COMFORT 0^2 RGP MATERIAL STUDY

INTRODUCTION

David Thomas Contact Lenses (Northampton, UK) have launched a new rigid gas permeable lens material in the UK and in Europe. The Comfort O² material is reported to have increased comfort compared to conventional RGP lenses, and even the claim 'Silicone hydrogel RGP contact lens' has been introduced for this. The increase in comfort is said not to be achieved by a material coating, but by an entirely new solid lens material. This two and a half month study is carried out independently by *the* Nether*LENS* to evaluate the comfort of this new lens material in a controlled setting. The Netherlands is known for having a very high proportion of RGP lens wearers, and therefore this platform was chosen for this study.

David Thomas Contact Lenses Limited is the exclusive supplier of the Comfort O² material for Europe and the exclusive manufacturer of Comfort O² lenses in the UK. The Comfort O² material is manufactured by The Lagado Corporation of Englewood Colorado, in the USA and marketed under the name ONSI-56 (onsifocon A) and has FDA marketing clearance.

METHODS

Included in this study were 29 patients (58 eyes) with myopia between 1.00 and 15.00D, free from pathological eye conditions. K-readings ranged between 7.30 and 8.20mm, and corneal astigmatism was limited to 2D. All practitioners in this multi-centre study (four locations) were experienced RGP lens fitters and the four practices were located in four different regions of the country. Informed consents were discussed and signed at entry by every patient.

All patients were existing RGP lens wearers. Inclusion criteria did not require ocular discomfort with current lenses, but problem cases were not excluded either. Comfort was graded based on a set of questions and by completion of a visual analog scale (VAS) for ocular comfort on a scale from zero (pain) to 10 (do not feel the lenses at all), separately for the right and left eye. Patients were asked to wear the lenses for a minimum of 5 hours (and preferable close to 5 hours) at the time of each follow-up examination.

Advice to the practitioner was to discontinue lens wear for a minimum of three days before refitting, but this decision was left up to the judgment of the practitioner in every individual case. 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). Standard lens diameter was 9.6 mm, but adjustments could be made if required. Lenses were fit based on K-readings and vertical visual iris diameter and on corneal topography according to the practitioners' knowledge and clinical experience. 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 existing 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 dye and a yellow barrier filter. The tear layer thickness was graded as either optimal, slightly too thick or too thin but acceptable (suboptimal = 1) or not acceptable (rejected = 2) as shown in *Table 1*. Diameter, movement and centration was

graded following the same system: optimal (0), acceptable (suboptimal, 1) or non-acceptable (rejected, 2). Any grade 2 was considered unacceptable (for old and for new lenses) and any patient that 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 consequent visit. Lens debris and wettability of the lens was evaluated on a three point scale.

At the dispensing visit, patients were wearing their existing lenses. The first comfort evaluation with the new lenses was done 20 minutes after dispensing. At all follow up visits patients were asked to wear the lenses for about 5 hours. Evaluation of corneal and conjunctival health was performed using the Efron grading scale. For evaluation of corneal staining, fluorescein and a yellow barrier filter was be used. Corneal oedema, bulbar conjunctival redness, palpebral conjunctival redness and roughness (contact lens induced papillary conjunctivitis, CLPC) were all evaluated and followed as well. Overrefraction and visual acuity was assessed to evaluate the stability of the material over the period the study was running.

Statistical analysis of the data was performed using SPSS 11.5. The data were tested for differences using the Student *t*-test.

RESULTS

Mean age of participants was 33.3 years (standard deviation ± 9.2): 16 years minimally to 53 years of age maximally. Gender: 17% male and 83% female (in the normal contact lens population the ration male female is on average about 33:66). All participants were experienced RGP lens wearers: mean amount of years that patients had been wearing contact lenses was 15.3 years (minimum 1 year, maximum 34 years of lens wear). One patient discontinued the study after 6 weeks due to a change in work and consequently drastic change in the environmental situation 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. 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).

Old lenses:

Concerning the existing lenses patients were wearing: mean comfort of theses was graded as 7.0 ± 1.6 on a 10 point scale. With their existing lenses, 27 patients reported to have some discomfort at some point during the day: 59% ‘sometimes’ followed by ‘often’ (36%) and only 6% reported to never have problems. Of the discomfort problems 68% was reported to occur in the evening, 13% complained of all day long 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 the Comfort O² material lenses was as 8.1±1.0: an increase of 15.7% and a statistically significant difference if favor of the new material ($p<0.001$). If asked specifically, 61% of patients reported the feel the new lenses less than their previous lenses, 33% felt no difference at this point and for 5% the awareness of the lenses was increased with the comfort 0^2 lenses. Mean best corrected visual acuity (BCVA) with the new lenses was

1.1 ± 0.2. Debris on the lens and wettability was evaluated to create a baseline: mean grade of debris found was 0.21 and the mean grade for wettability was 0.43.

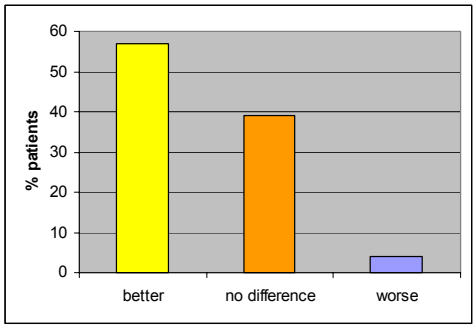
Two weeks:

Comfort at two weeks was reported to be 7.7 ± 1.3: a slight decrease compared to the dispensing data, but statistically significantly ($p<0.001$) higher than the old lenses. The new lenses were preferred by 50% of the patients compared to their old lenses, 39% found no difference and 11% preferred their old lenses. At this point 50% of the patients reported that the lenses were never uncomfortable (compared to 6% with their old lenses), 39% reported to be often uncomfortable and 11% sometimes. Of theses, 83% had these problems in the evening and 17% at variable times during the day). Severity of the discomfort was mild in 66% of the cases, moderate in 22% and severe in 12%: a decrease from the reported discomfort with their old lenses. Evaluation of lens debris gave an average grade of 0.48, a statistically significant increase ($p<0.001$) compared to the baseline debris at dispensing, and grade 0.39 for wettability (also a small but statistically significant increase compared to baseline at dispensing). Staining increased slightly to a mean grade of 0.59 and conjunctival redness increased to grade 0.69.

Eight weeks:

The final and most imported visit was the two months visit. Comfort evaluation of the comfort 0^2 lenses showed a mean grade of 8.1 ± 0.8, almost the same as the comfort at dispensing and again a statistically significant increase in comfort of compared to the old lenses.

At this point 57% said to prefer the comfort 0^2 lenses compared to their old lenses, 39% found no difference and 3.6% reported a decrease in comfort. At eight weeks, 63% reported to have sometimes discomfort during lens wear and 37% never. Time of appearance of the discomfort was still primarily in the evening (80%) followed by 'variable times during the day' (20%). For severity: 70% was reported to be mild, 25% moderate and 5% severe. Debris showed to be grade 0.31 (a statistically significant increase compared to baseline, but slightly less then at two weeks). While at dispensing 83% of the lenses appeared to have no debris buildup at all, at this point 69% of the lenses showed no debris built-up. For wettability, the mean grade stayed the same as at two weeks (0.39), but is still statistically significantly increased compared to baseline. Mean BCVA at this point was 1.1 ± 0.2: equal to the BCVA at dispensing. Corneal staining decreased slightly compared to the two weeks visit (grade 0.55) but still slightly higher than baseline. Redness decreased substantially and is with grade 0.29 lower than the baseline level (0.40). No increase in corneal oedema or CLPC was noted.

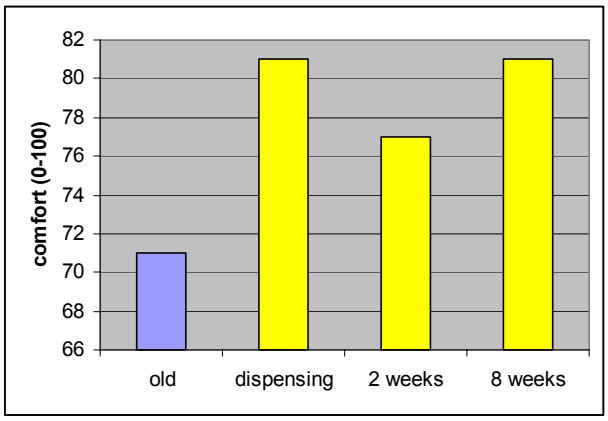


Preference of new lenses over old lenses at two and a half months

DISCUSSION

The aim of this study was to give a good estimate of the potential increase in wearing comfort of a new lens material, described as the comfort 0^2 material. This is not a double-blind/ masked study, with the risk of bias (especially on behalf of the patient since comfort is a subjective measure). However, patients were specifically asked to be objective and are not familiar with the company manufacturing this lens (which does not operate in the Netherlands), meaning that the risk of creating bias might be reduced. Another limitation of this study is that new lenses were ordered and were compared to old lenses. Unfortunately, the magnitude of this study did not allow us to refit the patients first with new lenses of their initial material before changing them to the new lens material, which is considered a disadvantage. On the other hand, the current protocol resembles more the clinical setting in which a practitioner refits the patient with a new lens/lens material and is interested to find out what the potential gain in comfort is with these new lenses made in the new material. Also, quality of lens fit could have influenced the results in a positive or negative way since all lenses were refitted. However, no lenses (either old lenses or new lenses) were allowed to have any grade 2 in tear layer thickness, meaning all lens fits at all times were graded as acceptable and therefore large aberrations in the results from lens fit are unlikely.

Under the given circumstances and limitations, comfort with the comfort 0^2 material was statistically significant improved compared to their old lenses by 15.7% immediately after dispensing of the new lenses and also after two and a half months of lens wear. The relative lower grade for comfort at two weeks is difficult to explain from a clinical standpoint, since overall comfort seemed increased. The so called 'rebound' effect caused by the patients initial positive perception of the new lens could be the cause of this phenomenon. However, comfort was back to the same level at the eight week visit. And in addition to the overall increase in comfort at eight weeks: 57% of patients said they preferred the new lenses, 39% found no significant difference and only 3.6% wanted to go back to their old lenses.



Mean change in comfort of lens wear over time with the old (blue) and new (yellow) material.

Furthermore it should be bore in mind that in some patients the increase in comfort is (much) larger than the 15.7%. For instance, when only patients are isolated who reported to prefer the comfort 0^2 material over their old lenses (57% of all patients), a 26% increase in comfort was gained in this group. For individual cases this can be even higher: in some patients a increase of more than 50% was noted and in one particular patient the increase was even more than 100%.

Grades of corneal staining and conjunctival redness increased slightly at two weeks, but the grades lowered again towards the eight week visit (for conjunctival redness the grade was even lower than the baseline level at that time). The differences are statistically significant, but very small in size which makes the clinical significance questionable. BCVA stayed stable over the course of the study which seems to imply that the material is – at least for two and a half months - stable and does not warp. Debris slightly increased over the test period and wettability slightly increased as well. These findings need long term evaluation in order to make any final conclusions regarding these parameters.

CONCLUSION

In summary: 96% of patients reported a better or the same comfort with the comfort 0^2 lenses compared to their old lenses. A statistically significant increase of 15.7% in comfort was found for the entire group. Whether this is clinically significant as well in addition to statistically significant is to be determined by practitioners, but it should be bore in mind that in some patients the increase in comfort is larger than the 15.7% and of significance to them. The amount of patients reporting severe discomfort decreased from 22% with their old lenses to 5% with the comfort 0^2 lenses and patients reporting moderate discomfort decreased from 40% to 25%. Corneal physiology seemed not altered clinically with the new material, but a larger and longer study is needed to conform this finding.

In conclusion: whether the claim 'RGP silicone hydrogel' in terms of comfort is a realistic one is still open to debate, but an overall increase in comfort can be expected with comfort 0^2 lenses when patients are refitted with good fitted lenses made out of this new material, and more so in specific cases where discomfort is present with currently worn RGP lenses.

For more information contact David Thomas Contact Lenses Limited on +44 (0)1604 646216.

Appendices:

Table 1. *Grading of tear layer thickness.*

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

Example lens fit: