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ORTHOKERATOLOGY AS A MODERN METHOD OF MYOPIA CONTROL

Bachelor thesis

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Declaration

I hereby declare that this bachelor thesis is my own work created under a supervision of RNDr. Mgr. František Pluháček, Ph.D., and that the information I used has been fully acknowledged in the text and included in the reference list.

In Olomouc 2. May 2015 ..... Ekaterina Smuglova

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Table of Contents

Introduction

According to epidemiological studies it has been a worldwide steady increase in the prevalence of myopia in recent decades. The most important medical and social problem is a complicated high degree myopia as one of the leading causes of blindness and low vision. As a result of a large-scale research in 1975 - 2000's myopia is ranked third (16 %) in the list of the disabling diseases of the eye in Russian Federation. [1]

At the same time, the increase of the number of the mild to moderate «school» myopia cases is also a subject of constant attention of ophthalmologists. According to some sources a low degree myopia growth outstrips the high degree complicated myopia. [2] The prevalence of myopia varies widely in different countries, reaching 70 - 90 % in some regions of Asia, which leads to the emergence of the concept of "an epidemy of myopia. [3] "Finding the optimal method of ametropia correction (myopia in particular) has led to the conclusion that there is no optimal way of correction. [4] Eyeglasses, contact lenses and surgical correction have their advantages and disadvantages, that means there is an individual approach of the method to be found. Despite significant success in the refractive surgeries field, the radical way to correct a myopic refractive error has a number of restrictions. They primarily concern children and adolescents during the period of growth and development of the whole organism and the eyesight in particular, when the process of eye development is not completed yet and the progression of myopia is often registered. On the other hand, in adulthood it is often difficult to determine the optimal postoperative refraction because of the predicted onset of presbyopia. Spectacle and contact lenses correction is often inconvenient for the people performing physical labor, working in unfavorable conditions or doing sport, that recently has become extremely common in almost all age groups. Until now it remains an urgent problem to choose the optimal method of myopic correction in individuals with non-stabilized refraction, especially when engaged in activities, poorly compatible with glasses and contact lenses wearing.

In recent years, a special method of a refractive error correction receives increasing popularity. Orthokeratology - a way to temporarily reduce or eliminate the refractive error, carried out by wearing rigid gas permeable contact lenses that change the shape and the optical power of the cornea. The method was first implemented within clinical practice in the early 60-ies of XX century [5] and began to develop rapidly since the 80's,

when modern orthokeratology lens design has been developed (OK-lens), that is being used until now. [6] In recent years, the orthokeratology method becomes more widely used around the world. However the publications about the effectiveness of orthokeratology and its impact on the eyesight are very few at the moment and that is the reason I have chosen this topic besides my personal interest and experience.

1. Introduction to Orthokeratology

1.1. Definition and history

Orthokeratology (also known as Overnight Vision Correction, Corneal Refractive Therapy or CRT, Ortho-K, OK therapy, OK) - a purposeful change of the cornea using a contact lens to temporarily correct refractive disorders, primarily myopia. Modern OK-therapy achieves this with the help of gas-permeable contact lenses (GPCL) interpretation worn during sleep. In the ophthalmological practice this is a relatively new technology. [7]

Despite the fact that orthokeratology has been gaining popularity only in the last few decades, this method has been known since the 60s of the last century and George Jessen is considered the founder. He was the first person who described a technique called orthofocus. [5] For the myopia correction Jessen used hard contact lenses made of PMMA - polymethyl methacrylate, that had flatter shape than the cornea. Eventually, he found out that even after the removal of such a lens from the eye, the achieved visual acuity maintained for some time. Over the next two decades, a technique was renamed to "orthokeratology" and many specialists had been working on it. However, the results of vision correction using the rigid lenses were unstable and poorly predictable. The first large-scale clinical trials in the orthokeratology field were held by Ronald Kerns, in the second half of the 70-ies of the last century. It was a three-year study of the myopic patients, that were divided into three groups: the first group used the OK-lenses, the second - lenses made of polymethyl methacrylate, and the third group - glasses. Kerns found out that the center of the cornea because of the effect of the OK-lenses takes a flat shape. That way, he was the first who identified the mechanism of action of the orthokeratology. In next few years, major clinical studies had been made in this field by several groups of researchers. However, the results of these clinical studies remained unstable and unpredictable. Any changes in refraction were temporary and the technology

required recurrent lens wear to maintain the effect. In those days, it caused lots of frustration among the researchers, as the main purpose of their work was a stable vision improvement. The interest was lost and only a small number of enthusiasts kept working in this field. However, in the 90-s the orthokeratology development have received a new impetus, due to the advent and availability of corneal topographer, new materials for the lenses and, most importantly, with the advent of the reverse geometry lens - the lens which periphery is steeper than the center (in usual lenses it is opposite). [8] A reverse geometry lens gave a quick and predictable effect of vision correction. From that moment the modern orthokeratology stage of development began. In 2002, the Quality control department of the US Food and Drug Administration (FDA) approved the very first night contact lenses. Modern OK-lenses have 4 (or even 5) surface zones. The parameters of each of these zones may vary to provide an optimal fitting of the lens and achieve the desired result as accurate as possible. [9]

1.2. Mechanism

Nowadays in the myopia correction three main methods are widely used: glasses, a contact method and a surgical method. Advantages and disadvantages of each of them are studied in a large number of works and they are very well-known. Especially the disadvantages of each of the existing methods for the refractive errors correction, provide the basis for the research and development of the alternative methods.

One of them is Orthokeratology - the purposeful corneal modification using a contact lens to temporarily correct refractive disorders. Currently, orthokeratology is mainly used for the correction of myopia, which forms a significant part of all existing refractive disorders. Orthokeratology principle for myopia is following: the OK-lens provides a predetermined change in shape of the anterior surface of the cornea, reducing its refractive power, which leads to reduction of myopia (Fig.1). The eye care specialists should be aware of the indications and contraindications using OK-lenses in patients with myopia, control dynamics and refractive state and take into consideration the age and the clinical form of myopia. Today's Ortho-k myopia reduction is achieved through the rapid changes in the front surface shape of the cornea as a result of complex forces produced by an OK-lens. After the lens removal the original form is slowly starting to recover. That ensures

a long period of clear vision without any additional correction. Forces applied to the tear film between the cornea and the lens, are causing a gradual steady redistribution of the epithelial cells from the center to the periphery. Due to the positive pressure generated over a flatter central part of the posterior surface of the lens, the center of the corneal epithelium becomes thinner. Simultaneously the midperiferic area becomes thicker due to the negative pressure generated by a reservoir of tears in the accumulation zone. Obviously, in this situation, an exact centering of the lens plays a crucial role. The degree of corneal flattening when wearing Ortho-K lenses and the rate of recovery of the corneal shape after the removal of the lens depend on the ability of the corneal epithelium to displace and also on the elasticity of the midperiferic stromal tissue. These parameters vary from patient to patient. The typical structure of a common gas-permeable lens (GP) is that in order to achieve a good fitting and mobility, the radius of the posterior curvature on the periphery is larger than the radius of the posterior curvature on the optic zone. In other words, the lens flattens from center to periphery.

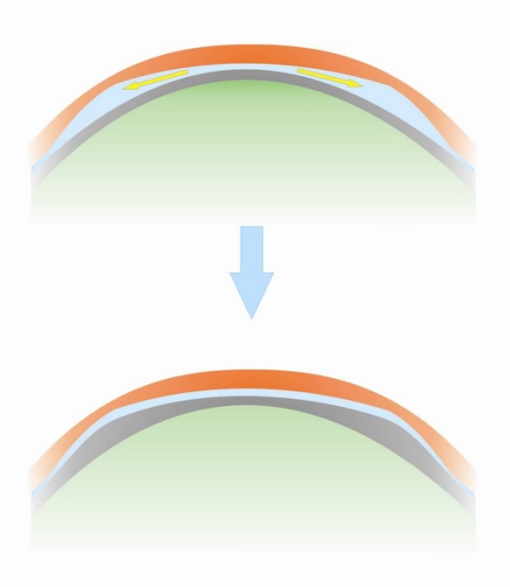


Figure 1 An Ortho-K principle [19]

In the most of modern Ortho-K lenses to achieve the right effect, the principle of the reverse geometry is used. In these lenses the radius of the secondary curve is smaller than the radius of the posterior curvature on the optical zone. This creates a circular tear fluid tank, leading to the displacement of the epithelial cells, which leads to thickening of the mid-periferic area of the cornea. Adding a third zone, which curvature corresponds with

the curvature of the periphery of the cornea, stabilizes the lens fitting. The peripheric zone - the last one, provides a lift of the edge of the lens.

The first zone is called the optical zone. Its posterior curvature is calculated so that it is flatter than the central curvature of the cornea. That creates positive pressure, that leads to the corneal epithelium thinning in the central area. The diameter of the optic zone ranges from 6.0 to 8.0 mm depending on its design. The second zone is commonly called the reverse curve zone or the steep secondary curve. It is usually 0.5 - 1.0 mm, or 3-5 D steeper than the back curve of the optic zone. It forms an annular shape tear tank around the central flat zone, which causes negative pressure and provides a space for the migration of epithelial cells and intercellular liquid. The width of the zone is 0.6 to 1.0 mm depending on the lens design. The third zone is known as the leveling curve, it is flatter than the reverse curve and fits tightly to the periphery of the cornea. It creates a support area for centering the lens. The angle and radius of this zone can be changed in order to obtain a looser or tighter fitting, to achieve the right alignment. For the same reason, sometimes an additional leveling curve is added. Its width is 1.0-1.5 mm depending on the lens design. The fourth zone or a peripheral curve is flatter than the leveling one, but steeper than in common GP lenses. This area provides design of the edge needed for maximum comfort, mobility and exchange of the tear fluid. The diameter of the Ortho-K lens tends to be more than GP lens diameter and it is 1.0 to 1.5 mm less than the horizontal diameter of the visible iridal area. OK-lens with the diameter of 5 mm is usually greater than the width of the pupil in most lighting conditions. If the corneal shape change is enough to eliminate the existing myopia, but the diameter of the impact area is smaller than the diameter of the pupil, the vision quality might suffer. The glares and halos might be present despite normal lighting conditions.

To produce the gas-permiable Ortho-K lenses, the materials with high oxygen permeability are needed. These lenses are notably thicker than common GP lenses and the oxygen supply to the cornea acquires a great importance. The low diffusion coefficient materials can lead to physiological issues, associated with hypoxia: a corneal edema, a corneal shape distortion or an epithelial damage. [10-12]

1.3. Patients selection

It is assumed that children respond to OK therapy much faster than adults. Preliminary studies and individual observations allow to expect that the OK-lenses can slow the progression of myopia down in children and adolescents. To confirm the information on these favorable effects of orthokeratology, the further investigations are needed.

In most cases, myopia up to 5.0 D (in the spherical equivalent) can successfully be corrected using the OK therapy, which includes with-the-rule corneal astigmatism up to 1.5 D. The against-the-rule astigmatism is much harder to reduce especially if it exceeds 0.75 D, since the cornea is flattened mostly along the vertical meridian. The upper limit of myopia and astigmatism that can be corrected by Ortho-k lenses depends on the shape of the cornea. Sometimes the good eyesight might be reached even when the myopia is more than 6 D and astigmatism is above 3 D. The success of the therapy also depends on the amount of residual myopia, that the patient is ready for. The most predictable results are obtained if the myopia is not higher than 4.0 D (in the spherical equivalent) and a with-the-rule astigmatism - 1.0 D. If nearsightedness and/or astigmatism is higher, it makes the results of the procedures less predictable and the failure rate increases significantly. Some of the parameters describing the shape of the cornea can also help making a prediction about the success of Ortho-K. In most cases, the cornea is oblong-elliptical, while it is more convex in the central area and flats toward the periphery. Its eccentricity is typically in the range from 0.3 to 0.7. The low values of eccentricity (<0.3) along with the flat central keratometry (<41.00), reduces the possibility of Ortho-K application and reduces success in myopic patients (greater than 4.0 D). In addition, the patients should be warned that achieving the desired correction can be difficult in case of irregular OK-lenses wearing. The effectiveness of orthokeratology is reduced when there is significant internal (lens) astigmatism, when the value of corneal astigmatism can not help in predicting the astigmatic component of the clinical refraction. The specialists also have to be cautious when the cylinder to sphere ratio is less than one, i.e. cylindrical component of myopia is greater than the spherical one. Patients who had previously wore the GP contact lenses are not the ideal Ortho-K candidates, it happens that it is difficult to predict a possible correction and many lenses need to be changed until the final suitable option is achieved. The cornea of these people may be somewhat deformed by the

previous GP lenses, but the rejection of wearing them for a long period for the corneal shape recovery before using the Ortho-K may not be appropriate for these patients. [12]

1.4. Indications and contraindications

The method is indicated for the myopic patients up to 4 D in the spherical equivalent. It is possible to apply orthokeratology in higher myopes but only if the patient is conscious of the residual myopia. Contraindications to the use of OK-lenses are the same as for all types of contact lenses: inflammatory diseases of the eye, a pronounced dry eye syndrome, etc. The presence of degenerative diseases of the epithelial or endothelial basal membrane, such as keratoconus and pellucid marginal degeneration, are also considered as a contraindication to the OK-purpose lens. [7, 12]

1.5. Safety

Overnight OK is a very popular method in young children, as it has a unique ability of providing unhindered vision during the day. However, problems with the treatment have been starting to sprout due to the fact of its growth in popularity as a treatment. With all that said, one must keep in mind that orthokeratology is only a temporary treatment of myopia.

One of these more serious problems is microbial keratitis (MK). Overnight OK has three factors, which have been seen to increase the risks of getting the infectious MK. There have been suggestions that the overnight wearing of the lens reduces the ocular surface's ability to defend itself against bacterial infection. Also, more time is thus given to the bacteria to find a way past the eyes' natural defense. The lens design also leads to problems, as the epithelial surface integrity gets reduced thus making the eye more open to infection. All this being said, it is important for practitioners to be more cautious when fitting children with the OK lens. Patients and parents should be educated about the various risks and proper utilization as well. Follow-up visits should be made routine to avoid these problems.

After several weeks of OK-lens usage, central corneal thinning and mid-peripheral thickening has been regularly reported to have occurred in a rather quick manner and to

have stabilized as well within this period of time. Due to this, there have been rising concerns as to the possibility of secondary corneal ectasia being induced, but due to the small magnitude of before mentioned thinning, the risk of ectasia developing is minimal. The mid-peripheral thickening as well as steepening is the major way of controlling myopia. One of the potent myopia inducing signals (peripheral retinal defocus) is thus shifted. Overall, this steepening and thickening has been witnessed to correlate with the level of pretreated myopia, thus corresponding to the central thinning and flattening. As of late, there are more recent designs attempting to induce more of this significant thickening and steepening.

There have also been concerns about possible short and long-term impacts on corneal endothelium, and this due to OK's predominantly overnight wearing modality as well as its long-term treatment application. Because of this, scientists have been doing baseline and annual observations to make sure that these concerns remain only concerns. Fortunately, so far there has only been evidence to reassure the world that OK is safe in terms of endothelium.

There are many types of corneal straining that could eventually present themselves: patchy central straining, whorl shaped straining, peripheral indentation ring, and sporadic diffuse punctuation straining. Peripheral punctuation straining has been, however, more associated with preexisting conditions, like lid margin disorders, sensitivity to contact lenses and so forth. Persistent central straining has been closely associated with suboptimal OK fitting and lens adherence to the corneal surface. One of the most urgent care visits in orthokeratology treatments is due to recurrent lens binding as well as superficial corneal abrasion on lens removal. There have been many proposed factors to help promote lens binding in the overnight OK such as decreased thickness, increased viscosity of post-lens tear film with overnight wear, coated lenses, eyelid pressure on OK lenses toward the cornea. Improving the fitting as well as promoting tear exchange through lens adjustment can often resolve recurrent lens binding. All in all, it is strongly indicated and advised to discontinue the overnight OK treatment on a temporary basis if observed persistent central corneal straining becomes worse than grade 2 on the Efron scale. [14]

2. Orthokeratology technique

2.1. Lens fitting principles: the method description

There are two methods of the Ortho-K lenses fitting: an empirical and the one that uses the trial set. In the empirical method the all necessary measurements should be performed, the data should be collected and transmitted to the lens manufacturer. There the data are analyzed and on the basis of the requirement, the lens selection is performed, the lenses are produced and sent to the customer. If the desired effect is not achieved, the customer provides additional information to the manufacturer, the manufacturer changes the design of the lens and produces a new pair, which is again sent to the customer.

In many cases, the fitting of OK diagnostic lenses are used. Typical inventory consists of a set of the rows of the lenses which vary depending on the design, its optical zone, a reverse curve, a peripheral curve and an alignment curve. For the convenience of specialist, the lens design details are reduced to two basic parameters, which are obtained when examining the patient: flat CK (flat central keratometry) and TP (target power, or the degree of the short-sightedness, which must be removed) - predetermined refraction in diopters, which must be removed. Varying these two parameters provides sets of inventory of various sizes, depending on the objectives the eye care specialist has. A big set that allows to choose the lens for almost any selected patient, consists of 195 unduplicated lenses. Same as the fitting process of the common RGP lens, a very necessary component is fluorescein in the liquid form, that helps to estimate the distribution of tears under the lens using a slit lamp with a blue filter beam. It is not difficult to take care of the Ortho-K lenses - there is no particular difference in care from the usual RGP lenses. When a pair of lenses is used more than one year, the abrasive cleaners additives have to be avoided. The parameters of the first trial lens are usually calculated using special nomograms or computer programs. These programs use topographic maps, containing the information to select the right initial lens. This information includes an apical radius, a sagittal height or eccentricity, horizontal visible iris diameter (HVID), the pupil size and refraction. It required to make more than one topography pictures (at least four) to provide the most accurate average parameters. Topograms with poor quality should be destroyed, because they can lead to the wrong choice of lenses. For a greater reliability, it makes sense to use a well calibrated manual keratometer too. It is very important for the selection of the first lens to ensure reliable initial data during the examination.

The fitting process of the OK lens from inventory kit uses three basic parameters indicated on the label: CK , TP and an eccentricity. The first two parameters are used to determine the base curve, which is also indicated on the label, and it is exactly that curvature at the flat meridian, to which the lens should modify the cornea (the base curve = CK - TP). All these parameters are corneal and not the lens parameters. For example, the patient's CK is 43 D, eccentricity is 0.38, and the prescribed glasses are -2.5 D/-0.75D x 170 (-2.875 D in spherical equivalent), the lens CK 43.00/TP -3.00/e 0.4 have to be chosen from the trial set. The diameter is standard 10.6 mm. During the fitting process it is convenient to use the set with the same eccentricity. Then the diagonal principe can be used - the change of CK and TP on the same absolute value allows to keep the same base curve parameter, even though the correlation and the curves of the zones of impact will differ. For example, the lenses CK 43.00/TP -4.50/e 0.5 and CK 43.50/TP -5.00/e 0.5 have the same base curve 9.18 mm. As for the eccentricity, the lenses CK 43.00/ TP -4.50/e 0.5, CK 42.50/TP -4.50/e 0.4 and CK 43.50/TP -4.50/e 0.6 are approximately the same in fitting and corneal impact. Therefore, the specialist should choose the one that fits the best. If the empiric method of fitting is used, a manufacturer defines the first lens, on the basis of data provided by a qualified specialist, who only has to do an evaluation of the fitting of the lens and its impact on the cornea. [6, 10, 12]

The soft contact lenses usage should be stopped before the test at least for a day, but better few days. The particular attention should be payed to those who had been wearing the other rigid contact lenses, those have to stop using them for a much longer period. It can take up to several months for the cornea to reach its initial state. Only then the accurate keratometric or topographic measurements can be done.

There are no special tools needed for the lens fitting process. However, it's important to have the basic materials that are used for the usual conventional contact lenses fitting

- Topographer (preferred) or keratometer (minimal)
- Slit lamp (biomicroscope)
- Autorefractometer, phoropter or universal trial frame
- Visual acuity charts
- Contrast sensitivity charts (may be helpful to quantify visual acuity) [6, 7]

2.2. Evaluation of the fitting

The lens is placed on the eye and the result is evaluated in a certain time (30 - 60 minutes), that way the lens can take a stable position. During this time a possible clinical information about a successful result for the patient appears. Changes in the shape of the cornea can be visible in 30 minutes. Centering of the lens is critical in the effectiveness of Ortho-K. Decentering downwards for 0.3 mm is permissible, because the lens tends to move upwards under the eye lid. The lens should move 1.0-2.0 mm vertically with every blinking movement, move over the center of the cornea without any bias upwards or sideways and should not go beyond the limb. The amount of tears greatly affects the assessment of the fitting. Excess tears may cause a lens fitting evaluation as free, whereas in fact it is normal or even tight. It should be noted that unlike the case of the common gas-permeable lenses, an evaluation of the Ortho-K lenses fitting limits by the verifying the permissible zones widths ratio in fluorescein distribution. The ideal distribution under the lens is shown by a dark disk in the center of the cornea, 3-4 mm in width (center contact), which is bordered by a bright green ring corresponding the back curve (accumulation area). Next there is a dark ring under an alignment curve (alignment zone), and all this is bordered by a narrow bright green ring under a lifted edge of the lens (peripheral zone). In the initial fitting process, the presence of some air bubbles is permissible in the accumulation zone. However, after the first night, this phenomenon disappears or decreases. Large air bubbles or foam should not be present, otherwise it indicates the large sagittal height of the lens.

In the fitting process of the common RGP lenses, it is usually considered as a steep or a flat one depending on changes of the BOZR (back optic zone radius). In the OK-lenses a term of the sagittal height is used. In a steep lens the sagittal height is too great, and the flat lens has a very small sagittal height. If the sagittal height is too great, it can be recognized by the following signs: a wide accumulation zone, a small area of central touch, an alignment zone is too dark and a peripheral zone is too narrow. This lens can also be decentered down and motionless. When it happens the lens has to be changed using the diagonal principle «down» - for example, instead of the lens CK 43.50/TP -5.00/e 0.5, the CK 43.00/TP -4.50/e 0.5 should be used. If the sagittal height is too low, the signs are different: wide accumulation zone, a wide area of central touch, a narrow

alignment zone with an excess of fluorescein and a wide peripheral zone. This lens is decentered upwards or downwards, very motile, its movements do not often correspond with blinking. In this case the lens should be changed using a diagonal principle «up» (instead of the lens CK 43.00/TP -4.50/e 0.5, the CK 43.50/TP -5.00/e 0.5 should be used). [7] [11] [12]

2.3. First night using the OK-therapy

After the lens is selected, the specialist has to know the impact of the lens after the first night to assess the patient's response to the Ortho-K therapy. Before the patient leaves the office, it is necessary to give him all instructions about how to put on the lens, to take it out and to take care of it. The instructions should also include advice about restoring the mobility of the lens when stuck. The patient should be examined the morning after with the lenses on, the tests are usually done within two hours after the patient has opened the eyes. Before the lens are removed, the evaluation of the fitting should be done as previously described. In this case, the position of the lens can be seen clear and the closed eyelids effect can be determined more accurately. A minimal movement or sticking of the lenses is acceptable after the awakening, it confirms the alignment of the lens over the pupil. A distribution of fluorescein might be even more distinct, with a wide dark central area and the alignment area. There should not be any bubbles in the central touching zone, however there might be a pointed epithelial coloring, which should disappear in two nights using the lenses. There should not be any pointed epithelial coloring in the the accumulation area - it is an evidence of poor tear exchange due to the tight lens fitting. Then the lenses must be removed, the visual acuity and refraction should be measured, the corneal topography should be done too. After the first night the well-fitted lens, depending on the magnitude of myopia, should provide at least 70% reduction of its desired drop. On the topographic corneal map, a well-centered picture of the «bull's eye» (Fig.2) should be seen. [7, 11, 12]

2.4. The further tactics

If the tests are favorable, the patient should continue to wear a lens 6 more nights. After that a visit should be made at the end of the day. It is necessary to verify the sight, the residual refractive error, the state of the eye and to do a corneal topography. By this time, the vision has to be stabilized at least until the evening. Such visits should be repeated in a month of wearing the lenses. Then the patient has to come every 3-6 months. An eye care specialist should always check the state of the eye and clean the lens with a special laboratory cleanser. The stabilization of the sight occurs within 1-3 months. The lenses should be changed to the new ones in 2-3 years or less, in case of the absence of proper care, the lenses can be damaged much faster. It should be borne in mind that the comfort of the OK-lenses (as at night they are fixed on the eye) has a back side: the patient might not give an importance to the fact that the lens is dirty, has deposits or a foreign body. He might keep using this lens since no discomfort is felt at night. Consequently, there are great problems that might arise: epitheliopathy, corneal erosion and even keratitis. Therefore, the patient should be carefully instructed about the lenses cleansing and potential problems even though they might be comfortable to wear. [7, 11, 12]

2.5. Topographical survey

Information about the shape of the cornea helps to define the lens parameters and predict the effect of the Ortho-K. In all the lens fitting methods, the topography comparison in the way «before and after» helps to quickly determine the size of the impact area, its location, the corneal curve and its optical power change. The last one can be also seen in skiascopy and refractometry. The accuracy of these measurements is set by the method of the videofixation, the number of Placido discs, the image processing program, the specialist experience, the cooperation with the patient, the width of his eye gap and the stability of the tear film. To achieve maximum accuracy, it might be helpful to check the calibration of the machine and perform at least three measurements on each eye of each new patient to determine the average radius of curvature of the cornea and the magnitude of the eccentricity. Depending on the accuracy of the topography instruments, more measurements might be needed.

Local changes in the corneal shape is clearly manifested in the comparative topograms. This includes the definition of the edges and location of the area of impact, as well as the identification of the central islands and dints. Axial comparative topogram shows the change in the axial optical power of the cornea and it can be associated with a reduction of myopia, measured subjectively.

Refractive comparative topography provides the best estimate of the diameter of the impact area, while the axial and tangential maps have a tendency to overestimate and underestimate it respectively. Comparison of corneal topographic maps taken before and after the fitting, detects the magnitude and location of the changes in the shape of the cornea caused by the lens. These data can be compared with the changes in the visual acuity and the refractive errors. Well-matched lens ensures a redistribution of the corneal tissue, and the symmetrical changes are visible on the comparative topograms. A wrong selected lens will cause the irregular and asymmetrical changes of the shape of the surface. Some of the topograms made in the process of wearing lenses, have specific names:

- A «bull's eye» picture (Fig.2) is what usually seen in the axial or the refractive topogram when the result is ideal. It is a flattened area of impact, located in the center and bordered with an even zone of an increased curvature.

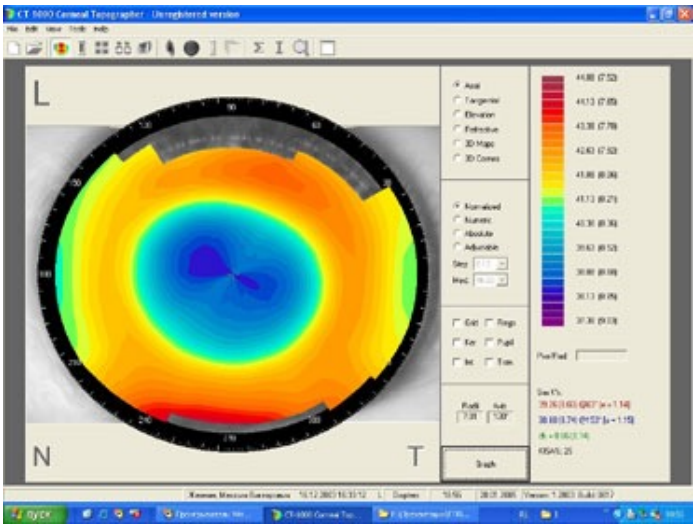


Figure 2 A «bull's eye» topography [19]

- A sharp crescent on the topographic map indicates that the lens have been displaced on the cornea in the opposite direction.

- By a «smiling face» meant an area in the shape of a sharp crescent visible on a comparative topogram in the lower sector of the cornea, which has arisen due to the lens shift upward.
- A «gloomy face» looks the other way round and it is a consequence of the displacement of the lens downwards.
- «Central islands» - small isolated areas with a greater curvature within the relatively flat area of impact. They are the result of a tight lens, which sagittal height is too great.
- A «dint» refers to a small area of considerable simplification or even the erosion of the epithelium due to too flat fitting lens, that rubs the top of the cornea. This diagnosis can be confirmed by using fluorescein and / or skiascopy. [7, 11, 12]

2.6. Lens fitting issues

If myopia had not dropped or fallen slightly after a night with the lens on, the lens should be changed. In case of the centered impact it is usually achieved by the diagonal principle «down» movement. For example, if the original lens is CK 43.00/TP -4.50/e 0.5, it is necessary to apply a lens CK 42.50 /TP -4.00 /e 0.5. In some cases, if the effect of the lens is centered, but the required visual acuity is not reached and stabilized for a few days, the lens can be changed by increasing TP. If the original lens is CK 43.00/TP -4.50 /e 0.5, it is possible to try on the lens CK 43.00/TP -5.00/e 0.5 instead.

If the sagittal height is too great, the central island may appear on the comparative topography. Central island does not always require the replacement of the lens, since the cornea is sometimes an area that responds to the impact slower than neighboring areas. If the curvature of the central island is higher than the original curvature of the cornea, and an island does not disappear in 2-3 nights, it is required to change a lens with the moving "down" on the diagonal principle as in the previous case.

Any expressed lens decentration, which leads to double vision, halos, excessive radiance etc., requires replacement of the lens. It is possible to easily notice the decentration using the comparative tomography. The picture of the «smiling face» means that the lens has

been moved up at night. Usually it is a consequence of a plane fitting (a lack of a sagittal height) and requires a replacement of the lens using the diagonal principle «up»: for example, if the original lens is CK 43.00/TP -4.50/e 0.5, it is necessary to apply the lens CK 43.50/TP -5.00/e 0.5. A picture of a «gloomy face» means that the lens has been shifted down at night. Usually it is a consequence of a tight fit (an excess sagittal height) and requires the replacement of the lens using the diagonal principle «down»: for example, if the original lens is CK 43.50/TP -4.50/e 0.5, it is necessary to apply the lens CK 43.00/TP -4.00/e 0.5.

It should be noted that these tactics are right to use in most cases, but not always. Sometimes in a «gloomy face» case the lens replacement diagonally «up» applies, and vice versa - in a «smiling face» case the replacement diagonally «down» is needed. First of all, it requires a careful evaluation of the fitting when the lens is replaced.

If the lens is decentered laterally, there is no universal procedure. Increasing the lens diameter can help, but it is not possible using standard lenses. The lateral decentration almost always requires a change of the base curve, that means rejecting the diagonal principle. The following tactics might be used: first, reduce the TP in the absolute value (for example, replace the lens CK 43.00/TP -5.00/e 0.5 with CK 43.00/TP -4.50/e 0.5. It often happens that after the application, the lateral decentration is replaced by a picture of a «gloomy face». After it is possible to use the diagonal principle, as described above. On the other hand, increasing the absolute value of TP might help, for example, replacing the lens CK 43.00/TP -4.50/e 0.5 with CK 43.00/TP -5.00/e 0.5).

«Sticking» lenses

The lens sticking on the cornea is always possible when the RGP lens is worn overnight. A typical sign of sticking - a ring-shaped impression or an imprint of the lens on the cornea. Ortho-K lens can get stuck even shortly after putting on, if too tight. If it happens the lens have to be replaced. The patient should be warned that in order to minimize "sticking" lenses he has to drip two drops of the recommended moisturizing liquid in both eyes or the artificial tears just before bedtime and once again upon waking. It is better if the lenses are not removed within about 30 minutes after awaking. Often the stuck lenses might start to move by themselves either after blinking or applying the drops. Improper removal of the sticked lens can damage the epithelium, that is why the patient should be

taught to recognize «sticking» lenses and how to proceed to avoid a trauma or complications.

«Rippling»

A big bubble, appeared between the lens and the cornea and divided into many small bubbles. Those form many small depressions or ripples in the epithelium. Biomicroscopy using fluorescein allows to see these formations. Usually, these types of bubbles' formations occur when the sagittal height is too great.

Low vision

In some cases, the visual acuity without correction may gradually decrease after the lens removal. It usually occurs because of the exposure area, that is too small and the corneal center flattening, that is insufficient. To reduce the degree of myopia, the lens can be replaced using the diagonal principle «down», or simply by increasing the absolute value of the TP. It can also be recommended to the patient to wear the lenses a bit longer after the awaking. In any case, when trying to achieve the maximum visual acuity, it is important to be sure and take into consideration the subjective feelings of the patient.

The above described method of the OK-lenses fitting provides a well predictable and an accurate orthokeratology effect. [7, 11, 12]

3. Myopia, its prevalence and negative consequences

Myopia is one of the leading causes of poor vision in the world, and this trend is increasing. The most difficult situation has been developed in the countries of Southeast Asia. In Taiwan, for example, 84% of school children have some degree of myopia (75% of boys and 93% girls) to 18 years (Fig.3).

The prevalence of myopia varies in different countries; the highest one is in Eastern Asia. In Europe, according to the last published data, almost 1/3 of the population is myopic; high myopia contributes 2.7 %. In young participants of the study (25 – 29 years old) the prevalence of myopia was significantly higher (almost 50 %); high myopia contributes more than 5 %. What can be seen from these numbers, is notable increase of growth rate of myopia prevalence, and especially of high myopia. It is time to talk about the epidemic character of myopia, at least in developed countries. And, whatever reasons would predispose to this situation, here it is:

- about 230 million of myopic persons in Europe
- about 20 million of them are high myopes
- the growth rate of myopia is increasing
- high myopia grows faster than low and moderate one

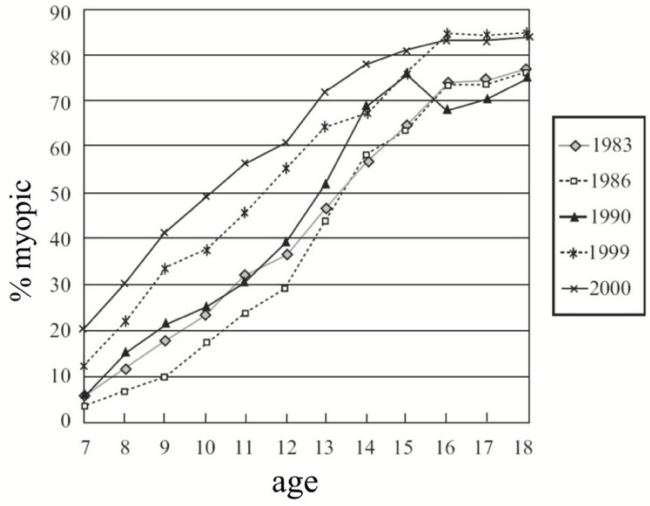


Figure 3 Prevalence of myopia in taiwanese schoolchildren. [13]

With the increase in myopia has also come an increase in financial expenditures for the correction of before mentioned health problem. It has been estimated that myopia correction has seen around $2 billion annually in the United States. This altogether means that finding the methods of myopia prevention are in urgent need. Due to this dramatic increase, controlling the problem properly is the primary target of scientists worldwide, and thus many methods of myopia intervention are now being investigated. [14]

3.1. Myopia and eye pathology.

The myopic refractive error by itself is just a symptom, but myopia is a real disease, an eyeball pathology. There is a term «pathological myopia», which mostly means myopia more than 6 D. This term might be confusing and reflects to the fact that in high myopia, the incidence of complications is much bigger than in low or moderate one, but it does not mean that low and moderate myopia is free of complications. Any myopia is a disease that alters the posterior pole of the eyeball. In this respect, first of all, myopia can lead to negative consequences. Secondly, it can interfere in the other ocular diseases, affecting their progression and treatment.

1. Idiopathic rhegmatogenous retinal detachment is urgent and sight-threatening pathology, in the patients older than 50 it is the 3rd main ocular cause of hospitalization (after cataract and glaucoma). Myopia is an unambiguous risk factor for this type of retinal detachment, and the higher myopia is, the higher is the risk.

2. Myopic retinopathy. This pathology manifests in different changes of the fundus, as posterior staphylomas, lacquer cracks, patch atrophy or choroid neovascularization. Myopic retinopathy prevails in elder patients (over 50 years old), and also reveals an obvious positive correlation with the level of myopia.

According to the data of World Health Organization, glaucoma and cataract are 2 of the 3 main global causes of blindness. The interrelations between cataract and myopia, as well as between glaucoma and myopia are not clear and quite controversial from the point of causation (what is the cause of what). However, the least we could say with assurance is that myopia affects the progression and treatment of cataract and glaucoma. Finally,

myopia is one of the leading causes of low vision and blindness all over the world, including Europe. [3, 15, 20]

3.2. Social burden of myopia.

First, about the persons who are visually disabled, especially blind persons. To live and not to see is a very serious problem, from the point of view of psychologists. We do not realize how much information we receive through our eyes, and how difficult is to substitute it.

The next social problem is that during waking hours the myopic patients are dependent on the traditional methods of vision correction - spectacles and contact lenses. The higher myopia is, this dependence is more, and sometimes the person with high myopia is helpless without glasses or contact lenses.

Another problem is that the spectacles and contact lenses create some restrictions for usual human activities, like professional occupations, active recreation and sport (especially in children). Some of professional occupations have special regulations concerning the lack of distance visual acuity and prohibit the use of spectacles or contact lenses (police officers, firefighters or pilots). For some other professions there are no such legal restrictions, but insufficient visual acuity and use of traditional means of correction can cause issues (house builders).

In sport, myopia brings two sorts of restrictions [3]:

- Non-visual restrictions relate to potential direct athlete's health harm due to myopia, that is mainly associated with the enhanced risk of retinal detachment. This is concerns the sports performing the head punches, like boxing, or frequent shakes of the body, like judo.
- Visual restrictions relate to the limitations of traditional visual correction, as mentioned above. One is the possible danger of the sportsman's health and life, for example, in slalom. Another limitation is possible decrease of sport performance. It also concerns a great number of sports: football, biathlon, fencing, etc.

Because of dependency on visual correction and activity restrictions, myopic patients have lower quality of life comparing to their non-myopic age mates. It is very important in children, because of worsening the formation of their social adaptation. [2, 15, 20]

Myopia is one of the leading causes of visual impairment all over the world. Due to that, myopia creates serious social burden for modern society, complications of myopia occur mainly after the age of 50 years, but the basis of these problems is being formed in childhood, between 7 and 17. These 10 years are crucial for intervention to prevent myopia progression.

4. Orthokeratology and myopia control.

During the last years, the topic of myopia control with overnight orthokeratology is well elucidated by different researchers, and a number of excellent reviews has been published. It is important to understand the perspectives that Ortho-K could have.

4.1. Scientific evidences.

The urgency of the issues associated with the ability to slow down the myopic progression is obvious. Many studies have been made and the results, that have been obtained are very convincing.

Today the part orthokeratology takes in scientific research is much higher than in practice. The scientific interest caused by the opportunities that orthokeratology promises to control the progression of myopia. There is a number of works published and performed concerning this subject, enough to perform an acceptable analysis. The retrospective work has been excluded and here is the result.

- The first prospective pilot work on the subject, that was attended by 35 children from 7 to 12 years old, using OK lenses, on control - 35 children with normal glasses (taken from an earlier study). The time of the lens wear - 2 years. [21]
- The next study involved 40 children from 8 to 11 years old have been started the study, 28 have completed in the OK group. A similar group - on control with SCL (soft contact lens) from an earlier study (CLAMP - Contact lenses and myopia progression). Another control group - RGP from the same study. Wearing period - 2 years. [22]
- The study by Swarbrick HA et al. involved 14 children and teenagers from 10 to 17 years, one eye using OK-lens, the second eye - RGP. After 6 months - a break during two weeks and tests, then the lens have been reversed, and children have been wearing them 6 more months. It was a year in total. This is a very unique type of the experiment, that is somehow difficult to compare the obtained data to the other published works. [23]

- The Japanese research by Kakita et al., that initially involved 105 children and teenagers from 8 to 16 years old: 45 (42 completed) - OK group, 60 (50 completed) - control (glasses). The time of the lens wear - 2 years. [24]
- Another work of the same group of authors published a year later, partly combined with the previous research and with a slightly modified design (maximum age was limited to 12-th years). 29 patients (22 completed) - OK group, 30 patients (21 completed) - control (normal glasses). The time of the lens wear - 5 years. [25]
- There is one more study made in Hong Kong and was registered as a clinical trial. The responsible performer - Pauline Cho. It began with 102 and ended with 78 children aged 6 to 10 years, randomly divided into OK- and control groups (control - regular glasses); this is the only study that randomized and masked. It was a two-year study, from 2008 to 2011. [26]
- An additional study of the same person - Pauline Cho (also registered as a clinical trial), where were 37 children from 7 to 12 years old, withe the same control group as the ROMIO study, also a two-year study. Here all children had myopic astigmatism from 1.25 to 3.50 D, and the OK-lenses were toric. [27]
- A study that was made in Spain. Children from 7 to 12 years, 31 child in the OK group, 30 in the control (monofocal glasses). A two-year study. [28]
- A dissertation of RR Toloraia, scientific director - EP Tarutta (Helmholtz Moscow Research Institute of Eye Diseases, Moscow, Russia). The study involved 312 children aged 7 to 18 years, there was no control. The lens wear period - from 2.5 to 7 years. [29]
- PG Nagorskiy et al. (Novosibirsk Branch of Fyodorov Eye Microsurgery Complex). The study involved 260 children and adolescents aged 7 to 18 years, 200 children were using OK lenses from 2 to 5 years, 60 children - the control group using glasses or SCL + treatment hardware. [30]

When we talk about the progression of myopia, an axial myopia, associated with an increase in the longitudinal dimension of the eyeball is meant. The diagnosis "progressive axial myopia" is confirmed on the basis of three main research methods: an objective

refractometry with cycloplegic, an ultrasound biometry and an optical biometry. Accordingly, the data obtained by researchers can be divided into three main groups.

- Changes of the objective refraction.
- Changes in the length of the eye, detected using specific A-scan ultrasound biometry.
- Changes in the length of the eye, detected using optical biometry (IOL-Master - partial coherence interferometry).

Here are three tables that summarize the published data. The data were standardized - annualized, so the results are presented as a parameter change per year. Unfortunately, the ways the experiments have been made, lead to different results, that is why it is not possible to accurately standardize the data obtained by different authors. However, there are some definite conclusions can be done.

When wearing OK lenses, the objective reliable refractometry data can be obtained only after stopping the OK therapy, in other words - until the topography of the patient no longer differs from the original one. Only two studies have measured refraction in these conditions (see Tab.1). Although the absolute value of refraction change varies considerably, the trend remains the same: in the OK group the annual increase of the myopic refractive error is significantly higher than in the control group. The last column shows how much.

Table 1 The objective refractometry. The first column - the name and year of the study, the second - the period of wearing lenses, the third - the refraction change in the group with the OK-lenses, the fourth - the Rx change in the control group, the fifth - the ratio of Rx changes in the OK group and the control group.

Study	Period	ΔR/D (OK)	ΔR/D (control)	ΔR Control /ΔR OK
LORIC (2005)	2 years	compared to OK	not published	--------
CRAYON (2009)	2 years	not published	not published	--------
Swarbrick et al. (2010)	1 year	not published	not published	--------
Kakita et al. (2011)	2 years	compared to OK	-0.62 a year	--------
Hiraoka et al. (2012)	5 years	compared to OK	-0.64 a year	--------

MCOS (2012)	2 years	compared to OK	-0.63 a year	--------
ROMIO (2012)	2 years	not published	not published	--------
TO-SEE (2012)	2 years	not published	not published	--------
Toloraia RR (2008)	2 years	not published	not published	
Nagorskiy PG (2012)	5 years	-0.29 a year	-0.72 a year	2.48

The next table (Tab.2) shows the data about the length of the eye changes, measured using A-scan. These data are sufficiently homogeneous, the only different study is the thesis of RR Toloraia - the annual change in eye length was 0.07 mm, and the data are statistically considerable.

This might be due to the fact that the measurements were made in different places using different instruments by different specialists; it is a known flaw of an ultrasound biometry. However, there is no such an issue in optical biometry. The data obtained using this method are quite uniform.

Table 2 Ultrasound biometry. The first column - the name and year of the study, the second - the period of wearing lenses, the third - the change in the anteroposterior distance (APD) in the group with OK-lenses, the fourth - APD change in the control group, the fifth - the ratio of changes between OK-group and the control group.

Study	Period	ΔAPD, мм (OK)	ΔAPD, мм (control)	ΔAPD Control/ ΔAPD OK
LORIC (2005)	2 years	0.15 a year	0.27 a year	1.8
CRAYON (2009)	2 years	0.13 a year	0.29 a year	2.23
Swarbric et al. (2010)	1 year	not done	not done	--------
Kakita et al. (2011)	2 years	not done	not done	--------
Hiraoka et al. (2012)	5 years	not done	not done	--------
MCOS (2012)	2 years	not done	not done	--------
ROMIO (2012)	2 years	not done	not done	--------
TO-SEE (2012)	2 years	not done	not done	--------
Toloraia RR (2008)	2 years	0.07 a year	not published	--------
Nagorskiy PG (2012)	5 years	0.12 a year	0.28 a year	2.33

Table 3 The optical biometry. The first column - the name and year of the study, the second - the period of wearing lenses, the third - the change in the APD group with OK-lenses, the fourth - APD change in the control group, the fifth - the ratio of changes in the APD between OK-group and the control group.

Study	Period	ΔAPD, мм (OK)	ΔAPD, мм (control)	ΔAPD Control/ ΔAPD OK
LORIC (2005)	2 years	not done	not done	-------
CRAYON (2009)	2 years	not done	not done	-------
Swarbric et al. (2010)	1 year	0.04	0.17	4.25
Kakita et al. (2011)	2 years	0.20 a year	0.31 a year	1.55
Hiraoka et al. (2012)	5 years	0.20 a year	0.28 a year	1.4
MCOS (2012)	2 years	0.24 a year	0.35 a year	1.46
ROMIO (2012)	2 years	0.18 a year	0.32 a year	1.7
TO-SEE (2012)	2 years	0.16 a year	0.32 a year	2.0
Toloraia RR (2008)	2 years	not done	not done	-------
Nagorskiy PG (2012)	5 years	not published	not published	-------

The only figures that differ (Tab.3) are the ones published by H.A.Swarbrick, but, as it was mentioned above, the peculiar conditions of this experiment make the comparison much difficult.

As we can see from the tables 1-3, none of the studies did not refuse the assumption of the orthokeratology inhibitory effect on the progression of myopia, on the contrary, they have confirmed this hypothesis. And it looks more like a scientific fact.

Japanese authors [25] analyzed the bonds between progression of myopia, the age and the original refraction.

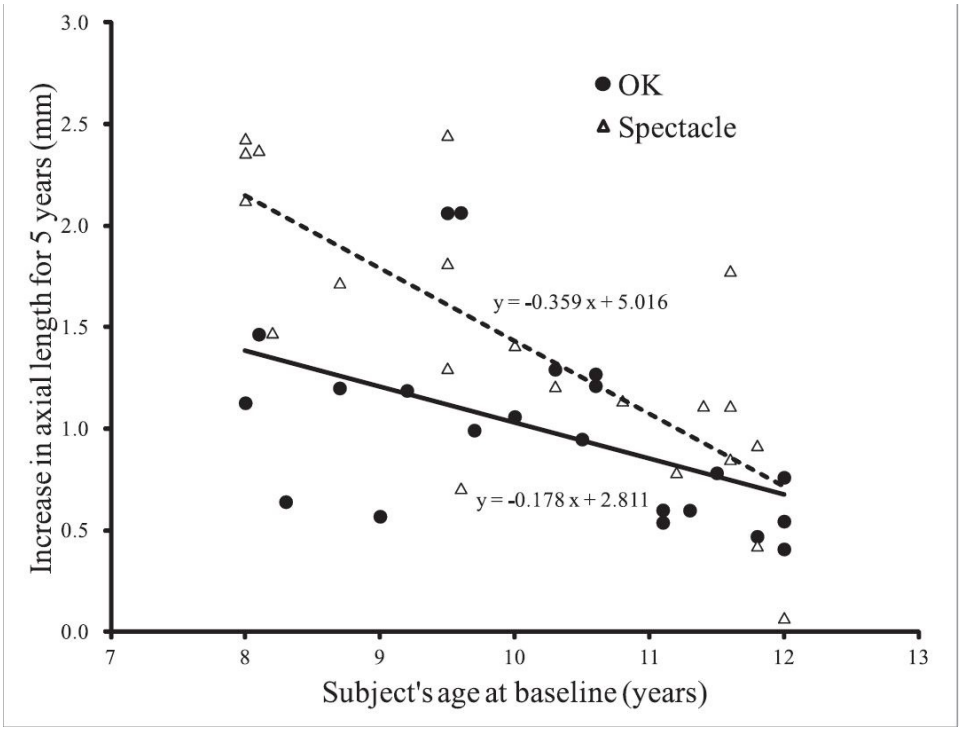


Figure 4 The regressive dependency between age and the initial increase in APD. [25]

They did a regression analysis and found a significant difference between the two groups according to age (Fig. 4). The authors concluded that the earlier the OK lenses wearing begins, the greater braking effect it will have on the progression of myopia. Regression analysis revealed no significant difference between the groups, depending on the original refraction.

Same data were obtained in ROMIO study - the authors also concluded that, there is no dependence on the original refraction, but the age. The earlier the patient starts wearing OK lenses, the greater the braking effect on the progression of myopia will be (Fig. 5.).

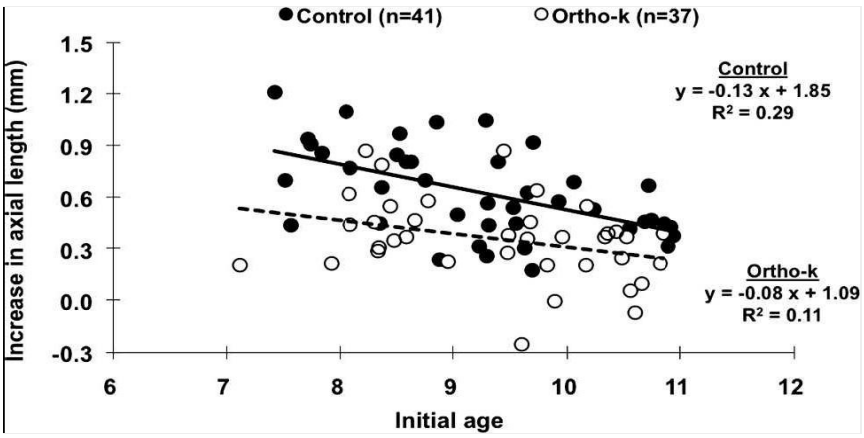


Figure 5 The regressive dependency between age and the initial increase in APD. [26]

In addition, orthokeratology favorably changed the dependence between the groups of slow, moderate or rapid progression of myopia, especially in children 6-8 years old (Fig. 6).

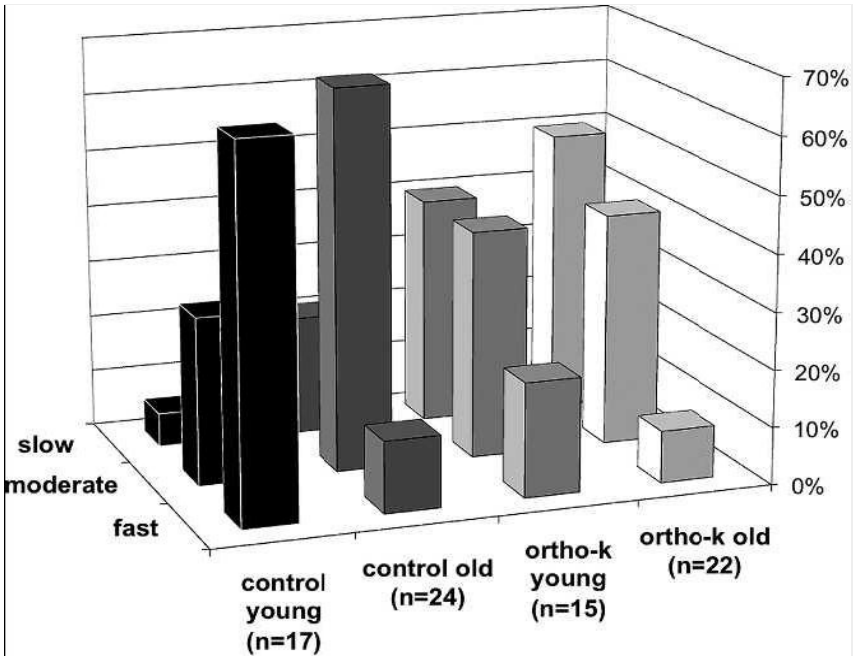
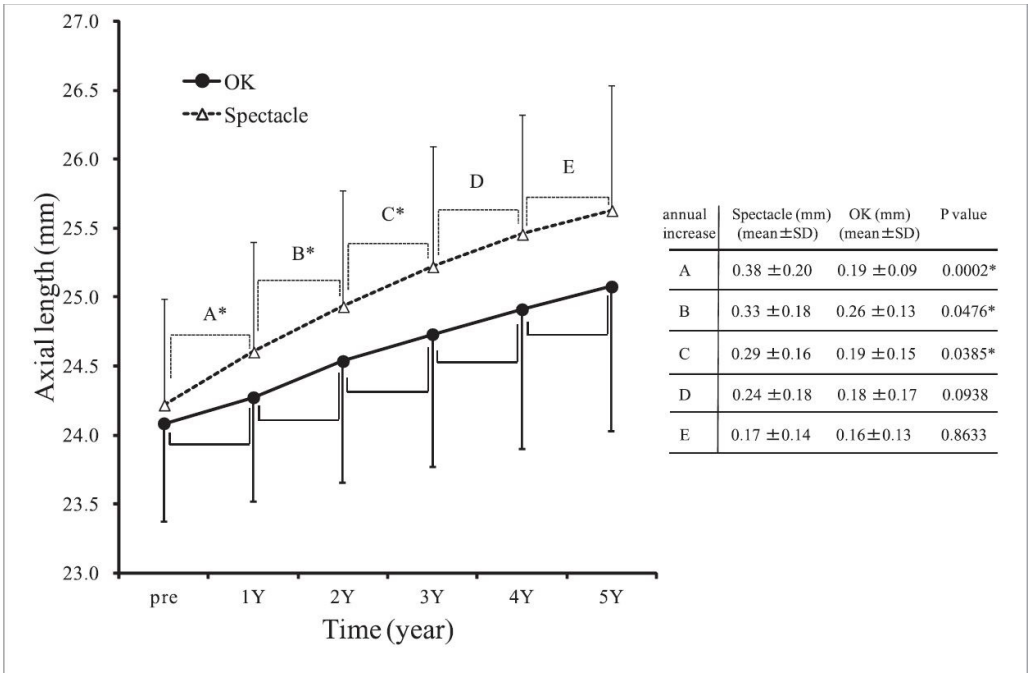


Figure 6 The ratio of slow (<0.18 mm per year), moderate (0.18 to 0.36 mm per year) and fast (> 0.36 mm per year) myopic progression in the young age-groups (the youngest 6 - 8 years old, the eldest 9 - 10 years old) in the control group and OK group. [26]

The Japanese studies have discovered that the difference in the rate of myopic progression between groups had gradually decreased until the complete disappearance after the 5-year wear (Fig. 7). Most probably it is due to maturation of the patients: by the end of the fifth year of study, their average age has reached 15 years, and the progression of myopia slows significantly and without any effects at this age. Actually, this graph shows that in the Orthokeratology group the APD increase in 5th year maintains almost the same, whereas in the group with glasses this rate falls by more than half compared to the 1st year.



annual increase	Spectacle (mm) (mean±SD)	OK (mm) (mean±SD)	P value
A	0.38 ±0.20	0.19 ±0.09	0.0002*
B	0.33 ±0.18	0.26 ±0.13	0.0476*
C	0.29 ±0.16	0.19 ±0.15	0.0385*
D	0.24 ±0.18	0.18 ±0.17	0.0938
E	0.17 ±0.14	0.16±0.13	0.8633

Figure 7 Dynamics of the APD in a OK group and in control group. [25]

To be repeated: none of the published studies has not refused the assumption of the inhibitory effect of OK therapy on the myopic progression, on the contrary, they have confirmed this assumption. Currently, the main mechanism considered, that underlies this phenomenon, is a change in the nature of peripheral refraction.

4.2. Peripheral retinal defocus.

The light rays entering the eye are focused on the different places on the retina. The rays going paraxial (parallel to the main optical axis of the eye, and not far from it), are focused in the macular region, and provide central vision. The rays entering into the pupil by different angles, are focused on the periphery of the retina and form an area called focal plane (in fact it's not a plane, but a figure resembling a hemisphere) - see Fig. 8. Several studies, firstly the one of Earl Smith III, provide quite convincing evidence, that the axial growth of the eye is affected by the peripheral focus, rather than the central.

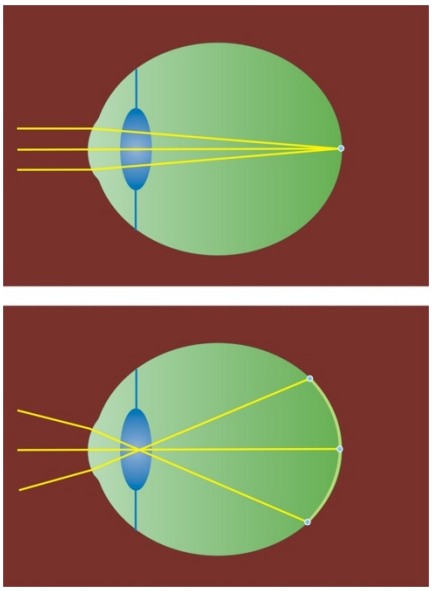


Figure 8 The upper picture - paraxial rays are focused on the macula (emetropy). The lower figure - slanting rays focusing on the retina and the periphery forming the focal plane (emetropy). [19]

Briefly, peripheral hyperopic focus stimulates the eyes growth in length, but peripheral myopic focus slows down this growth (Fig. 9). The back pole of the eye "strives" to meet the peripheral focus plane.

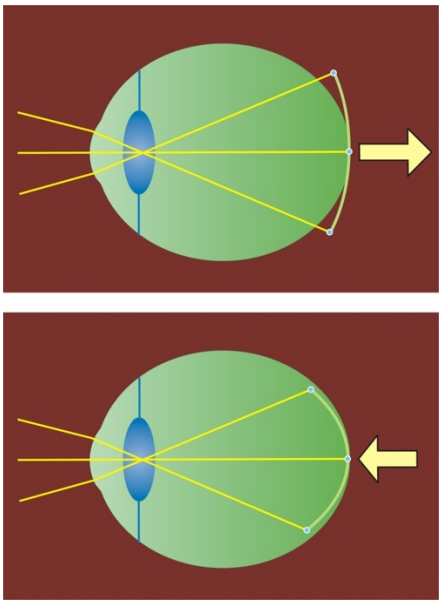


Figure 9 The upper picture - peripheral hyperopic focus. The lower picture - peripheral myopic focus. [19]

In this connection, the usual spectacle and contact correction, appeared to provide a central emmetropization that creates hyperopia in the periphery. In OK therapy case it was shown that during central emmetropization the peripheral myopia arises - apparently

due to an increase in the curvature of the cornea in the midperiferic zone (see Fig. 10). Today this mechanism is considered to be the baseline of the suppressing effect of OK-therapy in the myopia development. [16, 17, 18]

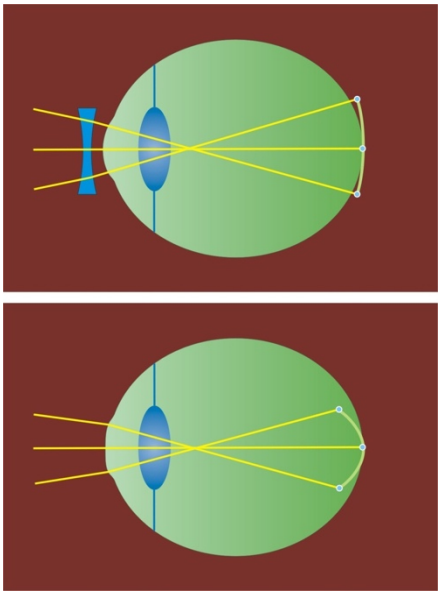


Figure 10 The top picture - central emmetropization and peripheral hyperopic focus using spectacle correction and soft contact lenses. The lower picture - central emmetropization and peripheral myopic focus using OK therapy. [19]

Conclusion.

Orthokeratology is a promising method of myopia control, a trustworthy, and sometimes the only alternative to glasses, daily contact lenses or laser correction. From a practical point of view, it is reasonable to say that OK therapy can and should be one of the first choice methods to correct myopia in children. Here are the statements that completely sum up the research I have done:

- OK therapy suppressing effect on the myopic progression is a proven scientific fact
- Ortho-K is unique by combination of its advantages, providing not only myopia control but at the same time high visual acuity and independence on the means of visual correction during waking hours
- The earlier the patient begins to use OK-lenses, the greater braking effect can be expected
- Although the myopization of the peripheral refraction is assumed to be a base of the suppressing effect of OK therapy in the myopia development, the identification of the detailed mechanism of this phenomenon is the subject of the future research
- Ortho-K, by the combination of its advantages, can seriously reduce social burden of myopia
- Ortho-K in children and adolescents bears additional risks of microbial keratitis, which should be taken into consideration in practice

Orthokeratology is generally a safe option to help correct and retard myopia, however its long-term success depends on a multitude of factors such as rigorous compliance of lens use and care regimen, adherence to routine follow-ups, timely and appropriate treatments to complications, and proper fitting of the lenses.

At the end I would like to highlight, that the eye care specialists have at least three options:

1. To be against Ortho-K and not recommend it for myopia control.
2. To be unconcerned – if the patient wants Ortho-K, it can be performed, if he doesn't – the Ortho-k therapy is not offered.
3. To recommend OK therapy to the patients, especially to control myopia, collecting and analyzing the information about complications of myopia.

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List of Figures

List of Tables