OPHTHALMIC SURGEONS AND EXPERTS SHARE THEIR SECRETS OF SUCCESS IN THE ASC

the Ophthalmic ASC

PentaVision

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THE FINANCIAL SIDE OF ASC PARTNERSHIP

Weighing the risks against the (many) rewards

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The most common non-ocular adverse reaction that occurred in patients treated with DEXTENZA was headache (1%).

Please see brief summary of full Prescribing Information on adjacent page.

References: 1. Sawhney AS, Jarrett P, Bassett M, Blizzard C, inventors; Incept, LLC, assignee. Drug delivery through hydrogel plugs. US patent 8,409,606 B2. April 2, 2013.
2. DEXTENZA [package insert). Bedford. MA: Ocular Therapeutlx, Inc: 2019.

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Douglas A. Parry • doug.parry@pentavisionmedia.com

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Production Director Sandra Kaden
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Subscription inquiries/address changes: 800-869-6882
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215-628-7754

Conference Coordinator
Laura Shepard
laura.shepard@pentavisionmedia.com
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julia.mcnamee@pentavisionmedia.com
215-431-6569

Digital Events Associate
Chelsea-Mia Pierre
chelseamia.pierre@pentavisionmedia.com
215-237-9128

EDITORIAL AND PRODUCTION OFFICES

321 Norristown Road, Suite 150, Ambler, PA 19002 • 215-628-6550

PentaVision

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President Thomas J. Wilson

Executive Vice President & Publisher, Ophthalmology Douglas A. Parry
doug.parry@pentavisionmedia.com

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rob.verna@pentavisionmedia.com
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Molly Bleil • 215-628-7748
molly.bleil@pentavisionmedia.com

Nicholas Vielhauer • 267-492-5217
nicholas.vielhauer@pentavisionmedia.com

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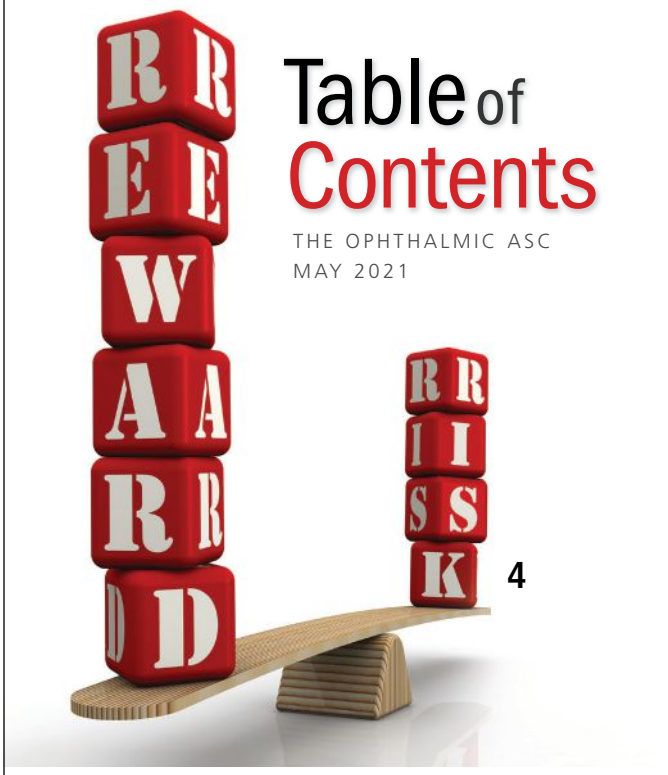

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MAY 2021

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CATHLEEN McCABE, MD
CO-CHIEF MEDICAL EDITOR

The Upside of Challenges

There are some changes that have evolved in our field during the pandemic that may persist, and others that will fade away as we move on to a post-vaccination world over the next many months. This past year highlighted a great need for efficiency, flexibility, and cross-training. Many of us found ways to do more with fewer staff, greater efficiency, and with an emphasis on safety while minimizing wait times.

Our ability to adapt and even flex with the challenges of the past year is dependent upon the speed with which we can make changes and pivot when adaptability is paramount. Ownership in an ASC allows for quicker decision-making and better control of the direction taken in times of crisis, which is one of the many reasons to invest in an ASC. For a complete discussion, see our article, "The Financial Side of ASC Partnership," on page 4.

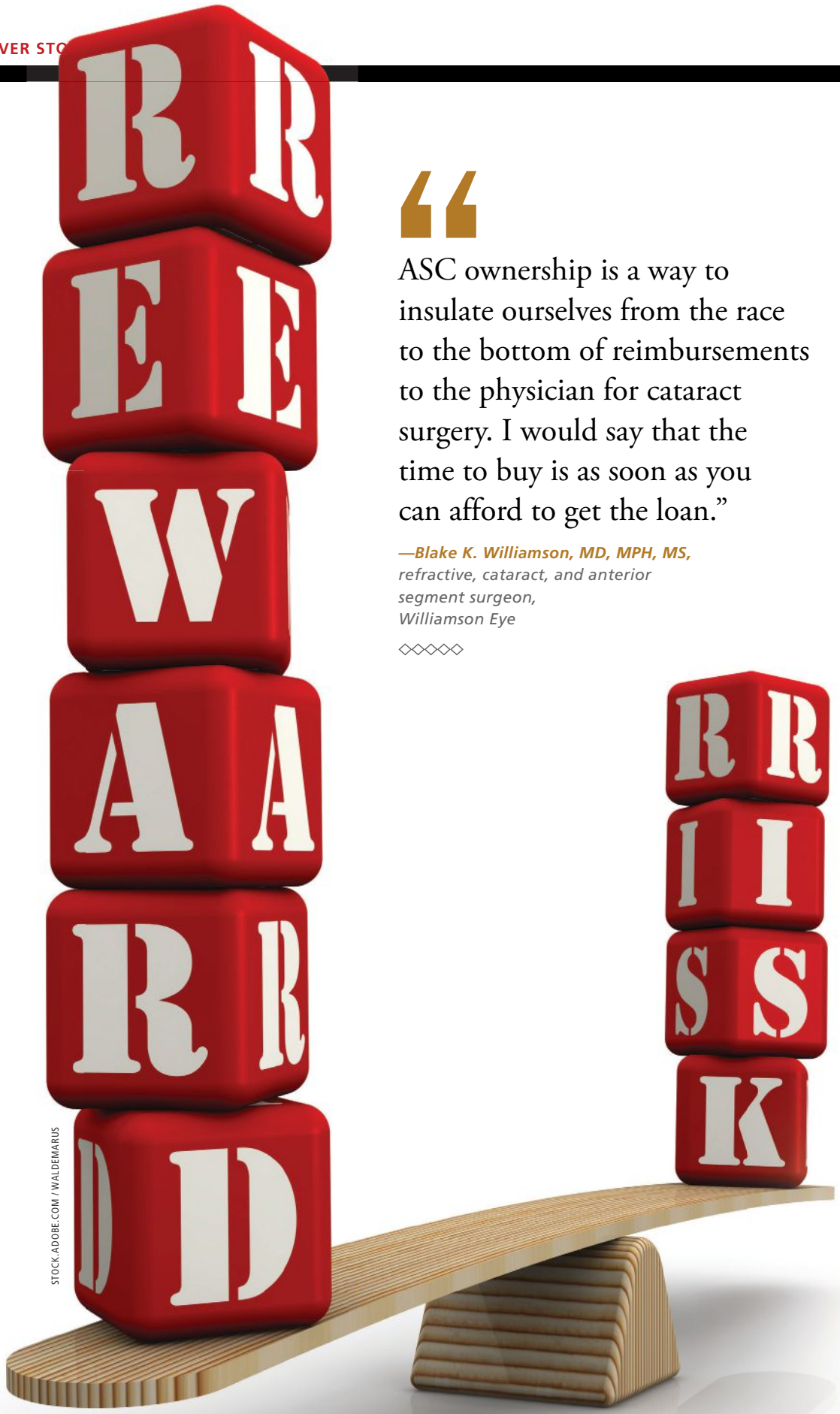
Once you are committed to investing in an ASC, you may elect to buy into an existing business or you may pioneer a new entity as part of your own practice. Regardless of your path, there are many challenges along the way, including finding the right location, navigating Certificate of Need issues, funding the project, designing the space, and understanding the regulatory hurdles. Our article, "Update, Renovate, or Rebuild?" on page 12, explores the pros and cons of updating, renovating, or building an ASC to help streamline your decision-making process.

"Our ability to adapt and even flex with the challenges of the past year is dependent upon the speed with which we can make changes and pivot when adaptability is paramount."

On the topic of adaptability, we can always improve the ways in which we meet and exceed the goals of our patients. New technology in premium IOLs continues to raise the bar and allow us to reliably provide increasing independence from spectacles for an even greater number of patients. We will explore this changing landscape of premium IOLs in the article, "New IOL Technologies," on page 8.

Ophthalmology is an ever-changing profession, and I look forward to meeting the coming challenges together as we grow and adapt, always remaining flexible and focused on providing the best eye care possible for our patients. ■

Dr. McCabe is the president of OOSS as well as chief medical officer of Eye Health America and medical director of The Eye Associates in Bradenton, FL.



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“ASC ownership is a way to insulate ourselves from the race to the bottom of reimbursements to the physician for cataract surgery. I would say that the time to buy is as soon as you can afford to get the loan.”

—Blake K. Williamson, MD, MPH, MS,
refractive, cataract, and anterior segment surgeon,
Williamson Eye

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THE FINANCIAL SIDE OF ASC PARTNERSHIP

Weighing the risks against the (many) rewards

BY LINDSEY GETZ, CONTRIBUTING EDITOR

Making the decision to invest in an ophthalmic ASC can feel daunting. But industry experts say the best time to invest in an ASC is, essentially, as soon as possible. With cataract surgery reimbursement continuing to decline, and the continued push by health plans and consumers to shift outpatient surgeries to the ASC setting, the time is ripe for ASC investment.

Blake K. Williamson, MD, MPH, MS, refractive, cataract, and anterior segment surgeon with Williamson Eye in Baton Rouge, LA, says buying into an ASC is probably the best financial decision a busy surgeon can make. And he advises doctors to consider it as soon as they're financially able.

"While the cataract reimbursement fee continues to get cut—and we know that's not going to stop—the payments to the ASC have actually gone up," Dr. Williamson says. "ASC ownership is a way to insulate ourselves from the race to the bottom of reimbursements to the physician for cataract surgery. I would say that the time to buy is as soon as you can afford to get the loan."

Many physicians feel as though they should wait until they have enough personal capital to make the financial leap into an ASC, but given the missed earning potential of waiting, most industry experts say taking a loan makes a lot of sense.

"There are financial companies that will loan money using the ownership of the ASC as collateral," says John Grant, division president, AMSURG, who partners with physicians at more than 250 ASCs across the United States. "While the debt may be daunting, once you become a partner or owner in an existing surgery center, there should be immediate cashflow back. While a portion of the cash distribution will go toward repayment of the loan, you should have a complete return within two to four years if you've performed your due diligence. Then anything after that is excess return."

Performing Your Due Diligence

Ensuring that you're making a wise decision starts with performing your due diligence. According to Stephen C. Sheppard, CPA, COE, managing principal of Medical Consulting Group, LLC, who has assisted many physicians with ASC ownership, the process should start with a detailed financial pro forma which should include the total project cost of the facility—both of the building and the equipment—but also the funds needed to get through a regulatory process to get a license in the state and certification in the Medicare program.

➔ **REVENUES:** "In terms of a financial prediction, CMS does us a favor with their fee schedule on ASC reimbursement in each location by CPT code," Sheppard

PASSING THE TORCH

For senior ASC partners looking to reduce their workload, or even retire, there's an appealing alternative to private equity takeover: passing the torch to next generation of owners.

Blake K. Williamson, MD, MPH, MS, surgeon with Williamson Eye in Baton Rouge, LA, says he'd prefer to sell out to a lower multiple to a junior physician and be able to mentor them in the ownership role.

"Looking beyond pure financials, that is more intellectually stimulating to me, and therefore more appealing to me," he says. "After many years of invested time in this field, I think you have to look at what will be most fulfilling—and for me, it's passing that knowledge and experience on."

John Grant, division president, AMSURG, believes young surgeons are the future of ASCs—and it's critical to bring them into centers as early as possible.

"For senior doctors who built the ASC from the ground up—it's their legacy," Grant says. "If they want it to continue on with their vision, they need to ensure that young doctors have some ownership. I find that most doctors are not only financially invested—but also emotionally invested—in their ASC, and involving young doctors is ultimately good for everyone."

Operating a surgery center and medical practice is a dynamic activity, not a static one, adds Stephen C. Sheppard, CPA, COE, managing principal of Medical Consulting Group, LLC.

"That means, if you're a 60-year-old physician, you should be thinking about how you will begin your transition when the time comes," he says. "How will you monetize the value you've built? You created a practice that grew into an ASC, and when you retire, you probably don't want to just turn off the lights and walk away. You may also not want to sell to private equity if you had a long-term vision for your practice. You'll need a strategy that will sustain your goals."

says. "For the last several years, that has been pretty stable. Therefore, you can do a very good job of projecting revenues based on your historic case volumes and practice payer mix. For anterior segment surgeons, obviously a good part of their volume will be Medicare—around 60% to 70%, generally. So, you need to look at those historic surgical volumes and the current reimbursement rates as you come up with your projections."

➔ **EXPENSES:** After that, Sheppard says it comes down to expenses. Most physicians already have a good idea of what those will be. The costs they're calculating now are essentially the same as their clinic—including rent, utilities, various taxes, and other routine operating expenses. These are fixed expenses that don't vary based on volume of activity, Sheppard adds. Whether you're doing 1,000 or 1,500 cataracts each month, your rent and many other costs remains fixed.

➔ **WAGES:** In ASCs, the major expense categories that successful operations can impact are the fully burdened labor and surgical supplies costs. For labor costs, you must consider new hires that you may not currently have, such as pre-op and recovery nurses, circulating RNs, surgical technicians, and sterile processing technicians. Certainly, you may already employ some of these professionals, Sheppard says, but you need to consider what additional personnel you might need in the ASC setting.

"Take a close look at what the wage rate looks like for surgical staff and nurses in the ASC setting and what your labor hours per week will be," Sheppard advises. "Then take those hourly rates and add an additional 25% to project benefits expense, including employer payroll taxes. That will help you calculate your overall labor cost."

➔ **SUPPLIES:** Equally impactful as labor expenses are surgical supplies expenses. Sheppard says that most doctors already have a good idea of their surgical supply cost based on their previous surgical experience and the major vendor they work with. Depending upon the implant or other techniques that you utilize, you can determine an average case cost. By factoring all of these elements, you should have a strong projection.

Between these two categories—labor costs and surgical supplies—you have accounted for about 70% of the operating costs of an ophthalmic ASC.

"In my 22 years of experience, I've said many times that there are only two ways this can really go awry," Sheppard says.

"The first is to overbuild—to have such a high construction cost that you can't carry the debt," he explains. "The second, and probably most common way, is to be unrealistic about your case volume. When you perform these calculations, you have to look at what cases you are currently able to bring to the ASC—that is, historic case volumes. You should not be performing these calculations with the idea that you're recruiting a ton of new cases."

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References
[1]US Patent NO: US8647383. [2]Data on file, BVI, 2019.

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New IOL Technologies: A Year of Exciting 'Firsts'

Surgeons get big capabilities, new go-to lenses, and a glimpse of the future

By Erin Murphy, Contributing Editor

For cataract and refractive surgeons, the past year-plus has tested, and even altered, ASC operations. However, a very bright thread has also run through this year: exciting, even groundbreaking, new intraocular lenses (IOLs). There are "firsts" in every major category—monofocal, multifocal, and extended depth of focus (EDOF)—and the first light-adjustable and violet-light-filtering IOLs on the U.S. market.

The Ophthalmic ASC talked to three surgeons who are feeling the excitement in their premium-based practices, and seeing new entry points for those who usually use standard monofocals.

"We have always struck a balance between gaining range of vision and sacrificing something else, like nighttime dysphotopsias. Now we can leverage optical principles in a scientifically sound way and gain something without giving anything up," says Daniel H. Chang, MD, cataract and refractive surgeon at Empire Eye & Laser Center, Bakersfield, CA, and president and founding member of the nonprofit Advanced Center for Eyecare. "If you learn the science and understand the evidence, you'll know how to help your patients the most."

➔ Monofocal Tecnis Eyhance

Optical aberrations decrease contrast sensitivity, but they also provide some extended range. If a lens eliminates all aberrations, it can provide excellent image quality and contrast, but the trade-off is a narrower focal range. The new Tecnis Eyhance (Johnson & Johnson Vision) monofocal lens offers the advantages of aberration correction while enhancing intermediate vision, according to Rex Hamilton, MD, cataract and refractive surgeon at Hamilton Eye Institute in Los Angeles.

"The Tecnis one-piece monofocal platform offers the best quality of vision because it corrects the most spherical aberration, but that results in a limited range of vision. The new Tecnis Eyhance makes use of optical aberrations to create a slightly extended range on a monofocal platform," he says.

Dr. Chang, who appreciates the Tecnis Eyhance as a great monofocal option, welcomes the lens' ability to balance visual quality, depth of focus, and dysphotopsias. "Fundamentally, when we try to correct presbyopia, we're exchanging some degree of visual quality and dysphotopsias for the extra depth of field. It's up to the surgeon to determine what balance is best suited for each patient," he explains.

Dr. Chang prefers to provide as much depth as possible without sacrificing visual quality and inducing minimal dysphotopsia, typically with an EDOF lens like the Tecnis Symfony (Johnson & Johnson Vision). "Tecnis Eyhance doesn't provide the same range as a multifocal lens, but my patients get about a 0.5 diopter increase in depth of focus, with minimal night vision symptoms," he says. "That's a functional advantage for a lot of patients, including those with concurrent pathology, with fewer side effects, less risk, and less out-of-pocket cost. I've talked with a number of my international colleagues who have had this lens for over a year, and they've had a very positive experience. I'm excited about adding this lens to my portfolio."

As someone who does a high volume of premium lenses, Dr. Hamilton suggests that Tecnis Eyhance Toric is a good first premium lens for surgeons primarily using standard monofocal lenses. He notes, "A lot of surgeons don't feel comfortable using premium IOLs because patients have to pay out of pocket, they have high expectations, there's a risk of halos, and so on. I see Tecnis Eyhance Toric as a great entry point for those surgeons. They'll have success because the lens is more forgiving. Because of its slightly wider range, it is easier to hit refractive targets, and there is less risk of halos."

> "We have always struck a balance between gaining range of vision and sacrificing something else, like nighttime dysphotopsias. Now we can leverage optical principles in a scientifically sound way and gain something without giving something up."
>
> —DANIEL H. CHANG, MD,
> *cataract and refractive surgeon at Empire Eye & Laser Center*

➔ Light Adjustable Lens

Implant power is calculated in part based on the estimated lens position. Because the cataractous lens is much thicker than the implant, the surgeon cannot know the final resting place of the IOL in advance of the surgery. Postoperatively, if the implant sits differently than predicted preoperatively, then that change, combined with posterior corneal astigmatism and incisional healing, can make surgeons wish they'd chosen a different power. Enter the first light-adjustable lens, the monofocal Light Adjustable Lens from RxSight.

"Flexibility is the real beauty of the light-adjustable lens. It's a game-changer for me. It is the world's most accurate implant with no close second, because three weeks after surgery, in response to healing variables, we can change the power of the implant inside the eye," explains Vance Thompson, MD, a cataract and refractive surgeon at Vance Thompson Vision, Sioux Falls, SD, who was a principal investigator in studies of RxSight.

"Because that adjustment makes it easier to hit 20/15 uncorrected distance in one eye, we can then hit -1.00D in the other eye and extend the range of vision. Very precise monovision correction makes it possible for patients to see quite comfortably all three distances."

To adjust the lens power postoperatively, doctors perform refraction and enter the data into the RxSight system. The patient sits in front of the Light Delivery Device slit lamp with a focusing lens, the surgeon pushes a foot pedal, and the lens is adjusted.

There are other ways to adjust vision postoperatively, such as LASIK and PRK, but by adjusting the IOL power, surgeons often can avoid a second surgery and the potential healing variables associated with corneal refractive procedures. This aspect of the lens may be particularly appealing to doctors who don't perform corneal refractive surgery.

In addition to reducing LASIK touch-ups, the lens has a long list of candidates, according to Dr. Thompson.

"It's a good choice for patients who want a premium result without the glare and halos associated with a multifocal lens, as well as for patients with decreased contrast sensitivity from conditions, such as glaucoma or epiretinal membrane," he says. "RxSight is particularly advantageous for patients who had previous PRK or LASIK, who enjoyed the results and strongly desire an accurate end result, but whose implant calculations pose a greater challenge. We can achieve their refractive endpoint without touching their cornea."

Although Dr. Hamilton is not using the RxSight, he views this technology as the future of IOLs. "Currently, I am hitting my refractive targets thanks to newer formulas, such as the Barrett and Hill-RBF, as well as intraoperative aberrometry, so I haven't used the RxSight. But this lens technology is the future," he says. "I'm excited for it to become available on multifocal and EDOF lens platforms, particularly for helping fine-tune patients with high expectations to achieve a full range of vision without glasses. It offers another level of precision to optimize outcomes with a simple procedure just sitting at the slit lamp, rather than with LASIK."

NEW TAKES ON EDOF

EDOF lenses are Dr. Hamilton's first choice for patients who have had previous refractive surgery, for whom multifocals would decrease contrast further and adversely affect their quality of vision. Today, he uses Tecnis Symfony and the new AcrySof IQ Vivity (Alcon) in these patients.

"The AcrySof IQ Vivity uses a newer technology of phase shifting, with a small central button on the optic and a refractive lens that elongates the depth

of field," he explains. "Because it does not cause much nighttime dysphotopsia, it's a good choice for surgeons with limited premium lens experience. If the lens falls short at near, I target nearsightedness, in the -0.75D range on the second eye."

The Tecnis Synergy (Johnson & Johnson Vision), a lens currently available outside the United States, combines multifocal and EDOF characteristics into a single presbyopia-correcting lens—virtually a new category, according to Dr. Hamilton. "The lens combines the great extended range of the Symfony lens and the multifocality of the higher add power of Tecnis Multifocal to give a full range of unaided vision," he says. "I look forward to using this promising new technology as soon as it is available in the United States."

Dr. Chang, who has been a clinical investigator of the technology, observes: "The Tecnis Synergy IOL leverages an even greater correction of chromatic aberration to provide the fullest range of any IOL that I have ever used—all while maintaining excellent visual quality. In my experience, patients had near vision as good as high-add multifocals with no perceivable drop-off anywhere in intermediate vision. I look forward to having this lens option when it becomes available in this country."

➔ AcrySof IQ PanOptix Trifocal IOL

The first trifocal lens to be available to the U.S. market is the AcrySof IQ PanOptix Trifocal (Alcon)—and the excitement is not lost on Drs. Hamilton and Thompson.

"I'm always re-evaluating my go-to lens when new technologies arrive, and the PanOptix is my current choice for patients desiring spectacle independence with otherwise healthy eyes," says Dr. Hamilton. "In my experience, it provides the best level of uncorrected near vision of any current lens. It does create night dysphotopsia and have some dropout at the 1 meter range, but overall it's an excellent lens because it gives patients a full range of vision."

Dr. Thompson has found that success is very high with the PanOptix lens—with the right patients.

"It's up to us surgeons to match the proper implant to the proper patient, and I'm looking for corneas that are optically clean with a healthy tear film," he says. "We also need to bring our 'A' game in analyzing the eye preoperatively, particularly analyzing the cornea for optical irregularities and quantifying the high-order aberrations, which can rule out a multifocal if they are too numerous. I also check for a healthy macula and optic nerve and look for posterior capsule opacification, which will reduce the image quality of the multifocal implant."

The result is many happy patients, Dr. Thompson says. "In the FDA-monitored trial, 99.2% of patients said they'd get the same lens again.[1] That's just amazing patient satisfaction! We see it in practice, too. If we put the PanOptix implant in healthy eyes, the chance of patient satisfaction is very high."

➔ Violet Light Filtering Tecnis Symfony OptiBlue

Blue-light filtering has been available in IOLs for some time, with a goal of protecting the retina and perhaps improving the quality of vision by reducing the dispersion of light. But there are drawbacks. The new Tecnis Symfony OptiBlue (Johnson & Johnson Vision) lens is designed to avoid some of those drawbacks, while offering some specific advantages.

"The issue with filtering blue light is that wavelengths in the blue spectrum are responsible for a larger proportion of vision in dim light than in bright light, so filtering it, particularly in a multifocal platform, can compromise dim light near vision," Dr. Hamilton explains. "The Tecnis OptiBlue filters out violet light, the shortest wavelengths of visible light, to reduce chromatic aberration without compromising near vision in dim light."

Adds Dr. Chang: "This technology has existed for years, and now it is finally becoming available in this country. The lens filters very specific, high-energy violet wavelengths that cause phototoxicity, free radical formation, and dysphotopsia while maintaining the blue light required for scotopic vision. It also preserves circadian rhythm entrainment, for which blue light must reach intrinsically photosensitive retinal ganglion cells (ipRGCs)."

TIPS FOR GETTING STARTED WITH NEW LENSES

"I find online forums incredibly useful when learning about new IOL technologies, particularly in the COVID era when in-person meetings are not available," Dr. Hamilton says. "I check the online forums for the Refractive Surgery Alliance as well as Cedars Aspens Society, and ask overseas colleagues what they're seeing. It's very important for me to learn what benefits my patients will get from the new lens."

Once surgeons are convinced by the data and their peers to try a new lens, they tend to feel comfortable with the procedure. Of the new lenses discussed here, the exception to this rule is the RxSight Light Adjustable Lens, which requires both a hardware investment and schedule adjustment.

While the preoperative workup and surgery for this lens are familiar, postoperative care is not. Patients must wear UV-protective goggles after surgery so that UV light doesn't change the shape of the implant. Unlike other premium lenses, which require visits at 1 day, 1 week, 1 month, and 3 months, followed by laser touch-up if necessary, a similar number of patient visits for light-adjustable lenses are condensed into 6 to 8 weeks. Visits are longer because patients need refraction, dilation, and light adjustment every time.

"There are things to teach your team, your patients, and your referring doctors about RxSight. It's a different pattern for scheduling visits, and there's a different timeline to wrapping up postoperative care and returning patients to their optometrists," Dr. Thompson says. "Patients need to understand that RxSight carries a higher investment in time and effort after surgery, including wearing goggles and having multiple dilated exams. But my patients have been excited about this lens, and they're willing to wear the goggles."

For a patient to get excited about wearing goggles for weeks—particularly when they know others who have not had to do so after cataract surgery—the attraction of RxSight must be strong. Dr. Thompson thinks he knows why.

"The light-adjustable lens takes a lot of pressure off the patient to choose the IOL they want. Unlike LASIK patients, they don't have the advantage of seeing their options before surgery, so they can only go on our description," he points out. "It amazes me to see how comforted patients feel when I say, 'Let's take out the cataract, put in the implant, and show you your options postoperatively so you can decide where you want your vision to be—both eyes clear at distance or one eye a little clearer up close.' They can make a commitment after they actually see the difference."

THE FUTURE

Dr. Thompson thinks the future holds more trifocal options and more light-adjustable lenses, including multifocals. He says, "Light adjustability and trifocality have been such game-changers in our practice. Premium cataract surgery has grown so much more with these two advancements in technology. And it's an evolution. There is always incremental improvement as well as innovation, and our patients are the beneficiaries." ■

Reference

1. AcrySof IQ PanOptix Trifocal IOL, Model TFNT00 DF

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Investing in Young Surgeons

As the financial landscape of ophthalmology evolves, one of the biggest trends to emerge has been the private equity acquisitions of an increasing number of ASCs. Some are questioning what this may mean for young surgeons—and what it means for the future of the field in the long-term.

"I believe that senior partners selling their shares at fair market value to junior partners is what's right in the long-run for ophthalmology," says Dr. Williamson.

"I think the generational transfer of knowledge and experience is one of the things that makes ophthalmology so special. Private equity may offer a higher multiple, and it's tempting to take that money and run—after all, senior doctors have worked very hard to build their ASC and were the ones to take the risk—the ultimate conglomeration of all of these ASCs in private equity may not be in the long-term interest of our field."

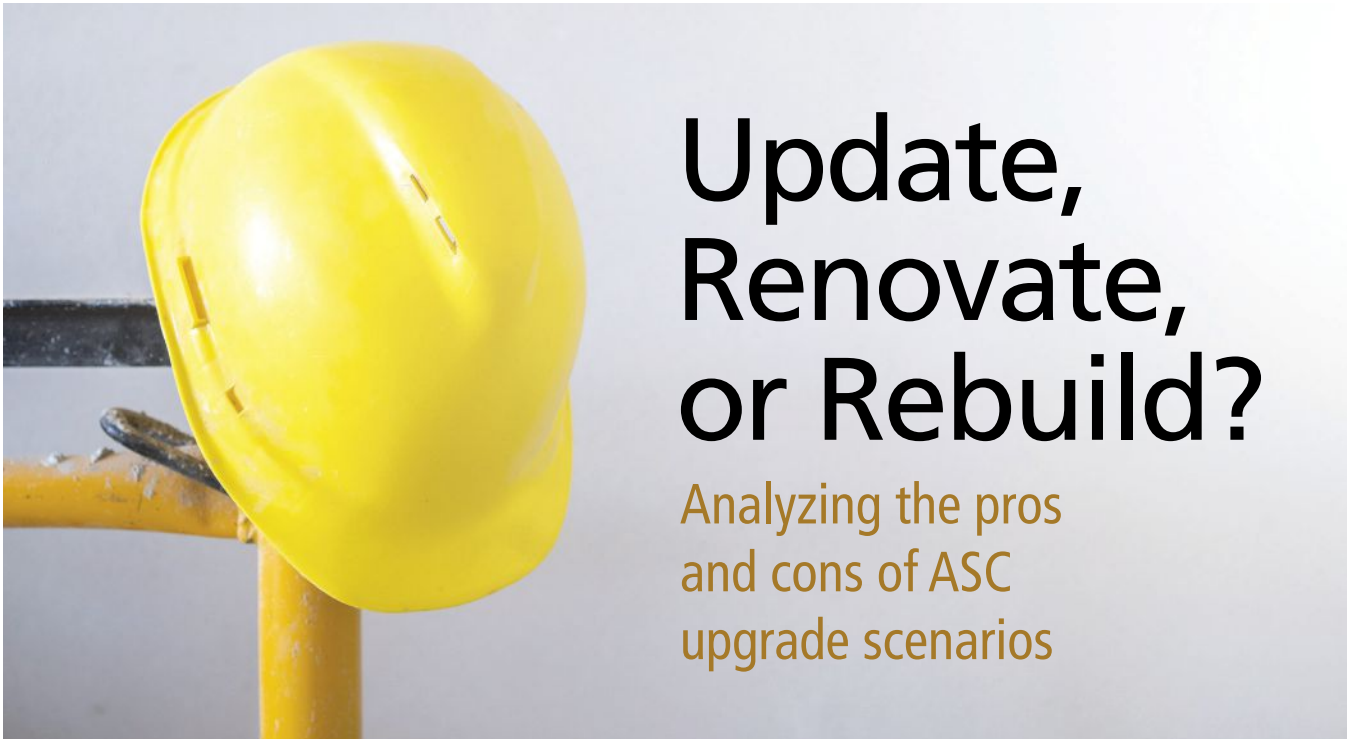
In fact, Dr. Williamson says that it could bring changes to way ASCs run—even in the operating room.

"I think private equity buyouts disincentivize being creative and nimble and efficient with our time in the operating room," he adds. "I really believe that surgery suites are best owned by doctors, and not corporations."

While Sheppard absolutely believes that now is the time for young doctors to think about ASCs—after all, the number of cataract surgeries only continues to increase—he also recognizes the barriers. In fact, in his own business, he's told more doctors *not* to build an ASC than he has told to build them. But, he says that when the proper due diligence is performed and the proper team is assembled, partnership can be an incredibly valuable decision.

"ASCs are expensive to get into, and as appealing as the potential profits may be, it's not something to do lightly," Sheppard advises. "The work performed on the front end must examine the financial feasibility with the utmost care. And the team you will need to pull together, from the consultant to the architects to the general contractor, and then all of the subcontractors, is a big undertaking. But if you've truly performed your due diligence and you've made sure that every piece works before anyone swings a hammer, then you can go into it confident, and knowing that it was a wise business investment.

"The bottom line is that you must get it right the first time," he says. "There's no going back once you jump in." ■



Update, Renovate, or Rebuild?

Analyzing the pros and cons of ASC upgrade scenarios

STOCK.ADOBE.COM / JOAO

By Stephanie K. De Long, Contributing Editor

If you haven't already, you will most likely face a situation at some point that pushes you to rethink the setup, footprint, or location of your ASC. Considerations revolve around whether you should undertake minor improvements to update it, do a major renovation to your existing facility, completely rebuild, or just ride it out.

To decide, you'll need to assess if and how your reach has changed. For example, is there another nearby geographic or physical location where you could dramatically increase the number of cataract or retinal surgeries? What's the age of the partners in your practice? Have you outgrown your surgical space? And perhaps the most defining variable in your decision: How much are you willing to spend?

We enlisted the help of two experts in the field to lead the discussion. Mark Kontos, MD, is senior partner of Empire Eye Physicians in Spokane and Coeur d'Alene, WA, (and co-medical editor of *The Ophthalmic ASC*) and has recently faced the challenges and rewards of rebuilding his ASC. Bruce Maller, founder and CEO of BSM Consulting in Incline Village, NV, has helped practices of all sizes make and execute these important decisions.

Here, they share their own experiences and the key considerations that go into the decision-making process, as well as the pros and cons of each option to grow your business—both in size and in profitability.

EVALUATE YOUR CURRENT SITUATION

"If I were an owner and had a voice in what we should do," explains Maller, "the question to ask is, 'Why would we do it?' There must be something prompting us to consider an update, renovation, or a rebuild." Make sure your partners (if you have them) agree on what that "why" is.

Before you do anything beyond that step, evaluate your current financial issues and do a baseline assessment of the business.

"That must include the current financial standing of the center and what the current capital structure is," explains Maller. "For example, are we carrying a large amount of debt? Is our balance sheet healthy? What do our margins look like? Is there anything that is constraining our margins, like fundamental issues with the physical space?"

Then, look realistically at your current and longer-term situation, Dr. Kontos adds. "Do you want to add more doctors, or hours? Determine

those needs and set objectives."

That means performing a deep-dive analysis of the condition of your current facility, and then working with your other stakeholders to determine your specific objectives. That may sound simple, but both experts agree that getting everyone to agree and deciding how to weigh each doctor's preferences on key issues can be tough.

And then there's financing.

"For something small, you can generally finance internally within the practice without having to go to an outside source," explains Dr. Kontos. Practices that are looking at leasing or going into a new building, however, will likely require external financing, he adds.

This means you'll have to look at the cost of borrowing money. That's one reason to maintain a strong relationship with a bank in your community.

Financing is just one of the items that need to be agreed on among the partners. And the more decisions there are to be made, the more likely it is that there will be some disagreement.

"That's something that practices need to navigate based on their partnership structure," says Dr. Kontos.

Only after all of this should you begin the process of cementing your goals and determining which option is best. It is not, to say the least, a speedy process.

"Get that good, solid financial assessment, along with feedback from the key principles. Take all of that together and prioritize, based on the feedback, what you think are your best opportunities to achieve those overall goals," advises Maller.

To help you with those decisions, here's a look at some of the pros and cons of each growth scenario—a modest update, a complete renovation, or a new construction.

A MODEST UPDATE

➔ **CONS:** It is likely a temporary fix, and one that may need to be replaced with either a renovation or rebuild in a few years. It doesn't buy you any flexibility to expand by adding a doctor or ASC space. For some, it's a Band-Aid at best.

➔ **PROS:** It's great if you're on a lease that ends in a few years, or if you plan to retire or relocate soon. It can also make a big difference in patients' perceptions of you. It's affordable, and something that can be done frequently. An added bonus: You can likely stay open during the process.

FULL RENOVATION

➔ **CONS:** Complex renovations, such as adding and upgrading surgical suites and imaging rooms, and then factoring in regulations and compliance issues, can sometimes result in costs that are almost as much as a new facility.

Dr. Kontos uses his own situation, which resulted in a rebuild, as an example. "We would have had the same size space that we'd had for the last 20 years. We've added a doctor, so renovating wasn't a good option."

It also doesn't make sense if some of the doctors are nearing retirement, or your lease is expiring in less than five years. Potential successor surgeons won't find that attractive, either. And, don't forget that renovation also likely requires you to be closed for a short time (but then, a rebuild on site usually does, too).

➔ **PROS:** If you can expand as needed in your current space—to add a doctor, staff, equipment, or to update—a renovation is great scenario. It sends a message to patients that you are investing in them and their health. And, it's a solid option if you have 10 years left on a lease or built-in renewal options for at least that long.

REBUILD/RELOCATION

➔ **CONS:** It's expensive, and you need experts on all sides, including some dealing with the endless red tape. Also, with private equity constantly changing the ASC landscape, you're in danger of one opening near you and impacting all your assumptions regarding growth, reach, competition, etc.

If you overbuild, it will be difficult (and beyond) to carry the related debt service. Also, if predictions for future OR hours, staffing requirements, technology, and compliance needs are off, you may well find yourself in trouble.

➔ **PROS:** Sometimes you have no choice. Dr. Kontos felt he didn't. A rebuild or new construction allows you the most control, assuming you collaborate every step of the way with the design and construction teams.

Also, you get what you want...or as close to it as (your) money will buy. You hopefully have built into the project the capability to increase doctors, staff, surgical set-ups, equipment, and regulatory compliance for the foreseeable future. No other format can accommodate all of that.

TAKE YOUR TIME

Wherever you are on the decision spectrum, both experts stress the importance of reviewing your current situation vs. these options on a regular basis.

As Dr. Kontos says, "Maybe you don't make any changes right now. However, it helps if you're constantly re-assessing and going through the scenarios." ■

Profiles in ASC Success

Cincinnati Eye Institute: "Franchising" for Success

*The second installment of a **four-part series** profiling ASCs and their strategies for success.*

By Joseph F. Jalkiewicz, Contributing Editor

It was 2014 when the Cincinnati Eye Institute (CEI), founded in 1945 and one of the largest private regional ophthalmic ambulatory surgery centers (ASCs) in the United Sates, reached a major milestone.

"We just couldn't do any more cases in that facility," says Todd Albertz, vice president of surgical and specialty services at CEI, based in Blue Ash, OH. "We were already running Saturday surgeries for a number of years to accommodate the volume of some of our specialties."

The Institute has since joined a private equity group, which formed CVP Physicians, and today it owns four ASCs of its own and manages two others in the Midwest region of CVP. All told, CEI's own surgery centers perform more than 25,000 eye surgery and laser procedures each year (see sidebar, page 16).

> "We pride ourselves on having the ability to look at the landscape and its demand for ophthalmology services, and bring that to the community."
>
> *— TODD ALBERTZ,*
> *vice president of surgical and specialty services, CEI*

Albertz credits CEI's growth largely to the same consistency that has helped franchise-based companies like Starbucks to scale their way to success: Consistency of layout. Consistency of technology. Consistency of personnel development and patient care.

Consistent Approach to Layout

Take the floor plan of each CEI surgery location. Using its Blue Ash, OH, location—at seven operating rooms its largest ASC—as a template, CEI has sought to replicate the ASC's layout at its other three surgery centers in and around the Cincinnati area.

"The philosophy behind it is that, as we have staffing needs at different facilities, we can reallocate staff from one facility to the other, and they feel perfectly comfortable because it's almost an identical model to where they normally work," Albertz says. "It's the same for our providers. When they're in the OR, they feel like they could be in the OR at any one of four different facilities."

Consistent Approach to Technology

The Institute takes a similar approach to technology. For example, all surgery centers are linked via the same electronic medical record (EMR) system. This enables Albertz and his team of administrators to log into any individual facility's EMR system.

"It gives me the ability to, from one location, go into any surgery center's EMR to conduct audits, look at patient flows, and look at specific things within the EMR system, because we've created this consistency across all of the centers," he explains.

The same is true of with respect to each ASC's clinical and surgical instrumentation. A retina surgeon traveling from one ASC to another that offers the same procedures, for instance, can be assured of having identical instrumentation and equipment on hand. The same is true for CEI's refractive specialists.

This level of uniformity also permits careful management of CEI's capital budget. Albertz says CEI has a "very deliberate" budgeting process involving not only its budget committee, but also its medical advisory board of nursing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managers and medical directors from each ASC, as well as one surgeon from each subspecialty.

"Because we have become so large, we can't just change microscope vendors on a whim. That would be a massive investment for a network like ours," he says.

"We have several hundred policies and procedures, and they run the gamut from how we handle patient check-in to how we clean instruments and maintain sterility in the OR," he notes.

Budget management is also required to help CEI to roll with the financial punches of almost continuous changes in state and federal healthcare regulations governing virtually every aspect of ASC operation.

Observing that 80% of CEI's procedure volume consists of cataract surgeries, he explains that these patients are typically older than 65 and on Medicare.

"The challenge is to maintain a profitable surgery center while working through cuts and adjustments to the payment system that can impact the two biggest variable costs in operating an ASC: materials and labor," he says.

"The challenge is to maintain a profitable surgery center while working through cuts and adjustments to the payment system that can impact the two biggest variable costs in operating an ASC: materials and labor."

— **TODD ALBERTZ,**
vice president of surgical and specialty services, CEI

Consistent Approach to Staff Development

CEI's emphasis on consistency includes its network-wide polices on staff training and development. Albertz says every ASC manager always starts on the ground floor and climbs through the ranks.

"Our director of nursing, who's been working with me for 12-plus years, started as a clinical tech, moved to the ASC as a scrub tech, became a nurse, was promoted to charge nurse and then to assistant director of nursing, and now is director of nursing," he says. "We've had that same kind of progression through our entire leadership team over the years."

This promote-from-within philosophy has served CEI incredibly well, Albertz adds.

"It's a huge benefit for staff because they know they can grow. Also, everyone who comes through our leadership team and then moves out to one of our satellite surgery centers takes what they learned regarding patient care, policies and procedures, and overall management to the other surgery centers. That culture of our regional facility is then instilled in that smaller facility."

Consistent Success

In terms of measuring its surgery centers' performance against other ASCs, CEI relies on criteria and data supplied by the Ophthalmic Outpatient Surgical Society (OOSS). The OOSS benchmarks a variety of factors within ASC operations, including patient safety, staff salaries, and cost per case—all based on surveys completed by its member surgery centers.

"OOSS shares the data, so we're able to see how our ASC compares to others," says Albertz, who reiterates his view that the focus on consistency provides the foundation for CEI's high standing in the markets served by its ASCs.

"We pride ourselves on having the ability to look at the landscape and its demand for ophthalmology services, and bring that to the community," he says. "We want to be everybody's resource for taking care of their ophthalmology needs.

"It is almost like establishing a franchise," he observes.

Starbucks would be impressed. ■

CINCINNATI EYE INSTITUTE ASCs BY THE NUMBERS

CEI owns four ophthalmic ASCs in and around Cincinnati:

Blue Ash

- 7 operating rooms
- 14,000 surgical cases and 3,500 laser procedures annually
- 90 employees, including 40 surgeons
- All subspecialties

Middletown

- 5 operating rooms
- 5,000 surgical cases and 1,000 laser procedures annually
- 25 employees, including 15 surgeons
- All subspecialties

Ivy Pointe

- 3 operating rooms
- 2,500 surgical cases and 700 laser procedures annually
- 20 employees, including 10 surgeons
- All subspecialties

Sydney

- 2 operating rooms
- 1,700 surgical cases and 700 laser procedures annually
- 8 employees, including 2 surgeons
- Cataract, plastics, and glaucoma surgeries only

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INDICATIONS FOR USE AND IMPORTANT SAFETY INFORMATION

INDICATIONS: The Light Adjustable Lens and Light Delivery Device system is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag in adult patients with preexisting corneal astigmatism of ≥ 0.75 diopters and without preexisting macular disease. The system also reduces the likelihood of clinically significant residual spherical refractive errors.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: The Light Adjustable Lens is contraindicated in patients who are taking systemic medication that may increase sensitivity to ultraviolet (UV) light as the Light Delivery Device (LDD) treatment may lead to irreversible phototoxic damage to the eye; patients who are taking a systemic medication that is considered toxic to the retina (e.g., tamoxifen) as they may be at increased risk of retinal damage during LDD treatment; patients with a history of ocular herpes simplex virus due to the potential for reactivation from exposure to UV light; patients with nystagmus as they may not be able to maintain steady fixation during LDD treatment; and patients who are unwilling to comply with the postoperative regimen for adjustment and lock-in treatments and wearing of UV protective eyewear. **WARNINGS:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting an IOL in a patient with any of the conditions described in the Light Adjustable Lens and LDD Professional Use Information brochure. Caution should be used in patients with eyes unable to dilate to a pupil diameter of ≥ 7 mm to ensure that the edge of the Light Adjustable Lens can be visualized during LDD light treatments; patients who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment; and patients with sufficiently dense cataracts that preclude examination of the macula as patients with preexisting macular disease may be at increased risk for macular disease progression. **PRECAUTIONS:** The long-term effect on vision due to exposure to UV light that causes erythropsia (after LDD treatment) has not been determined. The implanted Light Adjustable Lens MUST undergo a minimum of 2 LDD treatments (1 adjustment procedure plus 1 lock-in treatment) beginning at least 17-21 days post-implantation. All clinical study outcomes were obtained using LDD power adjustments targeted to emmetropia post LDD treatments. The safety and performance of targeting to myopic or hyperopic outcomes have not been evaluated. The safety and effectiveness of the Light Adjustable Lens and LDD have not been substantiated in patients with preexisting ocular conditions and intraoperative complications. Patients must be instructed to wear the RxSight-specified UV protective eyewear during all waking hours after Light Adjustable Lens implantation until 24 hours post final lock-in treatment. Unprotected exposure to UV light during this period can result in unpredictable changes to the Light Adjustable Lens, causing aberrated optics and blurred vision, which might necessitate explantation of the Light Adjustable Lens. **ADVERSE EVENTS:** The most common adverse events (AEs) reported in the randomized pivotal trial included cystoid macular edema (3 eyes, 0.7%), hypopyon (1 eye, 0.2%), and endophthalmitis (1 eye, 0.2%). The rates of AEs did not exceed the rates in the ISO historical control except for the category of secondary surgical interventions (SSI); 1.7% of eyes (7/410) in the Light Adjustable Lens group had an SSI ($p < .05$). AEs related to the UV light from the LDD include phototoxic retinal damage causing temporary loss of best spectacle corrected visual acuity (1 eye, 0.2%), persistent induced tritan color vision anomaly (2 eyes, 0.5%), persistent induced erythropsia (1 eye, 0.3%), reactivation of ocular herpes simplex Infection (1 eye, 0.3%), and persistent unanticipated significant increase in manifest refraction error (≥ 1.0 D cylinder or MRSE) (5 eyes, 1.3%). **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. **Please see the Professional Use Information Brochure for a complete list of contraindications, warnings, precautions, and adverse events.**

BY T. HUNTER NEWSOM, MD

Eliminating the Refractive Surprise of IOLs

Lens allows surgeons to finalize vision acuity after surgery

Getting RxSight's Light Adjustable Lens (LAL) has been a life-changing experience for my patients. Many can now see and function without eyeglasses for the first time in decades. They've ranked being able to see clearly among their happiest moments in life, right up there with getting married or having a baby. Some have even been in tears over the astounding results.

What differentiates RxSight's LAL from other "fixed shape" intraocular lenses (IOL) is that it's the first IOL that can be adjusted postoperatively to improve uncorrected visual acuity. Instead of trying to figure out or guess what IOL power is best for a patient, the lens allows surgeons to first implant the lens and then change the power afterward. The refractive surprise disappears.

PERSONAL SUCCESS

My first experience with RxSight's LAL was back in 2012, when I participated in FDA clinical trials. In the last 12 months, I have implanted the lens in almost 200 patients, and none of them have needed glasses for distance vision. Less than 10% of patients required glasses for reading and other close-up tasks, such as computer work. In the first 160 eyes I implanted, 80% could see 20/20 or better for distance and read 20/20 or better without glasses.

These results make the LAL the most accurate IOL in the world.

The Light Adjustable Lens is made of a special photosensitive material that changes the shape and power of your implanted lens in response to ultraviolet (UV) light.

The LAL is indicated for patients who have a cataract or a corneal astigmatism that is at least 0.50 diopters, or both conditions. Patients who don't have either condition, but aren't candidates for LASIK or photorefractive keratectomy surgery due to cataracts or presbyopia, are also good candidates. Patients should not have any significant preexisting macular disease and have good visual potential. Additionally, their pupil needs to dilate greater than 6.5 mm, which I check before scheduling the surgery.

HOW IT WORKS

The LAL is a three-piece silicone IOL with additional silicone macromers (microscopic particals) inside the lens. These movable macromers polymerize together with a photoactive component when exposed to UV light delivered by RxSight's light delivery device (LDD). During the first 48 hours after a light treatment, the macromers move in the IOL. This movement changes the IOL's shape, and either increases or decreases the optical power and treats astigmatism. The LAL is approved for adding or subtracting up to 2.0 D of sphere and up to 2.0 D of astigmatism per light treatment.

The LAL can be adjusted up to three times to fine tune distance, intermediate, or near vision. Additional patterns, such as extended depth of focus to treat presbyopia, are also possible and are currently undergoing an FDA trial.

The procedure is performed like any other cataract surgery. If a patient has an astigmatism, you don't have to make any special markings on the cornea to mark the axis of astigmatism for use with a toric or multifocal IOL. After surgery, the patient heals for three weeks and then returns to the office to have their lens shape adjusted. After a patient's eyes are dilated, we place their chin into the LDD (a slit lamp with an integrated UV light delivery device) and I push a foot pedal to activate the LDD. It focuses a blue light on the lens for about 60 seconds, which activates the movement of the macromers

and monomers. This movement changes the lens shape over the next 24 to 48 hours.

Patients try out their new lens shape for one week. Then, I evaluate their distance, intermediate, and near vision, and change the lens shape again to improve their desired results. This method of obtaining the patient's feedback allows the patient to dictate the visual results that work best for their individual needs.

We can change the shape of the IOL up to three times. With one week between adjustments, this timeframe allows the patient to try the new lens shape in the real world and choose the ideal shape before I lock in the IOL with a final light treatment so no more changes in shape can occur. Once locked in, the lens won't drift or change. I have followed patients for eight years, and their refraction has been stable over time.

RISKS AND POTENTIAL SIDE EFFECTS

Potential risks associated with LDD light treatments include mild, temporary alterations to color perceptions; temporary scratchiness, irritation, or dryness to the front part of the eye; and activation of a herpes eye infection. Certain medications can cause patients to be extra-sensitive to light, so patients should stop these medications before any light adjustment.

Longer-lasting and serious adverse events related to UV light exposure are possible. Fortunately, I have not seen or heard of any of these types of complications. Following surgery, patients must wear special UV-protective glasses during all waking hours for about four to five weeks and comply with their doctor's schedule of LDD light treatments.

A patient's failure to wear the UV-protective glasses can result in unwanted exposure of the IOL to the sun's UV light. This exposure could cause unpredictable changes to the IOL shape, producing unwanted visual changes or loss of vision quality. This may require a second surgery to remove the LAL from the eye and replace it with a new one.

There is a small chance that a patient's vision could worsen or that they may require additional surgery, a risk that exists with any cataract surgery. The risk of needing additional surgery is actually less with the LAL compared with a fixed-shape IOL. This reduction is because the most common reason for additional surgery is that a patient isn't happy with their refractive outcome. With the accuracy of the LAL, the need for surgery to improve refractive outcomes has been eliminated in my practice.

CLINICAL STUDY FINDINGS

FDA approval in 2017 was based on results of a U.S. randomized, pivotal study[1] comparing the LAL to a commercially available monofocal lens in 600 patients with preexisting astigmatism at 17 investigational sites. Patients receiving the LAL, followed by light treatment with the LDD, achieved UCVA of 20/20 or better at six months postoperatively at approximately twice the rate of patients receiving a monofocal lens.

Almost 92% of the LAL patients also achieved a result that was within 0.50 D of target manifest refraction spherical equivalent, which is similar to the refractive accuracy seen in recent LASIK studies. Study safety parameters were based on a comparison to the safety and performance endpoints for intraocular lenses (ISO 11979-7), and results showed that 100% of study eyes had a best corrected visual acuity of 20/40 or better at the 6-month postoperative visit. The approved device allows for correction of up to 2 diopters of postoperative sphere and/or -0.50 to -2 diopters of residual postoperative refractive cylinder.

My most recent data showed that 80% of patients achieved distant vision that was 20/20 or better, and near vision J1 or better without the use of glasses.

I plan to present these findings at the next AAO and ASCRS meetings.

FOOD FOR THOUGHT

More work is involved when using RxSight's technology, but if you're a surgeon looking for the best results, this will give you exactly that.

You already have the skills to implant the LAL; the only thing you'll need to learn is using the LDD—which is as easy as using a YAG laser—so the learning curve is minimal.

I think this is the most accurate IOL that the world has ever seen. It's the future of how we will be able to come up with the most perfect lens shape for each patient. There are probably designs we haven't even thought of yet for IOL technology which would push the limits of what we currently believe is the best visual potential for the human eye. ■

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1. Summary of safety and effectiveness data. Available at: https://www.rxsight.com/media/smdgdhqa/rxsight_ssed.pdf. Accessed March 1, 2021.

Dr. Newsom is the founder and medical director at Newsom Eye in Tampa, FL. He is also a lifetime visiting professor at University of Iowa. He is a consultant for RxSight.

BY RIVA LEE ASBELL

Silicone Oil Removal Conundrums Redux: 2021

A year ago, in *The Ophthalmic ASC* May 2020 issue, I presented a column titled, "2020 Retina/Vitreous Coding Conundrums for Silicone Oil Removal."[1] No progress has been made in establishing a Current Procedural Terminology (CPT) code or a revision of one, and so the conundrum remains. It's the same for removal of silicone oil in either the anterior or posterior segment: There is no specific CPT code for the surgery, nor have examples been officially amended to include removal of anything other than intraocular lenses.

In this review, some practical coding principles are presented, along with suggested coding solutions. Using a specifically named instrument does not necessarily equate to a given surgical procedure: e.g., using a vitrector does not equate to having performed a vitrectomy. As a Medicare specialist, the guidelines suggested in this article are those of CMS and may not reflect policies of other insurers.

SILICONE OIL REMOVAL AFTER MIGRATION INTO THE ANTERIOR CHAMBER

Paracentesis code descriptors for CPT codes 65800 and 65810 (often described as anterior chamber washout) are sometimes descriptive of the procedure, whereas at other times other CPT codes, such as 65920 (Removal of implanted material, anterior segment of eye), may be more appropriate.

The techniques most commonly found are listed in **Table 1**. It is important to select the CPT code that accurately describes the surgical technique employed.

SILICONE OIL REMOVAL AND REPLACEMENT DURING SECONDARY VITREO-RETINAL SURGERY PROCEDURES

Recurrent retinal detachment repair often involves removal of the previously inserted silicone oil with secondary insertion of new silicone oil. As a general rule, the

TABLE 1: COMMON CPT CODES USED FOR SILICONE OIL REMOVAL IN THE ANTERIOR AND POSTERIOR SEGMENT

CPT CODE	SEGMENT OF EYE	CPT CODE DESCRIPTION	INSTRUMENTATION EXAMPLES (USED IN SILICONE OIL REMOVAL)
67015	Posterior Segment	Aspiration or release of vitreous, subchoroidal or choroidal fluid, pars plana approach (posterior sclerotomy)	Cannula, syringe, cutting/ suction instruments
67036	Posterior Segment	Vitrectomy, mechanical, pars plana approach	Vitrector instruments *Note: Code not valid for secondary silicone oil removal (in author's opinion) since very little, if any, vitreous remains for secondary removal*
67121	Posterior Segment	Removal of implanted material, posterior segment; intraocular	Removal of implants or implanted material by manual cutting/suction instruments or aspiration
65920	Anterior Segment	Removal of implanted material, anterior segment of eye	Removal by aspiration, suction, vitrector, or other instrumentation
65800 **65810**	Anterior Segment	Paracentesis of AC …with removal of vitreous, etc.	Removal by irrigation Removal by various means for performing removal of vitreous. For mechanical anterior vitrectomy see CPT codes 67005 & 67010

Here is the 2021 table (not all-inclusive) revised from the 2020 article that lists examples of possible CPT codes that may come into play and be used for coding various types of cases. There are many options because there exists so many techniques that surgeons may use.

procedures for removal may be safely coded; however, the CPT codes for the secondary insertion are often bundled with the primary procedure, such as 67113 (complex retinal detachment repair) in the National Correct Coding Initiative (NCCI), and are therefore not eligible for reimbursement by Medicare. Each insurer will have its own rules.

The CPT codes describing paracentesis are most often bundled in the NCCI when coding more complicated surgeries.

CASE EXAMPLE

EXCERPTS FROM THE OPERATIVE NOTES

(Extracted by the author)

A paracentesis was made at 9 o'clock and a 25-gauge MVR blade was used to lyse the adhesions between the iris and the pupillary membrane. Iris hooks were used to retract the iris.

The vitrector was placed in the anterior chamber and used to remove the membrane, and also used to create an iridotomy at 6 o'clock. The retained silicone oil was removed from the anterior chamber using the vitrector.

Closed posterior vitrectomy was performed. There was extensive pre-retinal proliferation, with detachment of the anterior retina 360° up to the posterior equator. The membranes were extremely dense. There were several retinal breaks with a large retinal break temporally. The posterior retina, and specifically the macula, were attached.

The membranes were elevated and cut with the vitrector where possible. An anterior retinectomy was performed to relieve the traction on the retina. Endolaser was applied 360° to the edges of the attached retina.

Further vitrectomy and subsequent air/fluid exchange were performed.

The vitreous cavity was filled to the level of the lens with 5000 CS silicone oil.

DIAGNOSES	
The patient presented with a recurrent retinal detachment and the following diagnoses:	
1. H33.42	Traction and rhegmatogenous retinal detachment, left eye
2. T85.698A	Other mechanical complication of other specified internal prosthetic devices, implants and grafts
3. T85.398A	Other mechanical complication of other ocular prosthetic devices, implants, and grafts
4. H21.542	Posterior synechiae, left eye
5. H21.42	Pupillary membrane, left eye
6. Z98.890	Personal history of prior surgery

SURGICAL CODING		
CPT CODE	**MODIFIERS**	**ICD-10-CM DIAGNOSES**
67113 Repair of traction RD	LT	1, 6
67121 Removal of implanted material, posterior segment; intraocular	LT	2, 6
65920 Removal of implanted material, anterior segment of eye	LT	3, 6
65875 Severing of adhesions of the eye, posterior synechiae	LT	4, 6
66820 Discission of secondary membraneous cataract	LT	5, 6

TIPS:

- For Medicare coding, it is best to limit the CPT codes to five, as that is the number of codes that may be used before the claim is rejected from automatic processing and sent for individual consideration by an expert. This

can result not only in prolonged delays in payment, but also possibly lesser reimbursement.

- The complex retinal detachment repair CPT code (67113) is bundled with many other codes, because it is considered all-inclusive. I recommend choosing unbundled codes since excessive use of modifier 59 is an ongoing audit trigger.
- If you are simply removing silicone oil as a stand-alone procedure because its presence is no longer deemed necessary in the eye, you can use modifier 58 that is reimbursed at 100% of the allowable rather than 70% of the allowable that is paid for using modifier 78. Modifier 79 is not applicable. ■

REFERENCES

1. Asbell, R.L. 2020 Retina/Vitreous Coding Conundrums for Silicone Oil Removal. *The Ophthalmic ASC. May, 2020.*

2. Asbell, R.L. Coding Reassessment for Complex Retinal Detachment Repair. *New Retina Physician* (supplement to *Ophthalmology Management*). September, 2018.

Riva Lee Asbell is principal of Riva Lee Asbell Associates, an ophthalmic reimbursement firm specializing in Medicare reimbursement and compliance. She may be contacted at RivaLee@RivaLeeAsbell.com.

CATARACT DRUG CONFIRMED FOR SEPARATE PAYMENT

The **Centers for Medicare & Medicaid Services** (CMS) has confirmed that cataract surgery Omidria (Omeros) qualifies for separate payment under the non-opioid pain management policy when used in ASCs. Separate payment is effective retroactively, beginning October 1, 2020.

For information: *omidria.com/reimbursement/reimbursement-for-omidria.*

—OASC staff

BY JEFFREY WHITMAN, MD, AND DIANE BLANCK

The Significant Advantages of Ophthalmic ASC Ownership

Why it is a better business model than office-based surgery

Cataract surgery is one of the greatest success stories in medicine with a high success rate, low complication rate, and significant positive impact on the daily lives of patients. Because of their patient-centric culture and their commitment to the delivery of lower-cost and high-quality care in an appropriately regulated environment, the majority of the 3.8 million cataract procedures performed annually in the United States are furnished in the approximately 1,200 ASCs specialized in the provision of cataract and other ophthalmic surgeries. The U.S. Census Bureau estimates that there will be 83.7 million people age 65 and older by 2050, while the National Eye Institute projects that 50 million people will have cataracts by 2050.

The aging population and growth in cataract incidents indicate a growing need for accessible and efficient patient care in a safe surgical environment—the ophthalmic ASC.

Today's standard of care requires that cataract surgery be performed in ASCs and hospitals. ASCs—where more than 75% of cataract surgeries are performed—are Medicare-certified, state licensed, accredited, and highly regulated. Ophthalmic ASCs in the United States have the capacity to accommodate the growing demand cost-effectively in comprehensive, high-tech environments operated by professionals who are licensed in the intricacies of ophthalmic care and emergent care needs.

In recent months, the Outpatient Ophthalmic Surgery Society (OOSS) has been conducting a comprehensive evaluation of surgical facilities, specifically, the differences between ASCs and office-based surgery (OBS) suites. The articles in the last few issues focused on patient safety, accreditation, and oversight.

This article will highlight the business advantages of physician ownership of an ASC compared with OBS, and the key differences that should be considered when comparing them. In the next issue, we will discuss the financial benefits of ASC ownership.

Optimized Financial Performance

The ASC has proven economic benefits based on receiving a fair facility fee, combined with suitable volume and a predictable cost structure. Currently (and for the foreseeable future), OBS does not receive a facility fee for Medicare patients, who represent an estimated 45% of most physicians' cataract cases. Additionally, securing private insurance contracts is both challenging and unlikely. Combining the number of ineligible patients (due to insurance) and patients with comorbidities whose cases should not be performed in the essentially unregulated OBS, results in a maximum of 30% of patients who are good candidates for cataract surgery in an OBS suite. When projecting financial performance, those factors must be considered, indicating that the qualified OBS patient pool will be constrained to cash-paying healthy, younger patients.

Shared Ownership = Shared Risks

Building a new ASC requires a substantial investment. Syndicating into an existing ASC will cost less and may yield a bigger return, faster. For both new and existing ASCs, the financial risk can be shared by a group of physician owners or by an individual surgeon with ample volume to support the facility.

In a partnership scenario, the ASC revenue and productivity will grow as each physician's volume increases. All partners benefit from each physician's use of the facility. The ASC can recruit new ophthalmologists to use the center, add sub-specialties, and/or add new specialties to be performed at the ASC to grow volume and revenue.

The financial risk of owning an ASC is shared with other owners performing procedures at the ASC. Any vacations, long-term absences, or closures due to external reasons, such as COVID-19, are absorbed and shared by the group. When a single-owner ASC scenario is appropriate or desired, the physician can operate a very efficient, profitable, and

independent ASC, while building a separate asset from his or her practice.

The investment in building a new ASC, furnishing the technology and equipment, and operating it with professional, dedicated, trained staff is significant. Having multiple physicians invest in and provide surgical care in the ASC provides the opportunity for member physicians to share costs, to benefit from the growth of colleagues' practices, and to optimize the use of the facility and resources. Each physician can focus on growing the practice and surgical volume.

When a surgeon buys into an existing ASC, the investment can provide an immediate result; possibly receiving distributions the next month based on proven operations, revenue stream, and consistent past distributions, ultimately resulting in an accelerated ROI.

In the OBS structure, in contrast, lower surgical volumes that generate minimal to no facility fees (at least in the current payer environment) performed exclusively by physicians of the practice significantly limit financial performance. OBS currently receives minimal or no facility fees; therefore, very few cases can be furnished profitably in an OBS suite. A meaningful ROI is not feasible in current conditions in an OBS structure.

The surgeons' clinical risk is mitigated when performing surgeries in a Medicare-certified, state licensed, or accredited (AAAHC, JCAH, AAAASF) facility. An OBS suite may seek accreditation as an office, but these standards are substantially less rigorous than those applied to ASCs. Under state laws, OBS will likely only be utilized by surgeons affiliated with the practice, and these facilities will likely be limited to surgery on non-Medicare patients. OMIC and private medical liability insurers are currently evaluating the risk of OBS ophthalmic procedures for purposes of determining coverage and limitations.

Purchasing Power

The ASC benefits from economies of scale. It is utilized by multiple surgeons, can accommodate high volume with state-of-the-art technology and supplies, and has specially trained staff. The ASC will likely obtain better pricing of supplies, implants, instruments, and equipment given the purchasing power of the larger organization, and will have a larger and more diverse lens/implant consignment, providing the surgeons with flexibility and predictability in providing treatment options.

Access to Desired Technology

The ASC physicians will have better availability and access to desired technology and innovation because they will be sharing costs with other owners. The physicians will be able to invest in the latest innovative technologies, such as a femtosecond cataract laser, ORA, and endocyclophotocoabulation laser (ECP) to be used within the ASC.

The OBS suite owner will have the freedom to select desired technology, but will also bear the full-cost burden. The technology's lower usage due to volume may affect also affordability. The independent ASC owner will be able choose the desired and appropriate technology for patients' surgical care.

An additional consideration is that ophthalmic devices and implants, such as MIGS, that benefit patients clinically provide an additional physician fee of $300 to $500 and $800 incremental margin for the ASC. But they are not approved by Medicare or private insurance in a clinic or OBS suite.

Dedicated Staff

With a dedicated professional staff at the ASC and centers designed for ophthalmology, the physicians can perform the highest volume of procedures in minimal time, optimizing efficiency in the OR. The ASC staff is specifically trained for emergencies and complications.

In an ASC, the physician is focused on surgeries, assisted by staff dedicated to surgical care. In an OBS suite, the surgeon is responsible for the care of the patient, any medical emergencies that may arise, anesthesia complications, and management of staff and operations, in addition to practice accountabilities.

Building Physician Assets

The ASC has the potential to generate a significant ROI for the physician owner, becoming a high-value asset that is separate from the ophthalmic practice. With the ever-changing health care environment and reimbursement rates, it is in the physician's best interest to own two separate entities—the practice and ASC—and to align with a leading, progressive ASC.

The physician who builds a practice that includes an OBS suite has one business yielding less flexibility and more risk.

The ophthalmic ASC remains, after decades of proven results, the best solution for patients and physicians, and the best investment for physician owners.

Visit the OOSS.org for information, resources, and tools to evaluate your ophthalmic surgical facility options. ■

Dr. Whitman is president and chief surgeon of the Key-Whitman Eye Center in Dallas, TX.

Ms. Blanck is the executive director of the Outpatient Ophthalmic Surgical Society.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use LOTEMAX® SM safely and effectively. See full prescribing information for LOTEMAX® SM.

LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%

For topical ophthalmic use
Initial U.S. Approval: 1998

INDICATIONS AND USAGE

LOTEMAX® SM is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

DOSAGE AND ADMINISTRATION

Invert closed bottle and shake once to fill tip before instilling drops. Apply one drop of LOTEMAX® SM into the conjunctival sac of the affected eye three times daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.

CONTRAINDICATIONS

LOTEMAX® SM, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, in mycobacterial infection of the eye and fungal diseases of ocular structures.

WARNINGS AND PRECAUTIONS

Intraocular Pressure (IOP) Increase: Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, intraocular pressure should be monitored.

Cataracts: Use of corticosteroids may result in posterior subcapsular cataract formation.

Delayed Healing: The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

Bacterial Infections: Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

Viral Infections: Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungal Infections: Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

Contact Lens Wear: Contact lenses should not be worn when the eyes are inflamed.

ADVERSE REACTIONS

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. Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, delayed wound healing and secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

USE IN SPECIAL POPULATIONS

Pregnancy: Risk Summary: There are no adequate and well controlled studies with loteprednol etabonate in pregnant women. Loteprednol etabonate produced teratogenicity at clinically relevant doses in the rabbit and rat when administered orally during pregnancy. Loteprednol etabonate produced malformations when administered orally to pregnant rabbits at doses 4.2 times the recommended human ophthalmic dose (RHOD) and to pregnant rats at doses 106 times the RHOD. In pregnant rats receiving oral doses of loteprednol etabonate during the period equivalent to the last trimester of pregnancy through lactation in humans, survival of offspring was reduced at doses 10.6 times the RHOD. Maternal toxicity was observed in rats at doses 1066 times the RHOD, and a maternal no observed adverse effect level (NOAEL) was established at 106 times the RHOD. 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 loteprednol etabonate by oral gavage on gestation days 6 to 18, to target the period of organogenesis. Loteprednol etabonate produced fetal malformations at 0.1 mg/kg (4.2 times the recommended human ophthalmic dose (RHOD) based on body surface area, assuming 100% absorption). Spina bifida (including meningocele) was observed at 0.1 mg/kg, and exencephaly and craniofacial malformations were observed at 0.4 mg/kg (17 times the RHOD). At 3 mg/kg (128 times the RHOD), loteprednol etabonate was associated with increased incidences of abnormal left common carotid artery, limb flexures, umbilical hernia, scoliosis, and delayed ossification. Abortion and embryofetal lethality (resorption) occurred at 6 mg/kg (256 times the RHOD). A NOAEL for developmental toxicity was not established in this study. The NOAEL for maternal toxicity in rabbits was 3 mg/kg/day. Embryofetal studies were conducted in pregnant rats administered loteprednol etabonate by oral gavage on gestation days 6 to 15, to target the period of organogenesis. Loteprednol etabonate produced fetal malformations, including absent innominate artery at 5 mg/kg (106 times the RHOD); and cleft palate, agnathia, cardiovascular defects, umbilical hernia, decreased fetal body weight and decreased skeletal ossification at 50 mg/kg (1066 times the RHOD). Embryofetal lethality (resorption) was observed at 100 mg/kg (2133 times the RHOD). The NOAEL for developmental toxicity in rats was 0.5 mg/kg (10.6 times the RHOD). Loteprednol etabonate was maternally toxic (reduced body weight gain) at 50 mg/kg/day. The NOAEL for maternal toxicity was 5 mg/kg. A peri-/postnatal study was conducted in rats administered loteprednol etabonate by oral gavage from gestation day 15 (start of fetal period) to postnatal day 21 (the end of lactation period). At 0.5 mg/kg (10.6 times the clinical dose), reduced survival was observed in live-born offspring. Doses ≥ 5 mg/kg (106 times the RHOD) caused umbilical hernia/incomplete gastrointestinal tract. Doses ≥ 50 mg/kg (1066 times the RHOD) produced maternal toxicity (reduced body weight gain, death), decreased number of live-born offspring, decreased birth weight, and delays in postnatal development. A developmental NOAEL was not established in this study. The NOAEL for maternal toxicity was 5 mg/kg.

Lactation: There are no data on the presence of loteprednol etabonate 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 LOTEMAX® SM and any potential adverse effects on the breastfed infant from LOTEMAX® SM.

Pediatric Use: Safety and effectiveness of LOTEMAX® SM in pediatric patients have not been established.

Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma tk assay, or in the chromosomal aberration test in human lymphocytes, or *in vivo* in the mouse micronucleus assay. Treatment of male and female rats with 25 mg/kg/day of loteprednol etabonate (533 times the RHOD based on body surface area, assuming 100% absorption) prior to and during mating caused preimplantation loss and decreased the number of live fetuses/live births. The NOAEL for fertility in rats was 5 mg/kg/day (106 times the RHOD).

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Manufactured by: Bausch & Lomb Incorporated, Tampa, FL 33637 USA
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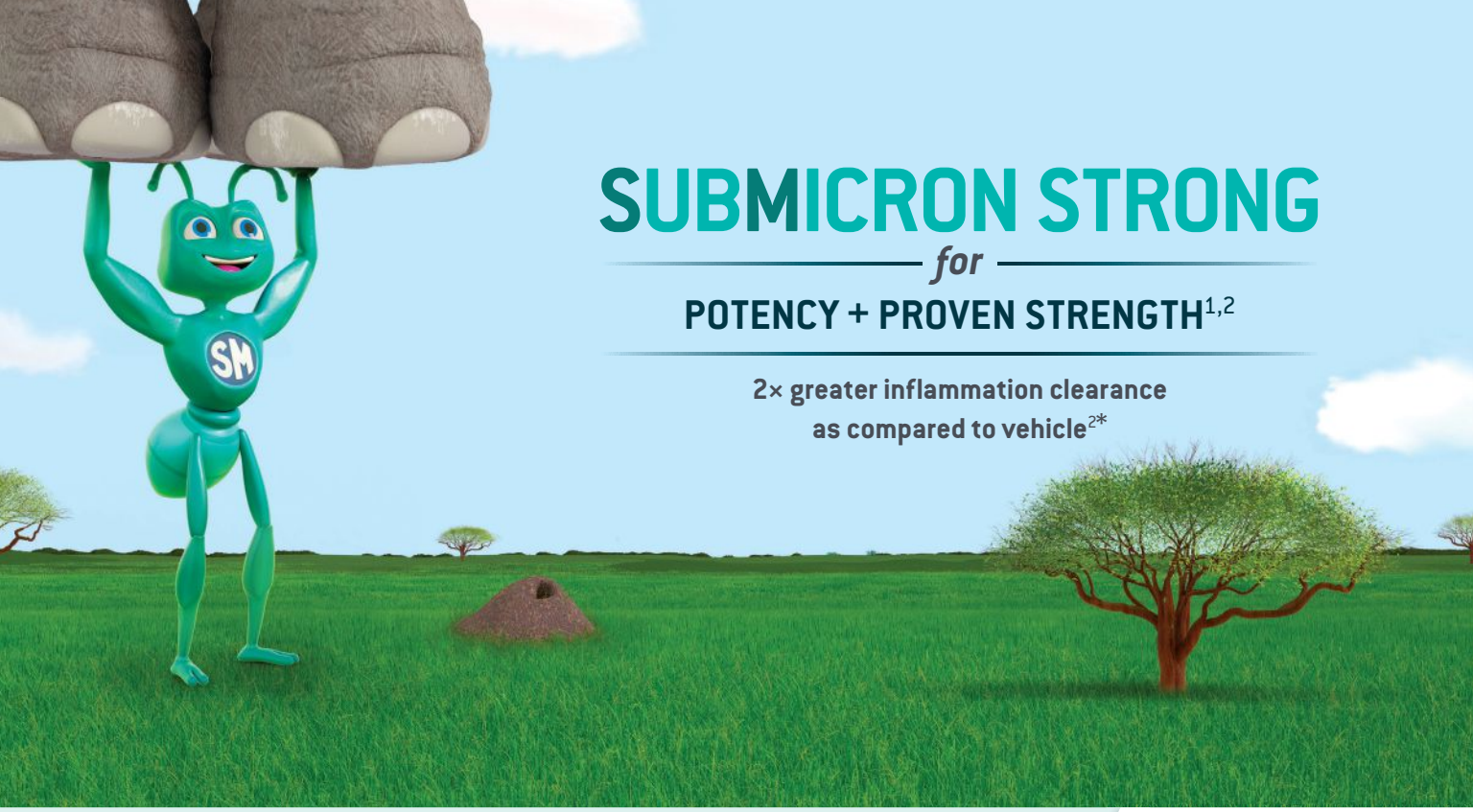

SUBMICRON STRONG

for

POTENCY + PROVEN STRENGTH[1,2]

2× greater inflammation clearance as compared to vehicle[2]*

SM TECHNOLOGY™

- **Engineered with SM Technology™ for efficient penetration at a low BAK level (0.003%)[1,3]**
- **~2× greater penetration** to the aqueous humor than LOTEMAX® GEL (loteprednol etabonate ophthalmic gel) 0.5%[3]

Clinical significance of these preclinical data has not been established.

LOTEMAX® SM
(loteprednol etabonate ophthalmic gel) 0.38%

SMALL & MIGHTY
SUBMICRON PARTICLES

*PROVEN STRENGTH

- **30% of LOTEMAX® SM patients had complete ACC resolution** vs vehicle (15%) at Day 8 (N=371, *P*<0.0001)[1,2†]
- **74% of LOTEMAX® SM patients were completely pain-free** vs vehicle (49%) at Day 8 (N=371, *P*<0.0001)[1,2‡]

†Pooled analysis of Phase 3 clinical studies. **Study 1:** 29% LOTEMAX® SM (N=171) vs 9% vehicle (N=172). **Study 2:** 31% LOTEMAX® SM (N=200) vs 20% vehicle (N=199); *P*<0.05 for all.

‡Pooled analysis of Phase 3 clinical studies. **Study 1:** 73% LOTEMAX® SM (N=171) vs 48% vehicle (N=172). **Study 2:** 76% LOTEMAX® SM (N=200) vs 50% vehicle (N=199); *P*<0.05 for all.

Indication

LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38% is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

Important Safety Information

- LOTEMAX® SM, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.
- Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If LOTEMAX® SM is used for 10 days or longer, IOP should be monitored.
- Use of corticosteroids may result in posterior subcapsular cataract formation.

Important Safety Information (cont.)

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those with diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infections.
- Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.
- Contact lenses should not be worn when the eyes are inflamed.
- There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

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**.

Please see brief summary of Prescribing Information on adjacent page.

References: 1. LOTEMAX SM Prescribing Information. Bausch & Lomb Incorporated. **2.** Data on file. Bausch & Lomb Incorporated. **3.** Cavet ME, Glogowski S, Lowe ER, Phillips E. Rheological properties, dissolution kinetics, and ocular pharmacokinetics of loteprednol etabonate (submicron) ophthalmic gel 0.38%. *J Ocul Pharmacol Ther.* 2019. doi: 10.1089/jop.2019;35(5):291-300.

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LOTEMAX® SM
(loteprednol etabonate ophthalmic gel) 0.38%