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MÀSTER UNIVERSITARI EN OPTOMETRIA I CIÈNCIES DE LA VISIÓ

TREBALL FINAL DE MÀSTER

NEW ORTHOKERATOLOGY LENS DESIGN FOR PRESBYOPIA

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NEW ORTHOKERATOLOGY LENS DESIGN FOR PRESBYOPIA

RESUM

La presbícia es defineix com una baixa funcionalitat de la visió próxima, degut a un descens de l'acomodació residual, donant com a simptomatologia la pérdua d'habilitat per enfocar objectes propers.
A nivel mundial, el fet de no corregir la presbicia causa una pérdua de visió a distàncies properes. Sobre els 55-60 anys, la símptomatologia de la presbicia ja està totalment establerta, i per una visió próxima cómoda l'ajuda de dispositius artificials es necessària.

L'objectiu d'aquest estudi es investigar l'eficàcia d'un nou disseny de lent rígida d'ortoqueratologia per a presbicia, durant 4 setmanes d'ús.
Divuit subjectes présbites, que mai abans habien utilitzat cap tipus de lents de contacte van ser examinats. Dels cuals set van participar fins a la finalització de l'estudi. Una lent d'ortoqueratología amb dos diàmetres de zones óptiques diferents es van evaluar en cada pacient. Mesures com l'agudesa visual tant de lluny com d'aprop sense correció, refracció, sensibilitat al contrast, corba de desenfoc, topografía corneal, aberracions corneals i salut ocular es mesuraven al començar l'estudi i es comparaven després de 4 setmanes d'ús de les diferentes lents, un disseny de 1.9mm de diàmetre de zona óptica i una altre de 3.0mm.

Ambdues lents vàren demostrar canvis estadísticament significatius. La lent d'1.9mm quasi va corregir l'ametropia en visió llunyana, mentres que la lent de 3.0mm va induïr una petita cantitat de miopía, en contraposició, en visió próxima la lent de 3.0mm va disminuir l'addició en una mitjana de 50.55%. La visió llunyana binocular es va mantnir igual i les visions próximes sense correcció van millorar. Les aberracions corneals induïdes van marcar una baixada de sensibilitat al contrast sobre les frqüències mitjanes i altes.

Com a conclusió podem dir que les lents de doble reservori llagrimal per a presbícia proporcionen una visió próxima funcional induïnt un canvi miopic com les lents multifocals de "centro cerca". Tot i les aberracions corneals induïdes, la visió llunyana binocular no ha estat alterada.

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NEW ORTHOKERATOLOGY LENS DESIGN FOR PRESBYOPIA

RESUMEN

La presbícia se define como una baja funcionalidad de la visión cercana, debido a una limitada acomodación residual, que da como sintomatología la pérdida habilidad para enfocar objetos cercanos.
A nivel mundial, el hecho de no corregir la presbicia implica una pérdida de visión en distancias proximas evitable. Entre los 55-60 años los síntomas de la presbícia ya están totalmente establecidos, dispositivos artificiales son necesarios para obtener una visión cercana cómoda.

El objetivo de este estudio es investigar la eficacia de un nuevo diseño de lente de ortoqueratología para presbícia, durante 4 semanas de uso nocturno.

Dieciocho sujetos présbitas, que nunca antes habían utilizado lentes de contacto fueron examinados. Sólo siete de los cuales participaron hasta la finalización del estudio. Una lente de ortoqueratología con dos diferentes diametros de zona óptica fueron eveluados en cada paciente. Medidas como agudeza visual no corregida en lejos y en cerca, refracción, sensibilidad al contraste, curva de desenfoque, topografía corneal, aberraciones corneales y salud ocular se mesuraban antes de empezar el estudio, y se comparaban después de 4 semanas de uso de las diferentes lentes, una de diseño de 1.9mm de diámetro de zona óptica y otra de 3.0mm.

Ambas lentes revelaron cambios estadísticamente significativos. La lente de 1.9mm casi corrigió por completo la ametropía en visión lejana, mientras que la lentre de 3.0mm indujo una pequeña cantidad de miopía, en contraposición en visión cercana la lente de 3.0mm disminuyó la cantidad de addición positiva requerida en cerca, sobre un 50,55%. La visión binocular lejana se mantuvo igual, pero las visiones cercanas sin corrección mejoraron. Las aberraciones corneales que se inducieron marcaron una bajada en la sensibilidad al contraste sobre las frecuencias medias y altas.

En conclusión, podemos decir que las lentes de doble reservorio lagrimal para presbicia dan una visión cercana funcional induciendo un cambio miópico como las lentes de contacto multifocales “centro cerca”. A pesar de las aberraciones corneales inducidas, la visión lejana binocular no fue alterada.

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MÀSTER UNIVERSITARI EN OPTOMETRIA I CIÈNCIES DE LA VISIÓ

NEW ORTHOKERATOLOGY LENS DESIGN FOR RESBYOPIA

ABSTRACT

Presbyopia is defined as an impairment in near vision, limitating the residual accommodation, hence losing the ability to focus on neal objects.
Throughout the world, uncorrected presbyopia causes common, avoidable vision impairment. When the symptoms are established, on a 55 to 60-year-old average, artificial assistance for comfortable close-up tasks is needed.

The aim of the study is to investigate the efficacy of a new presbyopic orthokeratology lens design, on a 4-week perios of presbyopic orthokeratology overnight wear.

Eighteen presbyopic new orthokeratology wearers, were reviwed. Only seven participants contributed to complete data. A double reservoir lens for presbyopia design with two with different back optical zone diameters was evaluated. Uncorrected distance and near visual acuity, subjective refraction, contrast sensitivity, defocus curve, corneal topography, corneal aberrations and anterior segment health examination were measured at baseline, and compared after a 4-week overnight wear, with designs of 1.9 and 3.0mm back optical zone diameters.

Both double reservoir lenses for presbyopia, revealed statistically significant changes.
The 1.9mm lens almost corrected distance ametropia, while 3.0mm lens induced a slight myopia, in contraposition, 3.0mm corrected near ametropia by decreasing a 50.55% of the near addition on average. Binocular distance vision remained equal, but uncorrected visual acuities improved after both lenses were used. Induced corneal aberrometries lead to a contrast sensitivity descrease in medium and high frequencies.

As a conclusion we can say that double reservoir lenses for presbyopia provide functional near vision by inducing a "center near" myopic shift. Eventhought corneal aberrations were induced, it did not alter binocular visual acuities.

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COVER LETTER

Dear Editor,

Attached you will find the paper entitled "New orthokeratology lens design for presbyopia", which we are submitting for publication in *Contact Lens & Anterior Eye* as an original research paper, to be considered for publication.

The aim of the study is to investigate the visual outcomes of a new presbyopic orthokeratology lens design, on a 4-week presbyopic orthokeratology overnight wear, in order to understand the relationship between factors such as, central steepened zone (CSZ), pupil diameter (PD) and back optical zone diameter (BOZD), in this treatment. Results showed that the induced corneal multifocality effect, for correcting presbyopia using DRLP lenses, can be achieved throughout corneal reshaping.

We state that the data submitted have not been published and are not under current considerations elsewhere, that all authors have contribuited significantly in the design, interpretation of data and all are in agreement with the content of the study.

We would be very grateful for any comments or suggestions you may wish to make.

Thanking you for the kind attention, we look forward to hearing from you at your convinence.

Most sincerely,

Sònia Travé Huarte, Principal Researcher.
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Title page and authors

New orthokeratology lens design for presbyopia

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Abstract

Purpose: To evaluate the efficacy of a new presbyopic orthokeratology (DRLP) lens and the relationship between central steepened zone (CSZ), pupil diameter (PD) and back optical zone diameter (BOZD).

Methods:
Seven out of eighteen presbyopic (46.50 ±17.19 years) patients were fitted with DRLP lenses. One design with 2 different BOZD was tested. Uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), contrast sensitivity (CS), central steepened zone (CSZ) and corneal aberrations (Coma/SphAb), were measured at baseline and compared after a 4-week overnight DRLP wear.

Results:
Both DRLP lenses revealed statistically significant changes from baseline after overnight wear. The 1.9mm BOZD lens, almost corrected distance ametropia, residual refractive error of 0.03±0.52 D(p=0.0095) and 3.0mm BOZD induced a -0.15±0.45 D (p=0.001). An average correction of 26% of near addtition was achieved with 1.9mm BOZD lens vs. 50.55% after 3.0mm BOZD lens wear. Refractive changes did not alter binocular distance vision. An increase in UNVA from N 16 to N 7.8 (p=0.004) was observed after 1.9mm BOZD, while a N 6 (p=0.02) average was achieved after the 3.0mm BOZD wear. Post 1.9mm BOZD lens wear, CSZ induced -0.03µm (p=0.05) coma and -0.05µm (p=0.035) spherical aberration, decreasing CS in medium and high frequencies. Post 1.9mm BOZD use, the induced CSZ was lower than predicted 1.77mm (p<0.001) vs. a 2.41mm (p<0.001) for a 3.0mm BOZD.

Conclusions: Overnight DRLP lenses successfully provided functional near vision. The induced CSZ was found to be reduced from the originally intended (BOZD), while a larger CSZ increased corneal aberrations, surprisingly it did not affect binocular visual acuity. Pupil diameter is still a key factor for deciding CSZ.

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Key words
Contact lens, Presbyopia, Presbyopic refractive correction, Corneal multifocality, Orthokeratology, Corneal reshape.

Conflict of Interests: Authors declare that they do not have any proprietary or financial interest in any of the materials mentioned in this paper. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Manuscript

1.0 Introduction

Presbyopia is defined as an impairment in near vision [1], limitating the residual accommodation, hence losing the ability to focus on close-up objects.

It is the most common age-related visual impairment affecting adults, being nearly universal in people over 55 years of age [2]. It is thought to be increasing globally up to 1.250 million by 2020 and 1.782 billion by 2050 [3].

Presbyopia doesn't have a specific age when refractive correction is needed, it depends on various factors such as individual variation in accommodative ability, distance refraction [4][5], climate [6], geographic location, demands and expectations, sex, and ethnicity [7].

Throughout the world, uncorrected presbyopia causes common, avoidable vision impairment. When the symptoms are established, (average 60-year-old European adult) [8] artificial assistance for comfortable near vision is needed.

Its pathophysiology remains poorly understood [9]. Even though two contradictory theories are in frequent use. Helmholtz, postulating that the symptoms are attributed to age-related elasticity changes, hardening of the crystalline lens and its capsule [10][11], resulting in the disability of the lens to round up and increase refractive power, therefore losing the ability of focusing in near objects [12], and Schachar, theorizing that lens sclerosis is a principal factor for presbyopia, occurring because of vectoral forces of the lens fibres which increases the equatorial lens diameter [13]. As a consequence when reaching the fifth decade of life, the resting tension on the zonulas is significantly reduced [9].

Changes in all ocular tissues are present, as the age increases. Apart from loosing the accommodative ability, the lens becomes more curved [14], suggesting that refractive error should become more myopic as the aging process goes on. The overall trend, turns out to be the contrary, a hyperopic shift in persons younger than 65 and a myopic shift for older ages has been found in diferent studies [15][16]. Blue Mountains Eye Study (BMES) reported a 0.4 D increase for the 49–54 years old group, and a myopic shift of -0.02 D for the 65–74 years old group [15]. This is referred as "lens paradox", as the center plateau of the lens of high reftactive index becomes wider and refractive index changes towards the edge of the lens [17].

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Some internal ocular parametres as anterior lens surface radius of curvature, equivalent lens refractive index, and lens equivalent power tend to reduce with age, while lens central thickness, anterior segment length, and axial length tens to increase [18], as well as external changes such as the tear film which after 45 years a significant evaporative component is present being greater in women than men [19].

Some external parameters change as well when near focusing is present, such as a vergence change. As medial rectus contraction leads to convergence, simultaneously a reduction of PD occurs due to constriction of the sphincter muscle of the iris causing miosis. Therefore, depth of focus increases facilitating and enhancement of accommodation. These three joined actions are named accommodative triad (AT).[20]

During the AT, PD plays a critical role in controlling the performance of all vision correction modalities. PD is affected by both age and refractive status, being most marked at low luminance 40-54yrs = 5.49mm, 55+yrs = 4.99mm ($p<0.001$) [21].
Mean pupillary constriction-ratio is 35%/3.6 D in a 40-year group, and 33%/3.1 D in the 50-year group, in comparison to 48%/7.2 D in the 20-year group and 46%/6.9 D in the 30-year group, for a maximum accommodative stimulus at 50 cm [22]. An age-related reduction of reflex contriction ratio, and a smaller PD is thought to be found in this study.

Optical performance declines, as the age increases, in some parameters such as CS, which is found to decrease in all spatial frequencies, having a greater decline in higher spatial frequencies [23]. Some studies have proven that above 60 years of age, loss of middle and high frequencies is present [24].

Optical yield is also affected by age-related ocular aberrations, mostly because of lens contribution [25], but in general, corneal coma increases at the same time as internal spherical aberrations rises [26].

Presbyopia con be corrected in different ways, but examples of current presbyopic correction can be;

1. Spectacles, either single vision correction for near, bifocals or progressive addition lenses (PALs).
2. Multifocal or bifocal, soft or rigid gas permeable contact lenses. Variation of power profiles across the lenses produces a depth of focus (DoF) enhancement. Because of the through-focus nature of the image, influenced by the distance and near focusing, variations with different factors such as lens centration, pupil diameter, and ocular aberrations (spherical aberration) can be found [27].
3. Monovision, compensating one eye for distance vision and the contralateral with the near correction.
4. Surgical procedures, either intraocular (phacoemulsification and replacement of intra ocular lens), or extraocular (corneal or scleral).

There are however, some benefits and drawbacks, in each visual correction method, such as artificial wearing devices, risk of surgical complications or decrease quality of vision.

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Without the use of artificial devices or surgeries, presbyopia correction has not been achieved [28]. Even though in some recent studies attempts of presbyopia prevention with supplements had been tried [29] [30].

Another correction modality, which is not used in correcting presbyopia yet, is orthokeratology (OK). Which had proved to be correcting myopia, hyperopia and astigmatism with good visual outcomes [31].

OK reshaping does a controlled redistribution of the corneal tissue, a rígid contact lens is used overnight with a moulding effect. Different controlled pressures within the cornea, redistributes its tissue leading to a correction of the refractive error and, optionally, any additional optical errors. Structural and Optical changes are present in the central corneal epithelium [32] during myopia treatment.

The epithelium is particularly malleable, with rapid steepening and flattening in little time [33], eventhough the histological mechanism for corneal reshaping is under debate.

Some studies said that epithelial cell migration is the major factor for refractive error changes [34], leading this corneal layer to play a major role in the induced changes [35], even if the fact of having cells moving around the corneal surface seems unlikely because of their thight bonds [36], it is thouhgt that small anterior stromal changes may contribute to the a small extent [37]. The exact nature of the epithelial change is still unknown.
It has been postualted that the maximal amount of central tissue thinning is 20µm (only central thinning [36].

OK has recently proved correcting hyoperopia, aside from myopia and astigmatism [38]. The hyperopic reshaping treatment is induced by a direct molding from the posterior surface of the lens involving hydraulic pressures achieved by the post lens tear film. An opposition of forces between central steepening induced by apical clearance [38] and a gently precise para-central flattening is thought to be the primary mechanism on hyperopic reshaping, which induces a myopic shift [39][40][41]. As the central steepening occurs as an aspheric surface in contraposition of an sphere, high order aberrations increase, affecting particularly the spherical aberration[42][43]. Because of the natural corneal shape, hyperopic OK tends to work more slowly in comparison to myopic ortho-k [41].

In some hyperopic corneal reshape studies, significant topographic and refractive changes had been found, after the first overnight wear, with a regression effect during the day, but having a longer retention after 7 nights of lens wear [38][44]. The CSZ was reducing alongside with longer periods of wear, even though the refractive effect was increasing [45], completely opposite of what happens in the central flattening treatment zone, in a myopic correction where the treatment zone diameter increases with longer overnight wear [46][47].

As suggested, increasing the CSZ leads to better visual outcomes in hyperopic patients, as well as a lack of change in binocular distance visual acuities [38][45].

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In most of the contemporary studies, presbyopic OK correction has been achieved through three different hyperopic reshape methodologies;

- Hyperopic monovision as in [38].
- Bifocal OK lens design presenting a centre distance design with a faint addition zone towards central treatment Zone [48].
- Hyperopic design in both eyes acting as a centre near correction [42].

Monovision implies sacrifizing binocular vision by having one eye corrected for far and the contralateral for near. The first point makes it hard to be accepted by most of the patients.

OK lenses used for hyperopic reshaping in other studies had been ESA lenses for Hyperopia, Dream Lens and Global HP2.

In this study, we considered the idea of hyperopic corneal reshaping to create a presbyopic multifocality correction on the cornea. Where a balance of CSZ and Annular Flattening Zone (AFZ) had to be achieved inside the pupil.
A simultaneous vision is induced on the cornea, both near and distance regions had to remain within the pupillary boundary, hence different light rays from both distance and near are focusing on the retina at the same time, as most popular hydrogel and GP multifocal designs do [49]. In this corneal reshape, multiple powers are positioned within the pupil, inducing a corneal multifocality, increasing the DoF. Suppression of the most blurred image, not desirable for a given task, explains the blur interpretation or tolerance of superposed images [49].

In order to provide clearly sharp images on the retina, for both distance and near, the induced treatment had to cover equal areas of the pupil [49].

With orthokeratology, the treatment is fully reversible [48][50]. As proven, after a 1 week washout period, the measured parameters returned to baseline in hyperopic OK after a 1 week overnight lens wear [38].

In this study, presbyopia was described as the need of a significant near optical correction added to the best distance correction, in order to improve near vision to a near visual acuity criteria of N8 [3][51]. Therefore, 1 M print (average newsprint N8) at 40 cm (2.5 D), which is about 3x or 5 lines better than normal threshold acuity of 20/16, represented a functional acuity of comfortable and prolonged reading period [52].

2.0 METHODS

2.1 Study Design

This study was a quasi-experimental multivariate based longitudinal studio, where Double Reservoir OK Lens for presbyopia – central steepened lenses (DRLP) were worn overnight by the subjects for 4 weeks.
One DRLP lens design with two different BOZD (1.9 and 3.0 mm) were fitted on each eye in this intrasubject study. Lens specifications were matched to provide the same post lens tear film profile on peripheral landing curves, in all subjects.

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An enlargement of the BOZD was calculated after the 4-week period of overnight personalized DRLP wear, in order to correct near ametropia. New lenses were then produced by Precilens Paris, with an average of 15-20 days. *Fig. (1, 2).* The overnight wear was repeated after a minimum washout (no lens wear) period of 1 week. Measurements were taken at baseline, and after each 4-week overnight wear. While the treatment was settling, comprehensive follow up visits after 1 night, 1 week and every 2 weeks were carried out after 2 hours of waking, and in the afternoon respectively.

The main outcomes of efficacy of corneal multifocality were determined by comparing the different results from baseline and after treatment in visual acuity, refraction, corneal topography, corneal aberrations, contrast sensitivity and defocus curve.

1.9mm BOZD 3.0mm BOZD

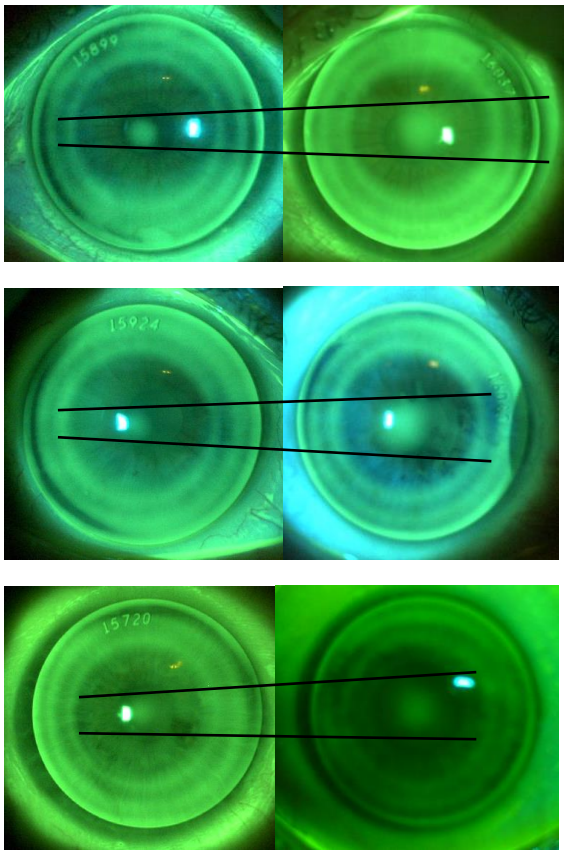

Fig. (1). 1.9mm BOZD DRLP lens compared to a. 3.0mm BOZD DRLP lens.

2.1.1 Subjects and recruitment

Twentyseven presbyopic subjects signed up for the study, nineteen of them were eliglible, from the nineteen only seven finished the study. Mean age was 46.50 years (range 44-64), 43% were under 55 years and 86% females (6F/1M). At the end of the study 100% of the subjects finished the overnight treatment as agreed.
DRLP – (Precilens, Paris), were fitted to all of the patients. Different BOZD designs were fitted. Lens specifications were matched to provide the same post lens tear film profile on peripheral landing curves in all the subjects. The subjects continuing the study, were followed during 3-4 months.

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Inclusion criteria required subjects aged between 40-65 years of age, having between +1.00 to -0.50 spherical dioptres (D) and less than 1.00 cylindrical dioptres (CD), with no previous surgery, free of ocular disease, presenting a best corrected visual acuity of 0.20 logarithm of the minimum angle of resolution (log MAR) or better, for distance, and a N=8.00 print average newsprint at 40 cm (2.5 D). Representing a functional acuity of 1/ 2.5 (0.4 Decimal), which is about 3x or 5 lines better than normal threshold acuity of 20/16 for near [52].
Spherical correction (SC) and Corneal Topography (CT) were measured at baseline to confirm the subjects were meeting the inclusion criteria.

None of the subjects participating had any ocular disease or insult other than hyperopia, astigmatism and presbyopia. None of the subjects were previously contact lens wearers.

Potential subjects were recruited through advertisements placed on the Faculty of Optics and Optometry in Terrassa, e-mailing student lists, as well as through word-of-mouth. Individuals calling were informed of the purpose of the study with a written document, via e-mail. The interested individuals were invited for a first evaluation, thus coming had a careful and comprehensive visual examination. Those individuals meeting the inclusive criteria were included. After all their questions had been answered, and before the study commencement all subjects gave informed written consent *(Annex 1).*

Table 1. Baseline measurments data of patients in the study

	(mean ± SD)
Age (y)	46.50±17.19
Sex (F:M)	6:01
Hyperopia (D)	0-+1.00 (+0.69±0.42)
Astigmatism (D) (Negative cylinder)	0--0.25 (-0,25±0.03)
Near addition	1.25-+2.75 (2.18±0.41)
UDVA (logMAR)	0.24--0.08 (0.07±0.12)
CDVA (logMAR)	0.02--0.10 (-0.05±0.06)
UDNVA (logMAR)	10-32 (16.67±5,55)
CNVA (logMAR)	3-4 (3.17±0.25)

UDVA = Uncorrected Distance Visual Acuity; CDVA = Corrected Distance Visual Acuity; UNVA = Uncorrected Near Visual Acuity; CNVA = Corrected Near Visual Acuity; SD = Standard Deviation

Documents such as summary of the study, research protocol, data collection records, written informative document, written consent, researcher's commitment, civil liability police from the catalan college of optometrists, economic memory, DRL CE certificate, DRL ISO Certificate, suitability of Teknon facilities, suitability of the main researcher and collaborators and main researcher's currículum vitae had to be wrote and presented to the ethics and research committee of the clinics.

Approval from the Centro medico Teknon, ethics and research commitee (CEIM), was obtained before study commencement (21st April 2017), according to the tenets of the declaration of Helsinki *(Annex 2).*

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2.2 Lens parameters and fitting guide

The OK lenses fitted were a new pilot design of an accelerated orthokeratology DRL for presbyopia, (Precilens, Paris, France). Near central zone was designed to be small with a purpose of fitting within the pupil boundaries, and in order to prevent distance vision hindering. As all the simultaneous vision corrective methods, this design is pupil dependant, and its centration the most import parameter.

The first lenses of choice were calculated according to the manufacturer's protocols considering the topographic values and refraction *(Annex 3).* Lenses from the trial box were tested corresponding to the resulting calculation of the manufacturer. All fittings were optimized varying the lens base curve (BC) in order to achieve perfect centration, lens movement of 1-2mm after blinking, "bull's-eye" fluorescein pattern (NaFl), a treatment zone of 5-6mm diameter, a 1-2mm mid-peripheric tear reservoir (suction force), and a double alignment zone of 0.5mm each one, until centration outcomes were achieved. (Fig. 1).

After finding the correct BC, the DRLP lenses were calculated and designed with a central steepened apical zone to provide corneal multifocality (Center-Near) and the same post lens tear film profile in all subjects. Diameters were ranging from 10.40 to 11.00mm.

DRLP lenses are made of hexafocon B material with an oxygen permeability of 141 barriers, to minimize hypoxic stress during lens wear. Refractive index of 1.424, Rockwell R hardness of 101 units, and wetting angle of 38 degrees measured with the captive bubble method. Lenses were daily cleaned with peroxide, and, when the lenses were not worn, they were dry-stored, according to manufacturer's recommendations.
Ever Clean and 0.4% hyaluronic acid, preservative free monodosis drops, were the indicated management for cleaning and wearing, respectively.

2.3 Measurement Tecniques

The main researcher Sònia Travé Huarte (ST) fitted all the lenses, always supervised by the co-author Jaume Pauné (JP). All the study measurements were taken by the leading investigator ST.
All measurements were carried out under photopic conditions, room ilumination 400 lux (luxometer PCE- 174 (PCE Instruments)), and the same optotype LCD (Vista vision. Version 4.4(1). LCD: 22-WIDE) screen (VVW).

At baseline and at the end of each BOZD overnight lens wear, clinical examinations included: visual acuity (VA), spherical refraction (SR), corneal topography (CT), corneal aberrations (CA), defocus curve (DC), contrast sensitivity (CS) and slit lamp anterior segment health examination (ASH). During the follow-up visits VA, SR, CT and ASH were measured to monitor any physiological changes.

After a 4-week period of overnight personalized DRLP wear, the previous mentioned tests were then measured, and compared with baseline
A washout period of a week has done between 1.9 and 3.0mm BOZD wear.
The lenses were then recalculated for a larger BOZD, lens wearing and measurement procedures were then repeated.

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2.3.4. Refraction

Non-cycloplegic best vision spherical correction (SC) was measured by a standardized manifest refraction performed by the same clinician ST. SC was recorded at all visits using standard optometric techniques. Additional spherical plus power required for near tasks was measured as, the minimum plus power required to reach their best corrected VA having a comfortable vision for reading.

The refractive data were converted from sphero-cylinder notation S/C x θ to spherical equivalent M, 90º-180º astigmatism component J_{180}, and 45º-135º astigmatism component J_{45}, and M Add. Notation (M, J0, J45, P, MAdd) was used for the purpose of analysis.

$$M = S + \frac{C}{2}$$
$$J_{180} = -\left(\frac{C}{2}\right) * \cos(2\theta)$$
$$J_{45} = -\left(\frac{C}{2}\right) * \sin(2\theta)$$
$$M\ Add = S\ Add + \frac{C}{2}$$

Fig. (2). M, J_{180}, J_{45}, *M Add formulas*

2.3.5. Best corrected visual acuity

Monocular and binocular best corrected distance visual acuity (CDVA) were measured in both eyes in the morning and afternoon visits, through full SC.
For near, monocular and binocular best corrected near visual acuity (CNVA) were measured. 1 M = N 8 print (average newsprint) at 40 cm (2.5 D), was considered as a functionally near visual acuity [52].

An electronic optotype VVW with high-contrast (100%) at a distance of 6 m, was used for measuring visual acuities (VA). VAs were reported in LogMAR [53] using the Early Treatment Diabetic Retinopathy Study protocol (EDTRS) [54].

2.3.6. Pupil Diameter

Under Photopic conditions (room ilumination 400 lux), average data for pupil diameter were exported from the CT for the calculations.

Pupil size was measured along the horizontal and vertical meridians. Measurements were taken using the calliper within the pupil.

2.3.7. Contrast sensitivity

Contrast sensitivity function (CSF) was measured monocularly in a trial frame, with the best SC at a distance of 6 meters, and the contralateral eye occluded. A fast 2-1 randomized CS programme was used in order to get the CSF. The subjects were providing verbal feedback to the researcher regarding the stimuli seen, the professional

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inputted the answers by clicking the arrows on a remote control. A 2-down-1-up staircase procedure [55] was used to control the contrast of the grating. Frequencies tested were 0.75, 1.50, 3.0, 6.0, 12.0 and 18.0 cycles per degree (cpd).

2.3.8. Defocus curve

Monocular DC measurements were tested on a trial frame by recording logMAR ETDRS distance visual acuities through trial lenses from -3.00 to +2.00 in 0.50SD steps. Randomized letters and lenses were used. Subjects were fully corrected with their distance refractive error prior testing, and the contralateral eye occluded.

2.3.9. Corneal topography & Central Steepened Zone

The Medmont E300 Studio (Verision 6.1.1.4, 12/2015) software was used to capture and analyse corneal topographies.
Eight images of each eye were obtained in the first visit, in order to have high repeatability results, and less than 0.05mm Standard Deviation (SD). Tangential maps were used in order to observe the smallest amount of corneal curvature change, data from three topographies taken per eye, at each visit were averaged. Differential tangential maps were made at each visit by subtracting the after-wear CT from the baseline, providing the curvature change. Tangential curvature data were averaged for each visit to demonstrate the corneal profile, in order to measure the CSZ, with the different lens designs.

In case of severe dry eye, buffered saline solution was instilled onto the patient's eyes in pursuance of a more regular tear film layer, and after a minute CT was repeated.

Measures such as pupil size, horizontal visible iris diameter (HVID), keratometry index and eccentricities were exported from the CT for analytical purposes.

CSZ was characterized in this study in order to compare the reshaping tissue in the CT on the before and after treatment. The measurement compares baseline and after treatment tangential CT, along the horizontal and vertical apical plotted meridian as shown in *Fig. (3).*

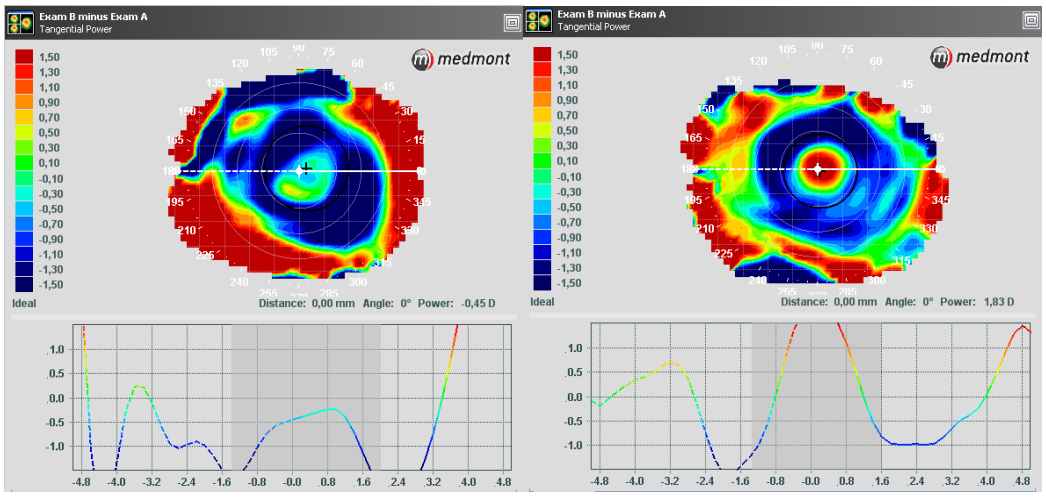

Fig. (3). CSZ induced by a 1.9 and 3.0mm BOZD DRLP lens.

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Annular Flattening zone (AFZ) refers to the wider mid-periphery tissue redistribution area, where the corneal curvature flattens in order to correct distance ametropia.
CSZ is defined by the change of corneal curvature (crossing 0.0mm) from negative to positive along horizontal and vertical apical plotted meridians. CSZ was directly measured with a calliper from the computer display [46].

2.3.10 Aberrations

Three non-dilated wavefront measurements were made per eye at baseline and at the end of each overnight lens wear, for a circular aperture of 3.5mm of pupil diameter. Coma and spherical aberration were averaged.

Medmont E300 Studio (Verision 6.1.1.4, 12/2015) software was used in the interest of capturing and analyzing corneal aberrometries (CA). [56].

2.3.11. Anterior segment health

A detailed biomicroscopic evaluation of the anterior segment health (ASH), including lid eversion and fluorescein staining was assessed at all visits using standard optometric techniques to monitor any physiological effects of overnight wear.

The ASH consisted, of a strict examination of lids and lashes, tear layer, Meibomian glands, conjunctiva and cornea with documentation of corneal anomalies if existence.

Topcon imagnet i-base version 3.16.0, was used in order to record different findings, alongside with the fluorescein patterns of the different DRLP lenses.

2.4. Data analysis

After a preliminary exploratory analysis, the quantitative variables were examined with Stata software (version 14), and a two-sample Wilcoxon rank-sum (Mann-Whitney). The Wilcoxon (Mann-Whitney) was used to test for SR, UDVA, UNVA, CT, CS, DC, CSZ and AB. The p-values were adjusted by the Stata software according to Bonferronni correction, such that a reports p-value <0.05 denotes a statistical significance throughout the study.
The two-samples Wilcoxon rank-sum was used to compare the baseline with the 1.9mm BOZD design, the baseline with the 3,0mm BOZD designs and the comparison between the post wear different designs outcomes (1,9mm BOZD and 3,0mm BOZD).
Non-parametric Wilcoxon rank-sum (Mann-Whitney) test was used to average the results.

3. RESULTS

Results from seven presbyopic subjects, (4 low hyperopic and 3 emmetropic) had been studied.
Subjects continuing the study, were followed during 4-5 months.

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3.1. Refractive Error

Spherical refractive error had a baseline M of +0.647±0.422 D. J_{45} and J_{180} were not present because there was not or very little astigmatism component. Subjective refraction (SR) changed significantly over time, with the first treatment 1.9mm BOZD there was a decrease of 0.62±0.071 D (p=0.0095), and after the 3,0mm BOZD wear a 0.80±0.024 D (p=0.0015) reduction. There were no statistically significant differences in outcomes between different BOZD, even though the 3,0mm BOZD induced -0.151±0.456 D in distance vision.

During lens wear, M Add went down from 2.083±0.414 D to 1.550±0.560 D after a 1.9mm BOZD treatment (p=0.0238), and to +1.059±0,619 D after the 3,0mm treatment (p=0.0113). The difference in post treatment addition (M Add) between 1.9mm BOZD and 3.0mm BOZD designs was not statistically significant.

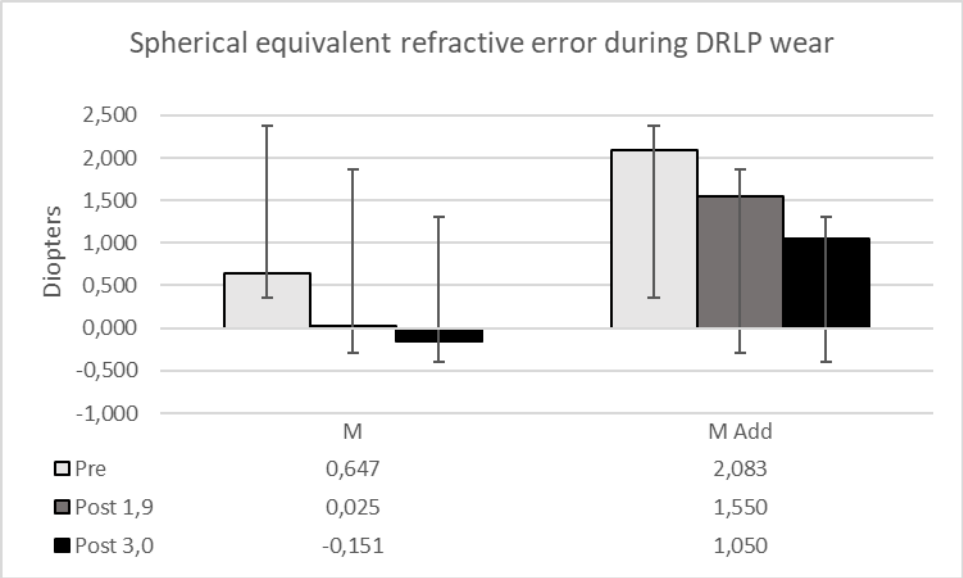

Fig. (4). M and M Add during DRLP 1.9 and 3.0mm wear.

3.2. Visual Acuities

Before treatment commencement, both monocular and binocular best CDVA was achieved on an average of -0.05±0.06 LogMAR.
There was no statistic significant difference in monocular UDVA after the first treatment, even thought, a loss of 3 logMAR letters, 0.01±0.11, was observed. After the 3.0mm BOZD wear, a decline of a line was present on the average 0.05±0.06 (p=0.003) for monocular distance vision. Moreover, for binocular UDVA no statistic significant changes were observed, although a letter improvement for distance was observed after the 3.0mm treatment -0.06±0.07 compared with baseline.
Previous commencement, best SC for near, achieved a monocular CNVA of N=3.17±0.25 and a binocular CNVA of N=3,17±0.41. After 1,9mm BOZD lens wear a N=7.80±1,79 for comfortable binocular vision (p=0.00) was found and a N=6,00±3,46 (p=0.00) after the 3.0mm overnight wear. There was no significant difference between 1,9 and 3,0mm BOZD designs.
Error bars represent the standard error of the mean (SEM).

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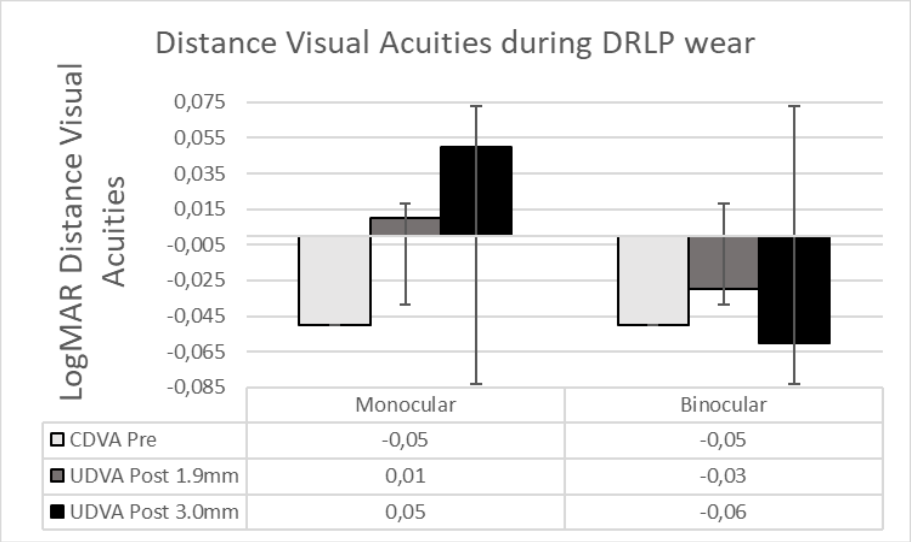

Fig. (5). Distance monocular and binocular VA comparison during DRLP wear.

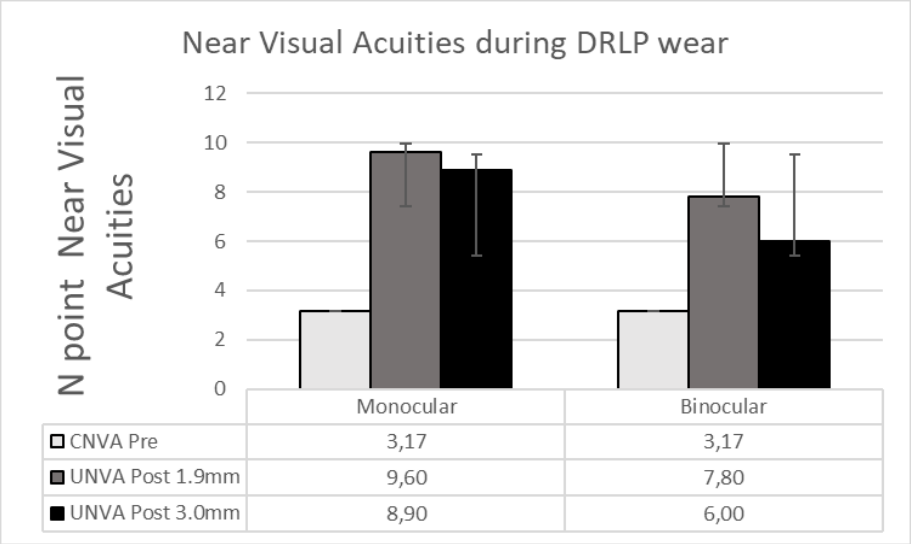

Fig. (6). Near monocular and binocular VA comparison during DRLP wear.

3.3. Contrast Sensitivity

Even though there is no statistical significance in any frequency for this test between baseline values and after both treatments, a dropping in medium and high frequencies was present. The frequency of 6cpg dropped from an average of 210cpd to a 159cpd after the 1.9mm BOZD design, and to a 111cpd after the 3.0mm lens. In addition to this, the 12cpd frequency had a 62.63% decrease after 1.9mm BOZD and a 61.53% after the 3.0mm BOZD wear.

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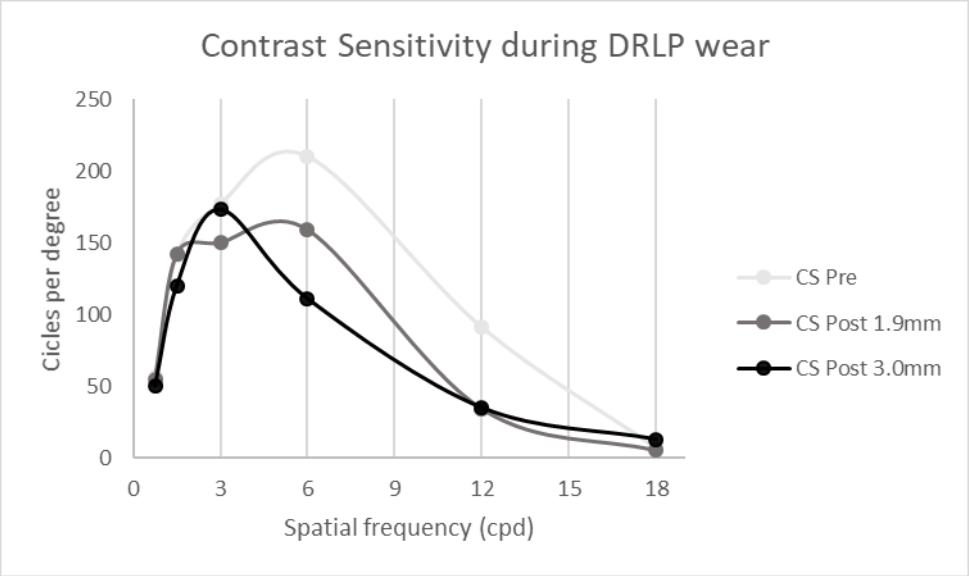

Fig. (7). Contrast sensitivity function comparison during DRLP wear.

3.4. Defocus Curve

The next figure shows the monocular mean defocus curves under photopic conditions. On baseline measurements, a wave like defocus curve pattern appeared, obtaining the best CDVA results at 0.00D, defocus equivalent to distance vision.

After the 1.9mm overnight wear a 2,5 line decrease was observed at 0 D ($p<0.001$), in the intermediate zone, no distinct peak was observed. Furthermore, from -1,50 D to +1.00 D, on steps of +0.50SD, significant statistical visual changes were observed having a respective decrease of 0.19 ($p=0.02$), 0.21($p=0.002$), 0.23 ($p=0.001$), 0.26 ($p<0.001$), 0.22 ($p=0.001$), 0.18 ($p=0.001$) lines each step.

Contrary to the first lens design, after the 3.0mm overnight wear a 2 line decrease was observed at 0 D ($p=0.002$), a second peak was present at −1.50 D, corresponding to a functional near vision. However, in the intermediate distance interval, the curve presented a statistically significant lower visual acuity when compared to baseline from -1.00 to +1.50SD on steps of +0.50 respectively, 0.43 ($p=0.09$), 0.29 ($p=0.002$), 0.18 ($p=0.003$), 0.25 ($p=0.002$), 0.37 ($p=0.001$), 0.54 ($p=0.001$), 0.68 ($p=0.03$).

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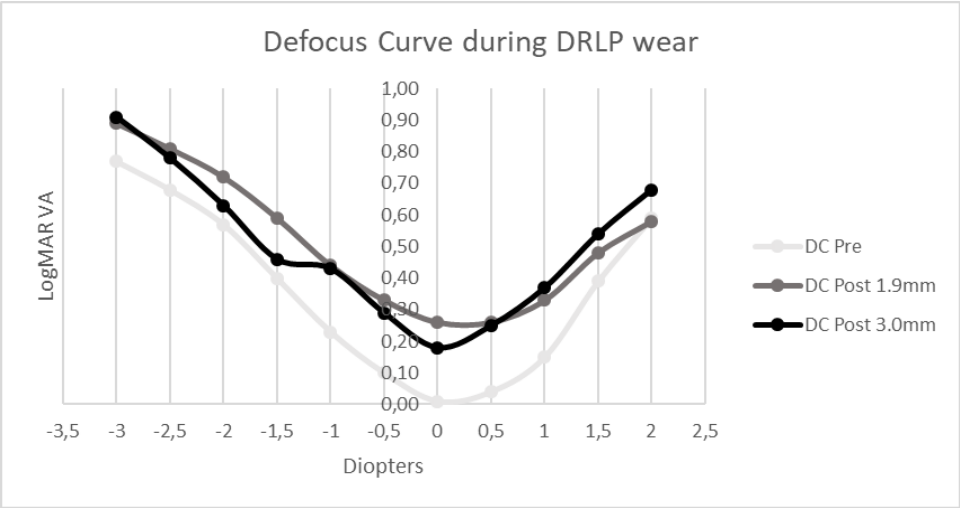

Fig. (8). Defocus curve comparison during DRLP wear.

There was no significant difference between 1.9 and 3.0mm BOZD designs. As there were not sharp drops in the curve, useful vision at intermediate distance was achieved, objective and subjectively.

3.5. Corneal topography & Central Steepened Zone

Baseline measurements were the horizontal and vertical meridian length within the pupils, where a refractive change, from positive to negative induced power was induced. Once 1.9mm BOZD overnight refraction wear was settled, an average of 1.73±0.32mm CSZ horizontally and a 1.81±0.58mm, was found to be induced ($p<0.001$). In other words, a 6.95% less steepening induced, than the predicted 1.9mm of BOZD.
There was a greater change in corneal curvature after 3.0mm BOZD lens wear, an averaged 2.40±0.43mm horizontally and a 2.42±0.36mm were induced ($p=0.0006$). Indeed a 19.77% less steepening induced, rather than the predicted 3.0mm BOZD.
In addition to this, a statistic significant difference was found between both treatments, having a difference of 0.66mm horizontally and 0.61mm vertically ($p=0.04$).

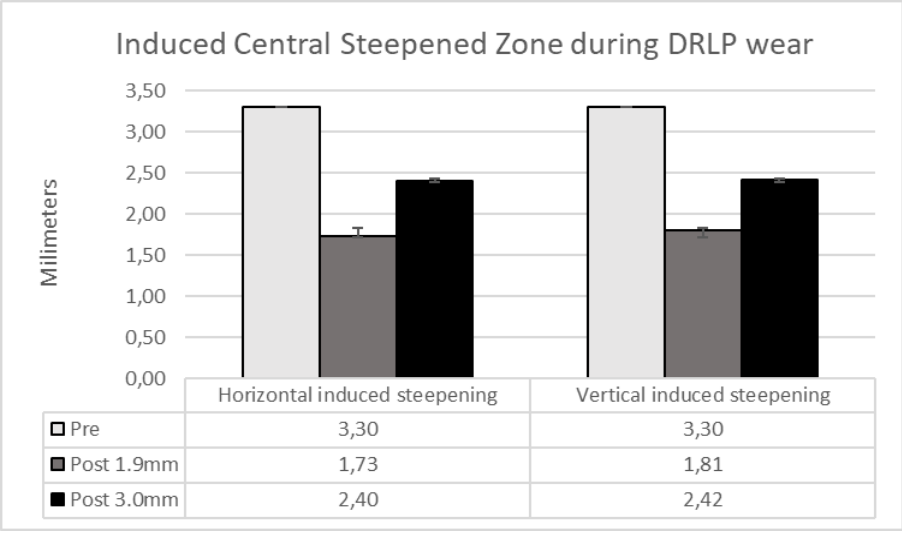

Fig. (9). Induced Central Steepened Zone comparison during DRLP wear.

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3.6. Aberrations

Figure 10 shows the variations of the optical quality of the anterior corneal segment over the time. Revealing a decrease of 0.099µm (p=0.05) after the 1.9mm BOZD wear, which in contraposition does not seem to happen after the 3.0mm BOZD use, where an increase of 0.012µm, is present.

As the grpahic displays a decrease of 0.081µm (p=0.035) was revealed after the 1.9mm BOZD. It can be seen as well after the 3.0mm BOZD lens wear, a non-statistical significant difference, where a -0.009µm induced aberration leads a change to a negative induced corneal aberration, minor to the prior treatment.

Error bars represent the standard error of the mean (SEM).

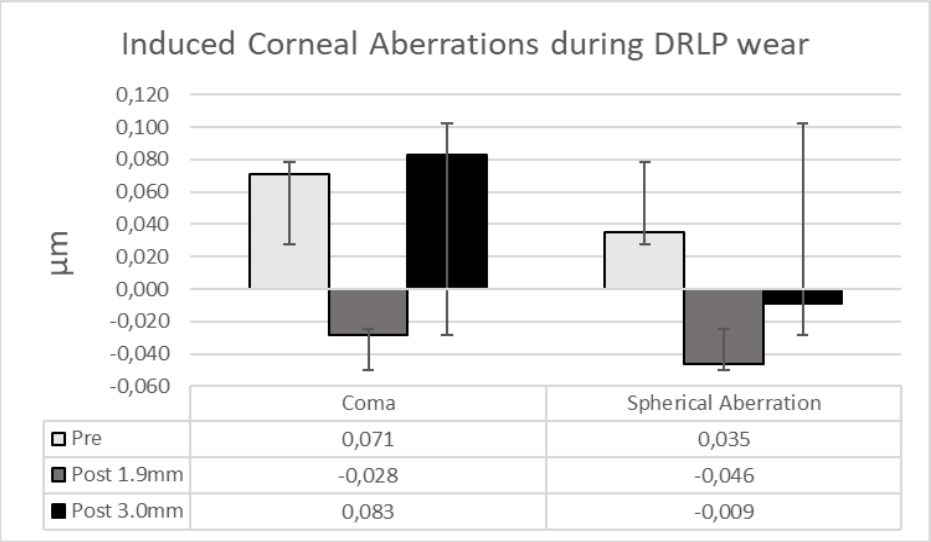

Fig. (10). Induced corneal aberrations comparison during DRLP wear.

4. DISCUSSION

We have demonstrated that a corneal induced multifocality effect for presbyopia can be achieved throughout corneal reshaping.
Taking into account the idea of hyperopic reshaping, this study was designed to evaluate the visual outcome of two different OK DRLP lens designs of 1.9 and 3.00mm BOZD which are based on central corneal steepening similar to hyperopic reshaping.

A regression effect was observed during the first days. Previous studies proved a greater clinical effect after seven overnight wear in hyperopia reshaping, and to follow, the lenses used in the current study appeared to provide similar clinical outcomes [44].

After 4-week overnight wear in presbyopic subjects, DRLP lenses induced an average refractive shift in SC of +0.025 D after the 1.9mm BOZD treatment, and a -0.151±0.45 D after the 3.0mm BOZD treatment, which was consistent once the reshape was settled.

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BOZD of the lens was fitted according to Jessen factor in order to provide the amount of correction required both for near refractive errors [57].

In this study, we found out that some emmetropic subjects had a low hyperopic refractive component of M=+0.69SD averaged, which was corrected apart from the near correction addition, having therefore two different powers within the pupil.
Binocular best corrected distance VA did not change from baseline, going from a -0.05 logMAR to a -0.03 after a 1.9mm, up to a -0.06 after the 3.0mm treatment, meaning that distance vision remained functional apart from near correction. When measured monocularly, DRLP-induced changes to refraction, which led to a decrease of UDVA about 3-4 letters.

UNVA was measured with N-point test, where a N8 at 40 cm (2.5 D) represened a functional acuity of comfortable and prolonged reading period [52]. Leading to near N-point vision of N=7.8 (p=0.00) after the 1.9mm and a N=6.0 (p=0.00) after 3.0mm BOZD wear.
Baseline values were N=16±5.55 for UNVA, N=4.75±1.35 with subject's reading glasses and N=3.17±0.25 after SC and near addition. A decrease of N=4.6 (p=0.00) lines was observed after the first 1.9mm BOZD, and a N=2.8 (p=0.00) after the 3,0mm BOZD, but near correction was achieved. An average of 26% decrease of the baseline 2.083 D near addition targeted was corrected after the 1.9mm wear, and a 50.55% reduction was observed after the 3.0mm lens wear leading to a 1.03 D, being able to have functional near binocular UNVA of N=7.80 after the 1.9mm lens wear and a N=6.00 after the 3.00mm, useful for most normal reading tasks.

As a general acceptance rule a 0.25D refractive change equals a 1-line logMAR 0.1, in our study this correlation was not found. Binocularly UDVA was better than the expected after the induced myopic shift. Once the multifocality was settled, even though there was a spherical residual component, UDVA had just 1 line decrease, similar results were also found in [38].

Despite a very small amount induced ametropia at distance, binocular UDVA increased once the treatment was settled, raising the probability that visual system may adapt to distance blurred images. As multifocal contact lens and intra oculars lens (IOL) do, decreasing the optimal image quality where CS is reduced despite having a functional UDVA [58], but a possible neuroadaptation is a possible explanation [38][59]. Further studies are required to prove if this neuroadaptation occurs while treating presbyopia with a reshaping modality.

In our study, a drop of medium (6cpd) and high (12cpd) frequencies was present, a probable increase of high-order aberration influenced contrast sensitivity, so that a decrease of the optical quality was present.

The induced multifocality was specifically observed during the defocus curve yield. When UDVA had 0.00 D (p=0.002), a decrease between 1 to 2 lines was present, in contraposition, the most important optical performance was the one induced at -1.50SD (p=0.02) after the 3.0mm BOZD design, representing the near correction, which did not appeard to be represented in ghe defocus curve after the 1.9mm BOZD lens wear.

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Both designs were inducing corneal multifocality due to the BOZD moulding within the pupil. The central button, reported as CSZ had a similar optical performance to a centre-near multifocal contact lens. CSZ was used for near tasks, versus AFZ which provided a clear focusing for distance. CSZ is a major factor for having a decrease on CS, and AFZ is a considerable parameter for having a diminished effect of steepening.

If the blending curvature is not aspheric or the lens is not completely centred, monocular diplopia can occur as a side effect.

Although in some cases, induced central steepening was more than 2.00 D, during the follow-up visits refractions, 100% of the patients referred a more positive addition was helping them achieve better near work performance.
All of the subjects had equal pupil round reacting to light and accommodation PERRLA. As the accommodation in presbyopic patients is reduced or there is almost none, constriction ratio is smaller than in younger patients [21][22].

A significant amount of CSZ and AFZ was present after both treatments. Figure 11 reveals the appearance of a wider CSZ 2.4mm ($p<0.001$) after the 3.0mm, versus a 1,76mm ($p<0.001$) after the 1.9mm. Although induced BOZD did not reach predicted steepening diameter, the changes were sufficient to provide functional near and distance NCVA. 1.9mm BOZD induced 6.95% less steepening than the predicted, and 3.0mm BOZD induced a 19.77% less steepening.

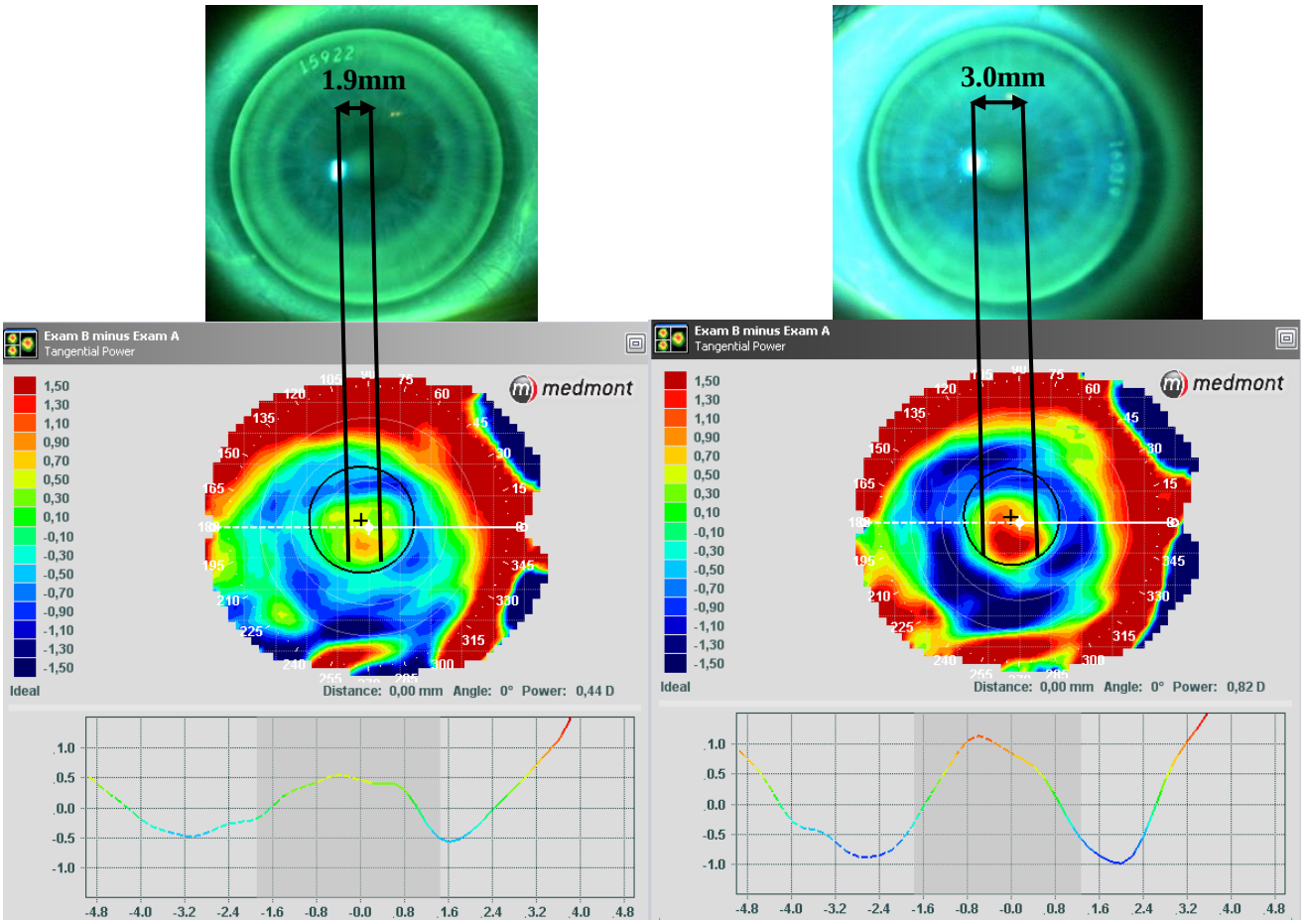

Fig. (11). Induced corneal steepened zone related to its fluorescein pattern.

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Pupil size has a lot of depending variables age, light, drugs... all of them affecting the overall pupil diameter, optical yield and DoF. The CSZ-pupil ratio was found to be different in every person. In order to provide good distance vision, apart from functional near addition, different CSZ diameters have to be induced. After the 1,9mm BOZD an average of 53% of the pupil was covered with the CSZ, but surprisingly near visual acuities were low, in comparison to a 73% after the 3.0mm induced CSZ, where near visual acuity was satisfactory. Further studies are needed to prove a standardized optimal induced CSZ for the highest optical performance.

It has to be stated that the induced CSZ was not the predicted, therefore all the measurements have been done after the overnight lens wear, with an average of 1.8mm after the 1.9mm BOZD and 2,4mm after the 3.0mm BOZD. Further studies on tissue redistribution on hyperopic and presbyopic OK are needed.

Because of the moulding effect of DRLP, creating the CSZ for near addition, a contrary side effect was present. Corneal aberrations such as Coma and Spherical Aberration increased significantly with a 3.5mm pupil. Coma changed from positive to negative after both BOZD designs, being statistically significant after the 1.9mm reaching -0.028 ($p=0.05$). Spherical aberration changed from positive to negative getting to an average of -0.046 µm ($p=0.035$) after 1.9mm treatment. Previous studies reported a decrease of visual quality after OK changes, compromising CS and a significantly increase of high order aberrations depending the amount of refractive error corrected [60].

An enhanced in CSZ diameter provides a better UNVA, and a functional UDVA, but is directly related to an increase in CA, and a decrease of CS.

Previous studies proved in hyperopic OK a decreasing refractive effect during the day, but presented a greater retention rate after increased overnight wear [44]. Also age was found to be an influential parameter on epithelium redistribution with reverse geometry lenses [61]. In our study, we found out that it took around 4-5 days in order to have a sufficient vision, but once the CSZ has been settled, age was not an altering factor.

Further studies are needed to verify the balance of BOZD within the pupil, even though pupil size depends on a variety of physiological factors.

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5. CONCLUSIONS

With the present study, we have demonstrated that a corneal induced multifocality effect for presbyopia using DRLP lenses, can be achieved throughout corneal reshaping. Significant distance visual quality deterioration was present because of negative induced aberrations, which reduced medium and high frequencies in contrast sensitivity.
Even though CSZ did not reach the intended diameter, a functional near and distance vision were reported by the subjects after the 3.0mm BOZD lens wear. As in our findings 3.0mm BOZD lens design slightly decrease UDVA and 1.9mm did not correct near ametropia, pupil diameter is a key factor for deciding CSZ, an in between diameter would probably be a possible functioning ratio for presbyopic OK.
Further studies are needed to evaluate refractive, topographic changes and optical quality with different induced diameters over longer periods of overnight. As well as a standardized ratio between near and distance zone diameter within the pupil which provides best visual acuities.

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Appendices:

A. Written consent for the study.
B. Approval from the Centro medico Teknon, ethics and research commitee (CEIM).
C. Manufacturer's fitting guide for DRL.
D. Contact Lens & Anterior Eye. Author Information.

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Annexus

A. Written consent for the study.

Evaluación de un diseño de lente de ortoqueratología para presbicia. Documento de Consentimiento Informado

INTROCUCCIÓN

Le invitamos a formar parte de este estudio de investigación que tiene como objetivo el desarrollo y optimización de un nuevo formato de corrección visual de la presbicia (vista cansada) sin cirugía, para permitir la visión próxima sin gafas en personas présbitas.

¿QUE INVOLUCRA EL ESTUDIO?

Esté estudio servirá para evaluar un diseño de la lente de ortoqueratología que produce una zona de tratamiento, moldeando el centro la córnea con la finalidad de obtener una bifocalidad que proporcione visión efectiva tanto lejana como cercana, sin necesidad de ningún tipo de corrección óptica (Gafas/Lentes de contacto.

Esta lente es de uso nocturno, se pone antes de ir a dormir, y se saca al levantarse, éstas nuevas lentes le proporcionarán visión normal a diferentes distancias, durante el día, sin necesidad de ningún otro tipo de compensación óptica (gafas o lentes de contacto).

Si finalmente decide participar, tendrá que someterte a un examen visual hecho por optometristas profesionales.

Primero será citado para una primera evaluación, en el cual se realizará un examen visual completo que culminará con todos los parámetros para pedir una lente personalizada y una explicación más detallada de todo el estudio. - Si entra dentro del criterio establecido para ser parte del estudio (Parámetros de exclusión delimitados más abajo), se le añadirá para pasar a formar parte de los sujetos del estudio.

La primera examinación consistirá en varios tests, objetivos y subjetivos, como Anamesis, Agudeza Visual, Refracción, Topografía, Aberrometría Biomicroscopía, Sensibilidad al Contraste y Curva de Desenfoque. Después de la examinación con todos los parámetros necesarios, una lente de Ortoqueratología se calculará para cada paciente individualmente, los resultados se enviarán a la fábrica Precilens en París para su fabricación (15 días aproximadamente).

Tan pronto como la lente haya llegado, haremos otra visita. Se le adaptará la lente, para observar sus características, movimiento en el ojo y el patrón de fluoresceína. Si todo es estable, la lente se te entregará para que pueda empezar a usarla como tratamiento. Pautas de cómo insertar /extraer, y su consecuente limpieza, se le explicarán y se le darán por escrito.

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Después de una noche de uso, le vamos a ver otra vez, para ver como se ha asentado la lente en su ojo y el efecto que ha tenido. Después de la primera noche, esperaremos 1 semana hasta la siguiente visita, 2 semanas, y cada 2 semanas durante los próximos 2 meses sucesivos (9 visitas en total). En cada visita se repetirán las mismas mediciones que en la primera visita, para saber el rendimiento de la lente en el ojo del paciente. La duración del examen estará aproximadamente sobre los 50 minutos.
Es razonable esperar los siguientes beneficios de esta investigación: Una nueva lente de ortoqueratología sin cargo alguno durante un año. Sin embargo, no podemos garantizar que pueda experimentar los beneficios de participar en este estudio.
Gracias a su colaboración, otros podrán beneficiarse en el futuro de la información que encontramos en esta investigación.

RIESGOS

No se esperan riesgos de salud ocular, sin embargo, existen, como en el caso de la adaptación de lentes de contacto convencionales el riesgo de irritación ocular, conjuntivitis o en determinados caso infecciones oculares. No obstante, estas complicaciones se resuelven con la interrupción del tratamiento de forma temporal o definitiva. La complicación más común es la tinción corneal, en otros efectos secundarios clínicamente insignificantes se incluyen depósitos epiteliales de hierro, líneas fibrilares prominentes y cambios transitorios de las propiedades biomecánicas de la córnea. En gran parte de la literatura existente, no se han encontrado defectos endoteliales con el tratamiento de Ortoqueratología a largo plazo. La única complicación potencialmente dañina para el ojo, en este tipo de tratamientos, es la infección y la úlcera corneal que se da en muy pocos casos (7.7 de cada 10.000 pacientes/año), relacionada con el contacto con agua o soluciones de mantenimiento contaminadas. En caso de infección es necesaria la atención y el tratamiento médico urgente. Aunque los riesgos son muy bajos, para no errar en precaución, nuestros pacientes tendrán acceso al teléfono de la investigadora Sònia Travé Huarte, que estará activo 24 horas al día, para cualquier consulta relacionada con sus Lentes de Ortoqueratología.
Cualquier otra sintomatología de complicaciones como dolor, picor, enrojecimiento ocular durante el tratamiento, se explorarán, y si es necesario, se derivarán a los oftalmólogos pertinentes.
"Ante un ojo rojo/secreción ocular, dolor o malestar ocular no pondremos la lente de tratamiento. Ante sintomatología extraña como ojo rojo/secreción ocular, dolor o malestar persistente, retiraremos la lente inmediatamente y contactaremos rápidamente con nuestro profesional de la visión.
A pesar de tener una buena visión con las lentes puestas, en ningún caso estas lentes se usarán en régimen de porte diurno, con los ojos abiertos, más allá del tiempo necesario tras ponerlas e ir a dormir. Si las lentes se usan durante un tiempo prolongado con los ojos abiertos pueden causar lesiones oculares."

MOLESTIAS

Debido a que estas lentes son rígidas, más pequeñas que las blandas, teniendo su apoyo en cornea, se puede notar una ligera incomodidad al principio. Se notan más en el ojo que las blandas debido a que material de las blandas no da resistencia al ojo, por eso, las

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blandas no funcionan para dar el moldeo corneal necesario, que sí dan las lentes de Ortoqueratología.
Sin embargo, las lentes rígidas tienen cierta sensación continuadamente, pero debido a que su uso es nocturno, la lente sólo se nota ligeramente al ponerla, después nos vamos a dormir, y la lente se posicionará en posición efectiva de tratamiento, dónde una vez con el ojo cerrado, la lente no se nota en absoluto.
El material de esta lente deja pasar gran cantidad de Oxígeno, siendo diseñadas especialmente para poder dormir con parpados cerrados, sin tener más complicaciones.
A mayor uso que se le da, menor incomodidad da.

BENEFICIOS

La córnea va a ser moldeada durante la noche (recomendación de 7-8h), de manera que al cabo de unos días no será necesario utilizar ningún medio de compensación óptica (Gafas o Lentes de contacto).
El efecto de la lente es reversible y temporal. Esto significa que las lentes de Ortoqueratología se deberán utilizar continuadamente, todas las noches, para mantener los efectos del tratamiento satisfactoriamente. Por tanto, la calidad visual dependerá del uso que se realice de las lentes de contacto.
El paciente se beneficiará del control exhaustivo de su visión y de la adaptación gratuita de lentes de contacto, durante un año. (Líquidos de limpieza y lágrimas humectantes se deberán abonar aparte).
Como consecuencia, el paciente se beneficiará de lentillas gratuitas durante 1 año y la ganancia visual sobre todo en Visión cercana que proporcionan estas lentes.

CARACTERÍSTICAS DE LA LENTES DE ORTOQUERATOLOGÍA

La lente de ortoqueratología para presbicia, tiene una geometría específica de la superficie posterior, calculada para cada paciente individualmente, para tratar la córnea dando visión satisfactoria en ambas distancias, lejos y cerca, sin uso de gafas ni lentes de contacto.
Con un material de alto paso de Oxígeno permite una muy buena oxigenación del ojo durante la noche, de manera que, el ojo sigue su metabolismo normal sin ningún problema.
Estas lentes de ortoqueratología, tienen una vida aconsejada de 1 año, después se vuelve a hacer un examen visual, y se fabrican nuevamente con las características para cada ojo.

UNA VEZ TERMINADO EL ESTUDIO

Las lentes entregadas al final del estudio son gratuitas y tienen una duración de un año. En años siguientes el paciente puede optar por continuar su uso, lo que incluirá un pago de 430 € anual por las dos lentes.
Al ser un tratamiento reversible, al dejar de usar las lentes de ortoqueratología, el ojo vuelve a su forma natural, devolviendo al ojo, la misma graduación que tenía antes de iniciar el tratamiento. Opciones al finalizar el estudio:

1. Seguir durante 1 año con las lentes de ortoqueratología. Al cabo de 1 año, adquirir las lentes o dejar el tratamiento (recuperación de su graduación y uso de gafas para visión cercana).

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2. Dejar el uso de las lentes de ortoqueratología, recuperación de su graduación y uso de gafas para visión cercana.

CONFIDENCIALIDAD

Los resultados de las diversas pruebas realizadas, así como toda la documentación referente a su persona son absolutamente confidenciales y únicamente estarán a disposición del/de la investigador/a principal, los/las colaboradores/as, y las autoridades sanitarias competentes, si es el caso. Todas las medidas de seguridad necesarias para que los/las participantes en el estudio no puedan ser identificados y las medidas de confidencialidad en todos los casos serán completas, de acuerdo con la Ley Orgánica 15/1999, de 13 de diciembre, de protección de datos de carácter personal, y en su reglamento de desarrollo. De acuerdo a lo que establece la legislación mencionada, usted puede ejercer los derechos de acceso, modificación, oposición y cancelación de datos, para lo cual deberá dirigirse a su médico del estudio, dirigiendo la correspondiente solicitud a Centro de Terapia Visual Marsden con dirección en Vilana 12, Consultorios Vilana, Despacho. 156, 08022, Barcelona.

SUS DERECHOS COMO PARTICIPANTE DE UNA INVESTIGACIÓN

La participación a éste estudio es voluntaria. Tiene el derecho de no participar o de dejar el estudio en cualquier momento. El hecho de dejar de participar o elegir dejar el estudio no tendrá penalización ni pérdida de los beneficios a los que tiene derecho, tampoco afectara a la relación con los investigadores Sònia Travé Huarte y Dr. Pauné.

CONTACOS PARA PREGUNTAS O PROBLEMAS

Puede contactar a Sònia Travé Huarte, Optometrista Investigadora del MUOCV (Master Universitario en Optometría y Ciencias Visuales) sonia_trave@hotmail.com, si tiene alguna duda o indecisión sobre sus derechos como participante.
También puede contactar con Dr. Pauné para su asistencia si es necesario a jpaune@paunevision.com.

Consentimiento Informado del Paciente o (Representante legalmente autorizado).

Yo con DNI he sido debidamente informado, por los investigadores, de la naturaleza y riesgos del tratamiento de ortoqueratología, estoy satisfecho con la información recibida, pudiendo formular todas las preguntas que he creído convenientes, siendo aclaradas todas mis dudas y he entendido mis riegsos y beneficions en éstudio, en consecuencia, presto voluntariamente mi consentimiento para la administración del tratamiento pudiendo, no obstante, revocarlo en cualquier momento. Y, para que así conste, firmo el presente documento, después de haberlo leído.

Firma del paciente o Representante Data

Al firmar, el sujeto o el representante legalmente autorizado recibirán una copia de este formulario. Él original se mantendrá en el registro de la investigación.

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