

AMERICAN COLLEGE OF EYE SURGEONS

GUIDELINES FOR CATARACT PRACTICE

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1.0 AN OVERVIEW

1.1. Introduction

These GUIDELINES FOR CATARACT PRACTICE were developed and approved by official action of the following organizations:

- a) The American College of Eye Surgeons.
- b) The Outpatient Ophthalmic Surgery Society.
- c) The Society for Excellence in Eye Care.
- d) The Society for Geriatric Ophthalmology.

1.2 Purpose

The purpose of the GUIDELINES is to enhance the quality, safety, effectiveness and availability of cataract care for the citizens of the United States. The GUIDELINES are intended to establish a current consensus, which may be useful to ophthalmologists, other physicians, optometrists, nurses, and other health care practitioners to evaluate the effectiveness and appropriateness of techniques of prevention, diagnosis, treatment and clinical management of the healthy adult patient with cataracts.

1.3 Process of GUIDELINES Development

The process of developing GUIDELINES for cataract practice has been greatly complicated by the rapid rate of the development of instruments and techniques. In just the past thirty years, cataract surgery has become a microsurgical technique, there has been a near total transition from intracapsular methods to extracapsular, artificial lens implantation has become essentially universal, the vast majority of surgical procedures have become ambulatory, and incisions have decreased in size and been redesigned to allow self-sealing closure without the need for sutures. Recognizing that the adoption of technologic change is neither uniform or instantaneous, the authors of these GUIDELINES have felt constrained to insure that valid established practices are not restricted by the GUIDELINES; that neither is new technology promoted nor old technology prohibited where both have a demonstrated valid place in contemporary practice.

In order to meet the challenge of the rapidly developing technology, the GUIDELINES have been written by a panel composed of highly experienced ophthalmic surgeons. These are people who have dedicated their practices to the development of techniques, the development of instrumentation and the teaching of their colleagues. While the foundation of medical practice is established, peer reviewed and confirmed published data, the areas of rapid technologic change must also include the consensus of public debate, professional presentations and the personal experiences of highly skilled clinicians.

These GUIDELINES should be read with a full understanding of this process. The GUIDELINES consist of recommendations for the provision of the highest quality of care for patients who have experienced the functional impairment of cataract; recommendations which represent a consensus reached by a highly experienced panel.

1.4 Organization of the GUIDELINES

To facilitate the application of these GUIDELINES to the care of patients with functional impairment due to cataract, they are organized into the following subjects:

- a) The definition of cataract and visual function.
- b) The natural history of cataract.
- c) Prevention of cataract development.
- d) Analysis of the risk factors in cataract development.
- e) Access to and referral for care of the cataract patient.
- f) The value and suitability of preoperative testing in the management of the cataract patient.
- g) Details in the treatment of the patient for cataract.
- h) The components of postoperative care of the cataract patient.

1.5 Responsibilities of the Parties:

The doctor/patient relationship is a unique bond developed through respect, confidence, loyalty, compassion and trust. The relationship is one of great virtue and should be maintained and enhanced by every interaction between the parties. The remarkable frequency of cataract development in our aging population results in the ophthalmologist having a widespread contact with his community, with the Medicare system and with other third party payers. In addition the emotional overlay regarding loss of visual function produces enormous anxiety and intense expectation in many patients. Consequently the physician is challenged to maintain and enhance his competence while exercising all possible compassion, respect and kindness in managing his patients.

In conflict with the needs of the patient and the normal concern of physicians to meet those needs, the frequency of cataract produces a heavy demand on the insurance and reimbursement system. Patients have been taught to expect care for all disabilities and the overall system has found it difficult to provide that care. The solution to this challenge will require a careful blending of scientific, economic and political considerations.

The physician has well established and firm responsibilities to his patient, including the responsibility for correctness in diagnosis, thoroughness of prognosis, and understanding in the evaluation of the patient's disability, needs and concerns. He is also responsible for completeness in informing and educating the patient regarding his disease and its potential treatment and the ultimate challenge in providing appropriate and competent treatment when the patient makes that elective choice.

The surgeon has the additional responsibility of providing or arranging for full time continuing care of the patient during the recovery period. This includes the responsibility to obtain consultations as appropriate, whether they be a second opinion for questionable diagnosis and prognosis, or for further evaluation of complications or disappointing responses to a therapeutic regimen.

Finally the surgeon has the responsibility to his patient of providing full and accurate records when requested.

The patient also has responsibilities within the doctor/patient relationship: the responsibility to take an active part in the treatment program, to attempt to understand information regarding the disease and its treatment, to make elective decisions about surgical intervention, and to follow instructions, comply with prescriptions, and notify the surgeon should evidence of complications arise.

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cited in Colwell v. Bannister, No. 12-5844 argued on September 12, 2014

2.0 CATARACTS AND VISUAL FUNCTION

2.1 Definition of Cataract and Visual Function

Cataract is generally defined as an opacity or loss of optical uniformity of the crystalline lens. The development of cataract is therefore a continuum, extending from minimal changes of original transparency in the crystalline lens to the extreme stage of total opacity. During the early stages of cataract development there may be no perceptible effect on the patient's visual function while in the late stage of opacity the patient's visual function may be reduced to the mere distinction between light and dark.

Visual function includes the following major factors:

- a) Resolution of high contrast objects, traditionally known as Snellen visual acuity.
- b) Contrast sensitivity.
- c) Field of vision.
- d) Stereopsis.
- e) Spatial orientation.
- f) Color perception.

Cataracts become significant to the patient when they interfere with visual function. There are a variety of techniques and instruments available for the measurement of these various factors. High contrast resolution or acuity is measured according to the standards established by Snellen. In the past, measurement of Snellen acuity was the only way that visual function was quantitated. Each of the other factors has a variety of different techniques available for its measurement in the evaluation of visual function. In each case there is no single established test. However, many techniques produce valid reproducible and useful measurements. In addition, the factor of ambient light level can be evaluated in its effect on the measurement of each of these aspects of visual function, and for this purpose several devices have been made available which simulate the glare production of intense light directed into the eye, light which is scattered by the developing cataract and may interfere with the patient's visual function in each category. The various aspects of pre-surgical testing and evaluation of the patient's vision will be discussed in the appropriate section of these GUIDELINES.

Interference with visual function is the disability experienced by the patient with cataract. A multitude of additional factors bear on the degree of disability experienced by any individual patient. The functional consequences of lens opacification include: loss of driving privileges, the hazard of falling in low light surroundings, inability to maintain an independent lifestyle, and loss of self confidence extending to withdrawal and even depression.

2.2 The Natural History of Cataract

In most instances, cataract development is considered part of the aging process. These GUIDELINES specifically deal with cataracts present in the otherwise healthy adult patient.

It is well known that cataracts develop at a varying rate under different clinical circumstances. The most common variety of cataract associated with the aging process is a progressive opacity of the lens nucleus. During its early stages the nuclear cataract frequently causes progressive artificial nearsightedness, thus resulting in what has been known as "second sight". With the progressive nuclear opacity there is also the development of a misty hazy limitation of distance vision associated with increasing glare effect from intense environmental lights.

Cortical cataracts most frequently begin their development in the periphery and initially have little effect on visual function. As the cortical cataract increases in its opacity and approaches the geometric center of the lens, glare production ordinarily ensues and finally an interference with distance vision, contrast sensitivity and resolution.

The posterior subcapsular form of cortical cataract frequently begins near the center of the posterior capsule of the lens. In that position the posterior subcapsular cataract (PSC) has its initial effect on reading (as opposed to distance function) and the production of glare. The posterior subcapsular cataract is commonly seen to advance rather rapidly such that many patients find a major limitation of their visual function developing over a period of just several months.

All three initial forms and other types of cataract may occur individually or in combination with any other. As each form develops to its more extreme stages, the entire lens becomes involved and reaches a state of "maturity," eventually becoming completely white and opaque.

During the development of cataract, in some patients the lens will expand in physical size and may become obstructive to the outflow system of the aqueous, thus resulting in a form of angle closure glaucoma. In the very late stages of cataract the lens may become a source of inflammatory reaction within the eye and cause a secondary inflammatory glaucoma. In other instances of late stage cataract, the development of a subtle inflammatory disease will result in dissolution of the lens capsule with spontaneous absorption of a portion of the lens tissue and rarely with dissolution of the zonule fibers and eventual dislocation of the entire crystalline lens structure.

2.3 Prevention and Cause of Cataract

There is no currently established proven medical treatment to prevent the development or progress of a cataract in the otherwise healthy adult eye. There are however, a variety of known and suspected risk factors and current research activities are directed toward the question of whether avoidance of risk factors may in fact be preventive for development of cataract.

2.3.1 Hereditary Risk

Familial cataracts may appear at the time of birth or shortly thereafter. However, there also are hereditary factors affecting the development of adult cataracts. Experienced surgeons are aware that in some families essentially all members develop cataracts at an early age and in other families cataracts are essentially unknown. The exact hereditary predispositions have

not been well established.

2.3.2 Alcohol

There is a reported relationship between heavy alcohol consumption and the development of cataracts. It has been speculated that the cataractogenic effect may be mediated through either malnutrition by reduced food intake or the direct inhibition of nutritional factors by the presence of alcohol.

2.3.3 Smoking

A significant relationship exists between smoking and the occurrence of cataracts in two large population groups thus far studied. Again, the mechanism of cataract development is not known.

2.3.4 Ultraviolet and Ionizing Radiation

It is well known that ionizing radiation causes posterior subcapsular cataract development. This has been demonstrated in both microwave and x-ray segments of the spectrum. More recent information implicates exposure to ultraviolet radiation with the development of cataract. Sunlight exposure appears to be statistically significant. It has been conjectured that the development of free radicals in retinal tissue is a mechanism of damage. The possibility of benefit from simply wearing sunglasses is receiving further evaluation.

2.3.5 Diabetes

Patients with diabetes are at higher risk for cataract and in addition have an increased risk of postoperative complication. Acute lens swelling and pseudomyopia is a well known but infrequent concomitant of rapid elevation of blood sugar. This however is a reversible phenomenon. In the diabetic population, posterior subcapsular, cortical and mixed opacities are more common at an earlier age than the general population.

2.3.6 Drugs

Several drugs have been proposed as potentially cataractogenic. The most widely recognized is the cortico-steroid series. Typically, the cataract is a posterior subcapsular variety and appears to be related to dose and duration of therapy. The mechanism of development is not yet known.

2.3.7 Reductions of Risks

From this risk list, it would appear that cataracts are a multifactorial disease process. One must of course consider the possibility that this multifactorial process includes a final common pathway. The investigations into aspirin and antioxidant vitamins are directed toward blocking the mechanism of phase reversal and denaturation of the normal lens protein. Clearly one is not able to control one's genetic make up, but one is able to make a personal choice regarding the use of alcohol and tobacco. However, it is possible that even these risk factors could be attenuated by enhancing the normal protective mechanisms.

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3.0 OBTAINING CARE

3.1 Referral Pathways

Cataract surgery is the most frequent procedure among Americans who are beneficiaries of the Medicare system. Consequently it is of great individual and societal importance to understand just how patients with functional impairment due to cataract receive care and how the process of interaction with the health care system influences outcome.

The process of evaluation and care for the patient with visual functional disability begins with awareness by the patient of his or her limitation. It then leads to consultation for the confirmation of diagnosis, the evaluation of prognosis and planning of appropriate therapy. Patients may become aware through self diagnosis, through conversation with family members or friends who have experienced similar visual functional disabilities or perhaps through a public service vision screening program.

Screening programs are of significant public benefit and are very common in seeking the risk factors associated with diabetes, hypertension, amblyopia, glaucoma, carcinoma of the breast, etc. The objective of screening programs is the identification of risk factors in patients who are asymptomatic with the purpose of establishing earlier diagnosis. Visual functional disability may reach an advanced stage in patients who feel entirely asymptomatic. This is the apparent explanation for studies which have shown that a lower incidence of automobile accidents occurs in states where visual screening for driver licensure is carried out relative to those where no such screening is performed.

The majority of cataract patients are referred to the ophthalmologist by self, family, or friends. However, many are referred by other medical care professionals: ophthalmologists, internists, family practitioners, optometrists, and opticians. In other instances, patients develop cataracts while under the routine care of ophthalmologists and optometrists. The various patterns of referral have a long established history throughout the United States, and have served well for many patients.

From the perspective of patient benefit, the purpose of referral is to establish a correct diagnosis of the cause of decreased visual function, and to assure that other diseases are not present. There are a variety of ocular, neurologic and systemic diseases, which may cause or complicate the visual impairment which results from lens opacities. These associated diseases may also develop in patients with a known diagnosis of cataract. It is in the patient's best interest that his visual disability lead to consultation with an ophthalmologist who has the skill requisite to confirm the diagnosis, properly evaluate the prognosis and assist in the planning of a course of treatment. However, the final decision for surgical intervention of cataract remains the responsibility of the patient after being fully informed of the diagnosis, the prognosis and the potential risks and benefits of treatment.

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4.0 THE SETTING OF CARE

4.1 Setting of Care

The primary criteria for the selection of the setting for cataract surgery are quality and safety.

Cataract surgery is almost exclusively an outpatient procedure, performed either in a hospital outpatient department or an ambulatory surgical center. The selection of the site is the responsibility of the operating ophthalmologist. It is he or she who is intimately responsible for the care of the patient and best qualified to judge the adequacy and safety of the surgical facility. The selection of a site for surgery should not be influenced by financial relations between the ophthalmologist and the surgical facility, nor by the financial arrangements of a third party.

In order to facilitate continuous care, most frequently the pre-operative evaluation, surgery and postoperative care are all provided in the same community. However, if the patient seeks surgery by an ophthalmologist in a distant community, it is the responsibility of the surgeon to educate the patient on the importance and expectations of the continuing care process, and further it is the responsibility of the surgeon to arrange for adequate postoperative care, including the capacity for dealing with complications and emergencies in a timely manner.

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5.0 THE PROVIDERS OF CARE

5.1 Providers of Care

The ophthalmologist who performs surgery has the responsibility and ethical obligation to provide or arrange for total care for each patient.

The operating surgeon has a unique and intimate knowledge of the surgery performed and therefore the expectation of the patient's postoperative condition. However, individual differences in cataract and in patient response to surgery may lead to variations in outcome, even resulting from an uncomplicated surgical procedure. If surgical or postoperative complications develop the surgeon will arrange for appropriate treatment, perhaps to include referral to other physicians. In unusually complicated circumstances, this may extend beyond the normal postoperative period.

The obligation of the surgeon continues until postoperative rehabilitation is complete. During that time, the surgeon has an obligation to educate the patient regarding the signs and symptoms of possible complications, the techniques of postoperative protection, any necessary limitation of activities, the use of appropriate medications, the expected frequency of postoperative visits and the mechanism for gaining access to emergency care. The patient has the obligation to follow the advice and instructions of the surgeon and to actively participate in his care by notifying the surgeon promptly if any problem should occur.

While the operating ophthalmologist cannot abrogate his or her responsibility for the patient's postoperative care, that care may be provided by the delegation of various components to one or more members of an appropriately trained professional team. Such a team may consist of physician associates, referring physicians, physicians in training, optometrists, ophthalmic technicians, visiting nurses, and other health care professionals.

A broad range of team organizations exist and the respective roles of the operating ophthalmologist, the optometrist, visiting nurse and other health care professionals are varied, vaguely defined and lack standardization. The operating surgeon remains responsible for the surgical outcome and for management of the team. It is his or her responsibility to:

- Analyze and be aware of the patient's needs, particularly as related to the eye, visual function, surgical complications, and any co-existent systemic diseases.

- Be aware of the type and degree of the competencies required to build the team.

- Delegate or refer care to other providers if it is appropriate and in the patient's best interest.

- Educate and advise the patient regarding the team members and responsibilities.

- Be aware of and consider costs in all aspects of the patient's care.

- Maintain sufficient communication among the team to co-ordinate care and monitor its quality.

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6.0 DIAGNOSIS AND PROGNOSIS

6.1 Diagnosis and Preoperative Testing

In order for the patient to consider a decision regarding surgical intervention, full information must be given regarding the correct diagnosis of cataract and the prognosis for return of visual function following the anticipated treatment.

The history of visual functional disability will be carefully evaluated, including the effect on both distant and near vision and the effect of varying ambient light circumstances. Many patients have a striking reduction in visual function with Snellen acuity reduced to less than 20/40, and a generalized interference with activities of daily life. Other patients may be disabled by less striking reductions in visual function. For example, an airline pilot may be prevented from performing his job, although his Snellen acuity is better than 20/40.

Contrast sensitivity is a measure of the contrast level required for detection of a specified size of test object. The Snellen measurement of visual acuity on the other hand determines the resolution ability of the eye for high contrast objects. Contrast sensitivity has been shown to be an excellent indication of the speed of recognition of visual targets for pilots and others dealing with rapidly moving test targets. The decreased perception of low contrast objects may be readily quantitated by the technique of contrast sensitivity.

6.2 Glare Testing

Many patients find that the visual effects of cataracts are highly variable depending on the level of ambient light. These patients often complain that their vision is sharply reduced in brilliant sunlight and in night time driving. Glare testing measures the effect of simulated glare on visual function. This allows a quantitation of the effect in those patients who have glare symptoms.

The visual disability of glare may be a significant safety factor in night time driving. Most often such disabling glare is the result of cataract development. Where symptoms indicate, appropriate glare testing may be carried out to explain and quantitate the symptom.

There are several studies which demonstrate the relationship of abnormal glare testing and the presence of cataract and also the improvement of glare test results following cataract surgery. The correlation between glare test results and visual function is high in patients with early posterior subcapsular cataract, cortical cataracts affecting the visual axis and advanced nuclear cataract.

In current practice, glare testing is performed as a part of the evaluation of patients who complain of glare responses where visual function would otherwise be considered satisfactory. On the other hand, where visual function is decreased in normal lighting circumstances, glare testing adds little to the diagnostic evaluation.

6.3 Macular Function Testing

Tests of macular function have been developed to aid in the analysis of prognosis for cataract surgery, i.e. whether the patient will see well following removal of cataract. Two basic types of tests are available: subjective and objective.

The most commonly utilized macular function tests are subjective, high brightness tests which present to the retina a high intensity image of appropriately sized Snellen style opti-types. In eyes with Snellen acuity of 20/200 or better, these tests often allow a very useful evaluation of macular function which when used in conjunction with the history and ocular examination aid the ophthalmologist in counseling the patient regarding the expected improvement from cataract surgery.

6.4 Corneal Endothelial Evaluation

The corneal endothelium is peculiarly sensitive to the trauma of surgery and its condition should be evaluated prior to any intraocular operation.

Specular photo micrography or video micrography is used to measure and record the evaluation of corneal endothelial cells. The techniques provide a permanent record of the magnified image that may be observed during slit lamp biomicroscopy of the cornea. They provide an opportunity to count cells as well as examine their morphology. Corneas with extremely low endothelial cell densities may decompensate, and become edematous and opaque with the passage of time. Patients with a pre-operative reduction of their endothelial cell density are unusually sensitive to the trauma of surgery and may not maintain adequate function in the postoperative period, resulting in corneal edema and leading to eventual corneal transplantation.

Many patients at risk for corneal decompensation can be identified through the history and clinical examination. However, the condition of the endothelium may not be accurately predicted by history and perfect corneal transparency often exists in patients with significant decrease in endothelial cell populations. Specular microscopy is useful in such cases to predict the unusual surgical risks.

6.5 Other Preoperative Tests

Patients who have other ocular diseases in addition to cataract will benefit from additional testing during the pre-operative work up. These special tests may include:

- B-scan ultrasonography
- Computerized corneal topography

- Corneal pachymetry
- Electrophysiological tests
 - External photography
- Fluorescein angiography
 - Formal visual fields
 - Gonioscopy
- Specialized color vision tests
- Tonography

Adequate testing of other diseases which are concurrently present in the cataract patient may be extremely important in the evaluation of the patient's prognosis. Such tests may protect the patient from a disappointing result where the cataract is not the major cause of visual functional disability and may serve as a relative contraindication to surgical intervention.

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7.0 SURGICAL INTERVENTION

7.1 Goal of Treatment

Functional rehabilitation through improvement of visual function is possible in the vast majority of cataract patients and is the goal at each stage of treatment.

7.2 Presurgical Management

In most circumstances, cataract surgery is elective. For the patient with gradually developing cataracts, management consists of reassurance, support and education about the cause of visual disability and its prognosis. During the development of nuclear sclerosis, myopia is induced and changes of spectacle lens prescription will often improve visual function. The use of strong bifocals, appropriate lighting, occasional magnification and other visual aids may satisfy the changing vision requirements as a cataract progresses. Therapeutic dilation of the pupil assists the occasional patient to see around central posterior subcapsular cataract, however, it may also increase glare and visual discomfort. During the early stages of cataract development measures such as these may allow the patients to temporize before deciding on surgical intervention. On the other hand symptomatic anisometropia, loss of driver licensure, or disabling glare may force a patient's decision.

7.3 The Decision for Surgical Intervention

The patient will make the elective decision regarding cataract surgical intervention. The decision will be based on full information regarding the correct diagnosis, the prognosis for improvement and a detailed discussion of the potential risks and benefits of the procedure.

7.3.1 Second Opinion

Second opinion may be useful in unusual cases of questionable diagnosis or prognosis. However, a second opinion does not relieve the examining surgeon of the responsibility for a thorough history and ocular examination and the determination of both diagnosis and prognosis. In the large majority of elective cataract surgery patients, routine second opinion is not beneficial and significantly increases the cost of appropriate care to the patient and to third party payers.

7.4 Indications for Surgery

The purpose of cataract surgery is to reduce and ideally eliminate functional impairment caused by the presence of a cataract. Only rarely is cataract surgery performed for other reasons. Cataract surgery is indicated when the cataract reduces visual function to a level that interferes with daily activities of the patient. The severity of the interference can range from simple glare recognized in intense lighting to reduced ability to perform recreational activities and reading, difficulty with driving, loss of employment, and prevention of independent living.

The appropriateness of cataract surgery at any level of disability depends on a complete assessment of the overall visual function and the needs of the well informed patient. Surgery for cataract is considered when medical, optical and environmental measures have proven inadequate for the patient's personal visual requirements.

The patient should consider the decision to intervene with surgery on the basis of the ophthalmologist's recommendation based on full subjective, objective and educational criteria. The indication for surgery, however, is founded on the patient's requirement for better vision and the patient's personal reasons. Surgery is not necessary solely because the cataract is present. The ultimate decision regarding the desirability and timing of cataract surgery is determined by the patient and the ophthalmologist who is to perform the surgery after a complete evaluation confirms the subjective and objective findings of visual disability related to the cataract.

The indications for surgery are considered for two levels of visual impairment, with 20/40, the common criterion for driver licensure, as the divider.

7.4.1 Visual Disability with the Snellen Acuity Reduced to Worse than 20/40

Cataract surgery is justified and appropriate when the following subjective, objective and educational criteria are met.

- **Subjective:** The subjective criterion is impairment of the ability to carry out needed or desired activities. The patient's decision depends on a personal assessment of visual disability (e.g. impact on driving, reading, watching television, special occupational or avocational needs) and perception of the impact of the disability on lifestyle such as loss of independence or loss of income.

- **Objective:** Visual function cannot be improved to 20/40 Snellen acuity. Evaluation of diagnosis and prognosis has established that cataract is the responsible factor in visual functional disability. The patient's mental status and medical health should permit surgical intervention to be performed safely. In this instance the objective criterion is based primarily on the best attainable level of Snellen visual acuity.

- **Educational:** The patient is educated about the diagnosis, prognosis, risks and benefits of cataract surgery, including the alternatives to treatment. The patient determines that the expected improvement in the visual function outweighs the potential risk, cost and inconvenience of surgery.

7.4.2 Visual Disability with the Snellen Acuity of 20/40 or Better.

Cataract surgery is justified and appropriate when the following subjective, objective and educational criteria are met:

- **Subjective:** The subjective criterion is impairment of the ability to carry out needed or desired activities. The patient's decision depends on the assessment of his or her visual disability (e.g. impact on driving, reading, watching television, special occupational/avocational needs) and perception of the impact of the disability on lifestyle, such as loss of independence or loss of income.

In this category it is expected that a greater disparity of visual function will be seen with varying special activities and environmental circumstances. The patient may experience severe difficulties with reading, while distance visual function is adequate. Conversely, visual function in the controlled living room atmosphere may be acceptable, while the glare of night time driving or open sunlight may be disabling. Careful historical information may clearly demonstrate these special factors in the visual functional disability experienced.

The patient may recognize reduced visual function and describe it in any of the following categories:

- Visual function disability fluctuates as a result of environmental factors, dim illumination or glare.
 - There are bothersome distortions of vision such as monocular diplopia, or multiple ghost images.
 - There is a significant disparity of visual function between the two eyes.
 - Binocular vision is prevented by disparate image sizes with anisometropia.
- **Objective:** Visual function can be improved to 20/40 or better under Snellen acuity standards. However contrast sensitivity and/or glare testing demonstrates a greater reduction of visual function which is consistent with the patient's subjective experience. The patient's mental status and medical health should permit surgery to be performed safely. In this category the objective criterion is based on the evaluation of visual function based on factors other than Snellen visual acuity.
- **Educational:** The patient is educated about the diagnosis, prognosis, risks and benefits of cataract surgery, including alternatives to treatment. The patient determines if the expected improvement in visual function outweighs the potential risk, cost and inconvenience of surgery. As a general rule, the better the Snellen visual acuity, the greater the need for verification and documentation of other aspects of visual function. Similarly, the better the Snellen visual acuity, the more significant the various risks become as measured against the potential benefit. Consequently, the importance of education is greatest for those patients where the visual functional disability is least.

cited in *Comall v. Baunister*, No. 12-1584 archived on September 12, 2014

7.4.3 Visual Disability Due to Cataract in the One-Eyed Patient

(See also Surgical Management Section)

A one-eyed patient is defined as one who has permanent legal blindness of the fellow eye.

The ophthalmologist who will perform the surgery has the obligation to inform and educate the patient of the risk of total blindness when considering potential benefits of cataract surgery. The same criteria apply for both levels of visual disability. The worse the vision in the fellow eye, the greater the need for caution when considering cataract surgery in the eye to be operated upon.

7.4.4 Other Indications for Cataract Removal

There are two other indications for cataract removal:

- Lens-induced disease
- The need to visualize the fundus.

Documented evidence of the presence of lens-induced diseases (phacomorphic glaucoma, phagolytic glaucoma, etc.) may necessitate cataract removal. Because of the risk of permanent damage to vision and possible loss of the eye, cataract extraction may be urgent.

It is necessary to visualize the fundus to adequately manage ocular conditions that would otherwise lead to worse or permanent visual loss in an eye that has the potential for sight (e.g., the patient has diabetes with significant risk of reduced visual acuity from diabetic retinopathy requiring management through visualization for diagnosis or clear media laser therapy) or when other special investigations demonstrate intraocular pathology where further attention is important and requires clear media.

7.5 Contraindications for Surgery

Surgery should not be performed under the following circumstances:

- The patient does not desire surgery.
- Glasses or visual aids provide functional vision satisfactory to the patient's needs and desires.
- Surgery will not improve visual function.
- The patient's lifestyle is not compromised.
- The patient is known to be medically unfit for safe surgical intervention.

7.6 Preoperative Medical Evaluation.

The primary purpose of the preoperative medical evaluation is to ensure a safe preoperative course for the patient. The secondary purpose is to medically evaluate patients who may not be receiving regular medical care. A common-sense approach to preoperative evaluation, sensitive to the medical judgment of a prudent physician and appropriate for evaluating an individual patient, should be used.

The majority of patients undergoing cataract surgery are elderly persons, a patient population with a high prevalence of concurrent multiple medical problems such as coronary artery disease, cerebrovascular disease, hypertension, diabetes mellitus, dementia, arrhythmias, chronic obstructive pulmonary disease, alcoholism, thromboembolic disease requiring anticoagulant therapy, and nutrition problems. Although the data are limited, anticoagulation does not appear to pose a substantial risk for seriously complicating ophthalmic surgery, whereas discontinuing these drugs may impart some increased risk for new thrombotic events in the patient with pre-existing cardiovascular, cerebrovascular, or thromboembolic disease. In addition, patients undergoing cataract surgery commonly have dysfunctional problems of aging, including psychosocial, economic and nutritional difficulties. Functional problems and their cause (often multiple and complex), defined as difficulties that interfere with daily routines, are often unappreciated when conventional histories and physical examinations are done.

Preoperative medical examination and appropriate testing should be done in all patients undergoing cataract surgery, whether the surgery is done in the hospital or elsewhere, and regardless of the type of anesthesia to be used. Preoperative medical management should be guided by the patient's age, the presence of concurrent medical illnesses, the patient's use of medicine and the patient's relative proximity to the location where surgery is performed.

General preventive health measures (e.g., for hypertension, diabetes, smoking, obesity, etc.) are suggested for patients who otherwise may have infrequent encounters with the health care system. This comprehensive health care approach may not be consistent with the patient's aspirations, but patients have the right to know what preventive measures are effective and appropriate in these circumstances.

Preoperative medical evaluation should include screening for functional or emotional disability. Elderly patients should receive special screening of functional status and particular attention should be given to the psychosocial and economic problems imposed by aging. This recommendation is in keeping with the ultimate goal of improving both the patient's overall long-term health and functional ability and maintenance of autonomy.

Areas of special importance to the individual such as cultural, ethical and spiritual values, along with the individual's own assessment of the quality of life, should be taken into consideration prior to surgery to optimally prepare the patient for surgery and recovery. The economic resources of the elderly person should be evaluated prior to surgery, since this often determines access to medical and personal care and influences options for living arrangements.

7.7 Anesthesia

Anesthesia for cataract surgery - general, local or topical.

The choice of general, local or topical anesthesia may affect visual outcome indirectly, through the effects of nausea, vomiting, coughing or sudden movement during the perioperative period. Many cataract patients are elderly with multiple medical problems, and thus at increased risk for morbidity during a period of general anesthesia.

On balance, properly managed local anesthesia is simpler and safer than general anesthesia, especially in patients with significant cardiac or pulmonary problems.

General anesthesia may be preferred, however, in the following situations:

- Extreme patient anxiety.
- Inability of the patient to cooperate with the surgical team.
- Inability to provide satisfactory local or topical anesthesia.
- Known allergy to local or topical anesthetic medications.
- The presence of disorders that may be better managed under general anesthesia, i.e., severe back pain, postural problems, etc.

Local and topical anesthesia involves decisions regarding patient monitoring and local anesthesia involves the choice of technique (peribulbar, retrobulbar, periocular, orbital epidural).

Monitored anesthesia by an anesthesiologist or anesthetist is strongly preferred to non-monitored care, particularly in the free-standing ambulatory surgical facility. The use of modern monitoring techniques is appropriate in cataract surgery given the age of the patients and the high incidence of associated medical problems. Good monitoring might affect visual outcome indirectly if it prevents sustained hypertension, hypotension or hypoxia. Monitoring by qualified anesthesia personnel is appropriate because the ophthalmologist is fully occupied in the surgical technique, and therefore unable to deal with emergencies in a timely manner. Monitored anesthesia includes physiologic monitoring with life support systems available. Full time monitoring by bedside anesthesia personnel may not be as necessary in the hospital environment in which anesthesiologists or anesthetists are readily available in the event of a cardiorespiratory emergency. In **all** settings the patient should have physiological monitoring with life support systems and the potential for intravenous access available.

Either peribulbar or retrobulbar injection (periocular, orbital epidural) is acceptable, and each has its own set of advantages and disadvantages. The injection should be administered by an individual physician, certified registered nurse anesthetist, or licensed anesthesia assistant; an appropriately trained professional who has demonstrated competence in these techniques. The use of sedative drugs (reversible and with reduced side effects) is appropriate to minimize pain and discomfort while local anesthesia is being administered. Both peribulbar and retrobulbar anesthesia should be administered to properly monitored patients with intravenous access established and oxygen/ambu mask available. It should include use of the following monitoring techniques:

- EKG
- Pulse oximetry
- Blood pressure
- Respiration

7.8 Surgical Techniques and Complications

The dramatic revolution in cataract surgery over the last 15 years has been spearheaded by the adoption of micro-surgical techniques. This includes transition to the extracapsular procedure and the development of safe, effective intraocular lenses, and the placement of the intraocular lens behind the iris. The widespread acceptance of intraocular lenses has permitted satisfactory visual rehabilitation of patients with monocular cataracts who formerly would have been dependent on aphakic contact lenses. It is generally acknowledged that with the changes in technique, complication rates have been reduced to the point where surgical intervention is now appropriate at a much earlier stage of visual disability than had hitherto been possible.

Although complication rates of modern cataract surgery are low, when they occur, they may be serious and vision-threatening. It is of particular importance that the ophthalmologist performing the surgery, or responsible for patient care during the postoperative period, diagnose and manage these conditions. Effective treatment may require extensive additional complicated surgical procedures, e.g., glaucoma surgery, retinal detachment surgery, therapeutic vitrectomy, penetrating keratoplasty, and anterior segment revision. Prompt diagnosis and management of these conditions is a basic tenet of appropriate medical care. In the absence of co-morbid conditions and complications, a postoperative corrected visual acuity in the 20/40 to 20/15 Snellen acuity range is a reasonable expectation (80-90 percent likelihood) for a patient with functional impairment due to cataract.

The motivation for using small incision techniques in the cataract surgery is enhanced safety coupled with a more rapid rehabilitation following the procedure. The rationale is that the smaller wound promotes less likelihood of wound dehiscence, more rapid healing and reduced postoperative astigmatism.

There is now evidence that (1) the use of small incision technique leads to a more rapid functional rehabilitation of the patient; (2) the use of phacoemulsification leads to less induced postoperative astigmatism; (3) specific or overall complication rates associated with small incisions by an experienced surgeon, compared to a large incision extracapsular procedure, are as good or better.

Studies in the literature demonstrate that cataract surgery results in significant improvement in visual function and overall functional status in the first postoperative year. It is not possible, however, to determine whether the use of phacoemulsification as compared to the other extracapsular procedures enhances the outcome at one year when measured by reduction or elimination of functional impairment due to cataract.

Ophthalmologists should use their best judgment in selecting the surgical techniques for individual patients with cataract. This decision about the appropriate technique should be made by the ophthalmologist who is to perform the surgery in accordance with his/her training and experience and after discussion and explanation with the patient.

It is the responsibility of the ophthalmologist who is to perform the surgery to do the following:

- Ensure that the patient has had a general medical history and physical examination as appropriate to the planned surgery and the type of anesthesia.
- Ensure that the appropriate keratometry and A-scan measurements have been performed if an IOL is to be implanted.
- Select the appropriate IOL power, and type to be used, if an IOL is to be implanted.
- Review the results of presurgical and diagnostic evaluation of the patient and discuss the findings with the patient or in appropriate cases with another responsible adult acting for the patient.

7.9 Results of Cataract Surgery

7.9.1 Results of Cataract Surgery: Positive Outcomes

There are no data that precisely define the risk and benefits of cataract surgery. However, some estimates can be made

based on literature reports of outcome and complications.

Cataract surgery is a highly successful procedure. In eyes without co-morbidity, a visual result in the 20/40 to 20/15 Snellen acuity range can be anticipated in 80-90 percent. Generally patients can expect an increase in well being and quality of life 80-90 percent of the time. The following is a list of benefits that can be expected to accrue from a positive outcome following cataract surgery. A positive outcome is defined as relief of the presurgical functional impairment and is defined by some or all of the following benefits perceived by the patient, members of the patient's family or the ophthalmologist who performs the surgery.

- Increased ability to read.
- Increased ability to perform minimal activities of daily living.
- Restoration of functional ability to pre-cataract level.
- Increased mobility.
- Increased independence, possibly including the ability to pass a driver's test.
- Better uncorrected vision.
- Improved color vision.
- Reduced glare disability.
- Improved contrast sensitivity.
- Improved depth perception.
- Ability to retain a quiet eye with no treatment-induced disorders.
- Patient satisfaction with the results of surgery.
- Improved sense of mental well-being.
- Improved self esteem.
- Relief from fear of going blind.
- Increased ability to avoid injury.
- Increased interpersonal contact and ability to identify others.
- Increased ability to have doctor observe internal eye for incipient or impending diseases.
- Increased ability to continue/resume function or occupation due to improvement in vision (work, play, drive).

cited in Colwell v. Bannister, No. 12-15844 archived on September 12, 2014

7.9.2 Results of Cataract Surgery: Negative Outcomes

Negative outcomes include failure to achieve expected positive outcomes or the failure to relieve or to improve the preoperative functional impairment as perceived by the patient, the patient's family or the ophthalmologist who performed the surgery. In addition, negative outcome refers to the development of complications that either impair the patient's visual function or consume resources. The following table lists some of the negative outcomes and the frequency of each. These should be considered to be approximate only.

Less than 1:100,000 Death*, Suicide*

Less than 1:10,000 Loss of eye*, Expulsive hemorrhage*, Systemic disease as a result of surgery*, Chronic pain*, Psychosis*

Less than 1:1,000 Loss of vision*, Double vision*, Endophthalmitis*, Depression*

Less than 1:100 Dislocated lens*, Dilated pupils*, Increased requirement of ocular medication*, Retinal detachment*, Bullous keratopathy

More than 1:100 Problems with glare, Intraocular Hemorrhage*, Glaucoma*, Cystoid macular edema*, Ptosis, Adverse effects from drugs used in the treatment*, Increased ultraviolet exposure**, Requirements of further surgery***

NOTE: * The rate increases when there are co-morbid conditions.

** If ultraviolet filtration is **not** included in the IOL;

*** This includes YAG laser capsulotomy.

The success rate of cataract surgery is reduced in the presence of ocular co-morbid conditions. Again, data are lacking to give precise estimates of this effect, but conditions such as corneal disease leading to loss of corneal clarity, glaucoma, and retinal disorders such as retinal detachment disease, macular degeneration, and diabetic retinopathy all contribute to loss of vision and therefore, loss of the effect of the cataract surgery. The effects may be immediate, that is, proximate to the time of the surgical effect, or may become manifest a considerable period after the surgery is complete.

In considering all possible risks and benefits, these conditions must be taken into account. The degree to which they are treatable or being treated or that surgery is modified to account for them will influence the outcome. Overall, in the presence of these conditions, the success rate of the surgery is reduced from the overall high level of expected outcome in the eye without co-morbid conditions. Visual loss, with these morbid conditions, may occur even without surgery.

7.10 Second Eye Surgery

Indications for surgery on the second eye are similar to those for the first eye surgery.

When an individual who has already had cataract surgery in one eye has or develops a cataract in the second eye, the patient and the ophthalmologist are confronted with the same issues regarding the decision for surgery that were present during the evaluation of the cataract in the first eye. In addition, the disabilities caused by a visual deficit in the second eye are significant, e.g., loss of binocularity and stereopsis. Restoration of binocular vision enhances visual functions such as acuity, stereopsis, and the visual field, thus justifying surgery in the second eye.

Surgery in the second eye is justified and appropriate when the subjective, objective, and educational criteria outlined in the discussion on **Indications for Surgery** are met.

There are no scientific data to indicate an optimal or minimal time interval for surgery on the second eye.

Other factors to consider are:

- The patient's ability to provide informed consent for surgery on the second eye after he/she has been able to evaluate the visual results and postoperative course of surgery on the first eye.
- The passage of an adequate time for the detection and treatment for the most immediate vision-threatening complications of cataract surgery.
- Vision in the operated eye has recovered sufficiently so that the patient is not at risk of injury due to functional impairment during the second eye cataract surgery and the immediate postoperative period, or in the event that vision has not recovered or is not recoverable, there is time to arrange for adequate assistance so the patient is not at risk of injury due to functional impairment following second eye cataract surgery.

The following factors may influence the patient's and physician's judgment regarding the timing for surgery on the second eye:

- The nearest available facility for surgery and the appropriate postoperative care.
- The patient has a need (e.g., occupational) for good binocular vision within a limited time after the first eye surgery.
- The patient is symptomatic due to anisometropia.

Early spectacle correction or decrease in the duration of the postoperative course alone are not always adequate justification for performing surgery on the second eye before the patient and the ophthalmologist have had a sufficient opportunity to evaluate the results from the surgery on the first eye. The final choice must remain in the hands of the patient combined with responsible counseling by his physician.

Evidence is now accumulating that earlier intervention leads to a more rapid rehabilitation time, and a shorter presurgical disability time, and also results in a lower complication rate. Cataracts which have been allowed to progress to a very advanced stage present several problems. These include:

- Hypermature and mature cataracts present a higher incidence of capsular rupture with vitreous loss and subsequent additional retinal complications.
- Dense nuclear cataracts may present increased danger to the corneal endothelium by requiring longer phacoemulsification times, or by their physical contact with the endothelium during extracapsular removal.

The timing of consideration for surgery on the second eye is the same as the indication in the first eye. It is inappropriate to prescribe any specific arbitrary waiting period between the two procedures. Prior to the development of intraocular lens implantation it was common in the United States to operate on the second eye on the second or third postoperative day while the patient was continuously hospitalized. This allowed the convenience and economy of simultaneous hospital recovery from both procedures. When intraocular lens implantation came on the scene, surgeons cautiously and correctly changed this procedure and initially chose a twelve-month waiting period between the two eyes. This was a very realistic action based on the primitive lens designs and procedures and the uncertainty of complications during the postoperative period. The safety and efficacy of lens implantation is now well established, and this surgical procedure is often described as the most successful of all major operations performed on the adult patient.

In the United States the legal climate has prevented the popularity of simultaneous bilateral cataract surgery. However, there are certain clinical circumstances where the patient's needs and health might suggest the consideration of such a procedure, such as advanced bilateral dense cataracts in a patient whose poor general health required that anesthesia be utilized. In that situation, one anesthetic may be safer than two.

The postoperative period for cataract surgery extends until the vision has "stabilized". With present day cataract techniques, stabilization of most patients occurs in the period from several days to several months following surgery, the larger number stabilizing within several weeks. Consequently, based on the variations of technique and patient factors, the postoperative period when it can be considered safe to perform the procedure on the second eye simply cannot be arbitrarily set. The decision should be left to the discretion of the patient, in assessment of his needs coupled with the advice of his surgeon. Most of the truly serious complications occur within the first several days following a cataract procedure.

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8.0 POSTOPERATIVE CARE

8.1 Postoperative Care

The operating surgeon is responsible to the patient for postoperative care. The number of postoperative office visits should be set individually according to the experience of the surgeon, the type of surgery performed and the individual needs of the patient.

During the past twenty years, improvements in the technology of cataract surgery have greatly changed the postoperative management of the cataract patient. The widespread transition from general to local anesthesia, the earlier visual rehabilitation with intraocular lens implantation, and the trend toward smaller and durable incision designs have resulted in a much earlier return to the activities of daily life. These changes have also reduced the need for direct face to face care by the operating surgeon. However, the postoperative care is the responsibility of the surgeon, personally or through delegation to colleagues. It is important that care be provided to the patient by competent surgeons, who are both aware of and able to manage any and all complications of the cataract procedure.

Today, the patient is often discharged from an ambulatory surgical facility within the hour of surgery. He or she is ordinarily contacted by telephone later the same day to reassure and reinforce postoperative instructions.

The postoperative patient is ordinarily examined on the first day following surgery, then again during the month following surgery. Additional visits are thereafter scheduled according to the surgeon's experience and the patient's needs. However, through the entire convalescent period, immediate and appropriate care must be readily available to the patient at any time of day or night. The surgeon continues to bear this ultimate responsibility.

From the patient's perspective, the period of postoperative care expands from the day of surgery until the goal of stable, improved visual function is achieved. In the absence of complications, most patients are prescribed a refractive correction when the point of stability is reached. At that point, healing is sufficiently advanced that the integrity of the eyeball has been reestablished and any intra or postoperative complications that may have occurred have been diagnosed and treated. If serious complications develop, the period of intensive treatment may extend well beyond the normal global period of postoperative care.

8.2 Patient Postoperative Education

The operating surgeon has the obligation to provide education and instruction to the patient regarding the following: resumption of activities, protection of the eye, the use of normal medications, the timing and scheduling of normal postoperative visits, the identifying signs and symptoms of possible complications, and detailed instructions for gaining access to emergency care. The patient of course has an obligation to actively participate in his or her care by following the surgeon's advice and instructions, and immediately notifying the surgeon should any evidence of problems arise.

8.3 Condition at Discharge

Following cataract surgery and very short recovery period, patients are normally discharged to their home or other local accommodation. The criteria for discharge after ambulatory cataract surgery include:

- Stable vital signs.
- Return to preoperative mental state.
- Absence of nausea and significant pain.
- Presence of a responsible escort or driver.
- An understanding of the postoperative instructions for the first 24 hours, including relief of pain, and method of gaining access to emergency care if needed.
- A written review of postoperative instruction.
- A clear understanding of the follow up appointment scheduled for the following day.

8.4 Postoperative Hospitalization

A small number of cataract patients may be hospitalized after surgery for either planned or unplanned circumstances.

8.4.1 Planned Postoperative Hospitalization

Possible indications for planned postoperative hospitalization include:

- The presence of medical conditions that will require prolonged post operative observation by nurses and or skilled personnel.
- The mentally disabled or demented patient who is functionally incapacitated and unable to maintain a level of self care.
- Disabling loss of vision in the fellow eye in patients who have insufficient companionship and help in the home.

8.4.2 Unplanned Postoperative Hospitalization

Possible indications for unplanned postoperative hospitalization are as follows:

Postoperative complications of an ocular or medical nature are possible indications for unplanned postoperative hospitalization. Ocular complications can include hyphema, infection, wound dehiscence, endophthalmitis, uncontrolled elevated intraocular pressure, threatened or actual expulsive hemorrhage, retrobulbar hemorrhage, severe pain or other ocular problems requiring acute management or careful observation. Medical complications can include cardiac instability, 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 acute management or careful monitoring.

8.5 Postoperative Visits

The frequency of the examination during the postoperative period is determined by the surgeon's experience and the patient's needs. The office examinations provide the opportunity to:

- Provide routine postoperative care as healing progresses.
- Educate and support the patient during the postoperative period.
- Identify, diagnose and treat any complications that may arise.

Fortunately, serious complications are extremely uncommon with contemporary cataract surgery. However, they occur unpredictably and when inadequately treated may have a devastating effect on the outcome of the surgical procedure. Consequently, the patient must be educated and frequently reminded of the need for professional evaluation of any abnormal occurrences during the postoperative period. Among the most serious complications are intraocular infections and secondary glaucoma. While the most serious and acute examples tend to be present within the first several postoperative days, such complications may arise even weeks or months later with potentially serious results. Consequently the scheduling of routine visits is a very general guide which should be expanded in the case of any unusual findings or complications and further expanded by raising the patient's level of suspicion regarding any untoward experiences.

The suggested guideline for normal follow up examinations of the patient without signs or symptoms of complication is:

- First visit, during the first day following surgery.
- Second visit, within the first month following surgery.
- Additional visits, as necessary throughout the global period.

8.6 Postoperative Examination

The postoperative visits should include the evaluation of visual function, the condition of the postoperative eye with special emphasis on possible complications and screening for undiagnosed preoperative conditions and concurrent ocular diseases. These examinations would include external, slit lamp examination, intraocular pressure, and as necessary, ophthalmoscopy.

The suggested components of postoperative examination include the following:

- Visual function, each visit.
- Intraocular pressure measurement, each visit.
- External examination, each visit.
- Slit lamp examination, each visit.
- Patient counseling/education, as necessary.
- Ophthalmoscopy appropriate to the patient's clinical circumstances.

Optical correction can be prescribed when the refraction is stable, usually 2 - 6 weeks after surgery, or earlier if warranted by patient needs.

8.7 Long Term Follow Up

Ambulatory surgery is an opportunity to fully recognize the rehabilitative needs of the cataract patient. The collaborative efforts of the surgeon, optometrist, ophthalmic nurse, ophthalmic technician and assistants and medical social workers result in a customized discharge plan for the full rehabilitation of the patient. The total care plan along with appropriate examinations and evaluations, patient education and family counseling will include all members of the treatment team and cover the pre and postoperative period. The process only begins in the physician's office.

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9.0 PATIENT REHABILITATION

9.1 Rehabilitation

Factors which influence the successful rehabilitation of the cataract patient include:

- Effectiveness of patient education.
- Timely management of postoperative complications.
- Patient compliance with physician instructions.
- The patients physical abilities and psychological state.
- The patients economic position.
- Multiple ethnic, cultural and environmental factors.

cited in Colwell v. Bannister, No. 12-15844 archived on September 12, 2014

9.2 Patient Education

The patient's education regarding cataracts and cataract surgery begins intensively during the initial evaluation and pre operative care. It often requires re-education of the numerous misconceptions and mis-information that the patient has previously attained. Many patients do not realize the extent of visual functional impairment because of the gradual progressive character of its development. This fact may explain the true value of public service visual screening programs. During the preoperative evaluations, the focus of the patient is likely to be directed to the diagnosis, prognosis and surgical procedure. However, education for the postoperative period also begins at that time. Following surgery the postoperative education is reinforced and frequently include in the education of responsible companions.

9.3 Management of Postoperative Complications

Complications following modern cataract surgery are both uncommon and unpredictable. Since early intervention usually results in a positive outcome, it is important to educate the patient to recognize the symptoms of these complications and to notify the surgeon immediately.

9.4 Economic Factors

The patient has a right to and deserves full disclosure of his economic responsibilities related to his medical care. Counseling should include not only the direct costs of surgery and the patients individual responsibility, but also the possibility of indirect expenses and the cost of complications should they arise.

9.5 Environmental Factors

The patient's home and neighborhood environment may affect his postoperative rehabilitation. Part of the social history may be needed to determine this.

9.6 Cultural and Ethnic Factors

Recognition of the mores and the presence of interpreters help to communicate the planning and developing of an appropriate plan of care.

9.7 Psychosocial Factors

The impairments of the elderly should be understood and dealt with to provide adequate postoperative care. For several reasons elderly people may not report their symptoms. As important as screening programs are in detecting functional impairment due to cataracts, it is equally important to deal with the psychosocial problems postoperatively as the patient is frequently more dependent during this period while he is simultaneously attempting to increase his independence. The rehabilitative plan should address this dichotomy to ease the patient's course.

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10.0 AFTER CATARACT

10.1 Posterior Capsular Opacification

Opacification of the posterior lens capsule (PCO) occurs frequently after all forms of extracapsular cataract surgery. As the opacification increases, the patient begins to notice a decrease in visual function that can lead to functional impairment.

Opening of the posterior lens capsule usually relieves the symptoms. It is most frequently performed with a Nd:YAG laser. Laser capsulotomy is a surgical procedure. Posterior capsulotomy may also be done by incising the capsule with a knife or needle, i.e., discission. Occasionally the capsule is opened at the time of the primary surgical procedure.

As with the cataract, impairment of visual function due to capsular opacification is evaluated by the history, special testing and physical examination. Patients often complain of progressive loss of visual function with increasing symptoms of glare and decreased contrast sensitivity. There may be measurable progressive myopia, and the examination will demonstrate physical changes in the posterior capsule.

Visual functional disability resulting from capsular opacification is the indication for posterior capsulotomy. The occurrence is seldom significant during the first three postoperative months unless there is residual opacity of the capsule at surgery or a significant inflammatory reaction. The rate of clinically significant capsular opacification increases from the first to fifth years postoperatively and may reach as much as 50%.

The management of functional impairment due to posterior capsule opacification resembles that for cataract, except that the risk/benefit ratio is altered by a generally perceived lower risk. Considerations of management include the following:

- Diagnosis
- Prognosis
- Indication for surgery
- Contraindication for surgery
- Surgical technique and complications
- Postoperative care and long term follow up

10.2 Diagnosis

Opacification of the posterior capsule may occur in any patient who has previously undergone extracapsular cataract surgery. In most instances the patient will have enjoyed considerable improvement in visual function following the cataract procedure and then a progressive decline in acuity and contrast with progressively increasing glare. In the context of this history, tests can demonstrate the reduced contrast sensitivity and increased glare effect. In addition pinhole testing frequently may demonstrate a major improvement in resolution and macular function testing may demonstrate a normal response. Examination of the eye will demonstrate a physical change in the posterior capsule and may demonstrate a distortion in the view of fundus details with the ophthalmoscope.

10.3 Prognosis

The prognosis for improvement by posterior capsulotomy is often established by demonstration by improved visual function on pinhole and macular function testing.

10.4 Indications for Posterior Capsulotomy

Posterior capsulotomy is indicated when the following subjective, objective and educational criteria are met.

- **Subjective:** The patient's visual function is decreased to the point of interference with needed or desired activities of daily life.

- **Objective:** The examination confirms the diagnosis of opacity of the posterior capsule, distortion of optics and has established a good prognosis for relief of symptoms through treatment.

- **Educational:** The patient has been educated regarding the diagnosis and prognosis and informed of the potential risks and benefits of the capsulotomy procedure.

As with cataract surgery posterior capsulotomy may occasionally be indicated for reasons other than the improvement of visual function, i.e. to provide better visualization of the posterior pole for diagnosis, evaluation or treatment of:

- Retinal detachment
- Macular disease
- Diabetic retinopathy
- Glaucoma and other conditions affecting the optic nerve
- Tumors of the posterior segment
- Other conditions requiring funduscopy examination

10.5 Contraindications

There are no absolute contraindications to the performance of a posterior capsulotomy in an appropriately evaluated and informed patient who meets the criteria for posterior capsulotomy. Incisional capsulotomy may be selected in those patients who cannot comply with the requirements for a YAG capsulotomy by reason of physical or mental impairment, or membrane thickness which would preclude successful laser surgery. In younger patients with lens cell proliferation, e.g., Elschnig's Pearls, causing the posterior capsule opacity, it may be desirable to preserve the posterior capsule and remove the lens material causing the functional impairment.

Routine or prophylactic posterior capsulotomy is not appropriate.

Other special tests may be indicated by additional concurrent diagnosis. Tests such as fluorescein angiography, B-Scan, Ultrasonography, formal visual fields, etc. are examples of such tests. The justification for these tests should be apparent from documentation in the patient's record.

10.6 Preoperative Medical Evaluation

In addition to visual acuity, tests of glare, contrast sensitivity and potential acuity may be of particular value in assessing the functional

impairment due to posterior capsular opacification and the benefits of posterior capsulotomy. Fluorescein angiography may be indicated when there is clinical evidence of macular disease and/or the degree of capsular opacity appears insufficient to account for the level of functional impairment. B-scan ultrasonography is indicated when the degree of opacification is of a severity that the posterior pole cannot be visualized and the degree of functional impairment is severe and seemingly unexplained by the degree of opacification. The reasons for these tests should be documented in the patient's record.

10.7 Preoperative Medications

Laser posterior capsulotomy ordinarily requires only topical anesthesia and optional pupillary dilation. The risk of these medications is small; however, it remains the responsibility of the operating surgeon to assess the medical suitability of the patient for the procedure and the use of these agents in the perioperative period.

10.8 Surgical Technique

Nd:YAG posterior capsulotomy laser surgery, the most common technique, is performed in the office, ambulatory surgical center or a hospital outpatient department, under biomicroscopic magnification. A contact lens may be used to enhance visualization of the posterior capsule and to stabilize the eye during the procedure. The energy used and the size and location of the opening are controlled to minimize the risk of complications.

10.9 Complications

The complications of laser posterior capsulotomy may be very serious although they are extremely uncommon. Retinal detachment, hyphema, dislocated intraocular lens and corneal decompensation are in the serious category. Cystoid macular edema and damage to the intraocular lens are less serious effects and occasional elevation of intraocular pressure post surgery is often prevented by prophylactic use of appropriate medications. It is the responsibility of the operating surgeon to ensure that the patient is adequately informed of the potential complications prior to the procedure.

10.10 Postoperative Care

The ophthalmologist who performs the capsulotomy has an ethical and legal responsibility to provide postoperative care for the patient. The postoperative period is considered to extend two weeks from the end of the procedure. Should complications develop, the ophthalmologist has the obligation to provide appropriate care to the patient or to refer the patient to another ophthalmologist.

cited in Colwell v. Bannister, No. 12-1584, Archived on September 12, 2014

10.10.1 Postoperative Care - Immediate

Patients who have undergone capsulotomy must be observed for an appropriate time for evidence of elevated intraocular pressure. If the pressure is elevated, appropriate treatment must be instituted and the patient followed until the problem is resolved.

10.10.2 Postoperative Care - 1-2 Weeks

Because most complications following posterior capsulotomy occur in the late postoperative period, the re-examination schedule should be established according to the patient's needs, the experience of the surgeon and other associated conditions of the eye.

The examination should include measurement of visual function, intraocular pressure, slit lamp examination of the anterior segment including the intraocular lens, if present, the capsular opening and a fundus examination as deemed appropriate by the examining surgeon. The patient should be instructed for the symptoms of retinal detachment and the need for immediate attention if they occur. Patients also should be informed of other long term risks and the need for periodic eye examinations.

10.1 Benefits of Capsulotomy

10.11.1 Results of Capsulotomy: Positive Outcomes

Posterior capsulotomy is a highly successful procedure. In eyes without co-morbidity, visual functional disability can be

expected to improve in a large majority of cases. The same positive outcomes outlined in the section on positive outcomes for cataract surgery apply to YAG capsulotomy (See Chapter 7).

10.11.2 Results of Capsulotomy: Negative Outcomes

Negative outcomes of capsulotomy include failure to achieve expected positive outcomes or the development of complications that impair the patient's visual function or consume their resources.

The success rate of posterior capsulotomy is reduced in the presence of co-morbid conditions such as corneal disease, preexisting glaucoma and retinal disorder, e.g., retinal detachment, macular degeneration and diabetic retinopathy. This may be immediate or become manifest after a considerable amount of time postoperatively.

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cited in Colwell v. Bannister, No. 12-15844 archived on September 12, 2014