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the dispensing data, but statistically significantly ($p<0.001$) higher than the old lenses. Fifty percent of patients preferred the new lenses compared to their old ones; 39% found no difference and 11% preferred their old lenses. At this point, 50% of patients reported that the lenses were never uncomfortable (compared to 6% with their old lenses); 39% reported they often felt uncomfortable and 11% sometimes. Of these, 83% had these problems in the evening and 17% at various times during the day. Severity of the discomfort was mild in 66% of patients, moderate in 22% and severe in 12% – a decrease from the reported discomfort with their old lenses. Evaluation of lens debris showed an average grade of 0.48 – a statistically significant increase ($p<0.001$) compared to the baseline debris at dispensing, and a grade 0.39 for wettability (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 important visit was after two months. Comfort evaluation of the Comfort $O^2$ 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 compared to old lenses (**Figure 2**).

At this point, 57% of patients said they preferred the Comfort $0^2$ lenses to their old lenses, 39% found no difference and 3.6% reported a decrease in comfort. At eight weeks, 63% reported to have sometimes felt discomfort during lens wear and 37% never. Discomfort remained primarily in the evening (80%) followed by 'variable times during the day' (20%). For severity, 70% reported this to be mild, 25% moderate and 5% severe. Debris was graded 0.31 (a statistically significant increase compared to baseline, but slightly less than at two weeks). At this point, 69% of the lenses showed no debris build-up. For wettability, the mean grade stayed the same as at two weeks (0.39), but was 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 week two visit (grade 0.55) but was still slightly higher than baseline. Redness decreased substantially and was, at grade 0.29, lower than the baseline level (0.40). No increase in corneal oedema or CLPC was noted.

## Discussion

The aim of this study was to estimate the potential increase in wearer comfort of the new lens material, Comfort $O^2$. This was 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 were not familiar with the company manufacturing this lens (which does not operate in the Netherlands). Another unfortunate limitation of this study was that new lenses were ordered and compared to old lenses.

Unfortunately, the size of the study did not allow us to refit the patients first with new lenses of their initial material before changing them to Comfort $O^2$. On the other hand, the current protocol resembled more the clinical setting, in which a practitioner refits the patient with a new lens/lens material and can gauge the potential improvement in comfort.

Also, the 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 or new) 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 were unlikely.

Under the given circumstances and limitations, comfort with Comfort $0^2$ was statistically significantly improved compared to the patients' old lenses – by 15.7% immediately after dispensing and also after 8 weeks of lens wear (**Figure 3**). The relatively lower grade for comfort at two weeks is difficult to explain from a clinical standpoint, since overall comfort seemed to increase. 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 week eight visit. In addition to the overall increase in comfort after eight weeks, 57% of patients said they preferred the new lenses, 39% found no significant difference and only 3.6% wanted to remain in their old lenses.

Furthermore, for some patients the increase in comfort was much greater than 15.7%. In some, an increase of more than 50% was noted and in one particular patient, the increase was over 100%.

Grades of corneal staining and conjunctival redness increased slightly at two weeks, but the grades lowered again towards the week eight 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 8 weeks, stable and does not warp. Debris increased slightly over the test period and wettability decreased. 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 similar, comfort with Comfort $O^2$ 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 is open to debate, but it should be noted that in some patients, the increase in comfort was greater than 15.7%. The number of patients reporting severe discomfort decreased from 22% with their old lenses to 5% with Comfort $0^2$ lenses, and patients reporting moderate discomfort decreased from 40% to 25%. The new material appeared not to alter corneal physiology, but a larger and longer study is needed to confirm this finding.

In conclusion, an overall increase in comfort can be expected with Comfort $0^2$ lenses, especially in patients who experience discomfort with their old RGPs.

## About the author

Eef van der Worp is a lecturer at the Hogeschool van Utrecht in the Netherlands, and has a research position at the University of Maastricht. He is Vice President of IACLE Europe and Chairman of the Cornea and Contact Lens Section of the Dutch Optometric and Contact Lens Association.

Comfort $O^2$ is manufactured by the Lagado Corporation of Englewood Colorado, in the USA, and marketed under the name ONSI-56 (onsifocon A). It has FDA marketing clearance and is available in the UK from David Thomas Contact Lenses.

*Figure 2*
Preference of new lenses over old lenses at two and a half months

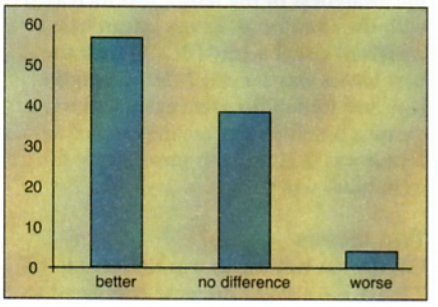


*Figure 3*
Mean comfort grades over time with the old and new material