Refractive Accuracy and Visual Outcome by Self-refraction using Adjustable-Focus Spectacles in Young Children: A Cross-sectional Non-inferiority Study

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Key Points

Question: Does self-refraction by children aged 5-11 years with adjustable-focus spectacles provide accurate refractive power and good vision compared with cycloplegic refraction?

Findings: In this cross-sectional non-inferiority study of 112 children (median age 9.00 [IQR 8.00-10.3] years, 46% boys), self-refraction resulted in more myopic power (-0.33 diopters) compared with cycloplegic refraction, but there was no difference in corrected visual acuity ≥20/25 between self-refraction (79.5%) and cycloplegic refraction (79.5%).

Meaning: Self-refraction using adjustable-focus spectacles in children may result in overminusing compared with cycloplegic refraction, but still may achieve good vison and help address uncorrected refractive error in under-resourced areas.

Abstract

Importance: Uncorrected refractive error is the most common cause of vision impairment in children. Most children ≥12 years can achieve visual acuity (VA)≥20/25 by self-refraction using adjustable-focus spectacles, but data on younger children are lacking.

Objective: To assess refractive accuracy, corrected VA, and factors associated with not achieving VA≥20/25 among children aged 5-11 years performing self-refraction with Adspecs adjustable-focus spectacles, compared with non-cycloplegic auto-refraction and cycloplegic refraction.

Design: Cross-sectional study, September 2, 2015-December 14, 2017

Setting: Academic pediatric eye clinic

Participants: We enrolled 127 consecutive children aged 5-11 years with uncorrected VA≤20/40 in ≥1 eye and without systemic/ocular conditions preventing best-corrected VA≥20/25. We excluded 15 children (1 withdrew, 2 did not fulfill study criteria, 12 had best-corrected VA<20/25).

Exposures: Children were taught to self-refract with Adspecs.

Main Outcomes and Measures: Spherical equivalent refractive error (using self-refraction, non-cycloplegic autorefraction, and cycloplegic refraction) and VA (uncorrected and using self-refraction, non-cycloplegic autorefraction, and cycloplegic refraction) for study eyes were evaluated. Potential predictors of failure to achieve VA≥20/25 with self-refraction were assessed using logistic regression.

Results: We included 112 children (52[46%] boys, median age=9.00 [IQR=8.00-10.3] years). Mean spherical equivalent refractive power ±SD was -2.00±1.52 diopters for self-refraction, -2.32±1.43 diopters for non-cycloplegic autorefraction, and -1.67±1.49 diopters for cycloplegic refraction. Mean difference in refractive power between self-refraction and non-cycloplegic autorefraction was 0.32 diopters (97.5% one-sided CI:0.11,∞; p<.0001) and between self-refraction and cycloplegic refraction was -0.33 diopters (97.5% one-sided CI:-0.54,∞; p=.77). The proportion with corrected VA≥20/25 was 79.5% (89/112) with self-refraction, 85.7% (96/112) with non-cycloplegic autorefraction, and 79.5% (89/112) with cycloplegic refraction (self-refraction versus non-cycloplegic autorefraction [p=.27] and self-refraction versus cycloplegic refraction [p=1]). Those failing to achieve best-corrected VA≥20/25 with self-refraction had higher astigmatism (odds ratio=10.6, 95% CI:3.1, 36.4; p<.001) and younger age (odds ratio=1.5, 95% CI:1.1, 2.2; p=.02).

Conclusions and Relevance: Self-refraction among children aged 5-11 years may result in more myopic power than cycloplegic refraction, but not necessarily to a clinically-relevant degree. While the proportion of children achieving VA≥20/25 with self-refraction using adjustable-focus spectacles did not differ from non-cycloplegic autorefraction or cycloplegic refraction, it was less common among younger children and those with higher astigmatism.

Introduction

Uncorrected refractive error is the most common cause of vision impairment in children, accounting for 12.8 million visually impaired 5-15 year old children globally.[1,2] In children, correction of refractive error significantly improves scholastic performance.[3-7] While vision impairment due to refractive error is easily and safely treatable with optical correction, limited global capacity for vision screening and refractive correction remains a significant barrier.[1]

Self-refraction with adjustable-focus spectacles provides a potentially cost-effective solution to uncorrected refractive error.[8] A variety of different devices have been available (e.g., Adspecs, Adlens, Eyejusters, FocusSpecs). While the refractive and visual outcomes of self-refraction with adjustable-focus glasses are comparable to non-cycloplegic autorefraction and cycloplegic refraction in children 12 years and older,[2,8-9,10] their use has not been evaluated in children younger than 12 years.

The purpose of the current study is to assess the refractive accuracy, corrected visual acuity (VA), and factors associated with not achieving corrected VA ≥20/25 among children aged 5-11 years performing self-refraction with adjustable-focus glasses, compared with non-cycloplegic autorefraction and cycloplegic refraction.

Methods

This prospective cross-sectional non-inferiority study was approved by the Duke University Health System Institutional Review Board and adhered to the tenets of the Declaration of Helsinki. CONSORT reporting guidelines were followed. Informed written consent was obtained from at least 1 parent/legal guardian for each participant. A $25 check was mailed to participants/guardians to compensate them for their time.

Eligibility criteria:

We recruited consecutive participants aged 5 to 11 years presenting to a pediatric eye clinic at Duke University from September 2, 2015 to December 14, 2017. Eligible children were scheduled to undergo a comprehensive eye examination including dilation of pupils in both eyes, had English as their preferred language, were capable of following instructions, and had uncorrected VA (UCVA) ≤20/40 in one or both eyes. Children were excluded if they had a systemic or ocular condition preventing them from achieving best-corrected VA ≥20/25 in at least one eye with UCVA ≤20/40 (Figure 1).

Overall study flow (Figure 1)

Per normal clinic routine, non-cycloplegic autorefraction and assessment of UCVA in each eye were performed by clinic personnel. For children fulfilling eligibility criteria and with consenting parents, UCVA was confirmed by study personnel using the study protocol (see below "VA Assessment"). If inclusion criteria were met, written informed consent was obtained from a parent/legal guardian. After instruction, study participants self-refracted twice with adjustable-focus spectacles (see below "Self-refraction with adjustable-focus spectacles"). Corrected VA was assessed separately for the refraction derived from non-cycloplegic autorefraction and the second self-refraction trial, with each placed sequentially in trial frames over each eye in a randomized order determined by balanced-block randomization, block size of 10 with 15 total blocks. As part of their routine clinical examination, participants were administered two sets of a locally compounded mixture of 1% cyclopentolate and 2.5% phenylephrine drops at five-minute intervals. A third drop was given if the pupillary reflex was still present after 15 minutes. At least 30 minutes after the first set of drops, cycloplegic refraction, via retinoscopy or subjective cycloplegic refraction, if possible, was performed by a pediatric optometrist (NLC, YMP) or ophthalmologist (SFF, SGP), masked to the results of self-refraction. The cycloplegic refraction was placed in a trial frame and VA was assessed separately for each eye.

Visual Acuity (VA) Assessment:

VA was assessed at 3 meters using the electronic VA (EVA) system (M&S Technologies, Niles, IL), consisting of a Dell laptop computer (Latitude E5540, Round Rock, TX) connected to an iPod Touch 16GB (model A1574, Cupertino, CA). Children <7 years were tested using the Amblyopia Treatment

Study (ATS) electronic protocol and those ≥7 years using the Early Treatment of Diabetic Retinopathy Study (ETDRS) protocol.[11,12] During VA assessment, study personnel directed participants to maintain a neutral head position and avoid squinting. Right eyes were tested first and the non-test eye was occluded with an adhesive patch. All VA assessments were performed prior to cycloplegia, except for VA assessment performed with cycloplegic refraction correction.

Lensometry and Auto-Refraction:

A Macro Lensometer (LM-101, Jacksonville, FL) was used to measure the power of the current spectacle correction (if worn) and of the adjustable spectacles to the nearest 0.25 diopter (D) for sphere and cylinder values, if applicable, and within 1 degree for axis. Using a Topcon autorefractor (RM-8800, Tokyo, Japan) with measurement step size of 0.25D for spherical and cylindrical power, 5 measurements per eye were taken and the mean recorded. Calibration of the auto-refractor was performed daily with a manufacturer-provided device.

Self-refraction with adjustable-focus spectacles:

The adjustable-focus spectacles (Adspecs, Adaptive Eyecare, Ltd, Oxford UK) contain two lenses, each consisting of two sealed membranes secured by a frame and filled with a liquid of refractive index 1.579. The front and rear faces of each deformable lens were protected by a rigid plastic cover, and the optical power of each lens was determined by the curvature of its surfaces, controlled independently by varying the volume of liquid in each lens through a user-controlled pump. The adjustable-focus spectacles used in this study had a spherical range between -6.50D to +1.50D. Prior to each self-refraction, lens power was set to zero and the participant's left eye was occluded with an adhesive patch. For the first self-refraction, a medical student (LZ, DN, MCW) began by instructing the participant to focus on an age-appropriate paper vision chart, either HOTV (<7 years) or ETDRS (≥7 years) (Precision Vision, La Salle, Illinois), at a distance of 3 meters (no mirror was used) and slowly turn the dial on the syringe counter-clockwise, creating a minus power lens, until the letters were as clear as possible. The participant then turned the dial clockwise, reducing minus power, until the smallest visible line began to blur, and lastly made small adjustments to optimize subjective visual clarity. The process was repeated for the left eye with the right eye occluded. The power of each lens was measured with lensometry (see above "Lensometry and Auto-refraction") and recorded. Each lens power was then reset to zero and a second self-refraction performed for each eye, with the power from the second self-refraction used to assess VA. Caregivers did not participate in the self-refraction process.

Sample size calculation

Based on estimates of the differences in refractive power between self-refraction, non-cycloplegic autorefraction, and cycloplegic refraction from previous studies using Adspecs in older children,[2,9] we calculated a sample size of 115 with non-inferiority margin of -0.25D, standard deviation [SD]=1 with a one-sided alpha=0.05, power=80%, allowing for a drop-out rate of 15%.[2,9]

Data Analyses

All data were entered into Microsoft Access (v.14.0, Microsoft, Redmond, Washington) and verified against participant data forms. Data analyses was performed using R (v.3.6.1, R Foundation for Statistical Computing, Vienna, Austria). Refractive power was expressed as spherical equivalent (SE, sphere + ½ cylinder) for data analyses. Better- and worse-seeing eyes were defined as the eyes with the better and worse UCVA, respectively. The eye with better UCVA was designated as the "study eye," except when UCVA >20/40 in the better-seeing eye, in which case the worse-seeing eye was designated the "study eye." Data analyses were performed on study eyes. A Bonferroni adjustment was made post hoc to adjust for multiple comparisons (p=.025).

Differences in refractive power were compared between self-refraction, non-cycloplegic autorefraction, and cycloplegic refraction. The refractive powers from the first and second self-refraction were compared using Bland-Altman plots. All remaining data analyses used the second self-refraction when evaluating self-refraction. One-sided non-inferiority paired t-tests (with 97.5% confidence intervals

[CI]) were used to compare differences in refractive power between refractive methods (i.e., between self-refraction and non-cycloplegic autorefraction and between self-refraction and cycloplegic refraction) using a pre-specified non-inferiority margin of -0.25D. The relationship between the difference in refractive power between refraction methods (i.e., between self-refraction and non-cycloplegic autorefraction and between self-refraction and cycloplegic refraction) and age was examined using Spearman's rank correlation test. The relationship between the difference in refractive power between refraction methods (i.e., between self-refraction and non-cycloplegic autorefraction and between self-refraction and cycloplegic refraction) and refractive power of cycloplegic refraction was evaluated using Pearson's correlation test.

The distribution of participant VA was examined and the proportion of participants with VA ≥20/25 was calculated for self-refraction, non-cycloplegic autorefraction, and cycloplegic refraction. The proportion of individuals with corrected VA ≥20/25 between self-refraction and cycloplegic refraction and between self-refraction and non-cycloplegic autorefraction were compared with McNemar's tests.

Differences in mean corrected VA between self-refraction, non-cycloplegic autorefraction, and cycloplegic refraction were compared using two-sided paired t-tests. The relationship between the difference in corrected VA between refraction methods (i.e., between self-refraction and non-cycloplegic autorefraction and between self-refraction and cycloplegic refraction) and both age and refractive power of cycloplegic refraction was examined using Spearman's rank correlation test.

Among study eyes, multiple logistic regression was used to assess the association between failure to achieve VA ≥20/25 with self-refraction and age, sex, current spectacle wear, and spherical and cylindrical power by cycloplegic refraction.

Results

Among 127 enrolled children, 15 (11.8%) were excluded: one (0.8%) withdrew from the study, one (0.8%) had UCVA >20/40 bilaterally, one (0.8%) was determined by an ophthalmologist not to have a vision deficit, and 12 (9.5%) did not have VA correctable ≥20/25 by any refraction method.

Of 112 children included in the study, the median age was 9.0 (interquartile range 8.00-10.3) years, 52 (46.4%) were boys, and 37 (33.0%) currently wore spectacles (eTable 1). Median UCVA for study eyes, better- and worse-seeing eyes were 0.5, 0.4, and 0.6 logMAR, respectively (Table 2).

The refractive powers from the first and second self-refraction were compared using Bland-Altman plots. The mean difference (limits of agreement) in refractive power between the first and second self-refraction was 0.08D (-1.81 to 1.97) (eFigure 2).

The mean ±SD spherical equivalent refractive power was -2.08 ±1.69D for the first self-refraction, -2.00 ±1.52D for the second self-refraction, -2.32 ±1.43D for non-cycloplegic autorefraction, and -1.67 ±1.49D for cycloplegic refraction (Table 3). Refractive power obtained from the second self-refraction was non-inferior to that of non-cycloplegic autorefraction (mean difference 0.32D, 97.5% one-sided CI:0.11, ∞; p<.0001), but was inferior and more myopic compared with cycloplegic refraction (mean difference -0.33D, 97.5% one-sided CI:-0.54, ∞; p=.77) (Table 4). Spearman's rank correlation test found no evidence of a definitive association between age and either difference in refractive power between the self-refraction and non-cycloplegic autorefraction (p=.48, rho=.07) or difference in refractive power between self-refraction and cycloplegic refraction (p=.09, rho=.16). Pearson's correlation test found no definitive association between the refractive power of cycloplegic refraction and the mean difference in refractive power of self-refraction and non-cycloplegic autorefraction (p=.07, rho=-0.17), but did find a negative association between the refractive power of cycloplegic refraction and mean difference in refractive power of self-refraction and cycloplegic refraction (p<.0001, rho=-0.36).

The proportion of children with corrected VA ≥20/25 was 79.5% (89/112) with self-refraction, 85.7% (96/112) with non-cycloplegic autorefraction, and 79.5% (89/112) with cycloplegic refraction (self-refraction versus non-cycloplegic autorefraction [p=.27] and self-refraction versus cycloplegic refraction [p=1], Table 2).

Mean corrected VA was 0.07±0.13 logMAR for self-refraction, 0.05±0.11 logMAR for non-cycloplegic autorefraction, and 0.07±0.11 logMAR for cycloplegic refraction (Table 2). Mean corrected VA did not differ between self-refraction and non-cycloplegic autorefraction (mean difference 0.020 logMAR, 95% CI:-0.0047, 0.044, p=.11) or between self-refraction and cycloplegic refraction (mean difference 0.0018 logMAR, 95% CI:-0.023, 0.027, p=.89). Spearman's rank correlation test found no evidence of a definitive association between age and either mean difference in corrected VA between self-refraction and non-cycloplegic autorefraction (p=.68, rho=-0.040) or mean difference in corrected VA between self-refraction and cycloplegic refraction (p=.74, rho=-0.032). Spearman's rank correlation test found no evidence of a definitive association between refractive power of cycloplegic refraction and mean difference in corrected VA of self-refraction and non-cycloplegic autorefraction (p=.59, rho=-0.052) or mean difference in corrected VA between self-refraction and cycloplegic refraction (p=.73, rho=-0.034).

Among study eyes, 20.5% (23/112) failed to achieve corrected VA ≥20/25 with self-refraction. In univariate logistic regression models, younger age (p=.006), greater spherical equivalent (p=.019), and higher astigmatic power (p<.001) were associated with a failure to achieve corrected VA ≥20/25 with self-refraction. In the multivariate model, only younger age (odds ratio [OR]=1.5, 95% CI:1.1, 2.2; p=.02) and higher astigmatic power (OR=10.6, 95% CI:3.11, 36.4; p <.001) remained statistically significantly associated with a failure to achieve corrected VA ≥20/25 with self-refraction (Table 5).

Discussion

Compared with non-cycloplegic autorefraction, we found self-refraction using adjustable-focus spectacles to be non-inferior and more hyperopic (mean difference 0.32D) among children 5-11 years. In contrast, a study among older children (12-17 years) in rural and urban Ghana using Alvarez spectacles found a significant myopic difference between self-refraction and non-cycloplegic autorefraction (mean difference -0.24 to -0.26D).[10] We did not find a definitive association between the mean difference in refractive power between self-refraction and non-cycloplegic autorefraction and either age or refractive power of cycloplegic refraction.

Consistent with previous self-refraction studies, we found a tendency towards greater myopic power, though no definitive difference, with self-refraction compared with cycloplegic refraction among children 5-11 years, likely due to non-cycloplegic accommodation.[13,14] The mean dioptric power inaccuracy reported in prior studies with older children (12-17 years) was -0.22 to -0.44D, similar to what we observed among 5-11 years olds (-0.33D).[8,10] We did not find a definitive association between difference in refractive power between self-refraction and cycloplegic refraction and age (i.e., no increased tendency to overminus with younger age). We found a negative association between the refractive power of the cycloplegic refraction and the mean difference in refractive power between self-refraction and cycloplegic refraction that suggests a tendency to overminus with decreasing myopia/increasing hyperopia. Similar observations have been made in prior studies with self-refraction among hyperopes,[9,15] likely due to the greater tendency to accommodate among hyperopes especially without cycloplegia.[16] Based on the existing literature,[17] we believe that clinically meaningful sequelae such as headaches would be unlikely due to the myopic difference observed in this age group.

In prior studies using fluid-filled adjustable-focus spectacles in rural and urban China, children aged 12-18 years achieved corrected VA ≥20/25 in better-seeing eyes by self-refraction in 92-97% of cases.[2,9] In prior studies using adjustable-focus spectacles with Alvarez optics in rural and urban Ghana, children aged 12-17 years achieved corrected VA ≥20/25 in 81.6-92.6-% of better-seeing/right eyes.[8,10] In the current study using fluid-filled adjustable-focus spectacles in a younger population of children (5-11 years old), we found corrected VA ≥20/25 in 79.5% and ≥20/32 in 93.8% of study eyes. We did not find a statistically significant difference in the proportion of the children who achieved corrected VA ≥20/25 by self-refraction compared to either non-cycloplegic autorefraction or cycloplegic refraction.

We found that failure to attain corrected VA ≥20/25 by self-refraction in 5–11 year-old children was associated with higher astigmatic power (OR=10.6, 95% CI:3.11, 36.4; p<.001) and younger age

(OR=1.5, 95% CI:1.1, 2.2; p=.02). The association with higher astigmatic power is consistent with prior self-refraction studies in urban (OR=2.43, 95% CI:1.80, 3.28; p<.001) and rural (OR=14.1, 95% CI:3.33, 59.3; p<.001) Chinese children.[2,9] To our knowledge, all currently available adjustable-focus spectacle technologies provide spherical but not cylindrical correction. Our findings with respect to age contrasted with a study in Ghana, which found greater likelihood of poor self-refracted vision outcomes with increasing age, albeit among older children (12-15 years).[8] Previous studies of self-refraction in children found that increased hyperopic and myopic power were associated with failure to achieve corrected VA ≥20/25,[2,8-9] consistent with the results of our univariate, but not multivariate, analysis. We suspect that the higher proportion of children in other studies with high myopia (SE ≥-6.0D), due to higher prevalence of myopia among older, Chinese children, contributed to this difference.[2,9] While previous studies found an association between lack of prior spectacle wear and failure to achieve good vision with self-refraction,[2,9] we did not find this association in our younger cohort.

Adjustable-focus spectacles could be deployed in the community through schools, where trained practitioners (e.g., teachers) would instruct and monitor children performing self-refraction with adjustable-focus spectacles. This model has been deployed successfully in urban and rural community settings.[2,9] We did not find a statistically significant difference between mean refractive power with the first or second self-refraction, suggesting that children might be able to achieve adequate vision correction with only one self-refraction. As we found that the refractive power obtained through self-refraction using adjustable-focus spectacles was non-inferior to that of non-cycloplegic autorefraction, the use of adjustable-focus spectacles would be more cost-effective than an autorefractor. In addition, children would be given the spectacles to use at the conclusion of self-refraction versus waiting for custom-made spectacles following non-cycloplegic autorefraction.

Our study had limitations. We did not adjust for VA assessment using the ATS electronic protocol in children <7 years and the electronic ETDRS in children ≥7 years, which may have resulted in an overestimation in VA findings in those <7 years. A previous study comparing the electronic ATS-HOTV to electronic ETDRS protocol among children 5-12 years found that VA assessment obtained using ATS-HOTV was on average 0.06 logMAR (i.e., 3 letters on a chart with 5 letters/line) better versus ETDRS,[18] suggesting final VA outcomes are unlikely to be clinically significantly different from what was reported. While we did not find a definitive relationship between age and either difference in refractive power or difference in corrected VA between refractive methods, our study was not powered for age-stratified analysis. Issues of safety and long-term compliance with wear, addressed elsewhere, were not the focus of this study and hence not evaluated.[19] A future study should evaluate compliance, safety, and satisfaction among children aged 5-11 years with adjustable-focus spectacles, as has been done for older children.[20] Previous studies in children have noted lower compliance with adjustable-focus versus standard spectacles, though quality of life measures were not statistically different between groups.[19,20] Finally, as this study was conducted in an ophthalmology clinic, future work should evaluate this younger cohort of children within a community setting, the type of setting where self-refraction might be most relevant.

References

1. Resnikoff S, Pascolini D, Mariotti SP, Pokharel GP. Global magnitude of visual impairment caused by uncorrected refractive errors in 2004. Bulletin of the World Health Organization 2008;86:63-70.
2. Zhang M, Riping Z, He M, Liang W, Li X, She L, Yang Y, MacKenzie G, Silver J, Ellwein L, Moore B, Congdon N. Self correction of refractive error among young people in rural China: results of cross sectional investigation. BMJ 2011;343:1-11.
3. Yue M, Congdon N, Shi Y, et al. Effect of a Local Vision Care Center on Eyeglasses Use and School Performance in Rural China. JAMA Ophthalmol 2018;136:731-7.
4. Hannum E, Zhang Y. Poverty and Proximate Barriers to Learning: Vision Deficiencies, Vision Correction and Educational Outcomes in Rural Northwest China. World Dev 2012;40:1921-31.
5. Glewwe P, West KL, Lee J. The Impact of Providing Vision Screening and Free Eyeglasses on Academic Outcomes: Evidence from a Randomized Trial in Title I Elementary Schools in Florida. J Policy Anal Manage 2018;37:265-300.
6. Ma X, Zhou Z, Yi H, et al. Effect of providing free glasses on children's educational outcomes in China: cluster randomized controlled trial. BMJ 2014;349:g5740.
7. Ma X, Congdon N, Yi H, et al. Safety of Spectacles for Children's Vision: A Cluster-Randomized Controlled Trial. Am J Ophthalmol 2015;160:897-904.
8. Ilechie AA, Abokyi S, Owusu-Ansah, A, Boadi-Kusi, SB, Denkyira AK, Abraham CH. Self-refraction Accuracy with Adjustable Spectacles among Children in Ghana. Optometry and Vision Science 2015;92:456-63.
9. He M, Congdon N, MacKenzie G, Zeng Y, Silver JD, Ellwein L. The child self-refraction study results from urban Chinese children in Guangzhou. Ophthalmology 2011;118:1162-9.
10. Ocansey S, Amuda R, Abraham CH, Abu EK. Refractive error correction among urban and rural school children using two self-adjustble spectacles. Paediatric Ophthal; 8 (1)
11. Pediatric Eye Disease Investigator Group. Amblyopia Treatment Study (ATS) Visual Acuinty Testing Procedures Manual. 2018:1-26.
12. Beck RW, Moke PS, Turpin AH, et al. A computerized method of visual acuity testing: adaptation of the early treatment of diabetic retinopathy study testing protocol. Am J Ophthalmol 2003;135:194-205.
13. Evans J, Risma T, Dumitrescu A. Pediatric Spectacle Prescription and Retinoscopy Made Simple. EyeRoundsorg 2017.
14. Lowery JPJ, Olson R, Peel J, Pearce NN. Autorefraction vs. retinoscopy: A comparison of non-cycloplegic measures in a pediatric sample. Journal of Behavioral Optometry 2005;16:3-8.
15. Annadanam A, Varadaraj V, Mudie LI, et al. Comparison of self-refraction using a simple device, USee, with manifest refraction in adults. PLOS One 2018; 13(2)
16. Zhao J, Mao J, Luo R, Li F, Pokharel GP, Ellwein L. Accuracy of Noncycloplegic Autorefraction in School-Age Children in China. Optometry and Vision Science 2004; 81 (1): 49-55
17. Pediatric Eye Disease Investigator Group, Chen AM, Holmes JM, et al. A Randomized Trial Evaluating Short-term Effectiveness of Overminus Lenses in Children 3 to 6 Years of Age with Intermittent Exotropia. Ophthalmol 2016; 123:2127-36.
18. Rice ML, Leske DA, Holmes JH. Comparison of the amblyopia treatment study HOTV and electronic-early treatment of diabetic retinopathy study visual acuity protocols in children aged 5 to 12 years. Am J Ophthalmol 2004; 137 (2): 278-282.
19. Wang CY, Zhang G, Tang B, et al. A Randomized Noninferiority Trial of Wearing Adjustable Glasses versus Standard and Ready-made Spectacles among Chinese Schoolchildren: Wearability and Evaluation of Adjustable Refraction III. Ophthalmol 2020;127:27-37.
20. Ilechie AA, Abokyi S, Boadi-Kusi S, Enimah E, Ngozi E. Self-adjustable Spectacle Wearing Compliance and Associated Factors Among Rural School Children in Ghana. Optom Vis Sci 2019;96:397-406.

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Conflict of Interest: Professor Congdon works as Director of Research for Orbis International, a non-governmental organization working through partners to provide global eye health services, including children's refraction. The authors have indicated that they have no other potential conflicts of interest to disclose.

Access to Data and Data Analyses:
Qing Wen (Centre for Public Health, Queen's University Belfast, Belfast, United Kingdom) had full access to all the data in the study, was responsible for data analyses reported in this manuscript, and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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eTable 1: Age, gender, and use of spectacles at time of enrollment among 112 study participants

Age (years)	Boys n (%)	Girls n (%)	Currently wearing spectacles n (%)
5	1 (33.3)	2 (66.7)	0 (0)
6	1 (25.0)	3 (75.0)	1 (25.0)
7	7 (50.0)	7 (50.0)	1 (7.14)
8	11 (45.8)	13 (54.2)	4 (16.7)
9	9 (47.4)	10 (52.6)	6 (31.6)
10	9 (45.0)	11 (55.0)	11 (55.0)
11	14 (50.0)	14 (50.0)	14 (50.0)
Mean (standard deviation)	9.10 (1.59)	8.92 (1.68)	N/A

Table 2: Distribution of visual acuity without correction and with various refraction methods, grouped by study eye and better- and worse-seeing eyes

Visual Acuity logMAR (Snellen)	Study eyes (n=112)				Better-seeing eyes (n=112)				Worse-seeing eyes (n=112)			
	UCVA	VA by SR	VA by NCAR	VA by CR	UCVA	VA by SR	VA by NCAR	VA by CR	UCVA	VA by SR	VA by NCAR	VA by CR
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
≥ -0.1 (≥20/16)	0 (0)	15 (13.4)	15 (13.4)	11 (9.8)	1 (0.9)	14 (12.5)	15 (13.4)	8 (7.1)	0 (0)	13 (11.6)	13 (11.6)	14 (12.5)
0.0 (20/20)	0 (0)	41 (36.6)	49 (43.8)	47 (42.0)	6 (5.4)	43 (39.4)	53 (47.3)	45 (40.2)	0 (0)	39 (34.8)	48 (42.9)	41 (36.6)
0.1 (20/25)	0 (0)	33 (29.5)	32 (28.6)	31 (27.7)	8 (7.1)	34 (30.4)	31 (27.9)	33 (29.5)	0 (0)	41 (36.6)	35 (31.3)	38 (33.9)
0.2 (20/32)	0 (0)	16 (14.3)	12 (10.7)	17 (15.2)	20 (17.9)	18 (16.1)	8 (7.1)	19 (17.0)	0 (0)	9 (8.0)	13 (11.6)	12 (10.7)
0.3 (20/40)	28 (25.0)	2 (1.8)	2 (1.8)	4 (3.6)	15 (13.4)	2 (1.8)	3 (2.7)	5 (4.5)	15 (13.4)	3 (2.7)	2 (1.8)	3 (2.7)
0.4 (20/50)	23 (20.5)	4 (3.6)	0 (0)	1 (0.9)	16 (14.3)	0 (0)	0 (0)	1 (0.9)	19 (17.0)	6 (5.4)	1 (0.9)	2 (1.8)
0.5 (20/63)	21 (18.8)	0 (0)	2 (1.8)	0 (0)	13 (11.6)	0 (0)	2 (1.8)	0 (0)	21 (18.8)	1 (0.9)	0 (0)	1 (0.9)
0.6 (20/80)	9 (8.0)	1 (0.9)	0 (0)	1 (0.9)	9 (8.0)	1 (0.9)	0 (0)	1 (0.9)	12 (10.7)	0 (0)	0 (0)	0 (0)
0.7 (20/100)	11 (9.8)	0 (0)	0 (0)	0 (0)	8 (7.1)	0 (0)	0 (0)	0 (0)	15 (13.4)	0 (0)	0 (0)	1 (0.9)
0.8 (20/125)	7 (6.3)	0 (0)	0 (0)	0 (0)	6 (5.4)	0 (0)	0 (0)	0 (0)	9 (8.0)	0 (0)	0 (0)	0 (0)
0.9 (20/160)	5 (4.5)	0 (0)	0 (0)	0 (0)	3 (2.7)	0 (0)	0 (0)	0 (0)	6 (5.4)	0 (0)	0 (0)	0 (0)
1.0 (20/200)	1 (0.9)	0 (0)	0 (0)	0 (0)	1 (0.9)	0 (0)	0 (0)	0 (0)	4 (3.6)	0 (0)	0 (0)	0 (0)
1.1 (20/250)	5 (4.5)	0 (0)	0 (0)	0 (0)	4 (3.6)	0 (0)	0 (0)	0 (0)	5 (4.5)	0 (0)	0 (0)	0 (0)
1.2 (20/320)	1 (0.9)	0 (0)	0 (0)	0 (0)	1 (0.9)	0 (0)	0 (0)	0 (0)	2 (1.8)	0 (0)	0 (0)	0 (0)
≤ 1.3 (≤20/400)	1 (0.9)	0 (0)	0 (0)	0 (0)	1 (0.9)	0 (0)	0 (0)	0 (0)	4 (3.6)	0 (0)	0 (0)	0 (0)
Median logMAR [IQR] (Snellen)	0.5 [0.4, 0.7] (20/63)	0.05 [0.0, 0.1] (20/22.5)	0.0 [0.0, 0.1] (20/20)	0.0 [0,0.1] (20/20)	0.4 [0.2, 0.6] (20/50)	0.0 [0.0, 0.1] (20/20)	0.0 [0.0, 0.1] (20/20)	0.1 [0.0, 0.1] (20/25)	0.6 [0.4, 0.8] (20/80)	0.1 [0.0, 0.1] (20/25)	0.0 [0.0, 0.1] (20/20)	0.1 [0.0, 0.1] (20/25)
Mean logMAR Value (SD)	0.54 (0.25)	0.070 (0.13)	0.050 (0.11)	0.068 (0.11)	0.43 (0.30)	0.061 (0.11)	0.045 (0.11)	0.079 (0.11)	0.63 (0.28)	0.074 (0.13)	0.051 (0.098)	0.069 (0.13)

CR, cycloplegic refraction; logMAR, logarithm of the minimum angle of resolution; NCAR, non-cycloplegic autorefraction = the average of 5 measurements taken with a Topcon autorefractor (RM-8800, Tokyo, Japan); SR, self-refraction; UCVA, uncorrected visual acuity; VA, visual acuity.

better-seeing eye = eye of study participant with better uncorrected visual acuity
worse-seeing eye = eye of study participant with worse uncorrected visual acuity
study eye = the eye with better uncorrected visual acuity, except when uncorrected visual acuity >20/40 in the better eye, in which case the worse eye was designated the "study eye"

Table 3: Distribution of spherical equivalent refractive power of study eyes and better- and worse-seeing eyes by various refraction methods

Spherical Equivalent (SE)	Study eyes (n=112)				Better-seeing eyes (n=112)				Worse-seeing eyes (n=112)			
	1st SR	2nd SR	NCAR	CR	1st SR	2nd SR	NCAR	CR	1st SR	2nd SR	NCAR	CR
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
-7<SE≤-6	4 (3.6)	4 (3.6)	3 (2.7)	1 (0.9)	4 (3.6)	4 (3.6)	3 (2.7)	1 (0.9)	4 (3.6)	2 (1.8)	1 (0.9)	0 (0)
-6<SE≤-5	4 (3.6)	4 (3.6)	3 (2.7)	3 (2.7)	3 (2.7)	5 (4.5)	3 (2.7)	3 (2.7)	9 (8.0)	8 (7.1)	6 (5.4)	4 (3.6)
-5<SE≤-4	10 (8.9)	4 (3.6)	7 (6.3)	3 (2.7)	10 (8.9)	4 (3.6)	6 (5.4)	3 (2.7)	5 (4.5)	8 (7.1)	10 (8.9)	4 (3.6)
-4<SE≤-3	16 (14.3)	13 (11.6)	13 (11.6)	8 (7.1)	18 (16.1)	12 (10.7)	12 (10.7)	6 (5.4)	11 (9.8)	13 (11.6)	12 (10.7)	12 (10.7)
-3<SE≤-2	26 (23.2)	30 (26.8)	41 (36.6)	20 (17.9)	17 (15.2)	22 (19.6)	34 (30.4)	18 (16.1)	32 (28.6)	30 (26.8)	41 (36.6)	21 (18.8)
-2<SE≤-1	32 (28.6)	39 (34.8)	38 (33.9)	64 (57.1)	32 (28.6)	39 (34.8)	38 (33.9)	57 (50.9)	32 (28.6)	35 (31.3)	35 (31.3)	56 (50.0)
-1<SE≤0	14 (12.5)	15 (13.4)	4 (3.6)	8 (7.1)	22 (19.6)	25 (22.3)	11 (9.8)	18 (16.1)	13 (11.6)	12 (10.7)	5 (4.5)	10 (8.9)
0<SE≤1	4 (3.6)	1 (0.9)	1 (0.9)	1 (0.9)	5 (4.5)	1 (0.9)	3 (2.7)	2 (1.8)	4 (3.6)	2 (1.8)	0 (0)	1 (0.9)
1<SE≤2	1 (0.9)	1 (0.89)	0 (0)	2 (1.8)	1 (0.9)	0 (0)	0 (0)	2 (1.8)	1 (0.9)	1 (0.9)	0 (0)	2 (1.8)
2<SE≤3	0 (0)	1 (0.9)	1 (0.9)	0 (0)	0 (0)	0 (0)	2 (1.8)	0	0 (0)	1 (0.9)	1 (0.9)	0
3<SE≤4	1 (0.9)	0 (0)	1 (0.9)	1 (0.9)	0 (0)	0 (0)	0 (0)	1 (0.9)	1 (0.9)	0 (0)	1 (0.9)	1 (0.9)
4<SE	0 (0)	0 (0)	0 (0)	1 (0.9)	0 (0)	0 (0)	0 (0)	1 (0.9)	0 (0)	0 (0)	0 (0)	1 (0.9)
Median [IQR]	-2.00 [3.00, -1.00]	-1.63 [-2.52, -1.00]	-2.25 [-2.75, -1.63]	-1.50 [-2.13, -1.00]	-1.50 [-3.00, -0.98]	-1.50 [-2.50, -1.00]	-2.00 [-2.66, -1.38]	-1.38 [-2.00, -1.00]	-2.00 [-3.00, -1.00]	-2.00 [-3.10, -1.00]	-2.25 [-3.00, -1.63]	-1.50 [-2.30, -1.10]
Mean (Standard Deviation)	-2.08 (1.69)	-2.00 (1.52)	-2.32 (1.43)	-1.67 (1.49)	-1.97 (1.67)	-1.89 (1.55)	-2.12 (1.49)	-1.50 (1.54)	-2.14 (1.74)	-2.15 (1.56)	-2.44 (1.46)	-1.76 (1.54)

CR, cycloplegic refraction; NCAR, non-cycloplegic autorefraction = the average of 5 measurements taken with a Topcon autorefractor (RM-8800, Tokyo, Japan); SR, self-refraction.
better-seeing eye = eye of study participant with better uncorrected visual acuity
worse-seeing eye = eye of study participant with worse uncorrected visual acuity
study eye = the eye with better uncorrected visual acuity, except when uncorrected visual acuity >20/40 in the better eye, in which case the worse eye was designated the "study eye"

Table 4: Distribution of difference in spherical equivalent refractive power between the second self-refraction and non-cycloplegic autorefraction and between the second self-refraction and cycloplegic refraction in study eyes[1]

	Second self-refraction vs. non-cycloplegic autorefraction n (%)	Second self-refraction vs. cycloplegic refraction n (%)
< -2.0D	3 (2.7)	11 (9.8)
< -1.75D to -2.00D	1 (0.9)	2 (1.8)
< -1.50D to -1.75D	0 (0)	1 (0.9)
< -1.25D to -1.50D	7 (6.2)	0 (0)
< -1.00D to -1.25D	1 (0.9)	6 (5.4)
< -0.75D to -1.00D	6 (5.4)	6 (5.4)
< -0.50D to -0.75D	2 (1.8)	4 (3.6)
< -0.25D to -0.50D	7 (6.2)	15 (13.4)
< 0 D to ≤ -0.25D	7 (6.2)	15 (13.4)
No difference	6 (5.4)	7 (6.2)
> 0 D to 0.25D	10 (8.9)	9 (8)
> 0.25D to 0.50D	10 (8.9)	16 (14.3)
> 0.50D to 0.75D	13 (11.6)	9 (8)
> 0.75D to 1.00D	13 (11.6)	4 (3.6)
> 1.00D to 1.25D	10 (8.9)	4 (3.6)
> 1.25D to 1.50D	5 (4.5)	3 (2.7)
> 1.50D to 1.75D	5 (4.5)	0 (0)
> 1.75D to 2.00D	4 (3.6)	0 (0)
≥ 2.0D	2 (1.8)	0 (0)
Mean (SD, Range)	0.32 (SD: 1.1, [-4.38, 3.13])	-0.33 (SD:1.15, [-4.38, 1.50])
Median (IQR)	0.50 (-0.25, 1.00)	-0.25 (-0.75, 0.50)
97.5% CI (p-value)	0.11 to ∞ (<.0001)	-0.54 to ∞ (.77)

[1]study eye = the eye with better uncorrected visual acuity, except when uncorrected visual acuity >20/40 in the better eye, in which case the eye with worse UCVA was designated the "study eye"

Table 5: Logistic regression model of factors potentially associated with failure to achieve a visual acuity ≥20/25 with self-refraction using adjustable-focus spectacles in study eyes[1]

Independent Variable	Effect/level	Univariate analysis (n=112)		Multivariate analysis[2] (n=112)	
		Odds Ratio (95% Confidence Interval [CI])	P-value	Odds Ratio (95% CI)	P-value
Age (years)	Per year decrease	1.5 (1.1, 2.0)	.006	1.5 (1.1, 2.2)	.02
Gender (Male)	Female (reference)	-	-	-	-
	Male	0.545 (0.210, 1.42)	.21	0.456 (0.140, 1.48)	.19
Wearing vision correction	No (reference)	-	-	-	-
	Yes	1.10 (0.420, 1.42)	.84	-	-
Spherical equivalent cycloplegic refraction (Diopters)	Per diopter increase	1.59 (1.08, 2.34)	.019	1.08 (0.63, 1.85)	.78
Cylinder (Diopters)	Per diopter increase	9.34 (3.10, 28.2)	<.001	10.6 (3.11, 36.4)	<.001

[1]"Study eye" is the eye with better uncorrected visual acuity (UCVA), except when UCVA>20/40 in the better eye, in which case the eye with worse UCVA was designated the "study eye."
[2]Including age, gender, and variables associated with change in productivity with significance of $p<0.05$ in the univariate analysis.

Figure legends:

Figure 1: Flow diagram of pre-consent screening, enrollment, and study procedures.

eFigure 2: Bland-Altman plot of agreement in refractive power between the first and second self-refraction among study eyes. The mean difference (limits of agreement) in refractive power between the first and second self-refraction was 0.079 diopters (-1.81 to 1.97).