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RESEARCH ARTICLE

Hanita Intensity, a New 5-Focal Intraocular Lens for Cataract and Refractive Lens Exchange Patients: Eighteen-Months Results

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Abstract

Ninety-one implantations of the Hanita Intensity, intraocular lens, including 34 patients in both eyes were performed over 18 months. In the majority (55 eyes), implantation was performed during refractive lens exchange, and in the remaining 36 cases, it was performed because of cataract. The qualifying examination, apart from the evaluation of standard parameters, included the evaluation of kappa and alpha angles, value of higher-order aberrations generated by the cornea, and pupil size. High postoperative satisfaction due to very good vision parameters (more than 80% of operated patients achieved vision to far distances ≥ 0.1 logMAR in the cataract group and 87% in the refractive lens exchange group, and almost 100% vision to near distances at the level of D-0.5 (Snellen chart) in the refractive lens exchange group) allows us to recommend this lens model in the most demanding group of patients qualified for refractive lens exchange. Statistical analysis showed that patients with the Hanita Intensity lens had significantly better visual acuity to far distances after surgery than those with the PanOptix (Alcon) lens.

Conflict of Interest declaration. The authors declare that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

Keywords: Hanita Intensity, Panoptix, Cataract, Refractive Lens Exchange, Visual Acuity, Intraocular Lens.

1. Introduction

In cataract and lens-based refractive surgeries, new optical designs have been introduced in recent years to provide patients with good (or excellent) visual acuity for distance, near, and intermediate vision. Many patients hope for or even expect spectacle independence postoperatively. Hanita Intensity is a newer model of multifocal intraocular lenses used to correct postsurgical aphakia. Its structure improves vision at the distance, intermediate, and near positions, while maintaining sufficient visual acuity. The complex five-focal structure of the lens may initially give ophthalmologists the misleading impression that the quality of vision after its implantation will be worse than that of lenses with a less complex structure. However, this lens model has a complex yet innovative structure that makes the quality of vision exceptionally good. Studies conducted by developers of this lens indicate a loss of visual contrast of only approximately 6.5%. (Fig.1).

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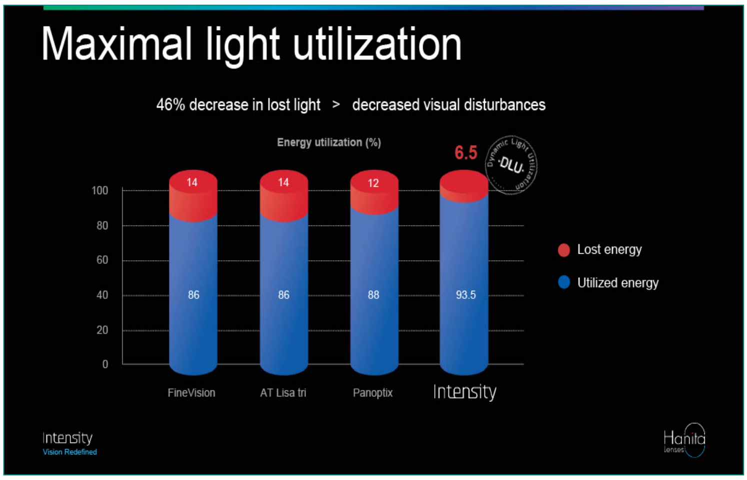

Figure 1. *Maximal light utilization Loss of contrast sensitivity at the level of 6,5%, which gives possibility for having a clear vision at the whole range of vision.*

The reason for this positive result lies in the structure of the lens, which uses innovative elements that allow, for example, independence of the pupil size. These innovations include Pupil Aperture Optimization (Fig. 2a), Optimal Light Distribution (Fig. 2b), and Dynamic Light Utilization (Fig. 2c),[1].

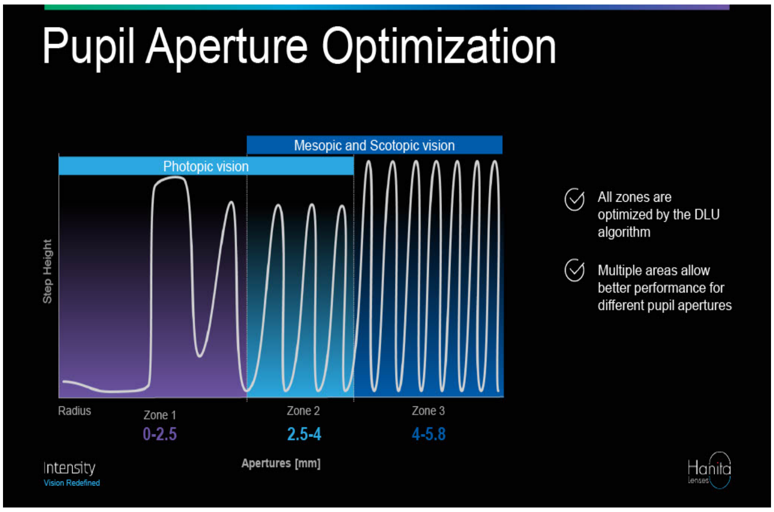

Figure 2(a). *Pupil Aperture Optimization Three zones, each of which is optimized by the Dynamic Light Utilization algorithm. Multiple areas allow for better performance, diverse pupil sizes and all lighting conditions. The special division of zones, derived from the Dynamic Light Utilization Algorithm, helps to obtain higher MTF values at far vision for large pupils.*

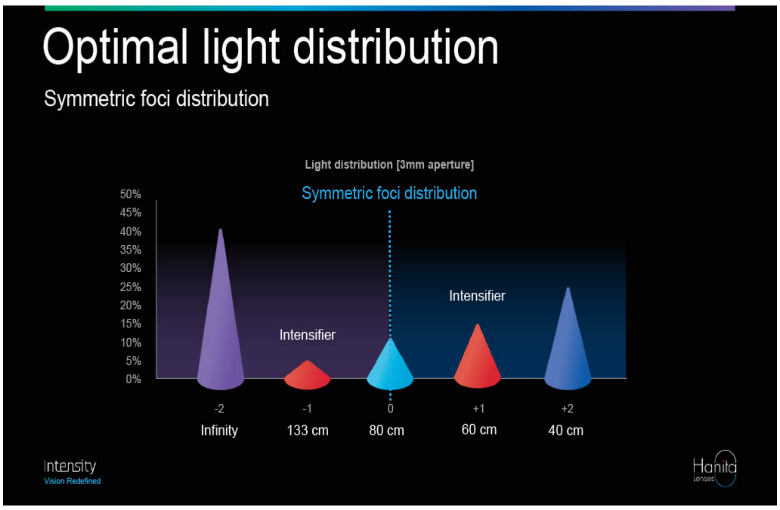

Figure 2(b). *Optimal Light Distribution The modulated transfer function (MTF) is increased in the area between far intermediate and intermediate to near, enabling a continuous defocus curve.*

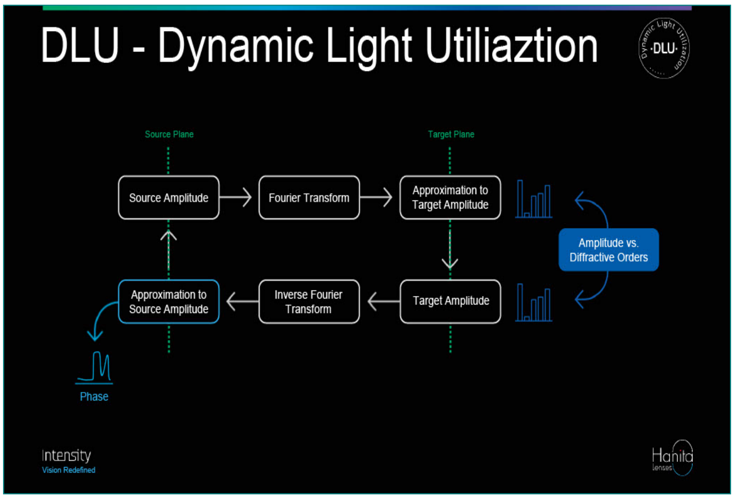

Figure 2c. *Dynamic Light Utilization. Works on a concept of multiple loops between target plane and source plane in order to maximize light intensity utilization. It proposes phase solutions at the source plane in order to get the desired target intensity and results.*

One of the features of the five-focal design of the lens is the avoidance of vision loss that occurs with the trifocal models. The anterior surface of the lens has a spherical structure, and the posterior surface has an aspheric diffractive structure. The addition of +3.0D sph (spherical) at a near distance allows for sufficient quality of vision from 40 cm to infinity. According to the manufacturer, the structure of the lens allows for the maintenance of good-quality vision under photopic, mesopic, and scotopic conditions.

1.1 Purpose

Assessment of distance, near, and intermediate visual acuity and quality of vision after implantation of Hanita Intensity spherical or toric lenses. The results were compared with those obtained after implantation of the PanOptix®/PanOptix® trifocal toric lens (Alcon). The gold standard for intraocular lens selection includes preoperative assessment of pupil diameter, alpha and kappa angles, and corneal higher-order aberrations measured using the iTrace analyzer.

2. Methods

Implantation was performed after removal of the natural lens because of opacity or unacceptable refractive error. The results obtained were analyzed and compared with the author's own results after implantation of the PanOptix®/PanOptix® toric trifocal lens (Alcon) in 49 eyes, as described in a previously published study [2].

2.1 Preoperative Evaluation and Inclusion Criteria

Patients diagnosed with cataract and refractive errors qualifying for refractive lens exchange (RLE), with loss of accommodation being the primary factor qualifying for RLE. The type and extent of corrected errors included mild and moderate hyperopia and myopia combined with astigmatism in some cases. The kappa and alpha angles in the RLE group should not exceed 0.500 µm; however, in the cataract group, only a few eyes had values above 0.500 µm.

These angles were examined using an iTrace analyzer. Low corneal-generated higher order aberrations (HOA)only can be accepted. The HOAs were measured using an iTrace analyzer. Pupil size was measured under phototopic conditions. Values between 3.0 mm and 5.3 mm qualified for surgery.

The exclusion criteria were pathologies of the cornea, lens (e.g., subluxation), optic nerve, and macula that could significantly affect postoperative visual acuity. It is worth mentioning that patients who had previously undergone posterior vitrectomy and qualified for cataract removal were not excluded as long as there was a good prognosis for postoperative vision.

2.2 Indication for Toric Lens Implantation

Diagnosis of corneal astigmatism greater than 0.75D cyl as assessed by corneal topography. The examination also revealed astigmatism of the posterior corneal surface. Refraction showing a total optical system astigmatism of less than 0.75D cyl despite corneal astigmatism of 1.0-1.25D cyl was not an indication for toric lens implantation.

All procedures were performed by one surgeon in one day at the headquarters of the Silesian Eye Treatment Center in Zory, Poland, and were usually performed separately with a one-week interval between the first and second eye. For the RLE procedures, the non-dominant eye was operated on first. Each patient provided written consent for lens extraction and IOL implantation after reading information about postoperative complications and risks of the procedure. In the case of cataracts, the lens was removed by phacoemulsification, whereas in the case of RLE, it was most often removed by aspiration. In each case, the lens was placed in the capsule. Purkinje image-guided centration in the eyes.

Preoperative best-corrected visual acuity for distance (BCVA, on logMAR charts) and near (Snellen charts) was compared with postoperative best-corrected visual acuity (UCVA) assessed 5-6 months after surgery. Intermediate visual acuity was assessed by asking the subjects to read text in standard font on a computer at approximately 80-90 cm.

The quality of postoperative vision was assessed by asking each patient for any comments regarding their postoperative vision.

2.3 Statistics

The significance level was set at p= 0.05. The results indicated a significant correlation between variables ($p < 0.05$). The types and names of the tests used in the statistical analysis are described below. Calculations were performed in the statistical environment R ver.3.6.0, the PSPP program, and MS Office 2019.

3. Results

A total of 91 implantations of this lens model were performed, including 16 toric lenses.In 34 patients, the procedure was performed in both eyes. Another six patients were waiting for implantation of the same lens model in the other eye. Two patients (two eyes) had IOL manufactured by a different company removed and replaced with the Hanita Intensity spherical model. The most common reason for implantation of the Hanita Intensity lens in one eye was the lack of cataract in the other eye, impossibility of implantation due to the lack of fulfilment of the eligibility criteria, or previous surgery in the other eye at another facility. The youngest patient implanted with the spherical version of the Hanita Intensity was a 7-year-old boy. The procedure was performed because cataract was diagnosed after posterior vitrectomy due to retinal detachment. The child's parents agreed to the choice of this lens model after obtaining comprehensive information about, among others, the potential growth of the eyeball with age and the possibility of refractive errors that require correction over time.

In six eyes, the limbal relaxing incision (LRI) procedure was additionally performed 4-6 weeks after surgery, in situations where corneal astigmatism was ≥ 1.0 D cyl, and UCVA to far distances was worse than 0.0, most often 0.1- 0.2 logMAR. The procedure improved the quality of vision in all patients. In four eyes, visual acuity improved by one line, in one eye by two lines, evaluated on logMAR charts; in the other eye, only the quality of vision, including near distances, improved.

Hyperopia was the main reason for RLE, which was performed even in individuals over 60 years of age. Females decided to undergo RLE more often than men did.

3.1 Preoperative Refractive Error

a) The range of corrected values in the RLE group is:

- Hyperopia in the range from +0.75D sph to +2.25D sph.
- Myopia in the range from -0.5D sph to -3.5D sph.
- These errors occur in combination with astigmatism.

b) The range of corrected values in the cataract group is:

- Hyperopia in the range from +1.0D sph to +3.25D sph.
- Myopia in the range from -0.5 D sph to -8.0 D sph, although due to the presence of opacity (density of the lens structure), the evaluation of these values did not make much sense. These values differed from the actual refractive error resulting from the length of the eyeball and refractive index of the cornea.
- The range of the corrected astigmatism value was -1.0 to -2.5D cyl (astigmatism -1.00Dcyl to -2.5Dcyl).

3.2 Visual Acuity

Visual acuity values were analyzed separately for both groups.

a) Cataract Patients

- The study group comprised 55 patients. Some had previously undergone posterior vitrectomy due to retinal detachment (four eyes) and complications after central retinal vein occlusion (complete resolution of post-occlusal changes documented before the procedure: one eye).
- In the case of postoperative visual acuity for far distances lower than 0.0 logMAR, attention was paid to the value of corneal astigmatism.

- Lower visual acuity to near distances without correction was observed in the eyes of the Hanita group previously subjected to posterior vitrectomy.

b) Patients after RLE

- *Visual Acuity for Far Distances*

Visual acuity for far distances ≥ 0.1 was achieved in 87% of the total Hanita group. A BCVA value of 0.0, obtained preoperatively in 38 eyes was maintained postoperatively (UBVA) at the same level in 32 eyes (84%). Visual acuity ≤ 0.2 was achieved in 16% of patients, with baseline preoperative values being the same.

- *Visual Acuity for Near Distances*

Only one patient (one eye) in the Hanita group had postoperative visual acuity without correction that did not reach the value of -0.5 D, but only -1.0 D, which required additional correction.

- *Vision for Intermediate Distances*

As previously mentioned, the patients were tasked with reading text from a computer with a standard font size (size 12). In the Hanita group with cataract, the problem with reading without correction, was experienced by people whose visual acuity to near distances was worse than -0.75 D. Correction improved their ability to read.

It is worth noting that, in virtually every case, reading with both eyes improved the quality of vision and visual acuity.

3.3 Side Effects

"Halo," poor vision for near distances under photopic conditions, blurred vision to far distances, circles and halos around light sources were reported. Most of them subsided over time, although symptoms such as seeing circles in the field of vision (elements of the lens structure), particularly under scotopic conditions, were reported even after six months. However, the patients added that their perceptions of these phenomena decreased over time.

"I can't see well for far distances." This statement, despite achieving a visual acuity of 0.0 or 0.1 log Mar, was common after surgery of the first (non-dominant) eye in patients with low preoperative hyperopia. In addition, it was intensified if the patient did not use a correction for distance before surgery.

After surgery of the dominant eye, usually performed a week after the previous surgery, the effect of blurred vision on far distances disappeared. The same was applied to patients who were preoperatively hyperopic and opted for RLE surgery in one eye to "regain" vision for near distances without correction. When asked: "Which eye can see better for far distances?", they always pointed to those who did not undergo surgery for uncorrected hyperopia.

3.4 Further Analyses

The non-parametric U-Mann-Whitney test was used to determine whether this lens type significantly differed in postoperative visual acuity at distance and near. The independent-samples t-test results are shown in Table 1.

Table 1. *The results of the U Mann-Whitney test for independent samples, which shows significantly differentiates in postoperative distance visual acuity in the Hanita group.*

				Descriptive statistics		
		U	p	Min	Max	Me
lens	UBVA postop. to far	1,499.00	0.001			
	PanOptix			-0.10	0.40	0.10
	Hanita Intensity			0.00	0.50	0.10
lens	UBVA postop. to near	2,139.00	0.435			
	PanOptix			0.50	1.00	0.50
	Hanita Intensity			0.50	3.00	0.50

U – test statistics; p – statistical significance; Me – median; Min – minimum result; Max – maximum result

Despite identical medians, Hanita Intensity wearers had statistically significantly ($p < 0.05$) better visual acuity (lower value) to far distances, as 25% of PanOptix wearers did not score higher than Q25 = 0.10 and 25% of Hanita Intensity wearers did not score higher than Q25 = 0.00, and 75% of Hanita Intensity wearers did not score higher than Q75 = 0.10. These differences were not statistically significant ($p > 0.05$). This means that the lens type did not significantly affect postoperative near-visual acuity. Therefore, this hypothesis is rejected. The distribution of the variables is shown in Figure 3 (distance vision)and Figure 4 (near vision).

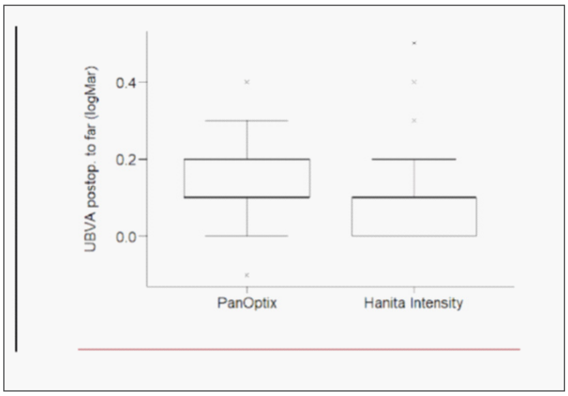

Figure 3. *UBVA to far distances achieved postoperatively in the two groups showed statistically better results in eyes with Hanita Intensity lens implantation.*

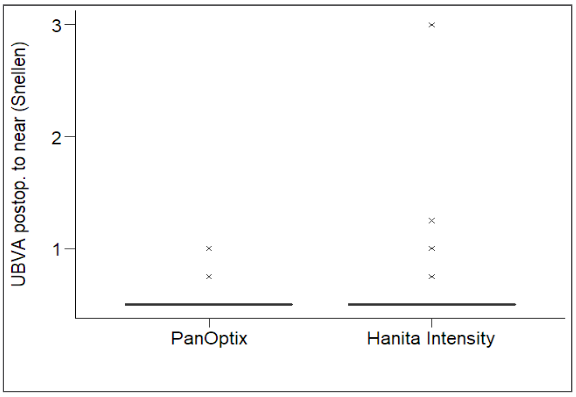

Figure 4. *UBVA to near distances achieved postoperatively in the two groups. No statistically changes were observed.*

There was a statistically significant correlation ($p < 0.05$) between spherical equivalent and postoperative visual acuity at a distance in patients with cataracts. The correlation was moderately strong, as indicated by a rho coefficient value ≤ 0.5. This was a negative correlation, which means that the higher the preoperative spherical equivalent, the lower the postoperative visual acuity at a given distance (i.e., the better the postoperative visual acuity). However, there was no statistically significant correlation ($p > 0.05$) between the preoperative spherical equivalent and near visual acuity in cataract patients or between the far and near visual acuity in refractive lens exchange patients.

We also evaluated whether the type of IOL and surgery significantly affected postoperative changes in near visual acuity. A two-way repeated measures ANOVA was used to compare the means of visual acuity between tests, considering the pre- and postoperative visual acuity according to the lens type and surgery. It was shown that near visual acuity did not change significantly between tests and that lens type and surgery did not significantly affect this change (Figure 5).

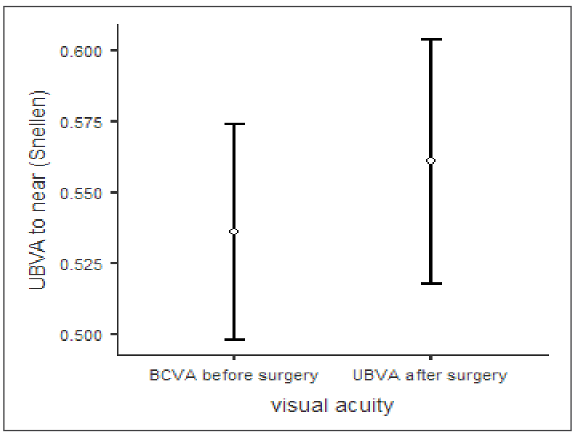

Figure 5. *Comparison between preoperative BCVA to postoperative UBVA haven't seen any statistical changes*

4. Discussion

The growing interest in RLE places great responsibility on surgeons to select the best lens for implantation. With today's lifestyles, work patterns, and demands, patients want to see as well as possible near, far, and intermediate distances, and computer use has become standard for most people. This forces manufacturers to create products that provide all these visual capabilities. If we look only at our activities in the field of refractive surgery, we can see how the number of people interested in correcting unwanted refractive errors in private centers, where there are no financial limits to treatment, has increased significantly. Approximately 20 years ago, only completely opaque lenses had been removed. The preoperative vision threshold shifted significantly over time. In our study group, the number of patients who underwent RLE surgery was almost twice the number of eyes operated on for cataract. How do patients learn about RLE? The main reasons include the desire to eliminate a refractive error, recommendations from friends who have undergone the procedure, and, perhaps most importantly, information about the possibility of surgical correction of an unwanted error provided during a routine eye doctor or optometrist appointment. Increasingly, people with no refractive errors other than presbyopia are requesting RLE and wondering if they qualify for the procedure. Their main motivation for the procedure is the "restoration" of reading ability without the need for correction, which is most often observed in people who have previously undergone such surgery. The latter group is growing and becoming the most demanding.

Hanita Intensity is an interesting new optical concept that has been approved by the author (who has extensive experience with other lens models, including bi-, tri-, and multifocals, and those with an EDOF structure).The lens offers a high degree of predictability to achieve good vision at virtually any distance. However, proper preoperative patient selection is critical to achieve these results. In the study group, certain qualifying limits were assumed to allow the patient to undergo surgery with the discussed lens, including the assessment of alpha and kappa angles, pupil size, and the range of corrected refractive errors. Low corneal-generated HOA values are required for qualification. In our study group, the lens met the expectations of both the practitioner and patients who underwent the procedure.

It is worth noting that, except for one person, virtually no patient reported vision problems under conditions of lower light intensity, which is of great importance in the implantation of lenses with a "pure" EDOF structure [3].

Considering the large number of lens models available in the market, their complexity is often detrimental to the visual acuity and quality of vision. Studies comparing different intraocular lens models clearly state that virtually none of the most complex lens models are truly sufficient to achieve good vision at all distances [4,5].

Current intraocular lens design technologies make it virtually impossible to create a lens model that meets the criteria for good vision at all distances in all patients regardless of the extent and type of preoperative refractive error.

For example, in a person with high preoperative hyperopia, in whom the alpha angle is also large, implantation of a monofocal lens is sufficient, and the patient will be able to see well at near, intermediate, and far distances, whereas implantation of a trifocal model in this eye could be disastrous in terms of deterioration of visual quality and functioning under scotopic conditions [6]. In contrast, lenses with a simpler structure, such as bifocal, assuming good vision at distance and near, practically do not allow comfortable vision at intermediate distances without additional correction or changing the patient's working distance [7,8,9]. Thus, intraocular lenses with a small addition, approximately +1.5D sph, cannot provide a comfortable reading without additional correction, assuming that we do not want to "rob" the patient of spatial vision in both eyes by using so-called micro-monovision.

Regarding the authors' own results and the question of comparing visual acuity after implantation of the Hanita and PanOptix lenses, typical statistical analyses were not performed because of the heterogeneity of both groups in terms of the number of eyes undergoing the procedure, number of spherical and toric lens models implanted, and different observation periods. However, there was a significant difference in the postoperative distance visual acuity.

5. Conclusion

The five-focal spherical and toric intensity lens led to good visual results in the correction of aphakia after cataract removal but also in a more demanding procedure, that is, refractive lens exchange. Correction of small and moderate refractive errors in myopic and hyperopic eyes provided reproducible and stable results in the far, near, and intermediate visual fields. Considering the wide range of pupil sizes (3.0-5.3 mm) observed in patients who underwent the procedure, the quality of vision and visual acuity obtained suggests that implantation of this lens model is not dependent on pupil size. Statistical analysis showed that patients with the Hanita Intensity lens had significantly better visual acuity at a distance after surgery than those with the PanOptix (Alcon) lens.

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