Recently, a contact lens sensor (CLS) has become available to telemetrically monitor the intraocular pressure (IOP) pattern continuously over 24 hours in an ambulatory setting. This technology is based on the assumption that a 1 mmHg variation in IOP causes a 3 µm change in the corneal radius of curvature. Three completed clinical trials have investigated whether healthy subjects and patients with glaucoma would tolerate 24-hour CLS wear.\(^3,5\) In addition, a repeat exposure within one week was investigated in one of the three trials.\(^6\)

In trial I only the medium size CLS was used. The mean duration of CLS wear for all subjects by trial was 23.2, 23.1 and 24.0 hrs for trial I, II and III, respectively. Mean duration of CLS exposure was not statistically significantly different between healthy subjects and glaucoma patients (trial II) or glaucoma suspects and glaucoma patients (trial III). No subjects used contact lenses during the 2 years.

The number of CLS exposures was 128 with a mean duration across the 3 trials of 23.8 hrs.

Mean duration of CLS exposure for all subjects by trial was 23.2, 23.1 and 24.0 hrs for trial I, II and III, respectively. Mean duration of CLS exposure was not statistically significantly different between healthy subjects and glaucoma patients (trial II) or glaucoma suspects and glaucoma patients (trial III), nor between 2 sessions 1 week apart (trial III).

No significant differences were observed for age, gender, CLS exposure duration and VAS between healthy subjects and glaucoma patients in trial II.

No significant differences were observed in trial III between glaucoma suspects and glaucoma patients. Pooling of VAS of subjects is therefore appropriate for trial II and III, showing similar mean VAS, 24.3 and 27.3 (S1) and 23.8 (S2), respectively.

Repeated exposure to the CLS at a weekly interval in trial III equally resulted in similar VAS and all subjects completed the two 24-hour sessions, suggesting that subjects did not experience discomfort in the first session preventing them to not undergo the second session.

The VAS outcome represents that for 78 subjects, corresponding to 118 24-hour sessions of CLS exposure.

The subject-specific SCS remained consistent throughout the duration of CLS wear (trial I; see Figure 2).

Converting the VAS and SCS into a percentage, the comfort was similar across studies and across study subjects (Figure 3).

The wear of the CLS is well tolerated by healthy subjects and patients with glaucoma for 24-hour IOP monitoring.

REFERENCES:
3. De Brand S, Merouane A, Schrader C, J Glaucoma 2011 May 9 (Epub)

The clinical trials were supported in part by Sensimed AG, Lausanne Switzerland.

Figure 1: Photo of the Triggerfish™ CLS containing an embedded microprocessor (square), whereas rings and a central circular magnet go into position in the CLS.

Figure 2: Graph showing modified subject comfort percentage and standard deviation converted by the

Table 1: Summary of subject baseline characteristics and disposition, and CLS exposure by population

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Baseline characteristics</th>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Healthy</td>
<td>Age: 25-55 yrs; Gender: 50% male</td>
<td>128 sessions</td>
</tr>
<tr>
<td></td>
<td>Patients</td>
<td>Age: 65-85 yrs; Gender: 50% male</td>
<td>118 sessions</td>
</tr>
</tbody>
</table>

**Subject disposition and baseline characteristics (see Table 1)**

- A total of 88 subjects across 3 trials, 29 healthy subjects, 21 glaucoma suspects and 38 patients with established glaucoma, reported tolerability to 24-hour wear of the CLS.
- Mean age and gender distribution were not statistically significantly different between healthy subjects and glaucoma patients (trial II) or glaucoma suspects and glaucoma patients (trial III).
- No subjects used contact lenses during the passed 2 years.
- The number of CLS exposures was 128 with a mean duration across the 3 trials of 23.8 hrs.
- Mean duration of CLS exposure for all subjects by trial was 23.2, 23.1 and 24.0 hrs for trial I, II and III, respectively. Mean duration of CLS exposure was not statistically significantly different between healthy subjects and glaucoma patients (trial II) or glaucoma suspects and glaucoma patients (trial III), nor between 2 sessions 1 week apart (trial III).

Mean VAS for all subjects by trial was 24.3 and 25.5 for trial II and III, respectively. Mean VAS was not statistically significantly different between healthy subjects and glaucoma patients (trial II) or glaucoma suspects and glaucoma patients (trial III).

In trial III all patients completed the two CLS wear sessions. No statistically significant difference was observed for the mean VAS between the two 24-hour IOP monitoring sessions in trial III.

No CLS sessions were prematurely terminated due to adverse events in the trials.

All subjects used artificial tears.

**Methods**

- Three prospective, open cohort clinical trials were designed to assess the tolerability while recording the 24-hour IOP pattern using the SENSIMED Triggerfish™ in healthy subjects and patients with glaucoma.
- Trials I, II and III were conducted by investigators in Lausanne, Mainz and San Diego, respectively.
- The primary endpoint of these trials was to assess the comfort level as scored by the subject to contact lens sensor (CLS) exposure.
- The SENSIMED Triggerfish™ system (SENSimed, Lausanne, Switzerland) contains a CLS that measures circumferential changes in the area close to the corneo-scleral junction as a surrogate of IOP changes.
- All subjects pursued their routine daily activities and their sleep behavior was uncontrolled.
- Contact lens wear in the preceding 2 years was an exclusion criterion.
- In trial I and II, subjects underwent a single 24-hour IOP pattern monitoring session, whereas in trial III subjects were exposed to the CLS during two consecutive 24-hour sessions (S1 and S2), 6 to 9 days apart.
- In trial I and II, only the medium size CLS was used (diameter of 14.4 mm with base curve (r) of 8.7 mm). For trial III, flatter (r=8.4 mm) CLS were available too.
- The subjects were recommended to use artificial tears during CLS wear.
- To assess the comfort level of CLS wear a subjective comfort score (SCS), ranging from 1 (no comfort) to 10 (perfect comfort) was used in trial I. The two other trials used a visual analogue scale (VAS) for the subject to mark the discomfort level, ranging from 0 (no discomfort) to 100 (very severe discomfort) applied immediately after the end of CLS wear.
- This study summarizes and reviews the subjective tolerance to CLS wear as provided by the subject across the three aforementioned trials.