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# NetraKit: Evaluation of a Low-Cost Refractive Screening Kit Against Snellen Chart Readings and Reference Refraction, with Public Health, Policy and Implementation Analysis

Aditya Gupta[1]
[1]adityaguptauni@gmail.com

**ABSTRACT**

Background: Uncorrected refractive error is the leading cause of distance vision impairment in India, yet refraction services remain concentrated in cities and specialist clinics. NetraKit is a low-cost screening kit, priced at about ₹2,200, that estimates spherical refraction for each eye as the lens power at which the top line of a distance target becomes comfortably clear.

Objective: To evaluate NetraKit against reference refraction and Snellen chart readings, identify factors associated with its error, and examine the public health, economic, legal and implementation context of its deployment.

Methods: A cross-sectional method-comparison analysis of 225 participants (450 eyes) aged 5–62 years used monocular testing and a structured questionnaire. Agreement was assessed with Bland–Altman analysis, equivalence testing against ±0.25 D, Cohen's kappa and multiple linear regression, alongside a policy, cost, legal and implementation analysis.

Results: NetraKit placed 94.2% of eyes within ±0.25 D of the reference (97.3% in children aged 5–10 and 91.3% in older participants), with a bias of −0.04 D, 95% limits of agreement of −0.43 to +0.34 D, equivalence within one lens step ($p < 0.001$) and categorical agreement of $\kappa = 0.94$. In regression ($F(33, 416) = 1.48$, $p = 0.046$; adjusted $R^2 = 0.03$), error was associated with myopia (B = −0.05 D), pterygium (B = −0.20 D) and left-eye cataract surgery (B = +0.34 D), the last two in very small groups and therefore exploratory. Accuracy appeared similar across residence and gender, although rural participants were few (n = 28). An illustrative cost model estimated ₹13–26 per person screened.

Conclusions: NetraKit programmes could train screeners to avoid over-minus correction, refer people with pterygium or previous cataract surgery, and prioritise underserved communities; these proposals require prospective validation.

**Keywords:** *refractive error; vision screening; myopia; pterygium; health equity; India*

## 1. INTRODUCTION

Uncorrected refractive errors are the biggest cause of distance vision impairment in the world and are one of the simplest refractive errors to correct. According to the World Report on Vision, at least 2.2 billion people are affected by a vision impairment, which is estimated that about half of these could have been prevented or treated; of these, the majority are due to uncorrected refractive error (World Health Organization, 2019). Spectacles were identified by the Lancet Global Health Commission on Global Eye Health as being one of the most cost-effective health interventions available, and coverage for refractive services was lowest in low- and middle-income countries and among rural, poor and older people (Burton et al., 2021; Resnikoff et al., 2008; Flaxman et al., 2017).

This burden is increasing. According to Holden et al. (2016), nearly half of the world's population will be myopic in 2050 and near to one billion people will be affected by high myopia, which is associated with the risk of retinal detachment, maculopathy and glaucoma. In childhood, myopia typically develops and has been associated with excessive near work, less exposure to sunlight and digital devices (Morgan et al, 2012; Rose et al, 2008), and hypermetropia is common in young children and older adults. A good screening test should therefore be able to identify both types of error, over a broad age span.

India is a big contributor of this burden. With the help of a national survey, conducted in the period 2015-2019, the two most important causes of visual impairment in adults above fifty years of age were found to be cataract and uncorrected refractive error (Vashist et al., 2022). A survey on refractive error in children conducted in the urban centres of New Delhi compared to the rural regions of Andhra Pradesh showed higher prevalence of myopia in urban children than in rural children and that many children requiring correction were not using them (Dandona et al., 2002; Murthy et al., 2002). Myopia prevalence in Delhi was reported to be higher than thirteen per cent with continuing incidence and progression (Saxena et al., 2015; Saxena et al., 2017), and a meta-analysis of 40 years of data from India indicated that there was a definite upward trend with near 50 per cent of children in urban India being predicted to be myopic by 2050 (Priscilla & Verkicharla, 2021; Sheeladevi et al., 2018).

A standard refraction needs to be conducted by a trained optometrist or ophthalmologist and is more complicated than visual acuity screening using a Snellen chart, which can be done by both teachers and community health workers, and only indicates whether vision is reduced or not (Snellen, 1862; Bailey & Lovie, 1976). Simpler methods, such as self-refraction using adjustable spectacles and acuity screening via smartphone have demonstrated that screening can be performed by non-specialists (He et al., 2011; Bastawrous et al., 2015), thus potentially allowing for a low-cost screening tool in between a pass/fail acuity screen and a full clinical refraction. NetraKit is designed to take that place. It is a portable kit that costs approximately ₹2,200 and consists of a distance target to be seen through a series of spherical lenses, and the power (in 0.25 D steps) at which the top line could be seen clearly without strain for each eye. This output is thus a per-eye dioptric estimate which can be compared directly to reference refraction and to readings from Snellen charts.

This paper reports a cross-sectional evaluation of NetraKit in 225 participants (450 eyes) recruited from a community eye testing camp (Ek Prayas NGO) located in Kohat Enclave, Pitampura, New Delhi, 110034, on May 13th 2026, as well as the public health, economic, legal and implementation context in which the kit would be used.

### 1.1. Rationale and objectives

There is good prevalence data in the existing literature in India, but little in terms of practical methods for non-specialists to achieve an acceptable dioptric estimate at the time of screening. Previous Indian studies have been based on cycloplegic retinoscopy or autorefraction by trained personnel (Dandona et al., 2002; Murthy et al., 2002; Saxena et al., 2015) which are suitable for epidemiology and are challenging to implement in a routine school/community screening program. There is promising evidence from abroad (He et al. 2011; Bastawrous et al. 2015) but this has come primarily from outside India, from populations with different age structures, and with different refractive profiles and patterns of ocular and systemic disease. Any tool developed for Indian context should be tested in a manner consistent with the users of the tool.

This is especially because of two aspects of the Indian context. Firstly, screening programmes are seldom restricted to one age group. It is not only children that are targeted in school health programmes but adults of working age and older adults in large numbers are targeted in community camps and the same kit will be used for all of them. An evaluation framework can therefore be useful that incorporates children as young as five, adolescents, working-age adults and older adults, and test the accuracy within each of these groups as well as across the entire range. Second, many of those who come to screening already have other eye problems or illnesses. A cataract, diabetic retinopathy, glaucoma and age-related macular degeneration are some common diseases among older Indian adults (Vashist et al., 2022; Yau et al., 2012; Tham et al., 2014; Wong et al., 2014), and diabetes can influence refraction due to fluctuations in blood glucose (Okamoto et al., 2000). Patients who have had a cataract operation and have intraocular lenses may have near-emmetropic vision in one or both eyes. A screening tool that is effective only in otherwise healthy young eyes would be of little use.

In this study, the conceptual approach that has been adopted is not only classification, but also as a measurement problem. It is useful to have a binary classification into “needs referral” and “does not need referral”, but that is discarding information. The framework enables the questions: How close do each of the methods get to the reference method, do these errors occur systematically (bias), do these errors occur randomly (spread), do the errors depend on the size of the refractive error; and do categorical decisions like "myopic", "emmetropic", and "hypermetropic" agree? This method is based on method comparison studies suggested by Bland and Altman (1986) and reporting principles of STARD 2015 for diagnostic accuracy studies (Bossuyt et al., 2015).

The study makes three contributions. The first is a well-defined monocular protocol, with each eye tested while the other is closed, and it involves reporting results for the right eye (OD) and left eye (OS) separately under each protocol, as well as a pre-specified analysis plan that uses continuous agreement

statistics, categorical agreement and subgroup analysis. The second is an application of this protocol to 225 participants (450 eyes). The third is an analysis of the broader system in which NetraKit would operate, including public health gaps which drive its need, the public health eye care system in India, gaps between policy and practice, a cost-based analysis of deployment at a price of approximately ₹2,200, legal and regulatory requirements, a proposed system of deployment and referral pathways, and social and institutional factors that influence implementation.

## 2. LITERATURE REVIEW

### 2.1. Refractive error epidemiology

There are estimates that refractive errors are the most common eye problem in all age groups globally. In a systematic review and meta-analysis, Hashemi et al. reported pooled estimates of myopia, hypermetropia and astigmatism in different regions of the World Health Organization (WHO) and highlighted the wide inter-regional, age and measurement variability. Holden et al. (2016) predicted that the prevalence of myopia would rise rapidly in the coming years, with some urban areas in East Asia already having rates of over 80% of young adults with myopia. A normal emmetropisation pattern was demonstrated in the studies with higher prevalence of myopia in urban children and relatively higher hypermetropia in the youngest children, in India. (Dandona et al., 2002; Murthy et al., 2002). Sheeladevi et al. (2018) reviewed various studies on the prevalence of refractive error in Indian children and found that the results were highly variable, primarily due to the diversity in the age groups, settings, cycloplegia use and definition used.

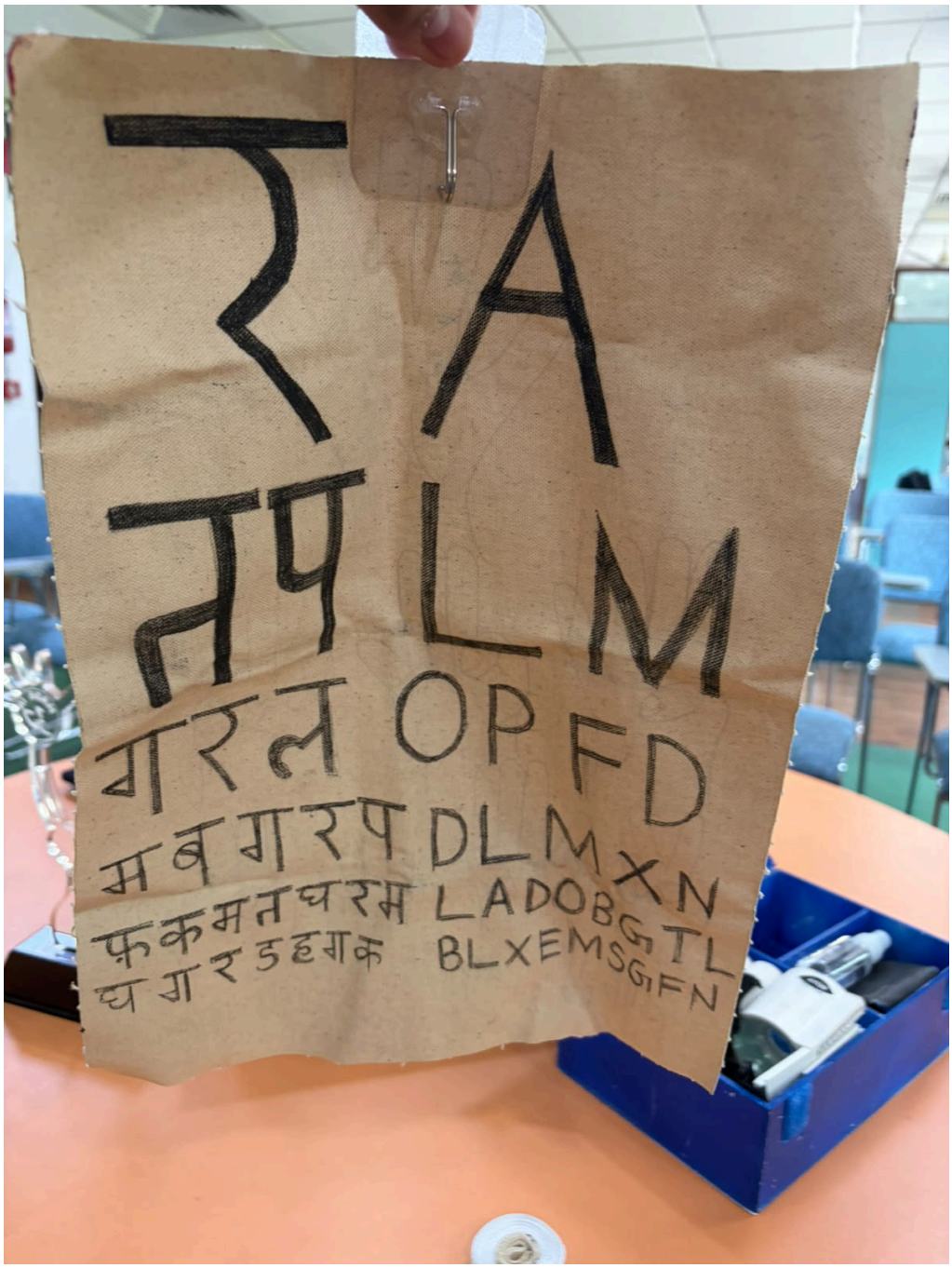
### 2.2. Factors that may increase the risk of becoming short-sighted.

Both genetic and environmental factors are thought to play a role in myopia, but strong genetic influences are unlikely as myopia has increased in prevalence over a few generations (Morgan et al., 2012). More time outdoors is the most consistently protective factor supported by cohort evidence (Rose et al., 2008) and by a cluster randomised trial that found that provision of additional time spent outside in school reduced incidence of myopia (He et al., 2015). While most of the findings are cross-sectional and based on self-reported screen time, there is a growing body of evidence that has linked increased digital screen time with higher risk of myopia (Foreman et al., 2021). Myopia in Delhi has been linked to near work, limited outdoor activities and family history, and the prevalence of myopia and refractive error has been increasing over time (Saxena et al., 2015; Saxena et al., 2017).

### 2.3. Field measurements of vision and refraction

Although the steps between the lines of Snellen's chart are not equal, logMAR designs (Snellen, 1862; Bailey & Lovie, 1976; Ferris et al., 1982) are the most common acuity test. However, acuity is not enough to assess refraction, and therefore cycloplegic retinoscopy and autorefraction (Negrel et al., 2000) were added to the RESC protocol. Self-adjustable spectacles can be used to optimize user self-refraction (Douali & Silver, 2004), and in Guangzhou, self-refraction was sufficiently accurate for most children, while some accepted excessive minus power (He et al., 2011); and simple alternative means had

approached to conventional refraction in many cases (Smith et al., 2010). The Peek smartphone test was found to be congruent to standard tests (Bastawrous et al., 2015) and was used to screen teachers in Kenya, with problems of follow-up after referral (Rono et al., 2018).




Note: The data collection was done via a standard Snellen Chart, however, another eye testing chart (with

same sizing and standardisation as a Snellen Chart) was created for deployment of this device in underserved regions.






**Fig: Images of NetraKit**

### 2.4. Factors that make screening more difficult.

Many older adults may have combined eye disease. Nuclear cataract tends to cause myopia and near-emmetropia is typically the desired refractive outcome following cataract surgery. Common and increasingly prevalent (Wong et al., 2014; Tham et al., 2014; Yau et al., 2012) are age-related macular degeneration (AMD) and glaucoma, and diabetes can result in transient refractive changes (Okamoto et al., 2000). A best-corrected acuity may be affected in children by amblyopia and/or strabismus. The eye will not be able to obtain clear vision making subjective endpoints less reliable, hence the eye and systemic history are taken.

### 2.5. Research gap

The few validations that were done on low cost methods were outside India, in limited age ranges, and predominantly in binocular situations and did not include people with multiple diseases. Not much is offered regarding the way to assess a NetraKit-type tool for all ages, with medically complex participants included in the recording. This paper fills this gap.

## 3. METHODS

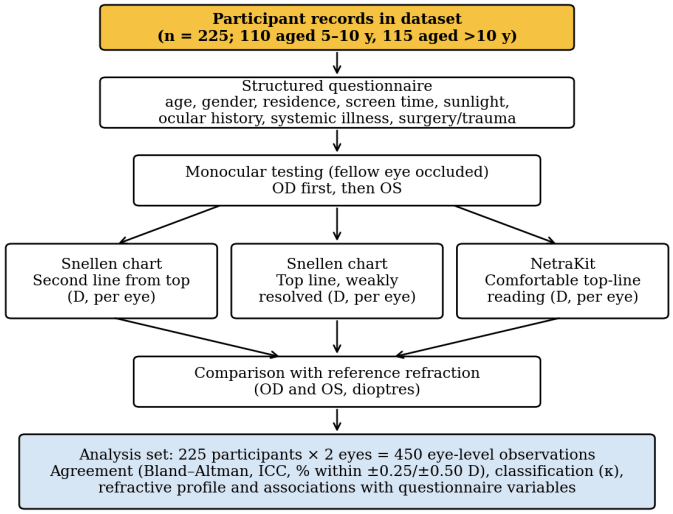
### 3.1. Study design

The study was conducted as a cross-sectional method comparison study and each participant was scanned for three index measurements and a reference measurement in one session, following STARD 2015 (Bossuyt et al. 2015) and analysed by Bland–Altman analysis (Bland & Altman 1986). For agreement the eye was the unit of analysis and the participant for descriptive analyses. The protocol is shown in Figure below.

Because the two eyes of a participant are highly correlated ($r = 0.990$; Section 4.2), they were not treated as fully independent. Agreement statistics are reported separately for right and left eyes (225 eyes each), in which each participant contributes one observation; pooled results (450 eyes) are presented descriptively. The equivalence test used one value per participant, and the regression was re-estimated with standard errors clustered by participant.



**Figure 1:** Study protocol and analysis flow




### 3.2. Participants and setting

The study analyzed 225 participant records (NK-001 to NK-225) ranging in age from 5 to 62 years, and both sexes, urban, suburban and rural living and both myopic and hypermetropic refraction. All refractions were recorded in 0.25 D steps. All refractions were recorded in 0.25 D steps. The purpose of the study was to estimate the accuracy of NetraKit in the field, not the prevalence or risk factors of refractive error. The identity of the participants was not revealed and the results were generalised.

### 3.3. Recruitment and eligibility

The study involved children aged 5 years and older from schools and community locations who were able to read or match chart symbols, as indicated, with assistance of a parent, teacher or screener as appropriate. Exclusion was not made for those who have had previous eye disease, surgery, or systemic illness, as this is an overestimation of performance, and those who have acute infection or injury were referred. Adults were asked for consent and after institutional ethics approval, parents and guardians of children were asked for consent and children were asked for assent.





### 3.4. Variables

The records include a gender, age, age group (5-10 years or >10 years), OD and OS reference refraction, previous eye disease and type, screen time in hours/day, and ongoing systemic illness and type, past ocular surgery or trauma, exposure to intense sunlight, and residence and refractive category.

### 3.5. Measurement procedures

All measurements are monocular: first right eye (OD) using the left eye closed, then left eye (OS). Every participant made 2 observations of each eye level in each comparison.

#### 3.5.1. Reference refraction

The spherical refraction of each eye is the reference value. It was obtained in the field study by objective refraction with subjective refinement under cycloplegia (Negrel et al., 2000) when appropriate for young children.

### 3.5.2. Snellen chart readings

The participant was asked to read a standard Snellen chart at the designated distance as lenses are offered in 0.25 D increments (Snellen, 1862). These two end points were measured for each eye: The power at which the second line from the top was readable, and the power at which the top line was weakly visible. Although logMAR charts have better design properties (Bailey & Lovie, 1976; Ferris et al., 1982), the Snellen chart is the most commonly available chart in Indian schools and camps.

The chart serves only as the visual target; the recorded value is the power of the trial lens in place at each endpoint, not a measure produced by the chart itself.

### 3.5.3. NetraKit reading

While standing through the power of the lenses in the NetraKit, the participant examines the target with one eye closed and writes down the power where the top line was "comfortably clear." The emphasis on comfort, not first visibility, is designed to help minimize over-minus responses in young myopes and accommodation in hypermetropes.

## 3.6. Definitions

The classification of myopia, hypermetropia, and emmetropia were determined at the eye level as being $\leq -0.50$ D, $\geq +0.50$ D, and between $-0.50$ and $+0.50$ D, respectively. The mean refraction of both eyes was calculated for each participant for description: low ($-0.50$ to $-3.00$ D), moderate (beyond $-3.00$ to $-6.00$ D) or high (beyond $-6.00$ D); and anisometropia was the absolute OD–OS difference.

## 3.7. Statistical analysis

Categorical variables are presented as numbers and percentages; continuous variables are presented as numbers, means, standard deviations (SD), medians and range which were tested with chi-square, Spearman correlation and Mann–Whitney U tests and the two eyes were compared with Wilcoxon signed-rank test. The difference between the methods (method – reference) was calculated for each method and the bias and 95% limits of agreement (LOA) were determined separately for each method for OD, OS and both eyes pooled (450 eyes). The mean absolute difference (MAD) and the intraclass correlation coefficient (ICC) for absolute agreement (Koo & Li, 2016) were also reported and the proportional bias was explored by correlating differences with the reference. Categorical agreement was evaluated using Cohen's kappa (Cohen, 1960) with interpretation following Landis and Koch (1977). Three additional analyses were pre-specified for NetraKit. The equivalence was first established using two one-sided t-tests (TOST) with a margin of ±0.25 D (one lens step) with the mean difference between the two eyes for each participant, so each participant gave one contribution. Second, the percentage of eyes within ±0.25 D was compared to a standard of 80% with a one-sided binomial test. Third, a multiple

linear regression modelling was performed to find factors associated with NetraKit error: participant serial number (to check for the drift across the order of testing), gender, age, previous eye disease type, reported screen time consumed, ongoing systemic illness type, previous ocular surgery or trauma, intense sunlight exposure, residence, refractive category, and eye. Model fit was summarised using $R^2$, adjusted $R^2$ and an overall F test and the residuals were analysed using histograms, Q–Q plots and normality tests. To assure that the results were not obtained due to any random variation, the model was re-estimated using standard errors clustered by participants as a sensitivity analysis and each participant having two eyes. Analyses were conducted in Python (pandas, SciPy, statsmodels, Matplotlib) and significance was considered as $p < 0.05$. As described in Section 3.1, the two eyes of each participant were treated as correlated; because the binomial test and Cohen's kappa pool both eyes, they may slightly understate uncertainty, and the per-eye results in Table 2 allow this to be checked.

## 4.RESULTS

### 4.1. Participant characteristics

A total of 225 participants (450 eyes) were included. There were 115 females (51.1%) and 110 males (48.9%), aged five to sixty-two years (mean 22.5, SD 19.0; median 11). Of these, 110 (48.9%) were aged 5 – 10 years and 115 (51.1%) were older, including 46 aged 46 – 62. The majority resided in urban areas (57.8%), suburban (29.8%) and rural (12.4%) areas; 43.6% said they were in the sun a lot; the mean was 3.04 hours of screen time/day (SD 1.17, range 0.5 – 6.1).

Table 1: Characteristics of participants (n = 225)

| Characteristic | Category | n (%) or value |
|---|---|---|
| Gender | Female | 115 (51.1) |
| | Male | 110 (48.9) |
| Age (years) | Mean (SD) | 22.5 (19.0) |
| | Median (range) | 11 (5–62) |
| Age group (dataset field) | 5–10 years | 110 (48.9) |
| | Older than 10 years | 115 (51.1) |
| Age band (descriptive) | 5–10 | 110 (48.9) |
| | 11–17 | 22 (9.8) |
| | 18–30 | 27 (12.0) |
| | 31–45 | 20 (8.9) |
| | 46–62 | 46 (20.4) |
| Residence | Urban | 130 (57.8) |
| | Suburban | 67 (29.8) |
| | Rural | 28 (12.4) |
| Exposure to intense sunlight | Yes | 98 (43.6) |
| Screen time (h/day) | Mean (SD) | 3.04 (1.17) |
| | Median (range) | 3.0 (0.5–6.1) |
| Previous eye disease | Yes | 64 (28.4) |
| Ongoing systemic illness | Yes | 54 (24.0) |
| Past ocular surgery/trauma | Yes | 15 (6.7) |

**4.2. Refractive profile**

In total, 157 participants (69.8%) were myopic and 68 (30.2%) hypermetropic (Table S1). The mean refraction in both eyes was −0.87 D (SD 2.10). Myopic participants had a mean of −2.01 D in each eye (range −4.50 to +0.25 D) and hypermetropic participants +1.75 D (range −0.25 to +4.25 D).

Of the myopic participants, 106 had low myopia, 33 moderate myopia and 18 were close to emmetropia (Figure S1). The two eyes were closely matched (r = 0.990; mean difference 0.006 D; Wilcoxon p = 0.65). Of the participants, 35.1% had identical OD and OS, 46.7% had a difference of 0.25 D, 16.9% had a difference of 0.50 D and 1.3% had a difference of 1.00 D, all of whom had undergone surgery on one eye for cataract.

**4.3. Refractive category and questionnaire variables.**

The refractive category and questionnaire variables are shown below. There were no significant differences in myopia prevalence among age group, gender, residence or sunlight exposure, and there was no significant correlation between reported screen time and refraction (all p > 0.2).

**4.4. The agreement between methods and reference refraction.**

Agreement statistics are given in Table 2 and Figure 2.

**4.4.1. Snellen chart: second line from top.**

Across 450 eyes that the study examined, the second-line reading had a bias of −0.02 D, SD of differences 0.26 D and 95% limits of agreement of −0.53 to +0.50 D. It matched the reference precisely in 38.2% of eyes, within ±0.25 D in 83.6% and within ±0.50 D in all eyes, with a mean absolute difference of 0.20 D, and an ICC value of 0.992. Results were very similar for both eyes.

**4.4.2. Eye chart: top line weakly visible**

The top-line reading agreed slightly more closely, with a bias of −0.03 D, limits of −0.51 to +0.46 D, 36.7% exact, 88.4% within ±0.25 D, all eyes within ±0.50 D, a mean absolute difference of 0.19 D and an ICC of 0.993.

**4.4.3. NetraKit comfortable top-line reading**

NetraKit readings were similar to the reference in nearly all eyes (Table 2; Figure 2c). The absolute mean difference between the readings and the reference was 0.13 D with a 95% limits of agreement of −0.43 to +0.34 D and an ICC of 0.996. 55.3% of eyes had a difference of exactly 0 D, 94.2% of eyes a difference between 0 and 0.25 D, and 99.6% of eyes a difference between 0 and 0.50 D. Accuracy was higher in children aged 5–10, with 97.3% of eyes within ±0.25 D (214 of 220; limits −0.37 to +0.31 D), than in participants older than ten, with 91.3% (210 of 230; limits −0.48 to +0.37 D). The greatest difference (+/- 0.75 D) was seen primarily in older participants and those with previously diagnosed eye disease; 87.5% of such eyes had an error of +/- 0.25 D, whereas 96.9% had an error of +/- 0.25 D among those with no previous eye disease. Although the small negative bias, similar to other subjective and smartphone-based

refraction devices (He et al., 2011; Tousignant et al., 2020) was reported, NetraKit tended to read a little more myopic.

These descriptive results were confirmed by the pre-specified tests. The bias was not different from zero overall and in both age groups within ±0.25 D (TOST $p < 0.001$) and the percentage of eyes within ± 0.25 D was greater than 80% in both age groups (binomial $p < 0.001$) and overall.

Figure 2: Bland–Altman plots of agreement with reference refraction (450 eyes). Solid line, mean difference; dashed lines, 95% limits of agreement. Small random jitter has been added to separate overlapping points.

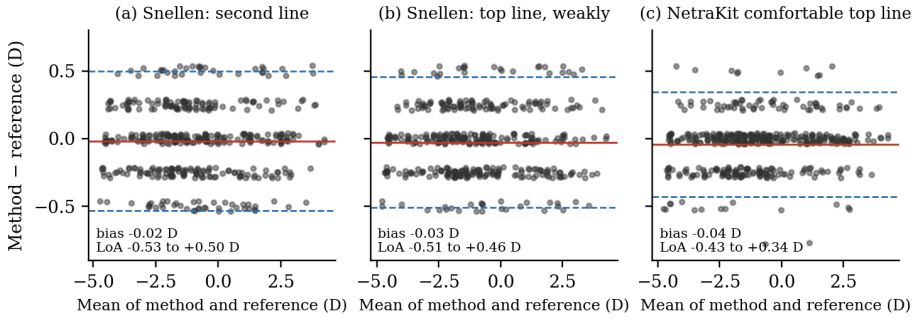



Table 2: *Agreement of each method with reference refraction, overall and for NetraKit by participant group*

| Method | Eye | Bias (D) | SD of diff. (D) | 95% LoA (D) | Exact (%) | ±0.25 D (%) | ±0.50 D (%) | MAD (D) | ICC |
|---|---|---|---|---|---|---|---|---|---|
| Snellen: second line | OD | −0.02 | 0.27 | −0.55 to +0.50 | 36.9 | 82.7 | 100 | 0.20 | 0.992 |
| | OS | −0.01 | 0.26 | −0.52 to +0.50 | 39.6 | 84.4 | 100 | 0.19 | 0.992 |
| | Pooled | −0.02 | 0.26 | −0.53 to +0.50 | 38.2 | 83.6 | 100 | 0.20 | 0.992 |
| Snellen: top line, weakly | OD | −0.03 | 0.25 | −0.51 to +0.45 | 39.6 | 87.6 | 100 | 0.18 | 0.993 |
| | OS | −0.02 | 0.25 | −0.51 to +0.46 | 33.8 | 89.3 | 100 | 0.19 | 0.993 |

| Method | Eye | Bias (D) | SD of diff. (D) | 95% LoA (D) | Exact (%) | ±0.25 D (%) | ±0.50 D (%) | MAD (D) | ICC |
|---|---|---|---|---|---|---|---|---|---|
| | Pooled | −0.03 | 0.25 | −0.51 to +0.46 | 36.7 | 88.4 | 100 | 0.19 | 0.993 |
| NetraKit comfortable top line | OD | −0.04 | 0.20 | −0.44 to +0.36 | 55.6 | 92.4 | 99.6 | 0.13 | 0.995 |
| | OS | −0.04 | 0.19 | −0.41 to +0.33 | 55.1 | 96.0 | 99.6 | 0.12 | 0.996 |
| | Pooled | −0.04 | 0.20 | −0.43 to +0.34 | 55.3 | 94.2 | 99.6 | 0.13 | 0.996 |
| NetraKit by participant group (both eyes pooled) | | | | | | | | | |
| Age 5–10 years | 220 eyes | −0.03 | 0.17 | −0.37 to +0.31 | 59.5 | 97.3 | 100 | 0.11 | 0.995 |
| Age 10+ years | 230 eyes | −0.05 | 0.22 | −0.48 to +0.37 | 51.3 | 91.3 | 99.1 | 0.15 | 0.996 |
| Urban | 260 eyes | −0.03 | 0.19 | −0.41 to +0.35 | 55.8 | 95.0 | 99.6 | 0.12 | 0.996 |
| Suburban | 134 eyes | −0.04 | 0.21 | −0.45 to +0.36 | 52.2 | 93.3 | 99.3 | 0.14 | 0.995 |
| Rural | 56 eyes | −0.09 | 0.17 | −0.43 to +0.25 | 60.7 | 92.9 | 100 | 0.12 | 0.995 |
| Female | 230 eyes | −0.04 | 0.19 | −0.42 to +0.33 | 56.5 | 94.3 | 100 | 0.12 | 0.996 |
| Male | 220 eyes | −0.04 | 0.20 | −0.44 to +0.36 | 54.1 | 94.1 | 99.1 | 0.13 | 0.995 |
| No previous eye disease | 322 eyes | −0.04 | 0.18 | −0.40 to +0.31 | 55.0 | 96.9 | 99.7 | 0.12 | 0.996 |

| Method | Eye | Bias (D) | SD of diff. (D) | 95% LoA (D) | Exact (%) | ±0.25 D (%) | ±0.50 D (%) | MAD (D) | ICC |
|---|---|---|---|---|---|---|---|---|---|
| Previous eye disease | 128 eyes | −0.04 | 0.23 | −0.49 to +0.41 | 56.2 | 87.5 | 99.2 | 0.14 | 0.995 |

Note. Bias, mean of (method − reference); LoA, limits of agreement; MAD, mean absolute difference; ICC, intraclass correlation coefficient (two-way, absolute agreement, single measures). OD and OS n = 225 eyes each; pooled n = 450 eyes.

**4.4.4. Proportional and subgroup bias**

Snellen errors did not depend on the magnitude of refraction ($\rho = -0.07$, $p = 0.31$ for the second line; $\rho = -0.06$, $p = 0.35$ for the top line). No age group or refractive category had a bias exceeding −0.04 D, or one 0.25 D step of a lens. NetraKit, however, showed a low and non-significant correlation between difference and reference refraction ($\rho = 0.12$, $p = 0.08$). The difference in bias between myopic and hypermetropic eyes may reflect accommodation (He et al., 2011).

**4.4.5. Factors associated with NetraKit error.**

A multiple linear regression was performed to determine what were the predictors of the difference between the two measures: NetraKit vs the reference refraction. The sample size of 450 valid observations is the number of cases included in the model, and thus the statistical inferences and estimates of the parameters are based on all eyes in the sample.

**Model fit and explanatory power**

This model was found to have a limited ability to account for the variability of NetraKit errors. The coefficient of determination ($R^2$) was 0.10 indicating that the model explained 10% of the variability in the outcome and the adjusted R2 was 0.03, which is not very high given the number of predictors and sample size. The Pearson correlation coefficient (R) was 0.32, indicating a weak linear relationship between the predictors and the criterion, and the standard error of the estimate was 0.19 D, suggesting that the standard deviation of the criterion from the regression line is 0.19 D. This can be clearly seen in the observed vs. predicted difference plot (Figure S3) where the predicted values are grouped within approximately 0.25 D of zero, and the observed values are distributed on the 0.25 D lens-step grid. The overall regression model was still statistically significant, $F(33,416) = 1.48$, $p = .046$, meaning that the predictors together contribute to a significant amount of variance, compared to an intercept-only model.

**Significant predictors**

A multiple linear regression model was fitted with the NetraKit–reference difference as the outcome

variable. Statistical significance was assessed using conventional standard errors and, as a sensitivity analysis, using standard errors clustered by participants to account for the inclusion of both eyes (Table 3; full coefficients in Table S4). Most terms showed no significant association with NetraKit error.

The refractive category showed the most consistent association. After adjustment for the other terms, NetraKit readings were 0.05 D more negative in myopic eyes than in hypermetropic eyes (B = −0.05 D, 95% CI −0.09 to −0.01, p = 0.021; clustered p = 0.017). The mean difference in hypermetropic eyes was −0.01 D. This pattern is consistent with a slight over-minus tendency in myopic eyes.

A history of pterygium was associated with a larger negative difference (B = −0.20 D, 95% CI −0.34 to −0.06, p = 0.005; clustered p = 0.006). In 9 of the 10 eyes of the five affected participants, NetraKit readings were equal to or more negative than the reference.

Previous left-eye cataract surgery with intraocular lens implantation was associated with a positive difference (B = +0.34 D, 95% CI 0.04 to 0.65, p = 0.029). However, this estimate derives from a single participant whose operated eye read 0.50 D more hypermetropic than the reference, and a clustered standard error could not be estimated.

Given the small number of participants in these two subgroups and the number of terms tested, the associations with pterygium and cataract surgery should be regarded as exploratory.

Table 3: Terms significantly associated with NetraKit error (multiple linear regression, 450 eyes)

| Term (reference category) | n | B (D) | 95% CI (D) | p | p, clustered SE |
|---|---|---|---|---|---|
| Refractive category: myopia (hypermetropia) | 314 eyes | −0.05 | −0.09 to −0.01 | 0.021 | 0.017 |
| Previous eye disease: pterygium (none) | 10 eyes (5 people) | −0.20 | −0.34 to −0.06 | 0.005 | 0.006 |
| Previous eye disease: cataract, IOL implanted, left eye (none) | 2 eyes (1 person) | +0.34 | +0.04 to +0.65 | 0.029 | — |
| Model summary | | | | | |
| Overall model (n = 450 eyes): F(33, 416) = 1.48, p = .046; R = 0.32; $R^2$ = 0.10; adjusted $R^2$ = 0.03; SE of estimate = 0.19 D | | | | | |

| Term (reference category) | n | B (D) | 95% CI (D) | p | p, clustered SE |
|---|---|---|---|---|---|
| All other terms (age, gender, screen time, sunlight, residence, eye, other eye conditions, systemic illnesses) | | | | > 0.05 | |

Note. Outcome variable: NetraKit − reference refraction for each eye. Model included 33 predictor variables. Clustered standard errors account for two eyes per participant; not estimable for a single-participant category. Findings for pterygium and left-eye cataract surgery rest on very small groups and should be treated as exploratory.

The other variables, such as age, gender, screen time, sunlight exposure, residence, eye, other eye conditions and all systemic illnesses, did not show a statistically significant association with NetraKit error ($p > 0.05$). The response B for the constant term was not significantly different from zero ($B = −0.00$, $p = .944$) and thus, the difference predicted for the reference group was very close to zero. Equity (no clear difference by residence or gender in this descriptive comparison) is relevant in itself; the proportion of eyes within ±0.25 D was 95.0% in urban, 93.3% in suburban and 92.9% in rural participants and 94.3% in females and 94.1% in males (Table 2).

***Residual diagnostics***

The results of the residual analysis suggest that the assumptions of linearity and homoscedasticity are mostly fulfilled (Table S5). The prediction residuals were not systematically biased (mean 0.00) and were centred near zero (median 0.02, SD 0.19). The standardised residuals were within the range of −3.85 to 2.90: One was the value of −3.85, suggesting that the model overestimated the difference by a considerable amount, and another was 2.90, meaning that the model underestimated the difference by a significant amount. On inspection these values were found to be plausible values for −0.75 D and +0.50 D respectively and not due to data entry error and were retained as such, to show non-normality or undue influence.

**Normality of residuals**

Four tests, Kolmogorov-Smirnov test (KS test 0.10), Lilliefors-corrected Kolmogorov-Smirnov test (LKS test 0.10), the Shapiro-Wilk test ($W = 0.97$) and the Anderson-Darling test (5.62) were used to assess the assumption of normally distributed residuals. All gave $p < .001$, which resulted in formal rejection of normality (Table S5). However, the Shapiro–Wilk test is very sensitive to the sample size and a deviation of only a few points is considered significant with 450 observations, although the Shapiro–Wilk statistic is 0.97, which indicates a distribution close to normal. Visual inspection is thus more informative (Figure S4). The histogram displays a tapered distribution with a slight skew towards the right and centered at

zero, while the Q–Q plot displays points that are generally near the reference line in the middle, with some minor deviations at the ends, likely due to the 0.25 D measurement scale. The effects this non-normality might have on the validity of the conclusions of the model are thus likely to be negligible, and the results were similar when the standard errors were clustered by participant.

### 4.5. Categorical agreement

The reference classified 294 eyes as myopic, 123 as hypermetropic and 33 as emmetropic (Table S2). The second-line and top-line readings were in close agreement with this classification, with 95.3% and 96.7% of eyes ($\kappa = 0.91, 0.93$) in the "almost perfect" (Landis & Koch, 1977) range. NetraKit's classification rate was in agreement with the reference classification in 97.1% of eyes ($\kappa = 0.94$). Disagreements were at the cut-off lines for all three methods and no eye was switched from myopia to hypermetropia or vice versa.

### 4.6. Past eye disease, systemic disease and surgery

Sixty-four participants (28.4%) had a previous eye disease across eleven conditions (Table 4; Figure S2a), most commonly allergic conjunctivitis (9), cataract with intraocular lens implantation (8) and blepharitis (8), followed by dry eye, amblyopia, pterygium, strabismus, recurrent conjunctivitis, diabetic retinopathy (4), age-related macular degeneration (4) and glaucoma (3). However, younger people (mean age 11.2 years for amblyopia and 12.6 years for strabismus) and older people (58.5 years for AMD, 56.3 years for glaucoma, 51.3 years for diabetic retinopathy) were more likely to have amblyopia, strabismus, and degenerative conditions, respectively. Fifty-four participants (24.0%) had one of ten systemic illnesses (Figure S2b), led by asthma and hypertension (8 each) and type 2 diabetes (7); all participants with diabetic retinopathy had diabetes, and 25 had both an eye and a systemic condition.

Table 4: Previous eye disease and ongoing systemic illness

| Condition | n | Mean age (years) | Age range (years) |
|---|---|---|---|
| Previous eye disease (64 participants) | | | |
| Allergic conjunctivitis | 9 | 23.1 | 5–61 |
| Cataract, IOL implanted (5 bilateral, 2 right, 1 left) | 8 | 57.6 | 52–62 |
| Blepharitis | 8 | 25.1 | 7–57 |
| Dry-eye symptoms | 7 | 18.7 | 5–50 |
| Amblyopia | 6 | 11.2 | 5–16 |

| Condition | n | Mean age (years) | Age range (years) |
|---|---|---|---|
| Pterygium | 5 | 50.2 | 30–62 |
| Strabismus | 5 | 12.6 | 9–22 |
| Recurrent conjunctivitis | 5 | 18.4 | 5–39 |
| Diabetic retinopathy | 4 | 51.3 | 43–61 |
| Age-related macular degeneration | 4 | 58.5 | 55–62 |
| Glaucoma | 3 | 56.3 | 52–62 |
| Ongoing systemic illness (54 participants) | | | |
| Asthma | 8 | 13.1 | 6–30 |
| Hypertension | 8 | 48.1 | 26–60 |
| Type 2 diabetes | 7 | 51.4 | 35–61 |
| Allergic rhinitis | 6 | 24.7 | 6–55 |
| Thyroid disorder | 5 | 44.4 | 21–62 |
| Hyperlipidaemia | 5 | 50.4 | 39–60 |
| Migraine | 5 | 25.2 | 15–40 |
| Type 1 diabetes | 4 | 17.0 | 5–43 |
| Epilepsy | 3 | 11.3 | 6–21 |
| Rheumatoid arthritis | 3 | 40.0 | 33–47 |

Note. IOL, intraocular lens. Each participant has at most one condition recorded in each field; 25 participants have both a previous eye disease and a systemic illness.

Fifteen participants (6.7%) reported past surgery or trauma, including eight with cataract surgery (five bilateral, three unilateral) aged 52–62 (Table S3). Snellen reading remained within 0.50 D in each eye and NetraKit reading was within ±0.25 D in 14 of 16 eyes of these participants, corresponding to a slight myopic target.

## 5.DISCUSSION

### 5.1. Principal findings

NetraKit showed close agreement with reference refraction, with small bias and narrow limits of agreement. The bias of both the Snellen end points were negligible, although other studies of subjective methods report wider limits, particularly among younger children and eyes with other pathology (He et al., 2011; Smith et al., 2010). The pattern of errors is revealed by the categorical results; that is, errors in the level of emmetropia or low error do not seem to have much impact, while errors in the level of myopia and hypermetropia seem to have serious impact, with no method producing errors of this kind.

### 5.2. The accuracy of NetraKit in the context.

The accuracy of NetraKit in this dataset is 94% within one lens step and with a slightly myopic bias, which compares favourably with published results for other low-cost methods, although study designs differ. Self-refraction with adjustable spectacles yielded mean differences of almost zero (He et al., 2011) and median errors of about 0.60 D for an unassisted smartphone refractor (Tousignant et al., 2020).

### 5.3. Public health implications of the significant predictors.

The important predictors were examined and discussed in terms of their public health implications. Myopia and over minus errors. The average myopic eye error is only 0.05 D, but is significant because a NetraKit programme would be targeting the largest group of school children who are myopic. A tendency to accept a little extra minus power is well documented in subjective and self-refraction especially in children that can accommodate (He et al., 2011). Spectacles are not to be worn if they are too strong, and this is a part of the problem of Indian school programmes, which is already poor spectacle wear (Gajiwala et al., 2021). The practical answer is procedural not technical: we propose that screeners be trained to select the smallest minus they can, which will allow the top line to be clearly seen, and ready-made spectacles for children who are myopic could be provided at, not above, the NetraKit reading; this requires prospective validation.

Pterygium, sunlight and workers working outdoors. Pterygium is a fibrovascular epithelial proliferation of the cornea that is highly associated with UV exposure, and is more prevalent in hot and sunny environments and rural areas (Liu et al., 2013). It causes flattening of the corneal surface and may cause an astigmatism that is often irregular and cannot be easily measured using conventional refraction (Maheshwari, 2007). This type of astigmatism cannot be detected by a sphere-only type instrument like NetraKit, and may help account for the higher error in these participants. We propose that programmes in rural and high sunlight areas consider incorporating a simple anterior segment check into the screening process, and refer any individual with a visible pterygium, since agricultural and outdoor workers have poorest access to eye care. The discovery also backs the inclusion of the wearing of eye protection (e.g., brimmed hats or UV-blocking sunglasses) into occupational and community health messaging.

Refraction and cataract surgery. The NPCBVI performs millions of cataract surgeries in India every year, many eyes operated thereafter require spectacles for residual refractive error. The improvement seen in the operated eye of one participant does not form the basis for generalisation, but it shows the importance of operating eyes with P.C.O. or some residual astigmatism being sent to the optometrist for review instead of screening only. Concurrently, an opportunity exists: a low cost tool at the primary level that could help identify operated patients who require spectacles, without the need for a return trip to the surgical centre.

Caution in interpretation of these findings. Only 10% of the variation in NetraKit error is accounted for by the model, with two of the three terms with significant effect being based on very small groups (five with pterygium, and one with cataract surgery on the left eye). One or two statistically significant results would be found by chance after trying 33 of the terms. The findings should therefore be considered as hypotheses; future studies should pre-specify pterygium and pseudophakia as subgroups with adequate numbers. More broadly, all agreement, equivalence and regression results come from a single-site pilot sample.

### 5.4. Interpreting agreement in a screening context

Usually refractions repeat within 0.25 D and ready-made spectacles are available in 0.25 or 0.50 D increments. In this paper (and subsequently in other examples) a reasonable pre-specified standard is that at least eighty per cent of eyes fall within 0.25 D, with proportional error of zero and bias of no more than one lens step.

### 5.5. Children and accommodation

Nearly half of the data is from children between the ages of 5 and 10. Because they have a large range of accommodation they are able to focus with a plus lens and to wear too much minus lens, subjective estimates of hypermetropia without cycloplegia tend to be underestimated (Negrel et al., 2000; He et al., 2011). The "comfortably clear" instruction is designed to minimize this, and the effect of the instruction should be tested directly in future studies

### 5.6. Elderly and concurrent eye disease

This is because retaining the older people who have cataract surgery, AMD, glaucoma and diabetic retinopathy is indicative of attendance at community camps (Vashist et al., 2022; Wong et al., 2014; Tham et al., 2014; Yau et al., 2012). The top line may never be clear in a person with advanced retinopathy or AMD, and best acuity is limited in children by amblyopia; therefore the field study results are reported separately for eyes with previous eye disease (Table 2).

### 5.7. Public health and policy / implementation

Any screening tool is just as effective as the system in which it is used. It explores why there is a need for NetraKit, its place in India's eye care system and policies, its cost, legal issues it may create, its deployment, and how India is doing compared to other countries and the social factors that will influence its success or failure.

#### 5.7.1. Public health gaps: why a tool like NetraKit is needed

There are four gaps in the case for NetraKit. The first is a burden gap. The two major contributors to visual impairment in older adults in India are uncorrected refractive error and cataract (Vashist et al., 2022), while childhood myopia is increasing, especially in urban areas (Agarwal et al., 2020; Priscilla & Verkicharla, 2021). The second is a labor shortage. In India, there are approximately 9,000 optometrists who have completed four years of degree education, and 40,000 ophthalmic technicians and assistants with two years of diploma training out of the population of over 1.3 billion people (Arvind et al., 2021). Optometrists are also grouped together in urban areas and rural areas are very dependent on periodic camps. The third is a passage opening. In India, the screening programmes commonly have two stages: first, a trained teacher conducts a visual acuity screening and children with poor scores are referred to a health centre for further screening by an ophthalmic assistant, who then performs a refraction. Each subsequent step along this pathway has the potential for the families to drop out, such as the trip to the health centre. The fourth one's a continuity gap. Many children don't wear glasses, even if they are given for free. In a multi-site Indian study, only 29.8% of children were found to still be wearing the spectacle provided through the children's screening (Gajiwala et al., 2021), and in a study in Tamil Nadu, approximately 20% of children were not wearing their free spectacle at follow up, primarily because the spectacle had been lost or broken (Pawar et al., 2023).

The aim of NetraKit is to close the pathway gap in specific. If a trained non-specialist could obtain a per eye dioptric estimate at the first point of contact, then three things became possible: ready made spectacles could be offered to children and adults with simple, symmetrical refractive error immediately, the number of people who had to travel to a health centre could be reduced and those with more complex needs could be referred with a specific referral reason rather than with a general failed screening label. Whether NetraKit is able to do this safely will depend on how accurate it is in practice and on the decision rules for dispensing and referring (Section 5.7.7).

#### 5.7.2. Public provision for eye care services

The National Programme for Control of Blindness and Visual Impairment (NPCBVI), established in 1976, is India's public eye care program that has been in place since then, and includes screening for children in schools and free spectacles for children (Gajiwala et al., 2021). The role of Ayushman Arogya

Mandirs (AAMs/Health and Wellness Centres) at the primary level is clearly defined in vision screening, outreach camps, record keeping and linkage with Rashtriya Bal Swasthya Karyakram (RBSK) school teams for free spectacles, and specialist care is provided in district hospitals and tertiary centres (National Health Systems Resource Centre [NHSRC], 2021). There is significant capacity building from non-government programmes: the Orbis-led REACH programme has reached more than two million children in over 10,000 government schools which are largely rural, with 8.6% referred for detailed evaluation by partner hospitals (Sil et al., 2022). NetraKit would be located at the primary level and would be used by teachers, RBSK staff, community health officers or trained camp volunteers.

### 5.7.3. The gaps between policy and practice and eye testing policies

Indian policy promises free school screening and spectacles, screening at primary care facilities and referral to specialist care (Gajiwala et al., 2021; NHSRC, 2021). Table 5 presents an overview of these intentions compared to gaps reported and the potential role of NetraKit.

Table 5: Policy intentions, reported gaps and the potential role of NetraKit

| Policy or scheme element | Intended function | Reported gap | Potential role of NetraKit |
|---|---|---|---|
| NPCBVI school eye screening | Teachers screen acuity; ophthalmic assistants refract children who fail; spectacles provided | Two-step pathway with drop-out between screening and refraction; limited quality assurance of screening | Per-eye dioptric estimate at first contact; fewer referrals needed for simple cases |
| Free spectacles for school children | Remove the cost barrier to correction | Only 29.8% using spectacles within two years in a multi-site study; about 20% not wearing free spectacles, mostly lost or broken | Supports on-site dispensing linked to follow-up; does not by itself solve compliance |
| Eye care at Ayushman Arogya Mandirs (AB-HWC guidance) | Vision screening, outreach camps, NPCBVI records, RBSK linkage for spectacles | Staffing and equipment vary; eye care competes with many other primary care duties | Low-cost tool usable by community health officers with standard electronic records |

| Policy or scheme element | Intended function | Reported gap | Potential role of NetraKit |
|---|---|---|---|
| RBSK school health teams | Screen children and link them to free spectacles | Broad mandate in which vision is one of many conditions | Short, structured refraction step within existing school visits |
| Referral to secondary and tertiary care | Specialist diagnosis and treatment | Travel costs, lost wages, lost referral slips and low attendance | Referral with a specific reason; appointment booked at screening |
| Workforce regulation (NCAHP Act, 2021) | Standardise optometry education and registration | About 9,000 four-year trained optometrists and 40,000 two-year trained technicians and assistants for over 1.3 billion people | Task-sharing under a defined protocol with remote optometrist review |

Note. Sources: Gajiwala et al. (2021); Pawar et al. (2023); NHSRC (2021); Sil et al. (2022); Arvind et al. (2021); Government of India (2021).

There are three distinct patterns. Policies assess outputs – children screened, children given spectacles – not outcomes – children who are wearing the right glasses months later. They take a holistic view of the staff from the teacher to the ophthalmologist, which is rarely true in reality. There is little discussion about quality assurance of non-specialist screening. None of the above can be answered by NetraKit, but NetraKit can help to cut down the time taken in the chain and, if electronic records are implemented, it can make outcomes easier to track.

### 5.7.4. The accessibility gap

It is sometimes said that having access to health care has multiple dimensions: is health care available, is it accessible, is it affordable and is it acceptable to those who use it? (Tanahashi, 1978; Levesque et al., 2013). All these dimensions are of significance in refractive care in India.

Availability is restricted due to a shortage of practitioners as mentioned above and because optometrists and ophthalmologists tend to be more concentrated in urban areas. It may be difficult to access vision centres and district hospitals, which could be many kilometres from rural villages, and a journey to access the service may take a full day. If a person works by the day, the expenses of going to a district hospital can lead to a loss of a day's wages and transport charges may be a major part of the total. Social attitudes influence acceptability: wearing spectacles could be considered as a weakness, not becoming engaging, or having concerns that the glasses could affect the marriage prospects of the daughter or make her eyes

"dependent" on glasses (Gajiwala et al., 2021). Older people might feel they've developed deteriorating vision as part of the ageing process and not need treatment.

These dimensions are not evenly spread. Rural communities, women and girls, older people, persons with disabilities and households from the Scheduled Castes and Tribes experience multiple disadvantages along various dimensions. Rural participants made up only 12.4% of our sample, a typical challenge in screening programmes: rural people who are most difficult to reach are the least likely to be included in the study. A NetraKit deployment in the context of reducing inequity would have to be strategically focused on rural schools, tribal areas and urban informal settlements, and not simply targeted at the "low hanging fruit" of well organised urban schools.

**5.7.5. An analysis of costs, and economics.**

The price of NetraKit is around ₹2200 per kit. This is the most obvious difference between it and traditional refraction devices but the price of the kit is just one component of the cost of a screening programme. The time taken by user(s) to use the realistic cost analysis, costs for training, consumables, provision of spectacles and costs of referrals for those requiring additional services should also be considered.

A simple model was created to demonstrate the structure of these costs. The model assumes that each kit will be used for three years, the costs of maintenance/cleaning materials and replacement parts are the same for each kit (₹300 per year), the cost of providing one day of training to the screener is ₹1,000, and a community health worker is paid the same amount per day (₹500 per day) as an opportunity cost. Three scenarios were developed for modelling. The low use scenario is 50 days per year with 20 people screened a day, the base scenario uses 100 days per year with 30 people screened a day, and the high use scenario uses 200 days per year with 40 people screened a day. Table 6 shows the results. All numbers are for planning purposes only and should be replaced with locally measured costs in future work.

Table 6: Illustrative cost per person screened with NetraKit (kit price ₹2,200; three-year life)

| Item | Low use | Base case | High use |
|---|---|---|---|
| Assumptions | | | |
| Screening days per year | 50 | 100 | 200 |
| People screened per day | 20 | 30 | 40 |
| People screened over three years | 3,000 | 9,000 | 24,000 |
| Cost per person screened (₹) | | | |

| Item | Low use | Base case | High use |
|---|---|---|---|
| Kit (₹2,200 spread over lifetime screenings) | 0.73 | 0.24 | 0.09 |
| Maintenance and consumables (₹300 per year) | 0.30 | 0.10 | 0.04 |
| Screener training (₹1,000, one day) | 0.33 | 0.11 | 0.04 |
| Screener time (₹500 per day) | 25.00 | 16.67 | 12.50 |
| Total cost per person screened | 26.37 | 17.12 | 12.67 |
| Screening cost per case identified (10% yield) | 263.7 | 171.2 | 126.7 |

Note. All inputs are indicative planning values and not actual costs. Excludes spectacles, validation, regulatory approval, supervision, data systems and referral care. The 10% yield is in line with the 8.6% referral rate recorded by Sil et al. (2022).

The model shows that the main cost for determining the cost per person screened is the time of the screener and not the kit. The cost of the kit over the life of the kit is only ₹0.24 per screening and the total cost per person screened is approximately ₹17 in base case. For the low use scenario, the total cost per person screened is about ₹26 and the kit cost is less than ₹1. In the base scenario, the cost of screening each person who is identified is approximately ₹171, which is comparable to the REACH programme's 8.6% referral rate (Sil et al., 2022). In case a pair of ready-made glasses needs to be included in the expense, then the total cost of identification and correction of one case is in the few hundreds of rupees.

Traditionally, the person who fails the acuity test will be required to attend a health centre or hospital and travel and lost working time to attend the test might cost more to the adult or accompanying parent than the test and the spectacles. Taking the costs of first contact to estimate refraction could reduce the impact on the household level and the number of people lost at each point along the pathway.

There's also an even larger economic one. The economic losses associated with Uncorrected Refractive Error are considerable (Smith et al., 2009) and the cost of establishing Refractive Services is estimated to be much smaller than the continuing losses due to URE (Fricke et al., 2012). Uncorrected refractive error can impair children's learning and school performance, and have long-term impact on their earnings. Whereas a low cost tool provided refractive services to people who are not currently getting a service, there might be significant returns, not only in the provision of a refractive service, but also in use and retention if the service is provided.

Several caveats apply. The cost of the field study, regulatory approval, supervision and quality assurance, data systems, and management of people referred for specialist care is not included in the model, and will be higher if pterygium patients, patients who have had previous cataract surgery and patients who have other eye disease are routinely referred for specialist care. It also assumes that NetraKit is accurate

enough to use for dispensing decisions, which is yet to be proved. If a large amount of results were required to be reviewed by an optometrist cost savings would be less. Additionally, adherence of the children to the use of their glasses also plays a crucial role in the effectiveness or cost-effectiveness of a screening programme – the adherence to spectacle use as seen by Gajiwala et al (2021) is quite low at 1 in 3 children after 2 years, which means the effective cost is about triple that of dispensing the glasses. Therefore, investment in compliance (such as better frames, follow-up and education) may be as important as screening investment. NetraKit is thus not marked as cost-effective, which calls for measured programme costs, referral costs, effectiveness and the outcomes of the patients.

The kit is likely to be under the routine (NPCBVI and RBSK) procurement budget and may be made use of for corporate social responsibility funding at the price of ₹2200 (this has not been evaluated).

**5.7.6. Tackling legal and regulatory matters.**

NetraKit is developed and deployed in the backdrop of certain laws and regulations. The first is about medical device regulation. In India, medical devices are governed by Medical Devices Rules, 2017, which categorize the medical devices according to risk classes A to D. The classification of a device must be verified with reference to the official list of classification kept by the Central Licensing Authority, and, if not listed, the classification must be first obtained from the Central Licensing Authority. In addition, the investigational medical devices also need approval from the Central Licensing Authority pursuant to the clinical investigation provisions of the rules (CDSCO, 2024). It would then be the responsibility of the NetraKit developers to seek formal classification, and if successful, the developers would also need to secure a manufacturing licence; and the field validation study could be a clinical study for which a licence would be required.

The second has to do with scope of practice of a profession. For the first time in the history of optometrists, ophthalmic assistants and vision technicians have a formal regulatory framework in the form of state registers and minimum educational standards as laid out in the National Commission for Allied and Healthcare Professions Act, 2021 (Government of India, 2021). The regulations for the registration under the Act were published in the Gazette in September 2026. The importance of distinguishing between screening and refraction/prescribing will become a growing challenge with the introduction of this framework, and this may not be a specialty role. A NetraKit reading is not meant to be a prescription, but it is to be a screening estimate, which will then direct a decision towards a ready made spectacles under a specific protocol or referral. Specifications in the deployment protocol should specify any actions that can be performed by the screener and which are required by the optometrist, possibly with remote review.

This is the third area, data protection and consent. The personal health data would come from the use of NetraKit screening, and often would involve children. The Digital Personal Data Protection Act, 2023 (Government of India 2023) provides for the processing of the personal data of a child to be limited to cases where the parents/legal guardians give verifiable consent and the processing is likely to impact the wellbeing of a child. Screening programmes also should include parental consent and only gather

information that is necessary, secure data storage mechanisms and an identification system for data access. Ethical guidelines for biomedical and health research with human participants published by Indian Council of Medical Research (ICMR, 2017), for consent and assent from children and ethics committee review should also be followed in research conducted using NetraKit data.

Consumer protection and liability is the fourth area of concern. There may be a question of liability if the spectacles are issued on the NetraKit reading and the correction is wrong or if a serious eye disease is not diagnosed because the NetraKit result was considered satisfactory. The most effective way for participants and screeners to be protected is through having established protocols, documentation of training, informed consent (with an explanation of the limitations of screening), and referral processes for individuals who present with warning signs. Finally, the Rights of Persons with Disabilities Act, 2016 (Government of India, 2016), which classifies blindness and low vision as disabilities, further reinforces the agenda of public programmes to increase access to screening and correction services for people with disabilities.

**5.7.7. This is protocol for deployment of NetraKit.**

A proposed five-phase deployment plan is shown in Table 7, which has been based on the NHSRC (2021), Sil et al. (2022) eye health programmes.

Table 7: Proposed protocol for deploying NetraKit

| Phase | Key activities | Responsible | Safeguards and indicators |
|---|---|---|---|
| 1. Pre-deployment | Device classification with the Central Licensing Authority; ethics approval; field validation against optometrist refraction; standard operating procedures; procurement | Developer, research team, state NPCBVI cell | Regulatory classification and licence if required; validation results meet pre-specified agreement criteria |
| 2. Training and certification | One to two days of training for teachers, RBSK staff or community health officers; practical certification against an optometrist; refresher training | District programme manager, optometrist trainers | Certification only if most test eyes fall within ±0.50 D of the trainer; annual recertification |
| 3. Screening session | Parental consent and child assent; questionnaire; acuity with chart; NetraKit reading for OD then OS; electronic recording | Certified screener | Standard distance and lighting; data minimisation and secure storage |

| Phase | Key activities | Responsible | Safeguards and indicators |
|---|---|---|---|
| 4. Decision and action | Dispense ready-made spectacles when criteria are met; otherwise refer; book appointment and send reminders; optional remote optometrist review | Screener with remote optometrist | Refer if: vision does not improve with correction; OD–OS difference ≥ 1.00 D; power outside ready-made range; significant hypermetropia in young children; history of DR, glaucoma, AMD, amblyopia, strabismus, pterygium or cataract surgery; red-flag symptoms. Dispense the weakest minus lens that gives comfortable clarity |
| 5. Follow-up and quality assurance | Spectacle wear check at 3–6 months; replacement of lost or broken spectacles; re-examination of a random sample by an optometrist; equity monitoring | School health team, optometrist, district team | Coverage; referral completion; spectacle wear rate; screener agreement; results by gender, caste, tribe and location |

Note. DR, diabetic retinopathy; AMD, age-related macular degeneration; OD, right eye; OS, left eye. This protocol is proposed and requires prospective validation.

The rules for referral are designed to be conservative: persons whose vision does not improve with correction, with an OD–OS difference of 1.00 D or more, a power outside the ready-made range, significant hypermetropia in young children, a history of eye disease (diabetic retinopathy, glaucoma, AMD, amblyopia or pterygium), previous cataract surgery or red-flag symptoms would be referred instead of issued spectacles under this proposed protocol. It is noted that 28.4% had previously had an eye disease and 24.0% a systemic illness, meaning the proportion of people who will be able to be treated first time will be less than the proportion with refractive error and plans should allow for referrals. Quality assurance is incorporated via re-examination by the optometrist of a random sample, and follow-up at 3 to 6 months is regarded as a form of screening.

**5.7.8. Appointments, referral and continuity of care**

One of the most common problems with screening programmes is that fewer people attend than are referred for screening. The Kenyan study on the use of a smartphone for screening children in school showed that it improved the identification of children with visual impairment, but children who were referred did not attend follow-up appointments (Rono et al., 2018). The same issue is also prevalent in

Indian programmes. Parents may not understand the need to follow through on a referral, or they may not have the time, and it's easily forgotten by the child when taken home.

There are several aspects which could reinforce this connection in a NetraKit programme. Screening appointments might be scheduled at the screening time with a designated place, date and time, not on the parents' agenda. Reminders could be given via SMS or voice call; even in households with no smart phones. Specialist review could be introduced where possible to the community in the form of planned outreach days at schools or Ayushman Arogya Mandirs instead of the individual having to travel to a district hospital. Continuity could benefit from digital health infrastructure: If screening results are stored with the health identifier of the patient under Ayushman Bharat Digital Mission, then the results will be sent with the patient to the referral clinic; If the questionnaire data and results from NetraKit are provided on the teleconsultation platform, an optometrist could review it remotely and decide if an in-person visit is required. There should also be a process to monitor referral completion as an indicator and districts or schools with low completion can be identified for support.

**5.7.9. A comparative study with other models from outside the country.**

There are several countries that provide models for organization of vision screening in school and community (Table 8).

Table 8: International and domestic models of vision screening compared

| Model | Who screens | Target group | Key features | Lessons for a NetraKit programme |
|---|---|---|---|---|
| United Kingdom | Orthoptists or staff trained and supervised by orthoptists | Children aged 4–5 years | National Screening Committee recommendation; funding moved to local authorities in 2015; about 6% of local authorities reported no screening | Clear national standards help, but coverage erodes when funding is fragmented |
| China | Schools with medical and health institutions | Children and adolescents | 2018 national plan led by the Ministry of Education; regular vision monitoring; electronic vision records; prevalence targets in government performance evaluation | Link screening with prevention, records and accountability |

| Model | Who screens | Target group | Key features | Lessons for a NetraKit programme |
|---|---|---|---|---|
| Kenya (Peek) | Teachers using a smartphone acuity test | School children | Validated app; cluster randomised trial; more children identified but many did not attend referral | Technology extends reach; referral completion must be designed in |
| India (REACH, Orbis) | Trained screeners with partner hospitals | Children aged 5–18, mostly rural government schools | Over two million children screened; 8.6% referred for detailed evaluation; electronic data | Large scale is feasible through partnerships, but depends on hospital capacity |
| India (NPCBVI school screening) | Teachers, then ophthalmic assistants | School children | Free spectacles; two-step pathway | Wide mandate, with gaps in follow-up, compliance and quality assurance |

Note. Sources: British and Irish Orthoptic Society (2020); Jan et al. (2020); Bastawrous et al. (2015); Rono et al. (2018); Sil et al. (2022); Gajiwala et al. (2021).

All children aged 4–5 years should have vision screening, which should be organised and led by orthoptists, and the primary goal of the vision screening should be to identify amblyopia before it can be treated; this is recommended by the National Screening Committee in the UK. The funding of this screening in England, however, was devolved to local authorities in 2015 and a survey of the local authorities revealed that approximately 6% did not have a vision screening programme for this age group, showing how a good national screening plan can be undermined by decentralised funding (British and Irish Orthoptic Society, 2020). In 2018, China officially launched a national strategy for the prevention and control of childhood and adolescent myopia with the Ministry of Education leading the way, along with other government bodies (Jan et al., 2020). The plan will also include measures to increase outdoor time at school, and regular vision screening and electronic vision health records for every student, and will include specific goals to help decrease the prevalence of myopia by no less than 0.5% per year, which will be a part of the government's performance evaluation. In Kenya, the Peek programme demonstrated the potential for teachers to be trained to use a smartphone-based acuity test to screen large populations of school children, and to provide referrals; however, the difficulty of getting children referred to for care was also noted (Bastawrous et al., 2015; Rono et al., 2018).

Adopting these models indicates that India should learn the following lessons. The first is that funding responsibility and continuity is as important as technical design, as is evidenced by the English experience, where some screening has broken down because responsibility for funding has been split.

Secondly, screening is most effective when it is coupled with prevention and with electronic records that follow the child as in China. The third is that there is a trade-off between the two types of screener, between specialist-led screening (as in the UK) and teacher-led screening (as in Kenya and much of India), because specialist-led screening may be more accurate, but teacher-led screening can reach more children at lower cost. NetraKit could be seen as one approach to increasing accuracy and utility of non-specialist screening, allowing for the implementation of teacher and community worker models while reducing the accuracy difference from specialist-led screening; the country of India can implement these approaches while retaining the reach of community and teacher led screening approaches.

**5.7.10. The implementation gaps: a social science perspective**

Policy-practice gap is a key issue in the social science of public policy. Pressman and Wildavsky (1973) demonstrated that programs that involve a multitude of actors are open to failure at every decision point and that, therefore, even well-designed programs can achieve significantly less than intended outcomes. As Lipsky (1980) pointed out, policies are "actually" made by the "street-level bureaucrats" who are tasked with providing those policies to citizens, in this case teachers, health officials, and clerks, whose workloads, incentives, and discretion determine what citizens actually receive. These are two important lessons that can be applied to eye screening in India. A school screening programme includes the health department, the education department, the school principals, teachers, ophthalmic department, spectacle suppliers and parents. Teachers requested to screen children in addition to their teaching tasks and frequently are only given one day of training and little supervision; it is reasonable that the task is not given high priority.

Outcomes are also influenced by social and cultural factors. Teasing and stigma, the appearance of frames and parents' beliefs regarding the effects of spectacles all affect spectacle wear among children (Gajiwala et al., 2021). The reasons why people do not wear free spectacles were predominantly due to the loss or breakage of the free spectacles in the study done in the State of Tamil Nadu which suggests that the frames need to be long lasting and the free spectacles can be easily replaced (Pawar et al, 2023). A trial in government schools in the vicinity of Bangalore showed that the proportion of children wearing ready-made glasses was similar to that wearing custom-made glasses in a group where all children were eligible for glasses, indicating that a programme with NetraKit for dispensing ready-made glasses on-site may not compromise compliance, provided that children with more complex prescriptions are referred (Morjaria et al., 2017).

There is also a gender and hierarchical aspect. Girls are perhaps less likely to receive subsequent care or to be motivated to wear glasses; women may depend on the availability of a family member to accompany them for care. The communities from the SC/ST groups could find that they are not being served by services or they may doubt the institutions that have failed them earlier. Older people might consider vision loss to be a normal part of life. A NetraKit programme that is oblivious to these factors can easily replicate inequalities and be seen by the easiest populations but not by the poorest.

The fact that these observations suggest that the success of NetraKit will be more strongly related to embedding of the kit in local systems suggests that the surrounding contexts will be more important than the actual kit itself. Some practical solutions are to acknowledge and reward the screening efforts of teachers and health workers; engage community leaders and selfhelp groups to promote screening and use of spectacles; provide a range of attractive and durable designs; follow up screening in schools, rather than relying on the families' return; and track coverage and results by gender, caste, tribe and location to identify gaps. To sum up, NetraKit can reduce the technical gap between screening and correction, but gaps in the implementation need to be addressed to close the gap between the tool and the people, institutions and social norms through which it will be delivered.

### 5.8. Limitations

Spherical refraction is the only refraction that is being recorded in the dataset. Screen time was self-reported and sunlight exposure was assessed as a single binary variable, reducing the ability to analyze risk factors; and the study was cross-sectional, which prevents drawing conclusions about cause and effect, even if associations were seen in data. The policy and legal discussion is based on an assumed position at the time of writing and the cost analysis is an illustrative one and not based on measured programme costs as regulations under the NCAHP Act and the Medical Devices Rules will continue to develop.

## 6. CONCLUSION

This study evaluated NetraKit against reference refraction and Snellen-target endpoints, and a low-cost kit for estimation of spherical refraction for each eye has been presented. The framework includes monocular testing, a structured questionnaire and a pre-specified analysis using Bland–Altman agreement, lens-step accuracy, ICC and kappa and subgroup analysis. It was applied to 225 participants and 450 eyes, and yielded complete data, with negligible bias for Snellen readings (limit of about half a dioptre, with more than 80 per cent of eyes within ±0.25 D) and within one lens step for NetraKit eyes (97.3 per cent within ±0.25 D in children aged 5–10 and 91.3 per cent within ±0.25 D in older participants; bias was −0.04 D). The error was slightly higher in myopic eyes (NetraKit tended to over minus) and pterygium eyes, and no clear difference between rural and urban or female and male participants in this sample.

There is more to it than accuracy. India's eye care schemes are restricted by a two-step approach, availability of fewer optometrists, poor adherence to spectacles, cost of the household and poor follow-up. The cost of NetraKit is approximately ₹2,200, and the illustrative cost model estimated approximately ₹13–26 per person screened, mostly screener time. We propose training screeners to avoid over-minus correction, and referral of those with pterygium or previous cataract surgery to an eye specialist, along with classification of the device, a clear distinction between screening and prescribing, parental consent and data protection, booking appointments and follow-up with a screening device, and purposeful targeting of under-served communities; these proposals require prospective validation. Experience both

domestically and internationally indicates that programmes that result in an outcome, as opposed to recording activity, are characterized by the consistency of funding, clear accountability, electronic records, and focus on completion of referrals.

A sample size calculation, repeatability testing and measures of feasibility in Indian schools and communities with independent masked refraction (IMR) will be the next step. NetraKit could reduce the time taken from screening to correction for one of the most common and most correctable drivers of vision loss across all ages if it puts the majority of eyes within half a dioptre of clinical refraction, even in the presence of other eye conditions.

## DECLARATIONS

### Ethics Statement

This study was carried out with respect to ethical standards for research with human subjects. Before taking part, all participants received information regarding the aim and process of the study and the use of the NetraKit to assess their vision. There was complete voluntary participation, and participants were told they could refuse to participate in the study or withdraw at any time and for any reason with no consequences. All adult participants gave informed consent prior to data collection; for participants under 18, a parent or guardian gave informed consent and the child gave assent. Participants were not asked for information beyond what was necessary for the study and personal identifying information was handled confidentially. Data was anonymized and only collected and used for research purposes. The study protocol was reviewed and approved by the Institutional Review Board of Ek Prayas NGO, Kohat Enclave, Pitampura, New Delhi, on 13 May 2026, before data collection began at the organisation's community eye testing camp. The study was conducted using non-invasive vision assessment using the NetraKit and participants were told the device was being tested for research.

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### Conflicts of Interest

The author declares no conflicts of interest.

### Use of Artificial Intelligence

No Artificial Intelligence was used during the course of this paper.

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