Optometric Glaucoma Foundation
6th Annual Educators Meeting
in Honor of Douglas Anderson

With support from the

OPTOMETRIC GLAUCOMA SOCIETY

September 10, 2022

Bascom Palmer Eye Institute

Miami, Florida

OGF Educators Meeting
in Honor of
Douglas Anderson

Saturday, September 10, 2022
Bascom Palmer Eye Institute
Miami, FL

Co-Chairs:
Mark Dunbar, Murray Fingeret,
John McSoley, V. Michael Patella

Session 1 - Structure/Function

8:00 am	Introduction and Welcome
8:10am – 8:50am	How changing structural and functional assessments have affected my decision making in glaucoma over 40 years- **Richard Parrish**
8:50-9:00am	Discussion
9:00am – 9:40am	Optic Nerve Evaluation- **Douglas Anderson**
9:40am -10:00am	Discussion
10:00-10:30	Break

Session 2 - A Look at Glaucoma

10:30-11:10am	Natural history and pathological processes of the glaucomas - **Douglas Anderson**
11:10-11:20 am	Discussion
11:20 – 12:00	Glaucoma decision making- **Elizabeth Hodapp**
12:00 – 12:10	Discussion
12:10-1:10pm	Lunch

Session 3 - Therapy

1:10-1:50pm	Glaucoma Medical and Laser Therapy – What has changed in the last decade - **David Greenfield**
1:50-2:00pm	Discussion
2:00pm – 2:40pm	Glaucoma Surgical Care – What has changed in the last decade - **Steve Gedde**
2:40-2:50pm	Discussion
2:50-3:20pm	Break

Session 4 - Clinical Trials

3:20pm-3:50pm	The Normal Tension Glaucoma Treatment Study- **Douglas Anderson**
3:50-4:00pm	Discussion
4:00-4:40pm	How have the Glaucoma Clinical Trials Changed How I Practice - **Paul Palmberg**
4:40-4:50	Discussion
4:50-5:20pm	An Update on Perimetry - **Murray Fingeret, Douglas Anderson, V. Michael Patella**
5:20pm – 5:30 Discussion	
5:30pm	Reception & Dinner Novecento- Brickell 1414 Brickell Ave. Miami, Florida 33131

Douglas R. Anderson, MD

Douglas R. Anderson, AB, BS, MD, FARVO, was born in Memphis, Tennessee in 1938, the son of William Arnold Douglas Anderson, MD (a world-renowned pathologist and text-book author) and Harriott Isabelle Gates, MD (active in the pioneering Red Cross blood-banking program during World War II).

The family moved to Florida in 1953, where his father became the founding chairman of the Department of Pathology of the new University of Miami School of Medicine. After completing high school, he studied at the University of Miami College of Arts and Sciences, where he earned AB *magna cum laude* (Chemistry, Philosophy) and BS *magna cum laude* (Biology, Mathematics, Physics) degrees. He then earned an MD degree from Washington University (1962), which included extracurricular research with the electron microscope and a rotating Internship at the University Hospitals of Cleveland (1962-3). Douglas held the rank of Surgeon (Lt. Commander) with the US Public Health Service assigned as a research Staff Associate to the National Cancer Institute (1963-5), studied as an Ophthalmology Resident at the University of California San Francisco (1965-8), and completed his training with a Glaucoma Research Fellowship at the Howe Laboratory of Massachusetts Eye and Ear Infirmary (1968-9).

He then joined the faculty of the Bascom Palmer Eye Institute of the University of Miami School of Medicine (active 1969-2016, now Professor emeritus). His research interests centered on glaucoma, pathogenesis of optic nerve damage, clinical evaluation of the optic nerve and of visual fields, and principles behind quantifying progression in cases of glaucoma.

Among his professional honors are: a gold medal for best scientific exhibit at the annual meeting of AAOphOto (1972); Robert N. Shaffer Lecturer, AAO (1987); Jackson Memorial Lecturer, AAO (1987); Mildred Weisenfeld Award, ARVO (1997); Georg von Bartisch Medal for contributions to Glaucoma Research, Dresden University (2002); International Glaucoma Review Global Glaucoma Special Recognition (2002); Hans Goldmann Medal (2003); International Perimetric Society Honored IPS Lecturer (2004); Optometric Glaucoma Society Honoree (2004), Distinguished Faculty Scholar Award, University of Miami (2007); Tadeusz Krwawicz Gold Medal [jointly awarded by the International Council of Ophthalmology, the World Congress of Ophthalmology, and the Polish Ophthalmological Society] (2008); Optometric Glaucoma Society Founders' Award (2011), Karen Walker-Brandreth Award, UC Berkeley School of Optometry (2012); a Life Achievement Honor Award, American Academy of Ophthalmology (2015); and the American Glaucoma Society President's Award (2010 and 2020).

His professional services include editorial positions for American Journal of Ophthalmology (1973-90), Investigative Ophthalmology and Visual Science (1978-82), Eye (2009-2011), and Ophthalmology (1985-2012). He was on the Visual Sciences A Study Section (1972-76, Chairman 1975-76), and the National Eye Advisory Council, NIH (1982-86), a Director of the American Board of Ophthalmology (1988-95), member of the Association for Research in Vision and Ophthalmology (ARVO) since 1969 [Chairman of the Anatomy section (1972-73) and of the Glaucoma section (1975-76), Trustee (1983-88), President (1987), Gold level Fellow (FARVO) (2009)]. He has also been a fellow of the American Academy of Ophthalmology since 1971 [Board of Councilors (1984-86), Committee on Medical Information Technology]. He has been an American Ophthalmological Society member since 1981 [Awards Committee (Chairman 2008-2009)], and member of the American Glaucoma Society [Founding Member in 1985, President (1990-1992)].

He has been author or co-author of several books, which include particularly a series on manual kinetic perimetry and automated static perimetry. He published peer-reviewed scientific reports on such subjects as microanatomy of the optic nerve and its vascular supply, the first demonstration of IOP-induced alteration of optic disc physiology (i.e., axonal transport), the clinical characteristics glaucomatous cupping (with Ralph Kirsch, MD), relief of acute angle closure by corneal indentation, the embryology of human trabecular meshwork and its abnormal development in congenital glaucoma, a new statistical method to determine sensitivity and specificity of a diagnostic test without an external ("gold") standard, in vivo demonstration of normal and abnormal vascular autoregulation in human optic disc, laboratory studies on the likely role of pericytes in capillary control of neuro-retinal circulation, and the use of OCT in glaucoma. He collaborated in the initial study of 5-FU in glaucoma surgery, was on the executive committee and a leader of the optic disc reading center for the Ocular Hypertension Treatment Study, and was co-PI (with Stephen Drance, MD, OC) of the 15-year multi-center study of Normal-Tension Glaucoma.

Among the notable professional contributions:
Described the recognition of glaucomatous cupping by attention to the vertical meridians of the optic nerve head.
Demonstrated interruption of rapid axonal transport in the optic nerve, and later that the blockage was not caused by mechanical mechanisms.
Wrote several books on clinical testing of visual fields.
Demonstration of normal and abnormal regulation of blood flow in the human optic nerve.
Laboratory studies of the potential role of pericytes in autoregulation of blood flow.
Study of the normal embryonic development of the human trabecular meshwork and the abnormality that occurs in congenital glaucoma.
Leader of the multicenter randomized clinical trial that showed that intraocular pressure plays a role in normal-pressure glaucoma, and the benefit of lowering pressure.

He married Wirtley Anne Raine in1964, and they have three children: John Douglas Anderson (17 November 1967), Wendy Anne Anderson (Hoffhines) (31 October 1968), and Michael Allen Scott Anderson (27 July 1973).

He is an Honorary Life member of the Optometric Glaucoma Society

When asked to speak at this program, Paul Palmberg responded as follows:

Dear Murray, Mark, John and Mike,

Of course, I would be delighted to attend and speak at the Foundation meeting held in honor of Douglas Anderson. Since I am in my 42nd year of remedial Fellowship with Dr. Anderson, trying to make up for his decision to invite me to interview for the BPEI Faculty, this would give me an opportunity to express to him my gratitude for taking a chance on a rookie to join his team.

I recall that I had an opportunity to speak at the Banquet Bascom Palmer gave in his honor many years ago. In it I recalled my early experience in Miami in asking him about things related to living here. I told him that we had cockroaches and he gave me some boric acid powder to sprinkle below the drawers in our kitchen. It worked! But then we got red ants. I told him that we had gotten rid of the cockroaches but that... He broke in and said "Red ants." He then gave me something for getting rid of them. Later, we found that we needed to replace a stem on a hot water faucet and soon found that no local hardware store had those parts. I asked him about it and he said "Stern Brothers Plumbing, 8920 Bird Road." Sure enough, Stern Brothers were manufacturing outdated plumbing parts and had what I needed! Doug did not tell me that a few weeks earlier he had gone to half a dozen hardware stores until he found the elusive source!

The same sort of thing happened several times when I asked if he knew anything about such things as how the optic nerve was damaged in glaucoma or how the mechanism of congenital glaucoma. He would just slightly frown and hand me a reprint of his seminal article on the subject, which somehow had been a missing part of my training as a glaucoma specialist in St. Louis.

He is SO modest that when we drove to Sarasota one year for ARVO and I asked him if he wanted to have dinner that night, he just said that he had a meeting. I was unaware that he was becoming the President of ARVO. When I was appointed to a Study Section of the NEI I told him that I was happy about that opportunity to review cutting edge research proposals he did not mention that he was on the NEI Advisory Council that reviews the results of the Study Sections and makes final decision.

Doug looked for opportunities to affirm and encourage me and later Rich Parrish and all who followed as Fellows or Faculty in Glaucoma at BPEI. He asked me to see a patient with him to perform gonioscopy as he said he thought I was better at it than he was. In 1982, I asked him to watch me perform gonioscopy on a patient I found had plateau iris syndrome and to tell me if he thought that the hump sign was due to forward rolled ciliary processes as I hypothesized. He said, I think that you are right since you are pushing so hard on the gonioprism that the last roll of the iris is draping over individual ciliary processes.

Doug's parents were both remarkable people. Doug's parents moved the family to Miami from Milwaukee when his father became Chair of Anatomy at UM. He had written a popular medical school textbook. HIs mother had been in charge of blood banks in World War II.

Doug finished undergraduate studies at UM in record time, I think under 3 years, and attended Medical School at Washington University in St. Louis. He had mentioned to Dr. Norton that he would like to return to Miami after training. While Doug was away in his Residency at the University of California in San Francisco, fortuitously Don Gass came to Dr. Norton and said that he would like to devote his career to medical retina, combining retinal photographs with the new technique of fluorescein angiography and then pathologic studies of any donated eyes of patients he would follow. Dr. Gass had trained in ocular pathology at the Armed Forces Institute of Pathology. But, he said, to do that he had to get rid of the glaucoma patients who were filling up his clinic. Dr. Norton said to Dr. Gass (according to Dr. Gass who told me this story), that he would call Robert Shaffer in San Francisco and ask him to show a special interest in Doug Anderson to entice him to want to go into glaucoma. Indeed, that seems to have worked, as Doug took a Fellowship at Mass Eye and Ear with Drs. Chandler and Grant, also fulfilled his military obligation with some Public Health work in which he learned electron microscopy and returned to Miami as the first full time Glaucoma Specialist. To follow were his work in electron microscopy of the optic nerve head, the seminal work on axoplasmic flow blockade in glaucoma, the work on the embryology of anterior chamber angle, the participation with Mike Patella and others on Humphrey Visual Field testing and teaching its interpretation, and the Normal Tension Glaucoma Treatment Trial.

Doug trained well over 100 Glaucoma Fellows and empowered them on their way to outstanding careers. Harry Quigley, Rich Parrish, Don Budenz, Francisco Fantes, Dale Heuer, Lee Alward, Greg Skuta, Alana Grajewski, and Martha Wright were among the early ones. They in turn have trained perhaps 20% of the glaucoma specialists in the US. Glaucoma specialists have a short gestation period, so we multiply like rats! At any AGS or AAO Glaucoma Sub-specialty Day many of Doug's academic progeny are in leadership and giving featured lectures. The existence of the AGS owes much to the Annual Northamerican Glaucoma Learning Ensemble (ANGLE), a think tank meeting that he and Jonathan Hershler began, and which morphed into the AGS, which Doug served as a founding member and an early President.

And that is probably only the half of it.

Paul Palmberg

Speakers

David Greenfield, MD

David S. Greenfield, MD is Professor of Ophthalmology and serves as the Douglas R. Anderson Distinguished Chair in Ophthalmology, Vice Chair for Academic Affairs for the Department of Ophthalmology, Co-Director of the Glaucoma Service, and Director of the Glaucoma Fellowship Program at the Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami, FL. He earned his medical degree from the New York University School of Medicine in 1990 and completed his residency at the New England Eye Center, Tufts University School of Medicine, Boston, in 1994. Dr. Greenfield completed a 1994-5 Heed Fellowship in Glaucoma and a 1995 Heed-Knapp Fellowship in Neuro-Ophthalmology at the Bascom Palmer Eye Institute, University of Miami School of Medicine. He previously joined The New York Eye & Ear Infirmary in 1996 as Clinical Assistant Professor of Ophthalmology and Neurology.

Dr. Greenfield is a clinician, surgeon, and scientist, and has held prestigious leadership positions throughout Ophthalmology. Dr. Greenfield is the Past President of the American Glaucoma Society and the American Glaucoma Society Foundation (2014-16). He is the co-founder of the International Society for Imaging in the Eye (ISIE) and served as Secretary-Treasurer from 2002 – 2007, and is the Executive Vice President and co-founder of The Florida Glaucoma Society. Dr. Greenfield is a member of the editorial boards of Journal of Glaucoma and International Glaucoma Review, and has served as the Executive Editor of American Journal of Ophthalmology and Associate Editor of Ophthalmic Surgery Lasers and Imaging. Dr. Greenfield has served as past Chair of the AGS Scientific Program Committee, Bylaws and Strategic Planning Committees, and member of the AAO Glaucoma Subspecialty Day Committee, Technology Assessment Committee, and EyeCare America Glaucoma Education Committee. Dr. Greenfield has served as Co-Chair of the Glaucoma Subspecialty Day of the American Academy of Ophthalmology (2003-4), and was awarded the 2010 AGS Clinician-Scientist Lectureship, 2011 American Academy of Ophthalmology Senior Achievement Award, 2015 American Academy of Ophthalmology Robert N. Shaffer Lectureship, and 2016 AAO Secretariat Award.

Dr. Greenfield has taught and published extensively in all aspects of glaucoma diagnosis, monitoring, and therapy and has an H-index impact factor of 46. His research interests include optic disc and retinal nerve fiber imaging, reflectance properties of the retinal nerve fiber layer, normal-tension glaucoma, bleb-related ocular infection, and complex glaucoma filtration surgery. He was the recipient of a National Eye Institute consortium grant studying advanced imaging technology in glaucoma, and received continuous funding from the NIH from 1999-2013. He has delivered numerous guest lectures and named lectures nationally and internationally, and has published over 300 original scientific papers, abstracts and book chapters with an H-index impact factor of 53. He has trained numerous clinical and research fellows, many of whom hold distinguished academic positions worldwide.

Elizabeth Hodapp, MD

Dr. Elizabeth Hodapp obtained her medical degree degree from Harvard Medical School and did her ophthalmology residency and glaucoma fellowship at Barnes-Jewish Hospital-Washington University. She is practicing at Bascom Palmer Eye Institute where she is an associate professor of clinical ophthalmology. She is an esteemed author and is a co-author with Drs. Parrish and Anderson of the important text, Clinical Decisions in Glaucoma.

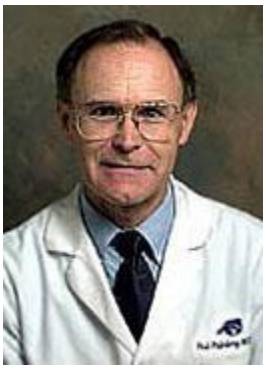
Steven Gedde, MD

Steven J. Gedde, MD, is Professor of Ophthalmology and Vice Chair of Education at the Bascom Palmer Eye Institute. He received his medical degree from Vanderbilt University School of Medicine. Dr. Gedde completed his residency training in ophthalmology at Wills Eye Hospital, where he also served as Chief Resident. His clinical glaucoma fellowship was done at the Bascom Palmer Eye Institute.

Dr. Gedde has lectured nationally and internationally. He has authored or coauthored more than 350 articles, book chapters, and abstracts. He is Editor of the second edition of Curbside Consultation in Glaucoma: 49 Clinical Questions, and he has served on the Editorial Boards for Ophthalmology, Journal of Academic Ophthalmology, EyeNet, Ocular Surgery News, Ophthalmology Management, and EyeWorld. Dr. Gedde has been listed among America's Top Doctors, Best Doctors in America, and Florida Super Doctors. He received an Achievement Award in 2006, Senior Achievement Award in 2012, and Secretariat Award in 2017 from the American Academy of Ophthalmology. He served as the Residency Program Director at the Bascom Palmer Eye Institute from 1999 to 2021. He was selected as the Excellence in Health Care Educator of the Year in 2009, and he received the Straatsma Award for Excellence in Resident Education in 2016. Dr. Gedde is a member of the American Ophthalmological Society. He has served on the Board of Directors of the American Glaucoma Society and the American Board of Ophthalmology since 2017. He is Chair of the Glaucoma Preferred Practice Pattern Panel. Dr. Gedde is a study chairman for the Tube Versus Trabeculectomy (TVT) Study and Primary Tube Versus Trabeculectomy (PTVT) Study, multicenter randomized clinical trials comparing tube shunt surgery with trabeculectomy.

Richard K. Parrish, II, MD

Richard K. Parrish, II, MD, is the editor-in-chief of the American Journal of Ophthalmology (AJO) and has served as president of the American Ophthalmological Society. A widely published author has delivered 35 named lectures and served as a member of the editorial board of Archives of Ophthalmology. His academic career includes more than 100 peer-reviewed original scientific publications. In 1994, he was named Vice-Chair and a Principal Investigator of the National Eye Institute's (NEI) landmark Ocular Hypertension Treatment Study (OHTS and OHTS II) and served in this capacity for OHTS III, a 20-year follow-up investigation. He was the Project Chairman of the NEI's Fluorouracil Filtering Surgery Study, the first multicenter randomized clinical trial in glaucoma surgery in the United States and served as the Principal Investigator of the Optic Disc Reading Centers for the NEI-sponsored OHTS and OHTS II, the Collaborative Initial Glaucoma Treatment Study, and the Advanced Imaging for Glaucoma.



Paul Palmberg, MD, PhD

Paul Palmberg, MD, PhD, Professor of Ophthalmology at the Bascom Palmer Eye Institute, University of Miami School of Medicine. He received MD and PhD in Biochemistry degrees from Northwestern University, and completed a Residency in Ophthalmology, Chief Residency, Clinical and Research Glaucoma Fellowships at Washington University in St. Louis. Dr. Palmberg introduced the term “target pressure” in 1988 and has helped define the relationship between intraocular pressure and visual field progression, receiving the World Glaucoma Association Award (world glaucoma prize) in the year 2000 for the Advanced Glaucoma Intervention Study (AGIS) paper that showed that sufficient lowering of pressure can halt glaucoma damage in most cases. He has investigated the use of antimetabolites in filtering surgery since 1982, and developed techniques to avoid or treat hypotony maculopathy, painful, failing or leaking blebs, and techniques to make aqueous drainage implant surgery safer. Dr. Palmberg gave the Shaffer Glaucoma Lecture at AAO in 2005, and received the AAO Lifetime Honor Award , AGS Surgery Day Lecture in 2014 and AGS Educator Award in 2018, twice Professor of the Year at the Bascom Palmer Eye Institute, Past-President of the Miami Ophthalmological Society and the Pan-American Glaucoma Society. Dr. Palmber has authored or coauthored 97 journal articles and 12 book chapters.

Optometric Glaucoma Foundation 4th Annual Educators Program
Saturday, September 12, 2020 *Virtual*

Optometric Glaucoma Foundation 3rd Annual Educators Program
Saturday, September 14, 2019 Illinois College of Optometry

Optometric Glaucoma Foundation 2nd Annual Educators Program
Saturday, September 8, 2018 UC Berkeley School of Optometry

Optometric Glaucoma Foundation 1st Annual Educators Program
Friday, October 27, 2017 SUNY College of Optometry

We invite you to attend the Optometric Glaucoma Society's 20th Annual Meeting in San Diego, CA.

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		
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	**Jenelle 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		
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**
Session 3		
1-1:30pm	Glaucoma Neuroprotection	**Derek Welsbie MD, PhD**
1:30-1:40pm	Discussion and Questions	
1:40-2:10pm	Update on IOP-independent Glaucoma Treatments	**Jiun Do MD, PhD**
2:10-2:20pm	Discussion and Questions	
2:20-2:45pm	Smoking and Glaucoma	**Sasan Moghimi, MD**
2:45-2:55pm	Discussion and Questions	
2:55-3:25pm	Afternoon Break (opportunity to visit vendor exhibits)	
Session 4		
3:25-4:15pm	Clinical Case Presentations	**Shira Kresch, OD, MS & Panel**
4:15-4:40pm	What is next for glaucoma?	**Robert Weinreb, MD**
4:40-5:15pm	Panel Discussion	**All Speakers**
5:15-6:15pm	Reception	
6:15-9pm	Dinner & Banquet	

OGS/AAO Joint Symposium *Wednesday, October 26, 2022*		
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	Glaucoma Neuroprotection	**Derek Welsbie MD, PhD**
9:25-9:40am	Panel Discussion	

The Optometric Glaucoma Foundation would like to acknowledge the generous support of the following Sponsors.

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

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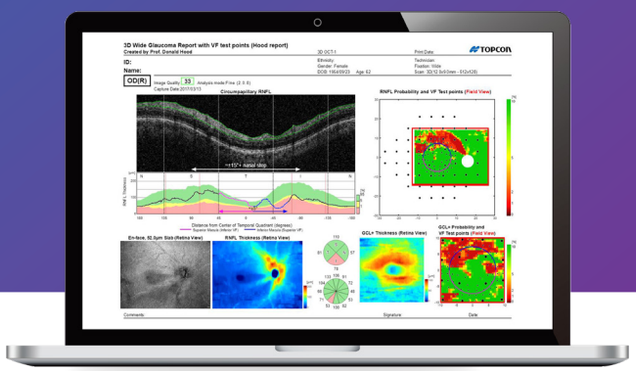
YOUR GUIDE FOR GLAUCOMA DIAGNOSTICS

THE HOOD REPORT FOR GLAUCOMA

MAESTRO2

- OCT and true color* fundus photography
- Fully automated image capture
- Novel report simplifies & accelerates glaucoma diagnostic decision-making
- Retinal thickness analysis (RNFL/GCL) + optic nerve metrics in one scan



*True, full color fundus image simultaneously captured with white light, 24-bit color.

MCA #4860

TOPCON Healthcare

SEEING EYE HEALTH DIFFERENTLY

VYZULTA®
(latanoprostene bunod ophthalmic solution), 0.024%

THE HORSEPOWER YOU NEED TO LOWER IOP

Powerful IOP reduction with excellent tolerability[1,2]

VYZULTA delivered **up to 9.1 mmHg mean IOP reduction** from baseline in pivotal trials.[1,2*]

TAKE A TEST RIDE AT VYZULTAHCP.COM

*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 ≥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.

BAUSCH+LOMB

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 ≥ 20 µg/kg/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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