

**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 MOTION TO RECONSIDER DECISION
ON PRE-HEARING MOTIONS**

Respondent, Dr. David S. Chase, hereby respectfully requests that the Board reconsider its July 12, 2006 Decision on Pre-Hearing Motions in certain respects. In support of his Motion, Dr. Chase submits the following Memorandum of Fact and Law.

I. Introduction.

The Board’s July 12, 2006 Decision on Pre-Hearing Motions (“Decision”) prohibits Dr. Chase from presenting the testimony of the majority of his hearing witnesses, all of whom will offer highly probative evidence of Dr. Chase’s innocence. The Board’s decision rests on errors of law and mistakes of fact that will jeopardize the integrity of these proceedings and all but guarantee reversal, remand, and a second merits hearing. That inefficient and wasteful result will benefit no one. Thus, Dr. Chase respectfully requests that the Board reconsider its Decision at this time, before the parties and the hearing panel invest the enormous time and energy entailed by the merits hearing. In the alternative, Dr. Chase asks the Board to delay any final ruling on the admissibility of certain of Dr. Chase’s witnesses until after the State has presented its witnesses and the parties and the Board are better positioned to determine what evidence is relevant and admissible to rebut the State’s charges.

II. Discussion.

A. The Board Should Allow Dr. Chase To Present His Own Patient Witnesses In Order To Directly Address The Issues Made Relevant By The State.

In its Decision, the Board ruled that the testimony of patients who are not the subjects of the State's charges "is not relevant to Respondent's conduct in relation to the patients who are subjects of the allegations." It excluded such testimony pursuant to the Vermont Rules of Evidence and the Vermont Administrative Procedures Act. The Board's one-sentence conclusion is incorrect: As a matter of law, Dr. Chase's patient witnesses will offer testimony that is relevant, indeed crucial, in a number of separate and important ways.

The Vermont Rules of Evidence, which are fully applicable to this proceeding, define relevant evidence to mean "evidence having *any tendency* to make the existence of *any fact that is of consequence* to the determination of the action more probable or less probable than it would without the evidence." V.R.E. 401 (emphasis added). The Rules go on to dictate that "all relevant evidence is admissible" unless it is specifically excluded by other rules. V.R.E. 402. Here, the testimony of Dr. Chase's patient witnesses is relevant, and therefore admissible, because it directly addresses several issues that the State has made consequential through its own explicit allegations.

1. The Patients' Testimony Will Address Whether Dr. Chase Reasonably Believed That Surgery Would Improve The 12 Patients' Vision, As Required By The American Academy Of Ophthalmology.

The State's primary allegation against Dr. Chase is that he recommended or performed medically unnecessary cataract surgery for the 12 patients included in the Amended Superceding Specification of Charges. (Amended Superceding Specification of Charges ¶¶ 29, 71, 120, 158, 187, 214, 242, 268, 301, 331, 360, 395.) The State and the Respondent agree that the standard for when cataract surgery is medically necessary is contained in the American Academy of Ophthalmology's Preferred Practice Pattern on Cataract in the Adult Eye ("AAO PPP"). (See

State's Proposed Hearing Exhibit Nos. 13 and 14, consisting of the AAO PPP published in 1996 and 2001.) That standard states: "The primary indication for surgery is visual function that no longer meets the patients' needs and for which cataract surgery provides a reasonable likelihood of improvement." (AAO PPP at 15 (2001).) As a result, the Board will be required to decide whether, prior to surgery, Dr. Chase properly concluded that cataract surgery offered a reasonable likelihood of improving the vision of the 12 complaining patients.

Dr. Chase's prior experience with other similarly situated patients is highly probative of whether or not he reasonably concluded that the State's 12 patients would likely benefit from cataract surgery. If, based on his 35 years of experience with other patients, Dr. Chase knew that patients with certain types of cataracts, test scores, and complaints were good surgical candidates, that fact would support his conclusion that other similarly situated patients also would benefit from surgery. Conversely, if Dr. Chase knew from past experience that surgery was not likely to help patients with those same attributes, it would tend to show that his surgical recommendations were wrong. Indeed, that is how good doctors make decisions every day: they draw upon their experience treating other patients and learn from the results of their prior treatments.

The evidence will show that most of Dr. Chase's patient witnesses are similarly situated to the 12 patients in the Superceding Specification: They had cataracts that did not yet cause them to experience a large drop in their Snellen visual acuity scores, but they complained of particular problems with activities of daily living, such as driving at night. Moreover, just like the State's patients, Dr. Chase's patient witnesses had decreased contrast sensitivity scores attributable to their cataracts. On the basis of all of these factors, Dr. Chase recommended surgery for his patient witnesses. They underwent surgery, and their ability to engage in their daily activities significantly improved as a result. Because they are similarly situated to the complaining patients, testimony and medical records directly support the reasonableness of Dr. Chase's determination that the 12

complaining patients, too, were likely to benefit from cataract surgery. As a result, their testimony more than meets the definition of relevance set forth in the Rules of Evidence: it directly shows that Dr. Chase's decisions to recommend surgery to the complaining patients was reasonable and therefore not unprofessional.

These same patients also directly rebut the main evidence upon which the State will rely in its attempt to prove that the 12 patients' surgery was unnecessary. It is expected that the State will argue that because the complaining patients' Snellen scores were good—often 20/30 or better—they could not have had difficulty in their activities of daily living and would not have benefited from surgery as a result. Many of Dr. Chase's patient witnesses also had cataracts and very good Snellen vision scores. Yet, they will testify that prior to surgery they could not see well enough to do the things they wanted or needed to do. They will go on to describe how cataract surgery remedied their visual problems. Thus, their testimony will directly rebut one of the State's main arguments and prove that patients with good Snellen scores, like the State's 12 complaining witnesses, often cannot perform certain activities of daily living and benefit greatly from cataract surgery.¹

The fact that the complaining patients have refused to submit to eye exams by Dr. Chase's experts renders the testimony of Dr. Chase's patient witnesses all the more important. Because the complaining patients have refused to consent to vision testing, it is only through his own patient witnesses that Dr. Chase can directly demonstrate that cataract patients with good Snellen scores, like many of the 12 complaining patients, may nonetheless exhibit significant real life visual deficits that can be remedied through cataract surgery—and therefore be proper surgical candidates. Indeed, without performing eye tests on the 12 patients themselves, Dr. Chase has few if any other ways to prove this important point.

¹ Similarly, as described in detail in Dr. Chase's Opposition to the State's Omnibus Motion in Limine, some of the patients will directly rebut the State's claim that Dr. Chase's standard presentation regarding cataract surgery and second opinions was designed to coerce them into surgery. (*See* Opposition at 23.)

In short, the testimony of Dr. Chase's patient witnesses not only has a tendency to make consequential facts more or less likely, it goes to the very heart of the State's allegations and Dr. Chase's defense. It must therefore be admitted. V.R.E. 401, 402.

2. Dr. Chase's Patient Witnesses Are Directly Relevant To The State's Explicit Allegations That Dr. Chase Acted Willfully And Immorally.

The State does not simply allege that Dr. Chase acted negligently in his treatment of the twelve patients. Instead, as a key allegation in support of its request to revoke Dr. Chase's license entirely, the State contends that Dr. Chase's cataract surgery recommendation as to each patient constitutes "*willful* misrepresentation in treatment." (Amended Superceding Specification of Charges ¶¶ 29, 71, 120, 158, 187, 214, 242, 268, 301, 331, 360, 395 (emphasis added).) Similarly, the State alleges that Dr. Chase's cataract surgical recommendations were not only incorrect but were "immoral" and "dishonest" because the twelve patients did not display sufficient cataract formation to justify surgery. (*Id.* at ¶¶ 33, 75, 124, 162, 189, 218, 246, 274, 305, 335, 366, 399.) In short, the State affirmatively asserts that Dr. Chase recommended surgery to twelve of his patients even though he allegedly knew that they did not need it and would not benefit from it. In an attempt to prove that Dr. Chase acted with this dishonest and purposeful intent, the State will present evidence that the 12 patients had good pre-surgical Snellen vision scores and cataracts that other physicians describe as "early." The State will then present evidence that other doctors recommended against surgery for the same patients. It is apparently the State's contention that no reasonable doctor could determine that these patients would benefit from cataract surgery.

The testimony of Dr. Chase's patient witnesses is directly relevant to the State's explicit allegations that Dr. Chase acted with a purposeful intent to provide his 12 patients with surgery he knew they did not need. As noted above, most of Dr. Chase's patients are similarly situated to the 12 patients in the Superceding Specification. Unlike the State's patients, they will testify that they benefited greatly from cataract surgery. That testimony demonstrates that Dr. Chase had good

reason—based on 35 years of treating cataract patients and continuing education regarding state-of-the-art diagnostic techniques—to expect that the State’s 12 patients would also benefit from cataract surgery, and were therefore proper surgical candidates according to the American Academy of Ophthalmology. Put differently, the testimony of Dr. Chase’s patient witnesses will show that Dr. Chase’s recommendations of surgery were anything but a willful misrepresentation of treatment or an immoral or dishonest attempt to charge patients for surgery that they did not need. Their testimony will show that, instead, Dr. Chase’s recommendations were the good faith result of the cumulative knowledge he had gained in treating other similar patients over the years, and that his experience with those patients provided support for his recommendations as to the 12 patients. In short, their testimony bears directly on Dr. Chase’s intent, which the State has put at issue.

3. The Patients’ Testimony Proves Motive, Which Is Always Relevant.

As noted above, the State alleges that Dr. Chase willfully, dishonestly, and immorally recommended surgery that he knew his patients did not need. It is expected that, at the hearing, the State will contend that Dr. Chase was recommending unnecessary surgery for reasons adverse to his patients’ ocular health, most likely out of a profit motive. While motive is never an element of a civil, administrative, or criminal charge, it is nonetheless always relevant, because a person’s motivations are highly probative of whether or not he or she took the actions at issue in the case. As one leading evidentiary authority put it: Because motive demonstrates the probability of ensuing action, it is *always* relevant. Wigmore on Evidence, vol. 1, § 118 (Supp. 2001). This is true whether the case is civil or criminal, and does not depend on whether the State is required to prove a specific level of intent. See *Sony Corp. v. Soundview Corp.*, 2001 WL 1772920 (D. Conn. 2001) (finding that motive is always relevant, even in a civil case). As a result, court after court has held that it is error to preclude a party from offering evidence of motive at trial. See *id.* at *3; *People v. Steele*, 37 N.Y.S.2d 199, 201 (1942) (exclusion of motive evidence reversible error); *United States*

v. Sriyuth, 98 F.3d 739, 747 (3d Cir. 1996) (evidence of motive is always relevant, and court properly admitted motive evidence introduced by government); *United States v. Day*, 591 F.2d 861, 875-76 (D.C. Cir. 1978) (same).

In this case, whether or not Dr. Chase was motivated to perform surgery out of a genuine desire to improve his patients' ocular health, or whether he was motivated instead by the prospect of profiting from that surgery, is directly relevant to whether he would perform surgery that he knew to be unnecessary, as the State contends. A number of Dr. Chase's former patients will testify that Dr. Chase recommended and performed cataract surgery even though he knew they had no insurance and could not pay for it. This testimony will coincide with the testimony of some of the former staff members who are on the State's own witness list, who will also testify that Dr. Chase made his surgical recommendations without regard for the financial consequences to his practice. Together, these witnesses will help prove that Dr. Chase always acted in what he believed to be the best interests of his patients and in disregard of his own financial well-being. That motive bears directly upon whether he would purposefully recommend unnecessary surgery, as the State contends and Dr. Chase strongly denies.

4. Exclusion Of The Patient Witnesses Violates Dr. Chase's Due Process Rights.

Finally, Dr. Chase has a due process right to present relevant witnesses in his own defense. "Just as an accused has the right to confront the prosecution's witnesses for the purpose of challenging their testimony, *he has the right to present his own witnesses to establish a defense.* This right is a fundamental element of due process of law." *Taylor v. Illinois*, 484 U.S. 400, 409 (1988) (quoting *Washington v. Texas*, 388 U.S. at 19) (emphasis added). As set forth above, the witnesses at issue here are offered for precisely the reasons identified by the Supreme Court in *Taylor*, namely, to counter the State's specific allegations with specific countervailing evidence. It

would be error of a constitutional dimension to preclude Dr. Chase from presenting their testimony to the Board in his defense.

5. The Patient Witnesses Will Not Consume Significant Hearing Time.

Finally, Dr. Chase's patient witnesses, while numerous, will not consume significant hearing time. To the contrary, each of these witnesses will likely testify for 10 to 20 minutes, just as they were allowed to testify in the criminal trial, where many of the same issues were litigated.

B. The Testimony Of Drs. Evans And Ginsburg Is Relevant And Non-Cumulative.

In its Motion in Limine, the State argued that the Board should exclude the testimony of Drs. Ginsburg and Evans as irrelevant. The State did not argue that their testimony was cumulative, and neither party presented arguments or evidence on that issue. Nonetheless, in its Decision, the Board issued a one sentence order excluding the testimony of Drs. Evans and Ginsburg as "cumulative and unduly repetitious." (Decision at 6.) The Board did not indicate which other evidence rendered their testimony redundant. As will become clear during the trial, the testimony of Drs. Evans and Ginsburg is both relevant and non-cumulative and is crucial to disproving the State's charges of unprofessional conduct.

The State has repeatedly attempted to downplay the complicated scientific and medical issues that the Board will need to decide in order to render a verdict in this case, arguing that the medical and scientific validity of contrast sensitivity testing ("CST") and brightness acuity testing ("BAT") are largely immaterial to the Board's decision. At hearing, the State will finally be forced to articulate its theory of this case. However, even at this pre-hearing stage, the State has been forced to concede that Dr. Chase's actual use of CST and BAT is central to the case, stating: "The issue with respect to contrast sensitivity and glare testing is whether Respondent's actual use of such testing was appropriate in the twelve particular cases before the committee." (State's Omnibus Motion in Limine at 9.) Similarly, when the Respondent asked the State to stipulate that Dr.

Chase's use of CST and BAT was appropriate, the State explicitly declined to do so. (*See* Letters between Eric Miller and Joseph Winn attached hereto as Ex. A.) In short, the State admits that the Board will need to determine whether Dr. Chase was properly using CST and BAT testing in his practice. Dr. Evans and Dr. Ginsburg are each uniquely suited to address this important question.

At trial, the State will show that Dr. Chase administered CST and BAT testing identically on nearly every cataract patient, including the 12 complaining witnesses. It will then attempt to prove that Dr. Chase's practice of performing CST using the BAT on its highest brightness setting was inappropriate and designed to overstate the level of his patients' visual disability due to cataract. It intends to introduce the product manual for Dr. Chase's Vector Vision CST device as evidence in support of its claims. It will also attempt to introduce the testimony of other ophthalmologists that use of the BAT on high is clinically inappropriate.

Dr. Evans' testimony is uniquely relevant to rebut the State's charges and evidence. ***Dr. Evans is the inventor and manufacturer of the very Vector Vision CST device that was used to test every patient identified in the Superceding Specification of Charges.*** He drafted the very product manual that the State is seeking to introduce into evidence. Based on his vast and direct experience, described more fully in Respondent's prior pleadings, Dr. Evans will testify that, directly contrary to the State's explicit allegations, Dr. Chase's use of the Vector Vision CST device, with the BAT on high, was proper and consistent with the manufacturer's intended purpose and use. He will also explain how to interpret the CST with BAT test results that are in the 12 patients' charts. His testimony could hardly be more relevant.

Dr. Evans' testimony will not be redundant of that provided by any other witness. Indeed, it could not be. He is the only inventor and manufacturer of the very testing device that is at the center of this dispute. He is uniquely qualified to testify that Dr. Chase properly used CST and BAT testing together to evaluate the 12 cataract patients. He must be allowed to do just that.

Similarly, Dr. Ginsburg will present unique testimony regarding the scientific validity of Dr. Chase's use of CST with BAT as to the 12 complaining patients. As described more fully in Dr. Chase's prior pleadings, Dr. Ginsburg is a vision scientist with vast experience in the fields of CST and glare testing. As part of his work in this case, Dr. Ginsburg performed an experiment specifically designed to determine if Dr. Chase's specific use of CST and BAT was designed to overstate his patients' functional visual disability, as the State contends. In performing his experiment, he tested subjects using the exact same equipment and in the exact same manner as Dr. Chase tested the 12 complaining witnesses. Dr. Ginsburg concluded that Dr. Chase's approach to testing the functional vision of the 12 complaining patients was "conservative and highly justified" from a scientific point of view. ("Analysis of CST and Glare Criterion Used By Dr. Chase for Cataract Surgery," Arthur P. Ginsburg, Ph.D., June 23, 2004," attached hereto as Ex. B). Those opinions are directly relevant to the very issue that the State has made consequential and which it refuses to concede: whether Dr. Chase's use of CST and BAT overstates his patients' visual deficits. There is no other witness who can or will testify to the results of Dr. Ginsburg's study. His testimony is unique and uniquely relevant to a central issue in the case.

In order to present their testimony regarding Dr. Chase's specific use of CST and BAT, Dr. Evans and Dr. Ginsburg may need to provide limited background regarding some of the basic principles of CST and its usefulness in evaluating the functional vision of cataract patients. As the Board is aware, Dr. Javitt is also prepared to address that topic. The Respondent, who has an interest in a streamlined hearing, will endeavor to eliminate any potential redundancies in their testimony. Moreover, to the extent that the three witnesses have overlapping testimony, the Board can limit that testimony at the hearing in order to exclude any evidence it deems unduly repetitious. However, until it has begun to hear Dr. Evans and Dr. Ginsburg in the context of the other evidence

presented by both parties at the hearing, it cannot deem their testimony cumulative of anything. It certainly cannot exclude it in its entirety on that ground.

Under any circumstances, to proclaim certain testimony to be repetitious without first hearing the supposedly redundant evidence would be clear error. It is even more improper where, as here, the State has failed to clearly and consistently articulate what it intends to prove at the hearing. Neither the Board nor the Respondent can yet be certain exactly which evidence will be necessary to rebut the State's charges. It is therefore premature to limit Dr. Chase's ability to mount his defense through expert witnesses. The Board must reverse its decision excluding the testimony of Drs. Ginsburg and Evans and reconsider the issue in light of the other evidence presented at the hearing.

C. The Board Did Not Rule On Dr. Chase's Request That The State Produce All Material Exculpatory Information And Witness Statements In Its Possession.

Dr. Chase asked the Board to order the State to turn over all of the material exculpatory information in its possession, as well as all witness statements it has. He argued that the State's obligation to produce these materials derives from the Due Process Clause of the Fourteenth Amendment to the United States Constitution. (*See* Dr. Chase's Motion for Disclosure of All Exculpatory Information And Witness Statements In The Possession Or Control Of The Board Or The State.) Due process requires the State to turn over information that may not fall within 26 V.S.A. § 1318 or Board Rule 19.1. Nonetheless, in addressing Dr. Chase's request, the Board simply ordered the State to produce all information required by section 1318(e) and Rule 19.1. It did not address, much less decide, Dr. Chase's claim that he is entitled to all material exculpatory information and witness statements in the State's possession, custody, or control, regardless of whether they fall within section 1318 or Rule 19.1. The Board must decide Dr. Chase's claim in this regard.

D. Applicable Caselaw Strongly Supports The Exclusion Of Those Complaining Patients Who Refuse To Provide Dr. Chase Access To Their Medical Records.

Finally, the Board must reconsider and reverse its decision not to exclude the testimony of the complaining patients who refuse to provide Dr. Chase access to their medical records. In its Decision, the Board offers extensive argument in support of the proposition that it cannot compel the 12 complaining patients to provide Dr. Chase access to their medical records. Dr. Chase did not argue to the contrary. Instead, he merely asks that the Board exclude the testimony of those witnesses who refuse to provide Dr. Chase that access—a remedy that is clearly within the Board’s powers. Nonetheless, in a single sentence, and without citation, the Board concludes that “neither the state of the evidence nor the law governing administrative hearings supports Respondent’s request.” (Decision at 5.) The Board’s conclusion is incorrect and must be reconsidered.

As the Board is aware, the Vermont Rules of Evidence are fully applicable to these administrative proceedings. 3 V.S.A. § 810(1). Under those Rules, a patient who puts his or her medical condition at issue waives the physician-patient privilege. V.R.E. 503. Where such a waiver has occurred, but the patient nonetheless refuses to provide access to his or her medical records, the proper remedy is exclusion of the patient’s testimony. *See State v. Skillicorn*, 944 S.W.2d 877 (Mo. 1997); *State v. Luna*, 921 P.2d 950 (N.M. 1996); *State v. Gonzales*, 912 P.2d 297, 303 (N.M. Ct. App. 1996); *State v. Shiffra*, 499 N.W.2d 719, 724-25 (Wis. Ct. App. 1993) (*abrogated on other grounds in State v. Green*, 646 N.W.2d 298 (Wis. 2002)). The State has not pointed to any cases holding to the contrary.

Here, each of the 12 complaining patients has put his or her medical condition at issue by filing a complaint against Dr. Chase accusing him of recommending or performing unnecessary cataract surgery. It is undisputed that most of the complaining patients have refused to allow Dr. Chase to inspect the recent records of their eye doctors. Thus, as a matter of law, the Rules of Evidence and notions of fundamental fairness require the exclusion of their testimony. The

undisputed facts and uncontested law permit no other conclusion. For these reasons, and those set forth in Dr. Chase's original Motion on this topic, the Board should reconsider and reverse its decision not to exclude the testimony of those patients who have refused to provide Dr. Chase with access to their current medical records.

Dated at Burlington, Vermont, this 26 day of July, 2006.

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EXHIBIT A

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PAUL D. SHEEHEY (1919-2004)

VIA FAX & U.S. MAIL
July 13, 2006

Joseph L. Winn, Esq.
ATTORNEY GENERAL'S OFFICE
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Re: In re: David S. Chase MD – Docket No. MPC 15-0203

Dear Joe:

I write to reiterate the Respondent's offer to consent to the State's use of prior trial transcripts of the State's physician expert witnesses in lieu of live testimony at the merits hearing in the above-captioned matter. We propose that the State designate the portions of those transcripts that it would like to use and that relate to the 12 patients in the Specification. We will then designate the relevant portions of the same witnesses' prior cross-examinations that we wish to use in response. If we can agree on the relevant portions of the prior direct and cross-examinations (and I am confident that we can for the vast majority of physician witnesses), the physicians will likely not be required to testify in person at the hearing, thereby saving the Board, the parties, and the witnesses enormous time and resources. Please let me know as soon as possible if this is acceptable to the State and, if so, indicate which portions of which transcripts you wish to use.

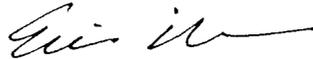
In addition, the State's recent filings suggest that it will not contest that Dr. Chase performed his CST and BAT in a valid and appropriate manner. If the State will stipulate to that fact, it will eliminate the need for Dr. Chase to put on evidence demonstrating that his performance of CST and BAT was proper. Please let me know if the State is willing to enter into such a stipulation, which would be filed with the Board prior to the hearing.

Joseph L. Winn, Esq.
July 13, 2006
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If you have any questions, please call me.

Sincerely,

SHEEHEY FURLONG & BEHM P.C.

A handwritten signature in black ink, appearing to read "Eric S. Miller", with a long horizontal flourish extending to the right.

Eric S. Miller

ESM\khs

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July 19, 2006

VIA FACSIMILE ONLY

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Re: *In re: David Chase:*
MPC 15-0203, et al.

Dear Eric:

This is in response to your faxed letter of July 13, 2006. In the letter Respondent offers to stipulate to certain unspecified portions of the transcript testimony of the State's "experts." The State assumes that "experts" refers to the single expert witness identified by the State (Dr. Morhun) and the testimony of the second-opinion doctors. After giving the proposal some consideration, the State declines Respondent's offer to stipulate to this testimony. The State has concluded that it will be far easier, in terms of both preparation and presentation, to have the testimony presented live.

In the letter of July 13th, Respondent also proposes that the State stipulate that Respondent properly performed CST with BAT. The State declines to so stipulate.

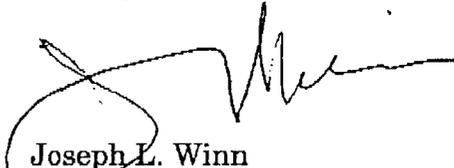

Joseph L. Winn
Assistant Attorney General

EXHIBIT B

VSRC

COPY

**ANALYSIS OF CONTRAST SENSITIVITY AND GLARE
CRITERION USED BY DR. CHASE FOR CATARACT SURGERY**

Arthur P Ginsburg, Ph.D., M.S.E.E.
Vision Sciences Research Corp
San Ramon, California
June 23, 2004

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Aim and Background

The objective of this study is to determine the scientific and clinical validity of the contrast sensitivity and glare criterion used by Dr. Chase to determine the necessity of cataract surgery.

Contrast sensitivity (CS) measures the level of contrast of objects that can be detected by a subject. The higher the contrast sensitivity, the lower the contrast level that can be detected. The Functional Acuity Contrast Test (FACT) and VectorVision CSV 1100 system measure contrast sensitivity using fundamental patterns of sine-wave gratings, which overcomes the limitations of high and low contrast letter charts in which letters of the same size can have different legibility and have less sensitivity and specificity to the size independent visual mechanisms that process contrast. The width of the gratings is referred to by its spatial frequency (the inverse of size); the higher the spatial frequency, the narrower the gratings, similar to the smaller letters in an eye chart. Testing with multiple spatial frequencies is an important consideration as contrast information from each frequency is processed by separate vision channels¹ (see contrast sensitivity.net). Low and middle spatial frequencies correspond to the overall form of an object while higher spatial frequencies correspond to the sharp details. The human eye has maximum contrast sensitivity to the middle spatial frequencies, with the peak, at 3-6 cycles per degree (c/d).² This peak contrast sensitivity has greater implications under low contrast situations as in nighttime conditions where information from middle spatial frequencies such as the gross outline of a car, contributes to initial detection while the smaller details such as the numbers on a license plate, require greater contrast to be perceived.

Dr. Chase measures contrast sensitivity with glare using the VectorVision contrast sensitivity system (CSV 1100) and the Mentor BAT glare system. Studies have shown the importance of contrast sensitivity and glare testing in cataract patients that provides more valuable information than standard visual acuity.^{3,4} Glare is a significant issue in cataract patients due to scattering of light caused even by mild lenticular opacities.⁵ This can significantly reduce visibility, especially under low contrast conditions.

Dr. Chase has established a cutoff of level 3 at 6c/d from the VectorVision system to determine contrast sensitivity loss that would affect functional vision and warrant cataract surgery. In order to determine the validity of that cutoff, there has to be a relationship made to visual function. The only available contrast sensitivity test that links to night driving abilities and other daily visual activities is the FACT test. In order to relate the FACT test to the VectorVision test, an experiment is done that compares the change in contrast sensitivity (CS) from normal between VectorVision and FACT charts in the presence of glare and with light scattering due to cataract simulated with haze glasses. That determination allows a link to be made between the VectorVision system and night

driving visibility and other daily visual activities. Finally, the Chase level 3 criterion is examined for clinical validity as a determinant for cataract surgery.

Methods

Subjects

CS was measured in 20 eyes of 10 subjects within the age range of 26 to 51 years (Mean age = 39 ± 8 years). All subjects had best-corrected Snellen acuity of 20/20 with no history of ocular anomalies.

Procedures

1. Informed consent was obtained prior to the start of study. A consent form is given to each subject explaining the general nature of the study. (Appendix)
2. The room illumination was kept low (<1 foot candle) with light from a reading lamp reflected off the rear wall, similar to the test conditions used by Dr. Chase.
3. The luminance of the FACT chart used at VSRC for CS testing was calibrated to match that of the VectorVision chart used by Dr. Chase, which has standard illumination from a light box. The luminance of gratings was measured at the spatial frequency of 6c/d, which is row C in FACT and B in VectorVision chart. The grating patch luminance in the middle of the FACT chart (C5), as measured with a Minolta photometer, was matched with the average luminance of B gratings in VectorVision chart by adjusting the illumination of light reflected from the FACT chart. The luminance of gratings at the four corners of the FACT chart was also measured to ensure uniform luminance across the chart.
4. Testing was first performed without glare from the recommended testing distances of 8 feet for VectorVision chart and 10 feet for FACT chart. The following were recorded for each eye with and without haze glasses-
 1. Standard acuity on VectorVision chart with high contrast letters.
 2. CS with VectorVision chart at 6c/d (row B) and 12c/d (row C).
 3. CS with FACT chart at 1.5, 3, 6, 12 and 18c/d (rows A through E).
5. CS was measured two times for each eye under each condition and average is taken.
6. The above tests were repeated with glare produced by the Mentor Brightness Acuity Tester (BAT) at high illumination for each eye with and without haze glasses. Adaptation time of 15-20 seconds was given to avoid recording falsely low measurements.
7. Subjects were given sufficient breaks in between tests to prevent fatigue.

Statistical Analysis

Mean and standard deviation of change in CS in logarithmic units under glare and haze visibility conditions are calculated. The normally accepted level of statistical significance is $P < 0.05$. This means that the significant difference between groups is stated with 95% confidence with only a 5% chance of error. $P > 0.05$ means that statistically, there is no significant difference between groups. Repeated measures test is performed since comparisons are performed between different measures in the same individual and not between two different groups of individuals. Paired t-test is chosen for comparison between two types of measures in the same individual, for example, between Vector Vision and FACT. When more than two measures are involved, as in normal, glare and haze conditions, doing multiple t-tests to determine statistical significance of differences can increase error rate. A more advanced Repeated Measures Analysis of Variance (RM-ANOVA) is used in such cases that better controls the error rate. Correlation and regression is used to assess the relationship between CS and night driving visibility distances.

Results

1 Decrease in Contrast Sensitivity under reduced visibility conditions of glare and simulated cataractous haze

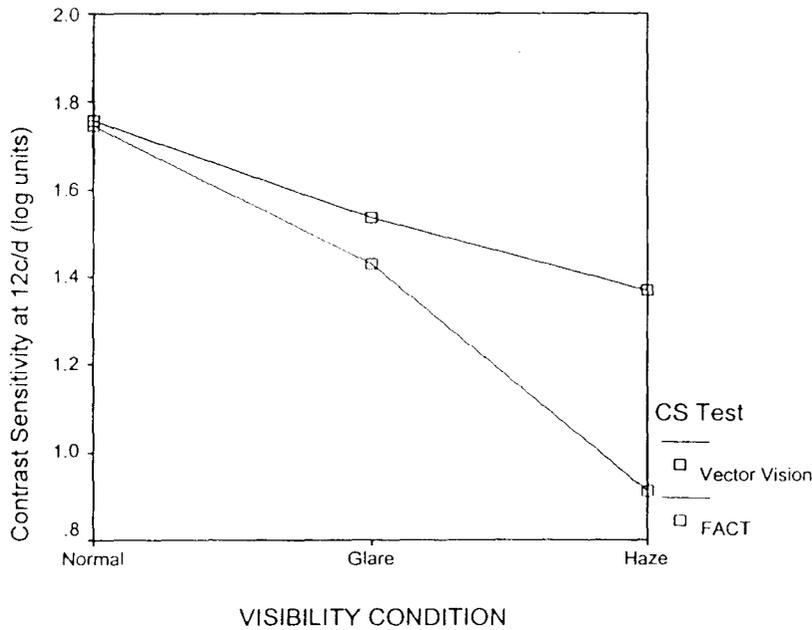
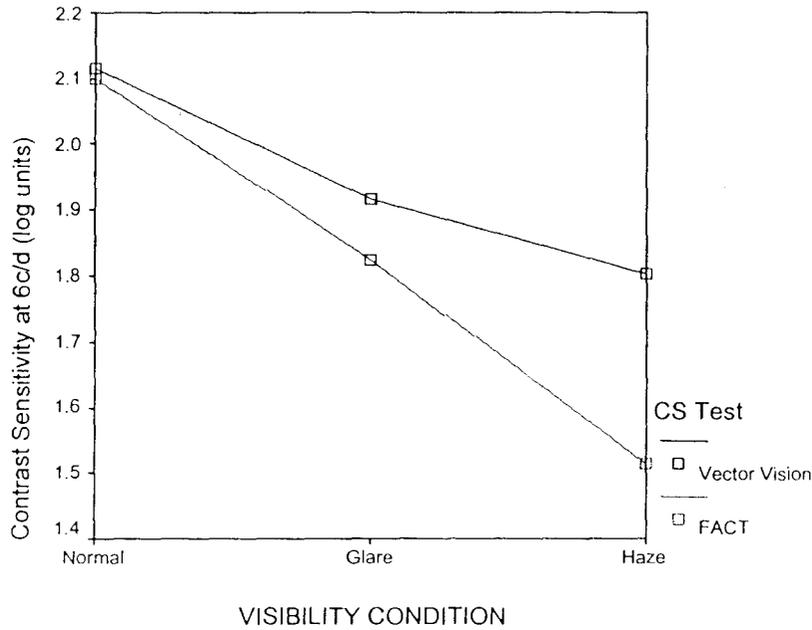
The mean CS (in log units) under normal, glare and simulated cataractous haze is shown below:

Spatial Freq	CS Test	Normal	Glare	Haze	Loss with Glare	Loss with Haze
6c/d	VectorVision	2.12±0.14	1.92±0.15	1.80±0.19	0.20±0.15	0.31±0.15
	FACT	2.10±0.09	1.82±0.09	1.51±0.17	0.28±0.14	0.59±0.13
12c/d	VectorVision	1.76±0.15	1.53±0.17	1.37±0.18	0.23±0.20	0.39±0.17
	FACT	1.75±0.17	1.43±0.16	0.91±0.34	0.32±0.19	0.84±0.27

RM-ANOVA showed that the mean decreases from normal under glare and haze conditions are highly significant at $P < 0.01$ with both VectorVision and FACT tests. Haze resulted in a significantly greater loss in contrast than glare. Contrast testing with haze and glare combined yielded no measurable results, as none of the subjects were able to identify any of the gratings or even see the gross details in the chart.

2 Difference between VectorVision and FACT CS tests under normal, glare and haze visibility conditions

There is significant interaction between type of CS test and visibility conditions at spatial frequencies of 6 and 12c/d by RM-ANOVA ($P=0.000$). Significant interaction means that the difference in observed CS between VectorVision and FACT tests is not constant across all visibility conditions.



As seen from the figures, CS measured by FACT overlaps with that of Vector Vision under normal conditions, is slightly lower under glare and far lower under haze. Statistically, there is no significant difference between VectorVision and FACT under normal conditions ($P>0.05$). Differences were significant under glare ($P<0.05$) and highly significant under haze ($P<0.01$) both at 6 and 12c/d.

With haze glasses, decrease from normal in CS at 6c/d is 0.6 log units with the FACT chart (from 2.1 to 1.51) and only 0.3 log units with the VectorVision chart (from 2.12 to 1.8). At 12c/d, average CS decreases by 0.8 log units with FACT (from 1.75 to 0.91) and only 0.4 log units with VectorVision (from 1.76 to 1.37). This shows that FACT is twice as sensitive as VectorVision. The VectorVision chart used by Dr. Chase is, therefore, a more conservative test for detecting loss in contrast in conditions such as cataractous haze. Thus, it is clear that Dr. Chase could not have over-estimated the loss in contrast in patients using the Vector Vision test.

3 Standard high-contrast visual acuity

The mean high-contrast visual acuity (in logarithmic units and Snellen notation) under normal, glare, haze and haze with glare conditions are as follows:

Visibility Condition	logMAR	Snellen
Normal	-0.07 ± 0.06	20/17
Glare	-0.01 ± 0.07	~20/20
Haze	-0.01 ± 0.07	~20/20
Haze with glare	0.67 ± 0.21	20/95

As seen from the table above, the standard high contrast visual acuity is approximately 20/20 and is not affected under haze conditions while CS, on the other hand, shows a significant decrease. Subjects reported view of the chart as hazy although they were still able to identify the letters in the visual acuity chart. This shows that high contrast letter charts that are conventionally used to evaluate vision are far less sensitive compared to contrast sensitivity tests and do not reflect the quality of vision.^{6,7} Loss in contrast can make the black letters gray and still be legible. Visual acuity decreases only in extreme reduced visibility conditions such as combining haze with high glare. Even under such extreme conditions, subjects were able to make out at least the large letters in the first one or two lines while they could not identify any detail in CS gratings except the gross outline of the whole chart.

4 Relationship between CS and night driving visibility distances –VSRC Validation study

The results of a VSRC Night Driving System validation study for 29 subjects within the age group of 23 to 65 years (Mean age=44.9±12.9 years) are presented here.

4.1 Spatial frequency that correlates best with night driving – 6c/d

The correlation between mesopic (nighttime) CS and night driving visibility distances was determined. CS was measured by FACT at each spatial frequency of 1.5, 3, 6, 12, 18c/d. Visibility distances were measured for road signs (text and warning signs) and hazards (pedestrians) in rural and city driving conditions by the VSRC Night Driving Simulator (NDS).

Normal nighttime viewing conditions – Rural

Mesopic Contrast sensitivity	Detection of road signs		Identification of road signs		Hazard detection
	Text	Warning	Text	Warning	Pedestrian
A (1.5 c/d)	0.051	0.326	0.277	0.247	0.120
B (3 c/d)	0.306	0.473**	0.571**	0.534**	0.261
C (6 c/d)	0.450*	0.453*	0.575**	0.679**	0.370*
D (12 c/d)	0.405*	0.407*	0.506**	0.504**	0.398*
E (18 c/d)	0.278	0.232	0.428*	0.524**	0.234

Normal nighttime viewing conditions – City

Mesopic Contrast sensitivity	Detection of road signs		Identification of road signs		Hazard detection
	Text	Warning	Text	Warning	Pedestrian
A (1.5 c/d)	0.059	0.117	0.067	0.157	0.232
B (3 c/d)	0.350	0.419*	0.422*	0.477**	0.324
C (6 c/d)	0.570**	0.591**	0.602**	0.658**	0.411*
D (12 c/d)	0.463*	0.514**	0.508**	0.569**	0.387*
E (18 c/d)	0.311	0.392*	0.483**	0.490**	0.238

* significant at 0.05 level

** highly significant at 0.01 level

The magnitude of the coefficient of correlations between mesopic CS and visibility distances of road signs and hazards are, in general, greater at 6c/d and statistically significant. The significant positive correlations imply that with decrease in CS at 6c/d, there is a corresponding decrease in visibility distances. This result is consistent with other studies showing that the peak of the contrast sensitivity function at the middle spatial frequencies is most sensitive to changes in contrast.² The spatial frequencies of 6 and 12c/d used by Dr. Chase agrees with this result, which confirms that his choice of spatial frequency for evaluating visual function in patients is appropriate.

4.2 Night visibility distance that relates best with CS at 6c/d - Recognition of road signs

Linear statistical regression is used to estimate equations that significantly predict night visibility distances from mesopic CS at 6c/d in the validation study. The regression measure, R^2 , indicates the percentage of variability in visibility distances that can be attributed to variability in CS at 6c/d.

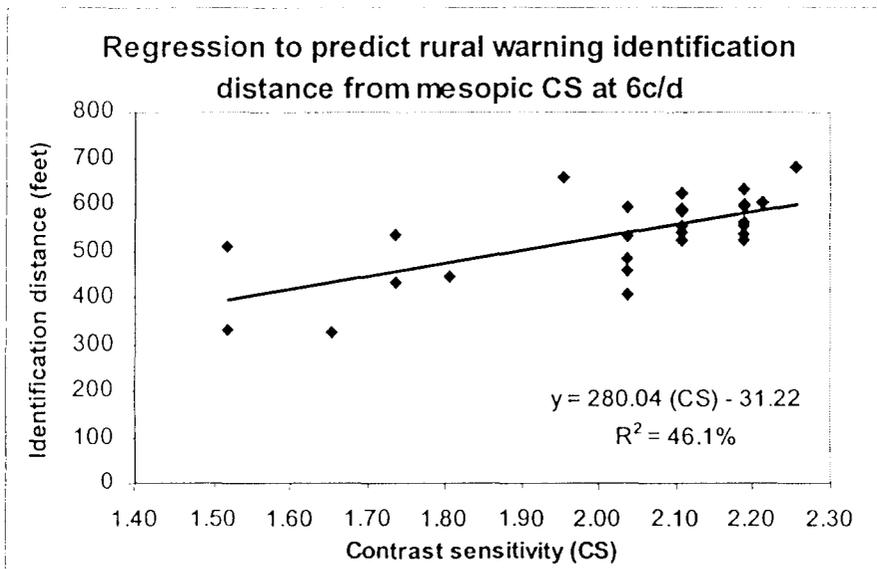
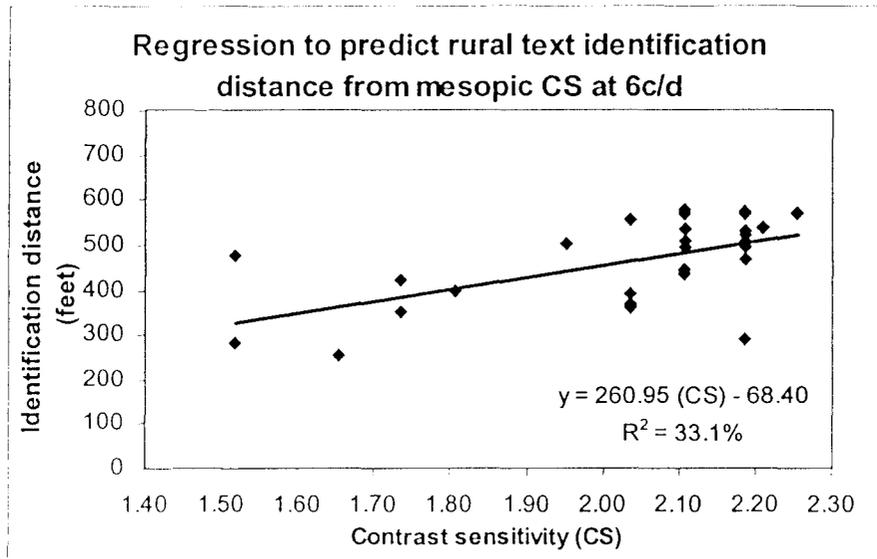
The regression equations for each detection and identification distance, R^2 and statistical significance are given below:

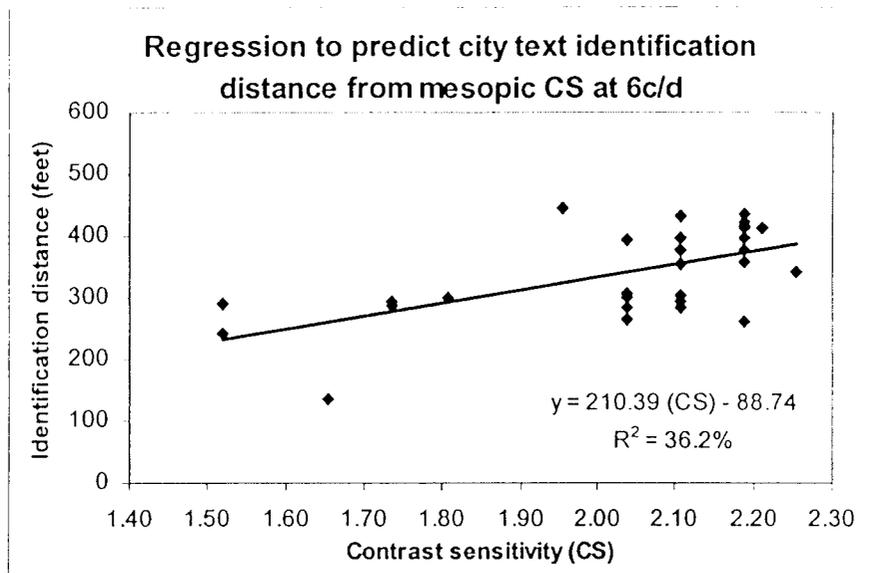
Rural		Regression Equation	R^2	Sig
Predicted variable				
Road sign detection	Text	56.14 (CS) + 597.15	20.2%	0.014
	Warning	80.30 (CS) + 518.33	20.5%	0.014
Road sign identification	Text	260.95 (CS) - 68.40	33.1%	0.001
	Warning	280.04 (CS) - 31.22	46.1%	0.000
Hazard detection	Pedestrian	88.36 (CS) + 452.27	13.7%	0.048

City		Regression Equation	R^2	Sig
Predicted variable				
Road sign detection	Text	199.99 (CS) - 29.21	32.5 %	0.001
	Warning	112.63 (CS) + 120.59	35.0 %	0.001
Road sign identification	Text	210.39 (CS) - 88.74	36.2 %	0.001
	Warning	130.00 (CS) + 78.96	43.2 %	0.000
Hazard detection	Pedestrian	88.36 (CS) + 452.27	16.9 %	0.048

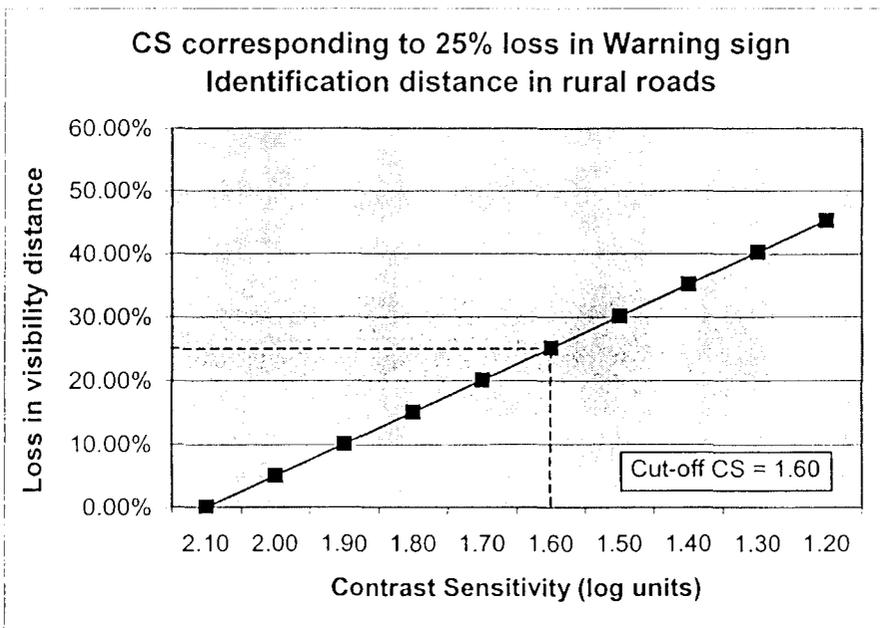
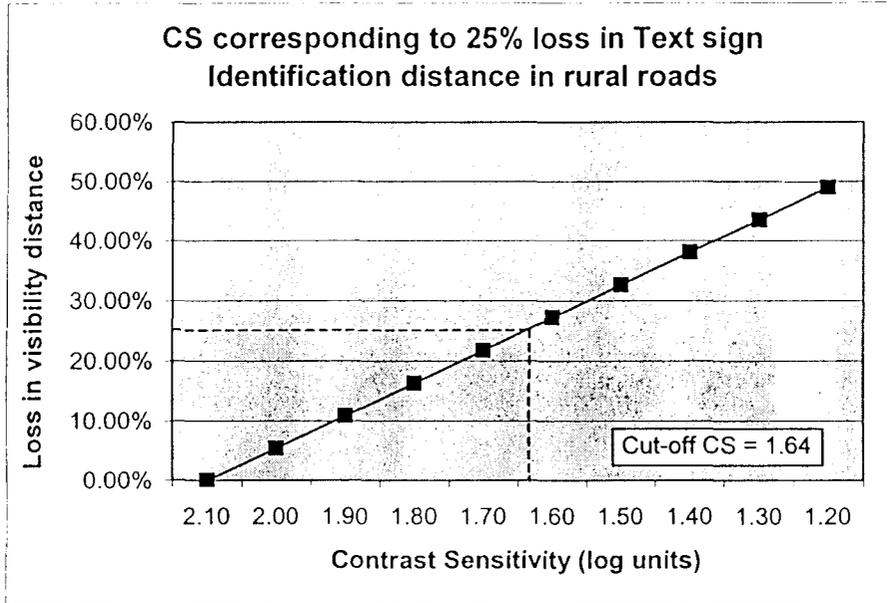
All regressions are statistically significant by ANOVA ($P < 0.05$). R^2 values are, in general, higher for identification of road signs, ranging from 33-46%. For instance, 46% of the variance in identification distance of warning signs can be explained simply by the variance in mesopic CS at 6c/d in rural roads.

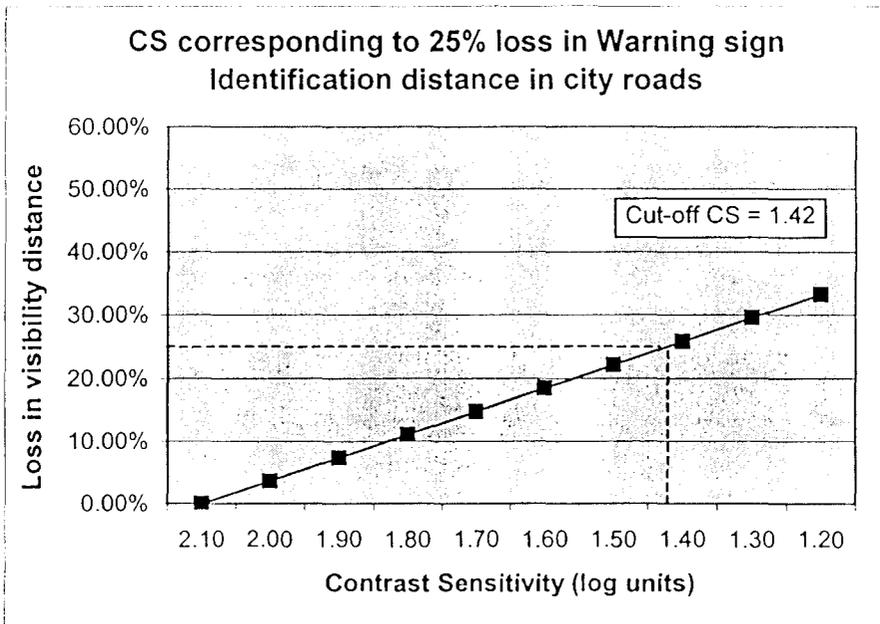
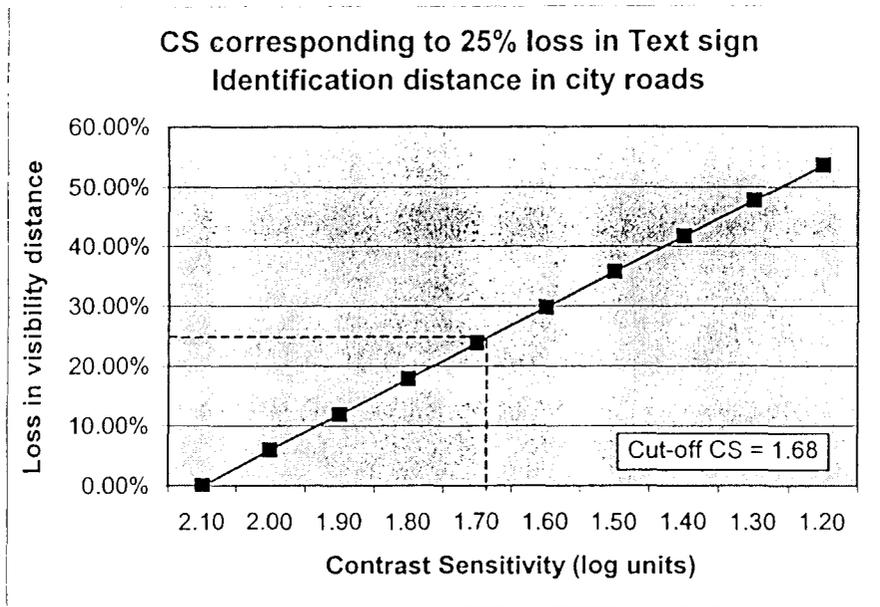
Regression plots of identification distances of road signs predicted from CS at 6c/d in rural and city roads are plotted below. These scatter plots from the data of individual subjects shows how night driving visibility distances decrease with decrease in CS.





conditions in this study was found to be 2.1 log units with both FACT and Vector Vision charts at 6c/d. The visibility distance corresponding to CS of 2.1 log units, as predicted from the regression equations, is regarded as normal visibility distance (0% loss).





Average cut-off CS at 6c/d corresponding to 25% loss in identification distance of road signs at night is 1.60 log units. This means that CS at 6c/d of 1.60 log units or less is associated with 25% or greater loss in night driving visibility distance. The criteria of CS used by Dr. Chase to evaluate decrease in functional vision and determine eligibility for cataract surgery was level 3 or less in gratings B (6c/d) in the Vector Vision chart, which is equal to 1.55 log units. This conforms very well with the FDA criteria of 25% or

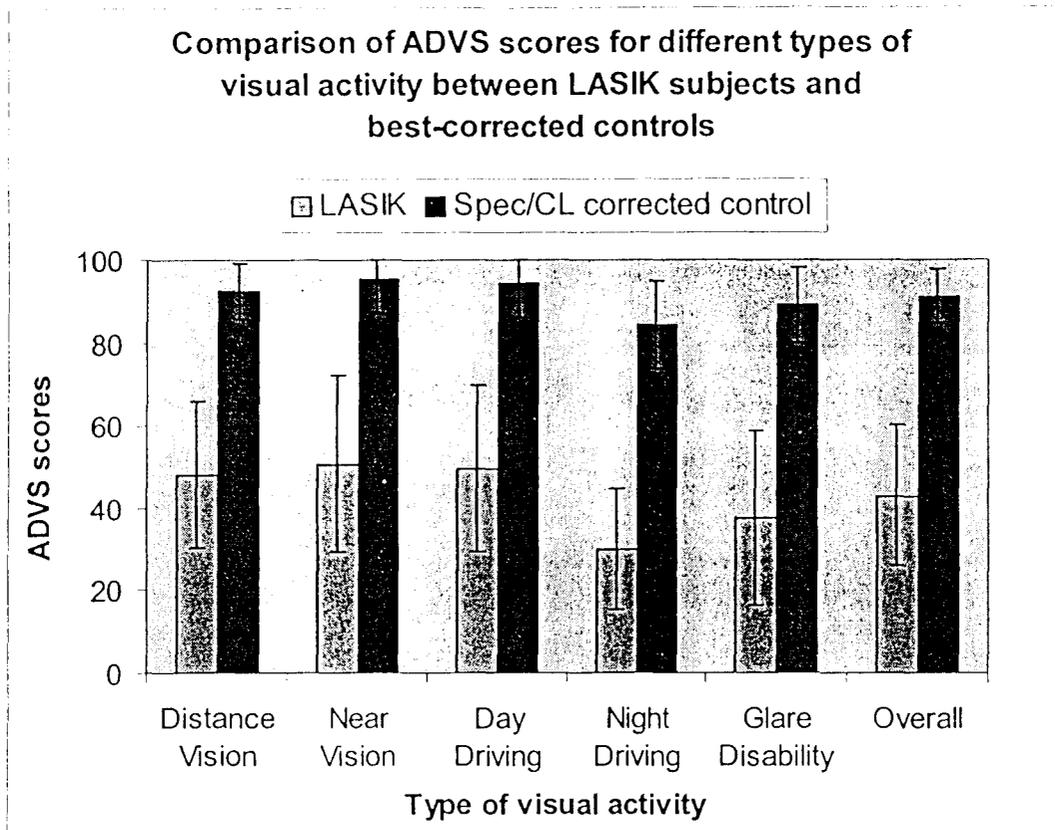
greater loss in functional vision. Moreover, as mentioned earlier, a 4-step decrease of 0.6 log units (74% loss) in FACT has the same effect as a 2-step decrease of 0.3 log units (51% loss) in the Vector Vision chart, which makes Vector Vision chart a less sensitive test. Thus the criterion of 1.55 log units (level 3) or less used by Dr. Chase has been used with a more conservative test.

5 Subjective scores of visual function

Visual symptoms of decreased clarity of vision, night vision difficulties and glare are seen in a variety of conditions that affect contrast, two common ones being cataract and refractive surgery. In both these conditions, a person might have near normal acuity of 20/20 and still have decreased quality of vision. Therefore, the decrease in subjective scores of visual function in LASIK subjects can also be applied to cataract subjects with similar loss in contrast, and vice versa.

The Activities of Daily Vision Scale (ADVS) questionnaire, related to 20 different daily activities, provides a useful measure of visual function from pre-surgical cataract patients for a variety of visual tasks.⁸ The degree of visual difficulty with which a specific activity is performed is rated from 1 to 5, i.e. from so difficult that the subject no longer performs this task to no difficulty at all in performing the task and then that number is transformed to a 0 - 100 scale.

The ADVS subjective scores of visual function of a group of 18 complaining LASIK subjects with loss in CS of 76% at 6c/d are shown in the figure below. This is similar to 74% loss at 6c/d obtained in the present study with simulated cataractous haze. The comparison graph shows the significant decrease in visual function for the complaining LASIK group experiencing a loss in CS compared to the normal controls for all types of daily activities involving distance, near, driving and glare, particularly night driving and glare. Therefore, these results show that cataract patients having a 74% loss or 4-step decrease with the FACT chart at 6 c/d or a 51% loss or 2-step decrease with the VectorVision chart can experience significant loss in everyday functional vision.



Conclusion

In summary, this study shows that the assessment of visual function in patients by Dr. Chase using a combination of visual acuity and grating CS tests with and without the effect of glare is a more comprehensive and appropriate approach to measuring functional vision of cataract patients than testing with standard high contrast acuity alone. This approach has been suggested by the Committee on Ophthalmic Procedures Assessment of the American Academy of Ophthalmology.⁹ This is also in accordance with the guideline of Agency for Health Care Policy and Research (AHCPR) which states that visual acuity is not the sole deciding factor to determine the eligibility for cataract surgery.¹⁰ CS testing overcomes the limitations of Snellen acuity and provides more useful information about the quality of functional vision.¹¹ Contrast and glare sensitivity tests are, in fact, recommended as routine tests in older individuals to ensure driving safety.¹² Disability glare from headlights of oncoming vehicles can impair night driving performance even in individuals with mild cataract changes.¹²

Dr. Chase's choice of spatial frequency at 6c/d for testing CS agrees with the rationale that the peak of the contrast sensitivity function at the middle spatial frequencies of 3-6c/d has the maximum sensitivity to functional vision. This is also observed in the correlations between CS and night visibility distances, which is highest and statistically

significant at 6c/d. Decrease in CS is associated with a decrease in night driving visibility distances, especially for recognition of road signs. As CS at 6c/d drops below 1.6 log units, percent loss in night visibility distance exceeds 25%, which is functionally significant, according to the FDA criterion. The criterion used by Dr. Chase is level 3 (1.55 log units) or less in gratings B (6c/d) with the Vector Vision chart. FACT detects a greater loss in CS with haze compared to Vector Vision and is a more sensitive test. The criterion and approach used by Dr. Chase is, therefore, conservative and is highly justified.

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EFFECT OF HAZE AND GLARE ON CONTRAST SENSITIVITY

This consent form describes your role as a participant. Please read this form carefully. Do not hesitate to ask anything about the information provided.

A. PURPOSE AND BACKGROUND

Differences in contrast perception can exist despite the presence of normal vision, as tested with black-on-white letters. This explains increased symptoms of visual difficulty in some people especially during night time, foggy conditions or in the presence of glare. The purpose of this study is (1) to compare contrast sensitivity differences among normal individuals in the presence and absence of glare and (2) to estimate the decrease in contrast sensitivity in case of simulated cataract with haze glasses.

B. PROCEDURE

You will be asked to point out the orientation of lines in gray backgrounds of varying contrasts with each eye. The test will be performed using two different test charts. The procedure will be clearly demonstrated and practice trials will be given prior to testing. Total testing time is not expected to exceed 3 hours. These tests will be self-paced and you will be given opportunities for breaks.

C. POSSIBLE RISKS

There are no anticipated risks involved in the study. Some people may experience some discomfort with the bright light used for glare, which usually resolves in a few minutes. You are allowed to take sufficient breaks in between tests to avoid fatigue.

D. POSSIBLE BENEFITS

The results of your test can be a part of the data used to evaluate the extent to which cataract (simulated by haze glasses) and glare can affect contrast perception that is not completely identified by conventional visual acuity testing. You will receive compensation of \$15/hour.

E. CONFIDENTIALITY

Your identity will be maintained with confidentiality as is possible within the limits of the law. However, auditors have the right to inspect all records regarding this study. No scientific reports by the researcher or the VSRC will use any identities.

F. QUESTIONS

You may ask any questions you have pertaining to vision tests to the primary researcher, Dr. Arthur P Ginsburg at (925) 837-2083. If you have complaints or questions you don't believe you can discuss with the researcher, you may call Independent Review

Consulting, an independent, impartial reviewer. You may reach IRC at 305 San Anselmo Avenue, Suite 305, San Anselmo, CA 94960 or at (415) 485-0717 during normal business hours.

G. AGREEMENT

I understand that this is the request for consent to use the data of my contrast sensitivity test in comparison studies. I may or may not wish to be a part of this study. By signing this form, I agree that all my questions have been satisfactorily answered and I give my voluntary and informed consent.

Having consented, I still have the right to withdraw at any time without any jeopardy to my relationship with the research establishment by notifying the researcher. I should be given a copy of this form for my reference. I may also request a copy of the California Experimental Subjects' Bill of Rights.

Date

Signature of Subject

Date

Signature of Researcher