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Purpose: Substantial microbial bioburden on contact lenses during extended wear and lid margins during daily wear have shown to be risk factors for the development of contact lens associated corneal inflammatory events (CIEs). This study assessed risk factors associated with substantial microbial bioburden of lids, cases, and silicone hydrogel contact lenses when worn daily wear Methods: 218 patients were enrolled in the Daily Wear Corneal Infiltrative Event study, fit to lotrafilcon A contact lenses, randomized to use either a preserved multipurpose solution (MPS) or a peroxide care system, and followed for 1 year. Lenses, lids, cases and transport saline were cultured at selected visits and considered to have substantial microbial bioburden when they harbored high levels of commensal or pathogenic organisms based on established criteria. Univariate and multivariate logistic regression analyses were conducted at the person level to examine which demographic and solution covariates were associated with significant bioburden at each

Results: Univariate analyses revealed current or past smokers (vs. never-smokers), clerical occupations, and solution type were associated with a greater risk of microbial bioburden on lenses, cases, or both. Neither gender, age, nor healthcare occupations were associated with significant bioburden in any of the locations examined; additionally, neither solution type nor other demographic factors were associated with lid bioburden or saline contamination. In multivariate analyses, clerical (vs. non-clerical) occupations had significantly greater risk of microbial contamination on lenses (OR = 2.7 (95% Confidence Interval (CI) 1.04-6.8)) and cases (OR = 3.4(95% CI 1.14-10.0)). Solution type was associated with microbial bioburden in cases (adjusted OR for the peroxide system = 7.5 (95% CI 3.8-15.1)) but not on lenses, lids or transport saline Conclusions: Clerical occupations were associated with increased microbial bioburden of contact lenses and cases during daily wear use of silicone hydrogel lenses. Although a hydrogen peroxide care solution (compared to a MPS) was associated with increased lens case bioburden, this association was not found with bioburden on lids, lenses, or in transport saline and case contamination was not a risk factor for CIEs in this study

Commercial Relationships: Ying Jiang, Alcon (F), Vistakon (F); Michael Jacobs, Alcon (F), Vistakon (F); Saralee Bajaksouzian, None; Altreisha N. Foster, None; Sara M. Debanne, None; Roger Bielefeld, None; Matt Garvey, None; Sangeetha Raghupathy BSOptom, None; Jami R. Kern, Alcon (E); Loretta B. Szczotka-Flynn, Alcon Laboratories (F), Alcon Laboratories (R), Vistakon (F), Bausch & Lomb (R)

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Program Number: 5480 Poster Board Number: A0179

Presentation Time: 8:30 AM - 10:15 AM

An Examination of the Effects of Evaporation on Antimicrobial

Efficacy of Contact Lens Care Solutions

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<u>Purpose:</u> Partial evaporation of contact lens care solutions, as can occur from failure to cap the contact lens case as directed, may result in loss of antimicrobial efficacy of the solution and lead to contact lens-related eye infections. This study evaluated the impact of partial evaporation on the antimicrobial efficacy of several contact lens care solutions when tested according to ISO 14729.

Methods: The solutions studied were - Investigational MPS-1: polyhexamethylene biguanide (PHMB) + poloxamer (PLX) and currently marketed Japan products MPS-2: polyquaternium (PQ1) + tetronic 1304 MPS-3: PHMB + poloxamine (PLA) and MPS-4: PHMB + PLX.

Solutions were evaporated under a stream of air to 2x and 4x concentrations and challenged with Pseudomonas aeruginosa (ATCC 9027), Serratia marcescens (ATCC 13880), Staphylococcus aureus (ATCC 6538), Candida albicans (ATCC 10231) and Fusarium solani (ATCC 36031). The assay was performed according to the standalone test outlined in ISO 14729:2001/A.2010. The test solutions were evaluated at 4 hours and compared to the non-evaporated product. The solutions were assessed for their ability to meet the criteria of 3 log reduction of the bacteria and 1 log reduction of fungi at the minimum time interval.

Results: After 4 hrs of inocula exposure, Investigational MPS-1 met criteria when non-evaporated and at the 2X and 4x evaporation level. MPS-2 failed to meet criteria when non-evaporated (for S. aureus and Candida) and also failed at the 2x and 4x levels (for S. marcescens, S. aureus, Candida and Fusarium). MPS-3 met criteria when non-evaporated and 2x level but failed criteria at 4x (for Candida). MPS-4 failed to meet criteria when non-evaporated (for S. aureus and Candida) and also failed criteria at the 2x and 4x (for S. marcescens, S. aureus and Candida).

Conclusions: The study demonstrates that, after partial evaporation up to 4X, modelling the potential error of not capping a lens case correctly, MPS solutions can lose significant disinfection activity. The solutions that failed to meet stand-alone criteria when non-evaporated showed more pronounced loss after evaporation. Of the solutions tested, only MPS-1 retained its full efficacy of stand-alone disinfection activity after being evaporated to a 4x level.

Commercial Relationships: Nancy Brady, Abbott Medical Optics (E); Marina Milenkovic, Abbott Medical Optics (E); Anthony Lam, Abbott Medical Optics (E)

Program Number: 5481 Poster Board Number: A0180 Presentation Time: 8:30 AM - 10:15 AM Evaluation of an auto-refractor for over-refraction with

multifocal contact lenses patients

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<u>Purpose:</u> To evaluate the utility of an auto-refractor for multifocal contact lenses over-refraction

Methods: Non-cyclopegic distance refractive error was measured in patients wearing multifocal contact lenses by means of the Grand Seiko Auto Ref/Keratometer WAM-5500 auto-refractometer and compared with subjective measurements. Three commercial multifocal contact lenses were evaluated: Air Optix Multifocal, Ciba Vision (refractive bi-aspheric lens with near vision in the centre), Proclear Multifocal, CooperVision (refractive lens with aspheric centre with near vision in it), Acuvue Oasys Multifocal, Johnson & Johnson (refractive lens with a multicurve design). 30 eyes of 15 healthy adults were measured in the study, with a mean ± SD in age

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of 27.67 ± 1.86 years (range: 25 to 30 years), subjective spherical refraction of -2.43 ± 3.56 D (+2.50 to -9.50 D), subjective astigmatic refraction of -0.48 ± 0.44 D (0 to -1.25 D), best corrected visual acuity in the logMAR scale of -0.21 ± 0.07 (-0.1 to -0.34). The results of over-refraction were evaluated in terms of M, J0 and J45. Results: The mean difference between auto-refractometer and subjective spherical over-refraction was $0.52 \pm 0.37D$ (range: ± 1.08 to +0.02D) for the Air Optix lens, 0.62 ± 0.43 D (range: +0.94 to $\pm 0.32D$) for the Proclear lens and $\pm 0.15 \pm 0.11D$ (range: ± 0.07 to ± 0.07) to 0.46D) for the Acuvue Oasys lens. The mean differences in astigmatic over-refraction in terms of J0 and J45 were -0.04 \pm 0.03D (range: ± 0.32 to ± 0.55) and ± 0.04 D (range: ± 0.15 to ± 0.31 D) for the Air Optix lens, $0.17 \pm 0.07D$ (range: ± 0.22 to $\pm 0.12D$) and 0.05 ± 0.04 D (range: ± 0.42 to ± 0.33 D) for the Proclear lens and ± 0.23 \pm 0.17D (range: +0.03 to -0.50D) and -0.05 \pm 0.03D (range: +0.17 to -0.29D) for the Acuvue Oasys lens.

Conclusions: We have measured the over-refraction in multi focal contact lenses users with an auto-refractometer and compared with subjective over-refraction. The results from our measurements highlighted a good agreement between subjective and objective values in both spherical and cylindrical refractions, although some discrepancies were found on patients with high refractive errors. Thus, we can conclude that auto-refractor is an useful tool for over-refraction in patients wearing multifocal contact lenses although care must be taken in highly myopic or hyperopic users.

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Program Number: 5482 Poster Board Number: A0181 Presentation Time: 8:30 AM - 10:15 AM

Evaluation of the effect of soft contact lens edge shape on conjunctival epithelium

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Purpose: To characterize soft contact lens edge profile effect on conjunctival epithelium using optical coherence tomography. Methods: Nine regular contact lens wearers were included in the study. 4 types of soft contact lenses were considered (3 monthly, 1 fortnightly, power ranged from -0.5 to -5.0D.). Subjects simultaneously wore two types of lenses (eyes were randomized). A week break was set between the 1st and the 2nd pair. All lenses evidenced acceptable fit. The inferior limbus area was imaged by SOCT Copernicus 40 minutes after lens application and after 2 weeks of daily wear. A novel method of differential analysis, overcoming problems associated with optical distortions, was applied to acquired images to evaluate the effect of contact lens edge shape on conjunctival epithelium. In particular, the difference in conjunctival deformation angle $(\Delta\theta)$ and the difference in the normalized contact lens imprint area (\Delta S) were chosen for the statistical analyses which included standard descriptive statistics and the two-sided rank sum test for medians (Wilcoxon).

Results: The largest difference in conjunctival topography between visits was experienced in SiHy lens with a round edge profile (group average±SD and median for $\Delta\theta$: 21.1±8.4° and 18.7° and for Δ S: 7.0±2.4% and 5.4%). The Si-Hy lens with two-sided edge profile resulted in $\Delta\theta$: 10.8±1.1°, Δ S: 3.6±4.6%; and medians of 9.8° and 5.4%, respectively. The smallest difference in the conjunctival deformation angle was observed in Si-Hy angle edged lens ($\Delta\theta$:

 $0.2\pm3.1^\circ; 3.0^\circ, \Delta S: 2.3\pm3.8\%; 5.3\%)$ while the difference in the normalized contact lens imprint area was negative (showing improvement) in Hy round edged lens ($\Delta\theta: 7.4\pm5.8^\circ; 0.2^\circ, \Delta S: -6.7\pm4.2\%; -9.0\%)$. Statistically significant differences in $\Delta\theta$ were achieved between angle edged and round edged Si-Hy lenses (p=0.046), and angle edged and two-sided edged lenses (p=0.001). ΔS showed significant difference between round edged Si-Hy and Hy lens (p=0.021).

<u>Conclusions:</u> The study indicates that the soft contact lens edge shape plays little role in the presumable conjunctival epithelium imprint and suggests that other lens parameters, such as the material properties, may play a more significant role in this phenomenon.

Commercial Relationships: Dorota H. Szczesna-Iskander, None; D Robert Iskander, Eaglet Eye (F), Eaglet Eye (I)

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Presentation Time: 8:30 AM - 10:15 AM

The Cause of Midday Visual Fogging in Scleral Gas Permeable Lens Wearers

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<u>Purpose</u>: Scleral gas permeable contact lens (SGP) patients may report midday foggy vision, necessitating lens removal. The present study attempts to determine causative factors.

Methods: Fifteen SGP wearers were enrolled after obtaining informed consent and divided into two groups - those able to wear lenses 8 hours per day or more (uninterrupted) and those that have to remove lenses temporarily before 8 hours (interrupted). The Texas Eye Research and Technology Center Dry Eye Questionnaire (DEQ) was completed and lens fit was assessed with biomicroscopy and Visante OCT imaging. Tear exchange was measured using a fluorophotometer (Ocumetrics FM-2 Fluorotron). Two microliters of high molecular weight fluorescein (FITC Dextran) was added to the lens bowl and then carefully inserted. Fluorescence was measured immediately and every 10 minutes for 1 hour. The amount of fluorescein present after 60 minutes (T60) was compared between patients.

Results: Of the 15 patients, 5 (33%) were interrupted wearers averaging 4.45 hours. Wearing time for uninterrupted patients (67%) averaged 11.75 hours. Uninterrupted wearers had an average DEQ score of 28±22 while the interrupted wearer's averaged 54±11. There was a moderate correlation between DEQ scores and average daily wear times (r = -0.528). Sixty percent of both groups exhibited an alignment fit. However, 80% of interrupted wearers exhibited a tight fitting edge compared to 40% of uninterrupted wearers. The average corneal vault for uninterrupted lens wearers was 0.29±0.24 mm while interrupted wearers averaged 0.71±0.44 mm. There was a moderate correlation between corneal vault and average daily wear times (r = 0.509). Fluorophotometry was conducted on 12 of the 15 patients. All patients had residual fluorescein remaining in the post-lens tear film. The T60 for the uninterrupted wearers was slightly lower than in the interrupted wearers (0.6671; 0.7539; p=0.23). However, the tear exchange decay rate was not statistically different.

Conclusions: Foggy vision, occurring in 33% of SGP lens wearers in this study, is a multifactorial phenomenon unique to these devices. Important factors include a predisposition to dry eye and significantly greater central corneal vault combined with lens edge tightness. This study documents, for the first time, post lens tear exchange in SGP lens wearers. Foggy vision is best countered by reassessment of lens edge fit and adjusting corneal vault.

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