# Petition to the
# U.S. Food and Drug Administration

*by*

The International Myopia
Prevention Association
A non-profit corporation

*for*

Enforcement Action Based On
National Eye Institute's 2004 Supplemental COMET Report
To Require Eye Care Professionals To Advise Parents
Of Children With Initial Myopia That
Distance (Minus) Lenses Worsen Myopia, And That
Myopia May Be Prevented By Using Reading (Plus) Lenses
For Computer Usage And Other Prolonged Close Work

*pursuant to*

21 U.S.C. §352(f)

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The undersigned submits this petition under 21 U.S.C. §352(f) to request the Commissioner of Food and Drugs to take the following enforcement action to prevent the unlawful misbranding of prescription distance glasses and contact lenses.

Before any child with initial myopia is prescribed or provided with distance (minus) lenses, the following written notification shall be given to a parent or other responsible adult.

### REDUCTION OR PREVENTION OF MYOPIA

Nearsightedness is the inability to see distant objects clearly. This is known as "myopia."

Distance (minus) lenses cause myopia to worsen progressively. In the long term, this can lead to retinal detachment and other serious problems.

Myopia may be reduced or prevented entirely if a child in the earliest stage of myopia uses prescribed reading glasses (plus lenses) for reading, viewing a computer monitor, or other prolonged close work. Proper instruction needs to be given to ensure that the reading glasses are used correctly for maximum beneficial effect.

You should ask your eye care professional whether reading glasses for computer usage and other prolonged close work should be prescribed at this time in an attempt to reduce or prevent myopia, rather than distance (minus) lenses.

## B. EXECUTIVE SUMMARY

In 2003, the U.S. National Eye Institute (which is part of the U.S. Government's National Institutes of Health) stated as follows:

> Myopia is a significant public health problem, affecting at least 25 percent of adults in the United States and a much higher percentage of people in Asia. Recent data suggest that these percentages are increasing. In addition to blurring vision at distance, high myopia is a predisposing factor for retinal detachment, myopic retinopathy, and glaucoma, thus contributing to loss of vision and blindness that cannot be corrected with glasses or contact lenses. The high prevalence of myopia and its prominence as a public health problem emphasize the importance of understanding the mechanisms of development and finding effective ways to prevent or slow its progression.[1]

The number of people with myopia is increasing rapidly, in this country and worldwide, because of the increase in prolonged close work, especially the use of computers. It is an epidemic.

In the vast majority of cases, myopia is caused by prolonged close work, such as reading or using a computer. This causes excessive *accommodation*, which is the focusing effort required to do close work. This results in progressive and irreversible elongation of the eye.

Myopia can be reduced or prevented in an individual with initial myopia by the use of properly prescribed reading glasses, provided they are used appropriately. This has been conclusively proved, including by the Myopter trial in Pennsylvania. However, consumers are not aware that myopia can be reduced or prevented by this means for the following reasons:

- Consumers believe that myopia is not a problem. They believe that glasses and contacts lenses are normal. In fact, as a result of clever marketing, they are even treated as a fashion accessory (which is unique and odd for a medical device) and associated with higher intelligence. Therefore, they have not demanded a preventive solution.

- Consumers are almost never told by their eye care professionals that distance (minus) lenses make myopia progressively worse.

[1] *See www.nei.nih.gov/news/statements/comet.asp*. This statement was made regarding the COMET trial, which is discussed extensively in this Petition.

- Consumers are almost never told by eye care professionals that myopia is a predisposing factor for retinal detachment, myopic retinopathy, and glaucoma, thus contributing to loss of vision and blindness, as the NEI says.

- Consumers are told by eye care professionals that myopia is hereditary and that nothing can be done to prevent it. This is wrong. Prolonged close work causes myopia, and any genetic factors are of marginal significance.

- Consumers are never told that myopia can be reduced or prevented if reading (plus) lenses (with a +3D add) are used for prolonged close work at the earliest stage of myopia.

- Consumers are almost never told about proper reading habits to preserve their eyes, that is keeping close work as far from the eyes as possible, interrupting close work by looking into the distance intermittently, ensuring that close work is perpendicular to the line of sight and not at an angle, and making sure that the close work is well lighted. (These rules are referred to as the "D-I-A-L" rules in this Petition.)

Glasses and contact lenses are prescribed and sold with no information about these matters whatsoever, which is extraordinary, reckless, and unfair.

Unfortunately, the subject is just too arcane and complex for consumers to understand. As a result, consumers have not challenged eye care professionals on this subject.

In fact, anyone who challenges the strict orthodoxy that myopia is genetic and cannot be prevented is instantly vilified as a heretic. Perhaps there is a perception that the prevention of myopia would challenge a comfortable existence of profitably prescribing and supplying distance (minus) lenses numerous times throughout a person's life.

No one is even questioning why consumers are told virtually nothing when they are prescribed or purchase glasses or contact lenses. Hopefully, this Petition will at the very least trigger a serious debate about what consumers should be told. Let the eye care professionals justify why consumers are not given the information that they need.

The time for change has come. Ophthalmologists and optometrists owe a duty of care to their patients to prevent myopia if they can.

What is new in this situation is the *second* report of the National Eye Institute's COMET group, which was published in 2004. Copies of two reports by the COMET group published in 2003 and 2004 are attached hereto. The Petitioner is highly critical of the COMET trial, which was badly flawed for reasons discussed herein. However, both reports, especially the second report, support this Petition.

In the second report, the COMET investigators found that reading (plus) lenses used for close work significantly slowed myopia progression in children with large accommodation lag. For the reasons discussed herein, this confirms that myopia can be prevented in all children if reading (plus) lenses are used as soon as the first sign of myopia appears (before the eyes have irreversibly elongated). This has been known and proven for many years, but it is now effectively confirmed by the second COMET report.

The continuing failure to advise consumers that myopia can be reduced or prevented by the use of prescribed reading glasses used appropriately constitutes unlawful misbranding under 21 U.S.C. §352(f). The FDA is required to take enforcement action.[2]

[2] Failing to advise patients of the possibility of reduction or prevention of myopia may also constitute legally actionable negligence.

## C. THE PETITIONER

The International Myopia Prevention Association (“IMPA”) is a Pennsylvania non-profit corporation founded in 1974 by Donald Rehm.

Mr. Rehm has dedicated his life to the prevention of myopia in children. He invented and built the “Myopter” optical viewer in 1972, and introduced it to the optometric profession at the 1973 Annual Meeting of the American Academy of Optometry in San Francisco. His paper, "The Myopter Viewer: An Instrument for Preventing, Improving and Eliminating Acquired Myopia", was subsequently published in the American Journal of Optometry and Physiological Optics. On May 13, 1975, he obtained U.S. Patent No. 3,883,225 on the Myopter.

In 1981, Mr. Rehm published a book entitled “The Myopia Myth” on the subject of myopia prevention, which is available through IMPA.

Mr. Rehm and IMPA have no commercial or financial interest in the outcome of this Petition.

This Petition is being filed purely in the public interest.

## SCIENTIFIC BASIS FOR PETITION

### D. THE GROWING WORLDWIDE MYOPIA EPIDEMIC

The National Eye Institute, which is part of the U.S. Government's National Institutes of Health, has stated:

> Myopia is a significant public health problem, affecting at least 25 percent of adults in the United States and a much higher percentage of people in Asia. Recent data suggest that these percentages are increasing.[3]

Myopia is on the increase in most of Asia, but in some countries such as Singapore it has reached extraordinary levels. In Singapore, 80 per cent of 18-year-old male army recruits are myopic, up from 25 per cent just 30 years ago. There is now public recognition that there is a myopia epidemic and that there is a pressing need to address and solve the problem.[4]

What is the reason for the increase? Genetics cannot change overnight. Something new has entered the picture. There has been a sudden and explosive growth of prolonged viewing of computer monitors by children in the past ten years. Children now routinely spend hour after hour viewing computer screens. Parents know that left to their own devices, children will spend hours surfing the internet, instant messaging, or playing video games. Uninterrupted sessions of five hours or more of computer viewing by children are not uncommon. The result is a spasm of the ciliary muscle in the eye, resulting in myopia.[5]

The effect of the age of computers on our children's eyes is a new and important fact. The FDA cannot be passive in the face of the epidemic. It has a responsibility, especially to our children.

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[3] *See* footnote 1.

[4] *New Scientist*, July 8, 2004, *www.newscientist.com/news/news.jsp?id=ns99996117*. Relevant studies confirming the epidemic and its causes include those conducted by Lin LL *et al* in Taiwan, and Au Eong KG *et al* in Singapore. Citations to the reports on these studies can be provided upon request.

[5] *See* Section F below.

The obesity epidemic crept up on us slowly and silently, but we have now come to recognize it as a serious public health problem. The myopia epidemic has also crept up on us slowly and silently, but we have not yet recognized it as a serious public health problem. The American public is completely unaware that myopia is an increasing epidemic and only a small percentage of the population realizes that myopia can eventually result in retinal detachment and other serious problems.

In this country, parents take for granted that myopia cannot be prevented in their children. As soon as their child's vision deteriorates, they run to LensCrafters or equivalent and obtain distance (minus) lenses for their children, not realizing that this only makes the myopia worse and that myopia can actually be prevented.

Optometrists and ophthalmologists are part of the problem. They have been content to prescribe and supply children with distance (minus) lenses without even mentioning the possibility of prevention or reduction of the myopic condition.

We need to break and change the mindsets of eye care professionals and the public. If this Petition is granted, we will move from an era of prescribing and selling distance (minus) lenses to children and adults with initial myopia to *eye care*.

## E. HOW MYOPIA DEVELOPS

Prevention requires an understanding of causes. We need to understand what causes myopia to develop in the first place and what makes it get progressively worse.

There is no doubt that as an eye becomes more and more myopic, it becomes more and more elongated. This has been confirmed by A-scan ultrasonography and other methods.

Figure 1 shows an eye that is highly myopic. Note how much the eye has become elongated compared to the round shape of a normal eye. Although not shown here, the coats of the eye become thinner as they stretch. This type of myopia is called *axial length myopia* because it clearly results from an abnormal increase in the length of the eye along its visual axis. It is associated with a prolonged increase of pressure in the vitreous chamber inside the eye.[6]

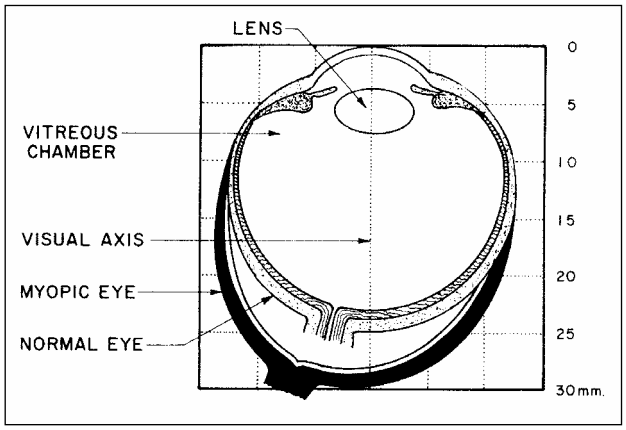


**Figure 1**

In fact, the eyes of most myopic people don't lengthen anywhere near the amount in Figure 1. A small change from the normal in the axial length of the eye along its visual axis is sufficient to cause blurring of vision. Note that the part of the eye in front of the lens does not change.

[6] See first report on COMET trial attached hereto at 1492 which measured the change in the axial length of the eyes of myopic children .

Myopia occurs in two stages:

1. The first stage is called *spastic myopia* and is reversible. It can be eliminated by removing the cause.

2. The second stage is the *axial-length myopia* mentioned above. It is irreversible.

Spastic myopia involves the lens and it precedes the development of axial-length myopia. The permanent stretching of the coats of the eye only occurs if the spastic myopia is permitted to exist for too long.

Our eyes have evolved slowly over many thousands of years and have become adapted to the world that we live in. However, there is one way in which they have not adapted well at all. Our eyes were intended to be used for distance vision with minimal close work. The invention of printing, the publishing of books, compulsory education, computers, and office work have imposed unprecedented demands on our eyes for prolonged close work. Our eyes were never designed for this type of use.

Normal eyes are at rest when looking into the distance. Looking at something close requires a strong focusing effort by the ciliary muscle which controls the shape of the lens of the eye. This puts the ciliary muscle under a more or less constant state of stress.

We can draw an analogy with weightlifting. By steadily increasing the weights used for training, the various muscles are repeatedly subjected to a condition of high stress. The muscles respond by getting bigger and stronger so that the work can then be done with less effort. In other words, the muscles adapt.

Something similar happens inside the eye during accommodation. The ciliary muscle doesn't get bigger or stronger - it develops a temporary spasm. This is the eye's adaptation to close work. If a lot of close work is done, this spasm may exist for months or years. We can use the expression *chronic ciliary muscle spasm* to describe this kind of spasm, to distinguish it from what we can call an *acute ciliary muscle spasm* that may develop for various other reasons.

It is the chronic ciliary muscle spasm that initiates a process whereby the eye elongates along its visual axis. As it becomes longer, it becomes more myopic. It becomes longer so that it does not have to work as hard to do the close work. Unfortunately, after the eye increases too much in length, it can no longer see clearly in the distance.

A ciliary muscle spasm does not develop in a few minutes or an hour and it cannot be eliminated in a short period of time. Accommodation must be maintained for long periods of time, day after day, before the spasm develops. To relax such a spasm, accommodation must be prevented or kept to a minimum for several weeks or longer.

The actual mechanism of eye elongation is as follows:

PROLONGED CLOSE WORK
*requires*
CONSTANT FOCUSING ON NEAR OBJECTS
*which causes*
CHRONIC SPASM OF THE CILIARY MUSCLE
*which causes*
IRREVERSIBLE STRETCHING OF THE COATS OF
THE EYE WHICH SURROUND THE VITREOUS CHAMBER
(over a period of time)
*which causes*
INCREASE IN SIZE OF VITREOUS CHAMBER
*resulting in*
A MYOPIC OR MORE MYOPIC EYE

Figure 2 shows the parts of the eye essential for this explanation. This is a normal eye making the necessary effort to focus a close object on the retina.

When viewed from the side, as in figure 2, the lens is seen to be thicker in the center than at the edge. It is this curved shape that enables the lens to bend light rays. The thicker the center is with respect to the edges (called the *periphery*), the more power the lens has and the more it will bend the rays passing through it. To focus close objects, the lens must be made thicker than is needed for focusing distant objects.

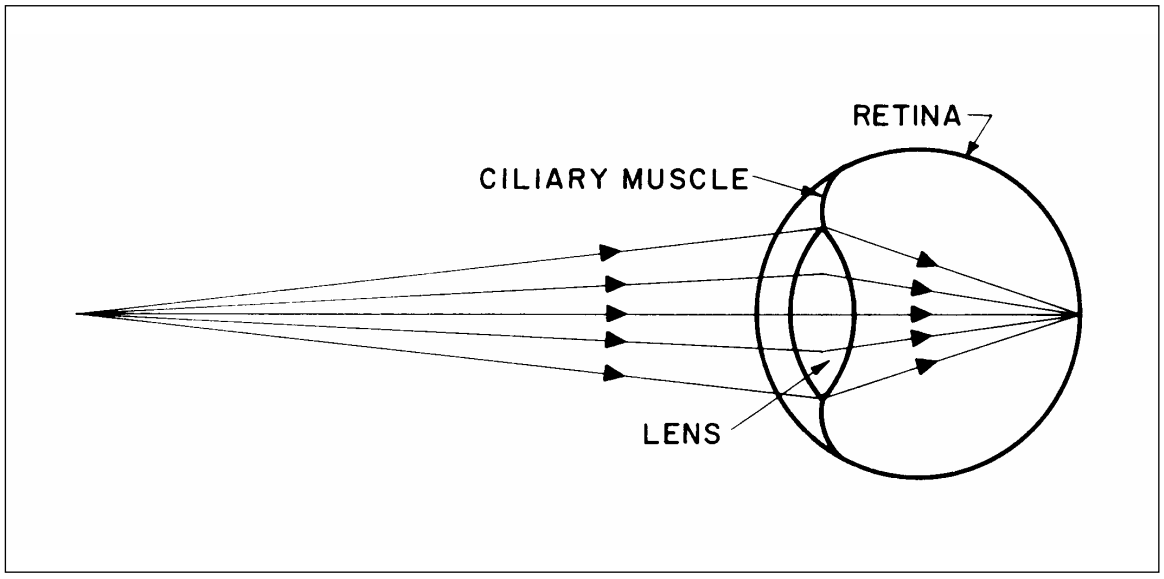


**Figure 2**

Figure 3 shows the lens viewed from the front. The shape of the lens is controlled by the ciliary muscle, which is located behind the iris. The ciliary muscle surrounds the lens in much the same way that a ring surrounds a finger. If the ring suddenly became smaller it would tighten around the finger. The ciliary muscle, when its circular fibers contract, tightens around the lens in a similar manner. The radial fibers are thought to aid in relaxing the muscle.

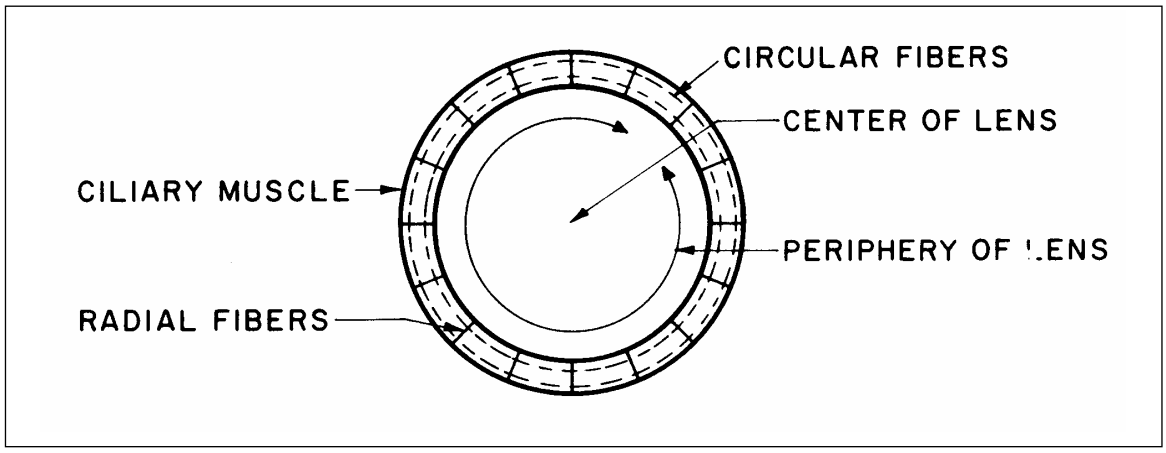


**Figure 3**

Referring to figure 4, note that the ciliary muscle passes through the suspensory ligament and attaches to the choroid, and that the choroid extends all the way around the vitreous chamber. The retina covers the inner surface of the choroid. When the ciliary muscle tightens around the lens, it causes the lens to bulge forward as indicated by the dotted line. This makes the lens more powerful and enables it to bend the light rays more.

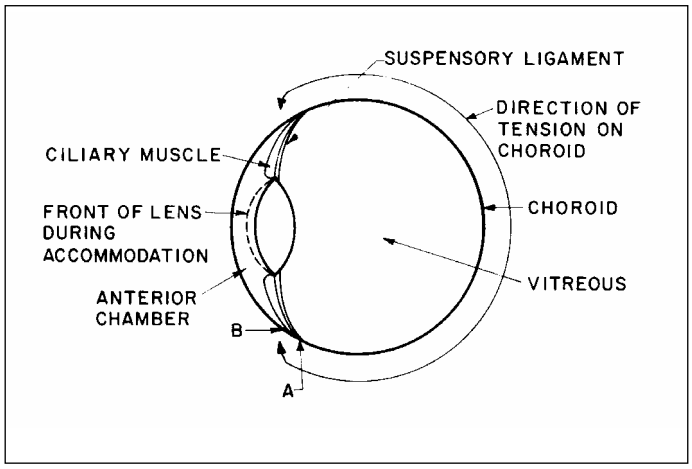


**Figure 4**

While the ciliary muscle is tightening around the lens, it is also putting tension on the choroid. Point A, where the ciliary muscle attaches to the choroid, is pulled forward to point B during accommodation. This tightening of the choroid around the vitreous chamber does not compress the vitreous fluid into a smaller volume (since liquids cannot be compressed as gases can), but it does cause an increase in the pressure in the vitreous chamber. When the pressure inside the eye (called *intraocular pressure*, or "IOP") is measured by conventional methods, instruments are used on the surface of the cornea that actually measure only the pressure in the anterior chamber. This is the method used to test for glaucoma. The pressure in the vitreous chamber can be much higher.

Tests on monkeys showed an increase in vitreous pressure of up to 6 mm Hg (six millimeters of mercury) during maximum accommodation. Since the normal IOP in these monkeys is on the order of 12 mm Hg, it can be seen that the pressure in the vitreous chamber can increase by 50% just by focusing on a close object. The pressure in the anterior chamber, conversely, does not increase during accommodation but actually decreases somewhat. The anterior chamber and the vitreous chamber are two entirely separate chambers.

During accommodation, the front of the vitreous body provides support for the rear of the lens as the ciliary muscle and choroid tighten. This tends to make the center of the lens bulge forward slightly into the anterior chamber and assists the ciliary muscle in making the lens thicker.[7]

It is the ciliary muscle pulling on the choroid that causes the eye to stretch. The rise in pressure is merely an indication of this pulling, not its cause. It is for this reason that squinting does not cause stretching of the eye, even though it can cause the pressure inside the eye to increase temporarily.

As the coats of the eye stretch over a period of time, additional fluid moves into the vitreous chamber to fill the increased volume. This fluid can come from the anterior chamber where aqueous fluid is continually being produced and from where it can also escape to the outside. It is for this reason that in high myopia the vitreous becomes more watery than normal.

If this great enlargement of the vitreous chamber in high myopia was due to heredity, one would expect to find the vitreous chamber filled almost entirely with the normal jelly-like vitreous material. The fact that we find a watery substance, in addition to the normal vitreous material, should make it obvious that this enlargement is not due to heredity, but that it is abnormal and due to some harmful influence on the eye.

A momentary increase in vitreous pressure does not mean that the eye will elongate. It is only after a ciliary spasm has developed and causes a chronic elevation of vitreous pressure that elongation occurs. The eye that does not develop this ciliary muscle spasm does not experience such overelongation.[8]

There is no known way to "shrink" the coats of the eye after they have been stretched. The situation is similar to some people in primitive societies who put weights on various parts of their bodies such as their ear lobes. Once these parts have been stretched, they will not return to normal even if the weights are removed.

Because of the irreversible nature of axial-length myopia, prevention is exceedingly important. The eye moves in only one direction - toward increasing axial length. However, the first stage of myopia - spastic myopia - is reversible by relaxing the

[7] D. Jackson Coleman, “Unified Model for Accomodative Mechanism,” American Journal of Ophthalmology 69 no. 6 (June 1970).

[8] Francis A. Young, “The Development of Myopia,” *Contacto* 15, no. 2 (June 1971).

spasm. *It is for this reason that children who have already become somewhat myopic can often be helped to regain normal vision rather quickly.*

Lengthening of the eyes due to close work is normal. It is not due to "weak eyes" or anything of the sort. In fact, the mechanism described above is meant to play an important role in the development of everyone's vision.

The growth of the eye that follows birth can be divided into two parts. The normal child is actually born farsighted. During the first three years, the growth of the eye is quite rapid and it attains near-adult size. This is called the *infantile* period and it leaves the eye still somewhat farsighted.

This is followed by much slower growth from age three to thirteen, called the *juvenile* or *definitive* period. During this period of slow growth, the "cushion" of farsightedness in the eye is used for the final refinements in the vision. This is a highly vulnerable period when maximum care must be taken to ensure that a child's eyes are not wrongly allowed to adapt to excessive close work at the expense of distance vision.

To see clearly, the farsighted eye of the child must accommodate even when used for distance. A ciliary spasm is *meant* to occur and reduce the farsightedness to near zero so that no (or very little) accommodation is needed for distance vision and the full amplitude of accommodation is available for close work. When this point is reached, the ciliary spasm is meant to relax of its own accord and halt the elongation of the eye. It is only when this process continues too far (because of an abnormal amount of close work), that the eye passes through the zero point into a myopic condition. The usual glasses that most myopic people wear actually make this process occur faster and go further than it otherwise would.

The eye is meant to attain its final size long before the body reaches its final height. In primitive societies where children are destined to do no significant amount of close work, the eye probably reaches nearly its final size not long after the age of three. The only reason that the eyes of many children in literate societies move into myopia and continue to elongate into the teens and twenties is that they do an abnormal amount of close work.

## F. MYOPIA IS CAUSED BY PROLONGED CLOSE WORK

As far as optometrists and ophthalmologists in this country are concerned, the "accepted" or "official" position is either that myopia is hereditary or that the cause or causes of myopia have not been determined. By taking this position, they do not feel constrained to help consumers prevent myopia. Any deviation from this strict orthodoxy is treated as heresy.

It would come as a surprise to most consumers to hear that there is still an active debate about the cause of myopia. One would have thought that something so basic and easily researchable would have been long-settled by now. *In fact, the overwhelming cause is now known and understood and beyond any reasonable dispute. Prolonged close work causes myopia.*

In Singapore, the vision of 421,116 males between the ages of 15 and 25 was examined. In 1974-84, 26.3% were myopic; in 1987-91, 43.3% were myopic. Both the prevalence and severity of myopia were substantially higher as the level of education increased. The prevalence rate was 15.4% in males with no formal education and increased steadily through the education levels to reach 65.1% among the university graduates in 1987-91. This huge sampling conclusively proves, beyond any doubt, that prolonged close work, including reading and computer usage, causes myopia.[9]

This conclusion has been confirmed by recent research reported in the July 10, 2004 edition of *New Scientist* in an article entitled "Lifestyle causes myopia, not genes."[10] Here is an extract from the article:

> Contrary to popular belief, people in east Asia are no more genetically susceptible to short-sightedness than any other population group, according to researchers who have analyzed past studies of the problem.
>
> The epidemics of myopia in countries such as Singapore and Japan are due solely to changes in lifestyle, they say, and similar levels could soon be seen in many western countries as lifestyles there continue to change.
>
> "As kids spend more time indoors, on computers or watching [television], we are going to become just as myopic," says Ian Morgan of the Visual Sciences Group at Australian National University in Canberra.

[9] M.T. Tay, K.G. Au Eong, C.Y. Ng and M.K. Lim, "Myopia and Educational Attainment in 421,116 Young Singaporean Males," Ann. Acad. Med. Singapore, 1992, Nov;21(6):785-91.

[10] *See www.newscientist.com/news/news.jsp?id=ns99996117*.

> Myopia is on the increase in most places, but in countries such as Singapore it has reached extraordinary levels. There, 80 per cent of 18-year-old male army recruits are myopic, up from 25 per cent just 30 years ago.
>
> Employers such as the police are having problems finding people who meet their requirements. There is also an increasing incidence of extreme myopia, which can lead to blindness.
>
> There is little doubt about at least one underlying cause. Children now spend much of their time focusing on close objects, such as books and computers. To compensate, the eyeball is thought to grow longer. That way less effort is needed to focus up close, but the elongated eye can no longer focus on distant objects.
>
> The argument is about why the rate of myopia is so much higher in east Asia than elsewhere. The conventional view is that people from the region have genetic variations that make them more susceptible. But after reviewing over 40 studies, Morgan and Kathryn Rose of the University of Sydney argue that there is no evidence to support this.
>
> The pair, whose work will be published in Progress in Retinal and Eye Research, use several lines of evidence to debunk the idea that genes can explain the Asian epidemics. For instance, 70 per cent of 18-year-old men of Indian origin living in Singapore have myopia, while in India itself the rate is roughly 10 per cent.
>
> Another study found myopia rates of 80 per cent in 14 to 18-year-old boys studying in schools in Israel that emphasize reading religious texts. The rate for boys in state schools was just 30 per cent.

In another study, researchers at Spain's Complutense University found that 31.3% of first-years were nearsighted. Among those four to six years older, in their final year, the rate was 49%. Research author Dr. Rafaela Garrido, who presented her findings to the 10th International Myopia Conference in Cambridge in July 2004, says:

> Some students are spending too long in intensive near work with their eyes. It is also a problem with people who spend too long on a computer or using a microscope. It's difficult to ask students to do less reading, as it is

essential to passing courses, *but we have to find ways to deal with the stress on the eyes*. (Emphasis added.)[11]

One of the saddest realities of contemporary "eye care" is that although there are a few vision specialists with at least a moderate interest in the cause and prevention of myopia, most of their colleagues show not the slightest interest in this work. They continue to claim that no one has ever *proven* that acquired myopia is not inherited, and that there is therefore no reason to believe that this problem can be prevented. It is difficult to understand how this hereditary theory can still persist in spite of decades of research proving beyond doubt that prolonged close work causes myopia.

Myopic parents do tend to raise myopic children, and for that reason it has therefore often been stated that heredity is the most important single factor in the cause of myopia. However, this tendency can be explained in another way. In those families where the parents are well educated and do considerable reading, the children will normally be well educated and do much reading also. The myopia of the children is not inherited but acquired, because they follow the training and example of their parents. Heredity can be a factor to the degree that reading ability or the desire to read is inherited, but it is the reading, not the hereditary factor, which is the cause of myopia.

Some people do not become myopic, even if they do prolonged close work. Even if there is a genetic factor *preventing* myopia in such people, that is not the same as saying that genetics *cause* myopia to occur. In the absence of prolonged close work, very few people will develop myopia.

The latest research makes it quite clear that acquired myopia develops from excessive accommodation. Myopia is therefore most common in advanced, literate societies and is rare in primitive, illiterate societies.[12] This is not to say that an illiterate person could not develop myopia. Even an illiterate person might be spending hours each day in some form of close work requiring excessive accommodation that could lead to the development of myopia.

If myopia is inherited, we would not have seen the tremendous increase in myopia that has occurred in recent decades. Genetically determined changes do not occur so rapidly.

At one time, most of the lenses produced by optical companies were plus lenses to correct hyperopia or presbyopia. Minus lenses to correct myopia made up only a small percentage of their production. Now this situation has reversed, and far more minus lenses than plus lenses are produced. This cannot have been caused by a genetic change.

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[11] *See http://news.bbc.co.uk/1/hi/education/3907893.stm*.

[12] William R. Baldwin, Some Relationships Between Ocular, Anthropometric, and Refractive Variables in Myopia, Ph.D dissertation, Indiana University, 1965 (Ann Arbor, Mich.: University Microfilms)].

Dr. Francis Young has performed invaluable research that confirms beyond any doubt that myopia is not hereditary. Dr. Young was the director of the Primate Research Center in Pullman, Washington for many years starting in 1957 and has had more than eighty-five scientific papers published, many of them on the cause of myopia. By pointing out the errors of some earlier researchers and by systematically seeking the facts, Young put together an accumulation of knowledge about myopia that is of tremendous importance. His many years of research have produced irrefutable evidence that there is no truth to the old belief that heredity is the cause of myopia. However, he has yet to receive adequate recognition and praise from the scientific community for his years of effort. Furthermore, his work has been mostly unknown to the public.

The work that he and his colleagues have performed falls into several categories. Some of these are: (1) the study of the development of myopia in monkeys; (2) the incidence of myopia in the Eskimos of Barrow, Alaska; and (3) vitreous pressure measurements.

### The study of the development of myopia in monkeys

The word "primate" refers to a group of animals having similar characteristics, and to which both monkeys and humans belong. Since certain monkeys, such as chimpanzees, have eyes that are almost identical to human eyes, tests can be conducted on these monkeys that would be impractical to conduct on humans.

By using a hood to restrict the vision of monkeys so that they could not see more than fifteen inches (38 cm) from the eye, in other words forcing prolonged close focusing, it was found that most of them develop myopia after a few months' time, just as humans do.[13] Monkeys living in the wild, on the other hand, do not develop myopia.[14]

The experiments also showed that the greatest amount of myopia developed when the level of illumination was around four foot-candles (which is relatively dark). At four foot-candles, there is maximum accommodation.[15]

It was also found that the juvenile monkeys did not begin to develop myopia as soon as the adult monkeys did under the test conditions. However, once the myopia began to develop, it progressed much faster in the juvenile monkeys than in the adults.

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[13] Francis A. Young, "The Development of Myopia," *Contacto* 15, no. 2 (June 1971).

[14] "Visual Refractive Errors of Wild and Laboratory Monkeys," E*ye, Ear, Nose, and Throat Digest* 27 (August 1965).

[15] Below four foot-candles, there is not enough light for the eye to focus properly and the eye does not make the attempt to focus or exert full accommodative effort. Above four foot-candles, the eye is able to focus and exert accommodative effort. As the light level increases still further, the eye needs to accommodate less and less because the pupil becomes smaller and the periphery of the lens is not used.

This indicates that a ciliary spasm is of greater magnitude in the younger individuals than in the older ones.

In order to confirm that prolonged accommodation was causing these myopic changes, a group of primates was placed under the hoods for four months until they were showing a change into myopia. At this point, the monkeys were left under the hoods but a drop of one-percent aqueous atropine was placed in each monkey's eyes every morning and evening. Atropine is a drug that paralyzes the ciliary muscle and makes accommodation impossible for as long as the treatment is continued. In using this drug on humans it has been found that it results in a reduction in the amount of myopia measured and a cessation in the progress of the myopia while the treatment is continued. This was found to be true with monkeys also. The amount of myopia was reduced by about 0.5D, and no further myopia progression was observed, showing that reducing accommodation reduces myopia.

All of the monkey studies clearly indicate that between 75% and 85% of the monkeys showed myopic changes, and the remaining 15% to 25% did not. The first stage is the development of a spasm of accommodation. Once the spasm develops, it is followed within two to four months by an increase in axial length. Some animals do not seem to develop this spasm and consequently do not experience axial-length myopia.

Since those animals that do develop myopia experience fairly high degrees of myopia (up to 7 or 8D) with corresponding axial-length increases of several millimeters, the effect of prolonged accommodation on the development of myopia is unmistakable.

### The study of Eskimos in Alaska

Dr. Young and his colleagues traveled to Barrow, Alaska, where they examined the vision of the Eskimo families.[16] The older generation had never attended school and was illiterate, while the younger generation had attended school and was literate. The older generation lived the typical outdoor Eskimo life with little close work. This then was a perfect opportunity to test the hereditary or genetic theory of myopia. If the hereditary theory was true, then there should be a similar amount of myopia in the children and in the parents in spite of the great difference in the amount of close work done by the two groups. Actually, just the opposite was found.

Of 130 parents, only two showed any myopia. One had -0.25D and one had -1.5D. All the rest had refractive errors between 0 and +3D. In other words they were somewhat *farsighted*, which can be considered normal.

As for the children of these non-myopic parents, a totally different picture was found. Fully 60% the school children examined showed measurable amounts of myopia. Of the fifty-three individuals who were between 21 and 25, 88% percent were myopic. There was a beginning of myopia generally at about age ten, with a steady increase in

[16] Francis A. Young et al., "The Transmission of Refractive Errors within Eskimo Families," American Journal of Optometry and Archives of the American Academy of Optometry 46, no. 9 (September 1969).

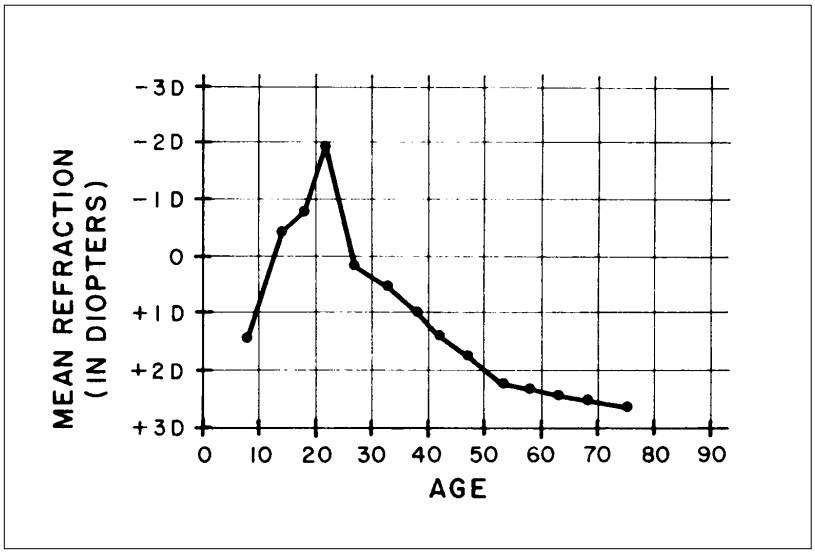


**Figure 1**

the proportion of the children showing myopia up to ages 21 to 25. This is shown in graph form in Figure 1. It is obvious that these myopic children did not inherit the myopia from their parents.

## Vitreous Pressure Measurements

In order to prove that a pressure increase in the eye could occur in a monkey merely by the act of accommodation, a pressure-sensitive transmitter was developed.[17] This is a small drum about the size and shape of an aspirin tablet that contains two flat wire discs separated by an air gap. An increase in pressure on the surface of the drum causes the discs to move closer together. Decreases in pressure cause the discs to move farther apart.

When an outside radio-frequency source is directed at the eye, the signal is amplified or attenuated according to the degree of separation between the two discs. The transmitter is surgically placed (under anesthesia) in the vitreous chamber of monkeys. When the monkeys have recovered from this simple procedure, it is then possible to measure changes in vitreous pressure without such artificial attachments as wires or needles and without the requirement of anesthesia. It is merely necessary to restrain the monkey's head during the measurements so that the radio-frequency source can be brought close enough to the eye (about two or three centimeters).

Studies with these monkeys have shown that the vitreous pressure is least when they are focusing on a distant object and that the pressure increases steadily as the object approaches the eye. The maximum increase is about 6 millimeters of mercury above the normal 12 millimeters of mercury. These studies thus show that there is a direct relationship between fixation distance and vitreous pressure; in other words, a tightening of the ciliary muscle.

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[17] Francis A. Young, :The Development and Control of Myopia in Human and Subhuman Primates," *Contacto* 19, no. 6 (November 1975).

### Conclusions to be drawn from Young's work

From these and his many other studies on both humans and monkeys, Young concluded: "It appears quite clearly that myopia results from a continuous level of accommodation, and if one prevents this continuous level of accommodation from occurring, very little myopia, if any, should occur."[4] This has nothing to do with genes.

Even if there is a genetic influence, Dr. Ian Morgan Visual Sciences Group at Australian National University in Canberra. states that the massive amount of close work that we do "is swamping out the genetic influence."[18]

### A compelling example disproving the genetic theory

There is a person whose is available for testing. He is living proof that the genetic theory of myopia is wrong. He has a congenital cataract on his right eye. He primarily uses his left eye for reading, not his right eye. He often spends ten hours per day on the computer and reading documents.

His eyes were tested in 2002 when he was 47 years old. The left (reading) eye was measured at -5.75D, while the right (non-reading) eye was measured at -1D. Clearly, genetic factors did not cause the myopia in the left eye to be 4.75D worse than the right eye. He has one set of genes, but two radically different degrees of myopia. It is quite obvious that accommodation caused the myopia in the left eye, not genes.

[18] *http://www.newscientist.com/news/news.jsp?id=ns99996117*.

## G. DISTANCE LENSES WORSEN MYOPIA BECAUSE THEY MAKE OBJECTS APPEAR TO BE CLOSER, THEREBY SIMULATING PROLONGED CLOSE WORK

Myopic people require *concave* or *minus* lenses to give them clear distance vision. Figures 1 and 2 show two forms of minus lenses. Both lenses are thinnest in the center and thickest at the outside or periphery.

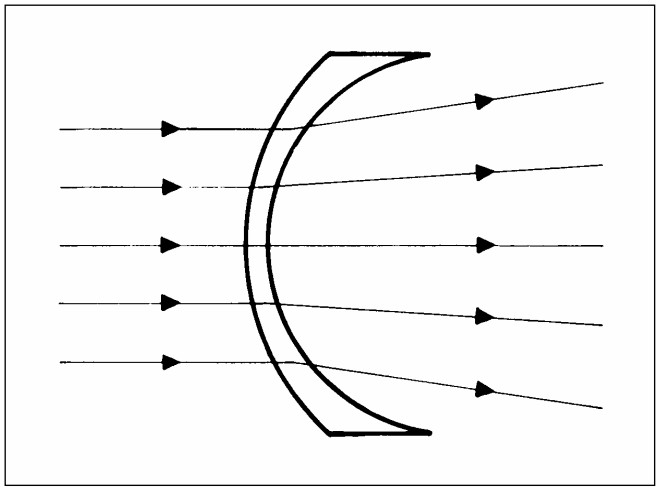

**Figure 1**

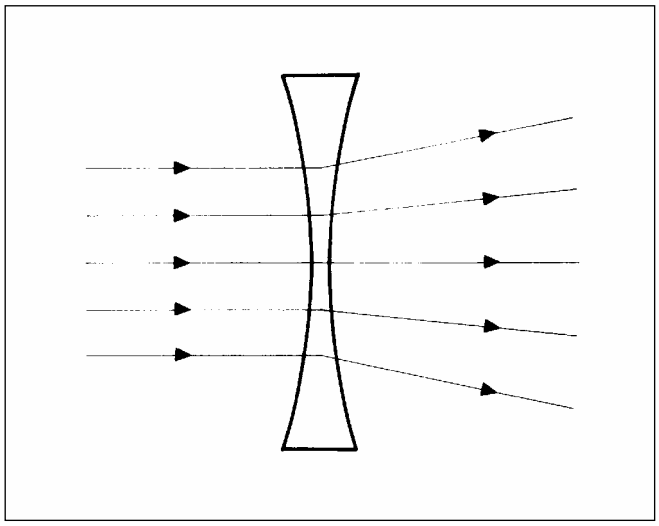

**Figure 2**

Figure 1 shows the shape of the lenses usually used for eyeglasses or contact lenses. Figure 2 is a simplified version, which we will use for the diagrams that follow. A minus lens causes rays to diverge as figures 1 and 2 indicate.

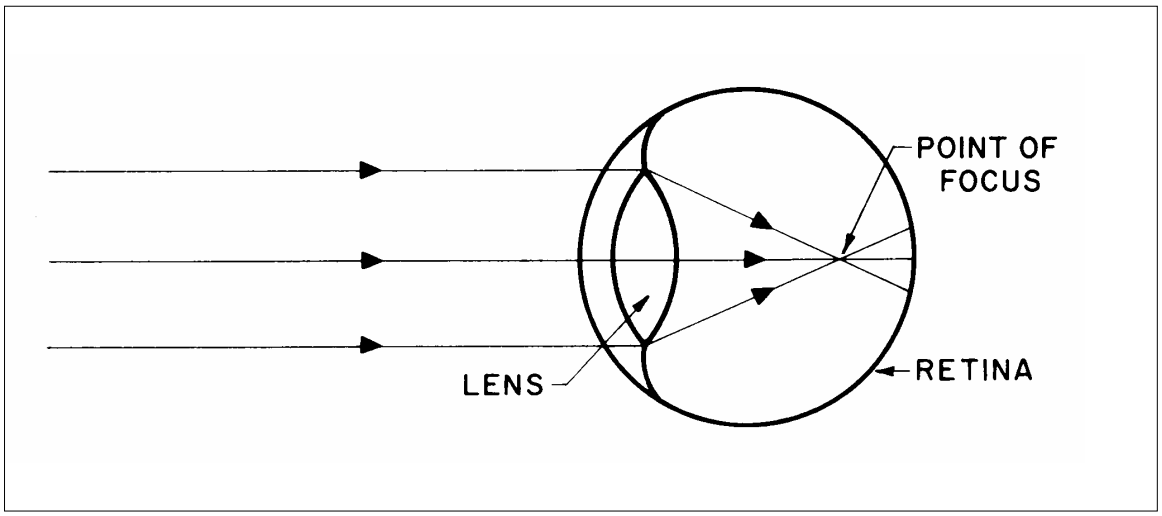


**Figure 3**

Figure 3 shows a myopic eye in which the amount of myopia is exaggerated for the purpose of illustration. As a result of the ciliary spasm caused by excessive accommodation, the lens cannot relax sufficiently to enable the parallel rays from a distant object to come to a focus on the retina. The object appears blurred.

Spectacles with distance (minus) lenses are then fitted. Figure 4 shows what happens.

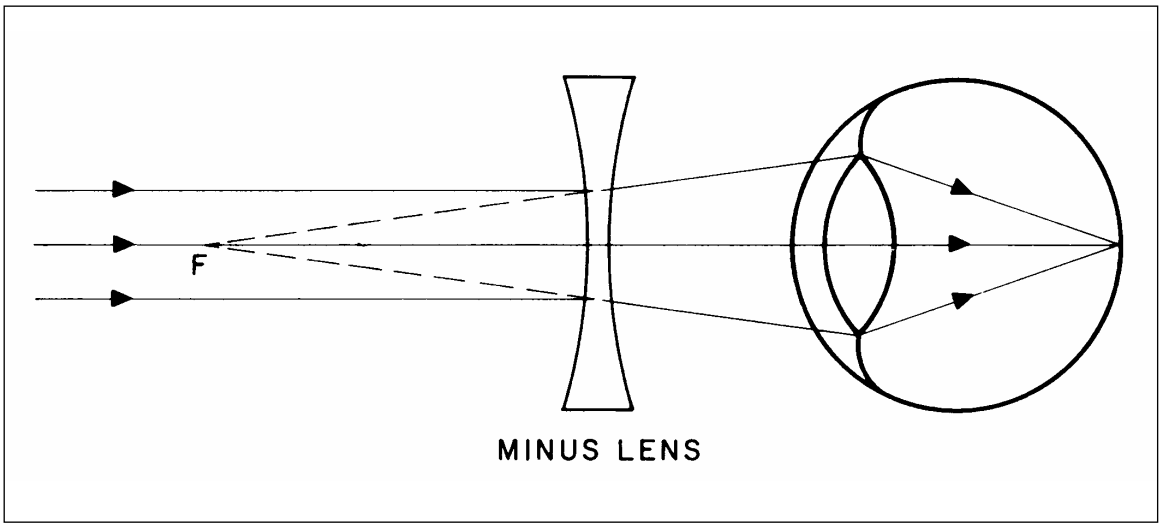


**Figure 4**

Such lenses cause the parallel rays to diverge just enough so that the eye can focus them on the retina. They make the eye feel (with regard to focusing effort, at least) that the viewed object is actually closer than it is. In fact, point F is where the viewed object appears to be. F is also the *focal point* of the lens. *Minus lenses thus move the world closer to the eyes*. Since the cause of myopia is too much close work, it is obvious that such lenses, by forcing the eye to do even more close work, will only *increase* the myopia.

Most of the damage occurs when such distance (minus) lenses are used for reading. Many people use their distance glasses for reading even though they could read without them, merely because the optometrist or ophthalmologist has never advised against it. There are also many people who must use their glasses for reading or viewing the computer monitor because their myopia has progressed to the point that if they remove their glasses they will find that even the reading material or monitor screen is blurred. Their *far point,* or limit of clear vision, is not far enough to reach the reading material or computer monitor.

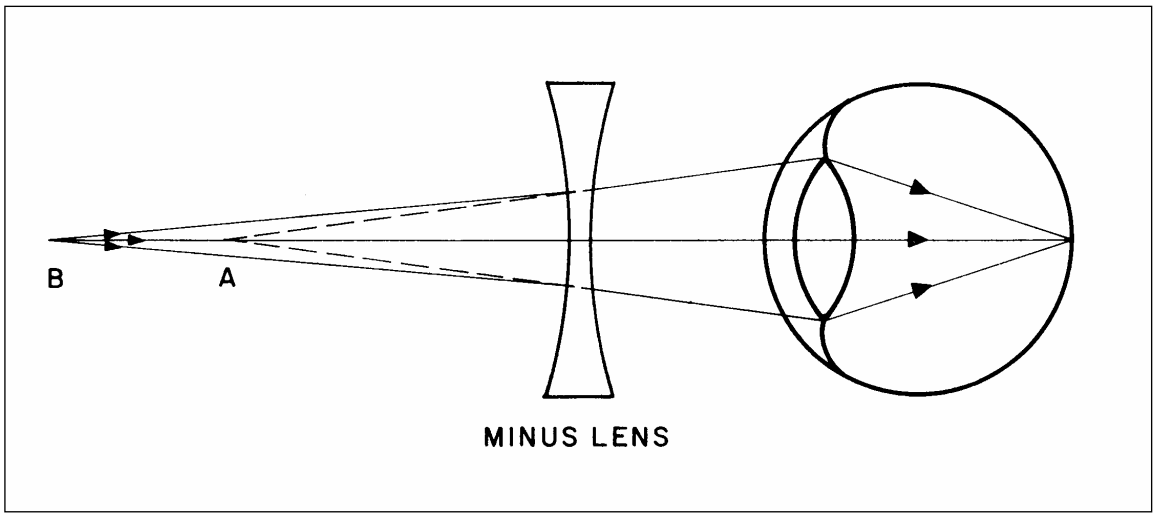


**Figure 5**

Figure 5 shows what happens when distance (minus) lenses are used for reading. The book, actually located at B, now appears to be at A which is closer to the eye. Now the eye, instead of focusing on the book at B, must accommodate more and focus at A. This simple fact explains why such distance (minus) lenses are so harmful.

*A vicious cycle now develops. The distance (minus) lenses bring everything closer, making increased accommodation necessary. The increased accommodation causes further lengthening of the eye with the resulting need for even stronger and stronger glasses as time goes on.*

If distance (minus) lenses were never prescribed, the myopia would only increase to the point where the usual close work could be done without the need for accommodation. There it would cease at a moderate amount, perhaps no more than 3D.

The present, almost universal, practice of not warning children against reading with concave distance (minus) lenses is ruining the vision of millions of children.

Figure 6 shows very approximately the percentage of myopic persons at various ages in the United States.[19] It is easy to see that the great increase in myopia begins during the early school years. When the school years are completed, the increase levels off. The reason is that if a person is going to develop myopia, it will usually have developed by the time adulthood is reached. Also, it is during the juvenile years, when the eyes are most flexible, that prolonged close work has the most damaging effect on the lengthening of the eyes. In adulthood, the coats of the eyes seem to lose much of their flexibility and do not stretch as readily as in earlier years.

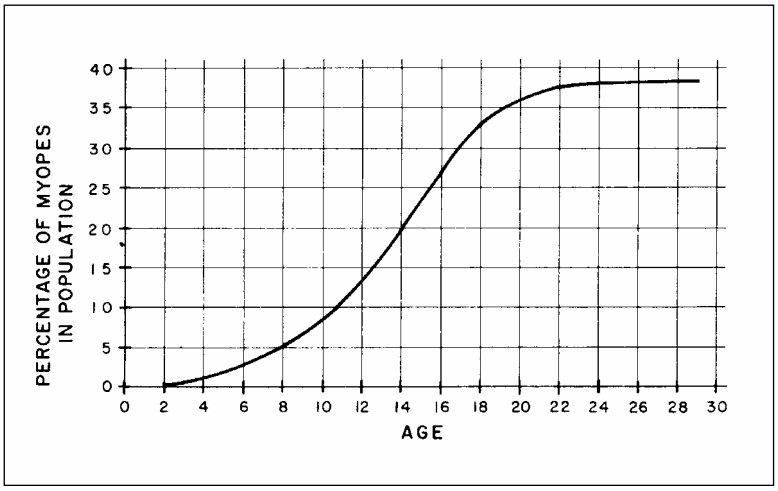


**Figure 6**

A small number of people do find their myopia increasing through adulthood. These are usually people who have become myopic at an early age and found their myopia rapidly increasing over the years. It may be that the coats of their eyes have become so stretched and so thinned an early age that they do not attain the strength of the normal adult eye. The coats of the eyes continue stretching from the stress of continued close work. Or, there may be other reasons, as yet unknown, why their eyes are unable to withstand the stress of close work as well as most adult eyes. Some doctors choose to call this *pathological myopia*, meaning that it is somehow different from simple myopia. There is, however, no basic difference. Both are simply *acquired myopia*.

If we were to draw a graph showing the rate at which a typical person becomes myopic, it would look quite similar to the one shown in figure 6. It would only be necessary to rename the vertical axis, as in figure 7, to read "amount of myopia" instead of "percentage of myopes in population."

[19] William R. Baldwin, Some Relationships Between Ocular, Anthropometric, and Refractive Variables in Myopia, Ph.D dissertation, Indiana University, 1965 (Ann Arbor, Mich.: University Microfilms).

The harmful effect of distance (minus) lenses is easy to demonstrate. If a myopic child is given distance (minus) lenses to read with for, say, thirty minutes, the distance vision after removing the glasses is often found to be appreciably worse than before. The vision can be tested before and after the experiment by using an ordinary wall chart. In other words, the eyes have adapted to the distance (minus) lenses by temporarily becoming more myopic. If this type of eye abuse is continued long enough, the distance vision will be permanently damaged.

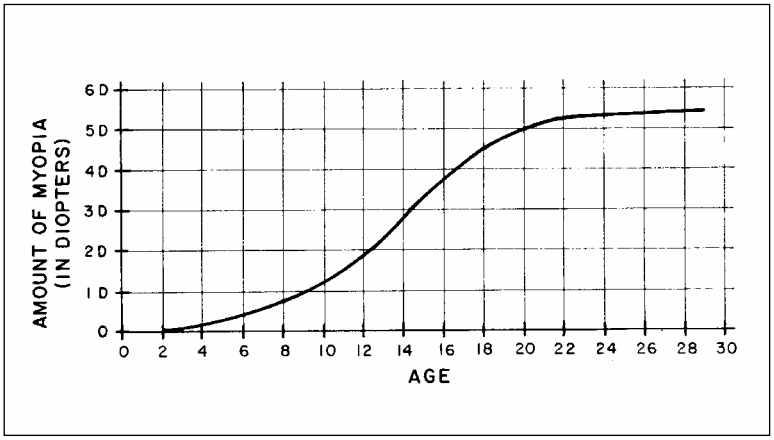


**Figure 7**

Distance (minus) lenses are “addictive” in that their use results in an ever-increasing dependency and a need for stronger and stronger lenses to achieve the same effect. Trying to withdraw from this “addiction” is futile since the eye will not return to its original shape.

Reading with distance lenses obviously tends to make the vision get worse, particularly in children. If the reading is done under conditions of poor lighting, the vision will generally deteriorate faster than if good lighting is used. The following diagrams will make clear why this is so.

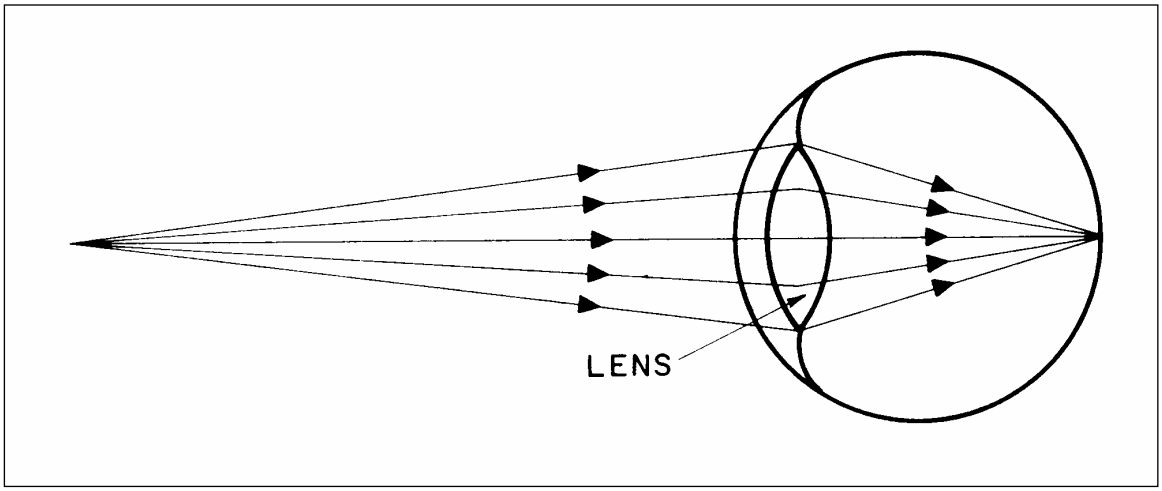


**Figure 8**

Figure 8 represents an eye where the pupil is very large (as it would automatically become under poor lighting), and the entire lens is being used to receive light rays. It is apparent that those rays farthest from the center of the lens must be bent more than those close to the center. In fact, the ray of light passing through the center of the lens does not have to be bent at all.

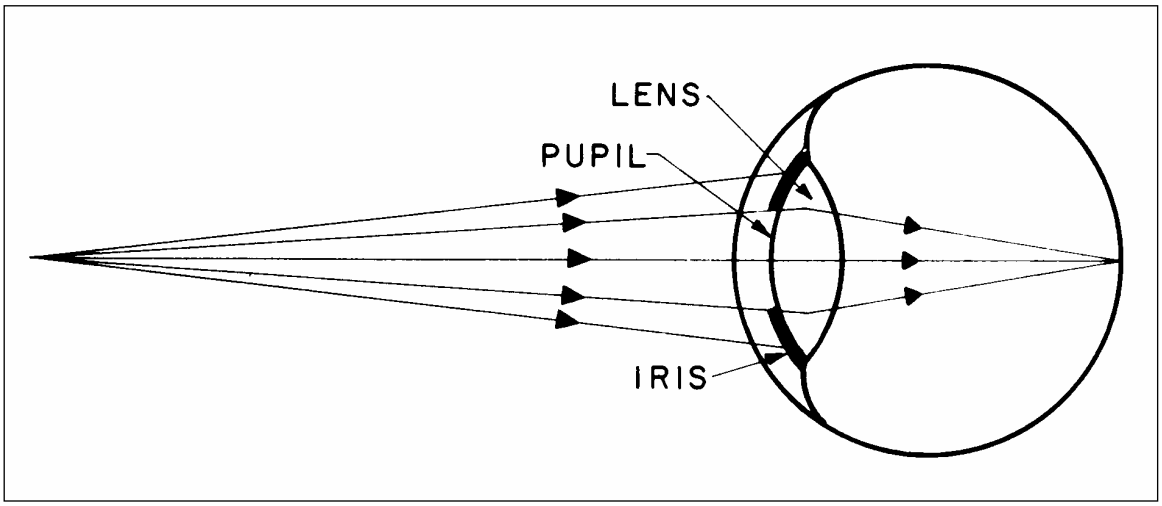


**Figure 9**

Figure 9 represents an eye that is being used under a high amount of illumination. The iris has contracted, making the pupil quite small. The periphery, or outer portion of the lens, is not being used. The only light rays passing through the lens are those near the center, which require little bending, while the most divergent rays do not reach the lens at all.

What this means is that the eye does not need to accommodate nearly as much when viewing an object in bright light as it does in poor light. It has long been recognized that the brighter the illumination, the less the accommodation. This is extremely important to the myopic person, since excessive accommodation is at the heart of the myopia problem.

## H. MYOPIA MAY RESULT IN RETINAL DETACHMENT AND OTHER PROBLEMS

Myopia may lead to serious problems in later years. Large numbers of people lose their sight each year due to complications of myopia.

Professor E. S. Perkins, a researcher with the department of ophthalmology at the University of Iowa, found that myopia was the fourth major cause of blindness, following senile macular degeneration, cataract and glaucoma. Myopia was the most common cause of blindness in age group 50-59. In age group 60-69, it was second only to diabetic retinopathy, but was considerably more important than that disease in terms of years of blindness.[20]

Few myopic people, faced with the prospect of blindness in old age, realize that their problems actually began in childhood when they were fitted with that first pair of distance (minus) lenses by someone who was unconcerned about the long-range results of that action.

### Retinal detachment

The lack of preventive measures coupled with the prescription of stronger and stronger distance (minus) lenses causes the eye to stretch more than it was ever designed to do. Any overelongation of the eye increases the risk of retinal detachment in later years. About one-third of retinal detachments are caused by myopia.

Of the three layers at the rear of the eye, the sclera (the outermost layer) and the choroid (the middle layer) are fairly elastic and can withstand considerable stretching without damage. However, the retina (the innermost layer) is fragile and relatively inelastic and will tear loose from its attachment to the choroid if the eye is stretched too much. This can happen slowly, or spontaneously as the result of a blow to the eye or head.

Methods are available to try to reattach the retina, but they are generally unsatisfactory. Even if a successful reattachment is made, further elongation of the eye can result in a second detachment.

### Macular degeneration

We know that the eye can get larger in advanced myopia. Note that it is only the vitreous chamber that enlarges. The front of the eye remains unchanged. Because of this stretching, the sclera can, in extreme cases, be reduced to one-quarter or less of its original thickness. At some point during the enlargement of the eye, a pathological state begins to develop. That is, we are no longer dealing with a case of simple myopia, but with a diseased eye. Among the main changes are generalized atrophy of the retina and choroid, and degeneration at the point where the optic nerve leaves the eye and in the macular area (where the fovea is located). Hemorrhages can occur at various places. Because of the atrophy at the fovea, central vision begins to be lost.

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[20] *Morbidity from Myopia*, Sightsaving Review (Spring 1979).

Similar mechanical and degenerative changes occur in the vitreous. Since the vitreous has become quite watery, large floating spots of degenerative material can be easily seen. The tearing and hemorrhaging of the retina lead to retinal detachment, allowing the watery vitreous to flow between the retina and choroid. The watery condition of the vitreous thus aggravates the tendency toward detached retina. If actual detachment does not occur, the degenerative changes can progress slowly until no useful vision remains. In either case, blindness often results.

### Aggravation of problems after cataract surgery

Many people develop cataracts in their later years. A cataract is a clouding of the lens of the eye that can progress to the point where light can no longer pass through the lens and the eye is totally blind.

When the metabolism of the lens becomes faulty, the lens fibers can become swollen or distorted, and gaps filed with fluid and debris form among them. When these degenerative changes begin to cause the incoming light to scatter rather than be transmitted, the person is said to have a cataract. The only solution at present is the surgical removal of the lens and the use of strong glasses, contact lenses or lens implants to compensate for the loss of the lens. Replacing the lens of the eye with an artificial lens risks infection or other complications, possibly resulting in blindness.

Both time and patience are required after surgery in order to adapt to the restored vision. If an artificial lens is not implanted, thick, heavy glasses must be worn to compensate for the lens that has been removed. Such glasses cause considerable distortion of the surrounding world, increased magnification of the image on the retina, decreased depth perception, and disturbances of the field of vision. Some people require many months to adapt to these effects and others never learn to tolerate them.

As aggravating as these problems are, they are almost insignificant when compared with the more serious problem that awaits many of these people. It is not widely known among the public that cataract surgery, by its drastic alteration of the tissues and of the hydraulic forces inside the eye, predisposes that eye to tearing or detachment of the retina. The typical person who suffers through two cataract operations, believing that they will result in clear vision from then on, may be totally ignorant of the fact that the operations can set up conditions that frequently result in serious retinal problems a few years later.

While this situation is bad enough for the non-myopic patient, a considerably worse situation exists for the moderate or high myope. The eye that has become overelongated and myopic from years of using distance (minus) lenses is predisposed to retinal deterioration even *before* cataract surgery. If the lens of such an eye is removed, this tendency is increased even further.

The fact that so many people develop cataracts is yet another reason why myopia must be prevented in our children. They will then have a better chance of avoiding blindness if a cataract operation should ever be required. Even a small amount of

myopia, if allowed to develop, unnecessarily increases the already present danger of retinal problems in those who undergo cataract surgery.

## Floaters

In the non-myopic eye, the vitreous chamber normally contains only a semi-solid, jelly-like substance called the vitreous body. Since the vitreous body fills the space between the lens and the retina, it provides solid support for the retina.

As myopia develops and the eye becomes longer than normal, the volume of the vitreous chamber becomes greater. Since the vitreous body is more firmly attached to the lens than to the retina, the support it provides for the retina becomes diminished. The vitreous becomes more watery, further decreasing retinal support. These changes, coupled with the stretching of the retina, make retinal detachment more likely in the myopic person than the non-myopic person.

Because of this watery substance in the vitreous chamber, myopic persons are more likely than non-myopic persons to be disturbed by floaters. These are odd-shaped spots that appear to float and jump around in the field of vision, particularly when looking at a white surface and making sudden eye movements. These particles are located in the vitreous chamber. They may have been present from birth and can occur in both myopic and non-myopic eyes. Others may develop during the myopic elongation of the eye. Usually, the floaters are not a cause for concern and they may not even be noticed most of the time. However, the watery vitreous of myopic eyes enables the particles to move around more easily, and they are thus more noticeable and disturbing than in non-myopic eyes.

People who ask their doctors about the "spots" they sometimes see are usually not told that the problem frequently arises only because myopia has been allowed to develop. Furthermore, if the floaters are increasing in number, this could be a sign that the myopia has progressed to the point where degenerative processes are taking place at the surface of the retina, and the particles of material resulting from this degeneration are leaving the retina and passing into the watery vitreous. A large number of floaters can thus be a sign that a retinal detachment is about to occur.

## I. PERSONS WITH INITIAL MYOPIA SHOULD BE PRESCRIBED READING (PLUS) LENSES FOR PROLONGED CLOSE WORK AND TAUGHT PROPER READING HABITS TO REDUCE OR PREVENT MYOPIA. DISTANCE (MINUS) LENSES SHOULD NOT BE PRESCRIBED UNLESS PREVENTION IS UNSUCCESSFUL

Reading glasses are convex (plus) lenses. By making the light rays less divergent, these glasses reduce the amount of accommodation required and lessen the likelihood of a ciliary spasm developing. *If strong enough lenses are selected, all the accommodation can be eliminated and the eyes will be completely focused for distance.*

Figure 1 shows how this happens, using an emmetropic or normal eye as an example. This helps the lens of the eye (also convex) to do its work more easily and with less accommodative effort to bring these rays to a focus on the retina.

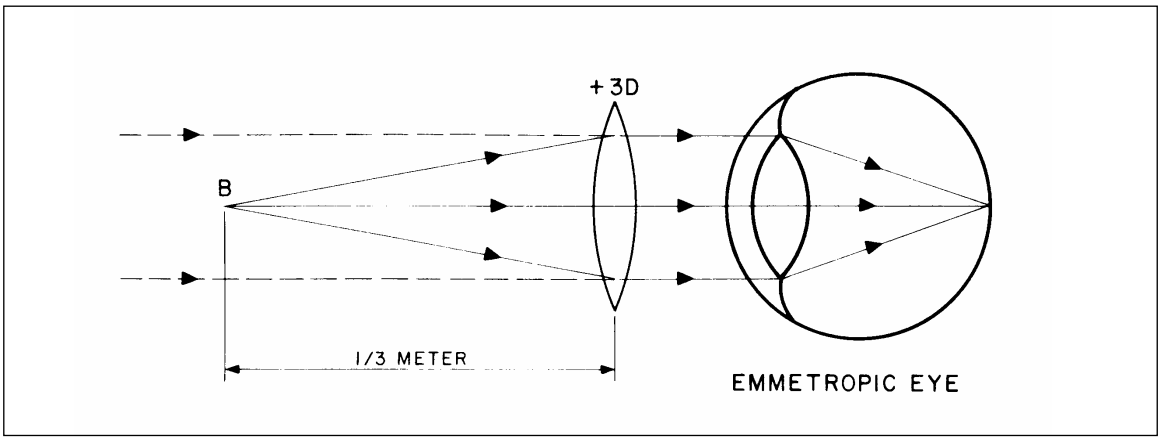


**Figure 1**

Suppose that the book is normally held at about a distance of one-third meter from the eyes, at B. Since a +3D lens has a focal length of one-third meter, if it is placed in front of the eye it will make the diverging rays become parallel before entering the eye. The dotted lines show that the eye is receiving parallel rays as if from a distant object. Thus, this eye can read without accommodation. This is called *reading at the far point*.

Now suppose that the book is pushed just a little farther away from the eyes so that it becomes a little blurred. Figure 2 shows this situation.

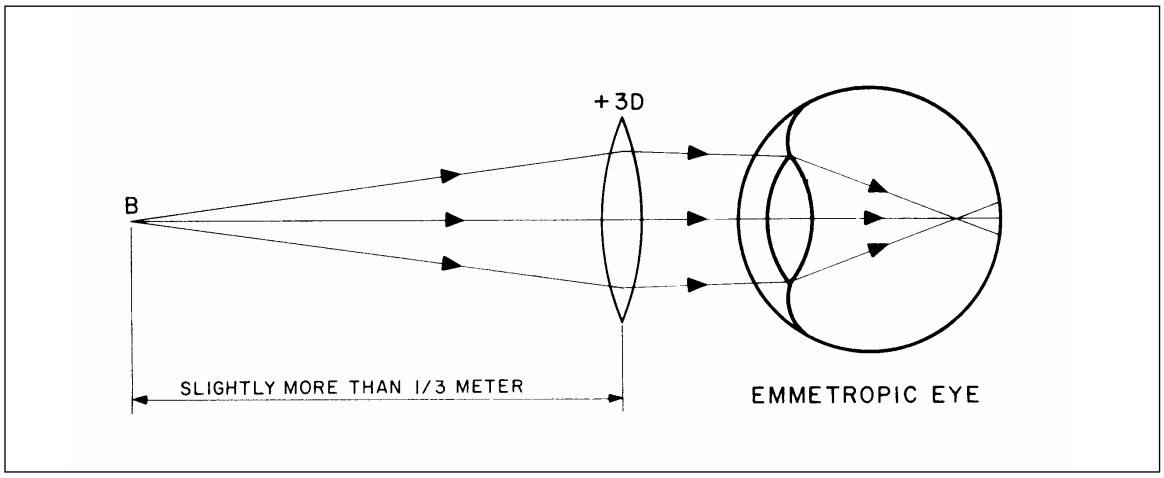


**Figure 2**

Now the eye is receiving converging rays, something which does not normally occur in everyday life. Only optical lenses make this possible. Notice that the lens of the eye is fully relaxed and cannot relax further. The rays are therefore bent too much and come to a focus slightly in front of the retina. The result is a slightly blurred image. This is called the *blurred image* or *fogging* technique because it purposely makes the vision a little blurred or foggy. This technique is especially useful in relaxing a ciliary spasm that is already present. However, in dealing with an eye that is already myopic, the true situation would be like figure 3 rather than figure 2.

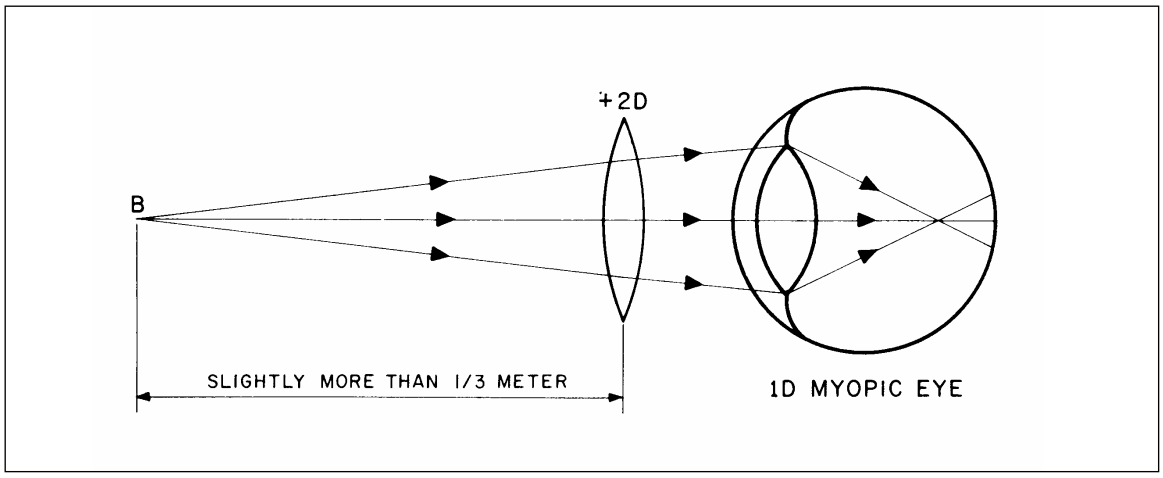


**Figure 3**

Figure 3 represents an eye that is already rather myopic so that even in its totally relaxed condition it requires diverging rays to see clearly. If the eye is 1D myopic, this means that it has + 1D more refractive power than it should have. Therefore, an additional +2D lens is all that is needed to give a total power of +3D and completely relax the eye for a one-third meter reading distance.

The above reasoning can be expressed in tabular form as in figure 4:

| Distance Prescription | Plus Lens Needed to Totally Eliminate Accommodation at 1/3 Meter Reading Distance |
|---|---|
| 0 | +3D |
| -1D | +2D |
| -2D | +1D |
| -3D | 0 |
| -4D | -1D |
| -5D | -2D |
| -6D | -3D |

**Figure 4**

The appropriate lens for each eye is selected individually since the two eyes do not always have the same refractive error. However, if the eyes are not too different in refractive power, the same eyeglass lens power can be used for each eye without difficulty. A special prescription for reading purposes is frequently called an *add* since the distance prescription is used as the starting point and the prescription for the reading glasses is added to it. To illustrate, if a person uses -5D lenses for distance and has a +2D add for reading, the reading prescription is -3D. This terminology is most commonly used with bifocals where the lower segment is the add. However, the same terminology can be used if the add is a separate pair of reading glasses.

The use of the fogging technique creates an active relaxation of the ciliary muscle and thus has a greater effect on relaxing a ciliary spasm than could be accomplished by merely eliminating the accommodation (with no fogging). The reason for this is that the ciliary muscle is composed of two separate sets of fibers. The circular fibers are obviously used to tighten the muscle and increase the accommodation. The radial fibers are used by the eye to relax the muscle and decrease the accommodation. This has been given the term *negative accommodation.* Thus, the fogging technique forces the ciliary spasm to relax, as the eyes attempt to see the blurred image clearly.

*It is crucial that the patient starts using the reading glasses as soon as the first sign of myopia appears because elongation of the eye is irreversible.* Once the eye has significantly elongated, there is no choice but to use distance (minus) lenses. Parents should check regularly to determine whether myopia is developing. The child can be asked to read small writing in the distance or an eye chart at home.

A very small percentage of children may have difficulty "accepting" a large add because of the strong linkage in the human visual system between accommodation and convergence (turning the eyes inward when looking at something close). As a viewed object approaches the eyes, accommodation and convergence increase in proportion to each other. Over thousands of years, the brain has learned that this is the normal situation. Consequently, accommodation stimulates convergence and vice versa. Thus, if we converge without accommodating the appropriate amount, or

if we accommodate without converging the appropriate amount, problems can develop for this small percentage of children such as eye fatigue, double vision, or other types of fusion problems. That is, the two images can no longer be fused together without discomfort. Normal binocular vision is interfered with. *For this reason, the book or other close object should always be held as far as possible from the eyes to reduce the amount of convergence needed.*[21]

In a study entitled "Bifocal Control of Myopia," Francis A. Young and Kenneth H. Oakley and described how they used bifocals with plus lenses on children to reduce their rate of myopia progression to a fraction of what it would have otherwise been.[22]

A study in Hong Kong also showed that wearing less than a full correction will slow the progress of the myopia. Children selected for the study were between the ages of 9 and 12. All were nearsighted, with 1D to 5D of myopia. The children were separated into three groups. Each group was given a different type of eyeglasses to wear for the two-year period of the study.[23]

- The first group wore single vision distance (minus) lenses with a full correction.
- The second group wore progressive lenses with a +1.5D add.
- The third group wore progressive lenses with a +2D add.

All children were examined at six-month intervals to check the progression of their myopia. Sixty-eight children completed the study. As expected, more undercorrection meant slower myopia progression.

The results of the Hong Kong study were as follows:

- First group - single vision distance (minus) lenses with full correction: 1.23D increase in myopia
- Second group - progressive lenses with +1.5D add: 0.76D increase in myopia
- Third group - progressive lenses with +2D add: 0.66D increase in myopia

As we can see, stronger reading (plus) lenses means less myopia.

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[21] In The COMET study, the report of which is attached hereto, only two out of 235 children who were fitted with Progressive Addition Lenses with a +2D add experienced vision problems.

[22] American Journal of Optometry and Physiological Optics, 52, No. 11, November, 1975.

[23] Leung JT, Brown B. Progression of myopia in Hong Kong Chinese schoolchildren is slowed by wearing progressive lenses. Optom Vis Sci 1999; 76:346, 354. Published 10/07/00.

The Hong Kong study was nowhere near as successful as it could have been because it suffered from the same primary flaw as the COMET trial, that is the failure to use +3D add single vision reading (plus) lenses with proper instructions for their use.[24]

In 1974, an optometrist working with Donald S. Rehm conducted a trial using children between the ages of 5 and 14. All achieved unaided 20/20 vision after using reading (plus) lenses for close work. For the purpose of the trial, the reading (plus) lenses were placed in a "Myopter," an instrument that also eliminates convergence and stereopsis. However, regular spectacle frames could have been used as very few children experience convergence and stereopsis issues. The results were as follows:[25]

**Case #1**
**20/20 vision achieved**

Maureen B., female, student. She was first seen on September 11, 1974 at age nine. Her spectacle prescription was:

Right -0.25D
Left -0.50D

She was given a Myopter with +2.00D lenses for all close work. *She was checked every four weeks and at the end of six months was 20/20.* She continued using a bifocal for all close work and held steady at 20/20. The bifocal was plano for distance with a +1.25D add for reading.

**Case #2**
**20/20 vision achieved**

Penny H., female, student. She was first seen on July 6, 1974 at age ten. Her spectacle prescription was:

Right -1.00D
Left -1.00D

She was given a Myopter with +2.00D lenses for all close work. Four weeks later, the lenses were changed to +2.25D. On September 8, 1974, the lenses were changed to +2.50D. *After using the instrument for another four months, she reached 20/20.* She was then checked once a month and stayed at 20/20.

[24] This is discussed below in Section L.

[25] *See*, Donald S. Rehm, "Some Case Histories," The Myopia Myth – The Truth about Nearsightedness And How to Prevent It, pages 101-106, Published 1981 by the International Myopia Prevention Assn.

**Case #3**
**20/20 vision achieved**

Luanne A., female, student. She was first seen on August 27, 1974 at age fourteen. Her spectacle prescription was:

Right -0.75 -0.25 x 90
Left -0.75

She was given a Myopter with +2.50D lenses for all close work. On September 21, 1974, an office visit showed no improvement so the Myopter lenses were changed to +3.00D. Four weeks later, her vision had changed to:

Right -0.50
Left -0.25

*On February 15, 1975, her vision had reached 20/20.* She continued using a plano bifocal with a +1.25D add for all close work. This held her vision at 20/20.

**Case #4**
**20/20 vision achieved**

James H., male, student. He was first seen on May 20, 1974 at age eight. His spectacle prescription was:

Right -1.00 -0.25 x 90
Left -1.00 -0.25 x 90

He was given a Myopter with +2.00D lenses. Two months later, his vision had improved to:

Right -0.75 -0.50 x 90
Left -0.50 -0.25 x 90

At this time, the lenses were changed to +2.50D. His vision was checked again on September 28, 1974 and had improved to:

Right -0.50
Left -0.50

*He was checked every six weeks and on March 15, 1975 he had reached 20/20.* He continued wearing a plano bifocal with a +1.25D add for all close work.

What these cases prove is that appropriately prescribed plus lenses will reduce or eliminate myopia. All four patients achieved 20/20 vision using appropriate plus lenses.

## J. IN CONJUNCTION WITH THE USE OF READING GLASSES, CHILDREN AND ADULTS SHOULD BE PROPERLY EDUCATED ABOUT OBSERVING THE D-I-A-L RULES TO REDUCE OR PREVENT MYOPIA

When a consumer goes to an optometrist or ophthalmologist to obtain corrective lenses, he or she almost never receives any training in good reading methods. This is an inexcusable failure by these professions to deliver "eye care."

Proper reading methods should also be taught in schools as soon as children enter the school system, but they almost never are. As schools require massive amounts of reading and computer usage by students, this is an inexcusable failure. Schools that fail to teach proper reading methods are unnecessarily ruining students' eyes. It is the job of the schools, as well as the parents, to teach proper reading habits. Teachers should remind their pupils daily about these habits. At present, this valuable information and training is being universally ignored. Ideally, eye care posters should be prominently displayed in schools.

*When using reading (plus) lenses to prevent myopia, children should also employ these methods to obtain maximum preventive effect.*

There is no controversy about appropriate reading methods. We can call them the "D-I-A-L" rules so that they are easy to remember.

- Distance
- Interrupt
- Angle
- Lighting

Distance. The book or other close object should always be as far from the eyes as possible. Myopia is caused by prolonged close work. The closer the object, the more the accommodation, which causes myopia.

Interrupt. Interrupt the close work by looking into the distance momentarily at the end of each paragraph, or at least at the end of each page, to relax the eyes.

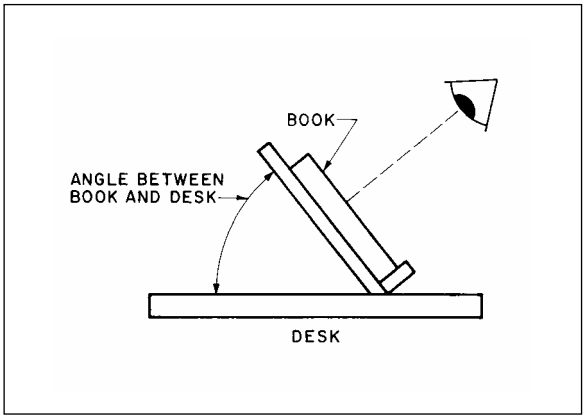


**Figure 1**

Angle. If a book is lying on a desk or table, the top of the book is obviously further from the eyes than the bottom of the book. This means that as the child reads down the page an increasing amount of accommodation will be required. It is better to raise the top of the book so that the pages are more perpendicular to the line of sight. See figure 1. The angle between desk or table and the book should be fifty or sixty degrees. It is possible to make or buy an elevating desk

with a surface that can be raised to various angles and locked in position for this purpose.

**Lighting**. Good lighting is extremely important in myopia prevention. Bright light causes the pupil of the eye to become smaller, requiring less accommodation. There should be as much light as possible when reading or doing other close work, as long as it does not cause glare or discomfort. Most people tend to use far too little light for their close work. Ceiling lighting is usually insufficient. A desk lamp is preferable. Our eyes were meant to be used in daylight, so we should sit by a window or outdoors in the sunlight to read whenever possible. It is rare to find indoor illumination that comes anywhere near approaching the intensity of natural sunlight.

## K. THE NATIONAL EYE INSTITUTE'S RECENT COMET TRIAL REGARDING THE USE OF READING (PLUS) LENSES TO REDUCE OR PREVENT MYOPIA WAS BADLY FLAWED, ALTHOUGH THE SECOND REPORT OF THE COMET GROUP IN 2004 CONTAINS SIGNIFICANT FINDINGS WHICH REQUIRE THE FDA TO ACT. THE FDA SHOULD COMMISSION A NEW TRIAL BASED ON SINGLE VISION PLUS LENSES WITH A +3D DIFFERENTIAL AND PROPER INSTRUCTIONS TO PARTICIPANTS

The National Eye Institute (NEI) was established by Congress in 1968 to protect and prolong the vision of the American people. As one of the Federal government's National Institutes of Health (NIH), the NEI is required to conduct and support research that helps prevent and treat eye diseases and other disorders of vision.

Notwithstanding its clear mandate, *the NEI has largely ignored and neglected the issue of myopia prevention*. In the NEI's "Mission Statement," the only mention of myopia is in relation to laser treatment.[26] Given that myopia is the most common eye disorder, this is a glaring and troubling omission.

Part of the NEI mission is to develop public and professional education programs to help prevent blindness and reduce visual impairment. The NEI has established the National Eye Health Education Program, a partnership of over 65 professional, civic, and voluntary organizations and government agencies concerned with eye health. Incredibly, myopia is not even included in the National Eye Health Education Program mission.[27] *The NEI apparently sees no reason to educate the public about myopia.*

The NEI has conducted one study on myopia prevention, known as the Correction of Myopia Evaluation Trial ("COMET").[28] As mentioned above, the COMET group published two reports, the first in 2003 and the second in 2004. Copies of both reports are attached hereto. The Petitioner is highly critical of the COMET trial, which was badly flawed for reasons discussed herein. However, both reports, especially the second report, support this Petition.

Here is the NEI's "Statement" based on the COMET trial *based on the first report of the COMET group in 2003*:

> <u>Statement on the Use of Progressive Addition Lenses vs. Single Vision Lenses to Treat Myopia in Children</u>
>
> Researchers have found that the three-year progression of myopia (nearsightedness) in a large group of ethnically diverse children who wore progressive addition lenses (PALs or no-line bifocals) was slightly less than that of children who wore single vision lenses

[26] *www.nei.nih.gov/news/statements/comet.pdf.*

[27] *http://www.nei.nih.gov/nehep/*

[28] *www.nei.nih.gov/neitrials/static/study9.asp.*

(SVLs), the conventional treatment for myopia. Although this small difference is greater than what would be expected by chance alone, from a clinical perspective it is not large enough to recommend a change in the way eye care professionals prescribe glasses for children with myopia.

From a research perspective, the results from this clinical trial, called the Correction of Myopia Evaluation Trial (COMET), shed light on mechanisms of myopia and will help to identify risk factors related to progression of myopia in children. These findings appear in the April 2003 issue of Investigative Ophthalmology and Visual Science. The study was funded by the National Eye Institute (NEI), part of the Federal government's National Institutes of Health.

Data were collected from 469 African-American, Asian, Caucasian, and Hispanic children at four clinical centers in the United States. All children had moderate amounts of myopia in both eyes and were six through 11 years old at the start of the study. Eligible children were randomly assigned to receive either PALs (n = 235) or SVLs (n = 234). Retention of children in COMET was outstanding, with 462 of the 469 children (98.5 percent) completing the three-year visit. The main result was that the difference in progression of myopia between the PAL and SVL groups after three years was 0.20 diopters (D). Increases in the overall length of children's eyes paralleled the changes in the amount of myopia in both the PAL and SVL groups.

The size of the treatment effect in COMET is similar to that reported in other recent lens studies for myopia control, even though there are differences in the study designs. While this modest treatment effect is not large enough to recommend a change in clinical practice for all children with myopia, ***results of COMET suggest that there may be some children for whom PALs may be beneficial for slowing the progression of myopia.*** This will require further study. (Emphasis added.)

Myopia is a significant public health problem, affecting at least 25 percent of adults in the United States and a much higher percentage of people in Asia. Recent data suggest that these percentages are increasing. In addition to blurring vision at distance, high myopia is a predisposing factor for retinal detachment, myopic

retinopathy, and glaucoma, thus contributing to loss of vision and blindness that cannot be corrected with glasses or contact lenses. The high prevalence of myopia and its prominence as a public health problem emphasize the importance of understanding the mechanisms of development and finding effective ways to prevent or slow its progression.

A key observation from COMET is that the treatment effect occurred in the first year and was sustained at the same level over the next two years. The early effect of an intervention to slow myopia also has appeared in results from previous studies of lens and drug therapies, although it has not been addressed in other reports. This result has implications for mechanisms of myopia and will be important for guiding future attempts to develop treatments for myopia.

A major advance in the last five years of myopia laboratory research supported by the NEI has been the demonstration that the growth of the eye and the development of refractive state (e.g., myopia) are guided by visual feedback. Studies have shown that images not focused on the retina guide the eye to grow to correct for this lack of focus. Research on animals funded by the NEI shows that there is a cascade of signaling mechanisms within the eye and, guided by visual feedback, these signals control the growth of the eye and its refractive state. Many studies have documented that the eyes of animals exposed to continuous retinal defocus become myopic.

The rationale for COMET was based in part on these findings. Retinal defocus resulting from poor accommodation (focusing of the eyes) when children with low amounts of recent onset myopia are engaged in close work may be a stimulus for increased eye growth and myopia progression. PALs may slow progression of myopia in these children by reducing retinal defocus. Results from COMET provide some support for the rationale. The difference between the PAL and SVL groups was greater in children with poorer accommodative response and lower amounts of myopia at the start of the study. An additional exploratory analysis combining these two factors showed a three-year treatment effect of PALs of 0.55D in children with both poor accommodative response and a low level of myopia at the start of COMET.

> The COMET data on progression of myopia in a large, ethnically diverse group of children complement other ongoing NEI-funded studies that are investigating factors related to development of myopia in infants, young children, and middle-aged adults. ***COMET has met one of the NEI program objectives by evaluating a treatment for slowing the progression of myopia.*** Additional analyses of the data will further address the objectives by identifying risk factors for progression of myopia and abnormal eye growth. (Emphasis added.)
>
> In summary, results of COMET suggest that PALs should not be prescribed routinely for slowing myopia progression in children. However, they still may be prescribed for other ocular conditions. Findings from this study will influence ongoing and future studies of myopia interventions and mechanisms of eye growth.[29]

The NEI's declaration that it has "met one of the NEI program objectives by evaluating a treatment for slowing the progression of myopia" is strongly disputed by Petitioner. The COMET study was fatally flawed and the conclusion of the first report is demonstrably incorrect for the following reasons:

1. The main conclusion of the study is that the benefit of wearing PALs "is not large enough to recommend a change in the way eye care professionals prescribe glasses for children." This is based solely on the *average* response. Some children will have had a much more positive response than others, but those results are lost in the averaging process. Averages are not important to individuals. Children who would greatly benefit from plus lenses are being denied the benefit of reading (plus) lenses because of averaging. This is unfortunate because there is no downside to wearing reading (plus) lenses for close work, only an upside. *As discussed in the next section, the second COMET report, published in 2004, evaluated a subset of children who greatly benefited from the PALs.*
2. The test should have been done on children who were just beginning to become myopic, that is when they were in the still reversible spastic myopia stage. Once they have moved into significant myopia, the eye has irreversibly elongated. Children who had previously worn distance (minus) lenses were accepted in the trial, meaning that they were already significantly myopic. Fortunately, the NEI apparently acknowledges this fact, *ex post facto*, in its Statement that "the difference between the PAL and SVL groups was greater in children with poorer accommodative response *and lower amounts of myopia at the start of the study*. An additional exploratory analysis combining these two factors showed a three-year treatment effect of PALs of 0.55D in children with both poor accommodative response and a low level of myopia at the start of COMET." *As we shall see, this subset of children was the focus of*

[29] *www.nei.nih.gov/about/mission.asp*

*the second report of the COMET group published in 2004, which is discussed in the next section.*

3. Children were given PALs with distance (minus) lenses at the top and a +2D add at the bottom for close work. *The top part of the lens would literally destroy the beneficial effect of the bottom part of the lens.* Distance (minus) lenses should not have been used at all.

4. If distance (lenses) were to be given, they should not have been full correction. If distance glasses are needed, they should have an undercorrection of 0.50 to 1.0 D to aid in relaxing the eyes. When children are outside playing, they should go without any distance correction at all, if possible. The children in the COMET study were told to use the glasses "during all waking hours." This *guaranteed* that the trial would not fulfill its potential.

5. A +2 add, even in a single vision plus lens, is inadequate because it still allows accommodation to occur. There should be a +3 add to eliminate all accommodation. When one realizes that many children who hold a book or other reading material too close use 8D or 10D of accommodation, reducing this by 2D cannot be expected to have much effect.

6. It is highly unlikely that the test subjects always looked through the lower portion of the PALs for close work. The children would see fairly well through any portion of the glasses. Computer usage provides an excellent example of this. While they might use the lower portion when looking at the keyboard, looking up at the screen without moving the head would cause the upper portion to be used. No one can naturally keep his or head held back for long periods to look at a computer monitor though the bottom (plus) half of a lens. It is unreasonable to expect anyone to do this. The children should have been given +3D add single vision lenses.

7. There is no indication that the children were told to follow the essential D-I-A-L rules identified above. It is particularly important to hold the reading material as far away from the eye as possible so that it is very slightly blurred, thereby eliminating the accommodation.

Despite all of these flaws, the users of the PALs still experienced less myopia progression that the users of the SVLs. *This demonstrates the immensely powerful effect of plus lenses in reducing or preventing myopia.*

*If the trial would have been done with +3D add single vision lenses for close work and only on children in the incipient stage of myopia, and the children had been instructed to adhere to the D-I-A-L rules, the result would have been a return to 20/20 vision, as in the Pennsylvania trial.*

The following section of the NEI Statement confirms everything that we are saying in this Petition:

> A major advance *in the last five years* of myopia laboratory research supported by the NEI has been the demonstration that the growth of the eye and the development of refractive state (e.g., myopia) are guided by visual feedback. Studies have shown that images not focused on the retina guide the eye to grow to correct for this lack of focus. Research on animals funded by the NEI shows that there is a cascade of signaling mechanisms within the eye and, *guided by visual feedback, these signals control the growth of the eye and its refractive state*. Many studies have documented that the eyes of animals exposed to continuous retinal defocus become myopic. The rationale for COMET was based in part on these findings. Retinal defocus resulting from poor accommodation (focusing of the eyes) when children with low amounts of recent onset myopia are engaged in close work may be a stimulus for increased eye growth and myopia progression. (Emphasis added.)

*This information has been known for far more than five years.* Donald S. Rehm's book, "The Myopia Myth," was published in 1981, and said exactly what the NEI now says that it learned only in the five years prior to 2003. Mr. Rehm has attempted for over twenty years to get the NEI to acknowledge what it now says that it has only recently learned.

It is not unreasonable to suggest that NEI has been dragging its feet on acknowledging the true state of scientific knowledge about myopia. Having now acknowledged it because it has no real choice, the NEI nevertheless produces a blatantly flawed study and presents incorrect conclusions. The result is that optometrists and ophthalmologists can comfortably point to the NEI Statement as a reason *not* to change in the way eye care professionals prescribe glasses for children with myopia. The NEI's Statement is a huge setback for the treatment of myopia, because its conclusion is plain wrong. However, as we shall see in the next section, the second report of the COMET group published in 2004 contradicts the NEI's statement that "results of COMET suggest that PALs should not be prescribed routinely for slowing myopia progression in children."

## L. NOTWITHSTANDING THE FLAWS IN THE COMET TRIAL, THE SECOND COMET REPORT PUBLISHED IN 2004 CONFIRMS THAT WHEN CHILDREN WITH INITIAL MYOPIA USE READING (PLUS) LENSES FOR CLOSE WORK, MYOPIA CAN BE REDUCED OR ELIMINATED

In 2004, the COMET group published a second report entitled: "Accommodation and Related Risk Factors Associated with Myopia Progression and Their Interaction with Treatment in COMET Children." The report identifies the subset of children who gained the most advantage from using PALs in the COMET trial. The results and conclusion report reported by the COMET group in the second report were as follows:

> RESULTS. Children with larger accommodative lags (>0.43D for a 33 cm target) wearing SVLs had the most [myopia] progression at 3 years. PALs were effective in slowing progression in these children, with statistically significant 3-year treatment effects (mean ± SE) for those with larger lags in combination with near esophoria (PAL – SVL progression = -1.08D - [-1.72D] = 0.64 ± 0.21D), *shorter reading distances* (0.44 ± 0.20D), *or lower baseline myopia* (0.48 ± 0.15D). The 3-year treatment effect for larger lags in combination with more hours of near work was 0.42 ± 0.26D, which did not reach statistical significance. Statistically significant treatment effects were observed in these four groups at 1 year and became larger from 1 to 3 years.
>
> CONCLUSIONS. The results support the COMET rationale (i.e., a role for retinal defocus in myopia progression). In clinical practice in the United States children with large lags of accommodation and near esophoria often are prescribed PALs or bifocals to improve visual performance. Results of this study suggest that such children, if myopic, may have an additional benefit of slowed progression of myopia.[30]

What this means is that the COMET group has confirmed that children in the earliest stage of myopia (less that 0.48D), and children who sit close to computers or hold reading material close to their eyes, *can* slow progression of myopia or prevent myopia completely. What the COMET group does not say is that the children in the COMET trial were prevented from receiving the full benefit of +3D add single vision lenses for close work and were not instructed to adhere to the D-I-A-L rules. Myopia can be prevented in virtually *all* children, not just the subset identified by the COMET group.

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[30] At p. 2143. *Accomodative lag* is the difference between theoretical and actual accommodation for near viewing distance. *Esophoria* means a tendency to overconverge which impacts binocular vision - the ability of both eyes to work together - and depth perception.

The NEI is conducting a follow-on trial "to determine if progressive addition lenses (PALs) versus single vision lenses (SVLs) slow the progression of low myopia in children with poor accommodative responses and near esophoria." This is known as COMET2. *In fact, the initial COMET trial has already established that, as confirmed in the second report, so COMET2 is redundant.* The NEI should be conducting a trial on children with initial myopia, giving them +3D add single vision lenses for close work and instructing them to observe the D-I-A-L rules.

*Despite the flaws in the COMET trial, the FDA must act on the second report and require eye care professionals to advise consumers that myopia may be reduced or prevented entirely if a child in the earliest stage of myopia uses prescribed reading (plus) lenses for reading, viewing a computer monitor, or other prolonged close work.*

## M. THERE ARE NO NEGATIVE EFFECTS ASSOCIATED WITH USING READING GLASSES FOR PROLONGED CLOSE WORK

Nothing in the COMET study indicates that there would be any negative effect whatsoever of having children and even adults in the incipient stage of myopia use +3D add single vision lenses. This is stated in a separate section of this Petition for emphasis. As there will be a substantial benefit, there is no reason for not taking the requested enforcement action.

## N. READING GLASSES FOR MYOPIA REDUCTION AND PREVENTION SHOULD BE PRESCRIBED AND FITTED BY QUALIFIED PROFESSIONALS WHO WOULD GIVE PROPER INSTRUCTIONS FOR THEIR USE AND MONITOR THE EFFECTS

A prescription is required for distance (minus) lenses. However, anyone can go to a drug store and other types of retail outlets without a prescription and buy reading (plus) lenses.

We do not advocate that anyone seriously interested in preventing myopia should purchase reading glasses off the shelf. Consumers need to have their eyes tested, so it can be determined how many diopters are necessary in the plus lenses to provide a + 3D add. Also, the reading glasses must be carefully fitted for interpupillary distance so as not to increase convergence. Correction of astigmatism would be left to the discretion of the eye care professional.

*It is not enough just to prescribe and supply + 3D add lenses.* It is crucial that the eye care professional also instruct parents and patients that the lenses must be used for all close work and that the D-I-A-L rules must be followed.

The eye care professional also needs to monitor the effect of the reading glasses by scheduling regular appointments (perhaps every three months) to examine the eyes, to ensure that the lenses are being used for all close work, and to ensure that the D-I-A-L rules are being followed.

## O. THERE WOULD BE NO NEGATIVE IMPACTS OF ANY KIND ON THE EYE CARE INDUSTRY

The optometry and ophthalmology professions are extremely defensive about myopia prevention. For example, an optometrist in another country has received the following letter:

> On behalf of the [Optometrists Board], notice is hereby given to you that, in consequence of a complaint made against you to the board, an inquiry is to be held into the following charges against you.
>
> That, you, being a registered optometrist, have made statements in leaflets about treatment and prevention of myopia which cannot be substantiated, namely the suggestion of using "positive convex lens" to effectively prevent the worsening of myopia and to assist people with myopia at the very early stage to recoup their normal vision, and that in relation to the facts alleged you have been guilty of unprofessional conduct.
>
> You are herby invited to answer in writing the above-mentioned allegation and also to appear before the board at the place and time specified, for the purpose of answering such allegations.

This is outright intimidation of a professional who is trying to practice responsible optometry.

The professions are overly concerned. Eye care professionals would actually *increase* their business if they engage in myopia prevention, because they would be *prescribing* reading glasses and monitoring the progress of the individualized comprehensive myopia prevention program for each patient. Preventing myopia will require *continuing supervision and monitoring*.

Any income that eye care professionals may lose in the long run from not prescribing or supplying distance (minus) lenses would be made up by prescribing or supplying reading (plus) lenses and continuing supervision and monitoring of each patient's progress in preventing myopia.

## LEGAL BASIS FOR PETITION

## P. DISTANCE LENSES ARE "MEDICAL DEVICES" THAT ARE SUBJECT TO THE LAWS AND REGULATIONS ADMINSTERED BY THE FDA REGARDING "MISBRANDING"

### 1. FDA authority regarding medical devices, including ophthalmic devices

Distance (minus) lenses and reading (plus) lenses, whether in the form of spectacles or contact lenses, are "medical devices" regulated by the FDA. Federal Food Drug & Cosmetic Act ("FD&CA") §201(h).

Ophthalmic devices are specifically regulated in 21 C.F.R. Part 886. Prescription spectacle lens are covered by 21 C.F.R. §886.5844 and are Class I medical devices. Contact lenses are covered by 21 C.F.R. §886.5925 and are Class II or III medical devices.

### 2. Misbranding of medical devices, including ophthalmic devices

FD&CA §502 addresses the "misbranding" of medical devices. It reads in relevant part as follows:

> A drug or device shall be deemed to be misbranded -
>
> (f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

### 3. Exemptions from "adequate directions for use" requirement

FD&CA §502(f)(1) provides that all medical devices must bear adequate directions for use, except if the Secretary has promulgated regulations exempting the device from such requirement.

In addition, under §502(f)(2), all medical devices must include adequate warnings against use by children where its use may be dangerous to health, or against methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. The Secretary is *not* permitted to promulgate exemptions from this requirement. Exemptions may only be given as to §502(f)(1), that is "adequate directions for use," not §502(f)(2).

The Secretary has promulgated exemptions as to §502(f)(1). These exemptions are contained in 21 C.F.R. Part 801. In this Petition, we are concerned with the labeling

of *prescription* distance (minus) spectacles and *prescription* distance (minus) contact lenses. These are covered by 21 C.F.R. §801.109, which reads as follows:

> A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act *if all the following conditions are met*:
>
> (a) The device is:
>
> (1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or
>
> (ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and
>
> (2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.
>
> (b) The label of the device, other than surgical instruments, bears:
>
> (1) The statement "Caution: Federal law restricts this device to sale by or on the order of a ____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and
>
> (2) The method of its application or use.
>
> (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, *effects*, routes, *methods*, and *frequency and duration of administration*, and any relevant *hazards*, contraindications, *side effects*, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however, That such information may be*

*omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device.* Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder—piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

Another exemption is contained in 21 C.F.R. §801.116 which reads as follows:

A device shall be exempt from section 502(f)(1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.

.

## Q. THE FDA IS REQUIRED TO TAKE THE REQUESTED ENFORCEMENT ACTION IN ORDER TO ENSURE COMPLIANCE WITH THE MISBRANDING LAW

### FDCA §502(f)(1) applies as no exemptions are applicable

FDCA §502(f)(1) requires eye care professionals to give "adequate directions for use" of distance (minus) lenses unless they are exempt under 21 C.F.R. §801.109 or §801.116. None of the exemptions are applicable with respect to the subject of this Petition.

Initially, we can dispose of 21 C.F.R. §801.116. The information that would be provided to consumers as a result of the enforcement action is not "known to the ordinary individual." There can be no serious dispute on this point.

To qualify for the exemption in 21 C.F.R. §801.109, the consumer must be provided with written labeling that contains "adequate information for [use of the device], including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented." This is not really an exemption; it is a minimum requirement.

21 C.F.R. §801.109(c) provides that such information may be omitted from the dispensing package "if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device." The question is whether the information that would be required to be given to consumers as a result of the enforcement action is "commonly known to practitioners." The answer is no. Perhaps if they knew, they could exercise their own discretion in deciding whether to tell patients, but they do not know.

### FDCA §502(f)(2) applies as there are no exemptions for that provision

FDCA §502(f)(2) requires "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." There is no exemption from this requirement.

Anything that may result in loss of vision and blindness is obviously dangerous to health. In its Statement on the COMET study, the NEI says:

> Myopia is a significant public health problem, affecting at least 25 percent of adults in the United States and a much higher percentage of people in Asia. Recent data suggest that these percentages are increasing. In addition to blurring vision at distance, high myopia is a

predisposing factor for retinal detachment, myopic retinopathy, and glaucoma, thus contributing to loss of vision and blindness that cannot be corrected with glasses or contact lenses.

Clearly, in order to comply with §502(f)(2), consumers must be warned that distance (minus) lenses worsen myopia and that myopia can result in retinal detachment and other serious health problems.

## Enforcement action is necessary to prevent unlawful misbranding

As things stand, consumers are not being told what the law requires them to be told. The requested enforcement action would provide them with the necessary information required by the misbranding law:

1. It would inform consumers that distance (minus) lenses cause myopia to worsen progressively.

2. It would inform consumers that worsening myopia can lead to retinal detachment and other serious problems in the long term.

3. It would inform consumers that myopia can be reduced or prevented entirely if a person in the earliest stage of myopia uses properly prescribed reading (plus) lenses for reading, viewing a computer monitor screen, or other prolonged close work.

4. It would inform consumers that proper instruction needs to be given to ensure that the reading (plus) lenses are used correctly for maximum effect in preventing myopia.

5. It would inform consumers that they should ask their eye care professional whether reading (plus) lenses for close work should be prescribed in an attempt to reduce or prevent myopia, rather than distance (minus) lenses.

Items 1 and 2 above must be included in the required notification so that the significance of items 3 and 4 above can be understood by the consumer.

## R. IN THE EVENT THAT THE FDA BELIEVES THAT THERE IS A SCIENTIFIC CONTROVERSY, IT CAN ESTABLISH A SCIENTIFIC ADVISORY PANEL OR ADVISORY COMMITTEE, BUT THIS SHOULD NOT DELAY THE REQUESTED ENFORCEMENT ACTION

To the extent that the FDA believes that there is a scientific controversy, the FDA may establish a scientific advisory panel or advisory committee. See 21 C.F.R. §10.75(2). Any such review by a scientific advisory panel or advisory committee "shall take place in a timely manner." 21 U.S.C. §360bbb-1.

When enacting the law that resulted in the foregoing regulation, Congress said that it intended that the FDA establish a process to "provide that important scientific issues will receive appropriate attention from independent scientists who can bring a fresh perspective to assure that the regulated industry receives a fair and impartial hearing and that the FDA receives sound recommendations and advice." H. Rep. No. 105-310 at 73 (1997).

Such a panel already exists: the Ophthalmic Devices Panel of the Medical Devices Advisory Committee (hereinafter the "ODP"). The ODP should invite public comments and hold a public hearing on the issues presented by this Petition as soon as practicable.

The FDA does not need absolute proof before taking the enforcement action requested herein. In 2004, the FDA required antidepressants to include a warning that their use may increase the risk of suicidal thinking and behavior in children and adolescents with major depressive disorder and other psychiatric disorders.[31] The FDA stated.

> While there are some findings among these data suggestive of an increased risk of suicidality for some of these drugs, there remain some inconsistencies in the results.

In other words, the FDA did not require conclusive "bulletproof" evidence. In fact, as stated in the required warning, no suicides occurred in the trials on which the decision to require the warning was based.

Further investigation such as a properly designed follow-on to the COMET trial, could take years, while millions of children unnecessarily become myopic. There is no downside to the requested enforcement action and it should be taken now without waiting for the results of further trials.

[31] *See www.fda.gov/po/indexes/2004news.html#october*.

## CONCLUSION

This Petition is based on sound science. Petitioner has identified a real problem that the FDA cannot ignore and is legally required to address in an effective manner. If myopia can be prevented, it should be prevented.

The FDA is an indispensable part of the answer to the myopia problem. Petitioner urges the FDA to take a proactive approach to this issue.

Petitioner requests that this Petition be granted and that the FDA take the enforcement action requested herein, or substantially similar enforcement action.

In the event that the FDA fails to take the enforcement action requested herein or initiate the process of inviting public comments within 180 days of the date of filing this Petition, Petitioner reserves the right to seek judicial intervention.

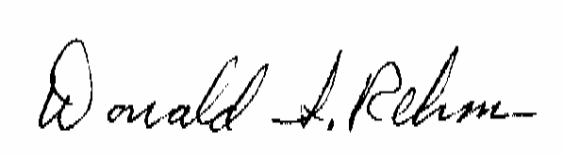
## CERTIFICATIONS

1. No environmental impact statement is required with this Petition.

2. The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Dated: April 28, 2005

THE INTERNATIONAL MYOPIA
PREVENTION ASSOCIATION



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