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A Randomized Trial Evaluating Short-term Effectiveness of Overminus Lenses in Children 3 to 6 Years of Age with Intermittent Exotropia

*Pediatric Eye Disease Investigator Group**
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Purpose: To evaluate the short-term effectiveness of overminus spectacles in improving control of childhood intermittent exotropia (IXT).

Design: Randomized, clinical trial.

Participants: A total of 58 children aged 3 to <7 years with IXT. Eligibility criteria included a distance control score of 2 or worse (mean of 3 measures during a single examination) on a scale of 0 (exophoria) to 5 (constant exotropia) and spherical equivalent refractive error between −6.00 diopters (D) and +1.00 D.

Methods: Children were randomly assigned to overminus spectacles (−2.50 D over cycloplegic refraction) or observation (non-overminus spectacles if needed or no spectacles) for 8 weeks.

Main Outcome Measures: The primary outcome was distance control score for each child (mean of 3 measures during a single examination) assessed by a masked examiner at 8 weeks. Outcome testing was conducted with children wearing their study spectacles or plano spectacles for the children in the observation group who did not need spectacles. The primary analysis compared mean 8-week distance control score between treatment groups using an analysis of covariance model that adjusted for baseline distance control, baseline near control, prestudy spectacle wear, and prior IXT treatment. Treatment side effects were evaluated using questionnaires completed by parents.

Results: At 8 weeks, mean distance control was better in the 27 children treated with overminus spectacles than in the 31 children who were observed without treatment (2.0 vs. 2.8 points, adjusted difference = −0.75 points favoring the overminus group; 2-sided 95% confidence interval, −1.42 to −0.07 points). Side effects of headaches, eyestrain, avoidance of near activities, and blur appeared similar between treatment groups.

Conclusions: In a pilot randomized clinical trial, overminus spectacles improved distance control at 8 weeks in children aged 3 to <7 years with IXT. A larger and longer randomized trial is warranted to assess the effectiveness of overminus spectacles in treating IXT, particularly the effect on control after overminus treatment has been discontinued. *Ophthalmology 2016;■:1−10 © 2016 by the American Academy of Ophthalmology.*

*Supplemental material is available at www.aaojournal.org.

Intermittent exotropia (IXT), the most common form of childhood exotropia,[1−4] is characterized by normal ocular alignment some of the time and a manifest exotropia at other times. Although surgery is often considered for treatment, many cases of IXT are treated using nonsurgical interventions such as overminus lenses or occlusion.[5−8] Overminus lens therapy involves wearing full-time spectacles that have additional minus power over the cycloplegic refractive correction and is prescribed by some eye care providers to improve control and/or to reduce the angle of the exodeviation as a primary treatment or a temporizing treatment in young children before surgery or orthoptic therapy is considered.[9] One proposed mechanism for improvement with overminus lens therapy is that stimulation of accommodative convergence reduces the angle of exodeviation or triggers reflex convergence.[5,10] An alternative hypothesis is that fusional convergence is exerted to control the exodeviation, inducing convergence accommodation and distance blur, and that overminus lenses may allow clear distance vision, facilitating fusion.[11]

In some patients, overminus lenses alone appear to be successful in treating IXT, with eventual weaning of the overminus lenses to a point at which the IXT is well controlled in the regular refractive correction.[12,13] Nevertheless, previous studies of overminus lens therapy have been limited to retrospective case series without comparison

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groups and have varied in terms of methods used to determine the amount of overminus power, treatment duration, and outcome measures.[10,12–19] The objective of this pilot randomized trial was to evaluate the initial, short-term effectiveness of prescribing overminus lens therapy to improve control of IXT among children aged 3 to 6 years to determine whether a full-scale randomized clinical trial should be conducted to evaluate its long-term effectiveness, particularly after overminus treatment has been discontinued.

Methods

The study was supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health and was conducted by the Pediatric Eye Disease Investigator Group at 21 clinical sites according to the tenets of the Declaration of Helsinki. The protocol and Health Insurance Portability and Accountability Act–compliant informed consent forms were approved by institutional review boards, and a parent or guardian of each study participant gave written informed consent. An independent data and safety monitoring committee provided oversight. The study is listed on www.clinicaltrials.gov (NCT02223650, URL accessed February 9, 2016), and the full protocol is available at www.pedig.net (URL accessed February 9, 2016).

Eligibility Criteria

The study included children aged 3 to <7 years with spherical equivalent (SE) refractive error between −6.00 diopters (D) and +1.00 D inclusive and IXT meeting the following criteria: (1) intermittent or constant exotropia at distance (mean of 3 baseline assessments of distance control[18–20] ≥2 points) (Table 1); (2) IXT, exophoria, or orthophoria at near (at least 1 of 3 assessments of near control at the baseline visit ≤4 points); (3) distance exodeviation at least 15 prism diopters (Δ) measured by prism and alternate cover test (PACT); and (4) near deviation not exceeding the distance deviation by >10Δ by PACT (i.e., convergence insufficiency type IXT excluded). Prior nonsurgical treatment for IXT was not permitted within the 6 months preceding enrollment. Appropriate spectacle correction was required to be worn for at least 1 week before enrollment for children whose refractive error met certain prestudy criteria for correction (Table 2, criterion #11, available at www.aaojournal.org). Previous IXT treatment with spectacles overminused by ≥1.00 D SE was an exclusion criterion; however, low levels of uncorrected hyperopia (±1.0 D) were not considered overminus. Additional eligibility criteria are shown in Table 2 (available at www.aaojournal.org).

Enrollment Testing

At the enrollment visit, control of the exodeviation was measured at distance (6 m) and near (1/3 m) using the Office Control Score,[19,20] which ranges from 0 (phoria, best control) to 5 (constant exotropia, worst control) (Table 1). Because of the variability of single measures of control, we used the "triple control score,"[21,22] a mean of 3 measures obtained at specific time points during a 20- to 40-minute office examination.

After an initial control assessment, near stereoacuity was assessed using the Randot Preschool Stereoacuity test (Stereo Optical Co., Inc., Chicago, IL) at 40 cm, and magnitude of exodeviation was assessed at distance (6 m) and near (1/3 m) using the PACT. The control assessment was then performed a second time, followed by measurement of monocular distance visual acuity (VA) by a certified examiner using the Amblyopia Treatment Study HOTV[23,24] testing protocol and binocular near VA testing using the Amblyopia Treatment Study 4 test (Precision Vision, La Salle, IL). Finally, a third control assessment was performed. All 3 control assessments and the PACT were performed by the same study-certified examiner (a pediatric ophthalmologist, pediatric optometrist, or certified orthoptist).

In addition to the clinical testing, the participant's parent completed a 7-item (Tables 3a-b, available at www.aaojournal.org) written survey of symptoms and problems that might be associated with over-minus spectacle wear, such as headaches and eye strain based on their observations in the past 2 weeks. Survey items were derived on the basis of expert opinion of pediatric ophthalmologists and optometrists on the study planning committee. The response options were a 5-point Likert-type scale based on frequency of observations: never = score of 0, almost never = 1, sometimes = 2, often = 3, and always = 4.

Randomization

After data were entered on the Pediatric Eye Disease Investigator Group website and eligibility was verified, participants were randomly assigned (using a permuted block design stratified by mean distance control score [2–<3, 3–<4, 4–5 points]) with equal probability to overminus treatment or observation.

Treatment Regimens

Participants assigned to the overminus group were prescribed spectacles with −2.50 D added to the sphere power of the cycloplegic refraction. Overminus spectacles were prescribed for all waking hours for 8 weeks, and no other IXT treatments were allowed during this time.

Participants assigned to the observation group received no treatment other than non-overminus refractive correction, if needed according to postrandomization correction criteria, which were more rigorous than the prestudy correction criteria in requiring correction of smaller amounts of astigmatism (>0.50 D) and anisometropia (>0.50 D). Observation group participants who did not need refractive correction were prescribed plano lens spectacles that were to be worn for outcome testing at the 8-week visit but were not to be worn in the interim. The sole purpose of the plano lens spectacles was to maintain masking of examiners for outcome testing at the 8-week visit by ensuring that all participants in both treatment groups would be tested while wearing spectacles.

Follow-up Visit

Follow-up consisted of a single visit 8 weeks (±2 weeks) after randomization. Before the clinical testing, parents completed the 7-item survey that asked about symptoms experienced by their child since the start of the study. An unmasked examiner assessed compliance with overminus spectacle wear. Compliance was judged to be excellent (glasses worn >75% of waking hours), good (51%–75%), fair (26%–50%), or poor (≤25%) on the basis of discussions with the parent. Afterward, clinical testing was performed in the same order as at enrollment with all participants

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