XX-XXX-XXX (Commodity Number to be inserted)

PRODUCT INFORMATION

Beaver-Visitec International, Inc.

FINEVISION HP Trifocal Intraocular Lens

(POD F GF)

DESCRIPTION

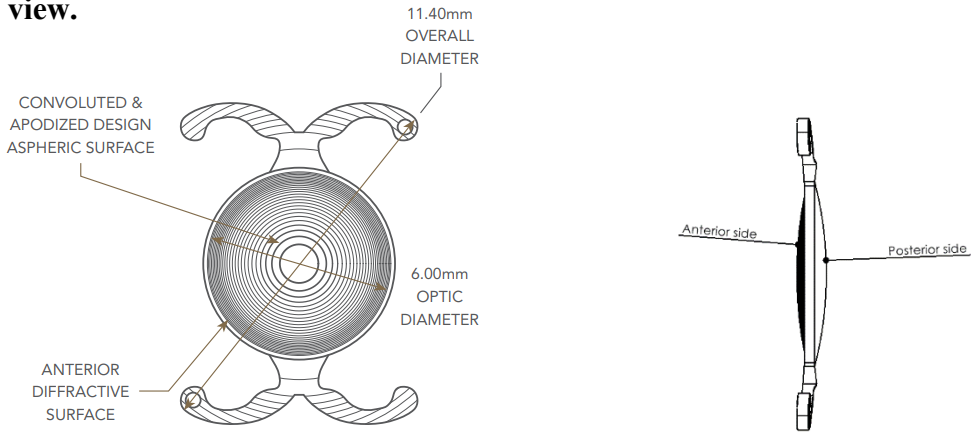
The FINEVISION HP Trifocal intraocular lens (IOL) is an ultraviolet absorbing and blue light filtering foldable multifocal IOL. Each IOL is a single-piece design with a central optic and 4 open-loop haptics (Double C-loop) (Figure 1). The optic consists of a proprietary high refractive index hydrophobic acrylic material with a UV absorbing filter (< 24% transmittance at 400 nm for a +20.0 D IOL) and a blue light filtering chromophore (< 64% at 450 nm for a +20.0 D IOL). The optic is biconvex and consists of a soft acrylic material capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. The optic is 6.0 mm in diameter and the lens has an overall diameter of 11.4 mm. After surgical insertion into the eye, the lens unfolds to its intended shape. The optic diffractive structure is convoluted and apodized on the entire front portion of the optic and divides the incoming light to create a +1.75 D intermediate and a +3.50 D near add power at the IOL plane. The anterior surface is designed with negative spherical aberration to partially compensate for the positive spherical aberration of the cornea. The physical properties of this lens are described in Table 1 and Figures 1, 2, and 3.

Table 1: Physical Characteristics of FINEVISION HP Trifocal IOLs

Physical Characteristic	Description
Optic type	Single-piece IOL with aspheric biconvex convoluted and apodized non-toric diffractive optic
UV cutoff at 24% T	400 nm for +20.0 D
Index of refraction	1.53
Spherical power	+6 D to +35 D (0.5D increments)

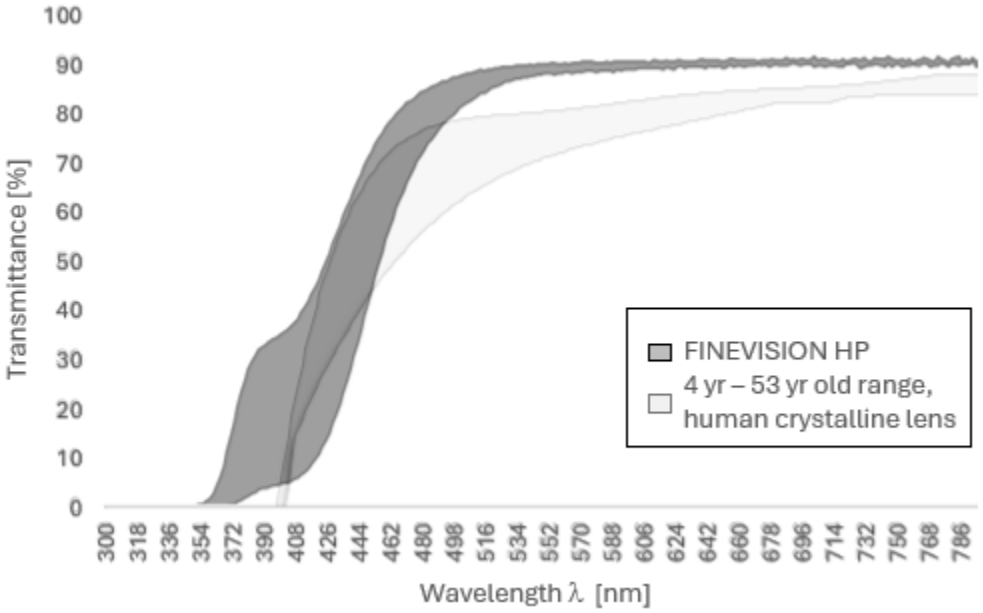
Add powers	+1.75D intermediate and +3.50D near add power at the IOL plane (representing +1.20 D and +2.40 D at the corneal plane after implantation, respectively, for the average human eye)
Haptic configuration	Double C-loop (POD) quadripode
Lens material	Ultraviolet light absorbing and blue light filtering Acrylate/Methacrylate Copolymer
Optic diameter	6.00mm
Overall diameter	11.40mm
Haptic angle	5°
Sterilization	Moist steam

Figure 1: Physical Characteristics of FINEVISION HP Trifocal IOL. (A) Front view. (B) Side view.



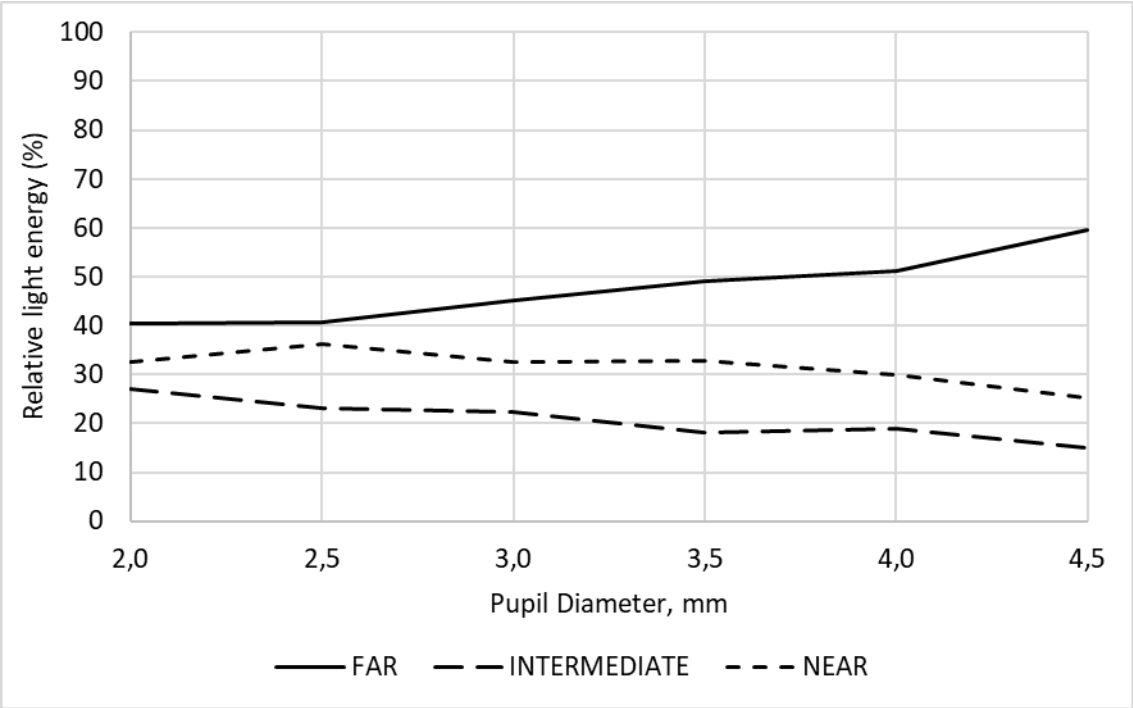
(A) Front view (B) Side view

Figure 2: Spectral Transmittance of FINEVISION HP for the entire marketed power range as well as data from human crystalline lenses of ages 4 to 53 years



Hammond, B. R., Jr., Renzi, L. M., Sachak, S., & Brint, S. F. (2010). Contralateral comparison of blue-filtering and non-blue-filtering intraocular lenses: glare disability, heterochromatic contrast, and photostress recovery. *Clinical Ophthalmology*, 4, 1465–1473.

Figure 3: Graph of theoretical light energy repartition between the 3 foci between 2.0- and 4.5-mm pupillary aperture by increments of 0.5mm at 546 nm



MODE OF ACTION

The FINEVISION HP trifocal IOL is intended to be positioned in the lens capsule in the posterior chamber of the eye, replacing the human crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. This IOL has a biconvex optic containing an aspheric design and a diffractive structure on the anterior surface. The diffractive structure divides incoming light to provide a range of vision from distance to intermediate to near. This IOL provides an option for clinicians to provide patients an intermediate add power of +1.75 D and a near add power of +3.50 D (in the IOL plane).

INDICATIONS

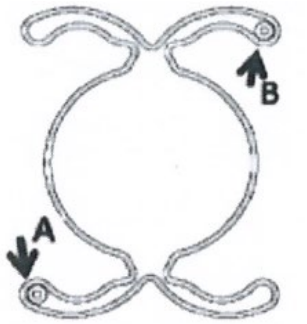
The FINEVISION HP trifocal intraocular lens is indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients who have less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed by phacoemulsification. The lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity compared to a monofocal IOL.

WARNINGS

- As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to, the following: Ocular infection (endophthalmitis, microbial keratitis), inflammatory reaction (e.g., uveitis, Toxic Anterior Segment Syndrome (TASS), hypopyon), anterior capsular contraction syndrome (phimosis), corneal edema, corneal endothelial damage, Cystoid Macular Edema (CME), secondary surgical intervention (including, but not limited to: lens repositioning, lens replacement, vitreous aspiration, iridectomy for pupillary block, wound leak repair, and retinal detachment repair), IOL dislocation, tilt, decentration, luxation, rotation, elevated intraocular pressure, pupillary block, Posterior Capsular Opacification (PCO), chromatic aberrations, dysphotopsia, loss of visual acuity, deviation from target refraction, hyphema, retinal detachment, iris or pupil damage, posterior capsular rupture, vitreous loss, wound leak (positive Seidel).
- Additional complications that may occur following implantation of a multifocal intraocular lens include: Objectionable visual quality under certain lighting conditions (e.g., chromatic aberrations, halos, night glare, decreased contrast), hazy/filmy images, "ghost" imaging of near and/or distant objects, diplopia and poor stereopsis. Some of these optical effects may be mitigated upon a patient's adaptation to the multifocal optic. However, some of the above listed complications may require secondary surgical intervention for intraocular lens exchange or explantation.
- Care should be taken to remove all viscoelastic from the eye prior to completing surgery.
- Rinse the intraocular lens with a sterile physiologic solution before loading it for implantation.

- This IOL is intended for implantation in the capsular bag only. There are no clinical data to demonstrate its safety and effectiveness for placement in the ciliary sulcus.
- The lens is to be implanted with the anterior side of the lens facing up towards the anterior side of the eye. The orientation of the IOL can be verified by visual inspection of the haptics. As illustrated in Figure 4, when the orientation haptic features are top right B and bottom left A, you are looking at the anterior side of the lens.

FIGURE 4: Anterior side of IOL



- No data is available for the combined use of any type of supplementary IOL in patients already implanted with FINEVISION HP IOL.
- No clinical safety and performance data is available for the device implanted in patients with congenital bilateral cataracts or with only one eye with potentially good vision or in pregnant or breast-feeding women. Therefore, the use of the device was not evaluated in these populations
- The physician should consider the following points that are unique to the diffractive multifocal platform:
    - It is recommended emmetropia be targeted for optimum visual performance.
    - Care should be taken to achieve lens centration, as lens decentration may result in a patient experiencing decreased visual quality under certain lighting conditions.
    - Prior to surgery, the surgeon must inform patients of the possible risks and benefits associated with the use of this device. The Patient Information Brochure can be found at ifu.bvimedical.com. Please provide a copy of the Patient Information Brochure to the patient.
    - When selecting a patient, the physician should consider that the central one millimeter area of the multifocal IOL creates a far image focus in accordance with the labelled power of the IOL, so patients with abnormally small pupils(<2 mm) should achieve the prescribed distance vision under photopic conditions. It is unclear whether such patients will derive any near vision benefit with abnormally small pupils.

- Autorefractors may not provide optimal postoperative refraction of multifocal patients, therefore manual refraction is strongly recommended.
- Recent contact lens usage may affect the patient's refraction. With contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power.
- Incorrect interpretation of the wavefront measurements is possible in a patient with a multifocal lens.
- As is the case for all multifocal IOLs with the light splitting into more than one focus, some patients may experience a reduction of contrast sensitivity compared to monofocal lenses (IOL) that may be more important in low lighting conditions and patients should exercise caution when driving at night or in poor visibility conditions.

- Some patients may experience some visual effects due to the superposition of focused and unfocused multiple images at different foci. These visual effects may be perceptions of halos and radial lines around point source of light under night-time conditions.
- Patients with significant preoperative (determined by keratometry) or expected postoperative astigmatism > 1.0D may not achieve optimal visual outcomes.
- Do not insert this lens without reading the specific instructions for use provided with the injector system. When the IOL injector is used improperly, the IOL may be damaged (e.g., the haptic may be broken.)

PRECAUTIONS

- Do not use an implant from a damaged package.
- The implant is SINGLE-USE ONLY: DO NOT RE-USE.
  - This product must only be used for one single patient to avoid any risk of cross-contamination. DO NOT RESTERILIZE.
  - If the implant is prepared for implanting but is not finally used or if the package is damaged, send the lens back to your supplier. Return the lens in a humid environment in its original package, indicating the serial number, the power and your reference.
- The protection package requires that the lens be used immediately when opened.
- To minimize marks on the lens due to folding, use clean instruments.
- Storage temperature range is 2–35°C.
- The lens may absorb substances with agents. Always rinse the implant in a sterile physiologic solution.
- Have a back-up IOL in the operating room, in case of damage to the initial FINEVISION IOL.
- A high level of surgical skill is required to perform intraocular lens implantation. Surgeons should have completed proper ophthalmic training where they assisted in numerous

implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.

- Do not use lenses past the expiration date.
- As with the implantation of any IOL, careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, and chronic pupil miosis may not achieve as good visual acuity compared to patients without these problems. The safety and effectiveness of FINEVISION HP IOL in patients with the conditions listed below have not been substantiated and alternative treatment should be considered:

- **Before Surgery**:
  - Chronic uveitis
  - Progressive eye disease (diabetic retinopathy, glaucoma)
  - Anterior or posterior segment inflammation of etiology
  - Extremely shallow anterior chamber
  - Patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases
  - A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible
  - Suspected microbial infection
  - Patients in whom neither the posterior capsule nor zonules are intact enough to provide support for the IOL
  - Congenital cataracts
  - Previous history of, or a predisposition to, retinal detachment
  - Patients with only one eye with potentially good vision
  - History or presence of, or predisposition to, degenerative visual disorders (e.g., macular degeneration, retinal detachment, proliferative diabetic retinopathy, or other retinal disorders) predicted to result in BCDVA worse than 0.2 LogMAR (20/32 Snellen)
  - Significant anterior segment pathology in either eye that might increase intraoperative risk or compromise IOL stability (e.g., pseudoexfoliation syndrome)
  - Presence of one or more clinically significant corneal abnormalities, including corneal dystrophy, irregularity, or edema
  - Previous intraocular, corneal, or retinal detachment surgery, including corneal transplant, LASIK, astigmatic keratotomy and limbal relaxing incisions in either eye
  - Rubella, congenital, traumatic or complicated cataract

- Severe dry eye

- **During Surgery**
  - Significant vitreous loss
  - Persistent bleeding
  - Significant iris damage
  - Uncontrolled positive intraocular pressure
  - Circumstance that would result in damage to the endothelium during implantation
  - Capsular rupture or capsulorhexis tear
  - Intraoperative complications during the phacoemulsification and IOL implant that require any other additional procedures or further intervention.
  - Significant detachment of Descemet's membrane
  - Significant corneal endothelial damage
  - Wound burn
  - Capsular tear, iris incarceration or damage, posterior capsular rupture, vitreous loss or prolapse, or zonular weakness, dehiscence or rupture
  - Excessive iris mobility or need for iris manipulation
  - Mechanical or surgical manipulation required to enlarge the pupil prior to or at IOL implantation
  - Other ocular conditions or complications that could compromise IOL stability
  - Bag sulcus, sulcus-sulcus or unknown placement of haptics
  - Any method of anterior capsulotomy other than circular continuous capsulorhexis (e.g., anterior capsular tears or any areas of 'can-opener' capsulotomy or FLACS)
  - Capsular fibrosis or other opacity
  - Optic and/or haptic damage/amputation
  - Inability to fixate IOL in desired position

CALCULATION OF LENS POWER

Accurate biometry is essential for successful visual outcomes. Preoperative calculation of required lens power for the FINEVISION HP Trifocal IOLs should be determined by the surgeon's experience and preference. A reference SRK/T (119.5) A-Constant value for optical biometry equipment is listed on the outer label. This reference A-Constant anticipates the use of both corneal power and axial length values from optical biometry equipment with standard settings for a typical patient population and a spectacle far point at 6 meters. IOL power calculation methods are often included with biometry equipment, and they are described in the references below.

In general, lens constants must be "personalized" to compensate for such things as differences in instrumentation, surgical techniques, and IOL power calculation that may exist between clinical practices. Physicians requiring additional information on lens power calculation may contact a local Beaver-Visitec International, Inc. representative.

Lens power calculation methods are described in the following references:

- Barrett, Graham D. F.R.A.C.O., F.R.A.C.S.a. An improved universal theoretical formula for intraocular lens power prediction. Journal of Cataract & Refractive Surgery 19(6):p 713-720, November 1993. | DOI: 10.1016/S0886-3350(13)80339-2
- Canovas C, Artal P. Customized eye models for determining optimized intraocular lenses power. Biomed Opt Express. 2011 Jun 1;2(6):1649-62.
- Shammas, H. J. (2004). Intraocular Lens Power Calculations. Thorofare, NJ: SLACK Incorporated
- Hoffer, Kenneth J. M.D.a. The Hoffer Q formula: A comparison of theoretic and regression formulas. Journal of Cataract & Refractive Surgery 19(6):p 700-712, November 1993.
- Holladay, Jack T. M.D.*; Musgrove, Kathryn H. M.D.; Prager, Thomas C. Ph.D.; Lewis, John W. M.D.; Chandler, Thomas Y. M.D.; Ruiz, Richard S. M.D.. A three-part system for refining intraocular lens power calculations. Journal of Cataract & Refractive Surgery 14(1):p 17-24, January 1988.
- Holladay, Jack T. MD, MSEEa. Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations. Journal of Cataract & Refractive Surgery 23(9):p 1356-1370, November 1997.
- Norrby, Sverker N.E. PHD. Unfortunate Discrepancies. Journal of Cataract & Refractive Surgery 24(4):p 433, April 1998.
- Retzlaff, John A., Sanders, Donald R., Kraff, Manus C. Development of the SRK/T intraocular lens implant power calculation formula. Journal of Cataract & Refractive Surgery 16(3):p 333-340, May 1990.

DIRECTIONS FOR USE

1. Examine the unopened IOL box for proper model, power, and expiration date. Check if the information on the carton box label is consistent with the information present on the secondary blister and self-adhesive labels (e.g. model, power and serial number).
2. Remove the sterilized secondary blister containing the IOL container, peel the secondary blister, open and place the IOL container in a sterile environment. Check to ensure there are no leaks.
3. Open the container and carefully remove the lens holder from the sterile storage solution. Keep the holder horizontal to prevent the IOL from slipping out. Two retaining clips on the holder secure the IOL in place. Handle the holder gently and avoid using excessive

force when removing the IOL. If necessary, bend the holder slightly backwards to facilitate the release of the IOL from the retaining clips.

4. The IOL can dry when exposed to air for too long. Therefore, the IOL should be loaded and injected without delay after removal from packaging and holder. OVD can also accelerate IOL drying and make it stiffer if it stays in contact for too long with IOL before injection.
5. All manipulations required for implantation must be performed using non-toothed forceps and polished instruments, especially when the IOL is folded prior to insertion.
6. The lens must be rinsed with BSS (Balanced Salt Solution) before implantation.
7. BVI recommends using approved Accuject 2.1 (Medicel) delivery system in combination with hyaluronate-based OVD for IOL injection:

Application instructions for the single-use IOL injector Accuject 2.1 (Medicel)

a. Open the blister in a sterile environment and remove the sterile injector.

b. Hold the injector so that the rear wing of the loading chamber can be guided with the index finger of your left hand.

c. Fill the conical tip with ophthalmic viscosurgical devices (OVD). Then apply two thin lines into the lateral grooves within the loading chamber.

- *It is recommended to flush the cartridge tip and the loading chamber with Balanced Salt Solution (BSS) before the application of OVD.*
- *Allow the OVD to react (30s). OVD can lose their lubricating properties if they are in contact with air for too long. Therefore, the IOL should be injected without delay after loading.*
- *Hydrophobic IOL types: The application of OVD is required. The exclusive use of BSS is not permitted.*
- *In addition, apply a drop of OVD to the silicone cushion.*

d. Open the loading chamber so that the IOL can be easily loaded. Position the IOL in the middle of the loading chamber with a concave orientation.

e. Use the sterile forceps to apply slight pressure to the IOL optics, this ensures that the IOL folds in a concave direction. Make sure that all haptics are inside the loading chamber under the grooves before further closing it.

f. At the same time, close the wings of the loading chamber until the „Click-Lock" mechanism engages.

g. Damaged or broken haptic can occur when the IOL injector is used improperly. To mitigate the risk of IOL damage:

- *Check that haptics are not trapped in the closing elements of the loading chamber, which could lead to haptics damage after the IOL is loaded and the loading chamber closed.*
- *Check that the IOL is moving freely, by exerting a gentle pressure forward onto the plunger.*
  NB: If the silicone cushion is tilted and cannot be inserted into the closed loading chamber, the silicone cushion can be aligned with the forceps.

h. Push the injector plunger forward until the silicone cushion reaches the front end of the injector housing. Pull back the injector plunger a few millimetres and then push it forward again. This step ensures that the IOL is always gripped correctly and not trapped by the blue cushion. The IOL is now loaded and ready for injection.

i. Slowly inject the IOL into the eye by applying pressure to the injector plunger.

j. The correct exit of the IOL can be supported by turning the injector slightly. Only push the injector plunger forward until the IOL has emerged completely.

k. If necessary, assist the IOL with the help of a suitable positioning hook during the exit and bring the IOL into its final position.

l. Thoroughly remove the viscoelastic material from the eye and IOL using standard irrigation and aspiration techniques.

8. Care should be taken to achieve lens centration, as lens decentration may result in a patient experiencing decreased visual quality under certain lighting conditions.
9. Dispose of the injector after use in accordance with applicable regulations regarding the disposal of biohazardous materials.
10. After IOL implantation, carefully eliminate any viscoelastic residues from the bag by aspiration, especially between the IOL and the posterior capsule.

PATIENT CARD

Complete the implant identification card included in the package and give it to the patient, with instructions to keep the card and show it to their eye care practitioners.

REPORTING

Events that reasonably suggest that the lens may have caused or contributed to death or serious injury, including events occurring as a result of failure of a medical device to meet its performance specifications or otherwise perform as intended, should be reported to Beaver Visitec International, Inc. This information is being requested from all surgeons to document potential long-term effects of intraocular lens implantation.

Use the following web site for reporting adverse events and complaints involving these intraocular lenses:

URL: https://www.bvimedical.com/contact-complaint/

CLINICAL STUDY RESULTS FOR FINEVISION HP TRIFOCAL IOL STUDY

Summary of Clinical Study

The clinical study was a prospective, multicenter, randomized, active controlled, vision assessor-masked pivotal study and was designed for bilateral implantation of 501 subjects in total, with either the investigational FINEVISION HP Trifocal IOL or the FDA approved AcrySof® monofocal IOL Model SN60AT (referred to as the Monofocal IOL below) in a ratio of 2:1 at 20 investigational sites in the United States. The subjects were followed up for 1 year post-operatively.

The purpose of this clinical study was to compare the monocular distance-corrected visual acuities of the FINEVISION HP Trifocal IOL against those of a monofocal lens, the AcrySof® Monofocal IOL Model SN60AT, in order to demonstrate comparable distance visual acuity and superior near and intermediate visual acuities.

All eyes with successful IOL implantation and at least one post-operative visit were considered evaluable for the All Implanted analyses Set (AAS). All eyes successfully implanted that had at least one postoperative visit and had no preoperative ocular pathology or macular degeneration at any time, and no major protocol deviations, were evaluable for Best Case analyses. The Best-Case data set was the primary data set for contrast sensitivity and defocus curve analyses. All randomized subjects (eyes) were included in the Intent-to-Treat (ITT) Set. All subjects with at least one eye implanted with a study lens were included in the Safety Analysis Set.

Clinical Study Results

The co-primary effectiveness objectives were to demonstrate statistical non-inferiority in mean photopic monocular Best Corrected Distance Visual Acuity (BCDVA) (non-inferiority margin of 0.10 logMAR) and to demonstrate statistical superiority of mean photopic monocular Distance Corrected Near Visual Acuity (DCNVA) for the first operative eyes at Month 6. Non-inferiority of FINEVISION HP IOL to Monofocal IOL was demonstrated as the 90% upper confidence limit of the difference of the means (0.059 logMAR) was less than the margin of 0.10 logMAR. The second co-primary effectiveness objective was also met because results demonstrated a statistically significant difference in population means for DCNVA of 0.39 logMAR in favor of FINEVISION HP IOL. The secondary effectiveness objective was to demonstrate statistical superiority of mean photopic monocular Distance Corrected Intermediate Visual Acuity (DCIVA) at 66 cm for first operative eyes at Month 6. A statistically significant difference in population means for DCIVA of 0.18 logMAR was observed in favor of FINEVISION HP IOL. The results were consistent between AAS and ITT Sets.

The first co-primary safety objective was to estimate the cumulative rate of secondary surgical interventions (SSIs) related to the optical properties of the IOL for the first operative eyes up to Month 12 (Visit 5). The non-inferiority of FINEVISION HP IOL to Monofocal IOL was demonstrated as the 90% upper confidence limit of the difference in the percentages (1.36%) was less than the non-inferiority margin of 1.4%. The second co-primary safety objective was to evaluate the mean monocular contrast sensitivity for the first operative eyes, with and without glare for photopic and mesopic conditions at Month 12 (Visit 5). The Best-case Set was used for analysis. In all testing conditions, contrast sensitivity was slightly better for the monofocal IOL group than the FINEVISION HP IOL group, however, the difference in means was not clinically significant.

The first secondary safety objective was to estimate rates of cumulative and persistent adverse events in first operative eyes at Month 12 in comparison to the ISO Safety and Performance Endpoint (SPE) rates as described in ISO 11979-7. Observed rates from the study for both FINEVISION HP IOL and AcrySof SN60AT IOL were compared to SPE rates from the ISO and were found in no cases to be statistically greater than acceptable rates defined by ISO 11979-7.

Another secondary safety objective was to estimate rates of visual disturbances using the Quality of Vision (QoV) questionnaire and QoV Supplemental Questions at Month 12 (Visit 5).. Most visual symptoms—such as glare, hazy or blurred vision, image distortion, double or multiple images, trouble focusing, difficulty judging distance or depth, and vision fluctuations—occurred at similar or slightly lower rates in the FINEVISION HP IOL group compared to the control group. However, two symptoms—starbursts and halos—were reported more frequently by participants with the FINEVISION HP lens than those with the monofocal control lens.

Outcomes of the QoV Supplemental Questions at Month 12 overall showed that subjects favored the trifocal IOL for near vision and slightly favored the monofocal IOL for distance vision. Perceived trouble with night driving was lower in the monofocal IOL group by a moderate margin, and trouble with color disturbances was comparable between the study groups. A larger proportion of participants reported they would have this device implanted again in the FINEVISION HP group as compared to the control group.

Subject Population

A total of 496 subjects were implanted in this clinical study with 332 subjects receiving the FINEVISION HP IOL and 164 subjects receiving the control Monofocal IOL.

The mean (± SD) age for the study population was 67.3 ± 7.21 years with 63.1% females. Stratifying by race, the proportions were 89.1% White, 6.0% Black or African American, 3.2 % Asian, 0.4% % Native Hawaiian or Other Pacific Islander, 0.2% American Indian or Alaska Native, and 1.0 % designated "Other". Ethnicity of the study population was reported as 6.9% Hispanic or Latino. The Best-Case cohort consisted of 312 FINEVISION HP IOL subjects and 152 Monofocal IOL subjects.

Visual Acuity

Visual Acuity was assessed using a computerized test system (CTS, M&S Technologies, Niles, IL, USA). **Table 2** summarizes the monocular visual acuity (VA) endpoint analyses.

The clinical study results demonstrate that the FINEVISION HP IOL is non-inferior to the Monofocal IOL in terms of distance visual acuity and superior in terms of near and intermediate visual acuities.

Table 2: Comparison of Photopic Monocular Distance Corrected Visual Acuity (logMAR) in First operative eyes, Intent-to-Treat Set, Primary imputation at Visit 4 (Day 150-180)

		FINEVISION HP (N=332)	AcrySof SN60T (N=164)
BCDVA 4 m	Mean (SE)[1]	0.018 (0.0050)	-0.028 (0.0065)
	Mean Difference (SE)[1]	0.046 (0.0084)	
	90% CI for Mean Difference[1]	(0.0317, 0.0593)	

	p-value[1]	<0.0001	
DCIVA 66 cm	Mean (SE)[1]	0.161 (0.0062)	0.342 (0.0102)
	Mean Difference (SE)[1]	-0.182 (0.0114)	
	95% CI for Mean Difference[1]	(-0.2040, -0.1591)	
	p-value[1]	<0.0001	
DCNVA 40 cm	Mean (SE)[1]	0.162 (0.0076)	0.550 (0.0110)
	Mean Difference (SE)[1]	-0.388 (0.0132)	
	95% CI for Mean Difference[1]	(-0.4137, -0.3618)	
	p-value[1]	<0.0001	

BCDVA = Best Corrected Distance Visual Acuity; DCNVA=Distance Corrected Near Visual Acuity; DCIVA= Distance corrected Intermediate Visual Acuity; CI = Confidence Interval; logMAR = Logarithm of the Minimum Angle of Resolution; SE = Standard Error.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed.

[1] Difference is computed as FINEVISION HP minus AcrySof SN60AT. Combined inference statistics are from multiple imputation methodology. Each imputed dataset is analyzed using a two-sample t-test.

Tables 3 and **4** provide details on the percentage of subjects achieving a Photopic Monocular BCDVA of 0.30 logMAR or better by visit for the first operative eyes.

Tables 5 to 10 provide descriptive statistics on photopic monocular visual acuity (BCDVA, UCDVA, DCIVA (66 cm), UCIVA (66 cm), DCNVA, and UCNVA.

Tables 11 to 16 provide descriptive statistics on photopic binocular visual acuity (BCDVA, UCDVA, DCIVA (66 cm), UCIVA (66 cm), DCNVA, and UCNVA.

Table 3: Percentage of Subjects Achieving a Photopic Monocular BCDVA of 0.30 logMAR or Better by Visit – All-Implanted Analysis Set – First Operative Eyes

			FINEVISION HP (N=332)		**AcrySof® SN60AT (N=164)**
Visit	**SPE Rate (%) [1]**	**m**	**n (%)**	**m**	**n (%)**
Visit 4 (Day 150 to 180)	92.5	320	319 (99.7)	159	159 (100.0)
Visit 5 (Day 360 to 420)	92.5	314	311 (99.0)	159	159 (100.0)

Abbreviations: BCDVA= Best Corrected Distance Visual Acuity; logMAR= Logarithm of the Minimum Angle of Resolution; SPE = Safety and Performance Endpoints for posterior chamber IOL from ISO 11979-7:2018; n = number of unique eyes meeting the criterion for each respective treatment group and visit; m= the number of eyes for each respective treatment group and visit with non-missing data for the population being analyzed. Percentages are based on "m".
[1] The SPE rate is from Table E.3 (Overall post-operative BCVA 0,3 logMAR or better) of ISO 11979-7:2018(E).

Table 4: Percentage of Subjects Achieving a Photopic Monocular BCDVA of 0.30 logMAR or Better by Visit – Best Case Set – First Operative Eyes

			FINEVISION HP (N=312)		AcrySof® SN60AT (N=152)
Visit	**SPE Rate (%) [1]**	**m**	**n (%)**	**m**	**n (%)**
Visit 4 (Day 150 to 180)	96.7	303	302 (99.7)	148	148 (100.0)
Visit 5 (Day 360 to 420)	96.7	296	293 (99.0)	147	147 (100.0)
Abbreviations: BCDVA= Best Corrected Distance Visual Acuity; logMAR= Logarithm of the Minimum Angle of Resolution; SPE = Safety and Performance Endpoints for posterior chamber IOL from ISO 11979-7:2018; n = Number of unique eyes meeting the criterion for each respective treatment group and visit; m= Number of eyes (m) for each respective treatment group and visit with non-missing data for the population being analyzed. Percentages are based on "m". [1] The SPE rate is from Table E.3 (Overall post-operative BCVA 0,3 logMAR or better) of ISO 11979-7:2018(E).					

Table 5: Photopic Monocular logMAR BCDVA at Month 6 (Visit 4) - All-Implanted Analysis Set – First Operative Eyes

Visit Category	**FINEVISION HP (N=332) n (%)**	**AcrySof® SN60AT (N=164) n (%)**
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	320	159
0.00 logMAR or Better	166 (51.9)	112 (70.4)
0.10 logMAR or Better	280 (87.5)	152 (95.6)
0.20 logMAR or Better	310 (96.9)	157 (98.7)
0.30 logMAR or Better	319 (99.7)	159 (100.0)
Worse than 0.30 logMAR	1 (0.3)	0
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
m	320	159
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	230 (71.9)	140 (88.1)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	296 (92.5)	155 (97.5)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	315 (98.4)	158 (99.4)

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
20/40^{-2} or Better (≤ 0.34 logMAR)	320 (100.0)	159 (100.0)
Worse than 20/40^{-2} (> 0.34 logMAR)	0	0
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	320	159
Mean (SD)	0.017 (0.0897)	-0.028 (0.0832)
Median	0.000	-0.020
Min, Max	-0.18, 0.34	-0.22, 0.26

Abbreviations: BCDVA = Best Corrected Distance Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 6. Photopic Monocular logMAR UCDVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	73 (22.6)	65 (40.6)
0.10 logMAR or Better	190 (58.8)	115 (71.9)
0.20 logMAR or Better	262 (81.1)	141 (88.1)
0.30 logMAR or Better	303 (93.8)	153 (95.6)
Worse than 0.30 logMAR	20 (6.2)	7 (4.4)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	115 (35.6)	89 (55.6)
20/25^{-2} or Better (≤ 0.14 logMAR)	223 (69.0)	134 (83.8)
20/32^{-2} or Better (≤ 0.24 logMAR)	284 (87.9)	149 (93.1)
20/40^{-2} or Better (≤ 0.34 logMAR)	309 (95.7)	153 (95.6)
Worse than 20/40^{-2} (> 0.34 logMAR)	14 (4.3)	7 (4.4)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.107 (0.1255)	0.056 (0.1339)
Median	0.100	0.040
Min, Max	-0.18, 0.64	-0.24, 0.62

Abbreviations: UCDVA = Uncorrected Distance Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 7: Photopic Monocular logMAR DCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	20 (6.2)	2 (1.3)
0.10 logMAR or Better	120 (37.2)	3 (1.9)
0.20 logMAR or Better	241 (74.6)	27 (16.9)
0.30 logMAR or Better	289 (89.5)	69 (43.1)
Worse than 0.30 logMAR	34 (10.5)	91 (56.9)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	55 (17.0)	2 (1.3)
20/25^{-2} or Better (≤ 0.14 logMAR)	162 (50.2)	9 (5.6)
20/32^{-2} or Better (≤ 0.24 logMAR)	271 (83.9)	42 (26.3)
20/40^{-2} or Better (≤ 0.34 logMAR)	298 (92.3)	87 (54.4)
Worse than 20/40^{-2} (> 0.34 logMAR)	25 (7.7)	73 (45.6)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.160 (0.1127)	0.343 (0.1291)
Median	0.140	0.330
Min, Max	-0.08, 0.68	-0.10, 0.62

Abbreviations: DCIVA = Distance Corrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 8. Photopic Monocular logMAR UCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	26 (8.0)	8 (5.0)
0.10 logMAR or Better	145 (44.9)	22 (13.8)
0.20 logMAR or Better	248 (76.8)	55 (34.4)
0.30 logMAR or Better	298 (92.3)	105 (65.6)
Worse than 0.30 logMAR	25 (7.7)	55 (34.4)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	74 (22.9)	12 (7.5)
20/25^{-2} or Better (≤ 0.14 logMAR)	191 (59.1)	36 (22.5)
20/32^{-2} or Better (≤ 0.24 logMAR)	279 (86.4)	74 (46.3)
20/40^{-2} or Better (≤ 0.34 logMAR)	305 (94.4)	122 (76.3)
Worse than 20/40^{-2} (> 0.34 logMAR)	18 (5.6)	38 (23.8)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.144 (0.1111)	0.264 (0.1440)
Median	0.120	0.270
Min, Max	-0.08, 0.54	-0.08, 0.68

Abbreviations: UCIVA = Uncorrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 9: Photopic Monocular logMAR DCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	43 (13.3)	0
0.10 logMAR or Better	133 (41.2)	0
0.20 logMAR or Better	217 (67.2)	0
0.30 logMAR or Better	280 (86.7)	3 (1.9)
Worse than 0.30 logMAR	43 (13.3)	157 (98.1)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	70 (21.7)	0
20/25^{-2} or Better (≤ 0.14 logMAR)	166 (51.4)	0
20/32^{-2} or Better (≤ 0.24 logMAR)	248 (76.8)	1 (0.6)
20/40^{-2} or Better (≤ 0.34 logMAR)	297 (92.0)	11 (6.9)
Worse than 20/40^{-2} (> 0.34 logMAR)	26 (8.0)	149 (93.1)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.159 (0.1376)	0.551 (0.1413)
Median	0.140	0.530
Min, Max	-0.16, 0.70	0.24, 1.00

Abbreviations: DCNVA = Distance Corrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 10. Photopic Monocular logMAR UCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	23 (7.1)	0
0.10 logMAR or Better	95 (29.4)	1 (0.6)
0.20 logMAR or Better	201 (62.2)	8 (5.0)
0.30 logMAR or Better	273 (84.5)	20 (12.5)
Worse than 0.30 logMAR	50 (15.5)	140 (87.5)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	44 (13.6)	0
20/25^{-2} or Better (≤ 0.14 logMAR)	145 (44.9)	2 (1.3)
20/32^{-2} or Better (≤ 0.24 logMAR)	238 (73.7)	10 (6.3)
20/40^{-2} or Better (≤ 0.34 logMAR)	288 (89.2)	29 (18.1)
Worse than 20/40^{-2} (> 0.34 logMAR)	35 (10.8)	131 (81.9)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.186 (0.1342)	0.494 (0.1622)
Median	0.160	0.500
Min, Max	-0.12, 0.60	0.10, 0.90

Abbreviations: UCNVA = Uncorrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 11. Photopic Binocular logMAR BCDVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	248 (76.8)	145 (90.6)
0.10 logMAR or Better	308 (95.4)	158 (98.8)
0.20 logMAR or Better	322 (99.7)	160 (100.0)
0.30 logMAR or Better	323 (100.0)	160 (100.0)
Worse than 0.30 logMAR	0	0
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	284 (87.9)	153 (95.6)
20/25^{-2} or Better (≤ 0.14 logMAR)	315 (97.5)	159 (99.4)
20/32^{-2} or Better (≤ 0.24 logMAR)	323 (100.0)	160 (100.0)
20/40^{-2} or Better (≤ 0.34 logMAR)	323 (100.0)	160 (100.0)
Worse than 20/40^{-2} (> 0.34 logMAR)	0	0
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	-0.032 (0.0757)	-0.077 (0.0705)
Median	-0.040	-0.090
Min, Max	-0.20, 0.22	-0.26, 0.20

Abbreviations: BCDVA = Best Corrected Distance Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 12. Photopic Binocular logMAR UCDVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	160 (49.5)	114 (71.3)
0.10 logMAR or Better	274 (84.8)	148 (92.5)
0.20 logMAR or Better	312 (96.6)	154 (96.3)
0.30 logMAR or Better	322 (99.7)	159 (99.4)
Worse than 0.30 logMAR	1 (0.3)	1 (0.6)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	214 (66.3)	135 (84.4)
20/25^{-2} or Better (≤ 0.14 logMAR)	297 (92.0)	152 (95.0)
20/32^{-2} or Better (≤ 0.24 logMAR)	318 (98.5)	154 (96.3)
20/40^{-2} or Better (≤ 0.34 logMAR)	322 (99.7)	160 (100.0)
Worse than 20/40^{-2} (> 0.34 logMAR)	1 (0.3)	0
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.022 (0.0950)	-0.022 (0.1005)
Median	0.020	-0.020
Min, Max	-0.20, 0.50	-0.26, 0.32

Abbreviations: UCDVA = Uncorrected Distance Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed

Table 13. Photopic Binocular logMAR DCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	72 (22.3)	2 (1.3)
0.10 logMAR or Better	237 (73.4)	17 (10.6)
0.20 logMAR or Better	295 (91.3)	70 (43.8)
0.30 logMAR or Better	318 (98.5)	124 (77.5)
Worse than 0.30 logMAR	5 (1.5)	36 (22.5)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	144 (44.6)	4 (2.5)
20/25^{-2} or Better (≤ 0.14 logMAR)	268 (83.0)	38 (23.8)
20/32^{-2} or Better (≤ 0.24 logMAR)	305 (94.4)	90 (56.3)
20/40^{-2} or Better (≤ 0.34 logMAR)	320 (99.1)	134 (83.8)
Worse than 20/40^{-2} (> 0.34 logMAR)	3 (0.9)	26 (16.3)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.077 (0.0886)	0.241 (0.1130)
Median	0.060	0.240
Min, Max	-0.16, 0.40	-0.12, 0.56

Abbreviations: DCIVA = Distance Corrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 14. Photopic Binocular logMAR UCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	106 (32.8)	20 (12.5)
0.10 logMAR or Better	255 (78.9)	54 (33.8)
0.20 logMAR or Better	304 (94.1)	111 (69.4)
0.30 logMAR or Better	319 (98.8)	143 (89.4)
Worse than 0.30 logMAR	4 (1.2)	17 (10.6)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	188 (58.2)	32 (20.0)
20/25^{-2} or Better (≤ 0.14 logMAR)	288 (89.2)	76 (47.5)
20/32^{-2} or Better (≤ 0.24 logMAR)	314 (97.2)	125 (78.1)
20/40^{-2} or Better (≤ 0.34 logMAR)	321 (99.4)	147 (91.9)
Worse than 20/40^{-2} (> 0.34 logMAR)	2 (0.6)	13 (8.1)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.054 (0.0859)	0.164 (0.1326)
Median	0.040	0.160
Min, Max	-0.18, 0.42	-0.16, 0.62

Abbreviations: UCIVA = Uncorrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 15. Photopic Binocular logMAR DCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	80 (24.8)	0
0.10 logMAR or Better	199 (61.6)	0
0.20 logMAR or Better	276 (85.4)	4 (2.5)
0.30 logMAR or Better	305 (94.4)	21 (13.1)
Worse than 0.30 logMAR	18 (5.6)	139 (86.9)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	113 (35.0)	0
20/25^{-2} or Better (≤ 0.14 logMAR)	242 (74.9)	0
20/32^{-2} or Better (≤ 0.24 logMAR)	292 (90.4)	7 (4.4)
20/40^{-2} or Better (≤ 0.34 logMAR)	310 (96.0)	38 (23.8)
Worse than 20/40^{-2} (> 0.34 logMAR)	13 (4.0)	122 (76.3)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.099 (0.1421)	0.446 (0.1302)
Median	0.100	0.420
Min, Max	-0.16, 1.10	0.16, 0.80

Abbreviations: DCNVA = Distance Corrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 16. Photopic Binocular logMAR UCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
m	323	160
0.00 logMAR or Better	47 (14.6)	0
0.10 logMAR or Better	175 (54.2)	4 (2.5)
0.20 logMAR or Better	280 (86.7)	21 (13.1)
0.30 logMAR or Better	307 (95.0)	50 (31.3)
Worse than 0.30 logMAR	16 (5.0)	110 (68.8)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		

Visit Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
m	323	160
20/20^{-2} or Better (≤ 0.04 logMAR)	85 (26.3)	0
20/25^{-2} or Better (≤ 0.14 logMAR)	226 (70.0)	11 (6.9)
20/32^{-2} or Better (≤ 0.24 logMAR)	293 (90.7)	34 (21.3)
20/40^{-2} or Better (≤ 0.34 logMAR)	314 (97.2)	68 (42.5)
Worse than 20/40^{-2} (> 0.34 logMAR)	9 (2.8)	92 (57.5)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.111 (0.1075)	0.383 (0.1566)
Median	0.100	0.380
Min, Max	-0.16, 0.46	0.06, 1.10

Abbreviations: UCNVA = Uncorrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (m) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Defocus Curves

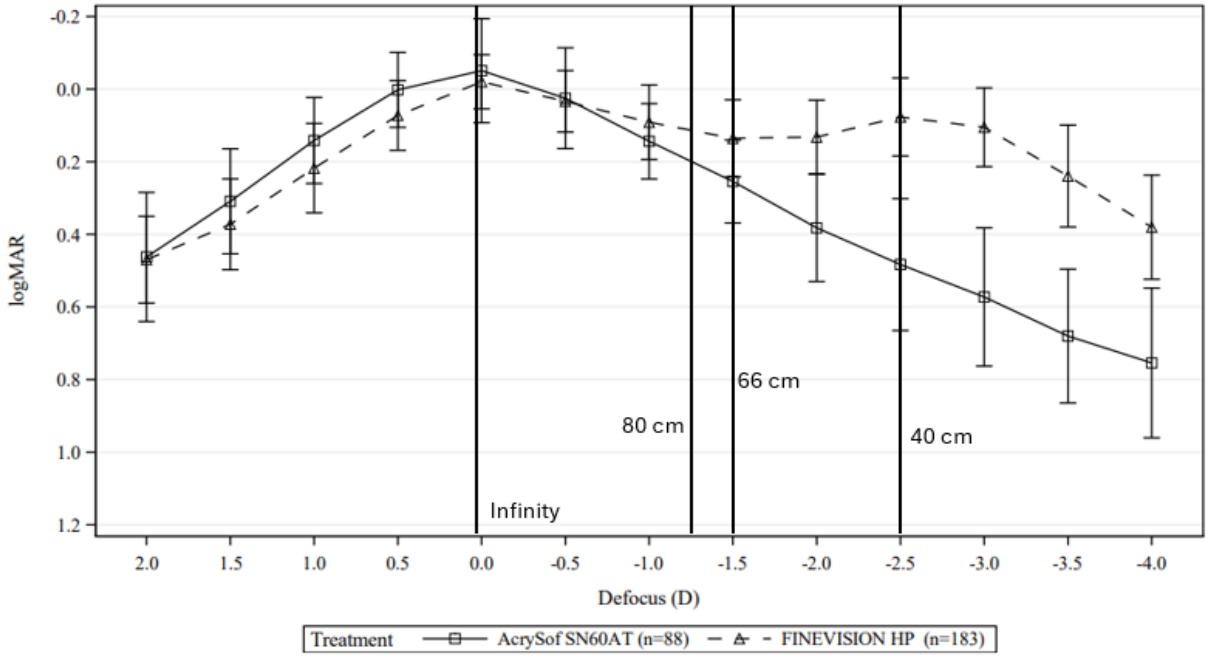
Monocular/Binocular defocus curves were obtained under photopic conditions at a test distance of 4 m at Visit 4 and Visit 5 for the FINEVISION HP IOL and the Monofocal IOL. All analyses were primarily conducted using the Best-Case Set. Each subject was defocused with spherical lenses from +2.00 D through -4.00 D over the subject's manifest distance correction in -0.50 D increments.

Binocular Defocus curve is shown in **Figure 5** with error bars representing 1 Standard Deviation. Vertical lines indicate the distance (optical infinity), intermediate (66 cm), and near (40 cm) visual acuity testing distance. An additional vertical line representing 80 cm testing distance has been added to the defocus curve as it is commonly used to represent functional intermediate vision and can be particularly relevant when illustrating the continuous range of vision—especially the transition between far vision and the standard intermediate distance of 66 cm. Binocular Defocus curves obtained at Month 6 stratified by post-operative pupil size are presented in **Figures 6-7**. For summaries of binocular defocus curves by pupil size, the average pupil size at Visit 4 computed over both eyes was used to determine the pupil size subgroup.

Data were obtained from best-case subjects in each arm using a computerized visual acuity test system (CTS, M&S Technologies, Niles, IL). For distance vision (0.0 D defocus which

corresponds to optical infinity) there was no notable difference between treatment groups in measured logMAR. At near distance (-2.5 D defocus which corresponds to 40 cm distance and -3.0 D defocus which corresponds to 33 cm distance) the FINEVISION HP IOL group had substantially greater measured logMAR values than the control group. The FINEVISION HP IOL provided mean performance of 0.2 logMAR or better vision (depth of focus) from -3.0 D to 0.00 D, corresponding to a range of distances from approximately 33 cm to infinity. Results of binocular defocus curves at Visit 5 by treatment group and by pupil size were comparable with the binocular defocus curve findings at Visit 4.

Figure 5- Mean Binocular Defocus Curves with Standard Deviation Error Bars, Best Case Set – at Visit 4 (Day 150 to 180)

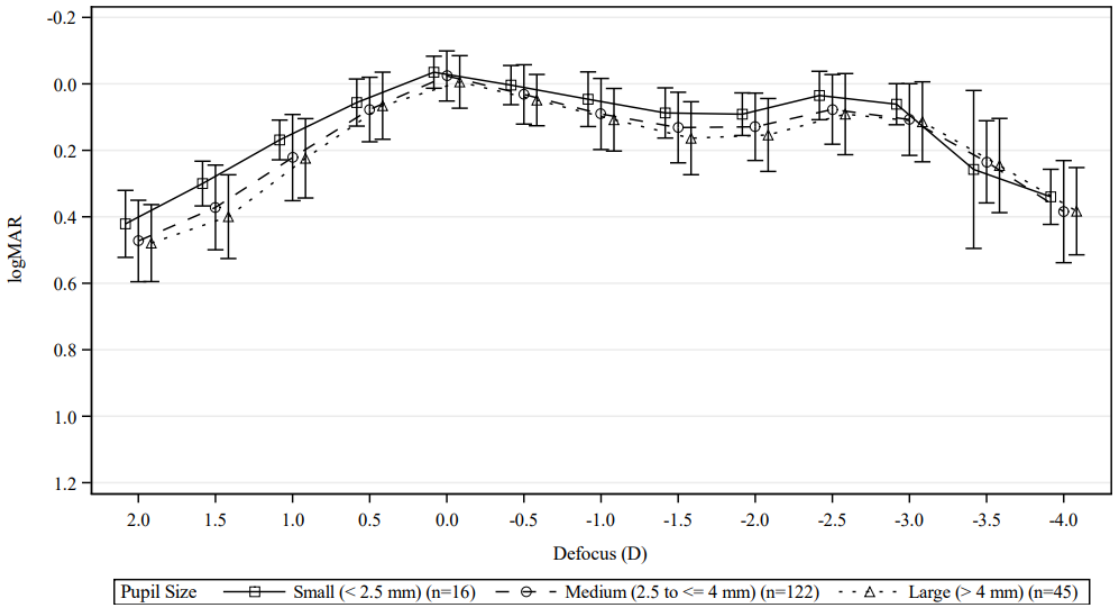


D = Diopters.

Note: n represents the number of subjects with non-missing data for the respective visit and treatment group.

Figure 6 -Mean Binocular Defocus Curves with Standard Deviation Error Bars by Post-Operative Photopic Pupil Size, Best Case Set – at Visit 4

Treatment= FINEVISION HP IOL

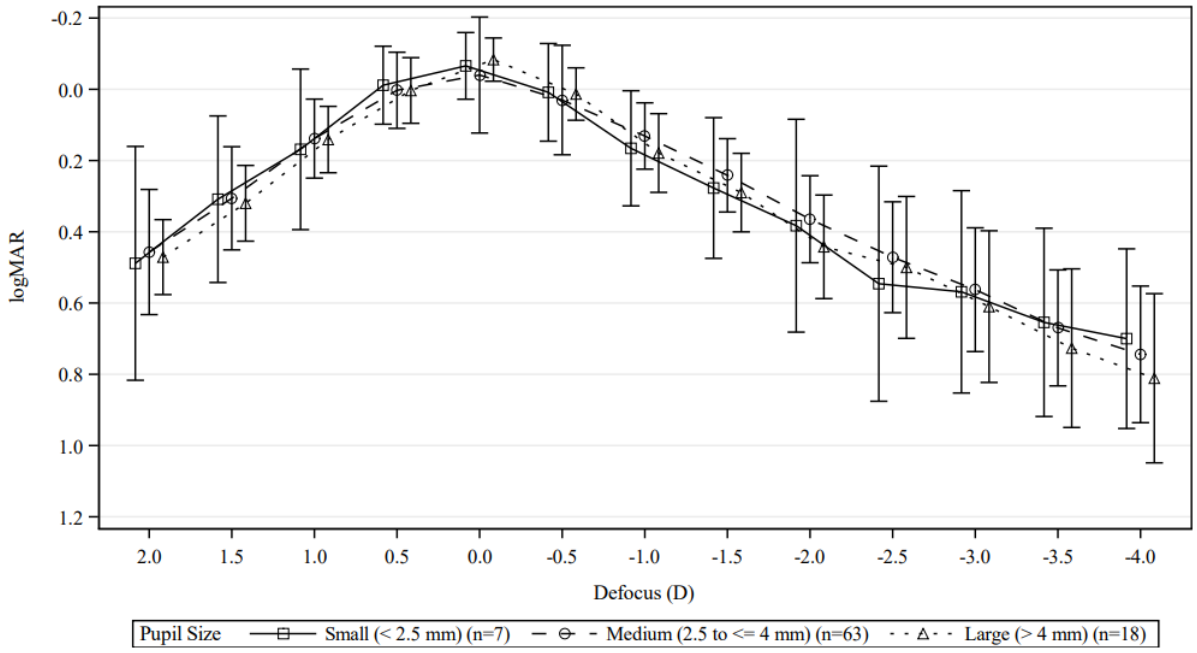


D = Diopters.

Note: n represents the number of subjects with non-missing data for the respective visit, treatment group, and subgroup. The average pupil size computed over both eyes is used to determine the pupil size subgroup. Photopic pupil size is from the respective visit. Defocus curves are offset for ease of reading.

Figure 7 -Mean Binocular Defocus Curves with Standard Deviation Error Bars by Post-Operative Photopic Pupil Size, Best Case Set – at Visit 4

Treatment= Monofocal IOL (AcrySof SN60AT)



D = Diopters.

Note: n represents the number of subjects with non-missing data for the respective visit, treatment group, and subgroup. The average pupil size computed over both eyes is used to determine the pupil size subgroup. Photopic pupil size is from the respective visit. Defocus curves are offset for ease of reading.

Secondary Surgical Interventions Due to Optical Properties of the IOL

The first co-primary safety objective was to estimate the cumulative rate of secondary surgical interventions (SSIs) related to the optical properties of the IOL for the first operative eyes up to Month 12 (Visit 5). Only one SSI related to the optical properties of the IOLs was reported in the clinical study as shown in **Table 17**. In the first operative eye for a FINEVISION HP IOL subject, there was an explant of the IOL due to subjective complaints of dissatisfaction with the level of vision. The non-inferiority of FINEVISION HP IOL to Monofocal IOL was demonstrated as the 90% upper confidence limit (1.36%) of the difference in the percentages was less than the non-inferiority margin of 1.4%.

Table 17: Cumulative Secondary Surgical Interventions Related to the Optical Properties of the IOL, Safety Set – First Operative Eyes up to Month 12 (Visit 5)

	FINEVISION HP (N=332)	AcrySof SN60AT (N=164)
Any Secondary Surgical Interventions Related to the Optical Properties of the IOL: n (%)	1 (0.3)	0
Difference in Percentages	0.3	
90% CI for Difference in Percentages [1]	(-0.76, 1.36)	

Notes: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (n) in each respective treatment group for the population being analyzed.

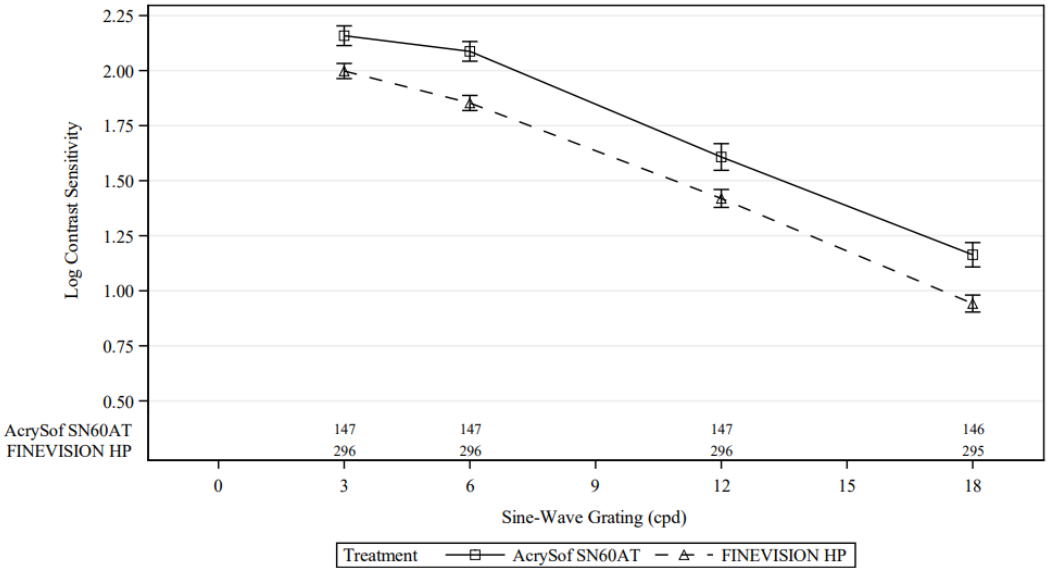
[1] Confidence interval (CI) computed using the Farrington-Manning method.

Contrast sensitivity

Contrast sensitivity was measured monocularly at Month 12 under four conditions: photopic without glare, photopic with glare, mesopic without glare, and mesopic with glare, using the M&S System (Clinical Trial Suite, M&S Technologies, Niles, IL, USA) for sine-wave gratings 1.5, 3, 6, 12 and/or 18 cycles per degree (cpd) at a test distance of 2.5 meters. The luminance for photopic testing was 85 cd/m^2. For mesopic testing, a neutral density filter was placed in front of the screen to reduce lighting to 3 +/- 0.5 cd/m^2. In all testing conditions, contrast sensitivity was slightly better for the monofocal IOL group than the FINEVISION HP IOL group, however, the difference in means was not clinically significant. The results are shown for the best-case set in Figures 8–11. More positive outcomes are indicative of better performance.

Figure 8: Mean Monocular Log Contrast Sensitivity at Month 12 with 95% CIs for Means, Best Case Set – First Operative Eyes

Light Condition: Photopic Without Glare

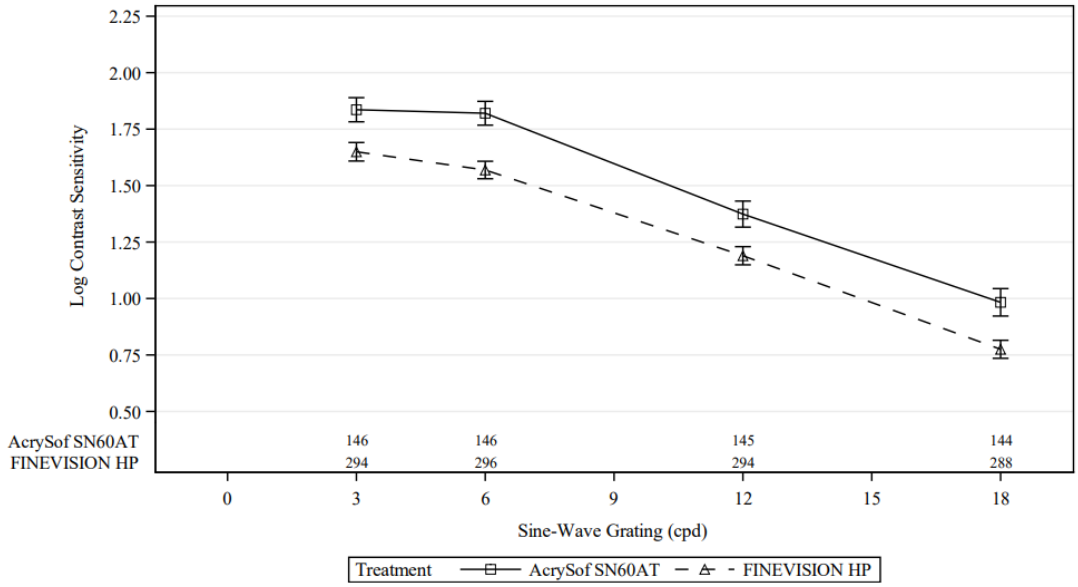


Abbreviations: cpd = Cycles per Degree.

Note: Numbers at bottom of figure are the number of subjects with non-missing data for the respective treatment group and sine-wave grating level. Raw data were collected as log10(contrast threshold) which were converted to log contrast sensitivities representing -log10(contrast threshold). 95% confidence intervals for means are based on the t-distribution.

Figure 9: Mean Monocular Log Contrast Sensitivity at Month 12 with 95% CIs for Means, Best Case Set – First Operative Eyes

Light Condition: Photopic with Glare

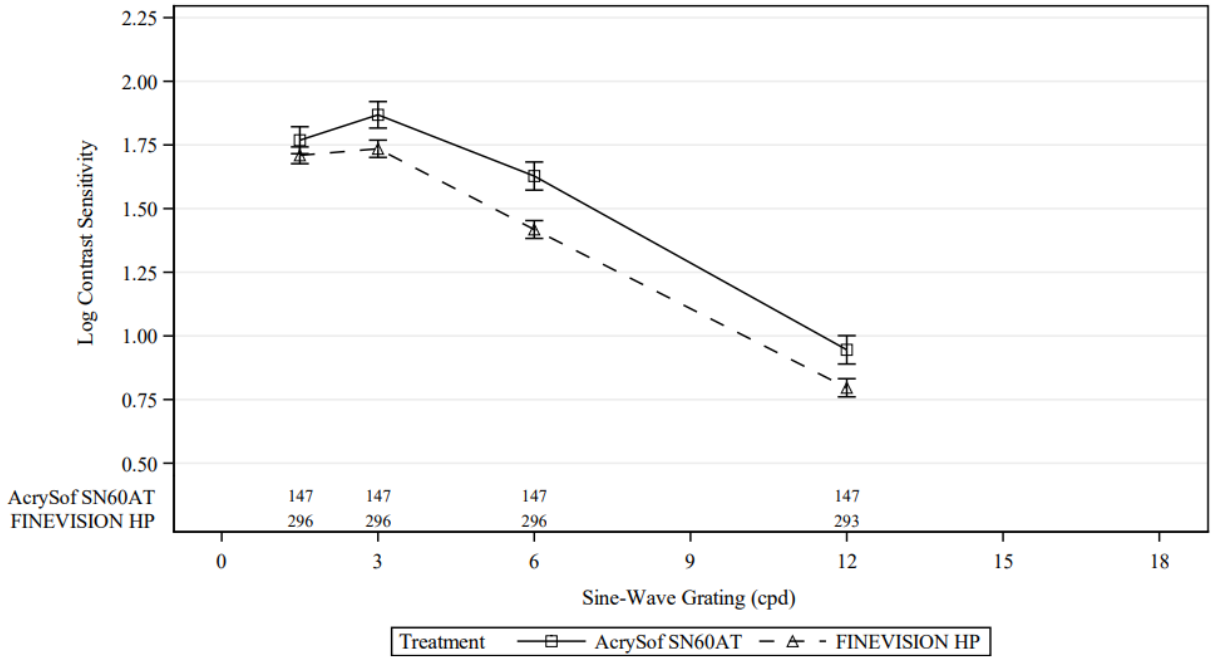


Abbreviations: cpd = Cycles per Degree.

Note: Numbers at bottom of figure are the number of subjects with non-missing data for the respective treatment group and sine-wave grating level. Raw data were collected as log10(contrast threshold) which were converted to log contrast sensitivities representing -log10(contrast threshold). 95% confidence intervals for means are based on the t-distribution.

Figure 10: Mean Monocular Log Contrast Sensitivity at Month 12 with 95% CIs for Means, Best Case Set – First Operative Eyes

Light Condition: Mesopic without Glare

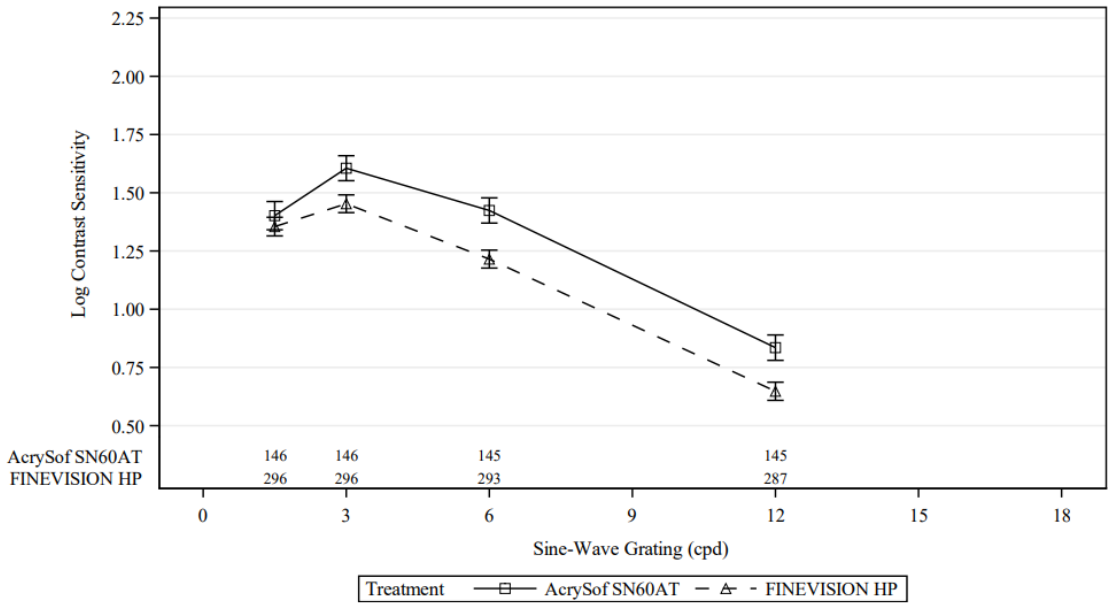


Abbreviations: cpd = Cycles per Degree.

Note: Numbers at bottom of figure are the number of subjects with non-missing data for the respective treatment group and sine-wave grating level. Raw data were collected as log10(contrast threshold) which were converted to log contrast sensitivities representing -log10(contrast threshold). 95% confidence intervals for means are based on the t-distribution.

Figure 11: Mean Monocular Log Contrast Sensitivity at Month 12 with 95% CIs for Means, Best Case Set – First Operative Eyes

Light Condition: Mesopic with Glare



Abbreviations: cpd = Cycles per Degree.

Note: Numbers at bottom of figure are the number of subjects with non-missing data for the respective treatment group and sine-wave grating level. Raw data were collected as log10(contrast threshold) which were converted to log contrast sensitivities representing -log10(contrast threshold). 95% confidence intervals for means are based on the t-distribution.

Cumulative and Persistent Adverse events rate

The incidences of cumulative adverse events for the FINEVISION HP IOL and the Monofocal IOL at Month 12 as compared to the ISO 11979-7 Table E.2 historical grid (SPE) rates are provided in **Tables 18 and 19**. If the same event occurred multiple times in an eye, only the first occurrence is counted in the tables below. All SPE rates for FINEVISION HP IOL or the Monofocal IOL group were below the SPE threshold as set forth by ISO 11979-7.

Secondary Surgical Interventions by category for the first and second operative eyes are presented in Tables 20 and 21, respectively.

The results of adverse events analyses based on the consensus definitions as set forth by American Academy of Ophthalmology's Task Force (Masket et al. Ophthalmology 2017) are shown in Tables 22 and 23.

Table 18: Cumulative and Persistent Adverse Events, Safety Set – First Implanted Eyes

Adverse Event	SPE Rate (%) [3]	FINEVISION HP (N=332) (m=315)		
		n (%)	2-sided 95% CI [4]	1-sided 95% Lower CL [4]
Cumulative				
Cystoid macular oedema	3.0	1 (0.3)	(0.01, 1.67)	0.02
Hypopyon	0.3	0	(0.00, 1.10)	0.00
Endophthalmitis [1]	0.1	0	(0.00, 1.10)	0.00
Lens dislocated from posterior chamber	0.1	0	(0.00, 1.10)	0.00
Pupillary block	0.1	0	(0.00, 1.10)	0.00
Retinal detachment	0.3	3 (0.9)	(0.19, 2.62)	0.25
Secondary surgical intervention [2]	0.8	6 (1.8)	(0.67, 3.89)	0.79
Persistent				
Corneal stroma oedema	0.3	0	(0.00, 1.16)	0.00
Cystoid macular oedema	0.5	0	(0.00, 1.16)	0.00
Iritis	0.3	0	(0.00, 1.16)	0.00
Raised IOP requiring treatment	0.4	0	(0.00, 1.16)	0.00

Abbreviations: CL = Confidence Limit; IOL = Intraocular Lens; IOP = Intraocular Pressure; SPE = Safety and Performance Endpoints.

Note: At each level of summarization, n represents the number of unique subjects with at least one specific event. Cumulative AEs are AEs which occur at any time during the study. If a subject experiences a specific cumulative AE more than once during the study, it is counted once for that specific cumulative AE. Percentages for cumulative AEs are based on the number of subjects (N) in each respective treatment group for the population being analyzed. Persistent AEs are AEs which are classified as ongoing at the time of study exit for subjects seen at Visit 5 (Day 360 to 420). A subject is counted once for a specific persistent AE. Percentages for persistent AEs are based on the number of subjects (m) seen at Visit 5 (Day 360 to 420) in each respective treatment group for the population being analyzed.

[1] Endophthalmitis is defined as inflammatory reaction (sterile or infectious) involving the vitreous body.

[2] Excludes posterior capsulotomies.

[3] The SPE rate is from Table E.2 (Posterior chamber IOL adverse event rates) of ISO 11979-7:2018(E).

[4] Confidence intervals and confidence limits for adverse event rates are computed using the Clopper-Pearson method.

Table 19: Cumulative and Persistent Adverse Events, Safety Set – Second Implanted Eyes

Adverse Event	SPE Rate (%) [3]	FINEVISION HP (N=329) (m=314)		
		n (%)	2-sided 95% CI [4]	1-sided 95% Lower CL [4]
Cumulative				
Cystoid macular oedema	3.0	5 (1.5)	(0.50, 3.51)	0.60
Hypopyon	0.3	0	(0.00, 1.11)	0.00
Endophthalmitis [1]	0.1	0	(0.00, 1.11)	0.00
Lens dislocated from posterior chamber	0.1	0	(0.00, 1.11)	0.00
Pupillary block	0.1	0	(0.00, 1.11)	0.00
Retinal detachment	0.3	2 (0.6)	(0.07, 2.18)	0.11
Secondary surgical intervention [2]	0.8	3 (0.9)	(0.19, 2.64)	0.25
Persistent				
Corneal stroma oedema	0.3	0	(0.00, 1.17)	0.00
Cystoid macular oedema	0.5	2 (0.6)	(0.08, 2.28)	0.11
Iritis	0.3	0	(0.00, 1.17)	0.00
Raised IOP requiring treatment	0.4	1 (0.3)	(0.01, 1.76)	0.02

Abbreviations: CL = Confidence Limit; IOL = Intraocular Lens; IOP = Intraocular Pressure; SPE = Safety and Performance Endpoints.

Note: At each level of summarization, n represents the number of unique subjects with at least one specific event. Cumulative AEs are AEs which occur at any time during the study. If a subject experiences a specific cumulative AE more than once during the study, it is counted once for that specific cumulative AE. Percentages for cumulative AEs are based on the number of subjects (N) in each respective treatment group for the population being analyzed. Persistent AEs are AEs which are classified as ongoing at the time of study exit for subjects seen at Visit 5 (Day 360 to 420). A subject is counted once for a specific persistent AE. Percentages for persistent AEs are based on the number of subjects (m) seen at Visit 5 (Day 360 to 420) in each respective treatment group for the population being analyzed.

[1] Endophthalmitis is defined as inflammatory reaction (sterile or infectious) involving the vitreous body.

[2] Excludes posterior capsulotomies.

[3] The SPE rate is from Table E.2 (Posterior chamber IOL adverse event rates) of ISO 11979-7:2018(E).

[4] Confidence intervals and confidence limits for adverse event rates are computed using the Clopper-Pearson method.

Table 20: Secondary Surgical Interventions by Category – Safety Set – First Operative Eyes

SSI Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Any SSI	8 (2.4)	4 (2.4)
Anterior chamber reinflation	0	1 (0.6)
IOL removal	1 (0.3)	0
Lens material removal	1 (0.3)	0
Paracentesis	2 (0.6)	1 (0.6)
Re-suturing of main incision	0	1 (0.6)
Retinal laser	0	0
Vitrectomy	4 (1.2)	1 (0.6)

Abbreviations: IOL=Intraocular Lens; SSI = Secondary Surgical Intervention

Note: Percentages are based on the number of eyes (N) in the respective treatment group for the population being analyzed.

Table 21: Secondary Surgical Interventions by Category – Safety Set – Second Operative Eyes

SSI Category	FINEVISION HP (N=329) n (%)	AcrySof® SN60AT (N=164) n (%)
Any SSI	6 (1.8)	2 (1.2)
Anterior chamber reinflation	0	0
IOL removal	0	0
Lens material removal	0	0
Paracentesis	3 (0.9)	2 (1.2)
Re-suturing of main incision	0	0
Retinal laser	1 (0.3)	0
Vitrectomy	2 (0.6)	0

Abbreviations: IOL=Intraocular Lens; SSI = Secondary Surgical Intervention.

Note: At each level of summarization, n represents the number of unique eyes with at least one specific SSI. Percentages are based on the number of eyes (N) in the respective treatment group for the population being analyzed.

Table 22: Ocular Treatment-Emergent Adverse Events based on a Modified Version of the AAO Task Force Consensus (Masket et al, 2017), Safety Set – First Implanted Eyes

	FINEVISION HP (N=332)			Monofocal IOL (N=164)		
Adverse Event	**n (%)**	**[95% CI]**	**E**	**n (%)**	**[95% CI]**	**E**
Chronic anterior uveitis	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Clinically significant cystoid macular edema	0	[0.00, 1.10]	0	1 (0.6)	[0.02, 3.35]	1
Visually Significant Corneal edema	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Endophthalmitis	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Mechanical pupillary block	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Increased IOP	12 (3.6)	[1.88, 6.23]	12	7 (4.3)	[1.73, 8.60]	7
Rhegmatogenous retinal detachment	3 (0.9)	[0.19, 2.62]	3	0	[0.00, 2.22]	0
Toxic anterior segment syndrome	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Secondary IOL intervention - Exchange	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Secondary IOL intervention – Removal	1 (0.3)	[0.01, 1.67]	1	0	[0.00, 2.22]	0
Secondary IOL intervention - Reposition	0	[0.00, 1.10]	0	1 (0.6)	[0.02, 3.35]	1

Abbreviations: AAO = American Academy of Ophthalmology; E = Events; IOL = Intraocular Lens; IOP = Intraocular Pressure; TEAE = Treatment-Emergent Adverse Event.

Note: At each level of summarization, n represents the number of unique subjects with at least one specific event and E represents the total number of the specific events. Percentages are based on the number of subjects (N) in each respective treatment group for the population being analyzed. Adverse events from "Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with Intraocular Lenses" by Masket, et al 2017. Ocular TEAEs for a respective eye include all AEs occurring or worsening during or after the operation for the respective eye. Confidence intervals for adverse event rates are computed using the Clopper-Pearson method.

Table 23: Ocular Treatment-Emergent Adverse Events based on a Modified Version of the AAO Task Force Consensus (Masket et al., 2017), Safety Set – Second Implanted Eyes

	FINEVISION HP (N=329)			Monofocal IOL (N=164) n (%)		
Adverse Event	**n (%)**	**[95% CI]**	**E**	**n (%)**	**[95% CI]**	**E**
Chronic anterior uveitis	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Clinically significant cystoid macular edema	1 (0.3)	[0.01, 1.68]	1	2 (1.2)	[0.15, 4.34]	2
Visually Significant Corneal edema	1 (0.3)	[0.01, 1.68]	1	0	[0.00, 2.22]	0
Endophthalmitis	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Mechanical pupillary block	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Increased IOP	13 (4.0)	[2.12, 6.66]	17	7 (4.3)	[1.73, 8.60]	7
Rhegmatogenous retinal detachment	2 (0.6)	[0.07, 2.18]	2	0	[0.00, 2.22]	0
Toxic anterior segment syndrome	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Secondary IOL intervention - Exchange	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Secondary IOL intervention – Removal	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Secondary IOL intervention - Reposition	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0

Abbreviations: AAO = American Academy of Ophthalmology; E = Events; IOL = Intraocular Lens; IOP = Intraocular Pressure; TEAE = Treatment-Emergent Adverse Event.

Note: At each level of summarization, n represents the number of unique subjects with at least one specific event and E represents the total number of the specific events. Percentages are based on the number of subjects (N) in each respective treatment group for the population being analyzed. Adverse events from "Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with Intraocular Lenses" by Masket, et al 2017. Ocular TEAEs for a respective eye include all AEs occurring or

worsening during or after the operation for the respective eye. Confidence intervals for adverse event rates are computed using the Clopper-Pearson method.

Device Deficiencies

There were 16 reported deficiencies for the FINEVISION HP IOL (2.4% of devices) and 3 for AcrySof SN60AT IOL (0.9% of devices). The most common deficiency was for device failure (7) [Torn haptic during loading/injection process], device malfunction (5)[Haptics severed from the optic during injector loading], and device misuse (2)[Broken haptic during injection process]. There were 5 "Other" device deficiencies[IOL Damaged upon loading into the injector, dropping of IOL before implantation].

Out of 661 total FINEVISION HP implants, 10 IOLs (1.5%) experienced a device deficiency related to the haptic being torn off during the IOL injection process. In 5 of these cases, the initial IOL was already inserted into the eye when the broken haptic was identified, requiring surgical removal of the initial IOL and implantation of the back-up FINEVISION HP IOL. A CAPA and root cause analysis was performed. Haptic breakage force testing did not find any manufacturing, haptic design or raw material cause. Simulated surgical testing was performed according to Section 5 of ISO 11979-2, which did not find a root cause. Additional testing which intentionally violated the directions for use (DFU) determined the root cause was likely related to improper loading of the IOL into the injector. Based on the CAPA findings, the DFU and warnings/precautions have been updated to mitigate future haptic breakage events. In addition, training will be available and provided as necessary to surgeons and support staff.

Visual Disturbances

Quality of Vision (QoV) Questionnaire developed by Dr. McAlinden and coworkers[1] was used in this clinical study to assess visual disturbances. Tables 24-26 report rates of visual disturbances in FINEVISION HP and Control groups.. Most visual symptoms—such as glare, hazy or blurred vision, image distortion, double or multiple images, trouble focusing, difficulty judging distance or depth, and vision fluctuations—occurred at similar or slightly lower rates in the FINEVISION HP IOL group compared to the control group. However, two symptoms—starbursts and halos—were reported more frequently by participants with the FINEVISION HP lens than those with the monofocal control lens.

[1]McAlinden, C., K. Pesudovs and J. E. Moore (2010). "The development of an instrument to measure quality of vision: the Quality of Vision (QoV) questionnaire." Invest Ophthalmol Vis Sci 51(11): 5537-5545

Table 24: Quality of Vision (QoV) Categorical summary of the frequency of each visual disturbance at Visit 5 (Day 360 to 420), Safety Set

	FINEVISION HP (N=332) (%)					Monofocal (N=164) (%)				
Visual Disturbance	**m**	**Never**	**Occasionally**	**Quite Often**	**Very Often**	**m**	**Never**	**Occasionally**	**Quite Often**	**Very Often**
Glare	315	38.4%	47.3%	11.1%	3.2%	159	38.4%	51.6%	8.2%	1.9%
Haloes	**315**	**22.2%**	**39.0&**	**21.0%**	**17.8%**	**159**	**70.4%**	**23.3%**	**3.8%**	**2.5%**
Starbursts	**315**	**50.2%**	**31.4%**	**11.7%**	**6.7%**	**159**	**61.6%**	**30.8%**	**5.7%**	**1.9%**
Hazy Vision	315	**67.9%**	**24.4%**	**5.1%**	**2.5%**	**159**	**67.3%**	**24.5%**	**5.7%**	**2.5%**
Blurred Vision	315	**61.3%**	**32.7%**	**4.8%**	**1.3%**	**159**	**50.9%**	**38.4%**	**18.2%**	**2.5%**
Distortion	315	**90.5%**	**8.6%**	**1.0%**	**0.0 %**	**159**	**91.8%**	**5.7%**	**2.5%**	**0.0%**
Double or multiple images	315	**88.6%**	**10.5%**	**0.6%**	**0.3%**	**159**	**88.7%**	**9.4%**	**1.3%**	**0.6%**
Fluctuation in Vision	315	**48.3%**	**42.5%**	**7.3%**	**1.9%**	**159**	**50.3%**	**44.0%**	**3.8%**	**1.9%**
Focusing Difficulties	315	**44.1%**	**47.9%**	**5.4%**	**2.5%**	**159**	**39.6%**	**46.5%**	**9.4%**	**4.4%**
Difficulty Judging Distance or Depth Perception	315	**73.7%**	**19.0%**	**4.4%**	**2.9%**	**159**	**66.0%**	**25.8%**	**6.3%**	**1.9%**

Note: N in the headers represents the number of subjects in the respective treatment group for the population being analyzed. Percentages are based on the number of subjects (m) with non-missing data for the respective treatment group for the population being analyzed.

Table 25: Quality of Vision (QoV) Categorical summary of the severity of each visual disturbance at Visit 5 (Day 360 to 420) excluding subjects who reported frequency of "Never", Safety Set-

	FINEVISION HP (N=332) (%)						Monofocal (N=164) (%)					
Visual Disturbance	**m**	**Not at all**	**Mild**	**Moderate**	**Severe**	**Missing**	**m**	**Not at all**	**Mild**	**Moderate**	**Severe**	**Missing**
Glare	**194**	**4.1 %**	**67.0 %**	**24.7 %**	**3.6 %**	**0.5 %**	**98**	**6.1 %**	**59.2%**	**31.6%**	**3.1%**	**0.0%**
Haloes	**245**	**3.3 %**	**52.7%**	**33.9%**	**9.8%**	**0.4%**	**47**	**6.4%**	**70.2%**	**21.3%**	**2.1%**	**0.0%**
Starbursts	**157**	**8.3%**	**54.8%**	**31.2%**	**5.7%**	**0.0%**	**61**	**8.2%**	**65.6%**	**23.0%**	**3.3%**	**0.0%**
Hazy Vision	**101**	**7.9%**	**65.3%**	**24.8%**	**1.0%**	**1.0%**	**52**	**7.7%**	**71.2%**	**15.4%**	**5.8%**	**0.0%**
Blurred Vision	**122**	**7.4%**	**73.0%**	**17.2%**	**2.5%**	**0.0%**	**78**	**3.8%**	**66.7%**	**24.4%**	**5.1%**	**0.0%**
Distortion	**30**	**13.3%**	**73.3%**	**13.3%**	**0.0%**	**0.0%**	**13**	**7.7%**	**69.2%**	**23.1%**	**0.0%**	**0.0%**
Double or multiple images	**36**	**8.3%**	**83.3%**	**8.3%**	**0.0%**	**0.0%**	**18**	**11.1%**	**61.1%**	**16.7%**	**11.1 %**	**0.0%**
Fluctuation in Vision	**163**	**9.2%**	**69.9%**	**17.8%**	**2.5%**	**0.6%**	**79**	**8.9%**	**75.9%**	**12.7%**	**2.5%**	**0.0%**
Focusing Difficulties	**176**	**12.5%**	**69.9%**	**14.8%**	**2.8%**	**0.0%**	**96**	**2.1%**	**71.9%**	**21.9%**	**4.2%**	**0.0%**
Difficulty Judging Distance or Depth Perception	**83**	**8.4%**	**68.7%**	**19.3%**	**3.6%**	**0.0%**	**54**	**1.9%**	**68.5%**	**27.8%**	**1.9%**	**0.0%**

Note: N in the headers represents the number of subjects in the respective treatment group for the population being analyzed. Percentages are based on the number of subjects (m) seen at Visit 5 (Day 360 to 420) who did not report a frequency of "Never" for the visual disturbance and treatment group for the population being analyzed.

Table 26: Quality of Vision (QoV) Categorical summary of the bothersomeness of each visual disturbance at Visit 5 (Day 360 to 420) excluding subjects who reported frequency of "Never", Safety Set

	FINEVISION HP (N=332) (%)						Monofocal (N=164) (%)					
Visual Disturbance	**m**	**Not at all**	**A little**	**Quite**	**Very**	**Missing**	**m**	**Not at all**	**A little**	**Quite**	**Very**	**Missing**
Glare	**194**	**15.5%**	**67.5%**	**10.8%**	**5.7%**	**0.5%**	**98**	**17.3%**	**62.2%**	**15.3%**	**5.1%**	**0.0%**
Haloes	**245**	**23.7%**	**47.3%**	**18.0%**	**10.6%**	**0.4%**	**47**	**25.5%**	**59.6%**	**12.8%**	**2.1%**	**0.0%**
Starbursts	**157**	**24.2%**	**46.5%**	**21.7%**	**7.6%**	**0.0%**	**61**	**21.3%**	**65.6%**	**9.8%**	**3.3%**	**0.0%**
Hazy Vision	**101**	**15.8%**	**63.4%**	**16.8%**	**4.0%**	**0.0%**	**52**	**21.2%**	**57.7%**	**13.5%**	**7.7%**	**0.0%**
Blurred Vision	**122**	**12.3%**	**68.0%**	**16.4%**	**3.3%**	**0.0%**	**78**	**12.8%**	**57.7%**	**20.5%**	**9.0%**	**0.0%**
Distortion	**30**	**23.3%**	**60.0%**	**16.7%**	**0.0%**	**0.0%**	**13**	**15.4%**	**53.8%**	**30.8%**	**0.0%**	**0.0%**
Double or multiple images	**36**	**22.2%**	**66.7%**	**8.3%**	**2.8%**	**0.0%**	**18**	**11.1%**	**61.1%**	**16.7%**	**11.1%**	**0.0%**
Fluctuation in Vision	**163**	**23.9%**	**63.8%**	**8.6%**	**3.1%**	**0.6%**	**79**	**16.5%**	**63.3%**	**13.9%**	**6.3%**	**0.0%**
Focusing Difficulties	**176**	**21.0%**	**61.9%**	**11.9%**	**4.5%**	**0.6%**	**96**	**12.5%**	**66.7%**	**15.6%**	**5.2%**	**0.0%**
Difficulty Judging Distance or Depth Perception	**83**	**10.8%**	**68.7%**	**14.5%**	**6.0%**	**0.0%**	**54**	**5.6%**	**74.1%**	**13.0%**	**7.4%**	**0.0%**

Note: N in the headers represents the number of subjects in the respective treatment group for the population being analyzed. Percentages are based on the number of subjects (m) seen at Visit 5 (Day 360 to 420) who did not report a frequency of "Never" for the visual disturbance and treatment group for the population being analyzed.

Fundus Visualization
There was no reported difficulty in fundus visualization at any postoperative visits for the first or second eyes in the study.

HOW SUPPLIED

The FINEVISION HP device is steam sterilized and supplied in polypropylene container with saline solution. The container is protected by a polypropylene blister-Tyvek pack as sterile packaging, with an indicator of its sterile state. Should any part of the packaging be damaged, do not use the device and send it back to the supplier. The expiration date is indicated on the outside of the lens package. Do not use the IOL after its expiration date.

EXPIRATION DATE
The use-by date on the lens package is the sterility expiration date. The lens shall not be implanted after the indicated sterility expiration date.

SYMBOL/EXPLANATION

	Manufacturer
	Date of manufacture
	Country of manufacture: Belgium
	Use-by date
	Batch code
	Sterilized using steam
	Do not resterilize

REF	Catalogue number
Rx Only	Federal Law (USA) restricts this device to sale by or on the order of a physician
MD	Medical Device
	Do not use if package is damaged
	Keep away from sunlight
	Temperature limit
	Do not re-use
	Consult electronic instructions for use
	Caution
CE	CE mark
SN	Serial number
	Double sterile barriers
UK CA	UKCA mark
UDI	Unique Device Identifier

	Keep dry
CH REP	Swiss authorized representative
	Patient name
	Name and Address of the implanting healthcare institution/provider
	Information website for patients
	Implant date
∅B	Optic body diameter
∅T	Total lens diameter
	Intraocular lens
	Hydrophilic Acrylic Material with 25% Water Uptake and UV&Blue Light Filter (HELIO25
	Hydrophilic Acrylic Material with 26% Water Uptake and UV&Blue Light Filter (HELIOFLEX)
	Toric optic
	Premium Preloaded IOL
	Hydrophobic Acrylic Material with UV and Blue Light Filter (GFY)
CYL	Cylinder power

ADD	Add power
SE	Spherical equivalent power