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A Randomized Clinical Study to Compare the Effectiveness of the Orthoptek Magnocellular Stimulator, Occlu-tab and Phakic Intraocular Lens in Refractive Amblyopia of Older Children and Young Adults

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ABSTRACT

Background: *The conventional management modality of refractive amblyopia is patching of the normal eye, which has high recurrence rates. Modern technological advancements have the potential to offer comprehensive visual rehabilitation and improvement in binocular single vision.*

Aims: *To compare the clinical efficacy of three novel interventions – Phakic intraocular lens (IOL), Occlu-tab and Orthoptek Magnocellular Stimulator – in managing refractive amblyopia in adolescents and young adults.*

Methods: *Young adults with refractive amblyopia who did not respond to occlusion therapy were randomized into three groups: Occlu-tab, Orthoptek and Phakic IOL. Pre- and post-treatment best-corrected visual acuity (BCVA), contrast sensitivity and stereoacuity were assessed.*

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Results: *All three modalities produced significant within-group improvements in BCVA, contrast sensitivity and stereoacuity ($p < 0.001$). Best-corrected visual acuity improved comparably across the three groups, including Orthoptek (mean gain 0.44), Occlu-tab (0.34) and Phakic IOL (0.29 logMAR). There was no statistically significant difference between groups ($p = 0.136$). Contrast sensitivity gains were higher for Occlu-tab (+0.78) and Orthoptek (+0.78) than for Phakic IOL (+0.59), with a significant between-group difference ($p = 0.003$). Stereoacuity has markedly improved with Occlu-tab (715.62 sec arc) and Orthoptek (713.54 sec arc)* versus *less improvement with a Phakic IOL (312.50 sec arc), with the between-group difference being highly significant ($p < 0.001$).*

Conclusion: *In terms of final binocular functional success rates, Orthoptek and Occlu-tab therapies were superior as compared to Phakic IOLs. A combination of amblyopia therapies should be the approach in the near future.*

Keywords: RCT, refractive amblyopia, Orthoptek Magnocellular Stimulator, Occlu-tab, and Phakic IOL.

BACKGROUND

Amblyopia, or lazy eye, is a neurodevelopmental ocular disease manifested as monocular and binocular impairments, including vision reduction, reduced contrast sensitivity, or even loss of stereoscopic vision. Objectively, it can be defined as a unilateral or, less commonly, bilateral reduction in the best corrected visual acuity that cannot be attributed directly to the effect of any structural abnormality of the eye or the posterior visual pathway with a difference of at least two lines. Consequences of amblyopia include poor stereovision, visual acuity, pattern recognition and low sensitivity to motion and contrast. The worldwide incidence of lazy eye is 4-5% and develops from birth to seven years of age. (1) The earlier the onset of amblyopiagenic factors, the greater the deficit. It is four times more common in premature children and six times more common in children with delayed milestones. Ingestion of certain drugs and alcohol during the gestation period also increases the risk of amblyopia. Refractive amblyopia is one of the major causes of visual impairment in children and young adults due to unequal refractive errors between the two eyes or high refractive errors in both eyes lead to disruption of normal visual development (2). The current standard treatment remains occlusion therapy of the fellow eye, but the recurrence rate is still high, ranging between 25–50%. Also, traditional therapies focus on correcting distant visual acuity only (3). Recent research has focused on the eye-brain ability to process motion, shape perception, spatial interaction, hyperacuity, contour integration and binocular single vision (BSV) components that can also be treated without cumbersome patching therapy (4). With technological advancements in optical and digital platforms, various novel modalities of amblyopia management are available. Despite the availability of dichoptic therapies, including Bynocs, CureSee and ReVital, their high costs make them less affordable. Newer treatment options like phakic intraocular lens implantation, Occlu-tab digital therapy and the Orthoptek Magnocellular Stimulator have shown promise in enhancing visual outcomes and achieving faster and sustainable binocular function (5-8). Orthoptek is a non-invasive instrument used in the treatment of amblyopia of different types and other ocular disorders, like nystagmus, fourth and sixth nerve palsies, loss of stereopsis and cerebral palsy. While using this instrument, there is a sequential stimulation of the magnocellular and parvocellular pathways within a stipulated interval of milliseconds, which leads to stimulation of the frontoparietal area, which in turn sends down to the foveal area in V1 a glutamatergic top-down modulating influence.

This top-down impulse is believed to facilitate cortical plasticity through activation of visual cortical pathways and modulation of neurotransmitter systems, resulting in recovery from suppression even in older children, adolescents and young adults beyond the traditional critical period of amblyopia treatment. Visual improvement is often subjectively noticed by patients after the

first few treatment sessions. (9) The present study was undertaken to compare the clinical outcomes of three contemporary treatment modalities – Phakic Intraocular Lens (IOL), Occlu-tab and Orthoptek Magnocellular Stimulator – in adolescents and young adults with refractory refractive amblyopia, with particular emphasis on visual acuity, contrast sensitivity and binocular single vision outcomes. ❑

METHODS

We conducted a prospective interventional randomized clinical trial (RCT) in patients with refractive amblyopia aged 10 to 23 years from January 2021 to August 2022 in a tertiary care center. We randomized 24 eyes of 22 patients to three groups, including the Orthoptek Magnocellular Stimulator (Carditek Pvt. Ltd., Bangalore, Karnataka, India), Occlu-Tab (Yaguchi Electric Corporation, Japan) and Phakic Intraocular Lens (Eyecryl, Biotech Pvt. Ltd., Ahmedabad, Gujarat, India). To ensure statistical rigor while including both unilateral and bilateral amblyopia cases, the primary analysis was to assess changes in logMAR visual acuity using either a generalized estimating equation or a mixed-effects model, which incorporated a random patient intercept to account for correlations between eyes. Allowing for a conservative dropout rate of 15%, a sample size of 24 eyes per group achieves 80% power to detect a clinically relevant difference of 0.15 logMAR (with a standard deviation of 0.15) in visual acuity improvement between three groups. Multiple comparisons were controlled by applying a Bonferroni-adjusted significance level of $\alpha = 0.0167$. We did the most rigorous double-block computer-generated randomization-sealed envelope method to generate the randomization sequence. This system creates unique randomized alphanumeric codes tied directly to the treatment assignments. It also defined three study arms and utilized randomly mixed block sizes to prevent investigators from predicting the final participant assignment in a block. For allocation concealment, the double block sizes remained concealed from researchers using a centralized Interactive Web Response System (IWRS) to acquire the assignment only after a participant had been enrolled.

Patients with bilateral refractive amblyopia were equally distributed in all three groups to observe effectiveness in all types of refractive amblyopia. The study was single-blinded, as the principal investigator did not assess the pre- and post-therapy parameters.

This study was initiated after due approval from the Institutional Ethics Committee and was conducted in accordance with the Declaration of Helsinki. In patients under 18 years of age, informed consent was documented from parents, and in those aged over 18 from the patient in addition to a minimum of one witness. This trial was registered with the Clinical Trial Registry of India (number CTRI/2021/01/030394).

The inclusion criteria comprised: patients aged 10–23 years with best corrected distance visual acuity (BCVA) recorded on the log of minimum angle of resolution (logMAR) chart in the amblyopic eye of less than 0.2; refractive amblyopia patients not improving with glasses or contact lenses and occlusion therapy for three months; and anterior chamber depth of >2.8 mm and endothelial density more than 2700 cells/mm^2 *as per* the standard protocol for Phakic IOL under aseptic conditions – for the safety of patients in the Phakic IOL group, we followed the strict surgical criteria *as per* the study by Morya *et al*. and the Amblyopia subsection on Phakic IOL on Eyewiki (5, 17); and refractive amblyopia of all types with stable refractive error for a year.

Patients with strabismic amblyopia or other amblyopias, those with history of glaucoma, active inflammation, cataract, previous intraocular surgery, or any other ocular disease, and patients who refused to be a part of this study or lost to follow-ups were all excluded.

A comprehensive ocular examination was performed on all patients. This included recording the demographics, unaided distant visual acuity (UCVA) and best-corrected visual acuity (BCVA) by digital logMAR chart; refraction; slit-lamp and fundus examination; Hirschberg corneal reflex for ocular alignment; cover, uncover, and alternate cover test; applanation tonometry for measuring intraocular pressure (IOP); optical coherence tomography (OCT); contrast sensitivity by Pelli Robson Chart; stereoacuity by Titmus Fly Stereo Test; corneal topography; pachymetry; and specular microscopy, which was performed on all patients. All patients randomized to the Phakic IOL arm fulfilled accepted surgical eligibility criteria, including sta-

ble refractive error for at least one year, anterior chamber depth greater than 2.8 mm, endothelial cell density greater than 2700 cells/mm^2, and absence of ocular pathology. Detailed counselling regarding treatment alternatives, benefits, and risks was provided before enrollment, and written informed consent was obtained from all participants or their guardians. Values beyond the measurable range of the test were recorded as 800 seconds of arc, which represented the ceiling value used for statistical analysis.

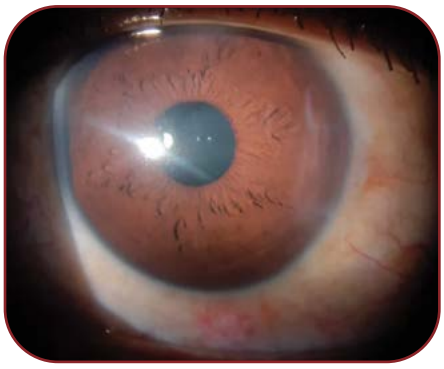


FIGURE 1. Phakic IOL in the eye

FIGURE 2. Occlu-tab therapy

FIGURE 3. Orthoptek Magnocellular Stimulator screen

All patients underwent occlusion therapy for three months before being randomized into the three interventional arms: Orthoptek Magnocellular Stimulator, Occlu-tab, or Phakic IOL. Patients in the Occlu-tab and Orthoptek groups were given binocular/dichoptic therapy after best-corrected glasses or contact lenses *as per* standard protocols for three months. Participants in all three groups were followed up at one week (early follow-up), two months (intermediate follow-up) and six months (late follow-up). Contrast sensitivity, stereoacuity, visual outcomes and any complications were duly noted at each follow-up visit. To avoid any confounding factors and heterogeneity in all the study arms, patients were not exposed to any other therapy during the total follow-up period of six months; otherwise, results would have been falsified.

Statistical analysis

Statistical analysis was performed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA). Data normality was assessed using the Shapiro–Wilk test. As BCVA, contrast sensitivity and stereoacuity data demonstrated non-normal distribution (Shapiro–Wilk $p < 0.05$), non-parametric statistical methods were employed. Continuous variables were expressed as mean ± SD and categorical variables as frequencies and percentages. Within-group comparisons across follow-up visits were analyzed using the Wilcoxon signed-rank test. Between-group comparisons involving all three treatment groups were performed using the Kruskal–Wallis test. When significant overall differences were identified, pairwise post-hoc comparisons were performed using the Mann–Whitney U test. Categorical variables were compared using the Chi-square test when expected cell frequencies were ≥5 and Fisher's exact test when expected frequencies were <5.

Since only two patients in each treatment arm contributed bilateral eyes, a sensitivity analysis restricted to one eye per patient demonstrated comparable results. Therefore, all eligible eyes were retained for the primary analysis. Temporal recovery trends were additionally illustrated using Kaplan-style recovery curves, while multidimensional treatment performance was

visualized using radar charts and violin plots. A p-value <0.05 was considered statistically significant throughout the analysis. ❑

RESULTS

The study included 72 eyes distributed equally among the three treatment groups, including Occlu-tab, Orthoptek and Phakic IOL. Baseline age and sex distribution were comparable across groups, with all three groups showing reduced baseline best-corrected visual acuity, poor contrast sensitivity and markedly reduced stereoacuity before treatment (Table 1). The Occlu-tab and Orthoptek groups were well matched at baseline in the uploaded comparative analysis.

Best-corrected visual acuity improved significantly in all three treatment groups (Table 2). Orthoptek showed the largest mean BCVA improvement, from 0.50 ± 0.32 logMAR to 0.06 ± 0.11 logMAR. Occu-tab improved from 0.42 ± 0.20 to 0.08 ± 0.07 logMAR and Phakic IOL from 0.40 ± 0.21 to 0.11 ± 0.13 logMAR. Although Orthoptek showed the greatest numerical gain, the between-group comparison for BCVA improvement was not statistically significant (Kruskal–Wallis p = 0.136), indicating that all three modalities produced clinically meaningful improvement without clear statistical superiority for BCVA alone. These findings are consistent with the comparative analysis showing significant within-group improvement but no significant Occlu-tab *versus* Orthoptek difference.

Contrast sensitivity improved significantly in all groups (Table 3). Occlu-tab and Orthoptek showed nearly identical final mean gains of +0.78, whereas Phakic IOL showed a smaller but still significant mean gain of +0.59. Orthoptek demonstrated the fastest early contrast sensitivity response, reaching 1.73 ± 0.15 at early follow-up, compared with 1.39 ± 0.20 in Occu-tab and 1.26 ± 0.15 in Phakic IOL. The

TABLE 1. Study groups and baseline profile

Parameter	Occlu-tab	Orthoptek	Phakic IOL
Sample size	24	24	24
Mean age, years	14.04 ± 3.62	14.67 ± 3.94	14.17 ± 3.50
Male:female	12:12	13:11	12:12
Baseline BCVA, logMAR	0.42 ± 0.20	0.50 ± 0.32	0.40 ± 0.21
Baseline contrast sensitivity	1.00 ± 0.21	1.00 ± 0.21	1.07 ± 0.22
Baseline stereoacuity, seconds of arc	800	800	800

BCVA: best-corrected visual acuity

TABLE 2. Best-corrected visual acuity (BCVA) changes over time

Time Point	Occlu-tab	Orthoptek	Phakic IOL
Baseline/pre-treatment	0.42 ± 0.20	0.50 ± 0.32	0.40 ± 0.21
Early follow-up	0.23 ± 0.13	0.25 ± 0.15	0.20 ± 0.11
Intermediate follow-up	0.12 ± 0.07	0.04 ± 0.06	0.14 ± 0.12
Final follow-up	0.08 ± 0.07	0.06 ± 0.11	0.11 ± 0.13
Mean improvement	0.34 ± 0.19	0.44 ± 0.27	0.29 ± 0.15
Within-group p-value	<0.001	<0.001	<0.001

TABLE 3. Contrast sensitivity changes over time

Time point	Occlu-tab	Orthoptek	Phakic IOL
Baseline/pre-treatment	1.00 ± 0.21	1.00 ± 0.21	1.07 ± 0.22
Early follow-up	1.39 ± 0.20	1.73 ± 0.15	1.26 ± 0.15
Intermediate follow-up	1.73 ± 0.15	1.81 ± 0.12	1.65 ± 0.22
Final follow-up	1.78 ± 0.08	1.78 ± 0.17	1.67 ± 0.21
Mean improvement	+0.78 ± 0.21	+0.78 ± 0.20	+0.59 ± 0.21
Within-group p-value	<0.001	<0.001	<0.001

TABLE 4. Stereoacuity changes over time

Time point	Occlu-tab	Orthoptek	Phakic IOL
Baseline/pre-treatment	800	800	800
Early follow-up	175.00 ± 51.08	110.42 ± 29.41	687.50 ± 93.22
Intermediate follow-up	116.67 ± 35.10	78.12 ± 8.45	587.50 ± 78.41
Final follow-up	84.38 ± 17.77	86.46 ± 35.34	487.50 ± 66.35
Mean improvement	715.62 ± 17.77	713.54 ± 35.34	312.50 ± 66.35
Within-group p-value	<0.001	<0.001	<0.001

Final outcome	Occlu-tab	Orthoptek	Phakic IOL
BCVA ≤0.1 logMAR	20/24 (83.3%)	22/24 (91.7%)	13/24 (54.2%)
Contrast sensitivity ≥1.8	23/24 (95.8%)	21/24 (87.5%)	16/24 (66.7%)
Stereoacuity ≤100 sec arc	23/24 (95.8%)	22/24 (91.7%)	0/24 (0%)

BCVA: best-corrected visual acuity

TABLE 5. Final functional success rates

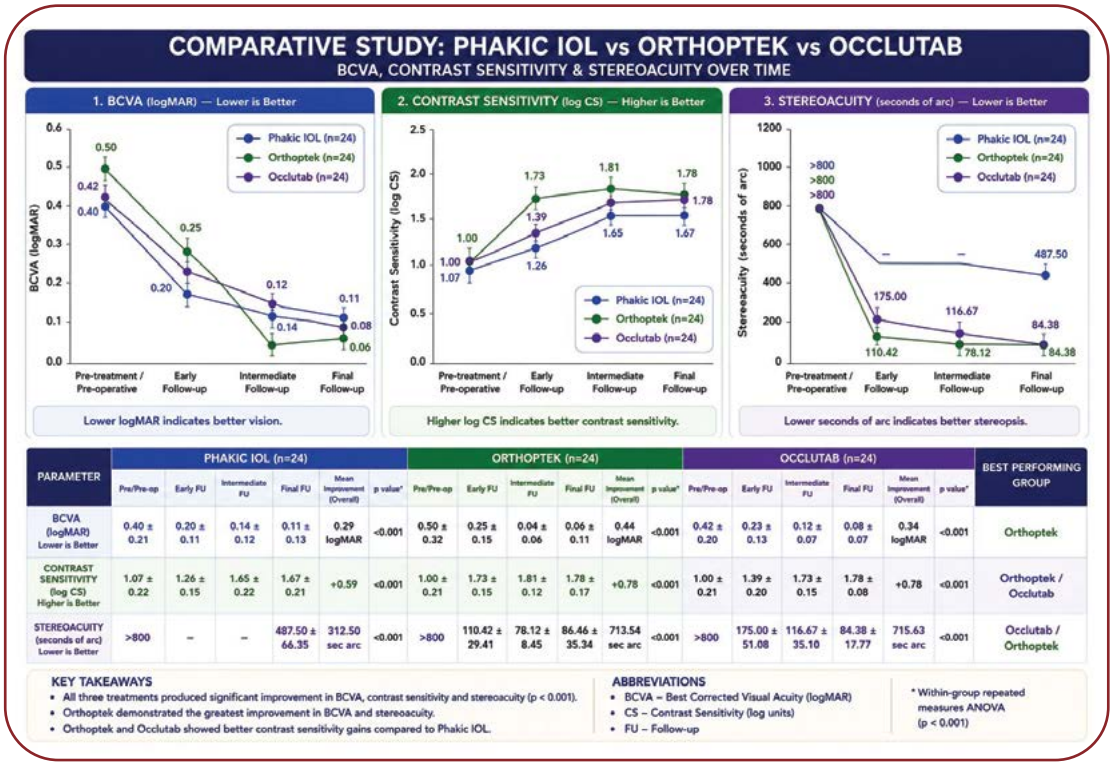


FIGURE 4. Final functional success rate-comparative chart

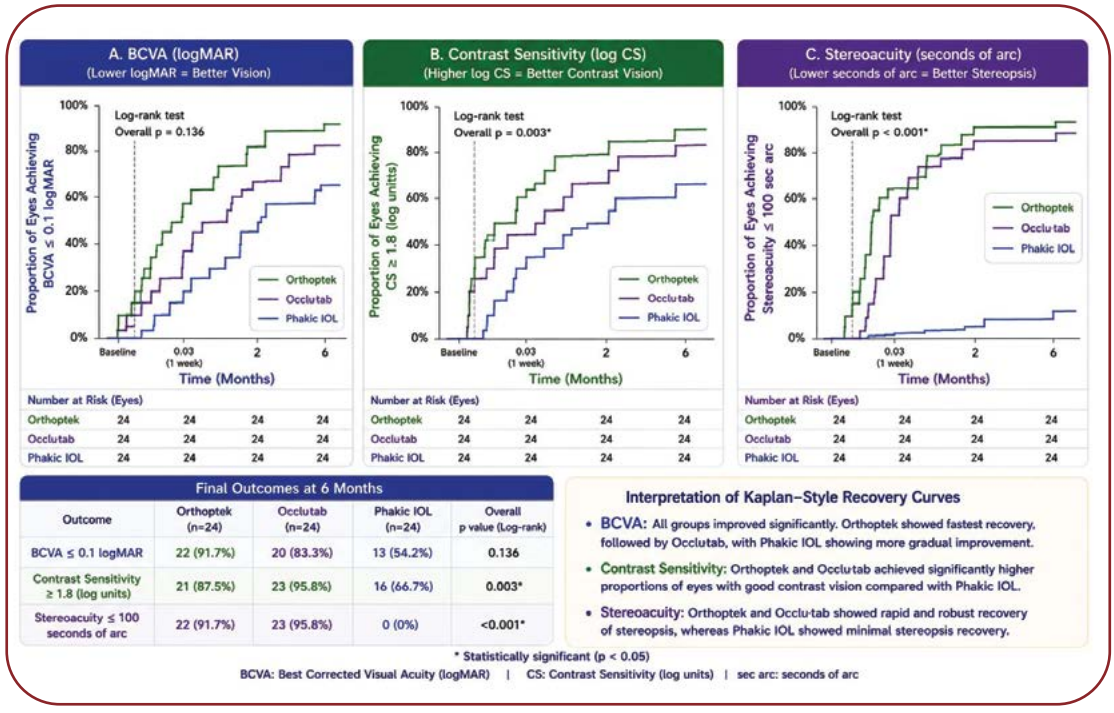
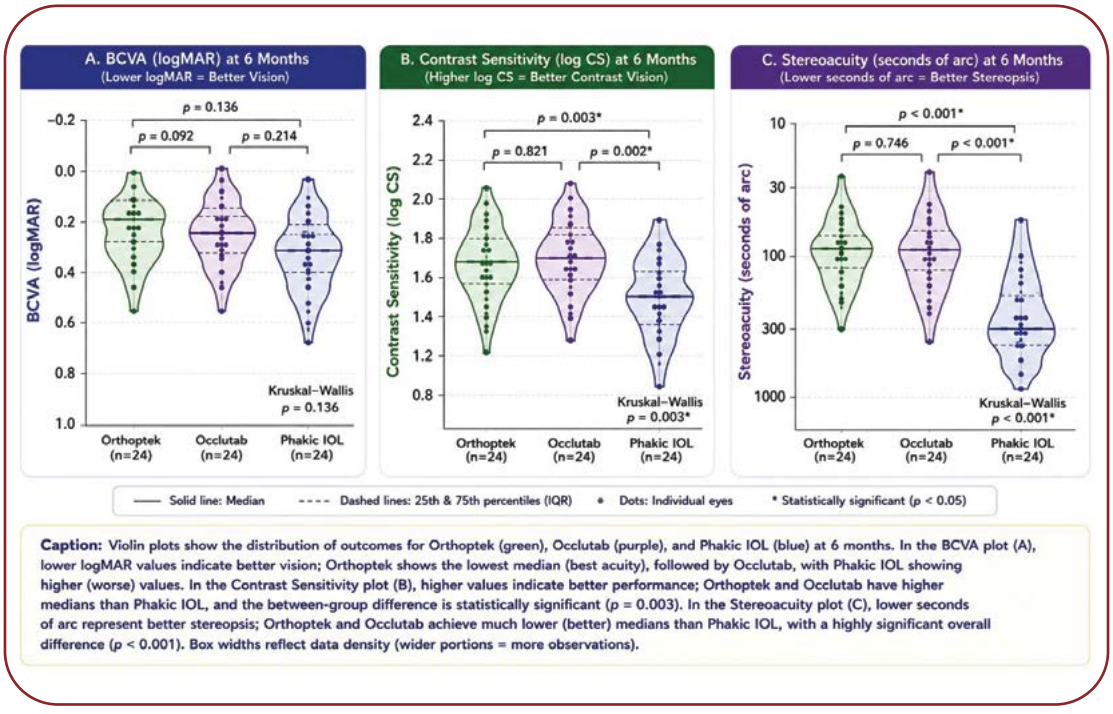
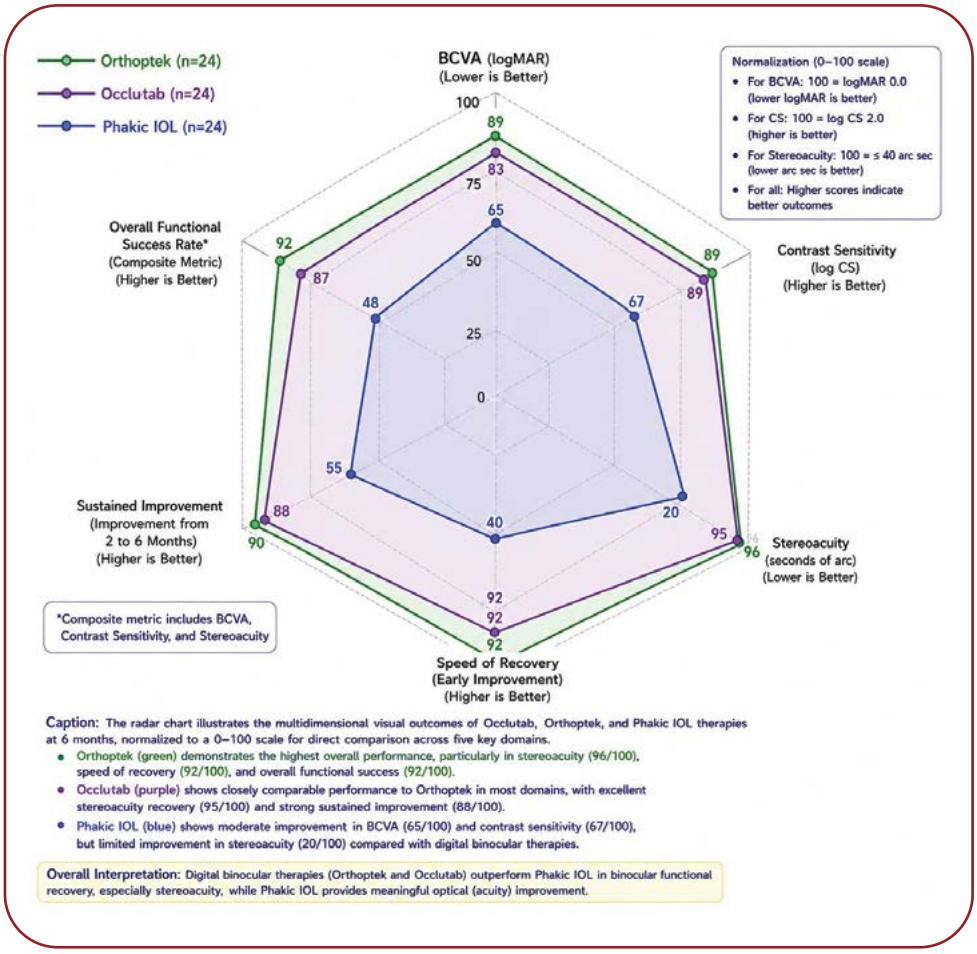


FIGURE 5. Kaplan-style recovery curves: Occlu-tab *vs* Orthoptek *vs* Phakic IOL



Caption: Violin plots show the distribution of outcomes for Orthoptek (green), Occlutab (purple), and Phakic IOL (blue) at 6 months. In the BCVA plot (A), lower logMAR values indicate better vision; Orthoptek shows the lowest median (best acuity), followed by Occlutab, with Phakic IOL showing higher (worse) values. In the Contrast Sensitivity plot (B), higher values indicate better performance; Orthoptek and Occlutab have higher medians than Phakic IOL, and the between-group difference is statistically significant ($p = 0.003$). In the Stereoacuity plot (C), lower seconds of arc represent better stereopsis; Orthoptek and Occlutab achieve much lower (better) medians than Phakic IOL, with a highly significant overall difference ($p < 0.001$). Box widths reflect data density (wider portions = more observations).

FIGURE 6. Radar chart of multidimensional outcomes at six months



Caption: The radar chart illustrates the multidimensional visual outcomes of Occlutab, Orthoptek, and Phakic IOL therapies at 6 months, normalized to a 0–100 scale for direct comparison across five key domains.

- Orthoptek (green) demonstrates the highest overall performance, particularly in stereoacuity (96/100), speed of recovery (92/100), and overall functional success (92/100).
- Occlutab (purple) shows closely comparable performance to Orthoptek in most domains, with excellent stereoacuity recovery (95/100) and strong sustained improvement (88/100).
- Phakic IOL (blue) shows moderate improvement in BCVA (65/100) and contrast sensitivity (67/100), but limited improvement in stereoacuity (20/100) compared with digital binocular therapies.

Overall Interpretation: Digital binocular therapies (Orthoptek and Occlutab) outperform Phakic IOL in binocular functional recovery, especially stereoacuity, while Phakic IOL provides meaningful optical (acuity) improvement.

FIGURE 7. Violin plots of treatment outcomes at six months

between-group difference in contrast sensitivity gain was statistically significant (Kruskal–Wallis $p = 0.003$), suggesting stronger functional visual quality recovery with Occlu-tab and Orthoptek than with Phakic IOL.

Stereoacuity was checked using the Titmus Fly Stereo test, showing the most striking difference between treatment modalities (Table 4). Occlu-tab improved from 800 seconds of arc to 84.38 ± 17.77 seconds of arc and Orthoptek from 800 to 86.46 ± 35.34 seconds of arc. These values indicate restoration of fine stereopsis in most patients. In contrast, Phakic IOL improved from 800 to 487.50 ± 66.35 seconds of arc, showing partial binocular recovery but not the same level of fine stereopsis achieved by the binocular therapy groups. The between-group difference in stereoacuity improvement was highly significant (Kruskal–Wallis $p < 0.001$). This supports the interpretation that Occlu-tab and Orthoptek are superior for binocular sensory rehabilitation, while Phakic IOL primarily improves optical clarity and visual acuity.

Final functional success was highest for the binocular therapy groups (Table 5). Occlu-tab and Orthoptek achieved high rates of good BCVA, high contrast sensitivity and fine stereoacuity, while Phakic IOL achieved meaningful BCVA and contrast sensitivity improvement, with none of the eyes reaching stereoacuity ≤100 seconds of arc at the final follow-up. The Kaplan-style recovery curve test was appropriate for measuring clinical visual improvement at specific time points. ❑

DISCUSSION

To the best of our knowledge, this is the first RCT comparing these three modalities in the treatment of amblyopia in adolescents and young adults. Each of the analysed interventions has been shown to be effective in treating amblyopia in children and young adults.

The effectiveness of treating amblyopia in children using a Phakic IOL has been established in several previous case series and has been described much earlier than Occlu-tab and Orthoptek, which are relatively more recent interventions. Lesueur *et al.* (10) showed good results with a Staar Surgical Phakic IOL in 12 eyes of 11 children with a mean postoperative BCVA of 20/63. Similarly, Althomali (11) reported significant improvement in spherical equivalent cycloplegic refraction and corrected distance visual acuity in a series of six patients. Similar benefits were seen in small series by BenAzra *et al.* (12). A recent study of Morya *et al.* (5) showed that children had an improvement in visual acuity of an average of 2.6 lines at three months, which was maintained at a year. Endothelial loss, thought to be a concern with this method of treatment, was noted to be insignificant in their study. While the Phakic IOL itself does not directly "revamp" the brain, it maximizes the optical input required to do so. By placing a clear, well-focused image on the retina of the amblyopic eye, the brain is encouraged to break cortical suppression as the phenomenon of aniseikonia is prevented (12).

The modality of a modified iPad or Occlu-tab was first described by Handa *et al.* (13) in their series of seven patients with promising results. Subsequently, Iwata *et al.* (14) found similar encouraging results in their series of 22 patients. The same group performed an RCT between glasses only and a combination of glasses with an Occlu-tab device, demonstrating superiority of the latter method in terms of visual acuity (15). They also showed that the compliance rate with the Occlu-tab device approximated 70% at six months. This indicates an improvement over occlusion therapy, in which low compliance rates of children remain a key concern. In a prospective study comparing eye-patch with Occlu-tab, Handa *et al.* (8) showed a significantly greater improvement in BCVA with Occlu-tab than with eye-patch. Similarly, a study conducted by Jethani *et al.* (7) in a younger cohort with a mean age of 6.8 years reported a significant improvement with supplemental Occlu-tab therapy in patients where partial occlusion had been unsuccessful. Kelly *et al.* (16) carried-out an RCT with 14 patients in each arm that compared Occlu-tab with patching. They showed that Occlu-tab was more efficacious than patching at two weeks, but their study had the shortcoming of a short follow-up of only four weeks.

The use of an Orthoptek Magnocellular Stimulator (OMS) was described by Santhan Gopal *et al.* in 2020 (9). This device is based on the principle of stimulating the overt attention center in the brain, which then stimulates the lateral occipital cortex. In a series of 35 patients, success was noted in 94% of subjects with significant im-

provements in stereopsis, visual acuity and strabismus.

The comparison between Phakic IOL and binocular rehabilitation therapies requires careful interpretation because these interventions target different components of amblyopia. Phakic IOL implantation primarily addresses the optical component by correcting high refractive error and reducing retinal image blur, whereas Occlu-tab and Orthoptek are designed to enhance cortical plasticity, binocular integration and sensory rehabilitation. No postoperative patching, perceptual learning, or binocular training was administered in the Phakic IOL group. Consequently, although Phakic IOL significantly improved visual acuity, its ability to restore fine stereopsis was inherently limited when compared with active binocular rehabilitation strategies.

In our study, all three treatment modalities, including Occlu-tab, Orthoptek and Phakic IOL, produced significant improvements in visual function in amblyopic eyes. Best-corrected visual acuity improved in each group, confirming that all three approaches can meaningfully contribute to visual rehabilitation. Although Orthoptek demonstrated the greatest numerical gain in BCVA over time, the differences between groups were not statistically significant.

Improvements in contrast sensitivity were observed across all arms. However, Occlu-tab and Orthoptek achieved stronger final gains than the Phakic IOL, with Orthoptek showing more rapid early recovery. These findings suggest that digital and binocular therapies may offer additional benefits beyond acuity, enhancing the overall quality of visual processing.

The most notable distinction between treatments emerged in stereoacuity. Occlu-tab and Orthoptek produced substantial recovery, shifting patients from poor baseline stereopsis into the fine stereopsis range by final follow-up. In contrast, Phakic IOL yielded only partial improvement. This indicates that Occlu-tab and Orthoptek are more effective at promoting *versus* visual recovery, a key goal in modern amblyopia management.

Limitations of the study

The present study included a small number of bilateral amblyopic patients, resulting in limited inter-eye dependency. Although sensitivity analysis demonstrated no meaningful change in outcomes, future studies employing generalized estimating equations or mixed-effects modelling would provide more robust adjustment for correlated ocular data. Additionally, the follow-up period was limited to six months, so a longer-term evaluation is required to determine the durability of binocular visual rehabilitation achieved with these treatment modalities.

CONCLUSION

In summary, Phakic IOL remains a valuable option for optical rehabilitation in selected amblyopic eyes with high refractive error, particularly when refractive correction is the primary barrier to vision. Nevertheless, Occlu-tab and Orthoptek demonstrated superior binocular functional outcomes, especially in stereoacuity and contrast sensitivity. Collectively, these results highlight digital binocular therapy as a central component of sensory rehabilitation in amblyopia, while positioning Phakic IOL as a useful adjunctive optical strategy rather than a standalone solution. ❑

Conflicts of interest: none declared.
Financial support: none declared.

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