Lack of positive results of a physiologically based treatment of amblyopia

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SUMMARY Recent reports have described marked improvement of visual acuity in amblyopic eyes of young children following monocular exposure to square-wave gratings presented at a variety of spatial frequencies and orientations for as little as 7 minutes. We sought to confirm and expand on these investigations, with emphasis on single-session results. Sixteen juvenile and 11 adult amblyopes and 26 control subjects were used. Visual acuity was determined before and after a 7-minute stimulation period using an E-chart that controlled for contour interaction. The 50% visual acuity threshold corrected for guessing was computer calculated by probit analysis. Results show that frequency, range, and magnitude of changes (either increases or decreases) in visual acuity following stimulation were approximately the same ($< \pm 10\%$ Snell-Sterling) in both amblyopic and control groups. These findings suggest that brief exposure to the grating patterns had little if any beneficial effect on visual acuity in amblyopic eyes.

The normal visual environment consists of objects of various orientations, contrast levels, and spatial frequencies. The cytoarchitecture and neuronal circuitry of the visual cortex, at least in cats and monkeys, are designed to analyse such sensory information,¹⁻⁵ and similar mechanisms are believed to underlie human form vision.⁶⁻⁹

Amblyopia, affecting approximately 2% of the general school age population,¹⁰ is a condition in which visual acuity is reduced in the absence of ocular or neurological disease, structural abnormalities of the eye or visual pathways, and uncorrected refractive error. If, as is commonly believed, amblyopia is a disorder primarily affecting the visual cortex, then perhaps pools of cortical neurons could be activated (or 'reactivated' or 'exercised') by receiving optimal visual stimulation, and this in turn might result in improved vision function in the amblyopic eye. Treatment for amblyopia using such a rationale, that is, gratings of a wide variety of spatial frequencies and orientations, has recently been proposed,¹¹ and preliminary positive results with only very brief periods of monocular treatment have been reported in young amblyopes.¹¹⁻¹⁵

We sought to confirm and expand upon these

initial grating treatment results using a carefully controlled method of obtaining visual acuity, as most of those authors' patients showed marked improvement of visual acuity in the amblyopic eye after only one 7-minute session. Furthermore, we performed several critical control experiments to help in interpretation of our results in juvenile and adult functional amblyopes.

Materials and methods

A device similar to the CAM vision stimulator¹¹⁻¹⁵ was used to stimulate the patient's amblyopic (or nondominant) eye. Square-wave gratings (on Kodalith paper) having a spatial frequency of either 0.5, 1.0, 2.0, 4.0, 8.0, 16.0, or 32.0, (and frequently 64.0) cycles per degree (equivalent to visual acuity levels of approximately 20/1200 to 20/10) were viewed for 1 minute each (some patients reported seeing a uniform, grey field when the higher spatial frequency gratings were used). Grating contrast was high (about 90%) in order to minimise effects of reduced contrast sensitivity¹⁶⁻¹⁹ and abnormally rapid visual adaptation²⁰⁻²³ believed to be present in some amblyopic eyes. The circular field subtended 8 degrees at the eye and slowly turned at a rate of 1 revolution per minute; this, all orientations, and a wide range of grating spatial frequencies were available to stimulate the amblyopic eye. Further,

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a field of this size allows for stimulation of the central retina (including the fovea and eccentric fixation locus) in the presence of increased amblyopic drift,²⁴ strabismus-induced saccadic intrusions,²³ and small (<2 degrees) magnitudes of eccentric fixation.

The gratings were placed perpendicular to the estimated visual axis of the patient's viewing eye, and fixation distance of 57 cm was maintained throughout the 7-minute session. The patient was instructed to fixate accurately the centre of the grating and to try to keep the stripes as clear as possible. The experimenters constantly monitored the patient's eye position by gross visual observation and continually asked the patient questions about the grating, such as orientation and changes in clarity and contrast, in order to maintain a high level of attention to the task and as accurate as possible focus on the stripes. This was especially critical in young children, where games were also invented as needed to keep the patient's attention on the grating. A Plexiglass cover over the stimulating field, as used by others,¹¹⁻¹⁵ on which their young amblyopes drew pictures and played games during stimulation periods, was purposely not incorporated into our apparatus, as it was our belief that the patient's hand, arm, and crayon would frequently obscure part of the small stimulating field. Moreover, it is difficult to keep a small child at a relatively long, fixed distance (in order to know precisely the effective spatial frequency of the stimulating field) while drawing, as children typically move close (with distance depending upon such factors as arm length, visual acuity, and attention) to the material of interest. Each patient received the grating stimulation individually.

Visual acuity, with refractive error corrected and the nontested eye fully patched, was first measured in the dominant eye of most patients and then in the amblyopic eye before and after a single 7-minute session. Visual acuity was assessed by having the patient either specify verbally or indicate with a large hand-held E the orientation of the 8 Es on each test card (75 ft-candles (800 lux) illumination) located 10 ft (3 m) away²⁵ (Fig. 1). With this test target configuration, contour interaction effects were maintained constant,²⁶⁻²⁸ thus reducing variability of visual acuity measures in amblyopic eyes, as may be particularly prominent when conventional Snellen whole-chart or whole-line acuity is measured.²⁹ Test letter sizes ranged from 20/277 to 20/9, but not all test letter sizes were required to obtain an acuity measure; test time per trial was 10-20 minutes. Percentage correct at each letter size, from the largest letter size to the smallest, was plotted to obtain an initial estimate of results (Fig.

Fig. 1 E chart used for measuring visual acuity with control for contour interaction.

2). Then visual acuity, both Snellen and Snell-Sterling,³⁰ was determined by probit analysis³¹ via a minicomputer.

Juvenile and adult amblyopes, as well as several controls, were used in our study (see Table 1). The first control group consisted of normal adults receiving no stimulation between 2 consecutive determinations of visual acuity separated by 7 minutes. Results here provided information on normal variability of acuity measures in adults by our method without influence of grating stimulation and concentrated fixation. The second control group consisted of normal adults receiving grating stimulation between 2 consecutive determinations of visual acuity separated by 7 minutes. Results here provided information on influence of grating stimulation, if any, in eyes of normal adults. A third control group consisted of normal children receiving no grating stimulation between 2 consecutive determinations of visual acuity separated by 7 minutes. Results here provided information on normal variability of acuity measures in children by our method without influence of grating stimulation and concentrated fixation. The fourth control group consisted of normal children receiving grating stimulation between 2 consecutive determinations of visual acuity separated by 7 minutes. Results here provided information on influence of grating stimulation, if any, in eyes of normal children. A fifth control group consisted of nonamblyopic children with a diagnosis of learning disability and associated hyperactivity receiving grating stimula-

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Table 1 Clinical and experimental data on patients

Patient	Age	Strabismus	VA _B	VA _A	ΔVA (% S-S)	Patient	Age	Strabismus	VA _B	VA _A	ΔVA (% S-S)
<i>Amblyopic children: grating stimulation</i>						33	22	XT	20/95.6	20/76.0	-9.5
1	6	ET	20/181.4	20/163.2	-4.2	34	24	ET	20/95.8	20/110.1	+6.1
2	6	ET	20/162.9	20/162.6	-0.1	35	28	NO	20/51.2	20/54.9	+2.5
3	8	NO	20/132.8	20/136.3	+1.1	36	23	ET	20/45.1	20/43.3	-1.2
4	9	ET	20/99.5	20/97.2	-1.0	37	21	NO	20/43.2	20/34.4	-7.5
5	13	ET	20/76.4	20/72.3	-2.3	38 ^d	34	NO	20/26.7	20/31.0	+5.5
6	7	ET	20/53.2	20/55.7	+1.7				20/26.5	20/28.3	+1.6
7	8	ET	20/50.6	20/48.8	-1.3	39 ^d	27	NO	20/175.6	20/168.5	-1.6
8	8	ET	20/45.7	20/38.2	-5.5				20/162.5	20/159.0	-0.9
9	7	ET	20/38.3	20/50.6	+8.9				20/180.6	20/171.8	-1.9
10	10	ET	20/28.4	20/24.8	-3.1				20/158.5	20/163.6	+1.3
11	7	ET	20/23.2	20/24.2	+0.9	40 ^e	39	ET	20/30.4	20/30.6	+0.1
12 ^a	9	ET	20/65.7	20/67.0	+0.8				20/31.0	20/28.1	-2.4
			20/63.9	20/65.0	+0.7				20/34.3	20/29.6	-3.8
			20/61.1	20/66.5	+3.3				20/23.6	20/22.9	-0.6
13 ^a	15	NO	20/48.3	20/45.9	-1.7				20/24.6	20/27.6	+2.5
			20/40.7	20/35.0	-4.4				20/27.3	20/27.9	+0.5
			20/28.5	20/26.0	-2.1	41 ^f	34	ET	20/61.3	20/46.3	-9.9
			20/12.4	20/14.8	+2.3				20/50.2	20/49.7	-0.4
14 ^b	12	NO	20/26.8	20/24.6	-1.8				20/46.5	20/39.0	-5.6
15 ^b	10	ET	20/23.9	20/18.7	-4.6				20/42.8	20/39.2	-2.7
16 ^b	13	ET	20/22.8	20/21.2	-1.5				—	20/33.3 ^g	—
<i>Amblyopic children: grey field stimulation</i>						<i>Amblyopic adults: no stimulation</i>					
17	9	ET	20/30.2	20/28.7	-1.3	42 ^h	27	NO	20/169.2	20/160.3	-2.2
18	8	XT	20/113.2	20/122.9	+3.6				20/181.7	20/167.8	-3.1
<i>Normal children: grating stimulation</i>						43 ^h	22	XT	20/74.8	20/71.6	-2.0
19	11	NO	20/14.9	20/18.7	+3.5				20/68.1	20/66.0	-1.2
20	12	NO	20/16.5	20/14.6	-1.2	<i>Normal adults: grating stimulation</i>					
21	9	NO	20/24.5	20/23.2	-1.1	44	25	NO	20/14.6	20/12.2	-2.3
22 ^c	10	NO	20/37.8	20/32.5	-4.1	45	31	NO	20/6.4	20/12.8	+6.3
23 ^c	8	NO	20/117.3	20/139.7	+7.6	<i>Normal adults: no stimulation</i>					
<i>Normal children: no stimulation</i>						46	23	NO	20/21.5	20/11.1	-9.7
24	5	NO	20/15.9	20/18.2	+2.1	47	26	NO	20/6.1	20/10.2	+4.0
25	6	NO	20/23.4	20/20.8	-2.3	<i>Organic amblyopic adults: grating stimulation</i>					
<i>Children with learning disability: grating stimulation</i>						48	19	NO	20/113.7	20/114.8	+0.4
26	9	NO	20/15.2	20/15.3	+0.2	(nystagmus)					
27	9	NO	20/16.0	20/10.7	-5.1	49	45	NO	20/98.7	20/104.0	+2.6
28	13	NO	20/17.6	20/17.5	-0.1	(histoplasmosis)					
29	8	NO	20/18.5	20/19.5	+0.9	50	60	NO	20/77.5	20/63.4	-8.0
30	8	NO	20/18.7	20/13.3	-5.0	(optic atrophy)					
<i>Amblyopic adults: grating stimulation</i>						51	69	NO	20/35.3	20/31.7	-2.9
31	46	NO	20/170.2	20/163.2	-1.8	(diabetes)					
32	25	ET	20/110.4	20/138.2	+9.8	52	67	NO	20/30.5	20/34.2	+3.0
						(cataract)					
						53 ⁱ	16	XT	20/70.0	20/67.5	-1.4
						(ptosis)					

a = Tested during orthoptics therapy; sessions separated by 2 weeks. b = Former amblyopes that had previously received orthoptics therapy; nearly normal visual acuity present. c = Uncorrected refractive error. d = Tested on consecutive weekly sessions. e = Tested on 6 consecutive daily sessions. f = Tested on 5 consecutive weekly sessions. g = Visual acuity following a weekend of stimulation 5 times per day. h = Tested on 2 consecutive sessions within a 1 hour period. i = Probable stimulus deprivation component to amblyopia resulting from severe congenital ptosis operated on at ages 5 and 12.

ET = Esotropia. XT = Exotropia. NO = None.

Fig. 2 Plot of letter size versus number of correct responses. Symbols: ● = Amblyopic eye before grating stimulation, △ = Amblyopic eye after grating stimulation. □ = Nonstimulated dominant eye. Computer-calculated 50% visual acuity threshold, corrected for guessing, in the amblyopic eye is 20/65.7 before stimulation and 20/67.0 after stimulation; it is 20/31.8 in the dominant eye. Note sharp fall-off of responses in dominant eye in contrast to gradual fall-off in nondominant (more amblyopic) eye as letter size decreases.

tion between 2 consecutive determinations of visual acuity separated by 7 minutes. Results here provided information on variability of acuity measures in children, in whom variability of measures in this selected group might be expected to be unusually high, by our method. The sixth control group consisted of amblyopic children receiving grey-field stimulation in place of the gratings between 2 consecutive determinations of visual acuity separated by 7 minutes. Results here separated effects of concentrated fixation from effects of grating stimulation. A seventh control group consisted of amblyopic adults receiving no stimulation between 2 consecutive determinations of visual acuity separated by 7 minutes. Results here provided information on normal variability of acuity measures in amblyopic adults without influence of grating stimulation and concentrated fixation. The last control group consisted of adults with reduced visual acuity resulting from ocular disease, who received grating stimulation between 2 consecutive determinations of visual acuity separated by 7 minutes. Results here provided information that would allow comparison between effects of grating stimulation and concentrated fixation on variability of acuity measures in functional and organic amblyopes.

Patients were recruited from the refraction and orthoptics clinics. All received a thorough examination of vision, including determination of refractive error (noncycloplegic), binocular status, and ocular health. No patients in the experimental groups had ocular or neurological disease or nystagmus. There were approximately an equal number of amblyopes whose condition could be attributed primarily to either strabismus or anisometropia. Most patients had esotropia. No patients had eccentric fixation greater than 3 prism dioptres as determined by visuoscopy. Most (about 70%) patients had astig-

matism, of 0.75 dioptre or greater, generally of either the mixed or compound myopic variety.

Results

Results are presented in Table 1. In general the use of the gratings had little if any effect on improving distance visual acuity in amblyopic eyes. Changes of visual acuity (either increases or decreases) with respect to magnitude, direction, and frequency were approximately the same in the amblyopic and control groups ($< \pm 10\%$ Snell-Sterling). In fact it is doubtful whether most of the computed visual acuity changes following brief grating stimulation could have been detected by conventional clinical procedures, that is, without use of a computer and with the use of whole-chart or whole-line Snellen measures, as they were generally so slight.

Discussion

We were unable to confirm the positive findings of Campbell and colleagues.¹¹⁻¹⁵ We believe that at least 3 factors are responsible for differences in results. The first and perhaps most important factor is method of measuring visual acuity. Campbell and colleagues employed Snellen, linear Sheridan Gardiner, and single Sheridan optotypes, and thus were not consistent in the use of a single procedure to obtain visual acuity in all patients. Further, with their method they did not control for contour interaction effects,²⁶⁻²⁸ a critical factor for accurate and repeatable determination of visual acuity in amblyopic eyes. We were consistent in our method²⁶ of determining visual acuity, which controlled for contour interaction by maintaining interletter separation with a fixed proportion of letter size.

The second factor is the use of controls. Although

Campbell and colleagues suggested that control studies should be conducted before widespread use of this technique is adopted,¹¹ and further stated that grey-field stimulation produced only slight improvement of visual acuity in some amblyopic patients,¹⁴ they did not provide quantitative findings for their controls. We provided quantitative findings in our controls and found that changes of visual acuity in controls were similar to those for our 'treated' amblyopic group, suggesting lack of a positive effect of the gratings on improving visual acuity in the amblyopic eyes of our patients. Changes of visual acuity noted in our control groups ($< \pm 10\%$ Snell-Sterling) could be attributed to normal variability of visual acuity. Further, small improvements of acuity could be attributed in part to practice effects, well known to vision care practitioners and reported in the literature.³²⁻³⁵ We believe that similar arguments apply to our experimental group. If we had obtained positive results in our amblyopes, an increased number of experimental and control subjects and additional control groups would have been essential on our part to factor out effects of short-term fixation training, short-term occlusion effects, practice effects, and/or normal variability of visual acuity from effects directly related to grating stimulation alone. While our sample size was not large, we believe that careful measures on a group of this size are preferable to testing a large group in the absence of appropriate controls and measurement techniques. Further, the consistent results we obtained do not demand that sample size be increased to provide a convincing argument.

The third factor is a history of previous occlusion therapy. In Campbell and colleagues' group 75% of the subjects had past history of partially successful occlusion therapy, while in our group only 33% did. One could speculate that patients having had some previous success with occlusion therapy might respond more favourably and rapidly to short-term occlusion during which motor activity is encouraged than those never having had such occlusion experience. Further, that favourable results in young amblyopes may follow brief periods of daily occlusion has been reported.³⁶ However, none of our amblyopes with history of occlusion therapy had significant gains in acuity after stimulation, though gains were the rule.

Other aspects related to the experimental methods deserve comment. We had patients view gratings without the addition of eye-hand sensory-motor feedback, as this was the procedure originally described.¹² This 'passive' procedure allows one to test those authors' original hypothesis on 'exercising' or 'activating' cortical neurons by viewing gratings

at a variety of spatial frequencies and all orientations in the purest form, that is, free from other factors such as eye-hand interactions, presence of hand and crayon in the visual field blocking the grating stimulus, presence of printed letters and game form in the field providing additional stimulus patterns, and the tendency of young children to move close to the grating during active visual tasks and thus change fixation distance and effective stimulus spatial frequency, since the 'game' surface was on top of the grating stimulus. All these became additional factors that one must consider potentially important during the stimulating period and which make results difficult to interpret when adequate controls are not provided. Further, we had individuals view the gratings at a carefully monitored and fixed distance perpendicular to the stimulating surface; in contrast, they had 2 patients playing games while viewing the grating, at least some of the time, at an oblique angle, thereby changing its effective size, shape, and spatial frequency.

Our negative results do not stand alone. Recent papers have reported similar results.^{37,38} With few exceptions an informal survey conducted by the first author of several clinical researchers testing the grating treatment also provided negative results. Lastly, lack of sustained effect of the treatment on visual acuity with concurrent lack of effect on the visually evoked response in 1 young amblyope has recently been reported.³⁹

In conclusion, under our test conditions the grating treatment appeared to have little effect on distance visual acuity in the amblyopic eyes of our juvenile as well as adult patients. We believe that conventional orthoptics procedures for the treatment of amblyopia, such as partial or total occlusion, training in monocular and binocular skills, and eye-hand co-ordination activities guided by the amblyopic eye, should not be discarded or minimised in the treatment of amblyopia until new techniques tested in amblyopes with proper controls and resulting in high success rates, independently confirmed by other laboratories, are available.

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