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Safety of a Red Diode Laser Source for Fetal Retinal Stimulation Studies

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Light sources are now being used in clinical research to study development of the fetal visual system (Eswaran et al. 2004). These studies are making use of a relatively new technique called magnetoencephalography (Eswaran et al. 2002) to study fetal development. The technique calls for placing a light wand (Fig. 1) on the mother's abdomen and recording the magnetic fields associated with optically-induced nerve signals from the fetus. Current methods use a wand of 5.0 cm x 9.0 cm with a total output power of 20 mW at 630 nm from an array of 200 high intensity light emitting diode sources. Plans are underway to develop a more intense source to enhance the physiological measurements. The irradiance associated with the next-generation light simulator needs to be quite high because the transmission of light through the tissue which separates the outside world from the fetal retina is very low. The high irradiance suggests the need for a hazard analysis to determine if the source presents an optical danger to the mother or the research staff. Sliney and Wolbarsht (1982) give an overview of the hazards to the eye and skin from lasers and high intensity light sources. The following analysis addresses the question of potential danger to the eye and skin of both mother and research staff due to the high intensity light simulator.

The 630 nm red light from a high power (500 mW) diode laser will be launched into a fiber optic cable with an exit port fitted with a diffusing disc. For the purposes of this analysis the disc is assumed to be an ideal diffuse transmitter so that the red light from the fiber end will be taken as 500 mW emitting in a pure Lambertian geometry, i.e. its intensity varies as the cosine of the angle relative to the emitting surface normal and its radiance is independent of angle. An emitting surface of 1.0 cm² is assumed. It can be shown (Williams and Becklund 1972) that for a Lambertian source, the total emitted radiant flux Φ (in units of Watts or W) is related to the radiant intensity normal to the surface I(0), which has units of Watts/steradian (W-sr⁻¹) by the following expression:

 $\Phi = \pi I(0).$

Since Φ is 500 mW in our case we can write

 $(0) = (500 \text{ mW})/(\pi) = 160 \text{ mW-sr}^{-1}$.

For a Lambertian surface the radiance L, which is independent of angle and is defined as the radiant flux per unit area of emitter



Fig. 1. A photograph of an optical wand used in a clinical study of light-evoked retinal response. The side facing the camera and lighted would be placed in direct contact with the mother's skin in this application.

 $(1.0 \text{ cm}^2 \text{ in our case})$ per unit steradian, is given by

 $L = 160 \text{ mW-cm}^{-2} \text{ sr}^{-1}$.

The primary concern with most optical sources is the potential hazards to the human eye. The standards for safe viewing of laser beams (Laser Institute of America 2000) are separated into two primary viewing situations: the first is a direct viewing of a collimated laser beam and the second is the viewing of a beam that is relatively large and is considered to be an extended source. The former situation (small-source viewing) assumes that the laser acts as a point source with perfect collimation, and the consequent imaging by the eye will not be resolvable into a geometric image, rather a diffractionlimited spot on the retina. For the extended source, the radiation can be resolved by the eye into an image of finite size.

Since the size of the source relative to the viewing distance will distinguish the two viewing situations, a calculation of the source angular subtense is necessary. This value must then be compared to the limiting angular subtense (α_{min}), the

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apparent visual angle in the safety standards that divides smallsource viewing from extended-source viewing. If the source angle exceeds α_{\min} , then extended source viewing is presumed, otherwise the limits for small-source viewing are applied. For wavelengths between 400 and 1400 nm $\alpha_{\min} = 1.5$ mrad. The angular subtense for a 1.0 cm² source at a viewing distance of 50.0 cm (a value representing a reasonable distance from the mother's stomach to her eyes) is $\alpha = 1.0/50.0 = .020$ radians = 20.0 mrad. Since α exceeds α_{\min} , the appropriate limits for extended source viewing must be applied.

The safety standards for extended source ocular exposure depend on wavelength and exposure duration (LIA-2000, Table 5b). For a wavelength of 630 nm and an angular subtense of 20.0 mrad the maximum permissible exposure (MPE) for a duration of 0.7 to 15.4 s (T_2 in Table 5b of ANSI) is given in terms of an integrated irradiance:

$$MPE = 1.8 C_{\rm F} t^{0.75} \times 10^{-3} \text{ J-cm}^{-2}, \qquad (1)$$

where t is the exposure time in seconds and C_E is the ratio of source angular subtense to α_{min} . In our case $C_E = 20/1.5$ or 13.3. For a 1 second viewing, MPE in terms of irradiance would be 24 mW-cm⁻². For continuous viewing, the maximum permissible irradiance (LIA-2000, Table 5b) is given by:

MPE =
$$1.8 C_{\rm E} T_2^{-0.25} \times 10^{-3} \text{ W-cm}^{-2}$$
. (2)

For the conditions in our case this latter equation yields a value of 12 mW-cm⁻². Extended sources that produce an irradiance less than 12 mW-cm² are within safety limits for continuous viewing.

A hazard analysis for the laser light simulator can now be done. Given a 1.0 cm² Lambertian source with a radiance of 160 mW cm⁻² sr¹, the resulting irradiance at a viewing distance of 50.0 cm would be L Ω , where Ω is the solid angle subtended at the eye by the source, i.e. $1/50^2$ or 0.0004 sr. Thus the irradiance for the mother would be, at most, 0.064 mW-cm⁻². The calculations above yield a 1.0 second viewing limit of 24 mW-cm⁻² and a long-term continuous viewing limit of 12 mW-cm², well above the actual value of 0.064 mW-cm⁻². The wand should present no hazard to the mother's eyes even under continuous longterm viewing from a distance of 50.0 cm. In order to achieve an exposure of 12 mW-cm⁻², the separation distance between diffusing disc and eye would have to be reduced to 3.7 cm.

One question that may arise is whether multiple 1.0 cm^2 sources, each of 500 mW/cm², placed side-by-side would constitute a hazard if viewed by the mother. For purposes of this analysis a 7.0 cm x 7.0 cm source (approximately 50 cm²) with an emittance of 500 mW-cm² is presumed. The radiance of the source will not change; it will still be 160 mW/cm² sr. The angular subtense α will now increase to 7/50 or 140 mrad. The value of C_E in (2) becomes 131. T₂ is now 100 s (LIA-2000, Table 6). Application of (2) yields an MPE of 75 mW-cm². With the larger source the exposure will be greater due to the larger value

of Ω , the solid angle formed by the source at the eye. With this larger value of Ω (0.02) the irradiance at the eye becomes 3.2 mW-cm², still well below the 75 mW-cm⁻² limit. For the smaller 1.0 cm² source and a viewing distance of 50 cm, exposure is 0.4 % of the limit; for the larger 50 cm² source exposure is 4.2% of the safe limit.

While optical radiation hazards for the skin are generally considered secondary to those for the eye, it is important to limit the exposure of the skin to high levels of optical radiation in order to prevent harmful thermal or photochemical effects. In our application the light simulator surface will be in contact with the mother's skin, thus maximizing maternal exposure to the optical radiation. The standards (LIA-2000, Table 7) for the safe use of lasers specify the maximum permissible exposure (MPE) for skin to a laser beam. This standard will be used to assess the safety hazard to the mother's skin and to set a limiting-exposure condition to guarantee a safe condition for the mother.

While the safety standards do give limits for various time exposures the most conservative case will be used in this analysis, i.e. the limits for continuous exposure will be determined and used to limit the operating parameters for the wand. For continuous exposure in the visible region of the spectrum to small areas (less than 100 cm²) the limit is 200 mW-cm⁻². For a conservative design with a margin of safety of 2 the maximum allowed irradiance is 100 mW-cm⁻². Since we assume the output of the simulator is 500 mW-cm⁻² and it is assumed to be in direct contact with the mother's skin, it is clear that continuous illumination is not a safe condition for the skin.

In order to ensure that a continuous limiting value of 100 mW-cm⁻² is achieved, a duty cycle of 20% would be necessary. Thus a 1.0 s on-time followed by a 4.0 second off-time would yield an effective continuous irradiance of 100 mW-cm⁻². Further reductions in on-time to full cycle period ratio will enhance the safety margin. As a reference check, the continuous level of 100 mW-cm⁻² is of the same order of magnitude as the maximum irradiance of the noonday sun on the skin for someone in Arkansas. Moreover, solar radiation contains a full spectrum of energies with a significant absorption component, whereas the red 630 nm radiation is absorbed less and should provide no photochemical threat to the skin tissue.

Here we consider only the effect of the optical radiation on the skin. In terms of the complete safety hazard analysis, we are assuming that there is negligible light absorption at the exterior surface of the simulator and that its temperature will not exceed body temperature even when in continuous contact with the mother's skin.

These calculations show that continuous viewing of the 630 nm light simulator wand with a radiance of 160 mW cm⁻² sr at a distance of 50.0 cm will not present a hazard to the eyes of the mother or the research staff. Also, if the source is pulsed with a 20% duty cycle the wand placed in direct contact with skin will not constitute a hazard to the skin.

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