INSTITUTE FOR DEFENSE ANALYSES

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About this Publication

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Executive Summary

Some non-lethal weapons (NLWs) like dazzling lasers employ light at wavelengths that are categorized as eye safe. However, program managers may wish to quantitatively evaluate the risk that these dazzling lasers or other versions potentially developed in the future could cause a retinal lesion requiring medical procedures and/or leading to permanent vision impairment. Per Department of Defense Instruction (DoDI) 3200.19, an injury caused by a NLW, such as a retinal lesion, is considered significant if "self-aid, buddy-aid, and combat lifesaver skills" are insufficient to treat the injury or if the injury results in death or "physical damage that restricts the employment or other activities of the person for the rest of his or her life." The objective of this project was to search the relevant literature to identify attributes of a retinal lesion that can quantitatively, accurately, and precisely predict the significance of the lesion.

We found a lack of quantitative information in the literature. First, the definitions of anatomical terms varied across documents, depending on the intended audience. For the purpose of our project, we used the histological definitions of structures of the eye, in which the macula (the center portion of the retina responsible for central visual acuity) is composed of the following concentric rings (with approximate outermost diameters): foveola (0.35 mm), fovea (1.5 mm), parafovea (2.5 mm), and perifovea (5.5 mm). Second, although tens of thousands of journal articles have been published on laser-induced retinal lesions, most articles focus on the dosages required to *cause* a lesion, a metric that is outside the scope of this project. Markedly fewer articles report data that could be used to estimate the metric of interest to this project—the probability that a lesion is significant, given that it has *already* occurred. Furthermore, these articles use language that is largely qualitative and subjective to describe both the initial lesions and the long-term outcomes of the lesions. Despite these challenges, however, we proposed a scheme for defining a retinal lesion as significant or not significant based on its attributes. We document the many assumptions on which this scheme is based.

We found that visual acuity and visual field are the most commonly used metrics to quantify vision impairment. The Veterans Affairs Schedule for Rating Disabilities (VASRD) employs a method for estimating the visual acuity in Snellen notation (where 20/20 vision is considered normal) and for estimating the remaining visual field in degrees (where an average of 62.5° is considered normal). All 50 U.S. states require a test of corrected, distant, visual acuity to obtain a driver's license; some states also employ visual field criteria.

We recommend that NLW developers quantify visual acuity impairment using Snellen notation (e.g., "20/XX"). As illustrated in Figure ES-1, we recommend that visual acuity impairment is defined as:

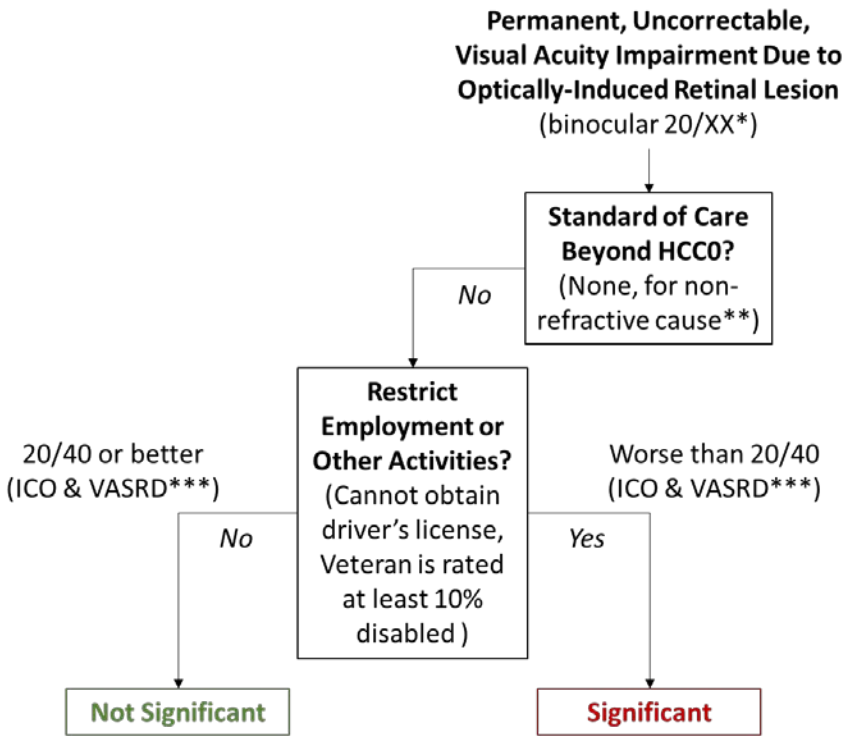
- **Significant, if best-corrected visual acuity is worse than 20/40.**
- ***Not* significant, if best-corrected visual acuity is 20/40 or better.**

This recommendation is based on (1) a recommendation from the International Council of Ophthalmology (ICO) that no driving restrictions be imposed for a visual acuity of 20/40 or better and (2) the VASRD criteria in which a veteran is rated as 0% disabled if his or her visual acuity is 20/40 or better in both eyes (provided the veteran has no other disabling conditions). We assume that a nonzero disability rating from the VASRD is a surrogate for "restrictions on employment" and that failure to obtain a driver's license is a suitable surrogate for both "restrictions on employment" and "other activities," to use language from DoDI 3200.19.

We also recommend that NLW developers quantify visual field impairment based on the average remaining field in degrees. As illustrated in Figure ES-2, we recommend that visual field impairment be defined as:

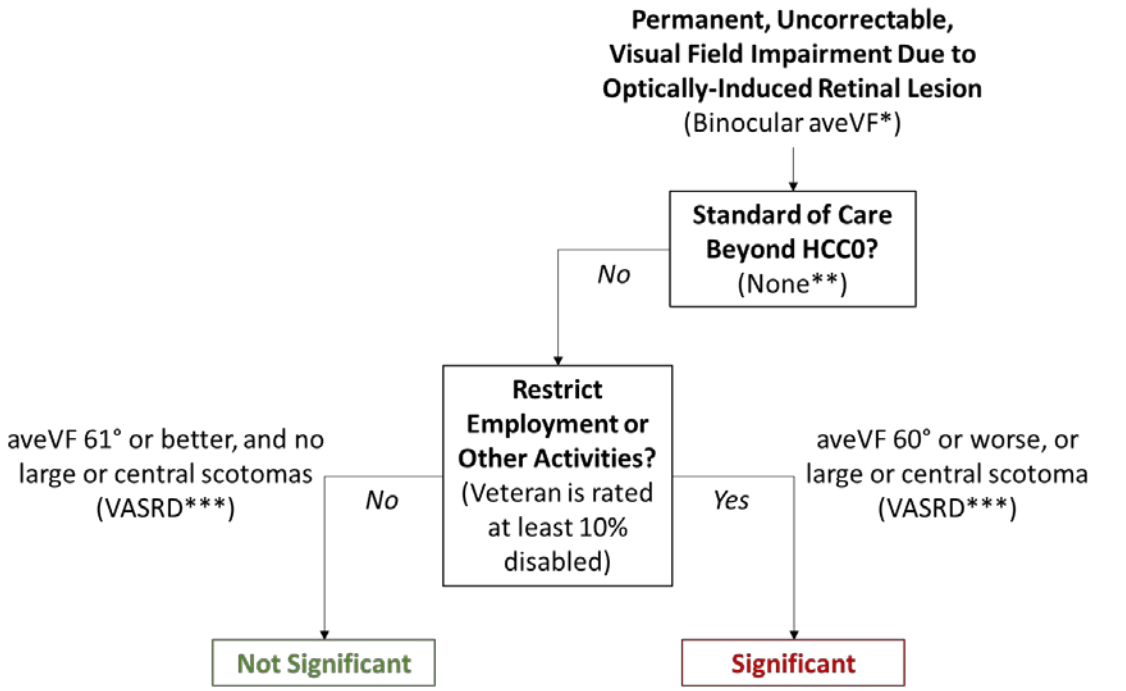
- **Significant, if the average remaining visual field is 60° or less, *or* if a scotoma takes up 1/4 or more of the visual field, *or* if a scotoma of any size is centrally located (i.e., within the macula, no more than 2.75 mm from the center of the foveola).** A scotoma is a spot in the visual field in which vision is absent or deficient.
- **Not significant, otherwise.**

This recommendation is based on the VASRD guidance that a veteran be rated as 10% or more disabled if his or her remaining average visual field is 60°or less *or* if a scotoma takes up 1/4 or more of the visual field *or* if a scotoma is centrally located. Once again, we assume that a nonzero disability rating from the VASRD is a suitable surrogate for "restrictions on employment," per DoDI 3200.19.



* "Binocular 20/XX" represents the visual acuity in Snellen notation for both eyes together.
** We assume corrective lenses will not aid a visual acuity impairment due to a non-refractive cause, such as an optically-induced retinal lesion.
*** We assume that failure to obtain a driver's license is an adequate surrogate for "restricting employment or other activities". The International Council of Ophthalmology (ICO) recommends no driving restrictions for visual acuity of 20/40 or better, but recommends that each case worse than 20/40 be considered individually. Furthermore, we assume that a non-zero Veterans Affairs Schedule for Rating Disabilities (VASRD) rating is an adequate surrogate for "restricting employment". The VASRD rates a veteran as at least 10% disabled if he or she has 20/40 vision in one eye and worse than 20/40 vision in the other eye.

Figure ES-1. Determining the Significance of Visual Acuity Impairment



* "Binocular aveVF" represents the average visual field in degrees for both eyes together.
** We assume there is no aid for a visual field impairment.
*** We assume that a non-zero Veterans Affairs Schedule for Rating Disabilities (VASRD) rating is an adequate surrogate for "restricting employment". The VASRD rates a veteran as at least 10% disabled if his or her remaining average visual field is 60° or worse, or if a scotoma is large (at least ¼ of the field of view) or central (which we assume is within the macula).

Figure ES-2. Determining the Significance of Visual Field Impairment

We analyzed the available literature to identify attributes of retinal lesions that associate with the visual impairment significance definitions proposed in Figure ES-1 and ES-2. First, we found that different dosages (e.g., power and exposure duration) of laser light can lead to different mechanisms of injury, each of which could contribute to degraded visual acuity and/or degraded visual field, including scotomas, and some of which may require medical intervention. In contrast to the photomechanical and photochemical mechanisms, the photothermal mechanism is the most relevant to the dosages used for non-lethal dazzling applications. Clinicians often assess photothermal lesions as subthreshold, threshold, and suprathreshold, based on their subjective, qualitative judgment of how well the lesion can be seen using a traditional ophthalmoscope or other similar methods. As illustrated in Figure ES-3, we recommend that a photothermal retinal lesion be defined as:

- **Significant, if the lesion is characterized as suprathreshold,** due to reports that suprathreshold lesions are associated with severe retinal damage and secondary effects such as hemorrhage, macular holes, and neovascularization. These complications can require hospitalization and prescription medications, above and beyond "self-aid, buddy-aid, and combat lifesaver skills," to use language from DoDI 3200.19. In the absence of further information, we assume

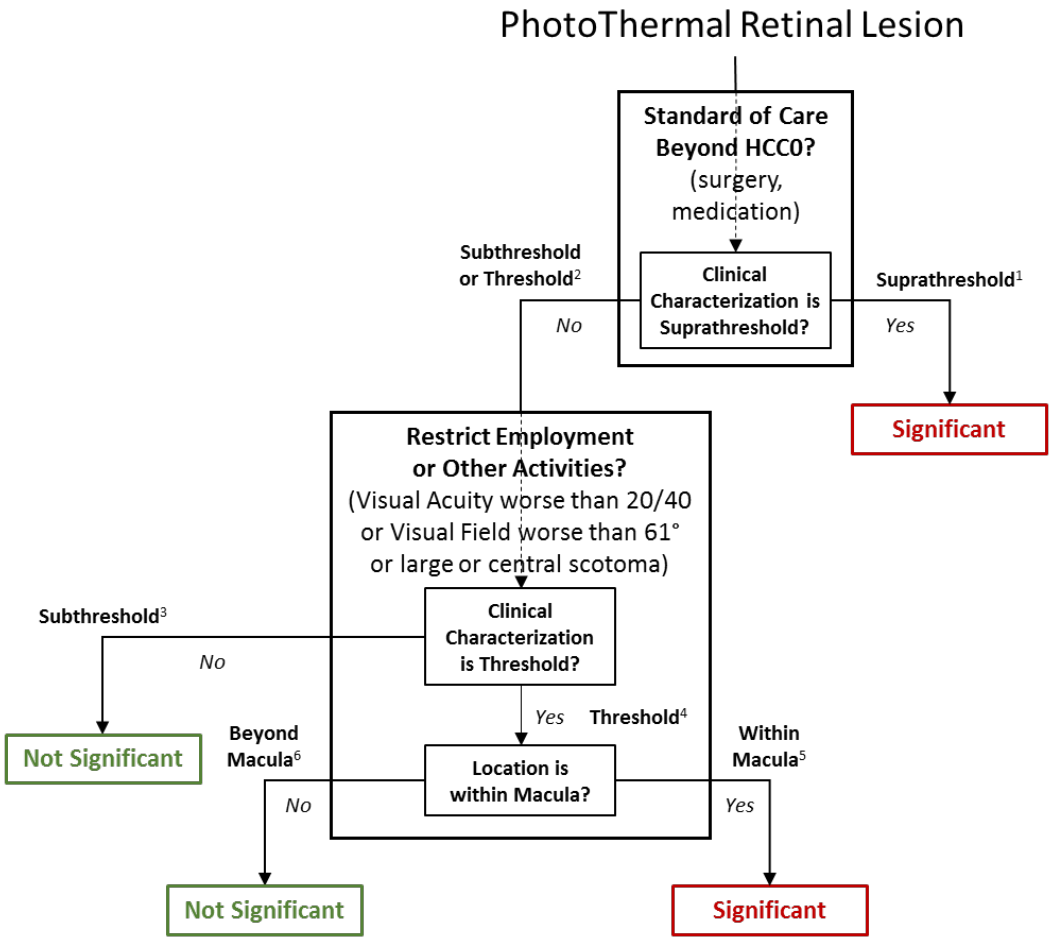
that suprathreshold lesions *always* lead to complications requiring hospitalization or prescription medications.

- **Significant, if the lesion is characterized as threshold and is within 2.75 mm of the center of the foveola,** due to reports that a lesion in the fovea can result in an individual being declared legally blind. In the absence of further information, we assume that threshold lesions in the macula (outer diameter approximately 5.5 mm, with a radius from the center approximately equal to 2.75 mm) will *always* lead to significant visual impairment, as defined in Figure ES-1 and ES-2 (which, in turn, are based on their own sets of assumptions).
- ***Not* significant, if the lesion is characterized as threshold and is at least 2.75 mm beyond the center of the foveola,** due to reports that a lesion in the equatorial or peripheral retina may produce no noticeable effect on vision. In the absence of further information, we assume that threshold lesions beyond the macula will *never* lead to significant visual impairment, as defined in Figure ES-1 and Figure ES-2 (which are based on their own sets of assumptions).
- ***Not* significant, if the lesion is characterized as subthreshold,** due to reports that subthreshold lesions caused by lasers used in photocoagulation therapy to treat diabetic retinopathy often lead to minimal or no apparent retinal damage. In the absence of further information, we assume that subthreshold lesions *never* lead to vision impairment.

Based on these recommendations, a combat developer could first predict the clinical characterization of the lesion (i.e., subthreshold, threshold, and suprathreshold). Then, the combat developer could use the assumptions summarized in Figure ES-3 to associate the lesion's clinical characterization to the medical intervention required to treat the lesion and the permanent visual impairment resulting from the lesion, as defined in Figure ES-1 and ES-2. The medical intervention and visual impairment would not need to be estimated directly.

However, our recommendations are based on a clinician's subjective and qualitative characterization of the lesion (e.g., subthreshold, threshold, and suprathreshold). We found little quantitative information in the literature regarding the relationship between a lesion's qualitative, clinical characterization and its quantitative attributes such as size and depth. However, the literature does provide some quantitative information regarding the relationship between lesions' clinical characterizations and the temperature incident on the retina: A study of photocoagulation therapy used to treat diabetic retinopathy showed that a peak temperature of 65 °C was almost 50% likely to produce a threshold lesion. Estimating the probability of producing a threshold lesion was outside the scope of this project. We recommend, however, that studies like these be explored in more depth to better associate the temperature at which threshold lesions occur and the temperatures that

can be estimated with computational models during the acquisition phase of a dazzling laser. Such an association could potentially be used to predict the clinical characterization of a lesion and, ultimately, the risk of significant injury of a dazzling laser.



[1]Suprathreshold lesions can lead to complications like hemorrhage, macular holes, and neovascularization (Barkana and Belkin, 2000), which can require HCC1+ treatment like surgery and medication (Alsulaiman, 2015; Grossniklaus and Green, 2004). Therefore, we assume that suprathreshold lesions *always* cause complications requiring HCC1+ treatment.

[2]Subthreshold and threshold lesions do not often lead to complications requiring HCC1+ treatment (Mainster and Turner, 2012). Therefore, we assume that subthreshold and threshold lesions *never* lead to complications requiring HCC1+ treatment.

[3]Subthreshold lesions rarely lead to noticeable visual impairment (Mainster, Stuck, & Brown, 2004). Therefore, we assume that subthreshold lesions *never* lead to significant visual impairment.

[4]Threshold lesions can lead to a noticeable visual impairment (Mainster, Stuck, & Brown, 2004). Cones are important for visual acuity and their distribution differs in different parts of the retina (Remington, 2012). Therefore, we assume the location of the threshold lesion affects the significance of the visual impairment.

[5]Threshold lesions in the peripheral retina may produce no noticeable effect on vision (Harris, et al., 2003; Marshall 1998). Therefore, we assume that threshold lesions beyond the macula *never* lead to significant visual impairment.

[6]A foveal lesion can lead to noticeable visual impairment (Marshall 1989). Therefore, we assume that threshold lesions within the macula *always* lead to significant visual impairment.

Figure ES-3. Determining the Significance of Photothermal Retinal Lesions

Contents

1. Introduction

A. Background

Department of Defense (DoD) Instruction 3000.03E defines non-lethal weapons (NLWs) as weapons, devices, and munitions that are explicitly designed and primarily employed to incapacitate targeted personnel or materiel immediately, while minimizing fatalities, permanent injury to personnel, and undesired damage to property in the target area or environment (DoD 2013). NLWs are intended to have reversible effects on personnel and materiel (DoD 2013). Examples of counter-personnel NLWs are dazzling lasers, acoustic hailing devices, flashbang grenades, stingball grenades, oleoresin capsicum dispensers (commonly known as pepper spray), human electromuscular incapacitation (HEMI) devices (commonly known as TASER®s), and the Active Denial System millimeter wave technology (Joint Non-Lethal Weapons Directorate (JNLWD) 2012).

As part of the deliberate acquisition process in the DoD, combat developers must compare the capabilities of NLW systems to requirements (AcqNotes 2015). This project has focused on NLW requirements written as Key Performance Parameters (KPPs) in Capability Development Documents (CDDs) and Capability Production Documents (CPDs). One particularly important requirement stipulates how well the NLW must avoid causing significant injury to the targeted personnel. This requirement is often quantified as the risk of significant injury (RSI).

DoD Instruction 3200.19 defines a significant injury as death, permanent injury, or injury requiring medical treatment with a Health Care Capability (HCC) index of 1 or higher (DoD 2012). Furthermore, per Department of Defense Instruction (DoDI) 3200.19:

- Permanent injury is defined as “physical damage to a person that permanently impairs physiological function and restricts the employment or other activities of that person for the rest of his or her life” (DoD 2012, 14).
- Medical treatment with an HCC index of 1 is defined as “first responder capability including resuscitation, stabilization, and emergency care” (DoD 2012, 13), while HCC 2 is defined as “forward resuscitative and theater hospitalization capabilities including advanced emergency, surgical, and ancillary services” (DoD 2012, 13).
- In contrast, HCC 0, below the bar for significance, is defined as “limited first-responder capability including self-aid, buddy-aid, and combat lifesaver skills” (DoD 2012, 13).

In short, an injury caused by a NLW is considered significant if "self-aid, buddy-aid, and combat lifesaver skills" are insufficient to treat the injury or if the injury results in death or "physical damage that restricts the employment or other activities of the person for the rest of his or her life."

Determining a NLW's RSI often involves the estimation of two quantities: (1) the probability that a particular injury will occur as a result of intended use of the NLW and (2) the probability that the injury is significant, given that it has occurred (Burgei et al. 2014):

$$RSI = P(\text{injury occured}) \times P(\text{injury is significant} \mid \text{injury occurred}) .$$

Several methods are currently used to estimate the first quantity, *P*(injury occurred). These methods include human and animal experimentation (Johnson 1998; Chan and Ryan 2012), as well as modeling and simulation (Price 2005; Chan and Ryan 2012; Irvin et al. 2007; Knox, Bonetti, and Perry 1993). Many of these efforts have proven to be relatively successful. Therefore, estimation of this quantity is outside the scope of this project.

Instead, this project involves the estimation of the second RSI quantity, *P*(injury is significant | injury occurred). To date, two methods have been attempted to estimate this quantity. One method involves convening a panel of medical experts to survey their opinions on the permanence of the injury, as well as the HCC index of the medical treatment required by the injury (Simonds et al. 2012). Unfortunately, research in the statistics literature has indicated that medical experts' opinions on topics like these can vary over time or differ with respect to others', due to several different kinds of biases (Gigerenzer 2002). Therefore, a medical expert panel's estimates of *P*(injury is significant | injury occurred) are likely to have low precision and possibly even low accuracy. As a result, this method was not used in this project. Instead, this project employed a second method, a detailed search of the relevant literature to identify which attributes of a given injury can predict the injury's significance. Early results from using this method have indicated preliminary success in predicting the significance of skin burns caused by heat-based NLWs (Naval Surface Warfare Center – Dahlgren Division (NSWCDD) 2015).

B. Objective

The purpose of this project was to:

- Define a taxonomy to organize injuries caused by NLWs.
- Select a particular injury for further analysis.
- Search the relevant literature to identify attributes of the selected injury that can quantitatively, accurately, and precisely predict the significance of the selected injury during the NLW's acquisition phase.

- Recommend a viable approach for creating a model that will estimate the injury's significance, based upon the identified attributes.

Different types of NLWs may produce different types of injuries. Our taxonomy for organizing injuries caused by NLWs was largely taken from the International Classification of Diseases (ICD), both 9th and 10th Revisions (ICD-9 and ICD-10)[1] (Centers for Medicare & Medicaid Services (CMS) n.d.a and n.d.b). Due to limited time and funding, we selected one type of injury potentially caused by one type of NLW for further analysis: optically induced retinal lesions caused by dazzling lasers, including the complications that may ensue from the lesions (e.g., retinal hemorrhage, choroidal neovascularization, macular holes) and permanent outcomes that may result from the lesions (e.g., vision impairment). This injury and its associated complications and permanent outcomes fall under ICD-9 codes 361–363 and ICD-10 codes H33–H35. The following chapters of this report discusses the results of our literature search for assessing the significance of these retinal lesions.

[1] ICD-10 billing codes went into effect in the United States as of October 1, 2015. At the time of the writing of this report, however, DoD guidelines had not yet been revised to use ICD-10 codes. For the purposes of this project, then, we focused on ICD-9 codes. Note that there is often only an approximate translation between the two sets of codes.

2. Challenges in Estimating the Significance of Retinal Lesions

To evaluate the RSI of a dazzling laser, the NLW community seeks methods to explore optical exposures on the targeted individual and evaluate the resultant risk of significant injury. Our study examined the literature to understand the feasibility of assembling an end-to-end model that associates optical exposures with the risk of causing injury requiring medical treatment with an HCC index of 1 or above, or causing injury restricting employment or other activities for the rest of a person's life, per DoDI 3200.19.

Ideally, a computational model could provide the means necessary to perform this analysis. One could input optical exposure parameters for the dazzling laser (i.e., wavelength, power, exposure duration) into the model. The model could then output estimates of the probability of requiring HCC1+ medical care and the probability of significant vision impairment.

Such capabilities exist for other sensory mechanisms, such as hearing. For example, Auditory 4.0 is a computational model that allows a user to input a waveform recording of an impulse sound. This model then evaluates the risk of that sound producing a permanent threshold shift (PTS) in hearing (Chan and Ryan 2012). King and Cazares (2015) have proposed a numerical threshold for what constitutes a significant level of PTS. Therefore, one can use Auditory 4.0 to estimate the probability that a sound-based NLW causes a PTS greater than or equal to that significant threshold level, thus estimating the RSI of the NLW. Auditory 4.0 and other similar models (e.g., the Auditory Hazard Assessment Algorithm for Humans [AHAAH]) are based on decades of research regarding how sound damages different parts of the inner ear and how those damages result in an overall hearing impairment (Price 2005; Johnson 1998).

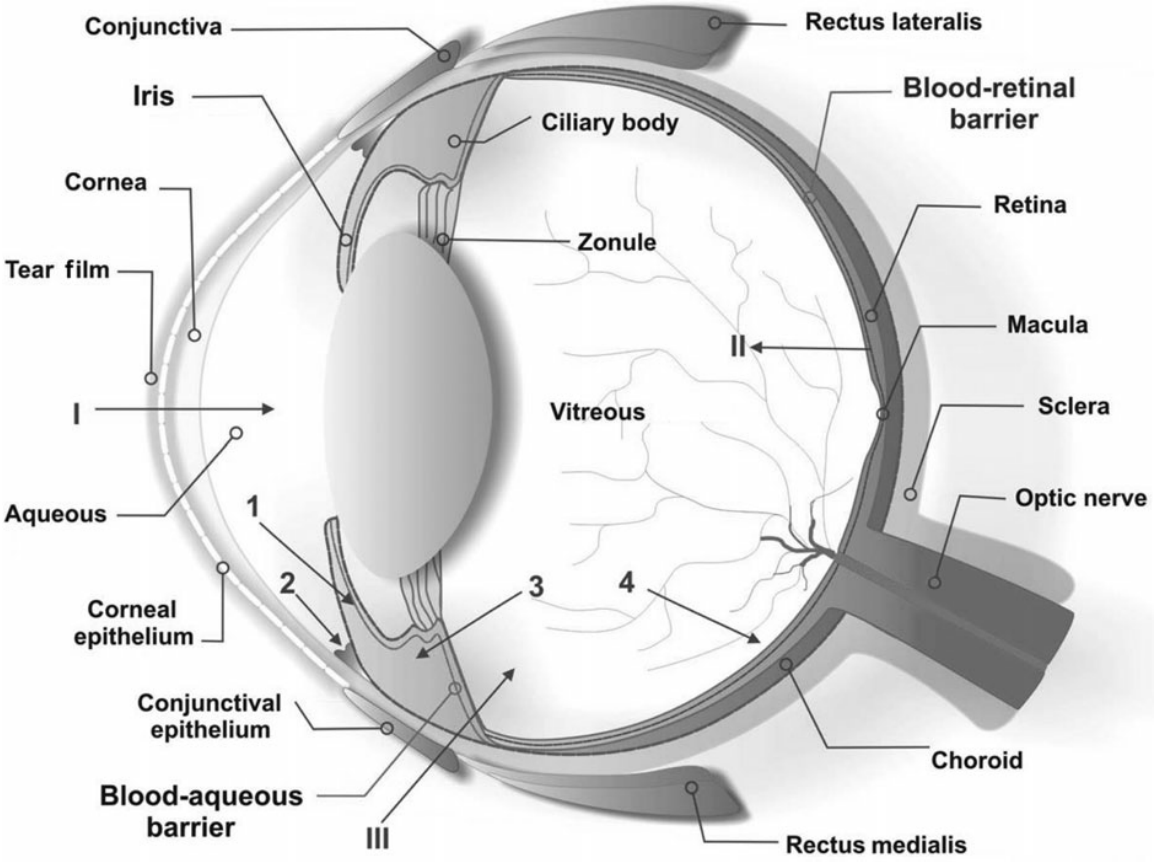
The NLW community, however, lacks an analogous capability to model the risk of vision loss due to intense light exposure. Existing models address the first part of the problem with tools like the Buffington, Thomas, Edwards, and Clark (BTEC) model. BTEC takes in parameters describing the laser's peak power, beam diameter, and exposure duration and estimates the temperature incident on living tissue and the resultant damage to the tissue (Irvin et al. 2007). BTEC lacks the ability to associate these lesions with the risk of significant vision impairment, however.

Therefore, our study considers the second half of this modeling challenge by exploring these associations in more detail. First, we review the anatomy and physiology of the eye. Then, we review existing standards for vision impairment and propose our own standards for what level of vision impairment should be considered significant, per DoDI

3200.19's definition of "permanent injury" and "HCC index 0, 1, and 2." Next, we review the different types of lasers and identify the most relevant mechanisms of injury for lasers used in non-lethal dazzling applications in the military. Finally, we review medical literature to associate the clinical characterization of a retinal lesion with our proposed standards for significant vision impairment.

3. The Eye

The human visual system takes in information in the form of light and processes it to allow a person to see. The eye collects light and transduces the information into electrical impulses that are carried along neural circuits to the brain for interpretation. The eye itself is a globe structure that is contained in the orbit of the skull, which protects the eye from damage. Further protection is provided by the eyelid and various structural and connective tissue surrounding the globe. Eye movement is obtained through the action of muscles attached to the surface of the globe exterior. Remington (2012) summarizes the structure of the eye, as paraphrased below. Figure 1 illustrates the anatomy of the eye.



Source: Willoughby et al. 2010.

Figure 1. The Structure of the Eye

A. Structure of the Eye

There are three spaces, or chambers, within the globe of the eye. The anterior chamber (labeled I in Figure 1) is bounded by the inner surface of the cornea and the outer surface

of the iris (labeled 1 in the figure). Behind the iris, the posterior chamber is bounded by the inner surface of the iris and the outer surface of the crystalline lens (the grey disk in the figure). The third and largest chamber of the eye is known as the vitreous chamber (labeled III in the figure), behind the lens.

Each chamber of the eye is filled with fluids called humors. Both the anterior and posterior chambers are filled with a salt and nutrient solution known as the aqueous humor. The aqueous humor supplies nutrients to the cornea and lens. The vitreous chamber is filled with the vitreous humor. Unlike the aqueous humor in the anterior and posterior chambers, the vitreous humor is more gel-like due to the presence of cells, structural proteins (collagen), and large macromolecules (hyaluronic acid). The vitreous humor forms attachments to the inner surface of the eye at various points, which allows it to be the structural support holding the retina against the inner surface of the eye, which is called the choroid and contains blood vessels supplying the retina. The gel consistency of the vitreous humor also allows it to act as the eye "shock absorber" protecting the retina and other eye components from assault and pressure changes from rapid motion of the eye or head. The vitreous humor also contains salts and nutrients that feed the lens and the retina.

B. Layers of the Eye

The eye globe consists of three layers, namely, the outer fibrous layer, the middle vascular layer, and the inner neural layer. Each layer is discussed below.

The outer fibrous layer contains the cornea and sclera structures and functions to protect the inner workings of the eye. Both the cornea and lens focus light onto the retina. The eye focused at infinity has a total refractive power of 60–65 diopters, of which approximately 45 diopters are attributable to the cornea and the balance of the diffractive power is provided by the lens.[2] The sclera serves as the structure that allows the eye to maintain its globe structure and provides attachment sites for extraocular muscles that control eye movement.

The middle vascular layer, also known as the uvea, contains three major structures of the eye, including the iris, the ciliary body, and the choroid. Blood flow and nutrients for the outer retina are delivered through blood vessels of the choroid. The sphincter and dilator muscles of the iris control the size of the aperture of the eye (the pupil), which regulates the amount of light entering the eye. Finally, the ciliary body, which surrounds the lens, has two main functions. First, it contains the ciliary muscles that alter the shape of the lens to accurately focus images on the retina by a mechanism known as accommodation.

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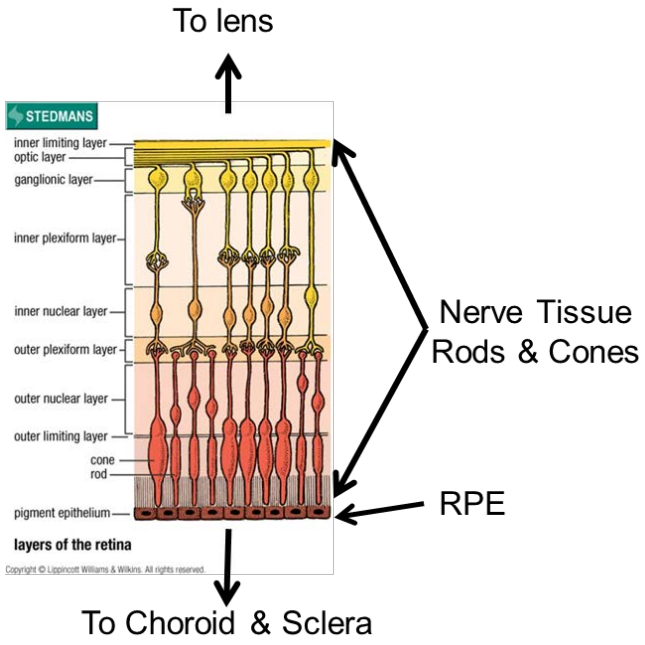
[2] A diopter is the unit of measurement of the refractive power of lenses. 1 diopter equals the reciprocal of the focal length (in meters) of the lens (and thus has units of m^{-1}). Thus, 60 diopters corresponds to a focal length of 0.0167 m, or 1.67 cm (Merriam-Webster 2015c).

Second, the epithelia cells of the ciliary body secrete the aqueous humor that occupies the anterior and posterior chambers of the eye.

The third layer of the eye is the inner neural layer, also known as the retina. The retina is a collection of photoreceptor cells (rods and cones) and neurons arranged into a layered structure (as described below) that transduces a light signal to an electrical signal that can be processed by the visual cortex of the brain. The retina accomplishes this task by a photochemical process called phototransduction. A photon striking the photoreceptor cells (rods and cones) of the retina excites a chromophore in the cone cells or 11-*cis*-retinal in the rod cells. This event initiates a biochemical reaction that hyperpolarizes the photoreceptor cell. An electric potential forms across the cell membrane, which signals a release of neurotransmitters to pass the signals to local neurons within the retina (bipolar, ganglion, horizontal, or amacrine cells). These various neurons organize and process the signal until it leaves the eye through the optic nerve.

C. Layers of the Retina

The retina consists of 10 layers that describe the traditional morphology of the retina. As knowledge of the retina's functional components has increased, it is now known that the designated layers do not necessarily describe functional boundaries of the retina. Despite this new knowledge, the traditional layer descriptions are still in use today. They are listed along the left side of Figure 2.



Source: Dirckx 2012.

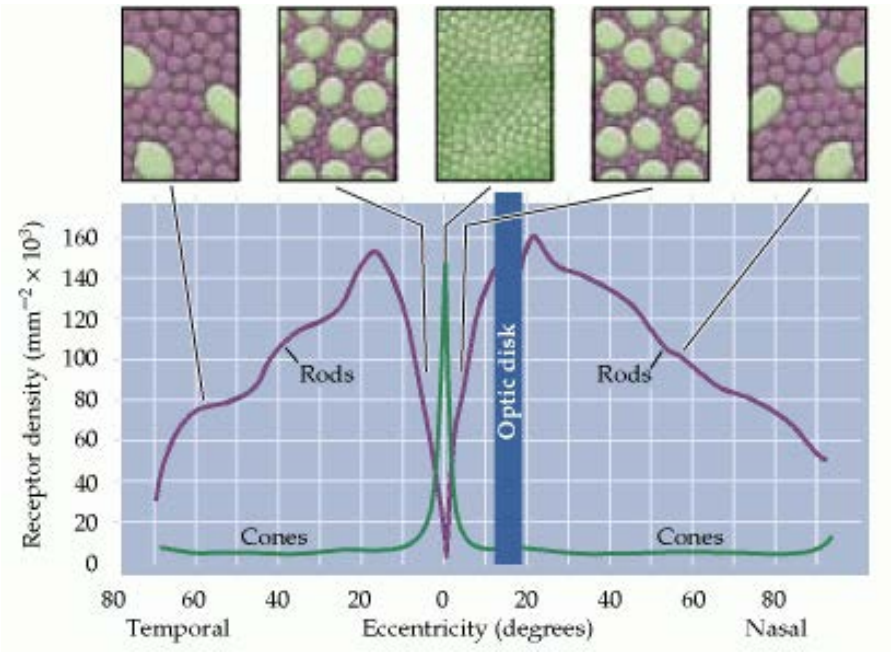
Figure 2. Layers of the Retina

The retinal pigment epithelium (RPE) consists of a single layer of epithelia cells and is the retinal layer that is closest to the outer surface of the eyeball (e.g., the bottom layer of Figure 2). The main function of the RPE is to provide nutrition and support for the photoreceptor layer. The photoreceptor layer is the next layer inward (e.g., the next layer upwards in Figure 2, colored in red). Phototransduction is performed mainly in the photoreceptor layer, which consists of rod and cone outer segment bodies containing appropriate chromophores. Rod and cone cells span the external (or outer) limiting membrane and extend into the outer nuclear layer. After phototransduction, the neural signal is processed through a network of neurons (yellow in Figure 2) and passed through the retinal layers to the ganglion cells. The major cell junctions between the photoreceptor cells and neuronal cells are located in the outer plexiform layer. The inner nuclear layer and inner plexiform layer consist of neuronal cell bodies and their synapses with ganglion cells, respectively. The ganglion cell bodies then form their own layer. Finally, the nerve fiber (optic) layer consists of ganglion axons that run parallel to the retinal surface covering the interior of the eyeball, toward the optic disc, where they exit the retina to the optic nerve.

The arrangement of retinal layers initially seems counterintuitive, since the photoreceptor cells (rods and cones, red in Figure 2) are buried in the retina underneath several layers of neural cells (yellow in Figure 2). This arrangement would seem to prevent photons from interacting with the photoreceptors. But as we will see below, many of these neuronal layers are not present in certain areas of the retina and do not interfere with the light path to the photoreceptor cells.

D. Regions of the Retina

Photoreceptor cells and neurons are not distributed evenly across the retina, as illustrated in Figure 3. Color vision cone cells (now colored green in Figure 3) are essentially absent from all areas of the retina except for an area known as the central retina. Their density diminishes with distance from the center of the fovea (defined below), measured in units of degrees eccentricity, where 1 degree of eccentricity spans approximately 0.3 mm of radial distance from the foveal center (Wandell n.d.). Rod cells (now colored purple in Figure 3) populate the rest of the retina, which is designated the peripheral retina. The different regions of the retina are described in more detail below.

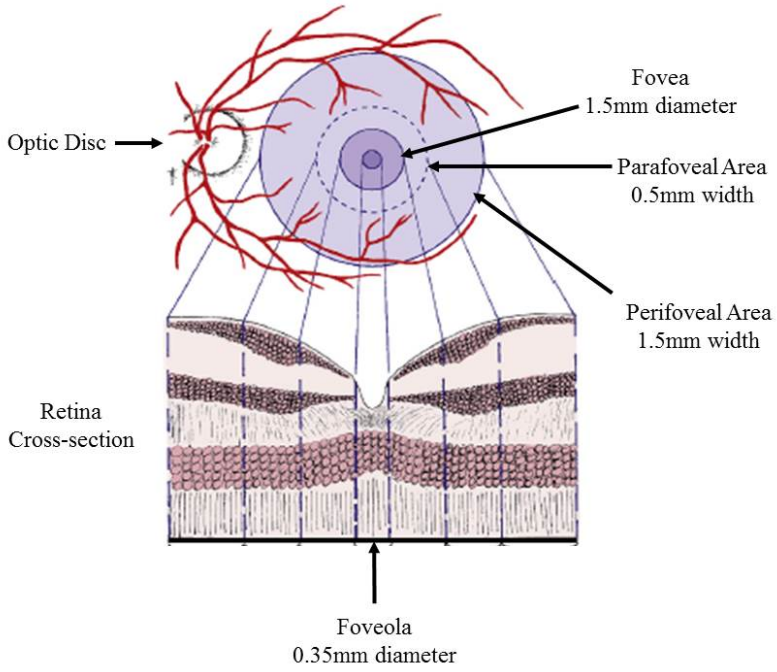


Source: Purves et al. 2001.

Figure 3. Distribution of Rods and Cones in the Retina

1. Macula Lutea

Within the central retina is a small area called the macula lutea, measuring approximately 5.5 mm in diameter, with a radius from the center of approximately 2.75 mm. It has a yellow appearance due to the presence of various pigments. The macula lutea is located at the center of an area of the retina approximately 9 mm in diameter that provides the useful color vision of the eye. As shown in Figure 4, the macular region contains several important structures for color vision, including the foveola, the fovea, the parafoveal area, and perifoveal area, which differ in neuronal and photoreceptor cell composition. Note that throughout the literature, the terms macula, fovea, and foveola are used interchangeably and imprecisely, depending on the intended audience. Clinicians often use the term "macula" to describe the pigmented area of the retina containing the foveola structure. However, a histologist would refer to this area as the "fovea." Similarly, the structure that a clinician would term the "fovea" would in fact be the "foveola" to a histologist. Sometimes histologists refer to the structures around and within the fovea as the "macular region." We will use the histological definitions of foveal structures in this report, with the following outermost diameters: foveola (0.35 mm), fovea (1.5 mm), parafovea (2.5 mm), and perifovea (5.5 mm). The corresponding radii from the center of the foveola are: foveola (0.18 mm), fovea (0.75 mm), parafovea (1.25 mm), and perifovea (2.75 mm).



Source: Remington 2012.

Figure 4. Structure of the Retina in the Macula Lutea

a. Fovea and Foveola

The shallow depression in the center of the macular region is known as the fovea centralis or fovea. The depression is approximately 1 mm deep and has a diameter of approximately 1.5 mm. The fovea is responsible for the highest visual acuity and color vision, and it accordingly has the highest concentration of cone cells in the entire retina. The concentration of cone cells falls off rapidly from approximately 150,000 cones per square millimeter in the center of the fovea to approximately 5,000 cones per square millimeter outside the fovea. The center of the fovea (approximately 0.4–0.5 mm across) is an area that lacks both blood vessels and outer layers of the retina, which allows light to pass unobstructed to the photoreceptor cells. This capillary- and rod-free region of the retina represents approximately 1–2 degrees of visual field. The parabolic depression (0.35 mm in diameter) at the center of the fovea is known as the foveola.

b. Parafoveal and Perifoveal Areas

In concentric rings about the fovea, the regions of the retina are known as the para- and perifoveal areas. All these regions vary in cell composition and contribute to color vision processing. As noted above, photoreceptor cell layers are concentrated here, and the neuronal layers are lacking at the center of the fovea. Moving laterally across the foveola, fovea, parafoveal area, and perifoveal area, the neuronal layers of the retina are increasingly represented. The parafoveal region contains the largest concentration of

neuronal ganglion cells, which process signals from the concentrated cone cells in the center of the fovea.

2. Optic Disc

Neuronal ganglion cells exit the retina through the optic disc, which is a flattened oval structure with a 1.7 mm vertical diameter and a 1.9 mm horizontal diameter. The edge of the disc is located approximately 3.5 mm from the macular region and is devoid of photoreceptor cells. Since no photoreceptor cells are present, the optic disc represents the physiological blind spot of the eye. Despite the blind spot's notable size, its effect on visual performance remains imperceptible due to the brain's ability to "fill in" the composite visual field using the other eye (Kandel, Schwwartz, and Jessell 1995).

4. Visual Function

Exposure to laser light can damage the retina, resulting in permanent vision impairment. Measurements of visual acuity and visual field are fundamental tests of visual function (Lennie and Van Hemel 2002). These are the two primary metrics used by both the U.S. Social Security Administration (SSA) (Lennie and Van Hemel 2002) and the Department of Veterans Affairs (DVA) (DVA 2009) for disability determination. Other aspects of visual function (e.g., muscle function, contrast sensitivity, stereoacuity, glare sensitivity, color vision, etc.) are generally secondary metrics that might add important information in cases where visual impairment is greater than what would be expected from the visual acuity measurement (Lennie and Van Hemel 2002).[3] Although some of these other aspects of visual function could be affected by laser light, we did not find a large body of literature discussing how these other aspects could be quantified to determine disability level. Therefore we focused our analysis on visual acuity and visual field only.

In this chapter, we first review different methods for quantifying visual acuity and visual field in the clinic. Then, we review standards that other organizations have set for levels of visual acuity and visual field required for different purposes. Finally, we propose standards that the NLW community could use to assess a particular visual acuity or visual field impairment as significant or not significant, per DoDI 3200.19.

A. Measuring Vision Impairment in the Clinic

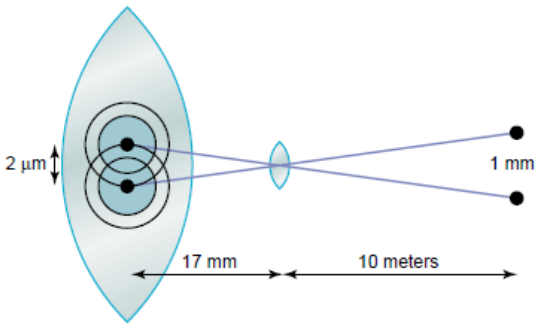
1. Visual Acuity

Visual acuity is the most common metric used to assess visual performance. Visual acuity, commonly known as sharpness or clarity of vision, is a measure of the spatial resolving power of the eye. This metric is the gold standard for primary outcomes of clinical trials (Kaiser 2009) and is the most commonly reported metric that we have seen throughout our literature review.

Maximum visual acuity in the human eye is about 25 seconds of arc, meaning the average young, healthy human can discriminate two point sources of light separated by 1 mm placed 10 meters away. As shown in Figure 5, the corresponding points on the retina are 2 μm apart, which is slightly larger than the width of one cone in the fovea. This maximum visual acuity occurs only in the 0.5 mm diameter area near the center of the

[3] Note that although the DVA's visual impairment rating system does consider muscle function, the degree of muscle dysfunction is assigned a corresponding visual acuity score (DVA 2009).

fovea, where cones are most highly concentrated; this is less than 2 degrees of the visual field (Guyton and Hall 1996).



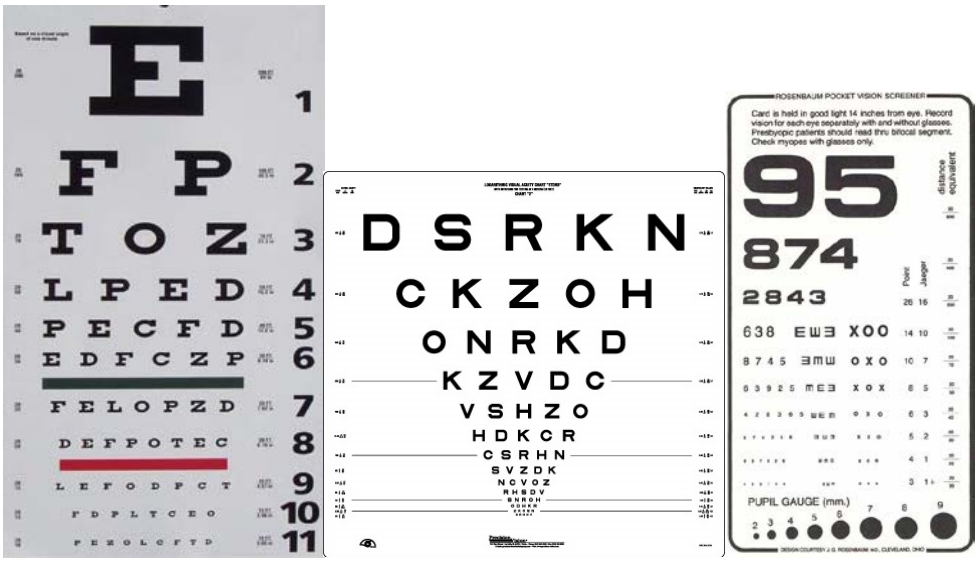
Source: Guyton and Hall 1996.

Figure 5. Maximum Visual Acuity of the Human Eye for Two Point Sources of Light

The standard test to measure visual acuity uses high-contrast printed or projected charts with rows of letters of decreasing size.[4] Historically, the chart introduced by Dutch ophthalmologist Herman Snellen in 1862 has been used to measure visual acuity at a distance (van Gijn and Gijselhart 2011). More recently, the chart developed for use in the Early Treatment Diabetic Retinopathy Study, or "ETDRS chart," has become the standard for clinical trials (Kaiser 2009). Similar charts, such as the Rosenbaum card, are held at a defined reading distance to measure near visual acuity. Figure 6 shows examples of each of these three kinds of charts. For the purposes of this project, we will focus on visual acuity measured at a *distance*. As will be discussed below, several organizations, including the individual U.S. military services, the DVA, and the SSA, base their assessments of a person's disability primarily on their *distant* visual acuity.[5]

[4] Letters, numbers, and other figures used to test visual acuity are referred to as "optotypes" (Merriam-Webster 2015a; van Gijn and Gijselhart 2011).

[5] The DVA factors in near visual acuity only for the case where near visual acuity is measured to be two or more steps worse than distant visual acuity. The final evaluation is still based on distant visual acuity but is adjusted to one step poorer than measured (DVA 2008a). Possible steps are given in Snellen notation, including 20/40, 20/50, 20/70, 20/100, 20/200, 15/200 (equivalent to 20/267), 10/200 (equivalent to 20/400), and 5/200 (equivalent to 20/800) (DVA 2008b).)



Source: Nexternal 2015; Visus 2015; and Rosenbaum 2014.

Figure 6. Charts Used to Assess Visual Acuity. Left: Snellen eye exam chart. Middle: ETDRS chart. Right: Rosenbaum pocket eye chart.

Optometrists use the charts in Figure 6 to measure visual acuity by determining the angular size of the smallest letters that can be identified.[6] Results are conventionally expressed in Snellen notation, which is the ratio of the test distance to the distance at which the critical detail of the smallest letter resolved would subtend 1 minute of visual angle. The standard definition of normal visual acuity at a distance is the ability to resolve 1 minute of visual angle (i.e., a "minimum angle of resolution" [MAR] of 1 minute) at a distance of 20 feet (NDT Resource Center n.d.). This is expressed in Snellen notation as 20/20. For example, consider a person for whom the minimum resolved letter at 20 feet represents a MAR of 10 minutes of arc, which is 10 times worse than the standard for normal distant visual acuity. A normal eye would be able to resolve this letter at 200 feet, 10 times farther than our example person. Visual acuity in this case would be expressed as 20/200, indicating that a normal person standing 200 feet away from the chart could see the chart as well as our example person standing only 20 feet away. Note that the person's MAR (e.g., 10 minutes of arc, in our example) is the reciprocal of the Snellen fraction (e.g., 20/200 = 1/10, in our example) (Kaiser 2009). There are several alternative means of expressing visual acuity, including metric notation where the reference distance is 6 meters (instead of 20 feet) or logMAR (logarithm of the MAR) (Kaiser 2009).

Ideally, visual acuity should be tested under binocular conditions (i.e., both eyes open) since this provides the most representative measure of an individual's vision (Lennie and Van Hemel 2002). As discussed in Lennie and Hemel (2002), "monocular acuity of

[6] Each letter on the chart subtends an angle of 5 minutes of arc at the appropriate testing distance, and each letter part subtends an angle of 1 minute of arc.

the better eye may sometimes lead to overestimates of binocular acuity, for example, under conditions in which inhibition is produced by the worse eye (Pardhan 1993; Taylor, Mission, and Moseley 1991)". Common clinical practice, however, is to measure only the two monocular visual acuities (Lennie and Van Hemel 2002). There appears to be no reliable way of predicting binocular visual acuity from the monocular acuity of each eye. Formerly, the American Medical Association (AMA) recommended a weighted average of the two monocular results, with a weighting factor of 3:1 biased toward the better eye (Rubin et al. 2000).[7] Later AMA guidance recommends a weighted combination of binocular and monocular visual acuity for a more accurate evaluation of visual function (Cocchiarella and Andersson 2001).

2. Visual Field

The visual field is the entire area seen by both eyes at the same time when gaze is fixed at one point. The visual field is expressed in terms of the angle subtended at the eye, measured from directly in front of the person towards the periphery of vision. A normal eye can see 60° nasally (toward the nose), 100° temporally (away from the nose), 75° inferiorly (down), and 60° superiorly (up) (Dersu et al. 2006). Available examination techniques can test the limits of peripheral vision, assess defects in the central field of vision, or evaluate the entire visual field.

A simple preliminary test to examine the limits of peripheral vision is a confrontation test. Here, a moving target, such as the examiner's hand, starts outside the visual field and is moved slowly central until the patient confirms visualization (Cummins et al. 2014). A second basic type of visual field test uses a pattern of straight lines forming perfect squares, called an Amsler grid, to look for defects in approximately the middle 10% of the visual field. This is a useful tool to detect vision problems caused by damage to the retina, particularly to the macula (Segre 2015). The patient is asked to stare at the central spot of the grid and identify any areas of the grid that are missing or distorted. Figure 7 shows two copies of an Amsler Grid, one as would be viewed by a normal eye (left), and the other as would be viewed by a damaged eye (right). The grid on the right shows a damaged eye's perception of a small scotoma below central fixation with surrounding distortion (Broadway 2012). A scotoma is a spot in the visual field in which vision is absent or deficient (Merriam-Webster 2015b).

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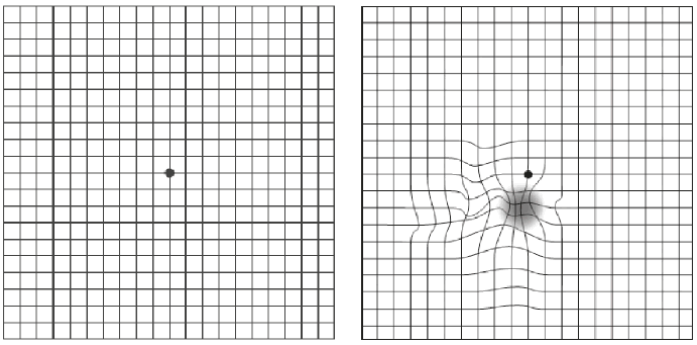
[7] For example, consider the case where one eye has a monocular visual acuity of 20/40 and the other eye is 20/100. It is our understanding that using the AMA's 3:1 weighting scheme, the binocular weighted average would be:

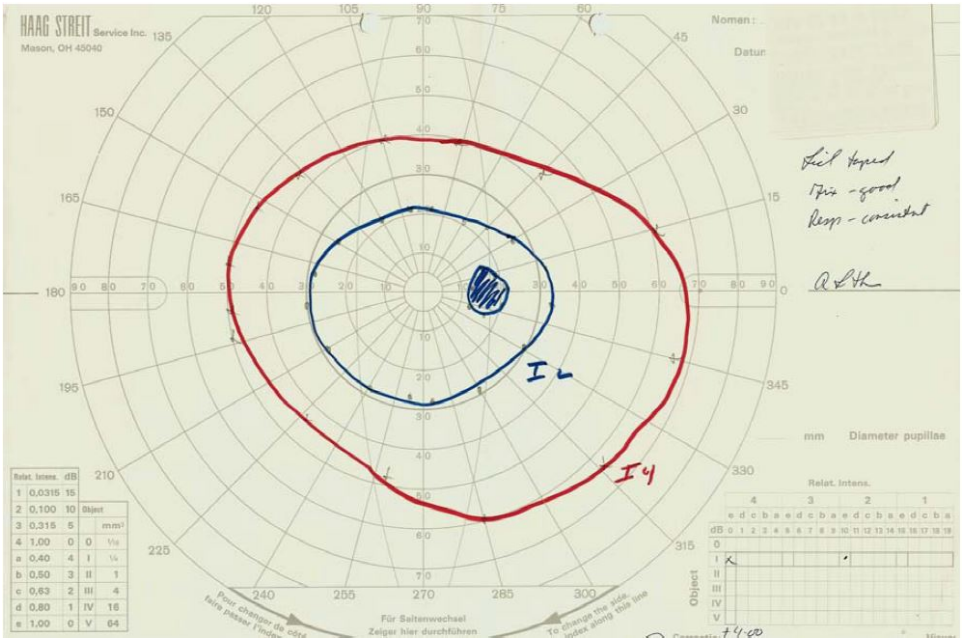
$$\frac{\left[3 \times \left(\frac{20}{40}\right) + 1 \times \left(\frac{20}{100}\right)\right]}{4} = \frac{[3 \times 0.5 + 1 \times 0.2]}{4} = \frac{1.7}{4} = \frac{20}{47}.$$



Source: Broadway 2012.

Figure 7. Amsler Grid Used to Assess Visual Field. Left: as viewed by a normal eye. Right: as viewed by a damaged eye.

Perimetry is a more sensitive and systematic examination of the entire visual field (Imaging and Perimetry Society 2008). A Goldmann perimeter is a hemisphere in which the patient's eye is centered and through which target spots or rings of light are shone while the patient fixates on a central spot. The usual mode of testing is known as kinetic perimetry, where an examiner moves a target of fixed width and brightness. Based on the patient's response, perimetry tests document the boundaries between seeing vs. not seeing the target to produce a drawing of the visual field (Broadway 2012). Figure 8 shows an example of the perimetry test results. The curves drawn are known as "isopters" and represent boundaries between seeing vs. not seeing the target (Broadway 2012). In this figure, two isopters, or the boundaries of seeing vs. not seeing targets with two different brightness levels, are shown. The inner and outer isopters mark the boundary for seeing the dimmer and brighter targets, respectively. The physiological blind spot is shown as the filled-in circle (Dersu et al. 2006).



Source: Dersu et al. 2006.

Figure 8. A Normal Goldmann Visual Field, Based on Two Isopters

Different types of perimetry tests can be administered. Static testing uses stationary targets that increase in brightness until seen. This test maps threshold sensitivity level throughout the entire visual field. These same tests can be performed using automated perimeters; the Humphrey Visual Field Analyzer is the most widely used (Zeiss 2015). For rating disability, the DVA mandates that examiners perform visual field testing using either Goldmann kinetic perimetry or an automated perimetry device with Goldmann kinetic perimetry capability and that results be recorded on a standard Goldmann chart (DVA 2012), as will be discussed below.

B. Vision Standards

Vision impairment such as permanent impairment of visual acuity or visual field could very well "restrict the employment or other activities of a person for the rest of his or her life," to use language from DODI 3200.19 (DoD 2012). An impairment of distant visual acuity (that cannot be corrected, such as with glasses or contacts lenses) limits a person's ability to read signs, drive, or recognize faces. A visual field impairment (that cannot be corrected) limits peripheral vision and thus limits the ability to react to things that are not being looked at directly and to estimate the speed of moving objects. There are many published standards for quantifying the level to which a person's life is restricted (i.e., the level to which they are disabled due to a determined impairment). Discussed here are standards set by the World Health Organization (WHO), the U.S. military services, the DVA, and the SSA.

1. World Health Organization

The categorization of vision impairment as included in the ICD-10 is based on the recommendation of a WHO Consultation (WHO 2003). WHO defined five categories of impairment as displayed in the first two columns of Table 1. The third column of Table 1 shows the level of visual field impairment that would also be classified under each of the WHO category descriptions, based on data compiled for an ICO report (Colenbrander 2002). Visual impairment is characterized by measuring a person's corrected visual acuity with either one or both eyes open (WHO 2015; Colenbrander 2002).[8]

Table 1. WHO Categories of Visual Impairment

Grade of Impairment	Snellen's visual acuity	Performance	Average visual field radius
0	Better than 20/70	Mild or no visual impairment	60° 50° 40°
1	20/70 to better than 20/200	Moderate visual impairment	30° 20°
2	20/200 to better than 20/400	Severe visual impairment (difficulty reading even with aids)	10° 8°
3	20/400 to better than 20/1200	Blindness	6° 4°
4	20/1200 to light perception	Blindness	2°
5	No light perception	Blindness	0°

Source: Compiled from WHO 2015.

2. U.S. Military

DoDI 6130.03 establishes medical standards for new recruits in the military services (DoD 2010). According to this instruction, current abnormality or history of any abnormality of the retina is a disqualifying condition. This includes, for example, retinal holes or detachments[9] and posttraumatic retinal scars.[10] Furthermore, current or history of abnormal visual fields due to trauma[11] is also listed as a disqualifying condition, without stating a particular level of visual field impairment.

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[8] In contrast, the WHO assesses *unaided* hearing loss, *without* the use of hearing aids.

[9] ICD-9 code 361.

[10] ICD-9 code 363.

[11] ICD-9 code 368.9.

DoDI 6130.03 further specifies that near visual acuity must correct to at least 20/40 in the better eye[12] and distant visual acuity must correct with spectacle lenses (i.e., glasses) to at least one of the following:

- 20/40 in one eye and 20/70 in the other eye,[13]
- 20/30 in one eye and 20/100 in the other eye,[14] or
- 20/20 in one eye and 20/400 in the other eye.[15]

Each service may specify more stringent requirements depending on the duty. Table 2 shows some examples from each service.

Table 2. Enlistment, Commission, and/or Special Duty Medical Threshold Values for Vision

Organization	Purpose	Visual Acuity Standard
Army, Standards of Medical Fitness AR 40-501 (U.S. Army 2011)	Entrance into United States Military Academy or Reserve Officer Training Corps	Distant visual acuity must correct to at least 20/20 in one eye and 20/40 in the other
	Officer Candidate School	Distant visual acuity must correct to at least 20/20 in one eye and 20/100 in the other
Navy, Manual of the Medical Department NAVMED P-117 (U.S. Navy 2015)	Commission and programs leading to commission	Near and distant visual acuity must correct with spectacle lenses (i.e., glasses) to 20/20 in each eye
Air Force, Medical Standards Dictionary (U.S. Air Force 2014)	Flying Class II pilot	20/400 uncorrected distant visual acuity, corrected to 20/20
Coast Guard, Medical Manual COMDTINST M6000.1F (U.S. Coast Guard 2014).	Aviation personnel	Depending on specific duty, from 20/50 to 20/400 minimum uncorrected distant visual acuity, corrected to 20/20
	Officers	Minimum 20/400 uncorrected distant visual acuity, corrected to 20/20
	Divers	Minimum 20/200 uncorrected distant visual acuity, corrected to 20/20

[12] ICD-9 codes 367.1 – 367.32.

[13] ICD-9 code 369.75.

[14] ICD-9 code 369.75.

[15] ICD-9 code 369.73.

Source: Compiled from AR-40.501 (U.S. Army 2011), NAVMED P-117 (U.S. Navy 2015), COMDTINST M6000.1F (U.S. Coast Guard 2014), and Air Force Medical Standards Dictionary (U.S. Air Force 2014).

3. U.S. Department of Veterans Affairs

The Veteran Affairs Schedule for Rating Disabilities (VASRD) details requirements for assigning a rating between 0%–100% to a veteran's conditions (DVA 2009). This is done to reflect the degree to which a condition impairs a veteran's ability to work (CBO 2014). The DVA's visual impairment rating system takes visual acuity, visual field, and muscle function into account to rate a vision disability (Military Disability Made Easy n.d.). Visual acuity and visual field are rated separately; muscle function is rated separately only if the condition of the eye does not affect the other two measures. If only one eye is affected, the total disability rating cannot be greater than 30% unless the eye is actually missing.

To rate distant visual acuity, the examining optometrist tests both near and distant vision using a Snellen's chart or equivalent. The tests are performed both with and without correction. Visual acuity, however, is rated only on *corrected, distant* vision.[16] Anything worse than 20/200 is considered blind; anything better than 20/40 is given the same rating as 20/40 vision. (That is, the rating scale saturates at 20/200 and 20/40.) After each eye is measured, the visual acuity rating is determined by the Table 3 below.[17] In the case for both eyes completely blind or missing, the rating is 100%.

Visual field is tested in the VASRD using a Goldmann kinetic perimetry test or a similar automated system as described above. Eight directions are used for rating: upward, downward, nasally (toward the nose), temporally (away from the nose), and once midway between each of these. As discussed above, kinetic perimetry tests map out an isopter, the boundary between seeing vs. not seeing a target of specific width and brightness—the VASRD regulations require the use of standard targets.[18] For the VASRD's purposes, a "normal" visual field is one that is not impaired. Such a field displayed in Figure 9 and is characterized as 65° down, 50° down nasally, 60° nasally, 55° up nasally, 45° up, 55° up temporally, 85° temporally, and 85° down temporally, for an average of 62.5°.

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[16] This is in contrast to hearing impairments, which the VASRD rates *without* the use of a hearing aid.

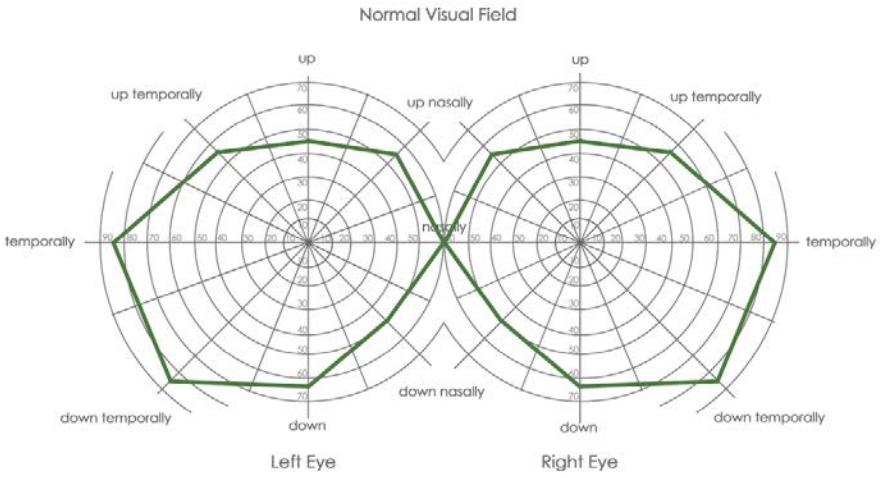
[17] There are some special circumstances, including: (1) If, in a single eye, the best corrected near vision is two or more steps worse than the best corrected distant vision, then the visual acuity is adjusted upward one step for the distant vision. (2) If the prescription in the worst eye is more than 3 diopters (reciprocal of the focal length in meters) different than the prescription for the best eye, then the worst eye can be rated on corrected or uncorrected vision, whichever results in better vision when both eyes are used together. (3) If one of the eyes is missing, and an artificial one cannot be worn because of a medical reason, then the rating for visual acuity increases by 10% (DVA 2008a).

[18] If the crystalline lens functions normally or close to normal with contact lenses or an implant, then the VASRD uses the standard III4e target. If the lens does not function normally or is absent or displaced, then the target used for rating purposes is IV4e (Military Disability Made Easy n.d.).

Table 3. VASRD Visual Acuity Ratings

Best Eye / Worst Eye	5/200	10/200	15/200	20/200	20/100	20/70	20/50	20/40
Complete loss of eye	100%	90%	80%	70%	60%	60%	50%	40%
Complete loss of vision (blind)	100%	90%	80%	70%	60%	50%	40%	30%
5/200	100%	90%	80%	70%	60%	50%	40%	30%
10/200		90%	80%	70%	60%	50%	40%	30%
15/200			80%	70%	60%	40%	30%	20%
20/200				70%	60%	40%	30%	20%
20/100					50%	30%	20%	10%
20/70						30%	20%	10%
20/50							10%	10%
20/40								0%

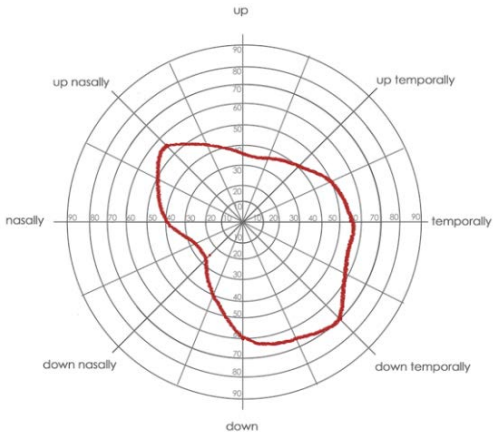
Source: Compiled from DVA 2008b.



Source: Military Disability Made Easy n.d.

Figure 9. VASRD Visual Field Chart Used to Score Visual Field for Rating Disability, Showing a Normal Visual Field in Both Eyes

To rate an impaired visual field, the examiner calculates the veteran's remaining field by averaging the measurements over the eight directions. For example, in Figure 10, the measurements are 35° up, 40° up temporally, 55° temporally, 70° down temporally, 60° down, 25° down nasally, 40° nasally, and up nasally 55°. The average of these eight measurements, and thus the average remaining field, is 47.5°. Disability due to visual field impairment is then rated according to Table 4. The VASRD also assigns an equivalent visual acuity score to a visual field impairment for evaluation purposes. It is our understanding that this does *not* mean that the visual field impairment results in the corresponding visual acuity impairment, but rather that the visual field impairment is assumed to affect the veteran's earning ability to the same degree as the corresponding visual acuity score.



Source: Military Disability Made Easy n.d.

Figure 10. VASRD Visual Field Chart Used to Score Visual Field for Rating Disability, Showing a Reduced Visual Field in the Right Eye

Table 4. VASRD Visual Field Ratings, with Equivalent Visual Acuity Scores

Remaining visual field	Disability rating		Visual acuity equivalent score
	One eye	Both eyes	
5° or less	30%	100%	5/200
6° to 15°	20%	70%	20/200
16° to 30°	10%	50%	20/100
31° to 45°	10%	30%	20/70
46° to 60°	10%	10%	20/50
61° or more	0%	0%	20/40

Source: Compiled from the U.S. Government Publishing Office (GPO) 2015.

When visual acuity and visual field are impaired in one or both eyes, the ratings are combined according to a table specified in the VASRD (DVA 1992). In addition, a scotoma is rated 10% if it affects 1/4 or more of the visual field or if it is centrally located. There is also a provision to rate retinal scars or other irregularities of the retina as 10%. Evaluating visual impairment due to either a scotoma or retinal scars or irregularities based on visual acuity may, however, result in a higher rating.

4. U.S. Social Security Administration

Similar to the DVA, the SSA evaluates visual disorders using measurements of visual acuity and visual field. The SSA uses these measurements to calculate a value for visual efficiency representing the remaining visual function (SSA 2015). Visual acuity is tested using Snellen or comparable methodology, and anything worse than 20/200 is recorded as 20/200. Visual acuity efficiency is determined according to Table 5 using the best *corrected* central visual acuity for *distance* in the *better* eye. Visual field is tested using automated static perimetry and reported on a Goldmann chart along the same eight directions displayed in Figure 9 for the VASRD evaluation (SSA 2015). Remaining visual field is calculated in the same way as the VASRD and then reported as a percentage of remaining field representing visual field efficiency. Only the visual field efficiency of the *better* eye is reported. Finally, an overall visual efficiency is calculated by multiplying visual acuity efficiency by visual field efficiency and dividing by 100. The SSA only considers visual efficiency "lost" if the value is below 20%.

Table 5. SSA Visual Acuity Efficiency

Snellen best-corrected central visual acuity for distance	Visual acuity efficiency (%)
20/20	100
20/25	95
20/30	90
20/40	85
20/50	75
20/60	70
20/70	65
20/80	60
20/100	50
20/110	45
20/120	40
20/140	35
20/160	30
20/200	20

Source: Compiled from SSA 2015 and Merrick 2007.

C. Significance of Vision Impairment

As discussed above, different organizations use slightly different standards for visual impairment. While all methods use visual acuity as one metric of visual impairment, only some methods state specific requirements for visual field. DoDI 6130.03, for example, has specific requirements for measurement of distant visual acuity for enlistment in the U.S. military, but makes a statement that a disqualifying condition includes "current or history of abnormal visual fields due to disease of the eye or central nervous system, or trauma," without more specific metrics (DoD 2010, 13). The VASRD and the SSA relate specific measurements for both visual acuity and visual field to an overall level of disability. To do this, the VASRD converts visual field impairments into an equivalent visual acuity score, and the SSA multiplies the visual acuity efficiency by the visual field efficiency to arrive at an overall visual efficiency score. Different methods were also created for different purposes. The WHO/ICO provides only broad categories for visual impairment; both the VASRD and the SSA quantify the level of impairment for compensation purposes; and DoDI 6130.03 uses its assessment of visual performance to determine who may enlist in the U.S. military. Methods also differ based on which eye or eyes are considered. The WHO/ICO, DoDI 6130.03, and the VASRD assess the visual impairment of both eyes, either together or separately first before combining the two scores. In contrast, the SSA

takes only the best eye into account, and the threshold for being considered "disabled" is set very high (e.g., a visual efficiency below 20%).

1. Visual Acuity

Table 1–Table 5 summarize different organizations' standards for *corrected* visual function. Visual acuity measurements due to *refractive* errors are manageable with corrective eyewear, contact lenses, or surgery (refractive eye surgery such as LASIK or PRK). These aids work by correcting the focusing power of the *cornea and lens* of the eye to form a sharp image on the retina. Retinal lesions, however, represent a loss of sensory neural function. We assume, then, that corrective lenses will provide little to no aid for visual acuity impairments caused by retinal lesions. Table 1–Table 5 are still useful for our assessment of vision impairment, though. The "corrected" standards summarized in these tables are based on the assumption that the tested vision represents the person's best possible vision. In this project, we are also interested in a person's best possible vision after being targeted with a dazzling laser, even if that best possible vision is uncorrectable because it is impaired by retinal damage.

To determine where we might set our thresholds for declaring a visual impairment significant, we first assume that failure to enlist in the U.S. military is a suitable surrogate for "restrictions on employment," to use the language set forth in DoDI 3200.19. The minimum vision requirements set forth in DoDI 6130.03 are the thresholds beyond which the DoD has determined that a potential new recruit would be unable to perform his or her duties in the U.S. military. We ignore the special cases listed in Table 2; we assume that the average person does not require the vision of, for example, a pilot, to maintain employment. As discussed above, DoDI 6130.03 cites three possible cases in which a recruit can meet the visual acuity criteria for military enlistment. Table 6 compares these cases to the standards discussed in the previous section.

Consider the last row of Table 6: the case in which a recruit just barely satisfies DoDI 6130.03's enlistment criteria with 20/20 distant visual acuity in her best eye and 20/400 (equal to 10/200) distant visual acuity in her worst eye. Based on Table 3, we see that the VASRD would rate this recruit as 30% disabled (assuming no other injuries or conditions). That is, per DoDI 6130.03, the military accepts recruits who, per the VASRD, are considered up to 30% disabled. The SSA would consider the visual acuity of this same recruit to be 100% efficient, though, since the SSA considers only her best eye. Based on her best eye only, the WHO would consider our example recruit to have "mild to no visual impairment." If the assessment was based on her worst eye only, however, then the WHO would consider her to have "severe visual impairment."

Table 6. Comparing DoDI 6130.03's Visual Acuity Standards for Military Enlistment to the VASRD, SSA, and WHO Standards

DoDI 6130.03 standard for distant visual acuity		VASRD visual acuity rating	SSA visual acuity efficiency	WHO category for visual acuity	
Best eye	Worst eye			Based on best eye	Based on worst eye
20/40	20/70	10%	85%	Mild to no visual impairment	Moderate visual impairment
20/30	20/100	10%	90%	Mild to no visual impairment	Moderate visual impairment
20/20	20/400	30%	100%	Mild to no visual impairment	Severe visual impairment

Similarly, consider the first row of Table 6. Here, a recruit could also barely satisfy the enlistment criteria with 20/40 distant visual acuity in her best eye and 20/70 in her worst eye. Table 3 shows that the VASRD would rate this recruit as 10% disabled. In fact, with 20/40 acuity in her best eye, a 10% disability rating would also be given for a worst eye acuity of 20/60 and 20/50.

Is it reasonable to base our standards for significance on DoDI 6130.03's visual acuity criteria for military enlistment? To explore this question, we briefly investigated the vision standards needed to perform various other jobs in the United States. A report commissioned by the Federal Aviation Commission reviewed occupational vision standards (Beard, Hisle, and Ahumada 2002). The main focus of this review was the use of vision in aircraft maintenance inspection, but standards for various other occupations were reported. Table 7 lists some examples of distant visual acuity standards for various occupations. We also considered the requirements for obtaining a driver's license in the United States. Table 8 shows example requirements for five states. In general, the requirements we examined for enlistment in the U.S. military, other employment in the United States, and driving in the United States all fall into the WHO's "mild or no visual impairment" category, which corresponds to a best corrected visual acuity of better than 20/70 (i.e., 20/40 and better, 20/50, and 20/60).

Uncorrectable vision loss that is severe enough to interfere with daily activities or, in other words, "not enough vision to do whatever it is you need to do" is known by eye-care professionals as "low vision" (VisionAware 2015). Low vision may be caused by disease or injury, and it is generally considered to be visual acuity of 20/70 or worse in the better-seeing eye or significant damage to peripheral vision that cannot be corrected by surgery, medicines, or lenses (VisionAware 2015).

Table 7. Vision Standards for Various Jobs in the United States

Job	Best corrected distant visual acuity
Air Transport Association Nondestructive Examination Personnel	20/50
American Welding Society Inspector	20/40
The American Society of Mechanical Engineers Nondestructive Examination Personnel	20/30
U.S Secret Service	20/20 each eye
Nuclear Materials Courier	20/20 each eye
Border Patrol Agent	20/20 each eye
U.S. Marshal	20/20 binocular
Bureau of Alcohol, Tobacco and Firearms	20/20 and 20/30
Surface Mine Reclamation	20/30 and 20/50
Mine safety and Health	20/30 and 20/50
Firefighter	20/30 and 20/70
Corrections Officer	20/30
Corrections Admin	“usable vision”
Security Guard	“good vision”
Agriculture Warehouse Examiner	“good in one eye”
San Diego Police Officer	20/20
Dallas Police Officer	20/20 each eye
Los Angeles Police Officer	20/40

Source: Compiled from Beard, Hisle, and Ahumada 2002.

Table 8. Vision Standards for Driving in the District of Columbia, Virginia, Maryland, Florida, and California

	Visual acuity	Visual field
Virginia	20/40 in one or both eyes	100° horizontal in one or both eyes
Virginia daylight only	20/70 in one or both eyes	70° horizontal or 40° temporal and 30° nasal in one eye
D.C.	1. No less than 20/40 in best eye OR 2. no less than 20/70	1. No requirement for 1. 2. 140° for 2.
Maryland	20/40 in both eyes	140°
Maryland restricted	20/70 in one or both eyes	110°, with at least 35° lateral to the midline of each side
Florida	20/70 in either eye or with both eyes	130°
California	20/40 with both eyes or 20/40 in one eye and at least 20/70 in the other eye	

Source: Compiled from DC DMV 2015; Virginia DMV 2015; Maryland DMV 2015; Florida DHSMV 2015; California DMV 2011.

Visual acuity worse than 20/70 is evidenced to be a common threshold for disabling visual impairment throughout our analysis of standards and disability ratings systems. Therefore, **we propose that injury to the retina resulting in a permanent, best corrected visual acuity of 20/70 or worse can be considered significant.**

On the other end of the scale is normal visual acuity. Although 20/20 visual acuity is the accepted standard for "normal" visual acuity, a young, healthy, human eye might have vision as good as 20/10 (Eye Care Fun n.d.). 20/20 is accepted by convention as the limit with which an individual can cope well enough in his or her job or in school that vision correction is not required (Evans 2006). Therefore, **we propose that injury to the retina resulting in permanent, best corrected visual acuity of 20/20 or better can be considered *not* significant.**

Visual acuity worse than 20/20 but better than 20/70 is more difficult to classify as either significant or not significant. The WHO would classify this range of visual acuity as "mild vision impairment" (see Table 1). 20/40 vision in both eyes is not considered a disabling condition by the VASRD, according to the rating system presented in Table 3, but 20/40 vision in one eye and 20/50 vision in the other eye is rated as 10% disability. We must explore if this mild visual acuity impairment would "restrict employment or other activities of the person for the rest of his or her life," per DoDI 3200.19.

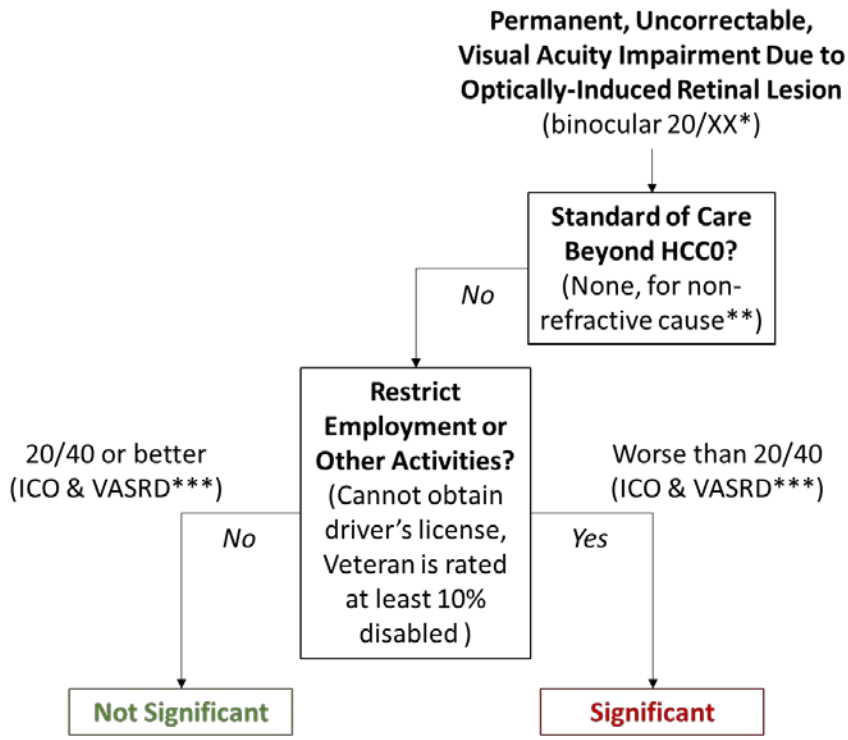
Vision correction is generally recommended for vision worse than 20/20 (Evans 2006), though when and how often that correction is used is determined by personal preference. Most individuals with 20/40 or 20/50 uncorrected vision in the United States may use corrective lenses on a limited basis, such as for driving or watching movies (Caster

n.d.). (This, of course, assumes that their visual acuity impairment is for refractive reasons, such that they can benefit from corrective lenses, unlike the targeted individuals we are considering in this project.) An individual with 20/40 or better corrected visual acuity would qualify to obtain a driver's license in all 50 states, but a few states have a laxer requirement or offer a restricted license for vision worse than 20/40 that permits driving only during daylight hours (Colenbrander and De Laey 2006). The ICO study recommended no driving restrictions for visual acuity 20/40 or better, but recommended that each case worse than 20/40 be considered individually and potentially include a road test for driving ability (Colenbrander and De Laey 2006). The ability to obtain a driver's license may affect the number and type of employment opportunities open to a person, as well as other activities of daily life.

Consider again the visual acuity standards for various occupations presented in Table 7 and for military special duty assignments in Table 2. Vision that does not correct to at least 20/20 would eliminate the most specialized, but not all, of the jobs listed. While an individual with, for example, 20/60 best corrected visual acuity could not qualify to be a military pilot or a Secret Service agent, he or she may still qualify for less restrictive jobs such as security guard or corrections administrator. Note that here the requirements are subjective (i.e., "good vision" or "usable vision") rather than quantitative. The American Optometric Association (AOA) recommends in general 20/40 visual acuity for tasks requiring coarse detail, 20/30 for medium detail, and 20/25 for fine detail (AOA 2015).

Based on the discussion above, **we propose that permanent, best corrected visual acuity equal to or better than 20/40 can be considered *not* significant, while worse than 20/40 can be considered significant.** This statement is largely due to our assumption that the inability to obtain a driver's license in most U.S. states without a case-by-case analysis is a suitable surrogate for "restrictions on employment and other activities for the rest of a person's life," to use language from DoDI 3200.19. Furthermore, we assume that a nonzero VASRD disability rating is a suitable surrogate for "restrictions on employment," since the purpose of the VASRD rating is to calculate the monthly financial compensation needed to "offset the average earnings lost as a result of [service-connected disabilities], whether or not a particular veteran's condition has reduced his or her earnings or interfered with his or her daily functioning" (CBO 2014, 1.) The VASRD rates a veteran as 10% disabled if he or she has 20/40 vision in the best eye and worse than 20/40 vision in the other eye.

Figure 11 summarizes these recommendations.



* "Binocular 20/XX" represents the visual acuity in Snellen notation for both eyes together.
** We assume corrective lenses will not aid a visual acuity impairment due to a non-refractive cause, such as an optically-induced retinal lesion.
*** We assume that failure to obtain a driver's license is an adequate surrogate for "restricting employment or other activities". The International Council of Ophthalmology (ICO) recommends no driving restrictions for visual acuity of 20/40 or better, but recommends that each case worse than 20/40 be considered individually. Furthermore, we assume that a non-zero Veterans Affairs Schedule for Rating Disabilities (VASRD) rating is an adequate surrogate for "restricting employment". The VASRD rates a veteran as at least 10% disabled if he or she has 20/40 vision in one eye and worse than 20/40 vision in the other eye.

Figure 11. Determining the Significance of Visual Acuity Impairment

2. Visual Field

As discussed above, both the DVA and the SSA have well-specified guidelines for how visual field impairments are to be tested and how the results of the tests are to be rated to determine level of disability. Here, each eye is tested separately because a defect present in only one eye could be missed when testing both eyes together—the visual field in one eye might mask the defect in the other eye. If each individual eye is not tested, a person may appear to have a normal binocular visual field, remaining unaware of visual field impairment in one eye (Broadway 2012). A visual field impairment in one eye can still be problematic, potentially resulting in accidents caused by a person not being aware of a nearby vehicle or other dangerous object.

When visual field requirements are stated elsewhere, such as for driving or job requirements, the requirements vary and the testing methods are rarely specified (Colenbrander and De Laey 2006). See, for example, the variety of visual field

requirements for obtaining a driver's license in Table 8. Not all states have a requirement for visual field to obtain a driver's license. The Federal requirement for commercial drivers is field of vision of at least 70° horizontally in each eye (Federal Motor Carrier Safety Administration n.d.). The ICO study (Colenbrander and De Laey 2006) suggests that the minimum requirement for safe driving is a binocular visual field of 120° horizontal and 40° vertical. According to this study, no consensus exists about the method used in screening visual field. The study further claims that persons with visual field defects have double the incidence of road accidents or traffic violations compared with persons with full visual field.

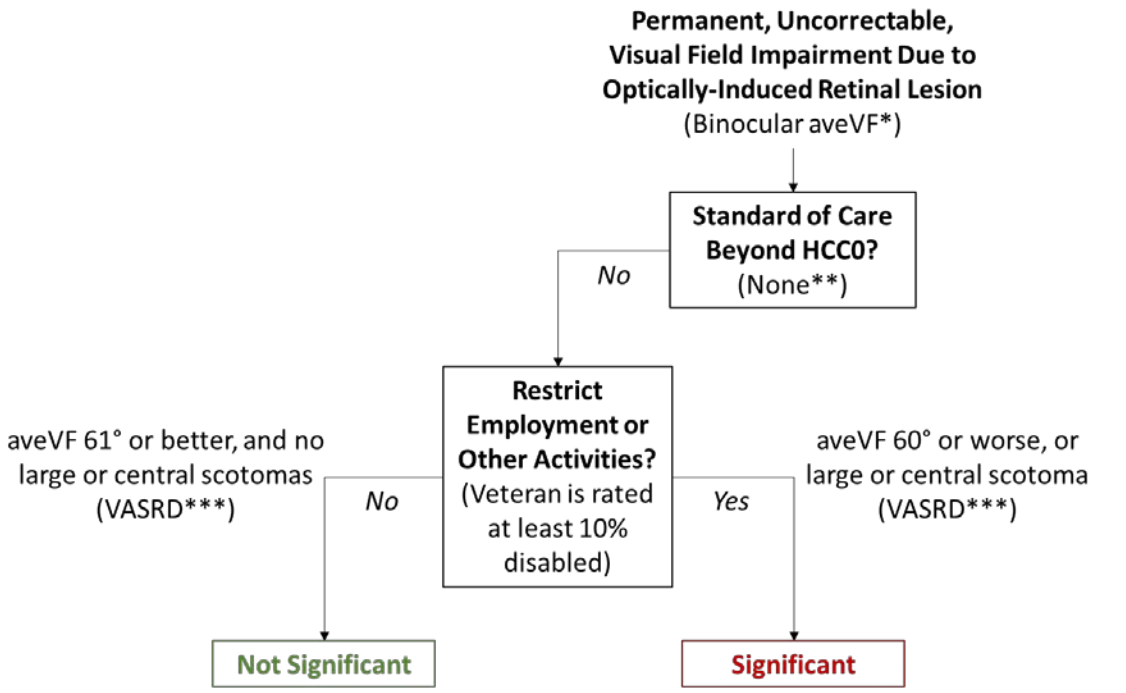
A 2002 NASA study (Beard, Hisle, and Ahumada 2002) noted a lack of cited empirical research to support most occupational visual field requirements. Beard, Hisle, and Ahumada (2002) noted one MED-TOX Health Services study (MED-TOX 2013) that looked at vision requirements for correctional officers. Correctional officers are responsible for supervising violent and dangerous criminals. To maintain the officer's own safety and the safety of the facility, excellent peripheral vision is critical to detecting inmate actions such as rapidly moving to attack an officer from the side or passing a weapon to another inmate. MED-TOX (2013) concluded that the drop-off in acceptable performance after 120° was severe.[19] Some occupations derive requirements from other fields. For example, the standard for forklift operators, who often work in crowded surroundings with other workers present, is set at 140° binocular, derived from the 70° horizontal for each eye requirement for commercial drivers (Beard, Hisle, and Ahumada 2002; AOA 2015). Other occupations simply state "normal" as a requirement without further defining what constitutes normal (Beard, Hisle, and Ahumada 2002).

Given the lack of well-quantified occupational vision standards for visual fields, our recommendations for significance of visual field impairments are based largely on the VASRD. Our final bar for visual acuity significance was worse than 20/40 (i.e., 20/50 or worse), which corresponds to an average visual field of 60° or less, as shown in Table 4. The VASRD rates this range of visual field impairment as 10% or more disabled. In addition, as discussed above, the VASRD rates a scotoma as 10% if it is large (1/4 of the visual field or more) or centrally located. The VASRD does not define what it means by "central," but as explained in Chapter 1, cones are responsible for central visual acuity, and their distribution drops off from a high of approximately 150,000 per square millimeter in the center of the foveola to approximately 5,000 outside of the fovea. To be conservative, then, we assume that any scotoma within the macula (i.e., within 2.75 mm from the center of the foveola) can be considered "central." Thus, **we propose that permanent visual field impairment can be considered significant if the remaining average radius is 60° or**

[19] Though not explicitly stated, we assume that this means a 60 + 60 = 120° binocular horizontal field of view, where each eye contributes 60° to the horizontal field of view.

less *or* a scotoma takes up 1/4 or more of the field of view *or* a scotoma of any size is in the macula (within 2.75 mm from the center), while all other permanent visual field impairments can be considered *not* significant.

Figure 12 summarizes these recommendations.



* "Binocular aveVF" represents the average visual field in degrees for both eyes together.
** We assume there is no aid for a visual field impairment.
*** We assume that a non-zero Veterans Affairs Schedule for Rating Disabilities (VASRD) rating is an adequate surrogate for "restricting employment". The VASRD rates a veteran as at least 10% disabled if his or her remaining average visual field is 60° or worse, or if a scotoma is large (at least ¼ of the field of view) or central (which we assume is within the macula).

Figure 12. Determining the Significance of Visual Field Impairment

5. Laser-Induced Retinal Lesions

Laser-induced retinal lesions *can* cause the significant visual acuity and visual field impairments discussed in the previous chapter. The purpose of this chapter is to determine which types of lesions *do and do not* lead that significant visual impairment. As such, we first describe different classes of lasers and explain how laser light is measured and how the photothermal mechanism (as opposed to the photomechanical or photochemical mechanism) is the most relevant mechanism by which dazzling lasers could significantly injure the retina. We then summarize literature regarding photothermal retinal lesions. Next, we describe methods used in the clinic to subjectively and qualitatively characterize a photothermal retinal lesion and explain the limitations of the literature in associating the clinical characterization of a photothermal retinal lesion to the concomitant impairment of visual acuity or visual field. Finally, we propose standards to assess a photothermal retinal lesion as either significant or not significant, based on a large number of assumptions regarding whether or not the lesion leads to a significant visual acuity or visual field impairment, as defined in the previous chapter.

A. Laser Classification

The American National Standards Institute has classified lasers by their Acceptable Emission Limit, which is based on the Maximum Permissible Exposure limit and the limiting aperture size. The aperture size is based on the worst case. Classification ranges from Class I (lowest power/least hazardous) to Class IV (highest power/most hazardous). Most germane to this paper are the Class II–Class III designations, which encompass most of the visible lasers considered for this study. Designations for Class II and Class III are described below (Occupational Safety and Health Administration (OSHA) 1999):

- **Class II:** Low-power visible lasers that emit above Class I levels but at a radiant power not above 1 mW. The concept is that the human aversion reaction to bright light will protect the person. Only limited controls are specified.
- **Class IIIa:** Intermediate-power lasers (continuous: 1–5 mW). Only hazardous for intrabeam viewing. Some limited controls are usually recommended.
- **Class IIIb:** Moderate-power lasers (continuous: 5–500 mW, pulsed: 10 J/cm^2 or the diffuse reflection limit, whichever is lower). In general, Class IIIb lasers will not be a fire hazard, nor are they generally capable of producing a hazardous diffuse reflection. Specific controls are recommended.

B. Mechanisms of Laser-Induced Retinal Lesions

Laser light is often described by its wavelength and dosage. Lasers with different wavelengths and dosages are used for different purposes. Figure 13 summarizes the types of light sources, wavelengths, dosages, and injury mechanisms often associated with laser-induced lesions. Pulsed lasers dosage is described by pulse energy and pulse duration. For a pulse of a given energy (e.g., mJ, µJ, or J/cm^2), shorter pulse durations concentrate the energy into smaller time frame (i.e. higher power), promoting more tissue damage. Conversely, continuous lasers dosage is described by average power (e.g., mW) and duration of exposure (e.g., s). For a continuous laser of a given power, longer exposures promote more tissue damage, since the energy absorbed by the tissue is the integral of the power over time.

	UV	Visible	Near-IR	IR
Wavelength	200 – 380 nm	380 – 700 nm	700 – 1100 nm	> 1100 nm
Application	Medical	Civilian, Military	Industrial, Medical, Military	Industrial, Military
Common laser types	Pulsed	Continuous or pulsed	Pulsed	Continuous or pulsed
Common Damage type	Chemical	Thermal	Mechanical	Thermal
Tissue damaged	Cornea	Retina	Retina	Cornea
Dosage for damage	> 1 mJ pulse < 20 ns	> 5 mW continuous > 0.5 s	> 1 µJ pulse < 1 ms	> 1 J/cm^2 pulse < 1 ms

Source: Compiled from Barkana and Belkin 2000 and Walsh, Flotte, and Anderson 1988.

Figure 13. Light Sources, Wavelengths, and Injury Mechanisms Associated with Laser-Induced Retinal Lesions

Different laser applications require different wavelengths of light. Lasers may radiate light in spectral regions spanning the ultraviolet (UV), visible, near infrared (near IR), infrared (IR), and beyond. Each spectral range tends to have its largest effect on different structures of the eye:

- At opposite ends of the spectrum, both UV and IR light are well absorbed by the cornea and lens (Wu, Seregard, and Algarve 2006), potentially causing damage to usually only those structures of the eye.
  - Refractive eye surgery (e.g., LASIK and PRK) exploit this property of UV light to reshape the cornea with great precision (Barkana and Belkin 2000).

  - IR lasers are often used in industry (steel cutting) and medicine (surgery) (Coherent, Inc. 2009; Omi and Numano 2014).

  Since UV and IR light are well absorbed by the cornea and lens, they do not generally reach the retina and therefore do not often cause retinal lesions (Wu, Seregard, and Algarve 2006). Furthermore, it is our understanding that dazzling lasers do not employ UV or IR light; therefore the corneal and lens injuries caused by UV and IR lasers are beyond the scope of this analysis.

- In the center of the spectrum, visible and near-IR light are well transmitted through and focused by the cornea and lens, reaching the retina, where lesions may result (Wu, Seregard, and Algarve 2006).
  - Near-IR lasers have many uses in military, medical, and industrial applications (Daly 1986; Hirsch et al. 2003; Manes 1992). Individuals are prone to injury from these classes of lasers due to (1) pulse energies that readily damage the retina, even with short exposure times; (2) a lack of eye protection when using these lasers; and (3) a lack of indication of the hazard of these lasers, due to the laser's invisibility (Mainster, Stuck, and Brown 2004).
  - Visible lasers are often used as laser pointers and for military dazzling applications (McLin 2013).

Dosage is described by the rate and duration at which the light energy is delivered. Ideally, dosage is described as the dose per unit area, which is fluence (J/cm^2) for pulsed lasers and irradiance (W/cm^2) for continuous lasers. The clinical literature often lacks this detail, however, instead only describing the total power or pulse energy of the laser:

- For pulsed lasers, the dosage is described by the energy per pulse (J/s) and the pulse duration (s). Pulsed lasers are used in a variety of medical, industrial, and military applications. Pulsed lasers are capable of concentrating laser energy into short pulses (picoseconds–nanoseconds) that readily introduce severe lesions (Mainster, Stuck, and Brown 2004).
- For continuous lasers, the dosage is described by the laser power (W) and duration (s). Many visible lasers are continuous, with consumer applications (laser pointers), commercial applications (scanning devices, light show entertainment), and military applications (warning/haling, dazzling) (Coherent, Inc. n.d.). It is our understanding that visible continuous lasers, such as those used as dazzling lasers in the military, are often lower power (<0.5 mW) with shorter exposure durations (≈0.5 sec) (McLin 2013), and therefore tend to produce different lesions than those associated with high-energy pulsed lasers.

Lesions derived from lasers may manifest in different forms. Exposure to different spectral wavelengths and dosage can introduce photomechanical, photochemical, or photothermal damage to different optical structures of the eye, as explained below.

1. Photomechanical Lesions

At sufficiently high electromagnetic field strengths, a dielectric breakdown occurs, resulting in an ionized gas, or plasma formation. The rapid formation and expansion of this gas introduces a localized mechanical disruption of the tissue. Localized boiling or vaporization of waterborne tissue can also produce rapid bubble formation and cavitation injuries. While such injuries may result from accident, medical therapies also exploit this behavior. Iris iridotomy uses this method to precisely deliver therapeutic lesions in the iris (Higginbotham 1994) and bladeless LASIK uses this phenomenon to cut the corneal epithelium (Sugar 2002). Requiring a high dosage of energy over a short time, photomechanical injuries are often associated with short-pulse/high-energy lasers, including Q-switched and mode-locked near-IR lasers (Mainster, Stuck, and Brown 2004). It is our understanding that such lasers have no known utility for the non-lethal dazzling applications considered in this project. Therefore, **we did not consider the photomechanical mechanism of injury in our analysis.** In the future, though, this mechanism should be revisited for any new laser weapon design that employs short pulse/high energy dosages.

2. Photochemical Lesions

Photochemical effects describe cases where light's wavelength energy is coupled with electronic states or bond energies that produce a deleterious effect. Depending on the wavelength of light considered, these effects range from severe to minimal. At certain UV wavelengths, strong protein absorption occurs and may produce significant lesions. This phenomenon is exploited in refractive eye surgery using UV excimer lasers to selectively ablate/reshape the cornea (Seiler and McDonnell 1995).

In the visible spectrum, photochemical effects are often associated with bleaching of sensory pigments and oxidative stress leading to cell damage. Often associated with arc welding or sun gazing, these effects often arise from chronic or prolonged exposure to visible light intensities that would be safe at lower exposure durations. Damaging exposures may last seconds to minutes. This effect depends upon wavelength and tends to align with absorption spectra of sensory pigments (rhodopsin) (Wu, Seregard and Algvere 2006). Initial effects may manifest in a yellow-white retinal lesion. Light adaptation associated with photoreceptor bleaching/turnover occurs with transient illumination intensity (e.g., exposure to a light flash or moving into a dark room). This effect can reverse itself over seconds or minutes (Guyton and Hall 1996) and is the effect and recovery sought by warfighters using dazzling lasers in various military scenarios such as vehicle

checkpoints. In such applications, it is our understanding that individuals targeted with a dazzling laser are likely to blink or otherwise shield their eyes, maintaining a short exposure time and thus a low dosage to which they are exposed.

At higher dosages caused by forced or consciously chosen long exposure times, however, lesions can take weeks to fade or even result in more severe foveolar distortion, pigment mottling, or macular holes (Mainster and Turner 2012). Common symptoms of these more extreme effects are blurred vision (i.e., low visual acuity), central scotoma, and erythropsia (i.e., objects appear tinged in red) (Mainster and Turner 2012)). Visual acuity immediately after exposure may range from 20/40 to 20/200, but typically returns to a normal range within 6 months (Mainster and Turner 2012). Due to the fact that the prolonged exposure times required to elicit this type of injury normally exceed the exposure times associated with intended use of non-lethal dazzling lasers, **we do not consider the photochemical mechanism of injury in our analysis.** However, this mechanism should be revisited in the future for any new laser weapon design that employs an extended exposure duration.

3. Photothermal Lesions

The retinal pigment epithelium (RPE), as its name implies, is highly pigmented or colored. Much like the black interior of a camera, the RPE's pigment absorbs and attenuates residual light within the retinal cavity to reduce glare image artifacts. Visible light delivered at sufficiently high powers and durations can heat the RPE. At about 47 °C (10 degrees of heating), tissue proteins begin to denature or coagulate and lose their function, producing a photothermal lesion (Mainster, Stuck, and Brown 2004). Coagulation often changes a tissue's light-scattering properties, readily observed as whitened lesions. This behavior is akin to the change in the appearance of an egg white during cooking. Lesions of this nature may occur with relatively short exposure durations (seconds or less) at laser powers slightly above Class IIIa eye-safe laser levels (power greater than 5 mW) (Mainster and Turner 2012). It is our understanding that dosages in this regime are closest to the dosages used for non-lethal dazzling applications. Therefore, we assume that **the photothermal mechanism of injury is the most relevant to the scope of this project.**

C. Literature on Photothermal Retinal Lesions

A very large number of journal articles have been published on laser-induced retinal lesions. Our initial search of Google Scholar for the terms "laser + retinal + lesion" resulted in 18,000 documents since 1980, and 49,000 documents with no date restriction. Similarly, our search for the terms "laser + eye + injury" resulted in 34,000 documents since 1980 and 111,000 with no date restrictions. Upon closer examination, though, most of these papers focused on the dosages required to *cause* a retinal lesion. Although these data are helpful in estimating the metric P(lesion occurred), this metric is outside the scope of this

project. Fewer papers focused on data that could be used to estimate the metric *P*(lesion is significant | lesion occurred), the objective of this project. That is, fewer papers discussed the medical treatments required by an existing retinal lesion or the effects of a retinal lesion on "the employment or other activities of a person for the rest of his or her life," (terminology from DoDI 3200.19). Those documents that did provide some information on these topics fell into two camps: accident reports and studies on photothermal coagulation therapy to treat retinal disorders.

1. Accident Reports

Workplace and military laser accidents are well documented (Harris et al. 2003; Mainster and Turner 2012). As mentioned earlier in this chapter, however, these accidents tend to involve higher power/pulsed (Class IIIb–IV) lasers, which operate in the non-visible regimes and at higher pulse powers that we assume are not considered relevant for non-lethal applications.

Perhaps more relevant to non-lethal dazzling lasers are accident reports of injuries from lower power Class IIIa–IIIb visible lasers. General-use laser pointers operate with a Class IIIa designation. Radiating less than 5 mW of power, these lasers are considered generally eye-safe, with few indications of reduced visual performance over extended periods of time. The literature mentions one case where a child intentionally stared at a laser pointer for 10 seconds. Visual acuity was reduced to 20/60 in the affected eye, and there were small lesions associated with pigment mottling. However, visual acuity and pigmentation were restored after several months (Mainster and Turner 2012). We note that such a case is highly unlikely for non-lethal dazzling application in military theater, where the targeted individual is prone to reflexively blink or otherwise shield his or her eyes, thus reducing the effective exposure duration.

There has, however, been a growth in reported accidents associated with visible Class IIIb lasers. These "handheld laser devices" operate with 5–500 mW of power. They are capable of causing permanent eye damage in a fraction of a second and are not considered eye-safe. Overseas Internet sales are making these devices more readily available to untrained individuals. In a reported injury case, vision post injury was 20/40, but restored to 20/20 2 months post injury (Ziahosseini, Doris, and Turner 2010). In another case, a 12-year-old boy, using a 125 mW laser, managed to induce severe subretinal hemorrhaging and photothermal lesions down to the RPE, resulting in 20/50 visual acuity. After 4 months, visual acuity improved slightly to 20/32 in his right eye and 20/25 in his left eye. Scarring remained, although no further information was provided (Wyrsch, Baenninger, and Schmid 2010).

2. Photothermal Coagulation Therapy

Photocoagulation therapy uses a visible laser to introduce an array of lesions across the retina, which helps to curb the growth of new vascularization or manage edema resulting from retinal disorders such as diabetic retinopathy. Studies have evaluated the risk of suffering a visual acuity impairment following treatment. Four months after treatment, the absolute percentage of patients treated with this therapy who suffered a decrease of 2–4 lines on a visual acuity chart was small (9.8% for the treated vs. 6.3% for untreated). The literature does not provide the patients' visual acuity before therapy. However, if one assumes the patients had 20/20 visual acuity before therapy, then a decrease of 2–4 lines on a visual acuity chart would correspond to 20/30 visual acuity after therapy. Note, though, that these studies consider patients with a degenerative eye condition and the data are confounded in later years due to the control group's natural degradation of visual acuity (without any treatment) (Fong, Girach, and Boney 2007).

We note that these studies have limitations that make it difficult to compare results to accidental injuries or effects from non-lethal dazzling technologies. Although optimization studies for photocoagulation therapies are well documented, they investigate a narrow window of laser powers (tens to hundreds of milliwatts), exposure durations (tens to hundreds of milliseconds), wavelengths, spot sizes (hundreds of micrometers), and locations on the retina (often non-foveal, to deliberately avoid causing vision impairment), resulting in lesions that are barely visible on examination, or not visible at all (Blumenkranz et al. 2006; Fong, Girach, and Boney 2007; Koinzer et al. 2012; Palanker and Blumenkranz 2012). Nevertheless, studies on photothermal coagulation therapy contain the only quantitative data we have found that could be used to assess the significance of a photothermal retinal lesion, per the definitions outlined in DoDI 3200.19. Therefore, we examined this literature carefully to determine how the clinicians in these studies characterized the lesions and how this characterization associated with visual impairment.

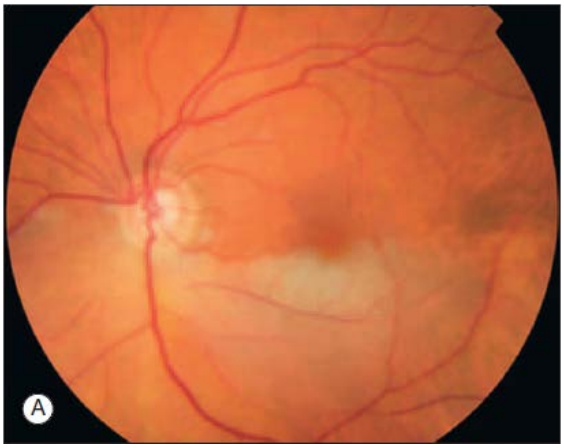
D. Methods for Clinical Characterization of Photothermal Lesions

Clinicians use several methods to characterize photothermal retinal lesions. These methods allow the detailed inspection of the surface and layers of the retina and include ophthalmoscopy and fundus photography, fluorescein angiography, and optical coherence tomography (OCT). We briefly summarize each method below.

1. Ophthalmoscopy and Fundus Photography

Of particular interest is the fundus of the eye, located at the posterior pole of the globe (back of the eye), which consists of the macula lutea and optical disc (Dirckx 2012). Simple examination of the posterior pole is performed with an ophthalmoscope, a simple optical device with an appropriate light source that allows an examination of the fundus. With the addition of film photography or digital charge-coupled device (CCD) cameras and optical

systems, an image of the fundus can be taken in the process of fundus photography (Yanuzzi et al. 2004). Commercially made fundus cameras can provide stereo images of the fundus. Figure 14 shows an example of a color fundus photograph.

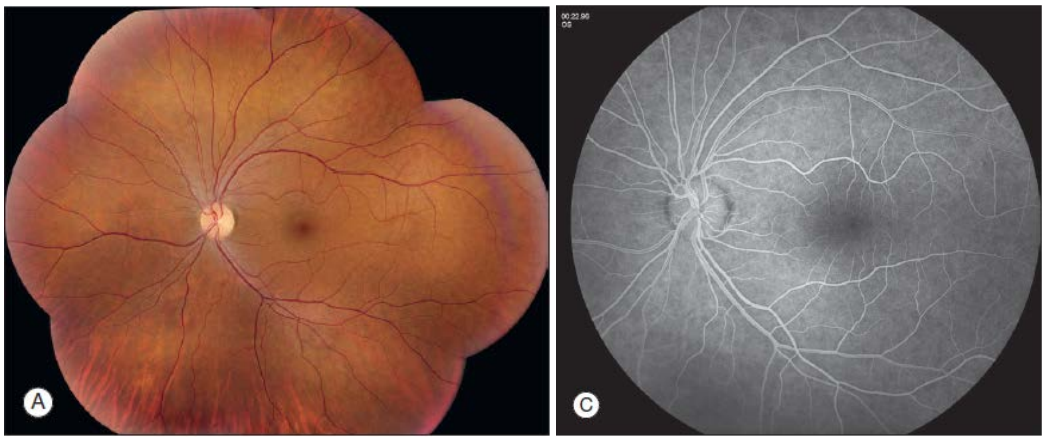


Source: Keane, Ruiz-Garcia, and Sadda 2012.

Figure 14. A Color Fundus Photograph of the Retina

2. Fluorescein Angiography

A companion technique to fundus photography is fluorescein angiography. The technique is important for investigating the integrity of the vasculature of the retina and choroid. Fluorescent dye (sodium fluorescein) is injected into the bloodstream of the patient. A fundus camera is then employed with appropriate filters to excite fluorescein at a wavelength of approximately 475 nm and then record an emission at 530 nm. In normal retinal tissue, fluorescein flows freely in the retinal and choroidal vasculature. No leakage of the dye should occur. In damaged or diseased tissue, leakage from blood vessels should register as hypo or hyper fluorescence, which is a decrease or increase of fluorescence, respectively. The left side of Figure 15 shows a montage of color fundus photographs of the retina, and a fluorescein angiography image of a similar area of the retina is on the right.

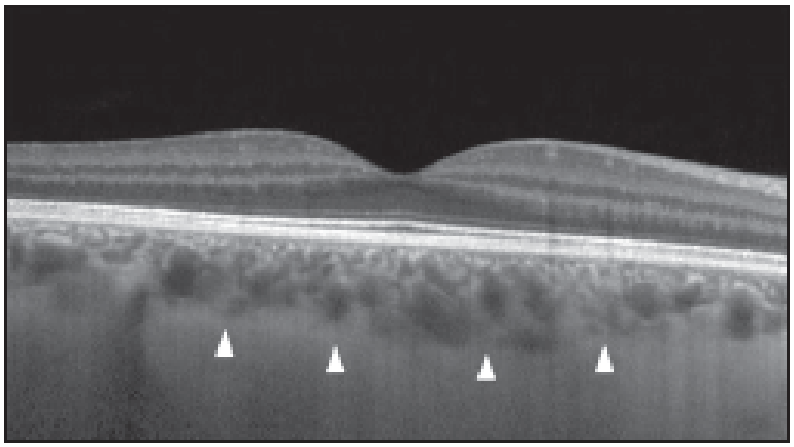


Source: Johnson et al. 2012.

Figure 15. Left: Montage of color fundus photography of the retina. Right: Fluorescein angiography image of a similar area of the retina.

3. Optical Coherence Tomography

OCT is a non-invasive imaging technique primarily used to image the retina and its various layers to detect retinal disorders or injury (Filho et al. 2012). OCT is based on the principle of low-coherence interferometry. Typically, using a Michelson interferometer, near-IR light is split into a sample arm and a reference arm. The sample beam is directed toward the tissue to be studied, and the resulting reflected and scattered light is then recombined with the reference beam. The resulting interference pattern is used to produce an A-scan, which contains information about the scattering properties of the sample. The sample beam is then scanned along a line generating multiple A-scans, which can be used to reconstruct a cross-sectional image of the sample tissue. Images using commercial or research instruments can be generated with an axial resolution of 2 μm and a lateral resolution of 20 μm. Figure 16 shows an OCT image of the retina. The foveal depression is clearly delineated, as well as the alternating light and dark bands of the retinal layers. White arrows indicate the outer boundary of the choroid.



Source: Filho et al. 2012.

Figure 16. Optical Coherence Tomography Image of Normal Retina with Foveal Depression

E. Significance of Photothermal Lesions

Clinicians use the methods described above (ophthalmoscopy or fundus photography, combined with fluorescein angiography or OCT) to assess the degree of injury, or severity, of a photothermal lesion. Lesions are often categorized as "subthreshold," "threshold," and "suprathreshold." Threshold in this case refers to whether a lesion is detectable by traditional ophthalmological or fundus photography methods (Mainster and Turner 2012):

1. Subthreshold Photothermal Lesions

Subthreshold lesions are invisible to traditional diagnostic methods, yet might be detectable using more advanced means, such as fluorescein angiography or OCT (Koinzer et al. 2012). As discussed above, photocoagulation therapy is often used to treat retinal disorders; studies have shown that the subthreshold lesions caused by this therapy often lead to minimal or no apparent permanent retinal damage (Mainster and Turner 2012). Further data is needed to quantify exactly how often subthreshold lesions create exactly how much permanent retinal damage. In the absence of further information, though, **we assume that subthreshold photothermal lesions, regardless of how they are caused, *never* cause permanent physical damage and can therefore be considered *not* significant.** Figure 17 illustrates our proposed scheme for classifying the significance of photothermal lesions.

2. Suprathreshold Photothermal Lesions

On the other end of the severity scale, suprathreshold lesions are the result of significant heat transfer, with transients that result in significant heating and thermal relaxation into surrounding tissues. Severe retinal damage and secondary effects such as periretinal and vitreoretinal hemorrhage, macular holes, and neovascularization are associated with these injuries (Barkana and Belkin 2000). These complications can require

HCC1+ treatment such as vitrectomy, internal limiting membrane peeling, gas tamponade, photocoagulation and photodynamic therapy, and anti-angiogenesis drugs (Alsulaiman et al. 2015; Grossniklaus and Green 2004). We did not explore exactly how often these complications occur, nor exactly how often they require HCC1+ treatment. In the absence of further information, then, **we err on the side of caution and assume that suprathreshold lesions, regardless of how they are caused, *always* lead to complications requiring HCC1+ treatment and can therefore be considered significant.** Figure 17 illustrates this assumption.

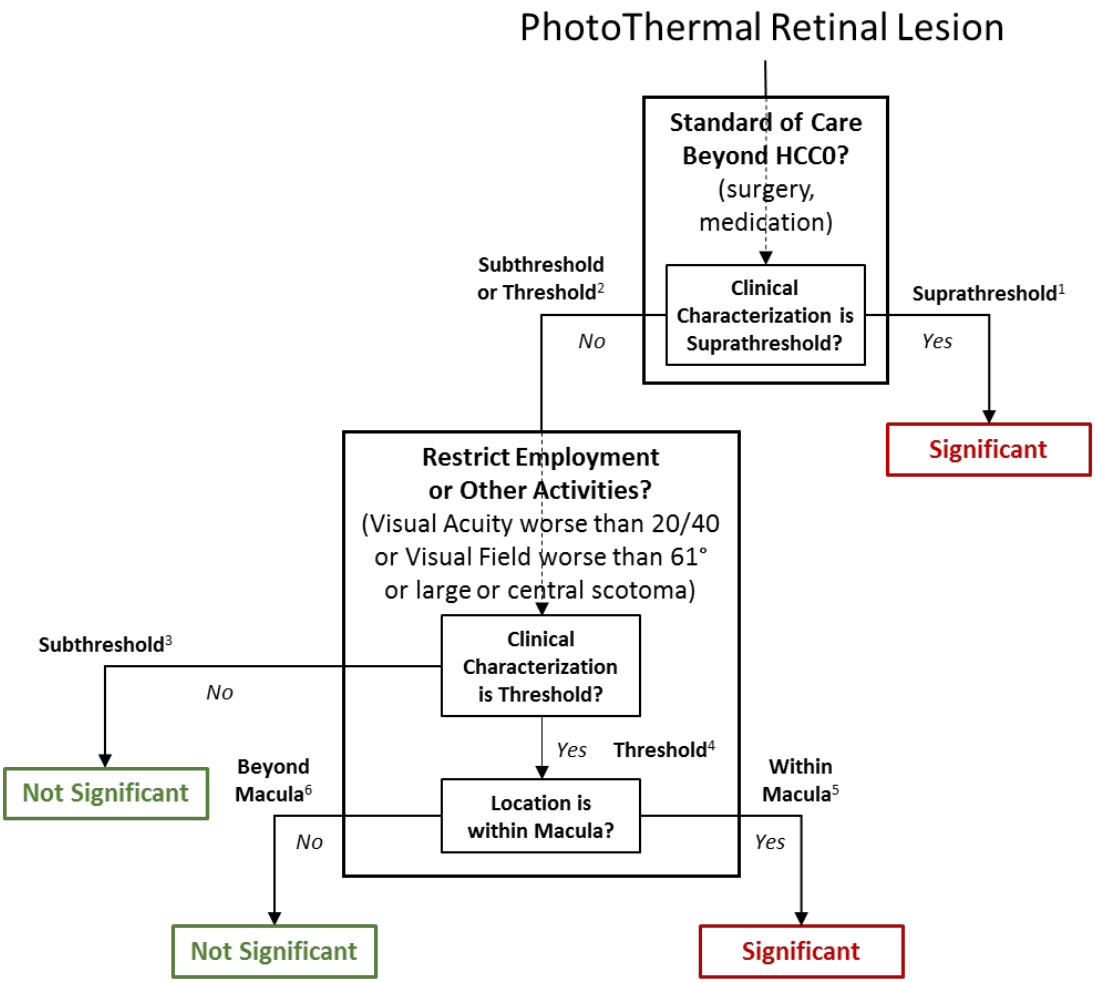
3. Threshold Photothermal Lesions

In the middle of the severity scale, threshold lesions are those with sufficient damage to display the typical whitening associated with modest thermal damage. Healing can be associated with minimal scarring and migration of neighboring photoreceptors into the damaged area to promote vision recovery, which occurs over the following months (Mainster and Turner 2012). However, lesions that are visible ophthalmoscopically or angiographically can also result in vision loss (Mainster, Stuck, and Brown 2004). We therefore assume that threshold and suprathreshold lesions (i.e., visible ophthalmoscopically) are those that may result in the significant vision impairment defined in the previous chapter. Of course, as discussed above, we have already classified suprathreshold lesions as significant, based on our assumptions regarding the HCC1+ treatment required by their related complications. Therefore, our task now becomes one of classifying *threshold* lesions as significant or not significant, based on assumptions regarding whether or not the lesion results in significant vision impairment. To proceed with this analysis, we consider the location of the threshold lesion within the retina.

As discussed above, the fovea is a small, approximately 1.5 mm diameter, area of the retina. Within the fovea lies the smaller, central foveola. A region only a few hundred microns in diameter, the foveola represents a couple degrees of an individual's field of vision, but is responsible for the majority of an individual's visual acuity. Extending about 0.5 mm beyond the fovea lies the parafovea, which is a transition region from an area dominated by cones (producing high color visual acuity) to a more dispersed rod-dominated area (producing high peripheral night vision). Lesions within the fovea are considered to strongly affect central vision and visual acuity. As discussed in the literature, a foveal lesion can result in an individual being considered legally blind, whereas threshold lesions in the equatorial or peripheral retina may produce no noticeable effect on vision (unless hemorrhage results) (Marshall 1989; Harris et al. 2003).

As described in Chapter 1, the clinical literature suffers from ambiguous use of terms describing the anatomical regions of the retina. This ambiguity leads to some of the critical assumptions of our analysis, in which we broadly interpret the literature's findings that "peripheral lesions" are less critical to vision, using the perifoveal area as boundary

between threshold lesions that do and do not affect vision. (Figure 4 illustrates how the perifoveal area is the area of the macula farthest from the center of the foveola.) In the absence of clear definitions of retinal anatomy and quantitative outcome data in the literature, **we assume that threshold lesions in the macula (i.e., within 2.75 mm of the center of the foveola) *always* lead to significant vision impairment as defined in the previous chapter and can therefore be considered significant. Conversely, we assume that threshold lesions beyond the macula (i.e., farther than 2.75 mm from the center of the foveola) *never* lead to significant vision impairment and can therefore be considered *not* significant.** Figure 17 illustrates this classification scheme.



[1]Suprathreshold lesions can lead to complications like hemorrhage, macular holes, and neovascularization (Barkana and Belkin, 2000), which can require HCC1+ treatment like surgery and medication (Alsulaiman, 2015; Grossniklaus and Green, 2004). Therefore, we assume that suprathreshold lesions *always* cause complications requiring HCC1+ treatment.

[2]Subthreshold and threshold lesions do not often lead to complications requiring HCC1+ treatment (Mainster and Turner, 2012). Therefore, we assume that subthreshold and threshold lesions *never* lead to complications requiring HCC1+ treatment.

[3]Subthreshold lesions rarely lead to noticeable visual impairment (Mainster, Stuck, & Brown, 2004). Therefore, we assume that subthreshold lesions *never* lead to significant visual impairment.

[4]Threshold lesions can lead to a noticeable visual impairment (Mainster, Stuck, & Brown, 2004). Cones are important for visual acuity and their distribution differs in different parts of the retina (Remington, 2012). Therefore, we assume the location of the threshold lesion affects the significance of the visual impairment.

[5]Threshold lesions in the peripheral retina may produce no noticeable effect on vision (Harris, et al., 2003; Marshall 1998). Therefore, we assume that threshold lesions beyond the macula *never* lead to significant visual impairment.

[6]A foveal lesion can lead to noticeable visual impairment (Marshall 1989). Therefore, we assume that threshold lesions within the macula *always* lead to significant visual impairment.

Figure 17. Determining the Significance of Photothermal Retinal Lesions

F. Modeling and Simulation of Photothermal Lesions

The goal of this project was to recommend a viable approach for creating a computational model to estimate the significance of a retinal lesion. After reviewing the literature, we recommend a two-step process: (1) develop a model of the laser-tissue interaction to predict the severity of the lesion and (2) given this characterization of the lesion, develop a model to predict the two factors critical to assessing the significance of the lesion: (a) the level of medical care required to treat the lesion and (b) the permanent visual impairment resulting from the lesion. We identified challenges with each step of this approach, however.

First, we did not find a large amount of quantitative data that could be used to develop a model relating the characterization of a lesion to the required medical care and resultant visual impairment (step (2) above). To overcome the challenge of developing this model in the absence of further data, we laid out several assumptions:

- subthreshold lesions *never* cause permanent physical damage to the retina,
- suprathreshold lesions *always* lead to complications requiring HCC1+ treatment,
- threshold lesions beyond the macula *never* lead to significant vision impairment, and
- threshold lesions within the macula *always* lead to significant vision impairment.

Based on these assumptions, a combat developer would only need to characterize the lesion (step (1) above); the assumptions could then be used to translate the lesion's characterization as either significant or not significant. The combat developer would not need to predict the lesion's required medical intervention and resultant visual impairment.

Second, most of the literature characterizes lesions using subjective and qualitative metrics—a clinician characterizes a retinal lesion as either subthreshold, threshold, or suprathreshold using traditional ophthalmoscopy. This qualitative characterization is a clinician's expert (and subjective) judgment. Combat developers need a quantitative and objective method to quickly and inexpensively estimate the lesion's clinical characterization in step (1) above, without subjecting humans to potentially damaging exposure levels and without relying upon a subjective judgment from a clinical expert.

To address this second challenge, we turn to modeling and simulation (M&S). During NLW acquisition, combat developers have access to computational models to characterize retinal lesions according to alternative criteria. As explained in Chapter 1, the BTEC model characterizes burns to living tissue by estimating how much damage is caused at different depths of the burn (Irvin et al. 2007). BTEC can solve the necessary equations in two dimensions, such that it can also provide an estimate of the expanse or size of the burn (Irvin et al. 2007). It may be theoretically possible to associate the clinical characterization of a photothermal lesion with the depth and size estimates output by BTEC. That is, it may

be that subthreshold lesions are small and shallow, which is why they are not visible using traditional ophthalmoscopy. In contrast, suprathreshold lesions may be large and deep, and threshold lesions may be somewhere in between.

Unfortunately, we could find little quantitative data in the literature on which these associations could be based. That is, we were unable to glean from the literature what numerical bars on size and depth should be used to bin lesions as subthreshold, threshold, and suprathreshold. Fortunately, the literature does provide some quantitative information linking the clinical characterization of a photothermal lesion to another output of BTEC, the temperature incident on the retina.

1. Relating Threshold Injuries to Temperature via Computational Modeling

Theoretical estimations of irreversible tissue damaged are well described. Computational models such as BTEC are based on a simple Arrhenius model, from which one can estimate the amount of irreversible tissue damage as a function of tissue temperature and time (Irvin et al. 2007):

$$dD(t) = -D(t) \cdot A \cdot exp\left(-\frac{E^*}{R \cdot T(t)}\right) dt$$

where $D(t)$ represents the concentration of healthy remaining cellular mass, E^* is the activation energy for inducing damage, A is a rate constant associated with the tissue, R is the universal gas constant, and $T(t)$ is the temperature over time. Application of these models often defines irreversible tissue damage by identifying the point at which a certain threshold percentage (e.g., 63%, or $1/e$) of tissue protein is damaged. For the RPE, the literature provides the following average parameters: $E^* = 340$ kJ/mol and $A = 1.6 \times 10^{55}$ (Palanker and Blumenkranz 2012). Figure 18 plots thresholds of irreversible tissue damage for different irradiation times (horizontal axis) and temperatures (vertical axis). Irreversible damage is achieved at lower temperatures for longer exposures. The dashed line depicts deviations from the Arrhenius model for longer exposure times (greater than 1 second) (Palanker and Blumenkranz 2012).

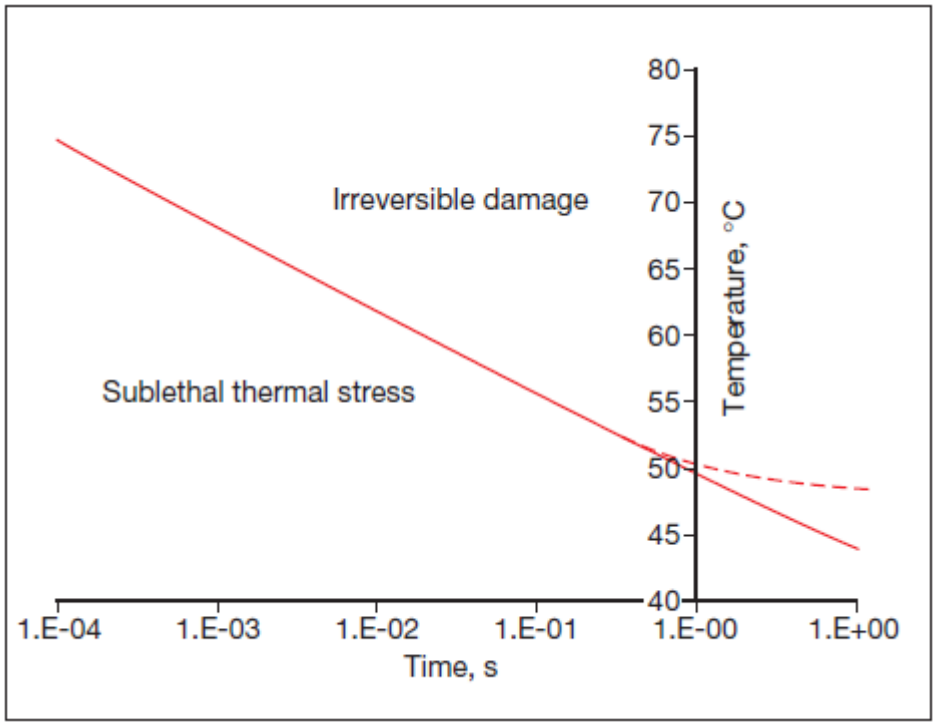
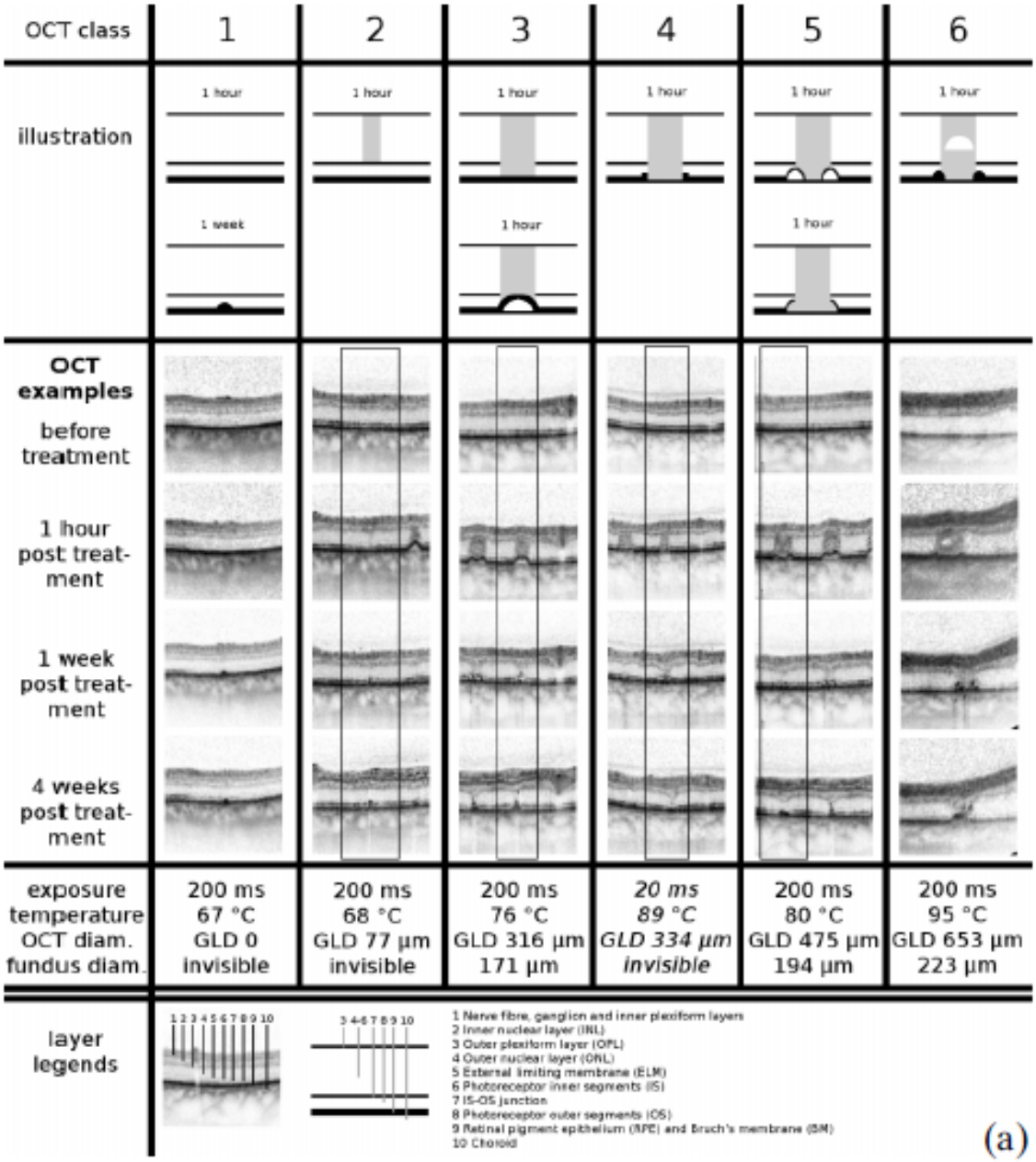


Figure 18. Thresholds for Irreversible Tissue Damage, Based on the Arrhenius Model

2. Relating Threshold Injuries to Temperature in the Clinic

Photocoagulation therapy studies have investigated this type of tissue damage on humans. These studies often examine patients undergoing treatment for a degenerative condition such as proliferative diabetic retinopathy. Studies employ sensitive diagnostic methods to evaluate lesions, such as OCT. As discussed above, compared to fundus photography or ophthalmoscopy, OCT offers greater detail regarding the retina's lamellar integrity (or lack thereof) following injury. A finer scale of damage is therefore described when using OCT. A recent study compared lesion visibility using traditional fundus photography and OCT while monitoring tissue temperatures. Figure 19 shows OCT images of tissue damage categorized on a scale from 0 to 6, with 0 representing no detectable damage and 6 representing disruption spanning all layers down to the outer nuclear layer (Koinzer et al. 2012).



Source: Koinzer et al. 2012.

Figure 19. Tissue Damage Visible via OCT, Ranging from 0 (no damage) to 6 (disruption spanning all layers)

While the study's findings are nuanced, results show that higher dosages generally lead to higher temperatures incident on the retina, which lead to higher OCT categories and greater likelihood of detection by traditional means. In particular, we highlight the findings for OCT Category 2 lesions: OCT 2 lesions include visible changes to the outer nuclear layer, but an intact neural inner and outer segment boundary. For these OCT 2 lesions, Koinzer et al. (2012) found a peak average temperature of 65 °C. In these cases, the lesions

were ophthalmoscopically visible 1 hour after treatment in 48% of cases. We surmise, then, that a peak temperature of 65 °C is about 50% likely to produce a threshold lesion. This benchmark might be considered as a proxy for a 50% dose factor based on thermal transport models like BTEC for retinal damage.

With further experimental results, these findings could potentially be used to estimate metrics such as *P*(threshold lesion occurs). For example, combat developers could determine via experimentation that a temperature of, for example, 60–70 °C *always* results in a threshold lesion. Therefore, per our proposed scheme in Figure 17:

- Conditions resulting in a retinal temperature of 60–70 °C *within* 2.75 mm of the central foveola could therefore be considered significant, and conditions resulting in a retinal temperature of 60–70 °C *beyond* 2.75 mm from the center of the foveola could therefore be considered *not* significant, based on the assumptions stated above that threshold lesions within and beyond the macula do and do not lead to significant vision impairment, respectively. The level of visual impairment itself would not have to be ascertained.
- Conditions resulting in a retinal temperature greater than 70 °C could be associated with suprathreshold lesions and therefore be considered significant, regardless of their location, based on the assumption discussed previously that suprathreshold lesions always lead to complications requiring HCC1+ treatment. The level of medical treatment required would not have to be ascertained.
- Conditions resulting in a retinal temperature less than 60 °C could be associated with subthreshold lesions and therefore be considered *not* significant, based on our assumption that subthreshold lesions never lead to permanent physical damage.

The exact values for these temperatures would need to be established and validated via animal experiments. Furthermore, a reliable and reproducible method of characterizing lesions as subthreshold, threshold, and suprathreshold in those experiments would have to be developed.

Despite the current uncertainty in the exact temperature values that should be used in a computational model, one could view these findings positively. In the literature we have reviewed, the dosage required to induce a threshold photothermal retinal lesion (often higher than 5 mW) is orders of magnitude higher that the dosage necessary to introduce temporary dazzling or visual impairment for non-lethal purposes (Koinzer et al. 2012; McLin 2013). Thus, *P*(threshold lesion occurred) is likely to be very low. This safety margin minimizes the risk of a significant photothermal retinal lesion. That is, even if *P*(threshold lesion is significant | threshold lesion occurred) is high (i.e., equal to 1 if the

threshold lesion occurs in the macula), the low value of *P*(threshold lesion occurred) will make the overall RSI very small, once these two quantities are multiplied together.

6. Conclusions

We conclude with a summary of our findings and recommendations.

A. Findings

We found that:

1. Throughout the literature, the terms macula, fovea, and foveola are used interchangeably and imprecisely, depending on the intended audience. Throughout our analysis, we used the histological definitions of macular structures, with the following outermost diameters: foveola (0.35 mm), fovea (1.5 mm), parafovea (2.5 mm), and perifovea (5.5 mm). The corresponding radii from the center of the foveola are: foveola (0.18 mm), fovea (0.75 mm), parafovea (1.25 mm), and perifovea (2.75 mm).
2. Cone cells in the retina are responsible for central visual acuity. The concentration of cone cells in the macula falls off rapidly from approximately 150,000 cones per square millimeter in the center of the fovea to 5,000 cones per square millimeter outside of the fovea.
3. Visual acuity and visual field are often used to assess visual function:
    a. Visual acuity is commonly known as sharpness or clarity of vision and is a measure of the spatial resolving power of the eye. This metric is the gold standard for primary outcomes of clinical trials and was the most commonly reported metric that we encountered throughout our literature review.
    b. The visual field is the entire area seen by both eyes at the same time when gaze is fixed at one point. In the literature we reviewed, visual field was not reported or referenced as often as visual acuity. There is a lack of cited empirical research to support most occupational requirements for visual field.
4. Different organizations use slightly different standards for visual impairment:
    a. While all methods use visual acuity as one metric of visual impairment, only some methods state specific requirements for visual field:
        1) DoDI 6130.03 has specific requirements for measurement of distant visual acuity for enlistment in the U.S. military, but makes a statement that a disqualifying condition includes “current or history

of abnormal visual fields due to disease of the eye or central nervous system, or trauma," without more specific metrics (DoD 2010, 13).

2) The VASRD and the SSA relate specific measurements for both visual acuity and visual field to an overall level of disability:

1. VASRD converts visual field impairments into an equivalent visual acuity score.

2. SSA multiplies the visual acuity efficiency by the visual field efficiency to arrive at an overall visual efficiency score.

b. Different methods were also created for different purposes:

1) The WHO/ICO provides only broad categories for visual impairment.

2) Both the VASRD and the SSA quantify the level of impairment for compensation purposes.

3) DoDI 6130.03 uses its assessment of visual performance to determine who may enlist in the U.S. military.

c. Methods also differ based on which eye or eyes are considered:

1) The WHO/ICO, DoDI 6130.03, and the VASRD assess the visual impairment of both eyes, either together or separately first before combining the two scores.

2) The SSA takes only the best eye into account, and the threshold for being considered "disabled" is set very high (e.g., a visual efficiency below 20%).

5. Different dosages of laser light can lead to different mechanisms of retinal injury:

a. Photomechanical injuries require a high dosage of energy over a short time and are often associated with short-pulse/high-energy lasers, including Q-switched and mode-locked near-IR lasers. It is our understanding that such lasers have no known utility for the non-lethal dazzling applications considered in this project. Therefore, we did not consider the photomechanical mechanism of injury in our analysis. In the future, though, this mechanism should be revisited for any new laser weapon design that employs short-pulse/high-energy lasers.

b. Photochemical injuries require prolonged exposure times that exceed the exposure times assumed with intended use of non-lethal dazzling lasers. That is, individuals targeted with dazzling lasers are likely to blink or otherwise shield their eyes, effectively reducing the exposure time and

therefore the dosage to which they are exposed. Therefore, we did not consider the photochemical mechanism of injury in our analysis. However, this mechanism should be revisited for any new laser weapon design that employs a prolonged exposure duration.

c. Photothermal lesions may occur with relatively short exposure durations (seconds or less) at laser powers slightly above Class IIIa eye-safe laser levels (power greater than 5 mW). It is our understanding that dosages in this regime are closest to the dosages used for non-lethal dazzling applications. Therefore, our analysis focused on the photothermal mechanism of injury.

6. Tens of thousands of journal articles have been published on laser-induced retinal lesions:

    a. Most articles focus on the dosages required to cause an injury and may therefore be helpful in estimating the metric *P*(lesion occurred). This metric is outside the scope of this project.

    b. Fewer articles report data that could be used to estimate the metric *P*(lesion is significant | lesion occurred). Estimating this metric is the objective of this project.

7. Clinicians often assess photothermal lesions as subthreshold, threshold, and suprathreshold:

    a. On the low end of the severity scale, subthreshold lesions caused by photocoagulation therapy often lead to minimal or no apparent permanent retinal damage.

    b. On the high end of the severity scale, suprathreshold lesions caused by significant heat transfer are associated with severe retinal damage and secondary effects such as hemorrhage, macular holes, and neovascularization. These complications can require treatment with an HCC index of 1 or above, including vitrectomy, internal limited membrane peeling, gas tamponade, photocoagulation and photodynamic therapy, and anti-angiogenesis drugs.

    c. Threshold lesions are in the middle of the severity scale:

        1) Healing of threshold lesions can be associated with minimal scarring and migration of neighboring photoreceptors into the damaged area to promote vision recovery.

        2) Threshold lesions can also result in vision impairment:

1. A lesion in the fovea can result in an individual being declared legally blind.
2. A lesion in the equatorial or peripheral retina may produce no noticeable effect on vision.

8. We found few quantitative data in the literature regarding the relationship between the clinical characterization of a retinal lesion (i.e., subthreshold, threshold, or suprathreshold) and the size and depth of the lesion.
9. The literature provides some quantitative information regarding the relationship between a lesion's clinical characterization and the temperature incident on the retina: A study of photocoagulation therapy showed that a peak temperature of 65 °C was almost 50% likely to produce a threshold lesion.
10. Although outside the scope of this project, we found that is likely that *P*(threshold lesion occurred) is very low for dazzling lasers. The literature that we have reviewed shows that the dosage required to induce a threshold photothermal retinal lesion is orders of magnitude higher than the dosage required to introduce temporary glare effects. Therefore, even if *P*(threshold lesion is significant | threshold lesion occurred) is high, the product of these two metrics is likely to remain small, leading to a low RSI for current (and likely future) dazzling lasers.

B. Recommendations

We recommend that:

1. **Permanent, best corrected visual acuity equal to or better than 20/40 should be considered *not* significant, while worse than 20/40 should be considered significant.** This statement is largely due to our assumption that the inability to obtain a driver's license in most U.S. states is a suitable surrogate for "restrictions on employment and other activities for the rest of a person's life," to use language from DoDI 3200.19. Furthermore, we assume that a nonzero VASRD rating is an adequate surrogate for "restricting employment." The VASRD rates a veteran as 10% or more disabled if he or she has 20/40 vision in the best eye and worse than 20/40 vision in the other eye.
2. **Permanent visual field should be considered significant if the remaining average radius is 60° or less *or* a scotoma takes up 1/4 or more of the field of view *or* a scotoma of any size is in the macula (within 2.75 mm from the center of the foveola), while all other permanent visual fields can be considered *not* significant.** Given the lack of well-quantified occupational vision standards for visual fields, our recommendations for significance of

visual field impairments are based largely on the VASRD. Again, we assume that a nonzero VASRD rating is an adequate surrogate for "restricting employment."

3. **Subthreshold photothermal lesions should be considered *not* significant.** This statement is based on the assumption that subthreshold lesions never cause permanent physical damage.
4. **Suprathreshold photothermal lesions should be considered significant.** This statement is based on the assumption that suprathreshold lesions always lead to complications requiring HCC1+ treatment.
5. **Threshold lesions *within* the macula (i.e., within 2.75 mm of the center of the foveola) should be considered significant**. This statement is based on the assumption that lesions of this nature always lead to the significant levels of visual acuity or visual field impairment defined above in recommendations 1 and 2, which are based on their own set of assumptions.
6. **Threshold lesions *beyond* the macula (i.e., beyond 2.75 mm from the center of the foveola) should be considered *not* significant.** This statement is based on the assumption that lesions of this nature never lead to the significant levels of visual acuity or visual field impairments defined above in 1 and 2, which are based on their own set of assumptions.
7. Published results from photocoagulation studies should be explored in more depth to better determine the temperatures at which threshold and suprathreshold lesions occur, and the temperatures should be estimated with computational models such as BTEC. Such associations may lead to estimates of *P*(threshold lesion occurs) and *P*(suprathreshold lesion occurs), thus enabling the full estimation of a dazzling laser's RSI.

Illustrations

Figures

Tables

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Abbreviations

AHAAH	Auditory Hazard Assessment Algorithm for Humans
AMA	American Medical Association
AOA	American Optometric Association
BTEC	Buffington, Thomas, Edwards, and Clark
CCD	charge-coupled device
CDD	Capability Development Document
CMS	Centers for Medicare & Medicaid Services
CPD	Capability Production Document
DoD	Department of Defense
DoDI	Department of Defense Instruction
DVA	Department of Veterans Administration
ETDRS	Early Treatment Diabetic Retinopathy Study
HCC	Health Care Capability [index]
HEMI	human electromuscular incapacitation
ICD	International Classification of Diseases
ICO	International Council of Ophthalmology
IR	infrared
JNLWD	Joint Non-Lethal Weapons Directorate
KPP	Key Performance Parameter
LASIK	laser-assisted in situ keratomileusis
MAR	minimum angle of resolution
NLW	non-lethal weapon
NSWCDD	Naval Surface Warfare Center – Dahlgren Division
OCT	optical coherence tomography
OSHA	Occupational Safety and Health Administration
PRK	photorefractive keratectomy
PTS	permanent threshold shift
RPE	retinal pigment epithelium
RSI	risk of significant injury
SSA	Social Security Administration
UV	ultraviolet
VASRD	Veterans Affairs Schedule for Relating Disabilities
WHO	World Health Organization

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14. ABSTRACT

Some non-lethal weapons (NLWs) like dazzling lasers employ light at a specific wavelength. Theoretically, there is a risk that this light could cause a retinal lesion leading to permanent vision impairment. Per Department of Defense Instruction (DoDI) 3200.19, an injury caused by a NLW, such as a retinal lesion, is considered significant if "self-aid, buddy-aid, and combat lifesaver skills" are insufficient to treat the injury or if the injury results in death or "physical damage that restricts the employment or other activities of the person for the rest of his or her life." The objective of this project was to search the relevant literature to identify attributes of a retinal lesion that can quantitatively, accurately, and precisely predict the significance of the lesion.

15. SUBJECT TERMS

Non-Lethal Weapon, NLW, dazzling laser, laser dazzler, laser, retinal lesion, scotoma, Risk of Significant Injury, RSI, Health Care Capability, HCC, vision, eye, visual acuity, visual field

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