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# Monitoring ocular discomfort using a wrist-mounted electronic logger

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## Abstract

**Purpose:** To investigate ocular discomfort during contact lens wear using a wrist-mounted electronic 'lens awareness logger' (LAL). **Methods:** Thirty symptomatic contact lens wearers wore study contact lenses for three days. On the first two days, two lens types which are known to differ in end-of-day comfort (lens A: senofilcon A and lens B: balafilcon A), were worn as a matching pair (randomised order). On day three, a pair of lens B were worn. On each day, the participant wore a LAL. On day one and two, the participant pressed a button on the LAL whenever they became aware of their lenses due to discomfort. On day three, the participant used a multiple click protocol (1 = mild awareness to 3 = severe awareness). **Results:** LAL events were similar on days one and two (17.3 vs. 15.8 events per day). There were significantly more LAL events for lens B (21.6 events per day) in comparison with lens A (11.6 events per day) ( $p=0.006$ ). The LAL event profile highlighted peaks in awareness following lens application and towards the end of the wearing cycle. Comparison of the LAL event profile for the two lens types showed significant differences in lens awareness, particularly in the first half of the wearing cycle. LAL events on day 3, showed a uniform distribution of single and double clicks through the day, but a marked peak in triple clicks in the last two hours of lens wear. **Conclusion:** The LAL was able to differentiate between the study lenses and demonstrated differences in their LAL event profiles. Lens awareness associated with discomfort appeared to increase not only in frequency, but also in intensity towards the end of the wearing cycle. The ability of the LAL to track lens awareness suggests it is likely to be a useful tool in furthering understanding of ocular discomfort.

*Keywords:* Contact lens, Comfort, Discomfort, Lens Awareness Logger, End of day, Wearable.

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## 1. Introduction

The ocular surface is the most highly innervated tissue of the human body, with the density of pain receptors in the cornea around 300-600 times greater than the skin [1]. Given this, even mild disturbances

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4 to the ocular surface due to surgery, infection, mechanical or chemical irritation can result in the sensation  
5 of pain [2]. Eye care practitioners and researchers typically use questionnaires and/or visual analogue scales  
6 to assess ocular surface pain [3, 4]. Typically these metrics are assessed in a clinical setting and rely on the  
7 patient's recollection of symptoms, with the potential for recall bias [5, 6]. To more accurately characterise  
8 changes in ocular comfort with time and minimise the effect of recall bias, a range of approaches have been  
9 developed where such grading scores and/or questionnaires are captured outside of the clinic environment.  
10 This typically involves prompting the patient to complete a grading scale and/or questionnaire for ocular  
11 comfort at key time-points, typically with the use of a paper diary [7], via text messaging [8] or via the  
12 internet [9]. Although this allows the capture of ocular comfort data in the real world, there is often still a  
13 requirement for recollection of symptoms, the quality of the data is not always assured (e.g. poor compliance  
14 particularly with paper diaries [10]) and the patient is required to convert their issues with ocular comfort  
15 in to an arbitrary numeric scale. This can be particularly challenging in the fields of dry eye disease and  
16 contact lens wear, where symptoms are known to vary significantly through the day depending on a range of  
17 factors including environment, application of ocular lubricants, blink rate and visual task. For contact lens  
18 wearers and patients with mild dry eye disease, it is common for these episodes of discomfort to be transient,  
19 with prolonged periods with no symptoms. In order to address the limitations of existing approaches, the  
20 use of wearable technology offers a number of potential advantages including the ability to capture data  
21 in real time. Wearable technology in medicine is a rapidly growing area of research and is becoming an  
22 integral part of personal analytics, assessment of physical status, reading physiological parameters and  
23 informing a schedule for medication [11, 12]. Previous work has demonstrated that a novel wearable device  
24 for subjective reporting of contact lens discomfort - the Lens Awareness Logger (LAL) - was able to provide  
25 useful information on the clinical performance of contact lenses [13]. With this type of system, the perfect  
26 contact lens product or dry eye treatment would result in no episodes of ocular discomfort being logged, with  
27 increasing episodes indicative of a less optimal solution. This original LAL device allowed accurate logging  
28 of awareness events through the lens wearing cycle [13], but suffered from a number of limitations including  
29 that (i) it was attached to clothing rather than worn and thus could become separated from the participant,  
30 (ii) there was no way of checking compliance with the use of device, (iii) the device was not waterproof  
31 or robust to adverse environments, and (iv) the device was not always readily available to the participant  
32 (i.e. they had to remember where they had attached it to their clothing). It was therefore decided to move  
33 towards a wrist-mounted LAL device, which could log episode of lens-associated discomfort (termed lens  
34 awareness events) via a front-facing button, whilst also monitoring the other internal sensors (temperature,  
35 light and motion sensors) to confirm if the participant was compliant with instructed usage. The work  
36 described in this paper investigated if the wrist-mounted LAL device could detect differences in subjective  
37 lens awareness in a group of symptomatic contact lens wearers, when two brands of contact lenses, which  
38 have previously been reported to differ in end of day comfort (Lens A: senofilcon A and Lens B: balafilcon

39 A [14, 15]) were worn. Furthermore, to ascertain if participants could provide more detailed information  
40 about the intensity of any lens-associated discomfort, participants used a more complex reporting system  
41 (multi-click protocol) on the final study day.

## 42 **2. Methods**

### 43 *2.1. LAL device and clinical use*

44 The wrist-mounted electronic device used in this study was a GeneActiv logger (Activinsights Ltd,  
45 Kimbolton, UK), which is typically used as an activity monitor and has been used in a wide range of  
46 clinical research studies [16, 17, 18, 19]. This event logger was chosen as it is wrist mounted, includes  
47 movement/temperature/light sensors and has a event logging button with LED light confirmation (Figure  
48 1). The wrist-mounted nature of the device allowed it to be worn by the study participants in a minimally  
49 invasive manner, ensuring it was immediately available to the participants at all times. The environmental  
50 sensors (light, temperature and movement) allowed confirmation as to whether the device had been worn  
51 continuously during contact lens wear. The event logging button is located on the front surface of the device,  
52 allowing the convenient activation of the button during wear, resulting in a time/date logged recording for  
53 each button-press event. The LAL device was configured to sample all of the internal sensors at 10Hz,  
54 allowing it to be issued to the study participant for up to two-weeks, without requiring data download or  
55 recharging of the internal battery. Prior to clinical testing, the LAL devices were tested to ensure they were  
56 correctly logging button presses. This involved each LAL device being worn for a six hour period, with  
57 the button pressed when prompted by a hourly alarm. All LAL devices correctly logged the hourly button  
58 presses, with no unintended button presses recorded.

59 A LAL device was issued to each of the study participants, with the participants instructed to put on  
60 the LAL device immediately prior to lens application and remove the LAL device immediately following lens  
61 removal. To ensure compliant use of the LAL device, the participant received one-to-one training with the  
62 investigator and were issued with written instructions. During wear, the participant was instructed to follow  
63 a single-click protocol on study day 1 and 2, and a multiple-click protocol on study day 3. For the single-click  
64 protocol, the participant was instructed to click the button on the LAL device whenever they became aware  
65 of the contact lens due to reduced comfort (in this study termed 'lens awareness'). On day 1 and 2, the  
66 participants were informed that if they pressed the button more than once in a one-minute period then these  
67 later presses would be ignored during analysis (to provide sufficient time for the participant to forget about  
68 the reduction in contact lens comfort). On day 3, the participants were asked to follow a similar process, but  
69 for each episode of lens awareness they were instructed to grade its severity using a multiple click protocol (1  
70 click = mild awareness, 2 clicks = moderate awareness, 3 clicks = severe awareness). The definition of 'mild',  
71 'moderate' and 'severe' awareness was a subjective opinion of each individual participant. Multiple button

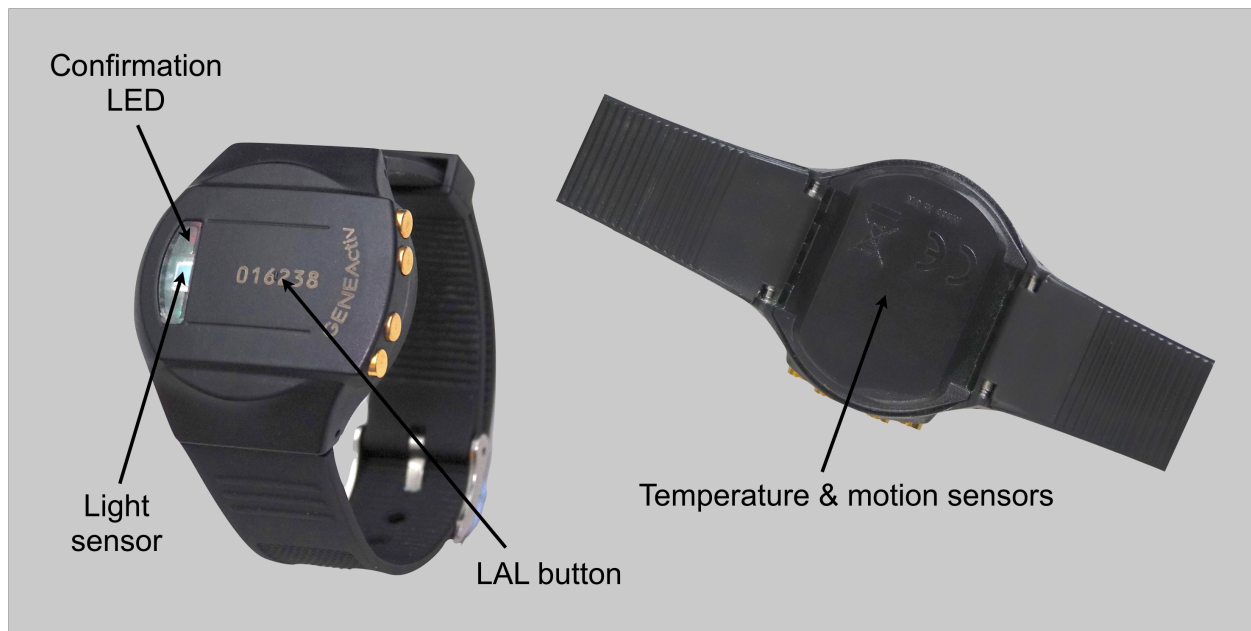


Figure 1: The wrist-mounted electronic logging device, the GeneActiv activity monitor from a front view (left) and a rear view (right) highlighting the sensors, LED and button.

72 presses had to be completed within a 10-second window, with button presses outside of this window then  
 73 disregarded for the next 50 seconds (to again allow the participant to forget about the reduction in contact  
 74 lens comfort). If lens awareness was still present after the 1-minute period, the participant was instructed  
 75 to press the LAL button again and to continue doing so (every minute) until the awareness settled. Using  
 76 this approach, each LAL event highlighted a minute period during contact lens wear, where the patient had  
 77 experienced ocular discomfort and were classed as discrete events even when they occurred in consecutive  
 78 minute periods. Once data collection had been completed over the three study days, the device was returned  
 79 to the clinic and placed into its docking station, with the internal data downloaded via a USB interface.  
 80 These data were then imported into custom MATLAB software (MathWorks Inc., Natick, NC.) where the  
 81 outputs from the various sensors and button could be visualised and the validity of these data confirmed  
 82 (Figure 2). The software allowed the investigator to confirm the time of lens application and removal, with  
 83 the software then calculating (i) time of lens application / removal (ii) the total number of LAL events, and  
 84 (iii) the number of LAL events per hour.

## 85 2.2. Clinical study

86 This was a prospective, controlled, randomised, participant-masked study where contact lens awareness  
 87 was monitored during wear of two different study contact lens types. This study was comprised of two  
 88 clinical visits separated by three lens wearing days, during which time participants recorded their lens  
 89 awareness with the LAL. The aim of this work was to investigate if the LAL was able to detect differences

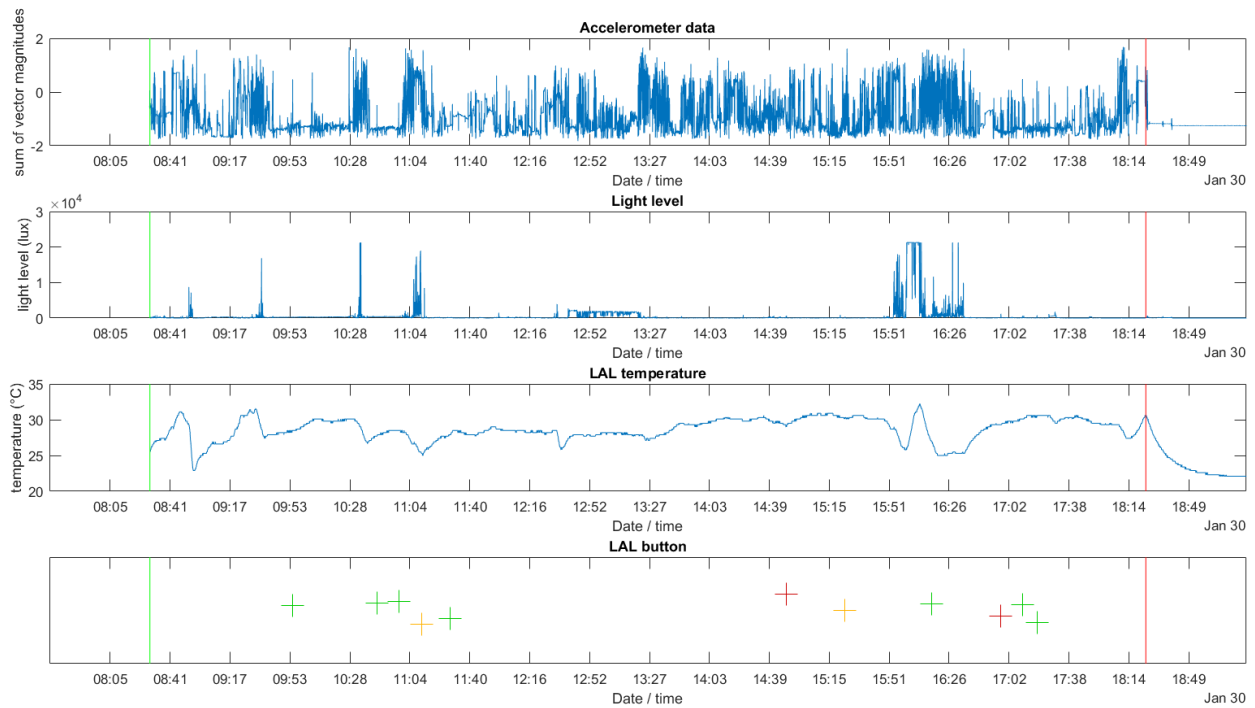


Figure 2: A typical screenshot of the LAL analysis software from study day 3, highlighting the output of the accelerometer, light and temperature sensor, in addition to the LAL button events (green line = lenses applied, red line = lenses removed, green cross = single LAL event, orange cross = double LAL event, red cross = triple LAL event).

90 in wearer awareness between two brands of contact lenses (Lens A: senofilcon A - Acuvue Oasys, Johnson  
91 & Johnson Vision Inc. and Lens B: balafilcon A - PureVision, Bausch & Lomb Inc.), that have been  
92 shown to demonstrate differences in end of day discomfort [14, 15]. Participants wore both lens types, as a  
93 matched pair, on day 1 and day 2 of the study (randomised order). Additionally, to ascertain if participants  
94 could provide more detailed information about the intensity of any lens awareness, participants used a more  
95 complex multiple-click reporting system on the third lens wearing day (only lens B worn). Lenses were worn  
96 on a daily wear, daily disposable basis (i.e. removed at night and discarded). This study was controlled by  
97 cross-comparison, with bias minimised by masking the participants to the lenses worn on each of the LAL  
98 days (by over-labelling of the lens blister packaging). Prior to starting the study, participants were evaluated  
99 on the CLDEQ-8 questionnaire and only participants with contact lens dry eye (CLDE) or marginal CLDE  
100 (as defined by Young et al.[20]) were eligible for this work. In total 30 participants were recruited.

101 All participants provided written informed consent before inclusion in the study. The study was con-  
102 ducted in accordance with the principles of the Declaration of Helsinki and The University of Manchester  
103 Research Ethics Committee provided ethical approval. Individuals with a history of ocular/systemic dis-  
104 orders that would normally contraindicate contact lens wear, a history of ocular surgery, who were using  
105 topical ophthalmic medication, who had corneal distortion, who were pregnant or breastfeeding, who had a  
106 history of anaphylaxis or severe allergic reaction or any infectious or immunosuppressive disease that would  
107 pose a risk to study personnel and users of either of the study lens types were excluded from participating  
108 in the study. Each participant was required to attend two clinic visits - an initial visit and a final visit (4-7  
109 days after initial visit). At the initial visit and prior to contact lens application, subjective ocular comfort  
110 was assessed using a 0-100 visual analogue scale (VAS). Refraction, visual acuity assessment and slit lamp  
111 biomicroscopy were then performed. Both study lens types were applied in sequence and their fit evaluated.  
112 The participant was then instructed on how to use the LAL (described in Section 2.1) and was asked to  
113 use the device on days where they were performing similar activities (e.g. normal work days or similar  
114 non-working days). The participant was then issued with the LAL and the three pairs of the lenses (two  
115 pairs of Lens B and one pair of Lens A to their own refractive prescription) and asked to return for the final  
116 visit, after completion of the three days of lens wear / LAL usage. On the first day of LAL use, the partici-  
117 pants applied a pair of study lens (either Lens A or Lens B). Lens awareness events associated with ocular  
118 discomfort were then recorded through the day using a simple single click protocol (i.e. a single click each  
119 time the participant had lens awareness). Participants were instructed to use the study lenses for as long  
120 as they were comfortable, with a target of at least 8 hours of study lens wear where possible. Immediately  
121 following lens removal, subjective comfort was assessed using a 0-100 VAS grading scale (relating to comfort  
122 experienced during contact lens wear). On the second day of LAL use, participants again used the LAL  
123 to record lens awareness events with the other lens type (single click protocol) and subjective comfort with  
124 the 0-100 VAS grading scale. On the third day of LAL use, all participants applied a pair of Lens B and

125 used the multiple click protocol. Following lens removal, subjective comfort was assessed using a 0-100 VAS  
126 grading scale (relating to the comfort during study contact lens wear). At the final clinic visit, participants  
127 were questioned on the ease of use of the LAL (using a five point Likert scale) and their use of the LAL  
128 device was reviewed to confirm it was used as instructed. The study participant was also asked to review  
129 the LAL data and to confirm whether it was representative of their use of the device. Refraction, visual  
130 acuity assessment and slit lamp biomicroscopy were then performed and the participant was exited from the  
131 study.

### 132 *2.3. Power analysis*

133 In previous work, the mean number of ‘lens awareness events’ was 1.2 per hour on the first day of use  
134 and 1.4 per hour on the second day of use [13]. Given this, it was proposed that a difference of 0.5 lens  
135 awareness events per hour may be of clinical significance. A power analysis indicated that to detect this  
136 magnitude of difference 26 participants would provide 0.80 statistical power, given a standard deviation of  
137 intra-participant day-to-day differences of 0.88 (from the previous LAL study [13]) and an alpha of 0.05.  
138 Thirty participants were therefore recruited to allow for any discontinuations.

### 139 *2.4. Statistics*

140 The main outcome measure in this work was lens awareness events per hour. The principal hypothesis  
141 to be tested in this work was that lens awareness as assessed with the LAL was equivalent for the two study  
142 lens types (Lens A and Lens B). Period of study lens wear, lens awareness events per day, lens awareness  
143 events per hour and 0-100 VAS comfort data were compared between the two study lens types and between  
144 the study days (days 1 and 2), using paired t-tests. To allow the LAL data to be summarised over the  
145 daily lens wearing period for the two study lens types, the data were normalised with respect to wear time  
146 (i.e. the contact lens wearing time for each set of LAL data was split into 10 evenly spaced periods and the  
147 number of LAL events within each period recorded). To compare the LAL profile for the two lens types,  
148 the difference in LAL events for each normalised time period were plotted, with a lack of overlap of the  
149 95% confidence intervals with zero indicating a significant difference between lens types. To investigate the  
150 relationship between 0-100 VAS subjective comfort scores and LAL metrics, Pearson correlation coefficients  
151 were calculated. A p-value of less than 0.05 was considered statistically significant. All data were analysed  
152 using JMP 14, Version 14.3 (SAS Institute Inc. Cary, NC, USA).

## 153 **3. Results**

### 154 *3.1. Single click protocol - study day 1 & 2*

155 Table 1 details the participant demographics and CLDEQ-8 questionnaire scores for the participants  
156 habitual contact lenses. Of the 30 participants recruited, 29 participants completed the clinical study, with



157 one participant lost to follow-up. On reviewing the LAL data, the data from three participants was discarded  
158 from analysis due to non-compliance with the LAL device (e.g. removing the LAL device during contact  
159 lens wear or otherwise not following the study instructions). The LAL analysis therefore included data from  
160 26 participants. The study contact lens wearing period did not differ significantly between the two study  
161 days ( $p=0.10$ ; Day 1:  $13.2 \pm 1.6$  hours / Day 2:  $12.7 \pm 2.0$  hours) or between the two study lens types  
162 ( $p=0.31$ ; Lens A:  $13.2 \pm 1.9$  hours / Lens B:  $12.8 \pm 1.8$  hours). The mean contact lens wearing time was  
163  $13.0 \pm 1.8$  hours (range: 9.7 to 16.0 hours). On reviewing the LAL data at the follow-up visit, all subjects  
164 confirmed that the data captured were representative of their lens wearing experience

Parameter	Females	Males	Overall
Number of participants	18	8	26
Age	$31.0 \pm 9.5$ (19 to 49)	$22.7 \pm 4.3$ (19 to 31)	$28.7 \pm 9.1$ (19 to 49)
Best Sphere (D)	$-2.77 \pm 1.28$ (-6.00 to -1.00)	$-2.34 \pm 1.03$ (-3.50 to -1.00)	$-2.65 \pm 1.22$ (-6.00 to -1.00)
Cylinder (D)	$-0.31 \pm 0.24$ (-0.75 to 0.00)	$-0.27 \pm 0.23$ (-0.75 to 0.00)	$-0.30 \pm 0.24$ (-0.75 to 0.0)
CLDEQ-8 (habitual lenses)	$13.9 \pm 4.5$ (8 to 27)	$12.8 \pm 4.8$ (8 to 20)	$13.6 \pm 4.6$ (8 to 27)

Table 1: Participant demographics and CLDEQ-8 questionnaire scores relating to the participants habitual contact lenses (mean  $\pm$  standard deviation with range in parentheses).

165 The LAL events per day did not differ significantly between the two study days (Day 1:  $17.3 \pm 17.4$   
166 events, Day 2:  $15.8 \pm 16.6$  events;  $p=0.72$ ), but was significantly higher for Lens B ( $21.6 \pm 21.0$  events)  
167 compared to the Lens A ( $11.6 \pm 9.2$  events ;  $p=0.0063$ ; Figure 3A). A similar trend was observed for the  
168 mean LAL events per hour data which did not differ significantly between the two study days (Day 1:  $1.4$   
169  $\pm 1.6$  events/hour, Day 2:  $1.3 \pm 1.6$  events/hour;  $p=0.87$ ), but was significantly higher for Lens B  $1.8 \pm$   
170  $2.1$  events/hour) compared to Lens A ( $0.9 \pm 0.7$  events/hour;  $p=0.01$ ; Figure 3B). The distribution of LAL  
171 events through the daily lens wearing cycle is shown in Figure 3C. The daily LAL event profile highlighted  
172 increased lens awareness following lens application (thought to be related to contact lens settling) and prior  
173 to lens removal (thought to be related to end of day discomfort). Figure 3D details the LAL event profile  
174 by study lens type, highlighting minimal initial lens awareness for Lens A in comparison with Lens B,  
175 although both lens types appeared to show an increase in lens awareness towards the end of the lens wearing  
176 period. Analysis of difference in the LAL events profile between the two lens types (Figure 3E) highlighted a  
177 significant difference between the lens types (i.e. where the 95% confidence intervals of the mean difference  
178 do not cross zero) at 10%, 20%, 30%, 50% and 80% of the total daily lens wearing period. This highlights  
179 a greater difference in lens awareness between the lens types earlier in the lens wearing period, with a less  
180 marked difference in lens awareness as the day progressed (as highlighted by the trend for the LAL data to  
181 generally converge through the lens wearing period for the two lens types, shown in Figure 3D).

182 Subjective comfort scores (0-100 VAS grading scale) for the two study lens types are shown in Table 2.  
183 Mean 0-100 VAS comfort scores were highest following lens application, followed by the overall score, with

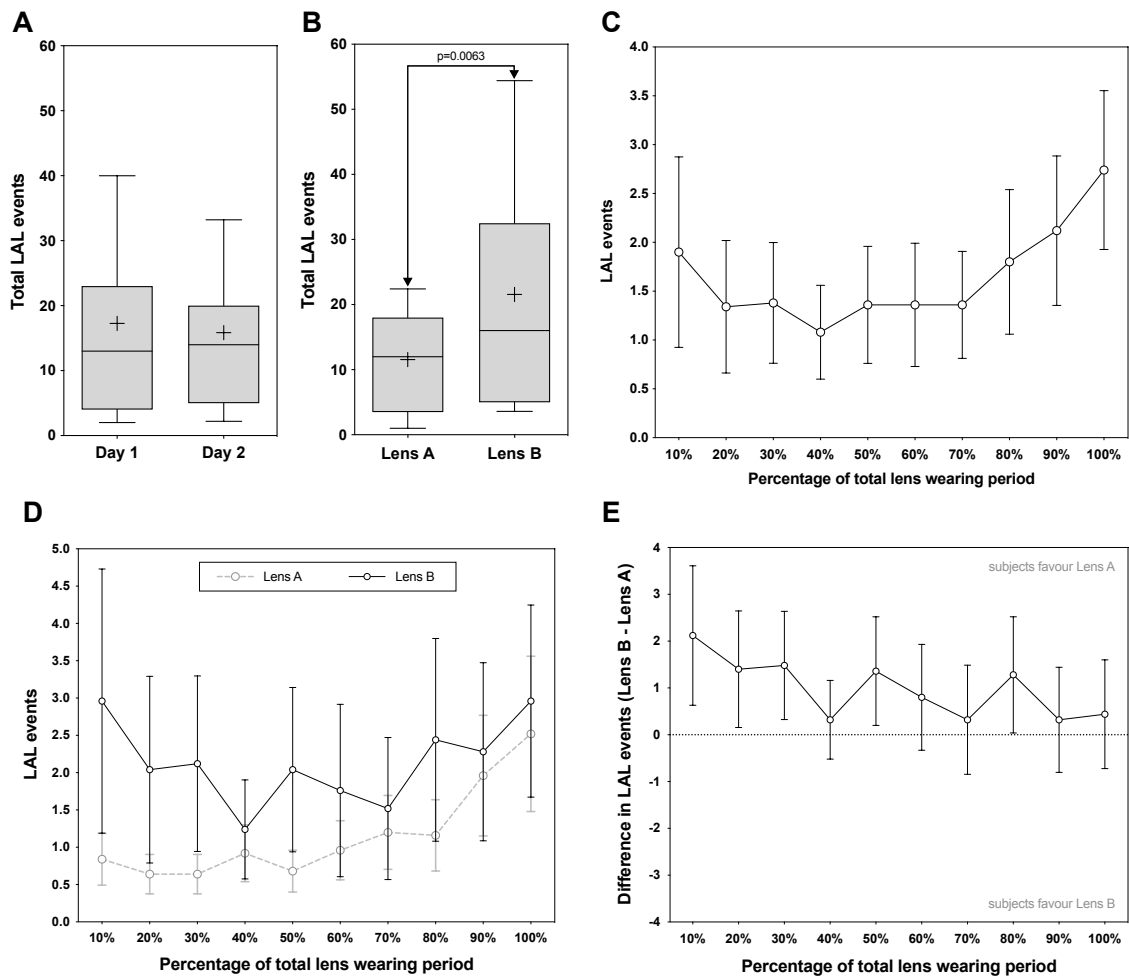


Figure 3: The total number of LAL events (A) and LAL events per hour (B) for the two study lens types. The lens awareness profile through the lens wearing period (C) and by lens types (D). The difference in LAL response between the two study lens types (E). For the box and whisker plots, the cross indicates the mean, the line the median, the box the 25th and 75th centiles and the whiskers the max and min values. For the line plots, the error bars indicating the 95% confidence intervals. All data in this Figure relate to the single click protocol during study day 1 and 2 only.

184 the lowest mean comfort score recorded immediately prior to lens removal. Lens B showed a consistently  
 185 lower mean comfort score (typically around 10 points lower on the 100 point scale), although the difference  
 186 was only statistically significant for the initial comfort ( $p=0.03$ ) and overall comfort ( $p=0.04$ ); and did not  
 187 reach significance for the end of day comfort ( $p=0.10$ ).

Lens type	Comfort on lens application	Overall comfort	Comfort prior to lens removal
Lens A	$90.9 \pm 8.7$	$78.0 \pm 12.9$	$64.4 \pm 19.0$
Lens B	$81.6 \pm 17.7$	$69.2 \pm 19.4$	$54.2 \pm 20.5$
P-value	$P=0.03$	$P=0.04$	$P=0.10$

Table 2: 0-100 VAS comfort scores captured at the end of the study day, immediately prior to lens removal, for the two study lens types (mean  $\pm$  standard deviation).

### 188 3.2. Multiple click protocol - study day 3

189 For data captured using the multiple click protocol, a significant difference was observed between the  
 190 mean number of single, double and triple clicks ( $p=0.0001$ ). The mean number of clicks per day was highest  
 191 for the single click (11.0 per day), followed by the double click protocol (6.9 per day) and lowest for the  
 192 triple clicks (3.1 per day). Figure 4A highlights the LAL profile for the multiple click protocol. There was  
 193 generally a low incidence of severe lens awareness (triple clicks) except at the end of the lens wearing day  
 194 where an increased incidence was observed. To summarise these findings in a single profile, each LAL event  
 195 was weighted by the severity of the symptoms (i.e. single clicks = 1, double clicks = 2 and triple clicks  
 196 = 3), as shown in Figure 4B. This highlighted the key periods of increased lens awareness (in the case of  
 197 Lens B this was again following lens application and prior to lens removal). This lens awareness was then  
 198 summarised into a single metric (the lens awareness index - LAI), by summing the average weighted scores  
 199 across the lens wearing period (mean LAI for Lens B = 32.1).

200 To investigate the relationship between overall comfort scores (0-100 VAS) and (i) LAL events (day one  
 201 and two), and (ii) LAI (day three) a correlation analysis was performed, as shown in Figure 5. A moderate  
 202 negative correlation ( $r=-0.76$ ) was observed between overall comfort and daily LAL events (day one and  
 203 two), which reached statistical significance ( $p<0.0001$ ). A moderate negative correlation ( $r=-0.79$ ) was also  
 204 observed between overall comfort and LAI (day three), which reached statistical significance ( $p<0.0001$ ).

205 At the final clinical visit the participant was asked to reflect on the use of the LAL device. Figure 6  
 206 highlights the participants agreement with the statements relating to ease to remember to log lens awareness  
 207 events, and ease of use of the LAL for the single and multiple click protocol. The participants were generally  
 208 in agreement with the statements around ease of use and remembering to use the device to log awareness,  
 209 with less than 15% of participants giving negative responses to the three questions. Where negative responses  
 210 were given this generally related to the button on the LAL device, which some participants found required

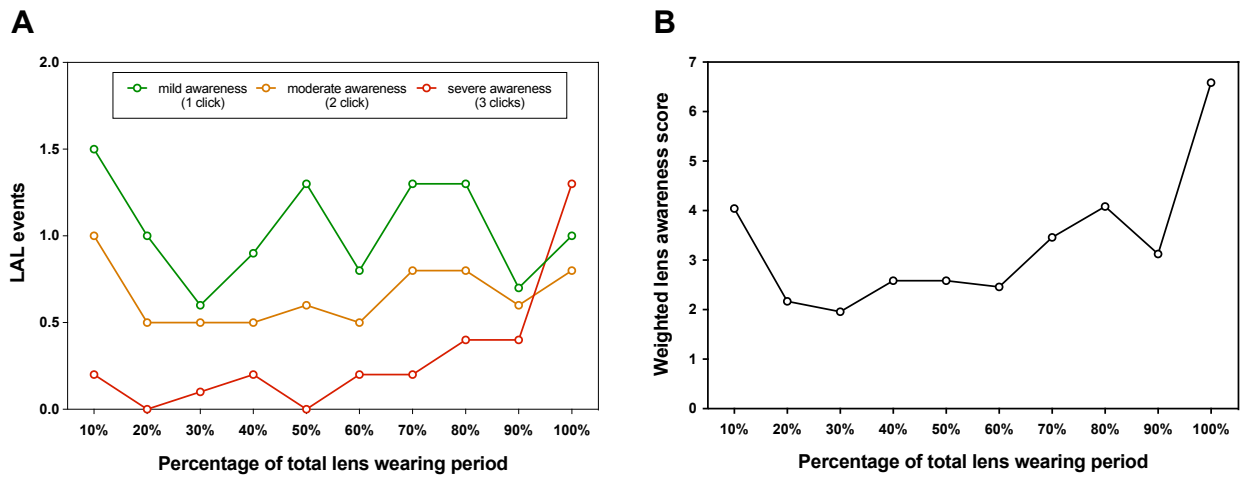


Figure 4: The lens awareness profile (A) and the weighted lens awareness profile (B) through the lens wearing period for the multiple click protocol (green line = mild lens awareness / single click, orange line = moderate lens awareness / double click and red line = severe lens awareness / triple click).

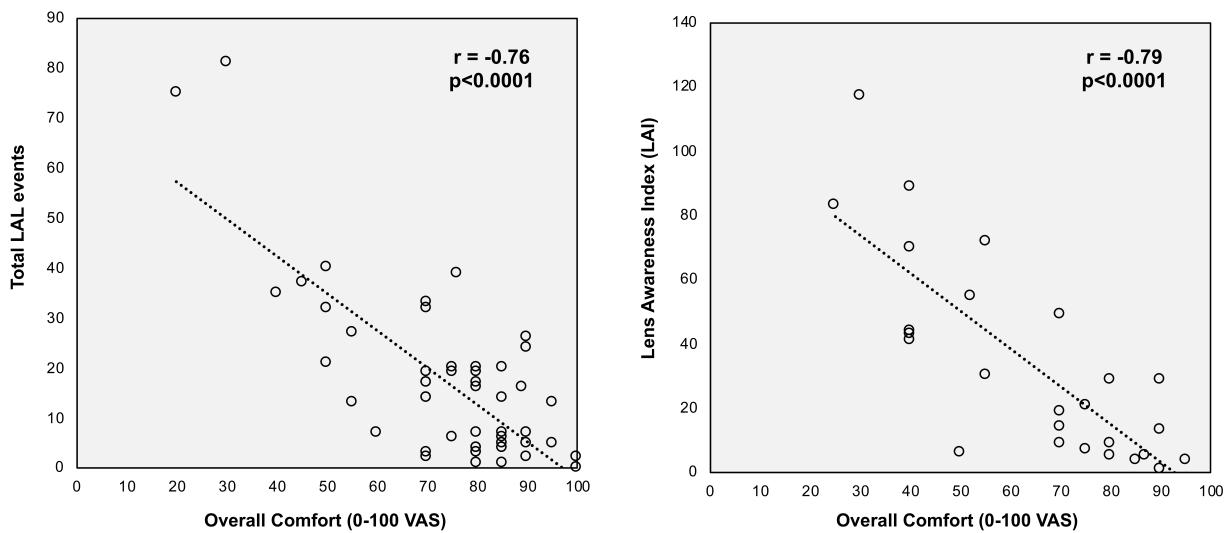


Figure 5: Correlation between total LAL events (study day 1 and 2) and subjective comfort scores (left) and LAI (study day 3) and subjective comfort scores (right).

211 a firm press to confirm a LAL event (the button is designed in this manner to avoid accidental activation  
 212 during wear).

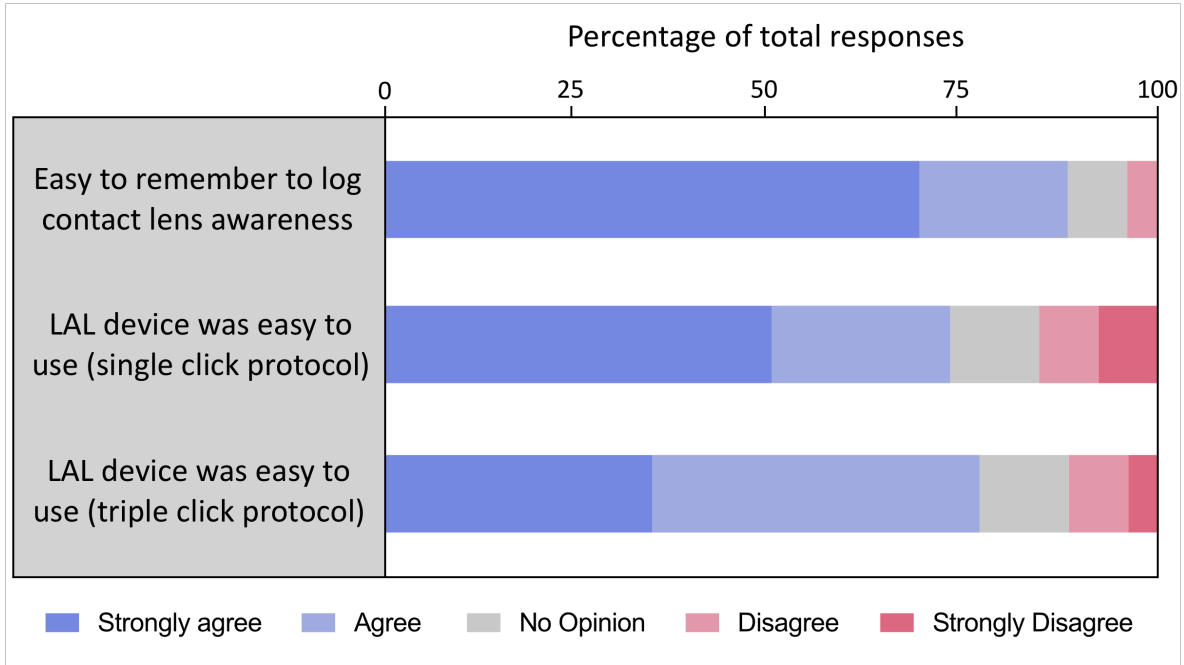


Figure 6: Horizontal stacked bar graph with the responses to three questions relating to the ease of the use of the LAL device, with the Likert responses detailed below.

#### 213 4. Discussion

214 Although contact lenses are worn on the most highly innervated tissue of the human body [1], the  
 215 combination of soft biocompatible materials and high precision manufacture allow contact lenses to be worn  
 216 with a high level of comfort for the majority of patients. However, it is thought that around 50% of the  
 217 contact lens wearing population still experience symptoms of dryness and/or discomfort at least occasionally  
 218 during lens wear [21, 22]. This reduction in comfort is typically not uniform through the wearing period,  
 219 but often intermittent, with ocular irritation occurring sporadically through the wearing cycle [13]. Scoring  
 220 of this type of transient and intermittent irritation is challenging and requires the patient to average out  
 221 the lens wearing experience through the period of wear. The LAL device has previously been used to  
 222 monitor ocular awareness, highlighting that symptomatic contact lens wearers had a greater number of  
 223 lens awareness events and more frequent symptoms later in the lens wearing period, in comparison with  
 224 asymptomatic contact lens wearers [13]. Given that symptomatic contact lens wearers are more prone to  
 225 contact lens discontinuation [23] and present a significant clinical management challenge, it was decided that  
 226 a symptomatic participant group would be the focus of this work.

227 The participant population was typical of the general contact lens wearing population, with a female bias,  
228 moderately myopic prescription range and an average age of around 30 years [24]. The use of the validated  
229 CLDEQ-8 questionnaire [25] allowed participants with contact lens related dryness symptoms to be recruited  
230 into the study, with the questionnaire scores suggesting a similar population to the symptomatic participant  
231 group in the previous LAL clinical study [13]. The daily lens wear period in this study was similar over the  
232 three study days and typical of that recorded in the literature for daily soft contact lens wear [26, 22, 21]. The  
233 subjective comfort grading scores (0-100 VAS scale) observed in this study confirmed the expected difference  
234 between lens types, with the Lens A on average scoring around 10 points higher on the 100 point VAS scale.  
235 By studying these lens types, it was therefore anticipated that these differences would be elucidated by the  
236 LAL testing methodology. The number of LAL events per day and the mean number of LAL events per hour  
237 were both shown to be significantly higher for Lens B, than for Lens A, highlighting the ability of the system  
238 to differentiate between lens types with different comfort characteristics. In agreement with the previous  
239 LAL study [13], the number of LAL events recorded was similar between study day 1 and day 2, indicating  
240 that a significant learning or fatigue effect was not evident during use of the LAL device. As was observed  
241 in the previous LAL study, the distribution of LAL events was not uniform through the lens wearing cycle,  
242 but was typically elevated after lens application and towards the end of the lens wearing cycle. This initial  
243 lens awareness is often termed lens settling and is thought to relate to tear film disruption, contact lens  
244 hydration changes and resultant dimensional/lens movement alterations after a contact lens is applied to  
245 the ocular surface [27], in addition to possible sensory adaptation to lens wear [28]. This process of lens  
246 settling is generally reported to last for up to 30 minutes [27], which coincides with the initial peak in lens  
247 awareness events observed for the study lenses. It is worth noting that the initial awareness due to lens  
248 settling is more marked in Lens B, suggesting that factors such as its higher modulus [29], higher surface  
249 friction [30], less wettable surface [31, 32] and/or rounded edges [14] may result in a lens that is less able to  
250 quickly settle on the ocular surface. This difference in the degree of lens awareness between the two study  
251 lens types, becomes less apparent later in the wearing cycle, with both lens types showing an increase in  
252 awareness in the last few hours of the daily lens wearing period. This increase in lens awareness typically  
253 observed later in the daily lens wearing period is often term 'end-of-day (EOD) contact lens discomfort', the  
254 cause of which is not fully understood [33]. Previous work has indicated that EOD discomfort associated  
255 with contact lens wear does not appear to be primarily related to an aging/degrading lens or to the time  
256 of day, but rather determined by the length of time lenses are in contact with the eye [34]. The findings of  
257 this study also highlight that the factors influencing EOD discomfort are likely to be different from those  
258 influencing initial settling, with the two lens types having very different mechanical, surface and lens design  
259 characteristics, but yet showing a similar trend for EOD discomfort.

260 An obvious limitation of the LAL device (in study day 1 and day 2) was that the single click protocol  
261 gave no weighting as to the severity of the lens awareness, rather allocating a binary event at points of

262 lens awareness through the wearing cycle. In an attempt to address this short coming, a multiple click  
263 protocol was evaluated on the third lens wearing study day. Here the participant logged either a single,  
264 double or triple click (mild, moderate or severe awareness respectively) depending on the severity of the lens  
265 awareness. This approach appeared well accepted by the study participants, who reported similar ease of  
266 use to that recorded for the single use protocol. The single-click (mild awareness) was generally the most  
267 frequently logged event, followed by the double-click (moderate awareness) and least commonly used was  
268 the triple-click (severe awareness). The profile of LAL events through the day followed a similar profile to  
269 that recorded previously, with increased awareness at the beginning and end of the lens wearing cycle. The  
270 triple click events were typically low in frequency (less than 1 event per 2 hours of lens wear on average),  
271 although towards the end of the lens wearing period the frequency increased dramatically ( $>1$  event per  
272 hour on average), indicating an increase in the severity of lens awareness events later in the wearing cycle.  
273 This increase in the severity of symptoms, has been previously observed later in the lens wearing cycle using  
274 both conventional grading and text messaging systems [35, 8]. By weighting the LAL events according to  
275 their severity, a more meaningful profile through the day was generated, which is thought to relate to how  
276 bothersome the contact lens had been, in addition to a single metric (LAI) which summarises the degree  
277 of awareness into a single value. The weighted profile and LAI metric are likely to be useful in future  
278 comparative clinical studies to highlight key differences in the lens awareness experience between different  
279 lens types and/or care systems.

280 The use of an electronic event logger to monitor comfort-related awareness events has allowed the mon-  
281 itoring of such unwanted episodes and is likely to be a useful tool in better characterising the clinical  
282 performance of contact lens designs, materials and care systems. This is a key area for improved under-  
283 standing, as it has been clearly shown that poor levels of comfort during lens wear is a leading cause of  
284 discontinuation from lens wear [21], limiting the size of the contact lens market. More broadly, the LAL de-  
285 vice could be used to characterise episodes of ocular discomfort in a range of optometric and ophthalmological  
286 conditions, such as dry eye disease, ocular allergy, the effectiveness of ocular analgesics or for monitoring  
287 recovery from ocular surgery. In addition, visual quality is a key property of an optical device and whilst  
288 single vision spectacles and contact lenses generally provide high quality and stable vision; multifocal and  
289 toric corrections are frequently associated with variable vision [36, 37, 38]. The LAL device could therefore  
290 also be used to monitor episodes of awareness associated with sub-optimal vision.

291 A further useful element of the LAL device is that whilst it is recording episodes of comfort/vision  
292 related awareness, it is also logging the output from a range of internal sensors. In this study, the intention  
293 of monitoring the light, temperature and accelerometer data was solely to ensure the device was worn  
294 by the participant as intended, by monitoring for change in the output from these three sensors. As the  
295 temperature sensor was monitoring body temperature (i.e. not environmental temperature), the light sensor  
296 could be obscured by clothing and the accelerometer data was not calibrated for physical activity, further

297 analysis was not possible in this study. However in future studies, the wear of the LAL device and setup  
298 of the sensors could be modified to investigate the relationship between episodes of lens awareness and the  
299 lens wearing environment, such as the light level (via the photo-diode sensor) with the performance of a  
300 multifocal contact lens or time spent outdoors (via the temperature and photo-diode sensor) with contact  
301 lens comfort. In addition, this awareness data could be linked with externally captured data such as activities  
302 being undertaken (using a detailed diary recording) or factors such as blink rate (using a head mounted eye  
303 tracker). Such an approach is likely to provide useful information on the factors which influence clinical  
304 performance. A possible future implementation of the LAL device could also allow it to capture more specific  
305 information about the symptoms experienced, either via speech input or a small digital touch screen display.  
306 However, by adding greater capability to the data capture system, there is a potential that this may interfere  
307 with the simplistic and minimally invasive nature of data capture present with the current LAL approach.  
308 Where additional complexity is added to the data capture system, the additional information gained with  
309 such an approach should be carefully weighed up against the increased burden on the participant.

## 310 **5. Conclusion**

311 In conclusion, the LAL device was able to differentiate between the two lens types, with Lens B, as  
312 expected, resulting in a greater number of LAL events per study day than Lens A. The distribution of  
313 LAL events through the lens wearing period also differed between the lens types, with Lens B resulting in  
314 more awareness, particularly in the first half of the lens wearing period. The multiple-click LAL protocol  
315 highlighted that discomfort-related lens awareness appeared to increase not only in frequency, but also in  
316 intensity towards the end of the lens wearing cycle. The LAL device was well accepted by the participants  
317 using both the single and multiple-click protocol, and the additional logging capabilities of the wrist-mounted  
318 LAL device allowed exclusion of non-compliant participant data. The ability of the LAL to track lens  
319 awareness suggests it is likely to be a key tool in furthering understanding of ocular discomfort.

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