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Friday, September 19th, 2003 - SESSION: New generation orthokeratology

Empirical advanced orthokeratology through corneal topography: the University of Houston clinical study
Sami El Hage - Eye care Associates, Houston, Texas, USA

Morphological changes of rabbit cornea by orthokeratology lens
Masao Matsubara - Dept. of Ophthalmology Tokyo Women's Medical University, Daini Hospital & New Vision Institute, Japan

Results of the first clinical study in France on overnight orthokeratology
Adrien Sarfati - Hopital Hotel-Dieu, Paris, France

Is Ortho-K - OK ?
Eef van der Worp - Private Ophthalmology Clinic, Amsterdam, The Netherlands

Saturday, September 20th, 2003 - SESSION: Orthokeratology

Microstructural corneal changes in orthokeratology
Gudrun Bischoff - Hamburg, Germany

A new customized esa-curve reverse geometry lens design for overnight orthokeratology
Antonio Calossi - Firenze, Italy

Models of posterior corneal change with overnight orthokeratology
Helen Owens - Department of Optometry & Vision Science, University of Auckland, New Zealand

Orthokeratology with overnight wear reverse-geometry contact lenses in practice
Ton Rouwen - Central Military & University Hospital, Refractive Surgical Centre, Utrecht, The Netherlands

EMPIRICAL ADVANCED ORTHOKERATOLOGY THROUGH CORNEAL TOPOGRAPHY: THE UNIVERSITY OF HOUSTON CLINICAL STUDY

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Introduction:
There is increasing evidence that reverse geometry rigid gas permeable (RGP) contact lenses when worn at night will flatten central corneal curvature resulting in improved unaided visual acuity in low to moderate myopes. Traditionally, these designs have characteristically required the use of diagnostic lenses to determine the best fit for a given wearer.
Objective:
The purpose of this study is to collect scientific and clinical data on twenty-five subjects and to determine the validity of fitting advanced accelerated orthokeratology lenses (CKR) empirically from corneal topography without the use of diagnostic lenses.
Method:
Seventeen subjects, 18-37 years of age having naturally occurring myopia of between -1.00 D. and -4.00 D. with astigmatism no greater than -1.50 D. who signed the informed consent document were entered into this six-months study. Corneal topography, Confocal microscopy, ultrasound corneal thickness, aberrometry, and slit-lamp biomicroscopy were used to assess changes occurring in the cornea. Unaided logMAR visual acuity, subjective refraction, and a questionnaire were used to monitor vision and subjective symptoms. Follow-up visits are scheduled at one day, one week, two weeks, one month, three months and six months.
Results:
To date seven subjects have completed their 1-month visit. Unaided acuity improved from 0.89±0.22 OD/0.74±0.30 OS to 0.03±.12 OD/0.01±.13 OS. Myopia was decreased from -2.61 D.±0.85 OD/-2.07 D.±0.29 OS to +0.07 D.±0.40 OD/Plano±0.32 OS. Shape factor as determined by corneal topography increased from 0.83±0.13 OD/0.82±0.07 OS to 1.26±0.24 OD/1.32±0.31 OS indicating a shift from a prolate to oblate corneal surface. Total central corneal thickness as determined by Orbscan pachymetry was 555.57±49.89 mm OD/551.57±46.88 mm OS at baseline and 548.71±43.61 mm OD/547.00±47.23 mm OS at 1-month. Total central corneal thickness as determined by Sonogage ultrasonic pachymetry was 549.71±37.88 mm OD/546.43±44.11 mm OS at baseline and 561.75±44.68 mm OD/565.50±47.22 mm OS at 1-month. Total central corneal thickness as determined by confocal microscopy was 517.52±69.15 mm OD/474.15±65.69 mm OS at baseline and 502.17±86.82 mm OD/544.00±48.23 mm OS at 1-month. Central corneal epithelial thickness measured with the Sonogage was 46.71±0.76 mm OD/46.86±0.38 mm OS at baseline and 47.25±1.26 mm OD/47.25±0.50 mm OS at 1-month. Central corneal epithelial thickness measured with confocal microscopy was 50.72±17.61 mm OD/44.85±7.03 mm OS at baseline and 53.53±9.13 mm OD/31.96±17.92 mm OS at 1-month.
Discussion:
The amount of myopia reduction found at the 1-week visit was clinically insignificant from the 1-month results indicating that the full effect is achieved by one week. However, neither total nor epithelial corneal thickness measurements show any significant changes from baseline regardless of the method used. Central and inferior corneal sensitivity measurements also showed no significant changes. These preliminary results demonstrate the effectiveness of the CKR lens design at reducing myopia and improving unaided visual acuity.

MORPHOLOGICAL CHANGES OF RABBIT CORNEA BY ORTHOKERATOLOGY LENS

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Purpose: To investigate the histopathological and physiological changes of cornea after the use of orthokeratology lens.
Methods: Orthokeratology lens (OK lens) (BE, Dreim or Contex. Targeted reduction; 3 or 6 D) was placed on right eyes of white rabbits for 7 hours daily. Eyes were enucleated after 1, 4 and 12 weeks, and served to light or electron microscopic study. Left eyes were used as controls. Eyes with OK lens (Euclid) for 2 or 3 weeks were served to histochemical study.
Results: With successful topographical reduction in refraction, epithelial layer was histologically stable after any periods of the schedule. Epithelial cells showed normal configuration at the center of the cornea. Histochemical staining suggested almost normal function of epithelial layer. Electron microscopic study revealed higher electron density in epithelial cells than in those of control. Glycogen granules in epithelial cell cytoplasm and proteoglycans in deep stroma slightly increased at the center.
No other apparent abnormal findings were observed.
Conclusions: Orthokeratology lens gave topographical change with very mild functional and morphological changes in rabbit cornea.

RESULTS OF THE FIRST CLINICAL STUDY IN FRANCE ON OVERNIGHT ORTHOKERATOLOGY

Dr. Adrien SARFATI Hopital Hotel-Dieu, Paris, France
Claude HATCHUEL, Aix-en-Provence, France

In this clinical study we investigated the performance of modern, overnight Orthokeratology using RGP lenses with reverse geometry design and high oxygen permeability. The patient group included persons of varied ages, and myopia of -1.00 D to-3.50 D.
We tested the clinical and optical efficacy of the procedure and the limits of reducing myopia by overnight wear of the Ortho K lenses over a period of three months.
All patients were regularly controlled for corneal complications. We determined the optimal fitting procedures and evaluated which patients would be eligible for overnight Orthokeratology.
Initial results confirm earlier studies: We obtained good results and good safety on patients with low myopia.

IS ORTHO-K – OK?

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Orthokeratology has recently gained renewed attention in the international literature and on conferences around the world. Reasons for the spectacular comeback of this mode of lens wear are primarily the development of new technology (corneal topography and better lens designs), new insights in the mechanisms of corneal reshaping, and the possibility of overnight wear. It is our task to evaluate whether this modified technique of orthokeratology is an acceptable mode of vision correction. Is Ortho-K OK?
The mechanism behind orthokeratology is still unclear. Central corneal thinning is reported in a number of occasions and is presumed to cause the refractive change. The central corneal thinning

appears to be epithelial in origin. Compression of epithelial cells, redistribution of epithelial cells or both might cause the effect. In the mid-periphery of the cornea, an increase in corneal thickness has been noted. According to the leading investigators in this field, this change is presumably stromal. Refractive change usually is restricted to low myopia, refractive error change of 2.25D +/- 1.00D is common. Unaided visual acuity of 20/20 in the morning is possible and is reported in most (74%) successful cases. Higher myopia will typically reduce the optical treatment zone and may result in visual compromise. Some lens designs seem better in treating higher myopia than others. Ortho-k is approved by the US Food and Drug Administration for up to -6.00D. Hyperopic and presbyopic corrections are in development, but not available at this stage.
The preferred method for myopia reduction for the vast majority of researchers and practitioners is overnight Ortho-k. Oxygenation of the cornea and the risk of bacterial epithelial binding is therefore an issue and will be discussed in this presentation. There are case reports in the international literature reporting corneal infectious ulcers, predominantly *Pseudomonas aeruginosa,* resulting in a loss of best corrected visual acuity after recovery in some cases. Most cases reported are from Asian countries, especially China.
Another potential risk in overnight Ortho-k is lens adherence, especially upon awakening. Tear film composition plays a vital role in this and tear supplements in the morning are usually recommended. Some lens designs have the tendency to create more lens adherence than others. In addition, corneal rings have been observed in some patients after wearing Ortho-k lenses. These rings are unknown in origin and similar rings have been found in post-PRK and post LASIK patients as well. The location of the corneal iron rings in Ortho-k coincided with the fitting curve of the reverse-geometry rigid contact lens, suggesting that the rings might have developed from tear pooling.

MICROSTRUCTURAL CORNEAL CHANGES IN ORTHOKERATOLOGY

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Orthokeratology is a method, which modifies the structure of the anterior corneal tissues. The older techniques and lens types damaged and folded the stromal collagen-lamellae. The question was, if the new technique and lens design is less stress-inducing and if possible changes are restricted to the epithelial cell layer, as the advertisement makes us believe. The cellular structures were pictured by a confocal microscope.
Investigated were OK-wearers of different contactological history and time of wearing OK-lenses. The result could not be covered under one headline. The spectrum of results came from no measurable changes to massive microcysts. Referring to age of patient and type of earlier worn lenses the changes to be found were predictable. Typical distortion of the collagen-lamellae was not detected.
So far the new method is more acceptable than the earlier type of OK-lenses, fitted 15 years ago.

A NEW CUSTOMIZED ESA-CURVE REVERSE GEOMETRY LENS DESIGN FOR OVERNIGHT ORTHOKERATOLOGY

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We developed and patented a new design and calculation method to customize a multi-curve reverse geometry lens. This new design is based on a biconic model on which we developed an esa-curve customize reverse geometry lens design. We present the results of a pilot study to evaluate the success and safety of treatment with these overnight orthokeratology contact lenses. Refractive error, corneal topography, and biomicroscopic data were collected to determine the amount of

refractive error change achieved, corneal changes, and a safety profile of overnight wear of these lenses for overnight orthokeratology. In this pilot study we treated 30 eye of 15 patients aged from 18 to 43 years, without any tear, corneal, ocular and/or systemic disease at the baseline time and without any previous ocular surgery. The baseline refractive error was from –1.00 to –4.00 D spherical equivalent, WTR astigmatism up to 1.50 D and ATR or oblique astigmatism up to 0.75 D. The preliminary results of our pilot study indicate that the cornea responds rapidly to the application of these customize esa-curve reverse geometry lenses, with significant central corneal flattening and improvement in visual acuity after just 60 min of lens wear; the corneal shape change from prolate to oblate asphericity after 1 night of wear; improvement in unaided visual acuity up to 20/20 can be obtained for at least 10 h after lens removal in an average time of 10 nights. Our data suggest that the corneal epithelium is able to be molded or redistributed very rapidly in response to the tear film forces generated behind this reverse-geometry lenses design. Up to 1 year of overnight wear, safety and efficacy of the procedure appear to be favorable; however, future studies are needed to determine the more long-term outcomes of treatment.

MODELS OF POSTERIOR CORNEAL CHANGE WITH OVERNIGHT ORTHOKERATOLOGY

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Background: The mechanism relating refractive change to corneal tissue changes following overnight orthokeratology remains uncertain, particularly with regard to the contribution from the posterior corneal surface. The aim of this work was to assess topographical changes in the posterior corneal surface following one month of overnight orthokeratology lens wear and to model those changes in relation to corneal oedema and moulding.
Methods: Corneal topography, subjective refraction, ultrasound corneal thickness and Purkinje imaging techniques were used to assess changes occurring in the cornea for 20 subjects over a course of one month, at four separate time periods. Biometric measurements concentrated on areas in the central 2.5mm and mid-peripheral 5mm of the cornea.
Results: Orthokeratology successfully reduced subjects' myopia in an exponential manner over the course of a month. The reduction in myopia was accompanied by flattening of anterior and posterior corneal surfaces, both centrally and mid-peripherally. Changes from baseline were significant at all times for the anterior cornea and significant over the initial 2 weeks for the posterior surface.
Conclusions: Our results demonstrate that the cornea bends during the initial 2 weeks of overnight lens wear. Models of the central cornea suggest that a combination of oedema and moulding is likely to account for these posterior corneal changes.

ORTHOKERATOLOGY WITH OVERNIGHT WEAR REVERSE-GEOMETRY CONTACT LENSES IN PRACTICE

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The goal of this presentation is to make the delegates familiar with the fitting process of these lenses in practice, to elaborate the limitations of the results attainable with these lenses and also to show methods to judge the final optical results of these lenses.
Reverse geometry OK lenses work by virtue of the eccentricity value of the corneal shape.

Correction of low-grade myopia with limited correction of corneal astigmatism depends on the actual eccentricity value of the cornea. The amount of correctable myopia can be calculated from the measured corneal shape. Low grade, not completely stable myopia in young patients is a good indication for this technique as compared to refractive surgery.
Together with refractive surgery this technique is a method to have 20/20 VA during the day without spectacle or contact lens wear.
The fitting procedure is completely different from normal RGP fitting as is the judgement of fluorescein fitting patterns. Calculation is made more easy, because we used a computer program made by NKL, the laboratory also manufacturing these BE Mountford/Noack Australian design lenses.
The topographic response after the first night sleep in the trial lenses is used to find the correct lens to order for successive wear. The correct assessment of these topographic (difference) plots after overnight trial lens wear is essential to get good results with this OK technique. On the basis of this response the calculating program often advises to refit with another trial lens in order to get the proper first night result and to find the definite recipe lens. The correct power in the final lenses is only used during the (early) night when the patients want to see more with large pupils or fading effect from lens wear the night before. On the other hand some patients are able to skip lens wear every other night, while keeping their correction.
Limitations in both refractive effect and topographical changes are shown on the basis of three actual fittings done in our clinic.
Additionally some common adverse effects are shown.