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Nonamblyopic eye visual acuity through Bangerter filters

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Abstract

Purpose—To describe the amount of visual acuity degradation induced by Bangerter filters in the better-seeing eye and to evaluate its stability over time in children with moderate amblyopia.

Methods—Visual acuity with and without a Bangerter filter was measured in the nonamblyopic eye of 186 children with moderate amblyopia who were then treated with either patching or with the Bangerter filters. A 0.2 filter was used for amblyopia of 20/80 and a 0.3 filter for amblyopia from 20/40 to 20/63. For the 89 children randomized to Bangerter filters, visual acuity was also measured in the nonamblyopic eye with and without the filters at both 6 weeks and 12 weeks after initiating treatment.

Results—Mean degradation in visual acuity of the nonamblyopic eye at baseline was 5.1 logMAR lines with the 0.2 filter and 4.8 logMAR lines with the 0.3 filter. The degradation with each filter did not always agree with the manufacturer's specifications. Over time, the amount of degradation with the filters decreased.

Conclusions—The 0.2 and 0.3 Bangerter filters degrade nonamblyopic eye visual acuity sufficiently in amblyopic children. Because the amount of degradation decreases over time, it is recommended to periodically apply a new filter when using this type of amblyopia treatment.

Bangerter filters (Ryser Optik AG, St. Gallen, Switzerland) are graded translucent filters used to treat amblyopia in children^{1–3} and intractable diplopia in adults.^{4,5} The filters vary in density and are intended to induce progressive degradation in distance optotype visual acuity and other modalities of visual functions, including near optotype acuity,^{6,7} vernier acuity,^{6,7} stereopsis,⁷ and contrast sensitivity.^{6–8} The filter label indicates the decimal acuity

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^{*}The members of the Pediatric Eye Disease Investigator Group (PEDIG) are listed in e-Supplement 1, available online at jaapos.org. **Publisher's Disclaimer:** This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

predicted by the manufacturer when the filter is placed in front of an eye with normal acuity. A 0.2 filter is predicted to degrade visual acuity to 20/100 and a 0.3 filter to 20/70. The acuity degradation in visually normal adults has been found to be inconsistent when compared with the manufacturer's specifications^{6,8}; however, evaluation of the degree of acuity degradation has not been reported in amblyopic children. Because the nonamblyopic eye is not necessarily "normal,"^{9,10} Bangerter filters may have a different effect on the visual acuity of the better-seeing eye in children with amblyopia. This report describes distance optotype visual acuity degradation in the nonamblyopic eye induced by 0.2 and 0.3 filters and evaluates whether degradation remains stable over time with the filter.

Methods

The Pediatric Eye Disease Investigator Group (PEDIG) completed a randomized trial comparing Bangerter filters to patching for moderate amblyopia in children 3 to <10 years old.¹ The study was supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health. The protocol and Health Insurance Portability and Accountability Act (HIPAA) compliant informed consent forms were approved by institutional review boards, a parent or guardian of each study subject gave written informed consent, and the subjects gave assent as required. The study adhered to the tenets of the Declaration of Helsinki and is listed on www.clinicaltrials.gov, under identifier NCT00525174. The full protocol is available on the PEDIG Web site (www.pedig.net) and is summarized below.

Between November 2007 and July 2008, 186 amblyopic subjects wearing spectacles were enrolled into a randomized trial of Bangerter filters versus patching. The average age was 6.3 years. Of these 186 subjects, 45% were female and 73% were Caucasian. Of 89 subjects randomized to Bangerter filters, 16 (18%) had amblyopic eye acuity of 20/80 and were assigned a 0.2 filter density, and 73 (82%) had amblyopic eye acuity of 20/40 to 20/63 and were assigned a 0.3 filter density. Additional baseline characteristics have been published.¹

At baseline, visual acuity was measured in each eye without cycloplegia using optimal spectacle correction, by a study-certified examiner using either the Amblyopia Treatment Study single-surround HOTV protocol (ATS-HOTV) for subjects aged 3 to <7 years or the Electronic Early Treatment Diabetic Retinopathy Study (E-ETDRS) protocol for subjects aged 7 to <10 years.^{11,12} Visual acuity was tested in the nonamblyopic eye of all subjects, including those randomized to patching, with and without the Bangerter filter. Subjects with 20/80 visual acuity were tested using a 0.2 filter density and those with 20/40 to 20/63 visual acuity were tested using a 0.3 filter density.

The same visual acuity testing protocols used at baseline were used in the Bangerter group for follow-up visits at 6 and 12 weeks (\pm 2 weeks). New filters were applied at each visit after completing visual acuity testing.

Statistical Analysis

For this report, the outcome for analysis was degradation in the nonamblyopic eye, calculated as the logMAR line difference in visual acuity with and without the filter, with a positive result indicating the visual acuity was degraded. Visual acuity with and without the filter was measured in all subjects at baseline and only in subjects treated with Bangerter filters at the 6- and 12-week visits. The amount of degradation at baseline produced by the 0.2 filter was compared with the 0.3 filter in an analysis of covariance using data from all subjects and adjusted for age and nonamblyopic eye visual acuity (without the filter) as potential confounders.

Difference in amount of degradation between baseline and follow-up visits for both filter densities in the Bangerter group only were estimated using a longitudinal analysis of covariance model with generalized estimating equations to account for correlation in repeated measures over time in the same subjects with adjustments for nonamblyopic eye visual acuity at the current visit (time-dependent covariate) and filter density as potential confounders. Linear contrasts were used to compare amount of degradation at the baseline to the average of the 6 and 12 week follow-up visits and the 6 week to the 12 week visits. Descriptive statistics were used to report nonamblyopic eye visual acuity in the Bangerter group over follow-up.

Analyses were conducted using SAS Version 9.1 (SAS Institute, Cary, NC).

Results

Table 1 shows the distribution of visual acuity degradation by the 0.2 and 0.3 filters. At baseline, among all 186 subjects, visual acuity was 3 or more lines worse in 34 of 39 subjects (87%) assigned the 0.2 filter and in 129 of 147 (88%) subjects assigned the 0.3 filter. No subjects in the 0.2 filter group and 3 subjects (2%) in the 0.3 filter group had 1 or less lines of degradation. The baseline distribution of nonamblyopic eye visual acuity differed in the two groups (median visual acuity in 0.2 filter group = 20/25, in 0.3 group = 20/20; Wilcoxon rank-sum test p < 0.001) and differed by age (correlation coefficient = -0.38; p < 0.001; mean nonamblyopic eye visual acuity was 0.11 logMAR in the 3- to 4-year-olds, 0.02 logMAR in the 5- to 6-year-olds, and 0.00 logMAR in the 7- to 9-year-olds). Further analyses were adjusted for age and baseline acuity without the filter. When adjusted for age and baseline acuity, the mean degradation induced by the 0.2 filter was 5.1 lines and by the 0.3 filter was 4.8 lines (adjusted p = 0.38).

For a given filter density and after adjusting for visual acuity without the filter in place, the mean amount of degradation for subjects in the Bangerter group (Table 1) using the assigned filter was 4.6 lines at baseline, 3.9 lines at the 6-week follow-up visit, and 3.6 lines at the 12-week follow-up visit (p < 0.001 comparing degradation at baseline vs the degradation average at 6 and 12 weeks combined). There were no meaningful differences comparing the amount of degradation at 6 weeks with that at 12 weeks (Table 1). There was also no suggestion of a meaningful change in visual acuity of the nonamblyopic eye without the filter from baseline to the 6-week and 12-week visits (Table 2).

Discussion

Freshly applied 0.2 and 0.3 Bangerter filters substantially degrade distance optotype visual acuity in the nonamblyopic eyes of children aged 3 to <10 years, with 88% of children experiencing 3 or more lines of degradation and the average degradation being approximately 5 lines. Similar to adults with normal vision,^{6–8} the filters did not always degrade visual acuity of the nonamblyopic eye to the manufacturer's specifications, nor did they degrade visual acuity to a predictable level. According to the manufacturer, the 0.3 filter should degrade visual acuity to 20/70 and the 0.2 filter to 20/100. At enrollment with the 0.3 filter, 66% of the subjects had acuity 20/70 or poorer while only 26% of the subjects had 20/100 or poorer with the 0.2 filter.

The study's protocol may account for the similar amount of degradation observed with each filter. Subjects were not randomized to either a 0.2 or 0.3 filter but were assigned the filter density based on the visual acuity of their amblyopic eye. Also, a 3-line interocular difference in visual acuity was required for eligibility. This combination may account for the

observed difference in the baseline distribution of nonamblyopic eye visual acuity in the two groups.

The amount of degradation with each filter declined after being worn for 6 weeks following enrollment. During this time, the visual acuity of the nonamblyopic eye did not change when tested without the Bangerter filter in place. At enrollment, visual acuity was measured with a fresh filter immediately whereas at follow-up visits acuity was measured with the same filter that had been worn for 6 weeks, possibly allowing for filter deterioration. We speculate that this difference may be because the material changes over time or there may be adaptation to the blur from the filter. If there is an adaptation to the blur, it appears to occur early since there was no meaningful difference in degradation from 6 to 12 weeks. Also, it has been suggested that filter density may not be uniform across the entire surface of the filter.⁶ Magnified inspection of Bangerter filters reveals that they consist of a characteristic pattern of microbubbles; the number of microbubbles in each filter being related to the degree of visual degradation.⁸ Subjects may learn to view through a clearer portion of the filter allowing for better visual acuity.⁶

As reported previously, although Bangerter filters do not always degrade visual acuity consistently to the manufacturer's specified levels, the 0.2 and 0.3 filters degrade nonamblyopic eye visual acuity sufficiently to treat amblyopia successfully.¹ Because the amount of degradation appears to decrease after the filter has been in place for some weeks, possibly due to filter degradation, it is recommended to periodically apply a fresh filter.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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SD, standard deviation; VA, visual acuity

 $^{d}\mathrm{Adjusted}$ for baseline visual acuity without the filter and age group

 $b_{\rm Less}$ than 1 logMAR line better to less than 1 line worse

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Table 1

Distribution of visual acuity degradation by Bangerter filter density

				Bangerter fi	llter density			
		0.2				0.3		
		Baseline	6 weeks	12 weeks		Baseline	6 weeks	12 weeks
	Overall	Bangerter group only			Overall	Bangerter group only		
	n = 39	n = 16	n = 15	n = 15	$\mathbf{n} = 147$	n = 73	n = 70	n = 66
	n (%)	n (%)	(%) u	u (%)	n (%)	n (%)	n (%)	(%) u
ines of degradation with filter								
21 lines better	0	0	0	0	1 (1%)	1 (1%)	0	1 (2%)
Voneb	0	0	1 (7%)	1 (7%)	0	0	3 (4%)	2 (3%)
to <2 lines worse	0	0	3 (20%)	1 (7%)	5 (3%)	5 (7%)	5 (7%)	4 (6%)
to <3 lines worse	5 (13%)	3 (19%)	3 (20%)	3 (20%)	12 (8%)	9 (12%)	6 (9%)	10 (15%)
to <4 lines worse	6 (15%)	4 (25%)	3 (20%)	2 (13%)	15 (10%)	6 (8%)	8 (11%)	12 (18%)
to <5 lines worse	6 (15%)	0	1 (7%)	4 (27%)	17 (12%)	8 (11%)	21 (30%)	21 (32%)
to <6 lines worse	8 (21%)	4 (25%)	4 (27%)	3 (20%)	45 (31%)	18 (25%)	13 (19%)	12 (18%)
26 lines worse	14 (36%)	5 (31%)	0	1 (7%)	52 (35%)	26 (36%)	14 (20%)	4 (6%)
dean (SD) lines worse ^d	5.1 (1.7)	4.9 (2.0)	3.7 (1.7)	4.0 (1.5)	4.8 (1.7)	4.6 (1.9)	4.1 (1.8)	3.6 (1.5)
Mean (SD) logMAR VA with filter ^a	0.55 (0.19)	0.52 (0.20)	0.41 (0.19)	0.44 (0.15)	0.52 (0.12)	0.50 (0.17)	0.45 (0.17)	0.40 (0.16)
Mean Snellen Equivalent ^a	20/71	20/66	20/51	20/55	20/66	20/63	20/56	20/50

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Table 2

Distribution of visual acuity without filter by Bangerter filter density (including only subjects assigned the Bangerter filter)

$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$				Bangerter fi	ilter density		
			0.2			0.3	
n =16 n =15 n =15 n =15 n =73 n =70 n (%) Nonamblyopic eye visual acuity $n (\%)$ n (%) n (%) n (%) n (%) n (%) Nonamblyopic eye visual acuity $20/16$ $2 (13\%)$ 0 $2 (13\%)$ $16 (22\%)$ $19 (27\%)$ $27 (39\%)$ $20/20$ $4 (25\%)$ $7 (47\%)$ $3 (20\%)$ $36 (49\%)$ $27 (39\%)$ $27 (39\%)$ $20/25$ $4 (25\%)$ $7 (47\%)$ $3 (20\%)$ $36 (49\%)$ $27 (39\%)$ $27 (39\%)$ $20/25$ $4 (25\%)$ $7 (47\%)$ $3 (20\%)$ $36 (49\%)$ $27 (39\%)$ $27 (39\%)$ $20/25$ $3 (19\%)$ $2 (13\%)$ $2 (13\%)$ $6 (\%)$ $17 (24\%)$ $20 (30\%)$ $6 (9\%)$ $6 (9\%)$ $6 (9\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ $20 (39\%)$ <td< th=""><th></th><th>Baseline</th><th>6 weeks</th><th>12 weeks</th><th>Baseline</th><th>6 weeks</th><th>12 weeks</th></td<>		Baseline	6 weeks	12 weeks	Baseline	6 weeks	12 weeks
n (%) n (%) <		n =16	n =15	n =15	n =73	n =70	n = 66
Nonamblyopic eye visual acuity 0 2 (13%) 0 2 (13%) 16 (22%) 19 (27%) 20/16 2 (13%) 7 (47%) 3 (20%) 36 (49%) 27 (39%) 20/20 4 (25%) 7 (47%) 3 (20%) 36 (49%) 27 (39%) 20/25 4 (25%) 3 (20%) 5 (33%) 15 (21%) 17 (24%) 20/32 3 (19%) 2 (13%) 5 (33%) 6 (8%) 6 (9%) 20/32 3 (19%) 2 (13%) 2 (13%) 6 (8%) 6 (9%) 20/40 3 (19%) 1 (7%) 2 (13%) 0 0 0 20/50 0 2 (13%) 0 0 0 0 0 Mean (SD) logMAR VA 0.11 (0.14) 0.13 (0.15) 0.12 (0.16) 0.02 (0.09) 0 0		u (%)	(%) U	u (%)	(%) u	u (%)	(%) u
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$	Nonamblyopic eye visual acuity						
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$	20/16	2 (13%)	0	2 (13%)	16 (22%)	19 (27%)	20 (30%)
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$	20/20	4 (25%)	7 (47%)	3 (20%)	36 (49%)	27 (39%)	24 (36%)
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	20/25	4 (25%)	3 (20%)	5 (33%)	15 (21%)	17 (24%)	11 (17%)
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	20/32	3 (19%)	2 (13%)	2 (13%)	6 (8%)	6 (9%)	9 (14%)
20/50 0 2 (13%) 0 <th< td=""><td>20/40</td><td>3 (19%)</td><td>1 (7%)</td><td>2 (13%)</td><td>0</td><td>1 (1%)</td><td>2 (3%)</td></th<>	20/40	3 (19%)	1 (7%)	2 (13%)	0	1 (1%)	2 (3%)
20/63 0 0 1 (7%) 0 0 0 0 Mean (SD) logMAR VA 0.11 (0.14) 0.13 (0.15) 0.12 (0.16) 0.02 (0.09) 0.02 (0.09) 0 Mean Snellen equivalent 20/26 20/27 20/26 20/21 20/21 20/21	20/50	0	2 (13%)	0	0	0	0
Mean (SD) logMAR VA 0.11 (0.14) 0.13 (0.15) 0.12 (0.16) 0.02 (0.09) 0.02 (0.09) C Mean Snellen equivalent 20/26 20/27 20/26 20/21 20/21 20/21	20/63	0	0	1 (7%)	0	0	0
Mean Snellen equivalent 20/26 20/27 20/26 20/21 20/21	Mean (SD) logMAR VA	0.11 (0.14)	0.13 (0.15)	0.12 (0.16)	0.02 (0.09)	0.02 (0.09)	0.02 (0.11)
	Mean Snellen equivalent	20/26	20/27	20/26	20/21	20/21	20/21

SD, standard deviation; VA, visual acuity