

***Clinical Evaluation  
3-month Follow-up  
Report***

***Of  
SeeLens HP  
Intraocular Lens***

***27 December 2010***

***version 1.1***

## Table of Contents

<b>TABLE OF CONTENTS</b> .....	<b>1</b>
<b>OBJECTIVES</b> .....	<b>2</b>
<b>EFFICACY AND SAFETY ASSESSMENTS</b> .....	<b>2</b>
<b>MEDICAL DEVICE SPECIFICATION AND ADMINISTRATION</b> .....	<b>3</b>
SPECIFICATIONS .....	3
1. <i>Device description</i> 3	
2. <i>SeeLens HP design</i> 4	
3. <i>Surgical Procedure</i> 6	
<b>METHODS</b> .....	<b>7</b>
STATISTICAL METHODS .....	7
<b>RESULTS</b> .....	<b>8</b>
A. IOL PERFORMANCE DURING IMPLANTATION.....	8
B. IOL LOCATION AND CENTRATION .....	9
C. POST-OPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) .....	9
D. INTRAOCULAR PRESSURE CHANGES .....	11
E. INTRA-OPERATIVE REPORT .....	13
F. ADVERSE EVENTS AS DEFINED BY ISO 11979-7 2001 .....	14
<b>CONCLUSIONS</b> .....	<b>15</b>
<b>SIGNATURE PAGE</b> .....	<b>16</b>

## Objectives

The objective of this study is to evaluate the safety and efficacy of the SeeLens HP IOL, implanted following cataract removal by phacoemulsification.

1. The key efficacy parameters are:
  - Best Corrected Visual Acuity (BCVA)
  - Predictability of refractive correction
2. The key safety parameters include:
  - IOL behavior during implantation and follow-up
  - IOL related infection and/or inflammatory reactions

## Efficacy and Safety Assessments

The efficacy and safety assessments were determined as defined by and according to the ISO 11979 directive. The following are the demands required by the directive:

1. Post Operative BCVA of at least 6/12 (20/40) within 88% of patients' population. For the "best cases" patients, BCVA 6/12 (20/40) or better, for at least 94% of the patients. (Requirements defined by ISO 11979-7 2001).
2. IOL related Post Operative complication and Adverse Events equal to or less then the allowed rate defined by ISO 11979-7 2001.
3. Refraction deviations criteria were established according to literature. The standard for accuracy for normal eyes was addressed in study "Benchmark standards for refractive outcomes after NHS cataract surgery." The authors concluded that the "benchmark" standard for refractive outcomes for normal eyes after cataract surgery should be within  $\pm 0.50$  D for 55% of cases and within  $\pm 1.00$  D for 85% of cases (Gale RP, Saldana M, Johnston RL, Zuberbuhler B, McKibbin M. Benchmark standards for refractive outcomes after NHS cataract surgery. Published on-line in Eye, 24 August 2007)

## Medical Device Specification and Administration

### Specifications

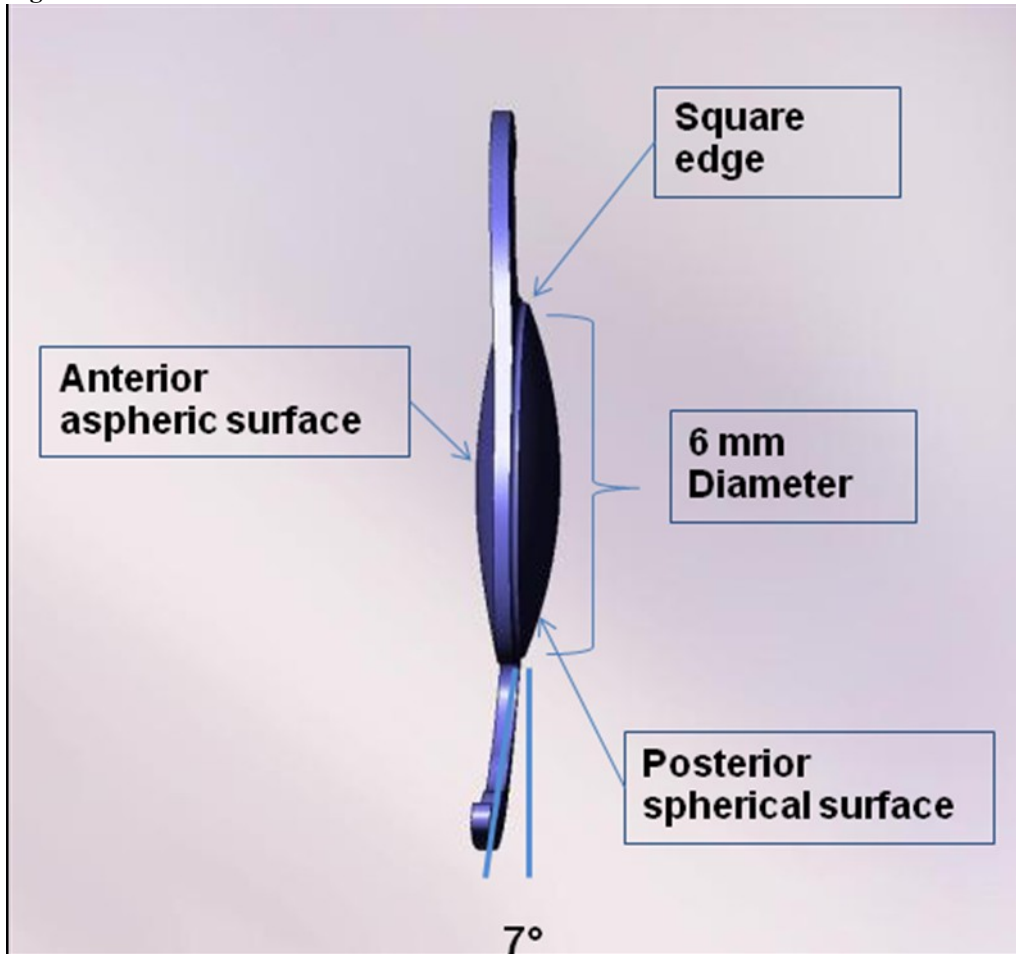
#### 1. Device description

The SeeLens HP is an aspheric asymmetric intraocular lens, which is CE marked since 2009.

SeeLens HP Specifications	
<b>Optic Diameter</b>	<b>6.0 mm</b>
<b>Power range</b>	<b>+10 to +30 (0.5 increments) +30 to +40 (1.0 increments)</b>
<b>Optic design</b>	<b>Asymmetric Bi convex aspheric lens</b>
<b>Lens design</b>	<b>Double square edge with stepped barrier</b>
<b>Haptic angulation</b>	<b>7°</b>
<b>Material</b>	<b>BENZ HF1 NATURAL YELLOW</b>
<b>Refractive index</b>	<b>1.485 (35° c)</b>
<b>YAG laser</b>	<b>Compatible</b>
<b>A constant</b>	<b>119.5</b>
<b>Placement</b>	<b>Capsular bag</b>
<b>Injection – incision size</b>	<b>2.4 mm incision</b>



Figure 1: SeeLens HP Intraocular lens

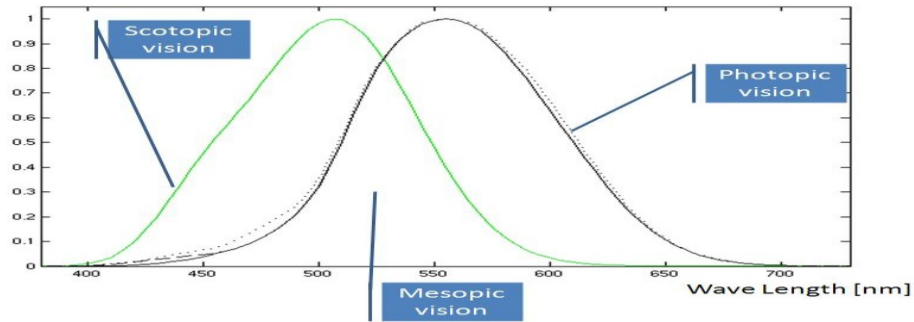


## 2. SeeLens HP design

### a. Motivation – visual acuity

Hanita Lenses search for vision quality improvements has a shared objective for both refractive and cataract surgery. The main goal for the refractive and cataract surgery is to provide the patient with the best *visual acuity* and good *post operative refraction* that current technology allows.

The quest for an improved visual acuity for the cataract patient led Hanita Lenses to develop an aspheric-shaped lens. Designed to allow the patient a sharper image in the regular photopic vision (daylight vision), and reduce the aberrations of mesopic and scotopic vision (twilight and night vision), which are noticed by some of the conventional spherical Intra Ocular Lens implanted patients.



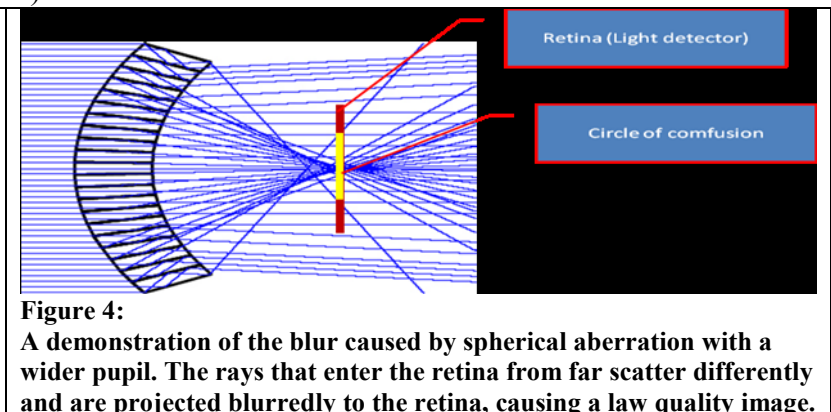
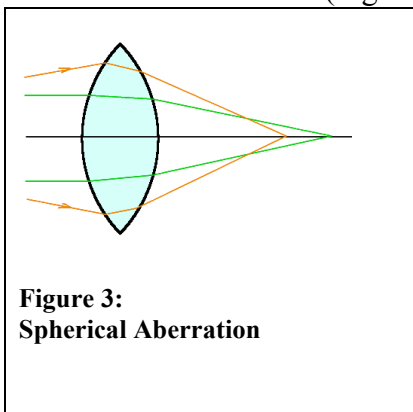
**Figure 2:**  
The Black line defines the photopic vision and the green line defines the scotopic vision.  
The area between the graphs defines the scotopic vision.

**b. Hydrophobic material – preventing PCO:**

The SeeLens HP is made of hydrophobic acrylic material, which is known to be superior in postponing the posterior capsular opacification (PCO), thus reducing the need for the YAG laser treatment. Moreover, hydrophobic materials are known to be more stable within the posterior capsule with respect to the hydrophilic lenses due to its higher stiffness with respect to the hydrophilic acrylic material. The SeeLens HP aspheric optical design is identical to the SeeLens AF, Hanita Lenses' premium product. The SeeLens HP is made of a different raw material, BENZ HF-1 Natural Yellow. This material has chemical composition very similar to the backbone structure of the BENZ IOL 25 Natural Yellow material.

**c. Spherical aberration:**

The spherical aberration is a well known phenomenon in the optic field. The spherical aberration occurs when rays of light that pass through different parts of the lens intersect at different points on the optical axis of the lens (Figure 3). Due to this aberration, a dot projected on the retina produces a larger circle, thus inducing low quality optics, an unclear vision and low contrast (Figure 4).



Contributors to spherical aberration (SA) in the eye are the cornea (average +0.27  $\mu\text{m}$ ) and the crystalline lens (negative in the young eye). Cataract surgery removes the lens component and leaves positive SA on average. Traditional intraocular lenses (IOLs) are spherical with positive SA, further increasing the SA of the pseudophakic eye.

**d. Clinical demand:**

As it gets darker and the pupil dilates, the spherical aberration becomes more apparent, and starts to be noticeable by the patient. Thus patients with conventional spherical lenses complain of unclear vision and poor contrast in the mesopic and scotopic conditions.

**e. Influence of tilt and decentration**

The SeeLens HP is based upon the mechanical design of SeeLens AF IOL. The SeeLens AF design was proven to have good stability and good resistance to tilt and centration as well. Moreover, the SeeLens HP Optical design was demonstrated by the ZEEMAX to have good resilience in terms of tilt and decentration as presented in the attached graph.

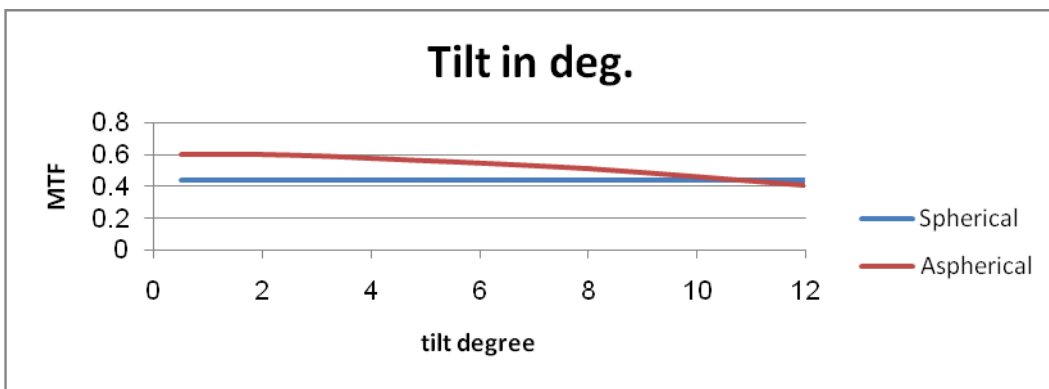


Figure 7: The influence of the degree of Tilt on the resultant MTF

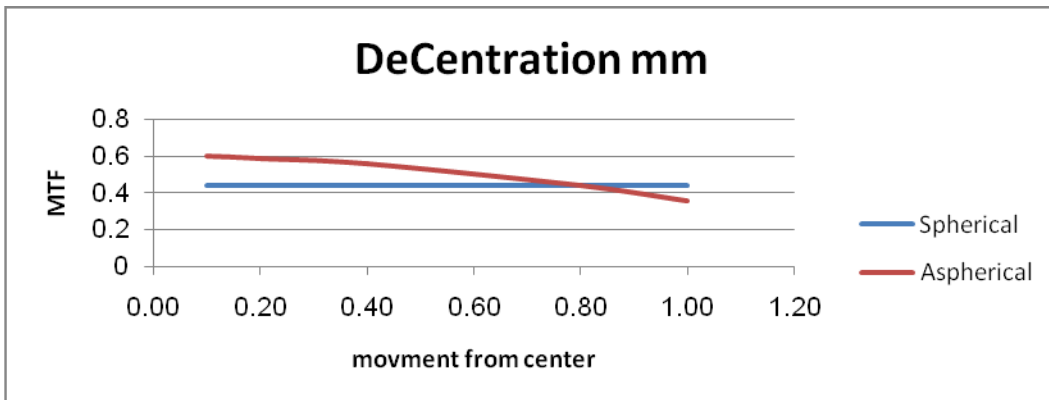


Figure 8: The influence of the degree of Tilt on the resultant MTF

**3. Surgical Procedure**

The study Surgery Procedure: cataract extraction by ECCE Phacoemulsification. Operation was performed according to the routine surgery technique of the investigative sites. The surgical procedure was conducted according to protocol.

## Methods

Sample size: a study of 20 patients, who meet the inclusion / exclusion criteria for the study protocol.

The study was carried out starting from July 2010.

The Investigative sites were:

Site	Number of implanted eyes	Number of eyes 3 months follow up
Dr. J. Novak <i>Regional Hospital Pradubice, Czech republic</i>	20	19

## Statistical Methods

The following analyses were used to describe the data in this report:

1. Descriptive statistics: continuous variables are described with mean  $\pm$  standard deviation (SD), median, minimum and maximum. Nominal scale variables are described with absolute and relative (percents) frequencies. Ordinal variables are described with means  $\pm$  SD and frequencies of the ordinal grades.
2. Comparisons between pre and post operative variables were done with paired-samples t-test. The critical level of significance is  $\alpha=0.05$ .
3. All analyses were done using Excel 2007 statistics tool package.

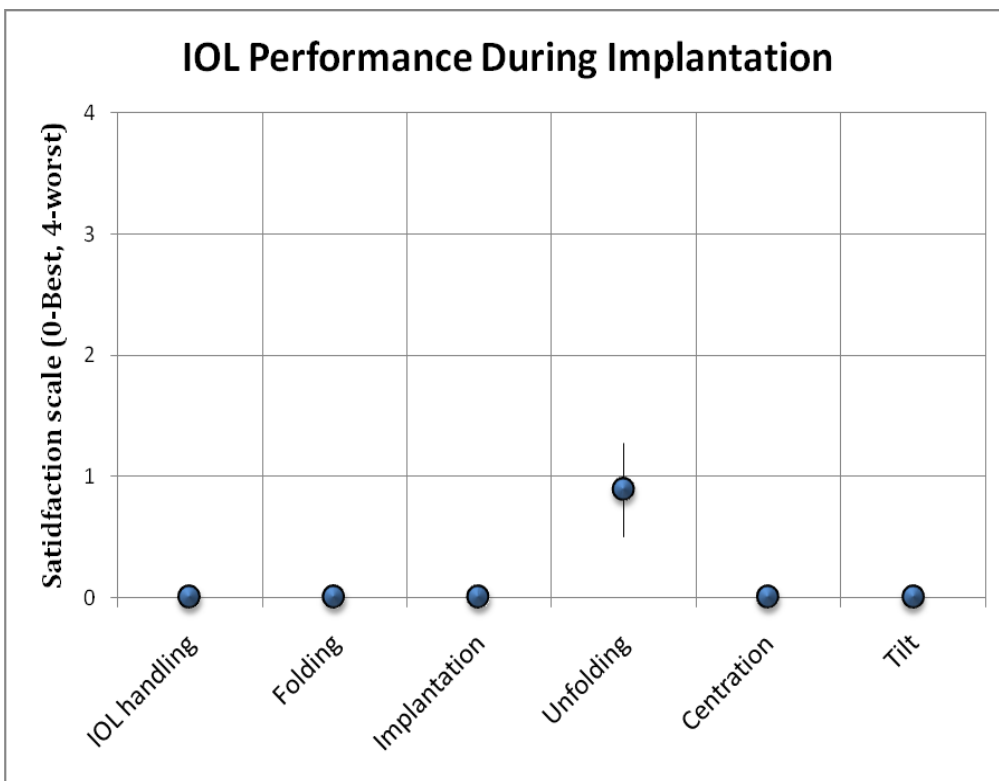
## Results

### a. IOL Performance During Implantation

Implantation parameters were measured to indicate the performance of the SeeLens HP IOL implantation during the standard cataract surgery. The implantation parameters that were measured during the implantation were SeeLens HP handling, folding, implantation, unfolding, need to manipulate the lens and the final centration and tilt of the lens position at the end of the procedure.

All parameters were graded on a 0 (best) to 4 (worst) scale, results are presented in Graph 1.

**Graph 1: IOL Performance During Implantation**



As can be seen in graph 1, the surgeon reported that the SeeLens HP handling, folding and implantation are easy and smooth. Moreover, no difficulties in IOL positioning and centration were reported.

The biggest score was observed in grading of unfolding. The unfolding in hydrophobic IOLs is known to be slower than hydrophilic IOLs. After collecting clinical data from dozens of SeeLens HP implantations, a new method for folding was developed in “Hanita Lenses”. This method caused a significant reduction in unfolding time as well as solving any sticking problem.

## b. IOL location and centration

Lens location and centration were noted and reported in all follow-up visits. Centration and tilt were graded on a 0 (best) to 4 (worst) scale. See protocol for more details.

All lenses during follow up visits including 3 months follow-up were reported as zero (Best) centration and tilt.

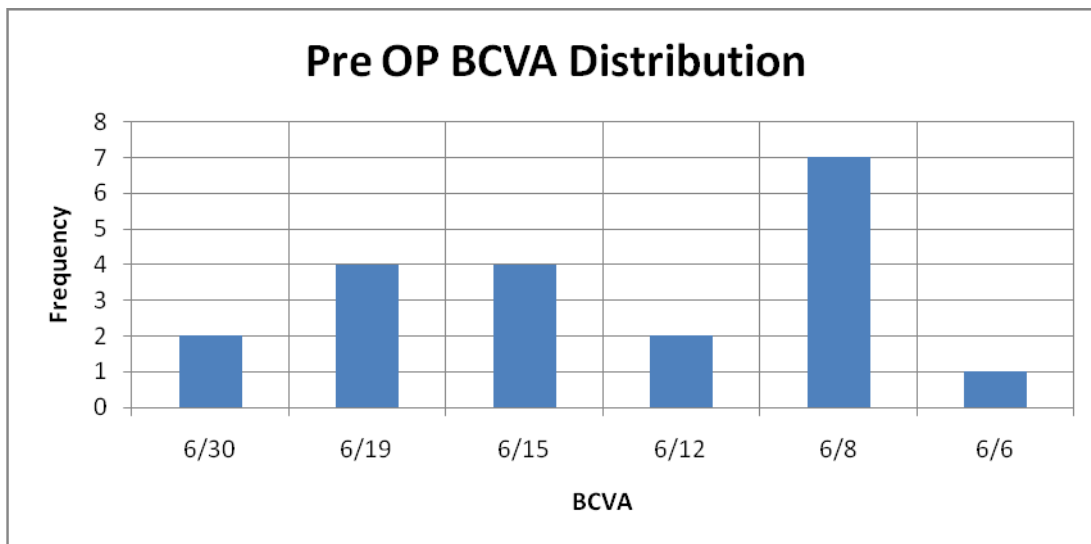
On top of that, on a scale of 0-4 for clarity, all lenses were reported as zero (Best).

Therefore, the SeeLens HP demonstrated good stability and centration from implantation throughout the 3 month follow-up period.

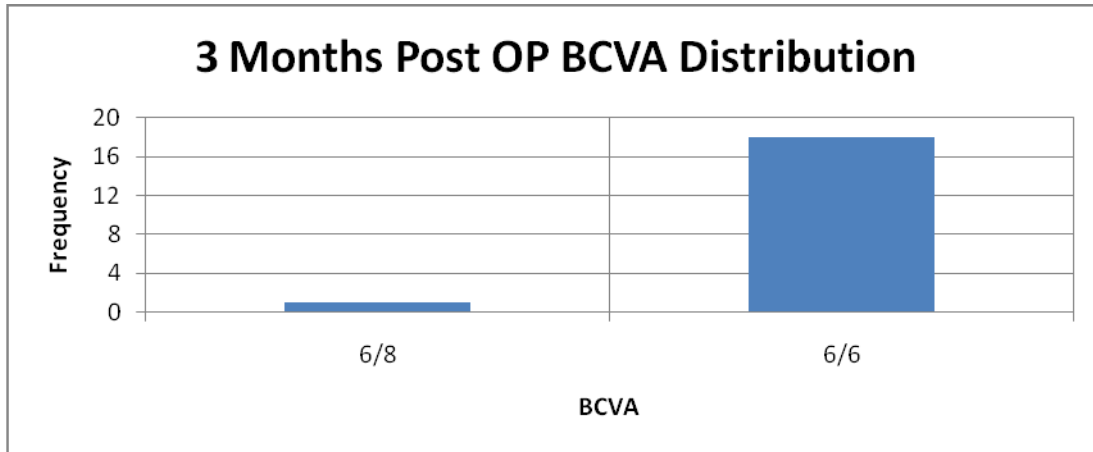
## c. Post-operative Best Corrected Visual Acuity (BCVA)

Best Corrected Visual Acuity (BCVA) was reported in the pre-operative and the three month follow-up visit. Pre-operative BCVA results are shown on Graph 2, and Post-operative BCVA results are shown on Graph 3.

**Graph 2: Pre-operative BCVA distribution**



**Graph 3: 3-month Post-operative BCVA distribution**



\* 3 months post OP BCVA of one patient from was not received (total of 19 patients).

As shown in graph 3, postoperative (3 months) BCVA of 6/8 or better was reported in 100% of the eyes.

Pre and post-operative BCVA are compared in Table 1:

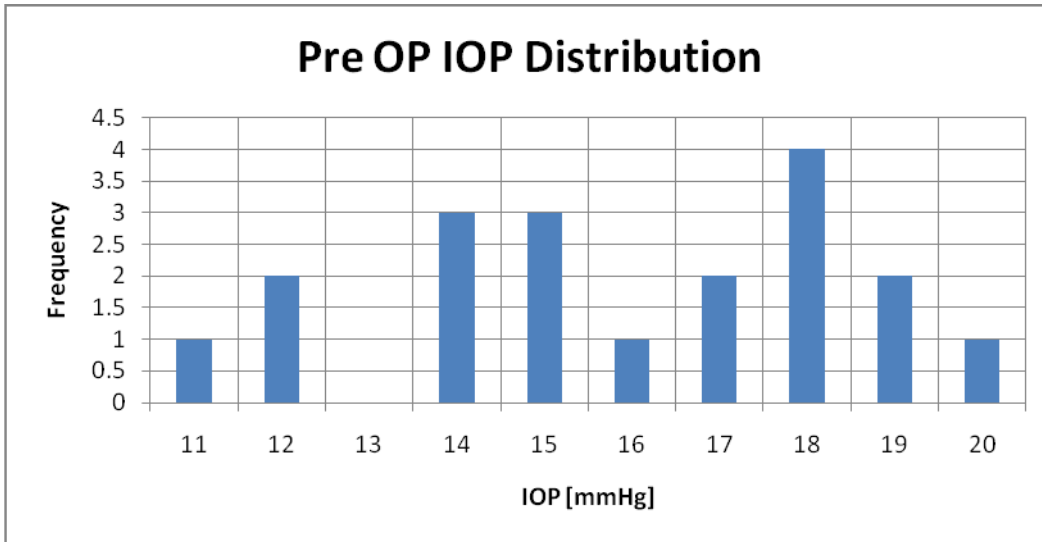
**Table 1: Pre-operative BCVA vs. Post-operative BCVA**

Mesured parameter	Average	Standard Deviation
Pre Op BCVA	0.54 (6/11)	±0.25
Post Op BCVA	0.99 (6/6.07)	±0.05

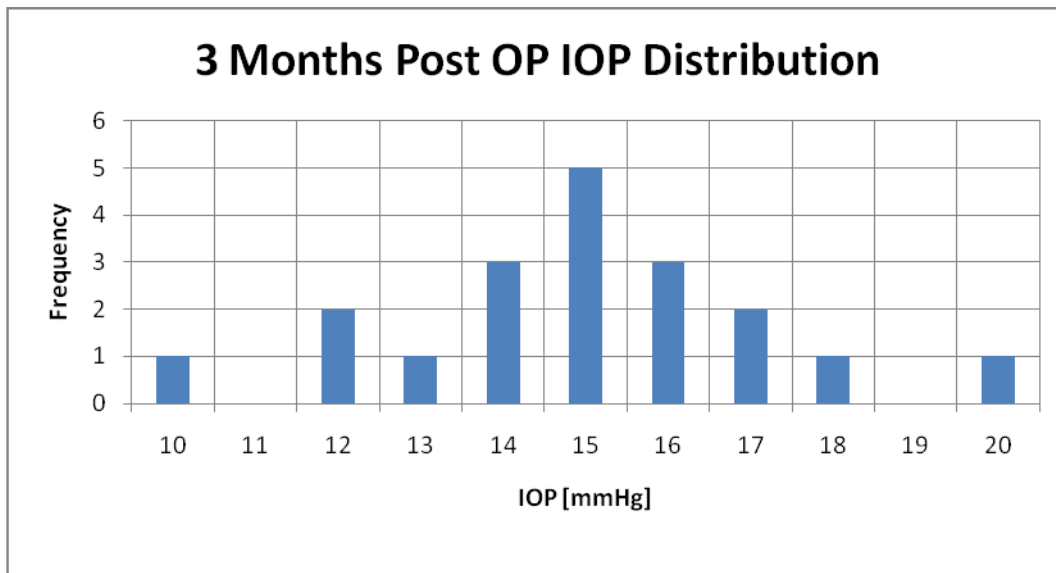
#### d. Intraocular Pressure Changes

Changes in intraocular pressure (IOP) from the pre operative to 3-month postoperative visit are shown in graphs 5-6 below.

**Graph 5: Pre operative IOP pressure**



**Graph 6: Post operative IOP pressure**



\* Post operative IOP of one patient was not received (total of 19 patients).

IOP remained within the normal range (7mmHg - 21mmHg) with in population in 100% of the eyes.

A decrease of the intra ocular pressure was observed in the comparison of the pre operative IOP to post operative IOP.

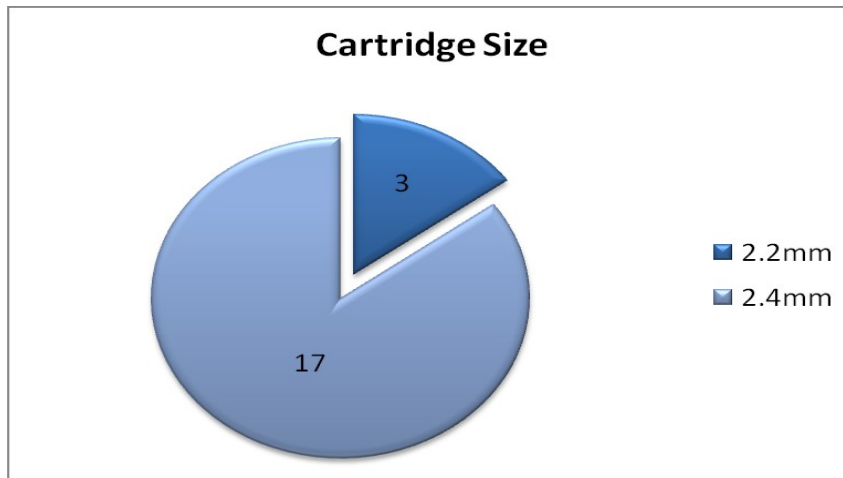
**Table 3: Pre operative IOP vs. Post operative IOP**

Measured parameter	Average	Standard Deviation
Pre Op IOP [mmHg]	15.89	±2.62
Post Op IOP [mmHg]	14.95	±2.3
Change in IOP	-0.95	±2.97

### e. Intra-operative Report

1. Incision Size – from total of 20 IOLs, 3 were implanted using a 2.2mm incision size cartridge and 17 lenses were implanted using a 2.4 mm incision size cartridge.

**Graph 7: Cartridge size**



**f. Adverse Events as defined by ISO 11979-7 2001**

Adverse Event	Maximal allowable rate as defined by ISO 11979-7 2001 ; 100 subjects	Score / measurement	Rate of adverse effect occurred at this study	Pass/Fail
Cystoid macular oedema	6%	No / Yes	0 %	Pass
HypHEMA	5%	0   1   2   3   4	0%	Pass
Hypopyon	1%	Measure in mm.	0%	Pass
Intraocular infection	1%		0%	Pass
Lens dislocation	1%	Measure in mm.	0%	Pass
Pupillary block	1%	No / Yes	0%	Pass
Retinal detachment	1%	No / Yes	0%	Pass
Secondary Surgical intervention (excluding retinal detachment and posterior capsulotomy)	2%	No / Yes, specify	0%	Pass
Corneal stroma oedema	1%	0   1   2   3   4	0%	Pass
Cystoid macular oedema	2%	No / Yes	0%	Pass
Iritis	1%	0   1   2   3   4	0%	Pass
Raised IOP req. treatment	2%		0%	Pass

As shown in table 3, no adverse event was reported in **100%** of SeeLens HP implanted eyes, in a sample size of 20 patients.

Thus, it can be concluded that the SeeLens HP's safety is fully in accordance to the ISO 11979-7 2001

This information supports the conclusions that were previously presented, and reassures that the SeeLens HP is a safe high quality predictable lens.


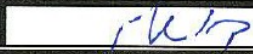
## Conclusions

The detailed data from the current study on 20 eyes shows the benefits of the **SeeLens HP** IOL:

- **Optical performance is in accordance to ISO 11979-7 requirements.**
- **The safety of the lens is demonstrated, as no adverse events and complications were reported.**

**Signature page**

Revision	Date	Change description	Name
1.0	05-December-2010	Document formation	Yuval Bonen
1.1	27-December-2010	Update IOL performance during implantation	Yuval Bonen

Title	Name	Signature	Date
Product Manager	Yuval Bonen		27/12/10
R&D Manager	Yakir Kushlin		3/02/11