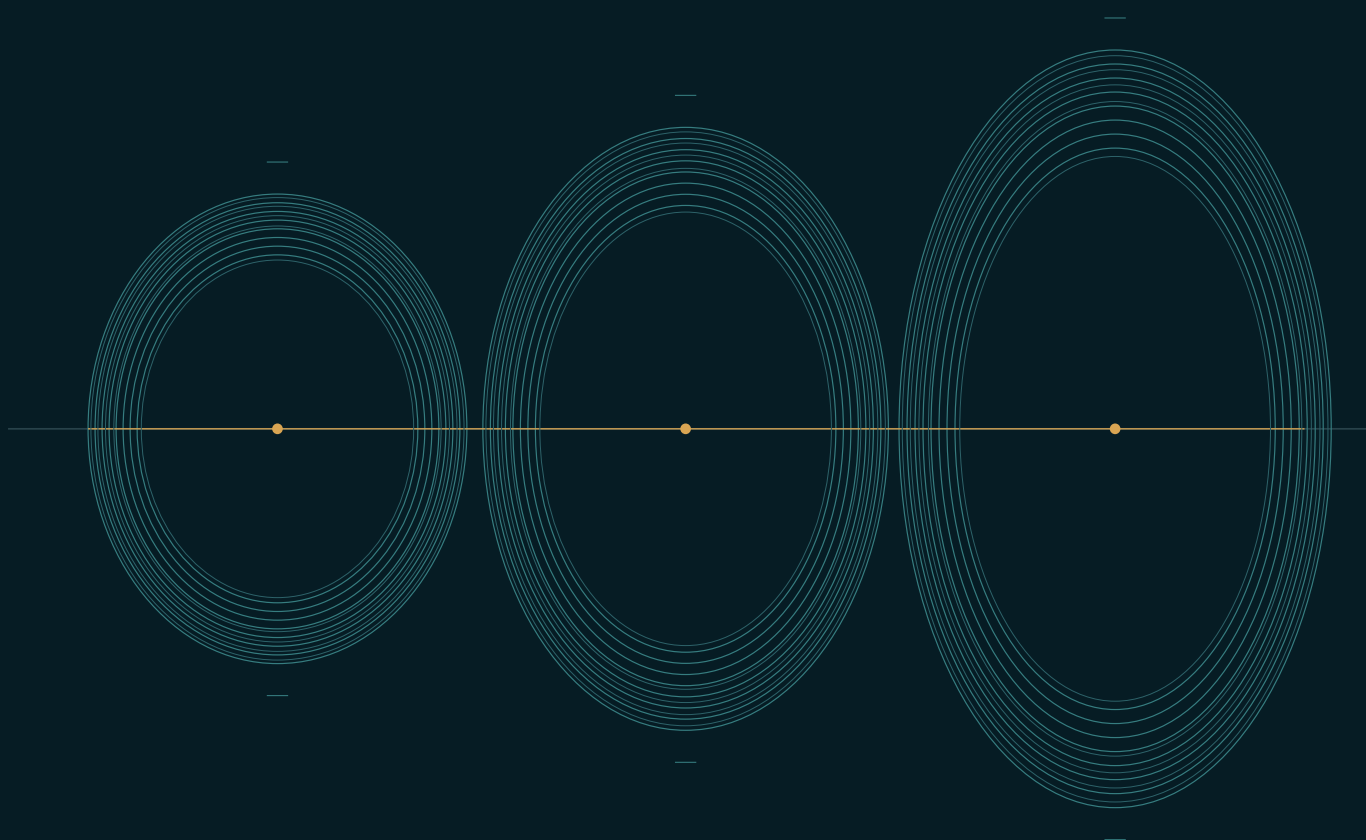


EVIDENCE REVIEW · 05

FINEVISION HP

Evidence, interpreted.



Established optical lineage.
Contemporary hydrophobic platform.

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VERSION 1.0 • SEPTEMBER 2026

Published 26 September 2026

Evidence cutoff: 26 September 2026

EXECUTIVE READ

The architecture is established. The HP evidence is becoming substantial.

01 OPTICAL LINEAGE

POD F GF carries the FineVision dual-add trifocal concept onto a hydrophobic acrylic platform. The longer family history is context, not HP-specific proof. [1, 6, 7]

02 CLINICAL RANGE

In the FDA randomized trial, distance BCDVA met prespecified non-inferiority; DCIVA at 66 cm and DCNVA at 40 cm met superiority criteria versus a monofocal IOL. [1]

03 QUALITY OF VISION

At 12 months, halos and starbursts were more frequent than with monofocal optics. Night-driving difficulty moderately favoured monofocal. [1]

04 MATERIAL TRANSITION

Two randomized 24-month studies found broadly comparable visual and refractive outcomes between hydrophobic POD F GF and hydrophilic POD F. [2, 3]

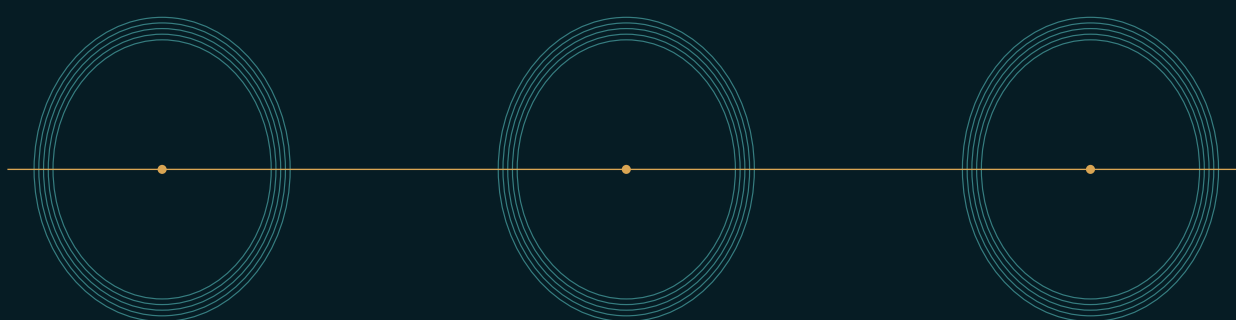
OIE INTERPRETATION

A credible trifocal range is paired with the familiar photic cost of distributing light across foci. The material change does not, by itself, establish clinical superiority.

MECHANISM

Three foci from one optical lineage

The apodized anterior diffractive surface apportions incident light to distance, intermediate and near foci. Apodization changes the theoretical distribution with pupil size. [1]



DISTANCE

baseline

Far focus

INTERMEDIATE

+1.75 D

~+1.20 D at corneal plane

NEAR

+3.50 D

~+2.40 D at corneal plane

PLATFORM AND GEOMETRY

POD F GF: hydrophobic acrylic; 6.0 mm optic; 11.4 mm overall diameter; double C-loop haptics, 5° posterior angulation. Anterior negative spherical aberration is intended to partially offset positive corneal spherical aberration. [1]

MECHANISTIC CAUTION

Optical design describes how focus is distributed; it cannot, on its own, establish patients' visual experience or a comparative clinical advantage.

Source: FDA PMA P240038, SSER, pp. 2-4. Diagram is an editorial schematic, not a measured energy-distribution chart.

EVIDENCE MATURITY

One optical family. Different evidence bases.

A mature design lineage cannot be substituted for direct evidence on the specific hydrophobic model.

FINEVISION FAMILY

97

Studies identified across Micro F, POD F, POD FT and HP variants, published 2012–2025. [7]

HP-SPECIFIC REVIEW

18

Clinical studies, 1,028 eyes, published 2019–2024; follow-up reported up to 24 months. [6]

2012

2019

2025

2026



Family literature

HP literature begins

FDA approval

Current synthesis

Evidence weight: the randomized FDA pivotal programme addresses POD F GF directly. Family publications explain heritage; they do not increase the sample size of the HP trial.

[1] FDA P240038 (approval 10 Sep 2025); [6] Ristvedt et al., PMID 39911861; [7] Gatinel et al., PMID 42676953.

PRIMARY REGULATORY EVIDENCE

The pivotal trial: distance preserved, intermediate and near extended

20 U.S. sites / prospective / randomized 2:1 / active controlled / double masked

332 FineVision HP subjects

164 SN60AT subjects

MONTH 6 · FIRST OPERATIVE EYES · PHOTOPIC MONOCULAR · ITT PRIMARY IMPUTATION

ENDPOINT	HP	MONO	RESULT
BCDVA · 4 m	0.018	-0.028	NON-INFERIORITY
DCIVA · 66 cm	0.161	0.342	SUPERIORITY
DCNVA · 40 cm	0.162	0.550	SUPERIORITY

HOW TO READ THE RESULT

Lower logMAR is better. Distance achieved the prespecified 0.10-logMAR non-inferiority margin; superiority pertains specifically to distance-corrected intermediate and near acuity. Monofocal is the comparator, not a contemporary trifocal.

[1] FDA SSED, pp. 12–13, 46–47, Table 24. ITT imputed means; the table’s “SN60T” header appears inconsistent with the study’s SN60AT designation elsewhere.

BENEFIT AND TRADE-OFF

Range of vision meets quality of vision

FDA 12-month patient reports capture what visual-acuity endpoints alone cannot. [1]

FUNCTIONAL GAIN

Intermediate and near acuity exceeded the monofocal control at prespecified endpoints. A larger proportion of HP subjects would choose the same implant again; no percentage is inferred here.

OPTICAL COST

Halos and starbursts were more frequent. Night-driving trouble moderately favoured monofocal. Monocular contrast sensitivity slightly favoured monofocal, without clinically meaningful differences in the FDA assessment.

MONTH 12 · FREQUENT SYMPTOMS (QUITE OFTEN + VERY OFTEN)

HALOS

38.8% vs 6.3%

STARBURSTS

18.4% vs 7.6%

Symptom frequency is not a measure of severity. The chart combines two response categories from the FDA QoV table: halos HP 21.0% + 17.8%, control 3.8% + 2.5%; starbursts HP 11.7% + 6.7%, control 5.7% + 1.9%.

[1] FDA SSED, pp. 28-38; QoV frequency denominators: HP n=315, control n=159.

MATERIAL TRANSITION

Does performance hold up at 24 months?

Randomized comparisons directly test POD F GF against hydrophilic POD F while keeping the FineVision optical design broadly shared. They support continuity of visual behaviour, with finite follow-up. [2, 3]

110 RANDOMIZED PATIENTS · 24-MONTH COMPARISON [2]

93.9%

POD F GF patients with binocular DCIVA
≥20/25 at 2 years

87.5%

POD F GF patients with binocular DCNVA
≥20/25 at 2 years

At 2 years, 81.8% of POD F GF eyes were within ± 0.50 D; the study reported similar mean spherical equivalent across material groups and visits (< 0.25 D). The comparison does not demonstrate identical outcomes in all subgroups.

SUPPORTING RANDOMIZED COHORT · 46 PATIENTS AT ENROLMENT [3]

Only 24 attended the 24-month visit (12 per arm). In each group, the authors reported 91% DCIVA and 83.3% DCNVA $\geq 20/25$ among the patients assessed at that time. Attrition narrows the certainty of the long-term inference.

OIE INTERPRETATION

The hydrophobic version appears to preserve the intended range. These trials compare material implementations, not modern competing trifocals.

[2] Khoramnia et al., PMID 38063832. [3] Ang et al., PMID 36852214.

EVIDENCE BOUNDARIES

Where the HP evidence is thinner

01 TORIC / ROTATION

Specific toric cohorts exist, including 66 eyes in a retrospective Japanese study; inference is model-specific. [8]

02 PCO / ND:YAG

Available observational reports cannot establish a robust material-specific advantage in PCO or laser rates.

03 GLISTENINGS

“GF” is part of model nomenclature. Material positioning should be distinguished from independently proven patient benefit.

04 LONGER TERM

Two 24-month comparisons inform stability. The family’s longer history cannot substitute for much longer POD F GF follow-up.

05 COMPARATIVE CLAIMS

A 53-patient randomized comparison with Triumf answers a narrow within-family question; it does not rank all contemporary platforms. [4]

[4] Nagy et al., PMID 39937980. [8] Toric cohort, PMID 39010936. Additional 2026 toric data: PMID 42544252. Evidence cutoff: 26 September 2026.

DEVICE-HANDLING NOTE

A specific injection finding in the FDA file

The pivotal programme records a procedural device-deficiency signal with a clear denominator and a documented mitigation response. [1]

10 / 661

1.5%

FINEVISION HP IMPLANTS WITH INJECTION-RELATED HAPTIC SEPARATION

In five cases, the IOL had already entered the eye when the broken haptic was noticed; removal and implantation of a backup IOL followed. Testing did not identify manufacturing, haptic-design or raw-material causes. Additional tests suggested improper injector loading as the likely cause.

The directions for use and warnings/precautions were updated; training was made available. This is a device-handling observation from the premarket trial, not an estimate of the current post-mitigation event rate.

[1] FDA SSEED, p. 46, Device Failures. FDA also lists 16 total device deficiencies (2.4% of 661 devices); the 10 above are the injection-related haptic subset.

OIE INTERPRETATION

A mature idea, with a defined clinical bargain

WHAT IS SUPPORTED

Regulatory randomized evidence supports maintained corrected distance acuity and useful distance-corrected intermediate and near acuity versus monofocal. Material-comparison trials support broad preservation of FineVision visual behaviour.

WHAT THE CLINICIAN TRADES

More frequent photic phenomena and some night-driving difficulty relative to monofocal optics, alongside the refractive precision and selection demands of any presbyopia-correcting implant.

WHAT REMAINS OPEN

Very long-term POD F GF outcomes, material-specific PCO/glistening implications, and broad comparative performance against current multifocal or full-range alternatives.

FineVision HP is best understood as a hydrophobic implementation of an established trifocal optical design. The direct HP evidence now includes a substantial randomized regulatory trial. It supports functional range while documenting a measurable quality-of-vision trade-off.

EVIDENCE MAP & REFERENCES

What carries the interpretation?

REGULATORY RANDOMIZED · HIGH

[1] FDA SSED: 332 HP / 164 monofocal subjects; 12 months.

RANDOMIZED CLINICAL · MODERATE

[2] 110-patient, [3] 46-patient 24-month material comparisons; [4] 53-patient Triumf comparison; [5] 25-patient paired-eye trial.

OBSERVATIONAL · CONTEXT

[8] Toric 66-eye cohort; [9] pupil/aberrometry 98 eyes; [10] axial-length cohort.

MECHANISTIC / TECHNICAL · CONTEXT

[1] FDA optical characterization; no inference of clinical superiority.

SECONDARY SYNTHESIS · MAP

[6] HP-specific 18-study review; [7] family-wide 97-study review.

READING HIERARCHY

Direct FDA endpoints anchor the interpretation. Material-comparison trials test preservation of the optical behaviour. Smaller observational cohorts describe selected indications. The 97-study family review maps history; it is not a pooled HP sample.

HOW TO USE THE SOURCES

Numerical claims in this issue point to the FDA SSED or original clinical articles. The full source register follows on page 12.

SOURCE REGISTER

Primary sources and evidence context

- [1] U.S. FDA. FINEVISION HP Trifocal IOLs. PMA P240038, Summary of Safety and Effectiveness Data. 2025. accessdata.fda.gov/cdrh_docs/pdf24/P240038B.pdf
- [2] Khoramnia R, et al. Long-term Clinical Outcomes After Bilateral Implantation of Two Trifocal Diffractive IOLs. J Refract Surg. 2023;39:798–807. PMID 38063832.
- [3] Ang RE, et al. Long Term Clinical Outcomes of Hydrophilic and Hydrophobic Versions of a Trifocal IOL with the Same Optical Design. Clin Ophthalmol. 2023. PMID 36852214.
- [4] Nagy ZZ, et al. Prospective Comparison of Clinical Outcomes After Bilateral Implantation of Diffractive Trifocal Extended Depth-of-Focus and Diffractive Trifocal Hydrophobic Intraocular Lenses. J Refract Surg. 2025. PMID 39937980.
- [5] Nagy ZZ, et al. Comparison of visual and refractive outcomes between hydrophilic and hydrophobic trifocal intraocular lenses sharing the same optical design. J Cataract Refract Surg. 2019;45:553–561. PMID 31030774.
- [6] Ristvedt S, et al. Clinical outcomes of a hydrophobic trifocal diffractive intraocular lens: a literature review. Front Med. 2025. PMID 39911861.
- [7] Gatinel D, et al. Clinical Outcomes of the First Diffractive Trifocal Intraocular Lens: A Literature Review. 2026. PMID 42676953. Family-level evidence map.
- [8] Hydrophobic Trifocal Toric Intraocular Lens Outcomes in Japanese Eyes After Cataract Surgery. Clin Ophthalmol. 2024. PMID 39010936.
- [9] Visual Performance Correlation with Corneal Aberrometric Profile and Pupil Size After Implantation of a Trifocal Hydrophobic IOL. PMID 39758752.
- [10] Visual and Refractive Outcomes of a Hydrophobic Trifocal Diffractive Intraocular Lens in Eyes with Different Axial Lengths. PMID 41425743.

PUBLICATION TRANSPARENCY

The author reports no conflicts of interest.

No external funding or manufacturer support was received for this publication.

Independently developed by Ophthalmic Intelligence Europe.