The treatment of senile cataract using MUCOKEHL eye drops

Results of a trial carried out in an eye hospital

by

B. Adamek, L. Samochowiec, J. Wojcicki

Semmelweis-Institut GmbH
Verlag für Naturheilkunde · 27318 Hoya · Germany

For a long time now ophthalmologists have been seeking remedies which will lead to the clearing of opacification of the lens or can at least retard further development of cataracts. To date, various substances have been introduced into the treatment of cataracts: cysteine, sodium thiosulphate, ascorbic acid, extracts from organs, adenine phosphate, sulphydryl com-pounds, methyl thiouracil (1–4). The content of some of these substances in a lens affected by cataract is at a reduced level compared to that of a normal lens. In this way an attempt is made to provide a substitute and thereby achieve normalisation of the physiological conditions.

In addition, various remedies which are said to have an anti-cataract effect are used for local application to the eyes. One remedy which is currently very popular here is sodium dihydroazapentacene polysulphonate. According to Ogina and his colleagues (5–7), the sulphydryl groups of the soluble lens protein are oxidised by chinone compounds occurring as the result of disruption of the metabolism by aromatic amino acids.

The sodium polysulphonate of the dihydroazapentacene has a strong affinity to the thiol group of the soluble lens protein and thus slows down the effect of the chinones. This substance is also supposed to activate proteolytic enzymes which are found in the fluid in the aqueous chamber of the eye. In presenting this example of the theory of the formation of a cataract and the effect of an anti-cataract remedy, it must be emphasized at the same time that conservative treatment of the cataract has to be varied as not all the mechanisms of the pathogenesis are known. For this reason it is not surprising that until now no successful remedy has been found which could bring about the clearing of the opacification of the lens. Despite the lack of convincing proof of the anti-cataract effect of the remedies used, they can retard the progress of the disease to a certain degree.

Metabolism of the eye tissue must be improved

Basically the aim of all our endeavours is to retard the process of lens opacification by improving the metabolism and nutrition of the eye tissue. The SANUM-Kehlbeck company endorses these efforts and provides an anti-cataract remedy in the form of eye drops. This is MUCOKEHL, one of the range of so-called biogenic stimulators. The active factor in MUCOKEHL is an extract of *Mucor racemosus Fresen* which is manufactured in accordance with the company's own regulations, taking into account the Homeopathic Materia Medica. MUCOKEHL stimulates the defence reactions of the organism and controls the resorption and regeneration processes. When applied in the form of eye drops, it regulates the metabolism of the eyeball. It works as a regulator of the viscosity of the blood, improving vascularisation and thus enhancing the nutrition of the eyeball.

The immunobiological effect of MUCOKEHL when used in cases of cataract makes this remedy all the more interesting, as recently the possibility of an antigenic effect on the lens proteins and antigenic and antibody reactions have been regarded as reasons why cataracts develop (8). Scientific trials to date (9) on the use of MUCOKEHL in the form of eye drops have described good therapeutic results in cases of eye diseases such as cataract, glaucoma, conjunctivitis and degeneration of the yellow spot (macula lutea).

Within the large group of cataracts, senile cataract (*Cataracta senilis)* is the form that occurs most frequently, generally appearing around the age of 60. Four stages can be differentiated:

1. *Cataracta incipiens* – incipient cataract (the lens begins to cloud over)

2. *Cataracta cuneiformis* – fusiform cataract (clouding of the peripheral radius)

3. *Cataracta intumescens* - intumescent cataract (increase in the clouding of the lens together with absorption of fluid)

4. *Cataracta matura* - mature cataract

The testing method

The trial was set up as a prospective, non-comparative study in the First Eye Clinic of the Academy of Medicine in Szczecin, Poland, under the direction of Professor Dr. L. Samochowiec with 30 patients of both sexes. The doctors carrying out the trial were informed about the pharmacological toxicological properties of the substance being tested. Following an explanation of the nature, importance and scope of the trial, 30 patients agreed to take part.

Criteria for inclusion and exclusion

The trial included female and male patients with a minimum age of 50 years. As well as patients with normal sight, patients who were long- or short sighted, with or without aids to seeing, were admitted. The patients were supposed to have been suffering from one form of cataract for at least one year. This included all forms of cataract from a predisposition to opacification of the lens to the mature cataract.

In principle, patients with previous damages to the eyes were excluded from the study, as too were cases of lens opacification caused by trauma *(Cataracta traumatica* – traumatic cataract), patients with tumours and patients with pathologically raised intraocular pressure. During the study, the patients were not allowed to use any other eye drop preparations.

The test substance

The test substance belongs to a range of isopathic remedies from SANUM-Kehlbeck. The mycelia of *Mucor racemosus Fresen* are used to make the remedy MUCOKEHL. A special manufacturing method guarantees that neither fungal spores nor aflatoxins are formed which could get into the extract. MUCOKEHL 5X eye drops are manufactured in accordance with the instructions of the Homeopathic Materia Medica (HAB 1). Comprehensive toxicological data (9) is available for the medicinal product *Mucor racemosus* 5X, providing evidence of its complete safety. The dosage was 1 drop of MUCOKEHL 5X eye drops in each eye twice daily for a period of 6 months. The doctors carrying out the trial were obliged to methodically record any side-effects. Any side-effects or epiphenomena which might occur were to be treated using established methods.

The patients

The study included 30 patients with all forms of senile cataract from Stage 1 to Stage 4. No breaks in the study were recorded: all the patients continued with the study for 6 months until the end of the treatment course. The patients included 21 women and 9 men aged from 50 to 83 years, with an average age of 69 years. The patients were given a thorough examination at the time they were accepted onto the study, after 3 months and again at the end of the treatment course after 6 months. Detailed examinations were made of their visual acuity (both distant and close), peripheral field of vision and intraocular pressure.

From the anamnesis it emerged that 19 patients had already used other eye drops before starting the treatment with MUCOKEHL 5X eye drops. Those courses of treatment had lasted up to 7 years (on average 3½ years). The other 11 patients had not previously used any eye drops to treat the cataract, although in the case of 5 patients a gradual deterioration of their visual acuity had been observed over the past 5 years. 6 patients gave no details of when they had begun to have problems with their sight and whether they had used any medication to treat senile cataract during the past 5 years. These 6 patients were at the higher end of the age scale.

In 9 cases it was found that the patient was myopic (short-sighted) and this was compensated for by a minus correction in one or both eyes. For 13 patients, their hyperopia (far-sightedness) was corrected with plus glasses. One patient had astigmatism. The other 7 patients could see without the need for any corrective glasses. It was found

that 16 patients had cataracts in both eyes. The other 14 patients had a cataract in only one eye.

MUCOKEHL eye drops were principally applied to both eyes (i.e. also to the healthy eye). At the same time the doctors monitored whether there was any progression of the opacification of the lens in either eye, leading to deterioration of the patient's visual acuity. Of the total number of eyes checked – i.e. 60; 46 were affected by senile cataract at various stages of opacity, including 4 eyes with mature cataracts where the visual acuity at a distance of 30 cm was limited to „hand movement" and „finger count". 14 eyes had a visual acuity of 1.0 either with or without correction but proved to have a potential predisposition to opacification of the lens.

The examination procedure

The acuity of the distant vision of each patient was determined for each eye separately at a distance of 5 m. The patient had to read the letters from the Snellen eye chart. The examination was carried out without corrective glasses or with the patient's own corrective glasses. If the patient did not have any glasses of his/her own, customised glasses were provided and the visual acuity was corrected as much as possible. This correction, which was carried out once at the start of the trial, was retained for the whole period of the study and not changed again. The figure determined for the acuity of the patient's distant vision was recorded as a decimal fraction.

The acuity of the patient's close vision was determined for each eye separately at a distance of 30 cm using the special table based on Snellen. The examination was carried out once without correction and then with glasses giving the maximum correction. The result of the determination of the acuity of the patient's close vision was also recorded as a decimal fraction. The intraocular pressure was tested using a Schiötz tonometer with the patient lying down, the result being recorded in mm on the mercury scale (mmHg).

The peripheral field of vision of each eye was tested separately using a Goldman perimeter. Each field of vision was planimetered three times and the average value given in planimetric units. With the pupil dilated, the front section of the eye was assessed using a corneal microscope. The results were calculated statistically with the aid of the Student's *t*-test for non-associated samples. The overall working plan for the study is shown in Table 1.

The examination results

For the purpose of analysis of the results of the tests of acuity of distant vision, the 60 eyes examined were divided into two groups as follows:

Group I: 46 eyes with senile cataracts with a visual acuity of < 1.0. From this Group I, two sub-groups were formed:

Sub-group Ia: 42 eyes with cataracts at various stages of lens opacification and a visual acuity of 1:50 to 0.9;

Sub-group Ib: 4 eyes with mature cataracts where the visual acuity at a distance of 30 cm was limited to „hand movement" or „finger count".

Examinations	Number of eyes			
	Group I		Group II	
	Ia	Ib	IIa	IIb
Acuity of distant vision	42	4	2	12
Acuity of close vision	46		14	
Intraocular pressure	60			
Peripheral field of vision	60			

Group I: Visual acuity less than 1.0
Ia: Visual acuity 1:50 to 0.9
Ib: Mature cataract
Group II: Visual acuity equal to 1.0
IIa: Without correction
IIb: With correction

Table 1: Examination procedure

Group II: 14 eyes with a predisposition towards opacification of the lens and with a visual acuity of 1.0 with or without correction;

Sub-group IIa: 2 eyes with a visual acuity of 1.0 without correction;
Sub-group IIb: 12 eyes with a visual acuity of 1.0 following the appropriate correction.

Analysis of the acuity of distant vision

In Sub-group Ia the acuity of the distant vision of 27 eyes (64.3 %) improved. The mean visual acuity of these eyes without correction at the start of treatment was 0.27, and after six months of treatment, it improved to 0.4. 11 eyes (26.2 %) showed no improvement or deterioration in the acuity of distant vision. Only in 4 eyes (9.5 %) was there some deterioration in visual acuity. In 2 cases the visual acuity dropped from 1:50 to „hand movement" at a distance of 30 cm. In a third case the visual acuity at the initial examination was 0.9 and at the last examination 0.7. Corrective glasses also made no improvement. The fourth patient had achieved a visual acuity of 0.6 in one eye at the initial examination, and this dropped to 4:50 at the final examination. Here too the corrective glasses made no improvement.

In one case in Sub-group Ib (mature cataract) the visual acuity improved from „hand movement" to 1:50 at the final examination. In the other 3 cases in this group the visual acuity did not change. In Sub-group IIa (vision 1.0 without correction) the visual acuity did not alter during the whole observation period.

In Sub-group IIb (vision 1.0 following correction) the acuity of distant vision did not change in 4 cases, remaining at 1.0. In 7 cases the mean visual acuity without correction improved from 0.53 to 0.66. In one case there was deterioration of the visual acuity from 1 to 0.2 despite corrective glasses being fitted. The patient had a mature cataract with a visual acuity of „hand movement" at a distance of 30 cm.

If the results for distant vision for all 60 eyes are combined, we find

- improvement of the visual acuity in 58 %
- no change in the visual acuity in 33 %
- deterioration of the visual acuity in 9 %.

Analysis of the acuity of the close vision

The acuity of the close vision within both Groups I and II was also analysed. In Group I 46 eyes were observed; in Group II the number of eyes was 14.

In Group I, no changes in the acuity of the close vision with or without correction were observed in 22 eyes (47.8 %). There was an improvement in the visual acuity of 20 eyes (43.5 %), with the mean visual acuity without correction being D-2.0 at the start of treatment and D-1.3 at the conclusion of treatment. There was a deterioration in the acuity

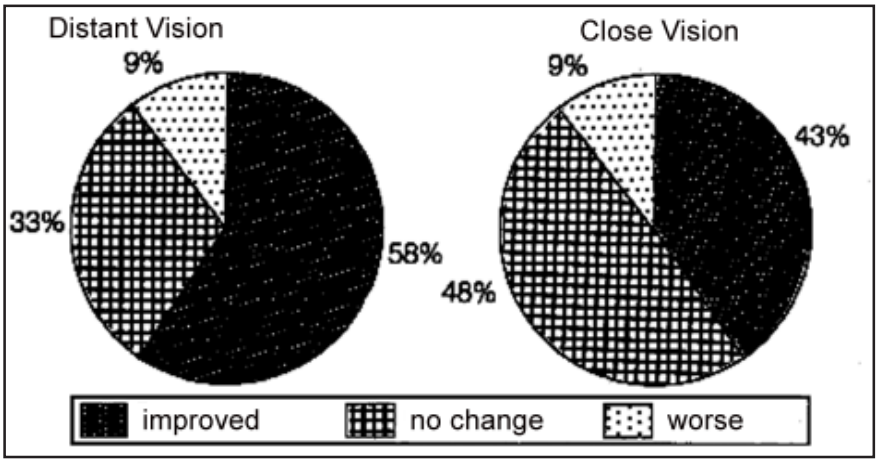

Fig. 1: The influence of MUCOKEHL eye drops on visual acuity

Visual acuity	improved	no change	worse
Distant vision (n = 60)	35 (58 %)	30 (33 %)	5 (9 %)
Close vision (n = 60)	26 (43 %)	29 (48 %)	5 (9 %)

Table 2: The influence of MUCOKEHL eye drops on visual acuity

Date of examination	right eye	left eye	total
Initial examination	918 ± 48	917 ± 47.6	918 ± 31.7*
After 3 months	960 ± 49.5	1010 ± 35.8	985 ± 30.7*
After 6 months	970 ± 59.5	1008 ± 39.2	989 ± 36.9*

Table 3: The influence of MUCOKEHL eye drops on the mean peripheral field of vision (given in planimetric units).
** = significance $p < 0.001$*

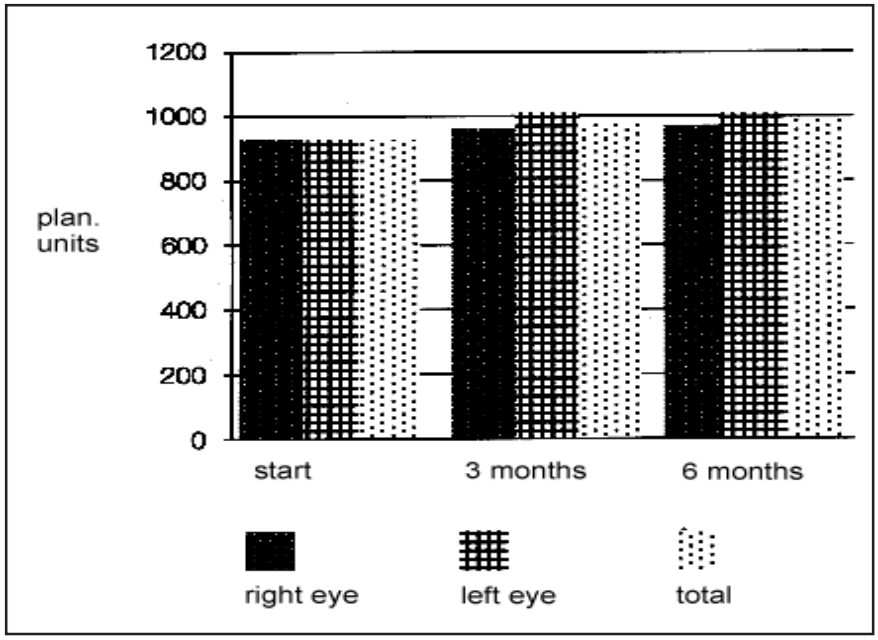

Fig. 2: The influence of MUCOKEHL eye drops on the mean peripheral field of vision

of close vision in 4 eyes (8.7 %). Here the mean visual acuity without correction changed from D-2.25 at the initial examination to D-2.6 at the final examination.

In Group II no changes in the acuity of close vision were found in 7 out of 14 eyes. In the case of 6 eyes (42.9 %) the mean visual acuity improved from D-1.8 to D-1.0. In one case (7.1 %) the acuity of close vision deteriorated from D-1.5 to D-2.0. Combining the results for close vision, the visual acuity improved for 26 eyes, whilst in 29 eyes no improvement was noted and 5 eyes showed some deterioration of the visual acuity (Fig. 1).

Intraocular pressure

The mean values of the intraocular pressure remained within the normal range for the whole observation period. The mean values of the intraocular pressure for both eyes at the time of each of the three examinations were 16.2 mmHg at the initial examination, 15.7 mmHg after 3 months and 16.2 mmHg at the final examination after 6 months – within the normal range of approx. 17 mmHg.

The peripheral field of vision

The mean peripheral field of vision improved slightly during the first 3 months and then remained almost constant until the final examination at the end of the six months. At the initial examination, the mean peripheral field of vision of both eyes was 918 planimetric units; this rose to 985 units after 3 months and remained at this level after 6 months with 989 units. The field of vision increased by approx. 70 planimetric units, equivalent to a percentage improvement of 7 % (Table 3, Figure 2).

Some authors have described (2, 7) a reduction in the level of opacification of the lens following conservative treatment. Since no medication has proved to be absolutely successful to date, it must be assumed that it is not possible to treat just the cataract with the pharmaceutical products used up until now (1, 3, 10). With MUCOKEHL 5X eye drops, however, success was achieved with cataracts that were at the initial stage. Moreover, the use of this remedy can be recommended for all processes that respond to activation of the metabolic status of the eye.

Summary and discussion

After a six-month course of treatment with MUCOKEHL

eye drops it was possible to achieve an improvement in the acuity of the distant vision of 58 % of the patients. For close vision, an improvement in the visual acuity was achieved in 43 % of the patients. In 33 % and 48 % respectively, neither a deterioration nor an improvement was observed. It must be stressed that following the six-month course of treatment of senile cataract with MUCOKEHL eye drops, the outcome in 91 % of the cases was no deterioration of the visual acuity.

Despite the positive results of the visual acuity examinations, in the examination using the corneal microscope, it was not possible to determine any lessening of the already existing lens opacification. Only in 5 cases were small peripheral areas found which had cleared, particularly where the cataract was still at the incipient stage. It was these patients with incipient cataract who showed improvement in their visual acuity. As there is no evidence of any clearing of the clouding of the lens, the improvement of the mean visual acuity can be ascribed to the stimulation of the metabolism in general, including that of the eye. The mechanism whereby this effect occurred also explains the increase in the mean peripheral field of vision.

As a result, the indications for MUCOKEHL eye drops are that their effect is not limited to cataracts. MUCOKEHL eye drops can be used wherever the optical metabolism needs to be stimulated – including cases where the eyes tire quickly or there is some sensitivity or strain.

Disorders of the intraocular pressure were not observed. The pressure remained within normal limits, and at 2 mmHg over all the examinations the fluctuation range was remarkably narrow. The patients tolerated the MUCOKEHL eye drops well and did not report any discomfort on inserting the drops into the conjunctival sac. No side effects of the medication were observed in connection with the treatment course using MUCOKEHL eye drops.

Bibliography

(1) *Müller, H.K.; Kleifeld, O.; Klin. Mbl. Augenheilkunde 137, 25–29 (1960)*

(2) *Pietrow, A.: Klin. oczna. 43, 409 (1973)*

(3) *Pojda, S.: TOM II, 492–495, Kattowitz 1986*

(4) *Vancea, P.: Klin. Mbl. Augenheilkunde 165, 71–75 (1974)*

(5) *Ogino, S.; Ichihara, T.; Amer. J. Ophthal. 43, 754–767 (1957)*

(6) *Katumori, Y.; Ogino, S.; Tojo, H.: Amer. J. Ophthal. 44, 94–105 (1957)*

(7) *Yasukara, K.; Ogino, S: Amer. J. Ophthal. 43, 936–949 (1957)*

(8) *Orlowski, W. J.: TOM I 197–198, Warsaw 1989*

(9) *Fischer, K. J.; Heidl, R.: personal letter*

(10) *Prost, M.: Klin oczna. 84, 71–72 (1982)*

First published in the German language in the Sanum-Post magazine (14/1991)