The Use of Optical Coherence Tomography for the Detection of Ocular Toxicity by Ethambutol in Newly Diagnosed Tuberculosis Patients

Dr. Aishwary Singh [1], Dr. Shubham Prakash Singh [2], Dr. Uzma Pervin [3], Dr. Aakash Makkar [4], Dr. Somesh Ranjan [5], Dr. Sarita Aggarwal [6*]

[1-4] PG 3rd Year, Department of Ophthalmology, Santosh Deemed to be University, Ghaziabad, Uttar Pradesh 201009, India

[5, 6] MBBS, MS (Ophthalmology), Associate Professor, Department of Ophthalmology, Santosh Deemed to be University, Ghaziabad, Uttar Pradesh 201009, India

* Corresponding Author: **Dr. Sarita Aggarwal**

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Abstract

Background: Ethambutol is a cornerstone drug in first-line antitubercular therapy but is associated with optic neuropathy, which can lead to irreversible visual loss if not detected early. Conventional clinical examinations often fail to detect early or subclinical optic nerve damage.

Objective: To evaluate the role of spectral-domain optical coherence tomography (SD-OCT) in detecting early structural optic nerve changes in newly diagnosed tuberculosis patients receiving ethambutol therapy and to correlate these changes with functional visual parameters.

Materials and Methods: This hospital-based prospective observational study was conducted at Santosh Medical College and Hospital, Ghaziabad, between 2024 and 2026. Ninety-one newly diagnosed tuberculosis patients (182 eyes) aged ≥18 years, receiving ethambutol as part of first-line antitubercular therapy, were enrolled. Comprehensive ophthalmic evaluation and SD-OCT-based retinal nerve fiber layer (RNFL) analysis were performed at baseline and at 2, 4, and 6 months. Functional assessments included best-corrected visual acuity (BCVA), color vision, and automated visual fields. Statistical analysis was performed using Stata MP-17.

Results: Progressive RNFL thinning was observed with increasing duration of ethambutol therapy, becoming significant after 3–4 months and pronounced at 6 months (mean RNFL loss: RE 6.6 ± 3.2 µm; LE 6.7 ± 3.4 µm; $p < 0.001$). Inferior and temporal quadrants were most frequently affected. Structural RNFL loss correlated strongly with BCVA, color vision defects, and visual field indices. Subclinical toxicity detectable only on OCT ± visual fields was observed in 17% of eyes, while clinical toxicity was seen in 7.7%.

Conclusion: SD-OCT is a sensitive, objective, and reliable modality for early detection of ethambutol-induced optic neuropathy. Structural RNFL changes precede functional visual impairment, emphasizing the need for routine OCT monitoring during ethambutol therapy to prevent irreversible visual loss.

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Keywords: Ethambutol, Optical Coherence Tomography, Tuberculosis, Optic Neuropathy, RNFL, Ocular Toxicity

Introduction

Tuberculosis (TB) is an infectious disease caused by Mycobacterium tuberculosis, which can attack any organ system, but mostly the lungs. Despite decades of medical progress TB remains a major global public health problem. This burden of disease and drug resistance has made effective,safe monitoring of treatment an important part of TB management as reflected in the World Health Organization (WHO) Global Tuberculosis Report, which has indicated that over 10 million people are infected each year,

with India alone contributing close to a quarter of the global TB cases. [1]

The first-line therapy of TB involves a combination of four drugs, namely isoniazid, rifampicin, pyrazinamide, and ethambutol. Ethambutol, especially, is popular because of its bacteriostatic effect and the prevention of the emergence of resistance to other medications. It operates by blocking arabinosyl transferase, a cell wall synthesis enzyme of M. tuberculosis. [2] but this advantage is at the expense of possible adverse responses, the most serious of them being optic neuropathy, drug induced ocular toxicity.

The visual function tests that are in use today like the Snellens visual acuity chart, Ishiharas plates, confrontational or automated perimetry provide subjective and in some cases unreliable measurements. Such tests might fail to detect the early degeneration of the optic nerve or retinal ganglion cells, particularly in asymptomatic cases. [3]

Optical Coherence Tomography(OCT) has transformed the field of ocular imaging in that it allows the visualization of the retina and optic nerve head in cross-sectional high-resolution images in a non-invasive way. It gives descriptive quantification of the retinal nerve fiber layer (RNFL), the ganglion cell complex (GCC) and the inner plexiform layer (IPL), which are involved in the pathophysiology of ethambutol toxicity. [4] Minute thinning in these layers, especially in the temporal quadrant of the RNFL and the macular ganglion cell layer, can be detected before any functional impair. [5]

A number of cross-sectional and longitudinal studies provided some evidence that OCT can be used as a useful biomarker to detect,monitor Ethambutol Optic Neuritis(EON). [6, 7] Serial OCT measurements can be used to detect a potential early neuroretinal damage even before the onset of subjective symptoms. OCT has the potential to make distinctions between optic neuropathy and other reasons of visual deficits, which makes it an effective supplement in clinical decision-making. [8]

. With progress in TB elimination initiatives, ocular safety of anti-TB drugs should be considered a priority, particularly in the context of vulnerable groups (e.g., the elderly, diabetics, or patients with renal failure) being at higher risk of getting EON. [9-12].

This paper aims to assess the usefulness of OCT in preventing the early onset of ocular toxicity in patients infected with newly diagnosed TB under ethambutol treatment. Comparing OCT parameters pre-treatment and post-treatment, in addition to traditional clinical measures.

Considering the high incidence of TB and the popularity of ethambutol in both drug-sensitive,drug-resistant TB treatment, the role of the timely and accurate detection of drug-induced complications should not be underrated. The study has the potential to improve clinical vigilance, early diagnosis, and add to more individualized, vision-sparing TB care plans.

Methods

Study Design and Setting

This is an institutional hospital-based prospective observational study. The clinical setting comprised a Tertiary academic center with dedicated department of ophthalmology and the studied was carried from April2024 to December 2025.

Study Population

Ninety-one newly diagnosed tuberculosis patients (182 eyes) aged ≥18 years, attending the ophthalmology outpatient department and advised first-line antitubercular therapy including ethambutol for six months.

Ethical Considerations

Approval was obtained from the Institutional Ethics Committee prior to commencement of the study (IEC approval no. (SU/R/2024/1350 [67]). Written informed consent was taken from all patients. The study adhered to the principles of the Declaration of Helsinki.

Inclusion Criteria

- Newly diagnosed pulmonary or extrapulmonary TB
- Ethambutol prescribed as part of first-line ATT
- Willingness to participate and comply with follow-up

Exclusion Criteria

- Pre-existing ocular diseases (glaucoma, diabetic retinopathy, AMD)
- Diabetes mellitus, hypertension, renal failure
- Pregnant or lactating women
- Previous ATT exposure
- Known ethambutol intolerance

Data collection

After obtaining informed consent, all participants underwent detailed history and clinical examination with Best Corrected Visual Acuity assessment (Snellen, converted to logMAR), Pupillary reflex evaluation. Detailed anterior segment examination was done using slit-lamp (SN:1509220260, Appasamy Associates, Chennai, INDIA), Intraocular pressure measurement done using Goldmann's Applanation Tonometer, Color vision testing done using Ishihara plates. Pupil was dilated using Tropicamide Phenylephrine eye drops (Tropac-P) and after full dilatation of pupil detailed posterior segment evaluation including fundus examination done with 90D lens (V90C, Volk Optical Inc., Ohio, USA), Visual field testing (Humphrey 24-2) was done using Automated Humphreys Perimeter (Appa Auto Perimeter AP901CTS GLAUFEILD LITE), Retinal Nerve Fiber Layer analysis done use Optical Coherence Tomography Machine (APPA OCT 2019 AMBATTUR CHENNAI). Follow-ups were conducted at 2, 4, and 6 months using identical protocols.

Data Analysis

Data were entered in Microsoft Excel 2010 and analyzed using Stata MP-17. Descriptive statistics were used for demographic and clinical variables. Parametric and non-parametric tests were applied as appropriate. Correlation analysis assessed structure–function relationships. $p < 0.05$ was considered statistically significant

Results

A total of 91 newly diagnosed tuberculosis patients comprising 182 eyes were included in the study and followed for a period of six months after initiation of ethambutol-containing antitubercular therapy.

The demographic and clinical characteristics of the study population are summarized in Table 1.

Most patients were young to middle-aged adults, with a predominance of males. Pulmonary tuberculosis was the most common clinical presentation. Baseline ophthalmic evaluation, including visual acuity, color vision, visual fields, intraocular pressure, central corneal thickness, and OCT-RNFL measurements, was normal in all participants, indicating the absence of pre-existing optic nerve pathology before initiation of ethambutol therapy.

Serial OCT analysis revealed progressive structural changes in the RNFL during the course of treatment (Table 2). A mild increase in average RNFL thickness was observed at two months in both eyes compared to baseline. However, this was followed by a statistically significant reduction in RNFL thickness at four and six months. By six months, mean RNFL loss was 6.6 ± 3.2 µm in the right eye and 6.7 ± 3.4 µm in the left eye ($p < 0.001$). Quadrant-wise assessment showed preferential involvement of the inferior and temporal RNFL fibers.

Changes in functional visual parameters during follow-up are detailed in Table 3. While only 2.2% of eyes demonstrated reduced best-corrected visual acuity at baseline, the proportion increased progressively to 6% at two months, 11% at four months, and 15.4% at six months. Color vision abnormalities were not present at baseline but developed in 3.3% of eyes at two months, 9.3% at four months, and 17% at six months. Similarly, visual field defects emerged during follow-up, affecting 2.2% of eyes at two months, 8.8% at four months, and 17.6% at six months.

The overall incidence and pattern of ethambutol-induced ocular toxicity are presented in Table 4. No evidence of toxicity was observed in 75.3% of eyes. Subclinical toxicity, detected only through OCT with or without visual field changes, was identified in 17% of eyes, while clinical toxicity involving visual acuity, color vision, or visual field impairment was observed in 7.7% of eyes. Inferior and temporal RNFL quadrants were most frequently involved, highlighting the preferential vulnerability of these fibers.

The relationship between RNFL loss, functional visual parameters, and potential risk factors is summarized in Table 5. RNFL thickness demonstrated a strong negative correlation with best-corrected visual acuity ($r = –0.62$, $p < 0.001$) and strong positive correlations with color vision scores ($r = 0.58$, $p < 0.001$) and visual field mean deviation ($r = 0.65$, $p < 0.001$). RNFL loss showed significant associations with increasing age, longer duration of ethambutol therapy, higher cumulative drug dose, and female gender, while no significant correlation was observed with central corneal thickness.

Discussion

Ethambutol remains an essential component of first-line antitubercular therapy; however, ethambutol-induced optic neuropathy (EON) is a well-recognized and potentially irreversible adverse effect. Early detection of optic nerve toxicity is critical, as visual recovery largely depends on timely drug modification or discontinuation. Saxena *et al.* [13] emphasized that optic nerve toxicity may occur even at recommended dosages, particularly with prolonged use. The present study evaluated the role of spectral-domain optical coherence tomography (SD-OCT) in detecting early structural changes in the retinal nerve fiber layer (RNFL) and correlated these findings with functional visual parameters.

This prospective observational study followed 91 newly diagnosed tuberculosis patients over a six-month period, allowing longitudinal assessment of RNFL changes. Although tuberculosis predominantly affected young and middle-aged adults, RNFL loss increased significantly with advancing age, confirming age as an important risk factor for EON. Similar findings have been reported by Jin *et al.* [14] and Chaitanuwong *et al.* [16] who demonstrated increased susceptibility to ethambutol toxicity in elderly patients, possibly due to age-related mitochondrial dysfunction and reduced axonal reserve.

Despite male predominance in tuberculosis incidence, greater RNFL loss was observed among female patients. Konnakkodan *et al.* [21] reported a similar trend. Differences in body composition, relatively higher effective drug exposure, and hormonal influences may contribute to this observation. No significant difference in RNFL loss was noted between pulmonary and extrapulmonary tuberculosis, indicating that ocular toxicity is primarily related to ethambutol exposure rather than disease site, consistent with earlier studies. [23, 30]

A characteristic biphasic RNFL response was observed, with mild thickening at two months followed by progressive thinning at four and six months. Early RNFL thickening likely represents reversible axonal edema secondary to mitochondrial dysfunction and impaired axoplasmic transport, preceding irreversible axonal loss. Similar temporal patterns have been described by Kim *et al.* [9] and Jin *et al.* [10] highlighting a critical window for early intervention.

Quadrant-wise analysis demonstrated preferential involvement of inferior and temporal RNFL fibers, consistent with previous reports by Konnakkodan *et al.* [21], Varan *et al.* [20], and Mandal *et al.* [23]. These fibers, particularly the papillomacular bundle, have high metabolic demands and are therefore more vulnerable to mitochondrial toxicity.

Functional visual deterioration occurred later than structural changes. Visual acuity reduction was observed in a smaller proportion of eyes compared with color vision and visual field abnormalities. Pavan Pavan Taffner *et al.* [6] and Kambella *et al.* [18] reported similar findings, while Mandal *et al.* [13] and Sarkar *et al.* [19] demonstrated preserved visual acuity despite significant OCT changes, confirming that visual acuity is a late and insensitive marker of early toxicity. Color vision abnormalities and visual field defects showed strong associations with RNFL thinning. Menon *et al.* [4] and Misra *et al.* [17] reported comparable incidences of color vision defects. The strong structure–function correlation observed in this study aligns with findings from Konnakkodan *et al.* [12], Mandal *et al.* [13], and Sen *et al.* [5], validating RNFL thickness as a clinically meaningful biomarker.

RNFL loss demonstrated a clear duration-dependent relationship with ethambutol therapy, becoming significant after three months. Saxena *et al.* [3] and Sabhapandit *et al.*[15]. similarly reported higher toxicity risk with prolonged ethambutol exposure. The overall ocular toxicity rate of 24.7%, with a substantial proportion being subclinical, highlights the limitations of symptom-based monitoring and underscores the need for objective screening tools.

Despite limitations such as short follow-up duration and lack of ganglion cell analysis, the prospective design, serial OCT evaluation, and strong structure–function correlation enhance the clinical relevance of this study.

Conclusion

This study demonstrates that ethambutol induces measurable and clinically significant optic nerve damage that can be detected early using spectral-domain optical coherence tomography. RNFL changes occur early during therapy and follow a characteristic pattern of initial thickening followed by progressive thinning in a dose- and duration-dependent manner.

Structural RNFL loss frequently precedes clinically apparent visual impairment, with a substantial proportion of patients exhibiting subclinical toxicity detectable only through OCT and visual field analysis. Strong structure–function correlations further establish RNFL thickness as a clinically meaningful biomarker of ethambutol-induced optic neuropathy.

Advancing age, longer duration of therapy, higher cumulative drug exposure, and female gender were identified as important risk factors for increased RNFL loss. The overall incidence of ocular toxicity was considerable, emphasizing that reliance on patient-reported symptoms alone is insufficient for safe monitoring.

In conclusion, spectral-domain OCT is a valuable, non-invasive, and reliable tool for early detection and monitoring of ethambutol-induced ocular toxicity. Routine OCT-based surveillance, combined with conventional visual function tests, should be considered an essential component of tuberculosis care to facilitate timely intervention and prevent irreversible visual loss.

Tables

Table 1: Demographic and Clinical Profile of Study Participants (n = 91 patients, 182 eyes)

Parameter	Number	Percentage (%)
Age Group (years)		
18–30	20	22
31–40	27	29.7
41–50	23	25.3
51–60	14	15.4
>60	7	7.6
Gender		
Male	56	61.5
Female	35	38.5
Type of Tuberculosis		
Pulmonary	68	74.7
Extrapulmonary	23	25.3

The majority of patients belonged to the young and middle-aged adult population, with the highest representation in the 31–40 years age group (29.7%), followed by 41–50 years (25.3%) and 18–30 years (22%). Patients above 60 years constituted 7.6% of the cohort. There was a male predominance (61.5%), and pulmonary tuberculosis was the most common clinical presentation, observed in 74.7% of patients.All participants demonstrated normal ophthalmic findings at baseline. Best-corrected visual acuity, color vision, visual fields, intraocular pressure, and central corneal thickness were within normal physiological limits. Baseline OCT evaluation revealed normal retinal nerve fiber layer (RNFL) thickness across all quadrants in both eyes, confirming the absence of pre-existing optic nerve pathology prior to initiation of ethambutol therapy.

Table 2: Longitudinal Changes in Average RNFL Thickness on OCT (µm)

Time Point	Right Eye (Mean ± SD)	Left Eye (Mean ± SD)	p-value
Baseline	101.2 ± 8.5	100.8 ± 8.6	–
2 months	102.1 ± 8.4	101.7 ± 8.5	NS
4 months	98.2 ± 8.1	97.7 ± 8.2	<0.01
6 months	94.6 ± 7.9	94.1 ± 8.0	<0.001

A mild increase in average RNFL thickness was observed at two months in both eyes compared to baseline. However, this was followed by a statistically significant reduction in RNFL thickness at four and six months. By six months, mean RNFL loss was 6.6 ± 3.2 µm in the right eye and 6.7 ± 3.4 µm in the left eye ($p < 0.001$). Quadrant-wise assessment showed preferential involvement of the inferior and temporal RNFL fibers

Table 3: Functional Visual Changes During Ethambutol Therapy (182 eyes)

Parameter	Baseline	2 Months	4 Months	6 Months
Reduced BCVA (%)	2.2	6	11	15.4
Color Vision Abnormality (%)	0	3.3	9.3	17
Visual Field Defect (%)	0	2.2	8.8	17.6

While only 2.2% of eyes demonstrated reduced best-corrected visual acuity at baseline, the proportion increased progressively to 6% at two months, 11% at four months, and 15.4% at six months. Color vision abnormalities were not present at baseline but developed in 3.3% of eyes at two months, 9.3% at four months, and 17% at six months. Similarly, visual field defects emerged during follow-up, affecting 2.2% of eyes at two months, 8.8% at four months, and 17.6% at six months.

Table 4: Incidence and Pattern of Ethambutol-Induced Ocular Toxicity

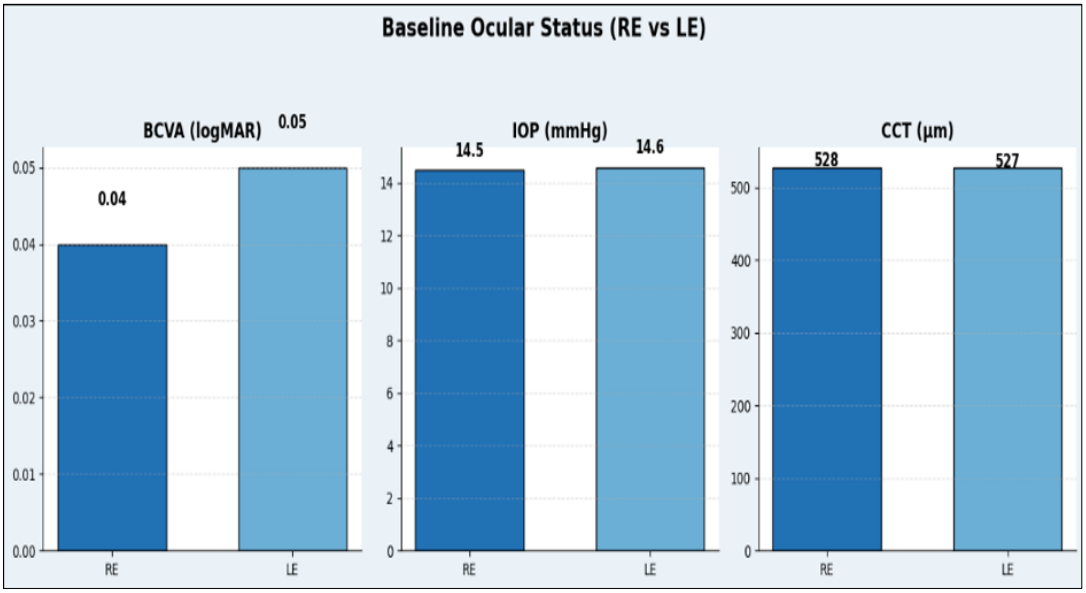
Toxicity Category	Eyes (n)	Percentage (%)
No toxicity	137	75.3
Subclinical (OCT ± VF only)	31	17
Clinical (BCVA / Color / VF affected)	14	7.7
Total Toxicity	45	24.7
RNFL Quadrant Involved	Eyes Affected	Percentage(%)
Inferior	113	62.2
Temporal	105	57.8
Superior	81	44.4
Nasal	57	31.1

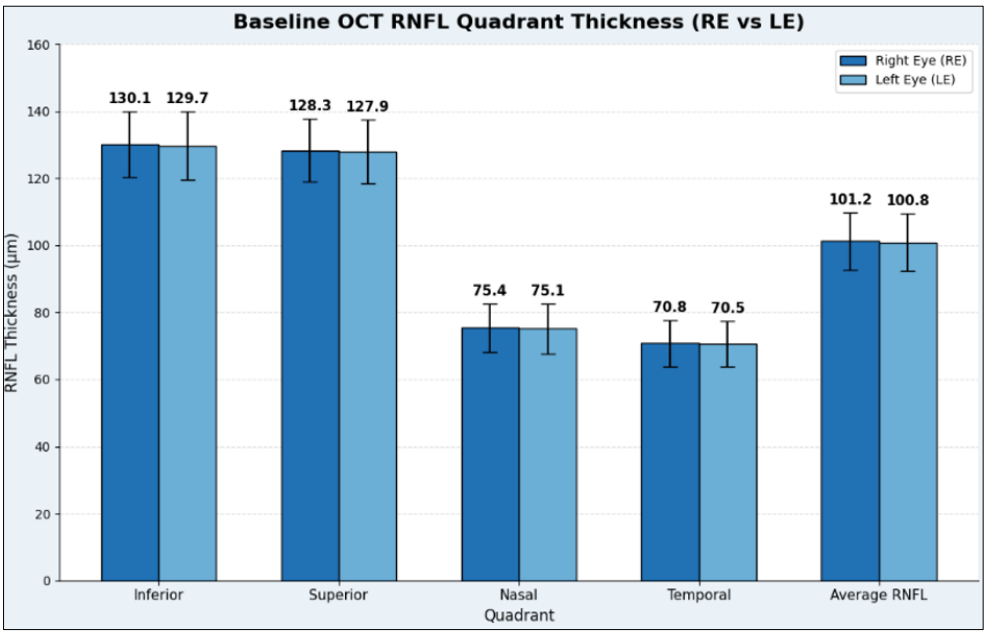
No evidence of toxicity was observed in 75.3% of eyes. Subclinical toxicity, detected only through OCT with or without visual field changes, was identified in 17% of eyes, while clinical toxicity involving visual acuity, color vision, or visual field impairment was observed in 7.7% of eyes. Inferior and temporal RNFL quadrants were most frequently involved, highlighting the preferential vulnerability of these fibers.

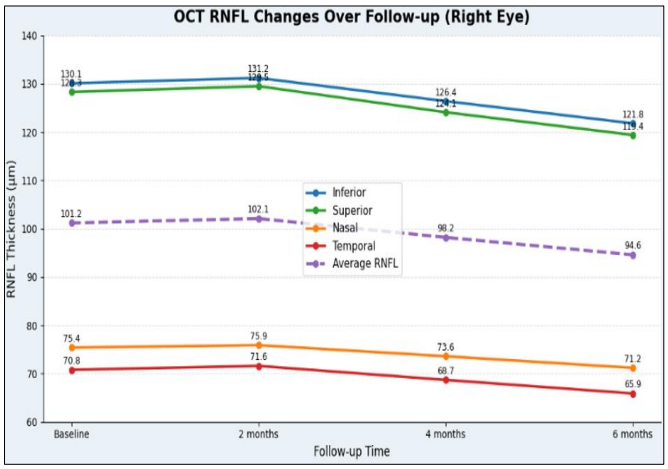
Table 5: Correlation of RNFL Loss with Visual Parameters and Risk Factors

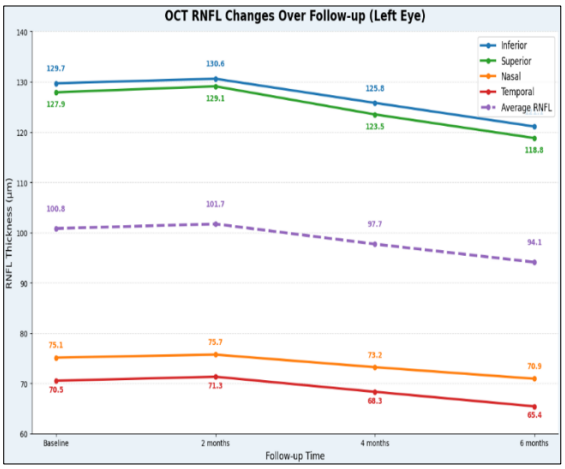
Variable	Correlation (r)	p-value
RNFL vs BCVA (logMAR)	–0.62	<0.001
RNFL vs Color Vision	0.58	<0.001
RNFL vs Visual Field MD	0.65	<0.001
Age	0.44	<0.001
Duration of Ethambutol	0.53	<0.001
Cumulative Dose	0.59	<0.001
Gender	0.21	0.04
Central Corneal Thickness	0.08	NS

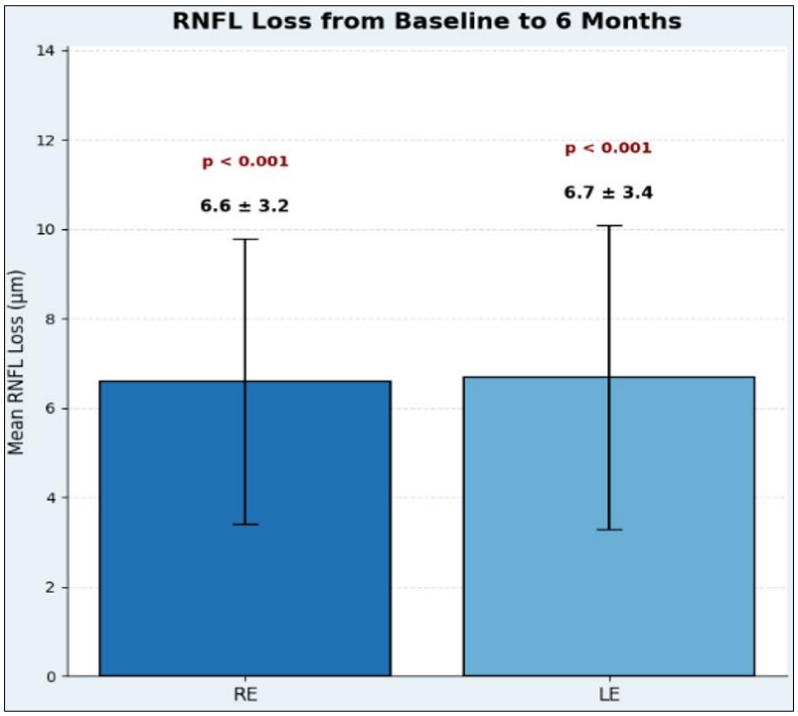
RNFL thickness demonstrated a strong negative correlation with best-corrected visual acuity ($r = –0.62$, $p < 0.001$) and strong positive correlations with color vision scores ($r = 0.58$, $p < 0.001$) and visual field mean deviation ($r = 0.65$, $p < 0.001$). RNFL loss showed significant associations with increasing age, longer duration of ethambutol therapy, higher cumulative drug dose, and female gender, while no significant correlation was observed with central corneal thickness.




Baseline OCT RNFL Quadrant Thickness (RE vs LE)
Right Eye (RE)
Left Eye (LE)
RNFL Thickness (µm)
130.1
129.7
128.3
127.9
75.4
75.1
70.8
70.5
101.2
100.8
Inferior
Superior
Nasal
Temporal
Average RNFL
Quadrant


OCT RNFL Changes Over Follow-up (Right Eye)
RNFL Thickness (µm)
Inferior
Superior
Nasal
Temporal
Average RNFL
Baseline
2 months
4 months
6 months
Follow-up Time


OCT RNFL Changes Over Follow-up (Left Eye)
RNFL Thickness (µm)
Inferior
Superior
Nasal
Temporal
Average RNFL
Follow-up Time


RNFL Loss from Baseline to 6 Months
p < 0.001
6.6 ± 3.2
p < 0.001
6.7 ± 3.4
Mean RNFL Loss (µm)
RE
LE

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