacuation of more easily expressed melted meibum.