

# Performance of the First Spiral Refractive Intraocular Lens for Continuous Full Range of Vision

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## ABSTRACT

**PURPOSE:** To evaluate visual performance of a novel full range of vision spiral intraocular lens (IOL) designed with artificial intelligence using preclinical and clinical metrics.

**METHODS:** Preclinical visual performance was assessed in healthy individuals using a pseudophakic vision simulation device, comparing monocular corrected distance visual acuity, contrast sensitivity, defocus curve, halo/glare size, and subjective preference between the spiral RayOne Galaxy IOL and diffractive RayOne Trifocal IOL (Rayner). Additionally, postoperative clinical outcomes were subsequently analyzed from 10 sites following bilateral RayOne Galaxy IOL implantation. At 3 months postoperatively, key endpoints included subjective refraction, monocular and binocular uncorrected and corrected distance visual acuity at multiple distances, defocus curves, and patient-reported dysphotopsia.

**RESULTS:** Preclinical evaluation demonstrated comparable

range of focus between the Galaxy and diffractive Trifocal IOLs. However, the Galaxy IOL exhibited significantly less halo/glare, with nearly all participants preferring it across all distances. In the clinical study, mean monocular corrected distance visual acuities were  $-0.03 \pm 0.08$  logarithm of the minimum angle of resolution (logMAR) for distance,  $0.05 \pm 0.11$  logMAR for intermediate, and  $0.08 \pm 0.14$  logMAR for near, with further improvement observed binocularly. Monocular/binocular defocus curves demonstrated a smooth plateau with binocular defocus maintaining visual acuity of 20/32 (0.2 logMAR) or better from +1.00 to -2.80 diopters (35 cm). Halo and glare symptoms were generally minor (> 95% of patients), with no severe cases.

**CONCLUSIONS:** The Galaxy IOL provides excellent monocular and binocular visual acuity across all tested distances, with a smooth and continuous defocus curve ensuring full-range vision. Preclinical testing demonstrated significantly fewer photic phenomena than the tested diffractive trifocal IOL, whereas clinical investigations found no indications of bothersome side effects, together demonstrating high visual comfort.

Cataract surgery has evolved beyond merely restoring clarity into a refractive procedure aimed at achieving seamless vision across all distances. Today, patients with cataract may no longer settle for improved distance vision alone; they may seek uncompromised visual range allowing them to navigate daily activities from using digital devices to reading fine print without the need for spectacles. To address this demand, advanced intraocular lenses (IOLs), including multifocal and extended depth-of-focus (EDOF) lenses, have been developed to enhance overall visual performance.<sup>1</sup> However, traditional diffractive trifocal IOLs, although effective at providing a full range of vision at three distinct focal points,<sup>2</sup> have notable limitations. Their optical design, which splits light into multiple foci, often through sharp transition zones on the optical surface, can lead to reduced contrast sensitivity and visual disturbances such as glare and halos.<sup>2-6</sup> These effects, especially noticeable in low-light conditions, can impact everyday activities such as night driving or reading under dim lighting.<sup>7</sup> Moreover, although trifocal IOLs provide clear

vision at distinct focal points, they may fall short in delivering optimal clarity at intermediate distances, due to the limited light allocation to this range. In contrast, EDOF IOLs provide a smoother visual transition but lack near-range performance for tasks like reading fine print or intricate manual work.

The RayOne Galaxy IOL is a new IOL featuring refractive spiral tracks engineered to provide visual performance across a continuous range of distances.

To validate advanced optical designs, preclinical tests that account for the complexities of the human visual perception are essential. Such evaluation serves to bridge the gap between laboratory-based studies and clinical outcomes, all while remaining non-invasive.<sup>3-5</sup> The importance of such systems has grown following the U.S. Food and Drug Administration call for improved models to better predict clinical outcomes of medical devices.<sup>6</sup> One such approach is virtual IOL implantation, which projects the optical properties of an IOL onto the patient's eye using an optical imaging system. This technology allows patients to experience vision through the lens as if it were already

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implanted, and it allows for a direct comparison of different IOLs, providing deeper insights into their optical performance. Several visual implantation devices, including VirtIOL (10Lens S. L. U.) and RALV (DEZIMAL GmbH), have demonstrated strong alignment between predicted optical outcomes and clinical findings, validating their role in preclinical IOL assessment.<sup>5,7</sup>

This is the first study to assess and present the clinical performance of the RayOne Galaxy (Rayner), a new class of full range of vision spiral IOL. This report presents a comprehensive assessment of this IOL's performance, combining preclinical visual assessments with clinical postoperative evaluations.

## PATIENTS AND METHODS

### IOL

The RayOne Galaxy RAO605G and Galaxy Toric RAO615X are single-piece, C-loop, hydrophilic acrylic IOLs with a non-angulated design. They have a 12.5-mm overall diameter and a 6-mm non-diffractive optic diameter with aspheric correcting profile ( $-0.17\ \mu\text{m}$ ). The central 1.1 mm of the optic is optimized for distance vision, whereas the spiral pattern extends from 1.1 to 3.2 mm to enhance the range of focus. Designed using a proprietary artificial intelligence engine, the refractive spiral tracks enable a continuous variance of power, focusing light across the entire defocus curve. This design results in a gradually transitioning optical surface without abrupt

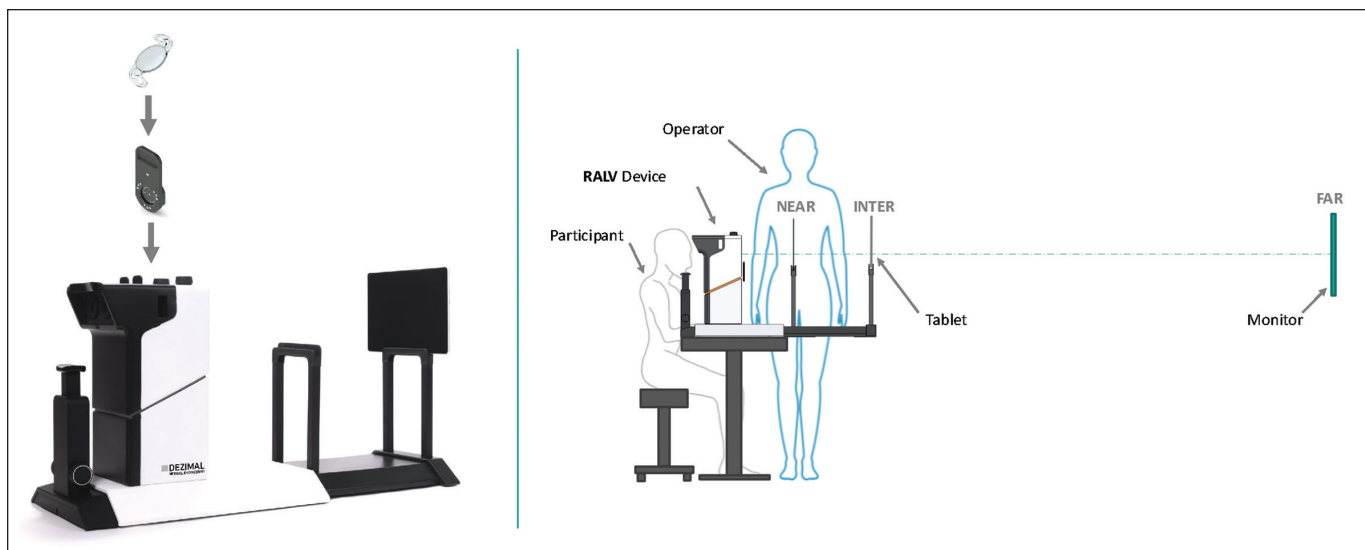
power shifts, aiming to provide a continuous range of vision while minimizing dysphotopsia and reducing light loss. Additionally, the lenses feature the Amon-Apple 360° enhanced square-edge design to reduce posterior capsule opacification,<sup>8,9</sup> and incorporate anti-vaulting haptic technology, for improved rotational stability and minimal decentration.<sup>10</sup>

The non-toric version is available in spherical powers ranging from +5.00 to +30.00 diopters (D) in 0.50-D increments. The toric version offers spherical equivalent powers from +6.00 to +25.00 D (0.50-D increments) with cylinder powers ranging from +0.75 to +4.50 D (0.75-D increments).

### PRECLINICAL VISION TESTING

A preclinical vision test using the optical system RALV (DEZIMAL GmbH) was performed to evaluate and compare visual acuity and perceived image quality between the RayOne Galaxy and the RayOne Trifocal RAO603F (Rayner). The study was approved by the local Ethics Commission of the Academic Teaching Hospital of St. John and conducted in accordance with the tenets of the Declaration of Helsinki and Good Clinical Practice. Informed written consent was obtained from all participants.

The RALV (Real Artificial Lens Vision) system is a non-invasive optical device that lets participants experience postoperative (pseudophakic) vision by viewing



**Figure 1.** Real Artificial Lens Vision (RALV) system for the evaluating visual performance in healthy participants using pseudophakic vision simulation. Left panel: illustration of the RALV device, showing the intraocular lens mounted in the shuttle. Right panel: Schematic of the experimental set-up, with the participant seated at the device viewing visual targets at three distances (near, intermediate, and far).

through real IOLs, as if the lens were already implanted (**Figure 1**). IOLs are mounted in fluid-filled shuttles that can be exchanged to compare different IOL models. The system uses two optical lens stacks with the IOL shuttle positioned in between. It replicates the retinal image quality (modulation transfer function at the fovea) of the implanted IOL by neutralizing the user's eye power and correcting optical aberrations. To correct the patient refraction, the first lens stack, including the IOL, can be precisely shifted along the optical axis. Further details regarding the RALV device design and functionality have been previously published by Brezna et al.<sup>5</sup> All tests were conducted using the dominant eye, which was treated with cyclopentolate to eliminate accommodation. The effective pupil size was constricted to 3.55 mm (3 mm on the anterior IOL surface) using an aperture positioned at a conjugated plane inside the RALV device.

The study evaluated visual acuity, contrast sensitivity and subjective preference at three distances (far 4 m, intermediate 74 cm, near 40 cm), and halo/glare size at distance. Visual acuity was assessed using black Landolt rings of varying sizes on a white background. Contrast sensitivity contrast sensitivity was measured with Landolt rings of a fixed size (7.5 cycles per degree equivalent to 20/80 Snellen, 0.6 logarithm of the minimum angle of resolution [logMAR]) presented at different contrast levels, with results expressed in logarithmic Weber contrast (logCSw). Halo/glare testing was conducted using a halometer, with a distant bright LED light source and light gray optotypes (20/80 Snellen, 0.6 logMAR,) on a black background, measured at decreasing radial distances until obscured by the halo. Defocus curves were recorded from +1.00 to -4.00 D

in 0.50-D steps. For subjective preference assessment, participants viewed images representing distance, intermediate, and near vision scenes and selected their preferred IOL. All tests were performed monocularly with best distance correction.

## CLINICAL STUDY

A pooled analysis of clinical outcomes following bilateral implantation of the RayOne Galaxy or Galaxy Toric IOL across 10 sites in Europe, Turkey, and New Zealand was performed to assess to clinical safety and performance of the Galaxy IOL. The sites were selected based on their established clinical routines and adherence to uniform data collection practices. All sites adhered to the tenets of the Declaration of Helsinki, Good Clinical Practice, and local ethical regulations. All participants provided informed consent.

## PATIENT SELECTION

Eligible participants were adults (22 years or older) scheduled for uncomplicated bilateral cataract surgery with the Galaxy or Galaxy Toric IOL. They had good ocular health, no pathology affecting visual acuity (other than residual refractive error and cataract), and an expected visual potential of 20/32 Snellen (0.20 logMAR) or better in each eye. Exclusion criteria included corneal pathology, previous refractive surgery, and preexisting ocular disease that could limit or affect visual potential.

## SURGICAL INTERVENTION

All surgeries were performed using a standard self-sealing clear corneal incision, capsulorhexis, and con-

TABLE 1  
**Demographic and Preoperative Data**

| Characteristic                      | Mean $\pm$ SD    | Range          |
|-------------------------------------|------------------|----------------|
| Age (years)                         | 62.45 $\pm$ 9    | 47 to 86       |
| Gender (M/F)                        | 35/38            | –              |
| IOL SE power (D)                    | 20.70 $\pm$ 3.20 | 7.50 to 27.00  |
| IOL cylinder power (D) <sup>a</sup> | 1.25 $\pm$ 0.73  | 0.75 to 3.00   |
| Axial length (mm)                   | 23.70 $\pm$ 1.25 | 21.64 to 28.51 |
| Anterior chamber depth (mm)         | 3.21 $\pm$ 0.34  | 2.26 to 4.10   |
| Lens thickness (mm)                 | 4.46 $\pm$ 0.36  | 3.56 to 5.25   |
| White-to-white distance (mm)        | 12.08 $\pm$ 0.43 | 11.00 to 13.14 |
| K1 (D)                              | 42.81 $\pm$ 1.6  | 38.93 to 47.03 |
| K2 (D)                              | 43.55 $\pm$ 1.71 | 39.50 to 48.15 |
| Delta K                             | 0.74 $\pm$ 0.52  | 0.00 to 2.54   |

D = diopters; IOL = intraocular lens; K = keratometry; K1 = flat keratometry; K2 = steep keratometry; SD = standard deviation; SE = spherical equivalent  
<sup>a</sup>For toric IOLs only (n = 60).

ventional phacoemulsification. Emmetropia was targeted in all cases with IOL power calculated using the Barrett Toric Calculator. Postoperative treatment and medication were given according to the routine procedure in each center.

## OUTCOME MEASURES

At 1 and 3 months postoperatively, subjective refraction was assessed along with monocular and binocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity were measured at 4 m (UDVA, CDVA), 66 cm (uncorrected [UIVA] and distance-corrected [DCIVA] intermediate visual acuity), and 40 cm (uncorrected [UNVA] and distance-corrected [DCNVA] intermediate visual acuity). Additional evaluations included monocular and binocular defocus curve (+1.00 to -4.00 D), contrast sensitivity (Vector Vision or Topcon CC-100XP, Topcon). Halo and glare were evaluated using an online simulator (Eyeland-Design Network GmbH) as previously described.<sup>11</sup>

## STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS software Version 23 (IBM Corporation) and R-Studio version 4.3.3 for the preclinical evaluation, and with R statistical package (The R Project for Statistical Computing) for the clinical study. Sample size for the preclinical testing was calculated for a two-tailed test with  $\alpha = 0.05$  and 95% power, based on detecting a true difference of 0.04 logMAR in visual acuity between IOLs and assuming a standard deviation of 0.05 logMAR.<sup>5</sup> The recommended sample size

was at least 24 participants. Descriptive statistics (mean  $\pm$  standard deviation) summarize patient demographics, baseline characteristics, and outcomes (refraction, visual acuity, contrast sensitivity, halo/glare). For preclinical evaluation, analyses using paired Wilcoxon signed-rank tests were applied. The binary, categorical data from the subjective preference tests were tested for significant difference to a 50:50 distribution using an exact binomial test.

In the clinical study, all analyses were conducted on the pooled dataset. Normal distribution was first tested, but not observed for any variable combination, so the Wilcoxon test for dependent samples was applied throughout. To account for multiple comparisons, *P* values were adjusted using the Holm-Bonferroni method. In all cases, a *P* value less than .05 was considered statistically significant.

## RESULTS

### DEMOGRAPHIC DATA

A total of 30 participants, aged between 18 and 40 years, were enrolled in the preclinical testing phase, whereas the clinical study included 146 eyes of 73 patients aged 62.45  $\pm$  9 years. The demographics of the patients enrolled in the clinical study are summarized in **Table 1**.

### REFRACTION

**Table 2** presents subjective refraction results from the clinical study of the RayOne Galaxy IOL measured preoperatively and at 1 and 3 months postoperatively. At 3 months, 87% of eyes were within  $\pm 0.50$  D and 99% were within  $\pm 1.00$  D from target manifest refraction spherical equivalent (**Figure 2C**). Additionally, 70.1% of eyes had a refractive cylinder between 0.00 and -0.25 D postoperatively, compared to 27% preoperatively (**Figure 2D**).

### VISUAL ACUITY

Comparison of visual acuity in preclinical testing (**Figure 3A**) showed no statistically significant differences between the Galaxy and the Trifocal IOLs for distance vision ( $-0.06 \pm 0.06$  and  $-0.04 \pm 0.08$  logMAR, respectively, *P* = .993) and near visual acuity ( $0.07 \pm 0.08$  and  $0.11 \pm 0.12$  logMAR, respectively, *P* = .315). However, at intermediate distance, the Galaxy demonstrated significantly better performance ( $0.03 \pm 0.07$  logMAR) compared to the Trifocal ( $0.08 \pm 0.09$  logMAR, *P* = .05).

In the clinical study at 3 months, mean monocular distance-corrected visual acuity with the Galaxy IOL exceeded 20/25 (0.1 logMAR) at all distances:  $-0.03 \pm 0.08$  logMAR for distance,  $0.05 \pm 0.11$  logMAR for intermediate, and  $0.08 \pm 0.14$  logMAR for near. All visual acuity outcomes are provided in **Table 2**.

TABLE 2  
**Visual and Refractive Clinical Outcomes Preoperatively and at  
1 and 3 Months After Implantation With the Galaxy IOLs**

| Variable                     | Preop       | 1 Month      | 3 Months     | P <sup>a</sup> |
|------------------------------|-------------|--------------|--------------|----------------|
| Subjective refraction (in D) |             |              |              |                |
| Sphere                       | 0.62 ± 2.91 | -0.18 ± 0.33 | -0.11 ± 0.31 | .244           |
| Cylinder                     | -0.78 ± 0.7 | -0.26 ± 0.29 | -0.24 ± 0.28 | 1.00           |
| MRSE                         | 0.21 ± 2.92 | -0.31 ± 0.34 | -0.23 ± 0.31 | .108           |
| Visual acuity (in logMAR)    |             |              |              |                |
| UDVA                         |             |              |              |                |
| Monocular                    | 0.51 ± 0.34 | 0.06 ± 0.12  | 0.03 ± 0.11  | .005           |
| Binocular                    | 0.42 ± 0.31 | -0.01 ± 0.10 | -0.02 ± 0.09 | .129           |
| CDVA                         |             |              |              |                |
| Monocular                    | 0.13 ± 0.18 | -0.02 ± 0.09 | -0.03 ± 0.08 | .249           |
| Binocular                    | 0.08 ± 0.12 | -0.05 ± 0.08 | -0.06 ± 0.07 | 1.00           |
| UIVA                         |             |              |              |                |
| Monocular                    | –           | 0.07 ± 0.11  | 0.05 ± 0.11  | .042           |
| Binocular                    | –           | 0.02 ± 0.1   | -0.01 ± 0.1  | .129           |
| DCIVA                        |             |              |              |                |
| Monocular                    | –           | 0.06 ± 0.10  | 0.05 ± 0.11  | .459           |
| Binocular                    | –           | 0.01 ± 0.10  | 0.01 ± 0.10  | 1.00           |
| UNVA                         |             |              |              |                |
| Monocular                    | –           | 0.11 ± 0.12  | 0.09 ± 0.13  | .108           |
| Binocular                    | –           | 0.07 ± 0.11  | 0.04 ± 0.12  | .138           |
| DCNVA                        |             |              |              |                |
| Monocular                    | –           | 0.10 ± 0.12  | 0.08 ± 0.14  | .073           |
| Binocular                    | –           | 0.06 ± 0.11  | 0.04 ± 0.13  | 1.00           |

CDVA = corrected distance visual acuity; D = diopters; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; preop = preoperative; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity

<sup>a</sup>P values indicate statistical significance of changes observed between 1 and 3 months.

The Galaxy IOLs are manufactured by Rayner.

As shown in **Figure 2A**, 84.25% of evaluated eyes achieved a UDVA of 20/25 (0.1 logMAR) or better at 3 months compared to 58.74% with a CDVA of 20/25 (0.1 logMAR) or better preoperatively. Postoperative UDVA was the same or better than preoperative CDVA in 81.8% of eyes (**Figure 2B**).

At 3 months postoperatively binocular UDVA of 20/20 (0.0 logMAR) or better was achieved in 82.19% of patients, whereas binocular UIVA and UNVA of 20/32 (0.2 logMAR) or better were observed in 100% and 95.89% patients, respectively (**Figure 4**).

## DEFOCUS

The preclinical monocular defocus curve demonstrated a smooth profile, consistently outperforming the diffractive trifocal from +1.00 D to approximately -2.50 D (**Figure 3B**).

In the clinical study distance-corrected monocular and binocular defocus curves at 3 months showed a sim-

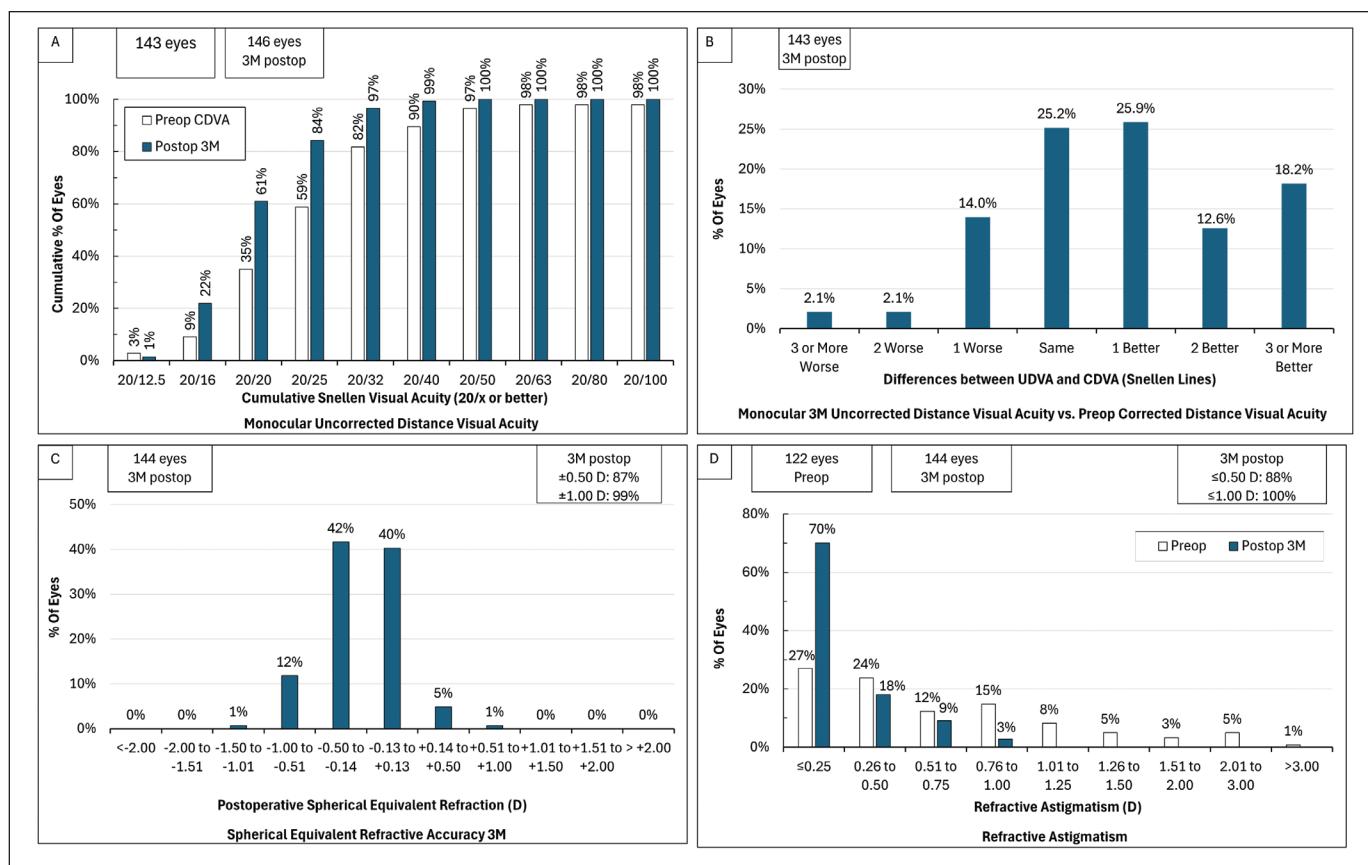
ilar pattern with a visual acuity of 20/32 (0.2 logMAR) or better extending to -2.50 D monocularly, and -2.80 D binocularly (**Figure 5**).

## CONTRAST SENSITIVITY

Contrast sensitivity (in logCSw) preclinical measurements (**Figure 3C**) showed numerically higher mean values with the Galaxy compared to the Trifocal with  $1.30 \pm 0.25$  versus  $1.14 \pm 0.21$  at distance and  $1.09 \pm 0.19$  versus  $1.03 \pm 0.18$  at intermediate, although these differences were not statistically significant ( $P = .051$  and  $P = .495$ , respectively). Near contrast sensitivity readings, on contrary, were significantly better with the Galaxy ( $1.05 \pm 0.16$  vs  $0.89 \pm 0.15$ ,  $P = .005$ ).

Clinical photopic and mesopic contrast sensitivity outcomes at 3 months are presented in **Figure 5B**. Contrast sensitivity remained within the normal range





**Figure 2.** Standard graphs for reporting visual acuity and refraction. (A) Cumulative Snellen preoperative monocular corrected distance visual acuity (CDVA) and postoperative monocular uncorrected distance visual acuity (UDVA) at 3 months. (B) Snellen line differences between monocular UDVA at 3 months and monocular CDVA preoperatively. (C) Postoperative spherical equivalent at 3 months. (D) Refractive cylinder preoperatively and at 3 months. D = diopters

across all spatial frequencies under both photopic and mesopic conditions.<sup>12</sup>

## GLARE AND HALO

Preclinical assessment showed that the halo/glare size was statistically significantly smaller with the Galaxy compared to the Trifocal ( $11.4 \pm 1.5$  and  $21 \pm 3.3$  mrad, respectively,  $P < .0001$ ).

At 3 months postoperatively in the clinical study, patients reported a mean halo size of  $31.8 \pm 22.5$  with a halo intensity of  $37.3 \pm 25.6$  and glare size and intensity of  $9.1 \pm 17.6$  and  $9.9 \pm 16.8$ , respectively, with representative illustration shown in **Figure 5C**. These scores indicate that 95.4% of patients experienced no or mild halos, and 100% experienced no or mild glare.

## SUBJECTIVE PREFERENCE

Subjective preference assessments during preclinical testing (**Figure 3D**) demonstrated a strong, statistically significant preference for the Galaxy over the Trifocal, with 83% of participants favoring the spiral IOL for dis-

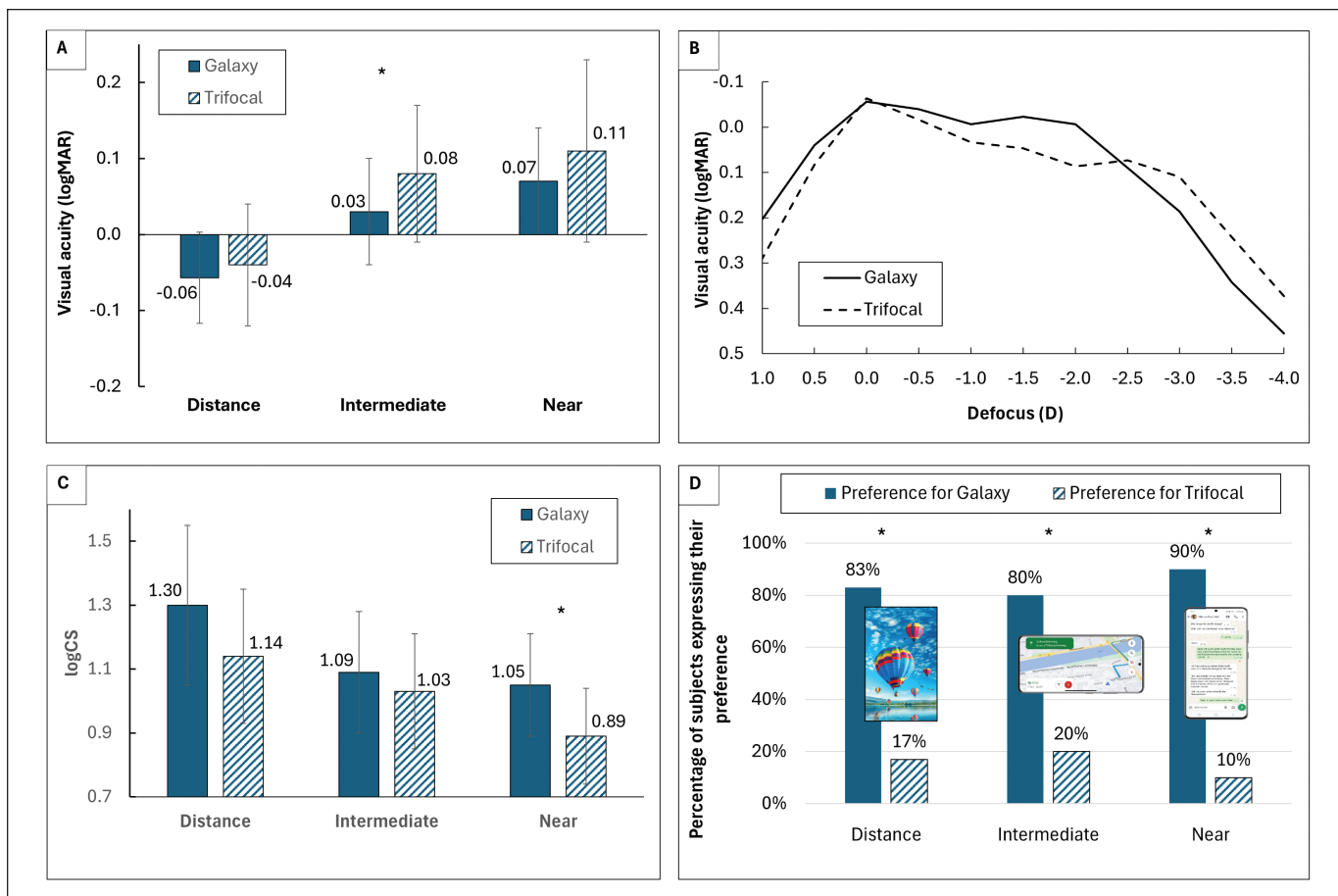
tance vision, 80% for intermediate vision, and 90% for near vision ( $P \leq .001$ ).

## DISCUSSION

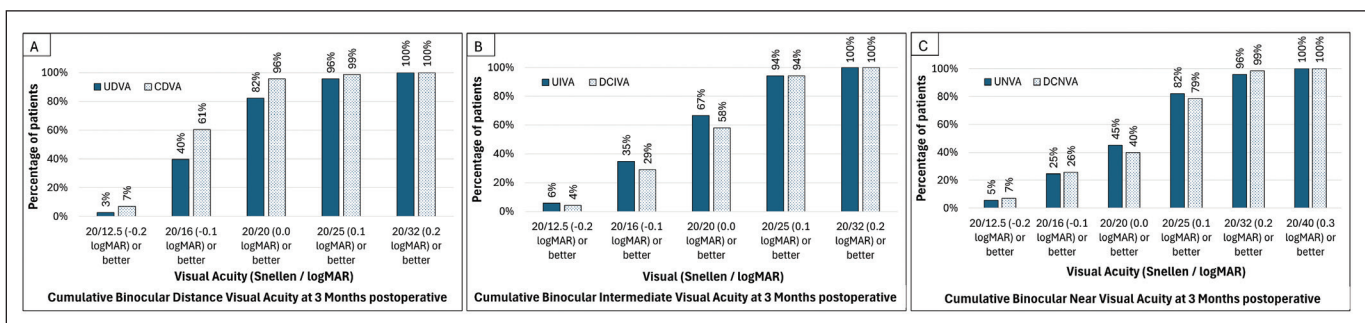
Diffraction optical design is commonly used in many multifocal and some EDOF IOLs to enhance visual quality and extend the range of vision following surgery. However, despite recent advancements, current diffractive optics can still result in reduced contrast, dysphopia, and suboptimal visual quality. The Galaxy IOL, featuring a refractive spiral design without diffractive elements, was designed to deliver a full range of vision while maintaining high visual quality.

This study is the first to evaluate the performance of the Galaxy IOLs through both preclinical and clinical testing, assessing the lens ability to provide a continuous full range of high-quality vision with minimal photic phenomena.

The clinical results demonstrated excellent monocular and binocular visual acuity at all distances. At 3 months postoperatively, binocular distance-corrected visual acuities (CDVA, DCIVA, and DCNVA) were con-



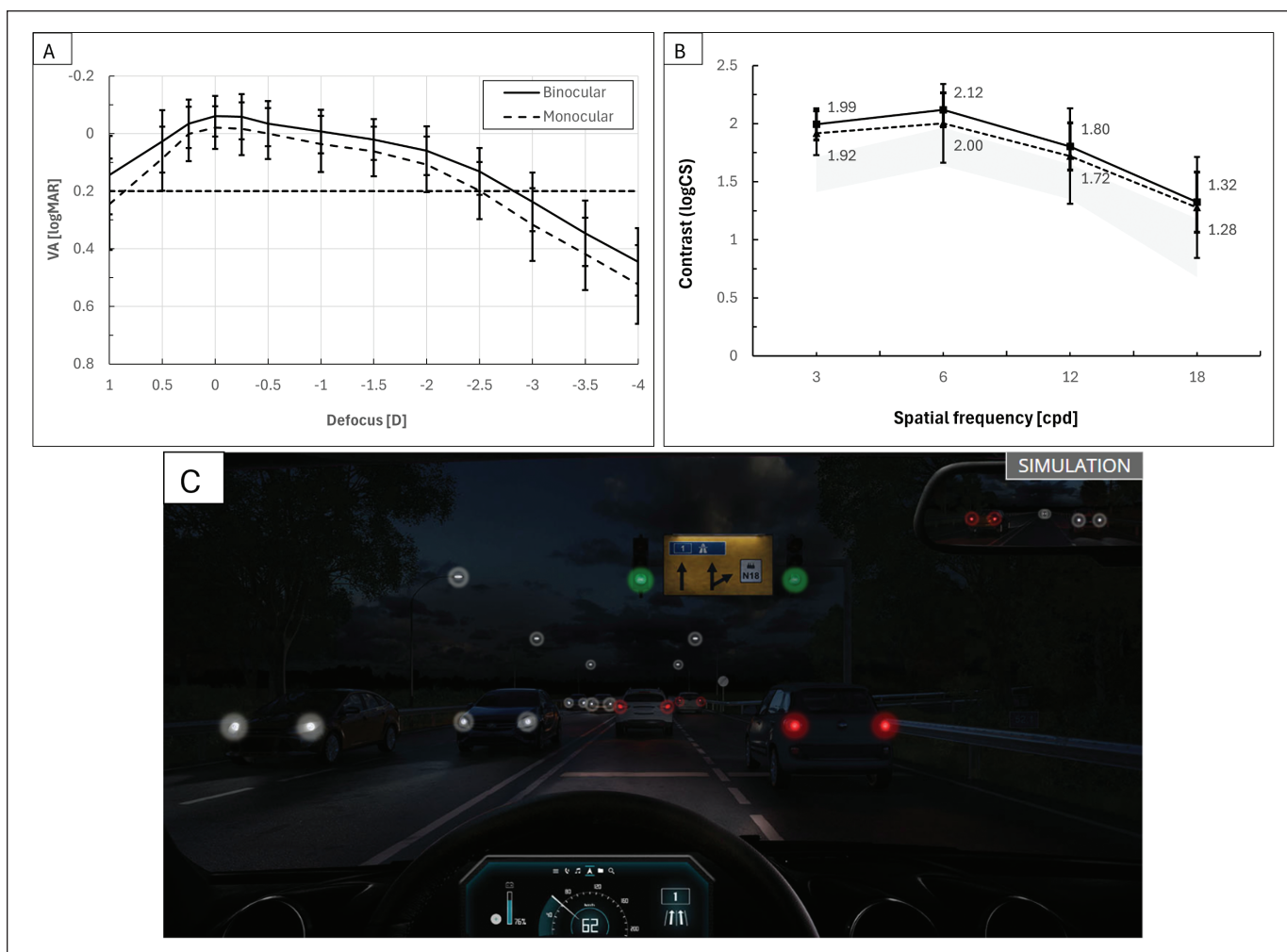
**Figure 3.** Results from the preclinical tests with RayOne Galaxy and RayOne Trifocal intraocular lenses (Rayner). (A) Visual acuity at far, intermediate, and near distances (in logarithm of the minimum angle of resolution [logMAR]). (B) Monocular distance-corrected defocus curve. (C) Contrast sensitivity at far, intermediate, and near distances. (D) Subjective preference test. Asterisks (\*) denote statistically significant differences ( $P < .05$ ). D = diopters; logCS = logarithm of contrast sensitivity



**Figure 4.** Cumulative binocular uncorrected and distance-corrected visual acuity at (A) distance, (B) intermediate, and (C) near, based on the clinical study at 3 months. DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; logMAR = logarithm of the minimum angle of resolution; UNVA = uncorrected near visual acuity; UDVA = uncorrected distance visual acuity

sistently 20/25 (0.1 logMAR) or better in 79% to 99% of patients across all tested distances, and 20/32 (0.2 logMAR) or better in 99% to 100% of patients. The mean monocular UDVA and CDVA were  $0.03 \pm 0.11$  and  $-0.03 \pm 0.08$  logMAR, respectively, whereas binocular values improved to  $-0.02 \pm 0.09$  and  $-0.06 \pm 0.07$  logMAR, respec-

tively. These outcomes closely align with visual outcomes reported for diffractive trifocal IOLs, where monocular UDVA ranges from -0.05 to 0.09 logMAR, as indicated in a recent Cochrane meta-analysis on diffractive trifocal IOLs.<sup>13</sup> Regarding intermediate and near visual acuities, the outcomes after Galaxy implantation were also com-



**Figure 5.** Additional metrics from the clinical study. (A) Monocular and binocular distance-corrected defocus curves at 3 months postoperative and (B) Contrast sensitivity under photopic and mesopic conditions at 3 months postoperative (C) Mean representation of patient-reported glare and halo symptoms at 3 months postoperative. cpd = cycles per degree; D = diopters; logCS = logarithm of contrast sensitivity; VA = visual acuity

parable to state-of-the-art trifocal technology, with mean monocular UIVA ( $0.05 \pm 0.11$  logMAR) and UNVA ( $0.09 \pm 0.13$  logMAR) consistent with reported values ranging between 0.06 and 0.45 logMAR for intermediate vision, and between 0.01 and 0.25 logMAR for near vision.<sup>13</sup>

The visual outcomes align with the recorded mean postoperative manifest refraction spherical equivalent of  $-0.23 \pm 0.31$  D. Despite a slight myopic landing, and prediction error of  $-0.17 \pm 0.31$  D, 63.2% of eyes achieved a manifest refraction spherical equivalent within  $\pm 0.25$  D, 86.8% within  $\pm 0.50$  D, and 99.3% within  $\pm 1.00$  D, aligning with current benchmarks standards for refractive outcomes,<sup>14</sup> and reported values with modern IOLs.<sup>10,15</sup> At the time of this evaluation, the initially suggested Barrett lens factor constant was used. However, during the preparation of this manuscript, the constants have been optimized and updated on IOLCon.org, which is expected to enhance the accuracy of the targeted postoperative refraction.

Optimized vision quality relies not only on acuity at specific distances but also on a continuous range of focus, minimizing gaps between focal points. Trifocal lenses with their distinct focal peaks improve vision at set distances but introduce defocus gaps between them.<sup>16,17</sup> In contrast, the Galaxy IOL features a refractive spiral configuration that produces a continuous and gradual variation in optical power, supporting light distribution along the defocus curve. This results in a continuous visual range of 20/32 (0.2 logMAR) or better over 4.00 D, extending down to approximately 35 cm ( $-2.80$  D) binocularly, and ensuring uninterrupted vision across all distances. Although the range of focus is similar to diffractive trifocal IOLs,<sup>10,15</sup> the Galaxy defocus curve showed no discontinuities, during intermediate tasks compared to IOLs with a discrete intermediate focal point.

A strength of this article is the inclusion of preclinical assessment through pseudophakic vision simulation



testing, allowing the same participant to compare multiple optical designs and experience the expected postoperative vision. Test participants showed a strong and significant preference for the Galaxy IOL over the diffractive Trifocal at far, intermediate, and near distances. This is likely attributable to the lens's continuous defocus profile, the reduced halos and glare, and improved contrast sensitivity.

Studies on trifocal diffractive IOLs show that achieving full-range focus often comes at the expense of visual quality, leading to reduced contrast sensitivity, halos, and glare.<sup>18-21</sup>

In our study, contrast sensitivity was assessed in preclinical evaluation, demonstrating an advantage for the Galaxy IOL over the diffractive Trifocal IOL, leading to a statistically significant difference at near (**Figure 3C**). Because both IOLs are made of the same hydrophilic acrylic material, the improved contrast sensitivity observed with the Galaxy IOL is most likely attributable to its non-diffractive optic design, which avoids splitting light and minimizes light loss.

Postoperative halos and glare in patients implanted with the Galaxy IOL were assessed in the clinical phase of the study using an established visual simulator. The findings demonstrated notably lower halo size (mean:  $31.8 \pm 22.5$ ) and intensity (mean:  $37.3 \pm 25.6$ ), compared to previous studies on diffractive trifocal IOLs using the same methodology. Kretz et al<sup>22</sup> reported halo size and intensity values of  $50.7 \pm 15.7$  and  $54.9 \pm 17.9$ , respectively, and Lwowski et al<sup>23</sup> scores of  $39.3 \pm 20.8$  and  $49.7 \pm 21.9$ , respectively, indicating a greater level of visual disturbances associated with diffractive IOLs. Similarly, the Galaxy IOL exhibited notably smaller glare size and intensity ( $9.11 \pm 17.58$  and  $9.95 \pm 16.83$ , respectively) compared to diffractive IOLs, with Kretz et al<sup>22</sup> reporting glare size and intensity of  $39.7 \pm 3.5$  and  $44.7 \pm 15.0$  and Lwowski et al<sup>23</sup> scores of  $10.1 \pm 14.5$  and  $21.7 \pm 24.8$ , respectively. The Galaxy IOL showed halo and glare scores in line with those reported for a non-diffractive EDOF IOL, which has been found to cause no bothersome night visual symptoms.<sup>11,24</sup> Given this similarity, comparable patient-reported outcomes may be expected with the Galaxy IOL.

The clinical findings were consistent with the RALV preclinical outcomes, where the Galaxy IOL exhibited significantly reduced halo and glare size compared to the diffractive Trifocal IOL. The absence of diffractive steps in the Galaxy IOL is likely a key factor in reducing postoperative dysphotopsia.

Additionally, these findings align with the preclinical subjective preference test, where a strong and statistically significant preference for the Galaxy over the Trifocal was demonstrated across all distances ( $P \leq .001$ ).

Limitations of the study include a relatively short follow-up period of 3 months, whereas some studies on traditional diffractive trifocal IOLs have suggested that complete neuroadaptation may take up to 6 months.<sup>25,26</sup> However, in our study, no statistically significant differences were observed in glare and halo perception between the 1-month and 3-month follow-up visits, indicating early stability in visual outcomes. Additionally, the clinical part of this study lacked a control group, limiting direct comparison between the novel spiral and existing technologies. Future comparative clinical studies, incorporating additional methods for assessing photic phenomena, will be valuable in further clarifying the potential benefits of the Galaxy IOL over traditional diffractive IOLs. Finally, a more in-depth evaluation of the toric variant of the lens would be beneficial, including vector analysis to accurately assess accuracy of astigmatic correction.

## CONCLUSION

The preclinical and clinical parts of the study consistently demonstrates that the Galaxy IOL provides excellent, uninterrupted full-range visual acuity. In preclinical testing, contrast sensitivity exceeded that of a diffractive trifocal IOL, presumably due to the non-diffractive design minimizing light distribution losses. Additionally, subjective preference was higher for the Galaxy over the Trifocal lens.

Preclinical testing indicates that photic phenomena were less intense compared to those associated with diffractive trifocal IOLs. Clinical outcomes further confirmed lower levels of halo and glare than previously reported in the literature, within thresholds considered non-bothersome perception levels.

## AUTHOR CONTRIBUTIONS

Study concept and design (CA-F, BB, FC, TBF, SM); data collection (CA-F, MA, GUA, BB, FC, DC, TBF, SM, AS, FL, AB); analysis and interpretation of data (CA-F, AB); writing the manuscript (CA-F, BB); critical revision of the manuscript (CA-F, MA, GUA, BB, FC, DC, TBF, SM, AS, FL, AB); supervision (CA-F, GUA)

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