Study supports promising therapy

Jennifer P Craig
PhD MSc BSc MCOptom FAAO FBCLA
University of Auckland NZ

MEIBOMIAN gland dysfunction (MGD) is the most common cause of dry eye and the most commonly observed ophthalmic condition in outpatient clinics. Perception of management success, both by patients and clinicians, remains poor with the majority of therapies providing only palliative support through transiently reduced symptoms, at best.

The current mainstay therapy for MGD centres on encouraging flow of the meibomian gland contents (meibum) onto the ocular surface by the application of heat, typically by regular patient application of warm compresses to the external eyelid or more recently, via in-office thermal pulsation treatment (LipiFlow) that applies heat directly to the inner eyelid.

Intense pulsed light (IPL) is a therapy recognised widely within cosmetic circles for its ability to reduce the appearance of skin pigmentation and eliminate unwanted body hair. Serendipitously, it was discovered by ophthalmologist Rolando Toyos, in the United States, that IPL applied by cosmetic colleagues to the upper cheek area to reduce the appearance of skin redness from telangiectasia in rosacea, concurrently improved the signs and symptoms of patients with coexisting MGD.

This discovery of the potential for beneficial effects in MGD ultimately led to the development by E-Swin in France of the E>Eye, the first medically-approved IPL device for MGD. Anecdotal retrospective reports of success with IPL technology prompted me to prospectively design and execute a double-masked, pilot clinical trial to evaluate this novel technology.[1] With my team at the Ocular Surface Laboratory in New Zealand, 28 participants with MGD were enrolled and reviewed throughout this six-week double-masked trial that involved three unilateral IPL treatments applied to only one eye.

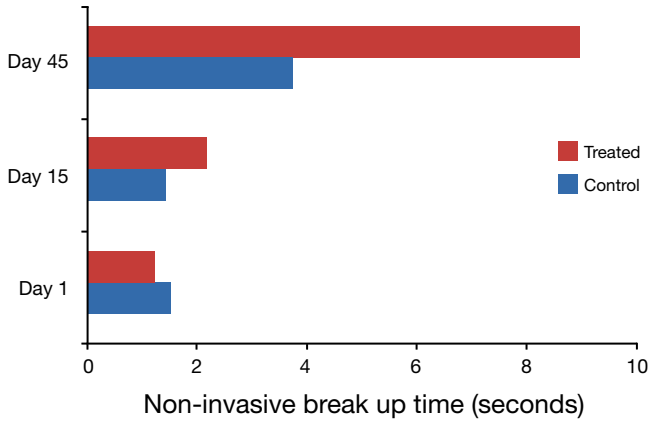

Figure 1. Patient reported symptoms six weeks post-IPL

For each participant, this was randomised to either the right eye or left eye and a sham treatment was performed on the contralateral eye each time, to maintain participant masking. Treatments were applied on Day 1, Day 15 and Day 45, as per the manufacturer's protocol by an operator independent of the clinical data collection to ensure investigator masking. Treatment allocation to the right or left eye was not revealed until the end of the study, after which participants were able to undergo matched treatments in their sham-treated eye.

Key outcome measures included lipid layer thickness grade and non-invasive break up time measurement with the Tearscope Plus, and symptoms measured unilaterally with the SPEED (Standard Patient Evaluation of Eye Dryness), and on a visual analogue scale. Parameters were compared between the control and treated eyes and over time relative to baseline.

Treatment was applied via four flashes that each delivers a controlled train of calibrated light pulses, with the fluence level titrated according to individual skin phototype. The participant was provided with protective metal goggles and conductive gel applied to the treatment zone, before the IPL therapy was applied to the upper cheek area, adjacent to the goggle edge.

Results showed cumulative benefit in both signs and symptoms following three treatments, with clinically and statistically significantly improvements in lipid layer thickness grade and tear film stability noted relative to baseline and relative to the control eye at the six-week time point (Figure 1).

A lipid layer increase of at least one grade on Guillon's grading scale was noted in 82 per cent of participants and an improvement of two or more grades in 65 per cent by Day 45. The mean non-invasive break up time showed a clinically-meaningful improvement of tear film stability in the order of nine seconds in the treated eye by Day 45.

Over all, symptomatic improvement was noted by 86 per cent of participants. Symptoms graded on the visual analogue scale (VAS) showed a pattern similar to that of the lipid layer and stability, of increasing improvement with time and inter-ocular differences identified between control and treated eyes by Day 45. The SPEED score showed statistically significant improvements from baseline for both eyes but not between the eyes.

While limitations exist in a modest sized, paired eye trial such as this,

Continued page 40

Study supports promising therapy

From page 39

the results of this double-blind pilot trial show promising effects of this new therapy, through indirect improvements in meibomian gland function.

Thicker, more stable lipid layers are recognised to be associated with a more robust tear film, protected against the drying effects of tear film evaporation, thereby reducing the risk of tear hyperosmolarity and ocular surface inflammation.

My fellow researchers at the University of Auckland and I are continuing explorations into the mechanisms responsible for effecting the benefit seen to date, by following up the positive outcomes of the pilot study in a larger clinical trial. ◆

1. Craig JP, Chen YH, Turnbull PR. Prospective trial of intense pulsed light for the treatment of meibomian gland dysfunction. *IVOS* 2015; 56: 1965–1970.