



Changes in the intraocular pressure value, when wearing orthokeratology lenses

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Abstract

Introduction: Quite new on the Swedish market are orthokeratology lenses, used for both correction and myopia control. At the moment there are 22 practitioners in Sweden fitting orthokeratology lenses and 5 of those stands for 75 % of all fittings. Measuring the intraocular pressure in the eye is an important part of an eye- examination, because high intraocular pressure can result in glaucomatous changes. When using the orthokeratology lenses the corneal thickness changes, it decreases in the central epithelium and increases in the mid-peripheral stroma. The corneal thickness is affecting the intraocular pressure value.

Aim: The aim of the study was to evaluate how the intraocular pressure, measured with a non-contact tonometer, changes when using orthokeratology lenses.

Method: 7 people were fitted with orthokeratology lenses. The intraocular pressure was measured before using the lenses, after the first night, after the third night and after the seventh night. 12 eyes were measured after the tenth night, because of drop- out of two eyes.

Result: Already after the first night a significant decrease in the intraocular pressure occurred with 1, 34 mm Hg ($p= 0,049$). Day ten the intraocular pressure had an average decrease of 2, 67 \pm 2, 14 mm Hg, which was a significant change ($p= 0, 002$).

Discussion: This study shows when wearing orthokeratology lenses a decrease in 2, 67 \pm 2, 14 mm Hg at day 10 can be expected.

Sammanfattning

Ett alternativ för tillpassning av mjuka kontaktlinser är orthokeratologi- linser. 2005 blev dreimlite konceptet introducerat i Sverige av Nordiska lins och för tillfället finns det 22 stycken tillpassare av orthokeratologi linser, 5 av dessa står för 75 % av alla tillpassade linser. En viktig del i en synundersökning är att mäta det intraokulära trycket i ögat. Högt intraokulärt tryck kan leda till sjukdomen glaukom, vilket kan resultera i synfältsdefekter och även blindhet.

Vid användning av orthokeratologi- linser ändras corneas tjocklek, den minskar centralt och ökar perifert. En minskning av tjockleken i cornea har visats ge ett lägre mätvärde av det intraokulära trycket i ögat.

Den här studien har inriktat sig på hur mycket vi kan förvänta oss att ändringen av det mätta intraokulära trycket blir vid användning av orthokeratologi- linser, mätt med en non- contact tonometer.

7 personer blev tillpassade med orthokeratologi linser. Alla som medverkade blev tillfrågade och de medverkade frivilligt. De synfel som krävdes var myopi från -0,75 D till -4, 50 D, astigmatismen fick inte överstiga -0, 75 i 90 grader eller -1, 50 i 180 grader.

De medverkande blev tillpassade med orthokeratologi- linser och det intraokulära trycket i ögat mättes innan användandet, efter första natten, efter tredje natten, efter sjunde natten och efter tionde natten. Det mättes alltid någon gång mellan kl 11 och 13 för att undvika det ödem som uppstår under natten, och gör att corneas tjocklek ökar, eftersom corneala tjockleken påverkar det uppmätta värdet av intraokulära trycket.

Redan efter första natten märktes en signifikant minskning av det uppmätta intraokulära trycket på medelvärdet $1,43 \pm 2,47$ mm Hg ($p=0,049$). Dag 10 hade det minskat med 2,67 mm Hg, jämfört med innan användandet (statistiskt signifikant $p=0,002$).

Den här studien har visat att användning av orthokeratologi linser inte har någon större påverkan på det intraokulära trycket vid dag 10 och det är därför inte nödvändigt att ta med det i beräkningarna när man använder linserna.

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Introduction

Quite new on the Swedish market is the concept of dreimlite orthokeratology lenses, it was introduced 2005 by a Swedish company, Nordiska lins. Orthokeratology lenses are an alternative fitting to the commonly used contact lenses. In a short timeframe the knowledge and expertise has been built up and now there are 22 practitioners in Sweden fitting orthokeratology lenses. Of those there are five who stand for 75% of the lens fitting (E- mail information from Peter Åström, Nordiska lins). Measuring the intraocular pressure is an important part of the examination of the eye, because a high intraocular pressure can cause glaucomatous changes (Benjamin, 2006). The theory behind orthokeratology lenses is that wearing these will change the corneal thickness, and changes in the corneal thickness has been shown by Murase et al, 2009 to get a different measured value of the intraocular pressure. This study will concentrate on how much change we can expect in the measured intraocular pressure value when using orthokeratology lenses, without measuring the corneal thickness.

Cornea

The cornea is a transparent outer layer of the eye (fig.1). It is ellipse shaped with an average horizontal diameter of 12, 6 mm and vertical diameter of 11, 7 mm.

The central cornea is thinner, 0, 52 mm, than the peripheral portion of the cornea, 0, 65 mm.

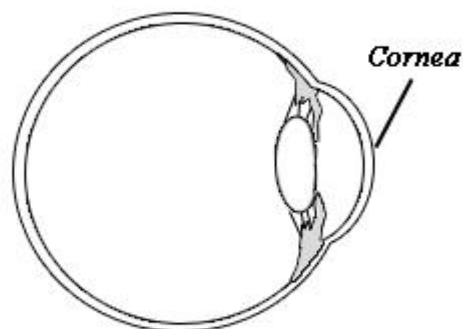


Fig. 1 Corneas placement by Emelie Nilsson

The normal corneal thickness and water content is temperature dependent. When cooled, the cornea swells but returns to its normal thickness when the temperature normalizes (Kaufman, Alm, 2003). The cornea consists of five layers; epithelium, anterior limiting lamina, stroma, posterior limiting lamina and endothelium (Bergmanson, 2005).

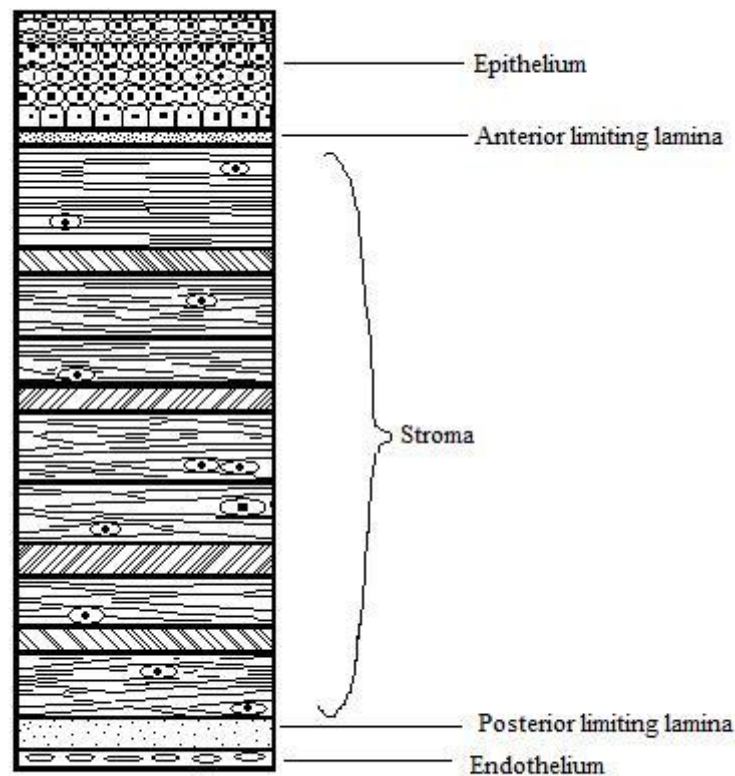


Fig. 2 The corneal layers. Based on a picture from *Clinical ocular pharmacology*, Bartlett, Jaanns, 2001, p. 21

Epithelium

The outer structure is the epithelium which is five to eight layers thick. The center of the epithelium is the thinnest and it increases more peripherally (Phillips, Speedwell, 2007). The epithelial surface forms a protective layer and prevents invasion of microorganisms, which is the primary function. Tear stabilizing, is another function of the epithelium, the microvilli on the surface of the epithelium stabilize the tears to avoid dry eyes (Bergmanson, 2005). The epithelium also absorbs excess fluid from the stroma which will keep the layer transparent. The organization in the epithelium is highly regular, which is important for the optical

properties of the cornea, and it has a constant cycle of shedding of superficial cells (Kaufman, Alm, 2003).

Anterior limiting lamina

The anterior limiting lamina, also called Bowman's membrane is acellular and modified stromal tissue made up of collagen. It enables epithelium adherence (Bergmanson, 2005).

Stroma

The thickest part of the cornea is the stroma which represents 90 % of its thickness. It is formed by collagen and keratocytes. The collagen is organized in bundles called lamellae and the keratocytes are found between the lamellae. The regular arrangement formed by the keratocytes, keeps the cornea transparent (Bergmanson, 2005). The stroma has a water content of 78% and it is maintained by the barrier and pump functions of the endothelium. If mechanisms that remove the fluid from the stroma do not work, the stroma will swell and comes opaque (Kaufman, Alm, 2003).

Posterior limiting lamina

The posterior limiting lamina is the thickest membrane of the body, also called Descemet's membrane (Bergmanson, 2005). The collagen fibrils, that the posterior limiting lamina consists of, are arranged in such a way that it has an elastic property. The posterior limiting lamina is very resistant to trauma, proteolytic enzymes and some pathological conditions. If it is damaged it can be regenerated without leaving any scars (Remington, 2005).

Endothelium

The endothelium is a single layer of hexagonal shaped cells which cannot be reproduced. The endothelium controls the fluid movement between the cornea and the aqueous humor. If it is balanced the cornea remains transparent, otherwise there will be oedema and the cornea will become opaque (Bergmanson, 2005).

Trabecular meshwork

The trabecular meshwork is located between the peripheral termination of the cornea and the angle recess. The resistance of the aqueous outflow occurs by the trabecular meshwork. Only particles smaller than 1- 2, 5 μm in diameter can pass through the trabecular meshwork (Bergmanson, 2005).

Aqueous humor

The aqueous humor is formed by epithelium of the ciliary body and transported into the posterior chamber. The fluid circulates through the pupil, towards the anterior chamber angle, where it drains via the outflow apparatus. 80 % goes via the trabecular meshwork with a resistance to the outflow and the rest goes to the uveoscleral pathway without resistance (Bergmanson, 2005). After that the aqueous humor goes into the episcleral veins, into the lumen and then to the blood circulation (Kaufman, Adler, 2003).

Active secretion accounts for 80-90 % of the aqueous humor formation and requires energy to secrete substances against a concentration gradient. Diffusion and ultra filtration are two passive processes and do not require any active cellular participation and account for the remaining 10- 20% of the aqueous humor formation (Kaufman, Adler, 2003).

The composition of the aqueous humor, whose production rate is 2- 3 $\mu\text{l}/\text{min}$, is electrolytes, low- molecular- weight compounds and some protein. The functions of the aqueous humor are transporting the necessary metabolites, oxygen and glucose to the lens and cornea, to remove toxic metabolic waste products of the iris and cornea and to maintain the intraocular pressure of the eye (Forrester et al, 2008).

Intraocular pressure

A function of the eye is to maintain an intraocular pressure between 10 and 20 mm Hg. That is achieved by the aqueous humor production and outflow (Forrester et al, 2008). The intraocular pressure represents the balance between the production and the outflow of the aqueous humor. Elevated intraocular pressure can result in glaucomatous changes, decreased vision and blindness (Benjamin, 2006).

Issues that have a long-term effect on intraocular pressure are: genetics, age, gender and refractive error. If anyone in a family has high intraocular pressure there is a larger risk that other members of the family also will have a higher intraocular pressure. After the age of 40, especially in females, there is a higher risk of raised intraocular pressure, caused by the lower level of estrogen (Bergmanson, 2005).

In the morning the intraocular pressure is higher than in the evening, normal change is from 3 – 6 mm Hg (Bergmanson, 2005). Myopes have longer eyes than emetropes and hyperopes. Because of the larger, thinner eyes, myopes tend to have higher intraocular pressure and have an increased risk for glaucomatous changes (Benjamin, 2006). Several drugs can affect the intraocular pressure. For example corticosteroids, which are used for treating ocular inflammation disease, reduce the aqueous humor outflow and therefore the intraocular pressure increases. Alcohol increases the osmotic pressure which leads to a lowered production rate, and the intraocular pressure is reduced (Bartlett, Jaanus, 2001).

Tonometry

Different tonometers can be used to measure the intraocular pressure in an eye. The standard tonometry is the Goldmann applanation tonometer but a non-contact tonometer can also be used (Benjamin, 2006). In Sweden optometrists are not allowed to use instruments that touch the eye, other than those needed for fitting contact lenses (SOFS 1995:4, 4§).

The thickness of the cornea is related to the intraocular pressure. A thicker cornea gives a higher intraocular pressure measure reading. According to Murase et al, 2009 the intraocular pressure changes by 0, 29 mm Hg, measured with the non-contact tonometer, for every 10 μ m change in the central corneal thickness. According to Dought and Zaman, 2000 a change of 10 %, approximately 50 μ m, in the central corneal thickness will give a change of 3, 4 mm Hg in the intraocular pressure, measured with the Goldmann tonometer, which will give a change in the intraocular pressure of 0, 68 mm Hg for every 10 μ m. It has been shown by Harada et al, 2008, when measuring the intraocular pressure, the non-contact tonometer is more affected by the corneal thickness than the Goldmann tonometer is.

Contact tonometer

The Goldmann tonometer is the most common way, worldwide, to measure the intraocular pressure. Anesthetic with fluorescein is applied to the eye and the Goldmann tonometer probe is applied to the cornea. When the probe is touching the cornea two yellow-green semi circles will be seen in the biomicroscope that the Goldmann tonometer is fixed to. By adjusting the force of the tonometer, the inner edges of semicircles will touch and the intraocular pressure can be read from a scale (Benjamin, 2006).

Non-contact tonometer

A non-contact tonometer does not require anesthetics. With the patient's head seated in the headrest the non-contact tonometer can be focused on the center of the eye. When focused it sends out a jet of air and the time it takes to flattening the central part of the cornea relates directly to the level of intraocular pressure (Kanski, 2007). Instead of changing the force to the cornea that Goldmann achieves, the non-contact tonometer uses a constant force against the cornea (Benjamin, 2006).

Tonometer CT 80 A

The tonometer CT 80 A measures the intraocular pressure in the eye on the central 3, 00 mm of the cornea. The result is calculated and presented in mm Hg (E- mail information from Göte Kalnins, Topcon 4/5 – 2009). This non- contact tonometer was used in this study.

Orthokeratology

Orthokeratology lenses reshape the cornea; the central cornea flattens in curvature and the mid-periphery steepens. There is an improvement in uncorrected visual acuity and a reduction in myopia and astigmatism (Mountford, et al 2004). Orthokeratology lenses are used as a refractive method and have also been showed to be a method for myopia control (Cho et al, 2005).

The method is that by wearing the orthokeratology lenses over night, for at least 8 hours; the required changes in corneal shape will be achieved and also maintained. How long the change will maintain depends on how long the lenses have been used and which refraction is corrected. Wearing the lenses over night has benefits. It is an increased efficacy of the procedure because the lens lies in a stable position on the eye. There are no environmental problems such as wind or dryness. The adaption problems are few or none, the risk of losing the lenses are low and not having to wear lenses during the day is an advantage. (Phillips, Speedwell, 2007).

Good candidates for orthokeratology lenses are those who have a refractive error within acceptable limits; myopia from -0, 50 D to -4, 50 D, and maximal astigmatism of -0, 75 D in 90 degrees or -1, 50 D in 180 degrees. The different astigmatism depends on the wider horizontal diameter of the cornea which is mentioned earlier. The astigmatism should not be from limbus to limbus, which is seen when taking topography pictures for ordering of the lenses. The candidates should wish to be free from spectacles and contact lenses during the day. Those who experience dry eyes or discomfort with soft contact lenses are also good candidates for orthokeratology (Mountford et al, 2004). Normal healthy cornea, lids and conjunctiva are also requirements for using orthokeratology lenses (Phillips, Speedwell, 2007).

When using orthokeratology lenses the epithelium and the stroma are affected, there is a thickening of the mid- peripheral stroma and a thinning of the central epithelium. According to Alharbi and Swarbrick, 2003, the corneal thinning is stabilized by day 10 and it decreases with $15, 8 \pm 3, 3 \mu\text{m}$ with overnight orthokeratology. The mid-peripheral stroma thickens with $10, 5 \pm 5, 9 \mu\text{m}$ and will be stabilizing by day 10.

Topography

An essential part of orthokeratology is corneal topography, not only for fitting but also for determining changes and to see the result of orthokeratology lens wearing. This is done by comparing the differences between the pre- and post-wear topography (Phillips, Speedwell, 2007). The perfect fitting will result in a mid-peripheral steepening around a zone of flattening which is centered over the middle of the pupil, called a Bull's eye pattern (fig. 3) (Mountford et al, 2004).

Autorefractor/ Topograph KR8100P

This instrument was used in this study and it is used as an autorefractor and also a topograph; it uses 11 placid discs that are projected on the cornea. The placid discs create a maximum of 3600 measuring points and each point is compared with a perfect sphere creating a map. It presents in different ways, for example a colored map, with warm colors as hills (red– yellow) and cold colors as valleys (blue– green) (E- mail information from Göte Kalnins, Topcon 4/5 – 2009).

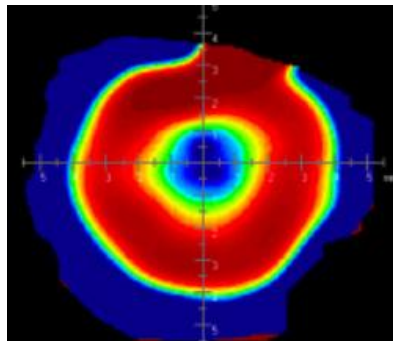


Fig. 3 Picture of a Bull's eye topography map, with permission from Göran Skjöld

Topography maps

Wearing orthokeratology lenses can lead to differences in the appearance of the topography maps. Bull's eye, the optimal picture with the ideal fit, is one of them; the other ones are smiley face, central island (fig. 4), frowny face (fig 5) and lateral decentration (fig 6) (Phillips, Speedwell, 2007)

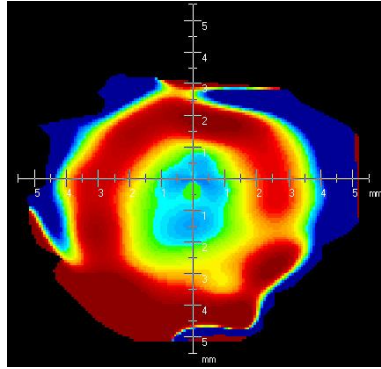


Fig. 4 Picture of a central island (the green zone in the middle) corneal topography map, taken by Emelie Nilsson

Central island pattern is usually caused by a steep lens, a too large total diameter or the lens is too tight in the alignment curve (fig 7). The alignment curve is the third curve on the back of the lens, it is near- alignment with the corneal surface and controls the centration of the lens. The central island pattern is a central steepening in the center and the unaided visual acuity is generally worse than having a bull's eye map (Phillips, Speedwell, 2007).

When the lens decenters inferiorly, caused by a tight alignment curve or a too small lens diameter, a frowny face pattern is shown on the topography map (fig 5). It leads to decreased visual acuity than if the lens is centered correctly, and an increase of flares and halos (Phillips, Speedwell, 2007).

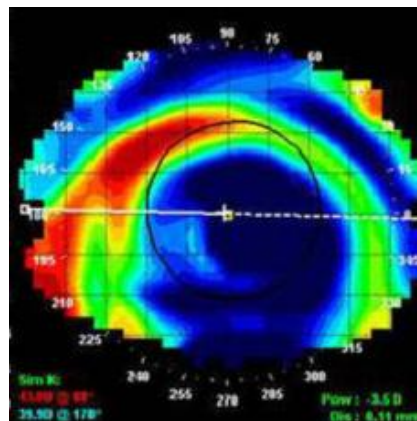


Fig. 5 Picture of a frowny face topography map, with permission from Göran Skjöld

A flat lens that has decentered superiorly will give a smiley face pattern on the topography map, since an area above the pupil will be flattened (it has the same appearance as the frowny face pattern (fig 5), but the red- green area is seen inferiorly and reversed instead. There might

be a reduction in myopia, but also an increased with-the-rule astigmatism (Mountford et al, 2004).

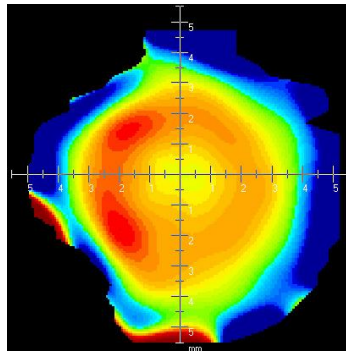


Fig. 6 Picture of a lateral decentration topography picture, taken by Emelie Nilsson

Lateral decentration is caused by a too small lens or the lens is too tight or loose (fig 6). The cornea is flattened more nasally than with an optimal fit (Phillips, Speedwell, 2007).

Lens design

Orthokeratology lenses are designed in three different ways, three- , four- and five- zone lenses (fig. 7).

The first lens design was the three- zone lenses, which had problems with decentration of the lenses. To solve the problem four- and five- zone lenses were constructed.

Four- zone orthokeratology lenses are designed with a central back optic zone diameter, the diameter that the back optic zone radius, the first curve, acts over. The back optic radius affects the cornea and changes the refraction. The next curve after the back optic zone radius is the reverse curve, and after that an alignment curve, which has been described in the topography map section. Last a peripheral curve is found, the final curve on the back surface. Five- zone orthokeratology lenses are designed the same way as four- zone lenses, only adding another alignment curve (fig. 7) (Mountford et al, 2004).

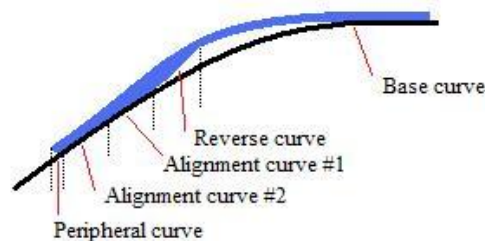


Fig.7 Construction of a five- zone lens. Based on picture from Mountford, Ruston, Dave, 2004 page 7

Fitting procedure

When orthokeratology lenses are fitted correctly an area of central touch is shown over the pupil zone. The minimum amount of tear layer visible under the lens is 20 μm . The reasons for the existence of the tear layer between the lens and the cornea, when using gas- permeable lenses, are to evaluate the fit of the lens by using fluorescein. The tear layer also helps prevent damages to the epithelium. Under the orthokeratology lens in the central zone the tear layer is less than 20 μm and for that reason the fluorescein will not be seen in this area (Mountford et al, 2004).

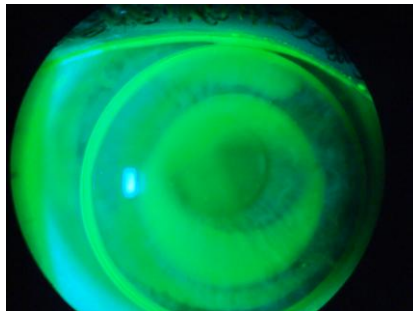


Fig. 8 Picture of an orthokeratology lens decentered inferiorly and laterally, with fluorescein applied to the eye, taken by Emelie Nilsson

There are three different ways of fitting orthokeratology lenses; empirical fitting, trial lens fitting and topography- based fitting (Phillips, Speedwell, 2007).

When using empirical fitting the patient's keratometer value, the radii of curvature in two meridians on the approximately 3 mm central cornea (Benjamin, 2006), and refraction are used to order the orthokeratology lens. The lens is designed by a laboratory and then sent to the practitioner. The result of wearing the lens is reviewed after the first night and a week later. If the result is not optimal, the laboratory will do modifications to the first lens, usually changes in the reverse curve or the alignment curve. The lens will be modified until expected results are achieved, a good uncorrected visual acuity has been reached or the patient is not a good enough candidate for orthokeratology lenses, and the refraction cannot be corrected (Phillips, Speedwell, 2007).

When using trial lens fitting, manufacturers give practitioners fitting nomograms in order to select the initial trial lens. The nomogram is usually based on a predetermined relationship between the lens design and the eyes corneal shape. The trial lens is then inserted and lens

movement, centration, and fluorescein pattern are analyzed. The practitioner is then able to prescribe a lens, from the data of the patient. (Mountford et al, 2004).

Topography fitting starts with taking pictures of the cornea with a topograph. Then the apical radius, eccentricity and elevation are calculated. The values are inserted in the orthokeratology lens manufacturer's software and after calculating; the first trial lens is determined and will be created by the manufacturer. After the lenses have arrived they are inserted in the patients eyes and the movement and centration of the orthokeratology lens are reviewed. If unexpected results are achieved it will be followed by modifications until expected effects are achieved (Phillips, Speedwell, 2007).

Complications

There is an increased risk, 5,4 times higher (Dart et al, 2009), of microbial keratitis with overnight wearing lenses. Closed eyelids, will give the contact lenses a higher temperature than wearing lenses during the daytime, the higher temperature makes the microorganism grow. When sleeping the blinking rate is lower than at daytime. No exchange of tear fluid results in no elimination of bacterial microorganisms, and makes it easier for the pathogenic microorganisms to bind to the cornea (Sun et al, 2006). Other risk factors for microbial keratitis are exposure to contaminated water and non-compliance with the practitioner instructions, for example not changing disinfection solution continually (Watt, Swarbrick, 2005).

Overnight wearing lenses can adhere to the cornea during sleep. Typically the lens is decentered, usually in the nasal position (Phillips, Speedwell, 2007). Lens binding occurs as a result of the changes on the corneal shape and the thinner tear film induced by the lens. It can appear after every night or be random, depending on the patient's tear viscosity (Mountford et al, 2004).

Bubble deformations under the lens can occur and with repeated blinking the bubbles can break down into smaller bubbles. When removing the lens and applying fluorescein on the eye, dimple staining will be seen caused by the small bubbles. It should not be mistaken for corneal staining, epithelial damage. After 1- 2 hours the cornea should have recovered and no sign of dimple staining should be seen (Mountford et al, 2004).

Loss of effect with the orthokeratology lenses can occur if there are heavy deposits on the back surface of the lens. When the lens is aged, the design may be affected, it can become steeper, flatter or warped, and the effect of the orthokeratology lens can therefore be decreased. Decentration of the lenses while sleeping can result in flattening of the wrong area of the cornea and cause poor vision (Mountford et al, 2004).

Similar study

A similar study to this one, measuring the intraocular pressure with a non- contact tonometer when using orthokeratology lenses, was made by Berke and Bruckmann, 2003. They had 43 participants which all were fitted in both eyes with orthokeratology lenses. The decrease in their study was $1,7 \pm 2,3$ mm Hg at day 14, not with a significant change $p > 0,05$ because of a large amount drop- outs, only 22 persons participated in the last measurement which occurred after 8 weeks. Berke and Bruckmann also measured the corneal thickness and could therefore see if the decrease in the measured intraocular pressure values was significant with the decrease in the corneal thickness.

By this gathering of information about how much the intraocular pressure will change it gives the optometrist facts for advising customers in regard to wearing orthokeratology lenses.

Aim

The aim of the study was to evaluate how the intraocular pressure, measured with a non-contact tonometer, changes when using orthokeratology lenses.

Method and Material

Material

The same room and instruments have been used in all the examinations.

The instruments used from Topcon were; Phoropter CV 3000, Autorefractor/ Topograf KR8100 P, Non-contact Tonometer CT 80 A, Biomicroscope SL-7F and a digital pupil distance measurer, PD-5. An occluding spade and a ruler have also been used.

All intraocular pressure measurements were taken between 11 to 13 o'clock, always without lenses in the eyes. When sleeping the corneal thickness increases and oedema occurs (CL Harper et al, 1996); therefore the intraocular pressure was measured a few hours after wakening since the oedema disappears a while after wakening. The intraocular pressure value increases with a thicker cornea (Murase et al, 2009).

Dreimlite

The orthokeratology lenses, that have been used, were ordered from Swedish Nordiska lens, and were of the brand Dreimlite, made by Procornea, Netherlands. Topography fitting was used and a picture of the cornea and the refraction error was sent to Nordiska lens.

Dreimlite orthokeratology lenses are made of the material Boston XO and are a 4 – zone lens. The basic design consists of a 10, 00 mm total diameter with a 6, 00 mm back optic zone diameter.

Care products

The subjects received hydrogen peroxide, with a lens case, of the brand AO Sept plus. When using hydrogen peroxide no rubbing is needed on the lenses, which is required for multi-purpose solutions (Phillips, Speedwell, 2007). AO Sept plus works by disinfecting the lenses and it also removes protein; no separate cleaner should be used together with AO Sept plus (Directions AO Sept plus, CIBA VISION). Boston conditioner was used for better comfort when inserting the contact lens (Directions Boston condition, Baush & Lomb). Sterile saline solution was used to wash the lenses if needed, and the subjects also received lubricants of the brand Aquify, to use when having dry eye sensation or in the morning when lens adherence occurred during the night. Aquify was used because it does not include any preservatives in

the eye (Directions Aquify, CIBA VISION). Preservatives can cause reactions in the eye for example conjunctival oedema and punctate epithelial staining. Stinging, burning and increased lens awareness are different signs of preservative reaction (Phillips, Speedwell, 2007).

Subjects

All subjects were found at the University of Kalmar and were asked to participate. The required correction went from -0, 50 to -4, 50D, the astigmatism was not allowed to be over -0, 75 D in 90 degrees or -1, 50 D in 180 degrees (Mountford et al, 2004). The subjects needed to be soft contact lens users to minimize the time it takes for lens handling and also to decrease the amount of time required for the participants to get used to the lenses on the eyes.

Method

Preliminary examination

In the first meeting the subjects were informed about the purpose of the study. They received information both verbally and on paper and their participation were voluntary.

A detailed history was taken, questions like problems with dry eyes, good ocular health and medical history were asked. Uncorrected visual acuity at distance was taken and corneal diameter was measured with a ruler to see the required lens diameter (Mountford et al, 2004).

The pupil distance was measured to center the phoropter and a binocular refraction, monocular fogging procedure, was used with a phoropter to find the spherical power and the Jackson cross cylinder to assess the astigmatism. The best corrected visual acuity was also measured (Elliott, 2003). The eyes were graded according to the Efron- scale with the biomicroscope SL-7F; to make sure they were in good ocular health and to be aware of any changes while wearing the orthokeratology lenses.

Finally, a corneal topography picture was taken with the topograph, for ordering Dreimlite lenses with the manufacturers program Dreamlite and to provide an original picture for analyzing the effects orthokeratology lenses had on the cornea (Mountford et al 2004).

Lens delivery

When the lenses had arrived a visit occurred sometime between 11 to 13 o'clock, because the intraocular pressure was always measured at that time. First a control and grading, according

to the Efron- scale, of the eyes outer segment was done to evaluate the ocular health with the biomicroscope. The subject practiced how to insert and remove the lenses.

At the end of the visit the intraocular pressure was measured with a non-contact tonometer to get a value to compare with the intraocular pressure measured when using orthokeratology lenses.

Day 1 and 3

The first and third visits occurred in the morning. A short history was taken and a control with the biomicroscope was done, with and without the lenses in the eyes. The centration and movement of the lenses were controlled, and the outer segments of the eyes were graded according to the Efron- scale. Visual acuity was taken without the lenses in situ, to see the improvement of the uncorrected visual acuity. After that the refraction were evaluated with a binocular refraction and the Jackson cross cylinder. The subject received, if it was needed for good visual acuity, one-day lenses to use during the following days (Mountford et al, 2004). A corneal topography picture was taken with topograph for following the corneal changes (Cho et al, 2008).

The intraocular pressure was measured with a non- contact tonometer sometime between 11 to 13 o'clock both day one and three.

Day 7 and 10

Sometime between 11 to 13 o'clock a visit took place. A short history was taken and the uncorrected visual acuity was measured. The corneal changes were seen by taking a topography picture with the topograph and the eye's outer segments were graded according to the Efron- scale using the biomicroscope SL-7F. In the end the intraocular pressure was measured with a non- contact tonometer.

Statistics

The intraocular pressure mean values, changes were calculated and the graphs were made in the program Microsoft Excel. A two sided paired t-test were done to calculate the p- value, to see if the changes were statistical significant.

Result

A total of seven persons were fitted with orthokeratology lenses, five women and two men, no one had ever tried orthokeratology lenses before. The mean age of all participants were $22, 8 \pm 2, 61$ years. All eyes received different powers of orthokeratology lenses. One person had to stop wearing the lenses at day nine because of staining. The result is therefore based on the fourteen eyes which participated until day seven and the last result at day ten is based on twelve eyes. See all measurements in appendix 3.

All the subjects complained about bad vision at distance, both blurry vision and halos, although they had good uncorrected visual acuity. They also thought the visual acuity was better outdoors than indoors. No sign of complications was found during the ten days the lenses were worn, except for one person, who got staining in one eye at day nine and was therefore considered to be an inappropriate candidate for wearing orthokeratology lenses

Eleven eyes got the same uncorrected visual acuity as the best corrected visual acuity; four eyes got it at day one, five eyes at day three, one eye at day seven and one eye at day ten. But none of the participants got the bull's eye topography pattern, which is the optimal topography picture (Mountford et al, 2004). Three eyes did not receive the same uncorrected visual acuity as the best corrected visual acuity.

In the first measurements of the intraocular pressure, the participants got normal values except for four eyes, according to Grosvenor, 2007 which states that normal values are up to 21 mm Hg. The eyes with higher intraocular pressure had the values of 23, 23, 21, 21 mm Hg, none of them reported any problems in the family, which made them eligible for the study. The intraocular pressure was taken three times in each eye and the mean value was calculated and used in the study.

Before starting to use the orthokeratology lenses the mean value of the intraocular pressure value was $16, 21 \pm 4, 37$ mm Hg. See the changed mean value of the intraocular pressure on fig 9. After the first night the intraocular pressure value had a mean decrease of $1, 43 \pm 2, 47$ mm Hg from day 0 (with significant change $p= 0, 049$). All eyes decreased in intraocular pressure value except three eyes, one stayed at the same value and two increased in intraocular pressure with 2, 00 mm Hg and 4 mm Hg.

After three days wearing orthokeratology lenses the intraocular pressure value had decreased with $1, 21 \pm 1, 80$ mm Hg from day 0 (with significant change $p= 0, 026$). Eleven eyes had a decreased intraocular pressure from day 0, one eye had the same value and two eyes increased with 2 mm Hg and 3 mm Hg. The decrease of $0, 21 \pm 1, 53$ mm Hg between day 1 and 3 was not statistically significant, $p= 0, 608$. Three eyes had the same intraocular pressure, six eyes were increasing and five eyes were decreasing.

The seventh day the intraocular pressure value had a mean decrease with $1, 14 \pm 2, 74$ mm Hg compared to the measurement before starting to wear the orthokeratology lenses (not statistically significant, $p= 0, 14$). Between day 3 and 7 there was an increase in the intraocular pressure value with $0, 07 \pm 1, 77$ mm Hg, which was not statistically significant ($p= 0, 88$). Five eyes had a decreased value, four eyes had an increased value and five eyes had no change in the intraocular pressure value.

After ten days the intraocular pressure had a mean decrease of $2, 67 \pm 2, 14$ mm Hg, with a statistical significant $p= 0,002$, compared with the measurement before using orthokeratology lenses. The mean intraocular pressure value of that day was $14, 42 \pm 3, 03$ mm Hg. One person had to stop wearing the orthokeratology lenses at day 9 because of deep staining on one eye; therefore the tenth value was calculated with 12 measured eyes. All eyes had a decreased intraocular pressure compared with the measurement before the subjects started to wear orthokeratology lenses. Between day 7 and 10 there was a decrease in the intraocular pressure with $0, 42 \pm 1, 93$ mm Hg (no significant change $p= 0, 47$). Six eyes had a decreased value, three eyes had a increased value and three eyes did not change in the intraocular pressure value.

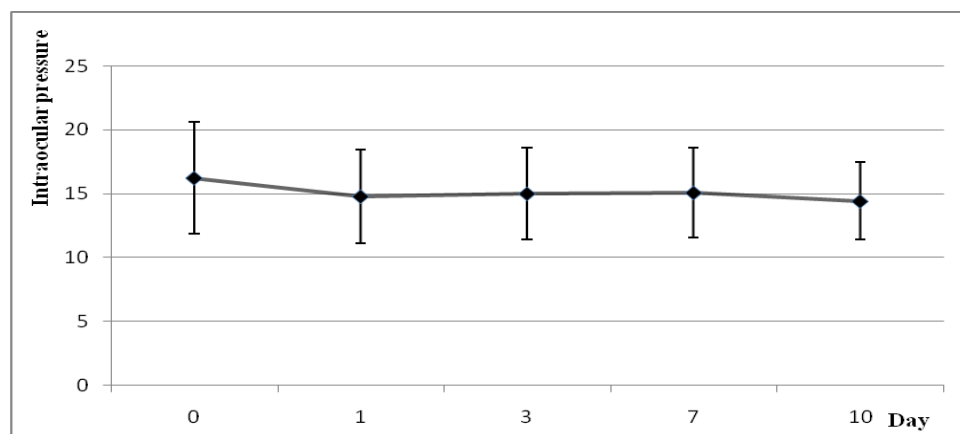


Fig. 9 The intraocular pressure changes with standard deviation

Discussion

Orthokeratology is an effective fitting method for reducing myopia and astigmatism. If a bull's eye topography pattern is not accomplished the uncorrected visual acuity could be good anyway. Therefore a topographic picture should be taken every visit for evaluation of the contact lenses' effect on the corneal change.

The participants all complained about bad vision although they had good uncorrected visual acuity. This is probably due to the corneal flattening not being finished; they did not have the bull's eye topography map which is the expected result when using orthokeratology lenses. The pupil size could have been bigger than the optical zone, since they stated their vision was better outdoors than indoors. (Mountford et al, 2004). It could also be explained by too short wearing time of the orthokeratology lenses or the wrong fitting of the lenses.

It has been shown by Mountford et al, 1994, that it takes approximately ten days to correct refraction errors with orthokeratology lenses. In this study twelve eyes got the same uncorrected visual acuity as the best corrected visual acuity before the procedure and none received the bull's eye pattern in the topographic pictures. It could be explained by decentration of the lenses, which can lead to for example lateral decentration maps resulting in poor uncorrected visual acuity. It could also be explained by the participants not wearing the lenses for at least 8 hours, which leads to not getting the required changes in the cornea.

Although only seven persons were measured, significant changes in the intraocular pressure could be seen from the first night. The optimal method would have been to measure the thickness of the central cornea, to know if the change of value in the intraocular pressure was comparable with the central corneal thinning. This, however, was not possible since optometrists in Sweden are not allowed to use instruments that touch the eye, except when fitting contact lenses.

The change between day one and three, day three and seven, and day seven and ten was not significant ($p > 0,05$), which is due to that the intraocular pressure decrease is flattening when the corneal thickness is not changing any longer and almost finished.

The similar study by Berke and Bruckmann, 2003, had a decrease in the mean intraocular pressure value with $1,7 \pm 2,3$ mm Hg at day 14, (not significant $p > 0,05$) In this study the intraocular pressure was measured until day ten and the mean decrease of the value was $2,67 \pm 1,93$ mm Hg. Berke and Buckmann's value were $0,97$ mm Hg lower than the results in the this study. It could depend on the large drop- outs of participants, although they had more participants throughout the whole study. If more people had participated in this study would the mean value of the intraocular pressure be something else?

By day ten the corneal topography map was not totally finished, the participants had not received the Bull's eye topography pattern. If the study had continued a few days more, the subjects may have received the optimal topography map. And if they had received it the intraocular pressure changes could have been different.

The topography pictures may have been taken incorrectly if the participants were sitting in the wrong position with the head, or not looking straight forward. The intraocular pressure could also have been measured not totally in the center of the cornea which could lead to an incorrect value.

According to this study the mean decrease in the intraocular pressure that can be expected when wearing orthokeratology lenses is $2,67$ mm Hg (significant change $p = 0,002$). Further investigation would be needed with a larger amount of measured eyes and the study should be continued until receiving the bull's eye topography map. The corneal thickness should also be measured to know if changed value of the intraocular pressure is correct.

This study shows a small decrease in the intraocular pressure value after ten days. It is therefore not clinically significant to recalculate the intraocular pressure when using orthokeratology lenses.

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School of pure and applied Natural Sciences
University of Kalmar
Optometry department

Information for you who are attending my study:

The purpose of this study is to see how the intraocular pressure in the eye can change when using orthokeratology lenses, overnight-wearing lenses.

At our first meeting I will exam your vision and eyes, and you will get fitted with orthokeratology lenses, this will take approximately 1,5 hours. You will get both verbal and written information about the lenses and how to use them properly. When the lenses have arrived you need to wear them every night during two weeks, under these weeks five visits will be required. The first and third visit will take around 30 minutes and have to be done in the morning with the lenses in situ. The pressure measuring that need to be done sometime between 11 to 13 o'clock, will be done on the following days; 1, 3, 7, 10 and 14'Th and will only take around 5 minutes.

Your participation is voluntarily and you can leave the study whenever you decide, without any reason. All personal records will be treated completely confidential, meaning that the results in this study cannot be associated with you. No compensation will be offered for participating.

If you have any questions or complications appear with the lenses, do not hesitate to contact either me or my supervisor.

Emelie Nilsson
XXX- XXXXXXX
en22dh@student.hik.se

Supervisor
Johanna Enbuske, Leg. Optiker
XXX- XXXXXXX
johanna.enbuske@hik.se

Thank you for your participation!

I give my approval for participating in this study:

Name

City and date

Signature

Patient record

Appendix 2

Preliminary examination

Name: _____ Age: _____ Telephone: _____

History: _____

Pupil distance: OD: _____ OS: _____

Uncorrected Visual Acuity: OD: _____ OS: _____ Binocular: _____

Corneal diameter OD: _____ OS: _____

Grading by the Efron-scale	OD	OS	Other
Eyelid			
Conjunctiva			
Cornea			
Tearfilm			
TBUT			

Refraction: H: _____ VA: _____

V: _____ VA: _____

Bin. VA: _____

Lens delivery

History: _____

Grading by the Efron-scale	OD	OS	Other
Eyelid			
Conjunctiva			
Cornea			

IOP: OD: _____ OS: _____

Day 1

History: _____

Grading by the Efron-scale	OD	OS	Other
Eyelid			
Conjunctiva			
Cornea			

Uncorrected Visual Acuity: OD: _____ OS: _____ Binocular: _____

Refraction: OD: _____ VA: _____

OS: _____ VA: _____

Bin. VA: _____

Daily-wear lenses:

OD: _____ VA: _____

OS: _____ VA: _____

Bin. VA: _____

IOP: OD: _____ OS: _____

Day 3

History: _____

Grading by the Efron-scale	OD	OS	Other
Eyelid			
Conjunctiva			
Cornea			

Uncorrected Visual Acuity: OD: _____ OS: _____ Binocular: _____

Refraction: OD: _____ VA: _____

OS: _____ VA: _____

Bin. VA: _____

Daily-wear lenses:

OD: _____ VA: _____

OS: _____ VA: _____

Bin. VA: _____

IOP: OD: _____ OS: _____

Day 7

History: _____

Grading by EFRON	OD	OS	Other
Eyelid			
Conjunctiva			
Cornea			

Uncorrected Visual Acuity: OD: _____ OS: _____ Binocular: _____
IOP: OD: _____ OS: _____

Day 10

History: _____

Grading by EFRON	OD	OS	Other
Eyelid			
Conjunctiva			
Cornea			

Uncorrected Visual Acuity: OD: _____ OS: _____ Binocular: _____
IOP: OD: _____ OS: _____

A compilation of the intraocular pressure measurements

Eye	Day 0	Day 1	Day 3	Day 7	Day 10
1	12	10	11	10	10
2	12	10	11	11	10
3	16	14	12	14	13
4	15	13	13	13	14
5	21	20	20	19	19
6	21	17	19	17	17
7	23	22	21	21	17
8	23	17	19	19	16
9	11	12	11	13	16
10	11	16	14	18	17
11	18	16	16	17	
12	17	17	16	16	
13	14	12	15	12	11
14	13	11	12	11	13