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OF OPHTHALMOLOGY®

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Glaucoma 2022

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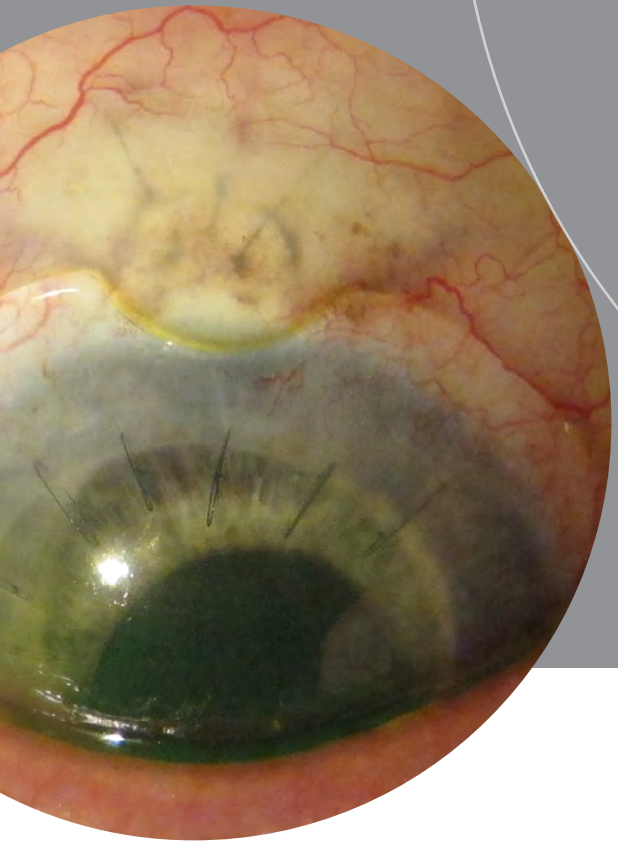

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INDICATIONS AND USAGE

Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once daily in the evening. If one dose is missed, treatment should continue with the next dose in the evening. The dosage of Rocklatan® should not exceed once daily. Rocklatan® may be used concomitantly with other topical ophthalmic drug products to lower IOP. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

- Increased **pigmentation** of the iris, periorbital tissue (eyelid), and eyelashes can occur. Iris pigmentation likely to be permanent.
- Gradual **change to eyelashes** may include increased length, thickness, number, and misdirected growth of lashes. Usually reversible upon discontinuation of treatment.
- Use with caution in patients with a history of **intraocular inflammation** (iritis/uveitis). Should generally not be used in patients with active intraocular inflammation.
- **Macular edema**, including cystoid macular edema, has been reported with latanoprost. Use with caution in aphakic patients, pseudophakic patients with a torn posterior lens capsule, or patients with known risk factors for macular edema.
- Use with caution in patients with a history of **herpetic keratitis**. Avoid use in cases of active herpes simplex keratitis.
- **Bacterial keratitis** has been reported with multiple-dose containers of topical ophthalmic products inadvertently contaminated by patients.
- Remove **contact lenses** prior to administration and reinsert 15 minutes after administration.

ADVERSE REACTIONS

The most common ocular adverse reactions were conjunctival hyperemia (59%), with 5% of patients discontinuing therapy for this reason, instillation site pain (20%), corneal verticillata (15%), and conjunctival hemorrhage (11%). Eye pruritus, visual acuity reduced, increased lacrimation, instillation site discomfort, and blurred vision were reported in 5-8% of patients.

Please see full Prescribing Information for Rocklatan® at Rocklatan.com

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Visit Rocklatan.com to learn more about this innovative IOP-lowering treatment[1,2]

Please refer to Brief Summary on the reverse side.

IOP, intraocular pressure.

ONCE-DAILY
rocklatan®
(netarsudil and latanoprost
ophthalmic solution) 0.02%/0.005%

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BRIEF SUMMARY
Consult the full Prescribing Information for complete product information.

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CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
Pigmentation
Rocklatan® contains latanoprost which has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as latanoprost 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, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Beyond 5 years the 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 Rocklatan® can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Eyelash Changes
Rocklatan® contains latanoprost which may gradually change eyelashes and vellus hair in the treated eye; these changes include increased length, thickness, pigmentation, the number of lashes or hairs, and misdirected growth of eyelashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation
Rocklatan® contains latanoprost which 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 because it may exacerbate inflammation.

Macular Edema
Macular edema, including cystoid macular edema, has been reported during treatment with latanoprost. Rocklatan® 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.

Herpetic Keratitis
Reactivation of herpes simplex keratitis has been reported during treatment with latanoprost. Rocklatan® should be used with caution in patients with a history of herpetic keratitis. Rocklatan® should be avoided in cases of active herpes simplex keratitis because it may exacerbate inflammation.

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.

Use with Contact Lenses
Contact lenses should be removed prior to the administration of Rocklatan® and may be reinserted 15 minutes after administration.

ADVERSE REACTIONS
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 clinical practice.

Rocklatan®
The most common ocular adverse reaction observed in controlled clinical studies with Rocklatan® was conjunctival hyperemia which was reported in 59% of patients. Five percent of patients discontinued therapy due to conjunctival hyperemia. Other common ocular adverse reactions reported were instillation site pain (20%), corneal verticillata (15%), and conjunctival hemorrhage (11%). Eye pruritus, visual acuity reduced, increased lacrimation, instillation site discomfort, and blurred vision were reported in 5-8% of patients.

Other adverse reactions that have been reported with the individual components and not listed above include:

Netarsudil 0.02%
Instillation site erythema, corneal staining, increased lacrimation and erythema of eyelid.

Latanoprost 0.005%
Foreign body sensation, punctate keratitis, burning and stinging, itching, increased pigmentation of the iris, excessive tearing, eyelid discomfort, dry eye, eye pain, eyelid margin crusting, erythema of the eyelid, upper respiratory tract infection/nasopharyngitis/influenza, photophobia, eyelid edema, myalgia/arthralgia/back pain, and rash/allergic reactions.

DRUG INTERACTIONS
In vitro drug interaction studies have shown that precipitation can occur when eye drops containing thimerosal are mixed with Rocklatan®. If such drugs are used, they should be administered at least five (5) minutes apart.

The combined use of two or more prostaglandins or prostaglandin analogs including latanoprost ophthalmic solution 0.005% is not recommended. It has been shown that administration of these prostaglandin drug products more than once daily may decrease the IOP lowering effect or cause paradoxical elevations in IOP.

For additional information, refer to the full Prescribing Information at Rocklatan.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Manufactured for: Aerie Pharmaceuticals, Inc., Irvine, CA 92614, U.S.A.

U.S. Patent Nos.: 8,450,344; 8,394,826; 9,096,569; 9,415,043; 9,931,336; 9,993,470; 10,174,017; 10,532,993; 10,588,901

References: 1. Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% Prescribing Information. Aerie Pharmaceuticals, Inc., 2020. **2.** Asrani S, Bacharach J, Holland E, et al. Fixed-dose combination of netarsudil and latanoprost in ocular hypertension and open-angle glaucoma: pooled efficacy/safety analysis of phase 3 MERCURY-1 AND -2. *Adv Ther.* 2020;37(4):1620-1631.

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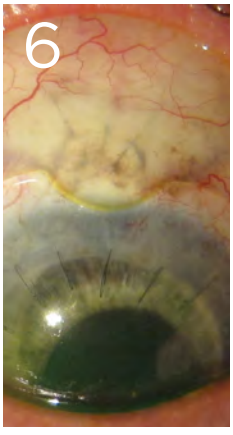

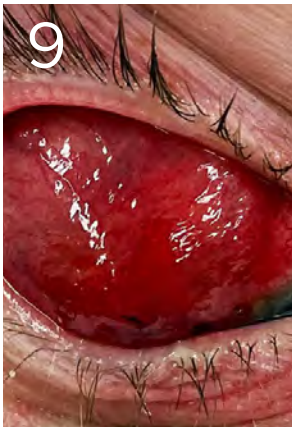

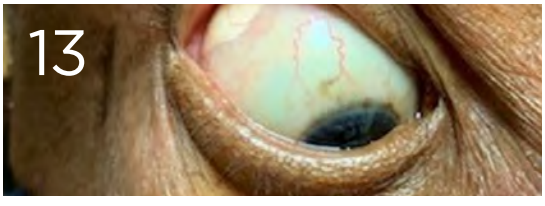

EyeNet Selections
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REPRINTS FOR
GLAUCOMA SUBSPECIALTY DAY
AT AAO 2022

COVER PHOTOGRAPH
Greg DeNaeyer

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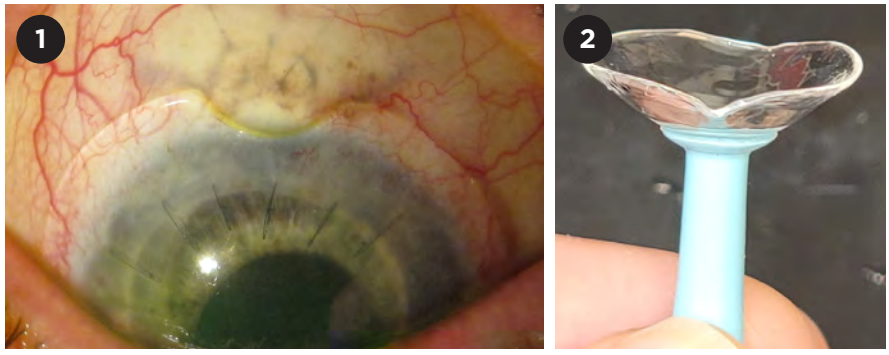
Navigating Surgical Blebs and Contact Lens Wear in Glaucoma Patients

Advanced glaucoma patients who are contact lens–dependent have long posed a challenge for both ophthalmologists and contact lens specialists. This is because bleb-producing trabeculectomy or tube shunt surgery may become necessary. As the point of friction between the bleb and contact lens can lead to breakdown of the tissue and cause infection, lens wear is generally contraindicated. Traditionally, patients with blebs must permanently transition to glasses or choose an alternative procedure, which may leave them drop-dependent.

However, new impression-based scleral lens technology and minimally invasive glaucoma surgery (MIGS) devices may give glaucoma specialists more tools in their arsenal to help advanced glaucoma patients who need contact lenses.



LENSES FOR BLEBS. *(1) A photo of a scleral lens with a notch bypassing a conjunctival bleb. (2) An EyePrintPRO lens.*

Blebs and Contact Lenses

A small but growing number of glaucoma patients wear contact lenses, said Michele C. Lim, MD, at the University of California Davis Eye Center in Sacramento. "When older style rigid lenses were the only option, most patients chose glasses. But with the advent of more comfortable soft, hybrid, and custom-fitted scleral lenses, we're seeing a shift." And for certain patients, contacts aren't just a preference, they're a necessity.

When patients need contacts. While some people can make the switch to glasses, others either are severely hyperopic, myopic, or have corneal disease that makes them reliant upon contact lenses for best vision.

"I take care of a lot of high acuity corneal patients. Some have keratoconus, Fuchs dystrophy, or corneal scarring from infection or injury. Others have had corneal transplants, and only contact lenses can smooth out the irregular corneal surface and help reestablish clear vision," said Lauren S. Blieden, MD, at the Cullen Eye Institute, Baylor College of Medicine in Houston. When these patients are faced with advanced glaucoma surgery, ophthalmologists generally steer them away from bleb-producing operations, she said.

The problem with lenses and blebs. "To date, advanced glaucoma patients who require contacts have generally been poor candidates for trabeculectomy or tube shunts because incisional surgery increases the risk of eye infection, and a contact lens can act like your kitchen sponge—a depot for bacteria to absorb and sit on the surface of the eye," said Dr. Blieden.

Every type of contact lens introduces unique challenges when it meets a bleb, according to Melissa Barnett, OD, a scleral lens specialist who works with Dr. Lim at the University of California, Davis Eye Center.

- Conventional soft contact lenses may not adequately cover the ocular surface, including the bleb. If the edge of the lens overlaps the bleb, blink-activated friction could slowly erode or thin the epithelial tissue causing leakage, breakdown, or infection, explained Dr. Lim.
- A corneal gas-permeable contact

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BY REENA MUKAMAL, CONTRIBUTING WRITER, INTERVIEWING **MELISSA BARNETT, OD, LAUREN S. BLIEDEN, MD, MICHELE C. LIM, MD,** AND **FRANCIS K. MANUEL, OD.**

Greg DeNaeyer, Christine Sindt, OD.

lens can cause mechanical insult to the bleb if it rides high. This can be magnified by spontaneous dislodgement, a common issue with these lenses, Dr. Barnett said.

- Standard scleral lenses—large diameter rigid gas-permeable (RGP) lenses—may compress a bleb, reducing its functionality, explained Dr. Barnett.

Unpredictable bleb morphology. To complicate matters, one can't predict how a bleb will form after surgery, how long it will take to heal, or whether it will transform over time. "An ideal bleb is low profile and has minimal vascularity," said Dr. Lim. Additionally, when the bleb forms more posteriorly to the limbus, it is farther away from the edge of a contact lens. "But you can do the same surgery on 10 different people and end up with 10 different blebs. Blebs can continue to remodel for years," she explained. That's because a bleb is "a living, breathing entity, subject to change at any time," said Francis K. Manuel, OD, the contact lens specialist who works with Dr. Blieden at Baylor.

Expanding the Toolkit

Customized scleral lenses. Contact lens technology is changing, with advances in lens materials, designs, imaging, and manufacturing techniques. This has fueled the innovation of customizable scleral lenses, flexible enough to fit a highly irregular eye, said Dr. Barnett. A notch, elevation, or impression mold can be incorporated into a scleral lens to avoid a glaucoma drainage device (Fig. 1). One such product is the EyePrintPRO (EyePrint Prosthetics), a large-diameter scleral lens, which is designed using a mold of the patient's ocular surface, she said. The mold is taken by a contact lens specialist, then scanned using millions of data points to create a 3D model. Dr. Barnett noted that every point on an EyePrint PRO lens is modifiable so that extra clearance may be created over the bleb to allow for micro changes of the bleb and so that the lens will not compress the conjunctival/scleral tissue over a tube. The lab transforms that model into a scleral lens that meets the physical shape and physiologic needs of the eye, said Dr. Manuel. "The accuracy of the EyePrintPRO is within a 6- to 7-µm range of matching the ocular surface anatomy. The lens edge can even make a 90 degree turn up and over a bleb [Fig. 2]," he said.

The EyePrintPRO was FDA-approved in 2016 and has become more widely available over the last couple of years, said Dr. Manuel.

There are no prospective, randomized, multiyear studies that assess the effect of scleral lenses on patients with glaucoma. "A highly debated topic is whether intraocular pressure is affected by scleral lens wear," said Dr. Barnett. Nonetheless, glaucoma surgeons see potential. "Impression-based scleral lenses are providing a new frontier," said Dr. Lim.

Xen and Preserflo. Two MIGS devices—the Xen Gel Stent (Allergan) and the Preserflo Microshunt (Santen)—come close to achieving the drainage success of a trabeculectomy, said Dr. Blieden. She added that both devices are less invasive than a traditional tube shunt, allowing for faster recovery.

The Xen, which was FDA approved in 2016, bypasses the diseased trabecular meshwork to drain aqueous from the anterior chamber to a subconjunctival bleb. Whereas a trabeculectomy creates a hole in the sclera with a variable flap, the Xen uses a 6 mm–long shunt to create a 45-µm lumen outflow. Similarly, the Preserflo MicroShunt, approved in Australia, Canada, and Europe, but not yet FDA approved, is an 8.5 mm–long shunt with a 75-µm lumen outflow, said Dr. Blieden.

Compared with trabeculectomy, both devices are designed to drain fluid farther away from the limbus (2 to 3 mm posterior for the Xen and 7 mm posterior for the Preserflo). "The greater the distance between the bleb and the limbus, the easier it is for the patient to wear a contact lens," said Dr. Lim.

There is much discussion among glaucoma surgeons about the blebs that these devices create. Some say they are more low lying, low profile, and diffuse than trabeculectomy blebs, said Dr. Lim. In Dr Blieden's experience, "Sometimes Xen blebs form more posteriorly, but not consistently. Preserflo blebs tend to be flatter and more posterior to the limbus, making them more amenable to contact lens wear. But we're still a way off from knowing what they will do in the long-term."

Surgical Considerations

Preoperative expectation setting. Before surgery, it is important to have a practical discussion with the patient about their preferences for contact lens wear. "I caution my patients who are traditional soft contact or RGP lens wearers that there is a decent chance they may not be able to be fit with that type of lens again. If appropriate, I educate them about the EyePrintPRO lens and its cost," said Dr. Blieden.

Trab or tube? For keratoconus patients or those who are truly lens-dependent for any other reason, she will also discuss the pros and cons of tube shunt and trabeculectomy procedures. This is because a tube shunt results in a more predictable limbal anatomy, better for contact lens wear. Its success rate is comparable to a trabeculectomy, although patients are more likely to require drops.[1] Dr. Lim agreed that a tube surgery gives patients a greater potential to wear contact lenses.

Ocular surface disease. Close communication with both the surgeon and patient preoperatively can be valuable for the contact lens specialist. "An evaluation before surgery allows me to assess anatomy and acuity potential and look for the presence of ocular surface disease [OSD]," said Dr. Manuel. Dr. Barnett added, "It's essential to optimize the ocular surface preoperatively for the best outcomes. Many patients with glaucoma have corneal irregularities. In addition, they are more likely to have OSD from long-term use of topical glaucoma medications. Multiple strategies can be used to manage their OSD, including eyelid hygiene, commercial eyelid cleaners, warm compresses, preservative-free eyedrops, topical immunomodulators, punctal plugs, and lifestyle changes."

Trabeculectomy incision. Evidence suggests that while the type of surgical incision—fornix-based versus limbus-based—doesn't have a measurable impact on the success rate of a trabeculectomy, it can affect the bleb forma-

tion. Compared with a limbus-based incision, a fornix-based incision may help create a lower, more diffuse bleb.[2] "A fornix-based incision makes a more diffuse bleb because the posterior aspect of the bleb is not limited by the scar tissue that forms for the closure of a limbus-based bleb," explained Dr. Blieden.

Mitomycin-C treatment. The method of mitomycin-C (MMC) application may also influence bleb construction. Blebs tend to be more diffuse and less vascularized when MMC is delivered via an injection rather than a soaked sponge.[3] Dr. Blieden said she has switched to the injection method for her fornix-based trabeculectomies.

Postoperative healing. Complete healing of the ocular surface and stability of IOP are essential before contact lens fitting. Complications such as hypotony, erosion, bleb leakage or failure, infection, and corneal hypoxia need to be addressed and resolved. With this in mind, Dr. Blieden won't recommend a patient for fitting for at least two months postoperatively, and Dr. Lim tells her trabeculectomy patients to wait about six months after surgery. This wait can be frustrating for lens-dependent patients, said Dr. Manuel. Indeed, "some patients are functionally on 'stop' until we can get contact lenses back on them," he said.

Scleral lens fitting. Dr. Manuel often fits advanced glaucoma patients with EyePrintPRO lenses. He said that the impression molding process is gentle and takes a few minutes, and once the mold is sent to the lab, lenses are generated in two to three weeks.

It can take time for patients to get accustomed to putting on a scleral lens. "Getting the eyelids out of the way is the biggest challenge," said Dr. Manuel. He noted that multiple tools are available to help with scleral lens application, such as a ring that is worn on the finger or a special applicator device with a guiding light.

Follow-up and collaboration. After being fitted for lenses, patients need regular follow-up with both their surgeon and lens specialist. "I'll see them once a month after the initial fitting, then at three- to four-month intervals. At each visit, I do a fit analysis to prevent impingement of the lens on the bleb," said Dr. Manuel. He uses a combination of anterior segment OCT scans and slit-lamp imaging to take cross-sectional pictures of the eye and lens. He targets 200-250 µm of clearance over the cornea and also checks for whiteness or blanching of tissue beneath the lens edge, and he relays what he sees at each visit to the surgeon.

Dr. Blieden makes sure contact lenses "are not fitting too tight across a tube shunt, compressing the bleb, or too loose and bumping into things they shouldn't be."

If the patient is on drops or topical medication, Dr. Barnett carefully monitors and manages OSD. Blebs in complex eyes are likely to keep transforming and may need contact lens refitting. "One of my EyePrintPRO patients with severe dry eye and an already large bleb just had a spontaneous bleb enlargement, requiring revision of the impression-based lens. But with careful monitoring and collaboration, glaucoma patients with blebs can succeed with scleral lenses," she said.

1 Gedde S et al. *Ophthalmology.* 2020;127(3):333-345.
2 Solus JF et al. *Ophthalmology.* 2012;119(4):703-711.
3 Esfandiari H et al. *Ophthalmol Glaucoma.* 2018; 1(1):66-74.

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Dr. Blieden is associate professor of ophthalmology, Baylor College of Medicine in Houston. *Relevant financial disclosures: Allergan: C.*
Dr. Lim is professor, vice chair, and medical director, University of California, Davis Department of Ophthalmology & Vision Sciences, Sacramento. *Relevant financial disclosures: Santen: C.*
Dr. Manuel is an optometrist specializing in glaucoma and ocular therapeutics and a faculty member at Baylor College of Medicine, Houston. *Relevant financial disclosures: None.*
See the disclosure key, page 5. **For full disclosures,** see this article at aao.org/eyenet.

MORE ONLINE. For an article on Xen and Preserflo, see the July 2021 *EyeNet* at aao.org/eyenet/archives.

Her "Bad Eye" Kept Getting Worse . . . and Worse

Polly Jones,* a 43-year-old woman, had noticed some discomfort in her right eye for a few days. Her right eye was her "bad eye," so she wasn't alarmed at first. However, after a few weeks of progressive injection, swelling, and pain, Ms. Jones decided that it was time to see her ophthalmologist.

We Get a Look

Presentation. When Ms. Jones presented to our ophthalmology clinic, she noted pain and redness in her right eye. She had not experienced any photophobia or changes in vision, and she said that her left eye was stable.

History. Ms. Jones had a history of herpes simplex keratitis in the right eye that had caused persistent corneal stromal scarring and inflammatory glaucoma. This condition ultimately required implantation of an Ahmed Glaucoma Valve in 2015 for IOP control.

Ms. Jones' herpetic keratitis had been clinically stable for the past several years on a maintenance dose of oral acyclovir. She was not using any other systemic or ocular medications and had no significant past medical history. She also said that she had no history of trauma.

During Ms. Jones' last follow-up visit to the ophthalmology clinic six months earlier, it was noted that she had a possible suture granuloma over the plate of her drainage implant. She had been scheduled for a bleb revision, but the procedure was postponed due to the COVID-19 pandemic. She had not returned until this urgent visit.

Exam. Ms. Jones' BCVA was stable at 20/300 in the right eye and 20/20 in the left. Her IOP was 20 mm Hg in the right eye and 15 mm Hg in the left. No afferent pupillary defect or ocular motility disturbances were present.

The slit-lamp examination showed significant swelling of her right upper eyelid. The conjunctiva of her right eye was diffusely chemotic and injected, with more severe injection directly over the plate of the tube shunt. Seidel testing of the conjunctiva along the length of the plate and tube was negative for leakage, and the previously noted suture granuloma could not be visualized. The cornea had stable scarring from past herpetic keratitis, and the anterior chamber and vitreous were quiet. The left eye exhibited no acute findings.

Initial management. Although the etiology of Ms. Jones' inflammatory process was unknown, we started her on prednisolone acetate 1% and moxifloxacin 0.5% four times a day in the right eye because of our concern about a possible tube shunt–related infection. We also referred her for an updated cornea evaluation to confirm that she was not having occult reactivation of her past herpetic eye disease.

Early improvement. When she returned for follow-up the next day, Ms. Jones reported improvement in her symptoms. Her cornea evaluation revealed stable, chronic corneal scarring consistent with previous disease, and no signs of active infection. We continued her on the prednisolone and moxifloxacin regimen four times a day, and she was followed closely with gradual improvement.

CLINICAL VIEW. *Preoperative appearance of chemotic hemorrhagic tissue over the Ahmed plate.*

A turn for the worse. Despite this apparent success, three weeks after her initial visit, Ms. Jones returned to the clinic with worsening pain, diffuse conjunctival injection, and chemosis as well as new-onset bloody tears. Her vision was still stable, but her IOP was now 6 mm Hg in the right eye.

The conjunctiva over the plate was now Seidel positive for leakage, and a new subconjunctival hemorrhage without purulence had developed (Fig. 1).

Differential Diagnosis

Our differential diagnosis included the following:

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BY **SHIVANI S. KAMAT, MD,** AND **RONALD L. FELLMAN, MD.** EDITED BY AHMAD A. AREF, MD.

- late infection of glaucoma drainage implant due to plate suture erosion and subsequent tube exposure
- tube erosion with subsequent infectious bacterial endophthalmitis
- bacterial conjunctivitis with subsequent tube erosion
- herpetic keratoconjunctivitis
- idiopathic orbital inflammation

Given the absence of purulence and intraocular inflammation, the underlying diagnosis at this point was unclear.

Prompt Action Needed

Nevertheless, the conjunctival erosion needed to be addressed promptly. The location of the erosion warranted surgical treatment, as management with a bandage contact lens and antibiotic drops was unlikely to repair the defect. A simple tube revision with an allograft pericardium patch graft (Tutoplast) was unlikely to provide a long-term solution because of the location of the exposure. Thus, we decided to take Ms. Jones to the operating room for an exploration and tube shunt explantation.

Making the Diagnosis

In the OR, we immediately noticed significant subconjunctival hemorrhage without purulence. The explanted plate was sent to pathology, and the hemorrhagic fluid was also plated for culture. At the end of the procedure, Ms. Jones was given subconjunctival cefazolin and dexamethasone, and the previous regimen of moxifloxacin and prednisolone was restarted.

To our surprise, the culture plates grew florid pansensitive *Staphylococcus aureus* (Figs. 2A, 2B). We then added oral cephalexin to Ms. Jones' topical regimen. Her symptoms and findings improved markedly within a few days of shunt explantation. By one month after surgery, all acute findings had completely resolved. Ms. Jones was tapered off her medications, and her IOP has remained controlled despite removal of the tube shunt.

Discussion

Tube shunt infection is a rare complication of tube shunt surgery. It is far less common than early and postoperative hypotony, capsular fibrosis, and tube or plate erosion.[1] Furthermore, tube infections typically present with some combination of injection, tenderness, or discharge and often display Seidel positivity somewhere along the length of the tube or plate. Our patient presented atypically, with diffuse injection and chemosis and no signs of Seidel positivity until later in the course of the infection.

Glaucoma drainage implant infections are more commonly related to erosion at the tube rather than the plate. Combined tube or plate erosions occur at a rate of 1% to 2% per year and increase the risk of infection. Tube exposure is more likely to occur in eyes with ocular inflammation, steroid use, prior ocular surgery, concomitant surgery, inferior placement, and smoking.[1,2] If the tube becomes exposed again after repair of a primary tube erosion, there is an even higher risk for infection. Reported risk factors for re-exposure include Caucasian race and use of non-scleral patch grafts.[3]

Careful slit-lamp examination of the conjunctiva in an eye with a tube shunt is imperative at every visit to detect any erosion or leakage. Medical management is rarely effective, and surgical revision is generally required.[4,5]

Proper rotation of the suture plate knot can help avoid late erosion and infection. Any exposed suture must be removed to avoid development of a nidus of infection and potential biofilm formation, which can lead to reduced topical antibiotic efficacy.

In our patient, unplanned delay of surgical revision due to the pandemic led to an occult infection that was difficult to recognize. Only after explantation and culture plating of the hemorrhagic fluid did we discover that the tube shunt was infected with *S. aureus.*

CULTURES. *(2A) Blood agar plate shows clusters of golden colonies; (2B) chocolate agar plate shows yellow pigmented colonies; these findings are characteristic of* S. aureus.

*Patient's name is fictitious.

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AAO 2022 gather

Grand Rounds: Real Cases From Around the World (Sym03). ***Chair:*** *Carolyn K. Pan, MD.* **When:** Saturday, Oct. 1, 9:45-11:00 a.m. **Where:** Room S406a.

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Shivani S. Kamat, MD.

LOWER THE IOP FLOOR[1,2]

Rhopressa® achieves an additional 20% IOP reduction regardless of current regimen or baseline pressure[1,2]

INDICATIONS AND USAGE

Rhopressa® (netarsudil ophthalmic solution) 0.02% is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once daily in the evening.

WARNINGS AND PRECAUTIONS

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.

Contact Lenses: Contact lenses should be removed prior to instillation of Rhopressa® and may be reinserted 15 minutes following its administration.

ONCE-DAILY rhopressa® (netarsudil ophthalmic solution) 0.02%

ADVERSE REACTIONS

The most common ocular adverse reaction observed in controlled clinical studies with Rhopressa® dosed once daily was conjunctival hyperemia, reported in 53% of patients. Six percent of patients discontinued therapy due to conjunctival hyperemia. Other common (approximately 20%) adverse reactions were: corneal verticillata, instillation site pain, and conjunctival hemorrhage. Instillation site erythema, corneal staining, blurred vision, increased lacrimation, erythema of eyelid, and reduced visual acuity were reported in 5-10% of patients.

The corneal verticillata seen in Rhopressa®-treated patients were first noted at 4 weeks of daily dosing. This reaction did not result in any apparent visual functional changes. Most corneal verticillata resolved upon discontinuation of treatment.

Please see full Prescribing Information for Rhopressa® at Rhopressa.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Visit Rhopressa.com to learn more about this innovative IOP-lowering treatment

Please refer to Brief Summary on the reverse side.

IOP, intraocular pressure; PGA, prostaglandin analog.

ONCE-DAILY
rhopressa®
(netarsudil ophthalmic solution) 0.02%

BRIEF SUMMARY

Consult the full Prescribing Information for complete product information.

INDICATIONS AND USAGE

Rhopressa® (netarsudil ophthalmic solution) 0.02% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once daily in the evening.

If one dose is missed, treatment should continue with the next dose in the evening. Twice a day dosing is not well tolerated and is not recommended. If Rhopressa® is to be used concomitantly with other topical ophthalmic drug products to lower IOP, administer each drug product at least 5 minutes apart.

WARNINGS AND PRECAUTIONS

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 previously contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

Use with Contact Lenses

Rhopressa® contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to instillation of Rhopressa® and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS

Clinical Trials Experience

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

The most common ocular adverse reaction observed in controlled clinical studies with Rhopressa® dosed once daily was conjunctival hyperemia which was reported in 53% of patients. Six percent of patients discontinued therapy due to conjunctival hyperemia. Other common (approximately 20%) ocular adverse reactions reported were: corneal verticillata, instillation site pain, and conjunctival hemorrhage. Instillation site erythema, corneal staining, blurred vision, increased lacrimation, erythema of eyelid, and reduced visual acuity were reported in 5-10% of patients.

Corneal Verticillata

Corneal verticillata occurred in approximately 20% of the patients in controlled clinical studies. The corneal verticillata seen in Rhopressa®-treated patients were first noted at 4 weeks of daily dosing. This reaction did not result in any apparent visual functional changes in patients. Most corneal verticillata resolved upon discontinuation of treatment.

For additional information, please refer to full Prescribing Information at Rhopressa.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-1088.

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U.S. Patent Nos.: 8,450,344; 8,394,826; 9,096,569; 9,415,043; 9,931,336; 10,174,017

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Characteristics and Management of Steroid-Induced Glaucoma

Steroids are commonly prescribed for various autoimmune and inflammatory conditions and are routinely used after intraocular surgery. Despite numerous benefits, steroids can have adverse systemic and ocular side effects, including cataracts, elevated IOP, and glaucoma. One-third of patients may experience a type of ocular hypertension known as steroid response.

Steroid-induced glaucoma is defined as elevated IOP and glaucomatous optic neuropathy in the setting of corticosteroid use. This iatrogenic disease is often difficult to manage, as patients may require continued steroid treatment for their underlying conditions. Steroid-induced IOP elevation is dependent on the route of administration, potency, dose, treatment duration, and type of steroid, in addition to patient-related risk factors.

Prompt diagnosis and early intervention are critical to prevent glaucomatous optic neuropathy and vision loss. Therefore, physicians must be mindful of the association between steroids and secondary glaucoma.

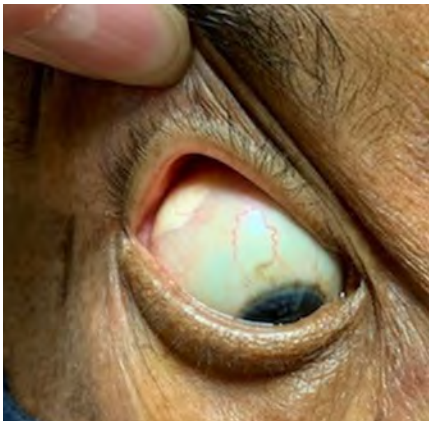
Epidemiology

The risk of steroid response varies among individuals, which contributes to the unpredictable nature of steroid-induced glaucoma. In the general population exposed to topical ocular steroids, 5% to 6% are high steroid responders (IOP elevation >15 mm Hg), 29% to 36% are moderate responders (IOP elevation between 6 mm Hg and 15 mm Hg), and 58% to 66% do not experience significant IOP elevation.[1,2]

In addition, Becker and Mills found that patients with primary open-angle glaucoma (POAG) exhibit marked IOP elevation and decreased aqueous outflow facility when exposed to topical ocular steroids.[1] Individuals with a first-degree relative who has POAG or with a diagnosis of glaucoma suspect are also more likely to develop ocular hypertension when treated with steroids. Other risk factors include previous steroid response, high myopia, angle-recession glaucoma, very young (<6 years old) or older age, type 1 diabetes mellitus, and connective tissue disease.[2]

Pathogenesis

Trabecular meshwork morphological and biochemical changes. Steroid-induced glaucoma is considered a secondary open-angle glaucoma. Although the exact mechanism is unknown, the main cause of the disease is increased aqueous outflow resistance at the level of the trabecular meshwork (TM), leading to IOP elevation.[2] Accumulation of extracellular matrix proteins including fibronectin, elastin, and hydrated polymerized glycosaminoglycans, as well as mechanical obstruction by steroid particles, is thought to reduce aqueous outflow.



PERIOCULAR STEROIDS. *Sub-Tenon steroid depot in a patient with uveitis resulting in secondary glaucoma.*

Moreover, steroids inhibit proteases and suppress the phagocytic activity of the TM, thus promoting the accumulation of aqueous debris and obstruction. Steroids also decrease the synthesis of prostaglandins and have a significant effect on the cytoskeleton structure of the TM through formation of cross-linked actin networks.

Genetics. Several genes are associated with steroid-induced glaucoma, including those encoding for myocilin, alpha 1-antichymotrypsin, pigment epithelial–derived factor, cornea-derived transcript factor 6, and prostaglandin D_2 synthase.[2] Although still poorly understood, myocilin has been extensively studied because of its link to juvenile and adult-onset open-angle glaucoma. Myocilin is highly expressed in trabec-

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BY **TERESA HORAN, MD,** AND **SARWAT SALIM, MD, FACS.** EDITED BY BENNIE H. JENG, MD.

ular cells exposed to glucocorticoids, and its expression shows a similar dose response and delay in onset as steroid-induced ocular hypertension. Further research into the genetics associated with steroid-induced glaucoma would be beneficial to identify patients at risk.

Steroid Administration

Steroid-induced ocular hypertension and glaucoma can occur after topical, periocular, intraocular, inhaled, nasal, systemic, or transcutaneous administration. Rarely, excess endogenous steroid production can cause ocular hypertension. Steroid delivery and potency are major factors in IOP elevation. In general, topical, periocular, and intravitreal administration account for most cases of steroid-induced glaucoma, with the topical route being the most frequently involved.

Topical steroids. The effect of topical ocular steroids on IOP depends on the potency of the drug formulation. Dexamethasone and prednisolone are more potent steroids. In one study, 0.1% dexamethasone was associated with an average increase of 22 mm Hg from baseline IOP, while prednisolone acetate, a commonly used postoperative medication, demonstrated an average IOP elevation of 10 mm Hg in patients who were previously identified as steroid responders.[3] Difluprednate is one of the most potent topical steroids, and approximately 3% of patients using difluprednate experienced an IOP increase of 10 mm Hg or more above baseline, compared with 1% in the placebo group.[4]

Less potent topical ocular steroids include medrysone 1.0%, tetrahydrotriamcinolone 0.25%, hydrocortisone 0.5%, and fluorometholone 0.1%. On average, these drugs raise the IOP by 1.0, 1.8, 3.2, and 6.1 mm Hg, respectively.[3] Newer medications such as loteprednol etabonate and rimexolone have less of an effect on IOP. It is important to note that the incidence rates of steroid-induced ocular hypertension and glaucoma vary among studies because of patient-related risk factors and different definitions of IOP elevation.

Periocular and intravitreal steroids. Periocular and intravitreal steroids include triamcinolone acetonide (TA), fluocinolone acetonide (FA), and dexamethasone (DEX). These medications have a longer duration of action compared with topical steroids. All periocular steroids can increase IOP, and the risk appears to be intermediate between topical and intravitreal administration.

There is limited literature comparing outcomes of different types of periocular steroid delivery, including subconjunctival, sub-Tenon, and retrobulbar injection. Among the periocular steroid routes of administration, sub-Tenon has the highest risk of IOP elevation.

Intravitreal steroids have become more widely used recently because of broader indications and successful outcomes in various conditions. The most popular intravitreal steroids are DEX and TA, with intravitreal TA being the more commonly used. Intravitreal TA has been shown to cause ocular hypertension in 30% to 45% of patients for up to nine months.[5] Intravitreal DEX is considered to have a lower risk of steroid response (11%-17%), with a shorter duration (lasting about one month) due to its water-soluble properties.

Sustained-release implants. The need for repeated intravitreal steroid injections has led to the development of sustained-release steroid implants. These devices include the nonbiodegradable FA implants Retisert, Iluvien, and Yutiq and the biodegradable DEX implant Ozurdex.

The risk of steroid response is higher with intravitreal FA implants. Bollinger et al. found that among patients who received an FA implant, 75% were prescribed topical glaucoma medications and 37% underwent filtration surgery.[6] Similarly, Kiddee et al. found that up to 45% of those with FA implants required surgery.[5] Most patients with ocular hypertension following a DEX implant can be managed medically, with only a small percentage (0.2%-3.2%) requiring glaucoma surgery.[5]

Clinical Course

Steroid-induced ocular hypertension typically occurs after several weeks of continued steroid treatment; however, an acute rise in IOP within hours has been reported. IOP elevation can occur within weeks with potent steroids or after several months with less potent forms. After four to six weeks of topical ocular steroids, 4% to 5% of patients have an IOP response greater than 16 mm Hg, one-third of patients have an increase of 6 mm Hg to 15 mm Hg (moderate steroid responders), and two-thirds of patients have no significant steroid response. Those with glaucoma have an increased risk of steroid response, as illustrated by Becker and Mills' study, in which the mean IOP elevation in those with glaucoma was 17 mm Hg compared with 4 mm Hg in the control group.[1] Upon cessation of steroids, IOP usually normalizes within one to four weeks.

Steroid-induced glaucoma develops if ocular hypertension persists and leads to progressive optic nerve damage. Clinically, steroid-induced glaucoma is very similar to POAG in presentation, aside from the significant history of steroid use. Patients present with elevated IOP, open angle on gonioscopy, optic nerve damage, and characteristic visual field changes. Adults and older children are usually asymptomatic, while young children may present with symptoms similar to primary infantile glaucoma (tearing, photophobia, blepharospasm). Steroid response can be more aggressive in infants and young children, with earlier onset of response and greater severity of glaucoma on presentation with signs of megalocornea and buphthalmos.

Management

The best way to manage steroid-induced glaucoma is to prevent its occurrence, if possible. It is important to review a patient's medication list and history to assess the risk of steroid response. The ophthalmologist should use steroids judiciously and avoid or reduce their use in patients who have glaucoma or are glaucoma suspects. If steroids are required, they should be prescribed at the lowest efficacious dose and administered by the safest route.

Monitoring. IOP should be determined at baseline before steroids are started and then measured every few weeks after initiation of treatment, as glaucoma can develop at any time.

Medical management. If a patient develops steroid response, steroids should be discontinued or minimized as soon as possible. Ocular hypertension usually resolves within four weeks. Unfortunately, in about 3% of cases, the steroid response is irreversible.

If the underlying disease requires treatment with continued steroids, the physician may consider using a different, less potent steroid such as fluorometholone 0.1% or rimexolone 1%. NSAIDs can also be substituted in certain situations. If ocular hypertension occurs in response to systemically administered steroids, steroid-sparing agents should be considered.

If steroids cannot be discontinued, topical glaucoma medications, specifically aqueous suppressants, are used as the first-line agents. Prostaglandin analogues are another option for decreasing IOP, but they are relatively contraindicated in certain inflammatory conditions. If needed, oral acetazolamide is an effective temporizing therapy. Excision of the steroid depot or vitrectomy for intravitreal steroids may be needed.

Laser therapy. Apart from medical management, there is growing evidence that laser trabeculoplasty may be an effective alternative therapy or bridging treatment to incisional surgery for IOP reduction. Prior studies have shown variable success rates with argon laser trabeculoplasty, but more recent studies have demonstrated that selective laser trabeculoplasty can provide a rapid and substantial reduction in IOP. A recent retrospective study by Maleki et al. in patients with quiescent uveitis and steroid-induced glaucoma reported a 50% IOP reduction at one year.[7]

Surgical treatment. Incisional surgery may be indicated if the IOP is markedly elevated, if there is progressive optic nerve damage or visual field loss, or if a patient requires long-term steroid treatment. Most patients receive either a glaucoma drainage device or trabeculectomy for medically uncontrolled glaucoma.

Overall, surgical management results in adequate control of IOP. For patients with steroid-induced glaucoma who underwent trabeculectomy, Iwao et al. reported surgical failure in 11.9% to 16.7% at the three-year follow-up.[8] A recent study in eyes with retinitis pigmentosa requiring long-term steroids for macular edema showed complete success in 77% of patients after Ahmed glaucoma valve (AGV) implantation at a mean follow-up of 38 months. There were no cases of failure in this study.[9] For patients requiring steroid depot, Malone et al. found that AGV combined with an FA implant in chronic, severe, posterior uveitis and ocular hypertension is safe and effective.[10] Goniotomy and canaloplasty have also been shown to be effective treatments for steroid-induced glaucoma.[11,12] Cyclodestructive procedures are reserved for refractory cases.

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See the disclosure key, page 5.

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Remote Monitoring Comes Into Focus

Early adopting glaucoma specialists share observations on home-monitoring technology and its implementation.

By Annie Stuart, Contributing Writer

WITH A TSUNAMI OF GLAUCOMA cases on the way—more than doubling from 2010 to 2050[1]—how will all these patients be monitored? asked L. Jay Katz, MD, at Wills Eye Hospital in Philadelphia. "We'll need to be creative to manage this, and many patients will likely be followed using remote patient monitoring."

During COVID, monitoring of glaucoma patients has not only occurred in medical office parking lots but also at home. In fact, telehealth services have mushroomed overall, and 40% of patients expect to continue using these services following the pandemic.[2]

What does this new age of remote patient-monitoring have to offer glaucoma patients? "To begin with, it may limit the number of doctor visits needed," said Dr. Katz, "but more importantly, it gives us the ability to more rapidly detect changes that may trigger more prompt, timely therapies to benefit our patients in the long run."

Although the utility of this technology is promising, it is only now starting to be used in some practices, bringing with it a mixed bag of benefits, challenges, and questions.

Why Home-Based Tonometry?

One big challenge with office-based tonometry alone is that IOP spikes can often occur at night or during early waking hours, said Barbara M. Wirostko, MD, at the University of Utah in Salt Lake City. In fact, 24-hour monitoring has shown that nearly two-thirds of patients experience peak IOP outside regular clinic hours, most often occurring at night.[3] Although unconfirmed, this may be due to blood pressure changes, sleep apnea, catecholamine release, or positioning, she said.

Hard to capture. "In the past, we couldn't easily gather this information," she said. "For example, we'd have to admit patients with normal tension glaucoma to the hospital, waking them several times to get their eye pressures." Other options, said Dr. Katz, have involved sleep laboratories or diurnal variation testing, with measurements taken in the office at two- to three-hour intervals throughout the day, looking for the highest readings to gauge the risk of progression. "All these options are impractical for most people," he said.

Easier at home. "With home monitoring, we now have additional data points, so we can more easily pick up pressure spikes that would otherwise be missed," said Kateki Vinod, MD, at New York Eye and Ear Infirmary of Mount Sinai in New York City. Dr. Wirostko strongly recommends that her patients get up during the night at various times to check pressures. "The benefit is incredible," said Ranya Habash, MD, at Bascom Palmer in Miami. "We instruct patients to measure their pressures anywhere from one to three times a day at home, depending on how concerned we are, but we still bring them into the office every three to four months as we normally would."

Pat Kinsella

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