Responsibilities and Ramifications of Pupillary Dilation: A Legal Perspective

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ABSTRACT: The standard of care now is for optometrists to routinely dilate patients' pupils for thorough examination. This not only has clinical implications for the patient but also has legal ramifications for the optometrist. Optometrists must recognize those circumstances when a patient's pupils should be dilated and when dilation is contraindicated. This paper suggests some of these circumstances and how to deal with legal issues such as documentation and informed consent. It offers recommendations for clinical issues such as which dilating drops to use for dilation and for reversal of dilation, and suggests some practice management techniques.

Prior to the diagnostic drug laws enabling optometrists to use pharmaceutical agents for dilating the pupil, some ophthalmologists and others were opposed to optometrists using the drugs. Now, they are insisting that they are used in virtually every case (1). Since the laws have been passed, there have been no reported lawsuits claiming improper use of diagnostic drugs by optometrists. There has, however, been a significant increase in the number and size of negligence claims against optometrists. The majority of these claims come from misdiagnosis of intraocular disease, primarily retinal detachment, open-angle glaucoma, and tumors (2). Most of these claims involve optometrists who failed to use diagnostic drugs for pupil dilation (3). Often the clinician did not act upon clues that were presented as preliminary signs or symptoms of a condition necessitating dilation.

There are several definite indications for pupillary dilation. These not only have ethical considerations for why we should dilate, they also have legal significance. These are not carved in stone as absolute statement of fact, but more of a summary of clinical preferences of one optometrist, and may vary from clinician to clinician.

Table 1: Indications for Dilation
Initial visit
Sudden visual acuity reduction
Sudden visual field compromise
Prechiasmal visual field defect
Flashes and/or floaters
Acute diplopia
Aphakia or pseudophakia (except iris-fixed IOLs)
Presence of a cataract preventing good view of the retina
All myopes over 3D
All patients with diabetes
Previous diagnosis of lattice degeneration, retinal holes or tears,
Prior retinal detachment
Marcus Gunn pupil
Trauma to the globe and/or head
History of metastatic cancer
Patients with unexplainable headaches
Lumps behind the iris
History of utilization of drugs with ocular side effects

Adapted from Alexander, LJ, Scholles J. Clinical and Legal Aspects of Pupillary Dilation. J Am Optom Assoc. 1987; 58(5): 432-7.

There are also circumstances where dilation is contraindicated. Some of these are debatable based upon the preparedness one has to deal with the complications that may occur. The decision to dilate is not always black and white. Some circumstances may warrant dilation, but one should dilate with caution. If a patient has been dilated before, it is advisable to document this fact in the patient's record also noting if the procedure was performed with or without complication (4).

Table 2: Contraindications for Dilation
Iris-fixed IOL
Gonioscopically narrow to closed angles/plateau iris
History of previous difficulties with dilation (pain)
Subluxated crystalline lens
Subluxated posterior chamber IOL

Adapted from Alexander LJ, Scholles J. Clinical and Legal Aspects of Pupillary Dilation. J Am Optom Assoc. 1987; 58(5): 432-7.

Table 3: Indications for Dilation With Caution
Marginal angles with a history of questionable sub-acute angle closure glaucoma
Positive shadow sign
Anterior chamber IOL's/Pupillary trap
Use of Tri-cyclic antidepressants or monoamine oxidase inhibitors if using an adrenergic

Adapted from Alexander LJ, Scholles J. Clinical and Legal Aspects of Pupillary Dilation. J Am Optom Assoc. 1987; 58(5): 432-7.

The patient has the right to refuse to have their pupils dilated, but the optometrist must be sure that the patient has received sufficient information to make an informed decision. Different states have different rules regarding requirements when communicating matters in informed consent. There are two distinct standards that apply when deciding how much information is necessary to give the patient in order for them to make an informed decision. Most states have a "patient-based" standard. This means that the information that must be given to the patient for informed consent is all that information the patient would consider significant in deciding whether to undergo a procedure or a treatment. The "physician-based" standard still applies in some states. This means that the physician must give all the information that is usually disclosed by physicians for informed consent to do a procedure or treatment. The "physician-based" standard means that an expert testimony would be needed in the case of a lawsuit. Expert testimony is not needed for the "patient-based" philosophy. Neither standard gives precise guidance, but here are some basic components of informed consent that are uniform in all states (see table 4) (5). Complicated procedures should be explained in lay terms. The informed consent communications

should be documented in the record. This may be through a handwritten entry or a disclosure form, and the patient's signature on either. It is the obligation to warn the patient of the potential adverse effects rather than the actual adverse effects that is most often the cause of litigation (6).

Table 4: Basic Components of Informed Consent

Possible diagnoses
Nature and purpose of the proposed procedure or treatment
Potential hazards of the proposed procedure or treatment
Probability of successful treatment
Alternative methods of treatment
Anticipated conditions that would result if consent were refused

Adapted from Classe JG. Optometric Malpractice. 257-66, 391-5.

There are still some optometrists who do not have their certification to use diagnostic drugs or choose not to dilate their patients. They are held to the same standard of care as those who do use diagnostic drugs. They have to same duty to diagnose the condition. If the patient is symptomatic the non-dilating doctor has the legal obligation to refer the patient to a practitioner who uses diagnostic drugs. The absence of symptoms does not free the non-dilating doctor from responsibility, though (4). It is estimated that one-half of all retinal detachments are asymptomatic (3). Should a later problem arise, the non-dilating doctor will still be held liable for a misdiagnosis from lack of diagnostic use (4).

Part of the process of avoiding complications with dilation is choosing the appropriate dilating drops, and the optometrist is under a legal duty to choose the agent that minimizes the risk of injury or complication (6). The mydriatics phenylephrine and tropicamide are the two drugs of choice. Based upon the patients ocular conditions, systemic health, and medications either one alone or a combination of the two may be more appropriate. For the purposes of this discussion, we will concentrate on purely the mydriatic effects rather than any cycloplegic effects. Phenylephrine is an adrenergic agent that is available in 2.5% and 10% concentrations, but only the 2.5% is indicated. The 10% concentration is more likely to cause side effects and the 2.5% yields sufficient dilation. Tropicamide is obtainable in 0.5% and 1% concentrations and is an

anticholinergic drug. Phenylephrine used alone activates the dilator muscle of the iris (4). With opposing forces then between the sphincter and the dilator muscles, the iris may be pulled back toward the crystalline lens. This gives the potential for pupillary block glaucoma (8). Most angle closure glaucoma is the result of pupillary block. Pupillary block is most likely to occur in the mid-dilated state, which is why most of the angle closures secondary to dilation occur 1-3 hours after the patient leaves the office (6). Although adrenergic agents like phenylephrine are more easily reversed by pilocarpine, for routine dilation it is preferable to utilize tropicamide because it inactivates the sphincter muscle. No opposing forces are created thus reducing the possibility of pupillary block (8). There is one instance when tropicamide is contraindicated. When a patient has had a peripheral iridectomy for acute angle closure glaucoma. For these patients it is preferable to use an adrenergic agent like phenylephrine rather than tropicamide (4). Whenever these drugs, or any drugs, are used, the optometrist must provide adequate documentation. Table 5 outlines the necessary components of documentation of drug use.

Table 5: Documentation of Drug Use

History of drugs used by patient
Current drugs being taken by patient
History of allergy to drugs
Previous adverse reactions to drugs
Drugs used during the examination including:
drug name, concentration, dosage, instructions for use and
Signs/symptoms of an adverse reaction if the patient has one
Management of the adverse reaction if the patient has one
Warnings of adverse effects of drug use and what to do if they
Referral or recall of the patient for treatment of an adverse reaction

Adapted from Classe JG. Liability and Ophthalmic Drug Use. Optom Clin. 2(4): 121-34.

The biggest risk of pupillary dilation is angle closure. Only 2-6 percent of the U.S. population have angles anatomically narrow enough to close. The doctrine of informed consent

requires a warning of the possibility of angle closure and to describe the benefit that is expected to come from the use of pupillary dilation. This allows the patient to weigh the risks versus benefits to decide for themselves if they wish to have the procedure. For the population who are not at risk for closure there is no observable risk to the procedure, therefore there is no obligation to warn about angle closure. If a patient is at risk for angle closure, it may be wise to dilate only one pupil, monitor the IOP very closely, and be prepared to manage an angle closure in a timely manner either by use of drugs or through a referral(6). In some states the law is restrictive of the optometrist in managing an angle closure an attack. The law may not allow the optometrist to use pilocarpine or other appropriate drugs. In such a case, it may be wise to refer the patient to an ophthalmologist for dilation or to have a standing order from an ophthalmologist or other physician allowing the optometrist to manage the situation (4).

Angle closure is not the only potential adverse effect of pupillary dilation that can lead to litigation. The most likely cause of a claim is a "slip and fall" caused by blur and photophobia of pupil dilation (3). What about a patient that attempts to drive a vehicle or operate dangerous machinery and suffers or causes and accident while dilated? There is a duty to warn the patient about these potential risks, too. Either the doctor or the staff needs to explain the effect dilation may have on visual acuity, glare problems, loss of accommodation, and so on (4). There have be cases where a doctor was held legally responsible for injuries suffered by a third party due to the negligence of a patient that was not adequately warned and was involved in a car accident (3).

The necessity and ability to dilate patients' pupils has had an impact on patient management from the time the appointment is made to long after the patient has left the office. Throughout that time, the optometrist has the legal duty to minimize the risk of injury to the patient. Appropriate management can be divided into four phases: appointment scheduling, patient flow, maintaining safe premises, and issuing and documenting warnings.

Appointment scheduling. The assistant or receptionist scheduling the appointments should be aware of the likelihood of pupil dilation and the length of time it requires in order to allot the proper amount of time. The receptionist should also advise the patient of the possibility

of pupil dilation and the possible side effects, so the patient may make prior arrangements for transportation or to be away from work. Those who schedule the appointments also have a legal obligation to triage patients according to the urgency of care. An optometrist can be held liable for staff that improperly triages a patient.

Patient flow. Coordination of efforts from the optometrist and assistants is a key part of smooth patient flow. After instilling the dilating drops the patient may be moved out of the exam room so another patient may be seen while the drops are taking affect. During this time the patient may visit the dispensary to select frames or lenses, receive a visual field test, or relax in the waiting room. During this time, though, they should be adequately monitored by staff since mydriasis and cycloplegia can impair the patients judgments.

Maintaining safe premises. The optometrist has a legal duty to maintain the premises in a safe condition both inside and outside. Much care should be taken to supervise patients while they are under the effects of the drops.

Issuing and documenting warnings. The doctor should warn the patients about blur and photophobia prior to leaving the office. The patient should be warned about driving, walking up or down stairs, or working around dangerous machinery. A comment should be made in the documentation that the warning was given. There may be a specific printed line on the record stating "Dilation Warning" with an adjacent line so the patient may initial the form when the warning was given. Before the patient leaves the office it should be made sure that he or she has a pair of sunglasses. If they do not, a pair of disposable mydriatic sunglasses should be provided. If this is the responsibility of an assistant, they should be stressed the importance of this (6).

Another way of dealing with the problems of the patient's photophobia and blur from dilation is the instillation of eye drops for reversing pupillary dilation. This may soon become a standard of care. Pilocarpine is one mydriatic antagonist that could be used. The drug works rapidly and fully in eyes dilated with phenylephrine and does not have as great of an effect when tropicamide was used. Some have argued that the use of pilocarpine in phakic eyes dilated with phenylephrine may cause displacement of the crystalline lens forward putting some patients at risk

for pupillary block, thus pilocarpine is not widely recommended for routine reversal of mydriasis (10).

Dapiprazole, or Rev-Eyes, is a relatively new eye drop and is reportedly "safe" from pupillary block Rev-Eyes blocks alpha-adrenergic receptors located in smooth muscle mostly in the dilator muscle of the iris and to a lesser extent the ciliary muscle. The drug competitively antagonizes alpha-agonists such as phenylephrine, thus permitting unopposed activity of the sphincter to produce pupil constriction. The drug does have some effect on accommodative recovery, also. There is debate as to whether the effects on accommodative recovery are due the direct effects on the smooth muscle of the ciliary body or the indirect effects of decreased pupil size on increasing the depth of field. The drug reportedly reverses the mydriasis produced by phenylephrine in about 30 minutes. If tropicamide is used alone or in combination with the phenylephrine reversal occurs in about 1-2 hours. Eye color does affect the rate of reversal with faster reversal in lighter irides. Use requires 2 drops applied to the conjunctiva of each eye, followed by another 2 drops per eye 5 minutes later. A common adverse reaction is conjunctival injection which lasts for approximately 20 minutes in 80% of patients. Burning upon instillation is reported in 50% of patients. The drop could have potential reactions such as conjunctival chemosis, lid edema, ptosis due to effects on Muller's muscle, allergic reaction, dizziness, chest constriction, and nausea. Dapiprazole has been shown to have little or no effect on blood pressure or heart rate. Use of dapiprazole is contraindicated in patients with acute iritis or if the patient has a hypersensitivity to any of the components. Use in pregnant women and children has not been tested (11).

Thymoxamine Hydrochloride is another competitive antagonist of the alpha-adrenergic receptors and works in a similar manner to Dapiprazole. It also has the inability to constrict of the pupils of darkly pigmented eyes and exhibits transient stinging with conjunctival injection that may last several hours. Thymoxamine does not have as rapid of an effect as Dapiprazole and is not widely used (12).

Whatever mydriatic antagonist is used, if any, documentation of the drug's usage should be included in the records just as any other drug. The patient should also be give proper warning and consent prior to the drug's instillation.

There are a few other patient management tips that can help avoid problems. When making a referral to another doctor, it is wise to schedule the appointment for the visit before the patient has left the office. Always document the referral in the patient's record. Document all recall appointments and "no shows" along with any efforts to contact patients to reschedule in the record. Even though an optometrist has no legal obligation to contact patients who "no-show" for a recall appointment, it is wise to attempt to reschedule in worrisome cases (3). Never alter the records. When making decisions, actively involve the patient. When patients express symptoms, especially children, believe them, and take the necessary actions to evaluate them properly (5).

CONCLUSION: Optometrists need to recognize when pupillary dilation is appropriate and when it is inappropriate. Misdiagnosis due to failure to use diagnostic drugs is the leading reason for negligence charges against optometrists, but the use of diagnostic drugs also has potential consequences for the patient, the doctor, and the doctor's practice. The risks for all may be reduced by proper identification of potential problems with dilation, proper dealing with any problems that arise, good communication with the patient, suitable documentation, good practice management techniques, and of course, a meticulous examination.

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