

### Contact Lens Update

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#### News and New Products

Goal is to connect most recent and basic science to increase understanding of mechanisms of action of new contact lens related technology

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#### Financial Disclosures

Stock holder: Envision, Access Media (not a major shareholder), Tree House, SMM

Consulting - Bausch+Lomb/Valeant, NovaBay (Avenova), Google, Allergan, Vistakon, Alcon, Eyescripts

Innovega, Valeant Pharmaceuticals Contract research

Mutual fund holdings: Novartis, J&J (I do not select these)

41 million CL wearers in US

Centers for Disease Control and Prevention:

40.9 million contact lens wearers in the United States age 18 +

16.7% of the U.S. adult population (Cope et al, 2015).

ABB Optical Group 2015 - 3.0% CL sales growth over Q1 2014, and Q2 and Q3 showed growth 7.5% and 8.6%

Jeff Johnson, OD, CFA - third quarter of 2015, the U.S. contact lens market grew just under 4%

Baird estimates that the 2015 worldwide contact lens market will finish at approximately

\$7.4 billion. ~ = 2014

US market in 2015 is valued at approximately \$2.7 billion.

The worldwide market share of the four largest contact lens manufacturers remained stable in 2015

CL Spectrum, GfK, Baird, Cleveland Research

Trends in CL business in practices responding

124 patients/week

39% are CL wearers – an increase of 5 %

Fits and refits/week = 29 – an increase of 5

Gross income from CL = 39% - a 25% increase! Is it DD?

Net income from CL 27% is stable

DD + ~ 20%, Monthly + 5 to 8%

1-2 weekly – 5%

Compliance

CL Spectrum, GfK and ABB

8% of respondents in our market research indicated silicone hydrogel daily disposables (68% in 2014), followed by silicone hydrogel multifocals (63% versus 65% in 2014), silicone hydrogel torics (50% versus 45% in 2014), cosmetic lenses (43%), and hydrogel daily disposables (42% versus 46% in 2014).

For presbyopic patients who wear contact lenses, most practitioners continue to indicate a strong preference for multifocal lenses (71% in 2015 versus 70% in 2014) compared with monovision (19% in 2015 versus 22% in 2014), and over-spectacles (10% for 2015 and 8% for 2014), which has been the case for several years now. In practice, more of your presbyopic patients are prescribed a multifocal (48% of your contact lens-wearing presbyopes versus 46% in 2014) compared with monovision (31% of your contact lens-wearing presbyopes versus 36% in 2014). Soft multifocals (42% of presbyopic lens wearers) and soft monovision (28%) make up the bulk of the presbyopic correction

CL Spectrum

Growth potential of several specialty lens options in 2014 (% respondents expecting growth)

custom soft lenses (47%)

hybrids (26%)

scleral lenses (20%)

orthokeratology lenses (7%)

Current Literature on CL associated MK risk

Daily Wear vs. Extended Wear 2.5x to 8.0x

Reusable lenses vs. Daily Disposable 12.5x

Smoking 4.0x\*

Corneal Infiltrates: Managing Risks With Soft Lens Wear; Loretta B. Szczotka-Flynn, OD, PhD, FAAO, and Robin Chalmers, OD, FAAO

CDC recently reported 930,000 office visits and 58,000 ER visit/year for keratitis or CL conditions

Which costs \$175million in health care expenditures

Cost of Contact Lens Infiltrative Event care

17K severe and 32K non-severe in 2010

\$1,500 to \$1,000 estimate cost per case to Tx

Smith and Orsborn 2012 March Eye and CL

The Impact of Poor Compliance: CDC Data

Nearly 1 million doctor's office, clinic, and ER visits for keratitis annually, related to:

Improper MPS use

Poor lens care hygiene

Accounts for 250,000 clinical hours and \$175 million in healthcare expenditures

These numbers are likely an underestimate because they do not take optometry visits into account

CL Rx – Is this an issue?

1-800 Contacts legislative campaign purported to undo contact lens unilateral pricing policies, forcing doctors to write generic contact lens prescriptions blocking eye-care professionals from dispensing contact lenses out of their own offices

The result is expired, incorrect and specious prescriptions being filled.

1-800 claiming UPP prevent it from offering “discounts, rebates, and incentives,”

stopillegalCLs@aao.org

Fairness to Contact Lens Consumers Act is up for review

There is some rumbling about making CLs substitutable or “generic”

Variation in performance, dryness, tiredness

Ask them what they are doing when...

New Peroxide Lens Care

Peroxiclear

Bausch+Lomb Valeant Pharmaceuticals

ClearCare Plus

Alcon Novartis

3 ingredients in Triple-Moist Technology™

Poloxamer 181 – surfactant

Propylene Glycol – moisturizer

Carbamide – moisturizer and platinum modulating agent

Mode of Action of PMC after approximately 60 minutes of exposure 10, 11

During neutralization

Changes in physical and chemical properties of the solution occur<sup>10</sup>

Changes are hypothesized to result in the PMCs returning to solution increasing the rate of neutralization

Disinfection efficacy you expect from a peroxide—in only 4 hours<sup>7</sup>

Can lens care product alone reduce dropout?

those with the highest propensity to drop out of lens wear (n=93) after switching to MP

90% of subjects significantly reduced their likelihood of dropping out of CL wear (P<0.0001).

Online interviews were conducted with 73 of the study participants 6 months after completion of the initial study. A total of 93% of participants responded that they were still wearing CLs at least once per week

Introducing  
CLEAR CARE® PLUS  
with HydraGlyde®

Cleaning and Disinfecting Solution

The Best of Both Worlds

Lens Care Challenges: Poor Compliance

85% of patients say they are compliant with lens care

Only 2% actually demonstrate good compliance

42% topped off their used contact solution occasionally or overnight

Robertson DM, Cavanagh HE. Non-compliance with contact lens wear and care practices: a comparative analysis. *Optom Vis Sci.* 2011;88(12):1402-1408.

CLEAR CARE® PLUS With HydraGlyde® Gives Patients The Best of Both Worlds

All the benefits of CLEAR CARE®

HydraGlyde® Moisture Matrix Technology

Unsurpassed Disinfection with  
CLEAR CARE PLUS®

99.99% reduction in bacteria and yeast

99.9% reduction in  
fungi

99% reduction of Acanthamoeba cysts

99.99% reduction  
of Acanthamoeba trophozoites

Exceeds FDA  
(510(k)) guidance  
and ISO standards

Gabriel MM, Bartell J, Walters, R, et al. Biocidal efficacy of a new hydrogen peroxide contact lens care system against bacteria, fungi, and Acanthamoeba species. Presented at: The American Academy of Optometry Annual Meeting; Denver, CO; November 12–15, 2014.

Private Label Solutions

<http://www.ferris.edu/HTMLS/colleges/michopt/vision-research-institute/PDFs/contact-lens-solutions.pdf>

Contact lens private label solutions summary

Ferris State

Michigan College of Optometry

Steve Martin, UK

Compliance

Treatment Adherence – Persuasion Science

Reciprocity – mints matter especially if you say they are special

Authority – your diploma matters

Liking – compliments matter, believe people like you

Consensus – buildings, towels and lens cases

Consistency – ask for small commitment like rub and fill

Yes!: 50 Scientifically Proven Ways to Be Persuasive

Noah J. Goldstein Ph.D. and Steve J. Martin

DD lenses

No lens care

Fresh for each wear

Healthiest way to wear CLs

New lenses including specialty

Use rebates to manage cost and drive compliance

Enroll Staff

Caution: discourage overnight wear – the 30% issue

MyDay® Contact Lenses: The End of Trade-Offs

Bringing Natural Wettability and Softness to DD SiHy

Smart Silicone™ Chemistry  
Optimal Breathability without Compromises

New: HydraLuxe™ Technology

Frictional Energy and Feeling of Tired Eyes

ACUVUE OASYS® 1-Day  
with HydraLuxe™ Technology

ACUVUE OASYS® 1-Day  
Additional Design Highlights vs. ACUVUE OASYS® 2-Week

ACUVUE oasys with HydraLux 1-Day

- Tear-infused material, complementing the natural tear film with an enhanced network of tear-like molecules, that integrates with contact lens wearers' own tear film each day
- Electrolyte-balanced packaging solution to mimic human tears
- Enlarged optics to help wearers to see clearly even when their pupils may be enlarged due to low-light
- Increased lens diameter to ensure full corneal limbus coverage during blinking.

Bausch+Lomb Ultra  
2-phase polymerization of novel silicones and

PVP is highly hydrophilic

High PVP creates high  
water content

Keeps moisture on the surface of the lens, away from hydrophobic silicones

Astigmatic lenses

Reason for drop out and new lenses

Under-prescribed yet can be as easy as fitting a sphere

Available in all Rxs and modalities

Proper use of current refraction data

ECP decision making were called out (G Young) BCLA 2014

Vision Problems and CL drop out  
from a Global Perspective

Uncorrected astigmatism

Wrong refraction

Not vertexed

Not understanding Spherical aberration

And other aberrations such as coma

CI matters as does other BV issues including anisometropia, vertical phoria

Erin Rueff work on confusion between BV symptoms and CL dryness issues

Toric Contact Lenses

Compared to spectacles

for astigmatism, the toric contact lens is under prescribed with

~ 24% of wearers maximum versus

Recent and Anticipated Specialty Offerings

And Trends

Cleveland Rsearch

J&J

B+L

Alcon

Cooper Vision

Recent launch success

Changes at Novartis and Alcon

clariti® 1 day Toric

First & only SiHy daily disposable, lens for astigmatism

Back surface toric

Prism ballast design

Aspheric front optic zone to  
minimize aberrations

Prism-free periphery for improved  
comfort and Dk/t

Constant edge thickness with 360°comfort chamfer

Location mark at 6 o'clock



clariti® 1 day toric  
broad parameter range

Putting Patient Needs into Perspective

Having options to meet your patients' needs

Biofinity® XR toric –  
available 2015

Multifocal CLs

Another major reason for drop out                      12% y/y growth

They are better! Why?

Better designs, better technology

Better clinical testing

Better fitting guides!!!

Help Meet the Needs of a Growing Presbyopic Population

Globally,

2.1 billion people—or 27%—will be presbyopic by 2020.2

Multifocal CL wear in Underprescribed  
yet numerous studies showing better results than monovision

Survey of 500 presbyopic wearers - only 8% of current contact lens wearers reported being told about multifocal contact lenses when first complaining about their near vision

Once informed, one-third of regular contact lens wearers and monovision wearers were likely to try them

clariti® 1 day multifocal  
SiHy daily disposable multifocal

!!! Follow the Fitting Guide !!!

Up-to-date spectacle refraction

Establish ocular dominance

Lens Selection (Refer to fitting Guide)

Allow Initial 20 minute adaption

Evaluation and Dispensing

clariti® 1 day multifocal (50)

Lipid layer of our tear film contains natural surfactants

A surfactant is added to material formulation, and is an integral part of HyperGel™

Surfactant is permanently enriched at outer surface during manufacturing process

Examples of Power Profiles across the Power Range

Example of Power Profiles Normalized

INTUISIGHT™ Technology

Uniquely-optimized optic zone design: Age

INTUISIGHT™ Technology

Uniquely-optimized optic zone design: Power

1-DAY ACUVUE® MOIST MULTIFOCAL

INTUISIGHT™ Technology

1-DAY ACUVUE® MOIST MULTIFOCAL

INTUISIGHT® Technology

1-DAY ACUVUE® MOIST MULTIFOCAL

Existing Multifocal Designs

Front surface optics may alter/distort as lens wraps over cornea

The complex optics of the aging eye requires additional attention to lens centration & conformity to corneal shape

Poor centration can misalign the complex optics zone relative to pupil

Precise Optics: Hybrid Back Surface Design

1-DAY ACUVUE® MOIST MULTIFOCAL

Aspheric center

Aspheric shape factor to more closely align the cornea to maintain the integrity of the complex front surface optics

Spherical periphery to optimize centration

Clinically tested with corneas having K's from 38.75D to 48.50 D (6.95mm to 8.71mm)

Precise Optics: Hybrid Back Surface Design

1-DAY ACUVUE® MOIST MULTIFOCAL

Step 1 – Distance Rx

Determine the maximum plus spherical refraction to achieve best visual acuity.

Apply BVD correction if  $> \pm 4.00D$

Select patients with  $<1.00DC$  astigmatism

Step 2 - Dominant eye

Viewing test chart binocularly unoccluded, place +1.00D alternately in front of each eye\*

Dominant eye is where 'least comfortable' or 'most blurred' vision is reported

\*or practitioner method of choice

Simple Steps to A Successful Fit

1-DAY ACUVUE® MOIST MULTIFOCAL

Step 3 - Reading add selection

Determine minimum required to give the patient satisfactory near vision

Refer to the table to select from

LOW, MID or HIGH add

Step 4 – Settling time

Allow 10 minutes to settle

The Simple Steps to A Successful Fit

1-DAY ACUVUE® MOIST MULTIFOCAL

Step 5 - Visual performance

Assess vision using real world examples (view across the road, mobile phone)

Patient to assess their far and near vision

If acceptable, begin the trial

If unacceptable, refer to the table to enhance distance or near vision

NOTE: Limit making changes on initial visit if at all possible

The Simple Steps to A Successful Fit

19MM people are interested, but only 2.4MM currently wear color contact lenses<sup>2</sup>

Targets and segments based on interest

Primary: Clear sphere contact lens wearers

6.9MM (36%)

Secondary: Current or former cosmetic contact lens wearers

2.4MM (13%)

Tertiary: Non-contact lens wearers

6.3MM eyeglasses (33%)

3.5MM plano (18%)

AIR OPTIX® COLORS contact lens printing and pattern design

FreshLook® COLORBLEND® contact lens inks printed directly on front surface of lenses

AIR OPTIX® COLORS contact lens inks printed on molds

FreshLook® COLORBLEND® contact lens printing process

3-in-1 color technology

Pad printing

The colored layers are applied to the front surface of the dry lens already formed in a previous step

The inks crosslink to the surface of the lens by a thermal reaction

No clear layer is applied on top of the colored layer, therefore the pigment is exposed to the surface.

The surface is less smooth than AIR OPTIX® COLORS contact lenses

Comparison of ink position on color contact lenses

AIR OPTIX® COLORS contact lens printing process followed by surface plasma treatment

The three layers of colored inks are applied to the base curve mold following the deposition of a clear layer that covers only the printed portion (not the 5 mm optical zone)

The clear layer ensures that pigments are not exposed to the surface in contact with the eye

The application of the inks is done by pad print technology (same as for FreshLook® products)

The ink adheres inside the lens, and it is not removed during cleaning cycles

The mold with the resulting “stack” of printed layers is then exposed to UV light, partially crosslinking the color, yet leaving a portion available for further crosslinking with the lotrafilcon B to form the front surface of the lens

A natural look in a full range of colors

9 colors—that each blend with the patient’s own eye color.

Parameter range – no refit required for  
AIR OPTIX® AQUA contact lens wearers<sup>1</sup>

Same unique AQUA moisturizing agent as AIR OPTIX® AQUA contact lenses

Cosmetic lenses in Asia  
Rapid growth! Safety issues?

A meta-analysis of studies on cosmetically  
tinted soft contact lenses, Rah et al Clinical Ophthalmology Oct 2013

Background: Concerns regarding the safety of cosmetically tinted contact lenses have been reported in the literature. The purpose of this paper is to evaluate the safety of cosmetically tinted contact lenses in a large number of patients across six clinical trials that varied from 1 week to 3 months in duration.

Methods: Lenses tested included: Naturelle limbal ring daily disposable, Lacelle limbal ring daily disposable, Lacelle colored cosmetic daily disposable, Lacelle limbal ring planned replacement at 2 weeks, and Alamode traditional/annual colored cosmetic lens. The primary safety outcome was slit-lamp examination, including epithelial edema, epithelial microcysts, corneal staining, bulbar injection, limbal injection, upper lid tarsal conjunctival abnormalities, corneal neovascularization, and corneal infiltrates. High contrast logMAR visual acuity with lenses, and lens wearing time, movement, and centration, are also presented. Results: A total of 871 subjects (1,742 eyes) and 23 clinical investigators participated in the six studies, with an average completion rate of 96.4% across all studies. The mean age of the patients was  $26.8 \pm 6.6$  years, and 86.7% of participants were female. The total number of slit-lamp examinations across the six studies was 2,456 visits by eye (1,228 visits by patient). There were no slit-lamp signs . grade 2 for any finding, with the exception of corneal staining in one study. In this study, grade 3 corneal staining was noted in one eye (0.1%) at follow-up visit 1 and four (0.6%) of all eligible dispensed eyes at follow-up visit 2, with no eyes requiring medical treatment. No adverse events were reported during any of the trials.

Conclusion: The cosmetically tinted lenses evaluated in this meta-analysis appear to be safe when properly prescribed by an eye care professional and used in a compliant manner.

J&J natural eye enhancement

J&J Vistakon launched 1-Day Acuvue Moist Define for “Natural eye enhancement”

Which don’t make the eyes “stand out” rather to have the “look you were born with”

50% of spectacle wearers are interested. “Not like limbal ring lenses in Asia”.

The pigment does not touch the corneal tissue and the surface is very smooth unlike other cosmetic lenses that “health care agencies around the world are sensitive to.”

Data presented to support the lens in posters and podium included, surface roughness, corneal swelling, TEM, and AFM.

“there is no visual or comfort compromise”

ABB Concise

Custom cosmetic tinted, starburst, and limbal ring lenses

Cosmetic lens safety

Do not share lenses

Do not use found lenses

Must have RX even for plano

Need follow up care like any other lens

Steve Martin, UK

Compliance

Treatment Adherence – Persuasion Science

Reciprocity – mints matter especially if you say they are special

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Yes!: 50 Scientifically Proven Ways to Be Persuasive

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CL Dryness Diagnosis

Richdale 24% of drop outs

DX

Rule out Allergic conjunctivitis

Lens care issues

Lagophthalmos

Blepharitis and MGD

Conjunctivochalasis

Hypothyroid

Sjogren's

BV and accommodation dx

Stop, treat and then restart

Pre-insertion OTC or Rx allergy med

Steroid or combo AB/Steroid treatment with discontinued CL wear

Lid scrubs

Lens and Lens Care change

CL Dryness Diagnosis

Lagophthalmos – KB lid-light

Rule out Allergic conjunctivitis

Lens care issues

Blepharitis and MGD

Conjunctivochalasis

Hypothyroid

Sjogren's Sjo Dx test

Pre-insertion OTC or Rx allergy med

Steroid or combo AB/Steroid treatment with discontinued CL wear

Lid scrubs

Lens and Lens Care change

Dryness vs Dry Eye Tx

But first get the Dx right

CL -> MGD?

MGD => CL Drop out?

Cease CL wear and heal including anti-inflammatories

(off label)

Lid physical therapy

Supplements such as omega- 3s, fish, HydroEye (SBH.com)

Hydrate          Blink

Azithromycin 250mg/day > doxycycline 200mg/dayX 5 days

Think about lens care not just lens type if you don't use DD

TFOS International Workshop on Contact Lens Discomfort  
The TFOS International Workshop on Contact Lens Discomfort:  
IOVS October 2013

Eye Lid Cleaning

Hot washcloth

Easy

Available

Rub and massage

Lid Scrubs continued

Debridement and BlephEx

OCuSOFT, Inc. has launched Retaine PM Nighttime Ointment for relief of severe dry eye.

Designed to keep eyes lubricated and comfortable while you sleep, Retaine PM is a preservative-free, oil-based formula. Retaine PM is packaged in a large, economical 5 gram tube which is 43% larger than traditional 3.5 gram tubes.

Retaine PM joins a growing line of Retaine brand eye care products, including artificial tears and nutritional supplements available through eyecare professionals. Introductory discount pricing is available to practitioners dispensing from their office, however, patients may also order online directly at [www.ocusoft.com/retaine](http://www.ocusoft.com/retaine).

For more information, call (800) 233-5469 or visit [www.ocusoft.com](http://www.ocusoft.com).

510 K Clearance

Medical Device

Rx under the supervision of an eye care professional



Indication – “for the removal of foreign material, including microorganisms from the skin”

Hypochlorous Acid .01%

Excellent activity against a broad range of pathogens

Fast acting onset of activity

Effective against pathogens commonly found on the lids & lashes

Demodex

Patient complained of itchy eyes, especially at night time. Epilation of two eyelashes from each eye were examined under a microscope and the picture shows an active critter. Demodex mites are known to cause increases in ocular allergies when the lights are turned off because they come out of the lash follicles to lay their eggs. Patient is to begin treatment with tea tree oil shampoo on scalp, Oasis lid foam every night on eye lids and every morning to use Cliradex lid scrubs. Follow up in one month.

Blinking instructions by Don Korb

Non-squeezed to touch

Pause

Squeeze lightly

Open

Repeat

Every hour every day

Dry Eye Treatment

Lid wipes, eye drops QID Systane Balance, 2X1,000 mg Omega 3 fa daily for 3 mos.

MGYLS increase

SPEED score decreased 32 to 14

Vs Warm compress

Note Warm compress did improve

2 AEs

Korb et al.

Shire submits application for Lifitegrast to treat DE in Adults

Small molecule integrin inhibitor

GP lenses and irregular cornea care with toric SCLs

New materials

New and current designs

Hybrids

Today's unique toric soft CLs for irregular cornea

Market Trends by Category

Scleral, hybrid, and soft options for regular, Keratoconus and other Irregular Corneas

Definition of Scleral Lens

A Guide to Scleral Lens Fitting

Extended literature search

Compiled with an international advisory board

Explores

Scleral shape

Scleral lens design

Fitting approach

Management

supported by an unrestricted educational grant from Bausch + Lomb.

Indications for Soft Lenses in Irregular Cornea

Naturally occurring ectasia

Younger children and adults with keratoconus

Forme fruste keratoconus

Pellucid marginal degeneration

Post Intacts and Corneal Cross-linking

Post-surgery ectasia

Post corneal graft

Intolerant to other lens systems

Authorized Laboratories

Art Optical Contact Lens, Inc.

Metro Optics

ABB Optical

TruForm Optics

Contact information available at [www.kerasoftic.com](http://www.kerasoftic.com)

Myopia Control

Fear of myopic degeneration – how real?

Atropine – 0.1 and 0.01% similar to CL results

Donald Tan, Singapore

No AEs, mild dilation, Off label

Less rebound with 0.01%

Numerous soft and orthok trials show safe results

CooperVision MiSight Hong Kong insights

BLINK study to start at Ohio States

<http://www.orthokacademy.com/>

Is it unethical not to recommend or explain?

Ideal Skirt Appearance

UltraHealth FC

UltraHealth FC

International Keratoconus Academy

Education and Scientific Development Advocacy

Live, social media, web-based education and publication

Clinical research support

Complimenting efforts of Professional Organizations and NKCF

Executive Board – B. Eiden, T. McMahon, A. Morgenstern, B. Tullo, C. Chang ODs, E. Donnenfeld, and Y. Rabinowitz MDs

and yours truly

Membership inquiries to [info@keratoconusacademy.com](mailto:info@keratoconusacademy.com)

New Instrumentation in Eye Health

Binocular OCT Comprehensive Eye Exam in a box

Smart Vision Labs

“Building a better way to do vision exams. The SVOne, our ultraportable smartphone-based autorefractor, enables you to perform simple, accurate, and fast refractions. “

Kiosk paranoia or detectors that lead to BICs?

EyeNetra to....

What’s next?

Oculus K5M

Topography, Meibomography, Imaging

“SMART” Contact lenses

Putting stuff in CLs to make then sense or effect vision or the eye

Triggerfish - IOP

Google and Novartis – diabetes and presbyopia

Microfabrication, nano technology, big data

Innovega – enabling technology to take augmented reality beyond

Drug eluting

THANK YOU

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