

**STATE OF VERMONT
BOARD OF MEDICAL PRACTICE**

In re:)	MPC 15-0203	MPC 110-0803
)	MPC 208-1003	MPC 163-0803
David S. Chase,)	MPC 148-0803	MPD 126-0803
)	MPC 106-0803	MPC 209-1003
Respondent.)	MPC 122-0803	MPC 89-0703
)		MPC 90-0703
)		MPC 87-0703

**DR. CHASE’S OPPOSITION TO THE STATE’S OMNIBUS
MOTION IN LIMINE**

Now comes the Respondent, David S. Chase, M.D., by and through counsel, and hereby opposes the State’s omnibus Motion in Limine.

I. Introduction.

The State wants the Board to hear only one side of this case. It has filed a Motion by which it seeks to both prevent the Board from hearing some of the most important evidence of Dr. Chase’s innocence and to stop Dr. Chase from confronting and cross-examining the State’s evidence against him. While the State’s proposals would result in a shorter hearing – no doubt a tempting proposition – they would also result in reversible error that would violate Dr. Chase’s statutory and constitutional rights, breach the rules that govern this Board’s proceedings, and lead to a reversal by the Supreme Court. The State’s effort to stop the Board from seeing and hearing live witnesses on both sides of this case speaks volumes of the merits of the State’s charges. In the end, there are no shortcuts to a just and fair conclusion in this matter. The Board should deny the State’s Motion.

II. Factual Background.

In order to understand why the State’s various motions enjoy no legal or factual support, it is first necessary to understand the basic medicine and science implicated in the State’s allegations that Dr. Chase was wrong when he made the complex decision to offer cataract surgery to the 12 patients named in the Superceding Specification of Charges.

A. Cataracts and Contrast Sensitivity.

A cataract is an opacity in the natural lens of the eye. Not all cataracts require surgery; some may cause little or no significant visual disability due to their nature or location. In fact, even the most severe cataract need not be removed if the patient is willing to live with the visual disability it causes. Conversely, cataract surgery is appropriate whenever a cataract causes a patient visual symptoms that do not allow the patient to comfortably perform occupational or recreational tasks that he or she needs or wants to perform. According to the American Academy of Ophthalmology (“AAO”), the largest and most conservative professional organization of ophthalmologists, cataract surgery is medically necessary when “visual function no longer meets the patient’s needs and . . . cataract surgery offers a reasonably likelihood of improvement.” *American Academy of Ophthalmology, Preferred Practice Pattern, Cataract in the Adult Eye*, at 15 (2001), a copy of which is attached hereto as Ex. A.

Vision has many components. One of those components is the ability to distinguish small, high-contrast objects, like a black cat on a white snowbank. That component of visual function is normally measured by the traditional eye chart, called a Snellen chart,¹ which consists of dark black letters of various sizes on a bright white background. A Snellen chart is also sometimes called a “Big E Chart,” in reference to the large letter “E” at its top. A Snellen score is normally expressed as a fraction, such as 20/20, 20/25, or 20/30.

A separate component of vision is contrast sensitivity, the ability to distinguish between objects of similar contrast, such as a grey truck traveling through fog, or the edge of a curb from the pavement beyond. The Snellen chart, which tests only a patient’s ability to resolve small black objects on a white background, is a poor test of this visual component. Vision scientists have

¹ The Snellen chart is named after its founder, Dr. Snellen, who invented the black-on-white letter vision test in 1862. It has remained virtually unchanged since then.

developed a number of ways to measure a patient's contrast sensitivity, including the use of low contrast letter charts and grey-on-grey sine wave gratings. These contrast sensitivity tests ("CST") are accepted as valid by doctors and insurance companies alike. A contrast sensitivity score may also be expressed as a fraction, such as 20/20, 20/25, or 20/30.

Cataracts may cause a loss of Snellen visual acuity, a loss in contrast sensitivity, difficulty seeing in bright or dim light, and problems with color perception among other symptoms. A loss in contrast sensitivity due to a cataract may be largely independent of a loss in Snellen visual acuity. As a result, a cataract patient may experience a loss of real world visual function that does not cause the patient a significant drop in visual acuity as measured on the Snellen chart. In a clinical practice, these patients may obtain very good Snellen vision scores, but nonetheless experience poor vision while performing everyday tasks. They may complain of significant visual problems such as poor quality vision, difficulty driving, or difficulty reading in dim light, among others.

In addition, because a cataract scatters light within the eye, cataract patients often experience their symptoms only, or most severely, in the presence of a glare source, such as bright sunlight or oncoming headlights. Vision tests are normally administered in a darkened exam room, with no source of external light. As a result, they do not replicate most real world visual conditions and particularly the conditions that cause cataract sufferers to experience significant symptoms. To remedy this limitation, ophthalmologists simulate glare in many different ways. One way of simulating glare is through use of a brightness acuity tester ("BAT"), which produces a hemisphere of light through which a patient can view different vision tests, including both the Snellen and CST.

B. Cataract Surgery.

Cataract surgery is the single most common surgery performed in the United States, except for routine circumcision. Even the State's experts agree that it is also one of the most safe and effective. During cataract surgery, the ophthalmologist removes the cloudy natural lens of the eye

and replaces it with a synthetic lens, called an intraocular lens (“IOL”). The IOL has two main advantages over the natural cataractous lens that it replaces. First, it is clear rather than cloudy, and therefore eliminates any blurriness or light scattering caused by the cataract. Second, each patient receives an IOL with a refractive power, or prescription, calculated to correct for any nearsightedness or farsightedness that the patient experienced prior to surgery. As a result, after successful cataract surgery, most patients experience clear and crisp distance vision without glasses, even if they needed glasses to see prior to surgery. In this sense, all cataract surgery is also refractive surgery.

The process of removing the natural lens and inserting the IOL is performed in as few as five or ten minutes using microscopic incisions and surgical tools that cause very little trauma to the eye. Cataract surgery is performed on an outpatient basis, normally in ambulatory surgery centers rather than hospitals. The patient is normally awake and alert the entire time and walks out of the surgery center at the conclusion of the operation. Many people return to their jobs and recreational activities the very next day.

Many high-volume surgeons perform upwards of 2000 cataract surgeries a year. It is not uncommon for ophthalmologists, including the State’s expert Dr. Patrick Morhun, to perform between 500 and 1000 per year. Dr. Chase performed approximately 300 cataract surgeries per year. Indeed, in the last 2 ½ years of his practice, Dr. Chase performed cataract surgery on 612 of the thousands of patients he saw. Many of these had been diagnosed with cataracts long before. During that time period, he diagnosed another 818 patients has having cataracts, but did not offer them surgery. Medicare pays ophthalmologists approximately \$650 to perform a typical cataract surgery. It also pays the surgical center a fee to compensate it for the expensive equipment, nurses, technicians, and anesthesiology staff that are necessary for the surgery.

C. Dr. Chase's Use Of CST And BAT In Diagnosing Visually Significant Cataracts.

Dr. Chase diagnosed cataracts just like every other good ophthalmologist in Vermont. He performed a full ocular examination, including a microscopic slit lamp examination of the lenses within his patients' eyes. In determining whether his patients' cataracts were causing them significant visual disabilities, Dr. Chase also did what every other good ophthalmologist did: He listened to his patients' subjective complaints regarding their vision and recorded them in his charts, often using questionnaires completed by the patients themselves. In addition, he did something no other ophthalmologist in Vermont did: He tested his patients' contrast sensitivity in the presence of a BAT glare source and recorded those results in his patients' medical charts.

Dr. Chase took this extra step because, as recognized by the AAO, insurers, and countless peer reviewed publications, standard Snellen testing is often a poor measure of visual disability due to a cataract. The AAO's Preferred Practice Pattern for treating cataracts, a copy of which is attached hereto, states that:

Contrast sensitivity testing measures the eye's ability to detect subtle variations in shading by using figures that vary in contrast, luminance, and spatial frequency. ***It is a more comprehensive measure of visual function than visual acuity, which determines perception of high-contrast letters and numbers [by use of Snellen testing].***

American Academy of Ophthalmology, Preferred Practice Pattern, Cataract in the Adult Eye, at 14 (2001) (emphasis added). The Preferred Practice Pattern similarly endorses glare testing, as used either with Snellen visual acuity or contrast sensitivity:

Cataracts may cause severe visual disability in brightly lit situations such as ambient daylight or from oncoming auto headlights at night. Visual acuity in some patients with cataracts is normal or near normal when tested in a dark examination room, but when these patients are retested using a source of glare, visual acuity (or contrast sensitivity) drops precipitously.

Id. Insurance companies, too, have adopted CST and BAT as valid measures of visual function in determining whether or not they will reimburse doctors for cataract treatment.

Contrast sensitivity and glare have been deemed so important to patients' functional vision that the FDA now requires that all new ophthalmic devices be rigorously tested to determine whether they cause a drop in contrast sensitivity in patients, both with and without glare. Although there are several types of contrast sensitivity tests available to clinicians, the FDA requires that ophthalmic device manufacturers use sine wave-based tests, administered with glare, in their studies. The contrast sensitivity test used by Dr. Chase meets the FDA criteria.

D. The State's Charges.

The State has charged Dr. Chase with violating the standards of professional conduct with respect to 12 patients. With respect to each patient, the crux of the State's allegations is that Dr. Chase recommended and/or performed cataract surgery that was not medically necessary and falsified his medical records to make it appear as if the surgery was warranted. As to each patient, the State alleges that Dr. Chase's decision to recommend unnecessary cataract surgery did not meet the applicable standards of care prevailing in ophthalmology. It also contends that Dr. Chase's surgery recommendation as to each patient went beyond negligence, and constituted "willful," "immoral," and "dishonest" conduct, in violation of 26 V.S.A. §§ 1354(a)(14) and 1398, because Dr. Chase was putting his own profits ahead of his patients' well-being. The State's allegations of purposeful misconduct are crucial to its efforts to permanently suspend Dr. Chase's medical license.

At trial, it is expected that the State will attempt to show that the 12 complaining witnesses were not appropriate surgical candidates because they had good Snellen vision scores. It will also try to demonstrate that Dr. Chase's use of CST with BAT, and his use of the BAT on its brightest setting, had the effect of overstating the extent of these patients' visual disability. As a result, the State contends the CST with BAT scores recorded in Dr. Chase's medical charts were false, indeed purposefully fraudulent. The State has also alleged and will attempt to prove that the 12 patients did not experience the visual symptoms recorded in their medical charts, despite the fact that those

symptoms were often recorded in the patients' own handwriting. Finally, the state will present evidence that it believes demonstrates that Dr. Chase's communications with his patients were purposefully designed to coerce them into having unnecessary cataract surgery. The State's assertions will rise or fall in large part on the medical and scientific validity of Dr. Chase's CST with BAT testing methods, diagnostic techniques, and informed consent procedures, which the evidence will show were performed uniformly as all of the 12 complaining witnesses. In order to prove its case, the State plans to rely upon the testimony of former patients, former employees, and other eye doctors.

D. Dr. Chase's Defense.

Dr. Chase contends that his treatment of the twelve patients was entirely honest, medically and scientifically appropriate, and exceeded the standard of care. Dr. Chase, too, will offer the testimony of former patients, employees, and physician and scientific experts. Dr. Chase's experts will testify, among other things, regarding the medical and scientific validity of the CST and BAT testing that Dr. Chase used to evaluate each of the 12 patients in the Superceding Specification. Based on peer reviewed literature and their own scientific studies, they will establish that Dr. Chase's CST and BAT testing regimen provided him with a far more accurate and comprehensive assessment of his patients' real world disabilities than Snellen testing alone. They will also testify about the proper use and recording of CST and BAT testing and patient complaints, and therefore whether Dr. Chase's practices with respect to the twelve patients were valid in this regard.

Dr. Chase will also offer the testimony of former patients who had very good Snellen visual acuity scores but nonetheless experienced significant real-life visual disabilities due to their cataracts. He will show that these patients' visual disabilities were more accurately captured by their CST and BAT scores and that they benefited enormously from cataract surgery, despite having Snellen vision of 20/20 prior to surgery. This testimony will directly rebut the State's claims that

patients with 20/20 and 20/25 Snellen vision, such as many of those in the Superceding Specification, could not have visual disability warranting surgery. It will also demonstrate that Dr. Chase honestly and properly believed that cataract surgery would significantly benefit such patients, thereby directly rebutting the State's claims that he purposefully and immorally recommended that the 12 patients undergo cataract surgery that he knew was medically unnecessary. To the contrary, these patients show that Dr. Chase reasonably concluded that cataract surgery would alleviate these patients' significant cataract-related symptoms, despite their good Snellen scores. Under the standard of care established by the AAO, this conclusion qualified the 12 patients for cataract surgery.

Dr. Chase, too, will offer the testimony of former staff members. The Board will hear their in-person testimony regarding how Dr. Chase treated all of his cataract patients, including those identified in the Superceding Specification, with care. They will testify about his single-minded dedication to his patients' ocular and overall health and his complete lack of any other motivation in offering cataract surgery to his patients. Together, these witnesses will demonstrate that the 12 patients identified in the Superceding Specification were treated well within the standard of care, and in fact received eye care that was superior to that provided by many other area ophthalmologists.

III. Discussion.

Against this background, the State requests that the Board exclude the testimony of most of Dr. Chase's trial witnesses and admit written transcripts of most of the State's own witnesses to prevent their cross-examination before the Board. In short, the State hopes to stop the Respondent and the Board from closely scrutinizing its own evidence and to keep the Board from even hearing most of Dr. Chase's evidence. Dr. Chase addresses each of the State's specious proposals in the order the State has raised them.

A. This Board Gave The Parties Permission To Supplement Their Witness Lists And Conduct Additional Discovery.

The State first contends that the Board should preclude Dr. Chase from calling at trial any of the witnesses that Dr. Chase disclosed on February 8, 2006, arguing that they were disclosed too late. The State's argument totally ignores the Board's January 13, 2006 Status Conference Report, which gave both parties permission to amend their witness lists and to conduct additional discovery.

On September 16, 2004, the Board stayed this case pending final resolution of the federal criminal charges against Dr. Chase. Dr. Chase spent the next year preparing to defend himself against those charges, which were substantially identical to those contained in the State's Superseding Specification of Charges. On December 18, 2006, after a three-month trial, a federal jury acquitted Dr. Chase.

On January 11, 2006, the parties attended a status conference with the hearing officer in order to determine how to proceed with this case. At that conference, Dr. Chase's attorneys requested an opportunity to update his witness list to reflect the knowledge and information they had gained in the preceding 15 months. The parties and the hearing officer discussed the request at some length. The hearing officer agreed to Dr. Chase's proposal and entered a Status Conference Report and Scheduling Order containing a timeline for further disclosures and discovery. (See January 13, 2006 Status Conference Report, attached hereto as Ex. B.) The schedule, which was "agreed upon" by the parties, (*see id.*) allowed the Respondent to make "any amendments to his witness list, and any revised requests concerning discovery, on or before 2/8/06." (*Id.*) The same schedule allowed the State to make "any revised discovery requests, and any amendments to its witness list, on or before 2/17/06," (*id.*), over one week after receiving Dr. Chase's disclosures.

In compliance with the Statute Conference Report, Dr. Chase amended his witness list on February 8, 2006 to add additional patient, staff, and physician witnesses. The State raised no questions or complaints regarding Dr. Chase's disclosures. The State did not disclose any

additional witnesses of its own. Nor did it seek additional discovery with regard to Dr. Chase's additional witnesses, as clearly allowed by the Board's order. Only now, almost four months later, does the State take the rather bizarre position that Dr. Chase has disclosed his additional witnesses without "explanation or excuse" and in violation of his obligation to "seasonably update discovery."

As noted above, the Board's hearing officer provided Dr. Chase with explicit permission to update his witness list on February 8, 2006. The reasons for allowing Dr. Chase to update his list were as sound as they were obvious. In the year-and-a-half after the Board stayed this case, Dr. Chase and his attorneys conducted substantial investigation into the criminal charges. Much of the information they learned bears directly on the State's administrative charges as well. Dr. Chase must have an opportunity to present, and the Board should want to hear, all of the admissible evidence that bears upon the State's serious charges. To rule otherwise would deny Dr. Chase his constitutional right to present the best available defense and would deprive the Board of the tools to make the best possible decision in this important case.

As the Board's prior Order recognizes, Dr. Chase's additional disclosures were not untimely. From September 16, 2004 through late-December 2005, these proceedings were stayed, and neither party was able to take any action or make additional disclosures. When the proceedings recommenced, Dr. Chase used the first available opportunity – the January 11th status conference – to raise the need to supplement his witness list. He then supplemented his list in compliance with the February 8, 2006 deadline set by the Board, six months before the trial in this case will likely begin. Yet the State raised no objection and chose to forgo its opportunity to conduct additional discovery. It is the State's objection, not the Respondent's disclosures, that is untimely.

The single case the State cites in ostensible support of its motion only serves to highlight the faulty logic of its position. In *White Current Corp. v. VELCO*, 158 Vt. 216 (1992), a party disclosed a new expert witness one-and-one-half years after the disclosure deadline and one day

before trial was to begin. *Id.* at 225-26. The Supreme Court held that the Public Service Board was within its discretion to exclude the expert's testimony in order to "prevent[] surprise" to the party's opponent. *Id.* Here, of course, Dr. Chase supplemented his witness list on the very day the Board instructed, and the State had at least six months before trial to perform additional discovery if it had chosen to do so, but it instead sat on its hands and now claims surprise. The State's claim is not credible, and its supposed legal support could hardly be less relevant.

B. Dr. Freeman Must Be Allowed To Testify.

One of the witnesses that Dr. Chase disclosed on February 28th was James Freeman, MD. The State now argues that Dr. Freeman's testimony should be excluded as irrelevant to the treatment of the 12 patients implicated in the Superceding Specification. Once again, the State is belatedly asking the Board to relieve it of the inevitable results of its conscious decision to forgo additional discovery as to the Respondent's most recently disclosed witnesses.

Dr. Freeman is an ophthalmologist. He testified for nearly three days during Dr. Chase's criminal trial. The subjects of his testimony included the basic principles of vision, vision testing, ocular physiology, and cataracts, the value of contrast sensitivity and glare testing, the validity of Dr. Chase's testing procedures, and his medical recordkeeping. Dr. Freeman then applied that testimony, and the knowledge it represents, to Dr. Chase's decisions to offer cataract surgery to some of the patients implicated in the criminal case. He concluded that Dr. Chase met the standard of care in each instance.

On February 8, 2006, Dr. Chase disclosed Dr. Freeman as an expert witness in this case and indicated that he will provide testimony consistent with his testimony in the criminal case. Dr. Chase offered to provide the State with a transcript of Dr. Freeman's prior trial testimony. The State did not respond to this disclosure in any way. It did not indicate to the Board or Dr. Chase that the disclosure was inadequate or the subjects of the disclosure were irrelevant. It did not seek

to depose Dr. Freeman, as it did with all of the Dr. Chase's other expert witnesses, in order to better understand the substance and bases for Dr. Freeman's anticipated testimony.

Having done nothing to learn more about Dr. Freeman's testimony, the State now seeks to have it excluded entirely. The basis for the State's objection appears to be its misunderstanding that Dr. Freeman will testify regarding Dr. Chase's treatment of particular patients who are not the subject of this case. He will not. As the Respondent's disclosure makes clear, Dr. Freeman will testify regarding the general subjects implicated by the State's charges, as set forth in his voluminous trial testimony. Applying that knowledge to this case, he will also testify regarding the propriety of Dr. Chase's treatment of the 12 patients in the Superceding Specification of Charges, just as he did regarding the patients set forth in the government's criminal Indictment. Some of those patients are the same as those involved in the criminal case, and others are different, but the substance of Dr. Freeman's testimony – that Dr. Chase's practices and surgical decisions were proper – is unchanged and is directly relevant to the allegations the Board must consider. The State simply misunderstands what Dr. Freeman will testify to at trial, and that misunderstanding is a direct result of the State's decision not to conduct any discovery with respect to Dr. Freeman.

To the extent the State claims that its lack of understanding regarding Dr. Freeman's testimony is the product of inadequate disclosures by the Respondent, its position is directly refuted by its own disclosures (or lack thereof) in this case. The State intends to rely upon the expert testimony of a dozen ophthalmologists or optometrists. That expert testimony is essential to its case: Without the expert opinions of other physicians, the State cannot even begin to address its central allegation that Dr. Chase's surgery recommendations were improper. Nonetheless, the State has made no disclosures as to the opinions, or the bases of the opinions, of any of its experts other than Dr. Morhun. In light of the State's failures to disclose, the Respondent took extensive depositions of the State's testifying doctors in order to better understand and prepare to meet their

anticipated trial testimony. Due to his diligence in discovery, Dr. Chase is now prepared to cross-examine the State's experts and to contradict their opinions where appropriate. The fact that the State may not be fully prepared to meet Dr. Freeman's testimony is the sole fault of the State, not Dr. Chase.

In light of the State's complete failure to disclose any expert opinions, it is unsurprising but highly relevant that, in nearly three years of litigation, it has never raised any objection to the adequacy of Dr. Chase's disclosures, which have been far more complete and substantive. While neither party has generally produced expert reports like those normally required in a civil case,² no such reports were ordered by the Board, none are required by the Board Rules, and neither party expected them. As both the State and Board have often pointed out in the past, usually to the detriment of the Respondent, the Rules of Civil Procedure do not apply in this administrative action. The State has never before demanded or provided more complete disclosures and cannot now credibly claim that they are entitled to more than they have received, or provided to the defense, in this case.³

C. The Testimony Of Drs. Javitt, Evans, and Ginsburg Is Highly Relevant And Must Be Admitted.

The State next asks the Board to exclude the testimony of Dr. Jonathan Javitt, Dr. David Evans, and Dr. Arthur Ginsburg as irrelevant to the State's charges. The State's argument betrays a fundamental misunderstanding of what this case, and Dr. Chase's defense, is all about. The

² The exception is Dr. Chase's disclosure of the comprehensive report of Dr. Arthur Ginsburg, one of Dr. Chase's contrast sensitivity experts. Despite the fact that Dr. Ginsburg provided the State with a report in advance of his deposition, exhaustively detailing his opinions and the bases therefore, the State failed to even question him regarding the vast majority of his report or his opinions at deposition.

³ Of course, even if the State were entitled to some additional information regarding Dr. Freeman's testimony (and it is not), it would not be entitled to the exclusion of his testimony at trial. It will likely be three months or more before Dr. Freeman testifies in Dr. Chase's case-in-chief. If the Board found merit to the State's anticipated argument that it was not made aware of the full scope of Dr. Freeman's trial testimony, the only proper remedy would be to order further disclosure and to allow the State to depose Dr. Freeman in advance of his testimony. To exclude his testimony altogether would constitute both a draconian sanction and reversible error.

testimony of these three doctors is directly relevant to the State's primary allegations: that Dr. Chase purposefully recommended and performed medically unnecessary cataract surgery and engaged in other improper diagnostic and informed consent practices with respect to the 12 patients included in the Superceding Specification of Charges. As a result, the Board should deny the State's Motion.

1. Dr. Javitt's Testimony.

Dr. Jonathan Javitt, an ophthalmologist, public health specialist, and epidemiologist, is recognized as a leading expert on issues related to cataract diagnosis and care. He teaches at the Johns Hopkins School of Medicine, has served as a public health and technology expert in two Presidential administrations, consulted with the Department of Health and Human Services regarding cataract care, and performed the single largest study of cataract practices in the United States. As he did in his deposition in this case and at Dr. Chase's criminal trial, Dr. Javitt will testify regarding general principles of ocular health, cataracts, cataract symptoms, and cataract surgery. He will testify that there is a broad range of medically appropriate treatment for cataracts, from surgically conservative to surgically proactive. He will testify, based on his review of certain of Dr. Chase's medical records as well as Dr. Chase's diagnostic procedures, that Dr. Chase's approach to cataract treatment was medically appropriate, contrary to the State's express allegations. He will testify that often patients will not self-report visual symptoms of cataracts and that, following surgery, they often do not recall or accurately report the symptoms that led them to choose surgery, thereby countering the anticipated testimony of the complaining witnesses that they had no symptoms. He will testify that CST and BAT are valuable cataract diagnostic tools and that they are valuable predictors of real-life deficits in functional vision. He will testify regarding a summary of Dr. Chase's medical charts for his surgical and non-surgical patients over the past six years. That summary demonstrates that Dr. Chase's surgical decisionmaking practices as applied to

all of his patients – including the 12 complaining witnesses – were medically sound. He will testify regarding the public health ramifications and benefits of early surgical treatment like that Dr. Chase provided to some of the 12 patients.

2. Dr. Evans' Testimony.

David Evans, Ph.D. is a vision scientist. Vision science deals with the understanding and quantification of visual mechanisms and processes that mediate everyday functional and clinical vision. Vision science is distinct from clinical ophthalmology, which deals with the detection, understanding, and where possible, the treatment of eye disease. However, ophthalmologists rely on vision science every day to aid them in the detection, quantification of visual impact, and treatment of eye disease. Like any medical discipline, ophthalmology applies science to treat patients.

Dr. Evans has a Ph.D. in ocular physiology from Indiana University and a B.S. in human factors engineering from the United States Air Force Academy. The focus of his training was evaluating the relationship between visual function and ocular physiology. After graduating from the Air Force Academy, Dr. Evans joined the Air Force Medical Research Laboratory Aviation Vision Lab, where he concentrated on quantifying and predicting the quality of vision and its relationship to real-world performance. Since 1984, Dr. Evans has played a major role in the commercial development of contrast sensitivity and glare testing products. In 1987, he founded VectorVision, where he developed and patented the first self-calibrating vision testing product. Dr. Evans is currently the President of VectorVision Inc., which sells the particular CST device used by Dr. Chase to evaluate all 12 patients named in the Superceding Specification.

Along with Dr. Arthur Ginsburg, Dr. Evans has demonstrated through peer reviewed studies that contrast sensitivity is a much better measure of many visual functions than is Snellen testing. This proposition is now well accepted within the ophthalmic community. Drs. Evans and Ginsburg

have also demonstrated, through peer reviewed studies and publications, that contrast sensitivity loss correlates better with many real life visual deficits than does Snellen visual acuity. Working closely with medical doctors, Dr. Evans and Dr. Ginsburg have demonstrated the usefulness of CST in detecting and verifying contrast sensitivity loss due to cataracts.

Dr. Evans will testify generally about the scientific validity of CST and its widespread use within the ophthalmic community, both of which are contested by the State. Based on his own published research and that of others, he will testify regarding the limitations of Snellen visual acuity in measuring loss of vision due to cataracts. As the developer of the VectorVision CST, Dr. Evans will testify that, contrary to the Government's arguments, Dr. Chase's use of the device was proper and consistent with the manufacturer's intended purpose and use. Based on his own experience, research, and the peer reviewed and published research of others, he will testify that contrast sensitivity deficits are strongly correlated with real-life problems of functional vision, such as difficulty driving at night or seeing in bright sunlight – the very symptoms reported by many of the complaining witnesses.

Dr. Evans has also reviewed the contrast sensitivity test results of all of the patients in the Supersceding Specification. Based on those scores, and his knowledge of the VectorVision CST, he will testify that the patients had visually significant contrast sensitivity deficits that were properly recorded on the test forms provided by his company. He will not testify regarding that the cause of those patients' deficits was their cataracts, because he is not a medical doctor. Based on his own experiments and experience, as well as the peer-reviewed research of others, Dr. Evans will testify that the use of a high glare source, such as the BAT on its highest setting, will not cause a patient with normal, healthy eyes to experience a visually significant drop in Snellen visual acuity or contrast sensitivity as measured by the VectorVision CST, in direct contrast the State's theory of its case.

3. Dr. Ginsburg's Testimony.

Dr. Ginsburg is also a vision scientist. He has a Ph.D. in biophysics from the University of Cambridge, England, an M.S. in bioengineering from the Air Force Institute of Technology, Wright-Patterson AFB in Ohio, and a B.S. in systems engineering from Widener College. Dr. Ginsburg is the founder and president of the Visual Forensics Corporation. Dr. Ginsburg has devoted most of his career to the research and development of advanced functional vision testing methods and products. In his work as a vision scientist, Dr. Ginsburg routinely tests subjects, develops clinical test equipment and protocols for ophthalmic clinical studies using contrast sensitivity, glare and night driving simulation. Dr. Ginsburg has invented and patented contrast sensitivity and glare test systems and visual analysis software. Like Dr. Evans, he is a member of the FDA subcommittee on vision standards, including contrast sensitivity and glare testing.

Dr. Ginsburg, too, will testify regarding the scientific validity of CST to measure deficits in contrast sensitivity and its ability to overcome many of the limitations of Snellen visual acuity testing. Based on general and well-accepted theories of vision science, Dr. Ginsburg also performed an experiment designed to determine whether or not Dr. Chase's use of CST and BAT on the 12 complaining witnesses was, as the State contends, likely to over-represent contrast sensitivity and glare disability. That experiment, the results of which were disclosed to the defense two years ago, confirmed what Dr. Evans knew from his own experience and peer reviewed literature: In the absence of a light scattering opacity such as a cataract, a person will not register a significant contrast loss on the VectorVision CST. Even utilizing the BAT on its highest setting, as Dr. Chase did, will not cause a person without cataracts to experience a significant decrease in CST as measured by the VectorVision test. This research validates Dr. Chase's use of CST and BAT in evaluating the 12 complaining witnesses.

Dr. Ginsburg then conducted a study designed to demonstrate that Dr. Chase's CST threshold as applied to the 12 patients corresponds to real world functional visual deficits as measured by his FDA approved night driving simulator. Dr. Ginsburg's study, also provided to the defense, showed that the CST threshold that Dr. Chase utilized in helping him diagnose visually significant cataracts correlated with a significant drop in real world driving reaction time. Indeed, Dr. Ginsburg concluded that this threshold was a conservative estimate of real world visual deficits due to contrast sensitivity loss. In short, Dr. Ginsburg's work will establish that Dr. Chase's surgery recommendations to the complaining patients were well-targeted to address real and significant visual deficits, as the AAO's standard for cataract surgery requires.

4. Each Of These Experts' Testimony Is Directly Relevant To Dr. Chase's Defense To The Superceding Specification Of Charges.

The State appears to contend that because Drs. Javitt, Ginsburg, and Evans do not intend to testify as to Dr. Chase's surgical decision with respect to any single particular patient, their testimony is irrelevant to all of those patients. The State's position does not comport with either law or logic, is at odds with the federal court's recent decisions admitting the testimony of the same experts in the criminal case, and is inconsistent with the State's own approach to proving its case. It should be rejected.

As an initial matter, the State's position – that because these three experts do not intend to discuss each of the 12 complaining witnesses individually, their testimony is irrelevant to the care of all of those patients – makes no sense. As the State has alleged and will presumably prove at trial, Dr. Chase employed certain testing, evaluation, and recordkeeping practices in treating his cataract patients. Indeed, the State has made much of the alleged uniformity with which Dr. Chase treated his cataract patients, including those 12 named in the Superceding Specification. The main issue the Board must decide is whether Dr. Chase's practices enjoy medical and scientific support and whether, as a result, they were within the standard of care. As set forth above, Drs. Javitt,

Ginsburg, and Evans will be testifying to those precise topics, addressing the scientific and medical validity of a number of Dr. Chase's testing, recordkeeping, and surgical decisionmaking practices. Dr. Chase will separately show how those practices were followed with respect to all of the 12 complaining patients, and are implicated in each Count of the Superceding Specification of Charges. The testimony of Drs. Javitt, Ginsburg, and Evans will not only assist the Board in determining whether Dr. Chase's treatment of the 12 patients constitutes unprofessional conduct, it is crucial to that decision.

It is for this reason that the United States District Court that oversaw Dr. Chase's criminal case allowed both the prosecution and the defense to present the jury with several weeks of just the sort of testimony offered by these experts. The criminal case was so similar to this one that even the State now argues that transcripts of testimony in that case should be used as evidence here. In an attempt to prove that Dr. Chase's methods of using and recording CST and BAT testing were invalid, the government presented the expert testimony of numerous scientific and medical experts, many of whom had not actually examined Dr. Chase's patients or his charts, but all of whom purported to have some knowledge of and expertise regarding the standards governing CST with BAT testing, clinical cataract evaluation, the medical necessity of cataract surgery, and proper recordkeeping practices, among others. Dr. Chase countered with his own experts, including Drs. Javitt, Evans, and Ginsburg, all of whom were accepted as experts in their fields and provided testimony deemed relevant by the court. While these experts had not examined the patients or the medical records implicated in the criminal indictment, and most did not address the specific care given to the 34 individuals named in the criminal case, their testimony was central to the jury's decision regarding whether Dr. Chase's practices were proper or not, and therefore whether he was criminally liable. They are similarly relevant and important to determining whether Dr. Chase is administratively liable.

Indeed, in putting together its own case, the State implicitly acknowledges that general expert testimony regarding the practices and procedures implicated in the care of the 12 patients is the proper, indeed only, approach to proving or disproving Dr. Chase's administrative liability. The State contends, as it must in order to prevail, that Dr. Chase's testing of all 12 patients was improper. In attempting to prove this fundamental component of its case, the State does not intend to present expert testimony of anyone who has actually examined Dr. Chase's charts as to these patients or performed their own CST with BAT testing on them. Instead, it will attempt to elicit expert opinion on the validity of Dr. Chase's general practices and then show that those practices were applied to the 12 individual patients. This is precisely what Dr. Chase will do through Drs. Evans, Ginsburg, and Javitt. To accept the State's nonsensical argument as to the relevance of Dr. Chase's expert evidence would exclude almost all of the State's own evidence as well.

Finally, the State suggests, without actually arguing or providing legal citation, that Dr. Evans and Dr. Ginsburg cannot testify because they are not medical doctors. The State misapprehends the proposed testimony of Drs. Ginsburg and Evans, neither of whom will offer medical testimony at trial. Moreover, the State's apparent reading of Vermont Rule of Evidence 702 as allowing only medical doctors to testify about human physiology is myopic. Rule 702 is a flexible one and reflects the reality that there are many different kinds of experts capable of testifying as to their different kinds of expertise. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999). Non-M.D. experts, such as physiologists and other biological scientists, are routinely qualified to testify as experts in cases involving medical matters or other cases involving issues of human physiology. *See e.g. Billone v. Sulzer Orthopedics, Inc.*, No. 99-cv-6132, 2005 WL 2044554, at *1,3 (W.D.N.Y. Aug. 25, 2005) (a mechanical engineer with Ph.D. in materials science and engineering, with over 30 years of mechanical engineering experience permitted to testify as expert as to why surgical knee implant failed); *McClain v. Welker*, 761 A.2d 155, 157-58 (Pa.

Super. 2000) (trial court erred in not qualifying as expert a witness based solely on lack of medical training where witness held a Ph.D. in neuroscience and psychobiology, had focused his career on brain function and behavior, had written numerous articles, and conducted research, all of which focused upon brain dysfunction); *see also Adel v. Greensprings of Vermont*, 363 F. Supp. 2d 683, 689-90 (D. Vt. 2005) (individual with Ph.D in microbiology and immunology, with extensive experience in area of drinking water quality permitted to testify as to cause of plaintiff's Legionnaires' disease). Dr. Evans and Dr. Ginsburg are qualified, both in fact and under the law, to render their scientific opinions in this case. Those opinions are directly relevant to the propriety of Dr. Chase's treatment of the 12 patients in the Superceding Specification. Accordingly, the State's motion to exclude their testimony, and that of Dr. Javitt, should be denied.

D. The Testimony Of Former Patients Is Directly Relevant To Dr. Chase's Defense That He Met The Standard Of Care And Did Not Purposefully Recommend Unnecessary Surgery.

The State intends to call 12 of Dr. Chase's former patients in its efforts to prove that his treatment of those individuals constituted unprofessional conduct. At the same time, the State asks this Court to exclude evidence related to Dr. Chase's treatment of anyone else, including the former patients on the Respondent's witness list. In support of its request, the State "assumes" that Dr. Chase is calling those patients in order to testify as to their "subjective experiences" with Dr. Chase and that, as a result, their testimony will not make "the existence of any fact that is of consequence . . . more or less probable." (Motion at 12.) Both the State's assumption and its legal conclusion are incorrect.

Dr. Chase has identified a number of former patients that may testify during his case-in-chief at trial. None of those patients will simply provide evidence of his or her "subjective experience" with Dr. Chase. Instead, each of those patients will offer testimony that is directly relevant to rebut the State's assertions. For instance, the crux of the State's argument is that Dr.

Chase fell below the standard of care when he recommended cataract surgery to patients who had good Snellen vision scores. In order to counter this evidence, Dr. Chase will call a number of former cataract patients who experienced disabling real-world visual symptoms, despite the fact that they achieved good Snellen scores when tested in Dr. Chase's office. Dr. Chase alleviated these patients' symptoms through cataract surgery. Although many of these patients' Snellen vision scores were identical before and after surgery, they will testify that their vision and ability to function in the real world is significantly improved. As noted earlier, under the standard of care as defined by the American Academy of Ophthalmology, cataract surgery is medically necessary when "cataract surgery provides a **reasonable likelihood of improve[ing]**" a patient's significant visual problems. *American Academy of Ophthalmology, Preferred Practice Pattern, Cataract in the Adult Eye*, at 15 (2001). Evidence of other former patients' symptoms, vision scores, treatment recommendations, and results demonstrates the reasonableness of Dr. Chase's belief that the 12 patients in the Superceding Specification, many of whom had similar symptoms and similarly good Snellen test scores, would also benefit from cataract surgery. It is therefore directly relevant to proving that his treatment of those 12 patients met the standard of care, in direct contravention of the State's explicit allegations.

These patients' testimony will also directly contradict the State's contention that Dr. Chase's CST and BAT testing overstated his patients' real-world disability. Like the 12 complaining witnesses, many of the patients to be called as witnesses by Dr. Chase had very poor CST with BAT scores, despite their good Snellen scores. These patients will testify that their poor CST with BAT scores more accurately reflected their real-world visual difficulties, further bolstering the propriety and reasonableness of Dr. Chase's decision to place reliance on those same scores with respect to the State's 12 complaining patients.

This same patient evidence will show that Dr. Chase lacked the purposeful intent that the Superceding Specification alleges. The State has not just charged Dr. Chase with failing to meet the standard of care. It has charged him with purposefully recommending unnecessary cataract surgery to each of the 12 patients, presumably in order to line his own pockets at the expense of those patients' or their insurers. Objective evidence that, through cataract surgery, Dr. Chase significantly improved the vision of other patients with good test scores but poor real-world vision is highly probative of his intent in offering surgery to the government's similarly situated 12 patients. It tends to show that he honestly believed that he could improve the vision of the complaining witnesses, in direct contravention of the State's argument that he offered them cataract surgery even though he knew it would not help them.

Other former patients will offer testimony aimed at rebutting different portions of the State's case. For instance, the government contends that Dr. Chase gave his patients "second opinions" as part of a "spiel" designed to coerce them into having cataract surgery that they did not need. His former technicians will testify that he gave a similar presentation to most of his potential cataract surgery patients. While the State's complaining witnesses will no doubt testify that they felt that Dr. Chase's presentation coerced or tricked them into having surgery, the former patients called by Dr. Chase will testify that the very same presentation provided them with all of the information they needed to make an informed and pressure-free decision regarding the propriety of cataract surgery. The testimony of these patients will directly rebut the State's position that Dr. Chase's communications with his patients, including the 12 complaining witnesses, were either purposefully or actually coercive.

Still other patients will demonstrate that Dr. Chase did not make his cataract surgical recommendations out of a profit motive, as the State contends. These patients will testify that Dr. Chase offered them free care or recommended cataract surgery for which he knew he would never

receive compensation. As every court and commentator to confront the issue has determined, motive is always relevant because it demonstrates the probability of action. *See, e.g.* Wigmore on Evidence, vol. 1, § 118 (Supp. 2001); *see also United States v. Chas. Pfizer & Co.* 281 F. Supp. 837, 848 (S.D.N.Y. 1968); *People v. Wallace*, 217 N.Y.S. 244 (1926) (because motive shows “the probability of appropriate ensuing action, is always relevant”). But it is particularly so where, as here, the State has specifically accused Dr. Chase of acting out of an “immoral” motive in recommending cataract surgery to his patients against their medical interests. The patients to be called by Dr. Chase show that he lacked any such motive and that his sole intent was to provide all of his patients, including the 12 complaining witnesses, with the best possible cataract care, whether or not he was likely to receive a dime in return.

The State’s concern that the testimony of these former patients will unduly prolong the trial is baseless. Each of these witnesses will testify for approximately 10 to 20 minutes, just as they were allowed to testify in the criminal trial, where intent and motive were also at issue. While very important, their testimony will be among the least time-consuming that the Board hears.

For all of these reasons, the testimony of Dr. Chase’s former patients is directly relevant to the State’s charges and Dr. Chase’s defense. The Board cannot preclude Dr. Chase from offering this important evidence.

E. The State Cannot Shield Its Witnesses From Cross-Examination Without The Consent Of The Respondent.

Many of the patient, staff, and physician witnesses identified by the State previously testified at Dr. Chase’s criminal trial, where he was acquitted of all of the charges against him. Although the State has repeatedly argued to the Board that the criminal and disciplinary cases are entirely different, it now claims that “the testimony provided by these witnesses in the criminal trial is essentially the same as the testimony that would be elicited” in this disciplinary case. (Motion at 13.) As a result, it seeks permission to provide the Board with written transcripts of all of that prior

testimony in lieu of live testimony before the hearing panel. If granted, the State's proposal would deprive the Board of the ability to hear and assess the credibility of those witnesses and would shield that evidence from further cross-examination by Dr. Chase. As a result, the Board cannot admit any prior trial testimony over the Respondent's objection. Moreover, many of the State's witnesses gave testimony at the criminal trial that is irrelevant to this proceeding, such as testimony regarding the second opinion examinations of patients not implicated here. Nonetheless, if the State wishes to designate the relevant portions of the trial testimony of some of its witnesses, the defense will consider consenting to their admission on a case-by-case basis if such admission does not compromise the ability of the Board to ascertain the truth.

The State is simply wrong to contend that it can admit the trial transcripts over the Respondent's objection. The State argues that, regardless of what the Rules of Evidence provide, the VAPA "allows the Board to admit otherwise inadmissible evidence 'if it is of a type commonly relied upon by reasonably prudent men in the conduct of their affairs.'" (Motion at 13 (quoting 3 V.S.A. § 810(1).) The government's recitation of this standard, and its quotation from the VAPA, is so selective as to be dishonest. What section 810(1) actually says is this:

The rules of evidence as applied in civil cases . . . shall be followed. When necessary to ascertain facts not reasonably susceptible of proof under those rules, evidence not admissible thereunder may be admitted (except where precluded by statute) if it is of a type commonly relied upon by reasonably prudent men in the conduct of their affairs.

3 V.S.A. § 810(1) (emphasis added). In short, the VAPA allows the Board to receive evidence that would be inadmissible under the Rules of Evidence ***only*** "when necessary to ascertain facts not reasonably susceptible of proof under those rules." The State conveniently omits this prerequisite because it dooms the State's request.

It goes without saying that the Rules of Evidence do not permit a party to simply offer, over objection, transcripts of prior testimony in lieu of live testimony and true cross-examination,

and the State does not argue to the contrary. However, the State has made no attempt to show that the facts it seeks to demonstrate are “not reasonably susceptible of proof” through proper admissible evidence. Nor could it. To the extent the State can prove any of its misplaced allegations, that proof can be accomplished through admissible evidence placed before the Board as required by the Rules of Evidence. As a result, the VAPA explicitly prohibits the Board from granting the State’s request over the Respondent’s objection, no matter how tempting it would be for the Board and the parties to shorten the hearing through the use of prior testimony. While the State is so determined to keep the Board from hearing its witnesses that it is willing to affirmatively misrepresent and disregard the law, the Board cannot be as cavalier.

The State’s citations to caselaw are similarly disingenuous and unconvincing. It points to *In re Segal*, 430 Mass. 359, 364-65 (1999), as standing for the proposition that transcripts from a criminal trial are admissible in lieu of live testimony in a subsequent disciplinary proceeding. The State fails to mention that, in reaching its decision, the *Segal* court relied on the fact that the Massachusetts Administrative Procedures Act explicitly states that the rules of evidence ***do not*** apply to its proceedings. *Id.* at 365 (quoting Mass. General Laws c. 30A, § 11(2)) (emphasis added). Similarly, in *Eichberg v. Maryland Bd. Of Pharmacy*, 50 Md. App. 189, 194-95 (1981), the Maryland Court of Appeals based its decision on a long-established Maryland rule that its “administrative agencies are not generally bound by the technical common-law rules of evidence” and “hearsay evidence is admissible into evidence at administrative hearings.” *Id.* at 193. As set forth above, in drafting the VAPA, the Vermont legislature explicitly rejected this position and made the Rules of Evidence, and their prohibition on hearsay, applicable to this administrative proceeding. The State’s case citations are therefore inapposite at best, dishonest at worst.

The State also totally ignores the VAPA’s explicit guarantee of cross examination: “In contested cases . . . [a] party may conduct cross-examinations required for a ***full and true***

disclosure of the facts” 3 V.S.A. § 810(3) (emphasis added). In ruling on prior motions in this case, the Board explicitly promised that Dr. Chase would have the opportunity to cross-examine the State’s witnesses at trial, stating: “Respondent will have *full opportunity to cross-examine witnesses*” (8/13/04 Decision, at 2 (emphasis added)). If granted, the State’s Motion would rob Dr. Chase of that opportunity and violate the express guarantee of the VAPA and the Board.

While depriving Dr. Chase the ability to cross-examine his accusers in front of this Board would no doubt prove more efficient than an actual contested trial, that efficiency may also come at the expense of Dr. Chase’s due process rights. In *Pointer v. Texas*, 380 U.S. 400 (1965), Justice Black wrote:

There are few subjects, perhaps, upon which this Court and other courts have been more nearly unanimous than in the expressions of belief that the right of confrontation and *cross-examination is an essential and fundamental requirement for the kind of fair trial which is this country’s constitutional goal.*

Id. at 405 (citations omitted) (emphasis added). This belief stems from the idea, deeply rooted in American jurisprudence, that the best way to determine the truth is to allow adversaries to present and test one another’s evidence. *See Lee v. Illinois*, 476 U.S. 530, 540 (1986). The State’s proposal to forego cross-examination, while promoting efficiency, would therefore deprive this Board of perhaps the single most important tool it has in its search for the truth.

The State’s proposal that the parties substitute transcripts of testimony from the criminal trial for live testimony in this matter over the Respondent’s objection is particularly troubling in light of the fact that the federal court that oversaw the criminal trial determined that the trial testimony offered by many of the State’s witnesses was badly tainted by the government’s misconduct. After the government failed to disclose material exculpatory information to the defense, Judge Sessions found that the government’s error infected the entire trial and particularly compromised Dr. Chase’s

right to confront and cross-examine the very experts the State is now trying to prevent him from cross-examining in this case. The Court stated:

Trial practice 101 says tells every lawyer that if they have an important . . . expert witness to be called, . . . that the subject matter of that testimony is used throughout trial. I have no doubt that if the defense knew [about the improperly suppressed evidence], that every one of the [government's] experts . . . would have been asked questions about [that evidence].

(Transcript of 12/8/05 Jury Trial at 4, attached hereto as Exhibit C.) Because Dr. Chase did not know of the suppressed evidence until the end of the trial, his cross-examination of many of the government's expert witnesses was incomplete. Although the federal court was so troubled by the reliability of the government's evidence that it nearly threw out the criminal case on the eve of the verdict, the State displays no similar compunction in seeking to recycle the same tainted testimony without providing the Respondent the opportunity to cross-examine the State's experts with the benefit of the previously undisclosed evidence.

The fact that the State is willing to stoop so low, and to perpetuate the effects of a proven and adjudicated violation of Dr. Chase's constitutional rights in order to avoid having its witnesses testify suggests yet another, hidden reason why the State does not want to actually call its witnesses to testify: The State correctly suspects that they no longer wish to testify against Dr. Chase. Indeed, in recent weeks, some of the complaining patients have informed the Respondent's counsel that they no longer want to pursue their complaints against Dr. Chase. They do not want the State to drag them through yet another trial, particularly after Dr. Chase was acquitted in the first one. Yet the Board has not contacted these patients for almost two years, and has made no effort to determine if they are still interested in pursuing their original complaints, all of which were filed in the immediate wake of the sensational press coverage that attended the summary suspension of Dr. Chase's license. In addition to denying the State's motion, the Board should require the Board to determine whether

its complaining witnesses are even still interested in pursuing their claims. Absent a complainant willing and able to testify at the hearing, the State must dismiss its charges for lack of evidence.

Moreover, much of the prior trial testimony of the State's witnesses is irrelevant to this case. For instance, many of the second opinion doctors and former staff members on the State's witness list testified at the criminal trial about the medical charts and examinations of patients who are not implicated in any way in this case. Their testimony would be both irrelevant and prejudicial if presented to the Board in this case. So far, the State has not specified which witnesses are subject to its request, or identified the particular testimony that it wants to present via written transcripts. As a result, neither the Respondent nor the Board is in a position to evaluate the full import of the State's request.

For all of these reasons, the Board cannot allow the state to substitute trial transcripts for live testimony for a group of unidentified witnesses over the objection of the Respondent. However, Dr. Chase concedes that there may be witnesses whose prior trial testimony and cross-examination were sufficiently complete and reliable that he would consent to its use in this proceeding in the name of efficiency. While it should deny the State's broad motion, the Board should also order the State to specifically identify the witnesses whose trial testimony it would like to admit, along with the portions that it believes are relevant to this case. The defense will promptly respond to the State's request, and the parties can notify the Board if they have been able to reach agreement as to the use of any prior testimony.

F. The State Avoids Calling The Second Opinion Doctors At Its Own Risk.

The State next asks that it be allowed to introduce the medical records of the so-called "second opinion doctors" without calling those doctors to testify regarding their records or their treatment of the 12 patients. Once again, the State can point to no reason why the VAPA does not require it to prove its case in a manner consistent with the Vermont Rules of Evidence, which require

the doctors' testimony to establish the admissibility of the medical records. That said, the Respondent has no objection to admitting the complete medical records of all of the 12 patients' second opinion doctors. Those records simply set forth the second opinion doctors' observations upon examining the patients. They say nothing about what those observations mean. They contain no opinions regarding the propriety of Dr. Chase's testing or recordkeeping. They do not speak to whether Dr. Chase's findings, conclusions, and recommendations met the applicable standard of care. If the State wishes to attempt to satisfy its burden of proof without calling the second opinion doctors to testify regarding their records or their conclusions, Dr. Chase will not stand in the State's way. However, he will also expect the Board to strictly hold the State to its burden of proving all of the charges against the Respondent through competent evidence admitted during the hearing.

G. The Board Must Consider The Admissibility Of Statements Of Counsel On A Case-By-Case Basis.

Finally, the State asks the Board to admit an unknown number of unspecified prior statements of Dr. Chase's attorneys as "admissions" of Dr. Chase. The State misconstrues and oversimplifies (to its own advantage) the rule regarding admissions by attorneys on behalf of their clients. The State is correct that in certain circumstances particular statements by attorneys are treated as admissions of their clients. However, the very authority upon which the State relies makes clear that other statements, such as outlines of anticipated proof, opinions or conclusions of counsel, and statements regarding a theory of the case, are strictly inadmissible. *See* 32 CJS, Evidence, § 451. For each particular statement of counsel, "what constitutes a judicial admission must be decided under the circumstances of each case." *Id.*; *see also Contractor's Crane Serv. v. Vermont Whey Abatement Auth.*, 147 Vt. 441, 451 (1986) (carefully evaluating the particular circumstances of the particular statement prior to deciding its admissibility as a party admission). Unless and until the State specifies the particular alleged admissions it seeks to place into evidence, neither the Respondent nor the Board can meaningfully evaluate the request. The Board must deny the State's

broad request to have unspecified statements of counsel admitted. Instead, it must consider and decide the admissibility of particular statements as the need arises during trial.

Dated at Burlington, Vermont, this 15th day of June, 2006.

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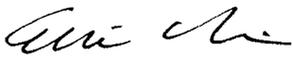
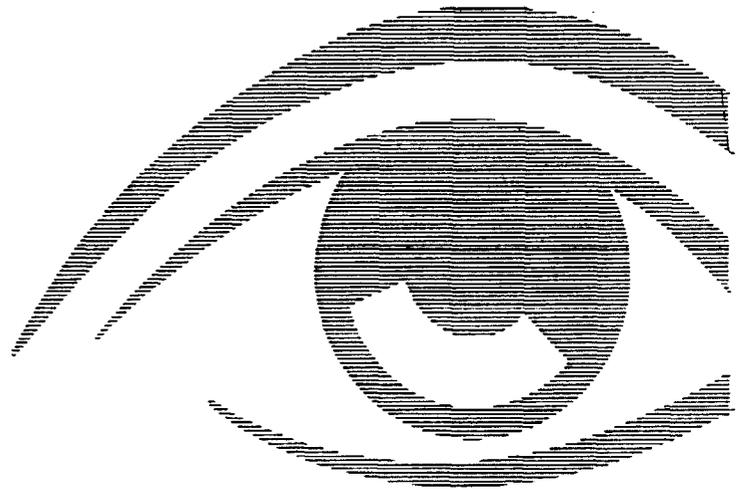
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EXHIBIT A



**CATARACT
IN THE
ADULT EYE**

Prepared by the
American Academy of Ophthalmology
Anterior Segment Panel

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This document is valid for 5 years from the "approved by" date above unless superseded by an earlier revision. All *Preferred Practice Patterns* are reviewed by their parent panel annually or earlier if developments warrant.

As a service to its members and the public, the American Academy of Ophthalmology is developing a series of guidelines called *Preferred Practice Patterns* that identify characteristics and components of quality eye care. These guidelines are particularly timely and appropriate as third-party payors and government grapple with the need to maintain quality care in the face of cost-containment, and as traditional attitudes of Academy members are challenged by changing patterns of health care delivery and emerging market forces.

These *Preferred Practice Patterns* are neither minimal nor aspirational; they represent quality eye care commensurate with present knowledge and resources. They are based on the best available scientific data as interpreted by panels of knowledgeable health professionals. In some instances, the data are particularly persuasive (as with results of carefully conducted clinical trials) and provide clear guidance; in other instances, the panels have had to rely more heavily on their collective judgment and evaluation of available evidence. As better data become available, these guidelines will be altered as appropriate.

The Academy encourages the development of new diagnostic and therapeutic methods that will improve eye care. Innovation in medicine is essential to assure the future health of the American public. *Preferred Practice Patterns* are not intended to stifle such new development, but rather to provide guidelines for current, state-of-the-art eye care.

Preferred Practice Patterns provide guidance for the pattern of practice, not for the care of a particular individual. While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Depending on a host of medical and social variables, it is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the propriety of the care of a particular patient must be made by the physician in light of all of the circumstances presented by the patient. Adherence to these *Preferred Practice Patterns* will certainly not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results.

Preferred Practice Patterns are intended to serve as guides in patient care, with greatest emphasis on technical aspects of our specialty. In applying this knowledge, it is essential to recognize that true medical excellence is achieved only when skills are applied in such a manner that the patients' needs are the foremost consideration. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.

Preferred Practice Patterns are not medical standards to be adhered to in all individual situations. The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.

It is the Academy's intention to update all *Preferred Practice Patterns* as new knowledge dictates. To ensure all Preferred Practice Patterns are current (and, where not, no longer applicable), each is valid for 5 years from the date of issue unless superseded by a revision.

P R E F E R R E D
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CATARACT
IN THE
ADULT EYE



INTRODUCTION

The Preferred Practice Patterns (PPP) series of guidelines has been written on the basis of three principles.

- Each Preferred Practice Pattern should be clinically relevant and specific enough to provide useful information to practitioners.
- Each recommendation that is made should be given an explicit rating that shows its importance to the care process.
- Each recommendation should also be given an explicit rating that shows the strength of evidence that supports the recommendation and reflects the best evidence available.

In the process of revising this document, a detailed literature search of articles in the English language was conducted on the subject of cataract for the years 1996 to 2000. The results were reviewed by the Anterior Segment Panel and used to prepare the recommendations, which they rated in two ways.

The panel first rated each recommendation according to its importance to the care process. This "importance to the care process" rating represents care that the panel thought would improve the quality of the patient's care in a meaningful way. The ratings of importance are divided into three levels.

- Level A, defined as most important
- Level B, defined as moderately important
- Level C, defined as relevant but not critical

The panel also rated each recommendation on the strength of evidence in the available literature to support the recommendation made. The "ratings of strength of evidence" also are divided into three levels.

- Level I includes evidence obtained from at least one properly conducted, well-designed, randomized, controlled trial. It could include meta-analyses of randomized controlled trials.
- Level II includes evidence obtained from the following:
 - Well-designed controlled trials without randomization
 - Well-designed cohort or case-control analytic studies, preferably from more than one center
 - Multiple-time series with or without the intervention
- Level III includes evidence obtained from one of the following:
 - Descriptive studies
 - Case reports
 - Reports of expert committees/organization
 - Expert opinion (e.g., PPP panel consensus)

Evidence is that which supports the value of the recommendation as it relates to the quality of care. The committee believes that it is important to make available the strength of the evidence underlying the recommendation. In this way, readers can appreciate the degree of importance the committee attached to each recommendation and they can understand what type of evidence supports the recommendation.

The ratings of importance and the ratings of strength of evidence are given in bracketed superscripts after each recommendation. For instance, “[A:II]” indicates a recommendation with high importance to clinical care [A], supported by sufficiently rigorous published evidence, though not by a randomized controlled trial [II].

The sections entitled “Orientation” and “Background” do not include recommendations; rather they are designed to educate and provide summary background information and rationale for the recommendations that are presented in the Care Process section. A summary of the major recommendations for care is included in Appendix 1.



ORIENTATION

ENTITY

Cataract in the adult eye (ICD-9 #366.1).

DISEASE DEFINITION

A cataract is a degradation of the optical quality of the crystalline lens through loss of clarity or change in color.

PATIENT POPULATION DEFINITION

Adults (18 years and older) with cataracts.

ACTIVITY

Management of cataracts that interfere with a patient’s functional status or an ophthalmologist’s ability to manage other ocular conditions.

PURPOSE

The primary purpose in managing a patient with cataract is to improve functional vision and the quality of life.

GOALS

- Identify the presence and characteristics of cataract.
- Assess the impact of the cataract on the patient’s visual and functional status and on quality of life.
- Inform the patient about the impact of a cataract on vision, functional activity, and natural history as well as the benefits and risks of surgical and nonsurgical alternatives so that the patient can make an informed decision about treatment options.
- Establish criteria for a successful treatment outcome with the patient.
- Perform surgery when there is the expectation that it will benefit the patient’s function and when the patient elects this option.
- Provide necessary postoperative care, rehabilitation, and treatment of any complications.
- Perform surgery when indicated for management of coexistent ocular disease.



BACKGROUND

EPIDEMIOLOGY

Cataract is the leading cause of blindness worldwide and remains an important cause of blindness and visual impairment in the United States.^{1,4} In the Baltimore Eye Survey, cataract was found to be the leading cause of blindness among the population over 40 years of age, and unoperated cataract was found to be four times more common among African Americans than Caucasian Americans.³ The Salisbury Eye Evaluation Study (n=2,520) found that after refractive error, cataract was the leading cause of visual impairment in African Americans and Caucasian Americans.⁴ In a study of nursing home residents in the Baltimore area, cataract was found to be the leading cause of blindness, contributing to blindness in 30% of eyes.⁵ In this study, blindness was defined as a best corrected visual acuity in the better eye of 20/200 or less. One in six nursing home residents was found to be bilaterally blind overall.

Two large population-based studies performed in the late 1980s, the Beaver Dam Eye Study⁶ and the Baltimore Eye Survey,³ documented the prevalence of cataract in the United States. In the Beaver Dam Eye Study, visually significant cataract in the worse eye was reported in 3.9% of men and 10.0% of women between the ages of 55 and 64, in 14.3% of men and 23.5% of women between the ages of 65 and 74, and in 38.8% of men and 45.9% of women 75 years old or older.⁶ Differences in the definitions of cataract and in the populations sampled in studies have limited the ability to generalize these findings to the population at large.

There are several different types of cataract: nuclear, cortical, posterior subcapsular (PSC), and mixed. Each type has its own anatomical location, pathology, and risk factors for development. Several systems are available to classify and grade lens opacities systematically by imaging. Nuclear cataracts consist of a central opacification or coloration that interferes with visual function. There are different types of nuclear cataracts, accompanied by either brunescence, opalescence, or both.⁷ Nuclear cataracts tend to progress slowly and affect distance vision more than near vision. In advanced cases, the lens becomes brown and opaque.

Cortical cataracts are caused by changes in the ionic composition and hydration of the cortex. Cortical opacities can be central or peripheral, and sometimes may best be appreciated by retroillumination or retinoscopy. Patients with this type of cataract commonly complain of glare. A mature cortical cataract occurs when the entire cortex becomes white and opaque.

Posterior subcapsular cataracts are associated with migration of lens epithelial cells to the PSC area and subsequent enlargement. The cell migration can cause significant visual impairment if it affects the axial portion of the lens. Posterior subcapsular cataracts are found more often in younger patients than nuclear or cortical cataracts. Patients often have glare and poor vision with bright lighting, and their near vision is more affected than distance vision. The Beaver Dam Eye Study found that of the three types, PSC cataract is associated with the greatest rate for cataract surgery.⁸

The Salisbury Eye Evaluation Study found racial differences in the prevalence of different cataract types. African Americans had a four times greater chance of having cortical opacities than Caucasian Americans, and Caucasian Americans were more likely to have nuclear and PSC opacities.⁹ For African Americans and Caucasian Americans, the prevalence of cortical opacities was 40.9% and 14.6%, respectively, in persons 65 to 69 years old, 60.0% and 21.0% in persons 70 to 74 years old, 61.3% and 32.0% in persons 75 to 79 years old, and 67.6% and 41.5% in persons 80 to 84 years old.

RISK FACTORS

Many potential risk factors have been linked with cataract development, but many of the studies are limited in their interpretation because they have not measured cataract development or measured exposure to the risk factor in a standardized fashion.¹⁰ Most studies are observational and can strongly suggest an association but they can not prove a causative effect. Studies of risk factors and cataract development are summarized in Tables 1 and 2 and Appendix 2.

Table 1
Possibly Modifiable Risk Factors for Cataract Development

Cataract Type	Associated Risk Factor	Finding	Type of Study
Subtypes not identified in study	Aspirin use	No evidence of benefit or risk	Randomized trials for 5 years of use; ¹¹⁻¹⁴ observational for 15 years of use ¹⁵
	Antioxidant vitamin and mineral supplement use	Inconsistent evidence of benefit	See Appendix 2
	Inhaled corticosteroid use	Increased risk in patients aged 40 and older	Cohort with nested case-control ¹⁶
Increased risk in patients aged 70 and older		Case-control ¹⁷	
Cortical	Abdominal obesity	Increased risk	Observational ¹⁸
	Ultraviolet B light exposure	Increased risk	Observational ^{19,20}
Nuclear	Smoking	Increased risk	Observational ²¹⁻²⁴
Posterior subcapsular	Systemic corticosteroid use	Increased risk	Observational ²⁵
	Inhaled corticosteroid use	Increased risk in patients aged 49 and older	Population-based cross-sectional ²⁶
	Alcohol use	Increased risk	Case-control ²⁷
Mixed	Ultraviolet B light exposure	Increased risk	Observational ¹⁹

Table 2
Other Risk Factors for Cataract Development

Cataract type	Associated Risk Factor	Finding	Type of Study
Subtypes not identified in study	Diabetes	Increased risk	Observational ^{18,28}
Cortical	Family history	Increased risk	Observational ^{20,29-31}
	Hypertension	Increased risk	Observational ¹⁸
	Diabetes	Increased risk	Observational ¹⁸
	Iris color	Increased risk with brown irides	Observational ³² Case-control ²⁴
Nuclear	Family history	Increased risk	Observational ^{20,31,33,34}
	Diabetes	Increased risk	Observational ¹⁸
	Iris color	Increased risk with brown irides	Inconsistent findings in 3 observational studies ^{32,35,36}
Posterior subcapsular	Iris color	Increased risk with brown irides	Observational ³⁶
Mixed	Iris color	Increased risk with brown irides	Observational ³²

In 1995, a major review of risk factors concluded that age-related cataract is a multifactorial disease and that there are different risk factors for the various types of cataract.³⁷ For all cataract types, lower education status and higher alcohol use appeared to be associated with higher rates of cataract. For cortical and PSC cataracts, risk factors appeared to be a history of ultraviolet exposure, diabetes, and the use of corticosteroids. For nuclear cataracts, smoking seemed to be a significant risk factor. A randomized clinical trial, undertaken as part of the Physicians' Health Study I, did not appear to confirm a relationship between ingestion of aspirin and the development and rate of progression of cataract. A 15-year post-trial follow up of the Physicians' Health Study members indicated no decreased risk of cataract in aspirin users and suggested a small increased risk of cataract in aspirin users.¹⁵

The Barbados Eye Study (n=4,314), based on a predominantly African American and African Caribbean population, found that 14% of the lens changes, primarily cortical opacities, were attributable to diabetes.¹⁸ Hypertension and abdominal obesity were also associated with an increased risk of cortical opacities but were of lesser significance. The high prevalence of diabetes, hypertension, and abdominal obesity could explain the increased rate of cortical cataracts in the African American population, which was found to be four times as high as the rate in the Caucasian participants.¹⁸ In the Beaver Dam Eye Study, an increased glycosylated hemoglobin level was associated with an increased risk of cataracts in patients with diabetes.²⁹

A population-based study of light exposure and cataract (n=2,584) found, after multivariate adjustment, that participants with higher ambient solar radiation had a 2.5 times increased risk of cortical cataracts, a 4.0 times increased risk of mixed cataracts, and a 2.9

times increased risk of cataract surgery.¹⁹ Another population-based study (n=3,271) found an increased risk of cortical cataract with increased average annual ocular ultraviolet B exposure.²⁰

The linkage between use of systemic corticosteroids and PSC cataracts has been well established.²⁵ Recent studies have suggested that prolonged use of inhaled corticosteroids also increases the risk of cataracts.^{16,17,26} A prospective follow-up of participants is planned to confirm these findings.

One population-based study found an association between brown irides and an increased risk of cortical, nuclear, and mixed cataracts;³² however, a longitudinal study did not find an association of iris color with nuclear cataract.³⁵ Another population-based study found that dark brown irides were associated with a higher risk of nuclear or PSC cataract than eyes with lighter color irides.³⁶

A study of age-related cataract in female twins (n=1,012) demonstrated a substantial genetic component to the development of nuclear cataract. The study found that the heritability of age-related nuclear cataracts accounted for almost 50% of the variation in the severity of the disease; age accounted for 38% of the variance among this study population.³³ In the same population, the heritability of cortical cataract was found to be 53% to 58%.²⁹

Two observational studies reported that longer duration of postmenopausal estrogen therapy was associated with a decreased incidence of nuclear cataract.^{38,39} Findings from the Nurses' Health Study indicate a positive association between cataract extraction and coronary heart disease in women.⁴⁰

A 1999 review of nutrition and the eye concluded, "Epidemiological evidence for the antioxidant hypothesis in humans has been conflicting."⁴¹ The Linxian Cataract Studies are two randomized, double-masked, controlled trials with vitamin and mineral supplements.⁴² In the first trial (n=2,141), multivitamin supplements appeared to reduce the risk of nuclear cataracts by 36% for patients 65 to 74 years of age. The second trial (n=3,249) found that the combination of riboflavin and niacin was associated with a 44% lower risk of nuclear cataract in patients 65 to 74 years of age. These studies were performed in a population that had significant nutritional deficiencies and therefore are limited in their applicability. A population-based study (n=3,684) found that the 5-year risk for any cataract was 60% lower among participants who, at follow-up, reported more than 10 years' use of multivitamins or any supplement containing vitamin C or E.⁴³

The Age-Related Eye Disease Study, a prospective, randomized, placebo-controlled trial of high dose supplementation with vitamins C and E, beta-carotene, and/or zinc in 4,629 participants, found no effect of treatment on the development or progression of lens opacities over a 6 year period.⁴⁴ A preliminary report from the Vitamin E and Cataract (VECAT) Study, a prospective, randomized, controlled trial of vitamin E supplementation versus placebo in 1,193 individuals, found no significant difference between the two groups in 4-year progression of either nuclear or cortical cataract, and no significant difference in the proportion of cases of cataract extraction [Robman LD, McCarty CA, Tikellis G, et al. VECAT study: The effect of vitamin E on the progression of lens opacification (preliminary results). *Invest Ophthalmol Vis Sci* 2001; 42 (Suppl):S508].

Other factors that increase the risk of lens opacification include blunt trauma to the eye, exposure to ionizing radiation, chemical or electrical injuries to the ocular surface, and conditions such as chronic uveitis and prior intraocular surgery such as vitrectomy or glaucoma filtration.

NATURAL HISTORY

The natural history of all types of cataract is variable and unpredictable and is related in some ways to type. Any portion of the lens can become opaque. With age the lens decreases in accommodative power and increases in thickness and weight. Continued production of lens fibers causes hardening and compression of the nucleus, known as nuclear sclerosis. Subsequently, the lens proteins undergo modification and aggregation, and they take on a yellow-to-brown coloration, changing the transparency and refractive index of the lens. Nuclear sclerosis and yellowing are considered a normal part of the aging process.

In the Barbados Eye Studies, individuals with pre-existing lens opacities had 4-year progression rates (defined as at least two-step increases in Lens Opacities Classification System II scores) of 12.5% for cortical, 3.6% for nuclear, and 23.0% for PSC opacities.³⁰

RATE OF CATARACT SURGERY IN THE UNITED STATES

In 1999, a total of 1.6 million cataract procedures were performed on Medicare beneficiaries who were not enrolled in health maintenance organizations (HMO). This figure may include multiple entries from comanaged patients (Drexler J, personal communication, 1999). In 2001, the total estimated allowed Medicare charges for cataract surgery will be approximately \$3 billion, based on an estimated volume of 1.6 million procedures and using the 2001 Medicare Fee Schedule.⁴⁵ The charges include the physician's surgical fee, facility fee, and cost of the intraocular lens (IOL) (but not charges for patients in HMOs).

When assessed across populations residing in different states or metropolitan areas, there is some variation in the rate of cataract surgery, but it is relatively low compared with variations observed in other surgical procedures. In one study, factors associated with a higher rate of cataract surgery are female gender, living in a more southerly latitude, a higher concentration of optometrists in a specific geographic area, and a higher allowed charge for cataract surgery. A higher concentration of ophthalmologists was not associated with a higher rate of cataract surgery. A decreased likelihood of undergoing cataract surgery was reported among African-American Medicare beneficiaries when compared with Caucasian Americans.⁴⁶

Across delivery systems, it has been suggested that there are significant variations in the rate of cataract surgery. A study of Medicare prepaid (HMO staff models and IPAs) versus fee-for-service (FFS) settings in Southern California found that FFS patients were twice as likely to have cataract surgery than prepaid beneficiaries ($P < .01$) after adjustment for age, sex, and diabetes status.⁴⁷ In each setting, there were similar factors associated with the likelihood of cataract extraction as well as differences. In particular, female FFS patients were twice as likely to undergo cataract extraction as male FFS patients, but this difference was not found in the prepaid settings. Also, the oldest FFS patients (85 years old and older) were more likely to undergo cataract surgery than the younger group (65 to 74 years old).

There are a number of characteristics that could account for the differences in utilization reported in this study. The prepaid settings limited access to ophthalmologists by using gatekeepers and utilization management, while the FFS patients could self-refer to ophthalmologists. The study could not determine which rate of utilization was appropriate. If there was overuse in the FFS setting, then there are implications for the added costs and risks of surgery. If there was underuse in the prepaid settings, then there are implications for access to appropriate care and uncorrected functional impairment. Further studies of the appropriate use of cataract surgery in each setting are needed.

A study performed at ten academic medical centers found that 2% of cataract surgeries performed were classified as inappropriate based on available records.⁴⁸ An inappropriate rating meant that the risks of surgery were deemed to exceed the potential benefits as rated by a panel. The percentage deemed inappropriate in this study correlates to earlier estimates of 2.5% by the 1993 General Accounting Office and a rate of 1.7% by the Inspector General.⁴⁸ The criteria for appropriateness were based on indicators of visual acuity and functional impairment, such as difficulty driving, reading, and other activities of daily living. The study did point out that there was variation in what information was recorded, particularly on functional impairment, and increased attention to documenting specific functional impairments is appropriate.

VISUAL FUNCTION AND QUALITY OF LIFE

Visual function has been described as having multiple components, including central near, intermediate, and distance visual acuity; peripheral vision;⁴⁹ visual search; binocular vision; depth perception; contrast sensitivity; perception of color; adaptation; and visual processing speed.⁵⁰ Visual function also can be measured in terms of functional disability caused by visual impairment.⁵¹ Many activities are affected by more than one of these visual components.

Health services researchers have increasingly emphasized function and quality of life as the outcomes of treatment that are most critical and applicable to the patient. As previously stated, the primary purpose in managing a patient with cataract is to improve functional vision and the quality of life. In well-designed observational studies, cataract surgery consistently has been shown to have a significant impact on vision-dependent function. The Cataract Patient Outcomes Research Team (PORT) reported that 90% of patients undergoing first-eye cataract surgery noted improvement in functional status and satisfaction with vision.⁵² The Activities of Daily Vision Study of elderly patients with a high prevalence of coexisting ocular and medical diseases reported improved visual function in 80% of patients at 12 months after surgery.⁵³ A National Cataract Study conducted in England of 1,139 patients who had cataract surgery found that preoperative functional impairment varied in relation to gender, age, and visual acuity. Men were more likely to have trouble with driving, glare, and employment, and women were more likely to have difficulties with activities of daily living and recreational activities.⁵⁴ Studies have found that regardless of the preoperative visual acuity in the better eye, most patients reported improvement in their ability to perform visually dependent tasks after undergoing cataract surgery.^{52,53,54}

Several studies have reported an association between improved visual function after cataract surgery and improved health-related quality of life.^{49,53,55,56} Visual function plays an important role in physical function, particularly in terms of mobility.⁵⁸ The loss of visual function in the elderly is associated with a decline in physical and mental functioning as well as in independence in activities of daily living,⁵⁹ including night-time driving, daytime driving, community activities, and home activities. Elderly patients with visual impairment only (and no other physical or mental impairments) were 2.5 times as likely to experience functional decline than elderly patients without visual impairment.

Improved visual function following cataract surgery can ameliorate the progressive deterioration of quality of life seen in elderly patients.^{49,53} In a cohort of 464 patients 65 years old and older, cataract extraction improved visual function and health-related quality of life. Patients with an improvement in their Activities of Daily Vision Scale (ADVS), a brief measure of vision-specific functional status,⁶⁰ had from 10% to 59% less decline in nearly all Short Form (SF)-36 dimensions.⁵³ The SF-36 is a generic global measure of multidimensional health-related quality of life.⁶¹ A nationally representative population of

7,114 persons who were 70 years old and older showed that limitations in vision correlated with decreased functional status.⁶² The unadjusted functional score of a person with reported poor vision was four times worse than the score for a person with excellent vision.⁶² This difference was comparable with the differences found in other chronic conditions such as arthritis. This relationship with vision persisted, even after adjustment for health, demographics, and economic status. Individuals who rated their vision as other than excellent reported worse functional status, even when controlled for the presence of other medical conditions, education, income, general health status, and other symptoms. By improving visual function, cataract surgery may play an important role in preserving overall functional status, reducing associated injuries and accidents, and preventing disability in at-risk elderly patients.⁵⁸

An analysis of the Medical Outcomes Study found that having blurred vision more than once or twice a month has a significant impact on functional status and well-being, particularly on problems with work or other daily activities as a result of physical health.⁶³ This impact was found to be greater than the impact of several other chronic conditions, such as hypertension, history of myocardial infarction, type 2 diabetes mellitus, indigestion, trouble urinating, and headache. In one study, patients planning to undergo cataract surgery assigned a mean preoperative preference value of 0.68 on a scale ranging from 0 to 1 (where 0 is death and 1 is excellent health), indicating that the visual impairment from cataracts had a substantial impact on their quality of life.⁵⁹ Visual impairment is an important risk factor for falls⁶⁴ and for hip fracture.⁶⁵ Specifically, the Study for Osteoporotic Fractures Research Group found that poor depth perception and decreased contrast sensitivity independently increased the risk of hip fracture.⁶⁶

Visual impairment, in particular a decrease of visual acuity and contrast sensitivity, has been shown to be associated with difficulties in driving.⁶⁷ In one study, older drivers with visually significant cataract were twice as likely as older drivers without cataract to report reduction in days driven and four times as likely to report difficulties in challenging driving situations.⁶⁸ Drivers with visually significant cataract were 2.5 times more likely to have had an at-fault involvement in a motor vehicle crash in the past 5 years compared with drivers without cataract.⁶⁸ This association was significant, even after accounting for other factors such as impaired general health, age, mental status deficit or depression. In this study, visually significant cataract was determined by reviewing the participant's medical record and most recent eye examination by an eye care specialist. The study required that cataract in both eyes was the cause of the visual impairment, based on the medical record; an additional inclusion criterion was best-corrected visual acuity in one eye of 20/40 or worse. A further study in the same group demonstrated that drivers with a history of crash involvement were eight times more likely to have a serious contrast sensitivity deficit (defined as a Pelli-Robson score of 1.25 or less) in the worse eye than those who had no history of crash involvement.⁶⁹ A severe contrast sensitivity deficit in only one eye was still significantly associated with crash involvement.⁶⁹

Binocular vision is better than the vision of a single eye. The simultaneous use of the two eyes is complex and requires the integration of disparate images from each eye. A study demonstrated that binocular vision resulted in better perception of form, color, and the relationship of the body to the environment, which facilitated manipulation, reaching, and balance, particularly under dim illumination.⁷⁰ However, if the vision of one eye is reduced due to cataract, visual performance can fall below the level of monocular vision by a mechanism known as binocular inhibition,⁷¹ which reduces patients' visual acuity and contrast sensitivity.⁷² A study of the Framingham Study Cohort found that poor vision in one or both eyes was associated with an increased risk of hip fracture. It also found that patients with good vision in one eye and moderately impaired vision in the other eye had a

higher risk of fracture than those with similar visual impairment in both eyes.⁶⁵ A study of 150 patients before and after cataract surgery found that poor binocular visual acuity was related to more problems in activities of daily living.⁷³ Another study, based on patients who reported no beneficial outcomes after first-eye cataract surgery in the National Swedish Cataract Outcome register, found that anisometropia was the reason for the poor outcome in one-third of cases.⁷⁴ These studies have shown that second-eye surgery is important to visual and physical function.

In summary, these studies demonstrate that physical function, emotional well-being, and overall quality of life can be enhanced when visual function is restored by cataract extraction.⁷⁵

Improved visual function as a result of cataract surgery includes the following:

- Better optically corrected vision.
- Better uncorrected vision with reduced spectacle dependence.
- Increased ability to read or do near work.
- Reduced glare.
- Improved ability to function in dim levels of light.
- Improved depth perception and binocular vision.
- Improved color vision.

Improved physical function as a critical outcome of cataract surgery includes the following:

- Increased ability to perform activities of daily living.
- Increased opportunity to continue or resume an occupation.
- Increased mobility (walking, driving).

Improved mental health and emotional well-being as a second critical outcome of cataract surgery includes the following benefits:

- Improved self-esteem and independence.
- Increased ability to avoid injury.
- Increased social contact and ability to participate in social activities.
- Relief from fear of blindness.



PREVENTION

Several studies show a linkage of smoking with nuclear sclerosis.²¹⁻²³ Findings in the Physicians' Health Study indicate a reduced risk of cataract in past smokers compared with current smokers, demonstrating a benefit from smoking cessation.²³ The use of nutritional or vitamin supplementation to delay the onset or progression of cataracts has been shown to be beneficial in populations with nutritional deficits;⁴² however, recommendations for their use cannot be made at this time due to inconsistent results reported in clinical trials.⁴¹ Cumulative lifetime exposure to ultraviolet-B radiation has been associated with lens opacities,^{19,20,76,77} rendering the use of sunglasses and the wearing of hats reasonable precautions to recommend to patients. Patients taking inhaled or oral corticosteroids on a long-term basis and patients with diabetes should be informed about the risks for cataract formation.



CARE PROCESS

PATIENT OUTCOME CRITERIA

Outcome criteria can vary for each patient, depending on the patient's needs, life-style, and medical condition. In general, outcome criteria include the following:

- Reduction of visual symptoms.
- Restoration of vision that meets the patient's functional needs.
- Achievement of desired refractive outcome.
- Improvement in quality of life.

Although cataract surgery is highly effective, it is important to identify the factors that can help predict which patients are more or less likely to achieve improvement in visual function. The Cataract PORT study identified preoperative characteristics that were independent predictors of improvement after surgery: age, comorbidity, cataract symptom score, and preoperative VF-14 (measure of visual function) score.⁷⁸ These investigators found that patients younger than 65 showed greater improvement than those over 65, and that patients with more severe symptoms and more severe dysfunction showed greater improvement than those with less severe symptoms or dysfunction.⁷⁸ Preoperative Snellen visual acuity was found to be unrelated to the likelihood of improvement in symptoms or self-reported visual function after cataract surgery.⁷⁸ In another study, a prospectively validated model found that predictors of improvement included younger age, a poorer preoperative visual function as measured by the ADVS, PSC cataract, and absence of age-related macular degeneration (AMD) or diabetes.⁷⁹ Even patients with diabetes and AMD, however, showed significant improvements after cataract surgery at a lower magnitude than patients without these conditions. These studies have shown that benefits are greater in those younger than 75 and that the improvement in quality of life in those 75 years old and older is still functionally and statistically significant.

DIAGNOSIS

The purpose of the comprehensive evaluation of a patient whose chief complaint might be related to a cataract is to diagnose cataract, confirm that the cataract is a significant factor related to the visual impairment and symptoms described by a patient, and exclude or identify other ocular or systemic conditions that might contribute to visual impairment or affect the surgical plan or ultimate outcome.

Evaluation of Visual Impairment

The impact of cataract on visual function can be assessed by self-reported functional status or difficulty with vision, and measures of that include contrast sensitivity, glare disability, or visual acuity. It is important to realize that patients adapt to their visual impairment and may fail to notice a functional decline because the development of cataract may be very insidious. There is no single test that adequately describes the effect of cataract on a patient's visual status or functional ability. Similarly, no single test defines the threshold for performing cataract surgery. Preoperative visual acuity is a poor predictor of postoperative functional improvement; therefore, the decision

to recommend cataract surgery should not be made on the basis of visual acuity alone.^{52,78}

Studies have indicated that measures of functional impairment related to vision provide valid and reliable information that is not reflected in the measurement of visual acuity.^{60,80} For example, visual functional status indices (e.g., ADVS and VF-14) have been shown to correlate more strongly with functional improvement and satisfaction with vision after cataract surgery than does Snellen visual acuity.⁵¹

During recent years, significant progress has been made in evaluating functional impairment. Two main categories of validated questionnaires for measuring function exist: those that measure general health status, for example the SF-36⁶¹ and the Sickness Impact Profile,⁸¹ and those that are vision-specific measures. Questionnaires that measure general health status are less strongly correlated with improvement following cataract surgery than are disease-specific measures.⁵⁷ Disease-specific instruments developed for cataract include one by Bernth-Peterson,⁸² the Visual Activities Questionnaire,⁵⁰ the ADVS⁶⁰ and the VF-14.⁵¹ These questionnaires provide a standardized approach to assess the patient's function, which can be analyzed and compared across time periods and populations. However, at this time there is no gold standard for functional impairment related to vision. The assessment of functional status is a pertinent part of the patient's history and can be obtained by means of an interview or a questionnaire. The patient should be asked specifically about near and distant vision under varied lighting conditions for activities that the patient views as important.^[A:III] Questionnaires used alone are not intended to be the basis for determining the need for surgery and should not be used to set a threshold of surgery.^[A:III] They contribute to the overall evaluation of a patient with cataract and can aid in the therapeutic decision-making process.

Ophthalmic Evaluation

The comprehensive evaluation (history and physical examination) includes the following components of the comprehensive adult medical eye evaluation⁸³ with special attention to those factors that particularly bear upon the diagnosis and treatment of cataract.

- Patient history (including patient's assessment of functional status).^[A:III]
- Visual acuity and refraction.^[A:III]
- External examination (lids, lashes, lacrimal apparatus, orbit).^[A:III]
- Examination of ocular alignment and motility.^[A:III]
- Assessment of pupillary function.^[A:III]
- Measurement of intraocular pressure (IOP).^[A:III]
- Slit-lamp biomicroscopy of the anterior segment.^[A:III]
- Dilated examination of the lens, macula, peripheral retina, optic nerve, vitreous.^[A:III]
- Assessment of relevant aspects of the patient's mental and physical status.^[B:III]

Patients should be informed that they should contact the ophthalmologist if they have a change in visual symptoms during the interval between the last examination and surgery.^[A:III]

Supplemental Preoperative Ophthalmic Testing

Supplemental preoperative ophthalmic tests are not specific for cataract but may help to characterize an individual's visual symptoms.

Cataract surgery is recommended when a patient with cataract-induced visual loss indicates that he or she is no longer able to function adequately with his or her present level of vision. In a large majority of patients, the ophthalmologist is able to determine that the cataract is responsible for the patient's visual loss by examining the patient and correlating the findings with the patient's specific symptoms. Occasionally, however, a patient presents with symptoms of glare or blurred vision that appear to be disproportionate to the degree of cataract formation or the Snellen visual acuity as measured in a dark examination room. Contrast sensitivity function and glare disability may be tested to measure vision loss and visual disability due to glare and loss of contrast sensitivity.^{82,84-87}

Glare testing determines the degree of visual impairment caused by the presence of a light source located in the patient's visual field. Cataracts may cause severe visual disability in brightly lit situations such as ambient daylight or from oncoming auto headlights at night. Visual acuity in some patients with cataract is normal or near normal when tested in a dark examination room, but when these patients are retested using a source of glare, visual acuity (or contrast sensitivity) drops precipitously.⁸⁸

Contrast sensitivity testing measures the eye's ability to detect subtle variations in shading by using figures that vary in contrast, luminance, and spatial frequency. It is a more comprehensive measure of visual function than visual acuity, which determines perception of high-contrast letters and numbers. In the patient who complains of visual loss and has lens changes, contrast sensitivity testing may demonstrate a significant loss of visual function not appreciated in testing of visual acuity.^{84-87,89,90} Decreased contrast sensitivity (as well as decreased visual acuity) may occur for a number of reasons, and this test is therefore not a specific indicator of visual loss due to cataract. In spite of substantial progress over the past few years, contrast sensitivity testing devices and methods continue to lack standardization.

Potential acuity tests attempt to predict the visual acuity that will be obtained following cataract surgery. Subjective potential acuity tests (suprathreshold pinhole device, Maddox rod test, laser interferometer, the Guyton-Minkowski Potential Acuity Meter, scanning laser ophthalmoscope with illuminated near card, and potential acuity pinhole) require the patient to respond to questions about visual stimuli presented. Objective potential acuity tests (electroretinography, visual evoked potential) measure electronically the response to visual stimuli presented. Potential acuity tests are most accurate in situations where they are needed least, e.g., mild to moderate degrees of cataract formation with normal macular function.^{75,91-94} There is no significant evidence that demonstrates that these tests predict the outcome of cataract surgery more reliably than clinical examination.

Specular microscopy, micrography, and corneal pachymetry have been used in patients with known preoperative corneal disease to help determine whether the cornea is likely to remain clear following cataract surgery. These tests are not needed routinely, but may be useful in eyes in which the corneal endothelial function is suspected to be abnormal, as a result of Fuchs' corneal dystrophy, previous ocular surgery, or trauma, for example. However, several studies suggest that specular micrography has low accuracy in predicting whether the cornea will remain clear following cataract surgery.^{95,96}

Additional specialized preoperative evaluations may provide valuable information in selected cases but are not routinely necessary. Corneal topography is useful when irregular astigmatism is suspected to be contributing to visual impairment. Additionally, corneal topography is employed when high astigmatism is present and corrective surgery is contemplated concurrently with cataract surgery. Fluorescein angiography is occasionally helpful in the presence of mild to moderate cataracts when the clinician suspects conditions such as diabetic or inflammatory macular edema, or submacular neovascularization. B-scan ultrasonography is appropriate when the fundus cannot be visualized or to diagnose staphylomas in highly myopic eyes. Visual fields, external and fundus photography, tonography, and special color vision testing have not been shown to be of value in routinely evaluating patients before cataract surgery. There is variation in the use of preoperative diagnostic tests between ophthalmologists and optometrists, especially in the use of visual fields, which are frequently used by optometrists but seldom ordered by ophthalmologists to evaluate the patient with cataract.^{97,98}

MANAGEMENT

Nonsurgical Management

Patients who are current smokers should be informed of the increased risk of cataract progression and the benefits of smoking cessation that have been demonstrated in several studies.^{21-23 [A:II]} Studies have found that smokers report that a physician's advice to quit is an important motivator in attempting to stop smoking.⁹⁹⁻¹⁰¹ Nonsurgical methods of management include informing patients about cataract-related visual symptoms and the generally elective nature of cataract surgery, providing reassurance about the cause of the visual disability, and prescribing new glasses where appropriate. In some patients with clinically significant cataract, a change in spectacle correction or use of specialized tints may be in order to restore acceptable vision for daily activities. Currently, there are no known pharmacological or nutritional treatments known to eliminate existing cataract or retard their progression.

Surgical Management

Indications for Surgery

The primary indication for surgery is visual function that no longer meets the patient's needs and for which cataract surgery provides a reasonable likelihood of improvement.^[A:III] Cataract removal is also indicated when the lens opacity inhibits optimal management of posterior segment disease or the lens causes inflammation (phakolysis, phakoanaphylaxis), angle closure, or medically unmanageable open-angle glaucoma.^[A:III]

Contraindications to Surgery

Surgery for visually impairing cataract should not be performed under the following circumstances.^[A:III]

- The patient does not desire surgery.
- Glasses or visual aids provide vision that meets the patient's needs.

-
- Surgery will not improve visual function.
 - The patient's quality of life is not compromised.
 - The patient cannot safely undergo surgery because of coexisting medical or ocular conditions.
 - An informed consent cannot be obtained from the patient or surrogate decision-maker.
 - Appropriate postoperative care cannot be arranged.

Preoperative Medical Evaluation

The ophthalmologist who is to perform the surgery has the following responsibilities.^[A:111]

- To examine the patient preoperatively (see Ophthalmic Evaluation).
- To ensure that the evaluation accurately documents the symptoms, findings, and the indications for treatment.
- To inform the patient or the patient's surrogate decision maker about the risks, benefits and expected outcomes of surgery, including anticipated refractive outcome and the surgical experience.
- To formulate a surgical plan, including selection of an IOL appropriate for the particular eye.
- To review the results of presurgical and diagnostic evaluations with the patient or the patient's surrogate decision maker.
- To formulate postoperative care plans and inform the patient or the patient's surrogate decision maker of these arrangements (setting of care, individuals providing care).
- To afford the patient or the patient's surrogate decision maker the opportunity to discuss the costs associated with surgery.

The best interest of the patient is served by having the operating ophthalmologist perform the preoperative evaluation, because this will allow the surgeon to formulate the surgical plan and to establish a relationship with the patient prior to surgery. Patients feel more comfortable and reassured knowing and meeting the ophthalmologist performing the surgery. Although the ophthalmologist is responsible for the examination and review of data, certain aspects of data collection may be conducted by another trained individual under the ophthalmologist's supervision and with his or her review.¹⁰²

The value of a comprehensive medical evaluation prior to cataract surgery has not been established based on the literature; however, all patients undergoing cataract surgery should have a history and physical examination relevant to the risk factors for undergoing the planned anesthesia and sedation and as directed by a review of systems.^[A:111] The use of preoperative medical tests varies among ophthalmologists, anesthesiologists, and internists.¹⁰³ For patients with chronic obstructive pulmonary disease, recent myocardial infarction, unstable angina, poorly controlled diabetes, or poorly controlled blood pressure a preoperative medical evaluation by the patient's physician should be strongly considered.^{104 [A:11]} The traditional approach for patients scheduled for cataract surgery has included extensive laboratory testing. A large, randomized, controlled, multicenter trial, Study of Medical Testing for Cataract Surgery, however, demonstrated that perioperative morbidity and mortality were not

decreased by the use of routine medical testing, which consisted of a 12-lead electrocardiogram; complete blood count; and measurements of serum electrolytes, urea, nitrogen, creatinine, and glucose.¹⁰⁵ Therefore, routine medical tests performed on patients before cataract surgery are unnecessary because they do not increase the safety of the procedure. However, laboratory testing as indicated by individual needs is appropriate.^{105 [A-3]}

Anesthesia

Cataract surgery may be performed using a variety of anesthesia techniques that include general and local (regional) anesthesia (e.g., retrobulbar, peribulbar, periorcular, sub-Tenons injection, topical, and intracameral). Sedation may be used with local or topical anesthesia to minimize pain, anxiety and discomfort. The outcomes of cataract surgery measured in terms of visual acuity, functional impairment, complications, and patient satisfaction have not been shown to differ significantly across these anesthesia techniques.^{106,107} The planned mode of anesthesia should be discussed with the patient so that the patient will know what to expect in terms of pain, comfort, consciousness level, and complications.^[A-11] The particular strategy employed for anesthesia and sedation is generally based on the patient's medical condition and the preferences of the surgeon and patient. Because of the systemic risks involved in general anesthesia, especially in elderly patients with cardiac or pulmonary conditions, local anesthesia is generally recommended.^[A-11]

The National Institutes for Health commissioned an Agency for Healthcare Research and Quality Evidence-Based Practice Center to review 195 studies on cataract surgery using local anesthesia and to assess and report on study quality and data in evidence tables. The investigators concluded that a variety of strategies for anesthesia management for cataract surgery are safe and effective and that no particular strategy was found to be sufficiently superior to make a recommendation for use.¹⁰⁶⁻¹⁰⁹ Therefore, anesthesia strategies should be determined by the patient's needs and the surgeon's preference.^[A-11] While all agents evaluated had high rates of pain control, topical anesthesia did not provide as much pain control as retrobulbar and peribulbar anesthesia. Anesthesia techniques with needle injection may be associated with complications such as strabismus, globe perforation, retrobulbar hemorrhage, and macular infarction not seen with topical, blunt cannula, and other non-needle injection techniques. The evidence was insufficient to define if any analgesic or sedation regimen was better than any other. A supplemental analysis in the report of patient experiences based on data from the Study of Medical Testing for Cataract Surgery showed that patients reported a high level of satisfaction with all types of anesthesia management.^{106,107} In this study, patients also reported greater pain intraoperatively with topical than with injection anesthesia.^{106,107}

The Evidence-Based Practice Center report found weak evidence to support the benefits of intravenous or intramuscular sedation or analgesia to improve pain relief, anxiety, or patient satisfaction.¹⁰⁶ The supplemental report from the Study of Medical Testing for Cataract Surgery showed that patients reported more postoperative drowsiness and nausea when intravenous agents were used and that reported nausea and vomiting increased significantly with the number of agents (opioid, sedative, hypnotic, diphenhydramine) injected.¹⁰⁷ In another report from the same study, the investigators found that the use of any intravenous agent during cataract surgery was associated with increased risk of an adverse intraoperative medical event and that the risk increased with the number of agents injected.¹¹⁰

Intravenous access is generally recommended because of the potential risk for cardiorespiratory depression.^{75 [A:III]} However, given a trend toward reduction or elimination of IV sedation, IV access may not be routinely necessary. Monitoring during administration of anesthesia and surgery should include electrocardiogram, pulse oximetry, blood pressure, and respirations. These should be performed by personnel other than the operating ophthalmologist who are qualified to monitor and manage the patient's status.^[A:III] A recent study demonstrated that a patient's medical history, laboratory values, and electrocardiogram were not predictive of the need for intervention by anesthesia personnel, and intervention was required in 37% of all cataract cases.¹¹¹

Infection Prophylaxis

The use of prophylactic antibiotics prior to surgery varies. While there are no studies that convincingly demonstrate the effectiveness of antibiotics in reducing the risk of endophthalmitis, there is evidence to support an association between the use of preoperative antibiotics on the day of surgery and a reduction in ocular surface bacterial colony counts.¹¹²

A 5% solution of povidine iodine placed in the inferior conjunctival sac prior to surgery has been associated with a reduction in bacterial colony counts taken from the ocular surface at the time of surgery and also a reduced rate of postoperative endophthalmitis.¹¹³ Therefore, use of a 5% solution of povidine iodine is recommended.^{113 [A:III]} More dilute solutions placed in the treated eye after surgery, however, also have been associated with a reduced bacterial colony count and may be considered.^{114 [B:II]}

The potentially severe consequences of endophthalmitis support the use of precautions to minimize the risk of infection. Controlled studies on endophthalmitis have been difficult to perform due to the low incidence, varied practice patterns, inconsistent definitions, and rapid evolutionary change in surgical technique. Known risk factors for endophthalmitis include rupture of the capsule, duration of the surgery, presence of diabetes, significant periocular skin disease, occlusion of the lacrimal system, immunodeficiency, and anterior vitrectomy.¹¹⁵

Although anecdotal case series¹¹⁶ and a large German survey¹¹⁷ suggest a reduced tendency for infection, there are no controlled studies to support the efficacy of antibiotics placed in the infusion solution for prevention of endophthalmitis. A recent review found little evidence to support its use.¹¹⁸ There is conflicting evidence about the benefits of subconjunctival or topical antibiotics at the close of surgery in reducing the risk of endophthalmitis.^{115,117,119-123} The administration of subconjunctival antibiotics at the close of surgery has been associated with risks, which may include macular infarction with the use of aminoglycosides.¹²⁴ There also is no evidence that postoperative antibiotics reduce the incidence of endophthalmitis. Because of the inconclusive evidence on the risks and benefits of antibiotics, it is up to the ophthalmologist to decide whether to use topical, intracameral, or subconjunctival antibiotics perioperatively.

Surgical Techniques

The preferred method to remove a cataract is extracapsular extraction, most commonly by phacoemulsification, which is now used in over 90% of cataract surgeries performed in the United States. The 2000 Learning Survey (26% response rate with 1,400 responses) highlighted the predominant trend of the small-incision,

phacoemulsification technique.¹²⁵ The questionnaire in this report was sent to members of the American Society of Cataract and Refractive Surgery (ASCRS) from the U.S. only, not to all ophthalmologists who perform cataract surgery. The findings were that many respondents use topical anesthesia with intracameral lidocaine, clear-corneal incisions, a no-suture technique, and foldable IOLs. Other nonultrasonic methods to remove the nucleus through a small incision have been developed and are evolving.

In a randomized trial of extracapsular cataract extraction (ECCE) and small-incision phacoemulsification, visual acuity following phacoemulsification was significantly better and more stable during the 1 year postoperative follow-up period compared to ECCE, with fewer surgical complications in the phacoemulsification group.¹²⁶ At 1 year, the incidence of posterior capsular opacification (PCO) was significantly higher in the ECCE group than in the phacoemulsification group.¹²⁶

The ideal technical elements of a successful cataract procedure currently include the following:

- Capsular fixation of an appropriate posterior chamber IOL.
- Little or no trauma to the corneal endothelium, iris, and other ocular tissues.
- Use of an incision design that minimizes surgically induced astigmatism or that serves to reduce pre-existing corneal astigmatism.
- Watertight closure of the incision, using either self-sealing construction or appropriate suture placement.

Intraocular steps that are commonly used during phacoemulsification include the following:

- Capsulorhexis,¹²⁷ which minimizes the risks of inducing radial tears that could extend into the posterior capsule and which preserves the integrity of the capsular bag for IOL implantation.
- Hydrodissection,¹²⁸ which insures that the nucleus and epinucleus are mobile, minimizing zonular stress during cataract removal.
- Some form of nuclear disassembly such as divide and conquer¹²⁹ or a chopping¹³⁰ technique, which facilitates safe removal of the nucleus.
- Complete removal of remaining epinucleus and cortex.
- Implantation of the IOL into a centered position within the capsular bag, or as dictated by surgical events, secure fixation of the IOL in the ciliary sulcus (with or without sutures) or anterior chamber.

Location, size, and design may depend on several factors, including the patient's orbital anatomy, the type of IOL to be implanted, the role of the incision in astigmatism management, and surgeon preference and experience. Smaller incisions (3 to 4 mm) induce less astigmatic change than larger incisions (≥ 5 mm)¹³¹⁻¹³⁵ and may also result in less early postoperative inflammation.^{136,137} There is a trend to making temporal incisions in the cornea or just at the junction of the cornea and limbus.¹²⁵ Advantages of the approach include easier access to the eye without obstruction by the brow, less early postoperative inflammation relative to true limbal or scleral incisions,¹³⁸ and less subconjunctival erythema or hemorrhage in the first several weeks postoperatively. Given these advantages for less induced astigmatism, small-incision surgery is generally preferred, when feasible.^{135 [A-1]}

When it is desirable to reduce pre-existing corneal astigmatism, the following approaches can be used:

- Operating within the steep corneal meridian and varying the incision characteristics in an attempt to achieve the desired amount of meridional flattening.¹³⁹
- Using an incision that induces minimal astigmatism combined with midperipheral or peripheral corneal incision¹⁴⁰ or relaxing corneal incision.^{141,142}
- Using an incision that induces minimal astigmatism combined with implantation of a toric IOL.
- Using excimer laser corneal ablation.

Intraocular Lenses

Intraocular lens implantation is the method of choice for the correction of aphakia optically, unless there are specific contraindications.^[A:III] The ideal IOL would be biologically inert,¹⁴³ be of low cost, and be placed through an unenlarged cataract incision. It would also optically mimic the human crystalline lens by providing for both distance and near function, handle with ease, remain stable indefinitely once positioned, and maintain clarity of the posterior capsule. Presently, there is no lens available that fits all of these criteria. However, cataract surgeons can choose from a wide variety of lens styles to find the appropriate one for their needs. Lens optic size and shape, optic and haptic configuration, optic edge design, surface modification,¹⁴⁴ and optic and haptic materials^{145,146} are engineered to give different lenses a variety of characteristics.

Available lenses can be classified as foldable or nonfoldable and subclassified further as toric vs. spherical, monofocal vs. multifocal, and plate vs. multipiece. The most experience has been with IOLs fabricated from polymethyl methacrylate (PMMA), which are nonfoldable. The three types of lenses classified as foldable are made from the following materials: polydimethylsiloxane (silicone); ethyl acrylate (acrylic), including hydrophobic (thermoplastic) and hydrophilic A (HEMA-based); and collagen/HEMA-copolymer-based. Foldable lenses made of silicone and acrylic materials are now more commonly used because of the trend toward small-incision cataract surgery. Each lens, however, is associated with its own unique set of positive and negative attributes. It is therefore incumbent upon each surgeon to have an understanding of these varied lenses.^[A:III] The surgeon should have access to and choose from a host of lens styles to find the most appropriate IOL for any given individual patient, making the decision based on variations in the preoperative state of the cataractous eye, the general health condition of the patient, the surgical technique employed, and patient expectations.^[A:III] As foldable IOL technology has evolved, so too have IOL insertion techniques. Initially, various folders and forceps designs were used. More recently, insertion injection devices were introduced.¹⁴⁷

In an attempt to improve quality of life and reduce spectacle dependence after cataract surgery, monovision has been put to use and multifocal IOLs have been developed. These two approaches are designed for patients who have a strong desire for spectacle independence, and they provide the possible advantage of good visual acuity for both distance and near tasks.¹⁴⁸ Patient selection is important because certain patient-related factors may be associated with suboptimal postoperative performance and patient satisfaction. Surgeons should be familiar with the relative indications and contraindications for using monovision and multifocal IOLs, based on physical and psychosocial factors.^{149,150} ^[A:III]

Occasionally, IOLs are unavailable in the necessary power as determined by preoperative biometry and keratometry. This is especially true for extremely short eyes. In these cases, implantation of more than one IOL has been used to achieve emmetropia.¹⁵¹ Although refractive results have been favorable in two small case series,^{152,153} consideration must be given and patients counseled about the development of interlenticular (between the IOLs) membrane formation with accompanied opacification resulting in a decrease in visual acuity.^{154,155} There is insufficient evidence to make a recommendation about a specific technique for combining IOLs.

The most common problem following cataract surgery is PCO, which has an incidence of up to 50% by 2 years postoperatively.¹⁵⁶ The relationship between lens style and PCO has generated interest in preventing PCO by changing IOL material¹⁵⁷⁻¹⁵⁹ and design. Design factors that have been implicated in reducing PCO include the convexity of the IOL optic¹⁶⁰ and the edge profile of the IOL optic.^{161,162} Truncated edge design has been associated with reduced PCO but with an increased likelihood of undesirable optical phenomena after surgery.¹⁶³⁻¹⁶⁵

Complications of Cataract Surgery

Complications that may result in a permanent loss of vision are rare. Major complications that are potentially sight-threatening include infectious endophthalmitis, intraoperative suprachoroidal hemorrhage, cystoid macular edema (CME), retinal detachment, corneal edema, and IOL dislocation. A synthesis of the literature published prior to 1992 found weighted mean complication rates of 0.13% for endophthalmitis, 0.3% for bullous keratopathy, 1.4% for CME detected by physical exam, 3.5% for angiographically demonstrated CME, 0.7% for retinal detachment, and 1.1% for IOL dislocation (see Table 3).¹⁶⁶

A number of other complications such as wound leak, retained lens material, or damage to the iris can be managed but may require further surgery. Less common but also sight-threatening complications of cataract surgery include secondary glaucoma, suprachoroidal effusion and/or hemorrhage, and vitreous hemorrhage. Rates for less severe complications, also garnered from literature synthesis, are 0.6% for wound gape, 0.2% for sterile hypopyon, 1.3% for iris damage, 3.1% for posterior capsule rupture, 0.8% for vitreous loss, and 0.8% for iritis.¹⁶⁶ Short-term or transient perioperative complications, as reported by the Cataract PORT study, include corneal edema (8.65%), hyphema (6.28%), and IOP greater than 30 mmHg (5.58%). Ocular and orbital consequences of anesthesia injection have been reported at 0.7%.⁵²

In comparing the rates of sight-threatening complications reported for the various techniques of ECCE, the only differences appear to be that expulsive suprachoroidal hemorrhage may be more common (although extremely rare) with techniques using a large sutured incision, and that loss of nuclear fragments into the vitreous cavity may be more common with phacoemulsification.¹⁶⁶

However, a more recent randomized trial comparing small-incision phacoemulsification and ECCE found that there were significantly fewer complications at surgery in the phacoemulsification group.¹²⁶ Seven percent (17/236) of the ECCE group had perioperative iris prolapse compared to none in the phacoemulsification group. Anterior chamber collapse or bleed, anterior capsule tear, and incomplete capsulorhexis also were significantly more common in the ECCE group. During the follow-up period, sutures had to be cut or removed significantly

Table 3
Proportion of Eyes Experiencing Complications Following
Cataract Surgery and Intraocular Lens Implantation

Complication	No. of Studies	Range of Complications Results (% of Eyes)	Total No. of Eyes	Pooled Result (% of Eyes)*	Results Phaco (% of Eyes)
Major, early					
Endophthalmitis	16	0 - 1.9	30,656	0.13 (0.06-0.17)	0.74‡
Major, late					
Bullous keratopathy	27	0 - 6.0	15,971	0.3 (0.2-0.4)	0.3
Clinical CME	43	0 - 7.6	20,671	1.4 (1.2-1.6)†	2.3
Angiographic CME	9	0.7 - 11.3	4,236	3.5 (2.9-4.0)	2.62
Retinal detachment	42	0 - 2.0	33,603	0.7 (0.6-0.8)	0.93
Other, early					
Wound gape/ iris prolapse	17	0 - 3.0	7,499	0.6 (0.4-0.8)	0.2
Anterior chamber hemorrhage	19	0 - 4.0	7,765	0.5 (0.4-0.7)	0.4
Hypopyon	10	0 - 2.0	3,864	0.2 (0.1-0.2)	2.0‡
Iris trauma	8	0 - 9.1	5,147	1.3 (1.0-1.6)	0.7
Zonular/posterior capsule rupture	38	0 - 9.9	19,052	3.1 (2.9-3.4)	1.8
Vitreous loss	26	0 - 4.0	14,622	0.8 (0.6-1.0)†	0.24
Vitreous hemorrhage	5	0 - 8.0	4,386	0.3 (0.2-0.5)	§
Choroidal hemorrhage	3	0 - 2.0	3,638	0.3 (0.1-0.5)	§
Other, late					
Uveitis	30	0 - 13.3	11,339	1.8 (1.5-2.1)†	3.1
Increased IOP (closed angle)	11	0 - 1.6	4,391	0.2 (0.1-0.3)	1.0
Increased IOP (open angle)	34	0 - 19.7	11,376	1.2 (1.0-1.4)	1.0
Posterior capsular opacification	41	0.7 - 47.6	14,677	19.7 (19.1-20.3)	17.0

SOURCE: Powe NR, Schein OD, Gieser SC et al: Synthesis of the literature on visual acuity and complications following cataract extraction with intraocular lens implantation. Arch Ophthalmol 1994; 112:239-52.

NOTE: This table is based on a synthesis of the literature and does not account for variation in follow-up intervals.

CI = confidence interval, CME = cystoid macular edema, IOP = intraocular pressure.

* Pooled result and 95% CI weighted by sample size of studies.

† Pooled result and 95% CI weighted by quality score and sample size.

‡ Only one study that reported data only for phacoemulsification.

§ No studies found that reported data only for phacoemulsification.

more often in the ECCE group compared to the phacoemulsification group. At 1 year, the incidence of PCO was significantly higher in the ECCE group than in the phacoemulsification group.¹²⁶

A national survey of over 100 hospitals in the United Kingdom from 1997 to 1998 found the following results on 18,454 patients 50 years old or older.⁵⁴ Seventy-seven percent of these patients had surgery performed by phacoemulsification. Rates for events that occurred during surgery were 4.4% for posterior capsule rupture and vitreous loss, 1.0% for incomplete cortical cleanup, 1.0% for anterior chamber hemorrhage and or collapse, and 0.77% for iris damage. Short-term (within 48 hours) perioperative complications included corneal edema (9.5%), increased IOP (7.9%), uveitis (5.6%), wound leak (1.2%), hyphema (1.1%), and retained lens material (1.1%).

A study comparing the results of the National Eyecare Outcomes Network (NEON) to the Cataract PORT study found no pertinent differences in the complications reported (Table 4).¹⁶⁶ NEON is a small volunteer registry of noncontrolled experience with cataract surgery in everyday practice and is probably not representative of all cataract surgery performed in the U.S. The study reported on 7,626 patients submitted with any data from 249 ophthalmologists and 2,603 patients with complete data who received cataract surgery during 1996 to 1997.

A study of the American Society of Cataract and Refractive Surgery National Cataract Database reported rates of intraoperative complications, with an overall rate of 2.8%, and a rate of 1.2% for posterior capsule break and 0.7% for vitreous loss (Data Analysis of the American Society of Cataract and Refractive Surgery National Cataract Database. First Year—January 1996. Unpublished data). For the year 1995, a highly selected group of 34 practices submitted data on 13,631 cataract procedures. For those individuals with other planned procedures, prior eye treatment, and other ophthalmic conditions, there was a higher rate of intraoperative complications, or 9.8%, 4.4%, and 3.7%, respectively. At 3 months, the overall rate of postoperative complications was 3.4%, including 1.1% with iritis and 0.8% with CME.

The European Cataract Outcome Study reported an average rate of intraoperative complications of 3.1% in 1999, with a rate of 1.8% for posterior capsule rupture and 1.3% for vitreous loss (Results of the European Cataract Outcomes Study, 2000. Unpublished data). This study was conducted in 14 countries with up to 40 participants over the years 1995 to 1999, and it collected operative and follow-up information on a total of 8,646 patients, including 3,033 patients in 1999.

A population-based case control study of Medicare beneficiaries found that an increased risk of retinal detachment was associated with Nd:YAG (neodymium: yttrium-aluminum-garnet) laser posterior capsulotomy, increased axial length (more than 26 mm), posterior capsular rupture during surgery, history of retinal detachment or lattice peripheral retinal degeneration in either eye, and ocular trauma after cataract surgery.¹⁶⁸

Complications specific to the IOL occur infrequently. They include decentration, incorrect power, dysphotopsia, and rarely, opacification.

Table 4
Perioperative Adverse Events

	NEON (All data)	NEON (N = 2603 with 5 data forms)	Cataract PORT (N = 717)
Intraoperative (%)			
Posterior capsular or zonular rupture	1.8	1.6	1.95
Iridodialysis/cyclodialysis/iris trauma	<1	0	0.84
Vitreous loss/anterior vitrectomy or aspiration	1.2	1.1	1.39
Loss of nuclear material into vitreous	<1	<1	0.28
Suprachoroidal hemorrhage	<1	0	0.14
Retrolubar hemorrhage	0	0	0
Postoperative *,†			
Wound leak or rupture	<1	<1	0.84
IOL dislocation, removal, or exchange	<1	<1	0.28
Endophthalmitis	<1	<1	0.14
Retinal tear, break, or detachment	<1	<1	0.14
Corneal edema	1.4	<1	1.95
Visually significant CME	<1	<1	NR‡
CME	NR‡	NR‡	3.21
Persistent iritis	<1	1.1	NR
Iris abnormalities	NR‡	NR‡	2.51

CME = cystoid macular edema, IOL = intraocular lens, NEON = National Eyecare Outcomes Network, NR = not reported.

* Occurring by time of final refraction visit for NEON patients.

† Occurring within 4 months following surgery for Cataract PORT patients.

‡ Either Cataract PORT or NEON did not collect data on this item.

Outcomes

Cataract surgery is a highly successful procedure. Pooled results of literature before 1992 showed that postoperative visual acuity reached 20/40 or better in 90% of all cases of cataract surgery and in 95% of cases without presurgical ocular comorbidity.¹⁶⁶ The Cataract PORT study showed an improvement in VF-14 in 89% of patients, an improvement in satisfaction in 85% of patients, and an improvement in self-reported trouble with vision in 80% of patients.⁵⁶ The Activities of Daily Vision Study of elderly patients with a high prevalence of coexisting ocular and medical diseases reported improved visual function in 80% of patients at 12 months after surgery.⁵³ A Swedish study found that regardless of the preoperative visual

acuity in the better eye, most patients reported improvement in their ability to perform visually dependent tasks after undergoing cataract surgery.⁵⁵ Poor predictive validity of visual acuity was also reported in other studies.^{78,169}

The NEON database also found similar rates of success, with an improvement in visual acuity in 92.2% of patients and improvement in VF-14 in over 90% of patients.¹⁶⁷ Best-corrected visual acuity of 20/40 was achieved by 89% of all NEON patients and 96% of NEON patients without preoperative ocular comorbid conditions.¹⁶⁷ Seventy-eight percent of patients were within ± 1.0 diopter (D) of target spherical equivalent. Ninety-five percent of patients reported being satisfied with the results of their surgery. Patients who were dissatisfied with the results of their surgery were slightly older and more likely to have ocular comorbidity. Patients rated the quality of the explanations that they received regarding the potential benefits and risks of surgery slightly lower than the quality of care they received.

The ASCRS National Cataract Database reported that at 3 months 85.5% of all patients had a 20/40 or better postoperative best-corrected visual acuity, 57.2% of patients had 20/25 or better postoperative best-corrected visual acuity, and 74.6% of patients were within ± 1.0 D of target spherical equivalent. Based on 5,788 responses, the mean visual function index score at 3 months was 70.3% compared with 55.0% preoperatively. (The score is based on a scale of 0 to 100, with 0 indicating an inability to perform any of the activities.) The European Cataract Outcome Study reported for 1999 that 89% of patients achieved a postoperative visual acuity of 0.5 or more, the average induced astigmatism was 0.59 D, and 86% of patients had an induced astigmatism within ± 1.0 D.

A National Swedish Cataract Register study using the Catquest questionnaire for the patients' self-assessed visual function found that 91% of patients reported a benefit from surgery.¹⁷⁰ Patients with an ocular comorbidity in the eye undergoing cataract extraction were characterized by a significantly higher frequency of deteriorated self-assessed visual function after surgery than patients with no ocular comorbidity. In another study from the National Swedish Cataract Register that used the Catquest questionnaire, 30% of patients 85 years old and older with an ocular comorbidity who reported no difficulties in performing most everyday activities preoperatively, reported no improvement in self assessed visual function 6 months following surgery.¹⁷¹ In general, the study found that cataract surgery in the age group of 85 years old and older had good results, and 94% of those without ocular comorbidity who had first eye surgery reported beneficial outcomes in self-assessed visual function.

Comorbidities

Preoperative ocular comorbidities have been found to have a significant effect on the outcomes of cataract surgery, and adjustments based on case mix should be made for meaningful comparisons across patient groups.^{52,169,172} Specifically, outcomes for patients with pre-existing AMD and diabetes have shown significant improvement, but of one-third the magnitude for patients without these comorbid conditions. The most important item to emphasize in managing patients with ocular comorbidities is to provide information about the risks and benefits of cataract surgery, because they may have expectations for improvement that are not commensurate with their visual potential.¹⁷³ Comorbid conditions found in patients with cataract and the special considerations that the ophthalmologist should anticipate are listed in Table 5. Most

comorbid conditions are associated with the potential for reduced improvement in visual function or best-corrected visual acuity. The impact of cataract-related vision impairment as it superimposes on the underlying comorbid condition should be discussed thoroughly, along with the expected outcomes of cataract surgery, so that the patient is adequately informed and counseled.^[A:III]

Table 5
Common Ocular Comorbidities

Comorbidity	Special Considerations
AMD ¹⁷⁴⁻¹⁷⁷	Occult subretinal neovascularization
Diabetic retinopathy ¹⁷⁸⁻¹⁸⁴	Worsening of retinopathy
	CSME
	Poorly dilating postoperative pupil
Fuchs' corneal endothelial dystrophy ^{185,186}	Reduced visualization during surgery
	Prolonged postoperative corneal edema
	Pseudophakic bullous keratopathy
Glaucoma ¹⁸⁷⁻¹⁹²	Higher IOP during the first postoperative week
	Reduced function of prior filtering surgery
Pseudoexfoliation syndrome ¹⁹³⁻¹⁹⁶	Intraoperative miosis
	Zonular laxity or instability
	Vitreous loss
	Floppy iris and tendency for iris prolapse into the cataract incision
	Accelerated PCO
	Anterior capsulorhexis contraction
	IOL tilt and decentration
	Late (decades) dislocation of IOL possible
Retinopathy of prematurity ¹⁹⁷	Intraoperative miosis
	Traction retinal detachment
	Loose zonules
Uveitis ^{144,198-201}	Posterior synechiae
	Protein and cellular deposits on the lens implant
	CME
	Secondary glaucoma

AMD = age-related macular degeneration, CME = cystoid macular edema, CSME = clinically significant macular edema, IOL = intraocular lens, IOP = intraocular pressure, PCO = posterior capsule opacification.

In addition to ocular comorbidities, other characteristics of the patient or eye may be associated with a higher risk for intraoperative and postoperative complications. High-risk characteristics include a history of previous eye surgery, eyes with special types of cataract, very large and very small eyes, deep set eyes, eyes with small pupils or posterior synechiae, and eyes with weak or absent zonules. Each set of circumstances poses unique challenges (Table 6). As with ocular comorbidities, a patient with high-risk characteristics should be informed about the specific impact of their condition on the expected course and outcome of surgery, along with options that may be exercised in the event that complications occur.^[A:III]

Table 6
High-Risk Characteristics for
Intraoperative and Postoperative Complications

High-Risk Characteristic	Special Considerations
Deep set eye, narrow lid fissure, or prominent brow	Reduced visibility
	Poor access to the superior limbus
	Pooling of irrigation fluid
Dense cataract (brunescant or black nuclear cataract) ^{202,203}	Concomitant zonular laxity and intraoperative miosis
	Little cortex to protect the capsule during phacoemulsification
	Increased phacoemulsification time with increased risk of postoperative corneal edema
	Greater risk of thermal and mechanical injury to the cornea and iris with phacoemulsification
High hyperopia ²⁰⁴⁻²⁰⁶	Increased risk of posterior capsule rupture
	Shallow anterior chamber with increased risk of endothelial trauma
	Increased risk of iris trauma and prolapse
	Difficulty calculating lens implant power
High myopia ²¹⁷⁻²¹¹	Intraoperative suprachoroidal effusion (particularly nanophthalmic eyes)
	Anterior chamber depth fluctuation
	Difficulty calculating lens implant power with posterior staphyloma
High risk for vitreoretinal surgery	Increased risk of retinal detachment
	Silicone IOLs may compromise subsequent surgical visibility
Prior glaucoma filtration surgery ²¹²⁻²¹⁴	Increased filtration through the bleb during surgery
	Decreased filtration or bleb failure following surgery
	Postoperative hypotony
	Zonular laxity

Table 6 (continued)
High-Risk Characteristics for
Intraoperative and Postoperative Complications

High-Risk Characteristic	Special Considerations
Prior keratorefractive surgery ²¹⁵⁻²¹⁷	Difficulty calculating IOL power
	Transient hyperopic shift immediately after surgery in eyes with a prior radial keratotomy
	Dehiscence of refractive keratotomy incision
Prior pars plana vitrectomy ²¹⁸⁻²²⁰	Conjunctival scarring
	Anterior chamber depth fluctuation
	Intraoperative miosis
	Increased nuclear sclerosis
	Increased frequency of posterior capsule plaques
	Weakened lens capsule and zonules
Prior penetrating keratoplasty ²²¹	Poor visualization
	Graft rejection or failure
	IOL power calculation inaccuracy
Prior scleral buckling surgery ²²²⁻²²⁴	Increased axial myopia
	Conjunctival scarring
Miotic pupil ²²⁵⁻²³⁰	Poor visualization
	Increased risk for capsule tear/vitreous prolapse
	Increased risk for iris damage and prolapse
Posterior polar cataract ²³¹⁻²³³	Defective posterior capsule
Posterior synechiae	Intraoperative miosis
	Prolonged postoperative inflammation
	Inflammatory deposits on IOLs
	Iris bleeding
Uveitis	Intraocular inflammation
	Macular edema
White cataract (mature cortical cataract) ²³⁴⁻²³⁷	Difficulty performing the capsulorhexis
	Lens intumescence
Zonular laxity or dehiscence ²³⁸⁻²⁴⁰	Phacodonesis
	Vitreous prolapse around the lens equator
	Loss of cataract into vitreous
	Postoperative lens implant decentration
	Increased difficulty in capsulorhexis and cortical clean-up

IOL = intraocular lens.

Systemic comorbidities that may be of importance intraoperatively are diabetes, pulmonary dysfunction, poorly controlled blood pressure, musculoskeletal disorders causing positional difficulties, tremor, severe hearing impairment, anxiety disorders, mental retardation, dementia, and coagulopathies. For patients with diabetes and other complex medical conditions, it may be beneficial to coordinate care with the patient's physician. Depending on the planned anesthesia and sedation, appropriate measures should be taken to stabilize the condition prior to surgery.^[A:III] Blood glucose should be checked preoperatively for individuals with diabetes treated with insulin or oral hypoglycemic agents.^[A:III]

There is no strong evidence favoring continuation or discontinuation of anticoagulants during cataract surgery for anticoagulated patients.²⁴¹ Several uncontrolled case studies reported minimal or no complications in patients who were maintained on their anticoagulants and undergoing intracapsular cataract extraction, ECCE, and phacoemulsification.²⁴²⁻²⁴⁹ The risk of discontinuing anticoagulants depends on the condition for which they were prescribed. Generally, patients can be left on anticoagulants if routine cataract surgery is anticipated. Alternatives to retrobulbar injections should be considered in patients who are anticoagulated, however.^[B:III]

There is no strong evidence favoring continuation or discontinuation of antiplatelet agents, but small case series do not show adverse effects from continuation of these agents when phacoemulsification is performed.^{242,250-252}

Recommendations from the American Heart Association for prevention of bacterial endocarditis do not list cataract surgery as a procedure for which antibiotic prophylaxis is necessary.²⁵³

Combined Surgery and Special Circumstances

Cataract and Glaucoma Surgery

When a candidate for cataract surgery also has glaucoma, surgical treatment options include cataract and IOL surgery alone, cataract and IOL surgery following filtration surgery, glaucoma surgery after cataract surgery, or cataract and IOL surgery combined with filtering surgery. The decision will be based on a number of factors, including the patient's response to medical or laser surgical treatment of the glaucoma, the degree of optic nerve damage, changes in the visual field, severity of the cataract, and the surgeon's experience. While cataract surgery with IOL implantation lowers IOP by 2 to 4 mmHg in long-term studies,^{189,191} a glaucoma procedure combined with cataract surgery lowers IOP more effectively (6 to 8 mmHg).²⁵⁴⁻²⁵⁶ An Evidence-Based Practice Center sponsored by the Agency for Healthcare Research and Quality reviewed 131 studies on the treatment of adults with coexisting cataract and glaucoma, assessed the study quality and data, and reported it in evidence tables.²⁵⁶

The investigators concluded that the following findings are strongly supported by the literature.

- Glaucoma surgery was associated with an increased risk of postoperative cataract.
- A glaucoma procedure added to cataract surgery lowers IOP more than cataract surgery alone.

These findings were found to be moderately supported by the literature.

- Limbus- and fornix-based conjunctival incisions provided the same degree of long-term IOP lowering in combined surgery.
- In combined surgery using phacoemulsification, the size of the cataract incision did not affect long-term IOP control.
- When used with combined procedures 5-fluorouracil was not beneficial in further lowering IOP.
- Mitomycin-C was efficacious in producing lower long-term IOPs when used with combined procedures.

There are several disadvantages to performing filtration surgery performed first, followed by cataract surgery 3 to 6 months after a mature bleb has formed. These include delayed visual recovery, increased perioperative and anesthetic risks, increased costs, and the possibility of inducing bleb dysfunction at the time of cataract surgery. Potential benefits of a combined procedure (cataract extraction with IOL implantation and trabeculectomy) are protection against the IOP rise that may complicate cataract surgery alone, more rapid visual recovery, and long-term glaucoma control with a single operation. Phacoemulsification combined with trabeculectomy provides good IOP control as well as improved corrected visual acuity compared with pre-operative vision.^{254,257,258} Despite these advantages, the literature does not support combined cataract-glaucoma surgery over two-stage surgery. Additionally, combined procedures are technically more complex and surgeons must be cognizant of potential complications and their management.

The benefit of the adjunctive use of antifibrotics (mitomycin-C,²⁵⁹ and 5-fluorouracil²⁶⁰) to reduce the potential for bleb failure in combined phacotrabeulectomy remains controversial. While it appears that mitomycin-C may be efficacious in producing lower long-term IOPs when used with combined procedures,^{256,259} 5-fluorouracil is not.^{256,260} Potential vision-threatening complications, such as bleb-related endophthalmitis,^{261,262} hypotony maculopathy,^{263,264} and late-onset bleb leaks²⁶⁵ must be considered in the decision to use these agents.^[A-111]

Cataract and Corneal Surgery

The presence of endothelial dystrophy presents a special challenge to the cataract surgeon who must predict how well the compromised cornea will function following cataract surgery. Assessment of the corneal endothelium is critical in evaluating the cataract patient preoperatively. A slit-lamp biomicroscopic examination that demonstrates microcystic edema, or stromal thickening, and/or central corneal pachymetry greater than 600 microns, and/or low central endothelial cell counts by specular microscopy or micrography indicates an increased likelihood of corneal failure following cataract surgery. Under these circumstances the patient may be best served by a combined procedure of cataract extraction, IOL implantation, and penetrating keratoplasty (PK).

There are several reasons for performing cataract surgery at the time of keratoplasty even in the presence of a mild cataract. These benefits include the following:

- Cataracts may progress more rapidly after keratoplasty.
- The common use of topical steroids following surgery may hasten PSC cataract development.
- Postkeratoplasty cataract surgery may traumatize the grafted endothelium.

-
- Surgery is limited to a single procedure.
 - Visual rehabilitation is more rapid.

Alternatively, many surgeons prefer to perform keratoplasty first followed by cataract removal later, because the corneal curvature after total healing is unpredictable following PK; therefore IOL calculations may be inaccurate, giving rise to visually significant anisometropia. If the cataract is removed following stabilization of corneal graft keratometry, a more predictable IOL power and hence refractive result may be possible. Secondly, the procedure done in this manner has the additional advantage of reducing the amount of time the eye is open during the keratoplasty procedure.

Cataract and Vitreoretinal Surgery

Cataract and vitreoretinal disease often occur simultaneously in patients. If vitreoretinal surgery is necessary, simultaneous cataract surgery and IOL implantation may be considered. Removal of an opaque lens would be necessary to enable the retinal surgeon an adequate view of the retina during vitreoretinal surgery. However, even if the cataract does not reduce visual function before surgery, lens extraction might be considered since the cataract often progresses postoperatively as a result of the vitreoretinal surgery and/or the concomitant use of intraocular gas or silicone oil used as an intraocular tamponade.

Combined vitreoretinal surgery and phacoemulsification with IOL implantation has been successfully employed.^{266,267} Advantages of this combined surgery are the single operative procedure and anesthesia, reduced costs, and reduced postoperative recovery time.

Possible disadvantages of simultaneous cataract and vitreoretinal surgery include difficulty visualizing the capsulorhexis because of a poor or absent red reflex, cataract wound dehiscence caused by globe manipulation during subsequent vitreous surgery, intraoperative miosis after cataract extraction, IOL decentration, and prismatic effects and undesirable light reflexes during vitreoretinal surgery if the IOL is implanted before the posterior segment procedure. Because of these latter problems, some ophthalmologists have recommended delaying IOL implantation until the conclusion of posterior segment surgery.

Finally, if future vitreoretinal surgery is likely, the IOL optic size, material, and configuration should be carefully considered. Lens implants that will not obscure the view of the fundus should be selected, especially if silicone oil or gas tamponade is anticipated.^[A:III]

Cataract Surgery Following Refractive Surgery

Patients who have undergone corneal refractive surgery pose two unique challenges to the ophthalmologist: how to accurately calculate IOL power and how to modify the surgical technique as dictated by the prior refractive procedure. Following corneal refractive surgery, the keratometer may not be an accurate means of measuring central corneal power for IOL calculations.^{268,269} Additional techniques, therefore, are applied, such as using the clinical history²⁷⁰ (this requires knowing refractive and keratometric data before and after refractive surgery), contact lens overrefraction,²⁶⁸ and, in some instances, computerized videokeratography.²⁷¹ It is recommended that third- or fourth-generation IOL calculation formulas (e.g., Haigis, Hoffer Q, Holladay 2, SRK/T) be used in these eyes of atypical length and altered corneal curvature,²¹⁶ ^[A:III] and patients must be counseled about the increased potential for inaccurate

optical results of surgery.^[A:III] Surgical considerations include avoiding the intersection of radial keratotomy incisions with clear corneal cataract incisions to prevent wound dehiscence.²⁷²

Cataract in the Functionally Monocular (One-Eyed) Patient

A functionally monocular (one-eyed) patient is one who is primarily dependent on the eye being considered for cataract surgery. There may be significant ocular comorbidity or other high-risk characteristics in such eyes.²⁷³ The indications for surgery in the functionally monocular patient are the same as for other patients; that is, when the cataract-impaired vision no longer meets the patient's needs and the anticipated benefits of surgery exceed the risks. Delaying surgery until the cataract is very advanced may increase surgical risk and retard visual recovery. When cataract surgery is contemplated in a functionally monocular patient, the ophthalmologist has an obligation to inform the patient that blindness is one of the risks of cataract surgery.^[A:III]

Second-Eye Surgery

When patients note improved visual function after first-eye surgery, it is common to desire second-eye surgery, which brings additional significant improvement in visual function.^{72,274-277} The indication for second-eye surgery is the same as for the first eye, i.e., when the cataract-impaired vision no longer meets the patient's needs and the anticipated benefits of surgery exceed the risks.^[A:III] The patient and ophthalmologist should discuss the benefit, risk, and timing of second-eye surgery when they have had the opportunity to evaluate the results of surgery on the first eye.^[A:III] In some patients, a byproduct of reducing ametropia in the first operated eye may be anisometropia. Lack of binocular vision may reduce a patient's ability to perform daily activities and sense of well being. In patients whose anisometropia interferes with visual function, second-eye surgery is appropriate at an earlier stage of cataract development.^{274 [A:III]}

Two studies comparing the outcomes of first- and second-eye surgeries after cataract extraction concluded that patients who underwent surgery in both eyes had greater improvement in functional status than those who underwent surgery in only one eye.^{275,278} Patients who had surgery in both eyes also have statistically significant greater satisfaction with vision than patients who had surgery in only one eye.^{275,276} Another study demonstrated that the cataractous eye interfered with the function of the pseudophakic eye, and after surgery for the second eye, multiple complaints of visual disability were eliminated.²⁷⁹ A British study found that stereoacuity increased from 32% of patients after first-eye surgery to 90% after second-eye surgery. Binocular horizontal field of vision increased in 36% of patients. The number of patients able to meet the driving standard increased from 52% after first-eye surgery to 86% after second-eye surgery.²⁸⁰ Cataract surgery for both eyes (almost invariably as separate events) is an appropriate treatment for patients with bilateral cataract-induced visual impairment.^{275,277 [A:II]}

Determining the appropriate interval between the first-eye surgery and second-eye surgery is influenced by several factors: the patient's visual needs, the patient's preferences, visual acuity or function in the second eye, the medical and refractive stability of the first eye, anisometropia, and the degree of need for binocularity. The logistical concerns of the number of visits to the physician's office are also a factor for consideration. Prior to performing second-eye surgery, the refractive error of the first

eye should be ascertained and the patient should perceive improved function.^[A:III] Sufficient time should have elapsed to diagnose and treat any early postoperative complications such as endophthalmitis, which has a peak occurrence of between 4 and 6 days,²⁸¹⁻²⁸³ and for the patient to evaluate the results of their first-eye surgery.^[A:III]

Simultaneous Bilateral Cataract Surgery

Most ophthalmologists do not perform bilateral simultaneous cataract surgery for fear of potentially bilateral blinding complications. In published reviews of simultaneous bilateral cataract extraction, no bilateral complications that resulted in visual loss were reported.^{284,285} Indications reported for simultaneous bilateral cataract surgery include the need for general anesthetic in the presence of bilateral, visually significant cataract; rare occasions where travel for surgery and follow-up care is a significant hardship for the patient; and when the health of the patient may limit surgery to one operation.^{284,285} Surgery should not be routinely performed in both eyes at the same time because of the potential for bilateral visual impairment and loss of the ability to adjust surgical plans for the second eye that are based on results from first eye surgery.^[A:III] However, there are occasional circumstances under which bilateral surgery may be indicated, but the potential benefits and risks to the patient should be critically considered.^[A:III]

Postoperative Care

The ophthalmologist who performs the cataract surgery has a unique perspective and thorough understanding of the patient's intraoperative course, postoperative condition, and response to surgery. The operating ophthalmologist is responsible for the care of the patient during the postoperative interval, the time in which most complications occur and within which stable visual function is achieved, and he or she has an ethical obligation to the patient that continues until postoperative rehabilitation is complete. The operating ophthalmologist should also provide those aspects of postoperative eye care that are within the unique competence of the ophthalmologist. If such follow-up care is not possible, the operating ophthalmologist must make arrangements before surgery to refer the patient to a properly licensed, qualified, health care professional for postoperative care with the prior approval of the patient and the health care professional.^{102 [A:III]} The operating ophthalmologist may make different arrangements for the provision of those aspects of postoperative eye care within the unique competence of the ophthalmologist in rare special circumstances, such as emergencies or if no ophthalmologist is available, as long as the patient's rights and welfare are the primary considerations.

The ophthalmologist who performs surgery has an obligation to inform the patient about appropriate signs and symptoms of possible complications, eye protection, activities, medications, required visits and details for access to emergency care.^[A:III] The ophthalmologist should also inform the patient of the patient's responsibility to follow advice and instructions provided during the postoperative phase and to notify the ophthalmologist promptly if problems occur.^[A:III] The patient should always have access to an ophthalmologist for appropriate care if serious problems arise.^[A:III]

Most ophthalmologists provide all postoperative care in their offices. Other members of a team of eye care professionals may also participate in the comanagement of postoperative care. The operating ophthalmologist is responsible to the patient for those aspects of postoperative care delegated to other eye care professionals.^{102 [A:III]}

Discharge

Criteria for discharge after ambulatory surgery are as follows:^[A-III]

- Vital signs are stable.
- Preoperative mental state is restored.
- Nausea and vomiting are controlled.
- Significant pain is absent.
- An escort is available if necessary.
- Postsurgical care has been reviewed with the patient or escort and written postoperative instructions have been provided.
- Follow-up appointment has been scheduled.

Operative complications of an ocular or medical nature are possible indications for unplanned postoperative hospitalization. In the Study of Medical Testing for Cataract Surgery (n=19,250 surgeries), there were 61 (0.3%) hospitalizations on the day of cataract surgery.¹⁰⁵ Ocular complications that may require hospitalization include hyphema, uncontrolled elevated IOP, threatened or actual expulsive suprachoroidal hemorrhage, retrobulbar hemorrhage, severe pain, or other ocular problems requiring acute management or careful observation. Medical complications can include cardiac or respiratory instability, a cerebrovascular episode, diabetes mellitus requiring acute management, uncontrolled nausea or vomiting, acute urinary retention, acute psychiatric disorientation, or other medical conditions requiring management in an acute care setting with careful monitoring. In the Study of Medical Testing for Cataract Surgery, the overall number of medical complications on the day of surgery was 375 of 19,250 surgeries (1.9%).¹⁰⁵

Situations under which planned postoperative hospitalization or admission to an overnight observation unit or a skilled nursing care facility might be warranted include the following:

- Medical conditions are present that require prolonged postoperative observation by nurses or other skilled personnel.
- Visual impairment in the unoperated eye is inadequate for safe ambulation.
- Patient is mentally debilitated or diagnosed as mentally ill.
- Patient cannot exercise self-care (or responsible care is unavailable) during the immediate postoperative period.

Postoperative Medications

There is no clear evidence about the benefits, safety, and efficacy of ocular hypotensive agents for all patients in the early postoperative period. Furthermore, postoperative use of topically applied antibiotics, steroids, and nonsteroidal agents varies among practitioners. There are no controlled investigations that establish appropriate regimens for the use of topical agents. At present, the decision to use any or all of these products singly or in combination should be left to the operating surgeon.^[C-III] Rarely, significant corneal reactions, potentially including epithelial defects and stromal ulceration and melting, have been reported with topical ocular nonsteroidal anti-inflammatory drugs.²⁸⁶⁻²⁸⁸

Postoperative Follow-up

The frequency of postoperative examinations is based on the goal of optimizing the outcome of surgery and swiftly recognizing and managing complications. This requires prompt and accurate diagnosis and treatment of complications of surgery, providing satisfactory optical correction, educating and supporting the patient, and reviewing postoperative instructions.

High-risk patients and functionally monocular patients, patients with glaucoma or who are glaucoma suspect, and patients who had intraoperative complications should be seen within 24 hours of surgery.^[A:III] A patient without high risks or signs or symptoms of possible complications should have the first postoperative visit within 48 hours of surgery to detect and treat early complications, such as infection, wound leak, hypotony, or increased IOP.^[A:III] For high-risk individuals, those with glaucoma, and those with intraoperative complications, a second visit should be performed within 4 to 7 days following surgery.^[A:III] For the routine patient following uncomplicated small-incision cataract surgery, a second visit should be performed 1 to 4 weeks after surgery when the optical results are likely to be stable.^{289 [A:III]}

Irrespective of the planned follow-up schedule, the ophthalmologist performing the surgery has the responsibility to ensure that the patient is informed about and encouraged to report signs and symptoms related to endophthalmitis. A reliable system of communicating with each patient should be established, and the patient must be informed of the risks of delaying examination in the event of symptoms of possible postoperative infection.^[A:III] It should be emphasized that a given proportion of patients with infection may not experience symptoms during the early phases of the disease. Patients should be instructed to contact the ophthalmologist promptly if they experience symptoms such as decreasing vision, increasing pain, progressive redness, periocular swelling, discharge from the eye, new floaters, photopsias, or field defects.^[A:III]

In the absence of complications, the frequency and timing of subsequent postoperative visits depends largely on the size or configuration of the incision; the need to cut or remove sutures; and when refraction, visual function, and the medical condition of the eye are stabilized. More frequent postoperative visits are generally indicated if unusual findings, symptoms, or complications occur, and the patient should have ready access to the ophthalmologist's office to ask questions or seek care.^[A:III]

Components of each postoperative examination should include:^[A:III]

- Interval history, including new symptoms.
- Patient's assessment of visual functional status.
- Measurement of visual function (e.g., visual acuity, pinhole testing, etc.).
- Measurement of IOP.
- Slit-lamp biomicroscopy.
- Counseling/education for the patient or patient's caretaker.
- Management plan.
- Assessment of compliance with postoperative medications.

A dilated ophthalmoscopic or slit-lamp microscopic examination is indicated if there are new visual symptoms or signs. In the absence of symptoms there is no evidence that a dilated examination yields significant benefits in terms of earlier detection of retinal detachment.

A final refractive visit should be made to provide an accurate prescription for spectacles to allow for the patient's optimal visual function.^[A:III] The timing and frequency of refraction will depend on patient needs, the amount of astigmatism, and the stability of the measurement. Sutures, if used, may be cut or removed by the ophthalmologist to reduce astigmatism. Optical correction can usually be prescribed between 1 to 4 weeks after surgery by phacoemulsification or manual nucleus fragmentation methods and 6 to 12 weeks after sutured large-incision cataract extraction surgery.

Posterior Capsular Opacification

Posterior capsular opacification occurs often following ECCE by any method and can cause a gradual decrease in visual function. Nd:YAG laser capsulotomy is an effective surgical procedure to clear the visual pathway and restore visual function, and to improve contrast sensitivity.²⁹⁰ In a recent randomized trial the incidence of PCO was significantly higher in the ECCE group than in the phacoemulsification group at 1 year.¹²⁶ The time of onset of posterior opacification from the time of surgery varies.^{291,292} The frequency with which Nd:YAG laser capsulotomy is performed also varies, reported in the range of 3% to 53% within 3 years' time.⁷⁵ The Cataract PORT study reported a 19.2% incidence of PCO occurring within 4 months of cataract surgery.⁵² The relationship of IOL material, design, and configuration to the risk of PCO is discussed in the section on Intraocular Lenses.

The indication for performing Nd:YAG laser capsulotomy is PCO consistent with an impairment of vision to a level that does not meet the patient's functional needs or that critically interferes with visualization of the fundus.^[A:III] The decision to perform capsulotomy should take into account the patient's needs, preferences, benefits, and risks of the laser surgery.^[A:III] The rate of posterior capsulotomy may be increased in patients with multifocal IOLs, presumably because these lenses reduce contrast sensitivity, which is further impaired by early PCO. The Nd:YAG laser capsulotomy should not be performed prophylactically (i.e., when the capsule remains clear).^[A:III] Same-day bilateral Nd:YAG laser posterior capsulotomy may be appropriate when indicated in both eyes.

Complications of Nd:YAG laser capsulotomy include transient increased IOP, retinal detachment, CME, damage to the IOL, hyphema, dislocation of the IOL, and corneal edema. The Agency for Health Care Policy and Research (now known as the Agency for Healthcare Research and Quality) Cataract Guideline estimated that there was about a 1% or greater rate of the following events after Nd:YAG laser capsulotomy: retinal detachment, glaucoma, failure to improve visual function, increased need for medication, and adverse effects from additional drugs.⁷⁵ One study that controlled for all other known risk factors for retinal detachment found a fourfold increase in the risk of retinal detachment or break in patients undergoing Nd:YAG laser capsulotomy after cataract surgery.¹⁶⁷ Axial myopia increases the risk of retinal detachment after Nd:YAG laser capsulotomy, as does pre-existing vitreoretinal disease, male gender, young age, vitreous prolapse into the anterior chamber, and spontaneous extension of the capsulotomy.²⁹³ In a study of eyes that underwent Nd:YAG laser capsulotomy after ECCE and sulcus-fixated IOLs, retinal detachment, CME, and

new-onset glaucoma each occurred at a rate of approximately 1%.²⁹⁴ One to eight years following phacoemulsification and capsular fixation of the IOL, 0.4% (6/1418) of patients had a retinal detachment in a reported series.²⁹⁵ Of these patients, there were no retinal detachments in eyes with an axial length less than 24.0 mm.²⁹⁵

In the absence of risk factors for IOP elevation, routine prophylaxis with glaucoma agents is not supported by the literature.²⁹⁶ In the presence of risk factors, however, a variety of pharmacologic agents have demonstrated efficacy at blunting IOP elevation.²⁹⁷⁻³⁰¹ In addition to the use of these agents, the surgeon should monitor the IOP at close intervals in the early postoperative period in order to modify the medication regimen if needed.^[A:III]

Follow-up visits after a Nd:YAG laser capsulotomy may vary in frequency, depending on the patient's condition and pre-existing comorbidities. The IOP of patients with compromised optic nerve status or without an IOL that provides a barrier to anterior migration of capsule debris, vitreous, etc., should be monitored after laser capsulotomy.^[A:III] Because retinal breaks or detachments are acute events that can occur weeks to years after laser capsulotomy, a routine dilated fundus examination is unlikely to detect retinal pathology that requires treatment in the absence of symptoms. Most importantly, all patients and particularly high-risk patients (e.g., young patients with long axial length, pre-existing lattice degeneration, or a history of retinal detachment in either eye) should be informed of the symptoms of posterior vitreous detachment, retinal tears and detachment, and the need for prompt examination if these symptoms are noticed.^[A:III]

PROVIDER AND SETTING

The process of identifying a cataract may begin when a patient presents to the ophthalmologist or is referred because of vision-related problems from a primary care physician or an eye care professional. It is the unique role of the ophthalmologist who performs cataract surgery to confirm the diagnosis of cataract and to formulate and carry out a treatment plan.^[A:III] Diagnosis and management require expertise, skill, and specialized equipment. Clinical judgment and experience are necessary to weigh the medical, ocular, and psychosocial factors involved in deciding the appropriateness and timing of surgery.

The performance of certain diagnostic procedures (e.g., measurement of IOP, refraction, implant power calculations) may be delegated to appropriately trained and supervised personnel. However, the interpretation of results and medical and surgical management of disease require the high degree of medical training, clinical judgment, and experience of the ophthalmologist.

Nearly all cataract surgery is performed in an outpatient setting, which may be in a hospital ambulatory surgical center or freestanding surgical center. The surgical facility should comply with standards governing the particular setting of care (e.g., the Accreditation Association for Ambulatory Health Care, Inc., Joint Commission for Accreditation of Healthcare Organizations, American Hospital Association).^[A:III] Inpatient surgery may be necessary because of the need for complex ocular care, multiple procedures, general medical and nursing care, or because of the presence of multiple ocular conditions.

COUNSELING/REFERRAL

Patients with functionally limiting postoperative visual impairment should be referred for vision rehabilitation and social services.^[A:III]



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APPENDIX 1. SUMMARY OF MAJOR RECOMMENDATIONS FOR CARE

INITIAL OPHTHALMIC EVALUATION

- Patient history (including patient's assessment of functional status).^[A:III]
- Visual acuity and refraction.^[A:III]
- External examination.^[A:III]
- Examination of ocular alignment and motility.^[A:III]
- Assessment of pupillary function.^[A:III]
- Measurement of intraocular pressure.^[A:III]
- Slit-lamp biomicroscopy of the anterior segment.^[A:III]
- Dilated examination of the lens, macula, peripheral retina, optic nerve, vitreous.^[A:III]
- Assessment of relevant aspects of the patient's mental and physical status.^[B:III]

Patients should be informed that they should contact the ophthalmologist if they have a change in visual symptoms during the interval between the last examination and surgery.^[A:III]

INDICATIONS FOR SURGERY

The primary indication for surgery is visual function that no longer meets the patient's needs and for which cataract surgery provides a reasonable likelihood of improvement.^[A:III] Cataract removal is also indicated when the lens opacity inhibits optimal management of posterior segment disease or the lens causes inflammation (phakolysis, phakoanaphylaxis), angle closure, or medically unmanageable open-angle glaucoma.^[A:III]

The indication for second-eye surgery is the same as for the first eye, i.e., when the cataract-impaired vision no longer meets the patient's needs and the anticipated benefits of surgery exceed the risks.^[A:III]

Management recommendations are described in the main body of the text.

Components of each postoperative examination should include:^[A:III]

- Interval history, including new symptoms.
- Patient's assessment of visual functional status.
- Measurement of visual function.
- Measurement of IOP.
- Slit-lamp biomicroscopy.
- Counseling/education for the patient or patient's caretaker.
- Management plan.
- Assessment of compliance with postoperative medications.

A final refractive visit should be made to provide an accurate prescription for spectacles to allow for the patient's optimal visual function.^[A:III]

POSTERIOR CAPSULAR OPACIFICATION

The indication for performing Nd:YAG laser capsulotomy is posterior capsular opacification consistent with an impairment of vision to a level that does not meet the patient's functional needs or that critically interferes with visualization of the fundus.^[A:11] All patients and particularly high-risk patients (e.g., young patients with long axial length, pre-existing lattice degeneration, or a history of retinal detachment in either eye) should be informed of the symptoms of posterior vitreous detachment, retinal tears and detachment, and the need for prompt examination if these symptoms are noticed.^[A:11]

PROVIDER AND SETTING

It is the unique role of the ophthalmologist who performs cataract surgery to confirm the diagnosis of cataract and to formulate and carry out a treatment plan.^[A:11]

Nearly all cataract surgery is performed in an outpatient setting, which may be in a hospital ambulatory surgical center or freestanding surgical center. The surgical facility should comply with standards governing the particular setting of care (e.g., the Accreditation Association for Ambulatory Health Care, Inc., Joint Commission for Accreditation of Healthcare Organizations, American Hospital Association).^[A:11]

COUNSELING/REFERRAL

The ophthalmologist who is to perform the surgery is responsible for informing the patient or the patient's surrogate decision maker about the risks, benefits and expected outcomes of surgery, including anticipated refractive outcome and the surgical experience.^[A:11] The ophthalmologist who performs surgery has an obligation to inform the patient about appropriate signs and symptoms of possible complications, eye protection, activities, medications, required visits and details for access to emergency care.^[A:11]

The patient and ophthalmologist should discuss the benefit, risk, and timing of second-eye surgery when they have had the opportunity to evaluate the results of surgery on the first eye.^[A:11]

Patients with functionally limiting postoperative visual impairment should be referred for vision rehabilitation and social services.^[A:11]



APPENDIX 2: SUMMARY OF NUTRITION AND CATARACT STUDIES

Table 1
Summary of Nutrition and Cataract Studies

Study	Date Published	Type of Study	Sample Size	Measure	Results
HIGH-DOSE VITAMIN C, E, BETA CAROTENE AND ZINC					
AREDS ¹	2001	Randomized placebo-controlled	4,629	Supplement use	No effect of treatment on the development or progression of lens opacities
MULTIVITAMIN SUPPLEMENT					
Linxian Cataract ²	1993	Randomized controlled	2,141	Supplement use	36% reduction in nuclear cataract
Nutritional Factors in Eye Disease ³	1994	Cross-sectional	2,152	Supplement use	Decreased risk of nuclear sclerosis
Barbados Eye Study ⁴	1997	Cross-sectional	4,314	Supplement use	Reduced risk of cortical cataract in patients over 70
Physicians Health Study ⁵	1994	Prospective cohort	17,744	Supplement use	Modest, marginally significant decrease
Nurses Health Study ⁶	1992	Prospective cohort	50,828	Supplement use	No association
Longitudinal Study of Cataract ⁷	1998	Prospective cohort	764	Supplement use	33% reduction in nuclear opacities
Blue Mountains Eye Study ⁸	2001	Cross-sectional	2,873	Supplement use	Reduced prevalence of nuclear cataract
RIBOFLAVIN/NIACIN					
Linxian Cataract ²	1993	Randomized controlled	3,249	Supplement use	44% reduction in nuclear cataracts
Lens Opacities Case Control ⁹	1991	Case-control	1,380	Total dietary intake	Lower risk of any type of cataract
Blue Mountains Eye Study ¹⁰	2000	Cross-sectional	2,900	Total dietary intake	Lower risk of nuclear cataract
Nurses Health Study ⁶	1992	Prospective cohort	50,828	Total dietary intake	No association

Table 1 (continued)
Summary of Nutrition and Cataract Studies

Study	Date Published	Type of Study	Sample Size	Measure	Results
VITAMIN E					
VECAT ¹¹	2001	Randomized controlled	1,193	Supplement use	No significant difference
Nutritional Factors in Eye Disease Study ¹²	1999	Prospective cohort	400	Serum tocopherol level	Association with nuclear cataracts
Lens Opacities Case Control ¹³	1991	Case-control	1,380	Serum level	Serum levels associated with lower risk of nuclear cataract
Italian-American Case Control ¹⁴	1991	Case-control	1,008	Serum level	No association
India-American Case Control ¹⁵	1989	Case-control	1,441	Serum level	No association
NHANES II ¹⁶	2000	Cross-sectional	4,001	Supplement use	No significant association
VECAT ¹⁷	2000	Cross-sectional	1,111	Supplement use	Association with absence of cortical opacity
Kuopio Atherosclerosis Prevention Study ¹⁸	1996	Prospective cohort	410	Serum level	Low plasma E associated with increased risk of progression of early lens opacities
Beaver Dam Eye Study ¹⁹	1999	Prospective cohort	1,354	Total dietary intake	No association in overall group
Physicians Health Study ⁵	1994	Prospective cohort	3,533	Supplement use	No association
Nurses Health Study ⁶	1992	Prospective cohort	50,828	Total dietary intake and supplement	No significant association
Baltimore Longitudinal Study on Aging ²⁰	1993	Prospective cohort	660	Serum level	Serum levels associated with lower risk of nuclear cataract
Longitudinal Study of Cataract ⁷	1998	Prospective cohort	764	Supplement use and serum levels	50% reduction in nuclear opacities in regular supplement users and higher serum levels

Table 1 (continued)
Summary of Nutrition and Cataract Studies

Study	Date Published	Type of Study	Sample Size	Measure	Results
VITAMIN C					
Blue Mountains Eye Study ¹⁰	2000	Cross-sectional	2,900	Total dietary intake	No association
NHANES II ¹⁶	2000	Cross-sectional	4,001	Serum level	1 mg increase in serum level was associated with 26% lower risk
Beaver Dam Eye Study ¹⁹	1999	Prospective cohort	1,354	Total dietary intake	No association with overall group
Physicians Health Study ⁵	1994	Prospective cohort	3,553	Supplement use	No association
Nurses Health Study ²¹	1992	Prospective cohort	50,828	Supplement use	45% lower risk of cataract extraction with 10 years or less use
Nurses Health Study ¹⁹	1997	Prospective cohort	247	Supplement use	77% lower prevalence of early lens opacities with use of supplements for more than 10 years



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Cataract
in the
Adult Eye
2001

EXHIBIT B

**STATE OF VERMONT
BOARD OF MEDICAL PRACTICE**

In re: David S. Chase, M.D.

)
) Docket No. MPC 15-0203; et al.
)

STATUS CONFERENCE REPORT

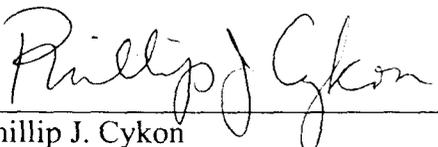
PARTICIPANTS (via Telephone Conference):

Joseph L. Winn, Esq.; Assistant Attorney General
Eric S. Miller, Esq.; Counsel for Respondent
(Respondent not participating)
Peggy Langlais, Medical Board Staff
Phillip J. Cykon, Esq.; Presiding Officer

On January 11, 2006, a Status Conference was held via telephone conference call concerning the above-captioned matter. The following matters were discussed and further schedules were agreed upon:

1. The Consent Order dated 4/9/04 and the Decision on Respondent's Motion to Stay Hearing and contained Order dated 9/20/04 were reviewed and acknowledged to remain in effect.
2. Counsel for Respondent shall file any motion regarding the status of the pending Superceding Specification of Charges, any amendments to his witness list, and any revised requests concerning discovery on or before 2/8/06.
3. The Attorney General's Office shall file it's response to the motion, response to any revised discovery requests, and any amendments to its witness list, on or before 2/17/06.
4. The parties should feel free to request a telephone status conference at any time if they feel one is necessary to advance the resolution of any issues involved in this matter.

FOR THE BOARD:



Phillip J. Cykon
Presiding Officer

1/13/06

Date

EXHIBIT C

1 So, I guess we will need to address that this
2 afternoon at this point. I don't see any particular
3 need to address it immediately, unless either side
4 wishes to?

5 MR. KELLY: I apologize.

6 MR. MILLER: No, go ahead.

7 MR. KELLY: Judge, I appreciate that. I am
8 happy to answer any questions the Court has, perhaps at
9 the end of the day, is fine. We obviously noted in our
10 paper that there is a remedy here, and we are offering
11 that, but perhaps your Honor --

12 THE COURT: You have offered the remedy of
13 calling -- or providing Dr. Kennedy to testify. Trial
14 Practice 101 tells every lawyer that if they have an
15 important witness, an expert witness to be called, that
16 that -- that the subject matter of that testimony is
17 used throughout the trial. I have no doubt that if the
18 defense knew about Dr. Kennedy's observations, not that
19 just Dr. Kennedy was a doctor, but that he in fact could
20 very well have been the auditor for MVP, that every one
21 of the experts, in particular Dr. Holladay, but
22 every one of the experts would have been asked questions
23 about, did you know that the -- that the auditor for the
24 largest insurance company in the state of Vermont would
25 have used BAT on high?

1 And now, at the end of the trial, to have Dr.
2 Kennedy testify I suppose is a remedy. It's up to the
3 defense. But that doesn't -- that doesn't address the
4 full thrust of the problem.

5 MR. KELLY: I apologize. Fair enough. And
6 I'm prepared to answer any questions you have. And I
7 will explain as best as I can, perhaps this afternoon,
8 at length, is the timing.

9 THE COURT: Well, what happened? I mean,
10 I'm -- I am just overwhelmed with this situation at this
11 point, after 12 weeks of trial.

12 How did this document become a part of the
13 disclosure and then disappear?

14 MR. KELLY: I will try to explain that right
15 now.

16 We had combined a number of databases related to
17 3500 material which you know is voluminous in this case.
18 Some of that was from agent reports, some of that was
19 from grand jury material, some of that was from
20 depositions that had been taken in the case, and were
21 scanned in and then were combined.

22 My recollection is that as to Dr. Castrina, and I
23 do not -- and I apologize, I should have a recollection
24 of Dr. Kennedy but I do not have a recollection of any
25 decision made one way or the other about his particular