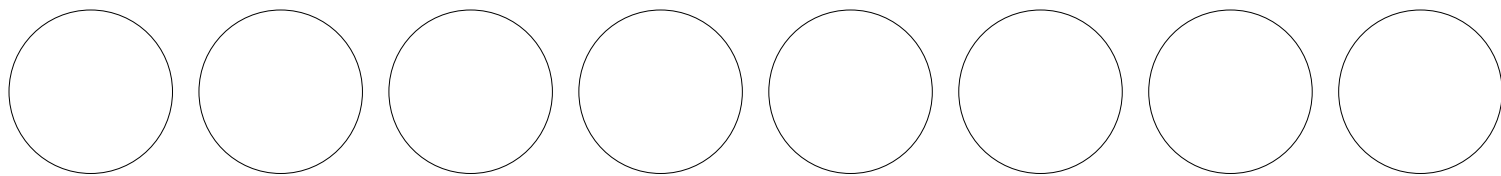


BAUSCH & LOMB INSIGHT





Our mission is to protect and
enhance the precious gift of sight
for every individual.



Bausch & Lomb



Bausch & Lomb has many partners in the eye care community, and we are particularly honored to support the American Academy of Optometry in its quest to enhance excellence in optometric practice. The support we give to the AAO and other organizations is just one aspect of our mission to bring visionary ideas to eye care and to protect and enhance the precious gift of sight for all.

At this year's meeting we again support two Ezell Fellowships through the American Optometric Foundation, as well as all of the Academy-supported resident travel grants. In addition, we are a patron sponsor of the meeting, including continuing education in the Section on Cornea and Contact Lenses and Refractive Technology. I want to especially thank Chris Snyder, OD, MS, FAAO, for his passionate leadership in representing Bausch & Lomb to the AAO.

There have been some new developments here at Bausch & Lomb. You have no doubt noticed our use of new formats for communicating with you, including my *Joe's View* columns (currently available to those in the United States and United Kingdom) and e-blasts to U.S.-based practitioners that discuss contact lens-related issues. This book is our latest initiative and it begins with a Q&A session with Peter Valenti III, Global President of Vision Care at Bausch & Lomb, which discusses his views on the future of health care and what healthcare providers can do to develop their practices in these turbulent economic times. We also introduce you to our global team and their roles representing optometry and eye care at Bausch & Lomb. In addition, we share our evidence-based science to further the care of your patients. The centerpiece of this book is a timeline of Bausch & Lomb's many achievements over its history.

The Center for Patient Insights™, which you can read about in more detail on pages 8-9, is now available to

U.S. eye care professionals and it offers information to help practitioners improve their communication with patients by better understanding their needs and desires.

Another new development at Bausch & Lomb is our recent adoption of AdvaMed's Code of Ethics on Interactions with Healthcare Practitioners in the United States. This was done in accordance with our belief that interactions and relationships with healthcare practitioners that are conducted appropriately and ethically are in the best interest of the patient. This move reflects the importance that we place on providing unbiased information to you and our support for accredited continuing education.

The history of Bausch & Lomb is full of innovations: from the first soft contact lens, to one of the first multipurpose contact lens solutions, to high DK GP lenses and leading lens care products, to one of the first silicone hydrogel lenses. Our teams in Clinical and Medical Affairs and Professional Services at Bausch & Lomb continue this tradition of innovation so that we can bring you new products and new treatments that improve eye health and patient quality of life.

I think back over my three decades of being an AAO Fellow and over two decades of being a Diplomate in the Section on Cornea and Contact Lenses and remember all the knowledge I have gained and the people I have learned from through the Academy, and appreciate deeply the partnership we have with our colleagues dedicated to the pursuit of bettering vision and eye health for our patients. I hope that you find your AAO experiences to be as rewarding and instructive.

Best wishes to the Academy at this meeting. We look forward to continuing our partnership with you in the years ahead.

Joe Barr, OD, MS, FAAO
Global Vice President
Clinical and Medical Affairs and
Professional Services
Bausch & Lomb
Vision Care



Bausch & Lomb's Global Medical Affairs – Vision Care Team (from left to right): Gary Orsborn, William Reindel, Joe Barr, Carla Mack, and Mohinder Merchea.

Gary Orsborn, OD, MSc, FAAO

Dr. Gary Orsborn is Director, Global Medical Affairs – Vision Care. He earned a Doctor of Optometry degree and a Master of Science in Physiological Optics from The Ohio State University College of Optometry. Since joining Bausch & Lomb in 1985, his responsibilities in the U.S. and international divisions have included management of field clinical studies of marketed and developmental contact lenses and care products, development of practitioner educational materials, world-wide professional relations, and marketing of vision care products. Dr. Orsborn is a Fellow of the American Academy of Optometry and a member of the British Contact Lens Association and American Optometric Association.

William T. Reindel, OD, MS

Dr. William Reindel is Director, Global Medical Affairs – Vision Care. He earned a Master of Science degree in Physiological Optics at The Ohio State University, and a Doctor of Optometry degree from Ferris State University. Dr. Reindel is responsible for overseeing clinical research for product performance evaluations in phase 3 and 4 clinical trials, as well as research grants and investigator-initiated trials. Since joining Bausch & Lomb in 1986, he has also held positions in global strategy, marketing, and clinical research.

Joe Barr, OD, MS, FAAO

Dr. Joe Barr attended The Ohio State University College of Optometry where he earned a Doctor of Optometry degree and Master's degree in Physiological Optics, and is currently an Emeritus Professor of Optometry and Vision Science at the college. Dr. Barr is an emeritus editor of *Contact Lens Spectrum* and founding editor of *Contact Lens Today*, and he has over 50 peer-reviewed publications in the area of contact lenses and cornea.

He is a member of the AOA, International Society for Contact Lens Research, and ARVO. Dr. Barr is a past chairman of the Section on Cornea and Contact Lenses of the American Academy of Optometry and a former director of the Collaborative Longitudinal Evaluation in Keratoconus Photography Reading Center at The Ohio State University. He is currently Global Vice President of Clinical and Medical Affairs and Professional Services for Vision Care.

Carla J. Mack, OD, MBA, FAAO

Dr. Carla Mack is Director, Global Medical Affairs – Vision Care. Prior to joining Bausch & Lomb in 2008, Dr. Mack was Director of Clinic Services and Associate Professor of Clinical Optometry at The Ohio State University College of Optometry, and previously served as Editor of *Contact Lens Spectrum* and the *Contact Lenses Today* e-newsletter. She is a Diplomate in the American Academy of Optometry Section on Cornea and Contact Lenses. Dr. Mack earned her OD degree from The Ohio State University College of Optometry, and an MBA from that university's Fisher College of Business. Dr. Mack provides support for academic institutions and eye care organizations, leads global and cross-regional public relations efforts, and serves as the spokesperson for Vision Care. She also contributes to clinical research and works with researchers to publish Bausch & Lomb's scientific information.

Mohinder M. Merchea, OD, PhD, MBA, FAAO, FBCLA

Dr. Mohinder Merchea is Director, Global Clinical Affairs – Vision Care, where he is responsible for clinical support for new lens and lens care solution development, core research, and leading the global Bausch & Lomb Research Clinic team. His research and clinical experience include refractive surgery, keratoconus, topography, wavefront aberrations, and contact lenses, and he has over 10 years of experience in medical device human clinical trials. At The Ohio State University, he earned his Doctor of Optometry from the College of Optometry and his Master of Science degree in Physiological Optics and Doctor of Philosophy in Vision Science, and later went on to earn his MBA from the Fisher College of Business. Dr. Merchea is a Diplomate in the Cornea & Contact Lens Section of the American Academy of Optometry and a Fellow of the British Contact Lens Association, and is a member of the American Optometric Association and the Association for Research in Vision and Ophthalmology.

Bringing Visionary Ideas to Eye Health

An Interview with Peter Valenti III, Corporate Vice President and Global President, Vision Care, Bausch & Lomb

The mission of Bausch & Lomb is to bring visionary ideas to eye health. Could you explain how this ideal is reflected in the corporate culture of Bausch & Lomb?

Bausch & Lomb has a 156-year history of innovation rooted in knowledge and insights, pioneering the use of novel technologies to bring vision to the eyes of the world. To maintain this important tradition, we have established four corporate pillars—innovation, partnership, leadership, and giving back—that serve as guideposts for everything we do. Innovation in areas ranging from surgery to pharmaceuticals to contact lenses remains the cornerstone of our business, and certainly our partners in the eye care community have come to expect this breadth of innovation from us. While a consistent champion of this community, we continue to seek new ways to strengthen our partnerships with eye care professionals. For example, we have recently developed a Center for Patient Insights™ to help U.S.-based eye care professionals interact more successfully with their patients. We believe that innovations such as these will help solidify our role as an industry leader, and allow us to better advocate for industry growth and increase our ability to give back to the eye care community. Being a leader in the industry means that we are building a foundation for the success of eye care professionals everywhere; we want the eye care professional to be the hero in this process.

A topic on everyone's mind is the economy and the future of health care in the United States. How is Bausch & Lomb positioned to navigate this new unknown environment?

Our belief is that, regardless of whether the economy is good or bad, successful eye care professionals and practices will remain successful as long as the health of the patient is placed front and center. And because Bausch & Lomb is a privately held company, we have considerably more flexibility than public companies when it comes to focusing on long-term goals and innovations. Rather than emphasizing short-term profits, we continue to make investments in our pipeline, partnerships, and charitable giving, with the ultimate goal of bringing “vision” back to

vision care. And irrespective of the political outcome of the healthcare debate in the United States, we are working to place eye care at the forefront of public consciousness. We know that eye care continues to suffer from low visibility compared with other areas of public health, such as dental care. Significant work remains in ensuring that eye care receives the public attention it deserves, including renewed emphasis on initiating appropriate eye care during childhood and continuing annual exams to assess age-related changes in eye health.



Could you tell us a bit about Bausch & Lomb's relationship with AAO over the years?

Bausch & Lomb has many partners in the eye care community, and we have always been, and will continue to be, a strong supporter of AAO. This organization has been extremely successful in advancing the science behind eye health and addressing the educational needs of the medical community. As a leader in the industry, we look forward to partnering with AAO to positively shape the future of eye health, particularly as it relates to new segment platforms that constitute an enormous opportunity for strengthening the relationship between eye care professionals and their patients.

What do you mean by “new segment platforms,” and what is the significance of this for the eye care professional?

When you consider contact lenses in North America over the last 10 years, market penetration and growth have only occurred during periods when new patient benefits were introduced. We believe that many patient segments, such as presbyopes, are opportunities to enhance growth, and other segments remain untapped. It's when you introduce a new segment platform for treatment and address unmet needs that you truly expand the market, drive patient traffic into the practice, and improve patient satisfaction and retention. We view our role at Bausch & Lomb as one of partnership with eye care professionals to help in understanding the needs of patients and to facilitate communication about new areas of eye care. Ultimately, this will help grow individual practices and the industry as a whole.

“We view our
role at Bausch
& Lomb as one
of partnership
with eye care
professionals
to help in
understanding the
needs of patients
and to facilitate
communication
about new areas
of eye care.”

– Peter Valenti III



Physical Properties of Multipurpose Lens Care Solutions

PURPOSE Multipurpose lens care solutions (MPS) come in contact with the eye during the insertion of contact lenses that have been cleaned, disinfected, and stored in the solutions. Solution formulations are designed to be compatible with the eye to minimize physiological impact on tears and ocular tissues. One of the factors influencing the biocompatibility of the MPS is their physical attributes. The purpose of this study was to investigate the physical properties of MPS in comparison to human tears.

METHODS The pH, osmolality, viscosity, and surface tension of 6 US commercially available MPS and 1 Bausch & Lomb investigational MPS* were measured.

RESULTS The pH range for MPS systems was 7.2 to 7.8. Four of the test solutions were outside the pH range reported for tears. The osmolalities of 5 of the 7 MPS examined were isotonic relative to tears in the range of 272 to 310 mOsm/kg. One of the commercially available MPS was hypotonic in comparison to tears, with an osmolality of 220 mOsm/kg. Most of the solutions tested had a surface tension similar to tears (43–46 nN/m). Two of the MPS had surface tensions below that of tears (38 and 40 nN/m), and 1 MPS had a surface tension of 49 nN/m. The viscosities of all of the MPS tested were within the range of tears (1–10 mPa.s).

CONCLUSIONS The physical properties of 7 MPS systems were tested and compared to human tears. The pH, osmolality, surface tension, and viscosity of 2 commercially available MPS and 1 investigational MPS all fell within the range reported for tears. One commercial MPS was outside the pH range for tears. Two other commercial MPS deviated from the pH and surface tension of tears. Another commercial MPS was outside the range of tears for pH, osmolality, and surface tension. Further study is needed to understand the clinical significance.

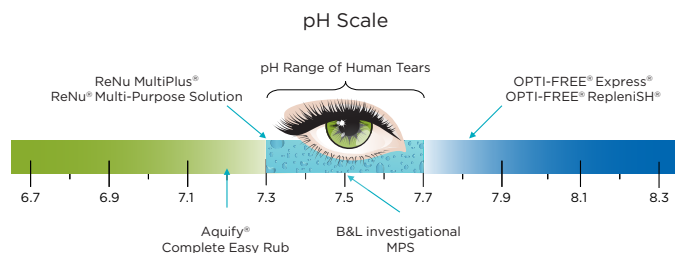
AUTHORS: Susan E. Burke, Krista M. Fridman, Catherine A. Scheuer, Vicki L. Barniak

AFFILIATION: Vision Care R&D, Bausch & Lomb Inc., Rochester, NY, USA

Paper presented at: Annual Meeting of the American Academy of Optometry; November 11-14, 2009; Orlando, FL.

“Eyes are our windows to the world, and optometric care requires an appreciation of patient concerns about the safety of any agent that comes in contact with them. In this study, we compared the physical properties of a range of multipurpose solutions to determine which of these compositions were most similar to human tears and, it is hoped, least likely to affect ocular tissue.”

— Susan E. Burke



*The investigational MPS solution has not been reviewed by the U.S. Food and Drug Administration and no determination of its safety or effectiveness has been made by the agency.



SUSAN E. BURKE received a PhD in Physical Chemistry from McGill University. She joined Bausch & Lomb in 2004. Dr. Burke is currently a Principle Scientist in Vision Care R&D and her duties include leading a group of formulation scientists focused on contact lens care product development and managing R&D project teams. Susan is an inventor on several patent applications and has co-authored over 20 peer-reviewed journal articles.

Adsorption and Controlled Release of a Polysaccharide Conditioning Agent From Soft Contact Lenses

PURPOSE Polymers included in some multipurpose lens care solutions (MPS) can impart properties such as improved surface wetting and enhanced lens hydration. The objective of this study was to examine adsorption and release of a polysaccharide conditioning agent found in a Bausch & Lomb (B&L) investigative MPS* to and from the surface of soft contact lenses.

METHODS Adsorption and release of a fluorescein-tagged polysaccharide in a B&L investigative MPS was monitored with fluorescence spectroscopy. Polymacon, etafilcon A, lotrafilcon B, lotrafilcon A, galyfilcon A, senofilcon A, and comfilcon A lenses were soaked overnight in the MPS. The amount of polysaccharide adsorbed to each lens was determined by difference of concentration before and after soaking. A 20-hour release profile was monitored with a saline rinse of soaked lenses at the rate of tear film secretions. Fluorescence of each aliquot was measured and polysaccharide concentration was determined.

RESULTS The polysaccharide conditioning agent of the B&L investigative MPS was found to adhere to all lens types tested, including silicone hydrogels. Release rates varied between lens types, with lotrafilcon A and senofilcon A exhibiting the slowest rates of release with more than 40% of the polysaccharide remaining on lenses after 20 hours. It is expected that the polysaccharide conditions the surface of the contact lens through hydrogen bonding. Interestingly, lens materials with more hydrogen bonding potential demonstrate greater polysaccharide retention.

CONCLUSIONS The polysaccharide conditioning agent of the B&L investigative MPS was found to adsorb to all traditional hydrogel and silicone hydrogel lenses studied. Adsorption and release of the polysaccharide to and from various lens types could be explained by the hydrogen bonding potential between the known lens surface chemistry and the polysaccharide.

AUTHORS: Catherine A. Scheuer, Krista M. Fridman, Susan E. Burke, Srin Venkatesh

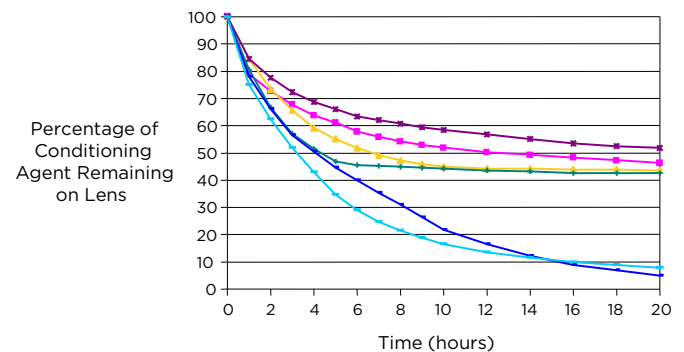
AFFILIATION: Vision Care R&D, Bausch & Lomb Inc., Rochester, NY, USA

Paper presented at: Annual Meeting of the American Academy of Optometry; November 11-14, 2009; Orlando, FL.

“Contact lens dehydration can lead to patient complaints of ocular dryness, potentially reducing overall satisfaction with the lenses and decreasing the length of time a patient is willing to wear them. While many advances have been made in the development of lens material that minimize dehydration, we wanted to assess whether an investigative multipurpose solution containing a conditioning agent could provide additional improvements in lens hydration.”

— Catherine A. Scheuer

Polysaccharide Release From Contact Lenses



*The investigational MPS solution has not been reviewed by the U.S. Food and Drug Administration and no determination of its safety or effectiveness has been made by the agency.

CATHERINE A. SCHEUER holds a Master of Science degree in Biochemistry from the University of Rochester. She is a Research Scientist in Vision Care R&D at Bausch & Lomb with a focus on contact lens care product development. Prior to joining Bausch & Lomb in 2004, Catherine held scientific positions at Wyeth and at the University of Rochester School of Medicine and Dentistry. She is co-author of 9 peer-reviewed journal articles and co-inventor on 7 patent applications.



THE CENTER FOR PATIENT INSIGHTS™ is Bausch & Lomb's latest initiative as a dedicated partner of eye care professionals.

This program was developed specifically for eye care professionals and its purpose is to deliver up-to-date news on industry trends, and insights on patient attitudes and beliefs. It is hoped that eye care professionals will utilize this research to seize growth opportunities for their practices by building more meaningful relationships with their patients. A great way to expand a practice is through patient loyalty, and customer allegiance is directly linked to satisfaction with the products as well as the services provided by the eye care professional.

Information is a vital component of every decision we make, but we live in an age where the volume of information available can be overwhelming. For instance, searching on Google for "contact lens fitting" will result in over 30 *million* listings. One goal of the Center is to provide easy access to a unique repository of research regarding patient attitudes and habits that will help eye care professional practices. To this end, the Center has created a Web site (www.centerforpatientinsights.com) that will provide brief PatientPoints and research insights that are downloadable and printable for future use and reference, as well as video

materials that eye care professionals can listen to or watch at their convenience. This site, which is just one component of the Center initiative, also includes a search function that allows users to easily locate specific information using keywords and categories. New content will frequently be developed and posted, and eye care professionals can opt to have these new materials e-mailed to them directly on a regular basis.

A recent study suggests that learning about your presbyopic patients' lifestyles and prescribing accordingly can really pay off.

PatientPoint from the Web site



CENTER FOR
Patient Insights™

The insights on consumer behavior that the Center offers are not tied to specific brands and are derived from proprietary data or from research conducted by outside sources, such as Gallup and Health Product Research. Some of the available topics include: patient health and vision conditions; patient preferences and behaviors; patient satisfaction and retention; time management; and market growth.

The Center for Patient Insights™ is a resource to support practice growth and increase the eye care professional's ability to retain patients through increased knowledge, deeper insight, and more productive dialogue. By knowing what patients want and need, and what their expectations are, eye care professionals can engage the patient so that they can work together toward the goal of optimal vision.

On cost, 65% of multifocal lens wearers stated that *“the benefits were worth every penny.”*

PatientPoint from the Web site



BAUSCH & LOMB
OPTICAL CO.

Bausch & Lomb
Over 150 Years
of Dedication to
Innovation



Bausch & Lomb: A History of Innovation

There are very few companies that have been around for over 150 years. It is an achievement that requires perspective in order to be truly appreciated. In 1853, John Jacob Bausch set up an optical goods shop in Rochester, New York. When the Bausch & Lomb Optical Company opened its doors ten years later, the United States consisted of only 35 states and the President in office was Abraham Lincoln. Despite the turbulence of the times, John Jacob Bausch and Henry C. Lomb had a vision of creating a company that made products to help people see.

Beginning with affordable spectacles, and then expanding into microscopes and telescopes so that people could

look at things that the naked eye could not see, Bausch & Lomb impacted people's daily lives as well as scientific achievement. From these beginnings, the company has continued with its tradition of innovation, creating the first soft contact lens and eventually extending into surgical treatments and pharmaceuticals. Bausch & Lomb was there when people sailed the skies in hot air balloons as well as when the first pictures of the moon were taken, and the company is still here today, working to help people see the next horizon.



1800-1899

John Jacob Bausch opens optical goods shop
1853

Set up 1st power lens grinding machine in the U.S.
1861

Bausch & Lomb Optical Company formed
1863



Started factory lunchroom
1863

Started mutual benefit association for employees unable to work due to illness
1863

Founded the Mechanics Institute (which would become the Rochester Institute of Technology)
1885



Moldable frame made from Vulcanized rubber
1853

B&L makes its first microscope
1872

Patent for incandescent lamp instead of mirror on microscope
1882

Grinds first photographic lens (1st Kodak camera had a B&L lens)
1883



Patent for Iris Diaphragm Shutter
1887

Telescopes and binoculars
1893

Optical machinery
1896

Toric ophthalmic lenses
1897

KEY: Hard lenses Devices Contact lenses Solutions Pharmaceuticals



B&L Scientific
Bureau is created
1905

1900-1949

Established an
unemployment
insurance fund for
local working people
1933



B&L Honorary
Science Award
for high school
students
1933

Admiral Byrd's
Antarctic Expedition
had B&L
microscopes and
photomicroscopic
equipment
1935

Provided
employees with
group life and
health insurance,
as well as paid
time off
1937



3 million lbs of optical g
produced for the war effort
including binoculars, rang
finders, and periscope
1941-1943

SS Henry Lomb
is christened
1943



Galamic
S

Slide projectors
1902

Car headlight
mirrors
1912

Binocular corneal
microscope and Ives
visual acuity meter
1917

Super Cinephor
projection lens
1922

Hemoglobinometer
1923

Keratometer
1928

Ultraviolet
radiation equipment
1929

X-ray stereoscope
1931



Ray-Ban aviator
goggles for
military pilots
1937

Ultraviolet
optics for o
1941

Received an Oscar
for its contributions
to the motion
picture industry

1955



Super Baltar Lenses on
Ranger 7 take first
pictures of the moon

1965



B&L Insurance
Company (insures
lenses from other
lens makers)

1980

Opened the
Rochester Optics Center,
a state-of-the-art
research and
development facility

1988

Research
Symposia

1985-1994

Eye Surgery Division
established, entering
cataract and refract
surgery markets

1997

1950-2000

lass
ort,
nge
es



The
CinemaScope
Lens

1952

Sun simulator
for Jet
Propulsion
Laboratory and
NASA

1962

Trifocal lens

1954

t microscope
ancer research

1949



Soflens®
(1st soft contact lens)

1971

Toric
contact
lenses

1979

B&L expands into a wide
range of new science
and health care fields,
including
pharmaceuticals, and
ear, mouth,
and skin products

1980s

Bifocal soft
contact lenses

1982

Moisture
Drops

1984

ReNu® line of
contact lens solution

B&L Allergy Drops
1987

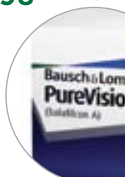


Vitrasert®

1996

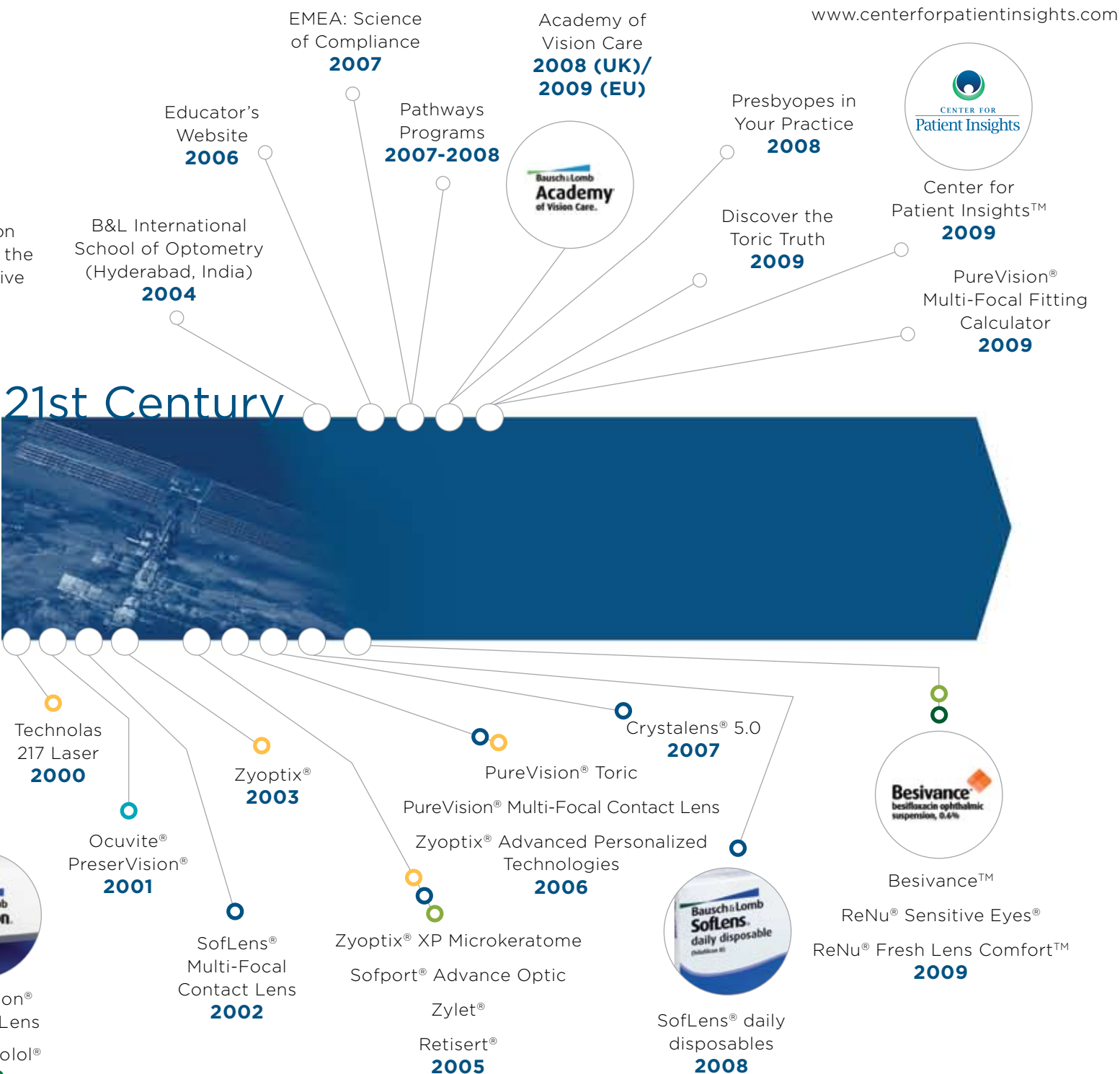
Alrex®
Lotemax®
ReNu®
Multiplus

1998



PureVision®
Contact
OptiPran®
1999

21st Century



Impact of Multipurpose Solutions on the Native State of Tear Film Protein

PURPOSE Proteins from the tear film deposit on contact lens material during wear. The deposits become more difficult to remove when the proteins are denatured. Multipurpose lens care solutions (MPS) may affect the protein denaturation process of tear film components and subsequent deposition on contact lenses. This study explores, in an *in vitro* setting, the ability of MPS to stabilize the tear film protein lysozyme from denaturation.

METHODS The antimicrobial protein lysozyme was dissolved in one Bausch & Lomb (B&L) investigative MPS*, and 4 commercial MPS. The resulting solutions were then exposed to the chemical denaturant sodium lauryl sulfate (SLS). The activity of lysozyme was investigated by adding each test solution to a tube containing a suspension of *Micrococcus luteus*. Native lysozyme is able to lyse the *M. luteus* cells causing the turbidity of the suspension to decrease. The percentage of lysozyme maintained in native form was determined by comparing the initial turbidity of the *M. luteus* suspension to its turbidity after exposure to test solution.

RESULTS The amount of lysozyme stabilized in its active form by the MPS was found to be $90.1\% \pm 0.6\%$ for B&L investigational MPS, $5.5\% \pm 2.9\%$ for one commercially available MPS, $4.3\% \pm 2.0\%$ for another commercially available MPS, $4.0\% \pm 2.9\%$ for a third MPS, and $3.6\% \pm 3.0\%$ for a fourth MPS.

CONCLUSIONS The data indicate that there are differences in the ability of MPS to help prevent denaturation of lysozyme by the chemical agent SLS. The interaction between lysozyme and the MPS systems depends on the composition and physical properties of the solution. The results suggest that further study is needed to understand the clinical significance.

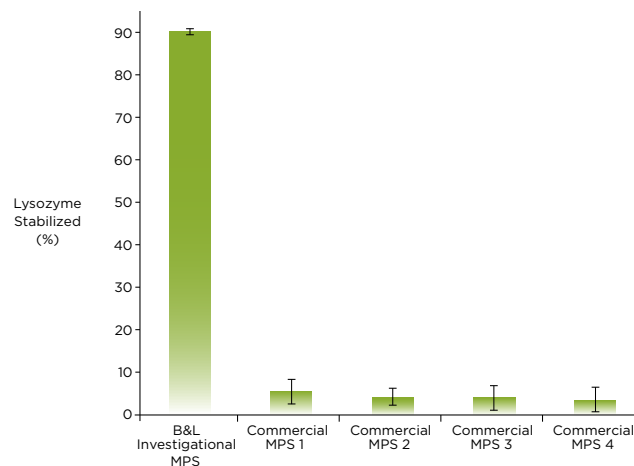
AUTHORS: Vicki L. Barniak, Susan E. Burke, Srini Venkatesh

AFFILIATION: Vision Care R&D, Bausch & Lomb Inc., Rochester, NY, USA

Paper presented at: Annual Meeting of the American Academy of Optometry; November 11-14, 2009; Orlando, FL.

“Ease of care and hygiene is a significant factor affecting patients’ satisfaction with their contact lenses. Because tear film proteins deposited on lens material are more difficult to remove after they are denatured, we conducted an *in vitro* study to determine whether multipurpose solutions vary in their ability to reduce protein denaturation.”

— Vicki L. Barniak



*The investigational MPS solution has not been reviewed by the U.S. Food and Drug Administration and no determination of safety or effectiveness of the solution has been made by the agency.



VICKI L. BARNIAK holds a Bachelor of Science degree in Molecular Genetics from the University of Rochester. She is a Senior Scientist in Vision Care R&D at Bausch & Lomb with a focus on contact lens care product development. Prior to joining Bausch & Lomb in 2004, Vicki held scientific positions at Wyeth and Protein Engineering Inc. She is co-author of 10 peer-reviewed journal articles, co-inventor on 2 patents, and co-inventor on 10 patent applications.

Direct Contact Cytotoxicity Assay: Optimization for Vision Care Solutions

PURPOSE Reliable cytotoxicity tests are needed to accurately predict the impact of contact lens solutions on the ocular environment. The ASTM and USP direct contact cytotoxicity tests differ in protocol design, including scoring criteria. We compared these two protocols to better understand the impact of their differences on the outcome of cytotoxicity evaluations of multipurpose lens care solutions (MPS).

METHODS MPS were evaluated for cytotoxicity using either the ASTM or the USP direct contact methodology. Contact lenses (Iotrafilcon B and etafilcon A) were soaked for 96 hours in MPS or control solutions in a standard lens case. The formulation-soaked lenses were incubated on the cell monolayer for 24 hours prior to visual inspection for cytotoxicity. To evaluate test article-associated mechanical damage, the lens orientation was controlled and in some studies negative control material was placed on the lenses to reduce movement.

RESULTS Contact lens movement and resulting mechanical damage to the cells could be mistaken for cytotoxicity using both protocols, if the cells were not evaluated carefully. Such apparent cytotoxicity likely represents a false-positive result since focal spots of cellular damage were observed along the path of contact lens movement. The most effective method for minimizing lens movement was to manipulate lens orientation while following the USP protocol. All MPS passed ($n = 3$) when evaluated using this optimized methodology. These data are consistent with the formulations passing the ISO ocular irritation study in rabbits ($n = 3$).

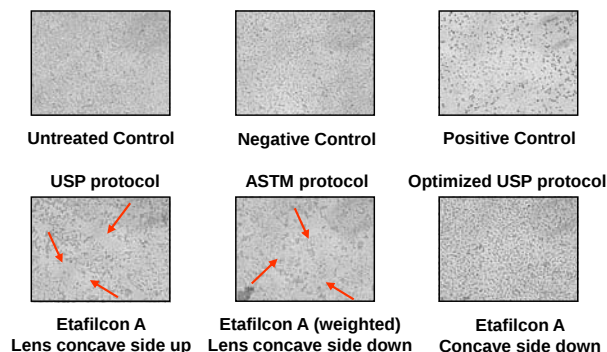
CONCLUSIONS Contact lens buoyancy impacts the accuracy of common cytotoxicity protocols via lens drifting and mechanical damage to cells. Considering the orientation of the lens, the USP direct contact cytotoxicity protocol is more suitable for MPS-soaked lenses than the ASTM protocol because it is better able to accommodate the unique characteristics of the test article to minimize false-positive results.

AUTHORS: David M. Lehmann, Daniel O'Mara, Karen L. Harrington, Mary Elise Richardson, and Keith W. Ward
AFFILIATION: Nonclinical Safety Department, Bausch & Lomb Inc., Rochester, NY, USA

Paper presented at: Annual Meeting of the American Academy of Optometry; November 11-14, 2009; Orlando, FL.

“Cytotoxicity assays are a critical step in assessing the toxicity profiles of contact lens care solutions, helping to ensure the highest level of optometric care for our patients. However, the buoyancy of contact lenses can produce misleading results in cytotoxicity assays, which prompted us to compare the reliability of two commonly used assays – the ASTM and USP.”

— David M. Lehmann



Optimization of the USP cytotoxicity protocol minimizes test article movement improving assay reliability. Etafilcon A soft contact lenses were soaked in PBS and placed on L929 cell monolayers and were evaluated using either the USP or ASTM direct contact cytotoxicity protocols. A single pre-soaked contact lens was cut in a “pinwheel” fashion (i.e., four 3-5 mm deep cuts approximately 90° apart around the perimeter of the lens) and placed in the center of the tissue culture well. Positive and negative control cultures received a sterile (1 cm x 1 cm) HDPE disk or latex placed directly on top of the cell monolayer. Areas denuded of cells are highlighted with arrows (red). Representative photos of the cells underneath the center of the test article were captured using a Nikon Eclipse TE2000-U microscope and RT Ke Diagnostic Instruments Inc. image capturing system.

DAVID M. LEHMANN is a senior research scientist in the Nonclinical Safety Department at Bausch & Lomb. He received his doctorate in Toxicology from the University of Rochester in 2005 and pursued postdoctoral training in Pharmacology and Physiology at this leading institution until 2007. Currently, one of his responsibilities is to develop and optimize the most appropriate cytotoxicity assays for vision care multipurpose solutions.



Differences in Toric Lens Performance: Lens Orientation and Orientation Recovery

PURPOSE Lens orientation and orientation recovery are fundamental to providing clear, stable vision for toric contact lens wearers. Two clinical studies were conducted to evaluate orientation and rotation recovery of 2 toric lens designs (Lo-Torque® and Accelerated Stabilization) across 8 different power and axis configurations.

METHODS In each study, 32 healthy subjects were randomly assigned a power/axis-matched Test and Control lens pairing on each eye. The studies compared the Lo-Torque® design of PureVision® Toric (PVT) to the Accelerated Stabilization designs of Acuvue Advance for Astigmatism (AA) and Acuvue Oasys for Astigmatism (OA). Primary Gaze Orientation (PGO) was assessed after 3 minutes and Orientation Recovery (OR) was assessed 1 minute after the lens was displaced 45° temporally from PGO. Distributions of PGO and OR were the measures of primary interest.

RESULTS The mean ($\pm$ SD) absolute PGO of the PVT lenses was 11.6° ($\pm$ 10.0°) and 10.6° ($\pm$ 9.4°) in the first and second studies, respectively. The mean absolute PGOs were 7.2° ($\pm$ 8.9°) and 9.0° ($\pm$ 9.3°) for the AA lenses and for the OA lenses, respectively. All designs tended to orientate temporally. All PGO means were significantly different from a 0° PGO position (T-test; $P < 0.05$).

The OR mean ($\pm$ SD) was 5.8° ($\pm$ 7.3°) and 4.3° ($\pm$ 4.3°) for the PVT lens in the first and second study, respectively. For the AA and the OA lenses, the mean OR was 10.7° ($\pm$ 13.5°) and 7.7° ($\pm$ 7.8°), respectively. There was a statistically significant difference in favor of the PVT lens in both studies for OR (T-test; $P < 0.05$ in all cases) and there was significantly less variability with PVT (Levene's Test; $P < 0.05$ in all cases).

CONCLUSIONS While PGO for Lo-Torque® and Accelerated Stabilization designs were similar, differences in OR were distinguishable. Further work is needed to understand the lid force and lens design interactions that have contributed to the Lo-Torque® design demonstrating a greater propensity to return the lens to its original position.

AUTHORS: Gerard Cairns, Paul China, Timothy Green, William T. Reindel

AFFILIATION: Bausch & Lomb Inc., Rochester, NY, USA

Paper presented at: Annual Meeting of the American Academy of Optometry; November 11-14, 2009; Orlando, FL.

“Toric contact lenses are designed to meet the special vision correction needs of people with astigmatism. But are all designs created equal? To help answer this question, we studied two different lens designs, Lo-Torque® and Accelerated Stabilization, to determine whether there were significant differences in rotational stability, which is critical in providing clear and stable vision.”

— Gerard Cairns



Image of a lens that is misoriented.



GERARD CAIRNS has a Bachelor of Science in Optometry from Glasgow Caledonian University in Scotland. He practiced in the UK and in New Zealand before enrolling in post-graduate studies and was awarded a PhD in Ophthalmology in 2005 from the University of Auckland, New Zealand. Gerard has over 12 years of clinical and research experience. He is a Fellow of the British Contact Lens Association and a Fellow of the American Academy of Optometry.

A Novel Method to Evaluate Secondary Images Associated With Contact Lens Multifocal Designs

PURPOSE The potential growth in presbyopic contact lens wearers highlights the need to offer optical designs that meet the vision needs of this population of patients. Multifocal (MF) designs can have optical characteristics that produce secondary images. The purpose of this study was to develop a method to quantify secondary images and compare MF designs.

METHODS Custom software was developed to calculate the distance between a white circle, with a radius of 187 twips (sub-pixel units for LCD screens), on black background to the edge of any secondary images. Two unique MF designs with similar near ads, PureVision® Multi-Focal (PV) and Oasys for Presbyopia (OP), were evaluated. Lenses were randomly presented on one eye of 23 presbyopic subjects. Secondary image extent was assessed at 2 object distances, 0.65 m and 1.50 m. Visual acuity (VA, measured in logMAR) at Distance, Intermediate, and Near was also recorded.

RESULTS The PV lenses exhibited significantly less secondary images at 0.65 m and 1.50 m compared to the OP lenses ($P < 0.05$). At 0.65 m, the difference was 17.5% (286 twips and 336 twips for the PV and OP lenses, respectively) and at 1.50 m the difference was 34.4% (393 twips and 528 twips for the PV and OP lenses, respectively).

While there were no significant differences for mean normalized distance High Contrast High Illumination (HCHI) VA between the PV and OP lenses ($P > 0.05$), there was a significant difference for mean normalized HCHI VA at 0.65 m ($P < 0.05$) and at Near ($P < 0.05$). The PV lenses exhibited 3.5 letters better VA at 0.65 m and 4.5 letters better Near VA compared to the OP lenses.

CONCLUSIONS Measurement of secondary images is a sensitive measure of vision quality with MF contact lens designs. The method revealed significant differences between the PV and OA designs that were not discerned with Distance VA measures. Furthermore, VA for Intermediate and Near was determined to favor the PV MF design. Significantly reduced secondary images could play an important role in patient acceptance of presbyopic contact lens correction.

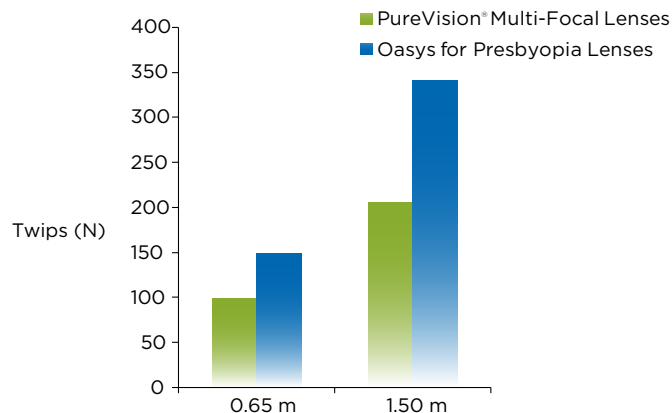
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Paper presented at: Annual Meeting of the American Academy of Optometry; November 11-14, 2009; Orlando, FL.

“We know that many of our patients with presbyopia avoid reading glasses for a number of reasons, including the fact that reading glasses remind them of their age and make them feel self-conscious. Multifocal contact lenses offer a promising alternative to reading glasses. A well-designed multifocal contact lens will moderate the formation of secondary images, haloes, and glare that may reduce patient acceptance. In this study, we used a novel technique to compare the production of secondary images in two unique multifocal designs.”

— Gerard Cairns



These values represent the extent (in twips) that the secondary images extend from the edge of the central target (radius 187 twips).

Evaluation of Multipurpose Solutions for *In Vitro* Biocidal Efficacy Against a Challenge of Ocular Clinical Isolates Including Methicillin-Resistant *Staphylococcus aureus* and Methicillin-Resistant *Staphylococcus epidermidis* Strains

PURPOSE To evaluate whether several multipurpose lens care solutions (MPS), including a Bausch & Lomb investigative MPS*, that have shown efficacy against the compendial challenge strains found in ISO 14729:2001(E), will demonstrate similar efficacy against strains of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Candida albicans*, *Fusarium solani*, methicillin-resistant *Staphylococcus aureus* (MRSA), and methicillin-resistant *Staphylococcus epidermidis* that have been isolated from ocular clinical sources.

METHODS Testing was performed according to methods described in ISO standard 14729:2001(E) to demonstrate the biocidal efficacy of 5 MPS, all within expiry, using the minimum recommended disinfection time only, against a battery of clinical isolates. The modification to the ISO procedure included the incorporation of organic soil in the preparation of the clinical isolates and measuring biocidal efficacy at the minimum recommended disinfection time point only for each product.

Isolates were chosen from cultures isolated from ocular infections that represented the same genus and species identified in ISO 14729. Additionally, several methicillin-resistant strains of *Staphylococcus* organisms were selected. Clinical isolates were prepared by using approximately 5×10^5 cfu/mL of each of the clinical isolates as the challenge inoculum for separate tests of each MPS. Each clinical isolate was tested 3 times against the various MPS.

RESULTS Although each of the MPS tested demonstrated biocidal activity against the challenge microorganisms, the mean log reduction values for the various MPS varied, ranging from approximately 2.5 to 4.8 for the bacteria and from 1.0 to 4.0 for the yeast and molds. When examining individual challenge results, some of the solutions showed either stronger or weaker efficacy against nearly all of the individuals of a particular strain. This included demonstrating weaker activity against the MRSA strains.

CONCLUSIONS The results of these evaluations show that each of the MPS demonstrated biocidal efficacy against the challenge isolates; examination of the individual results shows a

larger range of log reductions than do the means. Further study is necessary to determine whether these *in vitro* results could suggest clinical significance.

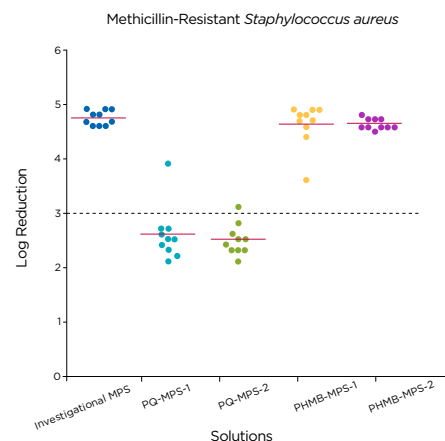
AUTHORS: Brien David, Denise Callahan, Deborah McGrath, Julie Strassburg, Tiffany Hilfiker, Jessica Tackabury, Susan Norton

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Paper presented at: Annual Meeting of the American Academy of Optometry; November 11-14, 2009; Orlando, FL.

“Although rare, microbial keratitis and other microbiological complications are a continuing source of concern for contact lens users. In this *in vitro* study, we found that biocidal effectiveness against bacteria, yeasts, and molds obtained from clinical sources varies considerably among multipurpose solutions. We believe that this study helps in understanding the role multipurpose solutions can play in reducing risks associated with contact lens use.”

— Brien David



*The investigational MPS solution has not been reviewed by the U.S. Food and Drug Administration and no determination of safety or effectiveness of the solution has been made by the agency.



BRIEN DAVID has a Bachelor's of Science degree in microbiology. His 25 years of experience in the pharmaceutical and medical device industry include the areas of anti-infective and cardiac research and development, *in vitro* assays and *in vivo* models of infection, electrophysiology, lens care disinfectant research and development, and over 12 years in quality assurance.

The human eye.

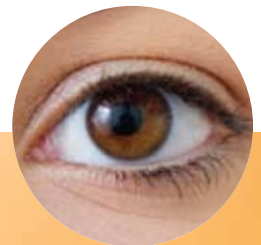
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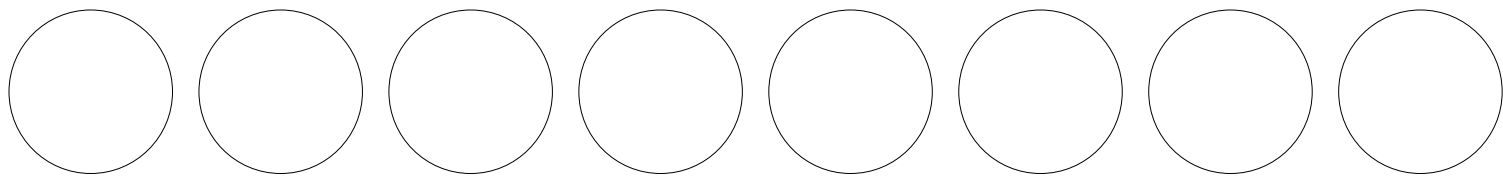
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