A Prospective, Multicenter, Randomized, Masked, Controlled Pivotal Trial to Assess the Safety and Effectiveness of an Eye-Tracking-Based Treatment for Amblyopia Under Binocular Conditions vs. Patching- Interim Results.

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Introduction

A pivotal RCT was conducted in 6 academic and community sites to evaluate the safety and effectiveness of a novel treatment for amblyopia using the CureSight, a binocular- eye-tracking- based device compared with the gold standard amblyopia treatment-patching





Methods

- A 16 weeks multicenter randomized controlled trial
- 100 anisometropic or mixed amblyopia patients were included (mITT)
- Children aged 4<9 years were randomized 1:1 to the CureSight or patching group

CureSight group

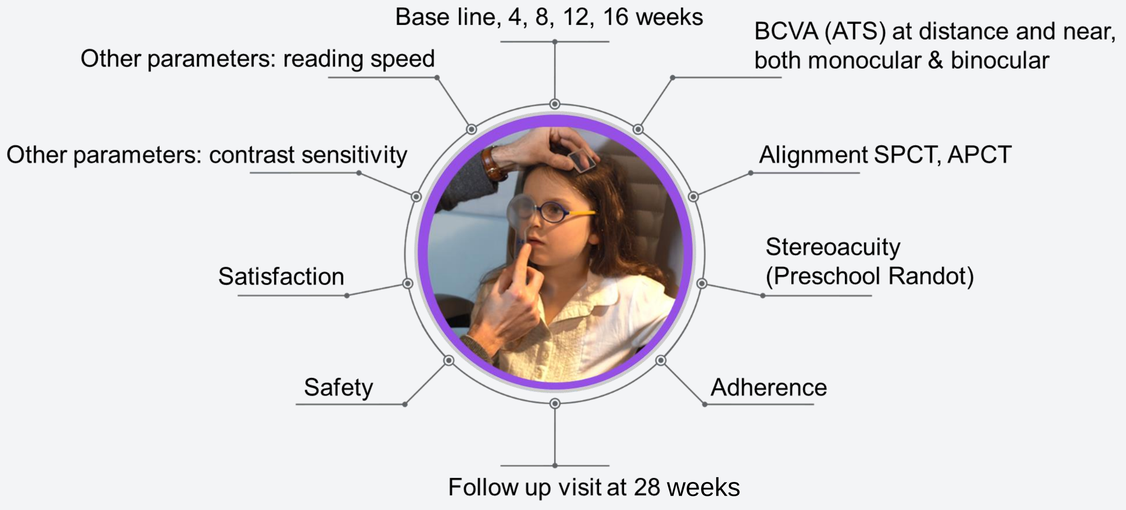


Hours a day 1.5 | Days a week 5 | Weeks 16

Patching group



Hours a day 2 | Days a week 7 | Weeks 16



- Primary endpoint: non-inferiority of amblyopic eye best corrected visual acuity improvement at 16 weeks
- Secondary endpoints: binocular VA and stereoacuity improvement
- Exploratory endpoints: adherence, satisfaction and other

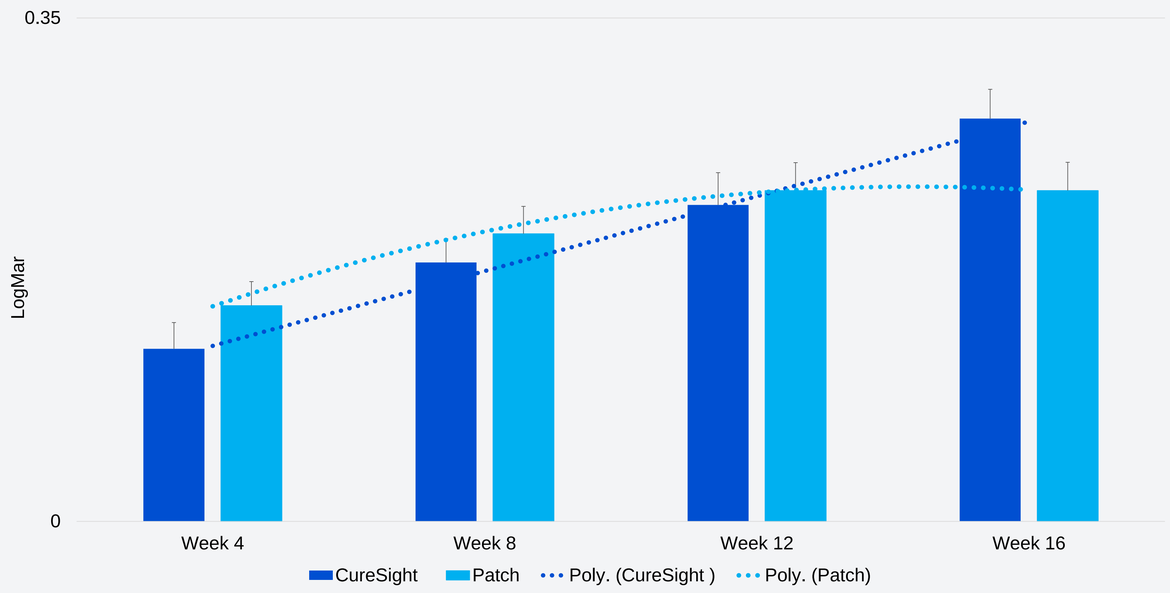
Financial disclosures:

Oren Yehezkel is a NovaSight employee
Michael Belkin Inventor and consultant to NovaSight
Tamara Wygnanski-Jaffe-NovaSight advisory board (unpaid)

Results

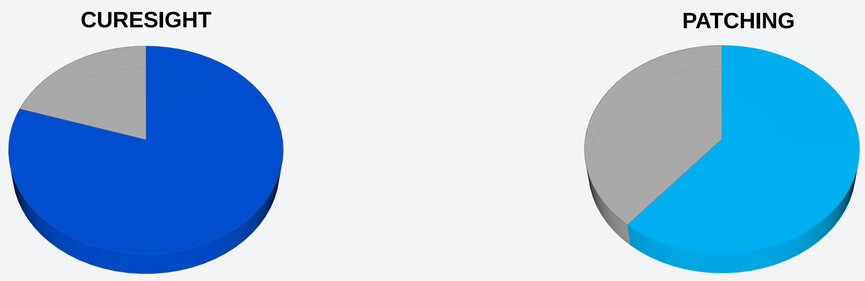
Visual acuity improvement

- Primary non-inferiority endpoint of distance VA improvement of the amblyopic eye VS. patching control group was met
- Distance VA of the amblyopic eye improvement was higher in the CureSight group vs. the Patching group in week 16
- Binocular VA improvement was higher in the CureSight group vs. the Patching group



Proportion with ≥ 2 Lines Improvement

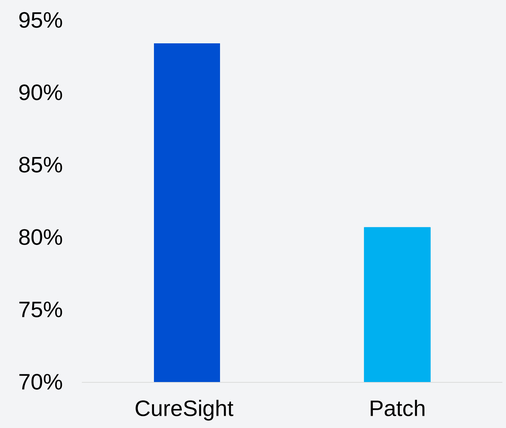
Out of the patients who reached the 16-week visit, proportion of patients with amblyopic eye BCVA improvement ≥ 2 lines:



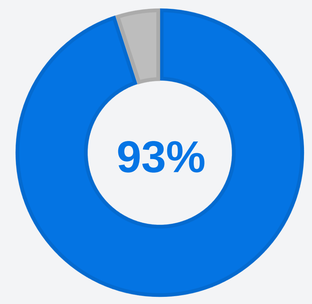
Stereoacuity improvement

Significant stereoacuity improvement was found in both arms

Mean adherence at 16 weeks



93% of the parents reported they are likely or very likely to choose the CureSight over eye-patching





No severe adverse events reported in the study

Conclusions

Binocular treatment with CureSight™ (NovaSight, Israel), as proven in this first successful pivotal RCT vs. patching in children, improves both visual acuity and binocularity at the comfort of the patient's home, with high adherence and satisfaction