

# "50 Tough Questions" for Your Doctor ... and Answers by Dr. Wallace

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<u>USAEyes.org</u> (previously known as the Council for Refractive Surgery Quality Assurance, or CRSQA) is a non-profit organization dedicated to providing quality information to people contemplating vision correction care such as LASIK. Dr. Wallace was a CRSQA-certified surgeon from early '03 through early '09. CRSQA developed and published their first "50 Tough Questions" in early '03 to help illuminate some of the features that distinguish the more experienced, committed surgeons from the 'also-rans' that perform LASIK. Over time, the questions have evolved, as have the procedures offered by vision correction specialists.

- 1. How long have you been performing refractive surgeries?
  - I got my initial training and experience in laser vision correction in 1993, in China. Excimer laser treatment did not receive FDA approval for use in the US until 1995. I have performed cataract and lens implant surgery since 1983, refractive lens exchange since about 1992, and phakic IOL (Visian ICL, VeriSyse) surgery since early 2006. I have been performing cataract and lens-replacement surgery since 1981.
- 2. How many laser- and lens-based refractive procedures have you performed total, excluding mechanical surgeries such as Radial Keratotomy ("RK") Astigmatic Keratotomy ("AK"), and Automated Lamellar Keratoplasty ("ALK")?

  I have performed over 19,000 laser corrective procedures (LASIK, PRK) and over 8,000 lens implant treatments. I have performed about 100 Visian ICL treatments, which rely on similar surgical technique as that used in cataract surgery with lens implant.
- 3. How many refractive procedures have you performed in the last 12 months? Approximately 1,000.

implantation, cataract surgery, intraocular lens implantation, and other procedures.

- 4. How many refractive procedures of the exact type you intend to use for me, with the same equipment, and the same refractive error, have you performed?

  Obviously, there is no one answer that would be correct here. We are certified in and proficient with LASIK, PRK (also known as "ASA" or Advanced Surface Treatment, LASEK, epi-LASIK), phakic lens
- 5. What percent of your refractive surgery patients receive Uncorrected Visual Acuity (UCVA) of 20/40 or better?
  - For LASIK, correcting nearsightedness and astigmatism, with a look-back period of over one year, we can now say that 100% of our patients achieve 20/30 or better uncorrected acuity; and nobody is 20/40 or worse. Please refer to our outcome statistics, published on our website at http://www.la-sight.com/los-angeles-lasik-prk-eye-surgery/lasik-results.aspx.

For Cataract or Refractive Lens Exchange, 99% For Visian ICL, 100%

6. What percent of your refractive surgery patients receive UCVA of 20/20 or better?

LASIK: For patients with myopia up to 6.00 diopters and astigmatism up to 2.5 diopters, 98.3% achieve 20/20 unaided acuity with a combination of primary treatment and enhancement treatment, should that be desired or advised. One additional qualification is that the potential visual

acuity of each eye was correctable to 20/20 prior to treatment. Above -6.00 diopters of myopia the percentages drop slightly. Farsightedness treatment up to +3.00 diopters also achieves excellent results. For further details, please refer to our web page listing published outcome statistics, at <a href="http://www.la-sight.com/los-angeles-lasik-prk-eye-surgery/lasik-results.aspx">http://www.la-sight.com/los-angeles-lasik-prk-eye-surgery/lasik-results.aspx</a>.

Cataract or Refractive Lens Exchange: 97% of eyes attain 20/20 after treatment.

**Visian ICL:** 100% of patients that were correctable to at least 20/25 before surgery have obtained 20/20 or better acuity with ICL care.

**Qualifying statement:** All results assume that there is no vision-limiting pathology or condition (retinal problem, lazy eye, corneal scarring, etc.) affecting visual performance. Eyes that have these conditions can receive care and achieve excellent results, but are excluded from this statistical analysis.

- 7. What percent of your refractive surgery patients report complications six months after surgery? This includes complications such as halos at night, starbursts, dry eye, etc.

  Well below 1%, perhaps as low as 1 in 600 to 1 in 2,000. I have suggested to CRSQA that this question be more specific, in order to distinguish, for instance, between "a little glare at night" and extremely severe glare making driving difficult". If you ask carefully, most people that wear contact lenses will notice some halo around headlights and streetlights. The amount of halo should not be significantly worsened by laser vision care. One of the reasons we use the Wavelight Allegretto laser in our practice is that this laser has demonstrated superior outcomes compared to other lasers with respect to glare, halo, and overall quality of night vision. In other words, people see better, and observe less glare and halo at night, due to the wavefront guided dynamics of Allegretto treatment.
- 8. What percentage of refractive surgery candidates do you decline?

In this practice, there are several reasons why we might advise against vision correction care. In aggregate, we find that about 6% of people we evaluate are not good candidates for corrective treatment. Reasons include (a) Prescriptions outside the acceptable range for laser treatment; (b) Keratoconus, or other cause of topographic asymmetry; (c) Unacceptably thin corneal tissue for the desired correction; (d) Unreasonable expectations; (e) Inability of laser treatment to restore close focusing (i.e. it is not a treatment for presbyopia); (f) Presence of other vision-impairing conditions including cataract, retinal problems, and other issues. Professionals will sometimes differ in their opinions about individual cases, though. I have done corrective surgery in certain cases where another surgeon has counseled that someone is not a good candidate, and have achieved very good results. I have also advised certain people that I did not think they were good candidates, when another surgeon has advised differently. As of November 2012, I advise ICL care in lieu of LASIK when the degree of myopia exceeds -9.50 diopters or when corneal thickness is not adequate to render care for the necessary LASIK treatment if below -9.50 diopters. This occurs in less than 2% of LASIK evaluations overall.

9. Have you had a refractive surgery malpractice claim settle for or award greater than \$30,000 to any plaintiff?

No. In over 25 years of practice I have not had a single malpractice claim result in any payment to any plaintiff.

10. Will you assess the wavefront pattern (measure the higher order aberrations of the eye) prior to recommending refractive surgery?

There is some confusion about "wavefront treatment". This is not available at all with Nidek lasers (those at most of the discount centers). Using the Visx laser, wavefront-guided treatment (marketing term "Custom LASIK" or "CustomVue") affords slightly better results compared to "conventional" LASIK without wavefront measurement. The laser that we use, the Wavelight Allegretto laser, performs "wavefront-optimized" treatment, which has been shown to be as good, if not better, than wavefront-guided treatment on a Visx laser. Wavefront testing is a component of every evaluation for laser corrective treatment at LA Sight. Every laser treatment rendered with our Wavelight Allegretto laser is either "Wavefront Optimized" or "Wavefront-Guided". This laser has demonstrated the best track

record of performance in the industry, with the highest percentage of "20/20" results, the lowest rates of re-treatment (enhancement) and the best quality of vision, day or night. The Wavelight Allegretto is the only laser having presented data to the FDA showing that night vision quality after treatment was better than it was best-corrected before treatment with either eye glasses or contact lenses. This is a huge and important fact, clearly demonstrating the superior quality of visual outcomes over other laser instruments, with attendant reduction in complaints of glare, halo, and contrast sensitivity reduction that are reported with other lasers.

## 11. What percentage of your patients have had secondary procedures or "enhancements"? Why this amount?

In the range of 2.6% overall. The national 'norm' for enhancement after laser treatment is ~8%, I am told. Some surgeons seek to keep their enhancement numbers low by discouraging patients from having such care. This is silly. I will perform enhancement if it is desired by and in my opinion will benefit the patient. Our enhancement rate with the Allegretto laser is significantly lower than when we used either the Visx or LADAR lasers. For patients with nearsightedness up to -6.00 and astigmatism up to -3.75, the aggregate enhancement rate within 12 months is now 1.2%

### 12. What is the worst refractive surgery outcome experienced by your own patient? How was it handled?

Several patients have experienced significant flap wrinkling leading to reduced vision and need for one or more corrective procedures. One patient has required corneal transplantation as the result of an unanticipated complication of PRK. One patient developed complications related to pre-existing epithelial basement membrane dystrophy ("EBMD") after LASIK; needing supplemental treatment to restore visual stability and ocular comfort. No patient has required cataract surgery, retinal detachment repair, or other invasive surgery as a consequence of laser vision correction care in my hands, to my knowledge. No patient has lost significant vision or become blind as a result of corrective care rendered by me.

#### 13. If you intend to use an excimer laser, is it broadbeam, variable spot, or flying spot?

This question is obsolete. I use the Wavelight Allegretto laser which is a scanning-spot laser. With this laser we observe greater accuracy, greater reproducibility, higher percentage of patients achieving 20/20 acuity, and better quality of night vision compared to other excimer lasers. By comparison, the Visx is a modified "broad beam" laser.

14. Have you ever had malpractice insurance coverage denied?

No.

- 15. Are you currently under investigation by the agency that provides the license that allows you to perform refractive surgery? Has this license ever been revoked, suspended, or otherwise restricted? Are you on any sort of license probation?

  No.
- 16. Have you ever had hospital or surgical facility privileges revoked?

No.

17. Have you ever had your DEA certification revoked, suspended, or restricted?

No.

18. Have you ever been convicted of a felony?

No.

- 19. Have you ever been arrested for being under the influence of any controlled substance?
- 20. Have you ever been treated for substance abuse or mental defect as an adult? No.
- 21. Have your ever been refused participation as a provider in a health insurance plan? No.
- 22. Is the laser and equipment you will use specifically approved by the FDA for the recommended procedure and intended parameters? If no, explain why it is not FDA approved and/or off-label use?

**Yes.** If we ever discuss 'off-label' use outside approved FDA parameters, we explain this up front and obtain an additional "off-label" consent. In my practice, this occurs with a frequency of less than 1 in 500 cases.

23. If an enhancement is required, what will you charge for the additional procedure?

Our fee used to be \$5,400 for both eyes, and at that fee we covered costs of enhancement care for one year after primary surgery. With our current pricing structure being much lower, our fee for enhancement care is \$250 per eye if done within one year of original care.

- 24. If an optometrist will be performing pre- and/or postoperative care, can I see you at any time without my optometrist's authorization?

  Yes, of course.
- 25. What should I expect my vision to be like for the first few weeks after surgery?

After LASIK, vision can be clear almost right away. For some, especially those with high corrections to start with, vision can be somewhat blurry and can fluctuate from morning to evening or day to day for up to a few weeks. After lens implant care and ICL, vision can be very clear right away, and gets better over 12 hours. Some people need both lens-based care (IOL or ICL) and LASIK if astigmatism needs to be treated; we usually perform the laser treatment about 3 weeks after lens implant care.

26. Will you perform a complete refractive examination including evaluating the medical health of my eyes both before and after surgery?

Yes. If the eyes appear healthy at the comprehensive exam before corrective surgery, we would advise a subsequent *complete* exam no later than at the one-year anniversary after care. This exam can be performed by our office, by the eye care professional that may have referred you to us, or by any competent local eye care professional.

27. Will my vision fluctuate after surgery? How long is the healing period?

See question 25, above. Healing varies depending upon amount of correction, age of patient, and other factors. Typically, optical stability occurs within several days, not weeks.

28. Will you perform a contrast sensitivity test before and after the surgery?

Typically not. We are one of a very few offices in Southern California that can do Pelli-Robson contrast-sensitivity testing, and we do so when necessary or requested. The US Customs Service, for instance, requires such testing after laser corrective surgery. See <a href="www.la-sight.com/measuring\_vision.aspx">www.la-sight.com/measuring\_vision.aspx</a>.

29. Will you perform a glare sensitivity test before and after the surgery?

At present, there is no standardized method of glare testing, and there are no "normal" values for such assessment. Therefore, we do not do such testing, and in my professional opinion it is not an appropriate component of even the most conscientious evaluation for laser corrective care.

30. Will you perform corneal topography before and after the surgery?

Yes. We perform topography with two separate instruments as a part of our consultations, and as a part of almost every post-op visit.

31. If you recommend LASIK, will you use a laser to create the flap or a mechanical microkeratome?

We use the Bausch & Lomb Hansatome XP microkeratome for the overwhelming majority of our LASIK procedures. This is the most widely-used keratome in the industry. We also have IntraLase capability in our office so can offer "All-Laser LASIK". Frankly, I think that "All-Laser LASIK" is mostly marketing hype, and creates additional cost burden (about \$300 per eye) for the prospective patient, without any significant increase in quality of visual outcome. While the system has some merit, it also carries some risk. See <a href="https://www.la-sight.com/all\_laser\_lasik.aspx">www.la-sight.com/all\_laser\_lasik.aspx</a>.

32. Will you perform a test to determine tear volume (Schirmer) and tear breakup time

#### ("BUT") prior to making a recommendation about surgery?

I typically do not perform such testing on a routine basis. I perform Schirmer testing if I recognize evidence of ocular surface disease or "dry eye" symptoms at the initial evaluation. I will always do this test when requested or if there is any reason for concern. Tear breakup time is not standardized, and is influenced by many factors including ambient temperature and humidity, the lipid component of tear film, and meibomian gland function. The results of such testing are vague and usually inconclusive. Reasonable professionals and experts differ in their opinion of the significance of tear BUT testing.

## 33. Will you measure the size of my pupils when naturally dilated in a dimly lit room prior to making a recommendation about surgery?

We measure pupil size more accurately, using either a Neuroptics digital instrument or a Colvard pupillometer, which is a night-vision scope adapted for this purpose. See <a href="www.la-sight.com/vision\_consultation.aspx">www.la-sight.com/vision\_consultation.aspx</a>.

#### 34. Will you use a different microkeratome blade (LASIK only) for each eye?

The standard of care in the industry is to use one blade for each patient, if both eyes are operated at the same time. We can use one per eye if requested.

# 35. Will you require me to be without contacts for a period of time before the examination that will determine final calculations? What is this period of time?

Yes. Soft contacts should be removed a day or two before surgery. RGP (gas permeable) lenses should not be worn for several weeks before surgery. Older style PMMA (hard plastic) contacts may need to be discontinued for a month or more if any evidence of corneal warpage is suspected or identified.

### 36. Will my treatment prescription be based on dilation (cyclopegic) refractive error as well as manifest refractive error?

Usually, yes. Cycloplegic refraction is performed for almost all patients before laser corrective surgery. Exceptions might include patients above 55 years of age, and patients that have previously had cataract surgery. When working with referring doctors who we know and trust, if this testing has already been performed, we do not necessarily repeat it.

### 37. Will you measure the thickness of my cornea prior to making a recommendation about surgery?

Yes. Corneal thickness measurement is an integral component to all corrective surgery evaluations.

### 38. If an excimer laser is to be used, what size will the optical ablation zone be, excluding the transition zone? Is this larger or smaller than my naturally dilated pupil?

We typically use an optical zone diameter of 6.5mm. The Wavelight Allegretto laser has the capability to treat up to an optical zone diameter of 8.0mm. The goal is to have the optical zone treated be at least as large as the maximum diameter of the naturally pupil in dark conditions.

# 39. Is a patient with more than 10 diopters myopia, more than four diopters hyperopia, or more than five diopters astigmatism a good candidate for laser corrective surgery?

At the ranges cited, I would not consider such patient a good candidate for laser corrective surgery. People with refractive errors above -9.00 diopters of myopia (nearsightedness) may be good candidates for procedures including Visian ICL care, or clear lens replacement (cataract-style surgery with IOL implantation), for instance. See <a href="https://www.la-sight.com/icls\_phakic\_lenses.aspx">www.la-sight.com/icls\_phakic\_lenses.aspx</a>.

#### 40. How often and when will you perform postoperative examinations?

We typically recommend visits at 1 day, 2 weeks, 2 months, 6-8 months, and yearly after surgery. We are available any time for questions, concerns, difficulties or problems.

#### 41. When will you provide me with a copy of your written informed consent?

We offer this on the day these materials are presented and reviewed. We would gladly provide this at any other time. We even have these materials posted on our website, and if you desire we can point you to the link to download.

42. Will you provide contacts for me to wear to simulate monovision prior to surgery? How long will you want me to wear these contacts before I make my decision about monovision?

**Absolutely. I recommend that people try contacts before LASIK if they have not already experienced monovision correction.** Typically we do not charge any extra for the extra care associated with such contact lens trial. I advise holding off on any surgical decision until you are comfortable with the vision obtained by such trial. We do not find that glasses as a monovision trial are helpful, as the vision obtained is different when corrected in front of the eye (as in glasses) compared to when it is corrected on the eye (as in with contacts or corrective surgery).

43. Will you provide me the names and contact information of at least ten previous patients who have had the exact same surgery with similar refractive error?

If you wish to speak with other patients, we will gladly arrange this. To safeguard the privacy and confidentiality of our current patients (including you!) we would not give out personal information (such as name and phone number, etc.). A member of my office staff would call or email such patients, ask their permission, and then either (a) give them your number to call, or (b) give you their contact info if approved by them. You can also browse our extensive list of over 250 Patient Profiles at <a href="http://www.la-sight.com/patient\_profiles.aspx">http://www.la-sight.com/patient\_profiles.aspx</a>.

44. Will you allow me to observe a surgery?

Yes. We encourage this for interested clientele. Our laser room has large picture windows to facilitate this process. We are also one of the only practices in the world to make digital video recordings of almost all treatments performed at our center. This is a part of our commitment to exceptional accountability, and also assists when I teach other surgeons.

45. Does my occupation, leisure activities, and hobbies have any bearing on my candidacy for refractive surgery?

Yes, absolutely. We ask about this and take it all into consideration as a part of the initial evaluation. Think of the work we do as being analogous to that of a custom tailor, personalizing treatment to suit the visual needs of our clients.

- 46. Does my medical and medication history have any bearing on my candidacy for refractive surgery?

  Yes.
- 47. Does being pregnant or contemplating pregnancy have any bearing on my candidacy for refractive surgery?

  Yes.
- 48. Who will pay for multiple corrective lenses if I experience fluctuation in visual acuity while healing?

A very small minority of patients (one in a few hundred) may need or benefit from use of glasses after laser corrective surgery, for a short term. If this is necessary at all, our office will typically offer to cover the cost of one pair of lenses. We do not operate our own optical dispensary, but can refer you to one of the many optical shops or optometry practices we work with to facilitate this.

49. Are there any reasons why I would not have excellent refractive surgery results?

I would offer that even in the most capable surgeon's hands, not every patient achieves "fairy tale perfect" results. Understanding the benefits, risks and limitations of laser vision care is an important part of the informed consent process. I point out that statistics may be useful when discussing large groups, but is not at all helpful in individual cases. If laser corrective care were 99.99% perfect (which it is not!), but if you are among the 0.01% for whom the results are unsatisfactory, for you the complication rate is 100%.

50. What certification do you hold, if any, from the American Board of Ophthalmology, the American Board of Eye Surgery, and/or similar entities?

I am board certified by the American Board of Ophthalmology.