

554 Contact Lens I

Thursday, May 5, 2011, 11:15 AM - 1:00 PM

Hall B/C Poster Session

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Organizing Section: Cornea

Program Number: 6473 Poster Board Number: D937

Presentation Time: 11:15 AM - 1:00 PM

Corneal Topographic Changes During Continuous Silicone Hydrogel Contact Lens Wear

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Purpose: To assess whether continuous wear (CW) with silicone hydrogel (SH) lotrafilcon A contact lenses induces changes in Orbscan II-derived corneal topographic indices.

Methods: Subjects were fitted with lotrafilcon A lenses for monthly CW and observed for 1 year. Orbscan II measurements of right eyes were taken at baseline, and after 1 week (n=151), 1 month (n=151), and 1 year (n=85) of wear. Slit images were reprocessed using a beta version (v 3.12) edge tracker software and the following indices were evaluated: anterior steep and flat simulated keratometry (simK), posterior corneal best fit sphere, posterior corneal elevation, and pachymetry at the thinnest 0.5mm corneal spot. Paired T-tests were utilized stratified by type of contact lens worn at study entry.

Results: No changes were noted in posterior corneal indices or pachymetry over time. For the entire cohort, significant changes were noted for anterior steep and flat simK values after 1 week of CW. Average steep simK flattened by 0.20 D (p=0.0016, range -4.14 to +2.79 D), 0.27 D (p<0.0001, range -4.11 to +2.82 D), and 0.29 D (p=0.003, range -5.12 to +1.78 D), after 1 week, 1 month and 1 year, respectively. Stratified by pre-study contact lens use, neophytes (n=47) showed no simK changes over time; SH lens wearers (n=24) showed the greatest amount of corneal flattening of 0.44 D, 0.38 D, and 0.59 D after 1 week, 1 month and 1 year, respectively (p<0.007); and low Dk lens users (n=71) had significant flattening at all time points of 0.21 D, 0.35 D and 0.30 D after 1 week, 1 month, and 1 year respectively, (p<0.039) and the greatest variability of all groups (range -5.12 D to +2.87 D).

Conclusions: CW of lotrafilcon A lenses did not alter the thinnest pachymetry, posterior corneal elevation or posterior best fit sphere in this sample. Subjects switching from low Dk lenses had the greatest variation in simK values, but subjects switching from other SH lens types had the greatest amount of average corneal flattening. These findings are valuable for clinicians when monitoring patients for refractive shifts during SH contact lens CW.

Commercial Relationships: Scott W. Yeates, None; Loretta B. Szczołka-Flynn, Alcon Laboratories (F, R), Baush & Lomb (R), Ciba Vision (F), InSpire (R), Menicon (R), Vistakon (R); Ashraf M. Mahmoud, None; Cynthia J. Roberts, None

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Clinical Trial: <http://www.clinicaltrials.gov>, nct00727402

Program Number: 6474 Poster Board Number: D938

Presentation Time: 11:15 AM - 1:00 PM

Antimicrobial Profile and Cleaning Efficacy of a H2O2 Test Solution

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Purpose: To investigate the antimicrobial and cleaning properties of a test H2O2 contact lens disinfecting system designed to prevent microbial growth after neutralization for extended time.

Methods: The antimicrobial efficacy of the test solution was evaluated against *Acanthamoeba castellanii*, *A. Polyphaga*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Candida albicans*, *Aspergillus niger* and *Fusarium solani*. Conventional and novel microbiological test included Stand-alone, Contact Lens Disinfection studies (Regimen), Preservative Efficacy Testing (PET), Stasis studies, Encystment studies as well as the newly designed Latency studies. Lysozyme cleaning efficacy of the test solution and two H2O2 solution controls (ClearCare® and Oxyssept®) was assessed on Acuvue® 2 lenses.

Results: After six hours of disinfection time, the new test solution showed more than 2 log kill against cysts of *A. castellanii* and *A. polyphaga* and caused no Encystment (<1%) for the trophozoites of these species. Stand-alone studies showed more than 12 log "combined" reductions for all three bacteria and more than 6 log "combined" reductions for both fungi. The regimen results for bacterial, fungal and *Acanthamoeba* spp. showed <10 cfu/lens after soaking for six hours in this new solution after application of the recommended cleaning steps. The results of Latency studies showed no growth after neutralization cycle for up to 35 days in the basket lens cases after a re-challenge at day 7. Lysozyme cleaning efficacy of the test solution was 18.0 ± 6.2% which was statistically lower than that of ClearCare® (32.7 ± 5.0%), but statistically greater than that of Oxyssept® (10.0 ± 3.6%).

Conclusions: In addition to the H2O2 test solution possessing antibacterial,

antifungal and antiameobal properties, we have demonstrated it to possess latency properties through various microbiological methodologies. Lysozyme cleaning efficacy was also demonstrated, which in the absence of surfactant was shown to function through an ion-exchange mechanism.

Commercial Relationships: Megan R. Callan, Alcon (E); Guimel Kappell, Alcon (E); Cindy McAnally, Alcon (E); Rhonda Walters, Alcon (E); Alyson Allen, Alcon (E); Linda McNamee, Alcon (E); Helen Trinh, Alcon (E); Peggy Stauffer, Alcon (E); Roya N. Borazjani, Alcon (E)
Support: None

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Presentation Time: 11:15 AM - 1:00 PM

Non-invasive High Resolution Imaging And Objective Quantification Of

Contact Lens Wettability

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Purpose: The purpose of this study was to develop a non-invasive, in vivo, high resolution, objectively quantifiable method of SCL wettability assessment using a standard slit lamp biomicroscope with minor alterations that could be employed in clinical practice or clinical trial settings.

Methods: A slit-lamp microscope was modified to emit only infrared illumination (to maximize the pupil size), the tear film over the SCL was imaged using a combination of specular reflection (SR) and retroillumination (RI) and was videotaped using a Point-grey (Point Grey Research, Richmond, BC, Ca) high resolution camera. The system was tested on 10 SCL wearing subjects who kept one eye open as long as possible while real time contrast sensitivity (CS) was simultaneously measured through a beam splitter. Four frames from each trial (spaced equally across the time of data capture) were selected and graded using the Contact Lens Evaluation of Wettability (CLEW) scale. Two quantitative SCL wettability analyses, tear break-up edge pixels (EP) and Purkinje size (PS) were calculated with custom MATLAB programs.

Results: The technique provided high resolution dynamic imaging of tear break-up over the SCL within the pupil. Changes in CLEW grades were significantly correlated with EP and CS (r=0.74, 0.64, Spearman's rho, p<0.05), but not with PS (r=0.053). The relative changes in EP within each trial increased with CLEW grade (AVG±SD); Grade 1 (571±420), Grade 2 (1063±492), Grade 3 (1369±295), Grade 4 (3034±165), with significant differences in EP between all grades except 2 and 3; the relative change in CS increased with CLEW grade (AVG±SD); Grade 1 (0.19±0.17), Grade 2 (0.42±0.32), Grade 3 (0.31±0.39), Grade 4 (0.93±0.02), with significant differences between grade 4 and others (p<0.05, ANOVA with Bonferroni post hoc).

Conclusions: This novel imaging technique provides high resolution, objectively quantifiable images of SCL wettability over the pupil that show a high correlation with visual function (CS). The method involves minor modification of a standard slit lamp biomicroscope and thus can be easily adapted and developed for a non-invasive assessment of the SCL or corneal surface in a clinical trial setting.

Commercial Relationships: Haixia Liu, None; Carolyn G. Begley, None; Trefford Simpson, None; Jun Zhang, None; Meredith E. Jansen, None; Nikole Himebaugh, None; Ziwei Wu, None; Pete S. Kollbaum, None
Support: None

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Presentation Time: 11:15 AM - 1:00 PM

Differential Distribution of Corneal and Conjunctival Staining in Contact Lens Wearers and Non Wearers

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Purpose: Evaluation of ocular surface integrity involves the grading of the corneal staining with sodium fluorescein and of the conjunctival staining with lissamine green. The data is usually reported as the severity of the staining observed without information as to its geographic distribution. Increased staining is postulated to be associated with contact lens wear. The aim of the current investigation was to quantify in a large population of non wearers and contact lens wearers who attended OTG R&C clinic the prevalence and geographic distribution of staining and its association with contact lens wear.

Methods: The study population of 270 consecutive patients (116 Male, 154 Female) age 18 to 66 years included non contact lens wearers (NonCL)(n=128) and contact lens wearers (CL)(n=142). Conjunctival staining with lissamine green dye was rated subjectively on a 5 point scale (0= None 4 = Severe) for each quadrant independently. Corneal staining using sodium fluorescein dye was reported on a 10 point scale (0= None, 1-3 = Micropunctate, 4-5 = Macropunctate, 7-9= patch) in each of the five corneal zones.

Results: The results obtained showed that:

- Corneal staining was more frequent in CL (Prevalence: 79%) than in NonCL (Prevalence: 54%) (p<0.001).
- For the NonCL group, corneal staining was present in less than 18% of eyes in all zones except in the inferior (Prevalence: 45%).
- For the CL group, corneal staining in the central, nasal and temporal zones was

similar and present in approximately 20% of cases. Staining was maximal in the inferior (Prevalence: 56%) and superior zones (Prevalence: 47%).
iv. Conjunctival staining prevalence was similar to that of corneal staining for both groups and again greater in the CL (73%) than NonCL (51%) group ($p < 0.001$)
v. Conjunctival staining was lowest in the superior (CL 5% NonCL 3%) and inferior quadrants (CL 13% NonCL 7%) and significantly greater in the temporal (CL 47% NonCL 28%) and nasal (CL 67% NonCL 43%) quadrants.

vi. For the CL group, there was no correlation between corneal and conjunctival staining ($p = 0.102$). For the NonCL group, the correlation between corneal and conjunctival was of low clinical predictability ($p < 0.001$ $r^2 = 0.077$).

Conclusions: The study confirmed the greater prevalence of both corneal and conjunctival staining in contact lens wearers than non wearers. Further it revealed a different geographic distribution, maximal staining occurrence being observed in the inferior zone for the cornea and in both the temporal and nasal regions for the conjunctiva.

Commercial Relationships: Cecile A. Maissa, None; Michel Guillon,

None; Stephanie Wong, None

Support: None

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Presentation Time: 11:15 AM - 1:00 PM

The Effect of Silver-Infused Silicone Hydrogel Contact Lenses on the Ocular Biota During Daily Wear

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Purpose: Silver-infused contact lenses (CLs) may provide benefits to CL wearers by reducing adherence of potential pathogens to CL surfaces; however, they have the potential to modify the normal ocular biota during CL wear. This study investigated the effect of silver-infused silicone hydrogel CLs on conjunctival flora over six months of daily wear.

Methods: A prospective, randomised, double-masked, contralateral study was conducted. Sixty subjects were randomly assigned to wear silver-infused (galyfilcon A with incorporated silver ions, test) and standard (galyfilcon A, control) silicone hydrogel CLs on a contralateral basis for six months of daily wear. Prior to assignment of the test and control CLs, all subjects were fitted with etafilcon A daily disposable CLs for a one week wear-in period. Conjunctival flora were cultured at screening/pre-baseline (with subjects' habitual CLs), baseline (after daily disposable wear) and four weeks, three and six months following commencement of test and control CL wear, using sterile calcium alginate swabs moistened with sterile unpreserved 0.9% saline.

Results: There were no statistically significant differences between the conjunctivae of test and control eyes in the incidence of positive cultures ($p > 0.05$), culture classification grades ($p > 0.05$), levels of microorganisms ($p > 0.05$) or the numbers of different types of microorganisms isolated ($p > 0.05$). Wear of the test CLs did not promote any fungal or yeast colonisation of the conjunctivae. The microorganisms most frequently isolated from the conjunctivae were Gram-positive bacteria considered to be part of the normal ocular flora, including *Coagulase-negative Staphylococci*, *Propionibacterium* spp, *Corynebacterium* spp, and *Micrococcus* spp.

Conclusions: Wear of the silver-infused CLs did not result in any statistically or clinically significant alterations to the ocular biota over six months of daily wear.

Commercial Relationships: Carol Lakkis, Alcon, AMO, B&L, CooperVision, Essilor, Vistakon (C), Vistakon (F, E, R); Frank Anastasopoulos, Vistakon (F); Jared Slater, Vistakon (F); Lauren May, Vistakon (E)

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Presentation Time: 11:15 AM - 1:00 PM

Application of Activated Protein C in Reducing Soft Contact Lens Associated Fungal Biofilms

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Purpose: Fibrin is a key component of biofilms acting as a conditioning layer or matrix during biofilm development. Activated Protein C (APC) is a potent physiologic anticoagulant with profibrinolytic properties. This study assessed the activity of APC against soft contact lens associated fungal biofilms using an in-vitro established soft contact lens fungal biofilm model.

Methods: *Fusarium solani* 6914 and *Fusarium oxysporum* 8996 were incubated with three different types of worn contact lenses (lotrafilcon A, balafilcon A, and etafilcon A) from three different subjects under conditions that facilitate biofilm formation. Both strains were obtained from patients with fungal keratitis. Biofilm was quantified using a tetrazolium XTT [2,3-bis (2-methoxy-4-nitro-5-sulphophenyl)-2H-tetrazolium -5-carboxanilide] assay. Susceptibilities of the fungal biofilm growth phases to 25 ug/ml of APC solution were assessed under two separate conditions: when the APC solution was added during the adhesion phase of biofilm development or after 48 hours of mature biofilm formation.

Results: APC was not effective against *F. solani* biofilm formation when added during the adhesion phase. However, when added after mature biofilm had been formed, APC significantly reduced *F. solani* biofilm activity by 69%, 72%, and 81% for etafilcon A, lotrafilcon A, and balafilcon A lenses, respectively, compared to phosphate buffered saline-soaked worn-lens controls ($p < 0.05$). *F. oxysporum* biofilm activity was reduced by 26%, 1%, and 1% on etafilcon A, lotrafilcon A, and balafilcon A lenses, respectively, compared to phosphate buffered saline-soaked worn-lens controls.

Conclusions: APC has potent antifungal activity against a *F. solani* soft contact associated biofilm using an XTT-based metabolic activity assay. There is variability in its effect as it was ineffective against *F. oxysporum* or when added prior to mature biofilm development. Nevertheless, further study is warranted as APC is an agent that may have novel anti-biofilm activity and it has potential to be used in combination with contact lens disinfecting products to reduce contact lens associated biofilms.

Commercial Relationships: Loretta B. Szczołka-Flynn, Alcon (F), Alcon, Bausch & Lomb, Vistakon (R); Mauricio Returcico, Alcon (F); Donghai Ho, None; Thomas Steinemann, None; Mahmoud Ghannoum, Alcon (F)

Support: Prevent Blindness America

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Radiochemical Kinetic Uptake of Three Lipids on Silicone Hydrogel and Conventional Hydrogel Contact Lens Materials

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Purpose: To analyze the *in vitro* kinetic uptake of radiolabelled cholesterol, triolein and phosphatidyl choline on silicone hydrogel (SH) and polyHEMA-based conventional hydrogel (CH) contact lens materials.

Methods: Four SH (PureVision®, balafilcon A [PV]; Air OPTIX®, lotrafilcon B [AOP]; Biofinity®, comfilcon A [Bio]; Acuvue OASYS®, senofilcon A [AvO]) and two CH (Acuvue 2®, etafilcon A [AV2] and ProClear®, omafilcon A [PC]) contact lens materials were incubated in a complex artificial tear solution (ATS) containing six common tear film lipids, proteins, mucin, salts and a trace amount of one of the radioactive lipids; ¹⁴C-cholesterol, ¹⁴C-triolein, or ¹⁴C-phosphatidylcholine. Lenses (n=4) were incubated for different durations: 1 day, 3 days, 7 days, 14 days and 28 to mimic wear patterns. Following incubation, each lens was extracted twice in 2mL of 2 chloroform: 1 methanol for three hours, evaporated under nitrogen, re-suspended in chloroform then scintillation cocktail. Extracts were counted in a LS6500 Beckman Coulter beta counter and raw data was translated into absolute amounts (µg/lens) via extrapolation from standard curves run for each of the test lipids.

Results: All three radioactive lipids showed continuous and accumulating lipid uptake throughout the 28 days of incubation. SH deposited statistically more lipid than CH lens materials and each of the three radioactive lipids had statistically significant repeated measures ANOVAs with $p < 0.001$. For ¹⁴C-cholesterol, the deposition order was: PV>AvO>Bio>AOP>PC>AV2 with PV depositing 3.14 ± 0.15 µg/lens and AV2 depositing 0.05 ± 0.003 µg/lens after 28 days. For ¹⁴C-triolein, the deposition order was: PV>AvO>AOP>Bio>AV2>PC with PV depositing 4.29 ± 0.67 µg/lens and PC depositing 0.53 ± 0.03 µg/lens after 28 days. For ¹⁴C-phosphatidylcholine, the deposition order was: AOP>PV>Bio>AvO>AV2=PC with AOP depositing 1.09 ± 0.08 µg/lens and AV2 and PC depositing 0.12 ± 0.004 µg/lens after 28 days.

Conclusions: This study demonstrated that cholesterol, triolein and phosphatidylcholine deposition was cumulative up to 28 days of incubation without a plateau. SH lens materials deposited significantly more than CH. In general, PV lenses accumulated the most lipid, with triolein.

Commercial Relationships: Holly I. Lorentz, None; Hendrik Walther, None; Miriam L. Heynen, None; Lise Kay, None; Lyndon W. Jones, None
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Presentation Time: 11:15 AM - 1:00 PM

Contact Lens Storage Case Hygiene Practice and Case Contamination

Ajay Kumar Vijay¹, Hua Zhu^{1,2}, Mark Willcox^{1,2}, Fiona Stapleton^{1,2}, Roya N. Borazjani³. ¹Brien Holden Vision Institute, Sydney, Australia; ²School of Optometry and Vision Science, University of New South Wales, Sydney, Australia; ³R&D, Alcon Labs, Fort Worth, TX.

Purpose: Persistent microbial contamination of contact lens (CL) storage cases is common and is associated with microbial keratitis and corneal infiltrates. This study investigated the ability of storage case care and cleaning regimens to remove robust microbial biofilms.

Methods: Test storage cases were inoculated with 2mL of 10⁶ CFU/mL of ocular isolates of either *P. aeruginosa* or *S. aureus* and incubated for 48 hours. Cases were subsequently treated with either a 10 second rinse (hot water or test multipurpose solution (MPS, containing polyhexamethyl biguanide and polyquid), soaking (MPS or 3% hydrogen peroxide), followed by air-drying for 6 hours or tissue wiping. The number of survivors were enumerated using standard techniques.

Results: Challenge biofilms comprised 8.3 ± 0.2 log CFU (*P. aeruginosa*) and 6.5 ± 0.2 log CFU (*S. aureus*). Rinsing with MPS or hot water and air-drying cases

had no significant effect on *S.aureus* biofilms and partially removed *P.aeruginosa* biofilms (3.2-6.8 log CFU survivors). Soaking in MPS for 4 hours caused no reduction of biofilm whereas hydrogen peroxide partially removed biofilms (6.1±0.7 log CFU survivors *P.aeruginosa*; 1.2±2.1 log CFU *S.aureus*). Rinsing or soaking cases with MPS, tissue wiping and air-drying showed the greatest reduction in biofilm (0.9±0.2 log CFU survivors *P.aeruginosa*; 3.4±1.2 log CFU *S.aureus*).

Conclusions: Biofilms formed by the *S.aureus* isolate were more resistant to hygiene procedures than those of the *P.aeruginosa* isolate. Rinsing (with MPS or hot water) followed by 6 hours of air-drying is insufficient to remove heavy biofilm. Soaking in the test MPS followed by tissue wiping or a long drying period was effective for both strains.

Commercial Relationships: Ajay Kumar Vijay, Alcon Research Ltd (F); Hua Zhu, Alcon Research Ltd (F); Mark Willcox, Alcon Research Ltd (F); Fiona Stapleton, Alcon Research Ltd (F); Roya N. Borazjani, Alcon Research Ltd (E)
Support: Brien Holden Vision Institute, Alcon Research Ltd

Program Number: 6481 **Poster Board Number:** D945

Presentation Time: 11:15 AM - 1:00 PM

Comparative Biocompatibility of Contact Lens Multi-purpose Disinfecting Solutions with Soft Contact Lenses - Potential Correlations with Lens Preservative Uptake and Release Profiles

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Purpose: To evaluate effects of contact lens multi-purpose disinfecting solutions (MPDS) by *in vitro* biocompatibility assessment using mouse fibroblast (L929) cells and in relationship to preservative uptake and release profiles with various soft contact lenses (CLs).

Methods: Revitalens OcuTecTM MPDS (RO) was evaluated against two currently marketed products, Opti-Free RepleniSH[®] MPS (OFR) and Opti-Free[®] Express MPS (OFE). Five soft CLs were examined: Soflens[®] 38TM (Bausch & Lomb), Acuvue[®] Advance[®] (Vistakon), O₂ Optix[®] (CIBA Vision), PureVision[®] (Bausch & Lomb) and Biofinity[®] (CooperVision) lenses. *In vitro* biocompatibility was assessed according to ISO 10993. MPS-treated CLs (100ml, 4 days, n=3) were placed onto L929 cells (24hrs). Cells were scored for reactivity according to USP Direct Contact Test criteria. Polypropylene pellets and latex rubber served as negative and positive controls, respectively. Comparative antimicrobial (alexidine dihydrochloride and polyquaternium-1 (PQ-1)) uptake capacity of lenses soaked in excess volume of RO, and subsequent release kinetics in buffered saline (1ml/lens, n=3-5), were determined out to equilibrium (28 days max).

Results: *In vitro* cytotoxicity showed that RO-treated PureVision[®] (grade 1), Acuvue[®] Advance[®] (grade 2), and O₂ Optix[®] (grade 2) lenses were less cytotoxic compared with OFR and OFE (grade 3-4). All MPS-treated Soflens[®] 38TM CLs demonstrated low cytotoxicity scores (grade 2). MPS-treated Biofinity[®] CLs displayed moderate cytotoxicity (grade 3-4). Lens uptake of alexidine ranged from 0 to 4.1 µg/mg dry lens showing Soflens[®]38 < O₂ Optix[®] < Acuvue[®] Advance[®] < Biofinity[®] < PureVision[®]. Lens release of alexidine ranged from 6.6 to 30.9 ng/mg dry lens showing O₂ Optix[®] < PureVision[®] < Acuvue[®] Advance[®] < Biofinity[®] < Soflens[®]38. No quantifiable uptake or release of PQ-1 from lenses was found.

Conclusions: RO was found to be less cytotoxic in a standard *in vitro* model employing saturation levels of active entities than OFR or OFE in MPS-CLs biocompatibility, as defined by lower *in vitro* cytotoxicity on L929 cells. Cytotoxicity scores with RO did not correlate with preservative uptake, but a weak correlation with alexidine dihydrochloride release was observed.

Commercial Relationships: Ling C. Huang, Abbott Medical Optics (E); Lauren Crawford, Abbott Medical Optics (E); Charles H. Powell, Abbott Medical Optics (E); Lisa Hoong, Abbott Medical Optics (E)
Support: None

Program Number: 6482 **Poster Board Number:** D946

Presentation Time: 11:15 AM - 1:00 PM

Evaluating Optical Performance of Presbyopic Contact Lenses via a Single-Pass Method

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Purpose: To investigate *in vitro* optical performance of several commercial multifocal contact lenses (MFCL) using an anatomically and optically equivalent model eye (ME).

Methods: The developed ME is capable of changing accommodative and refractive states, pupil size, and can be fitted with soft CLs to investigate their optical performances. The instrument was configured to simulate presbyopia with an axial refractive error, and was corrected with seven appropriate MFCLs with high and low-add powers, and a single vision control. Optical performance was evaluated at 3 pupils, 7 target vergences, and 5 different CL positions, via 2 input channels: 1) spatially filtered, monochromatic (632.8 nm) collimated beam, and 2) visual acuity charts (VAC). The active photo sensor situated at the retinal plane facilitated retrieval of single-pass (SP) information. Channel 1 was used to compute visual Strehl ratio (VSOTF) measures, while channel 2 yielded images casted of VAC objects. Centration of CLs was monitored by an integrated tracking camera.

Results: Overall, most MFCLs demonstrated a reduced peak performance for distance and considerable levels of through-focus performance relative to single vision control. Proclear (D) produced best through-focus VSOTF performance. Proclear (N) outperformed the rest for near. AirOptix demonstrated good performance at intermediate and far vergences. Purevision and Acuvue showed through-focus performances comparable to the rest, but only for pupils ≥4mm. Acuvue Oasys produced performance comparable to single vision control. Decentration of MFCLs demonstrated a substantial effect on the through-focus performance. None of the designs were free of haloes and ghosting. Ghosting effects were prominent for small pupils, where halos were minimal. At 4mm pupil, both ghosting and haloes became prominent. For pupils >4mm, halo effects dominated ghosting. In well-centered positions, center-distant designs produced ghosting at near, while center-near type demonstrated ghosting for intermediate and far. Reverse occurred when CLs were deliberately decentered. These observations were consistently true with both high and low add powers.

Conclusions: Novel result of this work is the direct acquisition of SP images obtained when MFCLs are used in conjunction with the developed instrument. We evaluated performance across several designs on an identical platform that employed a consistent and repeatable approach, thus offering original insight and progress in the field.

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Program Number: 6483 **Poster Board Number:** D947

Presentation Time: 11:15 AM - 1:00 PM

In Vitro Safety Evaluation of a Novel Contact Lens Care Solution Containing the Disinfectant Hydrogen Peroxide

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Purpose: A battery of *in vitro* tests evaluating viability and barrier function were used to determine whether residual amounts of H₂O₂ remaining after neutralization of an experimental borate-containing contact lens care solution adversely affects human corneal limbal epithelial cells. Effects of the neutralized test solution were compared to that of H₂O₂ in serum-free culture medium.

Methods: (1) Stratified HCLE cells were exposed to either H₂O₂ (0.01-0.3%) in culture medium or neutralized lens care solutions (full strength or diluted to 1-50% in culture medium) for 1 or 24 hr, followed by measurement of viability, fluorescein permeability and trans-epithelial resistance; (2) Contact lenses soaked in the test solution or Clear Care[®] (Ciba Vision) for 1-15 days (2 cycles/day) were applied to stratified cells in a lens overlay model for 24 hr followed by viability and permeability assays. In the overlay model a lens was placed on cells concave side up in the minimum volume of medium required to cover the lens.

Results: H₂O₂ in culture medium at concentrations > 0.2% caused a marked decrease in cell viability and loss of barrier function. The permeability of the constructs continued to increase when cells were returned to medium without peroxide. In contrast, residual H₂O₂ (< 0.01%) in the neutralized lens solutions, applied to cells at full (1 hr) or diluted (24 hr) concentrations had no effect on viability or barrier function. In the lens overlay model, lenses that were cycled in lens solutions and neutralized had no adverse effects on viability or permeability of stratified cells.

Conclusions: The experiments using H₂O₂ at concentrations > 0.2% in culture medium demonstrate that stratified HCLE cells are sensitive to peroxide and that the *in vitro* tests used in this study can detect cellular damage. Residual H₂O₂ in lens care solutions after neutralization had no cytotoxic effects. A lens overlay model developed for safety evaluation of contact lens-solution pairings confirmed these findings. Together, the results show that following neutralization, H₂O₂ containing lens care products do not adversely affect stratified corneal epithelial cells.

Commercial Relationships: Benjamin J. Konynenbelt, Alcon Research, Ltd (F); D. S. Mlnarik, Alcon Research, Ltd (F); M. P. Schotanus, Alcon Research, Ltd (F); A. K. Van Wyk, Alcon Research, Ltd (F); J. L. Ubels, Alcon Research, Ltd (F), Alcon Research, Ltd. (C, R)
Support: Alcon Research, Ltd.

Program Number: 6484 **Poster Board Number:** D948

Presentation Time: 11:15 AM - 1:00 PM

A Rapid Determination for Encystment Rate of Acanthamoeba using Flow Cytometry

Masaki Imayasu¹, Miya Nomachi¹, Kissaou T. Tchadre¹, H D. Cavanagh². ¹R&D Center, Menicon Co Ltd, Kasugai, Japan; ²Ophthalmology, Univ Texas Southwestern Med Ctr, Dallas, TX.

Purpose: The encystment process of *Acanthamoeba* spp is characterized by trophozoite rounding. It was reported that the incidence of *Acanthamoeba* keratitis (AK) in the United States was related to one specific multi purpose solution (MPS), COMPLETE MoisturePLUS, that induced the transformation of *Acanthamoeba* trophozoites into resistant cyst. In this study, we have developed a novel method to rapidly compare the encystment rates of *Acanthamoeba* treated with MPSS using

flow cytometry.

Methods: Encystment rates of *Acanthamoeba castellanii* (AC, ATCC50514) treated with eight commercial MPDS (7 PHMB-based and 1 POLYQUAD-based) were analyzed. For flow cytometry, 1.0×10^5 trophozoites were exposed to each MPDS for 24 hours. After dispensing the cell suspension into two aliquots, one aliquot was stained with 0.004% Congo Red (CR), a fluorescence dye to stain the inner cell wall of cyst, and the other aliquot was stained with a mixture of Congo Red and 10% Sarkosyl (CRS), a detergent to lyse the trophozoites. Flow cytometric analysis of the treated aliquots was carried out on EPICS ALTRA flow cytometer. The encystment rate and disinfecting efficacies (percentage of rounded trophozoites) were calculated by the rates of CR-stained and -non-stained part, and CRS stained part. Encystment rates were also calculated by direct counting under microscopy.

Results: Cysts and rounded trophozoites were stained with CR; however native (unrounded) trophozoites were not. Only cysts were stained with CRS. There was a high correlation between the encystment rates obtained by the flow cytometry and those by direct microscopy. The encystment rates of AC by 24-hour treatment of COMPLETE MoisturePLUS were 53.8% by flow cytometry and 57.3% by microscopy. Encystment rates (flow cytometry) of AC treated with other 7 MPDS were between 0.3% and 13.1%, which were significantly lower than COMPLETE MoisturePLUS.

Conclusions: The encystment rates of *Acanthamoeba* treated with MPDS were rapidly determined by the flow cytometric analysis using the intensities of CR fluorescence with or without treatment of Sarkosyl. Disinfecting efficacies of MPDS against *Acanthamoeba* were also evaluated at the same time. Not only high encystment rate but also low disinfecting efficacies of MPDS are thought to be associated with the incidence of AK.

Commercial Relationships: Masaki Imayasu, Menicon (E); Miya Nomachi, Menicon (E); Kissaou T. Tchadre, Menicon (E); H. D. Cavanagh, Menicon (C)
Support: None

Program Number: 6485 **Poster Board Number:** D949

Presentation Time: 11:15 AM - 1:00 PM

Effects of Multipurpose Disinfecting Solution Excipients on Corneal Cell Physiology and Cytokine Production

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Purpose: The use of certain multipurpose disinfecting solutions (MPDS) with certain silicone hydrogel contact lenses has been associated with corneal infiltrative events in recent articles. This study examines the contributions of the excipients nonaoyl EDTA (nEDTA) and propylene glycol (PG) on cell numbers, cell metabolic activity, and cell membrane integrity, as well as the production of cytokines by human corneal limbal epithelial cells (HCLE).

Methods: HCLE were exposed to dilutions of two MPDS (1-20%), nEDTA (0.01 - 0.2%) or PG (0.2 -5 %) for 2, 6 or 18 hours. Cells were enumerated using Cyquant, cell metabolism was quantified using MTT assay, and cell membrane integrity studied using LIVE/DEAD staining and confocal microscopy. Cytokines released into the culture supernatant were measured by ELISA

Results: Exposure of HCLE to either MPDS resulted in decreases in cell numbers at concentrations of MPDS >10%. Both MPDS slightly reduced cell metabolic activity. Exposure to MPDS containing nEDTA and PG resulted in a significant ($p < 0.01$) increase in cell membrane perturbation, especially at a concentration of 20%. When tested in isolation, nEDTA did not affect cell numbers or cell membranes even at the highest concentration used (0.2%), although it did slightly reduce cell metabolic activity at concentrations >0.05% ($p = 0.05$). PG reduced cell numbers and metabolic activity at its highest concentration (5%; $p < 0.02$) and increased cell membrane perturbation at 5% concentration, although this concentration was above that found in 20% MPDS. The nEDTA/PG containing MPDS (at 20%) resulted in significantly increased production of IL-8 (108.1 ± 12.5 pg/cell) and IL-6 (55 ± 6.3 pg/cell), but addition of nEDTA or PG alone did not increase cytokine production

Conclusions: The MPDS containing nEDTA/PG reduced cell numbers, increased cell membrane permeability and increased cytokine (IL-8/IL-6) production. However, exposing cells to the individual excipients did not replicate the results for the MPDS solution, suggesting that combinations of excipients should be tested.

Commercial Relationships: Nerida Cole, Bausch and Lomb (F); Linda L. Garthwaite, Bausch and Lomb (F); Mark D. Willcox, Bausch and Lomb (F)
Support: Funded by a grant from Bausch and Lomb Incorporated and by the Brien Holden Vision Institute.

Program Number: 6486 **Poster Board Number:** D950

Presentation Time: 11:15 AM - 1:00 PM

Apparent Tonicity of Contact Lenses: Part 2

William J. Benjamin¹, Huagang Chen², Owen Gan², ¹School of Optometry, Univ of Alabama at Birmingham, Birmingham, AL; ²Alcon Research, Inc., Ft. Worth, TX.

Purpose: To determine if apparent hypertonicity of a conventional and a silicone-hydrogel contact lens worn up to 8 hrs by wearers with end-of-day dry eye symptoms was influenced by conditioning in different contact lens care (CLC) solutions. Differences between CLC solutions were evaluated. The tonicity

progression and comparison of lenses were reported in Part 1 (*Optometry & Vision Science* 87: Abstract 105869, 2010).

Methods: Apparent Tonicity (AT) of soft lenses was assessed with a vapor pressure osmometer upon removal from the eyes of 4 wearers with end-of-day symptoms of dry eye. Lenses were treated overnight in 3 different CLC solutions before wear: ReNu MultiPlus (Bausch & Lomb, Inc., Rochester NY), Opti-Free RepleniSH (Alcon Laboratories, Inc., Ft. Worth TX), and Clear Care (CIBA Vision Corporation, Duluth GA). Lenses were measured at time 0 and then after 2, 4, & 8 hrs of wear. Identities of care regimens were doubly masked and new lenses were supplied for each period of wear because testing was destructive. Subjects participated for 18 days in which the CLC solution was staggered. A total of 192 osmotic readings were calibrated according to linear regressions derived from measurements after equilibration in reference solutions of 100, 300, & 500 mOsm/kg.

Results: An analysis of variance revealed a significant effect of CLC solution [$p = 0.0003$] but not interactions between CLC solution and wearing duration [$p = 0.2200$] or lens type [$p = 0.4474$]. The mean tonicities found at time 0 for ReNu (278 mOsm/kg) and Opti-Free (285) were significantly lower than that of Clear Care (319). The mean tonicities found from 2 to 8 hrs of wear for ReNu (356 mOsm/kg) and Opti-Free (343) were significantly lower than that of Clear Care (410).

Conclusions: Surprisingly, the apparent tonicity of soft contact lenses was influenced by the CLC solution in which the lenses were equilibrated even up to 8 hrs of wear. The apparent tonicity associated with equilibration in one CLC solution approached the average threshold for awareness of hypertonicity upon instillation of eye drops (430 mOsm/kg). More data on other types of soft contact lenses and CLC solutions are needed in order to see if these findings are representative over the spectrum of soft lenses and lens care products.

Commercial Relationships: William J. Benjamin, Alcon Research, Inc. (F), J&J/Vistakon, Inc. (C); Huagang Chen, Alcon Research, Inc. (E); Owen Gan, Alcon Research, Inc. (E)

Support: Project funded by Alcon Research, Inc.

Program Number: 6487 **Poster Board Number:** D951

Presentation Time: 11:15 AM - 1:00 PM

Wetting Agent Retention and Release from Hydrogel and Silicone Hydrogel Contact Lenses

Catherine A. Scheuer, Kyle Doty, Tesfaye Liranso, Susan Burke, Vision Care, Bausch & Lomb, Rochester, NY.

Purpose: Wetting agents, which reduce surface tension (ST) to improve lens wettability, are included in contact lens disinfecting solutions (CLDS) in effort to keep lenses moist. The efficacy of wetting agents is dependent upon the ability to interact with lenses and release slowly during wear. An *in vitro* model was developed to investigate how wetting agents interact with silicone hydrogel and hydrogel contact lens materials and to evaluate how the interactions may affect wetting agent release profiles.

Methods: Etafilcon A (Acuvue2), alphafilcon A (SofLens Toric), balafilcon A (PureVision), senofilcon A (AcuvueOasys), and lotrafilcon B (O₂Optix) lenses, after overnight equilibration in Hanks' balanced salt solution (HBSS), were soaked eight hours in CLDS including Biotrue, fresh, sensitive, Replenish, and Clear Care. CLDS soaked lenses were rinsed with HBSS at the rate of tear film secretion. Rinsates were collected every 2h for 20h. To detect presence of wetting agents, ST of rinsates were measured by tensiometry. A statistical analysis was performed to evaluate differences in ST and wetting agent release of contact lens and CLDS combinations tested.

Results: The ST of CLDS evaluated were between 39 - 45 mN/m; ST of HBSS was 77 mN/m. The ST of rinsates from all lens/CLDS solution combinations were initially reduced by 20 - 30 mN/m from that of HBSS. Over time, differences in extended presence of wetting agents were detected among various lens/CLDS combinations. In some cases, statistical differences were detected for up to 20 hours when compared to control lenses (Biotrue with senofilcon A and Replenish with etafilcon A). However, in other cases, statistical differences were observed for 8 or fewer hours (ClearCare with etafilcon A, Replenish with senofilcon A).

Conclusions: CLDS wetting agents are retained by hydrogel and silicone hydrogel lenses and are released over time with rinsing. The duration of retention depends upon the interactions between the wetting agent and lens surface and bulk chemical properties. Hydrophilic/lipophilic balance (HLB) value drives chemical interactions with lens material, while molecular weight influences penetration into lens bulk. The selection of CLDS providing extended release of wetting agents which reduce ST may lead to improved contact lens wettability.

Commercial Relationships: Catherine A. Scheuer, Bausch & Lomb (E); Kyle Doty, Bausch & Lomb (E); Tesfaye Liranso, Bausch & Lomb (E); Susan Burke, Bausch & Lomb (E)

Support: None

Program Number: 6488 **Poster Board Number:** D952

Presentation Time: 11:15 AM - 1:00 PM

Risk Factors for Corneal Infiltrative Events in Soft Contact Lens (SCL)

Wearers: A Case Control Study in 2010

Robin L. Chalmers¹, John J. McNally², Lisa J. Keay³, Jami R. Kern⁴. ¹Indiana University School of Optometry, Atlanta, GA; ²Centre for Contact Lens Research, Atlanta, GA; ³Injury Division, George Institute for Global Health, Missendon Road, Australia; ⁴Global Medical Affairs, R&D, Alcon Research Ltd, Fort Worth, TX.

Purpose: To evaluate the association of symptomatic SCL-related corneal infiltrative events (CIEs) with SCL material, LCP products and other risk factors.

Methods: Cases with symptomatic CIEs were identified in a retrospective, multi-center case control study at 5 academic eye care centers. Each case was matched to 3 controls each who had received eye care near the time of the case's last full exam at that center. Controls wore SCLs but were not matched for demographic or SCL factors. Clinical diagnoses were established by an expert panel who were masked to SCL and LCP brand. Univariate analysis was conducted and any factors that were significant at the $p=0.20$ level were placed in a multivariate conditional logistic regression model. Interactions were tested by removing all daily disposable (DD) and all extended wear (EW) cases in separate models.

Results: Clinical records from 166 patients with symptomatic CIEs and known EW status were reviewed, adjudicated and analyzed. Cases used >50 SCL brands and >10 LCP brands. Age, increasing CL Power, EW, reusable SCLs, silicone hydrogels and student status were significant univariate factors. In the multivariate analysis, age (1.05X/year; 1.03, 1.06 95% C.I.), EW (4.18X, 2.44, 7.15) and Reusable SCL (6.27X, 1.88, 20.97) were significant. Among daily wearers, the only significant factors were age (1.05X/year, 1.03, 1.08), reusable SCLs (11.48X, 1.41, 93.49) and silicone hydrogel SCLs (1.94X, 1.03, 3.66). Without DD, age (1.04X/year, 1.02, 1.06), EW (4.42X, 2.53, 7.71) and silicone hydrogel SCLs (1.80X, 1.01, 3.22) were significantly associated with CIEs.

Conclusions: Corneal infiltrative events were positively associated with younger patient age, EW, and reusable SCLs. The leading SCL and LCP brands were not significantly associated with development of CIEs in any model. Among DW users, silicone hydrogels were also significant risk factor for CIEs. Use of DD lenses was protective for CIEs. Improvements in SCL storage case hygiene and environment may be a mechanism for reducing risk of CIEs.

Commercial Relationships: Robin L. Chalmers, Alcon Research, Ltd, Bausch & Lomb, CIBA Vision, Johnson & Johnson Vision Care, Inc. (C), Bausch & Lomb, CIBA Vision, Johnson & Johnson Vision Care, Inc. (R); John J. McNally, Alcon Research, Ltd. (C); Lisa J. Keay, Alcon Research, Ltd. (C); Jami R. Kern, Alcon Research, Ltd. (E)

Support: Alcon Research, Ltd.

Program Number: 6489 **Poster Board Number:** D953

Presentation Time: 11:15 AM - 1:00 PM

Mesh Size of Soft-Contact-Lens Hydrogels

Csaba Kotsmar¹, Teresa Nadolski¹, Clayton J. Radke². ¹Dept. of Chemical and Biomolecular Eng., University of California at Berkeley, Berkeley, CA; ²Chemical Engineering, Univ of California, Berkeley, Berkeley, CA.

Purpose: Transport of solute molecules through soft-contact-lens (SCL) hydrogels, such as salts, wetting agents, nutrients, and drugs is important to on-eye behavior. Solute molecules larger than the sieve or mesh size, however, can not penetrate the gel. This work measure the mesh size of contact lens materials and demonstrate that solute diffusion coefficients increase with increasing mesh size.

Methods: To determine the mesh size of HEMA-based hydrogels with various crosslink densities, we utilize oscillatory shear rheometry. The zero-frequency storage modulus of the lens material is inversely proportional to the square root of the mesh size. We synthesize hydrogels from HEMA and MAA with varying crosslink densities and measure the storage modulus for MAA contents varying between 0 and 100 %. We use two-photon confocal microscopy to measure solute diffusion coefficients in the hydrogels. Transient concentration profiles are fit to classical theory to give the solute diffusion coefficients (D).

Results: For crosslink densities ranging from 0.1 to 1% in 30% MAA/70% HEMA, the mesh size decreases linearly from 9 ± 1.3 to 2 ± 0.5 nm. A typical fluorescein-dextran (4000 g/mol) concentration profile is shown in Figure 1. D increases from $2.1 \pm 0.1 \times 10^{-8}$ cm²/s to $8.3 \pm 0.1 \times 10^{-7}$ as the mesh size increases from 2 to 9 nm.

Conclusions: Using shear rheometry and polymer physics we successfully measure mesh sizes of SCL materials. As mesh size increases, solute diffusion rates increase, all else being equal. Mesh size now becomes a tool for designing contact lens materials for specific applications.

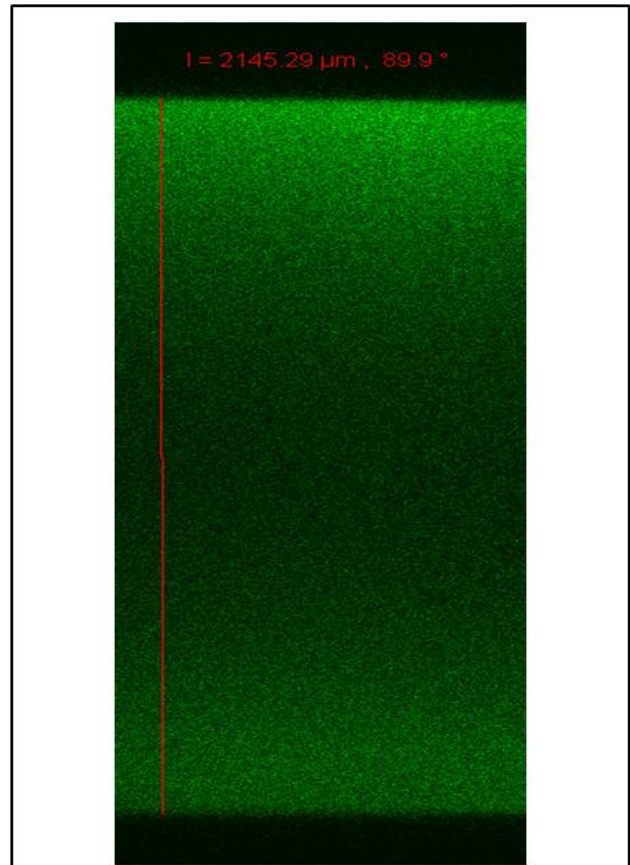


Figure 1. 4000 g/mol fluorescein-dextrane diffusion profile in 30% MAA/70% HEMA hydrogel with 0.1 % cross-link density, measured with confocal microscopy.

Commercial Relationships: Csaba Kotsmar, Alcon (F); Teresa Nadolski, Alcon (F); Clayton J. Radke, Alcon (F)

Support: Alcon Grant

Program Number: 6490 **Poster Board Number:** D954

Presentation Time: 11:15 AM - 1:00 PM

Is Contact Lens Comfort Influenced By Lens Replacement?

Daniel Tilia¹, Rebecca Weng¹, Percy Lazon De La Jara^{1,2}, Mark D. Willcox^{1,2}, Eric B. Papas^{2,3}. ¹Brien Holden Vision Institute, Sydney, Australia; ²School of Optometry and Vision Science, University of NSW, Sydney, Australia; ³Vision Co-operative Research Centre, Sydney, Australia.

Purpose: Previous reports have indicated contact lens replacement during the day does not improve end of day ocular comfort, when single use hydrogel lenses are used. This study assessed whether the same principle applies to silicone hydrogel lenses.

Methods: Twenty four participants (Pxs) were instructed to wear new, silicone hydrogel contact lenses for 10 hours on three separate days, with each day corresponding to one stage. During two of the stages, Pxs presented to the clinic after about 5 hours of wear when lenses were removed, then either new lenses were inserted or the same lenses were re-inserted. Pxs were masked to lens condition, and these stages were randomised. For the other stage, lenses were worn uninterrupted for 10 hours. Ocular comfort was assessed using a 1-100 numerical scale at insertion, and after 3, 5, 7 and 10 hours of wear. For those stages where lens wear was interrupted, ocular comfort was also reported prior to lens removal and following lens re-insertion. Mixed linear models were used for statistical analysis

Results: Relative to insertion, ocular comfort was significantly worse after 10 hours when lenses were worn uninterrupted ($p=0.02$). While lens removal and re-insertion was associated with a small improvement in comfort relative to uninterrupted wear, the difference was not significant ($p>0.05$). There were no significant differences between the 3 stages after 10 hours ($p>0.05$).

Conclusions: These results confirm that for this silicone hydrogel material lens replacement does not improve end of day ocular comfort. Taken with previous findings, this suggests that irrespective of lens type, end of day discomfort is not primarily caused by lens based deterioration but is more likely due to changes within the eye or its adnexa.

Commercial Relationships: Daniel Tilia, CIBA Vision (F); Rebecca Weng, CIBA Vision (F); Percy Lazon De La Jara, CIBA Vision (F); Mark D. Willcox, CIBA Vision (F); Eric B. Papas, CIBA Vision (F)

Support: CIBA Vision, The Brien Holden Vision Institute, Vision Co-operative Research Centre

Clinical Trial: <http://www.anzctr.org.au>, ACTRN12609000430235

Program Number: 6491 **Poster Board Number:** D955

Presentation Time: 11:15 AM - 1:00 PM

PHMB and PQ-1 Impact On A Liposome Corneal Surface Membrane Model
Frank V. Bright¹, Peter Maziarz², Micheal Liu², Jinzhong Zhang², Mohinder Merchea². ¹Chemistry, UB, SUNY, Buffalo, NY; ²Bausch + Lomb, Rochester, NY.

Purpose: Transient ocular surface fluorescence due to MPS preservative exposure has been implicated as an injury of the cornea. This study assessed molecular level interactions of the disinfectant agents PHMB or PQ-1 used in soft contact lens multi-purpose solutions (MPS) and corneal epithelium using an in-vitro cell model.

Methods: An anionic liposome model of the corneal epithelial surface was prepared by using a previously published protocol. 1,6-Diphenyl-1,3,5-hexatriene (DPH), a well-known lipid membrane probe, was used to assess the membrane integrity. Fluorescein was used as the fluorescent probe in association with the liposomes. The steady-state fluorescence anisotropy (a measure of interactions between molecules) was measured by using an SLM model 8100 spectrofluorometer. Liposome integrity was assessed by measuring the shift in melting point temperature (Tm) of model liposomes exposed to preservative concentrations from 0 ppm to 100 ppm. A reduction in integrity was indicative of a damaged cell membrane component.

Results: Free fluorescein demonstrated no statistically significant liposome interaction ($p > 0.05$). PHMB (tagged with fluorescein) demonstrated an association to the liposomes ($p < 0.0002$). The melting point temperature of liposomes at physiological temperature of 37°C demonstrated a) no statistically significant shift when exposed to PHMB from 0 ppm to 100 ppm ($p > 0.05$) and b) no statistically significant reduction in the melting point temperature of liposomes exposed to PQ-1 from 0 ppm to 6 ppm ($p > 0.05$). Exposure of PQ-1 at levels of 8 ppm or greater demonstrated liposome disruption.

Conclusions: PHMB and PQ-1 are used in varying concentrations in MPS. Preservative associated transient hyperfluorescence (PATH) has been interpreted as damage of the corneal surface based on its macroscopic clinical appearance, and is reported to occur more with PHMB in comparison to PQ-1. This study demonstrated that PHMB has a non-destructive interaction with the liposome surface chemistry. At concentrations 100x higher than found in commercially available MPS products, PHMB did not damage the phospholipid bilayer components that comprise the most superficial surface of the corneal epithelium. Alternatively, PQ-1 demonstrated a threshold of 8 ppm when disruption of phospholipid bilayer components was observed. This study suggests that evaluation of PATH clinically is an inappropriate assessment of cell surface integrity or biocompatibility. Further study is recommended to better understand MPS products and ocular tissue at the molecular level.

Commercial Relationships: Frank V. Bright, Bausch+Lomb (R); Peter Maziarz, Bausch+Lomb (F); Micheal Liu, Bausch+Lomb (F); Jinzhong Zhang, Bausch+Lomb (F); Mohinder Merchea, Bausch+Lomb (F)
Support: None

Program Number: 6492 **Poster Board Number:** D956

Presentation Time: 11:15 AM - 1:00 PM

Study Of The Discrepancies Between Optimal Contact Lens Fitting And Simulated Fitting With A Computerised Videokeratography Fluorescein Evaluation Software System

M del Carmen Seres, Genis Cardona, Roser Isern, Joan Gispets. Optometry, Technical University of Catalonia, Terrassa, Spain.

Purpose: The purpose of this study was to identify the sources of discrepancy between optimal rigid gas permeable contact lens fitting (OF) and simulated fitting (SF) based on a computerised videokeratography fluorescein evaluation software system.

Methods: The Oculus Easygraph (Oculus, Inc.) contact lens fitting software was employed to determine SFs (fluorescein pattern showing alignment "on K" and edge clearance of 0.5 mm) in a sample of 28 eyes (age 40 ± 11.5 years; spherical refraction from -1.00 to -6.00 D; corneal and refractive astigmatism < -0.75 D). Fluorescein patterns, lens movement and centration were evaluated after SF, and modifications in back optic zone radius (BOZR) and total diameter (TD) were performed to achieve OF, as judged by an experienced independent practitioner. Parameter changes (PC) were scored in an open scale by allocating one point for each 1 step modification in BOZR and TD. Eyelid position, eyelid tension and blink completeness were recorded.

Results: A median of 1 PC (range: 0 to 6) was required to achieve OF. A statistically significant correlation was encountered between PCs and eyelid position ($\rho = -0.54$; $p = 0.013$), with smaller palpebral apertures requiring less PCs than larger ones, probably related to the lid-attachment fitting commonly associated with these cases. Lid tension and PCs displayed a weak, although not statistically significant, correlation. The number of PCs was not influenced by blink completeness.

Conclusions: Computerised videokeratography software systems are helpful to determine the parameters of a theoretical first contact lens, based on corneal topography and the static evaluation of fluorescein patterns. However, contact lens

fitting, as a dynamic process involving multiple factors, may require one or various PCs before an optimum fit is achieved. The results from the present study suggest a direct association between eyelid position and the extent of these changes.

Commercial Relationships: M del Carmen Seres, None; Genis Cardona, None; Roser Isern, None; Joan Gispets, None
Support: None

Program Number: 6493 **Poster Board Number:** D957

Presentation Time: 11:15 AM - 1:00 PM

Pseudomonas aeruginosa Genotype and Adhesion to Conventional and Silicone Hydrogel Contact Lenses

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Purpose: To determine the genotype distribution among ocular isolates of *P. aeruginosa* and compare its adhesion to various contact lens materials

Methods: Two genotypes of *P. aeruginosa*, namely, invasive (*exoS*) and cytotoxic (*exoU*) have been reported with variable antibiotic sensitivity. We first determined the genotype distribution among ocular isolates of *P. aeruginosa* by multiplex PCR. The adhesion of these two genotypes of *P. aeruginosa* to a conventional hydrogel (etafilconA) and silicone hydrogel contact lenses (balafilcon A; galyfilcon A) was done by viable cell culturing method. Scanning electron microscopy (SEM) of these lenses with and without bacterial adhesion was performed to analyze surface characteristics of lenses.

Results: Cytotoxic genotype predominated among our contact lens-related microbial keratitis (CLMK) isolates while invasive genotype was more common in all ocular isolates. Analysis comparing contact lens adhesion between the two genotypes to a conventional hydrogel (etafilconA) and silicone hydrogel contact lenses (balafilcon A; galyfilcon A) found no statistical significant difference. With the same genotype, galyfilcon A had the least bacterial adhesion compared to etafilcon A or balafilcon A ($P < 0.05$). Among silicone hydrogels, balafilcon A had the highest number of attached bacteria. Surface characterization by scanning electron microscopy (SEM) of these lenses showed a prominent difference between surface treated balafilcon A lenses and non-surface treated galyfilcon A and etafilcon A lenses. Bacterial adhesion to the lenses was mostly on the surface of the lenses and not associated with the polymer's pores.

Conclusions: Contact lens material rather than *P. aeruginosa* genotype may more significantly affect in *P. aeruginosa* adhesion to contact lens surfaces.

Commercial Relationships: Elizabeth P. Shen, None; Ruey-Yug Tsay, None; Fung-Rong Hu, None
Support: None

Program Number: 6494 **Poster Board Number:** D958

Presentation Time: 11:15 AM - 1:00 PM

Vitrified Collagen Gels with High Optical Transparency and Mechanical Strength for Ocular Repair

Xiomara Calderon-Colon^{1A}, Jennifer L. Breidenich^{1A}, Qiongyu Guo^{2A}, Dan Mulreany^{2A}, Russell L. McCally^{1,2B}, Manny O. Uy^{1A}, Jennifer Elisseeff^{2A,2B}, Jeffrey P. Maranchi^{1A}, Oliver Schein^{2B}, Morgana M. Trexler^{1A}. ^AMilton Eisenhower Research Center, ¹Johns Hopkins University Applied Physics Laboratory, Laurel, MD; ^BDepartment of Biomedical Engineering, ²Department of Ophthalmology, ²Johns Hopkins University, Baltimore, MD.

Purpose: To optimize the mechanical and optical properties of collagen vitrigels for ocular repair.

Methods: Vitrigel preparation entails three main stages: mixing, gelation, and vitrification. Equal volumes of culture medium (Fetal Bovine Serum, 20 mM HEPES buffer in DMEM (Dulbecco's Modified Eagle Medium)) and 0.5% acid collagen solution are uniformly mixed. Gelation is initiated via incubation at 37 °C. During vitrification, time, temperature, and humidity are controlled. Following vitrification, the material is rehydrated with Phosphate Buffered Saline. Four vitrification times (0.5, 1, 2, and 5 weeks), 3 temperatures (5, 15, and 40 °C), and 3 humidity levels (20, 40, and 60 %RH) were explored using a design of experiments and correlated with resulting optical transparency and mechanical properties.

Results: Tailoring the synthesis parameters (time, temperature, and humidity) facilitates control of the transparency and mechanical strength of the biomaterial. Transparency is maximized ($91 \pm 9\%$ at 550 nm) via vitrification for 4.2 weeks at 21 °C and 20 % RH. For transparency, the most influential synthesis parameters are the quadratic and two-factor interactions of time*time, followed by temperature*temperature and temperature*humidity. Longer vitrification time yields higher strength and stiffness in preliminary mechanical testing.

Conclusions: Collagen vitrigels with optimized material properties can be synthesized by systematically controlling vitrification time, temperature, and humidity. These materials show promise for complex ocular reconstruction due to their biocompatibility, biodegradability, transparency and strength.

Commercial Relationships: Xiomara Calderon-Colon, Johns Hopkins University Applied Physics Laboratory (P); Jennifer L. Breidenich, Johns Hopkins University Applied Physics Laboratory (P); Qiongyu Guo, Johns Hopkins University (P); Dan Mulreany, Johns Hopkins University (P); Russell L.

McCally, Johns Hopkins University Applied Physics Laboratory (P); **Manny O. Uy**, None; **Jennifer Elisseff**, Johns Hopkins University (P); **Jeffrey P. Maranchi**, Johns Hopkins University Applied Physics Laboratory (P); **Oliver Schein**, Johns Hopkins University (P); **Morgana M. Trexler**, Johns Hopkins University Applied Physics Laboratory (P)
Support: None

Program Number: 6495 **Poster Board Number:** D959

Presentation Time: 11:15 AM - 1:00 PM

Contact Lens Complications In An Urgent Care Population: The UCLA Contact Lens Study

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Purpose: To study the prevalence of complications with contact lens wearers and investigate whether extended wear is more likely than daily wear to result in complications that drive patients into emergency ophthalmic department.

Methods: The current report is a prospective study with data collection over a 6-month period between January and July 2010. For this cross sectional study, we established a recruitment goal of 50 patients to obtain a reasonable analysis of CL related complications in an urgent care setting.

Results: 1369 patients presented to JSEI urgent care with symptoms of eye problems. Of these, 49 patients were identified with diagnosis etiologically associated with their contact lens wear. The 5 most common ocular signs found in our study were: epithelial staining or abrasion/epithelial defect, conjunctival injection, papillae, corneal neovascularization, and presumed microbial keratitis. The mean number of complications were 3.43 per eye. Majority of our patients reported some form of extended wear. Analysis of our patients with PMK showed that extended wear increased the rate of PMK. Average age of lens was 48 days. The most common lens was a 2 week replacement lens. Average overwear was 19 days. The highest average of CL overwear occurred with 2 week lenses. Most solutions utilized by patients were chemical cold sterilization. Average age of case was 266 days. There appeared no statistical difference in the number of complications per symptomatic eye with hydrogel and silicone hydrogel lenses. However, 13 of our 15 patients with PMK were SIH wearers.

Conclusions: 65% of our urgent care patients slept with contact lenses on their eye and 15 of 49 patients were diagnosed with presumed microbial keratitis (PMK). We studied various aspects of care and compliance in an urgent care population and found that overnight wear with silicone hydrogels was associated with the occurrence of PMK in our cohort. Age of lens, days of overwear, cleaning or rubbing lenses, water exposure, or age of CL case, were all not associated with PMK. At least 13 of our 15 patients diagnosed with PMK had worn silicone hydrogel lenses with at least 12 patients using these lenses as extended wear. None of our patients wearing daily lenses developed PMK. Separate analysis of the PMK group showed higher number of complications per symptomatic eye. When compared to an age and gender matched asymptomatic study group at UCLA, our cohort had a significantly greater average number of complications per eye and increased rate of PMK. Extended wear may be a risk factor leading to increased ER visits.

Commercial Relationships: Sharon Y. Lee, None; Yoon Hee Kim, None; Duncan Johnson, None; Bartley Mondino, None; Barry Weissman, None
Support: None

Program Number: 6496 **Poster Board Number:** D960

Presentation Time: 11:15 AM - 1:00 PM

Sodium Fluorescein Staining Of The Corneal Epithelium: What Does It Mean At A Cellular Level?

Kalika L. Bandamwar^{1A}, Qian Garrett¹, Eric B. Papas^{1B}, ^ASchool of Optometry and Vision Science, ^BResearch & Development, ¹Brien Holden Vision Institute, Sydney, Australia.

Purpose: In spite of its widespread use, the significance of sodium fluorescein (SFL) staining on the ocular surface is not yet known. The purpose of this study was to determine if SFL staining of the superficial corneal surface is associated with corneal epithelial cell damage using an ex-vivo model.

Methods: Rabbit eyes with no pre-existing corneal staining, excised within 3h postmortem, were exposed to various damaging stimuli; including ophthalmic preservatives (PHMB), hypertonic or hypotonic saline, and abrasion by filter paper disk. The corneas were subsequently stained with 1% SFL and evaluated using a slit lamp bio-microscope. Corneas were further stained with Propidium iodide (PI), Hoechst 33342(HO) and Annexin-V (AN-V) to identify dead, live and apoptotic cells, respectively and examined using confocal fluorescent microscopy (CFM). Untreated eyes were used as controls.

Results: Slit lamp observation confirmed the clinical appearance of superficial punctate SFL staining after exposure to all stimuli. Fluorescent cells observed with the slit-lamp could be seen to display hyper-fluorescence and early apoptotic membrane changes (AN-V +ve) on CFM evaluation. Controls had no apparent SFL staining on slit-lamp observation, but showed a uniform low level of fluorescence with CFM. These cells were judged to be healthy, with no AN-V or PI staining of the membrane or nucleus. Necrotic cells (PI +ve and AN-V -ve) showed

significantly lower SFL staining than normal healthy cells and were not visible during slit lamp observation.

Conclusions: Superficial punctate SFL staining of the corneal epithelium visualized with the slit lamp bio-microscope corresponds to the presence of damaged epithelial cells. Neither healthy cells with intact membranes nor necrotic cells with disrupted membranes are visible in these circumstances.

Commercial Relationships: Kalika L. Bandamwar, None; Qian Garrett, None; Eric B. Papas, None
Support: Brien Holden Vision Institute

Program Number: 6497 **Poster Board Number:** D961

Presentation Time: 11:15 AM - 1:00 PM

An Evaluation of Two Methods for the Ex Vivo Analysis of Lens Osmolality
Walter L. Nash, Mary Mowrey-McKee, Alan Landers, Biomaterials Science, Ciba Vision, Duluth, GA.

Purpose: To develop a reliable method to determine the contact lens osmolality of samples collected from clinical studies for *ex vivo* analysis taking care to reduce evaporation from lenses and assay materials.

Methods: In the first study, lotrafilcon A and comfilcon A lenses were collected from the eye by clinicians aseptically and placed directly into a pre-weighed eppendorf tube containing 200 μ L of a 100 mOsm/kg elution solution using clean forceps. In the second study, the same lens materials were collected from the eye by clinicians aseptically and placed directly into a pre-weighed eppendorf tube, no longer containing elution solution, using clean forceps. For the samples collected in the second study, eppendorf tubes containing only the lens sample were weighed and a 200 μ L of a 100 mOsm/kg elution solution was then added to each sample. In both studies, samples which contained elution solution and lens sample, were again weighed and then incubated for a minimum of 18 hours at 33 \pm 2 $^{\circ}$ C to equilibrate. Samples and controls were removed from the incubator, reweighed, and agitated on a vortex for approximately 15 seconds. Next the osmolality of each elution control was measured once, while the osmolality of each sample elution was measured in duplicate. Samples were then dried at 55 \pm 2 $^{\circ}$ C for a minimum of 20 hours with the eppendorf tube's cap off and subsequently reweighed. For both methods, the lens osmolality was calculated by determining the weight of the elution solution added to each tube, wet weight of the lenses, dry weight of the lenses, water weight of the lenses, % water content and weight change due to 33 \pm 2 $^{\circ}$ C incubation. These values were then used to calculate the final lens osmolality per sample.

Results: Lens osmolality data collected on worn lenses in the first study exhibited a relative standard deviation for comfilcon A and lotrafilcon A of 26 % and 51 %, respectively, and 15 % and 28 % using the modified methodology. A significant drop in lens osmolality was observed for both lens materials using the modified methodology.

Conclusions: Methods for measuring lens osmolality are highly dependent upon maintaining the lens water content volume and the elution solution volume throughout the procedure.

Commercial Relationships: Walter L. Nash, Ciba Vision (E); Mary Mowrey-McKee, Ciba Vision (E); Alan Landers, Ciba Vision (E)
Support: None

Program Number: 6498 **Poster Board Number:** D962

Presentation Time: 11:15 AM - 1:00 PM

A Method of Qualitatively Determining Lipid Deposition on Silicone Hydrogel Contact Lenses

Andrew D. Pucker, Jason J. Nichols, Optometry, Ohio State University, Columbus, OH.

Purpose: There is a significant interest in the total amount and types of lipids in the tear film since disruption of the lipid layer is thought to decrease tear film stability and cause dry eye. There is still much clinical uncertainty as to how a soft contact lens alters the lipid layer of the tear film. The purpose of this study is to determine Nile Red and Oil Red O's ability to detect the deposition of a common tear film lipid on lotrafilcon A lenses.

Methods: Eight unworn lotrafilcon A lenses were individually soaked in successively decreasing amounts of cholesterol oleate solution (5.6 mg/mL to 0.00 mg/mL) for one day in triplicate for each staining procedure. The sets of lenses were then stained with Nile Red or Oil Red O. The lenses were then individually visualized with a Nikon Eclipse 80i fluorescent microscope at 100x magnification, and two representative photos were taken of each lens.

Results: Nile Red gave a robust number of stained lipid deposits on the lenses soaked in 5.60 mg/mL cholesterol oleate solution and variable yet decreasing amounts of staining were detected at lipid concentrations greater than 0.09 mg/mL when compared to the negative control lenses. Staining was detected on all lenses at all concentrations of lipid with staining being found on half of the negative control lenses. Oil Red O gave a robust number of stained lipid deposits on the lenses soaked in 5.60 mg/mL lipid solution; approximately 25% the number of deposits were detected at 1.40 mg/mL when compared to 5.6 mg/mL, and approximately 25% the number of deposits were detected at 0.35 mg/mL when compared to 1.40 mg/mL. Lipids were not detected when lenses were incubated at concentrations of lipid solution of 0.09, 0.02, 0.01, or 0.00 (mg/mL). Rare staining was seen on the negative control lenses.

Conclusions: Nile Red is able to detect lipid on lenses when they have been

incubated in concentrations of lipid solution greater than or equal to 0.09 mg/mL while Oil Red O is able to detect lipid on lenses when they have been incubated in concentrations greater than or equal to 0.35 mg/mL. Oil Red O might make a better stain than Nile Red for silicone hydrogel lenses due to its superior image quality. **Commercial Relationships:** Andrew D. Pucker, None; Jason J. Nichols, Vistakon (C), Vistakon, CIBA Vision (F, R) **Support:** None

Program Number: 6499 **Poster Board Number:** D963

Presentation Time: 11:15 AM - 1:00 PM

Comparison of Success in Contact Lens Wearers Fitted as Children vs Teenagers

Jeffrey J. Walline, Andrew J. Emch, Anu Laul, Kathleen Reuter, Jason J. Nichols. College of Optometry, Ohio State University, Columbus, OH.

Purpose: The purpose of this study is to compare comfort, adverse events, and compliance of patients who were fitted in contact lenses as a child (≤ 12 years of age) versus those fitted as a teenager (≥ 13 years of age).

Methods: This was a two-phase study including both a survey and examination phase (only survey results are reported). Requests to complete online surveys were sent to Ohio State University students, staff, and faculty. Eligible subjects were 17 to 30 years of age who wore soft contact lenses for the past 10 years. Statistical comparisons were made on outcomes using unpaired t-tests and chi-square tests based on stratified comparisons of age when first fit (child-fit vs. teen-fit).

Results: The survey was completed by 175 respondents; 86 were fitted as a child (71% female) and 89 were fitted as a teenager (63% female). Child-fits currently wore their contact lenses 14.8 ± 3.4 hours per day; teen-fits currently wore their contact lenses 14.7 ± 3.6 hours per day ($p = 0.74$). Child-fits reported 1.1 ± 2.5 hours per day of uncomfortable wear time, and teen-fits reported 1.2 ± 2.7 hours per day uncomfortable wear time ($p = 0.92$). Approximately 22% of child-fits and 24% of teen-fits were able to wear their contact lenses for as many hours as they would like ($p = 0.81$). Having a red, painful eye that required a doctor visit since beginning contact lens wear was reported by 21% of child-fits and 19% of teen-fits ($p = 0.76$). Approximately 32% of child-fits reported currently rubbing their lenses and 42% reported rinsing their lenses when cleaning them, compared to 35% who reported rubbing and 45% who reported rinsing their lenses among the teen-fits ($p = 0.77$ for rub and 0.70 for rinse). The proportion of child- and teen-fits who replace their case every six months or more often was 53% in each group ($p = 0.95$). We have an adequate sample size with 80% power ($\alpha = 0.05$) to detect a difference of 0.5 hours per day wearing time, 0.4 hours per day comfortable wearing time, and 6% difference for adverse events and compliance.

Conclusions: Fitting children at 12 years or younger is not associated with a greater frequency of current poor comfort, prior adverse events, or poorer compliance after 10 years of soft contact lens wear.

Commercial Relationships: Jeffrey J. Walline, Vistakon (C, R); Andrew J. Emch, Vistakon (R); Anu Laul, None; Kathleen Reuter, None; Jason J. Nichols, Vistakon (F), Vistakon, CIBA (R)

Support: Johnson & Johnson Vision Care, Inc.

Program Number: 6500 **Poster Board Number:** D964

Presentation Time: 11:15 AM - 1:00 PM

Gaps in the Contact Lens Case History: Identifying Items for a Soft Contact Lens (SCL) Risk Questionnaire

Heidi Wagner¹, Robin L. Chalmers², G. L. Mitchell³, Meredith E. Jansen², Beth T. Kinoshita⁴, Dawn Y. Lam⁵, Timothy T. McMahon^{6A}, Kathryn L. Richdale³, Luigina Sorbara^{6B}. CLAY Study Group. ¹Nova Southeastern University, Fort Lauderdale, FL; ²School of Optometry, Indiana University, Bloomington, IN; ³College of Optometry, Ohio State University, Columbus, OH; ⁴Pacific University College of Optometry, Forest Grove, OR; ⁵Optometry - Cornea and Contact Lens, Southern California College of Optometry, Fullerton, CA; ^{6A}School of Optometry, ^{6B}School of Optometry-CCLR, ^{6C}University of Waterloo, Waterloo, ON, Canada.

Purpose: The purpose of this study was to retrospectively investigate scanned clinical records from SCL wearers presenting with infiltrative or infectious conditions in order to identify patient behaviors, risk factors and gaps in case histories that could prompt prevention of these events.

Methods: A multi-center retrospective chart review of de-identified clinical records from visits with infiltrative or infectious conditions among SCL wearers aged 8-33 years was performed. Reviewers were asked to note the presence or absence of various risk conditions in the patient case history at the presenting visit for the complication. Using the Turning Point™ software (Turning Technologies, Youngstown, OH) reviewers were polled in a focus group format to evaluate whether items generally existed in their records and to assess their importance for inclusion in a risk questionnaire (using a Likert scale).

Results: In the chart review of 248 events, disparities between existing documentation in the clinical chart (C) and panel perceptions (P) were noted for patient behavior, symptoms, and health status. Compliance issues had the largest gap between chart presence and reviewer rating of importance ((C/P)% strongly agree or agree); back-up spectacle wear (50/88), swimming (33/63) care regimen (50/75), wearing schedule (67/88), hot tub use (17/38), and lens replacement schedule (67/75). Chart presence and reviewer rating of importance converged for overnight wear (83/88). Respiratory status was the most important and reported

health system (50/75).

Conclusions: Important information on risk factors for SCL complications is often absent from the clinical case history. Development of a risk profile questionnaire will help define and document risk factors associated with SCL complications. Understanding these relationships can potentially improve the safety and efficacy of SCL wear.

Commercial Relationships: Heidi Wagner, CIBA Vision Corporation (F); Robin L. Chalmers, CIBA Vision Corporation (F); G. L. Mitchell, CIBA Vision Corporation (F); Meredith E. Jansen, CIBA Vision Corporation (F); Beth T. Kinoshita, CIBA Vision Corporation (F); Dawn Y. Lam, CIBA Vision Corporation (F); Timothy T. McMahon, CIBA Vision Corporation (F); Kathryn L. Richdale, CIBA Vision Corporation (F); Luigina Sorbara, CIBA Vision Corporation (F)

Support: CIBA VISION Corporation, Chancellor's Faculty Research & Development Grant, Nova Southeastern University

Program Number: 6501 **Poster Board Number:** D965

Presentation Time: 11:15 AM - 1:00 PM

The Influence of Lens Wear on Bacterial Adhesion to Silicone Hydrogel Lenses

Hua Zhu^{1,2}, Ajay K. Vijay¹, Jerome Ozkan¹, Duoqia Wu¹, Simin Masoudi¹, Roya N. Borazjani³, Mark D. Willcox^{1,2}. ¹Brien Holden Vision Institute, Sydney, Australia; ²School of Optometry and Vision Science, UNSW, Sydney, NSW, Australia; ³R&D, Alcon Labs, Fort Worth, TX.

Purpose: Incidence of contact lens related corneal infection or inflammation has not reduced with the use of silicone hydrogel lenses. These adverse events can be associated with bacterial adhesion to lenses. This study was designed to determine whether lens wear modulates bacterial adhesion to silicone hydrogel lenses.

Methods: Ten different silicone hydrogel lens types were used in the study. Nine unworn lenses and fifteen daily-worn lenses for each lens type were used for bacterial adhesion. Three strains of *Staphylococcus aureus* and *Pseudomonas aeruginosa* were grown overnight in minimum media containing 3H-uridine and then resuspended in PBS to 1×10^7 CFU/mL. After washing in PBS, lenses were incubated in bacterial suspensions for 18h. Following washing, the number of total (radioactive) and viable (CFU) bacteria adhered on lens surfaces were estimated.

Results: In unworn lenses, the highest adhesion of *S. aureus* was to lotrafilcon A lenses (4.4×10^5 CFU/lens), and the lowest to asmoofilcon A lenses (2.8×10^4 , $p < 0.05$). Lens wear increased total adhesion of *S. aureus* to all the lens types tested, with filcon II 3, narafilcon A and enfilcon A lenses showing significantly higher adhesion compared to unworn lenses ($p < 0.05$). Worn asmoofilcon A showed the least adhesion with *S. aureus*. There was no change in viable adhesion of *S. aureus* to different worn versus unworn lenses. Highest adhesion of *P. aeruginosa* was to comfilcon A lenses (3.2×10^6 CFU/lens), and the lowest was to asmoofilcon A or balafilcon A lenses (8.9×10^5 , $p < 0.05$). Lens wear significantly increased the total and viable adhesion of *P. aeruginosa* strains to narafilcon A lenses ($p < 0.001$), and significantly decreased the total and viable adhesion to comfilcon A lenses ($p < 0.05$). *P. aeruginosa* strains adhered least to worn asmoofilcon A lenses.

Conclusions: The differences in profiles of bacterial adhesion between worn and unworn silicone hydrogel lenses may be due to the diversity in the lens materials, including the silicone component, water content, surface treatment, hydrophobicity, and oxygen transmissibility, and the interaction of the material with tear components.

Commercial Relationships: Hua Zhu, Alcon Research Ltd (F); Ajay K. Vijay, Alcon Research Ltd (F); Jerome Ozkan, Alcon Research Ltd (F); Duoqia Wu, Alcon Research Ltd (F); Simin Masoudi, Alcon Research Ltd (F); Roya N. Borazjani, Alcon Research Ltd (E); Mark D. Willcox, Alcon Research Ltd (F) **Support:** Funded by a grant from Alcon Research Ltd, and the Brien Holden Vision Institute, Sydney, Australia

Clinical Trial: Australian New Zealand Clinical Trials Registry, ACTRN12609000230257

Program Number: 6502 **Poster Board Number:** D966

Presentation Time: 11:15 AM - 1:00 PM

A New Mechanism for Facilitated Re-wetting of Silicone Hydrogel Contact Lenses

James W. Davis¹, Robert E. Baier², Anne E. Meyer², Howard Ketelson¹. ¹Consumer Products, R&D, Alcon Laboratories, Fort Worth, TX; ²Department of Oral Diagnostic Sciences, State University of New York at Buffalo, Buffalo, NY.

Purpose: Current methods used to determine advancing contact angles (ACA) have some ambiguity in regards to the interpretation of wettability for lens surfaces. Low contact angles can stem from the eluted surfactants. Captive Bubble (CB), Sessile Droplet (SD) and Multiple Attenuated Internal Reflection InfraRed (MAIR-IR) Spectroscopy were used to investigate the means by which novel block copolymers of ethylene oxide and butylene oxide (EOBO) enhance the ability for Silicone Hydrogel (SiH) to be re-wetted by water after short duration air exposures of EOBO-based disinfectant treated contact lenses (PureVision® (PV)).

Methods: ACA data were collected from CB videos using OCA20-Beta software. *In vitro*, SD contact angle data on referenced Teflon foil and SiH lenses supported by MAIR-IR were used to study the water wettability.

Results: The apparent mechanism of sustained wettability improvement was

believed to operate through embedment of the BO copolymer segments into hydrophobic domains of the SiH lenses, exposing the water-loving EO copolymer segments at the lens/air interface. This was demonstrated by the low ACA's of PV treated lenses with the EOBO formulation in CB: initial ACA of 32° at 160 seconds with surface tension (SFT) of the air bubble was 72.1mN/m; after 10 UNISOL 4@ rinse cycles with 90 second air exposure an ACA of 60° at 160 seconds with SFT at 71.9mN/m. Rinsing demonstrated the substantivity of the EOBO formulations where EOBO eluted slowly from the hydrophobic PV lenses.

Conclusions: This mechanism of action supplements simple adsorption, absorption and reservoir/depot effects that can also take place with EOBO block copolymers. The data showed that block copolymers lacking EOBO's molecular geometry, molecular weight and hydrophilic-lipophilic balance may not be as effective and efficient to preferentially wet and re-wet hydrophobic contact lenses.

Commercial Relationships: James W. Davis, Alcon Laboratories (E); Robert E. Baier, State University of New York at Buffalo (F); Anne E. Meyer, State University of New York at Buffalo (F); Howard Ketelson, Alcon Laboratories (E) **Support:** Alcon Laboratories

Program Number: 6503 **Poster Board Number:** D967

Presentation Time: 11:15 AM - 1:00 PM

Galyfilcon A Silicone Hydrogel Lenses Infused With Silver Iodide Delay Or Inhibit In-vitro Surface Colonization By Bacteria And Fungi Associated With Adverse Ocular Events

Lauren L. May¹, Candace A. Williams¹, Shangtong Zhang¹, Donald Ahearn².

¹Biological Sciences, Vistakon, Jacksonville, FL; ²Biology, Georgia State University, Atlanta, GA.

Purpose: To evaluate the antimicrobial activities of silver salt-infused silicone hydrogel lenses in preventing or retarding in-vitro colonization of the lenses by bacteria and fusaria.

Methods: Unworn and worn silicone hydrogel galyfilcon A lenses and galyfilcon A lenses infused with silver iodide were challenged in wells of tissue culture plates in phosphate buffered saline or dilute tryptic soy broth with 10⁴ cells of *Pseudomonas aeruginosa* and other species associated with adverse ocular events. Cell populations of bacteria were recovered after 20 h and enumerated by standard dilution and plate count procedures. For *Fusarium*, unworn lenses were studied with and without 2-h exposures in Sabouraud's dextrose prior to inoculation. Worn lenses were exposed only to phosphate buffer. All lenses were inoculated with 10⁴ conidia and examined daily with light microscopy.

Results: Near 2-log fewer bacteria were associated in all instances with the silver iodide-infused lenses compared to control lenses (p < 0.05). For non-worn controls, germination of the conidia of *Fusarium* was delayed for at least 48 hours in the presence of the silver iodide-infused lenses. For worn lenses, none of the lens matrices of galyfilcon A lenses infused with silver iodide were invaded by hyphae after 14 days of incubation whereas greater than 40% of the control lenses were observed having been penetrated by *Fusarium* starting at day 4.

Conclusions: Galyfilcon A silicone hydrogel lenses with infused silver iodide delay or inhibit colonization by bacteria and fungi associated with adverse ocular events compared to lenses without silver iodide. Silver-iodide infusion of lenses may reduce the risk of the lens serving as a fomite in the transfer of microorganisms from the contact lens case to the eye.

Commercial Relationships: Lauren L. May, Vistakon, J&J Vision Care (F); Candace A. Williams, Vistakon, J&J Vision Care (F); Shangtong Zhang, Vistakon, J&J Vision Care (F); Donald Ahearn, None **Support:** None

Program Number: 6504 **Poster Board Number:** D968

Presentation Time: 11:15 AM - 1:00 PM

Adverse Events With Daily Wear Of Silicone Hydrogel Contact Lenses In Chinese Children

Padmaja R. Sankaridurg^{1,2}, Thomas Naduvilath^{1,2}, Percy Lazon^{1,2}, Xiang Chen^{3,2}, Julia Lin^{3,2}, Li Li^{3,2}, Jian Ge^{3,2}, Brien Holden^{2,4}. ¹Brien Holden Vision Institute, Sydney, Australia; ²Vision Cooperative Research Centre, Sydney, Australia; ³Zhongshan Ophthalmic Centre, Guangzhou, China; ⁴School of Optometry & Vision Science, University of New South Wales, Sydney, Australia.

Purpose: To report on the incidence and type of adverse events in a group of Chinese children wearing silicone hydrogel contact lenses (CL) over a 12 month period.

Methods: In a prospective clinical trial, 240 children, aged 8 to 14 yrs were enrolled to wear silicone hydrogel CL (Lotrafalcon B, both single vision and novel myopia control CL) on a daily wear, monthly replacement schedule. The trial was part of Vision CRC myopia control studies conducted at Zhongshan Ophthalmic Centre, Guangzhou, China. Adverse events observed during the 12 month period were categorised using the BHVI/LVPEI categorisation system as Serious, Significant and Non-significant events. The total number of patient eye years in the study was determined. Incidence was calculated as the number of adverse events divided by the total number of patient eye years and reported as Incidence per 100 patient eye years (Incidence %).

Results: The number of patient eye years in the study was 411. There were no serious adverse events. The incidence of first events of significant and non-significant adverse events was 7.5% and 1.5% respectively. Of the significant

events, incidence of inflammatory/ infiltrative events was 0.7% and included 3 events of Infiltrative Keratitis. The incidence of significant mechanical events was 7.1% and included Contact Lens Papillary Conjunctivitis (12 events, 2.9%), Superior Epithelial Arcuate Lesions (8 events, 1.9%) and Corneal Erosions (9 events, 2.2%). One subject had both SEALs and IK. The non-significant events were Asymptomatic Infiltrative Keratitis (2 events, 0.5%) and Asymptomatic Infiltrates (4 events, 1.0%). None of the events resulted in any loss of best corrected visual acuity or discontinuation from lens wear. When recurrent events were also considered, the incidence of significant and non-significant events increased slightly to 8.5 % and 1.9% respectively.

Conclusions: Mechanical events were the most frequently observed events. Overall, the low incidence of adverse events observed with daily wear use of silicone hydrogel CL is promising for CL wear as a modality for vision correction in children. However, it is important to understand the mechanisms underlying these events to try to further decrease their incidence especially as reduction in the rate of myopia progression has been observed with novel myopia control CL. **Commercial Relationships:** Padmaja R. Sankaridurg, Brien Holden Vision Institute (E), CIBA VISION (F); Thomas Naduvilath, Brien Holden Vision Institute (E), CIBA VISION (F); Percy Lazon, Brien Holden Vision Institute (E), CIBA VISION (F); Xiang Chen, CIBA VISION (F); Julia Lin, CIBA VISION (F); Li Li, CIBA VISION (F); Jian Ge, CIBA VISION (F); Brien Holden, Brien Holden Vision Institute (E), CIBA VISION (F)

Support: Australian Federal Government through the CRC program, Brien Holden Vision Institute and CIBA VISION

Clinical Trial: <http://www.chictr.org>, ChiCTR-TRC-00000232

Program Number: 6505 **Poster Board Number:** D969

Presentation Time: 11:15 AM - 1:00 PM

The Impact Of Lens Wear On In Vivo Wettability Of Silicone Hydrogel Contact Lenses

Nancy J. Keir, Craig Woods, Desmond Fonn. School of Optometry-CCLR, University of Waterloo, Waterloo, ON, Canada.

Purpose: To assess the impact of lens wear on *in vivo* wettability of silicone hydrogel contact lenses.

Methods: Two silicone hydrogel materials (lotrafalcon B (LB), balafilcon A (BA)) were worn by 19 subjects in a contralateral eye, dispensing study. Measurements were completed at baseline (BLN) and 4wks. *In vivo* wettability measures included graded wettability (0-4, 0=perfect) and pre-lens non-invasive tear break-up time (NITBUT, seconds). Differences between materials and individual changes were assessed.

Results: Mean±SD (range) graded wettability at BLN and 4wks was: 1.08±0.85 (0-2.75) and 1.33±1.01 (0-3.75) for LB and 1.86±1.14 (0-3.75) and 2.11±1.16 (0.25-3.75) for BA. Graded wettability was better for LB compared to BA (p<0.05) but did not change over time (p=0.06). NITBUT at BLN and 4wks was: 6.5±3.0 (3.7-16.1) and 5.6±2.2 (2.9-10.9) for LB and 6.2±2.9 (3.4-13.3) and 5.0±2.6 (1.3-12.8) for BA. There was no difference in NITBUT between materials, however there was a decrease over time (p<0.05). Individually, graded wettability decreased (>0.5 change in grade) with lens wear in 47% and 53% and improved in 26% and 37% of subjects for LB and BA, respectively. Pre-lens NITBUT decreased (>1 second change) with lens wear in 47% and 53% and improved in 16% and 11% of subjects for LB and BA, respectively.

Conclusions: *In vivo* wettability varied between subjects and differed between materials. While lens wear reduced *in vivo* wettability for most subjects, in some cases there was an improvement with wear. This would suggest that the tear film may act to enhance wettability in some subjects fitted with silicone hydrogels, and that initial wettability may not predict that seen over time.

Commercial Relationships: Nancy J. Keir, CIBA VISION (F); Craig Woods, CIBA VISION (F); Desmond Fonn, CIBA VISION (F)

Support: Financial support was provided by CIBA VISION

Clinical Trial: <http://www.clinicaltrials.gov>, NCT01010555

Program Number: 6506 **Poster Board Number:** D970

Presentation Time: 11:15 AM - 1:00 PM

Neutrophil-enhanced Pseudomonas aeruginosa Biofilms on Silicone Hydrogel Contact Lenses

Geoffrey W. Burnham¹, H D. Cavanagh², Danielle M. Robertson².

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Purpose: In animal models, extended contact lens wear with concurrent bacterial challenge results in significant neutrophil accumulation. Recently we have reported that *Pseudomonas aeruginosa* (PA) biofilms formed on hydrogel lenses are significantly increased in the presence of neutrophils. The purpose of this study is to evaluate neutrophil-enhanced PA biofilm formation on silicone hydrogel contact lenses.

Methods: A fully invasive corneal isolate that has been stably conjugated to GFP, strain PA6487, was used in all experiments. Neutrophils were isolated from human blood using a percoll gradient separation and activated by brief exposure to phorbol 12-myristate 13-acetate. Neutrophils were utilized at a concentration of 8x10⁶ cells/well. Unworn lotrafalcon A lenses were incubated in 1mL of bacterial suspension at a concentration of 1x10⁸CFU/mL for 2 hours. After being washed in

PBS, lenses were incubated overnight in RPMI with 2% Heat inactivated platelet poor plasma either with or without neutrophils. The lenses were incubated in their respective solutions for 24 hours at 37°C. Biofilm formation was evaluated using laser scanning confocal microscopy and colony forming unit (CFU) analysis.

Results: Primary attachment of PA was confirmed at 2 hours by confocal microscopy and CFU analysis. No bacteria were harvested from the non-bacteria exposed control lens. After a 24 hour incubation in the presence of neutrophils, confocal microscopy demonstrated increased density and an alteration of the architecture of the biofilm. CFU analysis confirmed an increase in viable PA in the neutrophil-enhanced biofilm ($p=0.002$).

Conclusions: These data demonstrate that intense corneal inflammation associated with PA contamination results in enhanced biofilm formation on silicone hydrogel contact lenses. Further studies are required to determine the efficacy of currently available cleaning regimens against neutrophil-enhanced biofilms on contact lens surfaces.

Commercial Relationships: Geoffrey W. Burnham, None; H. D. Cavanagh, None; Danielle M. Robertson, None

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Program Number: 6507 **Poster Board Number:** D971

Presentation Time: 11:15 AM - 1:00 PM

Susceptibility Of Ocular Isolates Of *P.aeruginosa* To Contact Lens

Multipurpose Solutions

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Purpose: Persistent microbial contamination of contact lens (CL) storage cases may be a feature of biofilm growth conferring resistance of organisms to CL multipurpose solutions (MPS). This study investigated the susceptibility of keratitis isolates of *P.aeruginosa* to MPS.

Methods: 47 isolates of *P.aeruginosa* recovered from corneal infections in Australia were grown overnight on Trypticase Soy (TS) agar and suspended to a concentration of 10^8 colony forming units (CFU)/mL. The susceptibility of planktonic organisms was assessed using serial dilutions of 2 MPS containing either polyhexamethyl biguanide (A) or polyquad (B) as their antimicrobial active and minimum inhibitory concentration (MIC) was estimated. 14 isolates capable of forming strong biofilms, were allowed to adhere for 24 hours in polypropylene CL storage cases. Washed biofilms were treated with 2.5mL of each of the MPS for the manufacturers recommended disinfection time. Two colorimetric assays; crystal violet for total biofilm and the 3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) for viable biofilm, were applied. Planktonic survivors, MICs, residual viable and total biofilm were enumerated and were compared between MPS.

Results: All planktonic isolates were susceptible to 100% MPS, however, the MICs were higher for MPS A compared with MPS B ($p<0.05$). Susceptibility was not associated with phenotype. The mean percentage reduction in viable biofilm was $54\pm 16\%$ for MPS A and $70\pm 20\%$ for MPS B ($p<0.005$). The mean percentage reduction in total biofilm was $40\pm 16\%$ for MPS A and $54\pm 12\%$ for MPS B ($p<0.05$).

Conclusions: This study has confirmed the widespread susceptibility of planktonic keratitis isolates of *P.aeruginosa* to contemporary MPS and MIC was not associated with a cytotoxic phenotype. There were variable effects of different MPS on viable and total biofilm using a colorimetric assay, which may in part explain persistence of organisms within storage cases despite compliance with manufacturers' guidelines

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Biofilm Bacterial Diversity: Association With Disease Severity in Contact Lens Related Keratitis

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Purpose: Biofilm formation in contact lens cases may predispose to the development of contact lens related keratitis. To better understand the composition of contact lens case biofilm, we used 16S ribosomal RNA (rRNA) gene sequencing to examine cases from patients with mild keratitis, keratitis with focal infiltrate, and contact lens related ulcers, as well as cases from asymptomatic controls.

Methods: Contact lens cases were obtained from 5 patients with mild diffuse keratitis, 8 with keratitis and focal infiltrates, and 4 with contact lens related ulcers. Eight cases from asymptomatic soft contact lens wearers were processed as controls. Biofilms were removed from lens cases by scraping and sonication, and DNA was extracted using the Mo Bio Microbial DNA Isolation Kit. Universal primers were used to amplify the bacterial 16S rRNA gene, PCR products were

purified, cloned into the pCR 4-TOPO vector (Invitrogen), then re-amplified and sequenced. Sequences were classified by BLAST analysis against GenBank. Each sequence was matched with at least one database entry at the genus level (identity $>95\%$).

Results: The number of bacterial types isolated from the case correlated with increasing severity of disease (Spearman rank order correlation $\Delta<0.000001$). There was a statistically significant difference between the number of bacterial types identified and the four clinical groups: normal, mild keratitis, keratitis with focal infiltrate and corneal ulcer, $p=0.0006$. All the affected groups exhibited more bacterial types than the controls (Mann-Whitney U test, $p=0.0013$). Presenting visual acuity was correlated with number of bacteria identified ($p=0.011$). *Achromobacter* and *Stenotrophomonas* were predominant isolates.

Conclusions: Bacterial diversity from contact lens cases was correlated with severity of disease and presenting visual acuity, and was greater than asymptomatic controls. *Achromobacter* and *Stenotrophomonas* are prominent residents of contact case biofilms.

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Exploratory Analysis of the Kinetic Rewetting Properties of an Experimental Disinfection Solution on Silicone Hydrogel Lenses

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Purpose: Current methods used to determine advancing contact angles (CA) typically rely on a single data point. This can be a disadvantage when measuring CAs on dynamic surfaces such as contact lenses, which are generally not at thermodynamic equilibrium in their use environment. These effects are the result of changes in surface chemistry over time due to the migration of hydrophobic groups to the air/lens interface. Alternative methods are needed to fully characterize the kinetic wetting and non-equilibrium effects that may occur on silicone hydrogel (SH) surfaces. This study summarizes an exploratory analyses of kinetic rewetting CA data generated from human worn (16 hours) SH lenses (PureVision™ (PV) and Acuvue® Oasys™ (AO)), treated with either an Alcon disinfection test solution (ADTS) or ReNu® Multiplus™ (RMP) (Bausch & Lomb) for seven days.

Methods: Advancing contact angle data were collected from captive bubble videos using OCA20-Beta software which was developed to extract angles and diameters from an intersection defined by the operator. Those contact angles measured between 100 sec and 200 sec were considered representative of lens rewetting for each lens-solution combination and were statistically analyzed by area under the curve (AUC) comparison. The outcome variable calculated was considered to describe the captive bubble test as a "kinetic rewetting rate" test, as water advances across the surface. OD and OS lens data were analyzed separately.

Results: AUC comparisons demonstrated solution differences for the most hydrophobic lens material, PV, with ADTS data (OD: 5118 ± 596 ; OS: 4701 ± 1035) significantly different from RMP (OD: 5672 ± 730 ; OS: 5589 ± 793) ($p<0.05$). Mechanistically, these data translate to differences in the efficiency by which water rewets the lens surface. No differences were found between ADTS (OD: 4652 ± 903 ; OS: 4601 ± 1096) and RMP (OD: 5019 ± 553 ; OS: 4744 ± 651) for AO lenses.

Conclusions: We present a novel method whereby a kinetic rate of dewetting can be calculated. Results demonstrated that for the most hydrophobic lens material, PV, the Alcon test solution significantly increased the rate of rewetting compared to RMP following 16 hours of wear.

Commercial Relationships: Michelle Senchyna, Alcon Research Ltd (E); Howard A. Ketelson, Alcon Research Ltd (E); James W. Davis, Alcon Research Ltd (E)

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***Pseudomonas aeruginosa* Association To Polyelectrolyte Hydrogel Lenses Is Modulated By pH And Divalent Ions**

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Purpose: Preventing *Pseudomonas aeruginosa* (PA) binding to hydrogel soft contact lenses (SCLs) may help reduce the incidence of lens-associated microbial keratitis. Understanding PA binding mechanisms is key to understanding antifouling methods. Previously, we reported that PA associated strongly to hydrogels consisting of methacrylic acid (a common SCL component). We hypothesized that this strong association was due to divalent cationic bridging between PA and the polyelectrolyte membrane, and that this bridging could be modulated by ion concentration and pH.

Methods: Hydrogels were synthesized by UV-initiated polymerization of MAA or AA with cross-linker (EGDMA), water, and acetonitrile. Mian's minimal media containing 5×10^6 cfu/ml PA strain PAK, was pumped through a flow chamber

containing a mounted membrane for 1-2 h at a constant shear rate (0.2 s⁻¹). Attachment dynamics were visualized and quantified by phase-contrast video microscopy. Hydrogel swelling and shrinking in solutions were visualized using drop shape analysis software.

Results: Hydrogels pretreated in PBS, pH 7.4, showed few bacteria associating: 750 ± 250 bac/mm². Within 20 min of incorporating Mg or Ca (10 mM or 5 mM, respectively) into the suspension, association rose to 5300 ± 2000 bac/mm². Increased association did not sustain and dropped to 1500 ± 500 bac/mm² after 1 h. Adding EDTA and then restoring Mg or Ca caused bacteria association to rise again to 5000 ± 1000 bac/mm². Pretreating hydrogels in water, pH 6.2, gave less PAK association: 1370 ± 61 bac/mm² even in presence of divalent ions. Due to carboxylic side group dissociation and self-repulsion of resulting anionic polymer chains, MAA hydrogels initially in water, pH 6.2, swelled 3.4 ± 0.5x their volume when placed in PBS pH 7.4. Upon adding 10-mM MgCl₂, MAA hydrogels shrank 37 ± 5% due to Mg²⁺ uptake and anionic polymer chain collapse. The apparent reason for enhanced PA uptake of anionic membranes is PA and surface bridging via divalent cations. Polymer chain collapse explains short-lived PA association.

Conclusions: *P. aeruginosa* strain PAK associated strongly to polyelectrolyte hydrogels in the presence of divalent ions due to divalent cationic bridging. However, this bridging only occurred when the hydrogels' polymer chains were extended. This study illustrates the sensitive dynamics of PAK binding to hydrogels due to charge interactions which can be modulated by pH, divalent ion concentration, and chelators.

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Evaluating the Biocidal Efficacy of Multi-purpose and Hydrogen Peroxide Solutions Against Fungal Isolates Associated with Ocular Infection

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Purpose: The biocidal efficacy of several multi-purpose solutions (MPS) and hydrogen peroxide solutions (H2O2) were evaluated against fungal isolates (including multiple strains of *Candida albicans*, *C. tropicalis*, *Fusarium oxysporum*, and *F. solani*) known to be associated with microbial keratitis.

Methods: Testing was performed on six MPS and two H2O2, all within expiry, to evaluate biocidal efficacy according to ISO standard 14729: 2001/(Amendment 1): 2010(E), modified to include organic soil in the preparation of the clinical isolates; and measuring biocidal efficacy only at the minimum recommended disinfection time point for each product. Challenge organisms had been isolated from clinical sources. Clinical isolates were prepared by using ~5X10⁵ colony forming units (cfu)/ml as the challenge inoculum for separate tests on each solution. Three separate lots of solution were tested against each isolate.

Results: Biocidal efficacy results ranged from no effect (0.0 log reduction from initial challenge levels) to > 4.0 log reduction for some solutions/isolates. ISO 14729 primary acceptance criteria (minimum 1.0 log reduction for yeasts and molds) were used as a guide for demonstrating efficacy in this non-compensial testing against the challenge organisms. Four solutions demonstrated efficacy against all of the challenge isolates. Of the remaining solutions, two were effective against >70% of the isolates, one was effective against 47% of the isolates, and one solution did not demonstrate efficacy by this measure against any of the challenge organisms. Mean overall log reductions per solution ranged from 3.0 or greater for three of the solutions; 2.0-2.9 for three of the solutions, 1.0 for one, and 0.2 for the last solution. Solutions showed strengths and weaknesses against different genera.

Conclusions: The results show that using clinical isolates can help distinguish *in vitro* performance differences of various MPS and H2O2. The use of methodology based on a modification of the ISO 14729 standard provides data that are easily understood and can be used to characterize the biocidal efficacy of solutions. Further study is needed to determine if these *in vitro* results could suggest clinical significance.

Commercial Relationships: Brien C. David, Bausch + Lomb (E); Patricia A. Walsh, Bausch + Lomb (E); Deborah McGrath, Bausch + Lomb (E); Denise Callahan, Bausch + Lomb (E); Juliann Mason, Bausch + Lomb (E); Julie Bair, Bausch + Lomb (E); Tiffany Hilfiker, Bausch + Lomb (E); Susan Norton, Bausch + Lomb (E)

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Effect Of Multipurpose Contact Lens Care Solutions On Membrane-associated Mucins Expressions In The Rat Cornea

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Purpose: To evaluate the effect of multipurpose contact lens care solutions (MPSs) on membrane-associated mucins (Muc 1 & 16) expressions in the cornea using SV40 transformed Human corneal epithelial Cells (HCET) and Rat cornea tissue sections. Membrane-associated mucins are one of the major components of the ocular surface that play a vital role in the maintenance of the ocular surface integrity.

Methods: Human corneal epithelial cells were treated with different concentrations of MPS-A, MPS-B, MPS-C, MPS-D, and MPS-E: 100% treatment for 30 minutes and 10% treatment for 24 hours. Membrane-associated mucins (Muc 1 and Muc 16) expressions were subsequently analyzed by Western blot. Wistar Rats were also subjected to MPSs (1 drop in the right eye every 10 minutes for 1 hour). The left Eye was used as control (1 drop of PBS every 10 min for 1 hour). Cornea sections and lysates were prepared from the eyes of the treated rats and used for the immunohistochemistry and Western blot analysis of membrane-associated mucins expressions. Western blot was also used to analyze the effect of 0.1% macroglycerol hydroxystearate (HCO), 0.1% poloxamer, 0.1% poloxamine, 5 pm polyaminopropyl biguanide (PHMB), 0.05% boric acid, and 0.1% boric acid, common MPSs ingredients, on membrane-associated mucins (Muc 1 and Muc 16) expressions in HCET after 24 hours treatment.

Results: Western blot results showed that MPSs containing boric acid down-regulate membrane-associated mucins in the cornea while MPSs without boric acid had no effect on membrane-associated mucins. Immunohistochemistry analysis of membrane-associated mucins expressions confirmed the results of the Western blot analysis.

Conclusions: Multipurpose solutions' composition should be clinically controlled because Mucins play a very important role in the ocular surface integrity maintenance and the tear film stability.

Commercial Relationships: Kissaou T. Tchadre, Menicon (E); Masaki Imayasu, Menicon (E); Yuichi Hori, None; H. D. Cavanagh, Menicon (C)
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Comparison of Three Contact Lens Care Regimens in Removal of Albumin and Lysozyme from Two Orthokeratology Lenses

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Purpose: To compare three types of contact lens care (multipurpose solution, MPS; hydrogen peroxide solution, HPS; and povidone iodine solution, PIS) in the efficiency of albumin and lysozyme removal from orthokeratology lenses under experimental conditions.

Methods: Emerald Lens (opriocoan A, fluorosilicone acrylate-based lens; Euclid Systems Corporation, VA) or Alfa Ortho-K Lens (fluorosilicone methacrylate-based lens; Alpha Corporation, Japan) were incubated in either protein-containing saline or saline (sham) for 15 hours at 36 degrees celcius. Protein concentrations were 0.54 mg/ml for albumin and 1.37 mg/ml for lysozyme, which represent concentrations in tear fluid after rigid lens wear. After incubation, lenses were either rinsed with saline (control) or washed by lens care solutions (MPS: Menicon O2 Care Milfa fresh, Menicon Corporation, Japan; HPS: AOEPT CLEAR CARE, CIBA VISION Corporation, Japan; PIS: Bioclen First Care CT, Ophthec Corporation, Japan) according to the manufacturer's instructions. Then, lenses were soaked in 1% sodium dodecyl sulfate, and protein was removed by sonication and vortex mixing. Protein concentration was quantified by Micro BCA Protein Assay Kit (ThermoScientific corporation). All statistical analysis was performed by Steel-Dwass multiple comparison test.

Results: Quantity of albumin deposits was higher (p<0.01) in fluorosilicone acrylate lenses (1.62 µg/lens) compared to fluorosilicone methacrylate lenses (0.49 µg/lens). There was no significance in lysozyme attachment between both lenses (fluorosilicone acrylate 1.86 µg/lens and fluorosilicone methacrylate 1.30 µg/lens; p>0.05). For fluorosilicone acrylate-based lens, the percentage of protein removal from lysozyme-deposited were MPS 100%, HPS 97.9%, PIS 94.0%, and from albumin-deposited lenses, MPS 95.3%, HPS 96.0%, PIS 97.5% compared to control lens. In fluorosilicone methacrylate-based lens the percentage of protein removal from lysozyme-deposited lenses were MPS 90.0%, HPS 72.5%, PIS 85.5%, and from albumin-deposited lenses, MPS 88.6%, HPS 100%, PIS 88.3% compared to control lens. All care regimens significantly removed albumin and lysozyme from lenses compared to control (p<0.01), and there was no significance between protein care regimens (p>0.05).

Conclusions: Multipurpose solution, hydrogen peroxide solution, povidone iodine solution showed equivalent efficacy for albumin and lysozyme removal from two types of orthokeratology lenses.

Commercial Relationships: Yoshie Itou, None; Nobuhisa Mizuki, None; Eiichi Okada, None
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The Relationship between Solution Induced Corneal Staining and Ocular Surface Sensitivity

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Purpose: We have previously demonstrated that increased levels of solution-induced corneal staining (SICS) correlates with increased conjunctival chemical sensitivity (IOVS, 2010). This study investigated the relationship between SICS and corneal and conjunctival sensitivity using a meta-analysis approach.

Methods: Four studies evaluating SICS and its relationship to pneumatic corneal and conjunctival thresholds (using a modified Belmonte esthesiometer) conducted at the Centre for Contact Lens Research between 2004 and 2009, were included in the analysis. A generalized linear model was employed to combine information from the studies, in which SICS at 2 hours after lens insertion (the time at which corneal staining is greatest) was used as the outcome variable and pneumatic corneal and conjunctival mechanical and chemical thresholds, masked solutions and experiments were used as predictor variables. In addition, symptoms (stinging and burning) were analyzed using the same statistical methods with staining, solutions and thresholds as predictors.

Results: The sample sizes of the individual studies varied from 18 to 48 subjects and the total number of cases in the analysis was 292. There were significant relationships between staining, thresholds and solutions (all $p \leq 0.05$); in all models, log transformation of conjunctival chemical thresholds was a significant predictor. The 'best' model using Akaike's information criterion (AIC) estimates included mechanical and chemical corneal and conjunctival thresholds, solution and study predictors. With symptoms as the outcome - and only corneal thresholds and staining in the model - log transformation of area of staining was a significant predictor.

Conclusions: This meta-analysis confirms that SICS is accompanied by an alteration in corneal and conjunctival chemical sensitivity. Conjunctival chemical sensitivity, in particular, appears to be a particularly robust predictor of the area of solution-induced corneal staining.

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The Effect of Lens Modulus on Insertion Comfort with Silicone Hydrogel Lenses

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Purpose: Non-inflammatory contact lens complications have been reported with higher modulus lenses. This study assessed the influence of lens modulus on comfort responses following lens insertion of ten marketed silicone hydrogel lenses.

Methods: Ten silicone hydrogel lenses (galyfilcon A [modulus 0.43], senofilcon A [0.72], narafilecon A [0.66], lotrafilcon A [1.4], lotrafilcon B [1.0], comfilcon A [0.75], enfilcon A [0.5], balafilcon A [0.91], asmoofilcon A [1.1], filcon II 3 [0.5]) were fitted to 30 subjects over four scheduled visits. Lenses were randomly assigned and worn bilaterally on a daily wear basis for approximately two weeks. After each lens type was fitted, subjects were asked to rate their ocular comfort immediately following lens insertion and five minutes following lens insertion (5-min ocular comfort). Subjects wear also asked to rate edge awareness and lens awareness sensation. Ratings were measured on a 1 to 100 scale in 1-unit steps.

Results: Mean comfort response immediately after insertion ranged from 84.0 to 94.2. Post-hoc analysis showed a significant difference in comfort immediately after insertion between lotrafilcon A and senofilcon A ($p=0.048$) or enfilcon A ($p=0.006$). There were no significant differences for 5-minute ocular comfort, lens awareness or edge awareness. There was a significant negative correlation between mean comfort and lens modulus suggesting that as modulus increased there was a corresponding decrease in 5-min. ocular comfort ($r=0.78$), edge awareness ($r=0.69$) and lens awareness ($r=0.68$).

Conclusions: A high lens modulus may adversely impact ocular comfort and sensations of edge or lens awareness. Further comparisons over the weekly/monthly wearing cycle are needed to confirm the influence of modulus on comfort with contact lens wear.

Commercial Relationships: Jerome Ozkan, Brien Holden Vision Institute (F); Mark D. Willcox, Brien Holden Vision Institute (F)

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Risk Factors For Contact Lenses Related Microbial Keratitis: A Prospective Multicenter Case-control Study

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Purpose: Microbial keratitis (MK) is a significant health concern for the million wearers of contact lenses (CL) with some potentially modifiable risk factors. Fortunately, MK remains a rare complication of CL wear, but is of interest because it is both a major cause of new cases of MK in the population, and the only sight-threatening complication of an otherwise safe method of vision correction. The aim of the study is to identify risk factors and to put into perspective the individual risk and the societal burden of CL-related MK patients.

Methods: A prospective multicenter case-control study was conducted in 12 French University Hospitals (Besançon, Bordeaux, Dijon, Fort de France, Grenoble, Limoges, Lyon, Nancy, Nantes, Paris, Marseille et Strasbourg) on all lenses wearers presenting with MK between July 2007 and December 2010. Patients had a complete ophthalmological examination and were interviewed by a 51 items anonymous "questionnaire" to determine subject demographics and lenses wear history. The CL related MK subpopulation (Case) was compared to healthy CL wearers (Control).

Results: Three hundred fifty six patients CL related MK and 410 healthy CL wearers were included. Patients wearing soft contact lenses had a higher risk for MK, as compared as rigid lenses wearers (Relative risk, 4.1 ; $p < 0.0001$). Among soft lenses, daily disposable CL (RR, 1.8 ; $p = 0.0443$) and 2 weekly replacement CL (RR, 1.9 ; $p = 0.0133$) had an increased risk of MK than monthly replacement CL, respectively because of some lacks in basic rules of hygiene (absence of hand washing) and the absence of a professional supervision for daily disposable CL and the overtaking of the deadline of renewal for 2 weekly replacement CL.

Conclusions: Consequently, uninformed CL wearers are experiencing acute vision-threatening infections, leading to a terrible personal and societal cost. With the increasing availability of CL, notably through internet or local market, this study serves to highlight the increasingly documented dangers of freely available CL without professional supervision and of the lack of information about the basic rules of hygiene and the basis of CL care and handling.

Commercial Relationships: Tristan Bourcier, None; Arnaud Sauer, None
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Corneal Staining and Barrier Function after Eight Hours of Silicone-Hydrogel Lens Wear

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Purpose: Solution-induced corneal staining (SICS) remains a contact lens complication, despite the evolution of improved lens materials and multipurpose solutions. The study purpose was to evaluate corneal staining and epithelial barrier function in lens wearers after 8 hours of wear.

Methods: This was a randomized, double-masked, controlled study in primarily young, full-time daily wearers of soft contact lenses. New balafilcon A lenses were soaked in 1) polyhexamethylene biguanide-based multipurpose solution, and 2) non-preserved saline solution as a control, then worn for 8 hours prior to corneal measurements. Corneal staining was evaluated with the modified Efron Grading Scale, and barrier function was characterized by the fluorescein penetration rate (Pdc) and stromal amount (in arbitrary fluorescence units) measured with an objective, scanning fluorometer.

Results: A total of 26 subjects completed the study. Total staining scores were 6.0 (± 2.4) and 4.3 (± 1.8) scale units (0 - 20 scale) for the test and control eyes, respectively ($p = 0.001$, one-sample t-test). The mean dye diffusion rates, Pdc (\pm SD) were 0.057 (± 0.04) and 0.058 (± 0.04) nm/sec for the test and control eyes, respectively ($p = 0.81$, one-sample t-test). Penetrated dye amounts were 150.3 (± 112) and 138.7 (± 104) arbitrary fluorescence units for the test and control eyes, respectively ($p = 0.638$, one-sample t-test).

Conclusions: Use of an objective, quantitative method suggests that only mild physiological perturbations occur at 8 hours of wear under these conditions, with no significant difference in barrier function between test and control eyes. Test eyes had more staining than control eyes at 8 hours, but the difference was low and likely not clinically significant.

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Clinical Trial: <http://www.clinicaltrials.gov>, NCT01015768

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Central And Peripheral Visual Performance Of A Novel Contact Lens Designed To Control Progression Of Myopia

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Purpose: We previously reported that a novel silicone hydrogel contact lens (CL) with a central aperture that corrects for foveal refractive error and a peripheral zone designed to reduce peripheral hyperopic defocus was able to slow the progression of myopia compared to spectacle wear. This study **determined** the central and peripheral visual performance of the novel CL compared to standard single vision CL (SVCL).

Methods: Central visual performance was assessed in a prospective clinical trial where 60 Chinese children (age 8-14 yrs; spherical equivalent $\leq -3.50D$; cylinder $< -0.75D$) each wore either a novel CL or a SVCL. Peripheral visual performance was measured in another trial involving 20 children and adolescents with myopia -0.50 to -4.50D, cylinder $<1.00D$. At baseline, 6 & 12 months, central high and low contrast visual acuity (VA) was measured using LogMAR charts and contrast sensitivity (CS) with a FACTS chart. Peripheral VA & CS was measured at 30° nasal & temporal eccentricity at a single visit with VA measured using an electronic screen (Landolt's C targets, LogMAR scale). Peripheral CS was measured by presenting either an annular sinusoidal grating at 2 cycles/° or a luminance-equivalent gray screen over two consecutive displays in a 4-alternative forced-choice task using a 3-down-1-up staircase technique. Differences between groups were analysed using linear mixed model and paired t-tests.

Results: At all visits, there were no differences for high and low contrast VA and central CS between groups ($p>0.05$). A significant improvement was observed for peripheral VA at both 30° nasal & temporal eccentricity (mean difference: 0.33 and 0.30 respectively; equivalent to 3 line improvement, $p<0.01$). Additionally, CS improved at 30° temporal eccentricity (mean difference 0.31, $p=0.008$)

Conclusions: Centrally the visual performance of the novel CL was comparable to SVCL but peripheral VA & CS were improved. The improvement in peripheral vision is most likely due to a reduction in peripheral defocus. Such lenses clearly have the capability of correcting central vision without blur, slowing the progress of myopia due to reduction in peripheral hyperopia and enhancing peripheral vision - a relatively unique and beneficial combination of effects.

Commercial Relationships: **Brien A. Holden**, CIBA VISION (F, R), US7025460B2, US20070296916, WO2009/055638A1, WO2009/129528A1 (P), Vision Cooperative Research Centre (E); **Padmaja Sankaridurg**, Brien Holden Vision Institute (E), CIBA VISION (F, R), US20070296916; WO2009/055638A1; WO2009/129528A1 (P); **Percy Lazon**, Brien Holden Vision Institute (E), CIBA VISION (F), WO2009/129528A1 (P); **Arthur Ho**, Brien Holden Vision Institute (E), CIBA VISION (F), US7025460B2; US20070296916; WO2009/055638A1; WO2009/129528A1 (P); **Earl L. Smith, III**, US7025460B2; US20070296916; WO2009/055638A1 (P); **Xiang Chen**, CIBA VISION (F); **Julia Lin**, CIBA VISION (F); **Thomas Naduvilath**, Brien Holden Vision Institute (E), CIBA VISION (F); **Jian Ge**, CIBA VISION (F)

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Clinical Trial: <http://www.chictr.org>, ChiCTR-TRC-00000232

Program Number: 6519 **Poster Board Number:** D983

Presentation Time: 11:15 AM - 1:00 PM

Compliance Factors Associated With Dry Eye In Soft Contact Lens Wearers

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Purpose: To determine if compliance factors are associated with contact lens related dry eye.

Methods: The data were derived from subject responses to a compliance survey in a cross sectional study of contact lens wearers with and without dry eye. Eligibility criteria for the study included soft contact lens wear for at least 1 year or more, ages 18 to 39 years, daily (non-overnight) lens wear and good systemic and ocular health. The Contact Lens Dry Eye Questionnaire (CLDEQ) score was used to determine dry eye status. The compliance survey included several questions on ease in contact lens care, rub and rinse practices, contact lens and lens case replacement frequency, solution replacement/ topping off and sleeping in contact lenses. Non parametric tests including the Mann Whitney test and Fisher's exact test were performed as applicable for statistical analysis of the data.

Results: The analysis included 24 asymptomatic lens wearers and 19 with contact lens related dry eye. Average age of all subjects was 26.4 ± 5.2 years and 59% were female. The following compliance factors were found to be significantly different between the asymptomatic and dry eye groups. For ease in lens care, the average for the non-dry eye group was 9.5 ± 0.9 , while the average for the dry eye group was 8.1 ± 2.2 ($p = 0.001$). For lens rubbing on both surfaces of the contact lens, only 17% of the non-dry eye group reported compliance, while 47% of the dry eye group reported compliance ($p = 0.046$). A few other non-significant trends were observed. 74% were female in the dry eye group in comparison to 42% in the non-dry eye group ($p = 0.063$). For lens rubbing time, the mean values were 5.8 ± 8.3 in the dry eye group and 2.2 ± 4.1 in the non-dry eye group ($p = 0.085$). No differences were detected in age and other compliance factors such as contact lens case replacement frequency, care solution topping off, lens rinsing and, sleeping in lenses.

Conclusions: Although perceived ease in lens care was rated lower by the dry eye group, their lens rub compliance was significantly better than the non-dry eye group. While this needs to be verified with a larger sample, the findings also

indicate that factors other than compliance could play a bigger role in contact lens related dry eye.

Commercial Relationships: **Padmapriya Ramamoorthy**, None; **Jason J. Nichols**, None

Support: AOF Ezell Fellowship (PR)

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Presentation Time: 11:15 AM - 1:00 PM

A Shift from 2 Week to 1 Day Lens - the Trends of the Japanese Contact Lens Market

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Purpose: From years 2006 to 2010, a total of 93358 patients purchased 2 week (2w) contact lenses from our clinic. From 2006 to 2009, the number of patients purchasing 2w lens decreased by average of 3.2 percent annually, a 9.3 percent decrease in total. We investigated the reason of this reduction by statistical evaluation and patient interview.

Methods: Patients whom purchased 2w contact lenses at our clinic from years 2006 to 2009 but did not buy 2w lenses in 2010 were defined as the "2w withdrawal group". The 2w withdrawal group was sorted into two groups, patients who purchased non-2w lenses in 2010 (= "switching group") and patients who did not buy any lenses in 2010 (= "lost group"). Next, interview was made to 165 patients, randomly chosen from patients of the switching group. Patients were asked to answer freely why they have stopped using 2w lenses.

Results: Out of 87736 patients, 43515 were considered as the 2w withdrawal group. The 2w withdrawal group was composed of 8217 switching group patients and 38298 lost group patients. The switching group patients switched to 1 day lens (7758 patients) > conventional soft lens (258) > rigid gas permeable lens (159) > 1 month lens (129) > 1 week lens (40), duplication allowed. In patients purchasing both 2w and 1 day lens (approximately 4000 to 6000 patients per month), the average ratio of 2w lens purchase to 1day lens purchase decreased from 68.56 % (January 2006) to 41.22 % (July 2010). From patient interviews, the main reason of 2w purchase arrestment was a changeover to 1 day lens (120/165), which was because of "pollen allergy or other eye disease (50/120)", "troublesome lens care (48/120)", and "1 day being more hygienic (30/120)" (duplicates allowed).

Conclusions: In patients who are continuing to purchase contact lenses from our clinic, the main reason of the decrease in the number of patients purchasing 2w lens was a shift to 1 day lens. This shift was supposedly because of allergy or other eye diseases, troublesome lens care, and health concern. Since these causes are difficult to exclude, it can be presumed that the shift from 2w to 1 day lens will continue on in the near future.

Commercial Relationships: **Eiichi Okada**, None; **Mai Nagasaki**, None; **Yoshie Itou**, None; **Nobuhisa Mizuki**, None

Support: None

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Presentation Time: 11:15 AM - 1:00 PM

Case Characteristics of Persons Presenting With Contact Lens-associated Infiltrative Keratitis (CLAIK) With Multipurpose Solutions and Contact Lens Combinations

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Purpose: To further describe common case characteristics and their association with severity in persons presenting with CLAIK who use multipurpose solutions (MPS) and contact lenses (CL) seen consecutively over 22 months.

Methods: Chart review of consecutive CL patients who presented for an urgent care visit with CLAIK, hyperemia, and decreased VA from Jan 2009 to Nov 2010. Lens type, MPS use, wear type, smoking status, number and location of corneal infiltrates, conjunctival injection, photophobia, and treatment regimen were documented. Patients presented with solution bottle for confirmation. The association of factors with overall incidence, symptoms, and severity was assessed. The most severe events were defined as those presenting with pain, photophobia, >2 injection, and more infiltrates than the overall mean.

Results: Over 22 months, there were 86 cases. Infiltrates were central (95.3%), numerous (mean 8.1), and most commonly +2 injected (mean 2.4). All but one case used silicone hydrogel lenses and 97.6% as daily wear. Of the most commonly used lenses, 61.6% wore senofilcon A (SA; Acuvue Oasys, Vistakon), 15.1% wore balafilcon A (PureVision, B+L), and 12.8% wore lotrafilcon A (Night&Day, CIBA). Alcon's Opti-Free RepleniSH (OFR=70.9%) was the most commonly used, followed by renu fresh (16.3%). Overall, 60.5% of cases were using both OFR and SA lenses. Factors associated with the most severe events were use of OFR (100%; $p=0.001$), SA lenses (87.5%; $p=0.005$), OFR/SA combined (87.5%; $p=0.003$), and bilateral presentation (79.2%; $p<0.001$). Smoking, younger age, and female sex were not associated with increased severity. All cases fully resolved with corticosteroids and/or artificial tears.

Conclusions: Use of certain MPS and silicone hydrogel lenses, especially combined, may be associated with both increased incidence and severity of CLAIK. The high number of cases using OFR and SA cannot be explained by market share alone (OFR <35%, All Vistakon <45% estimated 2010 market share). The incidence and severity of cases of CLAIK based on these observations should be considered in selecting MPS and lens material combinations.

Commercial Relationships: Thomas P. Kislán, AMO, B+L (C, R)
Support: None

Program Number: 6522 **Poster Board Number:** D986
Presentation Time: 11:15 AM - 1:00 PM

Scleral Contact Lenses in the Management of Keratoconus and Corneal Transplant Patients

Farid Afshar, Ken W. Pullum, Linda Ficker. Moorfields Eye Hospital, London, United Kingdom.

Purpose: To report our experience of scleral contact lenses in the management of keratoconus and corneal transplant (CT) patients.

Methods: Retrospective review of 612 patients managed with scleral contact lenses (SCL) at Moorfields Eye hospital, United Kingdom.

Results: There were 860 eyes of 612 patients included in the study. Mean age of patients was 56 years. 64.1% of patients were male. 77.7% of patients were post penetrating keratoplasty and 17.9% of patients had keratoconus. In the keratoconus group (n=160) the mean unaided visual acuity (VA) was 2/60 with 86.3% of patients recording VA \leq 6/60. With SCL the mean VA improved to 6/11 with 75% patients achieving VA \geq 6/12, and 23.8% achieving VA \geq 6/6. In the CT group (n=700) mean unaided VA was 3/60 with 81.9% patients recording VA \leq 6/60. Mean VA improved to 6/10 with SCL with 81.9% achieving VA \geq 6/12 and 37.9% achieving VA \geq 6/6.

Conclusions: Scleral contact lenses can lead to significant improvements in visual acuity and are a useful tool in the management of keratoconus and corneal transplant patients.

Commercial Relationships: Farid Afshar, None; Ken W. Pullum, None; Linda Ficker, None

Support: None

Program Number: 6523 **Poster Board Number:** D987

Presentation Time: 11:15 AM - 1:00 PM

A Quasi-2D Model For Oxygenation Of The Cornea With Contact-lens Wear

Sho C. Takatori, Clayton J. Radke. Department of Chemical and Biomolecular Engineering, University of California, Berkeley, CA.

Purpose: The peripheral cornea is about 40% thicker than at the center; soft-contact-lens (SCL) thickness may vary over 100 micrometers across its lateral dimension. To quantify the significance of cornea/SCL thickness variations on local oxygen demand, we develop a quasi-two-dimensional (2D) oxygenation model that accounts for aerobic and anaerobic metabolism and bicarbonate buffering.

Methods: Since metabolism is critical to corneal respiration, we extend the one-dimensional (1D), six-layer oxygen-metabolic model of Chhabra et al. (2009). About 99.6% of diffusion flux occurs normal to the cornea/SCL surfaces with essentially no lateral diffusion. Accordingly, we adopt the 1D reactive-diffusion metabolic model but apply it locally along the cornea/SCL extent. This "quasi-2D" approximation permits 2D assessment of oxygen consumption including the effects of respiratory metabolites carbon dioxide, glucose, and lactate, bicarbonate, and hydrogen ion.

Results: Figure 1 illustrates the importance of the quasi-2D respiration model to provide quantitative spatial resolution of corneal hypoxia. For a SCL with harmonic Dk/L of 56.4 hBarrer/cm, the open-eye, peripheral stroma is anoxic, whereas central and harmonic mean locations have 25 mmHg and 15 mmHg of oxygen supply available, respectively. These results accentuate the shortcomings of previous 1D models that neglect both respiration kinetics and radial-thickness variations. Our quasi-2D model not only predicts 2D oxygen concentration profiles but also profiles of carbon dioxide, glucose, and lactate, bicarbonate, hydrogen-ion for any cornea/SCL shape or transmissibility with minimal computation time.

Conclusions: The new quasi-2D respiration model indicates that both radial-thickness variations and respiration kinetics are critical for assessing the physiological performance of SCLs, especially near the lens periphery.

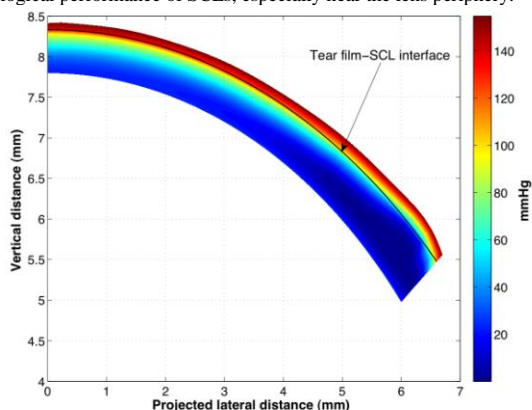


Figure 1. 2D open-eye, oxygen tension profile with harmonic Dk/L = 56.4 hBarrer/cm. Regions of dark blue indicate areas suffering from oxygen deprivation.

Commercial Relationships: Sho C. Takatori, None; Clayton J. Radke, None

Support: None

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Presentation Time: 11:15 AM - 1:00 PM

Application Of Thin Film Interferometry To Measurement Of Contact Lens Wettability In-vivo

Raied Fagehi, Alan Tomlinson, Velitchko Manahilov. Department of Vision Sciences, Glasgow Caledonian University, Glasgow, United Kingdom.

Purpose: To assess the wettability of soft contact lenses in-vivo by a new thin film interferometry measures.

Methods: Doane's interferometer connected to a digital camera captured images of the pre-contact lens tear film of 4 soft CLs representing the range of current soft CL materials. These were: Oasys (Acuvue, Johnson&Johnson); Soflens 38 (Bausch&Lomb), Night & Day (CibaVision) and ProClear (Cooper Vision). 5 healthy subjects (3 CLs wearers and 2 non CLs wearers aged 29 \pm 3.5 years, 3M 2F) were recruited. Subjects attended for 4 separate visit days and wore 1 of 4 lenses, chosen randomly. After 15 minutes adaptation subjects were seated at the interferometer, asked to blink once, and keep their eye open as long as possible. The camera captured images of the pre-lens liquid until the front surface became completely dry (no fringes). The procedure was repeated over 5 drying cycles and the resultant images were analysed by a MATLAB programme. Four new parameters were assessed: time to first break-up, onset latency (OL), duration of drying after first break-up (DD), maximum speed of drying (MS) and time to reach maximum speed (PL).

Results: The new measures offered a range of values in assessment of wettability across the CL types (Table 1). A one way ANOVA showed a significant difference between CLs for DD (p=0.008), a value close to significant was also found for MS (p=0.06). The other measures did not show significant differences between the lens types for the size of sample in this pilot study, at least in part, because of the variation in wetting as a result of individual tear chemistry. The sample sizes required to give sufficient power in measuring wetting with each of the measures were calculated, these are: n=177 (OL), 5 (DD), 8 (MS), 11 (PL).

Conclusions: This pilot study suggests that the technique of assessing CL wettability by interferometry, developed in-vitro can be applied in-vivo. Wetting measured by DD, MS and PL appear to be the most feasible for future experiments.

CLs	Table 1 (Mean \pm SD)			
	OL (sec)	DD (sec)	PL (sec)	MS (mm ² /s)
Soflens 38	13.4 \pm 13.5	47 \pm 51.7	30.6 \pm 39.5	1.0 \pm 0.81
ProClear	17.1 \pm 18	50.1 \pm 28.7	30.8 \pm 18	0.9 \pm 0.57
Night.&Day	15 \pm 11.3	107.2 \pm 57.9	57.9 \pm 29.6	0.42 \pm 0.44
Oasys	15.1 \pm 15.2	47.5 \pm 58.1	32.4 \pm 31.9	1.2 \pm 0.81

Commercial Relationships: Raied Fagehi, None; Alan Tomlinson, None; Velitchko Manahilov, None
Support: None

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Presentation Time: 11:15 AM - 1:00 PM

The Adaptation Of The Tear Proteome to Extended Wear Contact Lenses

Maria Markoulli^{1,2}, Eric Pappas^{1,2}, Nerida Cole^{1,2}, Brien A. Holden^{1,2}. ¹Brien Holden Vision Institute, Sydney, Australia; ²School of Optometry & Vision Science, University of New South Wales, Sydney, Australia.

Purpose: To establish the impact of contact lenses when worn in the extended wear schedule on the diurnal variation of the tear proteome.

Methods: Flush tears were collected from 9 healthy non-CL wearers at baseline, during the first day of CL wear and after one month of wear. Participants wore O₂Optix[®] on an extended (EW) schedule. Each time, tears were collected at midday and upon waking and analyzed for concentrations of total protein using the BCA method. Differential two-dimensional gel electrophoresis was then performed to detect biomarkers likely to be affected by CL wear. Samples were labeled with mass and charge matched fluorescent dyes and then separated so that there were two samples per gel. The presence of an internal standard in each gel allowed for the quantification between samples from different gels and hence the identification of biomarkers likely to be affected by CL wear. These spots were then cut and identified with mass spectrometry (LC/MS/MS).

Results: Thirteen protein spots were identified to differ across the visits (p < 0.05). Six of these proteins were unchanged from baseline after one night but increased after one month of wear. One increased after the first night of CL wear and remained elevated even after one month.

Conclusions: Initial CL wear in the extended wear schedule causes an upregulation

in some proteins and a down regulation of others, this profile continuing to change even after one month of wear.

Commercial Relationships: Maria Markoulli, None; Eric Papas, None; Nerida Cole, None; Brien A. Holden, None

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Presentation Time: 11:15 AM - 1:00 PM

Assessment Of The Optical Quality With A Double-pass System In Eyes With Contact Lens Induced Corneal Swelling

Victoria De-Juan¹, Mikel Aldaba², Raul Martin¹, Meritxell Vilaseca², Jose Maria Herreras¹, Jaume Puyol². ¹IOBA Eye Institute, University of Valladolid, Valladolid, Spain; ²Centre for Sensors, Instruments and Systems Development (CD6), Technical University of Catalonia, Terrassa, Barcelona, Spain.

Purpose: To quantify the effect of contact lens (CL) induced corneal swelling in the optical quality and intraocular scattering.

Methods: Optical quality (OQ) (Strehl ratio and OQAS values at contrasts 100%, 20% and 9% [OV100%, OV20%, OV9%]) and intraocular scattering (IS) (Objective Scatter Index, OSI) were monitored in 6 eyes (6 patients) with secondary corneal swelling due to CL wear with double-pass instrument (DP) (OQAS II, Visiometrics S.L., Spain). Corneal swelling was determined as the percentage change in the central corneal thickness (CCT) before and after CL wear using an OCT (3D OCT-2000, Topcon, Japan). This prospective study included five visits: Baseline and after sleeping with four different CL of +0.50D, +2.00D, +5.00D and +8.00D (Acuvue 2, Johnson & Johnson Vision Care, USA) on four different days. CL was randomized fitted in one eye and contra lateral was used as control. The relationship between OQ and IS and corneal swelling was analyzed by multiple ANOVA with Bonferroni correction and Pearson coefficient.

Results: Mean age was 26.33±4.41 years (Mean ± SD) and 50% were men. In baseline visit we found a mean CCT of 536.39±36.22 µm, and OQ and IS parameters were: Strehl ratio 0.26±0.03; OV100% 1.43±0.22; OV20% 1.60±0.25; OV9% 1.57±0.26 and OSI 0.50±0.13. After CL wear we found a mean CCT of 593.65±47.28 µm (corneal swelling of 10.67±3.53%); Strehl ratio of 0.19±0.06; OV100% of 1.32±0.25; OV20% of 1.25±0.37; OV9% of 1.07±0.43 and OSI of 0.70±0.34. Statistical differences were found between eyes wearing CLs and control eyes (p<0.05 MANOVA). Good correlation between corneal swelling and OQ and IS was found (Strehl ratio r=-0.87; OV100% r=-0.45; OV20% r=-0.76; OV9% r=-0.99 and OSI r=0.64).

Conclusions: CL-induced corneal swelling can cause a worsening of the optical quality of the eye that can be measured and quantified with a non-invasive double-pass technique.

Commercial Relationships: Victoria De-Juan, None; Mikel Aldaba, None; Raul Martin, None; Meritxell Vilaseca, None; Jose Maria Herreras, None; Jaume Puyol, Investor and consultant for Visiometrics S.L. (C)

Support: None

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Presentation Time: 11:15 AM - 1:00 PM

Effect Of Contact Lens Wear On Soluble Tear Mediators In Patients With Keratoconus

Bence L. Kolozsvari^{1A}, Mariann Fodor^{1A}, Goran Petrovski^{1A}, Beata Kettesy^{1A}, Beata Petrovski^{1B}, Eva Rajnavolgyi^{1C}, Peter Gogolak^{1C}, Andras Berta^{1A}, Georgina Szima^{1A}, Andrea Facsko^{1A}. ^AOphthalmology, ^BDivision of Biostatistics and Epidemiology, ^CImmunology, ¹University of Debrecen, Debrecen, Hungary.

Purpose: Keratoconus (KC) is a corneal ectasia with unknown etiology and with presumed association of extended contact lens (CL) wear. Our purpose was to study the effects of prolonged CL wear on different tear mediators in patients with KC.

Methods: In this cohort study, nonstimulated tear fluid samples were collected, at regular time intervals over 6 weeks, from 10 patients (10 eyes) with KC and 10 patients (19 eyes) with ametropia (AM) prior to and during continuous wear of CL. Patients with KC had worn rigid gas permeable (RGP) CL and patients with AM had worn silicone hydrogel CL, respectively. The concentrations of IL-6, IL-8, IL-13, RANTES, MMP-9, MMP-13, TIMP-1, NGF, EGF were measured by the cytometric bead array technology. Release of soluble mediators was calculated from their concentrations and the volume of tears collected for 2 minutes.

Results: Six weeks long RGP CL wear in KC patients caused threefold increase in MMP-9 release with a decrease of TIMP-1, RANTES and IL-13 levels (2-, 6- and 22-fold, respectively). The linear trend over time for IL-13 showed a significant decrease (p=0.047). Prior to CL wear (baseline) the release of NGF was lower (p=0.05), RANTES and IL-13 were 4.5-fold higher; MMP-9, TIMP-1, IL-8 and IL-6 were moderately higher in tears of KC eyes compared to AMs. At week 6 a significant difference between the two groups was found for MMP-9 release (p=0.008). Significantly lower level of IL-8 was found in AMs at week 6 (p=0.044). Between the groups the linear trend over time showed a significant difference for MMP-9 (increase in KC, decrease in AM, p=0.02) and for RANTES (decrease in KC, slight increase in AM p=0.03).

Conclusions: The level of various soluble mediators in tears of patients with

corneal ectasia with extended CL wear may contribute to the pathology of this disease and can have a predictive value in disease progression. According to our best knowledge this is the first comprehensive high-throughput study of real time follow up of selected soluble mediators.

Commercial Relationships: Bence L. Kolozsvari, None; Mariann Fodor, None; Goran Petrovski, None; Beata Kettesy, None; Beata Petrovski, None; Eva Rajnavolgyi, None; Peter Gogolak, None; Andras Berta, None; Georgina Szima, None; Andrea Facsko, None

Support: None

Program Number: 6641 **Poster Board Number:** D991A

Presentation Time: 11:15 AM - 1:00 PM

Factors Influencing Multifocal Contact Lens Choice

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Purpose: Multifocal contact lens fitting is often thought to be more time consuming than other methods of presbyopic correction and might be facilitated by information on the relative advantages of different multifocal brands. We evaluated the comfort and acuity at distance and near of two new silicone hydrogel multifocal contact lenses.

Methods: Thirty-five presbyopes between the ages of 43 and 65 were fitted with two brands of multifocal contact lenses (Vistakon Acuvue Oasys for Presbyopia (AOP) and CIBA Vision Air Optix Aqua Multifocal (AOAMF)) according to manufacturers' guidelines, and in a random order. The subjects had no prior multifocal or monovision contact lens experience. Acuity was measured binocularly at 4m and 40cm using Bailey-Lovie high and low contrast charts by a masked examiner. Subjects rated comfort and vision at distance and near on a 10 point rating scale.

Results: At distance, subjects read 2.4 letters (high contrast, p=0.001) and 4.3 letters (low contrast, p<0.0001) more with AOAMF. There was no significant difference between lenses in high or low contrast near acuity (p<0.70). Subjects rated comfort significantly better (9 out of 10) with AOP than with AOAMF (8 out of 10, p=0.001). A forward selection stepwise discriminant analysis identified the subjective quality of distance vision of the AOAMF and the comfort of AOP as the two most important factors in their lens preference. The subjective quality of near vision with each lens was a secondary but significant factor. The number of letters read at distance or near did not significantly influence lens preference. AOAMF was chosen by 60% (21/35) of subjects and AOP by 40% (14/35, p=0.31).

Conclusions: These two new multifocals had different relative advantages: AOAMF had better distance vision while AOP had better comfort. Patients used these differences in their selection of a preferred lens. Of note, subjects' qualitative assessment of vision and comfort was more clinically relevant than any measurement of visual acuity. This information might reduce chair time while fitting and increase subject satisfaction while wearing multifocal contact lenses.

Commercial Relationships: Shannon M. Zollinger, CIBA VISION, Vistakon (F); Kathryn L. Richdale, CIBA VISION, Vistakon (F); Donald O. Mutti, CIBA VISION, Vistakon (F)

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