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A randomized clinical trial to evaluate ready-made spectacles in an adult population in India

Lisa Keay,[1,2]* Monica Gandhi,[3] Christopher Brady,[1] Ferhina S Ali,[1] Umang Mathur,[3] Beatriz Munoz[1] and David S Friedman[1]

[1]Dana Center for Preventive Ophthalmology, Wilmer Eye Institute, Johns Hopkins University, Baltimore, USA, [2]The George Institute for International Health, University of Sydney, Sydney, Australia and [3]Dr Shroffs Charity Eye Hospital, New Delhi, India

*Corresponding author. Injury Division, George Institute for International Health, PO Box M201, NSW 2050, Australia. E-mail: lkeay@george.org.au

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Background Ready-made spectacles (RMS) have advantages; however, visual performance and satisfaction has not been evaluated.

Methods A 1-month, double-masked, randomized clinical trial comparing planned continued use and visual performance of RMS to Custom Spectacles (CS) in adults aged 18–45 years with $\geqslant 1$ diopter (D) of uncorrected refractive error (URE).

Results A total of 373 of 400 participants (93%) completed; mean age was 30 ± 9 years, and 58% were female. Average URE was 2.21 ± 1.31D and habitual vision was 0.58 ± 0.21 logMAR (logarithm of Minimum Angle of Resolution, $20/63^{+1}$ Snellen acuity). Ten participants with habitual vision better than 20/40 were excluded (3%). A lower proportion in the RMS group intended to continue to wear the study spectacles after 1 month (165/183, 90% vs 174/180, 97%, $P = 0.02$). Spectacle vision in the eye with lower URE was 0.08 ± 0.15 vs 0.02 ± 0.08, $P < 0.0001$ and higher URE was 0.12 ± 0.18 vs 0.02 ± 0.08, $P < 0.0001$ (logMAR) for RMS and CS. Subgroup analyses excluding participants with astigmatism $\geqslant 2.00$D and anisometropia $\geqslant 1.00$D (74/363, 20%) found no difference in planned continued use (139/143, 97% vs 141/146, 97%, $P = 1.0$) for RMS vs CS.

Conclusions While vision is slightly better with CS, 90% of an adult population with URE planned to continue to use their RMS at 1 month. Furthermore, if those without high astigmatism or anisometropia are excluded, virtually all are satisfied with RMS and there is no difference when compared with CS. The findings of this study support the use of RMS for the delivery of refractive services in settings where there is a high level of need, limited resources and low access to refractive services.

Keywords Refractive services, uncorrected refractive error, ready-made spectacles, public health, randomized clinical trial

Introduction

Uncorrected refractive error (URE) is a major cause of visual impairment and blindness globally. The World Health Organization has made refractive error correction a priority in the global initiative to eliminate avoidable blindness: Vision 2020—the Right to Sight.[1] It is estimated that 153 million people worldwide have distance vision worse than 20/60 due to uncorrected refractive error[2,3] and close to one-third of these live in India.[4]

Large population-based studies, such as the Andhra Pradesh Eye Disease Study,[5] confirmed that URE is a major cause of visual impairment and blindness in India. In this study, approximately two-thirds of adults with high amounts of refractive error [$\geqslant$3 diopters (D)] were not using spectacles.[6] The cost of spectacles, availability of refractive services, particularly in rural areas, and quality of refractive services are barriers to addressing URE.[3] The impact of poor vision due to refractive error is especially significant as many of those affected are working age.[7] Smith and colleagues[7] estimated that the global economic burden of uncorrected refractive error is in excess of $269 billion dollars in potential productivity loss and provision of care for those affected.

Spectacles are usually made to order ['custom spectacles' (CS)]; however, due to limited resources and a high level of need in developing countries, ready-made spectacles (RMS) may be preferred.[8–12] Despite anecdotal success, there is a paucity of research on the acceptability of RMS in comparison with CS.

We have previously reported that RMS were well tolerated in school-aged children in China.[13] Others have reported that ready-made reading spectacles improve vision-related quality of life in a presbyopic population in rural Africa.[14] To our knowledge there have been no prospective evaluations of RMS for simple refractive error in adults. We report a randomized trial to compare the performance of RMS and CS in an adult population with URE. Planned continued use, rate of remakes and visual performance are evaluated.

Methods

The performance of RMS was compared with CS using a prospective double-masked randomized clinical trial. The Johns Hopkins Medicine Institutional Review Board and the Dr Shroff's Charity Eye Hospital (SCEH) Human Research Ethics Committee approved the study protocol and this clinical trial was registered with the US National Institutes of Health Protocol Registration System (https://register.clinicaltrials.gov NCT00657670).

Participants aged 18–45 years were recruited from patients attending the SCEH outpatient clinic and outreach screening camps in Delhi, India. Those who did not want to participate in the study were referred to existing spectacle services at SCEH. Potential subjects were required to have at least 1D of spherical refractive error, and have habitual vision of 20/40 or worse in the better seeing eye to be eligible to participate. Unlike our concurrent trial in school-aged children in China,[13] which excluded higher levels of astigmatism and anisometropa, there were no exclusion criteria for complex refractive error.

After oral consent was obtained, participants were asked a series of questions about their socio-economic status, ocular and general health. Study enrollment and follow-up are summarized in Figure 1. Participants were evaluated when they received their

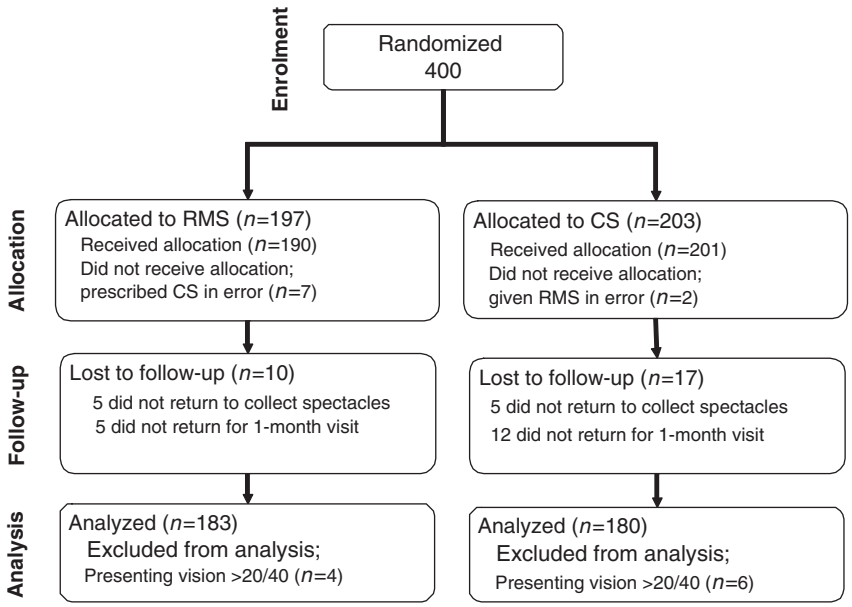

Figure 1 Flow chart of the progress of study participants in the clinical trial. RMS = ready made spectacles, CS = ready made spectacles

spectacles and after 1 month of wear. At the completion of the 1-month visit, all participants were given US$5 to compensate for travel costs and time. Those who were unable to attend the clinic for the final visit were instead interviewed on the telephone. All study personnel involved in data collection were masked to the treatment allocation.

Outcome data

The proportion who planned to continue to wear the study spectacles was the primary outcome. Secondary outcome measures included willingness to pay (WTP) and subjective impressions about whether or not vision was improved with the study spectacles. The need to adapt to the new spectacles and patterns of use were also compared.

The study participants were asked about the presence of a range of symptoms: blurred vision, distorted vision, headache, disorientation, dizziness, eyestrain and nausea when they first received their spectacles and after 1 month of use. Finally, visual acuity with the study spectacles was compared.

Vision testing

Visual acuity measurements were taken using tumbling E-charts (Precision Vision, Villa Park, IL, USA) with retro-illumination.[15] Visual acuity was letter scored with 0.02 logMAR (logarithm of Minimum Angle of Resolution, $20/63^{+1}$ Snellen acuity) assigned to each letter. The participants were asked to continue reading smaller rows of letters until four out of five were incorrectly identified.

Habitual vision, with either no correction or with the participants' own spectacles, was assessed at the first visit and at the return visit prior to receiving the study spectacles. The average of these two measurements was used in the analysis.

All participants had been refracted in the outpatient service of SCEH prior to enrolment and this was used as the starting point for the subjective refraction. The sphero-cylindrical refraction was finalized using bracketing with ±0.25D trial lenses and binocularly balanced using prism dissociation. The final refraction was the most plus correction that provided 20/20 vision. Spectacles were prescribed for distance refractive error only. The study optometrists recommended the CS prescription based on the full sphero-cylindrical correction and RMS prescription based on the spherical equivalent (SE) for the eye with lower refractive error but limited to the powers in the RMS inventory. Corrected vision was measured with the study spectacles at the dispensing visit.

Before analysis, the sphero-cylindrical refraction and spectacle prescription was converted into three Fourier coefficients: a spherical lens (M) and two cross-cylinders, one at axis 45° (J_{45}) and one at axis 0° (J_0) using the methods described by Thibos.[16] The 'defocus' due to spherical and cylindrical refractive error was estimated by the length of the power vector ($P = \sqrt{M^2 + J_0^2 + J_{45}^2}$).

Spectacles

Participants selected a frame from a choice of four metal frames. Both the CS and RMS were made to order using CR39 lenses in the optical shop at SCEH. The optical centre distance of the CS was matched to the participant's pupillary distance and, for the RMS group, the optical centre distance was 60mm. The spectacle lenses used in the RMS group were +1.00 to +4.00 in 0.50 steps, +5.00, +6.00 and +8.00, −1.00 to −6.00 in 0.50 steps, −7.00, −8.00, −9.00 and −10.00 and had the same power in each eye in order to mimic a limited inventory of 25 stock keeping units. Remakes were offered if the participant indicated that they did not intend to use their spectacles after 1 month of use.

Randomization

The study optometrists, coordinator and participants were masked to the type of spectacles received and remained masked during all study visits. After completion of the first visit, both the CS and RMS prescriptions, pupillary distance, frame choice and participant identification number were sent to the optical shop. The optical dispenser then referred to a computer generated (http://www.randomization.com) randomization grid with 400 entries and ordered the spectacles according to the group allocation for the given sequential participant identification number. There was no opportunity for the optical shop technician to change the participation identification number and thereby preferentially move the participant to a different location on the randomization table. Further, the optical shop attendant did not have knowledge of the relative advantages of CS vs RMS and would not be motivated to give one option over the other. The spectacles were verified as ordered by a technician at the optical shop according to standard parameters[8] before being dispensed.

Statistical analyses

Subjective responses to the study spectacles were compared using an intent-to-treat (ITT) analysis and Fisher's exact test or chi-squared test as appropriate. Spectacle vision was compared between the two randomization groups using a two-group *t*-test. Change in the rate of symptoms between the dispensing and follow-up visit was assessed using McNemar's test. We repeated all analyses for 'treatment received'.

Subgroup analyses were conducted excluding those with astigmatism of ⩾2.00D in at least one eye and excluding subjects with ⩾1D anisometropia[17,18] and for previous spectacle wearers. A series of analyses were conducted to evaluate the effect of various cut-offs on rate of continued use and other secondary outcome measures.

The study was powered to be able to detect a 15% difference in the rate of continued use of the study spectacles at a 5% level of significance with 80% power assuming base rate of continued use of 70%. We required 175 in each arm to complete the study and allowing for loss to follow-up enrolled 200 into each arm.

Role of the funding source

The funding sources were not involved in the study design, collection, analysis or interpretation of data and the decision to submit the paper for publication.

Results

Recruitment of 400 participants took place from May to September 2008 with 197 randomly assigned to the ⩾RMS and 203 to the CS group. There were nine errors in spectacle orders; seven participants allocated to the RMS group were provided CS and two allocated to the CS group received bilateral spheres. The analysis was repeated according to treatment received; however, the conclusions were not altered and these data are not presented.

In the RMS group, five participants did not return to collect their spectacles, and an additional five did not complete their 1-month visit and were not contactable by telephone. In the CS group, five participants did not return to collect their spectacles, and another 12 did not complete their 1-month visit. Thus, a total of 27/400 were lost to follow-up (7%). Furthermore, 10 participants were excluded from analysis because their presenting vision was >20/40; 4 from the RMS group and 6 from the CS group (Figure 1). There were no differences in any of the demographic, medical or ocular history or refractive characteristics between those in the final analysis ($n = 363$, Tables 4–7) and the 27 participants who were lost to follow-up (data not shown).

The two randomization groups did not differ by age, gender or socio-economic parameters (Table 1). The self-reported median household annual income was <60 000 rupees (RP) ($1250) with a median household size of three adults and two children. Approximately half of the participants were unemployed; the rest of the participants were labourers, office workers, professionals or maintained other employment (Table 1).

While there was a low rate of reporting of diabetes, hypertension and heart disease, the majority (63%) reported their general health as 'poor' (Table 2). A higher proportion of the CS group had seen an ophthalmologist previously but no other differences were observed between self-reported ocular and general health in the two groups. One participant in each group indicated that they had cataract but no other eye diseases were reported. Over half had worn spectacles previously and the majority were not wearing their old spectacles because they still had poor vision when using them.

There were no differences in the baseline refractive characteristics between the two groups (Table 3). The average habitual vision in the better seeing eye was 0.6 logMAR and the average refractive error in the study population was 2.18 ± 1.36D (power vector length). Close to three-quarters of the population (281/390, 72%) were myopic and ~50% of the population had astigmatism of ⩾0.75D in at least one eye. Anisometropia of >1.00 D but <2D was present in 5.6% and anisometropia of ⩾2D was present in 2.3% of the population.

There were no adverse events in the study. Almost all participants wore their spectacles to the study visit (95%) and had used them during the last month, full time or for part of the day (Table 4). Overall, there was a high rate of intention to use the study spectacles (93%) but a greater proportion of the CS group intended to continue to wear their spectacles. The refractions for those who did not intend to continue to wear their spectacles tended to show high levels of astigmatism and anisometropia (Appendix). These individuals were refracted again and provided with new spectacles free of charge.

While >90% of both groups agreed that their vision was better with the study spectacles, a higher proportion of those wearing CS reported better vision with their spectacles (Table 4). Similar to the findings on intended continued use and improvement in vision, WTP for the study spectacles was, slightly higher in the CS group ($P = 0.02$). For both groups, this amount was, on average, just over US$4.

The subjective responses are supported by the comparison of visual acuity with the two types of spectacles. Spectacle vision in the eye with lower URE was 0.06 ± 0.12 vs 0.01 ± 0.08, $P<0.0001$ and higher URE was 0.10 ± 0.15 vs 0.01 ± 0.08, $P<0.0001$ (logMAR) for RMS and CS, respectively (Figure 2).

Those prescribed RMS spectacles reported a lower rate of needing to adapt to their new spectacles (Table 4). However, despite this initial difference, the majority (299/363, 82.4%) had adapted within 1 week of receiving their spectacles.

Symptoms at the dispensing and follow-up visits varied between the two groups (Table 5). The proportion of individuals presenting with distorted vision, headache, disorientation and nausea were similar between the RMS and CS groups, and also between the baseline and follow-up. However, the percentage with blurred vision was significantly greater in the RMS group at the time of spectacle dispensing. While this percentage decreased with time, the difference in blurred vision between the two groups was still present at the 1-month visit. Further analyses indicate that much of this difference in blur can be attributed to individuals with anisometropia and/or higher degrees of astigmatism (Tables 6 and 7). Eyestrain was reported more frequently at the

Table 1 Demographics of study participants

	RMS ($n = 193$)	CS ($n = 197$)
Age, mean (± standard deviation)	30.4 ± 9.3	30.4 ± 9.3
Gender, *n* (% male)	82 (42.5)	83 (42.1)
Household annual income in RP, *n* (%)		
<60 000 (US$1500)	151 (80.3)	151 (77.8)
60 000–120 000 (US$1500–3000)	23 (12.2)	31 (16.0)
>120 000 (>US$3000)	14 (7.5)	12 (6.2)
Own following items, *n* (%)		
Television	140 (72.5)	141 (71.6)
Telephone	151 (78.2)	155 (78.7)
Bicycle	55 (28.5)	50 (25.4)
Scooter, motorcycle or moped	47 (24.4)	44 (22.3)
Car, jeep or van	12 (6.2)	4 (2.0)
None of the above	20 (10.4)	19 (9.6)
People in household		
Adults, median (inter-quartile range)	3 (2–5)	3 (2–5)
Children, median (inter-quartile range)	2 (1–4)	2 (1–3)
Married, *n* (%)	107 (55.4)	113 (57.4)
Education, *n* (%)		
Illiterate	30 (15.5)	25 (12.7)
Primary school	45 (23.3)	48 (24.4)
Secondary school	37 (19.2)	31 (15.7)
Higher secondary school	33 (17.1)	37 (18.8)
Graduate, post-graduate or professional	48 (24.9)	56 (28.4)
Occupation, *n* (%)		
Labourer	23 (11.9)	24 (12.2)
Office[a]	27 (14.0)	32 (16.2)
Professional	6 (3.1)	4 (2.0)
None	91 (47.2)	101 (51.3)
Other	46 (23.8)	36 (18.3)

CI = confidence interval.
[a]Includes government workers, office workers, salesman and businessmen.

1-month visit compared with dispensing for CS and the initial difference in eyestrain between the two types of spectacles was no longer evident at 1 month.

In subgroup analyses, when those with astigmatism of ⩾2D and anisometropia of ⩾1D or more were excluded, the principle outcome of planned continued use was no longer different between the two groups (Table 6). The rate of continued use was 97% in both the RMS and CS groups. The subgroup of previous spectacle wearers was similar in their responses to the whole group.

Cutoffs for optimal satisfaction were explored further in Table 7 for increasing degrees of astigmatism and anisometropia. The relationship between satisfaction and degree of astigmatism and anisometropia was linear, with increasing satisfaction with lower astigmatism and less difference in corrective lens power between the eyes. Participant self-report of blur at the time of spectacle dispensing was partially predictive of remakes at 1 month. In the group that had spectacles remade, 9/24 (38%) reported trouble with blur at dispensing as compared with 40/336 (12%) in the group who planned to continue to wear their spectacles ($P = 0.002$, Fisher's exact test).

Discussion

We have used a double-masked randomized clinical trial to evaluate the response to RMS and CS in an urban Indian population of adults with URE. Approximately 90% intended to continue to use

Table 2 Medical and ocular history of study participants

	RMS ($n = 193$)	CS ($n = 197$)
Hypertension, diabetes or heart disease	6 (3.1)	3 (1.5)
Smoker (collapse former/current)	15 (7.8)	14 (7.1)
Alcohol (collapse former/current)	11 (5.7)	7 (3.6)
General Health		
Excellent	9 (4.7)	12 (6.1)
Very Good	22 (11.4)	16 (8.1)
Fair	41 (21.2)	46 (23.4)
Poor	121 (62.7)	123 (62.4)
Seen ophthalmologist, *n* (%)	106 (55.0)	142 (72.1)
Spectacles experience, *n* (%)	108 (56.0)	116 (59.2)
If yes, where from?		
Hospital clinic	20 (18.2)	21 (17.7)
Optical shop	90 (81.8)	98 (82.4)
If yes, why not useful anymore?		
Broken	16 (14.6)	23 (19.3)
Lost	7 (6.4)	2 (1.7)
Vision poor	68 (61.8)	69 (58.0)
Frame not comfortable	6 (5.5)	6 (5.0)
Appearance	2 (1.8)	2 (1.7)
No reason	11 (10.0)	17 (14.3)

Table 3 Habitual visual acuity and refractive errors measured by subjective refraction at the baseline visit ($n = 390$)

Spectacle group	Uncorrected habitual vision in the better eye[a]		Degree of spherical equivalent refractive error[b]		Astigmatismin the more astigmatic eye		Anisometropia	
	logMAR	Snellen	Diopters	%Myopic	⩾0.75DC	⩾2.00DC	⩾1 & < 2D	⩾2D
RMS	0.56 ± 0.21	$20/63^{-3} \pm 2$ lines	2.22 ± 1.31	133 (68.9)	73 (37.8)	24 (12.4)	10 (5.2)	5 (2.6)
CS	0.57 ± 0.21	$20/63^{-3.5} \pm 2$ lines	2.34 ± 1.40	148 (75.1)	81 (41.1)	21 (10.7)	12 (6.1)	4 (2.0)
P-value		0.71	0.40	0.18		0.91		0.33

[a]The better eye is defined as the eye that had better corrected visual acuity.
[b]The estimate of the total defocus due to spherical and cylindrical refractive error and the average of right and left eye.
DC, diopters cylinder; D, diopters.

their RMS, which increased to nearly 100% when those with high degrees of anisometropia and astigmatism were excluded. The large improvement in vision and high rate of planned continued use of RMS in this study support wider use of RMS in refractive services programs in developing settings where spectacles are often not affordable and refractive services not accessible to those in need.

The advantage of RMS are that they are substantially cheaper than RMS and, when purchased in volume, good-quality spectacles can be obtained for as little as $US0.50 per pair of spectacles.[19] Further, RMS can be provided on a single occasion, which further reduces costs. The cost savings are clear, and conservatively at least twice as many people could be serviced with RMS compared with CS service. Developing countries in the Western Pacific who utilize RMS report that they are able to price the spectacles to achieve full cost recovery.[20] Other settings also utilize RMS as the mainstay of refractive services.[9,12,20] Our study population, which included all refractive errors and is therefore relevant to these programs.

Others have speculated that there are degrees of anisometropia (0.50–2.00D) or astigmatism (0.75–1.25D), where RMS are no longer appropriate.[18,21,22] In a parallel research study in China, we excluded 8% of students with astigmatism ⩾2.00D or ⩾1D anisometropia, and found RMS and CS to perform equally well.[13] The present study in adults in India

Table 4 Outcome measures at the 1-month follow-up visit ($n = 363$)

	RMS ($n = 183$)	CS ($n = 180$)	Difference (95% CI)	*P*-value
Plan to continue to wear, *n* (%)	165 (90.2)[a]	174 (96.7)[a]	−6.5 (−11.6, −1.5)	**0.02**
WTP in RP	213 ± 81	234 ± 84	21 (4, 38)	**0.02**
Vision is better with spectacles?				
Dispensing visit, *n* (%)	179 (96.8)	190 (99.5)	−2.7 (−5.5, 0.03)	0.06
Follow-up visit, *n* (%)	167 (91.3)	174 (96.7)	−5.4 (−10.3, −0.5)	**0.045**
How often worn?				
All day, *n* (%)	97 (53.6)	94 (52.5)	1.1 (−9.2, 11.4)	0.53
Part of day, *n* (%)	50 (27.6)	63 (35.2)	−7.6 (−17.1, 2.0)	
Only for distance vision, *n* (%)	32 (17.7)	21 (11.7)	6.0 (−1.3, 13.2)	
Only for near vision, *n* (%)	2 (1.1)	1 (0.6)	0.5 (−1.3, 2.4)	
Need to adapt, *n* (%)	168 (91.8)	175 (97.2)	−5.4 (−10.1, −0.8)	**0.036**
Time to adapt				
<1 day, *n* (%)	53 (31.6)	53 (30.9)	1.3 (−8.5, 11.0)	0.32[b]
1–7 days, *n* (%)	89 (53.0)	104 (59.4)	−6.5 (−16.9, 4.0)	
1–4 weeks, *n* (%)	23 (13.7)	18 (10.3)	3.4 (−3.5, 10.3)	
Still not adapted, *n* (%)	3 (1.8)	0 (–)	1.8 (−0.2, 3.8)	

Bold values indicate statistically significant values.
[a]Those who were not planning to use their spectacles were refracted again and the lenses replaced with a new prescription.
[b]Mantel–Haenszel chi-square.

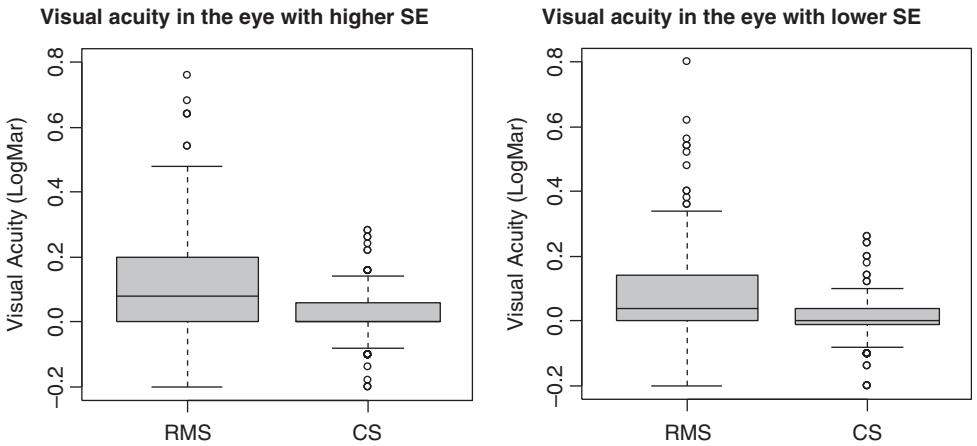

Figure 2 Average visual acuity with the study spectacles in the eye with higher refractive error and the eye with lower refractive error. SE, spherical equivalent refractive error; LogMar, Logarithm of the Minimum Angle of Resolution.

evaluated RMS on all types of refractive error, regardless of the degree of astigmatism or anisometropia. Similar to the findings in Chinese school children, RMS and CS were equally acceptable once the high astigmats and those with anisometropia were excluded. Our findings suggest that ~90% of adults with refractive error can be satisfied with RMS and the remaining 10% would benefit from CS.

While we found a linear relationship between increasing degrees of astigmatism and anisometropia and satisfaction with RMS, no clear cutoff defines who cannot benefit from RMS. One operational approach would be to offer RMS to all as a first option in refractive correction. Those with higher amounts of astigmatism who note blur when trialing RMS are more likely to be unsatisfied at 1 month, so allowing them to try on the RMS prior to purchase could identify the subgroup most likely to be unsatisfied. Completely removing all those with ⩾1D anisometropia and ⩾2D astigmatism would have excluded 20% of the study population, many of whom were happy with RMS. While further research is needed to see how best to implement a program using RMS, one option is to counsel individuals with

Table 5 Symptoms at the dispensing visit and follow-up visits in the two groups

	RMS ($n=183$)	CS ($n=180$)	Difference, % (95% CI)	*P*-value
Dispensing visit				
Blurred vision	40 (21.6)	10 (5.2)	16.3 (9.4, 23.2)	**< 0.0001**
Distorted vision	23 (12.4)	14 (7.3)	4.8 (−1.4, 11.0)	0.12
Headache	43 (23.2)	33 (17.3)	5.2 (−3.2, 13.5)	0.16
Disorientation	12 (6.5)	8 (4.2)	2.1 (−2.6, 6.8)	0.36
Dizziness	25 (13.5)	15 (7.9)	5.3 (−1.1, 11.7)	0.09
Eyestrain	39 (21.1)	19 (10.0)	10.8 (3.3, 18.2)	**0.004**
Nausea	6 (3.2)	6 (3.1)	−0.1 (−3.7, 3.6)	1.00
1-month follow-up visit				
Blurred vision	27 (14.8)[a]	7 (3.9)	10.9 (5.0, 16.7)	**0.0009**
Distorted vision	20 (10.9)	7 (3.9)	7.0 (1.7, 12.4)	**0.02**
Headache	47 (25.7)	35 (19.4)	6.2 (−2.3, 14.8)	0.17
Disorientation	13 (7.1)	10 (5.6)	1.6 (−3.5, 6.6)	0.67
Dizziness	25 (13.7)	11 (6.1)	7.6 (1.5, 13.6)	**0.02**
Eyestrain	43 (23.5)	32 (17.8)	5.7 (−2.6, 14.0)	0.19
Nausea	7 (3.8)	6 (3.9)	0.5 (−3.3, 4.3)	1.0

Bold values indicate statistically significant values.

Analysis limited to those who completed both dispensing and follow-up visits.

[a]McNemars test for change across time for RMS: blur was present at dispensing but not at 1 month in 27/181, 14.9% and not present at baseline but present at 1 month in 14/181, 7.7%, $P=0.04$, distorted vision $P=0.56$, headache $P=0.42$, disorientation $P=0.81$, dizziness $P=0.11$, eyestrain $P=0.58$, nausea $P=0.11$.

*McNemars test for change across time for CS: blur $P=0.53$, distorted vision $P=0.16$, headache $P=0.65$, disorientation $P=0.29$, dizziness $P=0.41$, eyestrain was present at dispensing but not at 1 month in 13/179, 7.3% and not present at baseline but present at 1 month in 28/179, 15.6%, $P=0.02$, nausea $P=0.56$.

higher degrees of astigmatism and anisometropia that they might benefit from CS, inform them of the increased cost and leave the decision to them.

The CS group, as intended, had 20/20 vision on average with their new spectacles; however, the RMS group was not fully corrected and vision was on average $20/20^{-3}$ in the eye with lower refractive error. The premise of using RMS is that a small amount of blur is acceptable and that the spectacles will still meet an individual's refractive needs.

The participants were asked about how much they would pay for their spectacles after they had worn them for 1 month. This is unlike real life, where spectacle purchase is required upfront, prior to use. In addition, this was a hypothetical question and the spectacles had already been supplied free of charge. Despite these limitations, these data provide useful information about the potential for cost recovery in refractive service delivery in this setting. The median price the participants were willing to pay was 200 Indian Rupees, which at the time of the study was equivalent to ~US$4, less than 1 weeks income.

As in other studies of spectacle tolerance,[23–25] almost all participants had to adapt to their new spectacles, but slightly fewer who were prescribed RMS required time to adapt. This might be explained by the difficulties encountered in adapting to meridional magnification or aneisikonic effects with full corrections for astigmatism and anisometropia. However, this difference did not have a clinically significant impact on the acceptability of CS, as all of the CS wearers were adapted to the new spectacles within 1 month.

The rate of remakes in this study was a key endpoint. In a published report where custom spectacles were prescribed, ~11% of spectacles were remade due to spectacle intolerance.[24] The rate of remakes in our study in the CS group was lower at 3%, and ~10% in the RMS group. The lower rate of remakes in this population may in part be explained by lower visual demands. It is also possible that our study population was reluctant to complain; however, remakes were provided at no cost if the participant indicated in a structured interview that he did not intend to use the spectacles, which should have minimized this effect.

Other prospective studies of spectacle use in developing countries have been completed in school populations, where unannounced visits are possible to assess compliance to spectacle wear.[26,27] This approach was not possible in our study population of adults who cannot be assessed in their daily activities for logistical reasons. Despite this limitation,

Table 6 Subgroup analyses for astigmatism <2.00D, <1.00D anisometropia, both exclusions combined and those with previous spectacle wear experience

	RMS	CS	*P*-value
Astigmatism <2.00D in both eyes	$n=164$	$n=170$	
Plan to wear, *n* (%)	152 (93.8)	154 (96.9)	0.20
Vision is better, *n* (%)			
Dispensing visit	160 (97.6)	169 (99.4)	0.21
1-month visit	152 (93.8)	154 (96.9)	0.29
WTP, mean ± SD	212 ± 81	221 ± 87	**0.02**
Blurred vision, *n* (%)			
Dispensing visit	29 (17.7)	9 (5.3)	**<0.0001**
1-month visit	19 (11.3)	6 (3.8)	0.01
Anisometropia <1.00D	$n=158$	$n=158$	
Plan to wear, *n* (%)	150 (94.9)	152 (96.2)	0.79
Vision is better, *n* (%)			
Dispensing visit	157 (98.1)	167 (99.4)	0.36
1-month visit	151 (95.6)	152 (96.2)	1.0
WTP, mean ± SD	210 ± 77	231 ± 83	**0.02**
Blurred vision, *n* (%)			
Dispensing visit	28 (17.5)	9 (5.4)	**<0.0001**
1-month visit	17 (10.8)	7 (4.4)	0.054
Anisometropia <1.00D and <2.00D astigmatism in both eyes	$n=143$	$n=146$	
Plan to wear, *n* (%)	139 (97.2)	141 (96.6)	1.00
Vision is better, *n* (%)			
Dispensing visit	157 (98.1)	167 (99.4)	0.36
1-month visit	151 (95.6)	152 (96.2)	1.0
WTP, mean ± SD	209 ± 74	216 ± 80	**0.03**
Blurred vision, *n* (%)			
Dispensing visit	21 (14.5)	8 (5.1)	**0.006**
1-month visit	12 (8.4)	6 (4.1)	0.15

SD = standard deviation.
Bold values indicate statistically significant values.

rates of intended use could be directly compared and these were universally high (>90%) in both studies.[13]

While we required at least 1D of distance refractive error, our study population would have included early presbyopes. For the 72% who were myopic this would not be problematic, as they could take their glasses off to see near. However, the hyperopes would be experiencing considerable problems with near vision. It was not within the scope of the study to evaluate presbyopia and we only corrected distance refractive error. Hyperopes may have had both distant and near vision improvement. Furthermore, some of those studied may have derived additional benefit from separate reading spectacles or bifocals, which were not offered. While RMS have been shown to be effective as reading glasses (for presbyopia) in rural Africa[14] additional research will be needed to confirm the effectiveness of RMS for the correction of refractive error in populations aged >45 years where there are higher degrees of anisometropia.[5,28]

The strengths of this study lie in the approach, low rate of loss to follow-up (7%) and minimal cross-over. All errors in spectacle orders were detected by comparing the measurements with the prescription and were low (2%). The treatment was randomly assigned and the similarity in demographic and socio-economic characteristics of the two groups indicates that randomization was successful. The masking of the participant and those involved in data collection reduced the likelihood of bias in subjective responses and lends further credibility to the study findings; although we acknowledge that the success of masking was not independently assessed. The rate of planned continued use was supported by differences observed in subjective impressions, WTP and rate of symptoms. Differences in performance were influenced by the

Table 7 Key outcome variables for the RMS group stratified by differing levels of anisometropia and astigmatism

	n	Plan to wear, *n* (%)	WTP (RP), mean ± SD	See better, *n* (%)	See better at 1 month, *n* (%)	No blur, *n* (%)	No blur at 1 month, *n* (%)
Astigmatism (D)							
<0.50	65	65 (100.0)	222 ± 76	64 (100.0)	65 (100.0)	59 (92.2)	63 (97.0)
0.50–0.75	49	47 (95.9)	211 ± 81	47 (95.9)	47 (95.9)	37 (75.5)	44 (89.8)
1.00–1.25	29	25 (86.2)	201 ± 84	28 (96.6)	25 (86.2)	22 (75.9)	22 (75.9)
1.50–1.75	19	15 (79.0)	202 ± 98	18 (94.7)	15 (79.0)	14 (73.7)	14 (73.7)
⩾2.00	21	13 (61.9)	221 ± 85	19 (95.0)	15 (71.4)	10 (50.0)	13 (61.9)
Anisometropia (D)							
<0.50	135	126 (93.3)	209 ± 75	129 (97.0)	127 (94.1)	109 (82.0)	115 (85.2)
0.50–0.75	33	30 (90.9)	223 ± 91	33 (100.0)	30 (90.9)	24 (72.7)	31 (93.9)
1.00–1.75	10	7 (70.0)	255 ± 107	10 (100)	8 (80.0)	7 (70.0)	8 (80.0)
⩾2.00	5	2 (40.0)	190 ± 124	4 (80.0)	2 (40.0)	2 (40.0)	2 (40.0)

amount of astigmatism and anisometropia in the study population.

In conclusion, this research provides detailed information on the comparative performance of RMS and CS for the first time in an adult population with URE. As predicted, those with more complex refractive errors are less satisfied with RMS. However, the high proportion of this clinic population satisfied with RMS and cost savings lends support for the use of RMS in refractive service delivery. As availability of custom optical services improves and resources permit, a natural transition to CS would be expected in developing settings.

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Conflict of interest: None declared.

KEY MESSAGES

- Refractive error is a leading cause of blindness and visual impairment with an estimated 153 million people world wide visually impaired simply because they do not have spectacles to correct their vision.
- RMS have been proposed as the mainstay of refractive services in developing settings due to cost advantages. We report that there are small differences in performance between RMS and CS.
- A high proportion of individuals with refractive error can benefit from RMS, supporting their use in settings where there is a high level of need and limited resources.

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Appendix

Table A1 Spectacle prescriptions for those who had their spectacles remade at the end of the study

Allocation		Right-eye subjective refraction (D)	Left-eye subjective refraction (D)
CS	Hyperopia	+2.50	+2.25
CS	Myopia	−3.00	−3.50/−0.50 × 125
CS	Myopia	−3.75/−0.75 × 10	−3.50/−0.50 × 10
CS	Myopia	−1.00/−0.75 × 10	−1.00/−0.75 × 180
CS	Myopic astigmatism	−0.75/−1.50 × 100	−1.00/−1.75 × 90
CS	Myopic astigmatism	−1.00/−2.00 × 90	−1.50/−0.75 × 90
RMS	Hyperopia	+2.25/−0.50 × 180	+2.00/−0.50 × 175
RMS	Myopic astigmatism	−0.50/−1.00 × 90	−0.25/−1.25 × 90
RMS	Myopic astigmatism	−1.00/−1.50 × 80	−0.75/−1.25 × 80
RMS	Myopic astigmatism	−0.50/−1.50 × 180	−1.00/−1.50 × 10
RMS	Myopic astigmatism	−1.00/−2.25 × 15	−1.50/−1.50 × 180
RMS	Myopic astigmatism	+0.75/−2.50 × 180	0.50/−1.75 × 180
RMS	Myopic astigmatism	−1.00/−3.25 × 180	−0.75/−2.25 × 180
RMS	Myopic astigmatism	+0.75/−3.00 × 180	+0.50/−2.00 × 170
RMS	Myopic astigmatism	−0.25/−1.50 × 180	0.00/−1.75 × 170
RMS	Myopic astigmatism	−0.50/−2.50 × 10	0.00/−3.25 × 170
RMS	Myopic astigmatism	−0.50/−2.00 × 90	0.00/−3.00 × 80
RMS	Myopic astigmatism	0.00/−4.50 × 10	0.00/−3.50 × 170
RMS	Myopic astigmatism & anisometropia	−8.00/−2.00 × 10	−7.00/−1.00 × 180
RMS	Anisometropia & astigmatism	+1.00	0.00/−1.25 × 180
RMS	Anisometropia & astigmatism	−3.50/−1.25 × 100	−1.50/−0.50 × 70
RMS	Anisometropia	−6.50	−2.50/−1.50 × 180
RMS	Anisometropia	−2.50/−0.50 × 180	−1.00/−0.75 × 180
RMS	Anisometropia	−5.75/−0.75 × 60	−3.25/−1.25 × 150

Anisometropia defined as >1D difference between eyes in spherical equivalent refractive error. Astigmatism defined as any cylindrical correction >1D.