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# A PILOT COMPARATIVE STUDY BETWEEN TWO CONTACT LENS DESIGNS FOR OVERNIGHT ORTHOKERATOLOGY: CRT AND DRL

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**Abstract**
Purpose: This study was conducted to see the effectiveness and predictability of the orthokeratology treatment through a comparison between two designs of lenses existing currently in the market: The Paragon CRT ® and Pauné DRL ® lenses.
Methods: Using topography data we fitted 12 eyes of 7 patients. First of all, with CRT ® design and with DRL ® lenses after we waited for 1 week for the washing out period so they recover the initial corneal morphology. Second we evaluated the effectiveness and the changes induced by each lens and compared the results obtained on each eye with both lenses.
Results: DRL ® lenses was more effective than CRT ® after one week of wearing it, creating a greater keratometry change for the same period of time (p = 0.01), reducing refractive error (p = 0.01) and generating better Visual Acuity after the third night of wearing them. Participants also feel DRL is more comfortable in eye wearing.
Conclusion: Both contact lenses (CL) present a result suitable for the myopia correction by corneal molding, but DRL lens was faster and more effective.

**Keywords: Orthokeratology, contact lens, reverse geometry, myopia, astigmatism**.

## INTRODUCTION

Orthokeratology (OK) is a clinical technique based on the use of Reverse Geometry Rigid Contact Lenses, to achieve temporary correction of refractive error for mild and moderate myopia, through corneal molding during overnight use. The purpose is to flatten the corneal curvature, with the aim to reduce the corneal power. Current studies (1) indicate that the flattening is obtained by thinning the epithelium in central cornea and by thickening mid-periphery. Although the idea of thinning was suggested to be due to cell migration from center to peripheral cornea, it seems that molding is the consequence of cell compression with no epithelial cell layers loss (2-3). The effects on cell integrity and function by compression are still unknown. Another effect attributed to orthokeratology technique is to slow down axial eye elongation on myopic children (4), so it seems promising to be useful in control myopia progression.

This study compared the effects of two different models of reverse geometry Rigid Contact Lenses, CRT and DRL, in order to evaluate the performance and effectiveness on corneal molding.

## MATERIALS AND METHODS

### Lens desings


**Figure 1. Profile of Paragon CRT lens**

We perform the comparison of the two models of reverse geometry lenses on 12 eyes of 7 patients. CL models used were Corneal Refractive Therapy (CRT®) lens (Fig. 1) (Paragon Vision Sciences, AZ, USA) and Paunevision Double Tear Reservoir Lens (DRL®) (Fig. 2) (Paunevision, Barcelona, Spain), which characteristics are summarized in Tables 1 and 2, respectively.

| **Table 1. Characteristics of CRT lens** | |
|---|---|
| Design | Optic Zone, Return Zone Depth (RZD), Landing Zone (LZ) |
| Total Diameter | 9.50-12.00 mm. Standard 10.50 mm |
| Back Optic Zone Radius | 6.50 to 10.50 mm in 0.10 mm. |
| Optic Zone Diameter | 5.00 – 7.00. Standard 6.00 mm |
| Return Zone Depth | Standard 500 to 600 microns in 25 microns steeps |
| Landing Zone Radius | Infinite |
| Angle Landing Zone | From 25º to 50º, Standard from 30 to 35º, steps of 1º |
| Landing Zone width | 0.5 to 2.75 mm for a 10.50 mm diameter lens. |
| Edge thickness | 0.04 mm. |
| Power | +0.50 D. |
| Central Thickness | 0.15+-0.01 mm. |
| Material | Pafluocon D. |
| Dk | 100 (ISO) $10^{-11}$ ($cm^2$/seg)/(ml x mm Hg) |

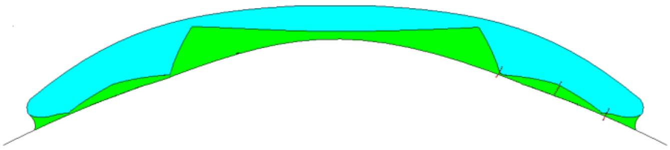

**Figure 2. Profile of DRL Paunevision lens**

| **Table 2. Characteristiques of DRL Lens** | |
|---|---|
| Design | Pentacurve; Optic Zone and Reverse curve (First reservoir), second alignment curve and third alignment curve (Second reservoir) and edge. |
| Total Diameter | 10.20 to 11.20 (Standard 10.80 mm.) |
| Back Optic Zone Radius | From 7.80 to 9.10 in 0.05 mm steps |
| Optic Zone Diameter | From 6.00 to 6.60 mm. |
| Power | From -25 to +25 in 0.25 D. Steps. Standart +1.00. |
| Central Thickness | 0.20 mm. |
| Material; | Hexafocon A |
| Dk | 100 (ISO) ) $10^{-11}$ ($cm^2$/seg)/(ml x mm Hg) |

## Participants

Before fitting the lenses, all subjects underwent a complete clinical examination (Table 3), including corneal topography to assess the participants eligibility according to study criteria. Subjects should have myopia between -0.75 and -3.75 D, astigmatism up to 1.00 D, corneas without pathology or alteration of the tear film and corneal eccentricities between 0.30 and 0.57.

| **Table 3. Clinic Test and exclusion pre-fitting parameters** | |
|---|---|
| Topography. | Regular shape of the cornea |
| | Values of keratometry between 7.20 mm to 8.40 mm. |
| | Eccentricity between 0.40 to 0.60 |
| Refraction | Myopia between -0.50 to -6.00 D. |
| Visual Acuity | 0.10 LogMar of better |
| Biomicroscopy | Any remarkable item |
| Pupil diameter in fotopic conditions | Less than 4 mm. |
| Tear quality and quantity | BUT more than 7 sec. |

The current limitations of these lenses used in this study are summarized in Table 4.

| **Table 4. Current Limits on CRT and DRL lenses for orthokeratology** | |
|---|---|
| CRT | Up to -6.00 D. of myopia and -1.75 D. of astigmatism |
| DRL | Up to -6.00 D. of myopia, -3.50 D. astigmatism and +3.00 in hyperopia. |

## Materials

For the measurements we utilized a Oculus Easy-Graph Topographer (Oculus, Postfach, Germany) Visual Acuity projector CPE60 (Essilor, Paris, France), the CSF was measured with a Topcon CC100 (Topcon, Tokio, Japan), the trial set of the two lenses, and the software for DRL calculation and a calculation table for CRT.

## Procedures

We compared the results achieved after one week of treatment with each type of lenses studied; CRT ® and DRL ®.

We fit the lenses in the eyes of the patients who submitted the characteristics of eligibility criteria. That means in some cases depending of the ametropia only one eye was fitted. Designs were tested on a sequential way, first CRT who was used for a week, then discontinued for a minimum washing out time of one week. Corneal topography was utilized to be sure that initial shape pre-adaptation was obtained.

To fit CRT we used eye parameters previously determined on clinical examination, and a first lens was chosen from the trial set using the system recommended from the manufacturer. Thereafter it was inserted into each eye of the patient under study. After 30 minutes wearing the lenses with eyes closed, to avoid the possible foreign body sensation. At this moment we evaluate for centration, movement, fluorescein and over correction, in order to meet the criteria of reverse geometry rigid gas permeable lens. When the fluorescein pattern was not correct a new lens was selected to obtain appropriate fitting. When everything was acceptable, the patient were instructed how to manipulate the CL.

After the initial fitting, the patient was instructed to wear the CL during a first night and was advised to return next morning without the lenses on the eye. Next we obtained data from one night wear. If everything was right, a one week appointment was given. If not, the lens was changed, repeating initial steps like fluorogram and refraction , waiting again one day without lens wear in order to return baseline, then do a new first overnight use. Measurement was repeated after one week of overnight wear, again in the morning without CL and the Contrast Sensitivity Function (CSF) was also determined.

| **Table 5. Clinical test after first overnight use** |
|---|
| Visual Acuity without lenses. |
| Refraction without lenses. |
| Topography and differential maps. |
| Biomicroscopy. |

As already noted, the patient was at least a week without CL until corneal topography and morphology returned to the parameters presented in the baseline. Then, according to the subject corneal parameters and with the specific software provided by the manufacturer, we proceeded to select the most appropriate DRL lens, from the trial set and inserted into each eye.

After waiting 30 minutes to washout foreign body sensation, centration, movement, refraction and a fluorogram were evaluated. If everything was correct, the patient was instructed how to manipulate the CL. If the lens did not meet the criteria the procedure was repeated until obtain an ideal fit.

At this point, the patient wore the lenses overnight and came back next morning after take out the lenses of your eyes when awakening. At that moment, we repeat the data collection shown in Table 5. Fluorescein parameters and topography (Figure 3) should be correct in order to scheduled next visit in one week. If not, we changed the lens, and returned to the initial steps with a new more suitable lens. When we got the right lens and after a week of use overnight, the patient returned for follow up, in the morning and without CL, and again the data shown in Table 5 were collected.

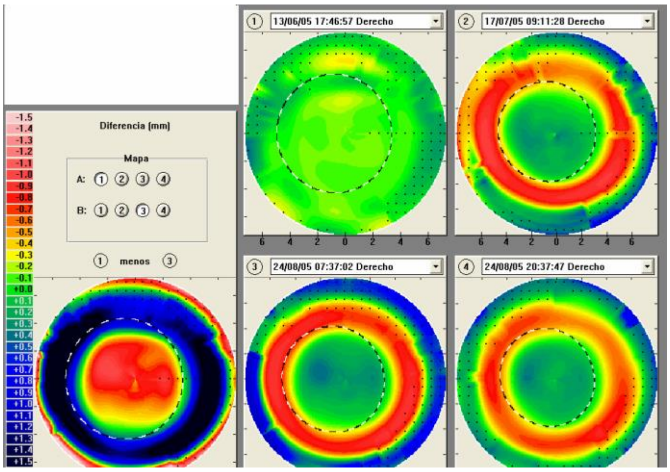


**Figure 3. Topography after one night, three nights and one week overnignt use. Bottom maps for the 7th day in the morning (left) and in the afternoon (right). On the left differential map from baseline to one week.**

Data collected from both two different designs are listed in Table 6.

| Table 6. Parameters evaluated after one week of treatment. | |
|---|---|
| 1 | Change in spherical refraction |
| 2 | Diameter of the treatment zone |
| 3 | De-centering of the Treatment Zone |
| 4 | Minimum spherical radius |
| 5 | Change in corneal eccentricity |
| 6 | Changes in Keratometric value |
| 7 | Change in keratometric astigmatism |
| 8 | Modification of peripheral astigmatism |
| 9 | Comfort |
| 10 | Changes on the Visual Acuity |
| 11 | CSF monocular and in fotopic conditions |
| 12 | Corneal irregularity from Fourrier analysis |

With its acquisition we valued:

1. The effectiveness and changes induced by each lens separately.

2. Comparison between results obtained with both lenses.

Statistical analysis was realized following a t-student test after validation of normal distribution of the sample, when a non normal distribution was encountered we applied the Wilcoxon test for a non-parametric distribution.

## RESULTS

In regard to the subjective feeling of comfort, all subjects unless one (who was indifferent) agreed that the DRL was more comfortable in eye open conditions, and with respect to the sensations with eye closed, all subjects (100%) indicated that both lenses feel equal.

The minimum radius of the spherical component of the cornea was obtained considering the decomposition of the zero-order wave of Fourier analysis (The equivalent to the arithmetic mean of each of the topographic rings). This value show no statistically significant differences between the lenses studied (Table 7).

| Table 7. Change of minimum radius of spherical component of Fourrier analysis | | | |
|---|---|---|---|
| | CRT (Mean ± SD) | DRL (Mean ± SD) | Statistical significance |
| Change after 1st night | 0.19±0.12 mm | 0.11±0.09 mm | p=0.052 |
| Change after 3 st night | 0.16±0.14 mm | 0.20±0.14 mm | p=0.259 |
| Change after one week | 0.26±0.15mm. | 0.39±0.29 mm | p=0.130 |

After analyze the changes in central Keratometric (K) radius, we only found a statistically significant difference between lenses after one week of treatment (Table 8 Figure 4).

| Table 8. Change in central K radius | | | |
|---|---|---|---|
| | CRT (Mean ± SD) | DRL (Mean ± SD) | Statistical significance |
| Change after 1st night | 0.11±0.07 mm | 0.14±0.07 mm | p=0.162 |
| Change after 3 st night | 0.15±0.05 mm | 0.17±0.09 mm | p=0.206 |
| Change after one week | 0.18±0.04 mm. | 0.26±0.07 mm | **p=0.010*** |

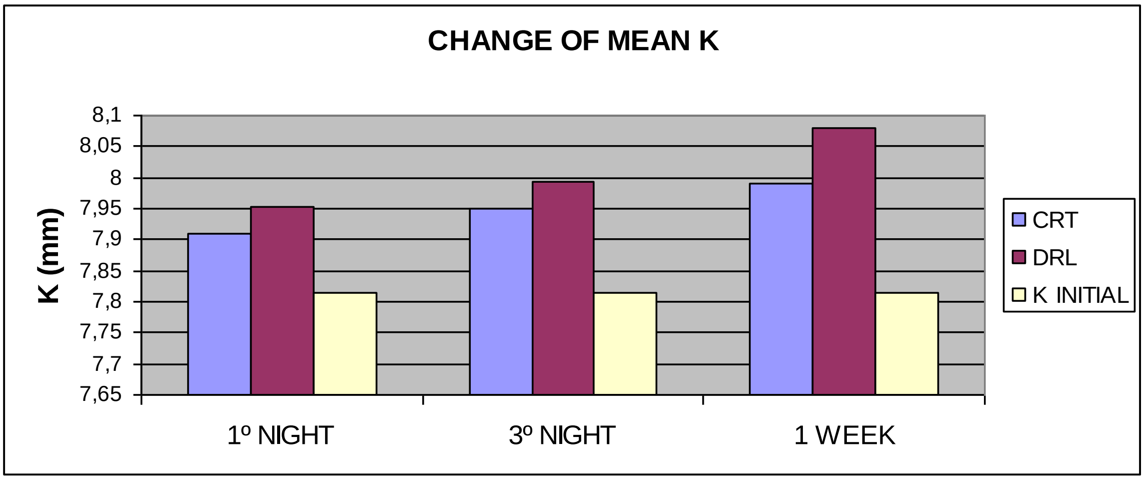


**Figure 4. Change of Mean Keratometry.**

DRL lenses showed a greater change mean effect in spherical component reduction in relation to the initial refraction, but there was a statistically significant difference between the two lenses after one week of use (p = 0.01) (Table 9 and Figure 5). We also compared in a graphical way the percentage of initial refraction corrected for a one, thee night and one week overnight use with both lenses tested. DRL lens shows a 109% of correction of the initial refraction in one week, being this significant with a p=0.031. This means that subjects remain slightly overcorrected, or hyperopes, after one week of treatment with DRL and under corrected (95% of correction of initial refraction) with CRT in the afternoon, following data collected.

| Table 9. Change in spherical equivalent | | | |
|---|---|---|---|
| | CRT (Mean ± SD) | DRL (Mean ± SD) | Statistical significance |
| Change after 1st night | 1.14±0.39 D. | 1.25±0.34 D. | p=0.234 |
| Change after 3 st night | 1.36±0.53 D. | 1.66±0.36 D. | p=0.071 |
| Change after one week | 1.68±0.51D. | 2.39±0.56 D. | **p=0.010*** |
| **In % respect initial Rx** | (% ± SD) | (% ± SD) | |
| Change after 1st night | 56 ±0.27 D. | 71 ± 0.35 D. | p=0.111 |
| Change after 3 st night | 77 ±0.35 D. | 90 ±0.34 D. | p=0.195 |
| Change after one week | 95 ±0.50D. | 109±0.22 D. | **p=0.031*** |

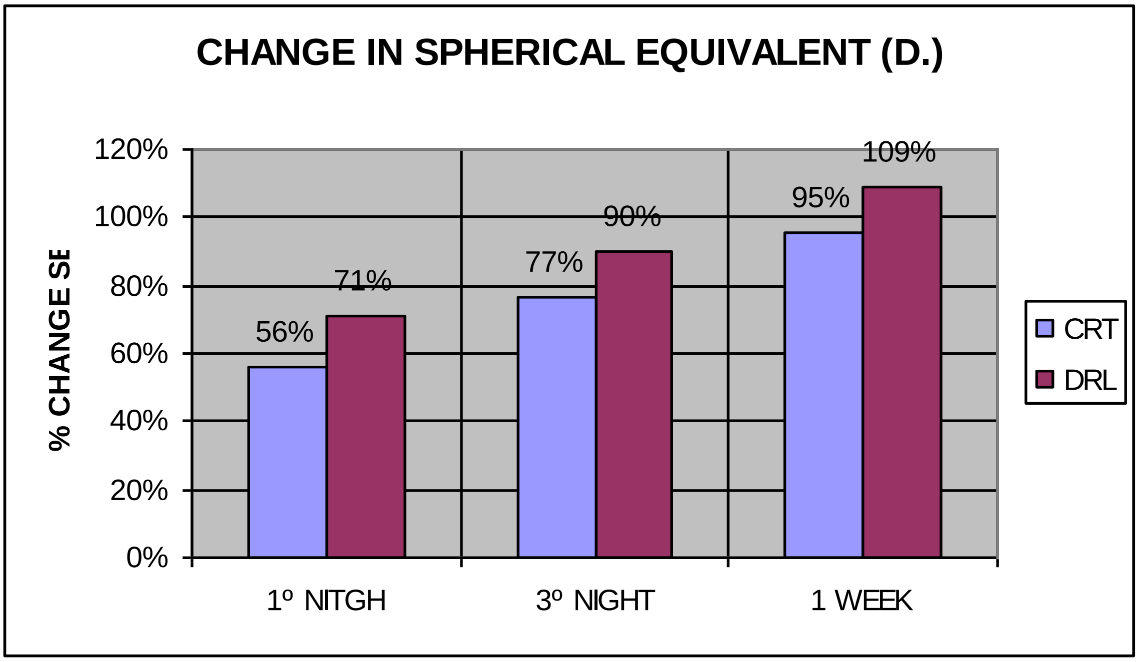


**Figure 5. Refractive error change after one, three and seven nights of overnight use. The percentage of change is related to the initial spherical equivalent.**

Eccentricity change showed a significant difference between lenses after the first night, but not longer. (Table 10) Nevertheless DRL lenses modified the corneal shape in a great way,

| Table 10. Change in eccentricity values | | | |
|---|---|---|---|
| | CRT (Mean ± SD) | DRL (Mean ± SD) | Statistical significance |
| Change after 1st night | 0.31±0.22 | 0.57±0.20 | **p=0.004*** |
| Change after 3 st night | 0.57±0.27 | 0.69±0.29 | p=0.161 |
| Change after one week | 0.82±0.27 | 1.03±0.19 | p=0.057 |

When we studied the improvement in Visual Acuity (VA) measured without optical devices, we found a significant difference between lenses, becoming higher and best VA with DRL after the 3rd night and after 1 week of use (Table 11 and Figure 6).

| Table 11. Change in visual acuity without correction (Senellen unities) | | | |
|---|---|---|---|
| | CRT (Mean ± SD) | DRL (Mean ± SD) | Statistical significance |
| Change after 1st night | 0.50±0.18 | 0.52±0.23 | p=0.403 |
| Change after 3th night | 0.62±0.24 | 0.82±0.30 | **p=0.045*** |
| Change after one week | 0.62±0.39 | 0.97±0.15 | **p=0.028*** |

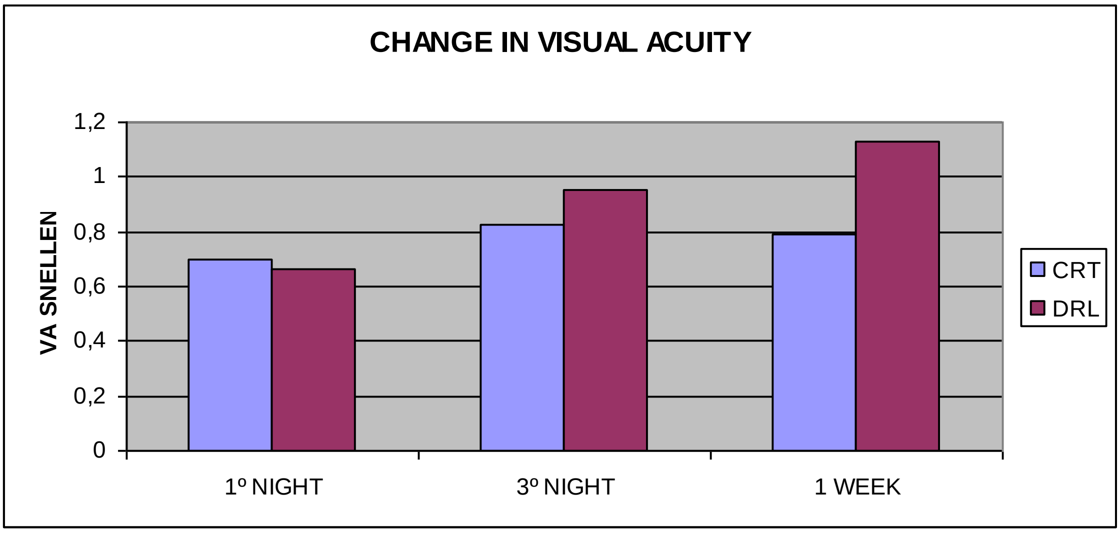


**Figure 6. Evolution of the Visual Acuity along the treatment time.**

Treatment Zone Diameter shows no difference between both lenses; DRL and CRT. (Table 12)

| **Table 12. Change of the optic zone diameter** | | | |
|---|---|---|---|
| | CRT (Mean ± SD) | DRL (Mean ± SD) | Statistical significance |
| Change after 1st night | 3.71±0.40 mm | 3.98±0.40 mm | p=0.059 |
| Change after 3 st night | 3.63±0.56 mm | 3.89±0.40 mm | p=0.114 |
| Change after one week | 3.77±0.26mm. | 4.02±0.54 mm | p=0.098 |

In the analysis of the treatment zone of the decentretion, measured on the differential refractive map, the DRL lens de-centered less than CRT, although we didn't found a statistical differences (Table 13).

| **Table 13. Variation of topographic de-centering on the refractive map in mm.** | | | | | | |
|---|---|---|---|---|---|---|
| | **3º Night** | | | **1 week** | | |
| | CRT | DRL | p | CRT | DRL | p |
| Nasal | 0.18±0.40 | 0.14±0.45 | 0.403 | 0.37±0.69 | 0.07±0.15 | 0.150 |
| Temporal | 0.30±0.43 | 0.30±0.44 | 0.500 | 0.26±0.38 | 0.20±0.42 | 0.387 |
| Superior | 0.00±0.00 | 0.05±0.15 | 0.170 | 0.00±0.00 | 0.00±0.00 | - |
| Inferior | 0.27±0.46 | 0.35±0.53 | 0.368 | 0.40±0.72 | 0.10±0.32 | 0.166 |

Studying the decentration index (in mm.), which indicates the maximum and the minimum of the first order of the Fourier wave and their orientation, although this was not being evaluated. No differences were found among the results obtained using both lenses (table 14).

| **Table 14. Change of the decentering index** | | | |
|---|---|---|---|
| | CRT (Mean ± SD) | DRL (Mean ± SD) | Statistical significance |
| Change after 1st night | 0.40±0.40 mm | 0.32±0.28 mm | p=0.295 |
| Change after 3 st night | 0.31±0.45 mm | 0.36±0.38 mm | p=0.383 |
| Change after one week | 0.62±0.59 mm. | 0.50±0.53 mm | p=0.325 |

## DISCUSION

One factor valued was the comfort, that is, the less feeling of foreign body sensation in open and closed eye. This was a totally subjective question, but the results of the questionnaires showed that subjects feel more comfortable in open eye conditions the DRL lenses, this could be attributed to the design, even when the thickness of the DRL is 33% higher than the CRT (0.20 mm DRL vs. 0.15 mm CRT). Therefore, the fact that DRL lenses have more curves (which is a double reservoir tear) could allow a better coupling to corneal shape and provide greater tolerance adaptation. In closed eye situation, as we have said, there were no differences.

In relation to the molding effect, the greatest dioptric reduction associated to the highest variation of central K changes correlates with the best improvement in Visual Acuity obtained with the design of Double Reservoir Lens (DRL) . This could be attributed DRL ® lenses are fitted after a calculation on the manufacturer software that in general provides a more mathematical accurate fit. This, in association to the existence of a second tear reservoir who generate higher suction forces could account to achieve faster and higher refractive results. Therefore, these lenses seem to work best when they are fitted slightly steeper. In similar comparative studies (5) did by Paune (Paune et al., 2004) authors comment that DRL lenses, by this design, may allow a better redistribution of corneal epithelium and provide greater alignment tolerance when it becomes something tight fit. Thus, this could allow to a shortened treatment time. Probably, in consequence of the results, DRL could theoretically to achieve a further reduction of myopia than current lenses, due suction forces generated in the two reservoirs.

In the study had done by Garcia-Monlleó et co-workers (6) (Garcia-Monlleó et al., 2008) authors shown that CRT lenses produced greater corneal molding after the first night. This molding was evidenced by a sudden change of the cornea from prolate to oblate, but in the next following controls (4 nights, one week and one month) they found no significant differences among lenses. In the present study we only found significant differences after one week, where DRL lenses generate greater molding effect. During the first night the results are similar among lenses and there is no significant difference. This discrepancy between both studies could be due to the method that is in contrast to us, they fitted only one lens per eye, so both eyes could have a different amount of myopia or different response to the molding. Also, because they fitted right eye with a CRT lens, which allows giving directly a lens with all myopia correction targets and on the other eye they fitted a trial set DRL lens, which has a constant -2.00 D target. The final correction amount results should be different.

Although both types of lenses were similar as a treatment area, CRT lenses de-centered a little bit more than DRL, despite a non statistically significant difference, which could be attributed to sample size. Daily de-centering is mainly vertical, while the topographies showed that after overnight use it is mainly horizontal, that could be explained because at night there is no interaction of the gravity or eyelids forces which could move the lens upward or downward. Total de-centering of a lens appears to affect about 50% to the treatment zone, the mean values of de-centering of one and the other lenses lay between 0.3 and 0.6 mm respectively.

Treatment zone diameter (TZD) is similar in both lenses and also do not suffer a large increase in at least one week. Stands around 3.80 mm, and it is probably related to the amount of myopia was corrected, but this association was not valued. Although this also depends on the map used for measurement, for example, when TZD it is measured in an axial map, values are higher than tangential maps used in this study. In fact the area of central vision corresponds to the area where there is a modification of the initial curvature. From the clinical point of view it appears that the diameter of this zone is related to the amount of diopters treated, wit a tendency to expand or reduce relative to the difference between the value K and the radius of the lens fitted. This study did not take account the correlation between both values.

DRL lenses significantly decreased the rate of eccentricity after the first night ($p = 0.04$), giving to similar results in this index for both lenses after one week time. Sagital corneal eccentricity did not differ, although the DRL averages are higher. In the study by Garcia-Monlleó (6) (Garcia-Monlleó et al., 2008) they concludes that DRL lenses produced a decrease in the eccentricity, slow and gradual, but reaching higher values than CRT lenses, finding after ten nights of treatment statistically significant differences between them ($p = 0.031$).

The minimum radius of the spherical component of the cornea, taken from the decomposition of the zero-order wave of Fourier (equivalent to the arithmetic average of each of the topographic rings) shows no statistically significant differences between lenses. And yet, the study of Garcia-Monlleo (6) (Garcia-Monlleó et al., 2008) states: The spherical aberration measured before treatment in both eyes, increases in a statistically significant way, being somewhat greater with the DRL lens than the CRT, which does not adversely affect visual acuity. Comparing the increase in spherical aberration with both lenses at the end of the study, we found no statistically significant differences. The results obtained by Villa (7) (Villa C. et al, 2005) in a study of the CRT lenses coincide with the present study in that orthokeratology treatment increase spherical aberration.

As for the effect on increasing the uncorrected VA, we found significant differences between both lenses, being higher in DRL after the third night ($p = 0.045$) and after 1 week ($p = 0.028$). But in the study by Garcia- Monlleó (6) (Garcia-Monlleó et al., 2008) they found the VA monocular obtained at the end of treatment similar for both lenses. This could be due to the same reasons of the design of the above mentioned study.

CONCLUSIONS

In the same of time of overnight use, DRL lenses achieved greater refractive correction. This was significant only after one week of treatment. Central keratometric variation, change of the spherical part of refractive error, and eccentricity modification was higher with DRL lenses. This relates to a faster improvement on Snellen Visual Acuity, who showed differences among both lenses after a third night and one week of use.

Spherical aberration increased with time with both lenses, but do not seem to affect visual acuity.

DRL provides great comfort in open eye conditions, probably due to the special design of the lens and the second tear reservoir, which induces less motion, and a lower edge lift.

In all the 12 eyes studied, only one in the case of CRT and four in the case of DRL have obtained the "final lens" with the theoretical calculation proposed by the manufacturer. Therefore is necessary a fluorescein subjective evaluation made by the well trained professional to obtain a better fitting at the beginning.

Both treatments increased higher order ocular aberrations (ie Coma-like and Spherical), which could decrease contrast sensitivity in mesopic and scotopic conditions and create halos. In our results this increase in aberrations, specially coma was clinically more pronounced with CRT lenses, although the results was not statistically significant.

Finally the outcome in orthokeratology probably depends on the baseline characteristics of the cornea and the amount of refractive error that will be treated. But predictability, efficiency and stability depends on the characteristics of the design of the lens used and the compliance of the patient. It seems DRL lenses could accomplish this in a more precise way.

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