Introduction

The landmark CLI study of 1989 identified the occurrence of microbial keratitis (MK) as 4 in 10,000 for DW and 21 in 10,000 for EW, respectively. These studies ranged in length from 2 weeks to 12 months, for a cumulative duration of 1.38 months (11.5 years), and provide over 2,200 patient-years of data and experience. Seven studies, including more than 2,100 patients, were 12 months in duration. There were no reports of MK or other serious sight-threatening adverse events. Other clinical signs were within expected norms.

Results

Nearly 4,800 patients completed 27 extended wear studies. These studies ranged in length from 2 weeks to 12 months, for a cumulative duration of 1.38 months (11.5 years), and provide over 2,200 patient-years of data and experience. Seven studies, including more than 2,100 patients, were 12 months in duration. There were no reports of MK or other serious sight-threatening adverse events. Other clinical signs were within expected norms.

Discussion

Improving the safety profile of an extended wear contact lens, may be defined by the significant reduction, or elimination of the incidence of serious sight-threatening adverse events (e.g. MK). It is widely recognized that improving the oxygen penetration of soft lenses will not, by itself, eradicate MK. Hypoxia, is, however, considered to be a significant factor contributing to the appropriate conditions for infectious keratitis. Minimizing hypoxia, therefore, should reduce the potential for MK.

Overnight corneal swelling:

Previous reports have shown that, relative to conventional hydrogel EW materials, lenses manufactured from balafilcon A cause less corneal swelling (see Figure 1). Indeed, levels of overnight corneal swelling with PureVision lenses is equivalent to wearing no lenses.

Bacterial binding:

Another important finding is that continuous wear of ultra-high Dk/t silicone hydrogel lenses has demonstrated reduced bacterial binding to epithelial cells compared to conventional hydrogel extended wear lenses (see Figure 2). Both of these factors, hypoxia and bacterial binding, typically considered risk factors to developing a serious sight-threatening adverse event such as MK, have been eliminated, or significantly reduced with PureVision lenses.

Cumulative clinical experience:

The results of this analysis yielded no reported cases of microbial keratitis in 2,210 patient-years of experience. This suggests that the incidence of MK in overnight wear of PureVision lenses may be significantly less than that reported in the landmark Contact Lens Institute (CLI) study. While an accurate figure of MK incidence will not be established until such time there is extensive data from both clinical trials and market experience, based on the conclusion of the CLI study, and on the number of patient-years (>2,200) accumulated in our extended wear clinical trials, one would have expected to observe up to five events of MK.

With more than 200,000 PureVision wearers worldwide, if all events occurred in the same year, the incident rate would be 0.015%. To gain a conservative estimate of incident rate, assuming a number of events go unreported, the above rate, if multiplied by a factor of 10, only equals 0.015%. In comparison to the rates calculated from the results of the CLI study (0.21% for extended wear and 0.04% for daily wear), it appears that the incident rate of MK for PureVision lenses, utilized in all modalities, is tracking dramatically lower.

Conclusion

Silicone hydrogel technology is a significant step forward for the soft contact lens industry. The cumulative experience of Bausch & Lomb’s Clinical Research suggests that the incidence of microbial keratitis will be less than that reported in the landmark CLI study of conventional hydrogel lenses. As such, practitioners may be confident with respect to the safety of this new generation of soft contact lenses for continuous wear.

References

5. Dk/t for −3.00D lens based on polarographic method: non-edge corrected

BAUSCH & LOMB

Cumulative Experience of Extended Wear Clinical Trials of a Silicone Hydrogel Contact Lens

FR Edmunds, OD, FAAO, TL Comstock, OD, MS, FAAO, TA Crescduino, BA, WT Reindel, OD, MS

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