Effect of Central Hole Location of Phakic Intraocular Lens on Visual Function under Progressive Headlight Glare Sources.

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Running head: Effect of phakic IOL decentering under headlight glare sources.

ABSTRACT

Purpose: To analyze the effect of central hole (CH) location of implantable collamer lens (ICL) on the quality of vision, including progressive headlight glare simulation, and quality of life (QoL).

Setting: IOBA-Eye Institute, Valladolid, Spain.

Design: Interventional case series.

Methods: CH location of 30 patients implanted with V4c-ICL for >6 months was determined by slit-lamp and dual Scheimpflug imaging. Visual acuity (VA), mesopic contrast sensitivity (CS), halogen glare CS, xenon glare CS, photostress recovery time after glare, de Boer scale and quality of life impact of refractive correction (QIRC) questionnaire were evaluated. Multiple regressions models were used to analyze the effect of the CH location on the parameters evaluated, using pupil center reference (PCR) and visual axis reference (VAR) systems based on both Cartesian and Polar coordinates.

Results: Safety and efficacy index were 1.13 and 1.12, respectively. Under all circumstances, VA and CS were not affected by CH decentration. Using VAR, worse QIRC values were associated with greater upward CH displacement (p=0.03) and less polar angle (p=0.008); also, greater halogen glare discomfort with higher radius (p=0.04). Using PCR, longer xenon glare photostress recovery time was associated with more nasal CH decentration (p=0.002).

Conclusions: CH-ICL patients show excellent visual performance, even under increasing glare sources, regardless of CH location. However, CH decentration may have an influence on perceived QoL, discomfort halogen glare and xenon glare photostress recovery time. Such complaints after the early postoperative period

might be managed with discrete ICL centration if the CH is decentered upward or nasally.

INTRODUCTION

The Visian Implantable Collamer Lens (ICL™, STAAR Surgical) is a posterior chamber phakic intraocular lens, which has already demonstrated its safety, predictability and efficacy.[1-4] The ICL implantation has become a common recommendation in patients who may not be appropriate candidates for corneal refractive surgery procedures.

ICL design has been continuously upgraded in order to improve the clinical outcomes and reduce the incidence of complications, mainly lens opacities and pupillary blocks.[5,6] Specifically, the ICL V4c model has a central hole (CH) that allows more natural aqueous humor circulation. As a result, its implantation does not require a peripheral YAG iridotomy or surgical iridectomy and therefore, related complications are eliminated.[7]

To date, previous studies have demonstrated that the presence of the CH does not affect visual acuity (VA) nor CS. [8,9] However, some studies have observed a relationship between the presence of the CH and a photopic phenomenon, such as ring-shaped dysphotopsia.[10,11] These findings suggest that the presence of the CH may affect negatively quality of vision. Thus, potentially quality of life (QoL) might be also affected under specific conditions, such as a scenario of oncoming car headlights when driving. Nonetheless, the abovementioned studies did not take into account the exact location of the CH in the ICL patients.[8-10]

To our knowledge, only two studies have analyzed the effect of the location of the CH in some clinical and visual parameters.[12,13] However, these studies did not analyze the exact ICL decentration regarding Cartesian or Polar coordinates system, nor evaluated the influence of glare sources that may play a key role in developing vision disturbances when driving. Likewise, they did not assess the quality of vision and the related quality of life from patient's perspective.

Consequently, the aim of the present study was to analyze the effect of the exact CH location of the ICL V4c in real ICL patients with respect to the pupil center and visual axis (based on angle kappa) on the quality of vision, including progressive headlight glare simulation under low mesopic conditions, as well as on the quality of life.

METHODS

This pilot interventional case series study was prospectively approved by the University Clinic Hospital Ethics Committee (Valladolid, Spain). The study was conducted in compliance with the tenets of the Declaration of Helsinki and written informed consent was obtained from all subjects.

Sample

This study included 30 far distance dominant eyes of 30 patients who underwent a myopic posterior chamber ICL V4c implantation. The ICL V4c power and size were determined according to the manufacturer's recommendation using the STAAR Company online calculator. The ICL was selected in order to achieve emmetropia and all implantations were performed by the same experienced surgeon (M.J.M.).

Inclusion criteria were patients with an age ≥ 21 years, at least 6 months since ICL surgery and a postoperative manifest spherical equivalent ranging from +0.50 D to -0.50 D. Additionally, exclusion criteria included cataract, glaucoma, retinal anomalies, amblyopia, macular diseases, or history of previous ocular surgery different from ICL implantation.

All tests were performed in both eyes. Outcomes from the dominant eye for distance was selected for statistical purposes, because it tends to have priority in visual processing.[14] The ocular dominance was detected by three successive consisting trials using the hole-in-card test.[14]

Parameters evaluated

All patients had a complete ophthalmologic examination. The evaluation included assessment of intraocular pressure[15] (ORA; Reichert Ophthalmic Instruments, Depew), objective central vault[16] - defined as the narrowest perpendicular distance between the lens and the anterior capsule crystalline- (OCT; Topcon 3D-2000, Topcon Corp.[17]), pupil diameter (Wavelight Topolyzer Vario, Alcon Laboratories, Inc.) and visual acuity (Early Treatment Diabetic Retinopathy Study chart, Lighthouse). Safety and efficacy indexes were also calculated.

Central hole location

The CH location of the ICL V4c model was monocularly determined with respect to the visual axis of each eye. The contralateral eye was always occluded during the measurement procedure. This measurement was taken following three steps.

First, the location of the center of the CH with respect to the pupil center was determined using slit-lamp biomicroscopy (Topcon, SL-8Z, Topcon Corp.) as follows. The patient was asked to open the eye and to look straight ahead. A photograph was taken with a 25x magnification under the illumination of a 5-mm width parallelepiped. The X and Y coordinates corresponding to the location of the center of the CH with respect to the pupil center, were measured in pixels using the caliper tool of the Topcon IMAGEnet i-base software (version 3.17, Topcon Corp.), and later converted into mm.[18] In this study, regardless of the eye evaluated, nasal side displacement of the CH along the X axis was considered a positive value, while temporal side displacement was considered a negative value.

Second, the location of the visual axis with respect to the pupil center (i.e., angle Kappa) was determined using dual Scheimpflug technology (Galilei G4, Ziemer Ophthalmic Systems AG). This device provides the abovementioned distance in Cartesian coordinates (X, Y) in mm. In addition, total corneal higher order aberrations (HOAs) were also obtained from this device for a 6-mm pupil.

Finally, to calculate the real displacement (in mm) of the CH location with respect to the pupil center or visual axis, values corresponding to X and Y coordinates that were obtained with the dual Scheimpflug device were subtracted from those obtained with the slit-lamp biomicroscopy procedure (Figure 1). Additionally, the CH location was determined using Polar coordinates too. In this case, the pupil center as reference system, the radius (r1 in figure 1B) was the total distance between the location of the pupil center (P in figure 1), and the center of the CH (H in figure 1) (by applying the Pythagorean theorem to the X and Y coordinates). In case of the visual axis as reference system, the radius (r3 in figure 1C) was the total distance between the location of the visual axis (V in figure 1) and the center of the CH. The polar angle in case of the pupil center system, was defined as the angle (p1 in figure 1B) between CH and pupil center, taking into account that X and Y values for visual axis were zero (i.e. the pole) (Figure 1B). While for the visual axis system, it was defined as the angle (p3 in figure 1C) between CH and visual axis, likewise X and Y values for pupil center axis were zero (Figure 1C).

Progressive Headlight Glare Simulator

The mesopic CS was assessed with a progressive headlight glare simulation system (IOBA Halogen-Xenon Mesopic Contrast Sensitivity Test). This simulation system consists of a room having no windows and walls covered with anti-glare paper. A Pelli Robson test located 1-meter distance from the seat patient, a focal light located 0.2-meter behind the patient seat and 2-meters height pointing ahead (to reproduce the ambient light produced by the driver's car headlamps reflecting on the road), and a headlamp programmed to produce the intensity of either a Halogen or Xenon car headlamp, situated aside the Pelli-Robson chart (Precision Vision), at 1.11-meter height. The light intensity of the headlamp situated next to the Pelli Robson chart was programmed to simulate dynamic nature of an oncoming car's headlight glare, as experienced during nighttime driving.

The center of the Pelli Robson chart was situated at 1.11-meter height to simulate the average driver eyes height while driving.[19] It was illuminated by a focal light simulating the illumination of a European UMTRI-50 (University of Michigan Transportation Research Institute-50) car light while driving at night.[20] CS measurements were performed after ten minutes of dark adaptation.[21] Mesopic CS was measured under this illuminance condition. Then, to simulate the headlights of oncoming cars, patients were submitted to five seconds of progressively increasing intensity using the halogen and xenon algorithms. This illumination algorithm reproduces the scenario of an oncoming vehicle approaching from 100 to 40 meters. CS was recorded during both situations: halogen glare CS and xenon glare CS. Finally, subjective glare bother caused by halogen and xenon lights was assessed using the de Boer rating scale, which ranges from 1 (unbearable) to 9 (unnoticeable) points.[22]

Quality of life

The QoL was quantified using the *Quality of life Impact of Refractive Correction* (QIRC) questionnaire. The QIRC was developed and validated to assess the QoL of people with a refraction correction, including those patients undergoing refractive surgery.[23] This questionnaire consists of 20 items and the responses were automatically converted into a Rasch-weighted QIRC score on a 0 to 100 scale. The higher the score, the higher the QoL of the patient is.[23]

Statistical analysis

Data analysis was carried out by a professional statistician (I.F.). The mean and standard deviation (SD) were calculated for normally distributed data. When data did not correspond to a normal distribution, the median and interquartile range (IQR, values between the 25th and 75th percentiles of the distribution) were used. Preoperative versus postoperative comparisons of normally distributed data were performed using the paired Student's t-test. Comparisons among postoperative CS variables (mesopic, halogen glare and xenon glare CS) were performed using the Friedman test and paired analysis using the Wilcoxon test with the Bonferroni correction. The possible association between corneal total HOAs and CH location or QIRC values was assessed using Pearson correlation coefficient. The effect of the CH location on the quantitative variables (VA, photostress recovery time, de Boer scale rating and QIRC questionnaire) was analyzed using multiple linear regression models considering the Cartesian coordinates (X, Y) or Polar coordinates (radius, polar angle) and postoperative time as independent variables. Regarding CS variables (mesopic, halogen glare and xenon glare CS), due to the low frequencies observed, they were transformed into dichotomous data and analyzed using logistic regression models. The mesopic CS values were grouped into ≤1.05 and >1.05 log units, halogen glare CS values into ≤0.75 and >0.75 log units and xenon glare CS values into ≤0.75 and >0.75 log units. Thus, odds-ratio (OR) coefficients were obtained to estimate the likelihood of achieving higher CS values. Finally, the pupil diameter was also included in the models in order to investigate whether pupillary aperture could affect the study parameters. Residual analysis was performed to check the assumptions of the regression models. Variance inflation factor was used to verify lack of multicollinearity. Two-sided P values ≤0.05 were considered statistically significant.

RESULTS

Study population

A total of 30 patients (22 females and 8 males) with a mean age of 32.4 ± 5.8 years and an average postoperative period of 19.9 ± 13.3 months (range, 6 to 46 months) were recruited. The mean preoperative and postoperative manifest spherical equivalent was -7.06 ± 4.04 D and 0.00 ± 0.20 D, respectively. The mean preoperative and postoperative corrected distance VA was -0.04 ± 0.05 and -0.09 ± 0.07 logMAR, respectively. The mean postoperative uncorrected distance VA was -0.08 ± 0.07. The safety index was 1.13 and the efficacy index was 1.12. The mean preoperative and postoperative IOPg was 15.5 ± 3.3 mm Hg and 15.1 ± 2.2, respectively. No statistically significant differences in mean IOPg were detected (p=0.52). The mean ICL vault was 428.1 ± 234.1 µm. The mean postoperative pupil diameter was 5.2 ± 1.0 mm. We did not find any association between total corneal

HOAs and CH location (Cartesian and Polar coordinates, Table S1) or QIRC values (r=0.20; p=0.35). Similarly, we did not find any influence pupil diameter or postoperative time for any models and any variables studied.

The mean decentration values of the CH location related to the pupil center (Figure 2A) were the following. The mean X coordinate value was -0.24 ± 0.14 mm, the mean Y coordinate value was 0.11± 0.22 mm, the mean *radius* was 0.34 ± 0.13 mm and the mean *polar angle* was 154.37 ± 43.7 degrees. The mean decentration values of the CH location related to the visual axis (Figure 2B) were the following. The mean X coordinate value was -0.33 ± 0.17 mm, the mean Y coordinate value was 0.21 ± 0.25 mm, the mean *radius* was 0.47 ± 0.14 mm and the mean *polar angle* was 151.55 ± 38.51 degrees.

Effect of CH Location on Visual Acuity

The ICL CH location related to both, pupil center and visual axis, showed no significant (p≥0.22) effect on the uncorrected distance VA using Cartesian and Polar coordinates (Table S2, S3 and S4. Supplemental Material).

Effect of CH Location on Progressive Headlight Glare Simulation

Contrast sensitivity measures.

The median mesopic, halogen glare and xenon glare CS values were 1.05 (IQR, 1.05 to 1.20), 1.05 (IQR, 0.75 to 1.05) and 0.75 (IQR, 0.75 to 1.05) log units, respectively. These values were significantly different among them (p<0.001). Mesopic CS was significantly higher than both halogen CS (p<0.001) and xenon CS (p<0.001), and halogen CS was also higher than xenon CS (p=0.004).

The effect of the CH location, with respect to the pupil center and visual axis, on the CS variables analyzed using the Cartesian and Polar coordinates as reference systems, is shown in tables S2 to S7 (Supplemental Material).

Contrast sensitivity photostress recovery time after glare.

Mean CS photostress recovery time after halogen and xenon glare were 1.44 ± 1.52 s (95% CI: 0.87, 2.01) and 2.27 ± 1.80 s (95% CI: 1.60, 2.95), respectively. The difference between both CS photostress recovery times were significant ($p=0.02$). The regression models using pupil center as a reference system to locate the ICL CH by means of Cartesian and Polar coordinates, showed no significance ($p \geq 0.56$) effect on CS photostress recovery time after halogen glare. Likewise, lack of significance ($p \geq 0.60$) was also observed for CS recovery time after xenon glare locating the ICL CH using Cartesian and Polar coordinates and the visual axis as the reference system (Table S2, S3 and S4. Supplemental Material). However, we found a significant ($p=0.01$) effect of xenon glare on CS photostress recovery time using Cartesian coordinates and the pupil center as reference system (Table S2. Supplemental Material). Specifically, there were a significant effect of the X coordinate value on CS photostress recovery time after xenon glare ($\beta=7.17$, 95% CI: 2.89, 11.44; $p=0.002$).

De Boer scale (Subjective bothersome).

Mean de Boer rating scale indicated more discomfort ($p<0.001$) for xenon glare (4.83 ± 2.02 units [95% CI: 4.08, 5.59]) than for halogen glare (6.53 ± 2.27 [95% CI: 5.69, 7.38]). The regression models performed using pupil center and visual axis as reference systems to locate the ICL CH by means of Cartesian or Polar coordinates showed no significant interaction on de Boer scale for halogen ($p \geq 0.16$) and xenon

($p \geq 0.62$) glare (Table S2 and S3. Supplemental Material). However, specifically, we found a significant effect of the *radius* distance on de Boer halogen scale when using Polar coordinates as reference system (β= -6.66, 95% CI: -12.91, -0.41; p=0.04).

Effect of CH Location on Quality of Life (QIRC questionnaire)

The mean QIRC was 51.59 ± 5.88 points. The regression models performed using Cartesian and Polar coordinates and the pupil center as the reference system to locate ICL CH showed no significant ($p>0.36$) effect on QIRC questionnaire values. Nevertheless, using Cartesian coordinates and the visual axis as reference system, we found a significant (β=-9.34, 95% CI: -17.80, -0.88; p=0.03) effect of the Y coordinate of the CH location on QIRC questionnaire outcomes. Regarding the use of Polar coordinates to locate the ICL CH (Table S3. Supplemental Material), the regression model showed a significant (p=0.04) effect on QoL. Specifically, we found a significant effect of the *polar angle* on QIRC score (β=0.08, 95% CI: 0.02, -0.14; p=0.008).

DISCUSSION

The present study aimed to assess the influence of the precise CH location of the ICL (V4c model) on the quality of vision and life for the first time to the best of our knowledge. We observed that a higher CH location (positive Y values) in the vertical axis as well as a lower *polar angle* (upward decentration of ICL CH) using visual axis as a reference system, was related to QoL worsening as measured with the QIRC questionnaire. Likewise, when patients subjectively evaluated light bothersome after halogen glare, we found that the longer the *radius* (magnitude of ICL CH decentration), the higher the bothersome. Additionally, time to recover initial CS after xenon glare was longer when ICL CH decentration was higher (positive values) in the X axis, using pupil center as a reference system.

Previous authors have reported that the location of the CH does not affect the VA, as we also observed. Park et al.[13] considered 3 different groups according to the degree of decentration showed by the ICL patients: within one, two or three hole-diameters from the pupil center. And they did not find significant variations among groups. In addition, Perez-Vives et al.[12] performed an experimental study using a visual simulator, and they did not find either any effect on the VA considering three predetermined hole locations (centered, decentered 0.3 mm and decentered 0.6 mm). Therefore, the CH location of the ICL, appears not to be an important factor affecting VA.

Other authors have also tried to analyze the effect of the CH on the CS.[9,24] Shimizu et al.[9] did not find an effect of the ICL hole under mesopic CS in ICL patients, however, they did not take into account the exact CH location as we did. We think that we provide robust evidence regarding this issue, because we evaluated real ICL patients under a simulation of common progressive glare sources encountered during nighttime driving, and considering the exact CH decentration in each case.

Mesopic CS under glare conditions has been previously studied in V4c ICL patients. Shimizu K. et al.[9] compared both ICL models (V4 vs V4c), and they concluded that the presence of the CH does not affect static mesopic CS. In the present study, we have evaluated CS under progressive halogen and xenon intensity glare sources (similar to oncoming car headlamps), as well as photostress recovery time after glare, and bothersome during a simulated night driving condition. We found that progressive halogen and xenon glare sources further decreased CS values in comparison with mesopic conditions without glare. Besides, we observed that the halogen glare source did not reduce CS as much as xenon glare source did. In addition, halogen-type glare allowed shorter photostress recovery time, and it was less bothersome than xenon-type glare. Our results can be explained by the fact that xenon illumination, compared with halogen one, is more intense, which makes driving more difficult during night conditions,[25] a finding typically reported by night drivers.

Our outcomes showed no relationship between CH location and CS after halogen and xenon glare. Some authors have previously described a dysphotopsia phenomenon for the ICL V4c model.[10,11] It has been observed during an experimental study[10] that the ICL hole produces an arc and ring images caused by light refraction from the inner surface of the CH. And, this ring-shaped dysphotopsia is possibly related to the merging of arc images caused by obliquely incident light. Moreover, the radiant power of stray light is higher with increasing angle of incidence of the incoming light rays.[11] Therefore, this phenomenon might play an important role in glare scenarios. However, in our clinical study, when we located the light source left to the CS chart simulating oncoming car headlights (oblique angle related to visual axis), no negative effect was observed on CS values. Thus, our results suggested that this dysphotopsia phenomenon has no major clinical influence in terms of CS values observed after halogen- and xenon-type glare, regardless of the CH location.

Our QIRC results (51.59 ± 5.88 points) were quite similar to those previously reported by Ieong et al.[26] in no-hole ICL patients reaching a mean score of 53.79 ±

5.60 points. However, our study patients showed lower QoL values associated to upward CH decentration along the vertical axis, and to lower *polar angles* with respect to the visual axis. Consequently, based on our subjective (QIRC) outcomes, in cases when a patient implanted with an ICL V4c model continues to complain in the long term, he or she may benefit from displacing the ICL slightly towards a lower vertical position in relation to the visual axis.

In our study, we found a significant relationship between total CH decentration (*radius*) and de Boer scale values after halogen glare using the visual axis as the reference system (the higher *radius,* the higher patient bothersome). This finding was not observed when the pupil center was used as the reference system. This difference in the study results may be attributed to the different CH decentration values recorded for both reference systems (pupil center and visual axis). The distance from the CH to the visual axis is higher than the distance from the CH to the pupil center. Besides, higher CH decentration in X coordinate is related to a longer photostress recovery time after xenon glare considering the pupil center as a reference system. However, the later finding was not observed when using the visual axis as a reference system. These outcomes emphasize the importance of selecting a proper reference system considering that both systems (pupil center and visual axis) are not interchangeable.

The main limitation of the present study is that our outcomes are related to our sample population, which means that they depend on the CH decentration values observed in our ICL patients. And the magnitude of ICL decentration found in our patients was not extremely large, as might be expected in habitual clinical settings. Thus, future studies including ICL patients with larger decentration values and longer follow-up times are required. Another limitation is that the CS was assessed binocularly taking into account that driving is a binocular activity, however, the CH location was determined monocularly. To minimize this limitation, the dominant eye for distance was selected for determining the CH location.[14,27]

In conclusion, the present study further support that CH ICL provides an excellent efficacy and safety profile, and that vision should not be affected by CH location under mesopic conditions without glare sources. Additionally, we have also proven for the first time that the CH location should not affect CS in ICL patients when being exposed to progressive halogen and xenon glare sources under mesopic conditions, as commonly occurs during nighttime driving. However, we also demonstrated that CH location in the far distance dominant eye matters. Because upward decentration can associate perceived QoL worsening, and longer *radius* (magnitude of CH decentration) can be related to higher halogen glare discomfort. Moreover, higher CH decentration in the X axis is likely to result in higher photostress recovery time after xenon glare. While experience tells that most visual complaints are frequent and transient in the early postoperative period,[28] ophthalmologists must be aware of these outcomes. And consequently, in case a patient continues to report such visual complaints in the medium or long-term, they might be managed with discrete IOL centration if the CH is decentered upward or nasally, particularly in the far distance dominant eye.

WHAT WAS KNOWN

- Implantation of posterior phakic intraocular lens having a central hole is a safety, predictable and efficacy option to correct moderate to high myopia in patients who are not suitable for corneal refractive surgeries.
- The presence of the central hole in the posterior phakic IOL does not affect the visual acuity nor contrast sensitivity, however, experimental settings have showed that ring-shaped dysphotopsia may be originated by light reflections from the lens surface.

WHAT THIS PAPER ADDS

- The central hole location of the posterior phakic IOL does not affect the visual acuity nor contrast sensitivity with and without dynamic headlights glare sources. However, a decentered location can produce a worsening in quality of life, photostress recovery time and bothersome after glare.
- Surgeons are recommended not to displace the posterior phakic IOL upward or nasally, in the case that exact centered positioning is not possible.

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FIGURE LEGENDS

Figure 1. Anterior segment image showing an implantable collamer lens (V4c model) with a central hole (A), and the schematic representation of the methodology followed to determine the ICL central hole location with respect to the pupil center (B) and visual axis (C). H: center of the ICL central hole. V: visual axis. P: pupil center. X_1: horizontal distance between pupil center and ICL central hole (Slit-lamp image based). $Y_{1:}$ vertical distance between pupil center and ICL central hole (Slit-lamp image based). r_1: *radius* distance between pupil center and ICL central hole. p_1: *polar* angle between pupil center an ICL central hole. X_2: horizontal distance between visual axis and pupil center. $Y_{2:}$ vertical distance between visual axis and pupil center. X_3: horizontal distance between visual axis and ICL central hole (Dual Scheimpflug based). $Y_{3:}$ vertical distance between visual axis and ICL central hole (Dual Scheimpflug based). r_3: *radius* distance between visual axis and ICL central hole. p_3: *polar* angle between visual axis an ICL central hole.

Figure 2. Scatter-plot of the central hole location (mm) in relation to the pupil center (A) and visual axis (B) for each implantable collamer lens (ICL) patient evaluated.

Figure 1

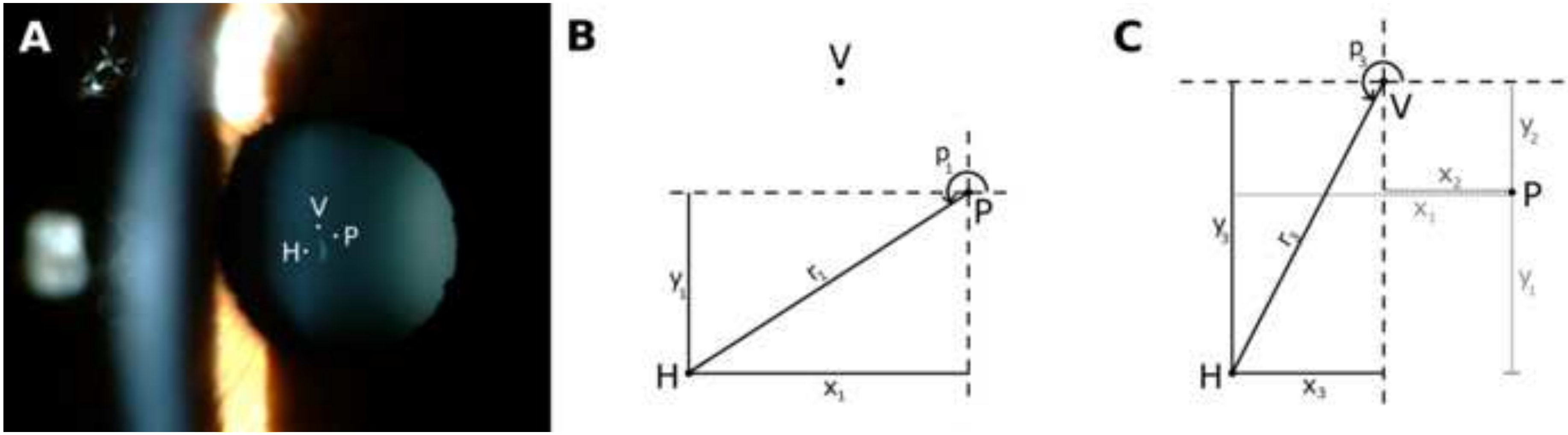
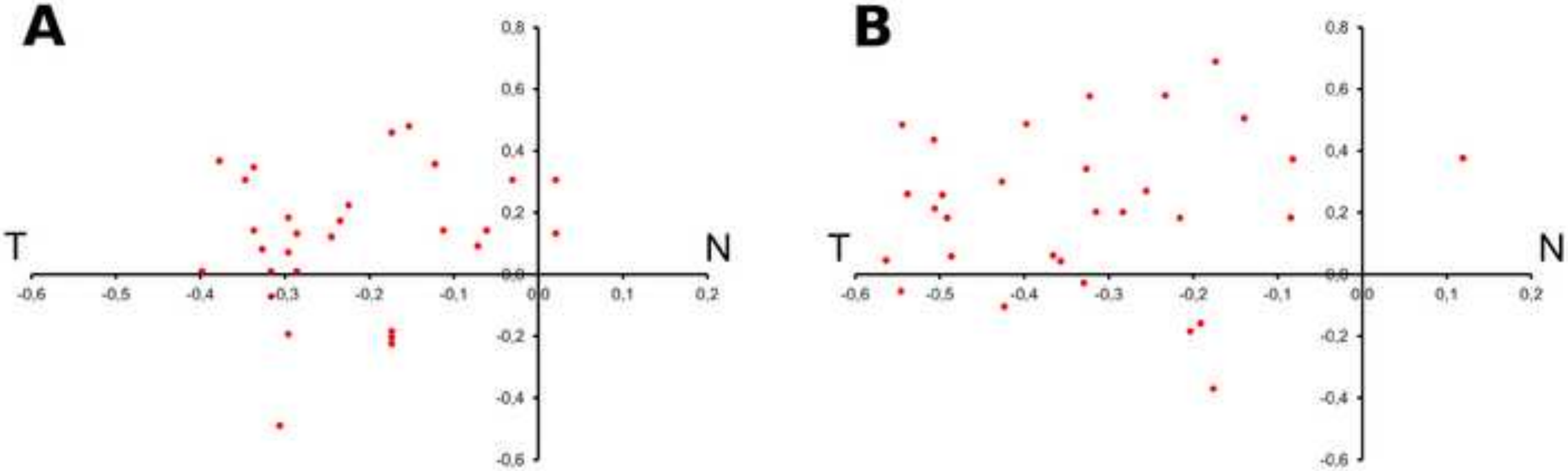


Figure 2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B
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