Clinical Investigation Plan

Assessment of Clinical and Refractive Outcomes of the Use of a Femtosecond to Treat the Symptoms of Presbyopia in a Patient with Implanted Mono focal IOLs

CIP number: PL-RIS01

Version: 2.0. dated 07.9.2023

Sponsor:

Perfect Lens LLC

17785 Sky Park Circle, Suite B

Irvine, CA 92614

Version history

Version	Description	Date
1.0	Initial submission version	2023-07-18
2.0	Supplemented detail added to enhance clarity of submission.	2023-09-04

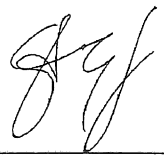
1 Signature page

I have read this version of the clinical investigation plan (dated 7.9.2023, version 2.0) in its entirety and approve all its contents.

I declare that:

- I agree to carry out and conduct this investigation, referenced as PL-RIS01, in strict compliance with the protocol (and its amendments), according to Good Clinical Practice and to all relevant and applicable regulations and guidance.
- This protocol contains confidential proprietary information with respect to **Perfect Lens, LLC** products and clinical studies. I agree to hold this information in confidence and not to disclose it to any third parties for a period of three (3) years after the completion of the investigation, or until said information shall become a matter of public knowledge or until a formal written agreement for that purpose has been entered into by the parties.

Principal Investigator	**Signature**	**Date**
MUDr. Pavel Stodůlka, Ph.D., FEBOS-CR Gemini Eye Clinic U Gemini 360 760 01, Zlin Czech republic		13/09/2023

Sponsor's Representative	**Signature**	**Date**
Steven Smathers Perfect Lens LLC 17785 Sky Park Circle, Suite B Irvine, CA 92614		9/7/23

Content

2 Synopsis

Title of the investigation	Assessment of Clinical and Refractive Outcomes of the Use of a Femtosecond to Treat the Symptoms of Presbyopia in a Patient with an Implanted Mono focal IOL
Clinical Investigation plan number	PL-RIS01
Investigational device	Perfector
Sponsor	Perfect Lens LLC 17785 Sky Park Circle, Suite B Irvine, CA 92614
No. of investigational site	Single center
Objective	The purpose of this research study is to evaluate the safety and efficacy of the treatment of the symptoms of presbyopia with a device (the Device") in a patient with an implanted monofocal IOL. The Device employs a generic femtosecond laser used in numerous other ophthalmic procedures. The Device uses low levels of energy from the femtosecond laser (the "Treatment") to create near vision in both eyes for a patient with an implanted mono focal intraocular lens ("IOL").
Clinical investigation design	This is a prospective, single-center, single-arm study. The Treatment utilizes a femtosecond laser creating a near vision foci in the implanted mono focal intraocular lens. The study will treat both eyes of a patient to ensure that the patient has effective multi focal vision. The Treatment for both eyes may be on the same day, assuming there are no issues with the initial validation Treatment. The duration of the study is expected to be 4 months for each patient. In addition to preoperative and operative visits, 3 postoperative visits are planned: 1 week, 1 month and 3 months postoperatively. With an overall Treatment period of 1 month, the duration of the entire study is expected to be 6 months in total.
Population	Patients implanted with a mono focal IOL in both eyes
Inclusion and exclusion criteria	**Inclusion criteria:** 1. Ability to understand study requirements, follow study instructions and to return for required study follow-up visits as confirmed by provision of written informed consent;

	2. Subject has undergone cataract surgery and has had a monofocal lens implanted in both eyes; 3. Subject has no significant residual visual issues which the Investigator believes would make the patient ill suited for the Treatment; 4. Both eyes have CDVA vision of 20/25 or better at 4m. **Exclusion criteria:** 1. Subjects not able to complete the informed consent form; 2. Clinically significant corneal abnormalities including corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy), inflammation, keratitis, keratoconjunctivitis, keratouveitis, keratopathy, keratectasia or edema per the Investigator's expert medical opinion; 3. Previous corneal surgery 4. Previous refractive surgery or proposed refractive surgery procedures throughout the entire duration of the subjects' participation in the clinical study (including, but not limited to LASIK, astigmatic keratotomy and limbal relaxing incisions); 5. History of or current retinal conditions or predisposition to retinal conditions including retinal detachment, diabetic retinopathy, age related macular degeneration which are assessed to by investigator to confound outcomes; 6. Amblyopia; 7. History of or current anterior or posterior segment inflammation of any etiology, or any disease producing an inflammatory reaction in the eye (e.g., iritis or uveitis); 8. Optic nerve atrophy; 9. Iris neovascularization; 10. Subjects with diagnosed degenerative eye disorders (e.g., macular degeneration or other retinal disorders); 11. Uncontrolled glaucoma; 12. Any subject currently participating in another investigational drug or device studies; and 13. Any subject disqualified by the Principal Investigator or Medical Monitor for any ocular issue.
Endpoints	**Primary endpoints:**

	There are three co-primary effectiveness endpoints at the 1-month post Treatment visit. Distance Corrected Near Visual Acuity (DCNVA) at 40 cm. The hypothesis tested for is to demonstrate superiority of the near vision of treated IOL to the near vision provided by the pre-Treatment IOL. Distance Corrected Intermediate Visual Acuity (DCIVA) at 66 cm. The hypothesis tested for is to demonstrate non-inferiority of the treated IOL to the pre-treated IOL (using a non-inferiority margin of 0.10 logMAR). Best corrected distance visual acuity (CDVA) at 4m. The hypothesis tested is to demonstrate non-inferiority of the treated IOL to the pre-Treatment IOL for corrected distance vision (using a non-inferiority margin of 0.10 logMAR).
Other outcome measures	The following is a list of additional outcomes measures: Uncorrected and corrected distance visual acuity (UDVA) Uncorrected and corrected intermediate visual acuity at 66 cm (UIVA) Uncorrected near visual acuity at 40 cm (UNVA) Corrected near visual acuity at 40 cm (CNVA) Defocus curve Contrast sensitivity Subjective manifest refraction Slit Lamp examination findings Fundus examination findings Intraocular pressure Spectacle independence questionnaire QoV patient questionnaire Treatment satisfaction Adverse Events Device deficiency
Examination schedule	Preoperative — Day -60 to day -1 Surgery visit — Day 0 Postoperative 1 week — Days 5 to 9 Postoperative 1 month — Days 21 to 42

	Postoperative 3 months Days 70 to 98
Sample size	A total of up to 24 eyes from 12 patients will be enrolled in this clinical investigation.
Statistical analyses	The study will use descriptive statistics to summarize quantitative and qualitative variables in the final report. For quantitative variables, it will provide measures such as mean, median, standard deviation, minimum, and maximum. For qualitative variables, it will present the number and percentage of patients in each category, including missing data.

3 Administrative structure

PRINCIPAL INVESTIGATORS:

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SPONSOR:

Steven Smathers
Perfect Lens LLC
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Irvine, CA 92614

4 Identification and description of the investigational device

4.1 Model/type and manufacturer

Model: Perfector

Manufacturer: Perfect Lens LLC
17785 Sky Park Circle, Suite B
Irvine, CA 92614

Classification as per MDR: Class IIb according to the European CE medical device classification (Regulation (EU) 2017/745)

4.2 Intended purpose, subject population and indications of the investigational device

4.2.1 Intended Purpose

The Device is intended to alter the refractive characteristics of an implanted IOL. The Device uses the energy from a femtosecond laser to break ester bonds within the IOL structure and create hydrophilic areas within the IOL. These hydrophilic areas incorporate water molecules into the molecular structure of the IOL and thus change the refractive characteristics of the IOL. In the present case the changed refractive characteristics gives the patient a second focal spot and affords the patient near vision.

4.2.2 Subject Population

Patients with an implanted mono focal IOL who do not exhibit any clinically significant conditions that would prevent them from benefits of multifocal IOL.

4.3 Description of the investigational device

4.3.1 Parts of the Device

The Perfector consists of (i) a femtosecond laser, (ii) a scanner capable of using light to capture two and three-dimensional images from within optical scattering media, (iii) a scanner (the "OCT"), which performs a non-invasive imaging test that uses light waves to take cross section pictures of the interior of the eye and is able to locate the implanted intraocular lens, (iv) an optical focusing system using lenses and mirrors, (v) an objective lens, (vi) a computer, (vii) a camera, (viii) proprietary software, which controls the relationship between the scanners, the laser and the focusing system, (ix) non-proprietary software produced by the manufacturers of the laser, 2D scanner, computer, and OCT, (x) patient attachment which attaches patient to system for Treatment, and (xi) a power supply, which includes an emergency power supply (the "UPS"). All components, except the proprietary software, are "off the shelf" items which are used in medical devices in the marketplace today. The Perfector is mounted upon a movable cart that measures 5 feet wide by 2½ feet deep, by 6 feet high. It is powered by a 220-240 VAC mains power supply.

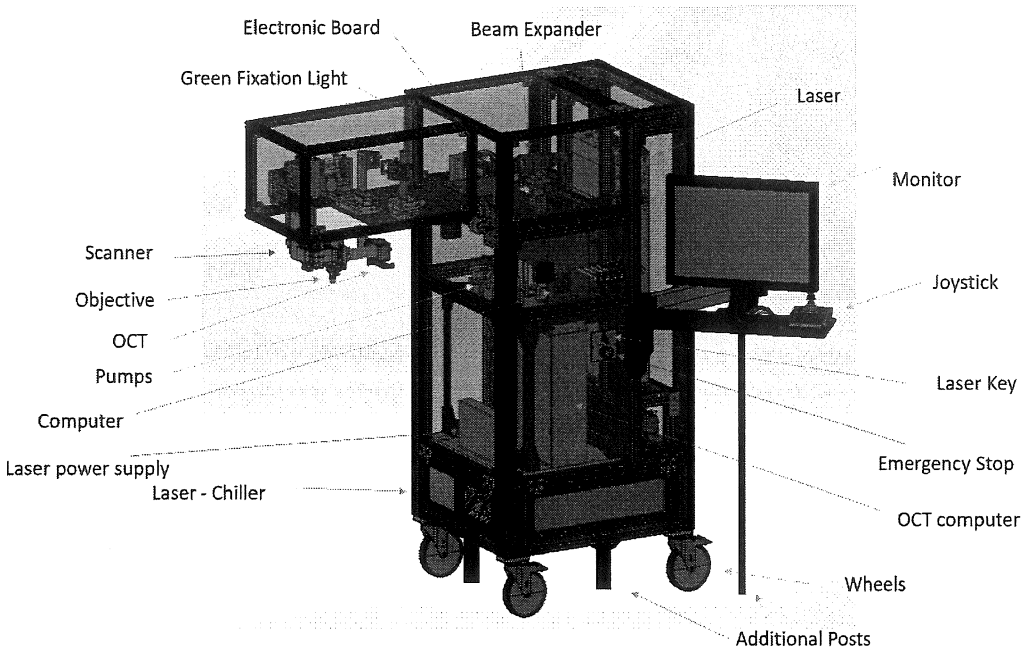

Figure 1 Scheme of the Perfector device

The Device alters the IOL by changing a thin disc in the interior of the IOL. It directs laser light to the IOL and alters the hydrophilicity of the treated area. By altering hydrophilicity of this treated area, the Device is able to create multi focality within the implanted lens. The exposure of the interior of the IOL to the femtosecond laser energy increases the hydrophilicity that is within the IOL by creating additional hydroxyl and acid groups. These acid and hydroxyl groups are hydrophilic and create a gradient which attracts water molecules. The addition of the water molecules changes the refractive properties of the IOL by reducing the refractive index of the treated area.

4.3.2 Use of the Device

The Device is used to alter the refractive qualities of an implanted IOL. In this case the goal is to creating near vision in a patient with an implanted mono-focal IOL. The science behind the change is explained above. The following is an image of the Device immediately before a Treatment

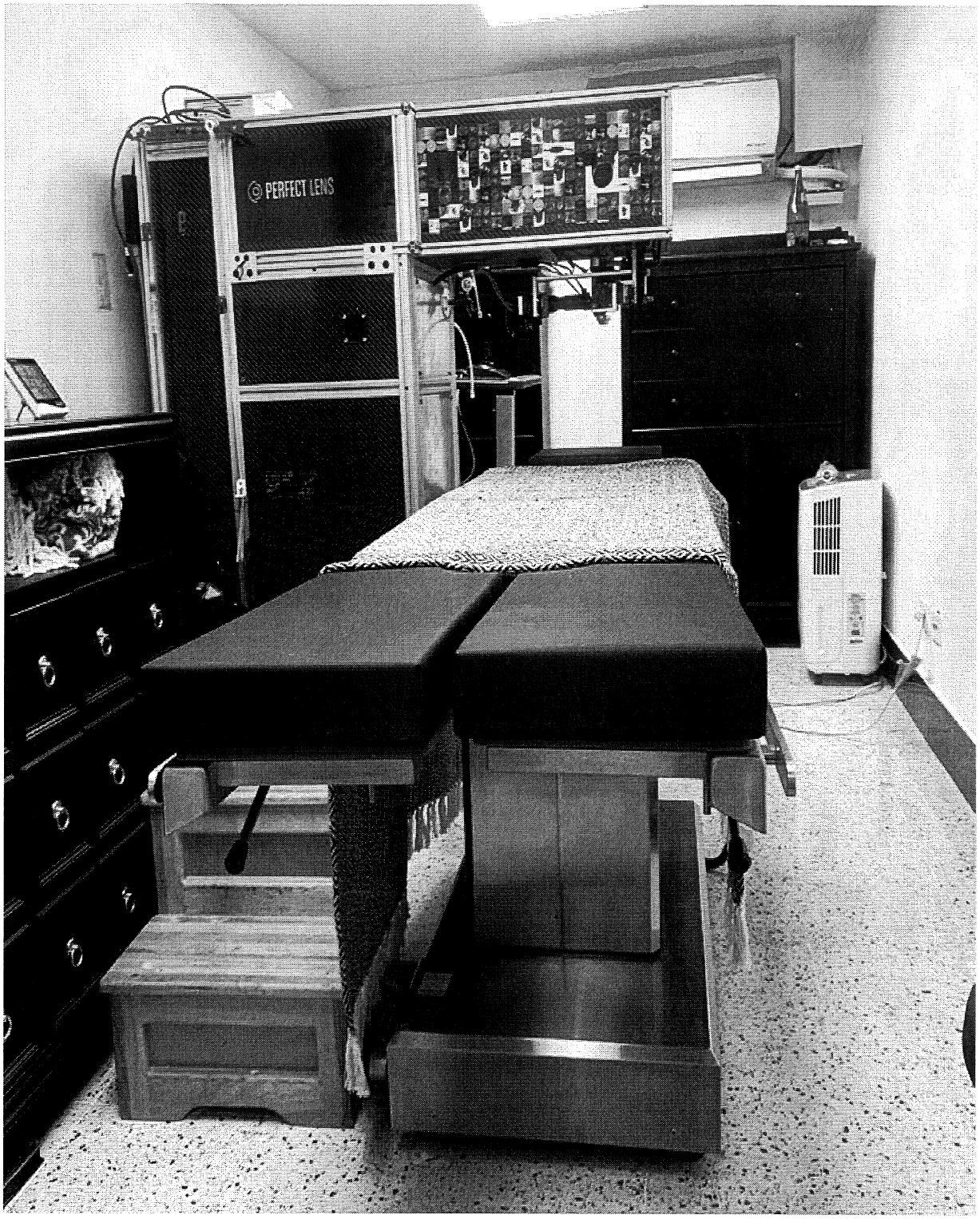

Figure 2 Perfect Lens laser system Perfector

The actual process for treating an implanted IOL consists of the following steps:

1) The nurse or physician i) dilates the eye and ii) administers numbing drops to the eye of the patient which is to be treated:
2) Once the patient's eye is sufficiently dilated the patient is placed on a table directly beneath the patient attachment which is attached to the Device;
3) The operator then enters the patient data and the change which is to be made to the IOL into the computer which guides the Device. The computer directs the scanner to create the exact laser exposure necessary to make the required change in the IOL;
4) The nurse or physician applies the eye speculum.
5) The patient is asked to focus on a alignment light inside the system. The operator measures the required tilt adjustement and the target is moved to the correct position.
6) The operator lowers the patient attachment to the patient's eye aligning the IOL with the scanning beam of the laser;
7) The patient's eye is attached to the Device using vacuum suction. The sclera of the eye is attached to the patient attachment in a docking procedure using a sterilized patient attachment. In the docking procedure the operator does not apply suction until the IOL is correctly aligned to the laser beam;
8) The operator of the Device can see the implanted IOL on the computer screen using the OCT and confirms that the laser is focused on the center of the implanted IOL;
9) Once the laser is focused the operator initiates the Treatment
10) Once the Treatment is completed the vacuum suction is released and the patient will be assessed.
11) Since there is no cutting or ablating of the eye the patient has minimal sclera irritation and good vision in the treated eye immediately after the Treatment but might be sensitive to light with their dialated pupil ; and
12) The change in the hydrophilicity of the implanted IOL will take up to 24-48 hours, thus the patient will not have near vision for that period; however, the patient's existing vision will be unaffected.

The Perfector is operated by a technician who has been trained in the use of the Device. Each technician has created over 50 multifocal lenses from monofocals in the laboratory and is trained for the operation of the Device.

5 Justification for the design of the clinical investigation

5.1 Background

Cataract surgery with intraocular lens (IOL) implantation is the most commonly performed surgical procedure in the world. The safety and effectiveness of modern-day cataract surgery are well described in the literature. In 2022, over 30 million procedures were performed worldwide.

The standard cataract surgery includes removal of the natural lens and replacement with an artificial lens; Intra-ocular lens (IOL). The surgeon chooses the power of the IOL to match the size of the eye. The target focal point is usually designed for far vision and thus all presbyopia patients require glasses for near vision.

Premium multifocal IOLs are designed to correct both distance and near vision. A patient who has a multifocal IOL has the advantage of spectacle independence. The multifocal lenses are expensive and require a patient to decide to choose this IOL before the surgery. Potential side effects include reduction of contrast sensitivity and visual disturbances such as halos and glares.

The Treatment, created by Perfector, uses a femtosecond laser to create a multifocal lens after the mono focal IOL lens has been implanted in an eye. This Treatment diverts light from the far vision foci, creating a near vision foci in addition to the far vision foci. The Treatment creates, in the IOL, a 60/40 light split with a newly created focal spot. The new focal spot gives the patient superior near vision. The diversion of the light to the new foci will diminish the patient's contrast sensitivity in low light situations but the patient will maintain equivalent far vision.

Femtosecond lasers have been used in ophthalmology since 2001 when they were introduced for the purposes of cutting corneal flaps in LASIK. The femtosecond laser was formally introduced into cataract surgery in 2009 to create corneal incisions. The use of the femtosecond laser to create corneal incisions, perform capsulotomies, and fragment existing cataracts (collectively the "Approved Femtosecond Methodologies") has received FDA and CE-Mark approval. Hundreds of thousands of patients undergo safe and effective femtosecond laser refractive and cataract Treatment every year.

5.1.1 Laser Energy

In the proposed study, Perfector intends to use, low-fluence, low-dose femtosecond laser energy at a fraction of the energy of used in capsulotomies. The chart of energy used is set forth below. The Treatment was used to make refractive changes to implanted lenses in a study in Panama. After an injury to a patient in the initial Treatment, the energy used in the Treatment has been reduced by over 90%. There was no adverse event in the last 12 patients treated with the lower energy levels. The energy used to create near vision in the implanted IO is less than the revised energy levels used to correct refractive errors in Panama. The energy used in this Study will less than the revised energy levels used in Panama, where there were no injuries.

The energy delivered in the Study is non-ablative – i.e., it does not cut eye tissue, but only modifies the refractive index of the implanted IOL. Unlike lens explanation or post-cataract

refractive surgery (LASIK/PRK), low-fluence femto-laser adjustment will not expose the eye to the risks of endophthalmitis, infection and many of the anterior segment and corneal problems associated with these procedures.

The Company has conducted an extensive laser safety study which is included in the investigator's brochure. The laser safety study states that the lack of energy and location of the energy focus is not hazardous to the eye. It is important to note that the procedure does not target any ocular tissue.

5.1.2 Mechanism of Action

The Device alters the IOL by changing a thin disc in the interior of the IOL. It directs laser light to the IOL and alters the hydrophilicity of the treated area. By altering hydrophilicity of this treated area, the Device is able to create multi focality within the implanted lens. The exposure of the interior of the IOL to the femtosecond laser energy increases the hydrophilicity that is within the IOL by creating additional hydroxyl and acid groups. These acid and hydroxyl groups are hydrophilic and create a gradient which attracts water molecules. The addition of the water molecules changes the refractive properties of the IOL by reducing the refractive index of the treated area.[2, 3, 4, 5, 6]

5.2 Pre-clinical testing

Summary of the preclinical testing that has been performed on the investigational device, together with an evaluation of the results of such testing, justifying its use in human subjects.

The index for all pre-clinical tests is attached as Exhibit B and is available for review. In summary:

The main preclinical material was the J&J material which is used during this study. The preclinical study literature is listing the J&J models (AAB00, ZCB00 or ZMB00). Additionally, the initial clinical study was performed on the same J&J material.

Study Name	Comment	Page # in Exhibit B	Material
Laser Safety Study	Optical hazard evaluation	1	NA
Exhaustive Extraction Study	No substantial differences between treated vs. untreated	43	J&J material
Leachable Study	No additional leachable created by the Treatment	53	J&J material

Bubble Creation Study	Bubbles created during Treatment contained no cytotoxic species	114	J&J material
Photostability Study	Showed no effect on treated IOL	179	J&J material
Hydrolytic Study	Accelerated Aging Study showed Diopter Stability and no additional leachable	184	J&J material
Glistening Study	Optimized Treatment created no glistening	208	J&J material
Safety Sensor Test using Start Test installed in Device	Safety Sensors do identify problems in the Device	213	NA
Inorganic Soluble Study	Laser adjusted lens free of significant amounts of inorganic solubles within FDA standards	219	J&J material
YAG Study	YAG Treatment had no adverse effects on adjusted IOL	241	J&J material
Intramuscular implantation of treated IOL Study	No calcifications created	280	J&J material
Patient Attachment Study	Minimal cytotoxicity, sensitization and ocular irritation	326	NA
Physical Property Study	Treatment had no effect on physical properties of IOL	413	J&J material
Light Transmission Study	No significant reduction in light transmission	441	Zeiss hydrophobic material
Light Scattering Study	No significant increase in light scatter	446	Zeiss hydrophobic material

5.3 Previous clinical testing

Perfect Lens conducted two clinical trials in Panama and treated a total of 14 patients.

5.3.1 First Clinical Trial

In 2018 Perfect Lens treated two patients. One patient had an adverse event and the study was stopped.

The adverse event was significant and was described as followed: Procedure site and site were correctly marked and patient went through treatment with only mild discomfort.

On post operative day one patient reported a new scotoma in the visual field of the treated eye. On examination anterior segment was within normal limits. Examination of the funds revealed a retinal lesion edematous dome with a approximate measurement of 1.5 the optic disc. The location was superior nasal to the fovea with in the macula. OCT confirmed full Retinal Thickness with significant edema

After that injury, the retina irradiance used was reduced from an average of 1.87W/cm^2 to 0.78W/cm^2.

5.3.2 Second Clinical Trial

There were no energy related adverse events in the second trial. The attached material contains the detailed results on the second trial. The retinal irradiance in the second trial was further reduced to enhance laser safety to 0.21W/cm2.

In 2020, 5 patients had been treated and efficacy results had been evaluated. Afterward hardware and software changes had been performed on the system and the trial was supposed to continue. Due to the Pandamic, the trial did not continue until 2022.

During the second part of the trial, a number of 6 patients were treated in 2022. The results from this group demonstrated that the treatment is able to successfully alter the refractive index of the implanted IOL.

2019 Results

The chart below set forth the results of the treatment for the last 6 patients:

PL	MRSE change [absolute]	UCDVA Goal UCDVA	BCVA	
			Screening	DAYS 90 - 120
PL08	0	20/32 to 20/40	20/16	20/12.5

2020 Results

The chart below set forth the results of the treatment for the last 6 patients:

PL	MRSE change [absolute]	UCDVA	BCVA	
			Screening	DAYS 90 - 120
PL004	0.125	20/63 to 20/40	20/20	20/16
PL027	0	20/40 to 20/30	20/16	20/20#
PL047	0.125	20/80 to 20/100	20/20	20/25
PL039	NA	20/40 to NA	20/25	NA
PL012	0.375	20/125 to 20/80	20/25	20/32

Patient PL027 returned in March 2022 and her MRSE had improved by 0.625D. She had both near and intermediate vision and was very happy with the outcome of the study. She inquired about getting treatment for her other eye. Movement impacts the how much of the actual RIS lens is shaped into the IOL. Therefore, in the case of strong movement a multifocal lens instead of a refractive lens was created. With the original refraction and the new refraction being the two foci.

2022 RESULTS

The chart below set forth the results of the treatment for the last 6 patients:

PL	MRSE change [absolute]	UCDVA UCDVA	Goal	BCVA	
				Screening	DAYS 90 - 120
PL202	1.85	20/40 to 20/20	20/20	20/25	20/20
PL204	0.25	20/50 to 20/32	20/20	20/20	20/20
PL205	1.25	20/40 to 20/40	20/20	20/20	20/20
PL210	1.5	20/40 to 20/40	20/40	20/32	20/32
PL211	0	20/40 to 20/32	20/20	20/20	20/20
PL212	0.875	20/40 to 20/16	20/20	20/16	20/16

Average Change in MRSE for the patients is 0.92D.

Mesopic Contrast Sensitivity Test

PL	Screening	After (Days: 90 to 120)

	With Glare	Without Glare	With Glare	Without Glare
PL202	89	82.6	98.2	102
PL204	18.3	92	67.3	98.7
PL205	51.9	98.9	49	78.6
PL210	51.9	39.8	45.6	80.6
PL211	52.8	76.3	109.9	133.6
PL212	95.4	91.6	104.4	109.2
Average	59.88333333	80.2	79.06666667	100.45

The mesopic contrast sensitivity changed with glare from an average value of 59.9 to 79.07 and improved with glare from an average of 80.2 to 100.5.

5.3.3 Conclusions

5.3.3.1 Second Trial, Part I

System Safety was demonstrated. Some safety feature implementations affected efficacy. The main components which contributed or allowed for patient movement had been identified and hardware changes had been implemented. Additional software changes had been implemented to allow for tracking of the movement / IOL stability.

5.3.3.2 Second Trial, Part II

1. The treatment is safe;
2. Best Corrected Visual Acuity was not affected; and
3. The treatment improved vision in all 6 patients, proving the theory of the underlying technology.

A first-in-human clinical trial for a novel medical device poses numerous challenges, primarily due to the inherent uncertainties and unknowns associated with venturing into uncharted territory. The primary obstacle lies in adapting the system and software to effectively operate and interact with the human body. Since the theory supporting the technology and the device effecting the change was new, its efficacy was largely untested, making it essential to carefully monitor and assess any potential adverse results. System and software adaptations are necessary as initial data is gathered, requiring agile adjustments and refinements to enhance device performance and user experience.
Additional information is provided in Exhibit C

5.3.4 Preparation for the current clinical study

The following adjustments have been made to ensure success in the new trial;

1. The patient attachment design and silicone stiffness have been adapted to minimize movement;

2. An improved eye tracking mechanism has been incorporated so the software can correct eye movement;
3. The Treatment has been optimized to reduce Treatment time (minimizing the effect of movement of the eye and enhancing safety); and
4. The device has been further stabilized to reduce setup time and increase patient

6 Risks and benefits of the investigational device and clinical investigation

6.1 Anticipated clinical benefits

The Treatment is designed to create a second focus spot in the implanted IOL which will give patient near vision without loss of far vision.

6.2 Anticipated risks

6.2.1 Primary Safety Analysis

The risks to the patients and the steps taken by Perfect to obviate those risks are set forth in the Risk Management Study attached as Exhibit A.

The principal risk to the patients is an injury from the laser energy. The last 12 patients treated using the Device in the Panama Study had no Adverse Events. The energy to be used in this study is less than the energy used in the human study in Panama where there was no injury and is less than 10% of the energy used when a patient has a serious Adverse Event from excess energy to the retina.

A second risk is that the IOL moves during the Treatment. If there is movement of the IOL Treatment is not effective. The Device and its components have been further stabilized to reduce the risk of movement. In addition, an IOL tracking system has been implemented to allow the operator to compensate for movement should it occur.

6.2.2 Additional Safety Analyses

See the Risk Management Study attached as Exhibit A for detail as to the management of all perceived risks. .

The following additional safety factors have been implemented for this Study to enhance the safety profile:

a) Reduction of energy level used in the Treatment; lower than the levels used in the prior human study, levels at which there were no injuries;

b) The patient attachment design and silicone stiffness have been adapted to minimize movement;

c) An improved eye tracking mechanism has been incorporated so the software can correct eye movement;

d) The Treatment has been optimized to reduce Treatment time (minimizing the effect of movement and reducing total energy);

e) The Device has been further stabilized to reduce setup time and increase patient comfort: and

f) The risks to the patients and the steps taken by Perfect to obviate any and all risks that might arise during the Treatment are set forth in the Risk Management Study attached as Exhibit A.

The principal risk to the patients is an injury from the laser energy. The energy used in the Treatment is within the ANSI safety standards for green light. The amount of energy used has been reduced to further enhance the safety profile. In addition, the laser exposure has been programmed to occur in short bursts with regular stops to avoid any heat build -up within the eye.

The Treatment is carefully monitored to ensure the subject eye is only exposed to the programmed amount of energy. The Risk Management study outlines the patient protections in the event there is an equipment failure. The Device has been equipped with safety shutdown mechanisms which cut off all energy to the eye in the event of any irregularity. The energy is cut off by a shutter which blocks the laser beam and protects the patient.

In this study the Sponsor will test the Device, prior to the Treatment of a patient ,and then retest and refocus the Device after each Treatment. Prior to a Treatment, the Sponsor will measure the energy levels at the site of the lens to insure it is at anticipated levels. Prior to treating a patient the Device conducts a series of self-tests for beam path, focus, intensity and the other issues outlined in the Risk Management Study.

The last 12 patients treated using the Device in the Panama Study had no Adverse Events. The energy to be used in this study is less than the energy used in the human study in Panama where there was no injury and is less than 10% of the energy used when a patient has a serious Adverse Event from exposing the retina to excess energy.

A second risk is that the IOL moves during the Treatment. If there is movement of the IOL Treatment is not effective. The Device and its components have been further stabilized to reduce the risk of movement of the IOL. In addition, an IOL tracking system has been significantly improved to allow the operator to compensate for movement should it occur.

6.2.3 Risk-to-benefit rationale

Benefits:

- Greater Predictability: The monofocal lens already has settled and the final outcome on vision and position is known.
- Improved Near Vision: The addition of multifocality can lead to a better near vision, allowing the patient to read and perform close-up tasks without the need of reading glasses.
- Depth of Vision: Depending on the lens design. The patient may experience reduced reliance on glasses for near and intermediate vision, enhancing convenience and overall visual experience.
- Enhanced Quality of Life: Improved vision and reduced dependence on glasses.
- Detailed Patient – Surgeon Discussion: The initial cataract surgery has different components and with the limited time of the ophthalmologist, the patient discussion about premium IOL features like multifocal lenses is limited. A post-surgery adjustment allows for a detailed discussion.

Risks:

- Adaptation Period: Some patients may require time to neuroadapt to the multifocal part of the IOL, during that time they might experience fluctuations in vision.
- Optical Compromises: Multifocal IOLs work by splitting light to provide clear vision at different distances. However, this design may lead to some loss of contrast or visual acuity compared to monofocal lenses. Studies for multifocal IOLs show excellent outcomes for patients with low residual refraction and low astigmatism. The inclusion criteria should minimize this risk.

Interpretation:

The benefit-risk ratio suggests that the potential benefits of creating multifocality after cataract surgery may outweigh the associated risks.

At this point there is a low level of risk as demonstrated by results of the prior human study and the pre-clinical testing.

6.2.4 Objectives and hypothesis of the clinical investigation

The objective of this research study is to evaluate the safety and efficacy of the Treatment of the symptoms of Presbyopia in an implanted mono focal IOL. The Device employs a generic femtosecond laser used in numerous other ophthalmic procedures. The Device uses low levels of energy from the femtosecond laser (the "Treatment") to change an implanted monofocal lens to a bifocal.

Exclusion and inclusion criteria had been selected to allow for the most favorable outcome for the patients while allowing for standard variations in outcomes for regular cataract surgery. Multifocal IOLs are sensitive to residual astigmatism, decentration and defocus of the implanted IOL. The best outcome for the patient requires to minimize the existing aberrations.

The lens design for this study enforces for a dominant far peak and adds the second foci 2.75D. Minimizing problems due to a large diopter add or a low far diopter MTF quality.

The Sponsor has demonstrated in the prior human study that the Treatment alters the vision of the treated patient. In that study the patient's vision improved in many cases but the patient's original vision acuity was not adversely affected by the Treatment even when the Treatment was unsuccessful.

7 Design of the clinical investigation

7.1 Study design

This is a prospective non-randomized patient controlled single centre design pilot clinical trial. One Study Cohort is planned with up to 12 patients and up to 24 eyes. The post Treatment eyes will be compared to the pre-Treatment eyes to determine if endpoints have been met. The study will treat both eyes of a patient to ensure that the patient has effective multi focal vision. The Treatment for both eyes may be on the same day, assuming there are no issues with the first Treatment.

7.2 Endpoints

There are three co-primary effectiveness endpoints at the 1-month post Treatment visit.

Distance Corrected Near Visual Acuity (DCNVA) at 40 cm. The hypothesis tested for is to demonstrate superiority of the near vision of treated IOL to the IOL pre-Treatment.

Distance Corrected Intermediate Visual Acuity (DCIVA) at 66 cm. The hypothesis tested for is to demonstrate non-inferiority of the treated IOL to the pre-treated IOL (using a non-inferiority margin of 0.10 logMAR).

Best corrected distance visual acuity (CDVA) at 4m. The hypothesis tested for the co-primary effectiveness endpoint #3 is to demonstrate non-inferiority of the treated IOL to the pre-

Treatment IOL (using a non-inferiority margin of 0.10 logMAR).

7.3 Other outcome measures

The following is a list of additional outcomes measures:

- Uncorrected and corrected distance visual acuity (UDVA)
- Uncorrected and corrected intermediate visual acuity at 66 cm (UIVA)
- Uncorrected near visual acuity at 40 cm (UNVA)
- Corrected near visual acuity at 40 cm (CNVA)
- Defocus curve
- Contrast sensitivity
- Subjective refraction
- Near addition
- Slit Lamp examination findings
- Fundus examination findings
- Intraocular pressure
- Spectacle independence questionnaire

- QoV patient questionnaire
- Treatment satisfaction
- Adverse Events
- Device deficiency

Note: All visual acuity assessment can be performed monocularly and binocularly as per the examination matrix and speciation of the measurements.

7.4 Investigational device

The Perfector is used in the procedure. The Device is attached to the patient by the use of a patient attachment. The patient attachment attaches to the sclera of the eye using vacuum pressure.

7.5 Comparator (control) arm

No comparator (control) arm is used in this investigation.

7.6 Subjects

7.6.1 Inclusion and exclusion criteria

Inclusion criteria:
1. Ability to understand study requirements, follow study instructions and to return for required study follow-up visits as confirmed by provision of written informed consent; 2. Subject has undergone cataract surgery and has had a mono focal lens implanted in both eyes; 3. Subject has no significant residual visual issues which the Investigator believes would make the patient ill suited for the Treatment; 4. Subject has in the treated eye of .5D or less; 5. Both eyes have UCDVA vision of 20/25 or better at 4m.
Exclusion criteria:
1. Subjects not able to complete the informed consent form; 2. Clinically significant corneal abnormalities including corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy), inflammation, keratitis, keratoconjunctivitis, keratouveitis, keratopathy, keratectasia or edema per the Investigator's expert medical opinion; 3. Previous corneal surgery 4. Previous refractive surgery or proposed refractive surgery procedures throughout

the entire duration of the subjects' participation in the clinical study (including, but not limited to LASIK, astigmatic keratotomy and limbal relaxing incisions);

5. History of or current retinal conditions or predisposition to retinal conditions including retinal detachment, diabetic retinopathy, age related macular degeneration which are assessed to by investigator to confound outcomes;
6. Amblyopia;
7. History of or current anterior or posterior segment inflammation of any etiology, or any disease producing an inflammatory reaction in the eye (e.g., iritis or uveitis);
8. Optic nerve atrophy;
9. Iris neovascularization;
10. Subjects with diagnosed degenerative eye disorders (e.g., macular degeneration or other retinal disorders);
11. Uncontrolled glaucoma;
12. Any subject currently participating in another investigational drug or device studies; and
13. Any subject disqualified by the Principal Investigator or Medical Monitor for any ocular issue.

7.7 Clinical Investigation duration and preferred visit windows

The involvement of the patient in the clinical investigation is for 3-5 months dependent on the time of the surgery. The Treatment period is planned for the 1 month hence the whole clinical investigation is planned to last up to 6 months.

Visit	Short term	Timeline
Preoperative Evaluation	PreTR	Day -60 to day -0
Treatment visit	TR	Day 0 (day of surgery)
Postoperative 1 week	1W	Days 5 to 9
Postoperative 1 month	1M	Days 21 to 42
Postoperative 3 months	3M	Days 70 to 98

7.8 Subject entry

Prior to enrolment in the clinical investigation, subjects from the standard post-operative cataract care population will be pre-screened via review of their medical charts to evaluate eligibility based on study inclusion/exclusion criteria. Study patients will be recruited from the Investigator's patient population, referrals, or IEC/IRB-approved recruitment materials.

The Informed Consent Process must be followed. Written informed consent for study participation is required prior to initiation of any study-specific procedure, and all subjects will be considered enrolled in the study upon their signature to the ICF.

All enrolled subjects will be assigned a single unique subject identifier at the preoperative visit, and this identifier will be used throughout the clinical investigation.

An enrolment log will be maintained at each clinical site. This log will be provided to the investigational sites by the sponsor or designated CRO and will be stored in the Investigator´s Site File. Current enrolment logs will be periodically provided to the sponsor or designated CRO as requested.

7.9 Preoperative Visit - This visit will occur prior to enrolment (Visit 0)

Below is a list of study procedures to be done at Visit 0. All assessments must be documented in the source documentation and electronic case report form (eCRF), if applicable. Data from the Investigator's previous routine clinical evaluation (e.g., slit lamp exam) may be used, if the data 1) meets the requirements of this protocol, and 2) were collected within the -90 to -1 day pre-Treatment time period.

1. Review study specific inclusion/exclusion criteria (e.g., age, previous ocular history) to ensure that a potential subject meets all qualifications for participation in the study.
2. For a potential subject meeting all entry criteria via pre-screening, invite him/her to participate in the study, and carry out the informed consent process if he/she is interested.
3. Collect subject demographic, medical history information, and concomitant medication use.
4. Evaluate subject against all entry criteria. If the subject fails the criteria, the subject shall be eliminated from the study.
5. Determine current medication and medical history related to ophthalmic issues.
6. Perform the following test procedures on the eye to be treated. All measurements shall be done on a consistent basis for all test procedures.
    a) Measure monocular and binocular uncorrected distance visual acuity (UDVA);
    b) Measure monocular and binocular corrected distance visual acuity (CDVA)
    c) Perform Manifest Refraction
    d) Measure monocular and binocular uncorrected near vision acuity (UNVA) at 40 CM,
    e) Measure monocular and binocular distance corrected near vision acuity (DCNVA),
    f) Measure monocular and binocular uncorrected intermediate vision acuity (UIVA),
    g) Measure monocular and binocular distance corrected intermediate vision acuity (DCIVA)
    h) Measure CNVA at 40 cm

i) Perform slit lamp biomicroscopy

j) Perform fundus Exam

k) Perform fundus and anterior segment OCT measurement

l) Perform biometry measurements to determine Keratometry, Axial Length and ACD

m) Perform tonometry to measure IOP

n) Perform ITrace measurement

o) Collect QoV patient questionnaire assessment for visual disturbances

p) Collect spectacle independence questionnaire

q) Collect a Defocus curve for patient's existing vision

r) Collect mesopic and photopic contrast sensitivity (with and without glare) using wave grating test CSV-1000

Any patient who falls within the exclusion criteria shall be considered a screen failure. The decision as to whether the patients fall within the exclusion criteria shall be made by the Principal Investigator and/or Co-Investigators.

7.10 Treatment Visit

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications
2. On the Treatment Visit the patient will be identified using two indicators (as described in Section 2B) and the site and side of Treatment will be identified;
3. The patient is treated as outlined in section 4.3.2
4. The patient will be observed post-Treatment and any Adverse Events and Device deficiencies will be recorded.

The Treatment for both eyes may be on the same day, assuming there are no issues with the first Treatment.

7.11 Post-Operative 1 Week Visit

This visit should occur at postoperative days 5-9. The following information will be captured for the study eye at this visit.

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications
2. The following tests shall be performed:
    a) Measure monocular and binocular uncorrected distance visual acuity (UDVA);
    b) Measure monocular and binocular corrected distance visual acuity (CDVA)
    c) Perform Manifest Refraction

d) Measure monocular and binocular uncorrected near vision acuity (UNVA) at 40 CM,

e) Measure monocular and binocular distance corrected near vision acuity (DCNVA) at 40cm,

f) Measure monocular and binocular uncorrected intermediate vision acuity (UIVA) at 66cm,

g) Measure monocular and binocular distance corrected intermediate vision acuity (DCIVA) at 66cm,

h) Perform slit lamp biomicroscopy

i) Perform fundus Exam

j) Perform tonometry to measure IOP

k) Adverse event assessment

7.12 Post-Operative 1 Month Visit

This visit should occur at postoperative days 21-42. The following information will be captured for the study eye at this visit:

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications
2. The following tests shall be performed:
    a) Measure monocular and binocular uncorrected distance visual acuity (UDVA);
    b) Measure monocular and binocular corrected distance visual acuity (CDVA)
    c) Perform Manifest Refraction
    d) Measure monocular and binocular uncorrected near vision acuity (UNVA) at 40 CM,
    e) Measure monocular and binocular distance corrected near vision acuity (DCNVA) at 40cm,
    f) Measure monocular and binocular uncorrected intermediate vision acuity (UIVA) at 66cm,
    g) Measure monocular and binocular distance corrected intermediate vision acuity (DCIVA) at 66 cm
    h) Perform slit lamp biomicroscopy
    i) Perform fundus Exam
    j) Perform tonometry to measure IOP
    k) Collect a defocus curve for patient's vision
    l) Collect mesopic and photopic contrast sensitivity (with and without glare)

m) Adverse Events assessment

7.13 Post-Operative 3 Months Visit

This visit should occur at postoperative days 70-98. The following information will be captured for the study eye at this visit:

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications
2. The following tests shall be performed:
   a) Measure monocular and binocular uncorrected distance visual acuity (UDVA);
   b) Measure monocular and binocular corrected distance visual acuity (CDVA)
   c) Perform Manifest Refraction
   d) Measure monocular and binocular uncorrected near vision acuity (UNVA) at 40 CM,
   e) Measure monocular and binocular distance corrected near vision acuity (DCNVA) at 40cm,
   f) Measure monocular and binocular uncorrected intermediate vision acuity (UIVA) at 66cm,
   g) Measure monocular and binocular distance corrected intermediate vision acuity (DCIVA) at 66cm,
   h) Measure CNVA at 40cm
   i) Perform slit lamp biomicroscopy
   j) Perform fundus Exam
   k) Perform tonometry to measure IOP
   l) Collect QoV patient questionnaire assessment for visual disturbances
   m) Collect spectacle independence questionnaire
   n) Collect a defocus curve for patient's vision
   o) Collect mesopic and photopic contrast sensitivity (with and without glare) using wave grating test CSV-1000

7.14 Unscheduled Visits

Unscheduled visits are those which are not required by the study protocol, but which occur due to a procedure performed on the study eye, or a subject complaint regarding this eye. No specific testing is required at unscheduled visits; rather, the Investigator and/or qualified investigational staff will perform the procedures necessary to evaluate the subject at these visits. Clinical data from these visits will be recorded on the relevant CRF.

7.15 Missed Visits

In the event that a subject misses a scheduled follow-up examination, site personnel will take prompt action to ensure the subject is examined as soon as possible, ideally within the same visit period. All communication attempts made to contact the subject should be thoroughly documented in the subject's chart for future reference and traceability.

If a subject fails to attend multiple consecutive examinations, site personnel are required to make a minimum of three documented attempts to contact the subject. These attempts can be made via telephone, email, or regular mail, ensuring multiple channels of communication are utilized.

In the event that the subject remains non-responsive to each of these follow-up attempts, the investigator may consider terminating the subject from the study, categorizing them as lost to follow-up. This decision will be made in accordance with the study protocol and ethical considerations.

7.16 Subject exit

Subjects are considered to have completed the clinical investigation if they have completed all follow-up examinations through 3 month-follow-up visit.

Currently there are no further follow up visits scheduled after the 3 month follow up. The chemical change and the lens diopter and quality are considered stable after the lens has soaked. Soaking refers to the time the water requires to penetrate into position. After 24 hours the main change will have occurred and within 7 days the soaking process is finalized.

Therefore, no follow up visit after 3 month is required for stability evaluation. Additionally, the standard follow up visit period for traditional multifocal intraocular lens implantation studies is 3 month. We are aware that the neuroadaptation might take longer but this would be beyond the scope of this pilot trial.

Exhibit B lists 3 accelerated aging studies which have been conducted to verify lens stability

The current study design is focused on a one-time treatment, invitro treatments have shown that multiple treatments are possible inside the same IOL. In an unsatisfactory outcome or with deterioration of near or far vision, a future possibility of an additional treatment would be possible. The conditions of the section treatment will still need to be defined and might be adjusted with future studies. In the laboratory successful additional treatments have been performed. Which included adding a cylindrical lens to a multifocal treatment, an additional spherical treatment to a multifocal treatment or adding or removing a multifocal treatment to a spherical lens which already had received a multifocal treatment.

7.16.1 Subject withdrawal or discontinuation

Subject participation is voluntary; any subject may discontinue participation in the clinical The clinical investigation will be conducted without prejudice, and subjects have the option to withdraw from the study voluntarily or be withdrawn by the Investigator or Sponsor. The Investigator has the authority to terminate subjects from the clinical investigation only if their continued participation in the study Treatment regimen would pose a risk to their health

and/or welfare. Efforts will be made to encourage subjects who wish to withdraw their consent to return to the clinical site for an exit visit assessment before officially withdrawing.

Subjects may be discontinued from the clinical investigation only when there are no other viable options. Reasons for discontinuation include, but are not limited to:

- Screen failure
- Subject's withdrawal of consent prior to Treatment
- Inability to continue participating in the study
- Subject's death
- Subject discontinued by the investigator (e.g., inadequate dilation on the surgical day)

A subject exit form must be completed for all subjects who complete, discontinue, or are terminated from the clinical investigation, providing the reason for their exit. Discontinued subjects will still be included in the analysis up until the point of their exit. Whenever feasible, all necessary clinical assessments will be conducted before the subject exits the investigation, even if the assessment was not originally scheduled for that particular visit.

The subject numbers assigned to discontinued subjects will not be reassigned to new participants.

Discontinued subjects will not be replaced, except in cases where they discontinued before receiving study Treatment.

7.16.2 Lost to Follow up

The clinical site is committed to conducting diligent follow-up on subjects who do not attend their scheduled examinations. A minimum of three documented attempts will be made to contact the subject, using methods such as telephone, email, or regular mail. If a subject remains unresponsive to these follow-up attempts, they will be categorized as "lost to follow-up." It is important to note that subjects who are classified as lost to follow-up will not be replaced with new participants.

To ensure proper documentation and record-keeping, a subject exit form must be completed for every subject who completes the study, discontinues their participation, or is terminated from the clinical investigation. The exit form should include the reason for their exit from the study, providing clarity and transparency regarding their status and any contributing factors.

7.17 Examination matrix

Examination data	Visit 1 - Screening	Visit 2 - Treatment	Visit 3 – 1W follow up	Visit 4 – 1M follow up	Visit 5 – 3M follow up
Informed consent	X				
Demographics, medical history	X				
Inclusion and exclusion criteria	X				
IOL laser adjustment		X			
Biometry measurements	X				
Slit lamp examination	X		X	X	X
Objective refraction	X		X	X	X
Intraocular pressure	X		X	X	X
Monocular UDVA, UIVA, UNVA	X		X	X	X
Binocular UDVA, UIVA, UNVA	X		X	X	X
Subjective manifest refraction	X		X	X	X
Monocular CNVA (with near addition)	X		X	X	X
Monocular CDVA, DCIVA, DCNVA	X		X	X	X
Binocular CDVA, DCIVA, DCNVA	X		X	X	X
Defocus curve	X			X	X
Contrast sensitivity	X				X
OCT	X			X	X
I-Trace	X				
Fundus examination	X		X	X	X
QoV questionnaire	X				X
Spectacle independence questionnaire	X				X
Adverse events, concomitant medication	X	X	X	X	X

7.18 Clinical-investigation-related procedures

7.18.1 Objective and subjective refraction

The assessment of refraction, which includes sphere (D), cylinder (D), and axis (°), will be conducted through subjective and objective methods. Objective refraction will follow standard clinical practice and will be performed by the Investigator or trained staff. Subjective testing will be conducted using trial frames instead of a phoropter. Consistency in the refractive technique should be maintained throughout the entire study duration. Test optotypes such as Sloan letters (e.g., ETDRS charts) will be used.

The cylinder value should be recorded in negative notation. Cylinder refraction should be performed for every patient. If the cylinder refraction is zero, the cylinder axis should be marked as not applicable. A pre-sign for the sphere is only necessary for negative values. If no pre-sign is entered, it indicates a positive value.

7.18.2 Measurement of visual acuities

Visual acuity assessment will be performed monocularly and binocularly using the ETDRS charts in photopic conditions. The device used will be document in the study documentation. For the intermediate and near VAs the ETDRS chart hand held charts (VectorVision) will be used. The following test will be performed as per the examination schedule.

- Uncorrected distance visual acuity (UDVA)
- distance corrected visual acuity (CDVA)
- Uncorrected intermediate visual acuity at 66 cm (UIVA)
- Distance corrected intermediate visual acuity (DCIVA) at 66 cm
- Uncorrected near visual acuity at 40 cm (UNVA)
- Corrected near visual acuity at 40 cm (CNVA)
- Distance corrected near visual acuity (DCNVA) at 40 cm

7.18.3 Biometry measurement

The equipment for assessing the clinical investigation variables is to the discretion of the investigator and his standard of care. For taking the biometry measurements the IOL Master 500 or 700 by Carl Zeiss Meditec AG should preferably be used though.

7.18.4 Aberrometer measurement - iTrace

Corneal, internal and total aberrometer data will be collected using iTrace device as per the standard operating procedure. Care will be taken to naturally induce as big pupil size as possible. No dilation will be used in this examination. The outcome values will be corneal, internal and total abertometry data – Higher Order Aberration, spherical aberration at 3 mm pupil and 4 mm pupil size.

7.18.5 Defocus curve

To assess the defocus curve the same optotype as for the distance visual acuity will be used. The test will be performed with the best distance corrected refraction and spherical additions

between -5.0 D to +1.5 D in 0.5 D steps. Defocus curve will be performed monocularly. The patient will be presented with the spherical additions in the order from -5.0 D to +1.5 D.

7.18.6 Contrast sensitivity

Contrast sensitivity testing will be performed monocularly with the distance-corrected study eye under photopic with glare, mesopic and mesopic with glare conditions using CSV 1000. The testing will be performed at spatial frequencies of 3, 6, and 12 and 18 cycles/degree.

Mesopic contrast sensitivity testing (3 cd/m2) using mesopic filter installed in the patient trial frame, will be performed prior to the photopic testing (85 cd/m2). A minimum of 5 minutes should be provided for the patient's eye dark adaptation before the beginning of the mesopic contrast testing in a room with photopic light conditions.

The ambient illumination should be lower or at most equal to the chart luminance. The mesopic testing without glare will be performed first before testing with glare source provided with the testing device.

7.18.7 Fundus examination

To examine the retinal integrity and document the safety of the procedure a full fundus examination will be performed using a slit lamp and dilated pupil for a clear view.

7.18.8 Slit lamp examination

Slit lamp examination will be performed using a slit lamp biomicroscope. The subject will be seated. During this examination the eyes might be dilated depending on doctors' decision. The following will be examined during the examination conjunctiva, cornea, anterior chamber, iris, eyelid. Magnification will be consistent with standard clinical practise.

The observation will be graded as normal or abnormal. In case of abnormal observations subjective graded according to the grading scales will be used. The abnormal grading will then be graded as clinical significant or not clinically significant. In case of clinically significant observation the event will be specified and will be collected as adverse events.

CORNEAL STATUS

1. Epithelial erosion, grade

0: Absent
I: Minimal
II: Mild
III: Moderate
IV: Marked
V: Severe

2. Corneal edema, grade

0: No corneal edema
1: < 3 mm in diameter

0: Completely clear cornea
1: Focal exudation in stroma

2: > 3 mm in diameter and < 5 mm in diameter

3: > 5 mm in diameter

2: Increase in stromal thickness

3: Severe increase in stromal thickness and exudation

SIGN OF INFLAMATION

1. **Anterior chamber cells, grade (Cells in field (size 1 mm by 1 mm slit beam)**

0	< 1
0.5+	1–5
1+	6–15
2+	16–25
3+	26–50
4+	> 50

2. **Anterior chamber flare, grade**

0	None
1+	Faint
2+	Moderate (iris/lens details clear)
3+	Marked (iris/lens details hazy)
4+	Intense (fibrin/plastic aqueous)

3. **Vitreous cells, grade**

0	No cells
0.5+	1-10
1+	11-20
2+	21-30
3+	31-100
4+	>100

4. **Hypopyon, grade**

H0	Absent
+	Less than 2 mm
++	Less than 5 mm (filling up half of anterior chamber)
+++	5 mm or more (filling more than half of anterior chamber

7.18.9 Intraocular pressure

The intraocular pressure (IOP) will be measured using air tonometry.

7.18.10 Optical coherence tomography (OCT)

Anterior segment OCT and fundus OCT will be taken as per the standard clinical practise. The findings will be recorded in the source documentation as either normal or abnormal. In case of abnormal findings the observation will be evaluated as clinical significant or not clinically significant.

7.18.11 Quality of life questionnaire

The questionnaire will be explained to the patient and handed over by staff. The translated version is enclosed in the Appendix 1.

7.18.12 Spectacle independence questionnaire

The questionnaire will be explained to the patient and handed over by staff. The translated version is enclosed in the Appendix 2.

7.19 Equipment

The equipment for assessing the clinical investigation variables is to the discretion of the investigator and his standard of care. The technicians and investigators should be familiar with the instructions for use of the devices and have prior experience with the devices before using it at the subject. The maintenance and (if applicable calibration) of the equipment shall be performed as required by the instructions for use.

7.20 Monitoring

A designated clinical monitor will oversee the clinical investigations in accordance with our established processes and applicable health authority regulations. The monitoring process will encompass the following components:

- The clinical trial monitor may conduct meetings with investigators before the start of the clinical investigation to evaluate the suitability of the subject population, facilities, and equipment in relation to the study requirements. These meetings also serve to familiarize the investigators with the clinical investigational plan.
- The clinical trial monitor may meet with the investigator(s) when subjects are being enrolled to ensure proper subject selection and accurate data recording.
- Throughout the clinical investigation, the clinical trial monitor retains the authority to visit the clinical site at any given time to review worksheets, eCRFs, and regulatory documents pertaining to the clinical investigation.
- Interim monitoring visits and telephone consultations will be carried out as necessary during the course of the clinical investigation to ensure satisfactory progress and comprehensive documentation of findings.
- Source Data Verification will be performed using a risk-based approach, with a

particular emphasis on primary and key secondary endpoints, as well as safety considerations. This verification process will be supported by remote monitoring. Detailed information regarding these procedures can be found in the Monitoring Plan.

- The clinical trial monitor has the prerogative to visit the clinical site at any time during the investigation to review worksheets, eCRFs, regulatory documents related to the clinical investigation, and patient source data records.
- Interim monitoring visits and telephone consultations will be conducted as required throughout the clinical investigation to ensure appropriate progress and comprehensive documentation of findings. Additional specifics can be found in the Monitoring Plan.

7.21 End of clinical investigation

The end of the clinical investigation is defined as the last patient last visit. Competent Authorities and all other applicable parties will be informed within 15 days after the end of the clinical investigation.

8 Statistical consideration

8.1 Sample size

A total of up to 24 eyes from 12 patients will be enrolled in this clinical investigation. Since this is a pilot clinical trial there is no proper sample size calculation performed. The number of the patients is chosen based on the estimated recruitment rate in the study duration and recommendation for pilot clinical trial in the literature [1].

8.2 Statistical analyses

Due to the nature of the study only descriptive statistical will be provided for the parameters in the final report.

The default summary statistics for quantitative variables will be the number of observations (n), number of missing observations (Nmiss), arithmetic mean, standard deviation (SD), median, minimum (min) and maximum (max) for those patients with data available.

For qualitative variables, the number (n) and percentage (%) of patients with non-missing data per category will be the default summary presentation, and where appropriate and present, the number of missing values as a separate category (Nmiss). For questionnaires, the missing values will be evaluated in an additional category of the variable.

Percentages will be calculated using a denominator of all patients in a specified population or Treatment group with available data. For questionnaires, the percentage will be based on all subjects in the respective Treatment arm attending the visit. If necessary, the denominator will be specified in a footnote to the tables for clarification.

The visual acuity data will be except the above mentioned characteristics also shown in cumulative frequency charts.

8.3 Clinical Study Reporting

Due to relatively short duration of the clinical investigation no interim analyses will be performed. Final report to the local ethics committee and authority will be send within the required time window upon the termination or completion.

9 Data management

Data Management procedures will follow applicable regulations, all details will be separately described in a study-specific Data Management Plan (DMP) prepared by the responsible data manager (DM) and finalized and signed by both DM and designee of Perfect Lens, LLC to the start of data entry for the first enrolled patient.

9.1 Ownership of the data

All the data or results from this study are the property of Perfect Lens, LLC.

9.2 Data reporting

All data will be collected using worksheets or into the medical documentation of the patients. A validated electronic data capture (EDC) system will be used for data entry. Access to the EDC application is through a secure website connected to a dedicated server. Each study team member will have a password-protected login with a unique username for individual identification. Access rights will be assigned based on pre-defined user roles relevant to their specific tasks in the clinical investigation.

Worksheets for preoperative, surgery, and postoperative visits will be provided if needed. These worksheets will align with the data entry pages (eCRFs) in the EDC system, serving as the source data when used by the site. Corrections to the worksheets or other source data will be made by crossing out the incorrect entry, recording the correct information, and initialling and dating the change. Both the study worksheets and the data entered into the EDC system will be audited by the Study Monitor.

Data entry into the EDC system will be pseudonymized, with each subject identified by a subject code rather than revealing the actual patient's identity. The EDC system will maintain an electronic audit trail for change control. Online checks for completeness and consistency will be performed during data entry, complemented by manual quality control from the data manager. System queries will be generated, and responses must be addressed within the EDC system.

The EDC system and data will be in the English language. Investigators will receive training on the impact of missing data on the integrity and credibility of the clinical investigation to minimize instances of missing data. To maintain data completeness and accuracy, computerized data checks will identify unusual entries for verification before statistical analysis. Any queries resulting from consistency checks will be addressed by the investigator or designee within the EDC system.

9.3 Data monitoring

Study monitor will review the source documentation to ensure participants safety and the data integrity. The monitoring will be performed as per the sponsor monitoring plan.

9.4 Clinical investigation report

Upon the conclusion or premature termination of the study, a comprehensive report will be prepared. The responsibility of drafting these reports lies with the sponsor, who will

collaborate with the coordinating investigator. Both parties are required to sign off on the reports.

In accordance with article 77(5) of the Medical Device Regulation (MDR), the clinical investigation report must be submitted within one year from the conclusion of the investigation or within 3 months if there is an early termination or temporary halt. The submission process to Ethic Committees and Authorities will be conducted in compliance with the local requirements.

9.5 Filling and archiving

The principal investigator bears the responsibility for organizing and maintaining all documents pertinent to the clinical investigation at their site. On the other hand, the sponsor is accountable for managing all sponsor-related documents, including the trial master file, the clinical investigational report, and associated data.

Following the conclusion of the clinical investigation, whether it reaches its intended completion or ends prematurely, essential clinical investigation documents must be securely archived and kept confidentially for a minimum of 15 years. This archival obligation applies both to the investigator and to the sponsor.

10 Amendments to the Clinical Investigation Plan

Throughout the course of the clinical investigation, necessary amendments might be made to the Investigator's Brochure (IB), Clinical Investigation Plan (CIP), Case Report Forms (CRFs), informed consent form, subject information, and other relevant clinical investigation documents. Each amended section of a document will be accompanied by a justification statement to provide a clear rationale for the changes made.

Proposed amendments to the CIP will be collaboratively agreed upon between the sponsor and the investigators. These amendments, along with any modifications to the subject's informed consent form, will be promptly notified to and approved by the Ethics Committee (EC) and regulatory authorities.

To facilitate transparency and clarity, in addition to the clean version of the documents, a redlined version in change tracking mode will be submitted, clearly highlighting the modifications made. This ensures that all parties involved can easily identify and review the specific changes.

It is essential to maintain a comprehensive record of the version number and date for each amendment made. This documentation helps track the evolution of the documents over time and ensures proper version control. Only after receiving approval or notification from the relevant authority or Ethics Committee, the new version of the documents will be distributed to each investigational site and implemented in the study.

11 Deviations from the Clinical Investigation Plan

The sponsor or investigator will ensure that the Ethics Committee and Competent Authority are promptly notified of any protocol changes in accordance with relevant regulations and established procedures of the Ethics Committee/Competent Authority. Investigators are not permitted to deviate from the protocol without written approval from the Ethics Committee/Competent Authority and the sponsor, except in cases of medical emergencies where the investigator must exercise judgment to remove the subject from immediate harm. Any significant changes or deviations from the protocol will require a protocol amendment, which must be pre-approved by the Ethics Committee.

In the event of an unexpected protocol deviation, the investigator must immediately inform the sponsor, and the deviation will be documented. If necessary, site staff will undergo re-training on the specific topics to prevent future deviations.

The sponsor is responsible for classifying each protocol deviation as major or minor. Major protocol deviations are those that could substantially impact the completeness, accuracy, and/or reliability of the study data, or significantly affect a subject's rights, safety, or well-being. Examples of major protocol deviations may include enrolling subjects who do not meet key eligibility criteria or failing to collect necessary data for interpreting primary endpoints. Minor protocol deviations include visits conducted outside the specified time window, missed ancillary measurements in subjects who did not return for visits, or incorrectly performed ancillary measurements. Additional details regarding the classification of protocol deviations will be provided in the study-specific Monitoring plan.

During the Data Review Meeting (DRM) protocol deviations will be reclassified as major/minor or critical/non-critical for the purpose of allocating subjects to the per-protocol cohorts on both eye- and subject-level. Only protocol deviations that could impact the evaluation of primary endpoints will be considered major when determining the allocation to analysis sets.

Unless otherwise required, only major protocol deviations with safety implications will be reported to the local Ethics Committee, including those that could potentially affect patient safety.

12 Device accountability

The device will be provided by the sponsor who will install and calibrate the device at the site.

The process of installation and, if applicable, de-installation will be meticulously documented in installation/de-installation reports. Copies of these reports will be stored in both the investigator site file (ISF) and the trial master file (TMF) for proper record-keeping. The original reports will be securely filed to ensure their safekeeping and accessibility.

13 Compliance

This clinical investigation will be conducted in strict adherence to the relevant recommendations established by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as well as subsequent revisions. It will also adhere to the European Committee for Standardization ISO 14155, which sets the standard for clinical investigation. Additionally, all applicable local and national regulations will be followed.

All parties involved in the conduct of the clinical investigation bear the responsibility for ensuring its ethical conduct, as per their respective roles. This includes obtaining approval from the Ethics Committee (IEC)/Institutional Review Board (IRB) and Competent Authority, obtaining prospective informed consent, monitoring the investigation's progress, ensuring the accuracy of data entered into the Electronic Data Capture (EDC) system or other employed methods, which may be carried out by the Sponsor or its designated representatives. The Sponsor will also retain records in accordance with MPKPV §10 section (7) and Regulation (EU) 2017/745 (MDR), Chapter VI, and Annex XV.

Furthermore, all parties involved will comply with the EU General Data Protection Regulation 2016/679 (GDPR) and the relevant national Data Protection Regulation. Data protection and privacy measures will be strictly followed to ensure compliance with these regulations.

The Sponsor holds the responsibility of obtaining the necessary approvals from the Ethics Committee (EC) and Competent Authority on behalf of the investigator before commencing subject enrolment in the clinical investigation. Additionally, the Sponsor is required to keep both the EC and Competent Authority informed about any serious side effects or adverse events that occur during the study, as well as any amendments made to the protocol.

The Principal Investigator at each investigational site bears the responsibility for ensuring the

proper conduct of the study in accordance with the aforementioned regulations, guidance documents, clinical study agreement, protocol (including amendments), and any additional conditions imposed by the reviewing EC, if applicable. The Principal Investigator must ensure the presence of an adequate number of qualified personnel and the availability of necessary facilities for the entire duration of the study, in order to conduct the investigation safely and appropriately. Furthermore, the Principal Investigator must ensure that all personnel involved in the investigation receive sufficient training on the protocol, investigational products, and their respective responsibilities and roles within the study.

The study must be carried out in accordance with the Standard Operating Procedures (SOPs) of the Sponsor or the delegated Contract Research Organization (CRO), as well as all other relevant regulations that apply to the investigation.

13.1 Insurance

For the purpose of this clinical investigation, a specific insurance policy will be obtained to cover subjects for clinical-investigation-related risks arising from their participation. Additionally, an insurance policy for commuting accidents will also be contracted. It is important to note that the responsibility for arranging these insurance policies lies with the sponsor, Perfect Lens. Prior to signing the patient informed consent, all subjects will receive detailed information regarding the insurance coverage.

The primary contact for the insurance provider is as follows:

HDI Versicherung AG, organizační složka
Jugoslávská 29
120 00 Praha 2
Tel: +420 220190210
Fax: +420 220190299
E-Mail: info@hdiczech.cz

HDI is responsible for providing national insurance certificates. The sponsor must submit these certificates to the Ethics Committee before the study commences. A copy of the certificates will be included in the Investigator Site File. It is crucial to emphasize that patients will only be insured after they have signed the consent form. Patients who undergo preoperative examinations that are consistent with the regular practices of refractive laser surgery clinics will not be covered by this insurance if they are only undergoing screening and not participating in the full study.

13.2 Publication policy and confidentiality

The clinical investigation will be registered in a publicly accessible database prior to the enrolment of the first patient.

14 Adverse events, adverse device effects and device deficiencies

During the course of the planned clinical investigation, utmost attention will be given to detecting any potential adverse events or unfavourable discoveries. Should any adverse event take place, the safety of the subject will be the primary concern, and suitable medical intervention will be provided promptly. All adverse events, regardless of severity and whether they are attributed to the investigational device or clinical investigation-related procedure, will be diligently recorded in the relevant sections of the subject's worksheets (CRFs).

All findings related to adverse events must be documented in the "Adverse Event (AE)" section of the subject's worksheets (CRFs). These events are categorized as either serious or non-serious, as well as related or unrelated to the investigational device/procedure. The method of reporting or documenting these adverse events varies depending on their category (serious or non-serious).

If the device operator, a bystander, or any third person experiences a severe adverse event possibly linked to the investigational device, it must be reported using an AE form along with a Device Deficiency form if applicable.

14.1 Definitions

The following are the definitions as per ISO 14155:2020

14.1.1 Adverse Event (AE)

Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated. This definition includes events related to the investigational medical device. This definition includes events related to the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices.

14.1.2 Adverse Device Effect (ADE)

Adverse event related to the use of an investigational medical device or to the procedure. This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

14.1.3 Device Deficiency (DD)

An inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety usability, safety or performance. Device deficiencies include includes malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling. This definition includes device deficiencies related to the investigational medical device. DD can become (might lead to) serious adverse events (SAE) if:

a) suitable action had not been taken, or

b) intervention had not been made, or

c) if circumstances had been less fortunate

These DDs are handled using the SAE reporting system.

14.1.4 Serious Adverse Event (SAE)

According to MDR 2017/745, serious adverse event means any adverse event that led to any of

the following:

a) death,

b) serious deterioration in the health of the subject, that resulted in any of the following:

   a. life-threatening illness or injury,

   b. permanent impairment of a body structure or a body function,

   c. hospitalization or prolongation of patient hospitalization,

   d. medical or surgical intervention to prevent life-threatening illness or injury or

   e. permanent impairment to a body structure or a body function,

   f. chronic disease,

c) fetal distress, fetal death or a congenital physical or mental impairment or birth defect;

According to the ISO 14155:2020: planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.

Any adverse events that do not satisfy these descriptions are defined as being non-serious.

14.1.5 Serious Adverse Device Effects (SADE)

Adverse device effect (ADE) that has resulted in any of the consequences characteristic of a serious adverse event.

14.1.6 Anticipated and Unanticipated Serious Adverse Device Effects (ASADE and USADE)

Anticipated serious adverse device effect (ASADE) is a Serious Adverse Device Effect (SADE) which by its nature, incidence, severity or outcome has been identified in the study protocol. An Unanticipated serious adverse device effects (USADE) is a Serious Adverse Device Effect (SADE) which by its nature, incidence, severity or outcome has not been identified in the study protocol.

14.2 Adverse event causality

In this study, the investigator is required to assess the causality of each adverse event (AE) based on the degree of responsibility of the investigational device itself or the procedure for implementing a medical device. The assessment should determine whether the AE is related or not related to the medical device, comparator, or study procedure, using the following categories:

- When the event shows no temporal relationship with the use of the investigational device or the procedures related to the application of the investigational device.

- When the serious adverse event does not follow a known response pattern to the medical device (if such response pattern is previously known) and is biologically implausible.
- When the discontinuation of medical device application or the reduction of the level of activation/exposure (if clinically feasible), followed by reintroduction of its use (or an increase in the level of activation/exposure), does not impact the occurrence of the serious adverse event.
- When the event affects a body-site or an organ that cannot be influenced by the device or procedure.
- When the serious adverse event can be attributed to another cause, such as an underlying or concurrent illness/clinical condition, an effect of another device, drug, Treatment, or other risk factors.
- When the event is not influenced by a false result given by the investigational device used for diagnosis, if applicable.

In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.

- **Possible:** There is a weak relationship with the use of the investigational device or comparator, but complete exclusion cannot be confirmed. Other potential causes, such as underlying or concurrent illnesses/clinical conditions, or effects of other devices, drugs, or treatments, are also plausible. Cases where relatedness cannot be assessed or when insufficient information is available should also be classified as possible.
- **Probable:** The relationship with the use of the investigational device or comparator appears relevant, and there is no reasonable explanation based on other causes. However, additional information may be required to further ascertain the connection.
- **Causal Relationship:** The event is undeniably associated with the investigational device or comparator or with procedures, leaving no room for doubt regarding the link between the event and the intervention

14.3 Adverse events severity

AEs will be graded on a 3-point scale (mild, moderate, severe) using the following definitions:

(a) Mild: Discomfort noticed, but there is no disruption of normal daily activity

(b) Moderate: Discomfort is sufficient to reduce or affect normal daily activity

(c) Severe: Subject is incapacitated as evidenced by the inability to work or perform normal daily activity

14.4 Follow-up of Adverse Events

AEs will be followed until resolution or stabilization of the event.

The outcome of each AE will be categorized into one of the following groups for reporting

purposes:

- Recovered/resolved
- Recovered/resolved with sequelae (specify type of sequelae)
- Ongoing
- Death

If there is more than one AE, only the AE leading to death will be attributed with a "fatal" outcome.

14.5 Expedited Reporting of Adverse Events

An AE should be classified as SERIOUS if it:

(a) Caused or led to death.

(b) Was life threatening (i.e., the AE placed the subject at immediate risk of death).

(c) Required or prolonged inpatient hospitalization (i.e., the AE required at least a 24-hour inpatient hospitalization or prolonged a hospitalization beyond the expected length of stay).

(d) Was sight threatening.

(e) Was disabling (i.e., the AE resulted in a substantial disruption of the subject's ability to carry out normal life functions).

(f) Resulted in a congenital anomaly/birth defect (i.e., an adverse outcome in a child or fetus of a subject due to participation in this study).

(g) Does not meet any of the above serious criteria but jeopardized the subject by requiring medical or surgical intervention to prevent one of the outcomes listed above.

14.6 Anticipated adverse events

All ocular AEs in the study eye must be reported on the relevant CRF. AEs will be categorized by degree of harm to the subject (mild, moderate, or severe).

Ocular conditions or diseases present at the time of study enrolment will be considered as "baseline." Changes in a chronic condition or disease that are consistent with natural disease progression are not considered SRAEs.

AEs that might occur include, but are not limited to, the following:

(a) Corneal abrasion

(b) Anterior chamber cell and flare requiring initiation of steroid Treatment.

(c) Corneal edema

(d) Cystoid Macular Edema

(e) Retinal issues

(f) Elevated IOP requiring Treatment

14.7 Timeline for reporting AE

All adverse events must be reported within 7 business days from the moment the investigators become aware of them. The reporting process involves electronically completing the designated page in the eCRF system.

For Adverse Device Effects (ADE) and Serious Adverse Events (SAE), the Investigator is required to report to the Sponsor within 2 business days of becoming aware of the event using the eCRF. This applies also to the events anticipated or anticipated events.

In case the eCRF is not functioning the investigator is obliged to use any means of communication and notify him within the defined timelines.

15 Vulnerable and dependent population

This investigation strictly prohibits the inclusion of any vulnerable population. Furthermore, individuals who may be dependent on the sponsor or investigator will also be excluded from participating in this clinical investigation.

16 Suspension or premature termination of the clinical investigation

The Sponsor retains the right to terminate or interrupt this investigation at any time, with the following reasons considered:

- Identification of device deficiencies indicating technical problems with the medical device that require attention.
- Incidence or severity of adverse events observed in this or other investigations, suggesting potential health risks to subjects.
- Unsatisfactory subject enrolment.

According to the Medical Device Regulation (MDR), specifically article 77, the Sponsor assumes responsibility for notifying all recruited investigators, Ethics Committees, and, in accordance with local regulations, Competent Authorities regarding the termination of the investigation. The Sponsor must inform Competent Authorities within 15 days, providing a justification. In the event of suspension or premature termination of the investigation due to safety concerns, the Sponsor is obliged to inform all Competent Authorities within 24 hours.

Furthermore, the Sponsor or its representatives reserve the right to discontinue participation at any individual investigational site. Reasons for discontinuation may include:

- Unsatisfactory subject enrolment.
- Inaccurate or incomplete data recording.

- Non-compliance by the investigator or Ethics Committee with current ICH Good Clinical Practice requirements or other applicable regulatory obligations.

In the event of termination of the clinical investigation, the following actions will be taken:

- Enrolment will cease.
- All subjects who have not received Treatment with the investigational device will be exited from the clinical investigation.
- Enrolled and treated subjects will continue with all planned follow-up visits.
- The Clinical Committee, as defined by the Sponsor will assess any safety-related reasons for the suspension or premature termination.

17 Reference

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3. Bille JF, Chhoeung S, Chan K, Engelhardt J, Volpp HR, Laghouissa AM, Motzkus M, Jiang Z, and R.Sahler, Chemical basis for alteration of an intraocular lens using a femtosecond laser, Biomedical Optics Express, Vol.8, Issue 3, pp.1390-1404 (2017).
4. Sahler R., Bille JF, Enright S, Chhoeung S, Chan K, Creation of a refractive lens within an existing intraocular lens using a femtosecond laser, J Cataract Refract Surg. 2016 Aug;42(8):1207-15.
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6. R. Sahler, JF. Bile. Refractive Index Shaping – In-Vivo Optimization of an Implanted Intraocular Lens (IOL). High Resolution Imaging in Microscopy and Ophthalmology. Chapter 15. Springer 2019

18 Appendix

18.1 Quality of life questionnaire in Czech version

Dotazník kvality vidění

ID: _____ Datum: _____

Ve Vašem každodenním životě:

1. A) Jak často vnímáte záři okolo světel?
   Nikdy Výjimečně Docela často Velmi často

   B) Jak silná je tato záře okolo světel?
   Vůbec Mírná Střední Velmi silná

   C) Jak moc Vás záře okolo světel obtěžuje?
   Vůbec Trochu Docela dost Velmi

2. A) Jak často vnímáte kruhy okolo světel?
   Nikdy Výjimečně Docela často Velmi často

   B) Jak silné jsou tyto kruhy okolo světel?
   Vůbec Mírné Střední Velmi silné

   C) Jak moc Vás kruhy okolo světel obtěžují?
   Vůbec Trochu ano Docela dost Velmi

3. Jak často vnímáte paprsky okolo světel?
   Nikdy Výjimečně Docela často Velmi často

   B) Jak silné jsou tyto paprsky okolo světel?
   Vůbec Mírné Střední Velmi silné

   C) Jak moc Vás paprsky okolo světel obtěžují?
   Vůbec Trochu ano Docela dost Velmi

4. Máte nějaké další potíže s Vaším zrakem?

18.2 Spectacle independence questionnaire in Czech version

ID:_____ Datum:_____

Dotazník nezávislosti na brýlové korekci

1) Potřeboval(a) jste za posledních 7 dní brýle nebo kontaktní čočky na...

	ANO	NE
Vidění do dálky (1,5 nebo více metrů)	☐ 1	☐ 2
Vidění na střední vzdálenost (0,5 metru do 1,5 metru)	☐ 1	☐ 2
Vidění do blízka (méně než 0,5 metru)	☐ 1	☐ 2

2) Jak často jste za posledních 7 dní nosil(a) brýle nebo kontaktní čočky na...

	Pořád	Většinu času	Jen někdy	Jen málo	Vůbec
Vidění do dálky (1,5 nebo více metrů)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vidění na střední vzdálenost (0,5 metru do 1,5 metru)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vidění do blízka (méně než 0,5 metru)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3) Dokázal(a) jste za posledních 7 dní fungovat pohodlně BEZ brýlí či kontaktních čoček na...

	Pořád	Většinu času	Jen někdy	Jen málo	Vůbec
Vidění do dálky (1,5 nebo více metrů)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vidění na střední vzdálenost (0,5 metru do 1,5 metru)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vidění do blízka (méně než 0,5 metru)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5