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14. Abstract

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Human Laser Retinal Dose-Response Model

Paper #1002

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Abstract

Probabilistic risk assessment is an acceptable technique for laser hazard analysis in uncontrolled environments. Risk is a combination of probability of exposure and probability of an injury resulting from that exposure. A dose-response model quantifies the probability of injury. In the present study, we developed a human dose-response model for laser induced retinal injuries. It consists of two sub-models, one for the mean and the other for the standard deviation of the dose-response probability distribution. The model for the mean fits experimental data to a simple three-parameter expression as a function of wavelength, exposure duration, and retinal tissue type. A scaling factor converts the fit to be appropriate for exposure of humans. A new human vulnerability model, based on the diversity of relevant physical characteristics within the human population, determines the standard deviation. Since the dose-response model is specific to retinal injuries, the variables are refractive error, ocular transmittance, and retinal absorptance. A Monte Carlo simulation with probability distributions for these variables, based on age, determines the standard deviation as a function of wavelength. We present details of the dose-response model along with their application to common human populations.

Introduction

The increased use of lasers in outdoor, uncontrolled environments, particularly for military operations using higher power laser systems, is driving the need for a probabilistic risk assessment approach as an alternative to the standard MPE based hazard assessment techniques. For controlled environments, safety with no possibility of injury is the criterion for the analysis. However, for uncontrolled environments, risk is the more appropriate criterion. While there is a finite probability of injury, this probability needs to be estimated and within an acceptable range. The transition to a risk-based approach to laser hazard analyses requires improved fidelity in models used to assess the risk.

Risk is the combination of the probability of exposure and the probability of an injury resulting from that exposure. A dose-response model quantifies the second probability in the field of laser hazards [1-3]. The model uses a cumulative log-normal distribution to calculate the probability of injury for a given dose. A log-normal distribution has two parameters – the mean and the standard deviation. The mean is the dose that results in a 50 % probability of injury (ED_{50}), while the standard deviation quantifies the width of the distribution. For laser hazards, these parameters are functions of wavelength and exposure duration.

Two models, ED_{50} and Slope, were recently developed. The model for the ED_{50} is derived from nonhuman primate experimental data and computes the mean effective dose for human retinal injuries [4]. The Slope Model accounts for the diversity in physical characteristics within the human population and addresses the standard deviation in the dose-response model [5]. These two models together calculate the probability of injury to the human retina resulting from exposure to a laser. This achieves the goal of improving fidelity in models used to assess risk from laser exposures in outdoor environments.

In the following, we present an overview of the dose-response model first, including the components of the model. Two new models for the ED_{50} and the Slope are motivated and then derived. The subsequent sections present an example of a probability of injury calculation and a conclusion.

Dose-Response Model Overview

The dose in a dose-response model is typically termed the effective dose with symbol ED. For laser damage, ED is either an energy or radiant exposure. The effective dose for which there is a 50 % probability of injury is termed ED_{50}. Similarly, the effective doses for 16 % and 84 % probabilities of injury are termed ED_{16} and ED_{84}, respectively. The Slope S is

$$S = \frac{ED_{84}}{ED_{50}} \text{ or } S = \frac{ED_{50}}{ED_{16}} . \quad (1)$$

The probability of injury P is given by the cumulative log-normal distribution,

$$P(q) = \frac{1}{\sqrt{2\pi\sigma^2}} \int_{-\infty}^{q} \exp\left[\frac{-(x-\mu)^2}{2\sigma^2}\right] dx = \frac{1}{2} erfc\left[\frac{-(q-\mu)}{\sqrt{2}\,\sigma}\right] , \quad (2)$$

where $q = \log_{10}(ED)$, $\mu = \log_{10}(ED_{50})$, and $\sigma = \log_{10}(S)$.

The illustration in Fig. 1 describes the complete human retinal dose-response model. The model input parameters include wavelength λ, population distribution $\mathcal{P}$, pupil diameter D_P, retinal tissue, effective dose ED, and exposure duration T. Both the ED_{50} and Slope Models are generalized to cover the retinal wavelength range, and the parameters resulting from the first three inputs are pre-calculated by these models. The effective dose and exposure duration for a specific laser exposure scenario are used with these parameters by the ED_{50} and Slope Calculation components to obtain the required inputs to the Probability Calculation component. The result is a probability of injury for a laser exposure to the human retina. The following sections detail all the components shown in Fig. 1. Our current implementation captures the essential physical features involved in the ED_{50} and Slope Models, but can be refined in the future as more experimental and modelling results are available and included.

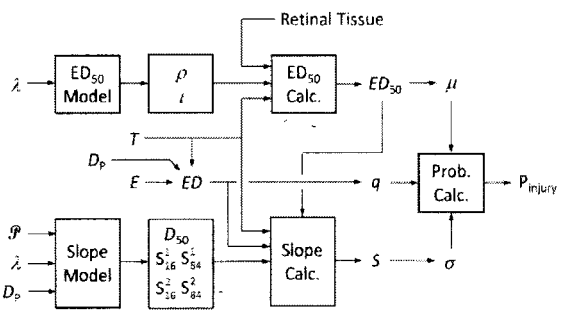

Figure 1. The components of the dose-response model, inputs, and data flow. The components are the ED_{50} and Slope Models, the ED_{50} and Slope Calculations, and the Probability Calculation. The inputs are the wavelength λ, population $\mathcal{P}$, pupil diameter D_P, retinal tissue, incident irradiance E, and exposure duration T.

Slope Model

This section presents a technique developed to quantify the variability in human response to laser exposure. This model is limited to retinal thermal injuries, so covers the wavelength range from 400 nm to 1400 nm and exposure durations longer than 25 μs. However, the general technique is applicable to other wavelength and exposure duration regimes. The obvious diversity in physical characteristics of the human population results in a variation to susceptibility to laser retinal damage. This variation is responsible for the slope in the dose-response model. Since experiments to determine the variability in human susceptibility to retinal laser damage are unavailable, a modelling approach is required to quantify the variability. This model uses a Monte-Carlo technique to generate synthetic effective doses (*sED*), from which four slopes are calculated [5].

The Slope Model is based on the effective dose of the human retina from laser exposure of the eye depending on three parameters – the transmittance τ through the eye, the absorptance α at the retina, and the spot diameter D_s of the illuminated area on the retina. The resulting model for a synthetic effective dose *sED* resulting from these parameters is given by Eq. (3). Fig. 2 provides an illustration of the computational steps for calculating the *sED*.

$$sED = \frac{1}{\tau}\frac{1}{\alpha} D_s^n . \quad (3)$$

The inputs to the Slope Model are the age distribution of the selected population f_A, the wavelength λ (nm), and the pupil diameter D_P (mm). The spot diameter D_s is determined from refractive error $\mathcal{R}$, which in turn depends on human age A. Random draws from probability distributions f obtain specific values for parameters.

The outputs of the Slope Model are the 50th-percentile spot diameter on the retina D_{50} (μm), and the slopes S_{16}^1, S_{16}^2, S_{84}^1 and S_{84}^2. The subscripts of these slopes correspond to the 16th- and 84th-percentile slopes, respectively, from Eq. (1). The superscripts correspond to linear (1) or quadratic (2) dependence on the spot diameter.

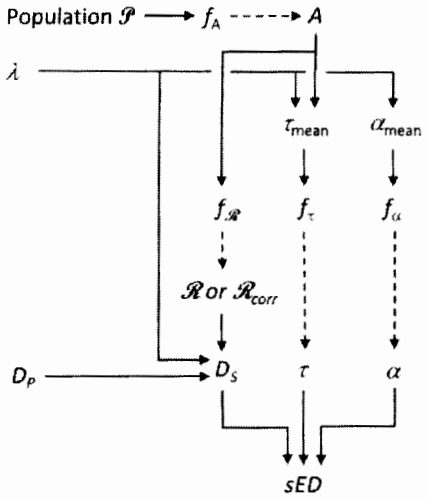

Figure 2. Computational steps for computing a synthetic effective dose *sED* from inputs of population, wavelength λ, and pupil diameter D_P. Probability distributions are indicated by *f* and random draws from these distributions by dashed lines. The three independent parameters are age *A*, transmittance τ, and absorptance α, with derived values for refractive error $\mathcal{R}$ and spot diameter D_S.

Age

The age distribution f_A of a population is required in a tabular format, with fraction of population as a function of age *A*. Age distributions for a wide range of populations are available at the United States Census Bureau International Data Base web site [6]. These distributions are provided by year for countries, regions, and development levels. The use of United Nations development levels is preferred, and are least, less, and more developed.

The inputs for generating ages from a population are the age distribution f_A of that population and the number *N* of random draws. The output is a set with *N* members with an age corresponding to each element of the set. This set with *N* members is termed the sample set. Note that the random draws are from a discrete probability distribution.

Refractive Error

The input for calculating the refractive error is the age *A* (years). The output is the refractive error $\mathcal{R}$ (diopters).

The refractive error has a bi-modal Gaussian distribution, designated Mode 1 and Mode 2, each having their own amplitude *a*, mean *m*, and standard deviation *s* and are shown in Fig. 3 as dashed curves. The probability distribution of refractive error $f(\mathcal{R})$ for a given age is

$$f(\mathcal{R}) = \frac{a_1}{\sqrt{2\pi}s_1}\exp\left(\frac{(\mathcal{R}-m_1)^2}{2s_1^2}\right) + \frac{a_2}{\sqrt{2\pi}s_2}\exp\left(\frac{(\mathcal{R}-m_2)^2}{2s_2^2}\right), \quad (4)$$

where the values for the amplitude *a*, mean *m*, and standard deviation *s* are detailed in [5].

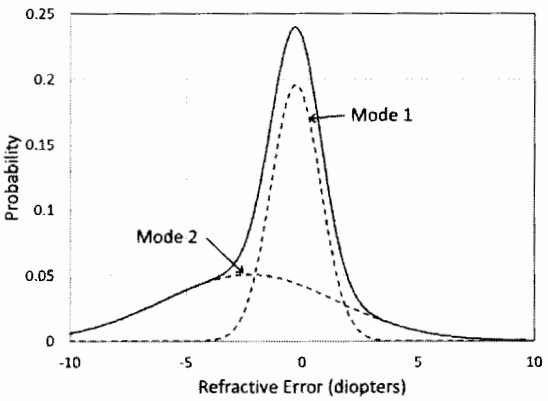

Figure 3. Refractive error probabilities for ages 30 years to 39 years. The solid curve is the probability for the entire population, while the dashed curves are the two Modes that combine to yield the solid curve.

For each element in the sample set, a random draw from the corresponding probability distribution of refractive error yields a refractive error for that element. The result is a refractive error corresponding to each element of the sample set.

Each population has the possibility of correction of the refractive error. For refractive error in the range between -0.5 and 0.5 diopters, the probability of correction is so small and considered negligible. If the refractive error is outside this range, the Slope Model considers the probability of correction. In our current implementation, the Slope Model assumes correction for spherical equivalent refractive errors outside of -1.00 to +3.00 diopters. These are termed the limits of toleration. The possible choices for correction are uncorrected, partially corrected, and fully corrected. For uncorrected, the refractive errors obtained in the procedure described above are retained. For fully corrected, if the refractive error of an element of the sample set is outside the range from -0.5 to 0.5 diopters,

a random draw from a uniform probability distribution over this range is performed to choose a new refractive error for that element. For partially corrected, a probability of correction at the threshold, P_t, is an input. The resulting probability of correction P_c is:

$$P_c(\mathcal{R}) = \begin{cases} \tanh[\alpha(\mathcal{R})\cdot(\mathcal{R}-0.5)] & 0.5 < \mathcal{R} \le 3.0 \\ 0 & -0.5 \le \mathcal{R} \le 0.5 \\ \tanh[\beta(\mathcal{R})\cdot|\mathcal{R}+0.5|] & -1.0 \le \mathcal{R} < -0.5 \end{cases}, \quad (5)$$

where

$$\alpha(\mathcal{R}) = \frac{\tanh^{-1}[P_t]}{2.5}\cdot\left(\frac{\mathcal{R}}{3}\right)$$

and

$$\beta(\mathcal{R}) = \frac{\tanh^{-1}[P_t]}{0.5}\cdot(\mathcal{R})$$

For each refractive error in the sample set, a probability of correction P_c is determined using Eq. (5). A random number between 0 and 1 is then drawn from a uniform probability distribution. If that number is less than P_c, another random draw from a uniform probability distribution over the range -0.5 to 0.5 chooses a new refractive error for that element. If the number is greater than P_c, the model retains the original refractive for that element of the sample set.

Spot Diameter

The spot diameter on the retina depends on wavelength λ (nm), refractive error $\mathcal{R}$ (diopters), and pupil diameter D_p (mm). For ease of computation and incorporation of refractive error, a reduced eye model determines the spot diameter [7]. This model has one spherical surface and a wavelength-dependent index of refraction. Fig. 4 outlines the basic elements of the reduced eye model

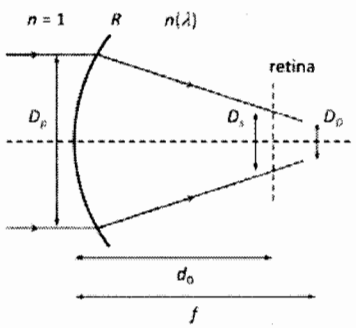

Figure 4. Schematic of the elements of the reduced eye model. The vertical scale is exaggerated for clarity.

The index of refraction $n(\lambda)$ of the reduced eye model as a function of wavelength is the Sellmeier equation,

$$n^2(\lambda) = 1 + \frac{B_1\lambda^2}{\lambda^2 - C_1} + \frac{B_2\lambda^2}{\lambda^2 - C_2} + \frac{B_3\lambda^2}{\lambda^2 - C_3}, \quad (6)$$

with the wavelength in units of microns (μm). The coefficients used in this equation, used by Vincellette [8], takes into account ocular dispersion. The radius of curvature R of the reduced eye model is

$$R = \frac{(n-1)\cdot R_0}{(n-1) + n\cdot R_0\cdot(\mathcal{R}/1000)}, \quad (7)$$

where n = 1.333 374 is determined at a wavelength of 589 nm and R_0 = 6.1 mm is chosen so that the focal length is equal to the eye thickness d_0 = 24.4 mm at this wavelength. The corresponding focal length f as a function of wavelength is

$$f(\lambda) = \frac{n(\lambda)}{n(\lambda)-1}R. \quad (8)$$

The minimum spot diameter D_0 is

$$D_0(\lambda) = 1.75\cdot\lambda\cdot f(\lambda), \quad (9)$$

and the corresponding Rayleigh parameter z_R is

$$z_R(\lambda) = \frac{D_0(\lambda)}{D_p} f(\lambda). \quad (10)$$

The spot diameter D_s as a function of wavelength is then

$$D_s^2(\lambda) = D_0^2(\lambda)\left[1 + \left(\frac{f(\lambda) - d_0}{z_R}\right)^2\right]. \quad (11)$$

Therefore, each element of the sample set will contain a spot diameter, based on the refractive error, with any corrections, the wavelength, and the pupil diameter.

Transmittance

The transmittance of human ocular media has been under comprehensive research. The CIE Publication 203:2012 encompasses a compiled version of the transmittance measurements and studies [9]. Determining the mean transmittance as a function of wavelength and age is divided between the visible (400 nm to 700 nm) and near-infrared (700 nm to 1400 nm) wavelength ranges. The standard deviation of transmittance over the entire wavelength range uses the data of Maher [10].

Determining the mean transmittance as a function of age and wavelength is divided between the visible (400 nm to 700 nm) and near-infrared (700 nm to 1300 nm) wavelength ranges. The CIE publication distinguishes between total and direct transmittance. Since the effective dose depends primarily on the image on the retina, direct transmittance is used. For visible wavelengths, the CIE publication provides equations for the direct transmittance as a function of age and wavelength. The optical density OD as a function of age A and wavelength λ is

$$\begin{aligned} OD(A,\lambda) = & \\ & 0.17 + (0.3 + 0.000031 \times A^2) \times \left(\frac{400}{\lambda}\right)^4 \\ & + 14.19 \times 10.68 \times e^{\left(-(0.057 \times (\lambda - 273))^2\right)} \\ & + \left(1.05 - 0.000063 \times A^2\right) \\ & \quad \times 2.13 \times e^{\left(-(0.029 \times (\lambda - 370))^2\right)} \\ & + \left(0.059 + 0.000186 \times A^2\right) \\ & \quad \times 11.95 \times e^{\left(-(0.021 \times (\lambda - 325))^2\right)} \\ & + \left(0.016 + 0.000132 \times A^2\right) \\ & \quad \times 1.43 \times e^{\left(-(0.008 \times (\lambda - 325))^2\right)} \end{aligned} , \qquad (12)$$

The mean direct transmittance is then

$$\tau_{mean}(A,\lambda) = 10^{-OD} . \qquad (13)$$

Table A.6 in the CIE publication provides direct transmittance as a function of wavelength, which are used for the mean direct transmittance at near-infrared wavelengths. For age dependence at near-infrared wavelengths, the results of Kessel [11] for the transmittance of the human lens is extrapolated from the dependence at 700 nm to obtain

$$\tau_{mean}(A,\lambda) = \tau(\lambda) \cdot \left[1 - \frac{0.1 \cdot A}{92.6}\right] . \qquad (14)$$

The results of Maher [10] on rhesus monkey eyes are used to calculate the standard deviation of transmittance. Maher provides tabulated data on absorption coefficients μ and associated uncertainties $d\mu$ for each ocular media at wavelengths from 400 nm to 1300 nm. These absorption coefficients and uncertainties, along with the dimensions of the human ocular media taken from Vincellette [8], calculate the relative standard deviation of direct transmittance as a function of wavelength. The standard deviation in transmittance, τ_{SD}, is

$$\tau_{SD} = \tau_{mean} \left[\sum_i \left(-l_i \cdot d\mu_i\right)^2 \right]^{1/2} , \qquad (15)$$

where l_i is the thickness of each ocular media, indexed by i. As shown in Fig. 5, the relative standard deviation of transmittance, τ_{SD}/τ_{mean}, as a function of wavelength is less than 10 % for much of the wavelength range.

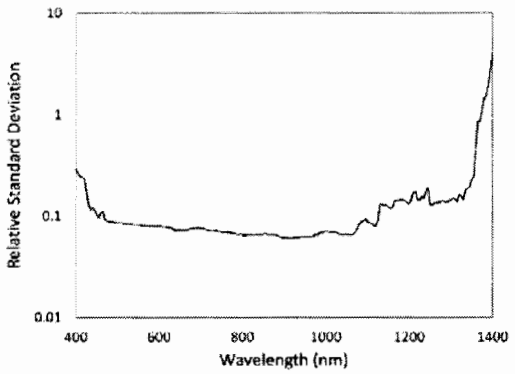

Figure 5. Relative standard deviation of transmittance as a function of wavelength.

The inputs for calculating the transmittance of the eye are age A (years) and wavelength λ (nm). The output is the transmittance τ. The mean transmittance is a function of both inputs, while the standard deviation is a function of only wavelength. A random draw from the probability distribution of transmittance determines its value. If the resulting transmittance is outside the range 0 to 1, additional random draws are necessary until the transmittance falls within that range.

Absorptance

In contrast to transmittance, there is limited data available on the absorptance of the retina, and even less on variations and the effect of age. The data of Mainster [12] is used to obtain the absorptance, comments in the literature are used to estimate the variation, and age is not considered. Mainster provides absorption coefficients μ for the two primary layers of the retina, the retinal pigment epithelium (RPE) and the choroid at wavelengths from 400 nm to 1300 nm. The thicknesses of these two layers, 10 mm for the RPE and 170 mm for the choroid, are from Jean [13]. The mean absorptance $\alpha_{mean}(\lambda)$ is given by

$$\begin{aligned} \alpha_{mean}(\lambda) &= 1 - \tau(\lambda) \\ &= 1 - \exp\left[-l_{RPE} \cdot \mu_{RPE}(\lambda)\right] \\ &\quad \times \exp\left[-l_{Choroid} \cdot \mu_{Choroid}(\lambda)\right] \end{aligned} , \qquad (16)$$

where l is the thickness of the layer. The resulting mean absorptance as a function of wavelength is shown in Fig. 6.

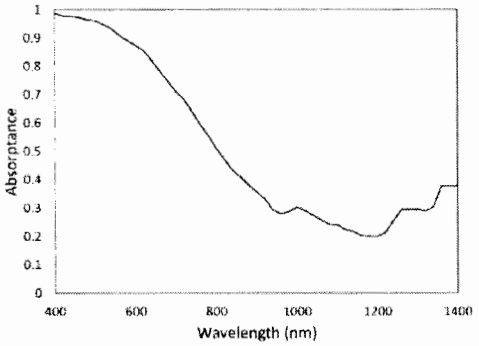

Figure 6. Mean absorptance as a function of wavelength.

Based on observations detailed in [2], the standard deviation of the absorptance, α_{SD}, is

$$\alpha_{SD}(\lambda) = 0.2 \cdot \alpha_{mean}(\lambda) \ , \qquad (17)$$

The only input for calculating the absorptance of the retina is wavelength λ (nm), with a corresponding output α. A random draw from the probability distribution determines the absorptance for each element of the sample set. If the resulting absorptance is outside the range 0 to 1, another random draw is performed until the absorptance falls within that range.

Outputs

The inputs for calculating the parameter values for the Slope Model is the sample set for a given population, refractive error correction, wavelength, and pupil diameter. This sample set contains N elements, each with a value for age A, spot diameter D_s, transmittance τ, and absorptance α. The outputs are the 50th-percentile spot diameter D_{50} (μm), the Slopes S_{16}^1 and S_{84}^1 corresponding to a linear dependence on spot diameter, and the Slopes S_{16}^2 and S_{84}^2 corresponding to a quadratic dependence on spot diameter.

The value for D_{50} is obtained by rank-ordering the values of D_s contained in the sample set and returning the 50th-percentile value. Synthetic effective doses sED for each element of the sample set are calculated using Eq. (3) with both $n = 1$ and $n = 2$. The resulting sED values are rank-ordered for each value of n, then the 16th, 50th, and 84th percentile values are determined. These values for $n = 1$ are designated sED_{16}^1, sED_{50}^1, and sED_{84}^1 for the corresponding percentiles, while the values for $n = 2$ are designated sED_{16}^2, sED_{50}^2, and sED_{84}^2. The corresponding slope values are $S_{16}^1 = \left(sED_{50}^1 / sED_{16}^1\right)$, $S_{84}^1 = \left(sED_{84}^1 / sED_{50}^1\right)$, $S_{16}^2 = \left(sED_{50}^2 / sED_{16}^2\right)$ and $S_{84}^2 = \left(sED_{84}^2 / sED_{50}^2\right)$. These values are then stored in a data file for later use.

ED50 Model

The ED50 Model is a generalized form for the ED_{50} experimental data across all applicable wavelengths (400 nm to 1300 nm) and exposure durations (1 ns to 10 s). This includes the transition from a thermo-mechanical damage mechanism to thermal damage that is a function of exposure duration [4]. In the thermo-mechanical domain (generally 1 ns to 10 μs exposure durations), the ED_{50} depends on wavelength but not on exposure duration. In the thermal domain (longer exposure durations), the ED_{50} is proportional to the three-quarters power of the exposure duration. The ED50 Model uses two parameters, the inflection point time between thermal and thermo-mechanical damage mechanisms, and the short-pulse ED_{50} value.

The logarithm of the inflection point time ι is

$$\iota(\lambda) = -5.75 + 1.5 \times 10^{-3} \lambda \ . \qquad (18)$$

The logarithm of the short-pulse ED_{50} value ρ is

$$\rho(\lambda) = \begin{cases} -6.1 - 1.2 \times 10^{-2}(\lambda - 530) & \lambda \le 530\ nm \\ -6.1 + 2.2 \times 10^{-3}(\lambda - 530) & \lambda > 530\ nm \end{cases} . \qquad (19)$$

The scaling factor F for the retinal tissue, to convert from non-human primate to human values of ED_{50}, is estimated in [4] as 0.125 for macular and 0.3 for peripheral retina. The logarithm of the mean effective dose for damage μ for a given wavelength, exposure duration, and retinal tissue is

$$\mu(\lambda, T, F) = F + \rho(\lambda) + \log_{10}\left[1 + 10^{0.75\{\tau - \iota(\lambda)\}}\right], \qquad (20)$$

where $\tau = \log_{10}(T)$ and the $ED_{50} = 10^{\mu}$.

This functional form is shown in Fig. 7 and Fig. 8, in which the retinal damage threshold data for collimated beams (small sources) is shown along with a plot of Eq. (20) and the current ANSI Z136.1-2014 exposure limit.

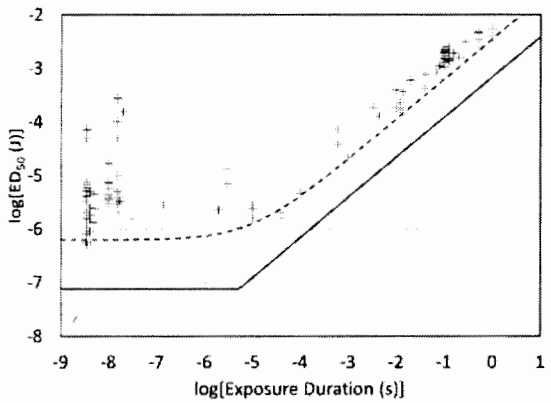

Figure 7. Approximation of mid-visible (500 nm to 550 nm) retinal ED_{50} damage threshold data for collimated beams from the literature. The solid line is the current ANSI Z136.1-2014 exposure limit, while the dashed line is an approximation using Eq. (20) when $F = 0$.

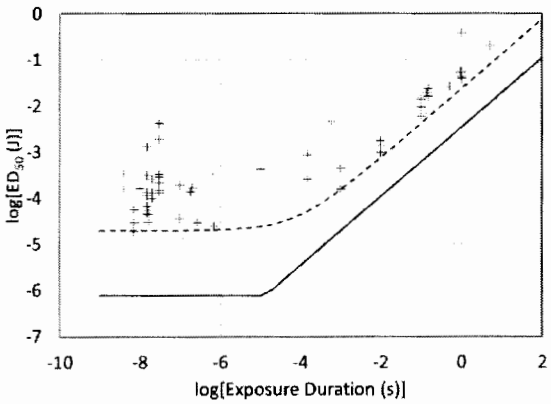

Figure 8. Approximation of infrared (near 1064 nm) retinal ED_{50} damage threshold data for collimated beams from the literature. The solid line is the current ANSI Z136.1-2014 exposure limit, while the dashed line is an approximation using Eq. (20) when $F = 0$.

The inputs for the ED50 Model and calculation are the wavelength λ (nm), exposure duration T (s), and retinal tissue (macula or peripheral retina). The output is the 50th-percentile effective dose ED_{50} (J) for the designated human retinal tissue.

Probability Calculation

The inputs to calculating the probability of injury for a specific laser exposure condition are the effective dose ED (J), the 50th-percentile effective dose ED_{50} (J), and the Slope S. While the ED_{50} (J) is calculated using the previously detailed ED50 Model, the effective dose ED is calculated for a specific laser exposure. Given the peak irradiance E_0 (W/m^2), exposure duration T (s), and pupil diameter D_p (mm), the effective dose ED is

$$ED = E_0 \cdot \frac{\pi}{4}\left(\frac{D_p}{1000}\right)^2 \cdot \sqrt{\frac{\pi}{8}} \cdot T \cdot erf\left(\sqrt{2} \cdot \frac{T_S}{T}\right), \qquad (21)$$

where T_s is the dwell time for the saccade movements of the eye, here taken to be 0.25s.

The Slope S is also calculated for a specific laser exposure condition. The inputs for calculating the Slope are the 50th-percentile effective dose ED_{50} (J), the effective dose ED (J), and the Slope parameters D_{50} (μm), S_{16}^1, S_{84}^1, S_{16}^2, and S_{84}^2, calculated and stored previously using the Slope Model, for a specific population, refractive error correction, wavelength, pupil diameter, and the exposure duration T (s).

Determining the correct Slope to use for a specific laser exposure condition involves a two-step process. First, two Slopes, S_{16}^1 and S_{16}^2 or S_{84}^1 and S_{84}^2, are chosen from the four based on the relationship between ED and ED_{50}. Second, a Slope is selected from the remaining pair based on the spot diameter dependence using a transition spot diameter D_t, which determines the transition from a linear to quadratic dependence on spot diameter. This transition spot diameter is based on the trends of the dependence of ED on spot diameter found in the ANSI Z136.1-2014 standard [14] and modified to set the minimum angular subtense at an exposure duration of 25 μs. The result is a single value for the Slope S. Given the ED_{50} (J), Slope S, and the effective dose ED, the probability of retinal injury for a specific laser exposure is calculated using Eq. (2).

Example

An example illustrates the steps detailed above for determining the appropriate Slope. For a less developed population without refractive error correction, a 3 mm diameter pupil, and a laser wavelength of 1064 nm, the human variability Slope Model yields the values given in Table 1.

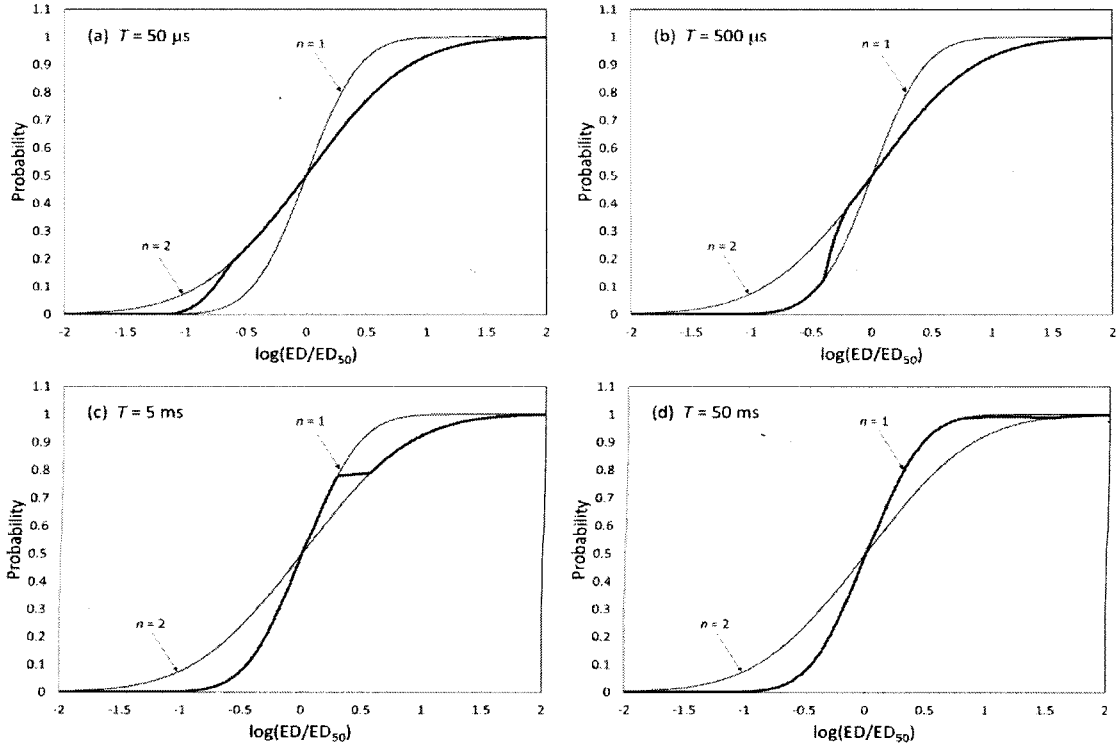

Figure 9. Probability of injury as a function of dose *ED* for different exposure durations *T*. The thin lines are the probabilities for the linear ($n = 1$) and quadratic ($n = 2$) dependencies on spot diameter, while the thick line is the probability using the procedure to determine the appropriate Slope for each dose.

Summary

Two generalized models, ED_{50} and Slope, were developed and presented. The ED50 Model covers the spectral and temporal range for retinal injuries resulting from exposure to a laser beam. The Slope Model quantifies the variability in response to laser exposure taking into account the diversity in physical characteristics within the human population. Combining the two models achieves the goal of improving the fidelity in models used to assess the risk to humans from laser exposures. The outcome is a human dose-response model for probabilistic risk assessment in uncontrolled environments.

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