Comfort O²
An independent clinical evaluation

This paper describes a two-month independent clinical evaluation of the RGP contact lens material, Comfort O². The study was carried out by NetherLENS in the Netherlands, a country which has a high proportion of RGP contact lens wearers.

To evaluate the comfort of lenses made of Comfort O² material compared to the old lenses that patients were using, 29 patients with moderate to high amounts of myopia and who were free from pathological eye conditions were included in this study. K-readings ranged between 7.30mm and 8.20mm, and corneal astigmatism was limited to 2D. All practitioners in this multi-centre study were experienced RGP lens fitters, and the four practices involved were located in different regions of the country. Informed consents were discussed and signed by every patient prior to commencement.

All patients were RGP lens wearers: inclusion criteria did not require ocular discomfort with old lenses, but problem cases were not excluded. Comfort was graded based on a set of questions and by completion of a Visual Analogue Scale (VAS) for ocular comfort on a scale from zero (pain) to 10 (do not feel the lenses at all). Patients were asked to wear the lenses for a minimum of five hours before each follow-up examination.

Practitioners were advised to discontinue their patients' lens wear for a minimum of three days before refitting, but the final decision was left up to the practitioner. The lens design was fixed and the back surface geometry consisted of a spherical central zone with a progressive eccentricity starting in the mid-periphery, and reaching out to the edge of the lens (the overall eccentricity equivalent of the lens was close to 0.45). The standard lens diameter was 9.6mm, but adjustments could be made if required. Lenses were fitted based on K-readings and vertical visual iris diameter. The first lens selection was based on a table provided by the manufacturer, and a trial set was provided for each practice in order to achieve the best lens fit. After lens refit, the patient continued wearing their old lenses until the study lenses were dispensed.

All lens fits were evaluated by the same investigator at the specific site by scoring the tear layer thickness in the central and mid-peripheral area, and at the edge of the lens in both the steepest and flattest meridian using fluorescein, cobalt blue light and a yellow barrier filter. The tear layer thickness was graded as either optimal, slightly too thick or too thin but acceptable (sub-optimal = 1) or not acceptable (rejected = 2) (**Table 1/ Figure 1**). Diameter, movement and centration was graded following the same system: optimal (0), acceptable (sub-optimal, 1) or non-acceptable (rejected, 2). Any grade 2 was considered unacceptable (for old and new lenses) and any patient who did not comply with this was excluded from the study.

Evaluation of comfort took place at three subsequent visits – at dispensing, after two weeks of lens wear and at two months. Comfort was scored for each eye separately at each subsequent visit. Lens debris and wettability of the lens was evaluated on a three-point scale.

The first comfort evaluation with the new lenses was done 20 minutes after dispensing. Corneal and conjunctival health were evaluated using the Efron grading scale and corneal oedema, bulbar conjunctival redness, palpebral conjunctival redness and roughness (contact lens-induced papillary conjunctivitis, CLPC) were all evaluated and monitored also. Over-refraction and visual acuity were assessed to evaluate the stability of the material over the course of the study.

Statistical analysis of the data was performed using the SPSS 11.5 software program. The data were tested for differences using the Student's t-test.

Results
The mean age of participants was 33.3 years (standard deviation ± 9.2), ranging from 16 to 53 years. Seventeen percent of participants were male and 83% female. All participants were experienced RGP lens wearers. The mean amount of years that patients had been wearing contact lenses was 15.3 years (ranging from one year to 34 years). One patient discontinued the study after six weeks due to a change of job and consequently, a drastic change in their working environment leading to severe ocular problems.

All patients were myopic, ranging from S-0.50D to S-13.50D (mean -4.66 ± 2.56D) and corneal astigmatism was limited to -1.75D. The mean E-value of all corneas was 0.40 ± 0.18. The mean amount of days that patients ceased lens wear before they were refitted with lenses made of the test material was 1.98 days (ranging from zero to 14 days).

Grade	
+1	Rejected thick
+2	Sub-optimal thick
0	Optimal
-1	Sub-optimal thin
-2	Rejected thin

» **Table 1**
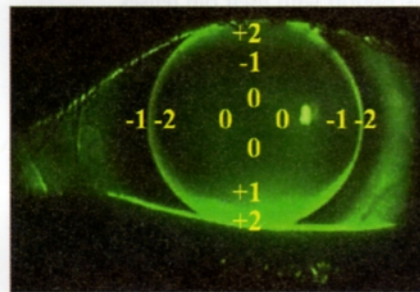Grading of tear layer thickness

» **Figure 1**
Example of tear layer thickness evaluation

Old lenses
The mean comfort of the old lenses was graded as 7.0 ± 1.6 on a 10-point scale. With their old lenses, 27 patients (94%) reported experiencing some discomfort at some point during the day – 59% 'sometimes', 36% 'often' and 6% 'never'. Of the discomfort problems, 68% occurred in the evening, 13% complained of daylong discomfort, 11% 'variable' during the day and 8% 'only in the morning'. The severity of the discomfort ranged from mild (38%) to moderate (40%) and severe (22%). Wearing their old lenses, a mean grade of corneal staining of 0.50 was found, and a 0.40 grade for conjunctival redness. No oedema or CLPC was noted.

Dispensing
At dispensing, the mean comfort of Comfort O² lenses was 8.1±1.0: an increase of 15.7% and a statistically significant difference in favour of the new material (p<0.001). If asked specifically, 61% of patients reported that they felt the new lenses less than their old lenses; 33% felt no difference at this point and for 5%, the awareness of the lenses was increased with the Comfort O² lenses. Mean best corrected visual acuity (BCVA) with the new lenses was 1.1 ± 0.2. Debris on the lens and wettability were evaluated to create a baseline. The mean grade of debris found was 0.21 and the mean grade for wettability was 0.43.

Two weeks
Comfort at two weeks was reported to be 7.7 ± 1.3 – a slight decrease compared to