Strabismus 0927-3972/01/$ 16.00

Strabismus – 2001, Vol. 9, No. 1, pp. 17–27

Accepted 11 October 2000

Preliminary report: Prescription of prism-glasses by the Measurement and Correction Method of H.-J. Haase or by conventional orthoptic examination: a multicenter, randomized, double-blind, cross-over study

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Abstract In a multicenter, randomized, double-blind, cross-over study in the Netherlands, the effectiveness of (prism-)glasses prescribed by the Measurement and Correction Method of H.-J. Haase (MKH) was compared to that of glasses prescribed by conventional orthoptic examination. Nine pairs of MKH-optometrists and orthoptists recruited patients who primarily presented with asthenopia, and each prescribed the patient (prism-)glasses. A questionnaire for asthenopia was developed that rated headache and tired eyes as 0–7 days per week and none-light-medium-severe, respectively. Light sensitivity, problems with focusing, near-work problems and burning eyes were each rated as: never-occasionally-often-always. A patient was eligible if he scored 'medium', 'often' or '5 days a week' twice; or 'medium' (etc.) once and 'light' (etc.) twice. Controls, in contrast to the patients, typically answered 'none' or 'never' to half of the complaints, but 37% of them would have passed the admission criteria. Among other criteria were: 18 to 40 years of age, horizontal angle < 4°, vertical < 1.7°, acuity ≥ 0.8, stereopsis threshold disparity <120″.

Seventy-two patients fulfilled all criteria and returned sufficient questionnaires. They wore the first glasses for six weeks, were without glasses for two weeks, and then wore the second glasses for six weeks. At the start, halfway and at the end of each 6-week period, questionnaires were filled out; 97% were returned. Only 19 of the orthoptists' glasses contained prisms (14 horizontal, 5 vertical; horizontal average

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Acknowledgements:
We thank Essilor for supplying the second pair of prism-glasses to the patients free (the patients only paid for one pair of glasses) and for financial support for the secretarial work of the study. We especially thank Mr. Kunkeler, director the Dutch division of Essilor, for his hospitality. There were no other commercial, financial or proprietary interests involved and none of the parties involved has put any constraints on the outcome of the

study. We thank Isolde den Tonkelaar, curator of the ophthalmic collection of the University Museum in Utrecht, for her hospitality. We thank ir. M.J.C. Eijkemans, Prof. Crone and Prof. Kommerell for advice and suggestions and, finally, we thank Mrs B. Simonsz-Tóth for the many hours spent in correcting the manuscript.

of all glasses 0.49 PD, vertical 0.05 PD). Five of the orthoptists' glasses were plano. All MKH glasses contained prisms, 53 of 72 both horizontal and vertical, 18 only horizontal and one only vertical (horizontal average of all glasses 2.83 PD, vertical 0.79 PD).

The starting levels of complaints were high and *both* glasses improved complaints dramatically. The starting levels were lower, but not significantly, in the second 6-week period and improvement was less outspoken. Because of these differences, the two periods had to be evaluated separately.

The primary outcome of the study was defined as the difference between the effect of the MKH glasses and that of the orthoptists' glasses in the first and second 6-week periods. For problems with focusing, in the first 6-week period, and for tired eyes, in the second 6-week period, the difference exceeded the difference that had been defined as clinically significant (one day per week less headache or half the distance light-medium or half the distance occasionally-often), but it did not reach statistical significance.

The statistical power was approximately 0.7 for demonstrating this clinically significant difference. Statistical significance was not reached in multivariate repeated measure ANOVA either.

Forty-four patients preferred to keep the MKH glasses, 25 the orthoptists' glasses, including one plano. It is striking that 25% of the patients did not prefer the glasses that, according to the questionnaire, improved their complaints the most. A year after the study, the questionnaire was sent again to all patients: The levels of complaints after a year were similar to those at the end of the second 6-week period, whether they had preferred the MKH or the orthoptists' glasses, and were similar to the levels in controls.

The most conspicuous finding was that both glasses improved the complaints dramatically. Apart from the prisms, other reasons could be: spherical and cylindrical correction, improved wearing comfort of the frame, placebo effect, Hawthorne effect and regression to the mean.

Key words Asthenopia; glasses; prisms; heterophoria; fixation disparity; optometry; orthoptics

Introduction Ophthalmologists, orthoptists, optometrists and opticians are confronted regularly with patients with asthenopic complaints. Asthenopia comprises, for instance, light sensitivity, headache, problems with focusing from far to near and *vice versa*, problems with near work, tired eyes, burning eyes, etc. The ophthalmologist excludes organic lesions that may cause the complaints. The orthoptist examines whether a phoria, a disturbance of motility, a convergence insufficiency, a fusion weakness or an insufficiently corrected hypermetropia is causing the problem. Patients in whom the ophthalmologist and the orthoptist cannot find any abnormalities are often seen by optometrists and opticians. In Europe, some of these examine the patient with the Pola-Test (Zeiss) according to the Measurement and Correction Method of H.-J. Haase (MKH). Haase thought that (1) asthenopia may result from fixation disparity (FD), (2) caused by a heterophoria in the

past, that (3) the phoria may have disappeared, but that (4) the sensory adaptation is reversible, also in adulthood.[1-6]

FD can be measured with, among others, the cross-test of the Pola-Test or with the device developed by Ogle.[7-11] In these tests, the patient looks with both eyes at a screen (about 2° × 2°) and sees two lines on the screen, one with either eye. In the peripheral macular area of both eyes the border of the screen is seen singly; this contour is used to fuse, whereas the foveolae are pointing towards the center of the screen. The precise projection of the two foveolae on the screen is determined by the two lines (in the Pola-Test these two lines form a cross, while in the device developed by Ogle the two vertical lines are above each other). If the two haploscopically seen lines are shifted, then there is FD.

In normals, FD occurs when, by placing a prism in front of either eye, divergence or large convergence is asked from the patient: The border of the screen is then no longer perceived perfectly single, but the patient fuses a few minutes of arc sensorically, within Panum's area.[12] This is called 'FD of the first kind', in MKH terminology. Some patients, however, perceive the lines spontaneously as shifted (horizontally, and sometimes vertically as well). This pathological, obligate FD ('FD of the second kind'), which is actually a bitemporal or binasal shift of the foveolae relative to the peripheral macular area of a few hundredths of a millimeter, may cause complaints; most will agree with that. Controversial, however, is whether compensation of pathological FD by means of prismatically induced FD leads to lessening of complaints. In Germany, Switzerland, Austria, Norway and other countries this discussion has led to deep-seated controversies between ophthalmologists and orthoptists on the one hand and MKH-optometrists on the other. It should be noted that another controversy, as to whether FD can induce a heterophoria and, hence, complaints,[11,13-15] is not a subject of the current study. Also, it must be emphasized that our study was limited to the first pair of prism-glasses in asthenopics without ametropia, strabismus or other eye disorders, thereby avoiding the high prism strengths that are more often a subject of controversy.

As the cooperation between orthoptists, optometrists and ophthalmologists is generally good in the Netherlands and most are research-oriented, the climate a few years ago was favorable for a multicenter, randomized, double-blind, cross-over study. A study group was formed and for each of the approximately nine MKH-optometrists a partner-orthoptist was sought in each of the nine cities where these optometrists worked. Each patient to be recruited could then be examined both by the optometrist and the orthoptist and two pairs of glasses could be prescribed that could be worn by the patient in a randomized, double-blind fashion. In 19 meetings of the participants in the study group, the contact between the participants was enhanced and, although often very controversial subjects were discussed and in some aspects of the study a unanimous interpretation of the findings could not be found, it has proved possible to complete the trial with some conclusions that will be presented below.

Initially, the primary question that the trial should address was discussed. It would have been ideal to prescribe two identical pairs of

glasses, with similar spherical and cylindrical values, differing only in prism strength, for each patient. Unfortunately, however, this is not practicable because controversy would arise about the spherical and cylindrical values.

Secondly, an objective measure was sought for improvement of the patient's complaints: an increase in visual acuity or stereopsis would have been a neat measure of improvement. However, most patients with asthenopia have visual acuity 1.0 or 1.2 and 60″ stereopsis disparity already, so that an improvement could not easily be demonstrated statistically.

Finally, it was felt that, in general, a clinical trial should examine methods that are currently practiced for the results to be relevant for current health care and that, in the present case, prescribing spherical and cylindrical glasses was part of the total method of treatment of asthenopics. Therefore, the main question of the study was formulated as: 'Do prism-glasses prescribed by the Measurement and Correction Method of H.-J. Haase improve asthenopia complaints more effectively than those prescribed by conventional orthoptic examination?'. The primary outcome measure of the study was defined as the difference in improvement in the levels of complaints resulting from either the MKH or the orthoptists' glasses.

Methods The study committee consisted of a chairman (HS, physicist), a secretary (HJS, ophthalmologist), an independent optometrist (DB), a biostatistician (JMR), nine orthoptists and nine optometrists (including JE). The nine MKH-optometrists volunteered to participate in the study; in each of their cities of residence an orthoptist was asked to join to form an optometrist-orthoptist pair.

Over a period of two years, about 100 patients were recruited, dispersed over the Netherlands. Each patient that expressed an asthenopic complaint spontaneously or answered with an asthenopic compliant when asked what the reason of their visit was, filled out a questionnaire with seven questions to define the level of asthenopia (Table 1). The questionnaire was also presented to a control group, consisting of 88 persons accompanying patients visiting ophthalmology outpatient departments or optometrists.

Headache and tired eyes were rated according to frequency: zero to seven days per week, and degree: none – light – medium – severe. Light sensitivity, problems in focusing from far to near and *vice versa*, problems with near work, estimating distance and burning eyes were rated as never – occasionally – often – always. The intermediate values, halfway between light and medium, for instance, could also be indicated by the patients, effectively resulting in a seven-point scale. An additional question, concerning problems in estimating distance while playing ball and estimating distance in traffic, was later excluded from analysis because many patients did not answer, stating they did not play ball or making similar remarks for estimating distance in traffic.

To facilitate statistical evaluation, here and in the rest of the study, zero to seven days per week were given zero to seven points and the estimates none – light – medium – severe and the estimates never – occasionally – often – always were given one, three, five and seven

points, respectively. This made statistical analysis more straightforward and powerful. It is of course arbitrary whether the distance between light and medium headache is equal to the distance between medium and severe headache, or to the distance between three and five days per week.

If a patient answered 'medium' at least twice, or twice 'light' and once 'medium' (or, accordingly, twice '5 days a week', etc.), the patient was eligible. Additional inclusion criteria concerned age: 18 to 40 years; furthermore, eligible patients had not worn multi- or bifocal glasses previously, had no signs of presbyopia, the latent angle of strabismus was smaller than 4° horizontally and 1.7° vertically in far and near with optimal correction, the visual acuity was greater than or equal to 0.8 with maximally one line right-left difference, the spherical equivalent of the glasses could not exceed +2.5 or −3.5, with maximally one diopter difference, the cylinder was smaller than or equal to 1.5 diopter, an oblique axis was not allowed and detected stereopsis disparity was smaller than 120″. Previous incorrect glasses, medication or drugs, neurologic or psychiatric disease all led to exclusion.

The first examiner of the pair faxed his prescription of the (prism-)glasses to Essilor and sent the patient to the second examiner of the pair, who also faxed his prescription to Essilor. Essilor forwarded the prescriptions to the study biostatistician, who randomized both the prescriptions and the order of treatment. An independent study optometrist (DB), who was thus unfamiliar with the origin of the prescription, checked the glasses, mounted the glasses indicated by the biostatistician in the frame and sent the glasses to the patient. The patient wore the first pair of glasses for six weeks. In weeks 0, 3 and 6 the patient filled out a questionnaire and sent these to the study statistician, the last one together with the glasses. The study optometrist mounted the second pair of glasses in the frame and sent the glasses to the patient again after two weeks, during which the patient wore no glasses. In weeks 8, 11 and 14 the patient again filled out a scoring questionnaire. All contact between the patient and the pair of examiners was strictly forbidden. Problems with the glasses were solved by the study optometrist. The six questionnaires, at the beginning, halfway and at the end of the two six-week periods, were almost the same as the admission questionnaires (Table 1).

To the questions concerning headache, problems in focusing, tired eyes and burning eyes, a question as to when the complaint was the worst was added: when getting up in the morning, constant during the day, getting worse during the day, or variable during the day. In the questionnaires at the end of both six-week periods, a question was added concerning the percentage of the time that the glasses had been worn. At the end of the second six-week period, the patient was also asked which pair of glasses he wanted to retain.

Occasionally, a questionnaire or an answer was missing. A substitution rule for missing questionnaires was formulated, based primarily on the finding that the levels of complaints at three and six weeks (first pair of glasses) were approximately the same, and that those at 11 and 14 weeks (second pair of glasses) were also approximately the same. If the questionnaire at zero weeks was missing, the admission question-

naire (levels of complaints approximately eight weeks previously) was used. If the questionnaire at eight weeks was missing (start of the second pair of glasses) the questionnaire at zero weeks was taken.

A clinically significant difference, to be used in statistical analysis, was defined as: one day less headache per week, half the distance from light to medium headache or half the distance from occasionally to often burning eyes, etc.

The orthoptists and the optometrists both formulated a guideline for examination and for the prescription of the prism-glasses. The guideline formulated by the optometrists reflected the general MKH method.

The guideline formulated by the orthoptists emphasized full correction of hypermetropia. Prisms were prescribed only when the latent angle exceeded one prism diopter of esophoria or two prism diopters of exophoria. Half of the horizontal latent angle at distance fixation was mounted as prism, three-quarters in case the fusion range was shifted. Vertically, the full latent angle was mounted.

Both the optometrists and the orthoptists afterwards felt that they had adhered sufficiently to the formulated guidelines (note that only approximately a quarter of the glasses prescribed by orthoptists contained a prism).

Results Recruitment was difficult and slow: The exclusion criteria were strict and patients were frequently excluded because they had a latent angle of strabismus over 4°, had already worn prism-glasses previously, or had retinoscopy values that exceeded +2.5 diopters. Especially men living in the larger cities in the Netherlands refused to

TABLE 1. Basic questionnaire used, with slight modifications, at recruitment and six times at the beginning, halfway and at the end of the two six-week periods. The question about problems with estimating distance while playing ball and in traffic (6) was later omitted from analysis. The same questionnaire was also sent to all patients one year after the second period.

1. Do you suffer from headaches?
   degree: none – light – medium – severe
   how often: 1 – 2 – 3 – 4 – 5 – 6 – 7 days per week
2. Are you light sensitive? (do you squeeze your eyes in strong light or use sunglasses often)
   how often: never – occasionally – frequently – always
3. Do you have difficulty focusing from far to near and *vice versa*? (for instance, when you read and then look in the distance, does it take some time until the image is sharp? or from far to near?)
   how often: never – occasionally – frequently – always
4. Do you have difficulty reading or doing other near work within 40cm distance? (Does the image become blurred, 'dance' or shift together?)
   how often: never – occasionally – frequently – always
5. Do you suffer from tired eyes?
   degree: none – light – medium – severe
   how often: 1 – 2 – 3 – 4 – 5 – 6 – 7 days per week

6a. Do you have difficulty estimating distance when playing ball?
   how often: never – occasionally – frequently – always

6b. Do you have difficulty estimating distance in traffic?
   how often: never – occasionally – frequently – always

7. Do you suffer from burning eyes?
   how often: never – occasionally – frequently – always

participate, while women from Friesland were over-represented. In the end, 78 patients were admitted to the study, 62 women and 16 men; 58 were recruited by optometrists and 20 by orthoptists.

The admission questionnaire was also presented to a control group, consisting of 88 persons. In contrast to the patients, they typically answered the questions of the questionnaire with 'none' or 'never' in half of the cases. However, 22 out of 60 controls younger than 40 years would have passed the admission questionnaire if they had presented with an asthenopic complaint. Therefore, the question is justified whether the admission criteria, i.e. twice a 'medium' complaint or once a 'medium' and twice a 'light' complaint, were too lenient. On the other hand, it proved to be very difficult to recruit patients for the study at all. After a short discussion it was decided that a primary criterion of the asthenopic patients was that they had reported an asthenopic complaint spontaneously and immediately, and this effectively distinguishes them from controls. Also of interest was the fact that the 28 controls over 40 years of age had no other or more complaints than the younger controls; only problems in focusing from far to near and *vice versa* and problems with near work occurred more frequently, as expected.

In the end, 78 patients were sent, apart from the admission questionnaire, all six main study questionnaires in weeks 0, 3, 6, 8, 11 and 14. Of the 468 questionnaires sent to the 78 patients, 97% were returned. Between 89% and 98% of the questions had been answered; the question about estimating distance while playing ball had only been answered in 80% of the cases, often accompanied by the remark that the patient did not play ball. As such remarks also often accompanied the answers concerning estimation of distance in traffic, estimating distance was left out of the analysis completely.

Five patients did not fill out two questionnaires or more, one patient was later found to have a latent angle of strabismus over 4°. Of the remaining 72 patients, 32 first wore the MKH glasses and 40 first the orthoptists' glasses. Only 19 of the orthoptists' glasses contained prisms (14 only horizontal, 5 only vertical), never exceeding 4 prism diopters (horizontal average of all glasses 0.49 PD, vertically 0.05 PD). Five of the orthoptists' glasses were plano. All optometrists' glasses contained prisms, 53 of 72 had a vertical prism in addition to a horizontal prism, 18 only horizontal and one only vertical (horizontal average of all glasses 2.83 PD, vertically 0.79 PD).

Statistical analysis was based on the findings in these 72 patients. The power of the study, calculated on the basis of the spread of the levels of complaints at the end of the first six-week period, was approximately 0.7 to demonstrate the clinically relevant difference of one day per week (or half the distance from light to medium) in these 72 patients. The primary outcome measure of the study was the difference in improvement in the levels of complaints brought about by either the MKH or the orthoptists' glasses (Table 2). Improvement was defined as the difference between the levels of the complaints at the beginning and at the end of the six-week periods.

The starting level of the complaints was high at the beginning of the first six-week period (Table 3); *both* glasses reduced the complaints enormously. The starting level was lower, but not significantly, in the

TABLE 2. The primary outcome of the study was defined as the difference between the effect of the MKH glasses and that of the orthoptists' glasses in the first and second six-week periods. In the first period, 32 patients wore the MKH glasses and 40 patients the orthoptists' glasses, in the second period this was the other way around. Effect is defined as (1) decrease in the number of days of headache or tired eyes, (2) decrease on the 1-to-7 scale for none – light – medium – severe headache or tired eyes, or (3) decrease on the 1-to-7 scale for never – occasionally – often – always for light sensitivity, problems in focusing from far to near, problems with near work and burning eyes. Note that the patients could choose intermediate values, e.g., halfway between light and medium headache, on the questionnaires. SEM: standard error of mean. For two complaints, the differences between the effects of the MKH and those of the orthoptists' glasses exceeded what had been defined previously as clinically significant. These were: frequency of problems in focusing from far to near in the first six-week period and frequency of tired eyes in the second six-week period (underscored p-values in the table). However, these differences were not statistically significant.

	1st six-week period			*2nd six-week period*		
	effect	*SEM*	*t-test: p*	*effect*	*SEM*	*t-test: p*
Headache rated none–light–medium–severe on a 1-to-7 scale:						
MKH glasses:	−2.22	0.37		−1.15	0.30	
orthoptist glasses:	−1.74	0.27		−0.40	0.34	
			0.300			0.104
Headache rated one to seven days per week:						
MKH glasses:	−1.84	0.41		−0.87	0.39	
orthoptist glasses:	−2.00	0.38		−0.17	0.37	
			0.782			0.207
Light sensitivity, rated never–occasionally–often–always on a 1-to-7 scale:						
MKH glasses:	−1.31	0.29		−1.00	0.32	
orthoptist glasses:	−1.15	0.30		−0.30	0.32	
			0.704			0.131
Problems focusing from far to near and v.v., rated never–occasionally–often–always on a 1-to-7 scale:						
MKH glasses:	−2.13	0.41		−0.82	0.32	
orthoptist glasses:	−0.95	0.31		−0.77	0.35	
			<u>0.023</u>			0.911
Problems with near work, rated never–occasionally–often–always on a 1-to-7 scale:						
MKH glasses:	−1.84	0.36		−1.03	0.33	
orthoptist glasses:	−1.40	0.28		−0.90	0.32	
			0.327			0.791
Tired eyes, rated none–light–medium–severe on a 1-to-7 scale:						
MKH glasses:	−1.94	0.28		−1.08	0.39	
orthoptist glasses:	−1.68	0.28		−0.63	0.39	
			0.513			0.432
Tired eyes, rated one to seven days per week:						
MKH glasses:	−1.86	0.53		−1.31	0.41	
orthoptist glasses:	−2.00	0.43		−0.18	0.37	
			0.838			<u>0.051</u>
Burning eyes, rated never–occasionally–often–always on a 1-to-7 scale:						
MKH glasses:	−1.25	0.24		−0.77	0.24	
orthoptist glasses:	−0.63	0.23		−0.33	0.23	
			0.064			0.208

second six-week period (it was only significantly lower for some complaints in the group that first wore the orthoptists' glasses). The improvement was less dramatic in the second period. The levels of complaints at three weeks were roughly equal to the levels at six weeks, i.e. improvement was most outspoken in the first three weeks; similarly, the levels at 11 weeks were roughly equal to those at 14 weeks.

For two complaints, the difference between the effects of the MKH and the orthoptists' glasses exceeded the difference that had been defined as clinically significant (Table 2). This concerned the frequency of problems in focusing from far to near in the first six-week period and the frequency of tired eyes in the second six-week period.

	mean	*SEM*
Headache, degree	4.83	0.18
Headache, days per week	3.68	0.23
Light sensitivity, frequency	5.14	0.18
Problems with focusing, frequency	4.25	0.21
Problems with near work, frequency	3.94	0.18
Tired eyes, degree	5.01	0.14
Tired eyes, days per week	4.65	0.22
Burning eyes, frequency	3.69	0.17

TABLE 3. Levels of complaints (and Standard Error of the Mean) at the beginning of the first period of the study. Zero to seven days per week were given zero to seven points and the estimates none, light, medium and severe were given one, three, five and seven points, respectively. Light sensitivity, problems with focusing or near work and burning eyes were each rated as: never – occasionally – often – always, corresponding to one, three, five and seven points, respectively.

However, neither difference reached statistical significance (set at 0.01 to safeguard against the effects of multiple testing).[16] In a repeated-measure, multivariate analysis of variance for all eight parameters, also incorporating the levels of complaints at three and eleven weeks, no statistically significant differences were found.

The main outcome of the study was improvement of the asthenopic complaints. The preference of the patient as to which pair of glasses he wanted to retain at the end of the study was a secondary outcome measure. Three patients did not choose either pair of glasses at the end of the study (requested their money back, for instance). Of the remaining 69, 31 had first worn the MKH glasses and 38 first the orthoptists' glasses. Forty-four patients preferred the optometrists' glasses, 25 the orthoptists glasses. One of the five plano glasses prescribed by the orthoptists was preferred. Interestingly, 25% of the patients did not prefer the pair of glasses that had improved the complaints the most according to the questionnaires.

To answer the question whether the patients would wear the glasses for a longer period after the study, an additional questionnaire was sent to the 69 patients after one year: 45 returned this questionnaire, 38 still wore the same glasses, 34 were content with these glasses, and an additional five had received new glasses in the meantime. The 45 also filled out the original questionnaire, in order to estimate their current levels of complaints. These were similar to their levels of complaints at the end of the study at 14 weeks, whether they had preferred the MKH or the orthoptists' glasses, and were similar to the levels of complaints in controls.

Discussion For two complaints, the differences between the effects of the MKH glasses and those of the orthoptists' glasses exceeded what had been defined previously as clinically significant (one day per week less headache, half the distance light-medium or half the distance occasionally-often) in favor of the MKH glasses. These were the frequency of problems in focusing from far to near in the first six-week period and the frequency of tired eyes in the second six-week period (Table 2). However, these differences were not statistically significant.

The most conspicuous finding of our study was that both pairs of glasses improved the complaints tremendously. This improvement was especially pronounced in the first six-week period. The improvement

was larger when the starting level of a complaint was high. Interesting is also that the levels of complaints were slightly higher, albeit not significantly, when the patients were recruited than at the start of the first six-week period, approximately two months later, although no glasses had been worn in between. Finally, the levels of complaints one year after the study were the same as the levels at the end of the second six-week period, the same as those in the controls, and the same for MKH and orthoptists' glasses. How can this improvement, which seems to occur, in part, independently of the wearing of glasses, be explained?

First, the patients received a better, or their first, spherical and cylindrical correction in most cases, although five of the glasses prescribed by the orthoptists were plano. This effect was certainly of importance but could, unfortunately, not be quantified: 56 out of 72 patients did not have a better measured visual acuity (as tested by the orthoptists before prescribing the glasses). Improved wearing comfort of the frame and the use of antireflective coatings may also have played a role. Finally, the wearing of the frame itself may have had a positive influence.

Apart from the changes in the physical world of the patients, various psychological and statistical phenomena may have occurred. The wearing of the first pair of glasses may have influenced the wearing of the second pair of glasses (carry-over effect), and the period between the first and the second pair of glasses, two weeks, may have been too short (too short a wash-out period).

A placebo effect may also have occurred: The patients expected to benefit from the glasses. Apart from the placebo effect, the Hawthorne effect[18] may have occurred: Everything surrounding the prescription of the glasses, the appointments, the choice of the frame, etc. enhances the patient's awareness of the complaints and could have had a positive influence.

Finally, the statistical phenomenon 'regression to the mean' may have played a role.[19] In any study in which the main question is partly identical to the inclusion criteria, a 'spontaneous cure' may occur. Every inclusion criterion, every complaint or every blood value will vary with time. Since patients who, by chance, happen to have a high level are more likely to be recruited, on average they will get better even without treatment. This phenomenon is called 'regression to the mean'. An example may make this clearer.

In a recent Australian cholesterol study,[20] patients with too high a cholesterol were recruited. The level of cholesterol not only fell in the group following a diet or with a different life style, it also fell in the control group, because the patients had preferentially been recruited at the moment that their cholesterol level happened to be high.

In our study, the contribution of each of the effects discussed above cannot be quantified. However, because of the randomized, double-blind design of the study, the comparison of the relative effects of the two pairs of glasses is still valid. However, future studies should at least incorporate a cross-over A-B-A design, a control group without treatment or sham treatment, and selection of a randomized sample for the study groups with less similarity between inclusion criteria and the primary outcome measure.

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