A Randomized Trial of Amblyz™ Intermittent Occlusion Glasses vs Traditional Patching for Treating Children with Moderate Unilateral Amblyopia

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Purpose: PEDIG studies suggest a 2-hour patching treatment is effective for children with moderate amblyopia. Amblyz™ liquid crystal occlusion glasses are able to occlude the eye intermittently for periods of 30 seconds. Therefore, we hypothesized that 4-hour daily intermittent occlusion from Amblyz™ glasses is equally effective to 2-hour daily patching occlusion. Although a previous nonrandomized pilot study suggested that liquid crystal occlusion glasses are effective treating amblyopia (Spierer et al. 2010), there has not been prior comparison to a patching control group. This randomized clinical trial is designed to compare the effectiveness of Amblyz™ glasses versus adhesive patching for treating moderate, unilateral amblyopia in children.

Methods: Children (N=28, age=5.3±1.4YR, 3- to 8-year-old) with previously untreated, moderate, unilateral amblyopia (visual acuity of 20/40 to 20/100 in the amblyopic eye) were enrolled. All subjects had worn optimal refractive correction (if needed) for at least 12 weeks without improvement and their amblyopia was associated with strabismus, anisometropia, or both. Subjects were randomized into one of two treatment groups: a 4-hour daily Amblyz™ Glasses Group with liquid crystal shutter set at 30-second opaque/transparent intervals, or the 2-hour adhesive Patching Control Group. For each patient, visual acuity was measured with ATS-HOTV methods before and after 12 weeks of treatment.

Results: At the conclusion of the first 12 week-treatment interval, visual acuity in the amblyopic eye improved an average of 0.22±0.11logMAR in the *Amblyz™ Glasses Group* and 0.21±0.16logMAR in the *Patching Group*. Vision improvements in both groups were clinically significant ($p<0.05$, over 2 lines). There was no statistically significant difference between groups (P-value=0.75). We did not find reverse amblyopia in the fellow eye. Compliance and treatment experience are reported in a related abstract.

Conclusions: Our pilot data showed that intermittent occlusion associated with Amblyz™ glasses is equally effective to patching occlusion when treating 3-8 year old children with moderate amblyopia. This new device is a promising alternative treatment for amblyopia. The apparent effectiveness of Amblyz™ glasses warrants further investigation with longer follow-up and larger sample size.

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