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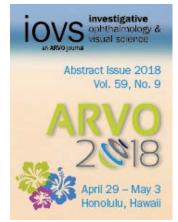
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July 2018 Volume 59, Issue 9

OPEN ACCESS

ARVO Annual Meeting Abstract | July 2018

Effectiveness and Safety of a phototherapeutic contact lens for Diabetic Retinopathy

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Investigative Ophthalmology & Visual Science July 2018, Vol.59, 5814. doi:



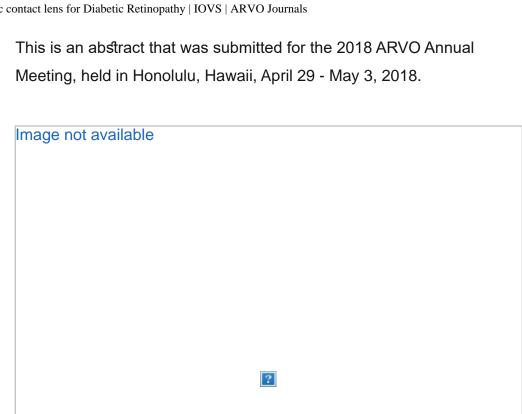
Abstract

Purpose :Diabetic retinopathy (DR) is a leading complication of diabetes. It is thought that increased rod metabolism under dark adaptation exacerbates hypoxia in diabetic retina. Nowadays most treatments for DR are invasive and need multiple clinic visits. Recently a phototherapeutic contact lens has been designed to provide illumination to retina as a means to supress dark adaptation. It may be possible to delay the progression of DR. The purpose of this study is to explore the bioactivity and safety of this device.

Methods :Six eyes from three healthy mature white New Zealand rabbits were used. The phototherapeutic contact lens was placed on treated eye. An non-phototherapeutic contact lens was used on the fellow eye as a control. To determine bioactivity of photoreceptors, an ERG was performed. Flash response, including amplitude and implicit time on scotopic condition were analyzed at different flash intensities (100, 300, 1000, 25000 mcd.s/m², respectively). Animals were under a 20-minutes period of dark adaption before any ERG. Then the contact lens were swapped on the eyes and the ERG were repeated. The whole process was performed in a dark room under dim red light. Once ERG were completed, the phototherapeutic contac lens was sutured to the eye for a long–term period (28 days) to verify safety. There will be a statistical analysis using Graph Pad Prism 7.0, determining the degree of correlation between the groups. Histological analysis will be performed to determine safety.

Results : The ERG showed that both the amplitude and implicit time of bwave in the treated eye were significantly shorter than the untreated eye under scotopic conditions (Figure 1). No significant difference in the amplitude and implicit time of a-wave was observed. A representative plot (Figure 2) shows significant depression of b-wave, both in the amplitude and implicit time (amplitude: p=0.01; implicit time: p<0.001).

Conclusions : The phototherapeutic contact lens can effectively reduce the bioactivity of the retina, without ocular side effects in an acute follow-up. Further studies should be performed for a long-term placement in both healthy and retinal ischemic animal models to determine whether this device can reduce oxygen consumption in retina and delay disease progression. Long-term histology from contact lens safety is on going and will be presented.



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