ABSTRACT (ENGLISH)

Numerous studies have shown that contact lens wear disrupts the tear film by separating it into a pre- and post-lens tear film altering its physiological functions. This leads to changes in the tear film compositions: lipids, proteins, mucins, and electrolytes. The pre-ocular tear film is constantly changing by undergoing a formation (build-up) phase directly after a blink, a fairly stable inter-blink phase and ultimately a tear film destabilisation that can lead to tear film break-up in subjects with dry eyes or when the eye is left open for a long period of time. There are differences in the build-up, stability, and thinning phases of tear film dynamics during the contact lens wear. The build-up and stability phase have been observed to be shorter and at times indistinguishable in contact lens wear than in non-contact lens wear. Upon the lens insertion, a thin layer of tears covers the lens. The tear film dynamic is dependent on both the lens material and the individual tear composition. Interaction between protein in the tear film and contact lens material alongside the change in the composition of tears are particularly a key issue for contact lens discomfort during contact lens wear. The lipid layer of the pre-lens tear film during contact lens wear is also much thinner than in the same eye without lens wear. Contact lens wear also has an influence on tear evaporation rate leading to the feeling of dryness and discomfort. Lipid deposition on contact lenses may play a role in disruption of the tear film due to poor surface quality between contact lens material and tear film. This phenomenon is called dewetting, leading to an increased pre-lens tear film evaporation rate and subsequent increase in tear osmolarity.

Many studies have concluded that *all* soft contact lens materials adversely affect tear film physiology. Differences have recently been shown to exist in in-vivo tear film surface quality, depending on lens type. Therefore, better techniques assessing tear film quality and its dynamic changes, enhance understanding of tear film compatibility with various contact lens materials may aid eye care professionals in recognising the nature of tear film behaviour with different lens range. It may also be helpful to practitioners in improving contact lens fitting to reduce contact lens discomfort and dropout. Although non-invasive clinical evaluation of lens-tear interaction makes the assessment of tear film possible, the challenge remains due to tear film dynamics and moulding the dewetting process, diversity in observer's analysis and software analysis (algorithm) leading to unreliable and at times unrepeatable measurements.

In addition, the knowledge on contact lens material and their compatibility with tear film is still confined.

This dissertation is an in-depth work focused on tear film quality during the wear of daily disposable contact lenses. The project was designed in accordance with the European Dry Eye Network (EDEN). The main research goals of this work were to better understand the effect of contact lens wear on tear film physiology, to assess the longitudinal effect of contact lens wear on clinically standard and non-standard ocular surface parameters, and to set guideline for optimised contact lens fitting. The expected outcomes of the study included better understanding of the relationship between ocular physiology and contact lens wear, the clinical utility and efficacy of non-invasive measurements of tear film, and the additional information for an eye care professional regarding contact lens discomfort and dropout.

It was only after careful considerations and contact with eminent researchers in the field from different institutions, over a period of one year, alongside thorough literature reviews that the methodology protocol for a longitudinal study was finally created. The first step was to design and undertake a pilot study to test the sustainability of fitting subjects with two daily disposable contact lenses of different materials: a silicone hydrogel (SiHy) lens and a hydrogel (Hy) lens. Following successful completion of the pilot project, the schedule of the main measurement acquisition part was confirmed.

The main study recruited 60 healthy, young, regular or occasional contact lens wearers (19 males and 41 females), aged (mean ± standard deviation) 25.5 ± 4.3 years, ranging from 20 to 37 by sending emails via university newsletters to inform about the longitudinal research project. The study protocol consisted of a qualifying visit (Baseline), contact lens fitting visit on the following day (Day 2), a control visit at two weeks (to ensure that the participants adhered to the study protocol). The control visit was also included in order to explain any further queries before the follow-up visits at three, six and twelve months. A sub-group of Hy and SiHy fitted subjects were recruited for the final Control Visit after completing the 12-month course of contact lens wear. The following measurements were included: assessing environmental factors by monitoring the laboratory temperature and relative humidity with a thermo-hygrometry device; the scores of Ocular Surface Disease Index questionnaire and Contact Lens Dry Eye Questinnaire-8 to report the symptoms; meniscus tear height measurement with the Keratograph 5M (K5M); Tear Film Surface Quality (TFSQ) assessment with High-Speed Videokeratoscopy (HSV); tear osmolarity by TearLab

Osmolarity System; non-invasive methods were used with K5M to assess break-up time and ocular redness. Additionally, a slit lamp biomicroscope with ×10 magnification, cobalt blue illumination, a Wratten 12 yellow-barrier filter and 1 mg fluorescein sodium ophthalmic sterile strips were used to observe ocular surface staining and the tear film break-up. Lissamine Green strips 1.5 mg were used to assess lid wiper.

The main results of this longitudinal study show clinically insignificant impact of contact lens wear on ocular surface physiology and, interestingly, reduced levels of tear osmolarity during the course of the study. These results are the first of its kind in this field.

Although tear film is affected by contact lens wear, in this study it has been concluded that, in general, there is no statistically significant difference in tear film quality between contact lens wear and non-contact lens wear. However, other studies show that tear film physiology has been adversely affected due to increased evaporation rate and tear film thinning with soft contact lens materials. Studies that are more recent have showed all contact lenses causing a significant reduction in TFSQ compared with bare eye measurements. Wearing soft contact lenses causes tear film instability, a decrease in blinking frequency, and increases symptoms of ocular irritation. Interestingly, in this study the result showsde a reduction in osmolarity, which is different from what the current literature supports; stable or a rise in osmolarity during contact lens wear. The corneal staining also reveals an improvement of ocular surface health at the final Control Visit while those of conjunctival staining showed no significant differences between the Baseline and the final Control Visit. Reduction in osmolarity may be due to the timing of the measurements done (shortly after contact lens removal) or it may be due to corneal desensitisation after prolonged contact lens wear – as the osmolarity values go even smaller during follow up visits. However, modern daily disposable materials and healthier contact lens wearing habits may indorse these improvements.

There is no restriction on contact lens choice in the country, where this research was conducted. Contact lenses are of competitive costs due to the ease of availability without prescription from multiple sources. There are similar contact lens markets in several other countries. An increased number of contact lens fittings is led due to this, and therefore more affordable options with subjects opting for monthly reusable economic lenses over daily disposable lenses (54% of participants in this study wore monthly and 25% fortnightly soft contact lenses). This behaviour may lead to poor fitting decisions, lack of follow-up by the eye care professionals and perpetuating risky habits. However, a combination of better

compliance, more moderate wearing schedule and appropriate contact lens fit and control, may have attributed to a decrease in osmolarity and stable ocular physiology shown in this study. Nevertheless, there is still need for continuous research to further understanding the mechanisms of ocular health with contact lens wear to overcome and improve this barrier.

Summarising, the study provides eye care professionals with new knowledge and guidelines on the mid-term effect of daily disposable soft contact lens wear on ocular surface physiology, provided that an advising optometrist implements a firm controlled regime.