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Oren Yehezkel, Tamara Wygnanski-Jaffe, Burton J. Kushner, Michael Belkin, Liu Hong, Bu Juan, Avital Moshkovitz, Wei Zhang, Rui Liu & The CureSight Pivotal Trial Group

A multinational randomized clinical trial of an eye-tracking-based binocular amblyopia treatment in children aged 4 to 9 years

Oren Yehezkel[a] PhD, Tamara Wygnanski–Jaffe[b,c] MD, Burton J. Kushner[d] MD, Michael Belkin[b,e] MD, Liu Hong[f] MD, Bu Juan[g] MD, Avital Moshkovitz[a] PhD, Wei Zhang[h] MD, PhD and Rui Liu[i,j] MD, PhD *on behalf of the CureSight Pivotal Trial Group*

a) NovaSight Ltd., Airport City 7019900, Israel
b) Faculty of Medicine, Tel- Aviv University, Tel-Aviv 69978, Israel
c) Goldschleger Eye Institute, Sheba Medical Center, Tel Hashomer 52621, Israel
d) Department of Ophthalmology and Visual Sciences, University of Wisconsin, Madison WI 53705-2276, USA
e) Goldschleger Eye Research Institute, Sheba Medical Center, Tel Hashomer 52621, Israel
f) Shanghai Children's Medical Center, Pudong New Area, Shanghai 200127, China
g) Peking University Third Hospital, Haidian District, Beijing 100191, China
h) Tianjin Eye Hospital, Heping District, Tianjin 300020, China
i) Eye Institute and Department of Ophthalmology, Eye & ENT Hospital, Fudan University, Shanghai, 200031, China
j) NHC Key laboratory of Myopia and Related Eye Diseases; Key Laboratory of Myopia and Related Eye Diseases, Chinese Academy of Medical Sciences, Shanghai, 200031, China

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Corresponding authors:

Wei Zhang, MD, PhD. Tianjin Eye Hospital, No. 4, Gansu Rd, Heping District, Tianjin 300020, China (zhangwei3066@126.com)

Rui Liu, MD, PhD Department of Ophthalmology Eye & ENT Hospital of Fudan University, 83 Fenyang Road, Xuhui District Shanghai, 200031 China (lratb1@aliyun.com)

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Members of the CureSight Pivotal Trial Group (sites are listed in order by number of participants enrolled into the study): Sheba Medical Center, Ramat Gan, Israel: Abraham Spierer, MD (I), Tamara Wygnanski-Jaffe, MD (SI), Nethanel Zitzer (E), Dan Cohen (E), Ahuva Shpigelman (E), Maoz Hadash (E), Ilya Ortenberg (E), and Rinat Cohen (C); Kaplan Medical Center, Rehovot, Israel: Hana Leib, MD (I), Majd Arow, MD (SI), Reut Parness, MD (SI), Luba Rodov, MD (SI), Alexandra Goz, MD (SI), Haia Katz, MD (SI), Anabel Bazov (C), Chaim Nissen (E), Gabriel Avraham (E), and Emad Borsha (E); Maccabi Healthcare Service, Tel Aviv, Israel: Idit Keynann, MD (I), Tali Aviv (E), Nathalie Corcos (C), and Keren Roll (E); Rambam Medical Center, Haifa, Israel: Eedy Mezer, MD (I), Vered Brucker (E), and Meital Abecassis(C); Shaare Zedek Medical Center, Jerusalem, Israel: Ronen Rabinovich, MD (I), Eran Laster (E), Ronit Politi (E), and Hila Givoni (C); Soroka Medical Center, Beer Sheva, Israel: Ahed Amitirat, MD (I), Chiya Robert Barrett, MD (SI), Adelina Zioni (E), Katty Kuperman (C). And Yael Corcos (clinical study manager). Personnel are listed as: investigator(I), sub investigator (SI), coordinator (C), and masked examiner (E). Eye&Ent Hospital of Fudan University, Shanghai, China: Rui Liu, MD (I) Tianjin Eye Hospital, Tianjin, China: Wei Zhang, MD (I),Rui Hao, MD(SI), Shanghai Children’s Medical Center, School of Medicine, Shanghai Jiao Tong University, Shanghai, China: Hong Liu, MD (I),Shu Wang,

MD(SI) Peking University Third Hospital, Beijing, China: Juan Bu, MD (I), Minshu Wang, MD(SI)

Additional Information

Declaration of Competing/Conflicts of Interest

TWJ and MB are scientific advisors, shareholders, and have stock options in NovaSight LTD.; BJK is a scientific advisor and has stock options in NovaSight LTD and is supported in part by an unrestricted grant from Research to Prevent Blindness. OY is employees of and has stock options in NovaSight LTD. AM has stock options in NovaSight LTD. MB and OY are inventors to a patent for a novel amblyopia treatment titled “Screening, Diagnosing, Assessing, Monitoring and Treating Eye Diseases and Visual Impairments Using Eye Tracking”US 16/334,666.

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Abstract

This randomized controlled study compared efficacy and safety of a novel binocular, eye-tracking–based home amblyopia treatment (CureSight) to patching. Three cohorts (China, Israel, U.S.) enrolled 197 children aged 4 to <9 years with anisometropic, small-angle strabismic, or mixed-mechanism amblyopia at 15 academic/community sites (modified intent-to-treat); 156 completed ≥60% of prescribed dosage (per-protocol). CureSight: 90 min/day, 5 days/week for 16 weeks (120 hours); patching: 2 hours/day, 7 days/week (224 hours). In the modified intent-to-treat dataset, visual acuity improvement from baseline to week 16 in the binocular group was noninferior to the patching group (0.028 logMAR; 95% CI −0.007 to 0.063). In the per-protocol dataset, binocular treatment was superior to patching (0.04 logMAR; 95% CI 0.004 to 0.076). Improvement was significantly affected by baseline

covariates of age, baseline vision levels, and previous amblyopia treatment. There was no significant between-group difference in the magnitude of improvement in stereoacuity in either dataset. Overall, CureSight was noninferior to patching in these amblyopia types and yielded better visual outcomes in children completing ≥60% dosage, supporting binocular therapy as an additional first-line option.

Introduction

Amblyopia affects an estimated 1.36% of children worldwide, representing a substantial pediatric vision burden with potential long-term consequences if not effectively treated[1]. Binocular amblyopia therapy is an emerging treatment option alongside traditional occlusion (patching) therapy[2,3], showing visual acuity (VA) improvements in randomized clinical trials (RCTs)[2,4–7]. Dichoptic treatment stimulates both eyes simultaneously by blurring parts of the image seen by the non-amblyopic eye, reducing interocular suppression (an underlying cause of amblyopia)[8,9]. As a result, physiologically, these therapies offer the advantage of promoting binocular cooperation, which is not achieved with monocular treatments like patching[2]. Furthermore, while traditional patching often suffers from poor adherence[10], digital dichoptic therapies have the potential to overcome this barrier through their entertainment value. CureSight (NovaSight, Airport-city, Israel) is an FDA, CE, and Chinese NMPA cleared binocular treatment that uses eye-tracking to blur the central visual field of the fellow eye under dichoptic conditions, while the child passively watches any streamed video content[4]. A recent RCT showed noninferiority of CureSight to patching and superiority limited to children with at least 60% of the prescribed dose.[11] Its lower treatment burden and sustained vision gains suggest a child-friendly, efficient alternative to traditional patching[10,12]. This study expands previous findings by adding a China-based cohort to earlier Israeli and U.S. cohorts, enabling pooled analysis of efficacy and safety in multinational participants (sTable 3) [4,13,14].

Results

A total of 197 children were randomized to either binocular treatment (n=100) or patching (n=97) (Figure1). Six participants were found ineligible and were excluded

from the modified intent-to-treat (mITT) analysis, after randomization. The per protocol (PP) dataset comprised all subjects in the mITT dataset without any major protocol violations (n=156) (Figure 1).

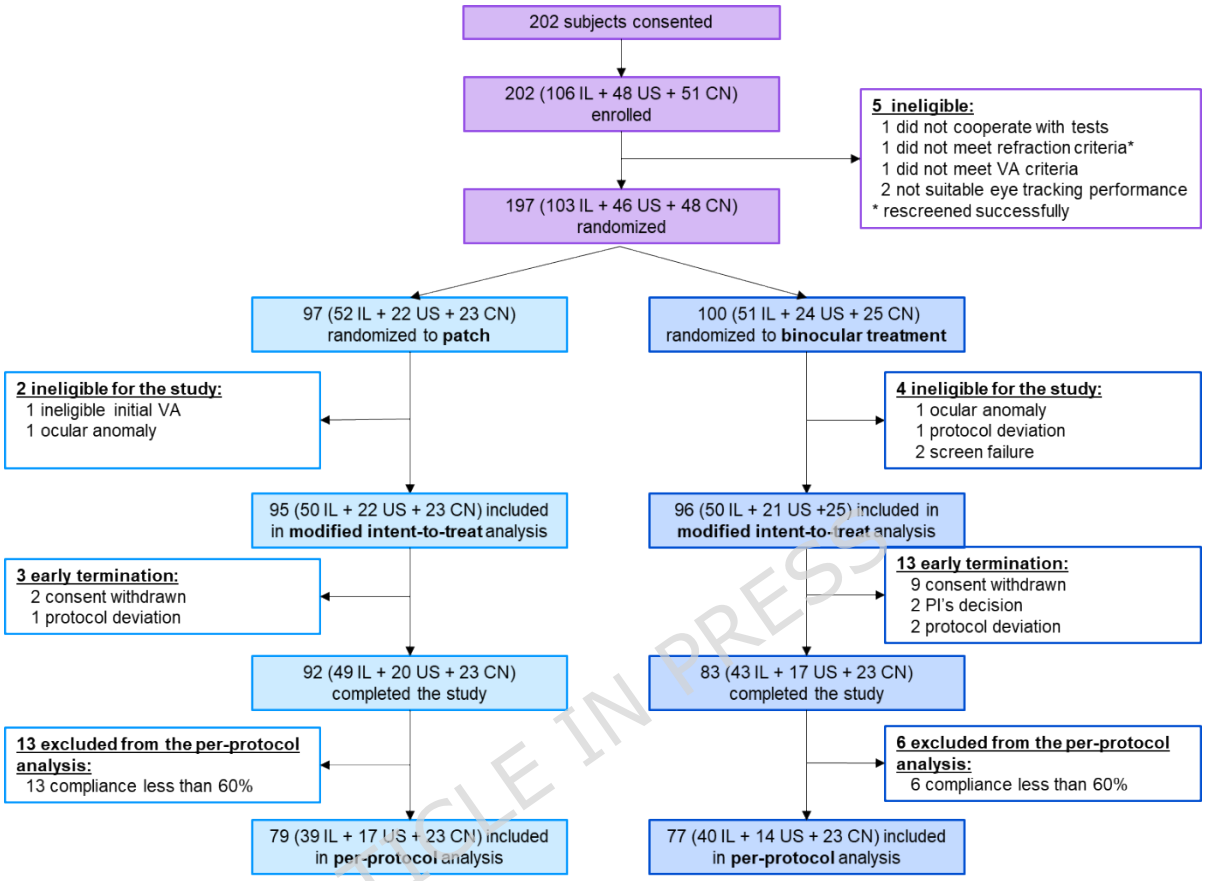

Figure 1 Consolidated Standards of Reporting Trials diagram of the trial. PI = principal investigator; VA = visual acuity.

Both groups were similar in age (mean±SD: 6.49±1.40 years for the binocular treatment and 6.71±1.42 years for patching), and 50.2% of participants were female. About half of the subjects (53.8%) were treatment-naïve, and a majority (84%) were diagnosed with anisometropic amblyopia (sTables 4A and 4B list demographics and baseline characteristics in the intent-to-treat (ITT) dataset, including age, gender, type of amblyopia, prior treatment and baseline AEDVA; sTable 5 lists sample size and gender distribution by cohort and dataset.

In the mITT population, baseline mean±SD AEDVA was 0.40±0.16 logMAR (binocular treatment) and 0.38±0.13 logMAR (patching). At week 16, both groups showed significant improvement: 0.26±0.13 logMAR (binocular T=18.72, p<0.0001) and 0.22±0.12 logMAR (patching T=17.60, p<0.0001, Figure 2A). LSmean change was

0.25 logMAR (SE 0.013) vs. 0.22 logMAR (SE 0.013), with a between-group difference of 0.028 logMAR (95% CI -0.007 to 0.063), meeting the primary noninferiority endpoint across all three prespecified margins (-0.1, -0.075, -0.05 logMAR, sTables 6A and 6B). Significant AEDVA gains were also observed in weeks 4 (binocular T=8.22 p<0.0001, patching T=11.22 p<0.0001), 8 (binocular T=11.61 p<0.0001, patching T=13.73 p<0.0001), and 12 (binocular T=13.46 p<0.0001, patching T=16.21 p<0.0001).

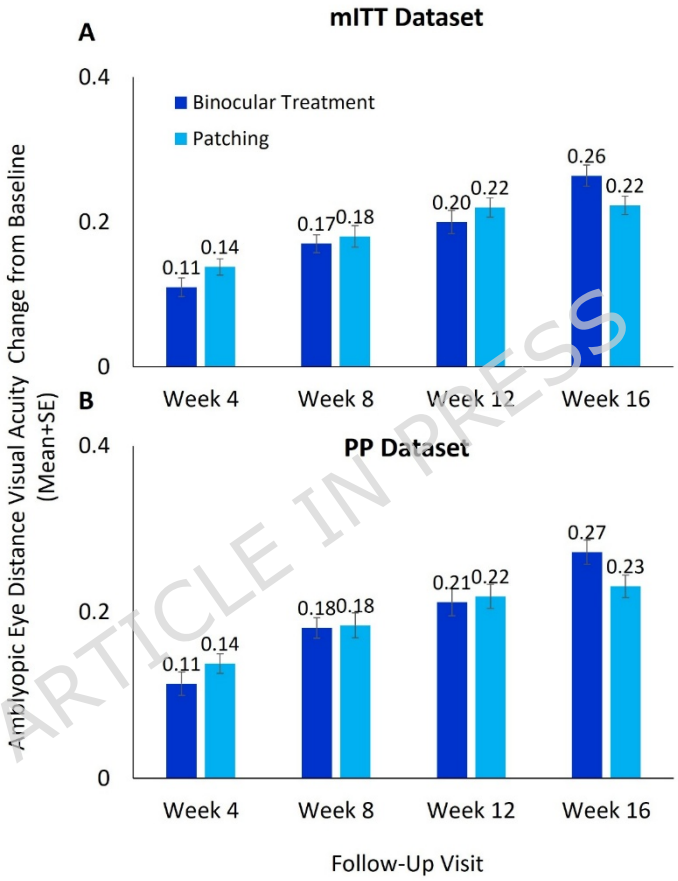

Figure 2 Bar graph showing the change in amblyopic eye distance visual acuity (AEDVA) from baseline at each follow-up visit at 4, 8, 12, and 16 weeks for participants in the binocular treatment group compared with the patching group for (A) the modified intent-to-treat (mITT) dataset (baseline AEDVA: 0.40±0.16 logMAR binocular, 0.38±0.13 logMAR patching) and (B) the per protocol dataset (PP) (baseline AEDVA: 0.38±0.15 logMAR binocular, 0.38±0.13 logMAR patching).

In the PP population, baseline mean±SD AEDVA was 0.38±0.15 logMAR (binocular) and 0.38±0.13 logMAR (patching). At week 16, both groups showed significant improvement: 0.27±0.13 logMAR (binocular T=19.17, p<0.0001) and 0.23±0.12

logMAR (patching T=16.61, p<0.0001, Figure 2B). LS mean change was 0.27 (SE 0.014) vs. 0.23 (SE 0.014), with a between-group difference of 0.04 logMAR (95% CI 0.004 to 0.076), demonstrating superiority of binocular treatment (sTables 6A and 6B). AEDVA improvement was also significant at weeks 4 (binocular T=8.24 *p*<0.0001, patching T=10.00 p<0.0001), 8 (binocular T=12.74 *p*<0.0001, patching T=13.30 p<0.0001), and 12 (binocular T=14.19 *p*<0.0001, patching T=15.14 p<0.0001).

In the mITT population, median baseline Randot stereoacuity was 2.60 log arcsec in both groups (Figure 3A; sTable 7A). At week 16, median improvement was 0.52 (range: -0.65 to 2.22, Wilcoxon one-sample test, S=1117.5 p<0.0001) in the binocular group and 0.30 (Range: -0.82 to 2.00, S=887.5, p<0.0001) in the patching group (sTable 7B).

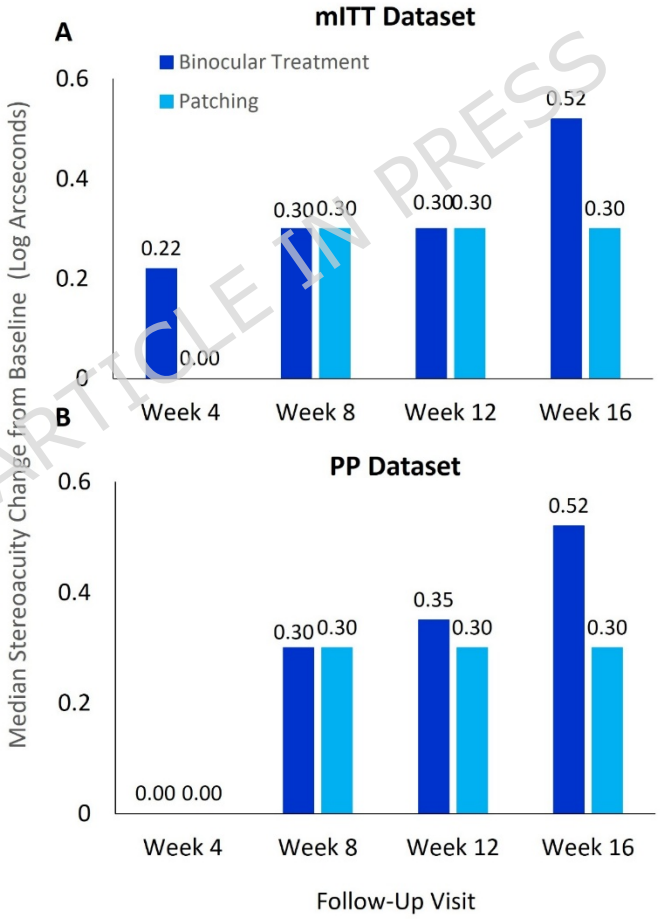

Figure 3 Bar graph showing the change in stereoacuity (Randot preschool test) in arcseconds from baseline at follow-up visits at 4, 8, 12, and 16 weeks for participants in the binocular treatment group compared with the patching

group for (A) the modified intent-to-treat (mITT) dataset and (B) the per protocol dataset (PP).

The between-group difference (difference, 0.22; 95% CI –0.01 to 0.45) was not significant (T=1.92 *p*=0.06; sTable 7C). Stereoacuity significantly improved at all visits in both groups (binocular week 4: S=494 p<0.0001, week 8: S=731.5 p<0.0001, week 12: S=896 p<0.0001 and patching week 4: S=391 p<0.0001, week8: S=704 p<0.0001 week 12: S=797 p<0.0001). Binocular VA also improved: 0.12±0.11 logMAR (binocular T=9.42, p<0.0001) vs. 0.09±0.10 logMAR (patching T=8.29, *p*<0.0001); between-group difference was non-significant (0.028; 95% CI –0.005 to 0.06; T=1.67 *p*=0.096).

In the PP population, median baseline stereoacuity was 2.60 log arcsec in both groups (sTable 7D). At week 16, median improvement was 0.52 (range –0.65 to 2.22) in the binocular group (S=990.5 p<0.0001) and 0.30 (range –0.65 to 2.00) in the patching group (S=570.5 p<0.0001; Figure 3B; sTable 7E). The between-group difference (0.22; 95% CI –0.02 to 0.47) was not significant (T=1.78 p=0.08; sTable 7F). Both groups showed significant stereoacuity gains at all visits (binocular week 4: S=365.5 p<0.0001, week 8: S=589 p<0.0001, week 12: S=779 p<0.0001 and patching week 4: S=234 p=0.0015, week8: S=447.5 p<0.0001 week 12: S=560 p<0.0001). Binocular VA improved by 0.125±0.11 logMAR (binocular T=9.72, p<0.0001) and 0.09±0.11 logMAR (patching T=7.53, p<0.0001), with a non-significant group difference (0.033; 95% CI –0.002 to 0.068; T=1.88 p=0.06).

Subgroup analysis of baseline covariates on AEDVA change in the mITT dataset showed no significant effect of amblyopia type (F[2,162]=2.49, *p*=0.086), but significant although not clinically meaningful differences by age group (F[1,164]=6.43, *p*=0.012), prior treatment status (F[1,163]=5.81, *p*=0.017), and baseline AEDVA (<0.3, 0.3–0.5, >0.5; F=5.12, p=0.007) (sTables 8A-D; see sTables 9A-D for PP dataset). At week 16, 77% (64/83) of the binocular group and 65% (60/92) of the patching group in the mITT dataset achieved ≥2 lines AEDVA improvement. Similarly, in the PP dataset, 81% (62/77) in the binocular group and 69.6% (55/79) in the patching group achieved ≥ 2 lines AEDVA improvement; this between-group difference was statistically non-significant (Figure 4; sTables 10A and 10B).

At week 16 in the mITT population, median adherence was similar between the binocular treatment group (97%; range, 18%-178%) and the patching group (95%; range, 22%-130%) (sTable 11A). In the PP population, median adherence was also

comparable: 97% (range, 63%-178%) for binocular treatment and 98% (range, 60%-130%) for patching (sTable 11B). Mean adherence favored the binocular group in both mITT (98% vs. 84%) and PP datasets (103% vs. 92%), but this did not reach statistical significance. Despite higher adherence, the binocular group had a significantly lower cumulative treatment dose (113.8±5 hours versus 180±8 hours for patching (p=0.03)), representing 63% of the patching group's dosage.

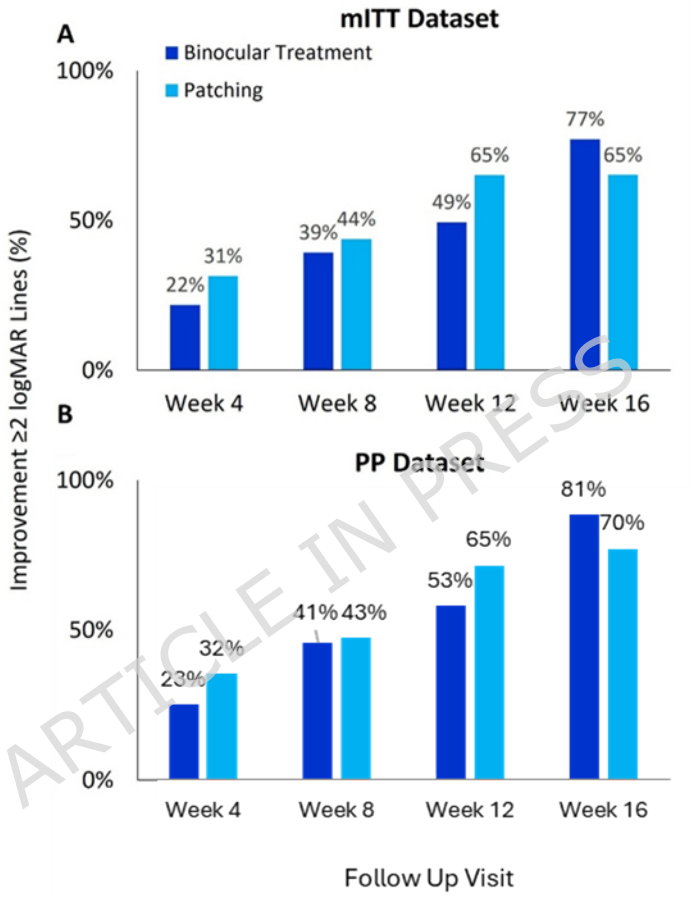

Figure 4 Bar graph showing the proportion of participants with improvement of 2 lines or more in amblyopic eye distance visual acuity (AEDVA) from baseline at each follow-up visit at 4, 8, 12, and 16 weeks for participants in the binocular treatment group compared with the patching group for (A) the modified intent-to-treat (mITT) dataset and (B) the per protocol dataset (PP).

There was no significant linear trend in fellow-eye VA change in either group (Week 4: Z=-0.1101, p=0.9123, week 8: Z=0.8774 p=0.3803, week 12: Z=0.0044 p=0.9965, week 16: Z=0.9691 p=0.3325, Cochrane-Armitage trend test). At week 16, two participants in each group showed a VA worsening of >1 line and <2 lines.

Parent/guardian questionnaires indicated 85% were satisfied with CureSight (score 8–10), and 87% reported they would likely or very likely choose binocular treatment over patching in the future (sTable 12).

No serious or unanticipated adverse events (AEs) occurred. Nonserious AEs were reported in 27.0% (27/100) of the binocular group and 25.8% (25/97) of the patching group. The most common AEs were pathogens (22.0% vs. 17.5%, mostly COVID) and allergies. Worsening VA occurred in 2.0% (2/100) of the binocular group and 1.0% (1/97) of the patching group; headaches in 2.0% vs. 4.1% (2/100 vs. 4/97); and new heterotropias were reported only in the patching group (2.1%, 2/97). See sTable 12 for full AE listings.

Discussion

This evaluator-masked, multicenter RCT showed that a binocular, eye-tracking-based home treatment is noninferior to traditional patching in improving visual acuity (VA) in children aged 4-9 years, and superior among those with ≥60% adherence, with a statistically significant although not clinically meaningful 0.04 logMAR advantage.

Both groups significantly improved in stereoacuity and binocular VA, with no statistically significant between-group performance differences. However, the binocular group achieved these gains with 63% less cumulative treatment time compared to patching. Importantly, the findings reinforce earlier results from our Israeli and U.S. cohorts and align with existing literature on stereoacuity improvements, although some studies report no effect[3,5,15–20]. Across binocular approaches, results vary by platform, dosing/adherence, age, and amblyopia subtype, contributing to heterogeneity across trials and meta-analyses[3,15–17]. Notably, "real-world" adherence to dichoptic treatments outside of a clinical trial environment remains to be fully established.

Consistent with prior evidence[2,10,21,22], younger age, better baseline VA, and no prior treatment were associated with greater VA improvement. Future investigations encompassing a wider and more balanced spectrum of baseline amblyopia severities are necessary to further delineate this relationship. Study limitations include the 16-week treatment duration, a narrow age range, and predominance of anisometropic amblyopia. Furthermore, while this study is limited by the lack of post-treatment follow-up beyond the 16-week endpoint, a recent 1-year observational study of the of

the CureSight binocular treatment[14] demonstrated that visual acuity and stereopsis gains were largely maintained without additional therapy, despite a partial reduction in visual acuity gain (0.085 logMAR) and an amblyopia recurrence rate of 20.4%. Nonetheless, the visual and functional benefits observed support binocular therapy as a viable, efficient, and child-friendly alternative, with a favorable safety profile, with no reports of diplopia, eye strain, or seizures.

In summary, the CureSight binocular, eye-tracking-based amblyopia treatment is noninferior to patching in children with anisometropic, small angle strabismus and mixed mechanism amblyopia and superiority limited to children with at least 60% of the prescribed dose. This study suggests binocular treatments as an additional treatment option for amblyopia, including children with low adherence or resistance to traditional methods[2,15]. Further studies in older children and adults are warranted.

Methods

Ethics

Three cohorts comparing binocular treatment with patching were enrolled in China, Israel and the U.S. The protocol has been previously published[4] and was conducted and reported in accordance with the CONSORT 2025 Statement[23] (see also *Supplementary Material: Protocol summary*). Briefly, this was a prospective, multinational, multicenter, randomized (1:1), evaluator-masked, controlled trial (sTable 1 lists participants per site). The study was listed on Chinese Clinical Trials Register (ChiCTR2200064915; date of registration: 21/10/2022), Israel national registry (MOH_2020-08-10_009227; date of registration: 10/08/2020), and clinicaltrials.gov (NCT05185076; date of registration: 23/12/2021), and adhered to tenets of Declaration of Helsinki; Ethics Committees in China and Israel and Institutional Review Board (Sterling IRB, Atlanta, GA, USA for all U.S.-based sites) approval was obtained at all participating sites. The parents or guardians of the study participants provided written informed consent prior to any study procedures. Written informed consent was obtained from parents for publication of identifying information/images in an online open-access publication.

Subjects

Participants diagnosed with amblyopia[2] were prospectively recruited from outpatient clinics of the participating centers. In China, enrollment began on March 1, 2022; the last subject completed the 16-week visit on July 21, 2023. In Israel, enrollment began on August 18, 2020; the last subject completed the 16-week visit on February 15, 2022. In the U.S., enrollment began on November 2, 2021, and the last subject completed the 16-week visit on April 20, 2023 (sTable 2 lists key entry criteria[2]).

Experimental Procedures

CureSight uses real-time image processing to present separate visual channels to each eye[4]. The system blurs the central visual field of the non-amblyopic eye using eye-tracking, encouraging use of the amblyopic eye's central vision, while viewing through anaglyph glasses (Figure 5).

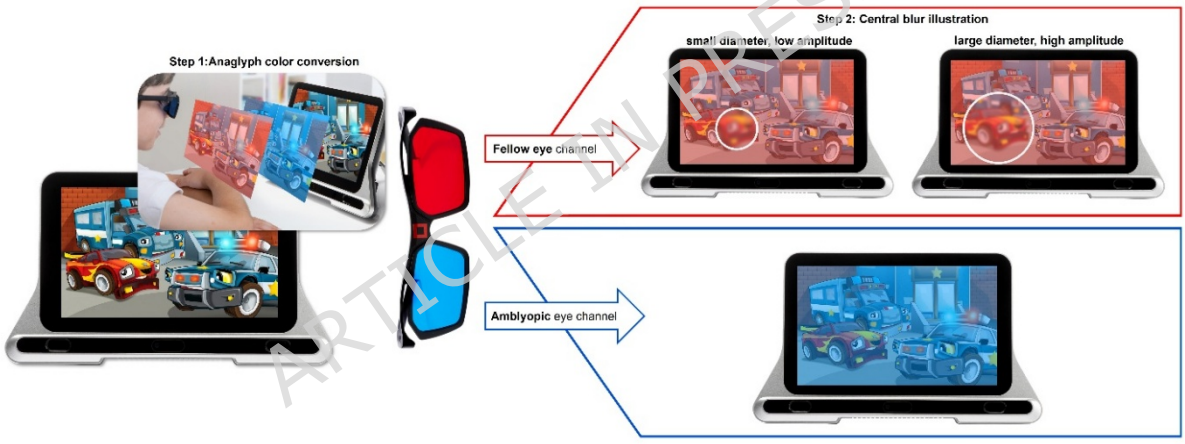

Figure 5 Diagram showing binocular treatment setup. Step 1: Streamed visual stimuli is converted into 2 anaglyph separate channels, blue for the amblyopic eye and red for the fellow eye and are presented superimposed. Step 2: Illustration of the blurred fellow eye channel (red) central visual area, a high-diameter blur area with a high amplitude blur (right) and a small-diameter blur area with a low blur amplitude (left). The amblyopic eye channel is not affected by the blur.

Participants were randomized (1:1) to either CureSight or patching[2]. The binocular group was prescribed 90 minutes/day, 5 days/week for 16 weeks (total: 120 hours). The patching group wore an adhesive patch (Ortopad, Italy) over the dominant eye for 2 hours/day [24][25], 7 days/week (total: 224 hours). Assessments occurred at weeks

4, 8, 12, and 16 (±1 week) post randomization, with masked examiners conducting distance VA and stereoacuity testing [26,27].

Statistical Analysis

The statistical analysis plan was pre-specified. The primary effectiveness endpoint guided the sample size calculation; this information is presented in detail in the *Supplementary Material*.

The primary effectiveness outcome was defined as the change from baseline to week 16 in amblyopic eye VA (AEDVA) in both study groups, combined across the three cohorts. The aim was to demonstrate that the CureSight device is noninferior to patching in improving AEDVA with a noninferiority margin of -0.10 LogMAR[20,28]; the description of how the null hypothesis was tested is detailed in the *Supplementary Material*.

Prespecified covariates included age, baseline amblyopic-eye VA, and prior amblyopia treatment status[21,22]. The final analysis employed an ANCOVA model. Secondary and additional outcomes included the change from baseline to week 16 in stereoacuity test scores and binocular VA. Safety was evaluated by the frequency, severity, and causality of adverse events (AEs).

Data Availability Statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request. The authors confirm that the data supporting the findings of this study are available within the article and its Supplementary Information. Ethics Committees in China and Israel and Institutional Review Board (Sterling IRB, Atlanta, GA, USA for all U.S.-based sites) approval was obtained at all participating sites.

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Author Contributions

All authors have approved the submitted version of the manuscript, have agreed both to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated, resolved, and the resolution documented in the literature. Specific contributions were: O.Y.: conceptualization, methodology, validation, investigation, resources, writing – original draft, review & editing, supervision; T.W.J.: conceptualization, methodology, validation, investigation, resources, writing – review & editing, supervision; B.J.K: writing – review, supervision; M.B.: writing – review, supervision; L.H.: investigation, data curation, project administration; B.J.: investigation, data curation, project administration; A.M.: data curation, project

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