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## Thermotherapy in meibomian gland dysfunction & results from Blephasteam® study

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## Delivering an effective treatment is a challenge



## Eyelid temperature and MG secretion

- Lipids vary in their melting point temperature
- In obstructive MGD, the melting point increases
  - In a normal subject starts at 32°C (Tiffany & Marsden, 1986)
  - In a patient with MGD starts at 35°C (Nagymihalyi et al, 2004; Terada et al, 2004)
  - 3°C higher melting point (Ong & Larke, 1990)
- Application of external heat increases the flow of the secretion from the gland
  - Nagymihalyi et al, 2004
  - Heat increases blood flow and melts waxy meibum

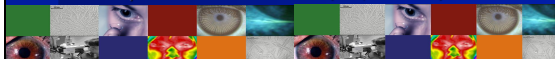
## Conventional treatment for MGD

- Conventional treatment includes:
  - Warm compress
  - Lid hygiene

But therapeutic efficacy of conventional treatment is variable:

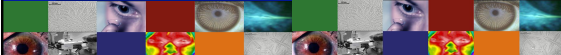
'Warm compresses' is a long-term, labour-intensive treatment that needs to be precise in temperature to be effective (Blackie et al, 2008)

It also needs at least five minutes at constant temperature to be effective (Korb, BCLA 2010)




## Warming the eye lids

- Previous approaches:
  - Hard-boiled eggs
  - Wheat sacks
  - Infrared compression device (LEDS in a mask)
  - Disposable, self-warming eye mask
- Latest evidence:
  - Several studies have shown that warm, moist therapy leads to improvements in lipid layer thickness, tear evaporation, tear film stability, visual acuity, and accommodation.



## New Blephasteam® device – thermotherapy using latent heat

- Humidity created by moist rings
- Sustained, controlled heat



## Blephasteam® action

- Warm and Moist heat action (saturated rings):
  - Increases the flow of Meibomian secretions by raising the temperature of lipids above their melting point
  - Resultant effect
    - Increases tear film lipid layer thickness & stability
    - ↓ MGD symptoms
    - ↓ evaporative dry eye due to MGD
    - ↑ ocular comfort
    - ↑ visual acuity

## Published evidence with Dr Fuller's early device

- Normal eyes
  - ocular comfort improvement in 75%
  - Lipid layer increase in 87.2%
- Dry eyes (with & without Sjogren's syndrome)
  - significant improvements in comfort and lipid layer thickness

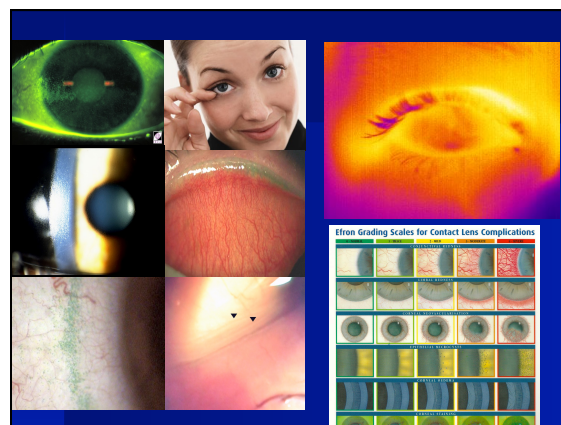
Mitra M, Menon GJ, Casini A, Hamada S, Adams D, Ricketts C, Fuller ET, Fuller JR. Tear film lipid layer thickness and ocular comfort after meibomian therapy via latent heat with a novel device in normal subjects. Eye 2005; 19 (6): 657-660.

Spatari A, Mitra M, Menon G, Casini A, Adams D, Ricketts C, Hickling P, Fuller ET, Fuller JR. Tear lipid layer thickness and ocular comfort with a novel device in dry eye patients with and without Sjogren's syndrome. J Fr Ophthalmol 2007; 30 (4): 357-364

## Clinical evaluation of Blephasteam® at Cardiff

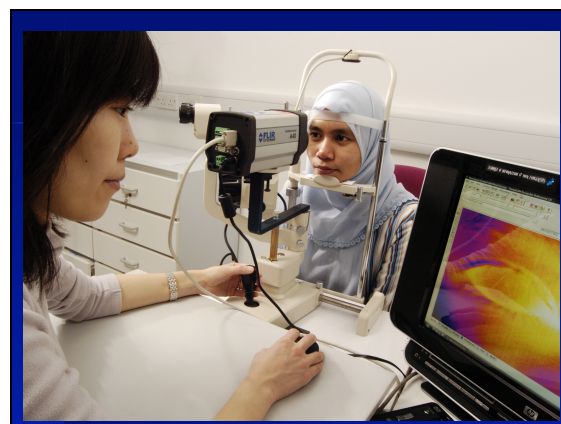


- **Title:** Clinical Safety study of an eyelid warming device, moist heat technology BLEPHASTEAM®
- **Methodology:** Phase I, prospective, non comparative study (1x25), open, monocentre and interventional.
- **Patient Number:** 25 healthy volunteers
- **Procedures:** Ocular surface signs, thermography, topography, comfort, intra-ocular pressure.....

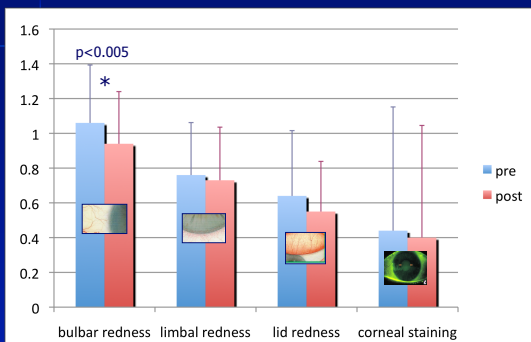


## Study design (n=25)

- Pre- and post-treatment :
  - High and low contrast VA
  - Ocular redness (limbal, bulbar, palpebral)
  - Tear film stability, tear meniscus, tear quality
  - Ocular thermography
  - Corneal topography
  - IOP
  - Comfort
  - Staining (Fluorescein and Lissamine green)
- Statistical comparison of pre- and post-measures in normal subjects

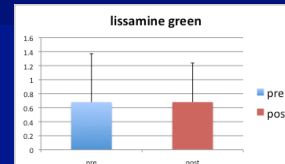
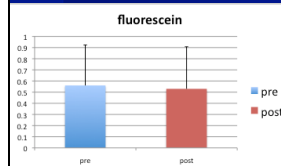


## Results – safety first

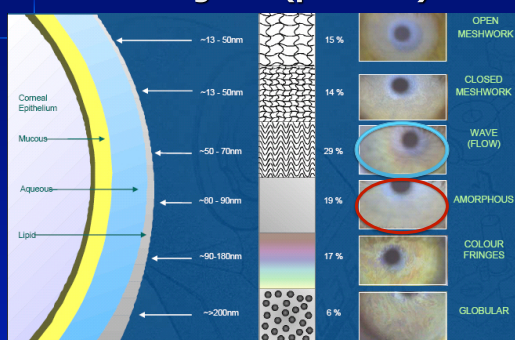


## Conjunctiva

No significant change in staining

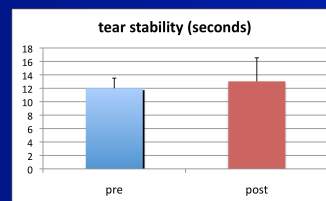


## Significant change in lipid layer thickness grade (p<0.005)



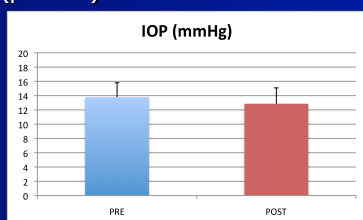
## Tear film stability

- NO significant increase (p=0.118)
- BUT.....these subjects had normal values to start with



## IOP

- Slight decrease, but not significant (p=0.09)



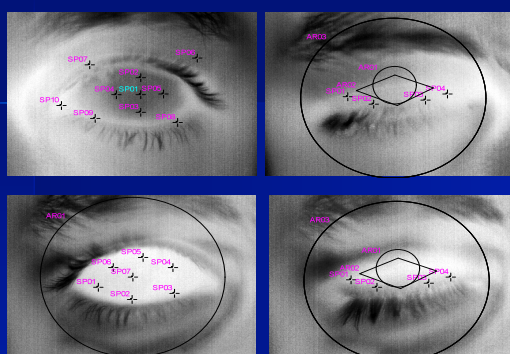
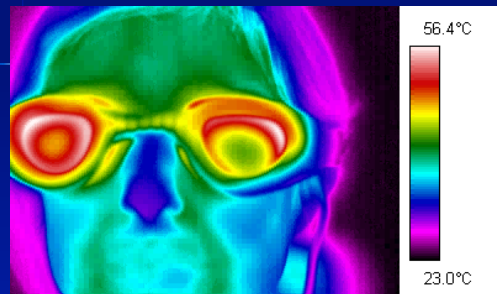
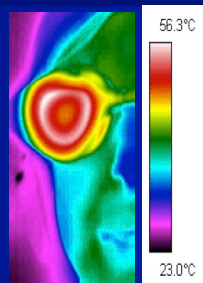
## Results – subjective feedback



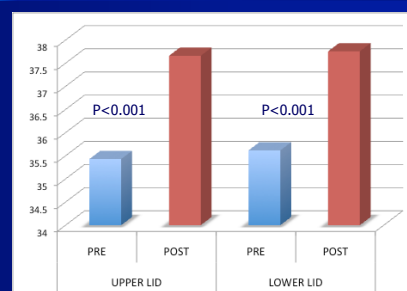
- 20/25 (80%) report improved comfort
- 24/25 (96%) 'pleasant to wear'
- 24/25 (96%) 'easy to use regularly'
- Average rating for the session – 2.6 out of 3 (where 3 is pleasurable)

## Thermography

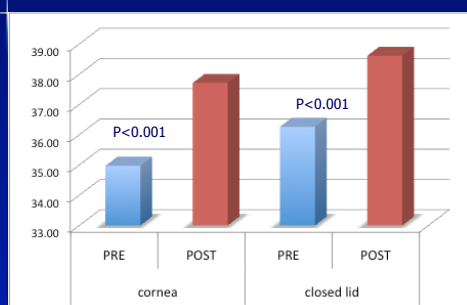
- Unique opportunity to measure temperature in non-invasive way
- High spatial and thermal resolution
- Static images or real time video capture possible



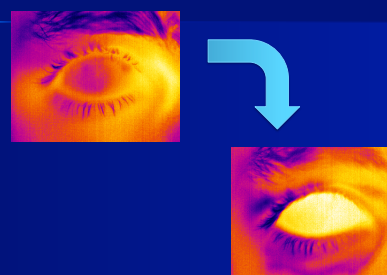
## Temperature changes at the lid margins



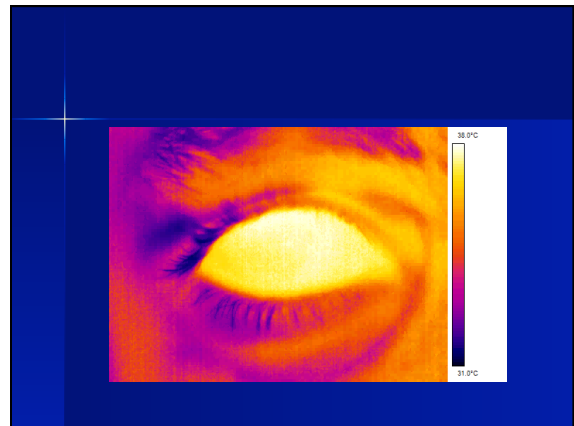
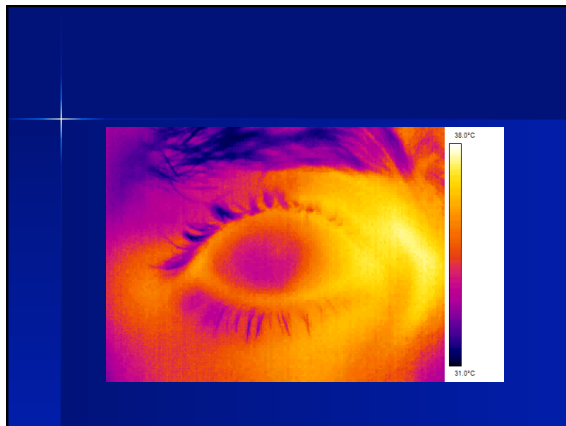
## Temperature changes at the cornea and closed lid



## Ocular surface temperature

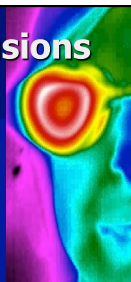






### **Blephasteam® Conclusions**

- Safe and effective device that produces gentle, constant warmth to lid area
- NO adverse responses in normal subjects
- NO adverse effects on ocular redness or staining
- Effective increases in temperature
- Improved comfort reported, even by normal subjects



**Thank you for your kind attention**

Dr Christine Purslow

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