CHAPTER 14

ORTHOKERATOLOGY OR CORNEAL RESHAPING TECHNOLOGY (CRT)

During the 1960's it was observed that fitting standard rigid lenses flatter than the flattest corneal curvature for myopia, and steeper than the flattest corneal curvature for hyperopia, created a temporary reduction in uncorrected refractive error [259]. This led to the development of "orthofocus"—the precursor to orthokeratology—and soon after, to the "recessed optic" lens, in which the optic zone was cut flatter than the periphery of the lens to improve centration [259].

During the 1980's with the advancement of lathing technology, a reverse geometry lens design was created [260–262]. The development of innovative materials and designs in the mid-1990s allowed faster, more reliable treatment effects and overnight orthokeratology [263–267]. All modern orthokeratology lenses utilise reverse geometry in their designs, and the variations among brands stem primarily from different assumptions made about average corneal shape. This chapter will provide an overview of general patterns of design and will not delve into specific lens brands.

Orthokeratology works by means of a squeeze film force between the lens and the cornea, acting tangentially across the corneal epithelium. The epithelium is thinned centrally and redistributed mid-peripherally [88] and the mid-peripheral stroma thickens (Figure 59). The thickening of the mid-peripheral stroma is thought to be due to the clamping effect of the reverse geometry lenses and corresponds with the mid-peripheral tear reservoir created under the steeper second curve of the reverse geometry lens [88, 268, 269].

Mid-peripheral corneal thickening and steepening is the main "myopia-controlling" stimulus, as it imposes significant myopic shift on peripheral retinal defocus, which is considered a potent myopia-inhibiting signal [270–273]. The overall magnitude of mid-peripheral corneal thickening and steepening, as well as central thinning and flattening induced by the treatment, correlates with the level of baseline (pre-treated) myopia [269]. Recent othokeratology designs have attempted to induce more significant mid-peripheral steepening independent of central thinning and flattening to enhance the "myopic-controlling" stimulus.

The Munnerlyn formula is used in refractive surgery to predict how much tissue needs to be removed for a given refractive error. In orthokeratology, this formula can be used to predict refractive change. Considering that the maximum change in central epithelial thickness is around 20 μm and the increase in mid-peripheral thickness is around 25 μm [264, 268, 274, 275] with orthokeratology, using the Munnerlyn formula for treatment zones of 6 and 4.0 mm would suggest anticipated maximum refractive changes of -1.75 and -3.75D. Some authors report that higher amounts of myopia can be corrected, but treatment zones to correct - 6.0D would have to be reduced to less than 3.0 mm leading to poor low contrast vision and halos [269]. Theoretically, the limit of myopia reduction is reached when corneal eccentricity is reduced to zero – in other words when the shape changes from a prolate ellipse to a slightly oblate shape [88]. As a rule of thumb, a change of 0.21 in corneal *e*-value is equal to a reduction of 1.00D in myopia [88]. The higher the initial eccentricity the greater

the refractive change possible [269]. Refractive change possible can also be determined by using the following formula [269]:

Eccentricity/0.21 = Refractive change possible

Munnerlyn Formula [276]:

$A = RD^2/3$

A = Ablation depth or central thinning

R = Refractive error

D = Diameter of the treatment zone

In summary, according to Helen Swarbrick, 2004 and 2006 the effect of orthokeratology is achieved not by overall corneal bending, but rather by subtle remodelling of the anterior corneal layers, specifically the corneal epithelium and stroma. The central corneal epithelium thins, probably due to water loss and dehydration, and the mid-peripheral stroma thickens, possibly due to oedema or deposition of stromal ground substance, due to the negative pressure generated under the mid-peripheral curve of the orthokeratology lens [264, 274]. Generally, the success of orthokeratology depends on; lid forces, duration of lens wear, type of fitting and lenses used, and the corneal biomechanics of the individual patient [88].

INDICATIONS FOR ORTHOKERATOLOGY [88]

- Young early myopes – myopia control
- Sport and vocation
- Occasional spectacle wearers
- Myopia up to -4.00 with low degrees of astigmatism
- High corneal *e*-values >0.50

CONTRAINDICATIONS FOR ORTHOKERATOLOGY [88]

- Myopia greater than -4.50D
- With-the-rule astigmatism over -1.25D
- Corneal astigmatism outside the treatment zone
- Against-the-rule astigmatism
- Residual astigmatism
- Low corneal *e*-values
- Large pupils – larger than the treatment zone
- Loose lids decreasing lid forces
- Keratoconus or other thin or irregular corneas
- Unrealistic patient expectations

THE ANATOMY OF A REVERSE GEOMETRY LENS

Modern orthokeratology lenses have between four and six zones, described below in order from central to peripheral.

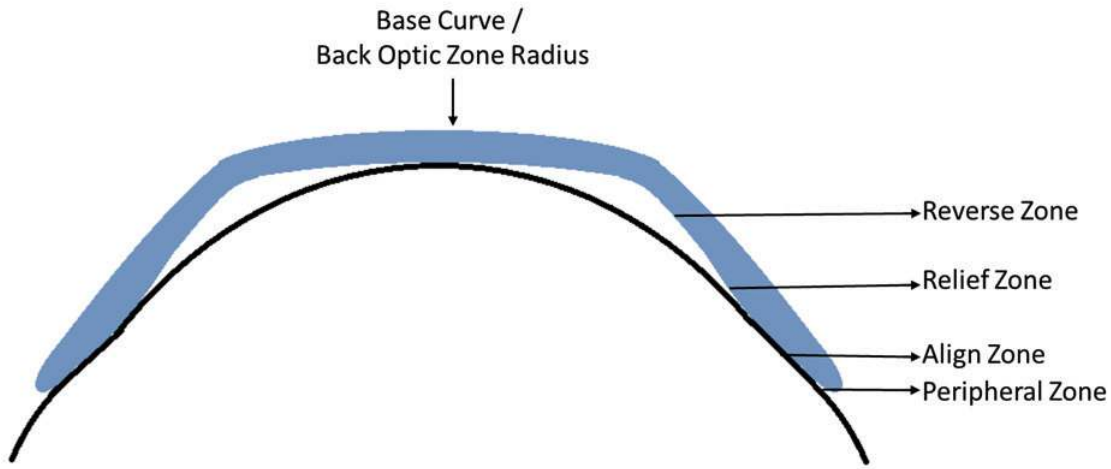

Figure 56: Anatomy of a reverse geometry orthokeratology lens [269]

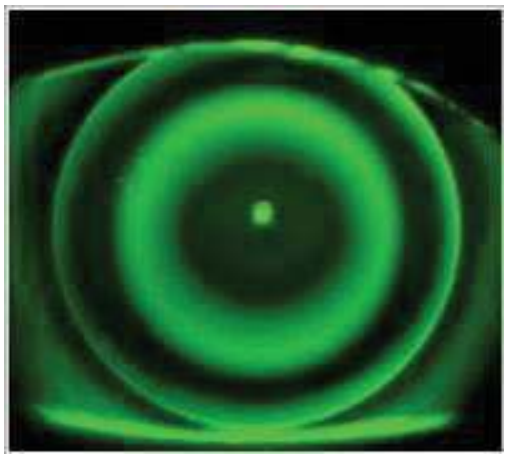

Figure 57: NAFL pattern of a well fitted orthokeratology lens

Base Curve (BC)

This central curve is typically between 5.0 mm to 8 mm in diameter and overlies the treatment zone on the cornea. The BC is chosen based on the amount of central corneal flattening desired. It is therefore related to corneal curvature and the amount of myopia treatment required. To determine the appropriate radius, many lens designs use a calculation called the Jessen Formula [269]. The first step in using this formula is to identify the amount of myopia correction desired, called the target Rx. This is often the spherical equivalent of the manifest refraction. The example below shows a manifest refraction of –4.00/–0.50 x 180. In this case, the target Rx is –4.25D [277].

The flat corneal meridian (flat K) is then identified in dioptric power from the corneal topography map and the BC is made flatter than flat-K by the target Rx (–4.25D), as well as an additional amount called the Jessen Factor (–1.25D). The Jessen Factor differs among lens designs, but ranges from 0.50D to 3.00D and every manufacturer has their own preference. The Jessen Factor is added to ensure that the desired treatment amount is achieved, and that it lasts throughout the day [259]. While a standard Jessen Factor may be adequate for some patients, flatter values may be required to achieve adequate treatment, especially in higher myopes [88].

Example of A Typical Calculation

Refractive error: – 4.00/-0.50x170

Target Rx: – 4.25D (spherical equivalent)

Flat-K: 42.75D (7.90 mm)

BC/BOZR = Target Rx (–4.25D) + Jessen Factor (–1.25D) = 5.50D flatter than flat-K

5.50D flatter than 42.75D = 37.25D (9.06 mm)

The amount of desired apical clearance under the BC is commonly 5 μm to 10 μm. It will therefore look as if the lens is bearing on the cornea when viewing the NAFL pattern as it falls below the 20 μm required to perceive NAFL beneath a contact lens [88]. Although this curve is usually spherical, an aspheric radius can be used to increase the amount of mid peripheral clearance, thereby creating more peripheral myopic defocus when desired [277].

Reverse Zone

This 0.5 mm to 1.0 mm wide zone joins the BC to the relief/alignment zones and is steeper than its neighbouring curves. The clearance under this curve is commonly referred to as the "tear film reservoir" and its depth is a function of the amount of myopia being corrected. With lower amounts of myopic correction, the tear film reservoir will be shallower than with higher amounts. For example, when correcting a –1.00D myope in one design, the tear film reservoir depth is calculated as 24 μm. Whereas, it is 79 μm for a –6.00D myope (with the same corneal shape) in the same lens design [277].

One of the primary functions of the reverse zone is to raise or lower the BC to create the desired amount of apical clearance. If the reverse zone is too steep, there will be excessive apical clearance, resulting in a topographical central island. If it is too flat, the lens will land on the corneal apex and not in the corneal periphery, resulting in lens decentration and a decentred treatment pattern [277].

Relief Zone

Not every orthokeratology design incorporates a relief zone, which aims to encourage proliferation of epithelial cells from the alignment zone toward the tear film reservoir. This may allow for more effective overall treatment in higher degrees of myopia. When present, the relief zone is 0.5 mm to 0.7 mm wide with a depth of 10 μm to 20 μm [277].

Alignment Zone

This 0.5 mm to 1.0 mm wide zone can be spherical, aspheric or a tangent. The shape of the alignment zone is best determined by considering the amount of eccentricity present along the flat meridian of the mid-peripheral cornea. Figure 54 shows, three corneas that have the same apical radius of curvature of 42.75D (7.90 mm) with three different eccentricities. The lower the eccentricity, the steeper the alignment curve needs to be to provide alignment. The higher the eccentricity, the flatter the curve needs to be. The fit of this zone contributes most to proper lens centration. This zone is where the lens lands on the eye, and minimal clearance (alignment) is desired. The greatest amount of epithelial thinning occurs under this curve; it is even greater than that in the central treatment zone [277].

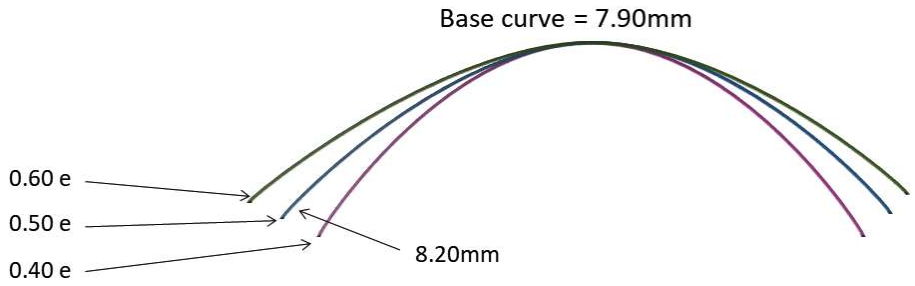

Figure 58: Eccentricity explained

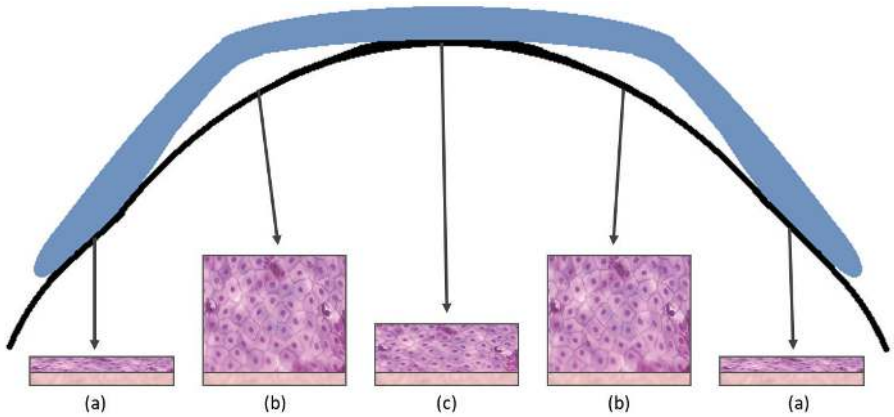

Figure 59: Effect of orthokeratology lens on the corneal epithelium

The central corneal and mid-peripheral epithelium thins (a & c), probably due to water loss and dehydration, and the mid-peripheral stroma (b) thickens, possibly due to oedema or deposition of stromal ground substance due to the negative pressure generated under the mid-peripheral curve of the orthokeratology lens [264, 274].

Secondary/Peripheral Zone(S)

In the periphery of a reverse geometry lens, two curves are commonly incorporated to create appropriate edge lift at the peripheral cornea. The secondary zone commonly has a width of 0.2 mm to 0.5 mm and a depth of approximately 20 μm, but it is not included in all lens designs. Its function is to form a smooth transition between the alignment and peripheral zones. The peripheral zone also has a width of 0.2 mm to 0.5 mm and its depth is usually between 80 μm to 100 μm [277].

Overall Lens Diameter

The overall diameter of a reverse geometry orthokeratology lens is often 0.8 mm to 1.2 mm smaller than the horizontal visible iris diameter (HVID). For example, if the corneal diameter is 12.0 mm, the lens diameter should be approximately 11.0 mm [277].

Lens Material

Modern lens designs, and orthokeratology principles are based on the current practice of overnight orthokeratology lens wear. This requires the use of high Dk/t lens materials to ensure proper oxygen transmission to the cornea. Transmissibility (Dk/t) of 87 or higher will limit overnight corneal swelling to levels comparable to those without a contact lens [29]. An increase in lens Dk/t appears to increase the clinical effects of overnight orthokeratology

reverse-geometry lens wear over the medium term. This adds further support to the recommendation that high Dk/t materials should be used for overnight orthokeratology not only to provide physiological advantages, but also to optimise clinical outcomes [278].

CLINICAL INFORMATION REQUIRED FOR LENS DESIGN

The primary measurements needed to design a modern orthokeratology lens include manifest refraction, HVID, corneal topography and corneal eccentricity [88, 277]. The corneal curvature at the apex is more relevant than that measured by keratometry at a 3 mm chord. The lens-to-cornea relationship at the corneal apex must be designed with a high level of precision to create the proper fluid forces responsible for effective treatment [277].

WHEN IS THE TORIC LENS REQUIRED?

A toric orthokeratology lens incorporates a spherical BC and toricity across all other zones. The aim of using toricity is to improve lens centration and ensure lens landing 360º around the mid-peripheral cornea, similar to the RGP lenses fitted on a toric cornea. This lens-to-cornea relationship is crucial for maintaining the fluid forces that drive epithelial changes in orthokeratology. A toric design is more likely required for eyes with limbus-to-limbus astigmatism than for those with central astigmatism [277].

DESIGNS FOR CHILDREN VERSUS ADULTS

Most myopia control designs use a smaller optic zone, around 5.4 mm to ensure delivery of the peripheral optics through the pupil. Larger optic zone sizes of 6.0 mm to 6.8 mm work well for adults, as they limit the amount of peripheral defocus reaching the retina. Of course, pupil size will affect the amount of peripheral rays entering the eye and should be considered when initiating orthokeratology treatment [277].

COMPLICATIONS AND SIDE EFFECTS OF ORTHOKERATOLOGY

Although the effects of orthokeratology are fully reversible on cessation of lens wear, complications can and do happen [264, 274]. Most of the complications experienced by orthokeratology wearers, are similar to those of standard RGP and soft contact lens wearers, which is covered in chapter 16 of this book. Orthokeratology is considered a viable option for temporary myopia control in children, and therefore its popularity will surely increase due to the drastic increase in the prevalence of myopia worldwide and the overall earlier onset of myopia [275]. Although the procedure is relatively safe a higher incidence of microbial keratitis, *Pseudomonas Aeruginosa* and *Acanthamoeba* have been reported, due to overnight orthokeratology use especially in Asia (less reports from Western countries). The higher incidence of microbial keratitis in this group has been attributed to questionable standards of practice and training [275, 279]. Other side effects include, corneal abrasions, corneal oedema, induced higher order aberrations (especially spherical aberration) and asymptomatic, reversible corneal pigmentation rings [275].

Orthokeratology is not recommended if any form of corneal pathology is present, especially not with any form of corneal ectasia such as keratoconus or pellucid marginal degeneration [269].

Microbial Keratitis (MK) In Orthokeratology

Infectious keratitis or microbial keratitis remains the most serious and devastating complication related to orthokeratology. At least three factors have been shown to increase the risks of MK in orthokeratology contact lens wear.

- Extended or overnight lens wear remains the most significant risk factor for infection [280]. It is likely that overnight modality allows time for bacterial biofilms to colonise the contact lens and adapt to the environment to become appropriately virulent [280]

- Overnight lens wear reduces the ocular surface's defence against infection due to compromised tear mixing between the pre– and post-lens tear compartments during blinking [281]
- Orthokeratology works by the means of a squeeze force film force between the lens and the cornea, acting tangentially across the corneal epithelium. The reverse geometry design creates compressive squeeze force which may reduce the epithelial surface integrity, increasing susceptibility to infection [282]

Considering the vision-threatening potential of MK, contact lens practitioners should use great caution in fitting children with orthokeratology lenses. It is important to provide extensive education to both patients and parents on rigorous compliance to lens caring regimen [275]. Finally, it is worth noting that *Pseudomonas Aeruginosa* and *Acanthamoeba* were the most commonly reported pathogens for orthokeratology associated microbial keratitis [279, 282, 283], both of which require early diagnosis and prompt treatment to minimise the risks of permanent vision loss. Therefore, both patients and parents should be made aware off and maintain high vigilance of possible related signs and symptoms of MK and seek routine and timely follow-up to minimise the risk of irreversible vision loss due to this complication [275].

Corneal Staining/Lens Binding

Corneal staining can be present in several distinctive patterns: sporadic or diffuse punctate staining, patchy central staining, especially whorl shaped staining, peripheral punctate staining and peripheral indentation rings [275]. Persistent central staining is associated with suboptimal fitting, as well as lens binding to the corneal surface. Lens binding causing superficial corneal abrasions on lens removal is one of the most common complications and reason for unplanned visits during treatment. The causes of lens binding are multiple and include [275]:

- Soiled or coated lenses
- Decreased thickness of the PoLTF
- Increased PoLTF viscosity with overnight lens wear
- Lid pressure on the lens toward cornea
- Negative hydraulic pressure in the PoLTF associated with the reverse geometry lens design binding the lens to the central corneal surface 37,61,107

Lens binding can be resolved by improving the fit to promote tear exchange [88]. This involves using a smaller overall diameter, altering the alignment curve and/or flattening the peripheral curve to increase edge lift [88]. Although mild-to-moderate corneal staining does not typically require cessation of daytime RGP lens wear, it is advisable to discontinue overnight orthokeratology until the staining resolves, in order to avoid more serious complications such as MK.

Epithelial Iron Deposit/White Lesion/ Fibrillary Lines

Pigmented ring shaped corneal deposits is a common finding in long term orthokeratology treatment. The exact aetiology is unclear, but it has been hypothesised that the pigmented ring may be related to the stress forces applied to epithelium and/or tear stagnation underneath the reverse geometry zone of the lenses. The pigmented rings/white lesions occur on the outside border of the flattened zone and are reversible when orthokeratology is terminated [284–289]. The rings do not occur in the visual axis and therefore do not interfere with visual function.

Fibrillary lines are fine, slightly curved and sub-epithelial, typically arranged in a concentric pattern in the corneal mid-periphery. The lines are not associated with epithelial staining and their origin is unknown. However, epithelial remodelling, corneal biomechanical stress and abrupt corneal curvature changes have been suggested as

contributing factors. Fibrillary lines do not affect vision or ocular health in the short-medium term but it is unclear what their role in long term wear may be [290, 291].

Endothelium in Orthokeratology

Evidence from large sample, longitudinal studies showed no significant short-term or long-term changes of endothelial cell density, corneal polymegethism or polymorphism, reassuring the long-term safety of overnight orthokeratology on the corneal endothelium [275, 292].

Corneal Biomechanics

CH and CRF are corneal biomechanical properties measured by Reichert Ocular Response Analyzer and are discussed in detail in chapter 13. Significant decreases in IOP, CH and CRF were reported within the first week after orthokeratology treatment. However, both IOP and CH gradually returned to baseline level at 1 month of lens wear and remained unchanged after 6 months [275, 293][124,190]. Despite the early temporary reduction of CH, there was no evidence suggesting that long term orthokeratology treatment altered corneal microstructure and its biomechanical properties [275].

Fitting Problems

The desired topography result of a well fitted orthokeratology lens is a centred bulls eye pattern, covering the pupil, which indicates good centration. “Central islands” and “smiley face” topographies are caused by incorrect alignment curves and sags leading to lens decentration [88, 269].

High and Low Riding Lenses [88, 269]

The cause of a high riding lens is to flat alignment curve or a tight upper lid. It can be remedied by: increasing the sag of the lens, steepening the alignment curve, using a larger diameter lens, increasing the lens mass or using lenticulation to reduce the superior lids influence on the lens.

Conversely the cause of a low riding lens is a steep alignment curve or a loose upper lid. It can be remedied by: decreasing the lens overall sag, flattening the alignment curve, decreasing the lens mass or changing the lens edge, shape and lenticulation to increase the effect of the superior lid.

Lateral Decentration [88, 269]

Lateral decentration is normally caused by a flat alignment curve, against-the-rule astigmatism or a decentred corneal apex. It can be corrected by: Increasing the overall sag, steepening the alignment curve or increasing the lens diameter.

Central Islands [88, 269]

These are areas of incomplete treatment caused by steep fitting lenses or treatment resistant areas on the cornea. These islands cause distortion and reduced acuity. If they don’t resolve spontaneously, they can be corrected by: Reducing the overall sag of the lens, fitting flatter to increase touch and improving lens centration.

Smiley Faces [88, 269]

Smiley faces are usually found inferior to the central treatment zone and indicate areas of localised corneal steepening typically caused by a flat fitting or insufficient sagittal depth lens. This leads to superior lens decentration and can be remedied by: increasing the overall sag, fitting a steeper lens or increasing the lens diameter.

CONCLUSION

Generally, orthokeratology is a safe option for myopia correction and retardation. However, the long-term success of the treatment depends on a combination of multiple factors including proper fitting of the lenses, rigorous compliance to lens use and care regimen, adherence to routine follow-up and timely, and appropriate treatment of complications.

Finally, the question remains: Is extended wear with silicone hydrogel lenses more beneficial and safer than orthokeratology or should one recommend orthokeratology lenses rather than extended wear lenses to patients requiring correction of their refractive error, who do not wish to remove lenses on a daily basis?

CASE

A 13-year-old female Caucasian patient was seen with progressive myopia. Her previous examination 12 months previously revealed moderate myopic astigmatism in both eyes. Refraction was:

R. -2.25/-0.75x170 6/6

L. -2.75/-0.75x5 6/6

The myopia progressed slightly, and the most recent refraction was:

R. -2.50/-0.50x165 6/6

L. -3.50/-0.50x15 6/6

Her Pentacam scans are shown below (Figures 60–63). She had no ocular pathology and was interested in orthokeratology.

Spherical equivalent powers plus Jessen factor was right -4.00 and left -5.00. Flat-K plus target Rx was right 38.4D (8.79 mm) and left 37.5D (9.00 mm). The final orthokeratology lenses ordered were VIPOK-II:

R. 8.79/11.00/+1.25

L. 9.00/11.00/+1.25

Over refraction with the lenses were plano and both NAFL patterns were acceptable. A wearing schedule was recommended, where the patient was instructed to sleep with the lenses and initially insert them during the day for a short period if required until the cornea stabilises. The second set of Pentacam scans show the effect of the orthokeratology lens one month later. At this visit, the refraction was -0.25DS in both eyes with 6/6 vision uncorrected. The corneas were clear, and the lenses moved and centred well. This young lady used the orthokeratology system until she was 21 years old. Her refraction after ceasing orthokeratology was:

R.-3.00/-1.00x165 6/6

L. -3.75/-1.00x15 6/6

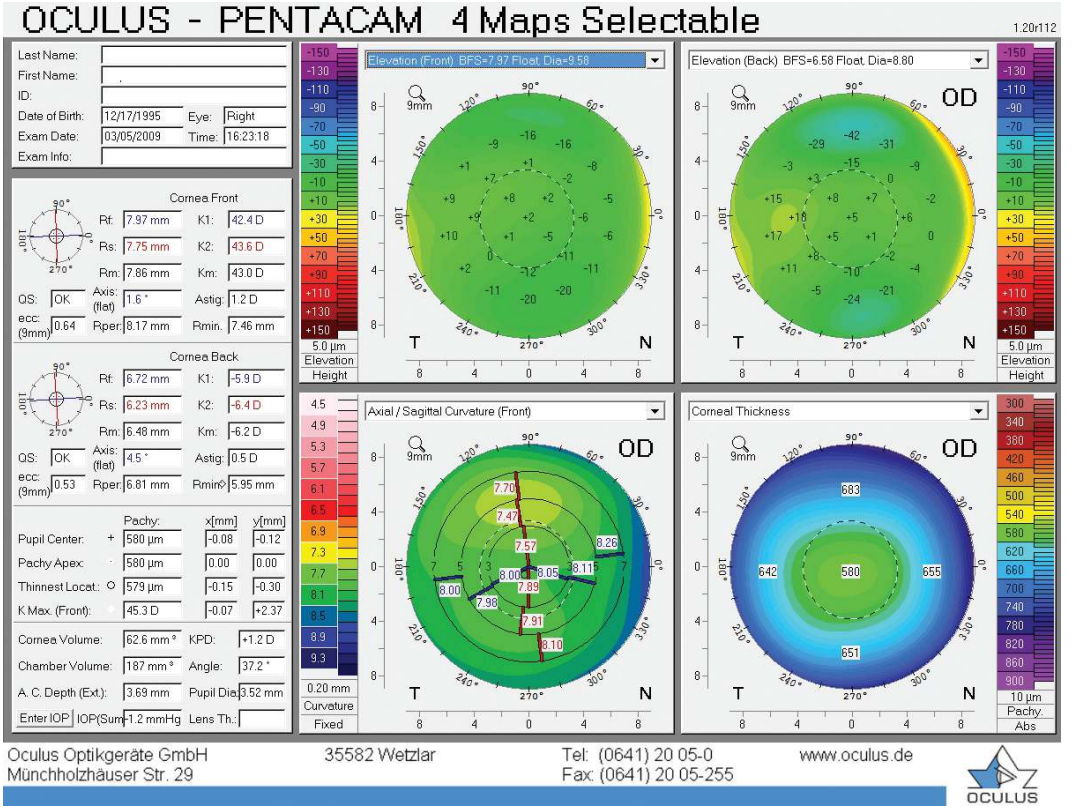

Figure 60: Pentacam scan of the right eye prior to orthokeratology fitting

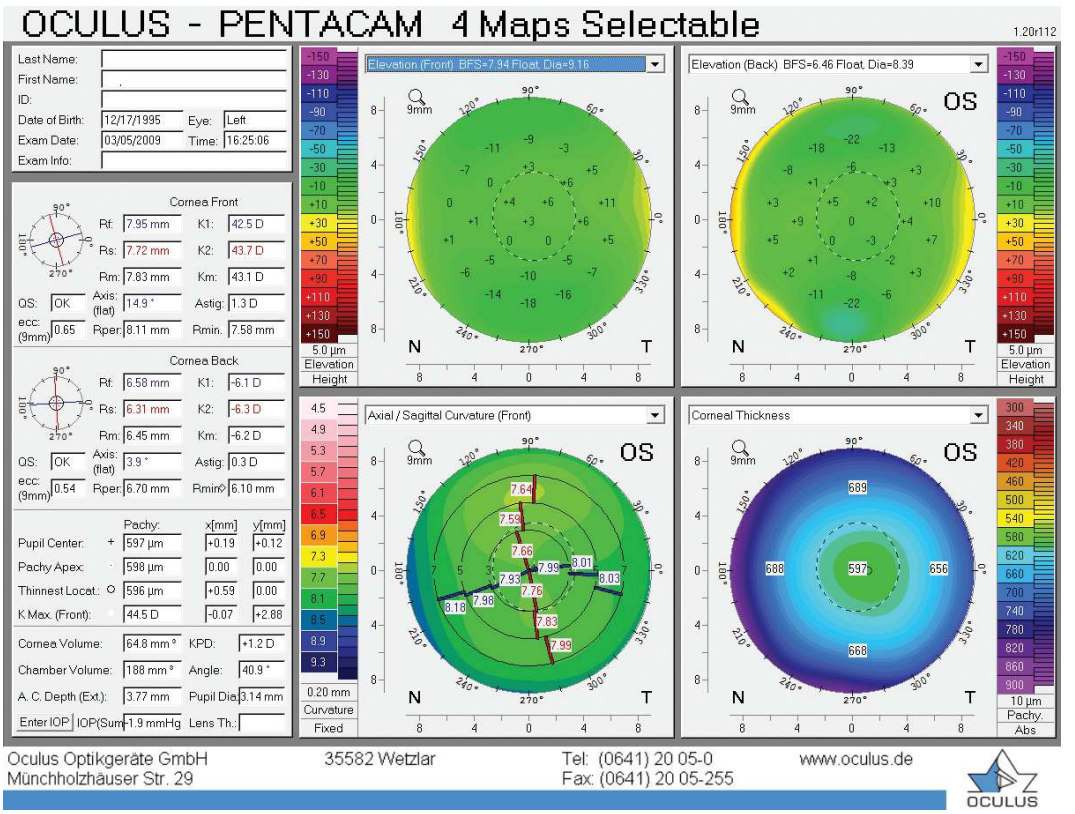

Figure 61: Pentacam scan of the left eye prior to orthokeratology fitting

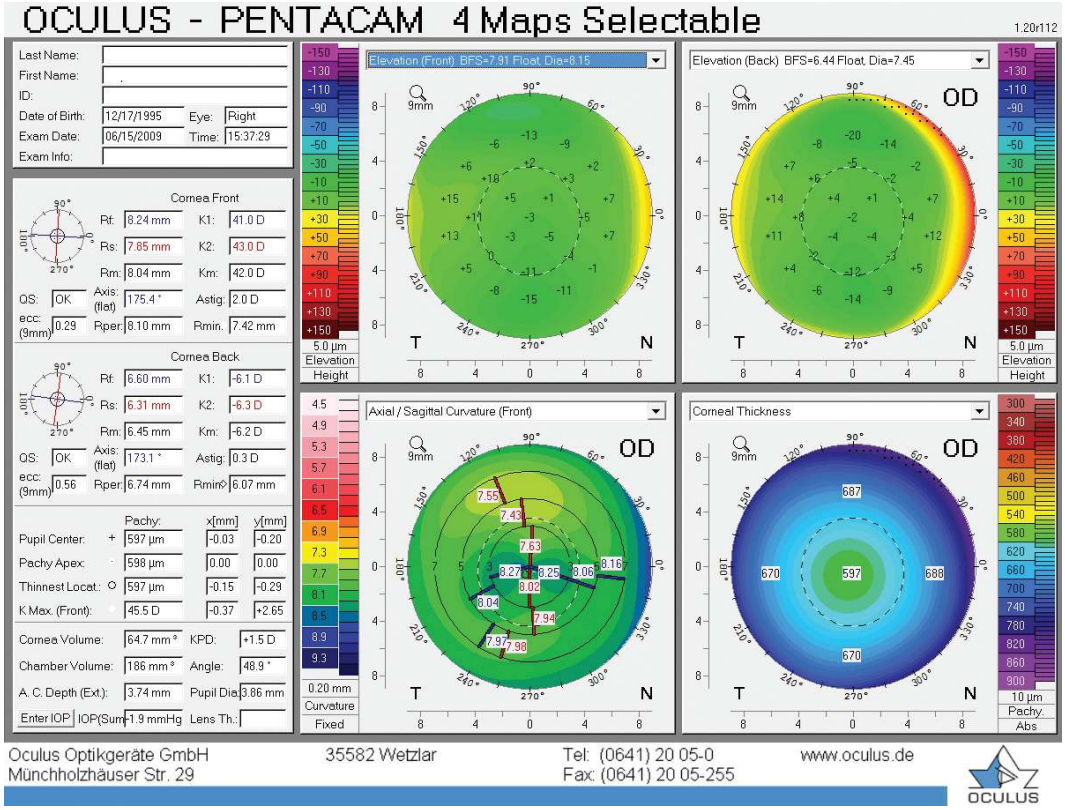

Figure 62: Pentacam scan of the right eye after orthokeratology fitting

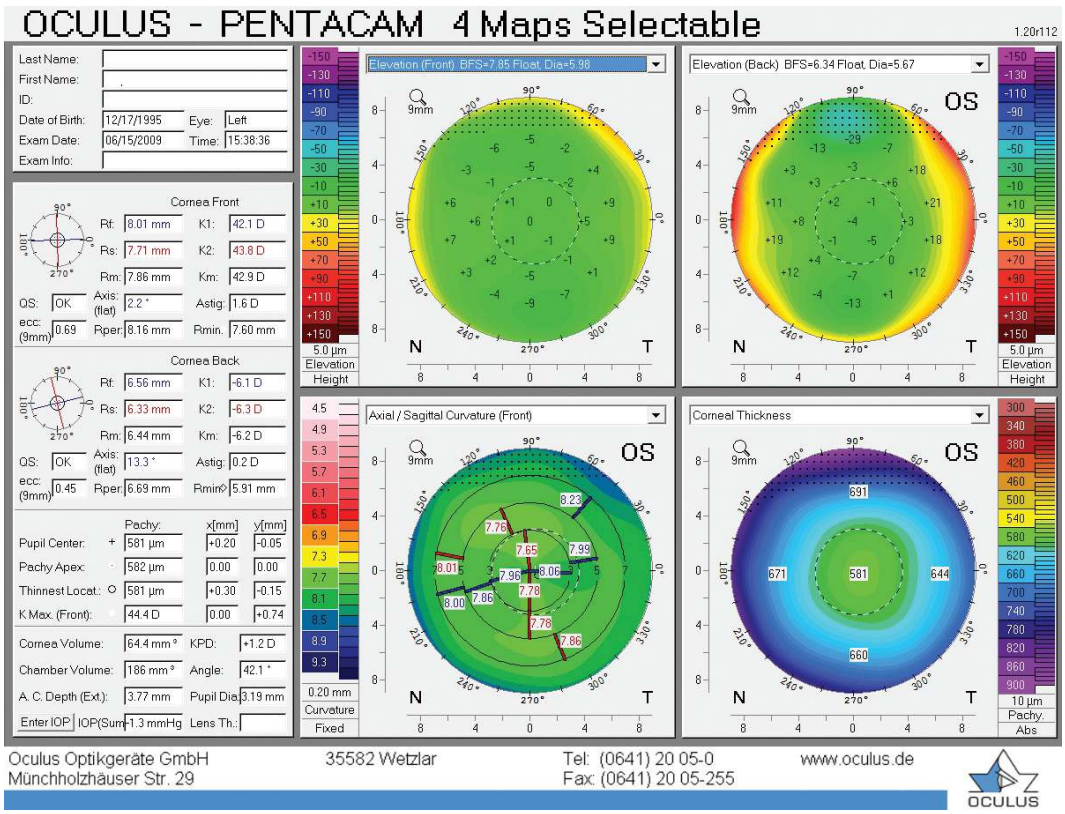

Figure 63: Pentacam scan of the left eye after orthokeratology fitting