# MONKEYS, SHARKS SHARKS BEARS ON MUSION

14

NEWSWORTHY Q+A with Robin Hamilton

SEEING LASERS Discover your path to seeing clearer

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SEEN<sup>®</sup> Magazine is an educational publication brought to you by Alcon, the global leader in eye care.

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CONTOURA® Vision precisely maps up to **22,000** unique elevation points on each eye.

Just like your fingerprint is completely unique to you, CONTOURA® Vision creates a procedure that's completely unique to your eyes.

Patients featured in this magazine received modest compensation for sharing their experiences. Although their results are typical, individual results may vary. Please refer to the Important Product Information on page 11.



# THINGS YOU DIDN'T KNOW ABOUT CONTOURA® VISION

#### > ASTIGMATISMS WELCOME.

In fact, CONTOURA® Vision may be especially well suited for individuals with astigmatism. This is because the ovular cornea that defines astigmatism is literally reshaped by the procedure.

# THE LASER ISN'T HOT.

It's natural to think of lasers as hot, because in movies, they're most often depicted melting through metal and burning through rope. Not the case here. CONTOURA® Vision uses a "cool-beam," highenergy laser that vaporizes targeted tissue. No heat? No sweat.



# 5

THERE'S **INTELLIGENCE INSIDE.** 

The lasers used in a **CONTOURA®** Vision procedure are the same ones used to create semiconductor and computer chips. That's right: humanity and machinery — all with the same laser. Technology!

#### IT'S FASTER THAN YOU. BY A LOT.

To ensure accuracy, all **CONTOURA®** Vision systems have high-speed video imaging to track the position of your eye. If you move, it moves, which means it has to be faster than you to ensure it keeps up. A human has a reaction time of 20 to 30 milliseconds. The laser? About 2 to 3 milliseconds.

#### THINKING ABOUT GETTING CONTOURA® **VISION** TOPOGRAPHY-GUIDED LASIK?

Make sure to get informed by doing your own research and asking your doctor if the procedure is right for you. To tide you over, here are seven things you may not have known about **CONTOURA® Vision**.

# 5

**NO, SERIOUSLY,** IT'S FAST.

The actual procedure takes about ten minutes per eye.

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#### RESULTS YOU CAN SEE. #PUNTASTIC

While it does take time for your eyes to experience the full effects of CONTOURA® Vision, differences are often noticed quickly. Many patients have even reported a significant change while still in the chair.

#### INSURANCE MAY **OFFER AN ASSIST.**

Though most insurance providers tend not to cover the cost of LASIK. some do offer discounts or forms of coverage through employee health plans and flexible spending accounts. Because it never hurts to ask, check with your individual insurance carrier(s) to learn more.



**CONTOURA® Vision** isn't the LASIK you think you know. It's laser vision correction that uses some of today's most advanced mapping technologies to create a highly personal and unique treatment for your eyes. And only your eyes.

Anyone who's had a CONTOURA® Vision procedure will tell you that the procedure itself is surprisingly fast. In fact, it takes on average about 10 minutes per eye. What else can you do in 10 minutes? We're glad you asked.

#### **READ 50 TWEETS.**

The rate at which the average person reads is approximately 300 words per minute. The average length of a single English word is

five letters, so a 280-character tweet averages out to 56 words (not counting emojis). So for every 10 minutes on Twitter, you read about 50 tweets.



... if you're Joey Chestnut. The American professional eater gobbled up 72 ballpark franks in 10 minutes at the 2017 Nathan's Famous International Hot Dog Eating Contest. If you're keeping track at home, that's a hot dog every eight seconds.

#### TAKE THE STAIRS — TO THE TOP OF THE EMPIRE STATE BUILDING.

Every year, the Manhattan landmark hosts the Empire State Building Run-Up, a race to the observation deck on the 86th floor via the building's



stairwell. Top finishers climb all 1,576 stairs in, of course, about 10 minutes.

REMEMBER: CONTOURA® Vision is not for everyone. You should not undergo CONTOURA® Vision if you are pregnant or nursing; if you have a collagen vascular, autoimmune or immunodeficiency disease; if you show signs of keratoconus or any other condition that causes a thinning of your cornea; or if you are taking isotretinoin (Accutane\*) or amiodarone hydrochloride (Cordarone\*).



Thanks to **CONTOURA® Vision**, these lovers can see clearly now

SPOTLIGHT

"I remember telling my wife that I could see the license plates," says Paul, recalling the drive home from his **CONTOURA**® **Vision** LASIK eye procedure.

Since his wife was due to have the same procedure the next morning, she was especially interested in hearing about his experience.

Paul's love life was never one of the numerous problems that came along with bad vision perhaps because he fell in love with someone who understood. "[Emma\*] had worse vision than I did."

Despite their less-than-perfect vision, these two lovers found each other. But it's hard to live happily ever after when you're fumbling with glasses.

"I like camping, [but] you don't want to worry about contacts or glasses," says Paul. Throughout his adolescence, Paul struggled playing football and lifeguarding when his glasses kept falling off and his contacts irritated his eyes. As an adult, the stakes only got higher for Paul, who served in the Marine Corps before becoming a police officer.

Emma, too, was frustrated. "We'd wake up and have to put our contacts or eyeglasses on before we could do anything."

So after years of stumbling around, "we decided to get [**CONTOURA® Vision**] together," says Paul. "I got my [procedure] on one day, and she got it the next day."

# DISCOVER MORE ABOUT PAUL AT CONTOURAVision.com

Then we ask if Emma had wanted to wait and see how his procedure went. Paul chuckles. "Yeah, most likely."

As Emma drove him home after the **CONTOURA® Vision** procedure, he described the world he was seeing in detail for the first time — the world that tomorrow, they'd see more clearly together.

"I used to be able to see leaves on trees, but now I can see the features of those leaves. You can see everything clearer and crisper. Everything is more defined."

To ease her nerves, he told her, "I didn't feel any pain whatsoever. It was less than five minutes per eye."

Less than five minutes per eye and "you're investing in your ability to see for the rest of your life."

For Paul and Emma, the investment was worth it. "This procedure's given us the ability to do whatever we want."

"I used to be able to see leaves on trees, but now I can see the features of those leaves. You can see everything clearer and crisper. Everything is more defined."

#### \*Name has been changed for the purposes of this article.

#### WHAT'S LASIK?

Its name may sound complicated ("LASIK" stands for *laser-assisted in situ keratomileusis*), but the LASIK procedure is actually fairly straightforward. For individuals who are nearsighted or farsighted or who have astigmatism, your vision challenges possibly stem from an irregularly shaped cornea. LASIK reshapes your cornea and allows the eye to heal naturally on its own while giving you almost immediate improvement in vision.

#### **SEEING LASERS**

Choosing to undergo any procedure can be scary. But then again, so were monsters when you were nine years old (and you got over that fairly well). The saying goes that knowledge is power. So let's get you powered up, by getting you up to speed.

#### CONTOURA® VISION, STEP-BY-STEP

Explaining in seconds what takes just a matter of minutes

#### STEP 1 — PREPPING

Before you get to the main event, your surgeon will perform a preliminary eye exam and give you anesthetic drops to numb your eyes.

#### **STEP 2 — MAPPING SUCCESS**

**CONTOURA®** Vision takes specific topographic measurements of your eye to deliver a customized approach to your treatment.

#### STEP 3 — LASERS!

Using light energy (editor's note: "light energy" is a fancy way of saying "laser"), the doctor will reshape your cornea. In minutes, the procedure is over and healing begins generally without pain or bandages.

**REMEMBER:** While **CONTOURA®** Vision has been shown to be safe and effective, there can be complications or side effects. Make sure to discuss the risks and benefits with your doctor so you can make an informed decision that's best for you.

INTERACTIVE QUIZ



# UNDECIDED

#### Still trying to wrap your head around LASIK? Take our quick and easy quiz to find out if **CONTOURA® Vision** may be right for you.

#### + DO YOU WANT BETTER VISION?

- A Yes.
- **B** Possibly?

**CONTOURA® Vision** may be able to give you the vision you've always wanted, without the need for contacts or glasses.

#### DO YOU HAVE A PREDICTABLE VISION PRESCRIPTION?

- A Yes, my prescription has been constant for years.
- **B** No, my prescription changes every time I get an eye exam.

If you're looking to get **CONTOURA® Vision**, it's important that your prescription has been stable for at least 1–2 years.

#### + DO YOU HAVE ASTIGMATISM?

- A Yes.
- **B** No.

Trick question: It doesn't matter. Even if you have astigmatism, **CONTOURA® Vision** may still be an option for you.

#### ARE YOU NEARSIGHTED (HAVE TROUBLE SEEING THINGS FAR AWAY) OR FARSIGHTED (HAVE TROUBLE SEEING THINGS UP CLOSE)?

- A Nearsighted.
- **B** Farsighted.

It doesn't matter if you're nearsighted or farsighted. There are LASIK treatment options that may be able to help you bring things into focus.

#### + ARE YOU AN ACTIVE INDIVIDUAL?

- A I'm always trying to be active.
- B No. Just no.

Looking for the freedom to fully engage in the active lifestyle you want? **CONTOURA® Vision** may be able to help deliver high-performance-type vision.

#### WHO DID YOU VOTE FOR IN THE LAST ELECTION?

- A Can we not? I'm SO tired of talking about politics.
- **B** The junior class student council president.

Sorry, kids: If you can't vote, you're stuck with glasses for the moment. You need to be at least 18, and in some cases 21+, to undergo LASIK.

TO LEARN MORE ABOUT **CONTOURA® Vision**, PLEASE SEE THE IMPORTANT PRODUCT INFORMATION ON PAGE 11.

#### IS **CONTOURA® VISION** RIGHT FOR ME?

Though LASIK has changed how millions of people view the world, it isn't always right for everybody. To determine whether you are an ideal candidate for **CONTOURA® Vision**, make sure to do the following:

#### **CONSULT WITH YOUR EYE DOCTOR**

With a quick series of tests and measurements, an eye surgeon can determine whether **CONTOURA® Vision** will work for you.

#### MAKE SURE YOUR PRESCRIPTION HAS BEEN STABLE

If your prescription has changed within the past 18 months, your eyes may still be changing and could continue to change after the procedure. This could result in the need for follow-up procedures when it would be better, and less expensive, to simply wait.

#### **REVIEW YOUR MEDICAL HISTORY**

Discuss with your eye surgeon any health conditions and medications you may be taking. Certain conditions, such as dry eyes and thin corneas, can affect your surgical options and need to be discussed before surgery.

# How Effective Is CONTOURA® Vision?

Sure, you have questions regarding LASIK, but perhaps the most important one is, will it work? Clinical evaluations on the safety and effectiveness of **CONTOURA®** Vision have reported some encouraging numbers.

AFTER 12 MONTHS, **CONTOURA® VISION** PATIENTS, WITHOUT THE AID OF GLASSES OR CONTACTS, EXPERIENCED THE FOLLOWING RESULTS<sup>1</sup> (ALTHOUGH THEIR RESULTS ARE TYPICAL, INDIVIDUAL RESULTS MAY VARY):



#### WHAT IS 20/20 VISION?

Having 20/20 vision means you have normal vision. To see 20/20 implies that what you can see at 20 feet is exactly what normal people can see at 20 feet. If, for example, you could read a line on the eye chart at 20 feet, but a person with normal vision could only read it from 15 feet, then you'd be diagnosed with 20/15 vision.

see at 16 feet.

In the end, the number we consider "normal" is a bit arbitrary. Some individuals naturally see better than 20/20 — others don't.

#### A LOT CAN HAPPEN IN 20 YEARS.

you can see at 20 feet.

What's happened in the last two decades? Aside from you not even knowing where your CD collection went, a scientific survey was conducted to discover the satisfaction rates of patients who have undergone elective procedures. Of those individuals, **98.4% of patients gave high marks to CONTOURA® Vision** — the highest satisfaction rate of any elective procedure surveyed.<sup>1,†</sup>

#### FACT!

The less refractive error you have, the greater the chance of achieving 20/20 vision after the procedure.

**REMEMBER:** The most common risks of **CONTOURA® Vision** include dry eye syndrome; the possible need for glasses or contact lenses after the procedure; visual symptoms, including halos, glare, starbursts and double vision; and loss of vision.

# LA\$IK

It takes just a few seconds of searching "LASIK" to discover that there's a wide spectrum of pricing options available to the potential patient. And while we won't tell you what to do, we will say this: You probably shouldn't pay a visit to the \$9.99 all-you-can-eat sushi buffet you keep passing on your way home from work. Seriously, just don't.

No matter what you choose, all LASIK procedures cost money. So here are a few ways you may be able to save a buck or two. You know, for better sushi.

#### 100% LASIK for 0%

A variety of lending institutions offer financing for LASIK, some even at **0% financing.** (Ask your doctor about your financing options).<sup>2</sup>

98.4%

**CONTOURA® Vision** again.<sup>1,†</sup>

(Ask your doctor if **CONTOURA® Vision** is right for you.)

of patients would get

#### That's major savings to you, soldier (Sorry, we had to)

Some branches of our military are now offering **financial support for LASIK procedures** — at ease, wallet.<sup>3</sup> (Oops, we did it again.)

#### Less taxing procedures

Flexible spending accounts allow you to use your pretax earnings on medical expenses. (Ask your employer if FSAs are available with your health plan options).<sup>2</sup>

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#### DID YOU KNOW?

CONTOURA® Vision outperformed glasses and contacts in 30.9% of eyes that received treatment.<sup>1</sup> You can experience reduced:<sup>1</sup>



#### REFERENCES

1. Stulting RD, Fant BS; T-CAT Study Group. Results of topography-guided laser in situ keratomileusis custom ablation treatment with a refractive excimer laser. *J Cataract Refract Surg.* 2016;42(1):11–18. Study Description: Prospective, nonrandomized, multicenter study of 249 eyes with myopia or myopic astigmatism of 6.0 D or less. Outcome measures included manifest refraction, UDVA, CDVA and visual symptoms up to 12 months. † In a subset analysis of 124 patients, 122 responded that they would have LASIK again. 2. Hill J. LASIK financing: how to afford LASIK surgery. All About Vision Website. http://www.allaboutvision.com/visionsurgery/lasik-financing.htm. Updated August 2017. Accessed November 8, 2017. 3. Warfighter Refractive Eye Surgery Program and Research Center (WRESP-RC) at Fort Belvoir. Commander's authorization for refractive surgery [application form]. Fort Belvoir, VA: Fort Belvoir Community Hospital WRESP-RC; February 2016. http://www.fbch.capmed.mil/Documents/Refractive\_Surgery\_Cmd\_Authorization.pdf. Accessed November 15, 2017.

THINKING ABOUT **CONTOURA® VISION**? VISIT **CONTOURAVISION.COM** TO DISCOVER MORE AND REFER TO THE IMPORTANT PRODUCT INFORMATION ON PAGE 11.

#### **REMEMBER:** While **CONTOURA®** Vision has been shown to be safe and effective, there can be complications or side effects. Make sure to discuss the risks and benefits with your doctor so you can make an informed

decision that's best for you.



# How a personalized procedure helped zoologist Melinda embrace an active lifestyle "I snorkel quite a bit. If you get water in your eyes and have blurry vision even for a short time, it certainly makes you more nervous." "Nervous" doesn't suit Melinda Settles. She's a kickboxing, snorkeling, scuba diving zookeeper

— her speech is peppered with phrases like "go ahead" and "take the plunge." It's clear that when Melinda wants to do something, nothing is going to stop her.

And yet ...

"Anytime you have issues seeing the world around you, it makes you a little more reserved, it makes you hold back a little bit. You want to be able to see what's in front of you, especially if it's a shark or something like that, or we have sea lions that we snorkel with."

We find it hard to disagree.

MONKEYS,

56

**SHARKS** 

But it wasn't only Melinda's hobbies (you know, or her life) that were in jeopardy. Her vision problems affected her professionally as well.

"Anytime you have issues seeing the world around you, it makes you a little more reserved, it makes you hold back a little bit."

**CONTOURAVision.com** 

**DISCOVER MORE ABOUT MELINDA AT** 

REMEMBER: While CONTOURA® Vision has been shown to be safe and effective, there can be complications or side effects. Make sure to discuss the risks and benefits with your doctor so you can make an informed decision that's best for you.



"As a zookeeper, my job was primarily outside. You're working in a dusty, sunny, hot environment, and I had a lot of contact issues and would end up in glasses for weeks at a time. Then I lacked peripheral vision. I work with primates, and they're very smart and active. I need to be aware of what they're doing, what's going on and where I am in their environment."

"You want to be able to see what's in front of you, especially if it's a shark or something like that, or we have sea lions that we snorkel with."

Glasses for Melinda were a safety hazard not that that ever stopped her from doing anything — as well as a drag on her job performance. "Whether you're looking for a little injury or you're looking to see what behavioral cues the animals are giving, if you can see details, it helps."

But most importantly, wearing glasses made it harder for her to find joy in her work. "Being able to see their interactions, getting to understand how they treat each other, how they're reacting to different things is really rewarding." Animal observation is her passion, and it's hard to observe when you can't see.

On some level, Melinda had always known she wasn't destined for a life with glasses. "I first learned about LASIK back in the eighth grade, and I thought it sounded amazing." So the idea had been in her head for a while, but it's only in the last few years that she seriously considered it.

Starting work at the San Diego Zoo was the final straw. "I was having eye issues when I first started, and it definitely affected my confidence. When you can't see, it affects how you carry yourself."

A kickboxing buddy of hers had recently gotten LASIK.

"I went to the same eye doctor he did. They had this brand new technology that would give me better vision and a better result than basic LASIK procedures — and it was called **CONTOURA® Vision**." Now Melinda grows animated. "I definitely feel like I got a custom job from **CONTOURA® Vision**. [They] took a multitude of pictures and images to assess the contours of my eyes specifically, and it made a unique map of my eyes in order to fix my vision the best that it could."

She likes the high-tech nature of the procedure. "As technology evolves it gets better. [CONTOURA® Vision] was the newest and best procedure. It sounded really exciting."

Exciting. Not the word most people associate with a procedure on their eyes, but for Melinda, it was more than that: it was a decision to embrace her life.

"On the day of the procedure, I had to show up at nine, and they said I should be heading home by ten. I was nervous, but excited about the fact that I was going to go in and in an hour have better vision."

It's only natural to feel nervous, but Melinda offers a glowing review: "The procedure was not painful at all — not at all what most people fear when they think of having [a procedure] on your eyes. They have you lay down, and the machine slides over the top of you. You just stay put, and they bring all of the technology to you."

It took only a few short minutes — and it completely changed her life.

"It has made my life more fun, more engaging, and given me confidence and the ability to go do whatever I want. Being able to just get up and go is really nice."

Her newfound vision has helped her at work, too: "With LASIK, I was able to see a lot of those different small details that I couldn't actually see with my glasses." She laughs. "If you lack that peripheral vision, you're more likely to run into things."

Melinda is now able to avoid these kinds of small hazards — as well as some larger, bear-sized hazards.

"Two weeks after I got my LASIK procedure, we went camping at Sequoia National Park. I woke up at night to a bear breathing on the tent. I was able to get out of the tent and go check out the bears without searching for glasses." This, for Melinda (as well as for us), was the WOW moment: "Wow, my life has changed here. If there's a bear, I can get up and get away pretty easy."

"Having the LASIK procedure has given me the flexibility and the confidence to live [my life] however I choose" — bears, sharks, monkeys and all.

Most people wouldn't think of being able to escape from bears as a benefit of LASIK. But then again, most people aren't Melinda.

"Having the LASIK procedure has given me the flexibility and the confidence to live [my life] however I choose" — bears, sharks, monkeys and all.



Patients featured in this magazine received modest compensation for sharing their experiences. Although their results are typical, individual results may vary. Please refer to the Important Product Information on page 11.

## A TREATMENT AS UNIQUE AS YOU ARE.



#### **Experience the WaveLight**<sup>®</sup> **Excimer Laser difference.**

We know that no two eyes are alike, so why should your treatment be any different? The WaveLight<sup>®</sup> Laser uses topography-guided technology to track the unique shape of your eye, allowing your surgeon to perform a Laser Vision Correction treatment that is specifically tailored to you and your eyes. **The result? Vision that's as clear and crisp as possible.** 

Talk to your doctor to learn more about the potential risks and benefits for laser refractive surgery, and to discover if topography-guided LASIK is right for you.

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If you've watched the news in any sort of capacity over the last few years, there's a decent chance you've seen Robin Hamilton. The DC-based journalist has reported on happenings and events all over the country, and recently, she sat down with *SEEN® Magazine* to discuss her own story about getting LASIK.

#### SEEN: WHEN DID YOU GET GLASSES?

**ROBIN:** I got glasses when I was eight. I remember I was in Mrs. Cook's math class, and I was having trouble looking at the board. I noticed things were getting fuzzier and fuzzier. [Later on], I started to do a lot more sports, so I begged my dad to let me get contact lenses.

#### **SEEN: WHEN DID YOU DECIDE TO GET LASIK?**

ROBIN: My husband convinced me. He had bad vision, and he ended up doing it. He said, "It's the best thing I've ever done. I loved it."

#### SEEN: WALK US THROUGH THE PROCEDURE ITSELF. WERE YOU SCARED AT ALL?

**ROBIN:** I was terrified, especially because I rely on my eyes so much for work and everything else. The day I did the procedure, I was really nervous — I actually had a moment where I said, "I don't think I can do this."

#### SEEN: WAS THE PROCEDURE PAINFUL?

**ROBIN:** That's what was surprising: it wasn't. They put these drops [in your eyes] that sting just a little bit, like you got shampoo in your eyes. Then you don't really feel anything. You see a little something in front of your eye, you hear the *tick-tick-tick* of the laser. ... It was less than a minute. I was waiting for something else to happen, but then [the doctor] said, "You're done."

#### **SEEN: DID YOU NOTICE A DIFFERENCE?**

**ROBIN:** Definitely. It takes a while to get out of the house [with contacts]. It's another step to take in the morning, and it didn't feel real that I didn't have to wear contacts anymore. I woke up thinking, "Oh my gosh, I don't have to do anything."

#### SEEN: HOW HAS THE PROCEDURE AFFECTED YOU PROFESSIONALLY?

**ROBIN:** It's been great. I used to have to look at a teleprompter a lot. If there was ever something in my contact, or my eyes were dry, that was a real problem. Also, when you edit, you spend a lot of time staring at a computer. My contacts would actually dry out and it would feel like I had something caked on my eye. Now I feel like I don't have to worry about something going wrong with my eyes. I can focus on the job that I need to do, and it gives me a lot of confidence in front of the camera.

#### SEEN: WHAT'S BEEN THE BIGGEST SURPRISE FOR YOU FOLLOWING THE PROCEDURE?

**ROBIN:** I didn't think it was going to be as liberating. When people talk in superlatives, like my husband did, I think it's an exaggeration. It's too much. But it's true. I know it's scary. I know it's expensive. But if you rely on your eyes — which all of us do — it's a tremendous investment. It will change your life.

Patients featured in this magazine received modest compensation for sharing their experiences. Although their results are typical, individual results may vary.

Please refer to the to the Important Product Information on page 11.

### GO TO CONTOURAVision.com to see what else robin has to say about lasik.

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![](_page_11_Picture_6.jpeg)

#### IMPORTANT PRODUCT INFORMATION ABOUT THE WAVELIGHT® EXCIMER LASER SYSTEMS

This information pertains to all WaveLight® Excimer Laser Systems, including the WaveLight® ALLEGRETTO WAVE®, the ALLEGRETTO WAVE® Eye-Q, and the WaveLight® EX500.

**Caution:** Federal (U.S.) law restricts the WaveLight<sup>®</sup> Excimer Laser Systems to sale by or on the order of a physician. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery (including laser calibration and operation) should use a WaveLight<sup>®</sup> Excimer Laser System.

Indications: FDA has approved the WaveLight<sup>®</sup> Excimer Laser Systems for use in laser-assisted in situ keratomileusis (LASIK) treatments for nearsightedness (myopia), farsightedness (hyperopia), and astigmatism, including mixed astigmatism. Astigmatism occurs if the shape of your eye causes light to bend and distort as it passes through your lens. With astigmatism, objects tend to appear blurry or unfocused. Mixed astigmatism occurs if you have symptoms of nearsightedness at the same time.

The WaveLight® Excimer Laser Systems are approved for the following specific LASIK treatments and ranges:

- Reduction or elimination of nearsightedness of up to 12.00 diopters of sphere and up to 6.00 diopters of astigmatism at the spectacle plane.
- Reduction or elimination of farsightedness up to + 6.00 diopters of sphere and up to 5.00 diopters of astigmatism at the spectacle plane, with a maximum manifest refraction spherical equivalent of + 6.00 diopters.
- Reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 diopters at the spectacle plane.
- Wavefront-guided reduction or elimination of nearsightedness of up to 7.00 diopters of sphere and up to 3.00 diopters of astigmatism at the spectacle plane. Wavefront-guided LASIK treatment takes into account small, complex imperfections in the shape of your eye that can affect your vision. Wavefront-guided LASIK is more highly customized than traditional LASIK procedures.

In addition, the WaveLight<sup>®</sup> ALLEGRETTO WAVE<sup>®</sup> Eye-Q Excimer Laser System, when used with the WaveLight<sup>®</sup> ALLEGRO Topolyzer<sup>®</sup> and topography-guided treatment planning software, is approved for topography-guided LASIK treatments for the reduction or elimination of up to -9.00 diopters of nearsightedness, or for the reduction of elimination of nearsightedness with astigmatism with up to -8.00 diopters of nearsightedness and up to 3.00 diopters of astigmatism.

The WaveLight<sup>®</sup> Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism), who have documented evidence that their refraction did not change by more than 0.50 diopters during the year before their preoperative examination.

Alternatives to LASIK: LASIK is just one option for correcting your vision. Alternative options include eyeglasses, contact lenses, photorefractive keratectomy surgery (PRK), and other refractive surgeries. Be sure to talk to your doctor to find out if LASIK is appropriate for your condition.

**Contraindications:** If you have any of the following situations or conditions, you should not have LASIK because the risk is greater than the benefit:

- You are pregnant or nursing. These conditions may cause temporary and unpredictable changes in your cornea and a LASIK treatment would improperly change the shape of your cornea.
- You have a collagen vascular, autoimmune or immunodeficiency disease, such as rheumatoid arthritis, multiple sclerosis, lupus or AIDS. These conditions affect the body's ability to heal.
- You show signs of keratoconus or any other condition that causes a thinning of your cornea. This condition can lead to serious corneal problems during and after LASIK surgery. It may result in need for additional surgery and may result in poor vision after LASIK.
- You are taking medications with ocular side effects, such as Isotretinoin (Accutane\*) for acne treatment or amiodarone hydrochloride (Cordarone\*) for normalizing heart rhythm, because they may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.
- You show symptoms of severe dry eye. If you have severely dry eyes, LASIK may increase dryness. This may or may not go away. This dryness may delay healing of the flap or interfere with the surface of the eye after surgery.
- Your corneas are too thin. If your corneas will be too thin after your doctor has cut a flap and performed the LASIK treatment, you cannot have LASIK.
- You have recurrent corneal erosion. This condition can lead to serious corneal problems during and after LASIK surgery.
- You have advanced glaucoma. It is unknown whether LASIK is safe and effective for you.
- You have uncontrolled diabetes. LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.

**Warnings:** If you have any of the following conditions, you should have LASIK only if your doctor evaluates the seriousness of your condition and believes the benefit of having LASIK is greater than the risk:

- Systemic diseases likely to affect wound healing. If you have a systemic disease such as a connective tissue disease, severe atopic disease or are immunocompromised, LASIK may be risky for you because it may affect the ability of your eyes to heal.
- Diabetes. If you have diabetes and depend on insulin, LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.
- History of Herpes simplex or Herpes zoster infection that has affected your eyes. If you
  have had a Herpes simplex or a Herpes zoster infection that affected your eyes, or have
  an infection now, LASIK is more risky for you.
- Symptoms of significant dry eye. If you have severely dry eyes, LASIK may increase dryness. This may or may not go away. This dryness may delay healing of the flap or interfere with the surface of the eye after surgery.
- Severe allergies. If you have severe allergies and take medicines for them, LASIK is more
  risky for you. These medicines may change the wetness level in your eye. If the medication
  changes the moisture of your eye, the accuracy of your refractive results may be affected,
  and topography-guided LASIK is more risky for you.
- History of glaucoma, increased pressure inside your eyes, have been diagnosed with ocular hypertension, or are being followed for possible glaucoma, because it is unknown whether LASIK is safe and effective for you.
- Your doctor is unable to obtain preoperative topography maps that are of good enough quality to use for planning a topography-guided LASIK treatment. Poor quality topography maps may affect the accuracy of the topography-guided LASIK treatment and may result in poor vision after topography-guided LASIK.
- Taking the medication isotretinoin (Accutane\*) for acne treatment, because this may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.

**Precautions:** If any of the following conditions or situations apply to you, you should discuss them with your doctor:

- Your nearsightedness, farsightedness, astigmatism or mixed astigmatism is getting better or worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after LASIK.
- You have an eye disease. It is unknown whether LASIK is safe and effective under this condition.
- You have had a prior eye injury or eye surgery. If your eyes are injured or you have had surgery, it is unknown whether LASIK will weaken the cornea too much. This may result in poor vision after LASIK.
- You have a corneal abnormality (e.g., scar, irregular astigmatism, infection, etc.). An
   abnormal corneal condition may affect the accuracy of the LASIK treatment or the way your
   cornea heals after LASIK. This may result in poor vision after LASIK.
- You take medicines that might make it harder for wounds to heal, such as sumatriptan succinate (Imitrex\*) for migraine headaches. It is unknown whether LASIK is safe and effective for people who take these medicines.
- You are younger than 18 years of age (21 years for mixed astigmatism). It is unknown whether LASIK is safe and effective for you.
- Your doctor may modify the wavefront-calculated ablation program in order to give you a treatment that does not fully correct distance vision. You should discuss the risks in depth with your doctor for any LASIK corrections that do not fully correct for distance vision, especially if performed only in one eye.
- You have a cataract or other problem with the lens or vitreous of your eye. It is unknown whether LASIK is safe and effective under this condition.
- You have any problems with the iris (colored part) of your eye or have had previous surgery
  on this part of your eye. The eyetracker on the laser may not work properly and LASIK may
  not be safe and effective for you.
- You are taking prescription or over-the-counter medications that may affect the ability of your eye to heal after surgery, including certain types of cancer drugs (antimetabolites).
- Your doctor plans to use a treatment zone with the laser < 6.0 millimeters or > 6.5 millimeters in diameter. It is unknown whether LASIK with these treatment zones is safe and effective for you.
- Your nearsightedness is worse than 12.00 diopters, or with astigmatism that is worse than 6.00 diopters. It is unknown whether LASIK is safe and effective for you.
- Your farsightedness is worse than + 6.00 diopters, or with astigmatism that is worse than 5.00 diopters. It is unknown whether LASIK is safe and effective for you.

- •Your mixed astigmatism is worse than 6.00 diopters. It is unknown whether LASIK is safe and effective for you.
- Your mixed astigmatism is > 4.00 diopters to ≤ 6.00 diopters. Due to the lack of large numbers of patients in the general population, there are few subjects with cylinder amounts in this range to be studied. Not all complications, adverse events, and levels of effectiveness may have been determined.
- You are considering topography-guided LASIK treatment for nearsightedness that is worse than – 9.00 diopters, or nearsightedness with astigmatism that is worse than – 8.00 diopters of nearsightedness or 3.00 diopters of astigmatism. It is unknown whether topographyguided LASIK is safe or effective for you.
- You have large pupils. Before surgery, your doctor should measure your pupil size under dim lighting conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see in conditions such as dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently when the entire prescription has not been fully corrected and perhaps in patients with pupil sizes larger than the treatment area.
- You have any other medical condition that is likely to increase the risk of LASIK surgery or make you an unsuitable candidate for LASIK surgery. Tell your doctor about all your medical conditions.
- You have a history of crossed eyes (strabismus). It is unknown whether LASIK is safe and effective under this condition.
- If you have a decreased vision in one eye, it is unknown whether LASIK is safe and effective under this condition.
- If there is an infection or problem with healing after the surgery, it is more likely that both
  eyes will be affected if both eyes are treated at the same session. If only one eye is treated,
  the difference in vision between the treated eye and the one without treatment might
  make vision difficult. In such a case, you might not have functional vision unless the second
  eye is treated with LASIK or by wearing glasses or contact lenses that compensate for the
  difference.

Your doctor should evaluate you for dry eye symptoms before surgery. You may have dry eye after LASIK surgery even if you did not have dry eye symptoms before surgery.

It is not known whether LASIK with a WaveLight® Excimer Laser System is effective over the long term (more than 12 months).

Adverse Events and Complications: Common risks of LASIK procedures include:

- developing dry eye syndrome, which can be severe;
- · the possible need for glasses or contact lenses after surgery;
- visual symptoms including halos, glare, starbursts, and double vision, which can be debilitating;

and

• the loss of vision.

The following adverse events and complications were reported in the clinical studies for the WaveLight® Excimer Laser Systems:

- Nearsightedness Study: In the myopia (nearsightedness) clinical study, 0.2% (2/876) of the eyes had a lost, misplaced, or misaligned flap reported at the 1 month examination. The following complications were reported 6 months after LASIK: 0.9% (7/818) had ghosting or double images in the operative eye; 0.1% (1/818) of the eyes had a corneal epithelial defect.
- <u>Farsightedness Study</u>: In the hyperopia (farsightedness) clinical study, 0.4% (1/276) of the eyes had a retinal detachment or retinal vascular accident reported at the 3 month examination. The following complications were reported 6 months after LASIK: 0.8% (2/262) of the eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface.
- <u>Mixed Astigmatism Study</u>: In the mixed astigmatism clinical study, two adverse events were reported. One patient suffered from decreased vision in the treated eye, following blunt trauma to the eye 6 days after surgery. The second event involved the treatment of an incorrect axis of astigmatism. The following complications were reported 6 months after LASIK: 1.8% (2/111) of the eyes had ghosting or double images in the operative eye.
- <u>Wavefront-Guided Nearsightedness Study</u>: The wavefront-guided myopia (nearsightedness) clinical study compared subjects treated with wavefront-guided LASIK (Study Cohort) to subjects treated with traditional LASIK (Control Cohort). No adverse events occurred during the postoperative period of the wavefront-guided LASIK procedures. One subject undergoing traditional LASIK treatment was treated on the incorrect axis of astigmatism. The following complications were reported 6 months after wavefront-guided LASIK in the Study Cohort: 1.2% (2/166) of the eyes had a corneal epithelial defect; 1.2% (2/166) had foreign body sensation; and 0.6% (1/166) had pain. No complications were reported in the Control Cohort.

• <u>Topography-Guided Nearsightedness Study</u>: There were six adverse events reported in the topography-guided nearsightedness study. Four of the eyes experienced transient or temporary decreases in vision prior to the final 12 month follow-up visit, all of which were resolved by the final follow-up visit. One subject suffered from decreased vision in the treated eye, following blunt force trauma 4 days after surgery. One subject experienced retinal detachment, which was concluded to be unrelated to the surgical procedure.

#### **Clinical Data:**

<u>Nearsightedness Study</u>: 782 eyes in the myopia (nearsightedness) study were included in an analysis of effectiveness at 6 months after surgery. Of these, 98.3% were corrected to 20/40 or better without wearing glasses, and 87.7% were corrected to 20/20 or better without wearing glasses. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher 3 months after surgery than at baseline: visual fluctuations (28.6% vs. 12.8% at baseline).

<u>Farsightedness Study</u>: 212 eyes in the hyperopia (farsightedness) study were included in an analysis of effectiveness at 6 months after surgery. Of these, 95.3% were corrected to 20/40 or better without glasses, and 67.5% were corrected to 20/20 or better without glasses. Subjects who responded to a patient satisfaction questionnaire before and after LASIR reported the following visual symptoms as "much worse" 6 months after surgery: halos (6.4%); visual fluctuations (6.1%); light sensitivity (4.9%); night driving glare (4.2%); and glare from bright lights (3.0%).

<u>Mixed Astigmatism Study</u>: 111 eyes in the mixed astigmatism study were included in an analysis of effectiveness at 6 months after surgery. Of these, 97.3% were corrected to 20/40 or better without glasses, and 69.4% were corrected to 20/20 or better without glasses. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher 6 months after surgery than at baseline: sensitivity to light (52.9% vs. 43.3% at baseline); visual fluctuations (43.0% vs. 32.1% at baseline); and halos (42.3% vs. 37.0% at baseline).

<u>Wavefront-Guided Nearsightedness Study</u>: The wavefront-guided myopia (nearsightedness) clinical study compared subjects treated with wavefront-guided LASIK (Study Cohort) to subjects treated with traditional LASIK (Control Cohort). 166 eyes in the Study Cohort and 166 eyes in the Control Cohort were included in an analysis of effectiveness at 6 months after surgery. Of the 166 eyes in the Study Cohort, 99.4% were corrected to 20/40 or better without glasses, and 93.4% were corrected to 20/20 or better without glasses. Of the 166 eyes in the Control Cohort, 99.4% were corrected to 20/40 or better without glasses, and 92.8% were corrected to 20/20 without glasses.

In the Study Cohort, subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher 3 months after surgery than at baseline: light sensitivity (47.8% vs. 37.2% at baseline) and visual fluctuations (20.0% vs. 13.8% at baseline). In the Control Cohort, the following visual symptoms were reported at a "moderate" or "severe" level at least 1% higher 3 months after surgery than at baseline: halos (45.4% vs. 36.6% at baseline) and visual fluctuations (21.9% vs. 18.3% at baseline).

Topography-Guided Nearsightedness Study: 247 eyes in the topography-guided nearsightedness study were included in an analysis of effectiveness at 3 months after surgery. Of these 247 eyes, 99.2% were corrected to 20/40 or better without glasses, and 92.7% were corrected to 20/20 or better without glasses. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "marked" or "severe" at an incidence greater than 5% at 1 month after surgery: dryness (7% vs. 4% at baseline) and light sensitivity (7% vs. 5% at baseline). Visual symptoms continued to improve with time, and none of the visual symptoms were rated as being "marked" or "severe" with an incidence of at least 5% at 3 months or later after surgery.

Attention: Please refer to a current WaveLight<sup>®</sup> Excimer Laser System Patient Information Booklet for your procedure for a complete listing of the indications, complications, warnings, precautions, and side effects. Ask your doctor for a copy of the current Patient Information Booklet for your procedure.

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![](_page_14_Picture_1.jpeg)

![](_page_14_Picture_2.jpeg)

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