

Optometric Glaucoma Society 20th Annual Scientific Meeting



OCTOBER 24-26, 2022

Hilton San Diego Bayfront
San Diego, California



OPTOMETRIC
GLAUCOMA
SOCIETY

President's Welcome



I am once again delighted to welcome you to the 20th Annual Meeting of the Optometric Glaucoma Society. The excitement around this meeting is always palpable, but seems even higher this year given our amazing faculty and wonderful location. This year our faculty features professors and surgeons from the Shiley Eye Institute of the UCSD School of Medicine. This is notable as the OGS owes a great deal of debt to the Chair of this Program, Dr. Robert Weinreb. It was through Rob Weinreb's and Murray Fingeret's vision that the OGS came to bear. The inaugural OGS meeting was held in San Diego 20 years ago. I personally want to thank Dr. Weinreb for his long term involvement with the OGS. Our Society's highest honor will be bestowed to the entire Shiley Eye Institute faculty this evening, as a small gesture of our gratitude.

Also on this year's program, two of our own members will be presenting talks as well as receiving awards. Drs. Linda Zangwill and Chris Johnson have both been members of the OGS for 20 years and it is very fitting that we will all have the opportunity to hear their presentations today and honor them this evening.

Speaking of this year's program, a huge shout out needs to be extended to Suresh Viswanathan, who has once again coordinated this program with great skill and care. This will be Suresh's last year as Program Chair for the OGS. He will be stepping down as Program Chair, a position that he has held for many years. Suresh has led this effort with great skill and care and has always shown a particular attention to detail that has amazed me. Suresh is a very humble human, so if you could seek him out today and say thank you that would be awesome. Thank you, Suresh!!!

I would like to single out a few others in our organization, Dr. Carl Jacobsen and Dr. Derek McDonald. Carl and Derek have been contributors and frankly the driving forces behind the OGS Perspective reviews that have been part of the Review of Optometry lineup for many years. They have both decided to step away from this role. Their leadership will be missed but, fortunately their shoes will be ably filled. Thank you, Derek and Carl! To our sponsors, once again a huge thank you! In an era where sponsorships are shrinking at meetings and where corporate partnerships are becoming harder to find, our sponsors of this meeting have not gone away. It is a tribute to both our Society and our Corporate sponsors that we continue to forge this great partnership. This meeting is made significantly easier to hold with their involvement. Please take the opportunity to share your time with them.

I would be remiss if I did not mention the OGS Board and the energy they provide to me and this organization. Danica, Justin, Sarah and many others whom I haven't named- I owe you a huge thank you and an adult beverage. Thanks so much for your advice and wisdom, both clinically and administratively. And finally, I want to give a huge shout out to our Executive Director, Kellie Rogers. Kellie is indeed the straw that stirs this drink. She does an amazing job keeping me on task, sweating the details and making sure that this meeting goes off without a hitch. The OGS, quite frankly, would not be what it is without Kellie. THANK YOU!!!

Agenda

Monday, October 24, 2022

Indigo 206

- 3:00-4:30pm *Executive Committee Meetings*
4:30-5:30pm *General Business Meeting (for all members)*

Odysea 200 Terrace

- 5:30-8pm *Welcome Reception*

Tuesday, October 25, 2022

Aqua Ballroom

- 7:20-7:50am *Breakfast (opportunity to visit vendor exhibits)*

- 7:50am *Welcome* **Eric Schmidt, OGS President**

Session 1 *Moderated by Mae Gordon, PhD*

- 8-8:30am *Detecting glaucoma in high myopia*

Linda Zangwill, PhD
President's Lecturer

- 8:30-8:40am *Discussion and Questions*

- 8:40-9:10am *Factors influencing macular structure-function concordance in glaucoma*

Janelle Tong, BOptom (Hons), BSc
OGS Ezell Fellow

- 9:10-9:20am *Discussion and Questions*

- 9:20-9:50am *Space Associated Neuro Syndrome (SANS)*

Alex Huang MD, PhD

- 9:50-10am *Discussion and Questions*

- 10-10:30am *Morning Break (opportunity to visit vendor exhibits)*

Session 2 *Moderated by Brett King, OD*

- 10:30-11am *Remote visual field testing: tablets, virtual reality headsets and secure internet web sites*

Chris Johnson, PhD
Research Honoree

- 11-11:10am *Discussion and Questions*

- 11:10-11:40am *Is gaze tracking useful with perimetry?*

Andrew Camp, MD

- 11:40-11:50am *Discussion and Questions*

- Noon-1pm *Lunch (opportunity to visit vendor exhibits)*

Session 3

Moderated by Richard Madonna, OD, MA

1-1:40pm	Clinical Case Presentations
1:40-2:10pm	Update on IOP-independent Glaucoma Treatments
2:10-2:20pm	Discussion and Questions
2:20-2:45pm	Smoking and Glaucoma
2:45-2:55pm	Discussion and Questions
2:55-3:25pm	Afternoon Break (opportunity to visit vendor exhibits)

Mark Dunbar, OD & Panel
Jiun Do MD, PhD

Sasan Moghimi, MD

Session 4

Moderated by Murray Fingeret, OD

3:25-4:15pm	Why is there still no glaucoma neuroprotection?
4:15-4:40pm	Panel Discussion
4:40-5:15pm	What is next for glaucoma?

Robert Weinreb, MD
All Speakers
Robert Weinreb, MD

5:15-6:15pm	Reception
6:15-8pm	Dinner & Banquet

Wednesday, October 26, 2022

OGS/AAO Joint Symposium **Moderated by John Flanagan, MCOptom, PhD**

8-8:30am	Visual field progression, what procedures should be used?	Chris Johnson, PhD
8:30-9:00am	Deep Learning Strategies to Diagnose and Monitor Glaucoma	Linda Zangwill, PhD
9-9:25am	Narrow Angles: So Simple, Yet So Complicated	Alex Huang MD, PhD
9:25-9:40am	Panel Discussion	

Speakers & Awardees



Andrew Camp, MD

Andrew Camp, M.D., is an Assistant Professor of Clinical Ophthalmology at the Shiley Eye Institute. Dr. Camp earned a dual Bachelor of Arts in Biochemistry/Molecular Biology and Psychology from Boston University. He obtained his medical degree from the University of Miami Miller School of Medicine. Dr. Camp completed an Ophthalmology residency at the Bascom Palmer Eye Institute and Glaucoma fellowship at the University of California, San Diego.

Dr. Camp's clinical focus is the medical and surgical management of adult and childhood glaucoma. He is actively engaged in clinical research and has presented his work at national conferences, published peer-reviewed articles, and participates in clinical trials of therapeutic drugs and devices. Dr. Camp's research interests include the development of novel intraocular pressure measurement devices, personalized glaucoma treatment regimens, national and international eye health in underserved populations, and anterior and posterior glaucoma imaging techniques.



Jiun Do, MD, PhD

Jiun Do, M.D., Ph.D., is an Assistant Professor of Ophthalmology at the Shiley Eye Institute, a board-certified ophthalmologist specializing in glaucoma, and a clinician-scientist. Dr. Do was an undergraduate at the University of California, Berkeley. He earned his M.D. and Ph.D. in Neurosciences from the University of California San Diego. Dr. Do completed his internship at Newton-Wellesley Hospital, his ophthalmology residency at the University of Southern California Roski Eye Institute, and his glaucoma fellowship at the University of California San Diego Shiley Eye Institute and the Hamilton Glaucoma Center.

Dr. Do's clinical focus is on the medical and surgical management of glaucoma. In the surgical treatment of glaucoma, he utilizes the latest in minimally invasive glaucoma surgeries and is also skilled in conventional surgeries. Dr. Do is actively engaged in clinical research and clinical trials investigating the monitoring of glaucoma, glaucoma medications, and surgical treatments for glaucoma. He has presented his work at national conferences, published peer-reviewed articles, and is an ad-hoc reviewer for scientific journals.

Dr. Do has a scientific interest in regenerating the optic nerve and is developing research programs to restore vision. He uses novel stem cell technologies to replace components of the eye that are lost in glaucoma and to regenerate lost connections between the eye and the brain. His long-term goal is to develop translational therapies to restore vision and to help patients with blinding diseases.



Alex Huang, MD, PhD

Dr. Alex Huang completed his MD/PhD at The Johns Hopkins University School of Medicine with Lasker Award-winning Dr. Solomon Snyder. He then completed his residency at USC/Doheny Eye Institute (DEI) and his glaucoma fellowship with Dr. Robert Weinreb at Shiley Eye Institute/UCSD. Dr. Huang became an inaugural faculty member of the DEI/UCLA affiliation. This year, Dr. Huang rejoins the Viterbi Family Department of Ophthalmology and Shiley Eye Institute/UCSD. Dr. Huang is a clinician-scientist who is supported by a National Institutes of Health (NIH) R01 and the National Aeronautics and Space Administration (NASA). His NIH research program focuses on improving glaucoma surgical outcomes by improving aqueous humor outflow understanding. His

NASA research focuses on understanding the cause of and developing countermeasures for Space flight-Associated Neuro-ocular Syndrome (SANS). The Ophthalmologist named Dr. Huang the #1 Rising Star in 2017 and recognized him on The Ophthalmologist Power 100 List in 2020. In 2021, Dr. Huang received the ARVO Foundation Pfizer Ophthalmics Carl Camras Translational Research Award.



Chris Johnson, PhD, DSc
Research Excellence Award

Dr. Chris A. Johnson is currently an Emeritus Professor in the Department of Ophthalmology and Visual Sciences at the University of Iowa Hospitals and Clinics and served as a faculty member there for 12 years. He is also an Adjunct Professor in the College of Optometry at The Ohio State University. Prior to this, he was a faculty member at the University of California, Davis Department of Ophthalmology for 20 years, followed by serving as the Director of Diagnostic Research at Devers Eye Institute in Portland, Oregon for 11 years. Dr. Johnson has more than 450 book chapters and publications in peer-reviewed journals, has received many honors and awards and has several patents related to ophthalmic diagnostic instrumentation. His main areas of interest are related to development and evaluation of non-invasive diagnostic instruments for evaluation of visual function, perimetry and visual field testing, imaging and quantitative assessment of retinal and optic nerve structures, assessment of glaucoma and other retinal and optic nerve diseases, defining the relationship between clinical visual function measures and activities of daily living and quality of life issues (including vision requirements needed for task performance, job requirements and daily functioning), and establishing guidelines for occupational vision requirements.

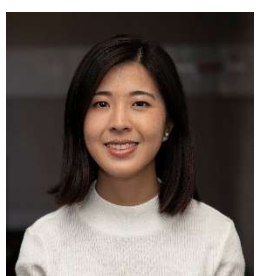


Sasan Moghimi, MD

Sasan Moghimi, MD, Associate Professor of Ophthalmology, is a glaucoma specialist and clinician-scientist. Dr. Moghimi earned his medical degree at Tehran University of Medical Sciences in Iran. He completed a residency in ophthalmology at Farabi Eye Hospital, and subsequently served as Professor and Vice-Chair. He completed fellowships in glaucoma at UC Los Angeles, and UC San Francisco.

Dr. Moghimi's clinical focus is glaucoma including angle closure glaucoma. His research interests include role of glaucoma imaging in detection and monitoring of the disease, lamina cribrosa and choroidal changes in glaucoma, and the role of blood flow in glaucoma.

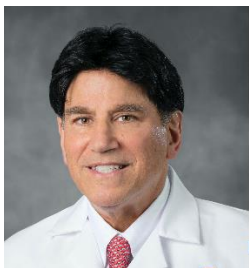
During his career, Dr. Moghimi has co-authored over 120 peer-reviewed journal articles and book chapters related to glaucoma and vision science. He is an associate editor of ophthalmology journals and an editorial board member of the International Glaucoma Review.



Janelle Tong, BOptom (Hons), BSc
OGS Ezell Fellow

Janelle graduated with a Bachelor of Optometry (Hons)/Bachelor of Science degree from UNSW Australia where she was awarded the University Medal. She is currently undertaking her PhD studies with a PhD titled 'Application of novel techniques enabling detection of early function deficits in ocular pathologies', and is involved in patient care at Centre for Eye Health UNSW as a senior staff optometrist. Her research focuses on developing new methods that enable the early, accurate detection of eye diseases such as glaucoma. During her candidature, she has been awarded several travel grants and the OGS Ezell Fellowship in 2021.

Speakers & Awardees



Robert N. Weinreb, MD

Robert N. Weinreb, M.D. is the Chairman and Distinguished Professor of Ophthalmology at the University of California, San Diego as well as Director of the Shiley Eye Institute and the Director of the Hamilton Glaucoma Center. He also holds the Morris Gleich MD Chair of Glaucoma and is appointed as Distinguished Professor of Bioengineering. Dr. Weinreb graduated from Harvard Medical School and completed his residency and fellowship at the University of California, San Francisco.

Dr. Weinreb is a clinician, a surgeon and a scientist. He oversees all clinical activities at the Shiley Eye Institute and within the Department of Ophthalmology. As the Director of the Hamilton Glaucoma Center, Dr. Weinreb also oversees a world-renowned team of scientists and staff dedicated to glaucoma. Patients from throughout the world seek his medical and surgical expertise.

Dr. Weinreb's clinical and research interests are diverse and range from the front of the eye to the back of the eye. They include glaucoma surgery, optic neuropathy and aging of the eye, imaging of the optic disc and retinal nerve fiber layer, mechanisms of optic nerve damage in glaucoma, neuroprotection of glaucoma, and cataract surgery.



Linda Zangwill, PhD

President's Lecture Award

Linda Zangwill, Ph.D, is Professor of Ophthalmology and co-Director of Clinical Research and Director of the Imaging Data Evaluation and Analysis (IDEA) Center at the Hamilton Glaucoma Center. Dr. Zangwill received her M.S. at the Harvard School of Public Health and her Ph.D. from Ben-Gurion University of the Negev.

Dr. Zangwill's research focuses on improving our understanding of the complex relationship between structural and functional change over time in the aging and glaucoma eye, developing computational and statistical techniques to improve glaucomatous change detection, and identifying risk factors that can predict rapidly progressing glaucoma.

As Director of the Imaging Data Evaluation and Analysis (IDEA) Center, Dr. Zangwill has developed and implemented protocols for utilizing diagnostic imaging instruments in national and international multi-center clinical trials of glaucoma and ocular hypertension.

Shiley Eye Institute of the University of California at San Diego

OGS Honoree

Since our founding in 2002, the Optometric Glaucoma Society has recognized an individual as Honoree at each scientific meeting. This year, we have expanded upon that idea by recognizing the many contributions of the faculty and staff of an institution, the Shiley Eye Institute of the University of California at San Diego. Under the direction of its Chair, Robert N. Weinreb MD, the Shiley Eye Institute's accomplishments in glaucoma research, education and glaucoma care excellence have established a standard that few institutions, if any, can match. The international recognition of its faculty and trainees, some of whom are contributing to this year's program, is unparalleled.

The list of individuals who trained in glaucoma at the Shiley Eye Institute and then went to lead other eye departments is legendary and a "Who's Who of Eyecare". Beginning almost forty years ago, the Hamilton Glaucoma Center at the Shiley Eye Institute consistently has led the way in development of ophthalmic imaging. Other notable areas of innovation include the pioneering use of 24-hour IOP measurements, development of alternative perimetric techniques, laboratory and clinical studies of both the outflow pathways and also glaucoma neuroprotection, as well as application of artificial intelligence to glaucoma diagnostics.

For these reasons and many others, the OGS is pleased to present its 2022 Honoree award to the glaucoma faculty and staff of the Shiley Eye Institute of the University of California at San Diego.

Welcome, New OGS Members

Judy C. Hu, OD

The Glaucoma Center
Bowie, MD

Alicia Lau, OD

Carl Zeiss Meditec
Dublin, CA

Nathan R. Lighthizer, OD

NSU Oklahoma College of Optometry
Tahlequah, OK

Dan Samaha, OD

Montreal University
School of Optometry
Montreal, Canada

Save the Dates

Optometric Glaucoma Foundation
7th Annual Educators Meeting
New York City, NY
September 9, 2023

Optometric Glaucoma Society
21st Annual Scientific Meeting
New Orleans, LA
October 10-11, 2023

Optometric Glaucoma Foundation

The mission of the Optometric Glaucoma Foundation is to support glaucoma education for the optometric profession. This includes supporting and developing educational programs for students, residents, educators and practitioners. The OGF will work with different groups to meet our goals including industry and educational institutions, as well as optometric and ophthalmologic organizations.



The 6th Annual Educators meeting took place at the Bascom Palmer Eye Institute (BPEI) Miami, FL on September 10, 2022, honoring Douglas Anderson. The meeting was hosted by the Optometric Glaucoma Foundation, the philanthropic arm of the OGS with the goal of educating the people who teach glaucoma in our schools and colleges of optometry. Meeting co-chairs were Drs. Dunbar, Fingeret, McSoley, and Patella. This year we had almost every school represented. Dr. Anderson, who is one of the giants in the world of glaucoma, has been a member and supporter of the OGS and frequently attended our annual meeting which led to a level of discussion not often seen at glaucoma meetings. Meeting faculty included members of the BPEI glaucoma staff including Drs. Gedde, Greenfield, Hodapp, Palmber, and Parrish as well as our own Michael Patella. Topics range from clinical decision making to the glaucoma clinical trials to new developments in perimetry. The program was recorded and available on YouTube as part of the OGS section.

The event was made possible, by the following sponsors:

- Aerie Pharmaceuticals
- Alcon
- Allergan
- Bausch + Lomb
- CATS Tonometer
- Glaukos
- Haag-Streit
- Heidelberg Engineering
- Topcon

Medical Education Grants were provided by Alcon, Bausch + Lomb, Santen, and Zeiss.

Optometric Glaucoma Society

The Optometric Glaucoma Society (OGS) mission is to promote excellence in care of glaucoma patients through professional education and scientific investigation. The society's major objectives are to promote education of optometrists related to all aspects of glaucoma; promote the acquisition of new knowledge about glaucoma, in part through the development of glaucoma research within optometry; facilitate the dissemination of information about glaucoma to healthcare providers and the public; and establish collaborative relationship with other related organizations.



OGS 2021 Annual Meeting Attendees, Boston, MA

OGS Leadership & Committees

Officers/Executive Committee

Eric Schmidt – President
Danica Marrelli – Vice President
Justin Schweitzer – Treasurer
Sarah Dougherty Wood – Secretary
Michael Chaglasian – Executive Vice President

Past Presidents

Murray Fingeret 2001-2008
John Flanagan 2008-2012
Ben Gaddie 2012-2016
Michael Chaglasian 2016-2020

Members at Large

Jennifer Gould
John McSoley

By-Laws

Daniel Roberts – Chair

Industry Relations

Chris Lievens

Nominating

Richard Madonna- Chair

Membership & Recruitment

Mark Dunbar – Membership Co-Chair
Tony Litwak – Recruiting – Co-Chair
Barry Frauens
Richard Madonna
Trennda Rittenbach
Justin Schweitzer
Sarah Dougherty Wood

Program

Suresh Visvanathan – Chair
Shira Kresch

E-Journal / PCON Newsletter

Carl Jacobsen – Chair
Derek MacDonald
Mark Eltis
Lisa Young

OGS Annual Meetings

<u>Dates</u>	<u>Location</u>	<u>President's Lecturer</u>	<u>OGS Honoree</u>
October 25, 2022	San Diego, CA	Linda Zangwill, PhD	Hamilton Glaucoma Center and Shiley Eye Institute at the University of California San Diego
November 2, 2021	Boston, MA	Pradeep Ramulu, MD, PhD	Felipe Medeiros, MD, PhD
September 12, 2020	Virtual		
October 21-23, 2019	Orlando, FL	Shan Lin, MD	Louis Pasquale, MD
November 5-7, 2018	San Antonio, TX	Robert Feldman, MD	L. Jay Katz, MD
October 9-11, 2017	Chicago, IL	David Friedman, MD, MPH, PhD	Robert Fechtner, MD
November 7-9, 2016	Anaheim, CA	Felipe A. Medeiros, MD, PhD	George A. Cioffi, MD
October 5-7, 2015	New Orleans, LA	Jonathan S. Myers, MD	Mae Gordon, PhD
November 10-12, 2014	Denver, CO	Steven L. Mansberger, MD, MPH	David Garway-Heath, MD
October 22-23, 2013	Seattle, WA	Anthony Realini, MD, MPH	Claude Burgoyne, MD
October 23-24, 2012	Phoenix, AZ	Brad Fortune, OD, PhD	Jost Jonas, MD
October 11-12, 2011	Boston, MA	Keith Martin, MD, FRCOphth	Jeffrey Liebmann, MD
November 15-16, 2010	San Francisco, CA	Kuldev Singh, MD, MPH	Wallace L.M. Alward, MD
November 9-11, 2009	Orlando, FL	Christopher A. Girkin, MD	George L. Spaeth, MD
October 20-22, 2008	Anaheim, CA	Theodore Krupin, MD	Robert Ritch, MD
October 22-23, 2007	Tampa, FL	David Greenfield, MD	Paul Kaufman, MD
December 5-6, 2006	Denver, CO	Balwantray Chauhan, PhD	Harry Quigley, MD
December 7, 2005	San Diego, CA		Stephen Drance, OC, MD
December 8, 2004	Tampa, FL		Douglas R. Anderson, MD
December 9, 2003	Dallas, TX		Anders Heijl, MD
December 11, 2002	San Diego, CA		Robert N. Weinreb, MD

OGS Ezell Fellows

2021 Janelle Tong,
BOptom (Hons), BSc
2020 Billie Beckwith-Cohen,
DVM, MBA, PhD
2018 Laura Pardon, OD, MS
2017 Nevin W. El-Nimri, OD, MS
2016 Jack Phu, BOptom, MPH
2015 Lakshmi Priya Rajagopalan,
BS, PhD
2013 Kevin Ivers, OD, PhD
2012 Kevin Ivers, OD, PhD
2011 Nimesh Patel, OD, PhD
2010 Nimesh Patel, OD, PhD
2008 Joe Wheat, OD, PhD

Distinguished Service Award

2021 Michael Chaglasian, OD
2016 Ben Gaddie, OD
2013 John G. Flanagan,
MCOptom, PhD
2012 Louis J. Catania, OD
2011 Tom L. Lewis, OD, PhD
2010 V. Michael Patella, OD
2008 Murray Fingeret, OD

Founders Award

2016 Gerhard Zinser, PhD
2015 Harry A. Quigley, MD
2012 Robert N. Weinreb, MD
2011 Douglas R. Anderson, MD

Research Excellence Award

2022 Chris Johnson, PhD
2021 Thomas Freddo, OD, PhD
2019 William Swanson, PhD
2014 Donald Hood, PhD
2013 Ronald S. Harwerth, OD, PhD
2009 Sir Peng Tee Khaw,
MD, FRCOphth

Corporate Partnership Award

2019 John Hawley
2018 V. Michael Patella, OD
2016 Rick Halprin
2013 Richard D. Bay

Award Descriptions

Optometric Glaucoma Society Ezell Fellow

The Optometric Glaucoma Society established an Ezell Fellowship in 2007, dedicated to fund post-graduate research in the area of glaucoma. The award is done in partnership with the American Optometric Foundation and meant to encourage talented individuals to pursue a career in research and education.

Founders Award

This award is provided to an individual who has made significant contributions in research or patient care to the glaucoma community throughout their career.

Distinguished Service Award

This award is provided to an individual who has provided outstanding service to the growth and administration of the OGS.

Research Excellence Award

This award is provided to an individual researcher whose lifetime of work has led to a better understanding of glaucoma.

Corporate Partnership Award

This award is provided to an individual who has made significant contributions to the glaucoma community through their passion and dedication for product development and improvement.

OGS Honoree

The recipient of the OGS Honoree is an individual who has achieved noteworthy accomplishments in glaucoma patient care, research and education. Scholarly and leadership activities throughout the individual's career should be evident. A collegial interaction with optometry is desirable.

Platinum Sponsor

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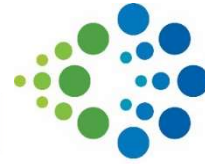
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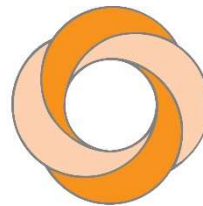
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Medical Education Grants

The Optometric Glaucoma Society would like to acknowledge the companies that have provided medical educational grants.

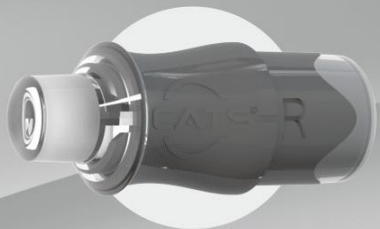
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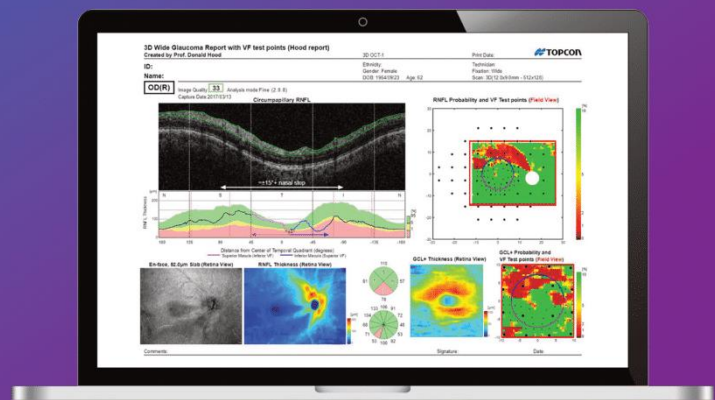
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*Pivotal study designs: Two Phase 3, randomized, multicenter, parallel-group studies, APOLLO and LUNAR, evaluating noninferiority of once-daily VYZULTA vs twice-daily timolol maleate 0.5% in patients with open-angle glaucoma or ocular hypertension. Primary endpoint was IOP measured at 9 assessment time points in study eye. APOLLO (VYZULTA, n=284; timolol, n=133) and LUNAR (VYZULTA, n=278; timolol, n=136).^{2,3}

INDICATION

VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024% is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

- Increased pigmentation of the iris and periorbital tissue (eyelid) can occur. Iris pigmentation is likely to be permanent
- Gradual changes to eyelashes, including increased length, increased thickness, and number of eyelashes, may occur. These changes are usually reversible upon treatment discontinuation
- Use with caution in patients with a history of intraocular inflammation (iritis/uveitis). VYZULTA should generally not be used in patients with active intraocular inflammation
- Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin analogs. Use with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema
- There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products that were inadvertently contaminated by patients
- Contact lenses should be removed prior to the administration of VYZULTA and may be reinserted 15 minutes after administration
- Most common ocular adverse reactions with incidence $\geq 2\%$ are conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%)

For more information, please see Brief Summary of full Prescribing Information on adjacent page.

References: **1.** VYZULTA Prescribing Information. Bausch & Lomb Incorporated. **2.** Weinreb RN, Scassellati Sforzolini B, Vittitow J, Liebmann J. Latanoprostene bunod 0.024% versus timolol maleate 0.5% in subjects with open-angle glaucoma or ocular hypertension: the APOLLO study. *Ophthalmology*. 2016;123(5):965-973. **3.** Medeiros FA, Martin KR, Peace J, Scassellati Sforzolini B, Vittitow JL, Weinreb RN. Comparison of latanoprostene bunod 0.024% and timolol maleate 0.5% in open-angle glaucoma or ocular hypertension: the LUNAR study. *Am J Ophthalmol*. 2016;168:250-259.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use VYZULTA safely and effectively. See full Prescribing Information for VYZULTA.

VYZULTA[®] (latanoprostene bunod ophthalmic solution), 0.024%, for topical ophthalmic use.

Initial U.S. Approval: 2017

1 INDICATIONS AND USAGE

VYZULTA[®] (latanoprostene bunod ophthalmic solution) 0.024% is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Pigmentation

VYZULTA[®] (latanoprostene bunod ophthalmic solution), 0.024% may cause changes to pigmented tissues. The most frequently reported changes with prostaglandin analogs have been increased pigmentation of the iris and periorbital tissue (eyelid).

Pigmentation is expected to increase as long as latanoprostene bunod ophthalmic solution is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of VYZULTA, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes are likely to be reversible in most patients. Patients who receive prostaglandin analogs, including VYZULTA, should be informed of the possibility of increased pigmentation, including permanent changes. The long-term effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with VYZULTA[®] (latanoprostene bunod ophthalmic solution), 0.024% can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly [see Patient Counseling Information (17) in full Prescribing Information].

5.2 Eyelash Changes

VYZULTA may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and the number of lashes or hairs. Eyelash changes are usually reversible upon discontinuation of treatment.

5.3 Intraocular Inflammation

VYZULTA should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation as it may exacerbate this condition.

5.4 Macular Edema

Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin analogs. VYZULTA should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

5.5 Bacterial Keratitis

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

5.6 Use with Contact Lens

Contact lenses should be removed prior to the administration of VYZULTA because this product contains benzalkonium chloride. Lenses may be reinserted 15 minutes after administration.

6 ADVERSE REACTIONS

The following adverse reactions are described in the Warnings and Precautions section: pigmentation (5.1), eyelash changes (5.2), intraocular inflammation (5.3), macular edema (5.4), bacterial keratitis (5.5), use with contact lens (5.6).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

VYZULTA was evaluated in 811 patients in 2 controlled clinical trials of up to 12 months duration. The most common ocular adverse reactions observed in patients treated with latanoprostene bunod were: conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%). Approximately 0.6% of patients discontinued therapy due to ocular adverse reactions including ocular hyperemia, conjunctival irritation, eye irritation, eye pain, conjunctival edema, vision blurred, punctate keratitis and foreign body sensation.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available human data for the use of VYZULTA during pregnancy to inform any drug associated risks.

Latanoprostene bunod has caused miscarriages, abortion, and fetal harm in rabbits. Latanoprostene bunod was shown to be abortifacient and teratogenic when administered intravenously (IV) to pregnant rabbits at exposures ≥ 0.28 times the clinical dose. Doses $\geq 20 \mu\text{g}/\text{kg}/\text{day}$ (23 times the clinical dose) produced 100% embryofetal lethality. Structural abnormalities observed in rabbit fetuses included anomalies of the great vessels and aortic arch vessels, domed head, sternebral and vertebral skeletal anomalies, limb hyperextension

and malrotation, abdominal distension and edema. Latanoprostene bunod was not teratogenic in the rat when administered IV at 150 mcg/kg/day (87 times the clinical dose) [see Data].

The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2 to 4%, and of miscarriage is 15 to 20%, of clinically recognized pregnancies.

Data

Animal Data

Embryofetal studies were conducted in pregnant rabbits administered latanoprostene bunod daily by intravenous injection on gestation days 7 through 19, to target the period of organogenesis. The doses administered ranged from 0.24 to 80 mcg/kg/day. Abortion occurred at doses ≥ 0.24 mcg/kg/day latanoprostene bunod (0.28 times the clinical dose, on a body surface area basis, assuming 100% absorption). Embryofetal lethality (resorption) was increased in latanoprostene bunod treatment groups, as evidenced by increases in early resorptions at doses ≥ 0.24 mcg/kg/day and late resorptions at doses ≥ 6 mcg/kg/day (approximately 7 times the clinical dose). No fetuses survived in any rabbit pregnancy at doses of 20 mcg/kg/day (23 times the clinical dose) or greater. Latanoprostene bunod produced structural abnormalities at doses ≥ 0.24 mcg/kg/day (0.28 times the clinical dose). Malformations included anomalies of sternum, coarctation of the aorta with pulmonary trunk dilation, retroesophageal subclavian artery with absent brachiocephalic artery, domed head, forepaw hyperextension and hindlimb malrotation, abdominal distention/edema, and missing/fused caudal vertebrae.

An embryofetal study was conducted in pregnant rats administered latanoprostene bunod daily by intravenous injection on gestation days 7 through 17, to target the period of organogenesis. The doses administered ranged from 150 to 1500 mcg/kg/day. Maternal toxicity was produced at 1500 mcg/kg/day (870 times the clinical dose, on a body surface area basis, assuming 100% absorption), as evidenced by reduced maternal weight gain. Embryofetal lethality (resorption and fetal death) and structural anomalies were produced at doses ≥ 300 mcg/kg/day (174 times the clinical dose). Malformations included anomalies of the sternum, domed head, forepaw hyperextension and hindlimb malrotation, vertebral anomalies and delayed ossification of distal limb bones. A no observed adverse effect level (NOAEL) was established at 150 mcg/kg/day (87 times the clinical dose) in this study.

8.2 Lactation

Risk Summary

There are no data on the presence of VYZULTA in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for VYZULTA, and any potential adverse effects on the breastfed infant from VYZULTA.

8.4 Pediatric Use

Use in pediatric patients aged 16 years and younger is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

8.5 Geriatric Use

No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Latanoprostene bunod was not mutagenic in bacteria and did not induce micronuclei formation in the *in vivo* rat bone marrow micronucleus assay. Chromosomal aberrations were observed *in vitro* with human lymphocytes in the absence of metabolic activation.

Latanoprostene bunod has not been tested for carcinogenic activity in long-term animal studies. Latanoprost acid is a main metabolite of latanoprostene bunod. Exposure of rats and mice to latanoprost acid, resulting from oral dosing with latanoprost in lifetime rodent bioassays, was not carcinogenic.

Fertility studies have not been conducted with latanoprostene bunod. The potential to impact fertility can be partially characterized by exposure to latanoprost acid, a common metabolite of both latanoprostene bunod and latanoprost. Latanoprost acid has not been found to have any effect on male or female fertility in animal studies.

13.2 Animal Toxicology and/or Pharmacology

A 9-month toxicology study administered topical ocular doses of latanoprostene bunod to one eye of cynomolgus monkeys: control (vehicle only), one drop of 0.024% bid, one drop of 0.04% bid and two drops of 0.04% per dose, bid. The systemic exposures are equivalent to 4.2-fold, 7.9-fold, and 13.5-fold the clinical dose, respectively, on a body surface area basis (assuming 100% absorption). Microscopic evaluation of the lungs after 9 months observed pleural/subpleural chronic fibrosis/inflammation in the 0.04% dose male groups, with increasing incidence and severity compared to controls. Lung toxicity was not observed at the 0.024% dose.

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