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Analyzing Real World Outcomes, Identifying Key Management Challenges, and Uncovering Distinct Patient Subgroups in Amblyopia Treatment Through a Large Scale Retrospective Database Study

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Abstract: *This study aims to evaluate real-world outcomes in amblyopia treatment, identify key challenges in long-term management, and characterize distinct patient subgroups using a large retrospective dataset of pediatric patients at a tertiary eye center. A total of 2,044 patients were analyzed using standardized IRIS7 and IRIS50 success criteria. Risk factors for treatment dropout were examined using multivariable logistic regression, and a predictive risk score was developed to estimate the probability of loss to follow-up (LTFU). The findings revealed that 71% and 81% of patients met success under IRIS7 and IRIS50 criteria, respectively. However, 23% were lost to follow-up, with six factors—such as lack of insurance, older age, and prior occlusion—predicting discontinuation. AUC for the LTFU risk calculator was 0.68, indicating moderate predictive ability. Additionally, patients with asymmetric bilateral amblyopia demonstrated comparable improvement with glasses alone versus early occlusion, suggesting a potential revision in treatment protocols. These findings underscore the importance of personalized amblyopia care, predictive follow-up tools, and standardized outcome measures to improve adherence and visual outcomes.*

Introduction

Amblyopia, commonly referred to as "lazy eye," is the leading cause of monocular visual impairment among children in developed countries, affecting approximately 2–4% of the pediatric population. It results from disrupted visual development during the sensitive period of neuroplasticity, often due to strabismus, anisometropia, or visual deprivation, which leads to under-stimulation of the visual cortex. Despite being a treatable condition, the efficacy of amblyopia interventions in real-world settings remains inadequately characterized. Most existing knowledge stems from controlled clinical trials conducted by groups such as the

Pediatric Eye Disease Investigator Group (PEDIG), which often exclude diverse patient populations and practical challenges faced in everyday clinical environments.

Real-world evidence (RWE) plays an increasingly important role in understanding the effectiveness of treatment protocols outside the idealized context of randomized trials. In amblyopia care, where early intervention and strict adherence are crucial to achieving optimal visual outcomes, variables such as socioeconomic status, insurance coverage, race/ethnicity, and follow-up compliance may significantly influence treatment success. Yet, few large-scale retrospective studies have investigated these factors systematically, leaving a critical gap in evidence-based approaches to amblyopia management.

Moreover, uniform benchmarks to define successful treatment outcomes have historically been lacking. To address this, the American Academy of Ophthalmology (AAO) proposed the IRIS7 and IRIS50 measures as standardized criteria to assess amblyopia therapy success. However, their adoption in clinical practice remains limited, and their validity in diverse real-world cohorts has yet to be comprehensively evaluated. In addition, the challenge of lost to follow-up (LTFU) persists as a significant barrier to long-term visual improvement, especially in vulnerable populations. Identifying predictive characteristics of LTFU is crucial to devising timely interventions and support strategies.

Another underexplored area is the characterization of specific patient subgroups, such as those with asymmetric bilateral amblyopia a rare but clinically significant variant where both eyes are amblyopic, yet with a notable interocular acuity difference. The optimal management strategy for these patients, particularly the timing of occlusion therapy relative to spectacle correction, remains controversial due to limited empirical data.

This study, based on a comprehensive retrospective database of over 2,000 amblyopia patients from a major pediatric ophthalmology center, seeks to bridge these evidence gaps. Specifically, it aims to (1) assess real-world treatment outcomes using IRIS7 and IRIS50 success measures, (2) identify demographic and clinical predictors of treatment discontinuation or follow-up loss, and (3) evaluate visual outcomes in the distinct subgroup of patients with asymmetric bilateral amblyopia. By integrating these objectives, this research provides a robust and multidimensional understanding of amblyopia care in practice, offering data-driven insights to inform clinical decision-making, enhance patient adherence, and support the development of targeted treatment protocols.

Although amblyopia has been extensively studied through randomized controlled trials, particularly those led by the Pediatric Eye Disease Investigator Group (PEDIG), there remains a significant gap in understanding how treatment protocols perform in real-world clinical settings. Most prior studies have focused on narrowly defined populations, often excluding patients with previous treatments, nonadherence patterns, or complex bilateral conditions, thereby limiting generalizability. Additionally, while the American Academy of Ophthalmology has proposed standardized metrics IRIS7 and IRIS50 for evaluating treatment success, these criteria have yet to be widely applied or validated in diverse clinical populations. A further gap lies in the limited understanding of the factors contributing to treatment discontinuation or loss to follow-up (LTFU), which poses a serious barrier to achieving

therapeutic outcomes but is rarely studied beyond initial screening failures. Moreover, distinct amblyopia subgroups, such as patients with asymmetric bilateral amblyopia, remain underrepresented in both prospective and retrospective research, leaving a void in evidence-based guidance for managing these atypical presentations.

This study offers several novel contributions to address these limitations. First, it applies both IRIS7 and IRIS50 criteria to a large, real-world cohort of amblyopia patients, directly comparing their effectiveness and predictive validity. Second, it introduces a multivariable, point-based risk score to predict LTFU at the time of diagnosis providing a proactive tool to guide clinical intervention. Third, it is the first to systematically evaluate treatment outcomes in patients with asymmetric bilateral amblyopia, comparing visual and stereopsis improvements between primary and secondary occlusion strategies. The findings suggest that spectacle correction alone may suffice in many cases, challenging conventional assumptions about early occlusion therapy. By utilizing a comprehensive retrospective database of over 2,000 patients across all amblyopia subtypes, this study bridges the gap between controlled trial data and the complexities of real-world patient care, offering critical insights to refine clinical practice and policy-making in pediatric ophthalmology.

Research Methods

This study employed a retrospective cohort design using a large-scale, single-center database drawn from Boston Children's Hospital (BCH), encompassing pediatric patients diagnosed with amblyopia between 2010 and 2014. Patient data were identified through ICD-9 billing codes (368.xx) corresponding to various amblyopia subtypes. Medical charts were manually reviewed to extract detailed information including patient demographics, family and ocular history, baseline visual acuity (VA), refractive error, stereopsis, sensorimotor findings, treatment types, and follow-up data. Best corrected visual acuity (BCVA) was measured by trained orthoptists using Snellen, HOTV, or LEA optotypes, depending on the patient's age and literacy, and recorded in logMAR format. Amblyopia type was categorized as anisometropic, strabismic, mixed, or deprivation, following specific clinical thresholds, while severity was classified based on BCVA ranges.

The study was structured into three analytic phases. First, to evaluate treatment success, patients aged 3–7 years without prior treatment and with sufficient interocular difference (IOD > 0.29 logMAR) were included for assessment using the American Academy of Ophthalmology's IRIS7 and IRIS50 criteria. Success rates were calculated, and predictor variables such as age, race, insurance type, initial VA, and treatment modality were analyzed using univariate tests and multivariable logistic regression models. Second, to investigate predictors of treatment discontinuation, a separate analysis was conducted on patients aged 2–12 years to determine loss to follow-up (LTFU) status, defined as failure to return after the initial visit. Predictive variables were tested using logistic regression, and a risk score calculator was developed by assigning weights to each independent predictor based on adjusted odds ratios. Receiver operating characteristic (ROC) curve analysis was employed to assess the model's predictive accuracy.

The third component focused on a rare but clinically important subgroup: patients with

asymmetric bilateral amblyopia, defined as bilateral BCVA ≥0.3 logMAR and IOD ≥0.18 logMAR. Patients meeting these criteria were divided into two treatment cohorts: those who received primary occlusion therapy (patching or atropine initiated at diagnosis) and those who received secondary occlusion therapy (initiated after spectacle correction showed improvement in the better-seeing eye). Visual outcomes including VA, IOD, and stereopsis were measured at baseline, 12–18 months, and last visit, then compared between groups using non-parametric tests due to skewed data distribution. Stratified analyses were also performed by amblyopia subtype to control for confounding factors.

All statistical analyses were conducted using Stata version 15.0, with a significance level set at $p < 0.05$. Ethical approval was obtained from the BCH Institutional Review Board, and the study adhered to the tenets of the Declaration of Helsinki. Informed consent was waived due to the retrospective nature of the study.

Result and Discussion

The analysis of a comprehensive dataset encompassing 2,037 pediatric amblyopia patients treated at Boston Children's Hospital revealed several critical insights into the effectiveness of amblyopia interventions in real-world clinical settings. When treatment outcomes were assessed using the IRIS7 criteria defined by the American Academy of Ophthalmology (AAO) as a final interocular difference (IOD) <0.23 logMAR at 12–18 months 71% of patients achieved successful results. This rate increased to 81% when using the IRIS50 metric, which broadens the definition of success to include (a) VA improvement of ≥0.18 logMAR, (b) final VA ≤0.18 logMAR, or (c) IOD <0.23 within 3–12 months. Notably, private insurance status and lower baseline IOD were significant independent predictors of success under IRIS7, while no variables showed predictive value under IRIS50. These results underscore the greater inclusivity and flexibility of IRIS50, especially for patients with more severe baseline visual deficits, and suggest it may be a more practical benchmark for diverse clinical populations.

The comparison between IRIS7 and IRIS50 further highlights differences in patient stratification and follow-up timelines. IRIS7 requires longer follow-up, potentially capturing more sustained improvement but also increasing the risk of patient attrition. In contrast, IRIS50 reflects shorter-term gains and may be more aligned with health system reporting requirements. This divergence is particularly relevant in real-world clinical settings, where patient adherence and timely return visits are inconsistent. Despite the robust outcome rates, it is concerning that only 19% of the total cohort met all inclusion criteria for IRIS-based analysis. A significant portion of patients were excluded due to prior treatment, insufficient IOD at baseline, or bilateral amblyopia. This finding illustrates a key limitation of current outcome metrics and signals the need for expanded or alternative criteria that accommodate the broader amblyopia spectrum.

One of the most significant challenges identified in this study was the high rate of loss to follow-up (LTFU)—a critical obstacle to long-term treatment success. Among 1,396 patients eligible for LTFU analysis, 23% failed to return after their initial visit. Multivariate logistic regression revealed that six variables were independently predictive of LTFU: lack of

insurance, previous atropine treatment, previous glasses treatment, requested follow-up interval ≥3 months, patient age >6 years, and African American race. The strongest predictor was lack of insurance, which conferred an odds ratio (OR) of 4.26, followed by previous atropine treatment (OR 2.48) and glasses (OR 2.23). These findings suggest that socioeconomic vulnerability and perceived treatment burden significantly impact continuity of care. Interestingly, previous treatment history—usually assumed to indicate commitment—was negatively associated with follow-up, possibly due to prior poor experiences or perceived futility.

To address this issue, the study introduced a multivariable LTFU risk score. This scoring system, developed by converting the regression coefficients into integer points, allows clinicians to stratify patients based on predicted risk of non-return. ROC curve analysis yielded an AUC of 0.68, suggesting moderate predictive value. While the score's performance falls short of high-precision diagnostic tools, its clinical utility lies in early flagging of at-risk patients, prompting proactive strategies such as shorter return intervals, patient education, or social work referrals. In an era of electronic medical record (EMR) integration, such tools could be automated and embedded into clinical workflows, enhancing decision support.

The third major contribution of this study lies in the evaluation of a relatively rare but clinically significant subgroup: asymmetric bilateral amblyopia, which affected 7.6% of the overall cohort. Among 98 patients meeting strict inclusion criteria, outcomes were compared between those receiving primary occlusion therapy (e.g., patching or atropine initiated at diagnosis) and those receiving secondary occlusion therapy (initiated only after spectacle correction failed to normalize interocular acuity). Both groups demonstrated significant improvement in VA of both eyes, IOD, and stereopsis over the study period. Specifically, median VA improvement was 0.4 logMAR in the weaker eye and 0.2 logMAR in the stronger eye, with no statistically significant difference between treatment strategies ($p \geq 0.48$). Furthermore, although the secondary occlusion group showed earlier gains by the 12–18-month interval, both groups reached similar visual acuity and stereoacuity levels at final follow-up.

Stratification by amblyopia subtype (anisometropic, strabismic, and mixed) did not alter these findings, although some baseline differences were noted. The primary occlusion group had a higher percentage of strabismic amblyopes and worse baseline stereopsis, while the secondary group included more anisometropic cases with relatively better binocular function. These variations underscore the clinical heterogeneity of bilateral amblyopia, but the lack of outcome disparity suggests that initial spectacle correction alone may be a sufficient first-line approach. Delaying occlusion therapy until refractive adaptation is complete may reduce treatment burden without compromising efficacy a critical insight for pediatric care, where adherence to patching or atropine can be especially challenging.

Importantly, this study also confirmed prior literature suggesting that measurable baseline stereopsis is a strong predictor of stereopsis recovery. Among patients who regained functional depth perception (≤100 arcsec), the majority had anisometropic amblyopia with some stereoacuity at baseline. Strabismic amblyopes particularly those excluded from surgical correction rarely achieved meaningful stereopsis, highlighting the limitations of non-surgical therapy in certain cases.

Taken together, these findings have several practical implications. First, they validate the real-world applicability of IRIS-based metrics and propose IRIS50 as a more inclusive and equitable standard for outcome evaluation. Second, they identify critical social and clinical factors contributing to treatment discontinuation and provide a tool to mitigate such risks. Third, they offer evidence-based guidance for managing complex amblyopia subtypes, particularly in minimizing unnecessary early occlusion therapy. Finally, by encompassing the full spectrum of amblyopia patients, including those often excluded from clinical trials, this study bridges the gap between research protocols and actual clinical care, supporting a more personalized, data-driven approach to pediatric ophthalmology.

Despite its contributions, the study is not without limitations. As a retrospective review, it is subject to potential inaccuracies in documentation, measurement variability, and unmeasured confounders such as parental understanding or socioeconomic background. The lack of objective adherence metrics for glasses and patching also limits conclusions regarding treatment compliance. Nonetheless, the large sample size, detailed manual chart review, and real-world setting lend strength and external validity to its conclusions.

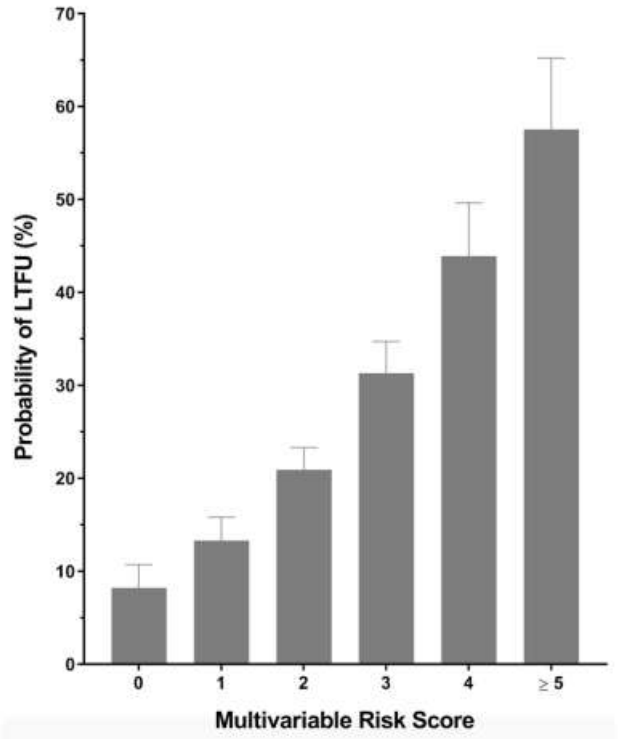

Figure 1. Probability of lost-to-follow-up status in amblyopia therapy based on multivariable risk score

Figure 1 illustrates the predicted probability of loss to follow-up (LTFU) among amblyopia patients based on a multivariable risk score derived from six independent predictors. Each patient was assigned a risk score ranging from 0 to ≥6 by summing integer weights corresponding to the presence of specific risk factors identified through logistic regression analysis. These included lack of health insurance, previous atropine treatment, previous use of glasses, follow-up interval of three months or more, age over six years at initial visit, and non-

white race (specifically, African American background). The scoring system was created by converting the regression coefficients (log-odds) into point values, which were then summed to produce an individualized risk score for each patient.

The curve demonstrates a positive correlation between cumulative risk score and probability of LTFU. At the lowest end, patients with a risk score of 0 had a predicted LTFU probability of only 8.2%, suggesting high adherence potential. In contrast, those with a risk score of 5 or higher faced a predicted LTFU probability of 57.5%, indicating substantial risk of disengagement from care. The shape of the curve is nonlinear, reflecting an accelerating likelihood of LTFU as multiple risk factors accumulate.

This figure highlights the clinical utility of the risk score model as a simple yet informative tool for identifying patients at high risk of treatment discontinuation early in the care process. By incorporating routinely collected demographic and clinical information, clinicians can proactively target these individuals with tailored interventions such as shorter follow-up intervals, enhanced patient education, or case management support. Although the overall discriminative ability of the model (AUC = 0.68) suggests moderate predictive accuracy, its integration into electronic medical record (EMR) systems could facilitate scalable, real-time decision support in pediatric ophthalmology settings. Ultimately, this risk-based approach aligns with precision medicine goals by improving retention and optimizing visual outcomes for amblyopia patients.

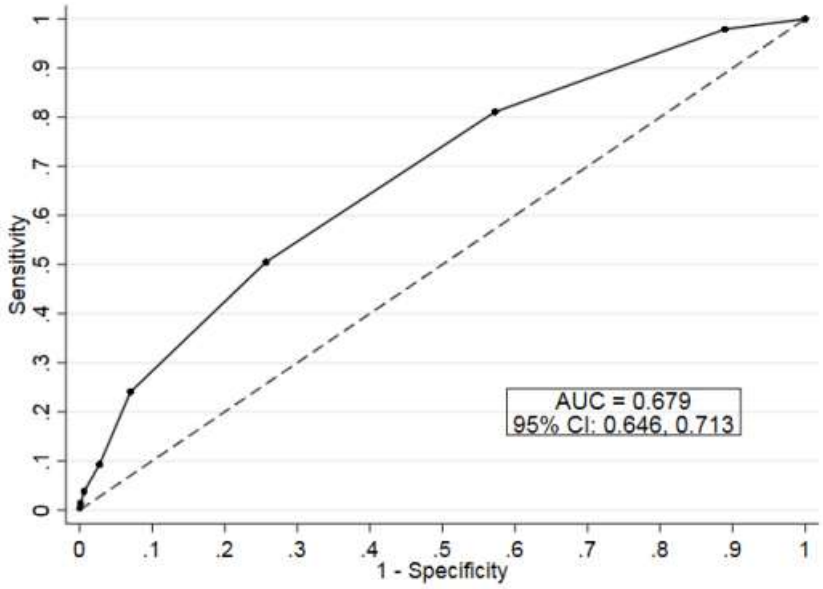

Figure 2. ROC curve for risk calculator predicting lost-to-follow-up status in amblyopia therapy

Figure 2 presents the Receiver Operating Characteristic (ROC) curve evaluating the performance of the multivariable risk calculator developed to predict loss to follow-up (LTFU) among pediatric amblyopia patients. The risk calculator was derived from six independent predictors identified via multivariate logistic regression and converted into a cumulative scoring system. The ROC curve plots the sensitivity (true positive rate) against 1-specificity (false

positive rate) at various threshold levels of the total risk score, offering a graphical representation of the model's discriminative ability.

The area under the ROC curve (AUC) was calculated to be 0.68 (95% CI: 0.65–0.71), indicating moderate predictive accuracy. An AUC of 0.5 denotes no predictive ability (equivalent to chance), while an AUC of 1.0 indicates perfect discrimination. Although the AUC in this study does not reach high diagnostic accuracy, the score still holds clinical value for early risk stratification. Notably, the model correctly identifies a substantial portion of patients at higher risk of LTFU, which is critical in amblyopia care where treatment adherence is time-sensitive and essential for visual development.

The curve's modest slope reflects the complex and multifactorial nature of patient adherence behavior, which may involve socioeconomic, educational, and psychosocial determinants not captured in the available dataset. Nonetheless, this tool serves as an initial framework for identifying high-risk patients and implementing targeted follow-up strategies. Integration of this scoring system into electronic health records (EHR) could facilitate automated alerts and decision support, improving patient retention and ultimately enhancing treatment outcomes.

Table 1. Demographics and visual acuity description of the entire cohort, IRIS analysis

Variable	n (%) or median (IQR)
N	238
Age at first visit	4.9 (4.1, 5.6)
Race	
Asian	7 (3%)
Black or African American	13 (5%)
White	144 (61%)
Other	26 (11%)
Unknown	6 (3%)
Unable/Declined to Answer	42 (18%)
Insurance Payer	
Public	71 (30%)
Private	164 (69%)
None/Self Pay	3 (1%)
Type of amblyopia	
Anisometropic	133 (56%)
Strabismic	31 (13%)
Mixed	47 (20%)
None	27 (11%)
Family history of amblyopia	73 (31%)
Starting VA in worse eye	0.6 (0.4, 0.8)
Starting IOD	0.5 (0.3, 0.7)
Starting log stereoacuity	5.99 (4.61, 9.21)
Surgery	10 (4%)
Amblyopia treatment type[a]	
Glasses	217 (91%)
Patching	90 (38%)
Atropine	5 (2%)

Table 1 summarizes the baseline demographic characteristics and visual acuity parameters of the 238 amblyopia patients who met inclusion criteria for analysis using the IRIS7 and IRIS50 success metrics. The median age at first visit was 4.9 years (interquartile range

[IQR]: 4.1–5.6), aligning with the targeted age group for early intervention in amblyopia. The cohort had a predominantly White racial composition (61%), with smaller proportions identifying as Black or African American (5%), Asian (3%), or other (11%). Notably, 18% of patients declined to provide racial or ethnic information.

In terms of insurance status, 69% of patients were privately insured, 30% had public insurance, and only 1% were uninsured or self-pay. This relatively high rate of private coverage may reflect the institutional catchment area but is also consistent with the association found between insurance type and treatment success under IRIS7 criteria.

Regarding amblyopia subtypes, the majority of patients (56%) had anisometropic amblyopia, followed by mixed-type (20%) and strabismic amblyopia (13%). Eleven percent did not meet criteria for a specific subtype based on available clinical data. A positive family history of amblyopia was reported in 31% of cases.

The initial median visual acuity (VA) in the amblyopic eye was 0.6 logMAR (IQR: 0.4–0.8), indicating a moderate level of impairment. The median interocular difference (IOD) was 0.5 logMAR (IQR: 0.3–0.7), while the median log stereoacuity was 5.99 (IQR: 4.61–9.21), reflecting varying levels of binocular dysfunction.

In terms of treatment modality, 91% of patients were prescribed glasses, 38% received patching therapy, and only 2% were treated with atropine. These treatment patterns reflect adherence to PEDIG guidelines, in which optical correction is typically the first-line intervention, followed by occlusion or pharmacologic penalization if necessary.

This table provides critical context for understanding the real-world population evaluated through the IRIS framework. It also emphasizes the heterogeneity in patient characteristics particularly in amblyopia subtypes, baseline acuity, and stereopsis that can influence treatment outcomes and guide future subgroup-specific interventions.

Conclusion and Recommendation

This study provides a comprehensive real-world evaluation of amblyopia treatment outcomes using a large retrospective dataset from a pediatric ophthalmology center, revealing both promising results and significant challenges. The findings confirm that a majority of patients met success criteria based on standardized IRIS7 and IRIS50 measures, with IRIS50 demonstrating greater inclusivity and practical relevance for routine clinical use. However, the study also identified a substantial proportion of patients 23% who were lost to follow-up, a factor strongly influenced by socioeconomic and clinical variables such as lack of insurance, older age, and prior treatment history. The development of a multivariable risk score offers a novel, evidence based tool to predict and potentially prevent LTFU, enabling early interventions to improve continuity of care. Additionally, the analysis of asymmetric bilateral amblyopia a subgroup often excluded from prior research showed that spectacle correction alone may be equally effective as early occlusion therapy, challenging conventional treatment approaches. These findings underscore the need for more personalized, data-driven strategies in amblyopia management and highlight the value of integrating predictive tools into clinical workflows. It is recommended that future studies validate these models in broader populations

and explore targeted interventions that address the systemic barriers contributing to follow-up attrition and suboptimal outcomes.

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