Baseline Refractive and Ocular Component Measures of Children Enrolled in the Correction of Myopia Evaluation Trial (COMET)

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Purpose. To describe baseline refractive and ocular component measures in children with myopia enrolled in the Correction of Myopia Evaluation Trial (COMET). COMET is a multicenter, randomized clinical trial to evaluate whether progressive-addition lenses slow the progression of juvenile-onset myopia compared with single-vision lenses.

Methods. Four hundred sixty-nine children with myopia between −1.25 and −4.50 D spherical equivalent and without eye or systemic conditions known to affect refractive development were recruited from four geographically and ethnically diverse communities in the United States. Their ages were 6 to 11 years inclusive, and 52% were girls. The main outcome measure for the overall trial is progression of myopia determined by cycloplegic autorefraction after inducement of cycloplegia with 2 drops of 1% tropicamide. Axial length, the secondary outcome measure, was assessed by ultrasonography. The distance correction was determined by subjective methods before cycloplegia, with noncycloplegic autorefraction values as the starting point.

Results. Because data were similar in both eyes, they are reported for the right eye only. The mean spherical equivalent measured by cycloplegic autorefraction was −2.38 ± 0.81 D. Young children had significantly less myopia than older children ($P = 0.03$), but the amount of myopia did not differ by gender or ethnicity. Mean axial dimensions were 4.0 ± 0.2 mm (anterior chamber), 3.4 ± 0.2 mm (lens), 16.8 ± 0.7 mm (vitreous chamber), and 24.1 ± 0.7 mm (axial length). Girls' eyes had significantly shorter axial length than boys' ($P < 0.0001$). Mean corneal radii were 7.73 ± 0.25 mm (horizontal) and 7.59 ± 0.24 mm (vertical). Ninety-five percent of the eyes had a ratio of axial length to corneal radius higher than 3.0.

Conclusions. These baseline measures provide cross-sectional data on a large group of ethnically diverse children with myopia. Refractive and axial component dimensions are consistent with data in other studies showing that myopic eyes have longer vitreous chambers than emmetropic eyes. The measures reported herein will serve as a basis for examining changes that occur over a minimum of 3 years of follow-up of children enrolled in COMET. (*Invest Ophthalmol Vis Sci.* 2002;43: 314–321)

Myopia is a significant public health problem, affecting at least 25% of adults in the United States[1] and a much higher percentage of Asians.[2] Myopia in the United States has been reported to be more prevalent in more recent birth cohorts.[3] As might be expected for such a highly prevalent condition, treatment costs are high, with annual estimates in the United States for eye examinations and correction of myopia ranging from $2.5 to $4.6 billion.[4,5]

It is not surprising that with myopia's complex etiology, numerous options for slowing or halting its progression have been evaluated, often in the absence of a sound scientific rationale. Many studies have methodological limitations, such as unmasked examiners and nonrandom assignment to treatment groups. Results of most previous studies using spectacle interventions, mainly bifocals, have been equivocal[6–8] or have applied to restricted populations.[9,10] Recently, the use of bifocals by a small group of children with nearpoint esophoria was reported to slow the progression of myopia by 0.25 D over 30 months, compared with progression in children randomized to single-vision lenses (SVLs).[9] Progressive-addition lenses (PALs) were reported to significantly slow the progression of myopia and axial elongation compared with SVLs in a small group of Chinese children.[10]

The preliminary results of the study using PALs in Chinese children, together with animal and human data suggesting that retinal defocus is a factor in myopigenesis, provided the rationale for the Correction of Myopia Evaluation Trial (COMET). COMET is a National Eye Institute–supported, multicenter clinical trial designed to evaluate whether PALs, which provide clear vision over a range of viewing distances, slow the rate of progression of juvenile-onset myopia when compared with conventional correction with SVLs. The secondary purpose of COMET is to investigate factors related to the natural history of juvenile-onset myopia in a group of children receiving conventional treatment.

COMET's main outcome measure is progression of myopia assessed by cycloplegic autorefraction, chosen for its reliability, objectivity, and standardization across examiners and locations. In a direct comparison of automated and subjective refraction, the automated refractions were found to be more repeatable, making them more suitable for a longitudinal study of myopia, such as COMET.[11] However, this measure typically is not used for prescribing glasses, either in the clinic or in research protocols, including COMET's. Most often, the distance prescription from which glasses are made is determined subjectively before cycloplegia, as is the case in COMET.

COMET's secondary outcome measure is axial length assessed by ultrasonography. Measurement of ocular components in COMET children is essential, because changes in the size of the eye or its components are responsible for changes

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TABLE 1. Inclusion Criteria

Aged 6 to 11 years inclusive at baseline
Refractive criteria determined by cycloplegic autorefraction:
Spherical equivalent: between −4.5 and −1.25 D inclusive in both eyes
Astigmatism: ≤1.50 D in either eye
Anisometropia ≤1.0 D (spherical equivalent between eyes)
Visual Acuity (with distance correction): 0.20 logMAR units or better (Snellen equivalent 20/32)
No strabismus by cover test at far (4 m) or near (0.33 m) wearing distance correction or at near wearing +2.0 over distance correction
Birth weight ≥ 1250 g
No known ocular, systemic, or neurodevelopmental conditions that might affect refractive development
No use of medications that might affect refractive development
No prior wear of progressive-addition or bifocal lenses
No prior wear of contact lenses

in the eye's refractive properties. Experimental myopia induced by visual manipulations in various animal species is related to elongation of the vitreous chamber.[12,13]

The purpose of this report is to describe baseline measures of refractive error and ocular components from the 469 children enrolled in COMET. Follow-up data will show whether PALs slow the progression of myopia in this ethnically diverse group of school-aged children in the United States.

METHODS

Study Design

The detailed study design has been described elsewhere.[14] Briefly, COMET is a multicenter, randomized clinical trial to determine whether there is a difference in progression of myopia between children with vision corrected by SVLs versus PALs (Varilux Comfort lenses with a + 2.0 D addition; Essilor International; St. Petersburg, FL). The progression of myopia will be assessed by changes from baseline measurements obtained by cycloplegic autorefraction and A-scan ultrasonography and will be reported at the conclusion of the study. The measures reported herein were obtained at the baseline examination, before lens assignment. These baseline data were collected by the study's optometrists, who used standard protocols and identical equipment at each of four clinical centers located at colleges of optometry in Birmingham, Alabama; Boston, Massachusetts; Houston, Texas; and Philadelphia, Pennsylvania.

Subjects

Four hundred sixty-nine children, aged 6 to 11 years inclusive at the start of the study and who met the remainder of the inclusion criteria (Table 1), were enrolled in COMET. This age range was chosen to include children with myopia that was likely to progress throughout the follow-up phase of the trial. Refractive eligibility criteria were determined by cycloplegic autorefraction. The minimum spherical equivalent correction was −1.25 D, to include only those children who were likely to wear their glasses. The maximum correction was −4.5 D, so that, over the 3 years of the study, the correction would be unlikely to exceed −6.0 D, a value that has been associated with pathologic changes in the eyeball.[15] Astigmatism and anisometropia were limited to small amounts.

Visual acuity with distance correction was 0.2 log minimum angle of resolution (logMAR) units (20/32) or better. Children could not have strabismus by cover test at far (4.0 m), near (0.33 m), or near with +2.0 D (the add power in the PALs) over their distance correction. A medical and ocular history was obtained from a parent, to exclude children with low birth weight or any known systemic, ocular, or neurodevelopmental condition that might affect refractive development. COMET children are ethnically diverse, with 26% (n = 122) African-American, 8% (n = 38) Asian, 15% (n = 68) Hispanic, 5% (n = 27) mixed/other, and 46% (n = 217) white, by parental report.

Before the baseline examination, children and parents agreed to accept either SVLs or PALs, as assigned by the randomization scheme; attend follow-up appointments twice each year for at least 3 years; and refrain from contact lens wear throughout the study. Children agreed to wear their COMET glasses during all waking hours. Data are reported for the 469 children who completed the baseline examination, fulfilled all eligibility criteria, enrolled in COMET, and were randomized to a treatment group. The COMET study and protocols conform to the tenets of the Declaration of Helsinki. The institutional review boards of each participating center approved the research protocols. Informed consent (parents) and assent (children) were obtained after verbal and written explanation of the nature and possible consequences of the study.

Procedures

Autorefraction. Progression of myopia assessed by cycloplegic autorefraction is the primary outcome measure. As with all the study measures, autorefraction was taken on both eyes by experienced optometrists who were trained and certified on study protocols. An autorefractor (ARK 700A; Nidek, Gamagori, Japan) was used to obtain five consecutive, reliable readings both before and after cycloplegia. Cycloplegia was induced with two drops of 1% tropicamide administered 4 to 6 minutes apart, after corneal anesthesia was induced with either proparacaine or benoxinate. The COMET protocol specified that cycloplegic autorefraction measures be taken 30 minutes after the second drop of 1% tropicamide was administered.

The child sat in front of the autorefractor and looked at the target, which was designed to minimize accommodation. Measures (in 0.25 D steps) were taken on the right eye first, followed by the left eye under pre- and postcycloplegic conditions. The reliability of each measure was indicated by an automatic numeric assessment (scaled from 5 to 9) provided by the autorefractor. Only measurements with reliability ratings of 7, 8, or 9 were accepted for study purposes, according to COMET protocol. Additional measures were taken, if necessary, to provide five reliable measures in each eye. Eligibility for the study was determined by the summary values provided by the autorefractor after cycloplegia.

Autokeratometry. Three autokeratometry measures were taken using the keratometry setting of the autorefractor-autokeratometer before any drops were administered. The mire rings of the ARK 700A (Nidek) are 3.3 mm in diameter, measured at the corneal surface.

Subjective Refraction. Subjective refraction was completed before cycloplegia according to a standard protocol used at all clinical centers. Standardization was enhanced by using a commercial system (Total Refracting System; Marco Technologies, Jacksonville, FL), which

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allows for preprogrammed lenses and targets at the start of each step of the refractive protocol. The starting point of the subjective refraction was the summary of five noncycloplegic autorefractor measures, taken from the autorefractor. The protocol included determination of monocular best sphere, cylinder power and axis (right eye followed by left eye), binocular balance, and binocular best sphere. Additional converging (plus) lenses were added initially and later at key points throughout the subjective refractive sequence. The spherical component of the refractive prescription was determined by the least correction of the myopia required for the child to read threshold letters at distance. All children received new glasses produced from the distance prescription (in 0.25 D steps) determined at the baseline examination.

Residual Accommodation. Residual accommodation was measured using another autorefractor (R-1; Canon USA, Lake Success, NY) to demonstrate the degree of cycloplegia obtained in COMET children. Tropicamide (1%) was found to be an effective cycloplegic agent in this group of children with myopia.[16]

Ocular Component Measures. After cycloplegic autorefraction, ocular components were measured by ultrasonography (A-2500; Sonomed; Lake Success, NY) using a 10-MHz focused (hard) transducer. After the cornea was anesthetized with either proparacaine or benoxinate, the child was positioned behind the slit lamp. The transducer was held in the tonometer mount and gently applied directly to the cornea. Axial measures were completed, using either the slit lamp technique (the first choice, according to study protocol) or a handheld technique, if necessary, for child comfort or safety. Five individual measures were attempted per eye, and at least three measures per eye were necessary for study eligibility. If any A-scan waveforms showed poor component definition or flattening of the anterior chamber (front of cornea to front of lens) compared with the other scans after review by the examiner, then these were deleted and replaced with acceptable measures. Substitute measures were taken to obtain axial length readings with a within-subject SD less than or equal to 0.1 mm. Mean variability in the right eye was 0.06 mm across all COMET children, as reported previously,[17] determined by first calculating the SD of the three to five measures of axial length in each eye and then the mean of these SDs.

Statistical Analysis

The refraction data, clinically written as sphere, negative cylinder power, and axis, were analyzed by using Fourier decomposition of the power profile, as described by Thibos et al.[18] Each refractive correction was broken down into three components, the spherical equivalent (M in the notation of Thibos et al.) and two Jackson crossed cylinders: one with its meridian of maximum converging power set horizontally (J_0) and the other with its meridian of maximum converging power set obliquely (J_{45}). The power vector components for sphere (S), minus cylinder (C), and axis (θ) were computed as follows: $M = S + C/2$; $J_0 = -(C/2) \cos 2\theta$; and $J_{45} = -(C/2) \sin 2\theta$.

Refractive data were summarized for each eye by the mean of five reliable measurements. Axial length data were summarized by the mean of three to five independent measures, with five measures obtained for most of the eyes (93.3% of right eyes and 97.8% of left eyes). Continuous variables were summarized for right and left eyes using means ± SDs. For each eye separately, comparisons were made between the different measures of refractive error—that is, between cycloplegic autorefraction and the distance prescription and between cycloplegic autorefraction and noncycloplegic autorefraction. For each comparison, the difference between the two measurements, respecting the sign of the difference, was plotted as a function of the mean of these measures using a mean-versus-difference graph.[19] The *t*-test for paired samples was used in univariate analyses, if the normality assumption was satisfied. Otherwise, the nonparametric Wilcoxon signed rank test was used. These analyses were performed primarily to guide the selection of potential predictors in the multivariate analyses, which mainly used the multiple linear regression approach.[20] Only noninteraction models were considered. Thus, each model produced coefficients reflecting the effect of one variable while adjusting for the

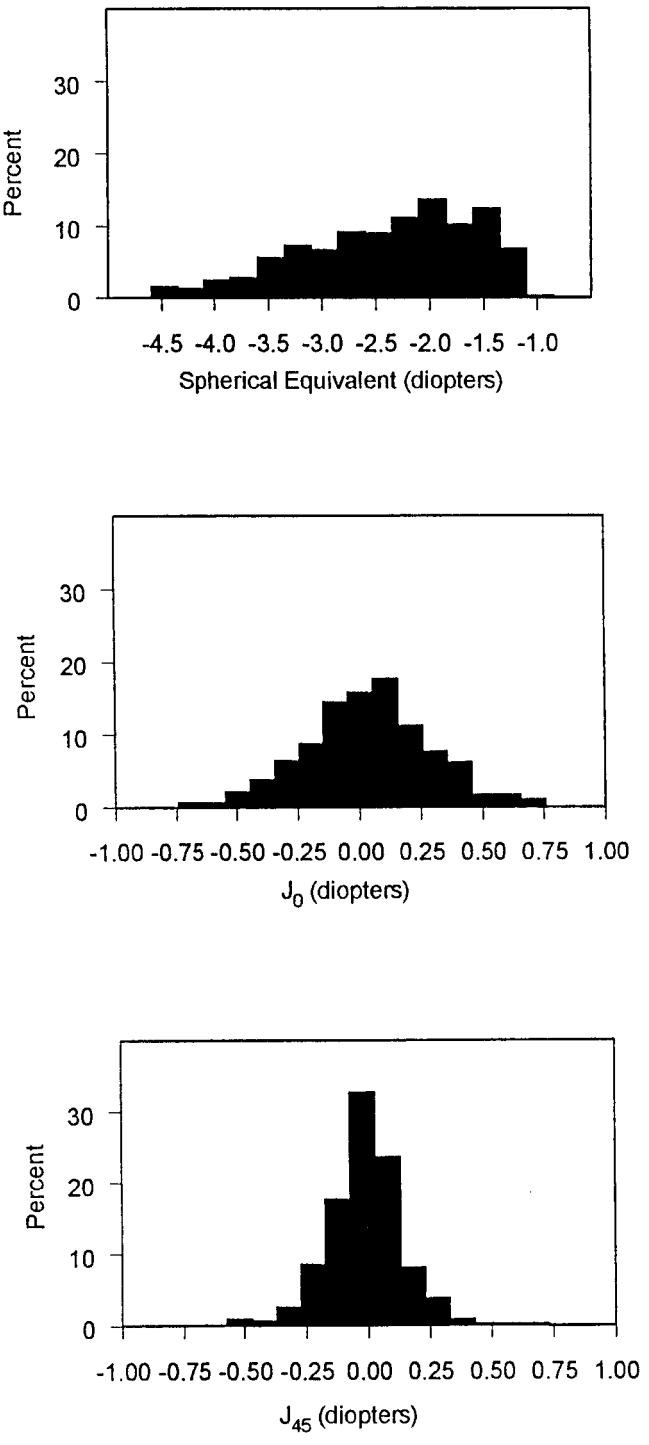

FIGURE 1. Distribution of M (spherical equivalent), J_0, and J_{45} assessed by cycloplegic autorefraction at baseline in the right eyes of 469 children in the COMET. Four percent of the plotted spherical equivalents extend beyond the eligibility limits, because they are means calculated by the coordinating center and not the summary values that were supplied by the autorefractor and used for inclusion in the study.

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TABLE 2. Spherical Equivalent Cycloplegic Autorefraction at Baseline

A. By Age and Gender

	Mean Spherical Equivalent ± SD in D (No. subjects)		
Age (y)	**Male**	**Female**	**Total**
6–7	−2.12 ± 0.65 (17)	−2.40 ± 0.87 (25)	−2.29 ± 0.79 (42)
8	−2.14 ± 0.83 (38)	−2.11 ± 0.74 (45)	−2.13 ± 0.78 (83)
9	−2.49 ± 0.85 (58)	−2.58 ± 0.81 (53)	−2.54 ± 0.83 (111)
10	−2.37 ± 0.72 (70)	−2.42 ± 0.89 (64)	−2.39 ± 0.80 (134)
11	−2.41 ± 0.79 (40)	−2.42 ± 0.80 (59)	−2.42 ± 0.79 (99)
Total	−2.35 ± 0.79 (223)	−2.40 ± 0.83 (246)	−2.38 ± 0.81 (469)

B. By Ethnicity

Ethnicity	**Mean Spherical Equivalent ± SD in D (No. subjects)**
African American	−2.47 ± 0.77 (122)
Asian	−2.56 ± 0.74 (35)
Hispanic	−2.23 ± 0.81 (68)
Mixed	−2.50 ± 0.90 (27)
White	−2.32 ± 0.82 (217)
Total	−2.38 ± 0.81 (469)

possible effect of the others. Because the results in both eyes were similar, data are presented for the right eye only, except when noted.

RESULTS

Refractive Measures

Figure 1 shows the distribution of M (spherical equivalent), J_0, and J_{45} determined by cycloplegic autorefraction. Overall, the mean spherical equivalent was −2.38 ± 0.81 D. Most children had myopia at the low end of the inclusion range, with only 43 (9.2%) of 469 of the spherical equivalents between −3.50 D and −4.50 D. J_0 and J_{45} were mostly zero or within ±0.25 D (68% for J_0 and 99% for J_{45}), indicating little or no astigmatism in this group of children. This is to be expected, based on an inclusion criterion of no more than 1.5 D of astigmatism.

The distribution of astigmatism was also determined using conventional notation, with the axis of the cylinder classified as against the rule (ATR) if it was between 67.5° and 112.5°, and with the rule (WTR) if it was between 0° and 22.5° inclusive or between 157.5° and 180° inclusive. Intermediate values were classified as oblique. Twenty-nine percent of the right eyes had no astigmatism. Seventy-four percent of the right eyes with astigmatism had small amounts (<0.75 D), whereas 26% had between 0.75 and 1.5 D. With respect to axis, half of the astigmatism (51%) was WTR, compared with 35% ATR, and 14% oblique.

Table 2A shows the distribution by age and gender of baseline myopia determined by cycloplegic autorefraction, and Table 2B shows the distribution by ethnicity. Results of a multivariate analysis adjusting for age, gender, and ethnicity showed that young children had significantly less myopia than older ones ($P = 0.03$), but the amount of myopia did not differ by gender or ethnicity.

The difference between the amount of myopia measured by cycloplegic autorefraction and the distance prescription, expressed as spherical equivalents, versus the mean of these findings, is presented in the mean-versus-difference plot in Figure 2. The mean difference in all subjects and the associated 95% limits of agreement were compared with the zero difference to evaluate for possible bias. The mean (±SD) difference between cycloplegic autorefraction and the distance prescription was negligible (−0.04 ± 0.27 D), although statistically significant ($P < 0.001$). The 95% limits of agreement were −0.57 to 0.49 D.

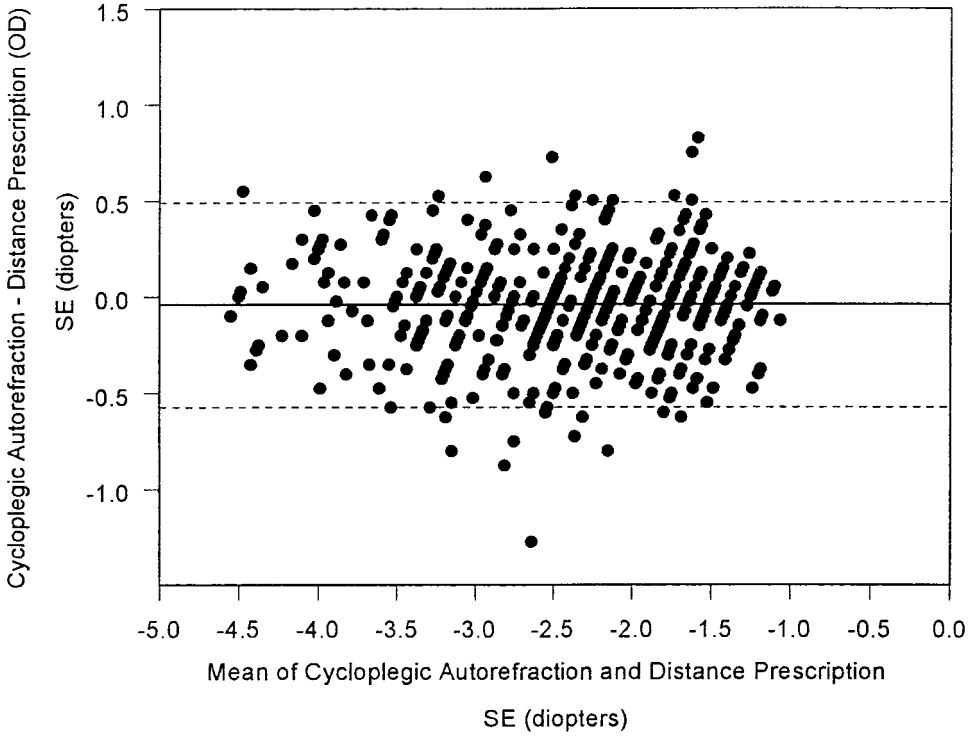

FIGURE 2. Difference-versus-means plot of baseline spherical equivalent refractive error determined by two methods. Cycloplegic autorefraction minus the distance prescription is plotted against the mean of the two measures in the right eyes of 469 children. *Solid line*: the mean; *dashed lines*: the 95% limits of agreement.

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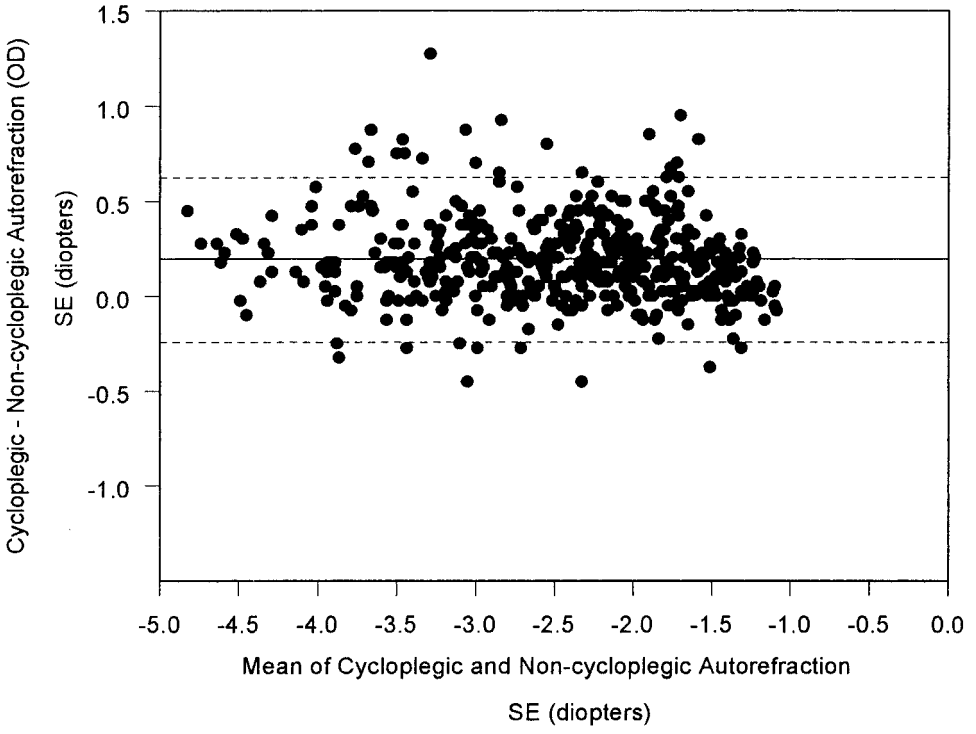

FIGURE 3. Difference-versus-means plot of baseline spherical equivalent refractive error determined by two methods. Cycloplegic autorefraction minus noncycloplegic autorefraction is plotted against the mean of the two measures in the right eyes of 469 children. *Solid line*: the mean; *dashed lines*: the 95% limits of agreement.

The distance prescription was identical with the endpoint of the subjective refraction in 83% of the children. In the other 17%, modified based on the examiner's clinical judgment, the mean spherical equivalent refractions differed by only 0.03 D, which was not statistically significant. Even smaller differences, also not statistically significant, were found in J_0 and J_{45}. Most (81%) of the changes were either in the spherical component of refraction or in the cylinder axis.

The difference between myopia measured by cycloplegic autorefraction and noncycloplegic autorefraction, expressed as spherical equivalents, versus the mean of these findings is presented in the mean-versus-difference plot in Figure 3. The mean (±SD) difference between cycloplegic autorefraction and noncycloplegic autorefraction was small but statistically significant (0.19 ± 0.22 D), indicating that cycloplegic values were slightly more positive. The 95% limits of agreement were −0.24 to 0.62 D.

Ocular Component Measures

Axial measures were completed with the slit lamp technique in 64% of right eyes (measured first) and 59% of left eyes (measured next). A handheld method was used for the remaining measures. The mean (±SD) axial length for the rights eyes of COMET children was 24.1 ± 0.7 mm. The mean (±SD) ocular component measures were 4.0 ± 0.2 mm (anterior chamber), 3.4 ± 0.2 mm (lens), and 16.8 ± 0.7 mm (vitreous). As mentioned previously, the SDs of each of the component measures were small, indicating good precision of these measurements across examiners and centers.[17]

Table 3A shows the distribution of baseline axial length measures by age and gender, and Table 3B shows the distribution by ethnicity. Results of a multivariate analysis adjusting for age, gender, and ethnicity showed that younger children had significantly shorter axial length than older ones ($P < 0.0001$) and that girls had significantly shorter axial length than boys (23.92 mm versus 24.36 mm, $P < 0.0001$). These differences in axial length were mainly due to differences in vitreous chamber depth (16.61 mm in girls versus 16.95 mm in boys, $P < 0.0001$). Axial length did not vary by ethnicity. The Pearson correlation coefficient (r) between axial length and spherical equivalent assessed by cycloplegic autorefraction was 0.32 in the right eye ($P < 0.001$) and 0.33 in the left eye ($P < 0.001$). Similar correlations ($r = 0.29$ in the right eye and 0.31 in the

TABLE 3. Mean Axial Length at Baseline

A. By Age and Gender

	Mean Axial Length ± SD in mm (No. subjects)		
Age (y)	**Male**	**Female**	**Total**
6–7	23.73 ± 0.40 (17)	23.56 ± 0.69 (25)	23.63 ± 0.59 (42)
8	24.31 ± 0.62 (38)	23.90 ± 0.58 (45)	24.09 ± 0.63 (83)
9	24.31 ± 0.61 (58)	23.92 ± 0.64 (53)	24.12 ± 0.65 (111)
10	24.45 ± 0.71 (70)	24.02 ± 0.79 (64)	24.24 ± 0.78 (134)
11	24.62 ± 0.64 (40)	23.97 ± 0.70 (59)	24.23 ± 0.75 (99)
Total	24.36 ± 0.67 (223)	23.92 ± 0.70 (246)	24.13 ± 0.72 (469)

B. By Ethnicity

Ethnicity	**Mean Axial Length ± SD in mm (No. subjects)**
African American	24.11 ± 0.68 (122)
Asian	24.29 ± 0.64 (35)
Hispanic	24.21 ± 0.75 (68)
Mixed	24.21 ± 0.58 (27)
White	24.08 ± 0.75 (217)
Total	24.13 ± 0.72 (469)

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TABLE 4. Selected Characteristics of Subjects in Four Studies Showing Axial Dimensions in Young Myopes and Nonmyopes

	n	Age (y)	Refractive Error (D)	Axial Length (mm)	Anterior Chamber Depth (mm)	Lens (mm)	Vitreous Chamber Depth (mm)
COMET	469	6–11	−1.25 to −4.5	24.13	3.95	3.41	16.77
Jensen[6]	159	6–12	−1.25 to −6.0	24.48	3.92	3.34	17.22
Zadnik et al.[25]	662	6–12	Nonmyopic	22.82	3.66	3.48	15.68
Larsen[27–29]	733	6–11	+5.0 to −2.0	22.37	3.62	3.47	15.28

All data are from right eyes, except in Larsen, who reported "eyes." Cycloplegic agents were 1% cyclopentolate in Jensen's and Larsen's studies and 1% tropicamide in the others. Larson's study includes data from 22 young myopes.

left eye, $P < 0.001$ in both eyes) were found between vitreous chamber depth and spherical equivalent.

Corneal Radii

The mean (±SD) corneal radii in the right eyes determined by keratometry were 43.7 ± 1.4 D (7.73 ± 0.25 mm) in the horizontal meridian and 44.5 ± 1.4 D (7.59 ± 0.24 mm) in the vertical meridian. There was a gender difference, with eyes in girls having significantly steeper corneas in both meridians. In the horizontal meridian, mean corneal radius in girls' eyes was 44.0 D compared with 43.5 D in boys' ($P < 0.001$), and in the vertical meridian mean corneal radius in girls' eyes was 44.8 D compared with 44.2 D in boys' ($P < 0.0001$).

The mean ratio of axial length to corneal radius was 3.12 ± 0.08 on the horizontal meridian and 3.18 ± 0.08 on the vertical. Ninety-five percent of the ratios on the horizontal meridian were higher than 3.0, a level that has been linked to increased risk of development of myopia.[21] Results of a multivariate analysis adjusting for age, gender, and ethnicity showed that younger children had significantly lower ratios than older ones ($P < 0.0001$) and that girls had lower ratios than boys (3.14 vs. 3.16, $P = 0.002$). The ratios did not vary by ethnicity after adjusting for the other covariates.

DISCUSSION

Baseline refractive and ocular component measures have been reported in 469 children enrolled in COMET, which represents a population of ethnically diverse children with moderate levels of myopia (mean spherical equivalent of −2.38 D by cycloplegic autorefraction and mean axial length of 24.1 mm in the right eyes). These results reflect the eligibility criteria for this clinical trial that sought to recruit children with myopia that would progress for at least 3 years of follow-up. These data will be used as baseline measures for later analyses of progression of myopia during the follow-up phase of COMET.

The amount of myopia measured by cycloplegic autorefraction in this group of 6- to 11-year-old children, who were selected to meet the specific refractive criteria shown in Table 1, is related to age, but not to gender or ethnicity. Because children were recruited to meet specific refractive criteria, COMET is not representative of the population of children with myopia in the United States. Therefore, the absence of a statistically significant difference among ethnic groups may be due to the relatively small differences in refraction among the groups or the limited power due to the modest sample size in the Asian and mixed groups.

The refraction values found in COMET show good agreement between the cycloplegic autorefraction and the distance prescription, which was based on the results of the subjective refraction. Cycloplegic autorefraction requires only brief fixation to a target, whereas the noncycloplegic subjective refraction is a relatively lengthy procedure that requires sustained attention from the child and interaction between the examiner and child. In the subjective refraction protocol, end points were determined by the child's ability to read more letters with added minus spheres, or to report differences in the perceived clarity of small dots observed through a series of cylindrical lenses. Because myopes are less sensitive to lens-induced blur than are nonmyopes,[22,23] spherical end points might be difficult to determine with subjective methods in children with myopia. Thus, the agreement between cycloplegic autorefraction and subjective refraction in these baseline measures is reassuring.

The difference between cycloplegic and noncycloplegic autorefraction is small—less than 0.25 D spherical equivalent in each eye. Our population was limited to children in whom myopia was confirmed by cycloplegic measures. Good agreement but larger differences have been reported between noncycloplegic and cycloplegic autorefraction in hyperopic children (0.77 ± 0.45 D more hyperopia using tropicamide and 0.91 ± 0.57 D using cyclopentolate).[24] Previous data in COMET children showed that residual accommodation to a target at 33 cm averaged less than 0.40 D, indicating that 1% tropicamide was an effective cycloplegia-inducing agent in this group of children with myopia.[16] Therefore, the cycloplegic value was not confounded by significant residual accommodation. Our data also show that, on average, these young children with myopia did not exhibit high levels of accommodation during noncycloplegic autorefraction and subjective refraction.

Ultrasound measures of axial length summarized in Table 3 show that the amount of axial elongation increased with age and that girls' eyes had shorter axial length than boys', despite their having similar amounts of myopia. Axial dimensions were similar in all ethnic groups. The COMET baseline ocular component measures are similar to those from a smaller, more homogeneous group of similarly aged Danish children with myopia.[6] Table 4 presents ocular component measures from these two groups of children with myopia as well as from two other large groups of same-aged children with primarily emmetropic refractive measures.[25–29] Both groups of children with myopia tended to have eyes with longer axial length compared with the eyes of emmetropes, with most of the increase in the vitreous chamber. The correlation between axial length and refractive error in COMET is lower than that reported by Jensen[6] ($r = 0.49$). In the Jensen study, the range of myopia (<1.0–6.0 D) was greater than in COMET, which could account, in part, for the difference in the correlation values. COMET children will be followed up for at least 3 years, allowing us to compare changes in axial components with the progression of juvenile myopia.

Although girls enrolled in COMET had a mean spherical equivalent refraction (−2.40 D) similar to COMET boys (−2.35

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D), their eyes had significantly shorter axial length ($P < 0.0001$), by 0.44 mm overall. Keratometry data showed that eyes in girls had significantly steeper corneas than in boys, which, in combination with shorter axial length, could account for the same amount of myopia. COMET data are similar to refraction and ocular component measures in a group of 383 Chinese children, with a mean spherical equivalent of −1.6 D in both genders, but with axial length in girls' eyes on average 0.42 mm shorter and with corneas steeper.[30]

Goss and Jackson[21] have suggested that a criterion of 3.0 for the ratio of axial length to corneal radius (based on the horizontal radius) in emmetropes may separate eyes that become myopic from those that remain emmetropic. It is clear from the baseline data that a ratio higher than 3.0 is associated with myopia, because the ratios of 95% of children enrolled in COMET fell into this category. At the end of the study, we will be able to relate changes in the ratio, if they occur, to the progression of myopia.

In summary, COMET has provided objective, reliable, standardized measures of myopia (autorefraction) and ocular components (A-scan ultrasound) taken after induction of cycloplegia. These baseline measures will be used to evaluate the progression of juvenile-onset myopia in this carefully observed, select group of children and to determine whether there is a difference in the progression of myopia in young children wearing PALs compared with SVLs.

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References

1. Wang Q, Klein B, Klein R, Moss S. Refractive status in the Beaver Dam Eye Study. *Invest Ophthalmol Vis Sci.* 1994;35:4344–4347.
2. Lin LL, Shih YF, Tsai CB, et al. Epidemiologic study of ocular refraction among schoolchildren in Taiwan. *Optom Vis Sci*. 1999; 76:275–281.
3. The Framingham Offspring Eye Study Group. Familial aggregation and prevalence of myopia in the Framingham Offspring Eye Study. *Arch Ophthalmol.* 1996;114:326–332.
4. National Advisory Eye Council. Vision research a national plan: 1994–1998. US Department of Health and Human Services: Bethesda, MD; 1994.
5. Javitt JC, Chiang YP. The socioeconomic aspects of laser refractive surgery. *Arch Ophthalmol.* 1994;112:1526–1530.
6. Jensen H. Myopia progression in young school children: a prospective study of myopia progression and the effect of a trial with bifocal lenses and beta blocker eye drops. *Acta Ophthalmol Suppl.* 1991;200:1–79.
7. Grosvenor T, Perrigin D, Maslovitz B. Houston myopia control study: a randomized clinical trial. Part II: final report by the patient care team. *Am J Opt Phys Opt.* 1987;64:482–498.
8. Goss D. Effect of spectacle correction on the progression of myopia in children: a literature review. *J Am Opt Assoc.* 1994;65:117–128.
9. Fulk G, Cyert L, Parker D. A randomized trial of the effect of single vision vs. bifocal lenses on myopia progression in children with esophoria. *Optom Vis Sci.* 2000;77:395–401.
10. Leung JT, Brown B. Progression of myopia in Hong Kong Chinese schoolchildren is slowed by wearing progressive lenses. *Optom Vis Sci.* 1999;76:346–354.
11. Bullimore M, Fusaro R, Adams A. The repeatability of automated and clinician refraction. *Optom Vis Sci.* 1998;75:617–622.
12. Norton TT. Animal models of myopia: learning how vision controls the size of the eye. *Inst Lab Anim Res.* 1999;40:59–77.
13. Wildsoet CF. Active emmetropization: evidence for its existence and ramifications for clinical practice. *Ophthalmic Physiol Opt.* 1997;17:279–290.
14. Hyman L, Gwiazda J, Marsh-Tootle W, Norton T, and the COMET Group. The Correction of Myopia Evaluation Trial (COMET): design and baseline characteristics. *Control Clin Trials.* 2001;22: 573–592.
15. Curtin BJ. *The Myopias: Basic Science and Clinical Management*. Philadelphia: Harper and Row; 1985.
16. Manny RE, Hussein ME, Scheiman M, et al. and the COMET Group. Tropicamide (1%): an effective cycloplegic agent for myopic children. *Invest Ophthalmol Vis Sci.* 2001;42:1728–1735.
17. Kurtz D, Manny R, Hussein M, and the COMET group. Reliability of ocular components measured by A-scan in children (Abstract). *Optom Vis Sci.* 2000;77:S286.
18. Thibos LN, Wheeler W, Horner D. Power vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. *Optom Vis Sci.* 1997;74:367–375.
19. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet.* 1986; 1(8476):307–310.
20. Draper N, Smith H. *Applied Regression Analysis.* 2nd ed. New York: Wiley Publications, 1981.
21. Goss DA, Jackson TW. Clinical findings before the onset of myopia in youth. I: ocular optical components. *Optom Vis Sci.* 1995;72: 870–878.
22. Gwiazda J, Thorn F, Bauer J, Held R. Myopic children show insufficient accommodative response to blur. *Invest Ophthalmol Vis Sci.* 1993;34:690–694.
23. Rosenfield M, Abraham-Cohen JA. Blur sensitivity in myopes. *Optom Vis Sci.* 1999;76:303–307.
24. Egashira SM, Kish LL, Twelker JD, Mutti DO, Zadnik K, Adams A. Comparison of cyclopentolate versus tropicamide cycloplegia in children. *Optom Vis Sci.* 1993;70:1019–1026.
25. Zadnik K, Satariano WA, Mutti DO, Sholtz RI, Adams AJ. The effect of parental history of myopia on children's eye size. *JAMA.* 1994; 271:1323–1327.
26. Larsen JS. The sagittal growth of the eye. I: ultrasonic measurement of the depth of the anterior chamber from birth to puberty. *Acta Ophthalmol* (*Copenh*). 1971;49:239–262.
27. Larsen JS. The sagittal growth of the eye. II: ultrasonic measurement of the axial diameter of the lens and the anterior chamber from birth to puberty. *Acta Ophthalmol* (*Copenh*). 1971;49:427–440.
28. Larsen JS. The sagittal growth of the eye. III: ultrasonic measurement of the posterior segment (axial length of the vitreous) from birth to puberty. *Acta Ophthalmol* (*Copenh*). 1971;49: 441–453.
29. Larsen JS. The sagittal growth of the eye. IV: ultrasonic measurement of the axial length of the eye from birth to puberty. *Acta Ophthalmol* (*Copenh*). 1971;49:873–886.
30. Lam C, Goh W. The incidence of refractive errors among school children in Hong Kong and its relationship with the optical components. *Clin Exp Optom.* 1991;74:97–103.

APPENDIX I

COMET Study Group

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COMMITTEES: *Data Safety and Monitoring*: Robert J. Hardy (Chair), Argye Hillis, Don Mutti, Richard Stone, and Sr. Carol Taylor.

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