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Evaluation of the Stability of Surface Water Characteristics of Contact Lenses Using Refractive Index Shifts after Wear of Daily Disposable Lenses

Contact information:
Robert Steffen, OD, MS
Bausch + Lomb
1400 N. Goodman Street, Rochester, NY 14609
Robert.steffen@bausch.com

Robert Steffen OD, MS; Jeffery Schafer OD, MS; Gary Mosehauer MS; Bill Reindel OD, MS, Katarzyna Wygladacz PhD; Steven Seyboth, BS

Introduction

Many factors can influence ocular surface homeostasis while wearing contact lenses. Increased oxygen permeability, a rise in water content, reductions in modulus and lens water retention have been cited as possible contributing factors in maintaining ocular surface homeostasis.[1,2,3] Dehydration resistance and the stability of surface water characteristics are important factors in contact lens performance.

Assessing the surface refractive index provides greater understanding of the moisture and optical characteristics at the lens-air interface. This investigation focused on evaluating the surface stability utilizing refractive index changes over wear time for kalifilcon A, nesofilcon A, delefilcon A and verofilcon A.

Methods

A total of 10 subjects participated in this evaluation. Subjects wore each of the three lens types for 5, 10 and 15 minutes in a randomly assigned fashion. After each wear period, the lens was removed and immediately measured by an operator for surface refractive index with the Metricon M-2010 Prism Coupler (refractive index accuracy of ± 0.0005). To establish baseline surface refractive index values, 10 unworn lenses of each lens type were removed from the original package and measured within 15 seconds. Two-sample t-tests were used to determine any statistically significant differences in surface refractive index between the unworn and worn lenses of each type, at each time point.

The study has obtained IRB approval by INTEGREVIEW IRB. NCT04555031.

Results

There was no meaningful change in the mean surface refractive index after 5, 10 and 15 minutes of wear for kalifilcon A, with means of 1.40 for both the unworn and worn lenses ($p<0.05$ in all cases) and similar to the reported refractive index of 1.401. The change in refractive index from baseline at 5 minutes was 0.00634 for kalifilcon A.

For nesofilcon A, there was no meaningful change in the mean surface refractive index, with means of 1.375 and for the unworn lenses and 1.378 at 5 and 10 minutes of wear and 1.379 after 15 minutes of wear ($p<0.05$ all times) and similar to the reported refractive index of 1.375. The change in refractive index from baseline at 5 minutes was 0.00315 for nesofilcon A.

There was a significant change in the mean surface refractive index for the delefilcon A lenses from 1.34 unworn, a surface refractive index typical of >80% water, to 1.43, 1.43 and 1.42 after 5, 10 and 15 minutes of wear, respectively ($p<0.05$ in all cases). delefilcon A has a reported refractive index of 1.42[4]. The change in refractive index from baseline at 5 minutes was 0.08696 for delefilcon A.

For verofilcon A the mean surface refractive index underwent a significant change from 1.34, also a surface refractive index typical of >80% water, for the unworn lenses to 1.42 after 5, 10 and 15 minutes of wear ($p<0.05$ in all cases). verofilcon A has a reported refractive index of 1.4[5]. The change in refractive index from baseline at 5 minutes was 0.08079 for verofilcon A.

Figure 1: Refractive index shift over 15 minutes of wear.

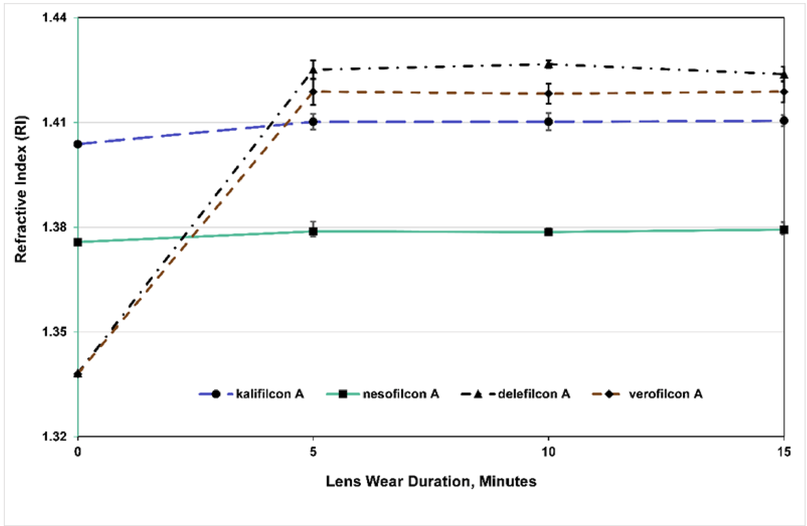

Figure 1 displays a dramatic shift of surface refractive index from very close to water (1.33) for delefilcon A and verofilcon A unworn to similar refractive indexes reported for the base material. The kalifilcon A and nesofilcon A demonstrate stable surface refractive index from unworn to all time points measured.

Figure 2: Refractive index change from baseline over 15 minutes of wear.

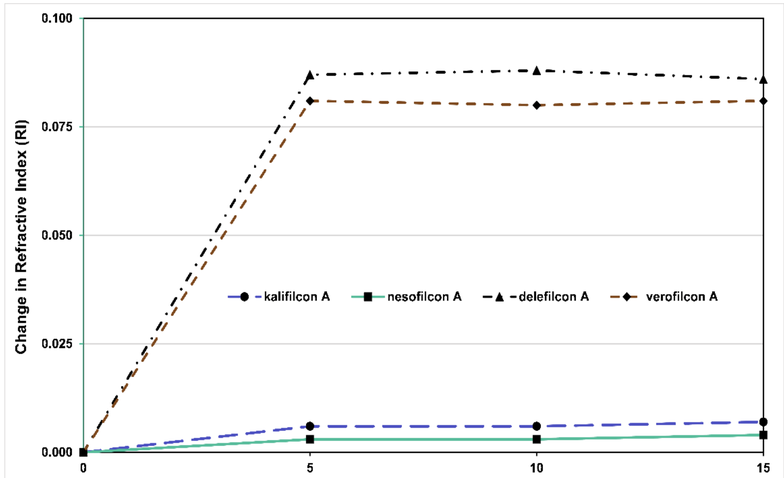

Figure 2 shows the change from baseline of refractive index for delefilcon A and verofilcon A, a log unit greater that the change from baseline for kalifilcon A and nesofilcon A at 5, 10 and 15 minutes.

Conclusion

Changes in surface water characteristics can have an impact on contact lens performance. Lens materials reported to have a high water-gradient at the lens surface (delefilcon A, verofilcon A) rapidly underwent a change in refractive index following insertion. It is unlikely that the water gradient[6] can significantly impact performance given that it is present for 5 minutes or less. Lens materials reported to have consistent water content throughout the lens (kalifilcon A, nesofilcon A) maintained a consistent refractive index following insertion and can have a favorable impact on performance.

References

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