Research Square

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Comparative Visual Performance of a Novel Trifocal IOL (D615L) and the AT LISA tri 839MP: A Propensity Score-Matched Prospective Study

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Research Article

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Abstract

Purpose: To prospectively compare postoperative visual performance between a novel trifocal intraocular lens(IOL) manufactured in China (D615L) and the Zeiss AT LISA tri 839MP using propensity score matching (PSM).

Methods: Patients with age-related cataract undergoing phacoemulsification and IOL implantation were enrolled. A 1:1 PSM was performed to control for baseline confounders, yielding 32 matched eyes (16 per group). Uncorrected distance, intermediate (66 cm), and near (40 cm) visual acuities (UDVA, UIVA, UNVA), spherical equivalent (SE), defocus curves, and Visual Function Index-14 (VF-14) scores were evaluated at 1 week and 1 month.

Results: At 1 week, D615L achieved significantly better UIVA than 839MP (0.05 vs. 0.13 logMAR, P = 0.046), while UDVA, UNVA, and SE showed no significant differences (P > 0.05). At 1 month, D615L maintained superior UIVA (0.03 vs. 0.10 logMAR, P = 0.006). UDVA, UNVA, and SE remained comparable between groups (P > 0.05). The 1-month defocus curve showed D615L was superior at 0 D (P = 0.002) and -1.5 D (P = 0.02), displaying a flatter profile from 0 D to -1.5 D. Mean VF-14 scores exceeded 97 in both groups with no significant difference (P = 0.70).

Conclusion: The D615L trifocal IOL provides comparable overall visual performance and patient satisfaction to the imported AT LISA tri 839MP, while demonstrating superior intermediate visual acuity likely attributable to its 60-cm intermediate focus designed for Asian viewing habits.

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Introduction

Cataract surgery has fully entered the refractive era, with patient expectations evolving from mere visual restoration to achieving spectacle independence across distance, intermediate, and near ranges to meet the demands of diverse daily activities such as driving, computer use, and reading. The continuous evolution of multifocal intraocular lenses (MIOLs) has provided pivotal technical support for achieving this goal[1]. Multiple studies have demonstrated that patients implanted with trifocal IOLs achieve better uncorrected intermediate and near visual acuity, higher rates of spectacle independence, and greater visual satisfaction[2,3].

The AT LISA tri 839MP (Carl Zeiss Meditec, Germany) is a representative fully diffractive trifocal IOL that has been widely adopted worldwide. This lens employs an asymmetric light distribution design and utilizes Smooth Micro Phase (SMP) technology to optimize the diffractive step edges, effectively reducing postoperative glare and halo while delivering satisfactory visual performance across all distances[4]. A six-year follow-up study demonstrated that the long-term efficacy of the AT LISA tri 839MP remained comparable to, or even better than, that reported at 12 months postoperatively[5]. Research reported that bilateral implantation of the 839MP in presbyopic patients yielded excellent distance,

intermediate, and near visual acuity with high patient satisfaction[6]. However, the relatively high cost of imported trifocal IOLs has limited their widespread clinical adoption, giving rise to an urgent need for cost-effective alternatives developed and manufactured in China.

In recent years, significant breakthroughs have been made in the development of novel intraocular lenses manufactured in China. In 2025, the Liangshian® (D615L, Tianjin Century Kangtai Biomedical Engineering Co., Ltd, China), a new-generation trifocal plus IOL, received marketing approval from the Chinese National Medical Products Administration (NMPA Registration No: CQZ2400897), becoming the first innovative trifocal medical device approved in China. The D615L features proprietary "intelligent targeted light field distribution" technology and employs a multi-zone diffractive-refractive hybrid optical design, achieving a light energy utilization rate exceeding 90%. Notably, the D615L is the first trifocal IOL with an intermediate focal point specifically set at 60 cm, which may offer advantages at closer working distances. Compared with other ethnic populations, East Asian individuals generally possess shorter upper limb lengths, which contributes to a closer preferred working distance for near tasks such as reading and electronic screen use. In contrast, imported trifocal IOLs such as the AT LISA tri 839MP are generally designed with an intermediate focal point of 80 cm—a distance that is comparatively long given the arm length and reading habits of Chinese users. By precisely setting the intermediate focus at 60 cm and the near focus at 40 cm, the D615L achieves a better match with the real-world visual demands of Chinese patients. Furthermore, the D615L is built on the Mercury platform and fabricated from a hydrophobic acrylic material with a proprietary “water balance technology.” Following implantation, the water content of the lens gradually equilibrates to approximately 4%, thereby combining the advantages of both hydrophilic and hydrophobic biomaterials., which may reduce glistenings and PCO risk, although these potential benefits require long-term investigation [7].

Although the D615L exhibits considerable advantages in optical design and material properties, and preliminary post-marketing multicenter clinical data have shown a favorable trend in postoperative visual acuity, there remains a lack of prospective, peer-reviewed clinical studies that directly compare the D615L with the AT LISA tri 839MP using rigorous statistical methods to systematically evaluate postoperative visual quality.

Therefore, this study employed a prospective cohort design with propensity score matching (PSM) to control for baseline confounding variables including age, axial length, anterior chamber depth, lens thickness, and white-to-white distance. The aim was to compare the postoperative visual acuity at all distances, defocus curves, and subjective visual quality (VF-14 questionnaire) between the D615L and the AT LISA tri 839MP, thereby providing evidence-based data to inform clinical decision-making and to support the substitution of imported premium IOLs with high-performance alternatives manufactured in China.

Method

Object

This prospective cohort study enrolled patients with age-related cataract scheduled for phacoemulsification with IOL implantation at Shanghai Tenth People's Hospital between April 2025 and February 2026. Inclusion criteria were: (1) diagnosed age-related cataract; (2) preoperative corneal astigmatism <1.0 D; (3) endothelial cell count >2000/mm²; (4) signed informed consent and ability to complete 6-month follow-up. Exclusion criteria: (1) prior corneal refractive, glaucoma or vitreoretinal surgery; (2) intraoperative posterior capsule rupture, zonular dehiscence or vitreous loss; (3) corneal pathology, macular edema or optic neuropathy affecting visual assessment; (4) active ocular inflammation, glaucoma, maculopathy or diabetic retinopathy; (5) uncontrolled systemic disease such as diabetes or autoimmune disorders. Participants chose the IOL type and were divided into two groups: the D615L group received a new domestic trifocal IOL (Liangshian® Plus, Tianjin Century Kangtai Biomedical Engineering Co., Ltd, China) and the control group received the AT LISA tri 839MP (Carl Zeiss Meditec, Germany). The study followed the Declaration of Helsinki, was approved by Institutional Review Board of Shanghai Tenth People's Hospital (approval identifier: 26K88), and registered in a public clinical trials registry (ClinicalTrials.gov identifier: NCT07571694) before study initiation. All patients gave written informed consent.

Preoperative Examination

All patients underwent complete ophthalmic examination: uncorrected and best-corrected visual acuity, manifest refraction, corneal endothelial count, axial length, keratometry, corneal topography (Pentacam HR, OCULUS, Germany), slit-lamp, fundoscopy, tonometry, and B-scan ultrasonography. Visual acuity was measured with a standard logarithmic chart. Biometry was performed with the IOLMaster 700 (Carl Zeiss Meditec, Germany), and IOL power was calculated using the Barrett Universal II formula targeting emmetropia.

Surgery

Patients received tobramycin-dexamethasone drops four times daily one day before surgery. Capsulorhexis and incision sites were pre-marked with a digital guidance system (Alcon GPS-WaveLight, Germany), and pupils were dilated to ≥8 mm with compound tropicamide. All procedures were performed by one experienced surgeon with over 200 trifocal IOL implantations prior to study initiation under topical anesthesia. After sterile draping, a 2.2 mm main incision and a side port were created under navigation. An ophthalmic viscoelastic device (OVD) was injected to stabilize the anterior chamber, followed by a continuous curvilinear capsulorhexis. After phacoemulsification and cortical removal, the IOL was implanted in the capsular bag. OVD was aspirated, incisions were sealed with stromal hydration, and tobramycin-dexamethasone ointment was applied before patching. Postoperative topical dexamethasone-tobramycin drops were continued for two weeks.

Postoperative Follow-up

Follow-up visits were at 1 day, 1 week, 1 month, 3 months and 6 months. As this intraocular lens has been in clinical use for only a short period, the preliminary analyses focused on the 1-week and 1-month

time points. Each visit included uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA, 66 cm), uncorrected near visual acuity (UNVA, 40 cm), manifest refraction, slit-lamp examination, non-contact tonometry and fundus examination. At 1 month, defocus curves were measured by adding lenses from +1.0 D to –4.0 D in 0.5 D steps over the best-corrected distance refraction. Subjective visual quality was assessed with the Chinese version of the Visual Function Index-14 (VF-14, Cronbach's α = 0.916~0.950[8,9]). All examinations were performed under photopic lighting conditions with undilated pupils.

Statistical Analysis

Analyses were conducted with R 4.6.0. Continuous variables were tested for normality; normally distributed data are presented as mean ± SD and compared by independent t-test, while non-normal data are presented as median (IQR) and compared with nonparametric tests. Categorical variables are shown as frequency (%) and compared by chi-square or Fisher's exact test. To reduce confounding, 1:1 propensity score matching was performed using age, axial length, anterior chamber depth, lens thickness and white-to-white distance. Balance was assessed with P values and standardized mean differences. Defocus curves plot mean ± SD visual acuity at each defocus step; between-group comparisons were made at every defocus point, and the area under the curve (AUC) from –4.0 D to +1.0 D was compared. All tests were two-sided and $P < 0.05$ was considered significant.

Result

Study Population and Baseline Characteristics

A total of 34 patients (59 eyes) were initially enrolled, comprising 9 patients (18 eyes) in the D615L group and 25 patients (41 eyes) in the 839MP group. No patients were lost to follow-up at 1 week postoperatively. At the 1-month follow-up, 1 patient (2 eyes) in the D615L group and 6 patients (7 eyes) in the 839MP group were excluded due to loss to follow-up, leaving 8 patients (16 eyes) and 19 patients (34 eyes), respectively. To minimize potential selection bias, a 1:1 propensity score matching (PSM) was performed on the 1-month completers, resulting in a final analysis population of 32 matched eyes (16 per group) (Figure 1).

Prior to PSM, there were noticeable imbalances between the two groups, most notably in axial length (AL, SMD = 0.58) and anterior chamber depth (ACD, SMD = 0.75, P = 0.02). After matching, the baseline characteristics were generally balanced, with the standardized mean differences for all covariates reduced to less than 0.3, except for AL, where a mild residual imbalance remained (SMD = 0.32, P = 0.42) (Table 1). For completeness, the uncorrected outcomes in the pre-matched cohort are reported in Supplemental Data 1 and Supplemental Data 2. Due to substantial baseline imbalance and notable disparity in sample size between the groups, formal inferential comparisons were not performed in the pre-matched cohort. All subsequent efficacy analyses were restricted to the propensity score–matched sample.

Postoperative 1-Week Visual and Refractive Outcomes

Detailed 1-week visual and refractive outcomes are presented in Table 2. Uncorrected intermediate visual acuity (UIVA, 66 cm) was significantly better in the D615L group than in the 839MP group, whereas uncorrected distance and near visual acuity and spherical equivalent were comparable between groups.

Postoperative 1-Month Visual and Refractive Outcomes

Detailed 1-month visual and refractive outcomes are summarized in Table 3. The D615L group maintained significantly better UIVA compared with the 839MP group, while uncorrected distance and near visual acuity and refractive outcomes remained similar between the two groups.

Subjective Visual Quality

Subjective visual quality was assessed at 1 month postoperatively using the Chinese version of the Visual Function Index-14 (VF-14) questionnaire. The mean VF-14 score was 97.87 ± 2.28 in the D615L group and 97.52 ± 2.56 in the 839MP group. Both groups achieved high levels of postoperative subjective visual satisfaction, and no statistically significant difference was observed between groups (P = 0.70, Figure 2).

Defocus Curve

The postoperative 1-month defocus curves for both groups are presented in Figure 3. Both IOLs demonstrated a typical trifocal configuration with distinct peaks at the distance, intermediate, and near foci. At the 0 D defocus level (distance focus), the D615L group showed significantly better visual acuity than the 839MP group (P = 0.002). At +1.0 D (within the distance range), the 839MP group performed significantly better than the D615L group (P = 0.01). At −1.5 D (intermediate focus), the D615L group again demonstrated superior visual acuity compared with the 839MP group (P = 0.02). No statistically significant differences were observed between the two groups at the remaining defocus levels (+0.5 D, −0.5 D, −1.0 D, −2.0 D, −2.5 D, −3.0 D, −3.5 D, and −4.0 D; all P > 0.05). Overall, the defocus curve of the D615L group exhibited a flatter profile in the 0 D to −1.5 D range, suggesting a potential advantage in intermediate visual quality. The area under the defocus curve (AUC) from +1.0 D to −4.0 D was 1.01 ± 0.24 logMAR·D in the 839MP group and 1.15 ± 0.52 logMAR·D in the D615L group. No statistically significant difference in AUC was observed between the two groups (Mann-Whitney U test, W = 124, P = 0.90), indicating comparable overall visual performance across the full range of defocus.

Discussion

In this prospective, propensity score–matched cohort study, we compared the 1-month visual performance of the D615L (Liangshian®, Tianjin Century Kangtai Biomedical Engineering Co., Ltd, China), a novel trifocal IOL manufactured in China, with that of the Zeiss AT LISA tri 839MP. No statistically significant differences were observed between groups in uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), spherical equivalent (SE), or the area under the defocus

curve (AUC), indicating largely equivalent overall visual function. Notably, the D615L group achieved significantly better uncorrected intermediate visual acuity (UIVA) than the 839MP group at 1 month.

Both IOLs delivered excellent distance and near visual acuity, consistent with the established performance of trifocal IOLs[10,11]. Compared with bifocal designs, trifocal IOLs have consistently demonstrated superior intermediate vision and a less steep decline in the defocus curve across the intermediate range, highlighting the benefits of the trifocal optical principle[3,12,13]. We attribute the D615L's intermediate visual advantage primarily to its dedicated focal-point design. While the 839MP targets an intermediate focus at approximately 80 cm, the D615L is engineered for a 60-cm intermediate focal distance, which therefore appears better aligned with habitual viewing behavior at closer working distances , translating into improved performance at the standardized 66-cm examination distance. However, direct behavioral data from Chinese populations are currently limited.

Both groups yielded defocus curves with the characteristic trifocal multi-peak configuration. At individual defocus levels, the D615L performed better than the 839MP at 0 D and –1.5 D, whereas the 839MP showed superiority at +1.0 D. The D615L curve was notably flatter between 0 D and –1.5 D, suggesting a smoother functional transition through the intermediate range. This can be explained by the asymmetric diffractive ring design of the D615L, which improves overall light energy utilization by directing a greater proportion of light to the distance, intermediate, and near foci while reducing light loss to non-functional diffractive orders. The resulting enhancement in retinal image quality contributes to better visual performance across the intermediate range. No significant between-group differences were detected at the remaining defocus steps. It should be noted that the point-by-point comparisons along the defocus curve were not adjusted for multiple comparisons; therefore, the significance at individual defocus levels should be interpreted with caution. The AUC—a semi-quantitative metric that integrates the defocus curve into a single value for comparing multifocal IOLs—did not differ significantly between groups, confirming comparable full-range visual performance from +1.0 D to –4.0 D.

Mean VF-14 scores exceeded 97 points in both groups at 1 month, in line with the high satisfaction levels reported in prior 839MP studies (range approximately 88–95). Although the 839MP group demonstrated slightly worse UIVA, its +1.66 D intermediate add still provides acceptable functional intermediate vision for most Asian eyes. In the pre-matched cohort, the 839MP group showed slightly higher VF-14 scores, suggesting that patients lost to follow-up may have differed in satisfaction levels. The uniformly high scores suggest that both IOLs met patients' visual demands, and that the modest objective advantage in intermediate acuity did not translate into a subjectively meaningful difference. Additionally, low response rates for the night-driving and fine-handiwork items may have reduced the discriminative capacity of the VF-14 in our sample.

Several limitations should be considered. First, the single-center design and relatively small matched cohort (32 eyes) restrict generalizability and preclude robust subgroup analyses, and the attrition rate of two groups remains a potential source of selection bias. Second, the 1-month follow-up did not permit evaluation of long-term endpoints such as posterior capsule opacification (PCO), refractive stability, or

rotational stability. Although the hydrophobic acrylic material and water-balance technology of the D615L are designed to mitigate PCO and glistenings, these potential benefits were not assessed. Third, despite rigorous propensity score matching, residual confounding by unmeasured variables cannot be excluded. Fourth, the ceiling effect of the VF-14 indicates that future studies should incorporate more sensitive measures, such as contrast sensitivity, objective scatter index, or reading speed.

In summary, among Chinese cataract patients, the D615L provided overall visual quality comparable to that of the AT LISA tri 839MP at 1 month. A statistically significant advantage in uncorrected intermediate visual acuity was observed, but its clinical relevance requires confirmation with more sensitive measures. These findings provide preliminary support for the clinical viability of high-performance trifocal IOLs developed and manufactured in China; validation through larger multicenter randomized trials is warranted.

Declarations

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Ethics approval: The study followed the Declaration of Helsinki, was approved by Institutional Review Board of Shanghai Tenth People's Hospital (approval identifier: 26K88), and registered in a public clinical trials registry (ClinicalTrials.gov identifier: NCT07571694) before study initiation.

Consent to Participate: All patients gave written informed consent.

Author Contribution

S.Y. and L.F. wrote the main manuscript text, and .Y. prepared all tables. All authors reviewed the manuscript.

AI Use: During the preparation of this work the authors used DeepSeek in order to improve the language and readability of the manuscript. After using this service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Tables

Tables 1 to 3 are available in the Supplementary Files section.

Figures

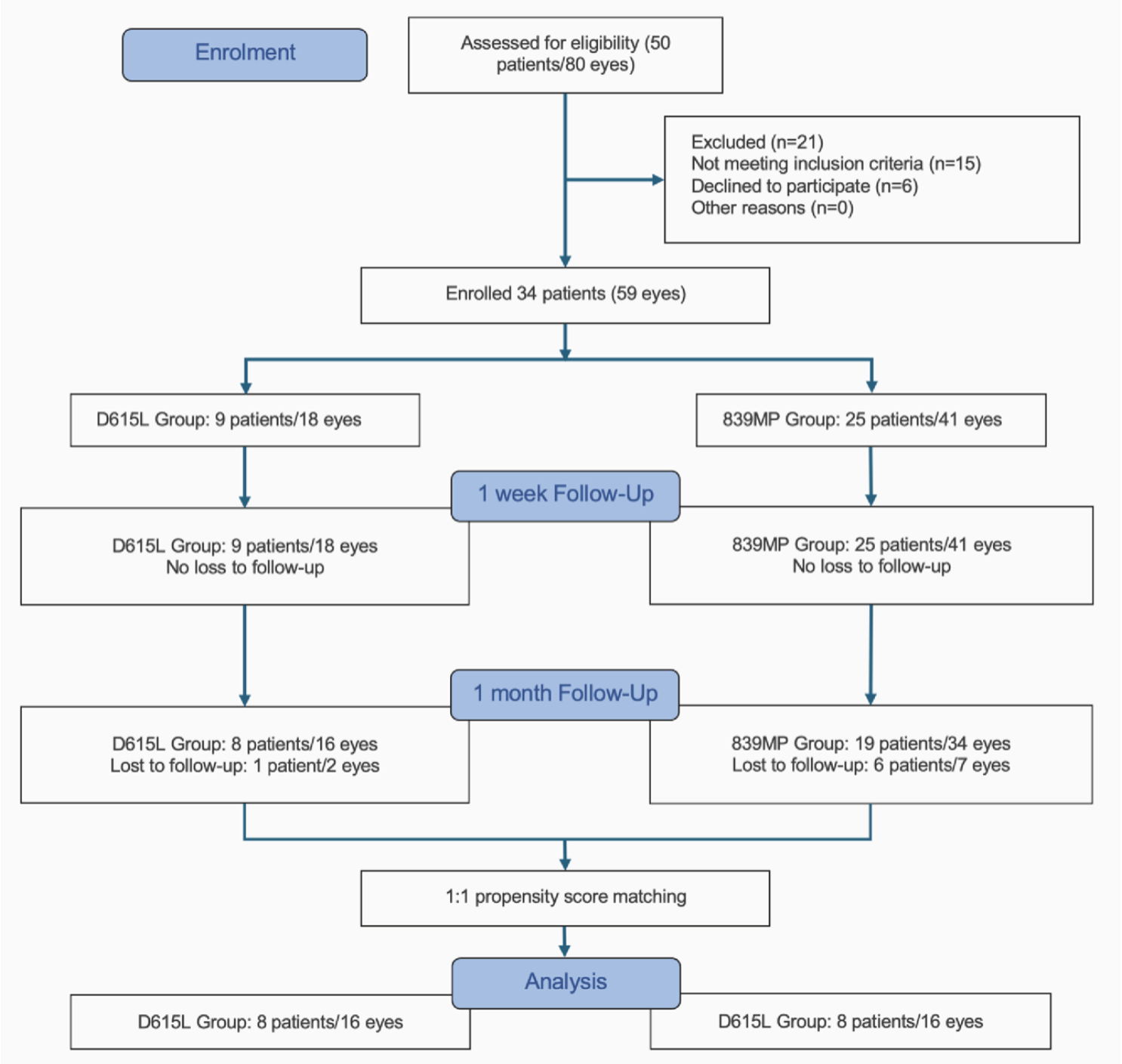

Figure 1

CONSORT Flow Diagram

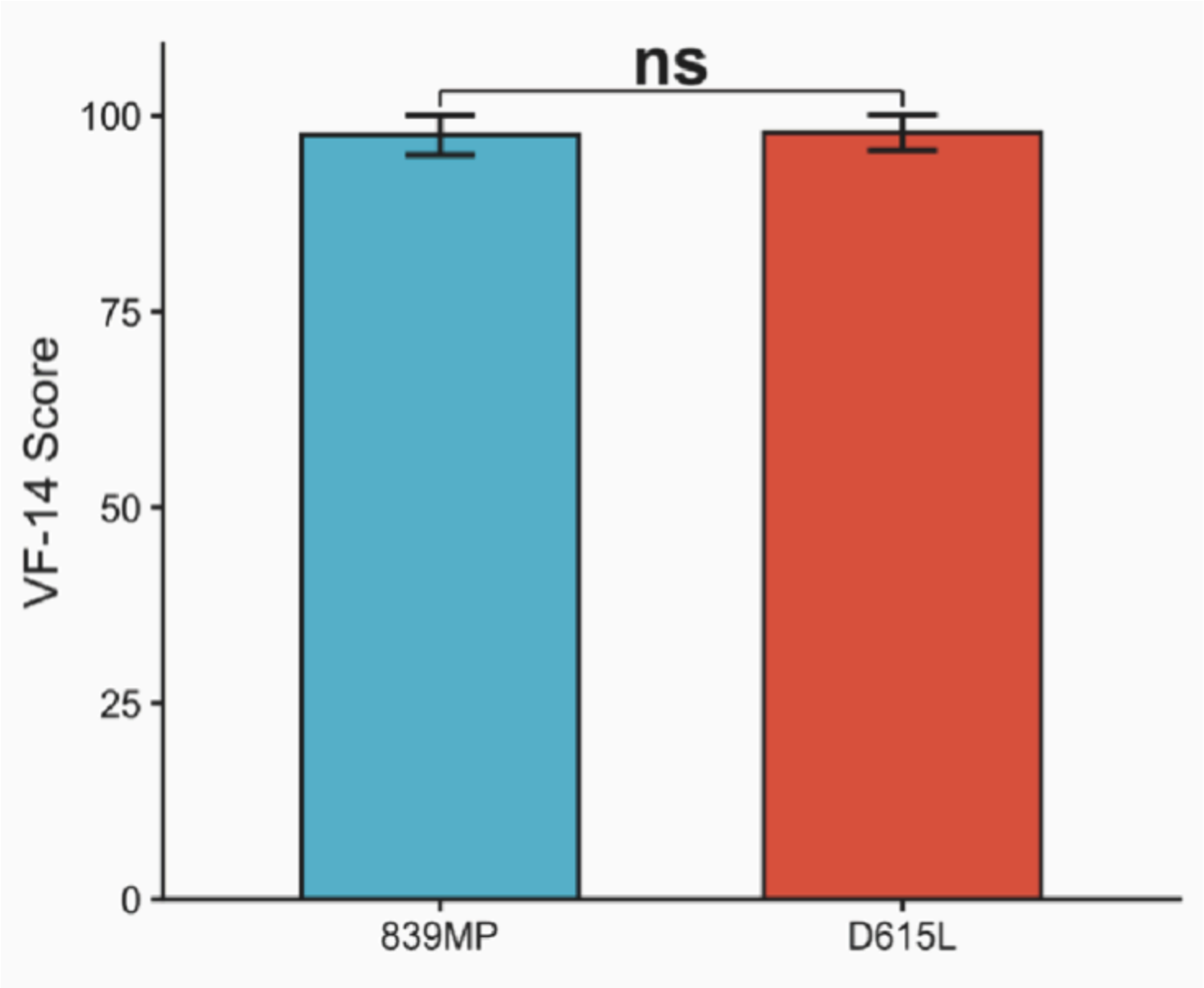

Figure 2

Comparison of VF-14 scores between the D615L and 839MP groups at 1 month postoperatively.

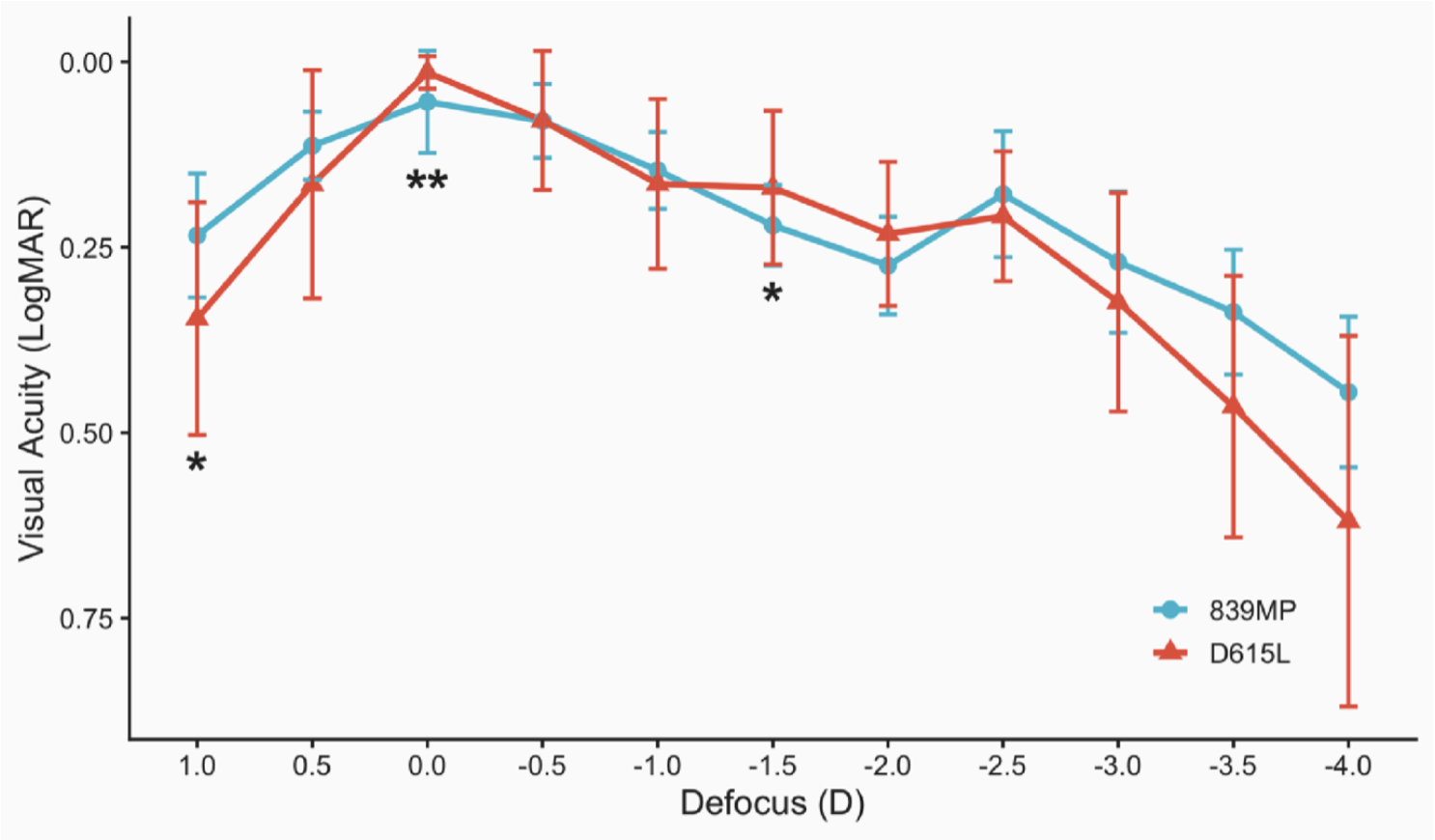

Figure 3

Defocus curves at 1 month postoperatively. *P < 0.05, **P < 0.01

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementalData1.docx
- SupplementalData2.docx
- Table1.docx
- Table2.docx
- Table3.docx