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A wearable device to monitor ocular comfort

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ABSTRACT

Purpose: To develop and evaluate a wearable device (the lens awareness logger, LAL) to record subjective lens awareness during contact lens wear.

Methods: The LAL is a compact electronic event-logging device incorporating a tactile switch and belt-clip. Forty contact lens wearers (20 symptomatic and 20 asymptomatic) took part in a clinical evaluation of the LAL device. Subjects were instructed to wear their habitual soft contact lenses for 2 days (> 8 h wear) and use the LAL device. Subjects activated the LAL device immediately prior to lens application and deactivated it following lens removal. If a subject became aware of their contact lenses at any point throughout the wear period they were instructed to depress the button on the LAL device.

Results: The mean number of lens awareness events per hour was 1.3, although there was substantial variation between subjects (standard deviation 1.4). The distribution of lens awareness events throughout the contact lens wearing period showed significantly elevated awareness following lens application and prior to lens removal ($p < 0.0001$). In addition, symptomatic subjects had a statistically higher percentage of LAL events in the second half of the lens-wearing day compared with asymptomatic subjects ($p = 0.02$). The LAL findings for each subject appear consistent across the two days (i.e. no fatigue or learning effect). The LAL device was well accepted by subjects with 38 of the 40 subjects reporting it was either 'very easy' or 'fairly easy' to use.

Conclusion: The LAL device was able to monitor ocular comfort throughout a period of contact lens wear and was well accepted by subjects. The ability of the LAL device to track ocular awareness events through the day, with high temporal resolution, means it is likely to be a key tool to further understanding of contact lens associated discomfort and dry eye disease.

1. Introduction

Discomfort with soft contact lenses continues to be the primary reason for discontinuation from lens wear and as such has a significant effect upon the size of the global contact lens market [1,2]. A significant research effort has focused on understanding the factors that influence contact lens comfort and how they can be modulated to improve contact lens performance [3]. A key part of this work is in developing robust research tools to measure subjective comfort during contact lens wear [4]. Historically, this has involved either questionnaires (*e.g.* CLDEQ-8 questionnaire) or numerical grading scales (*e.g.* visual analogue scales) [5]. Typically these comfort rating approaches are administered in the clinic or issued to the research subject as a paper diary to complete outside of the clinic. Both methods of data capture can require the subject to recall the levels of comfort experienced during contact lens wear, often hours or days later. This reliance on recollection has the potential to lead to inaccuracies in the data recorded and where these diaries are completed outside of the clinic, can result in non-compliant behaviour by the subject (*i.e.* retrospective completion or forward filling paper diaries) [6].

With modern soft contact lens designs and materials, the contact lens wearer is generally unaware of their lenses for the majority of the wearing period. However, at various points through the day, it is not uncommon for them to experience episodes of lens awareness. This work aimed to record episodes of lens awareness by developing a wearable logging device to capture real time contact lens discomfort events to improve understanding of (i) the typical frequency and distribution of such events during contact lens wear and (ii) how these observations differ between symptomatic and asymptomatic contact lens wearers.

2. Methods

2.1. Lens awareness logger

The Lens Awareness Logger (LAL) device is shown in Fig. 1. It is a

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Fig. 1. Lens awareness logger - viewed from below (left) and above (right).

small self-contained box, about the size of a matchbox, with a recessed on/off switch and a raised tactile button. The LAL device is based on a battery powered event logging device (Event101A data logger, MadgeTech Inc., MA) and was modified by the addition of a clip on the back of the device, allowing it to be clipped onto clothing. A raised tactile button (FSM series, TE Connectivity Ltd, Switzerland) was soldered to the internal connectors to function as the event logger button.

2.2. Study design

This was a prospective, observational, two visit, controlled clinical study. Ethical approval for performing this work was obtained from the University of Manchester Committee on the Ethics of Research on Human Beings. Participants provided written informed consent before entering the study. The study was conducted in accordance with the tenets of the Declaration of Helsinki. The study inclusion and exclusion criteria are shown in Table 1.

Due to the feasibility nature of this study, it was not possible to conduct a meaningful *a priori* power analysis. As such, 20 subjects in each group was considered to be likely to provide useful preliminary information. Prior to the initial study visit, subjects were evaluated using the contact lens dry eye questionnaire (CLDEQ-8) [7]. According to the responses given to this validated questionnaire, subjects identifed as 'dry' or 'marginally dry' with their habitual lenses (using the criteria detailed by Young et al. [8]) were classified as *symptomatic*, with the remaining subjects classified as *asymptomatic* for the purposes of this work. Forty subjects took part in this clinical evaluation (20 symptomatic and 20 asymptomatic lens wearers). Subjects were required to attend two study visits - an initial visit and a follow-up visit. At least 24 h prior to the initial visit, the subject received an information form outlining the study. At the initial visit, the subject was required to sign an informed consent form and a study summary form prior to enrolment. Copies of the signed forms were issued to the subject. Details of the ocular and contact lens wearing history of the subject were then recorded (including typical hours per day of lens wear and hours per day of comfortable lens wear) and a 0–100 visual analogue scale (VAS) was used to assess typical comfort on lens insertion and prior to lens removal.

The LAL device was issued to the subject and instructions given on its operation. Subjects turned on the device immediately prior to applying their habitual contact lenses, wore it during the day and pushed the lens awareness button whenever they became aware of their contact lenses. The LAL button had a positive tactile feedback to confirm that the button had been pressed. Subjects were informed that if multiple clicks were logged within a 1 min period, only one lens awareness event would be analysed. Immediately following contact lens removal, the subject was instructed to turn off the device. This daily monitoring protocol was completed on two separate lens-wearing days (consecutive days were allowed, with a maximum of 6 days between LAL evaluations), with the subjects instructed to wear their lenses for a minimum of eight hours on each day. At the follow-up visit, the subject returned the LAL device and provided feedback on its ease of use. The LAL data were downloaded from the device and presented to the subject, who was asked to confirm whether it was representative of their use of the LAL device. The subject was then exited from the study.

2.3. Statistical analysis

Statistical analyses were performed using JMP version 13 (SAS Institute Inc., Cary, NC). The principal hypothesis tested in this work was that lens awareness (as assessed with the LAL device) was the same for the two study groups (symptomatic and asymptomatic contact lens wearers). LAL device metrics (lens wearing time, total daily LAL events, LAL events per hour and the percentage of LAL events in the second half of the lens wearing period) were assessed using unpaired t-tests. A linear regression model was used to test for differences between the normalised time-points and between the study subject groups, with a Tukey post-hoc analysis used where appropriate. The statistical significance level was set at $p = 0.05$.

3. Results

3.1. Subject demographics

Subject demographics are shown in Table 2. All 40 subjects completed the clinical study. No adverse events were reported.

3.2. LAL data

The average contact lens wearing time and LAL event data over the two study days are shown in Table 3. The time between the first and second day of LAL evaluation differed between subjects, with 34 subjects undertaking LAL evaluation on consecutive days, three subjects with one day between LAL evaluation and three subjects with two days between LAL evaluation. On reviewing the LAL data at the follow-up visit, all subjects confirmed that the data captured were representative of their lens wearing experience.

Due to the variation in contact lens wearing periods (between subjects and between study days) the time data was normalised (*i.e.* the contact lens wearing time for each set of LAL data was split into 20 evenly spaced periods and the number of LAL events within each period recorded) to allow direct comparison of all the LAL data sets. Fig. 2 shows the normalised frequency distribution of lens awareness events through the lens wearing period. There was significantly elevated awareness following lens application and at the end of the lens wearing period ($p < 0.0001$). Table 4 compares the LAL data from the symptomatic and asymptomatic groups. All subjects were found to have worn the lenses for the minimum required lens-wearing period (8 h), with average wearing times in the region of 12 h. This was consistent across the two study days and between the two subject groups.

Fig. 3 shows the frequency distribution of lens awareness events through the normalised lens wearing period, for the asymptomatic and symptomatic subject groups. Both groups reported awareness events at the start of the wearing period, followed by a reduction in awareness

Table 1
Inclusion/exclusion criteria.

Inclusion criteria	Exclusion criteria
• 18 years of age and above. • They understand their rights as a research subject and are willing and able to sign a Statement of Informed Consent. • Willing and able to follow the protocol. • Agree not to participate in other clinical research for the duration of this study. • Wear soft contact lenses.	• An ocular disorder that would normally contra-indicate contact lens wear. • A systemic disorder that would normally contra-indicate contact lens wear. • Any infectious disease (e.g. hepatitis), or any immunosuppressive disease (e.g. HIV) or a history of anaphylaxis or severe allergic reactions. • Use of any topical medication such as eye drops or ointment. • Glaucoma (high pressure in the eye), cataract surgery or a history of recurring abrasions. • Undergone corneal refractive surgery. • Any corneal distortion resulting from previous hard or rigid lens wear or has keratoconus. • Pregnant or breastfeeding. • Ocular surface signs which would normally, in the opinion of the investigator, contraindicate contact lens wear. • Participated in any other clinical trial or research within two weeks prior to starting this study.

through the middle of the lens wearing period, with an increased in awareness events recorded toward the end of the wearing cycle, which appeared more pronounced for the symptomatic group. On average, subjects experienced 1–2 LAL events per hour, although this varied substantially, with the worst case being a subject who had a LAL event on average every 10 min.

The metric 'percentage of LAL events in the second half of the lens wear period' was developed to give a single number that would quantify the distribution of the LAL events. Here a low value ($< 50\%$) would indicate awareness predominantly associated with lens settling, a value around 50% would indicate somewhat uniform LAL distribution through the day and a high value ($> 50\%$) would indicate increased awareness associated with end-of-day discomfort. Table 5 shows the percentage of the LAL events in the second half of the lens wearing period, for the symptomatic and asymptomatic subject groups. Almost all subjects (38 of the 40 subjects) reported 'very easy' or 'fairly easy' use of the LAL device (Fig. 4).

4. Discussion

The symptomatic and asymptomatic subject groups were similar in age, sex, typical contact lens wearing time and the type of contact lenses worn, allowing a meaningful comparison between the subject groups. The habitual contact lens comfort data recorded at the initial visit confirmed that the criteria used to classify the subjects was appropriate, with symptomatic subjects typically being uncomfortable for over a third of the lens wearing period (versus less than 6% of the wearing period for the asymptomatic subjects) and having an average reduction in comfort across the day of $>$ 35 points on a 100 point scale (versus a reduction $<$ 10 points for the asymptomatic subjects).

During the study, the LAL devices appeared to reliably capture lens awareness events throughout the lens wearing period. The number of LAL events across the two study days was similar, showing that a learning or fatigue effect did not occur when using the device. A high variability in the number of LAL events per day was observed (ranging between 0 and 62), suggesting a very different contact lens wearing experience for the different subjects in the study. This high frequency of lens awareness (on average 1 event per hour) is perhaps surprising, but likely indicates the ability of the system to detect subtle symptoms that might otherwise be overlooked with retrospective grading. To confirm that the device was not over or under estimating this parameter, each subject was asked to review the LAL data at the follow-up visit, with all subjects reporting that the data capture was representative of their use of the LAL device. The data captured is therefore felt to be an accurate reflection of the subject's lens wearing experience.

When the distribution of LAL events was investigated, they were not typically spread evenly across the lens wearing period, but peaked at the beginning and end of the wearing period. The increase in lens awareness early in the lens wearing period (typically over the first 30 min of lens wear) is thought to be associated with lens settling after application. Traditionally this is assessed by grading comfort immediately after lens application and then following a period of lens settling, although the timing of these assessments can vary between studies [9]. Previous assessment using SMS grading has not been able to demonstrate this initial increase in lens awareness suggesting that use of a wearable device is able to provide more sensitive information. Given that this initial awareness appears to affect a significant number of the subjects (in both the symptomatic and asymptomatic groups), this highlights that further work is needed to develop lens materials, lens designs, blister packing solutions and/or lens application techniques that minimise this awareness.

Lens awareness was also observed to increase towards the end of the lens wearing period for both groups. Lens awareness in the symptomatic group was more marked and began earlier in the lens-wearing period, compared with the asymptomatic group. The increased awareness observed towards the end of the lens wearing period typically

Table 2
Subject demographics and habitual contact lens wearing characteristics.

	Symptomatic subjects	Asymptomatic subjects	All subjects
Age (years) with standard deviation in parenthesis	32.3 (10.2)	34.9 (10.7)	33.6 (10.5)
Sex (male/female)	10/10	11/9	21/19
Number of subjects / completed	20/20	20/20	20/20
Contact lens material type (silicone / conventional)	10/10	12/8	22/18
Replacement frequency (Daily frequent replacement)	10/10	7/13	17/23
Typical hours per day of contact lens (CL) wear	11.9 h	12.7 h	12.3 h
Typical comfortable hours of CL wear (% of day uncomfortable)	8.3 h (31.2%)	12 (5.9%)	10.2 (18.5%)
Typical reduction in comfort (0-100 VAS) through day (insertion – removal)	35.6	8.7	21.4

Table 3
Mean LAL event logger data for contact lens wear time, total LAL events per day and mean LAL events per hour, over the two study days (standard deviation in parenthesis).

	Contact lens wearing period	Total LAL events per day	Mean LAL events per hour
Day 1	12 h 1 min (2 h 6 min)	13.9 (12.9)	1.2 (1.2)
Day 2	12 h 8 min (2 h 24 min)	15.6 (16.9)	1.4 (1.6)
P-value	P = 0.668	P = 0.225	P = 0.136

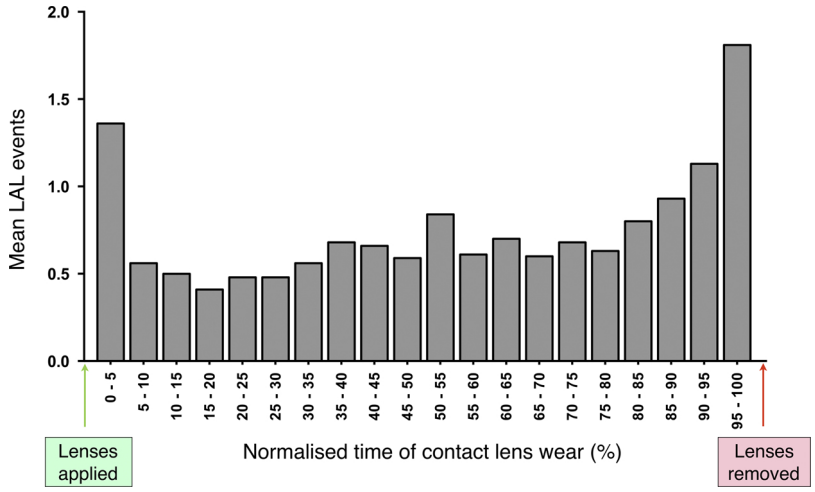

Fig. 2. Frequency histogram of mean lens awareness events following normalisation of the contact lens wearing period (all subjects).

Table 4
Comparison of the LAL data for the symptomatic and asymptomatic subject groups (standard deviation in parentheses). An asterisk indicates a statistically significant difference between the two subject groups.

	Contact lens wearing period	Total LAL events per day	Mean LAL events per hour
Symptomatic wearers	11 h 43 min (2 h 7 min)	17.4 (16.3)	1.6 (1.5)
Asymptomatic wearers	12 h 26 min (2 h 21 min)	12.2 (13.2)	1.0 (1.1)
P-value	P = 0.160	P = 0.121	P = 0.045*

exceeded that observed during lens settling and is thought to demonstrate 'end of day discomfort', which has been extensively reported in the literature [3,5,8,10]. This was also highlighted by the higher percentage of LAL events in the second half of the lens wear period for the symptomatic group (circa 65%), in comparison with asymptomatic lens wearers who had a value of around 50%. This metric therefore allows the LAL data to be summarised with a single number, although future work will focus on developing metrics to best characterise a subject's lens awareness symptoms.

Although the live monitoring of contact lens-related symptoms is a novel research approach, the results reported by the LAL device are in agreement with that observed in the literature. Morgan et al. [11] described the use of an SMS messaging system, where study subjects received text messages at set points through the day and responded with a score between 0 (very uncomfortable) and 5 (excellent comfort). This SMS-based system gave average scores of around 4 (where a score of five indicates no contact lens associated discomfort), indicating a degree of lens awareness for subjects through the lens wearing period, in agreement with that observed in this study. In addition, the same SMS system has identified a greater drop off in comfort through the lens wearing period with symptomatic contact lens wearers [10,11], again in agreement with that observed in this study. SMS-based systems offer an advantage over paper diary data capture in that they require recollection only over a short time period and that the response is time stamped to ensure subject compliance. The limitations of such a system are (i) that the SMS messages frequently remind the study subject about

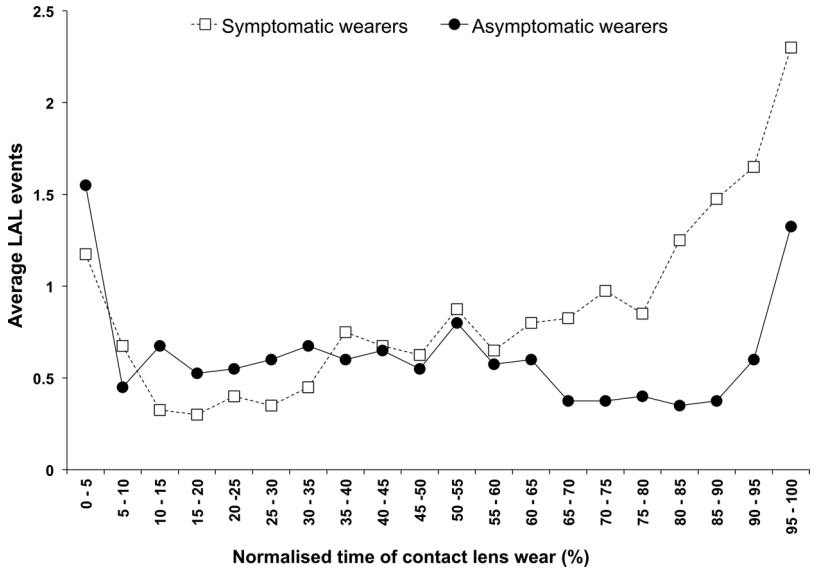

Fig. 3. Frequency polygon of average LAL events through the normalised contact lens wearing period for the two subject groups.

Table 5
Percentage of LAL events in second half of the lens wearing period (standard deviation in parenthesis). An asterisk indicates a statistically significant difference between the two subject groups.

	Percentage of LAL events in second half of lens wearing period
Symptomatic CL wearers	63.0 (25.6)
Asymptomatic CL wearers	49.7 (27.4)
P-value	P = 0.028*

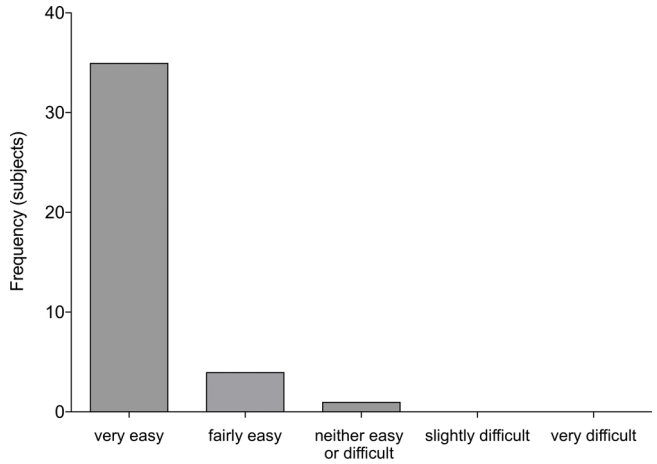

Fig. 4. Subject satisfaction with the LAL device (Question: How easy was it to use the LAL device?).

their contact lens wear and thus is not completely reflective of a typical lens wearing period, (ii) the subject requires a period of time to read and then complete a response, which is not always possible (*e.g.* if the subject is driving), (iii) a degree of recollection is still required, and (iv) the approach is less well suited to subjects who do not apply their lenses in the morning and remove their lenses in the evening (*e.g.* shift workers). In contrast, the LAL system allows live data capture in a non-invasive manner, which is flexible to the subject's lens wearing schedule and which provides date and time stamped data.

In this initial clinical study, the primary aim was to assess the feasibility of capturing ocular awareness events with an electronic logger. Given the useful information provided by the LAL device, this technique could be further developed to allow a greater degree of information to be captured. In this study, the subject was requested to log an event whenever they became aware of their contact lens. Feedback from the study subjects (when reviewing their LAL data) highlighted that the majority of the lens awareness events were associated with reductions in comfort, but a more robust breakdown was not undertaken in this study. Future studies could consider issues relating to comfort and vision independently, although care should be taken due to the known link between vision and ocular comfort [12]. Vision in particular is known to potentially be more compromised with toric and presbyopic contact lens designs, and future work should consider tracking the frequency and distribution of vision-related awareness to better understand visual satisfaction with such lens designs. In addition, reductions in comfort during contact lens wear are known to be a leading cause of discontinuation from contact lens wear, which is known to significantly impact the size of the global contact lens market [2]. The ability of the LAL device to characterise these lens awareness events, suggests that this technique has the potential to be a useful tool in understanding the phenomenon of end-of-day contact lens discomfort, with the ability to screen new contact lens materials, designs and care systems. More generally, ocular awareness and discomfort are the primary symptoms of dry eye disease (a potentially severe condition which can have a marked impact on the sufferers quality of life [13]) and the LAL device could be developed to be a useful tool to characterise dry eye symptoms and evaluate treatment strategies.

The idea behind the LAL device was to make it extremely easy for the subject to use. A belt clip allowed the subject to wear the LAL device, but with the current instrument there was no way of confirming whether the device was kept with the subject at all times. If the device was not kept with the subject at all times during the study, then the LAL data would potentially underestimate contact lens awareness. Future studies should consider use of a watch-based electronic logger (less obtrusive and unlikely to be removed), ideally also containing a movement and/or temperature sensor to confirm that the subject is compliant with the requested full-time wear of the device.

A further limitation of this initial implementation of the LAL device was that all lens awareness events were given an equal weighting, whereas it is likely that some lens awareness events were more troublesome than others. Future studies should consider using a multiple click approach (*e.g.* where a mild awareness events is a single click, a moderate event is a double click and a severe event is a triple click). Such an approach would allow the severity of each awareness event to be graded, allowing more meaningful metrics to be developed to

characterise symptomatology, whilst maintaining the simplicity of the system.

5. Conclusion

The LAL device was able to capture lens awareness events throughout a period of contact lens wear. The LAL findings for each subject appeared consistent across a two day lens wear period. Lens awareness was most marked following lens insertion ('lens settling') and towards the end of the lens wearing period ('end-of-day discomfort'). The symptomatic subject group showed significantly greater lens awareness towards the end of the lens wearing period than the asymptomatic participant group. The ability of the LAL device to track ocular awareness events through the day, with high temporal resolution, means it is likely to be a key tool to further understanding of contact lens associated discomfort and potentially in other areas such as dry eye disease.

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Conflict of interests

None.

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