CureSight versus Patching - A Multicenter, Pivotal RCT, to Assess the Safety and Effectiveness of an Eye-Tracking-Based Binocular Treatment for Amblyopia

Purpose:
The follow-up data of a randomized controlled trial in 103 children aged 4 to <9 years that supported the FDA clearance of CureSightTM the novel eye-tracking-based dichoptic home treatment for amblyopia, is presented. In this pivotal study, treatment over 16 weeks was found to be non-inferior to the gold standard treatment, patching (improvement of 0.28 ± 0.13 and 0.23 ± 0.14 logMAR respectively).

Methods:
The 95 participants had available 16-week outcome data and were included in the primary analysis. Eighty eligible patients were tested on the 28 weeks follow-up visit. Out of these, 39 patients were initially randomized to continue the binocular treatment (binocular treatment group), and 41 were initially randomized to the patching group, out of which 19 patients did not receive any additional treatment (patching group), whereas 22 patients were prescribed with the CureSight binocular treatment for 1.5 hours 5 times a week for further 12 weeks (patching crossover group).

Results:
At 28 weeks, the improvement of the amblyopic eye's visual acuity was maintained both as compared to baseline ($p<0.0001$ for all groups) and to 16 weeks ($p=0.2474$, $p=0.9641$, $p=0.7699$, for binocular treatment, patching, and the patching crossover groups respectively) with no statistical difference between the groups in the magnitude of change. The improvement in stereo acuity was also maintained in all groups both compared to baseline ($p<0.0001$, $p=0.0006$, $p=0.0011$, for binocular treatment, patching, and the patching crossover groups respectively) and to 16 weeks ($p=0.8344$, $p=0.8125$, $p=0.6426$, for binocular treatment, patching, and the patching crossover groups respectively). However, when considering the magnitude of change compared to baseline, the binocular treatment group showed a trend of further improvement in stereo acuity at the 28-week visit (from an improvement of 0.523 to 0.602 Log arcseconds), as well as the patching crossover group (from an improvement of 0.46 to 0.647 Log arcseconds), whereas the patching group showed a trend of deterioration (from an improvement of 0.699 to 0.523 Log arcseconds).

Conclusion:
Improvements induced by binocular treatment were maintained over 28 weeks in all visual functions, similarly, to patching, despite almost half of the dosing of binocular treatment compared to patching (53.5%) which was yet as sufficient to produce durable improvements. Moreover, a trend of further improvement in stereo acuity was observed in the binocular treatment and patching crossover groups, whereas an opposite trend towards deterioration in stereo acuity was observed in the patching group, suggesting that binocular treatment can be beneficial in cases of residual amblyopia, including in patients that were previously treated with monocular approaches.

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