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Letter to the Editor

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Retinal Safety of a Red Light Myopia Therapy Device

Dear Editor,

we read with interest the article by Ostrin and Schill[1]. While we agree with the author's report that the Eyerising device exceeds maximum permissible exposure (MPE) limits defined in ANSI laser standards, we believe that the conclusions regarding potential retinal risk warrant important clarification.

Firstly, ANSI Z136.1 and ANSI Z80.36 were not developed to define specific safety limits for therapies. Rather, "the Institute provides a framework for fair standards development and quality conformity assessment systems and continually works to safeguard their integrity."[2] Its standards are meant to try to enhance safety and quality by establishing voluntary, consensus-based guidelines. For lasers, ANSI classifies laser products and ophthalmic instruments for illumination and diagnosis. Therefore, their standards may not be applicable for a therapeutic device like the Eyerising product.

Secondly, exceeding an MPE does not necessarily mean a risk for retinal injury. Retinal exposure limits incorporate substantial safety factors relative to injury thresholds. By design, the injury threshold typically lies appreciably above the MPE, so crossing that limit is not necessarily equivalent to reaching damage thresholds.

Also, there is human volunteer evidence at substantially higher exposure levels that did not show retinal damage. Robertson et al.[3] exposed study participants to a 659nm laser with 5.1mW power for 15 minutes, using a well-collimated beam that produced a minimal retinal spot comparable to that of the Eyerising device. Although this study was in adults, to our knowledge, there are no relevant known differences in the susceptibility of pediatric to adult eyes. In the study by Robertson et al, participants reported only transient afterimages and no detectable functional, ophthalmoscopic, angiographic or histologic retinal change was identified.

From our laboratory measurements, the Eyerising device delivers approximately 1mW through a 7mm pupil, about one-fifth of the power used by Robertson, at an equivalent wavelength and geometry. For any photochemically induced hazards, well-established reciprocity permits an energy-based comparison: 5mW for 15 minutes is equivalent to 1mW for 75 minutes. With a 6-minute daily exposure for RLRL, the single-day energy margin versus the Robertson protocol is then 12.5-fold for a 7mm pupil, increasing further for smaller pupils. Furthermore, pupil constriction would occur when directly viewing the beam. Daily use can be conservatively addressed by applying a reduction factor of 4.5, derived from a repair model[4] for photochemical retinal injury and daily usage for 6 minutes. Overall, we would conclude a sufficient safety margin then remains between Eyerising exposures and levels shown not to induce retinal injury, even under conservative assumptions regarding pupil size.

In summary, the limited scope of these ANSI standards, the conservative nature of their MPEs, and the aforementioned human volunteer data provide a quantitative scientific basis to support the Eyerising device as safe for its intended use.

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