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Encouraging Visual Outcome of a New Accommodative Intraocular Lens: A Retrospective Long-Term Study with a Mean Follow-Up of 5.3 Years

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Abstract

Purpose: To assess the visual outcome after implantation of the new Hydrophylic IOL type 41 B/G accommodating intraocular lens (AIOL). **Methods:** The presented lens was implanted during cataract surgery. All patients were offered follow-ups, allowing two postoperative measurements to be performed at 3 months and between 2020 and 2021. The mean time between lens implantation and last follow-up was 5.3 years (min. 1 year, max. 10 years). Excluded were patients with age-related macular degeneration or amblyopia. Patients with a foreign lens implanted into the second eye were included in a separate control group. Corrected distance (CDVA) and uncorrected distance visual acuity (UDVA) at 5 m, and corrected near (CNVA) and uncorrected near visual acuity (UNVA) at 40 cm were assessed. Furthermore, the postoperative spherical equivalent (SE), the dependence on spectacles and the occurrence of optical phenomena were evaluated. **Results:** The final study cohort consists of 65 patients with 119 implanted AIOLs. Significantly better visual results were obtained in both postoperative follow-ups compared with the preoperative results. The mean values of the last follow-up for the UNVA, CNVA, UDVA, and CDVA were 0.107 ± 0.10; 0.039 ± 0.08; 0.097 ± 0.11; and 0.040 ± 0.09 logMAR, respectively. Visual outcomes remained on a high level for up to 10 years and showed significantly better results compared to the control group. Postoperative SE was significantly improved. Nearly 70% of patients were no longer dependent on glasses. Furthermore, the occurrence of disturbing optical phenomena was denied by all patients. **Conclusion:** The results of this AIOL are particularly promising, especially since gratifying visual results could still be measured 10 years after implantation.

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Keywords

Accommodative Intraocular Lens, Cataract Surgery, Monofocal Intraocular Lens, Visual Acuity

1. Introduction

For many patients, vision loss is usually associated with a severe reduction in quality of life. Cataract is the leading cause of avoidable blindness worldwide [1] [2]. Due to the high number of cases, cataract surgery is the most common and most frequently performed ophthalmologic surgery [3] and can be considered one of the most frequently performed surgeries in Germany. This has resulted in the constant development and evolution of surgical methods, techniques and intraocular lenses (IOLs). In the early 2000s, new IOLs were developed to mimic the physiological accommodation of the eyes through different principles. The mechanism of these accommodative intraocular lenses (AIOLs) was often based on the principle of the so called "optic shift", a (forward) movement of the lens to achieve a change in refractive power [4]. However, several studies have demonstrated that the optic shift principle allows only partial or no accommodation and does not improve near vision [5] [6]. This could be a possible reason why AIOLs have become less important [7] and nowadays hardly any literature is published on this topic. Thereby AIOLs represent in theory at least the best and simplest solution for cataract treatment, stepless change of focal length, no loss of contrast and hardly any optical phenomena [8]. Meanwhile, several (new) technologies seem to be under development to finally present a functional AIOL [9].

The aim of this study is to report the visual outcome of a new AIOL whose design and effect are based on known principles. Furthermore, it should be shown that not all long-term results of AIOLs have to be disappointing. We intend to provide a new impulse for the development and restoration of physiological accommodation using AIOLs.

2. Materials and Methods

In cataract surgeries, a novel AIOL from Morcher®GmbH (models Hydrophylic IOL type 41 B or 41 G, as of 2015) was implanted more than 4000 times between 2010 and 2020. These surgeries were initially performed at Park-Klinik Manhagen (Großhansdorf, Germany) and at AOB Augenärzte & Augentagesklinik Ballindamm (Hamburg, Germany) from 2010 to 2015. Subsequently, the surgeries were performed in the Augenarztpraxis Violeta Doci, MD (Hamburg, Germany). All surgeries were performed by the same ophthalmologist. The operated patients were all offered a follow-up examination between 2020 and 2021 to check the long-term results of the lens. 77 patients with 139 eyes participated in these follow-up examinations. A retrospective, non-randomized analysis was

conducted and data were anonymized before further analysis [10]. 12 patients were excluded due to age-related macular degeneration (AMD) or with amblyopia. The postoperative visual acuity of these patients was not expected to be representative due to their disease. This resulted in a cohort of 65 patients with 119 implanted AIOLs. In 6 patients of this cohort a previous cataract surgery with implantation of a foreign monofocal IOL in a different institution took place. These patients now underwent a second cataract surgery with implantation of the AIOL presented here in the respective other eye. We subsequently included these patients in a separate control group to validate our results. All studies were performed with the approval of the local ethics committee and in accordance with the Declaration of Helsinki.

2.1. Preoperative and Postoperative Assessment

Preoperatively, a complete ophthalmologic examination was performed. This included refractometry with the autorefractometer (NIDEK AR-1s) to quantify ametropias and astigmatisms (in diopters (D) and axial deviation in degrees, respectively), determination of intraocular pressure (tonometry), slit lamp examinations, determination of manifest refraction and fundoscopy. The corrected distance visual acuity (CDVA) was also determined monocularly with the help of visual charts projected by the Remote Chart Projector Tomey TCP-1000 LED under photopic conditions with 85 cd room illumination. So called logMAR charts were used at a distance of 5 m.

Postoperative follow-up examinations were performed 3 months (postOP 1) after lens implantation and between late 2020 and early 2021 (postOP 2). The mean time between cataract surgery and postOP 2 was 5.3 years (min. 1 year; max. 10 years). Postoperatively, the same examinations were performed as preoperatively, whereby the uncorrected distance visual acuity (UDVA) was additionally determined. Uncorrected and corrected near visual acuity (UNVA and CNVA, respectively) were determined with the Oculus© Close Reading Sample 2 at a distance of 40 cm. The number of the smallest line readable by the patient gave the corresponding near visual acuity, which was subsequently converted to logMAR.

2.2. Lens and Surgical Procedure

The implanted lenses are the monofocal lens models Hydrophylic IOL Type 41 B and 41 G from Morcher®GmbH (**Figure 1**). Both AIOLs have four broad-based T-haptics tilted 5˚ posteriorly. The diameter of the lens including the haptics comprises 10 mm, which spreads the capsular bag during implantation. The large contact surface of the haptics and the resulting capsular tension should reduce the risk of a decentered lens and ensure optimal power transfer from the capsular bag and ciliary body to the lens. The material thickness of the haptics was chosen with 0.3 to 0.5 mm in order to achieve an optimal balance between stability and sufficient flexibility for the forward movement of the lens during

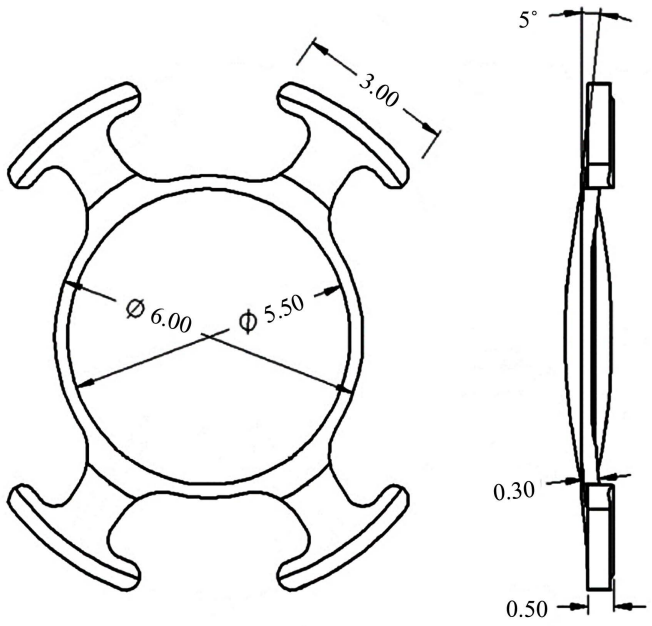

Figure 1. Graphic representation of the inserted accommodative intraocular lens. (a) Frontal view (from endothelium) of the lens with dimensions of haptics and optics. (b) Lateral view of the lens showing lens thickness and angulation of the haptics.

accommodation (in the sense of the optic shift). The shape of the optics is bi-convex and they measure 5.0 - 5.5 mm (model 41 B) or 5.5 - 6.0 mm (model 41 G) in diameter. The lenses have a standard refractive power (diopter power) of 22 D and are available from 10 - 30 D. Manufactured from foldable hydrophilic acrylic with 28% water content. In contrast to model 41 B, model 41 G also has an integrated UV filter. Patients were able to decide independently which lens model they preferred to have implanted. For lens implantation, surgical access was routinely created using paracentesis. Viscoelasticum was then introduced into the anterior chamber of the eye. This was followed by capsulorhexis using cannula or forceps, mobilization of the lens by hydrodissection as well as dissection and removal of the lens by phacoemulsification. Residuals of the lens cortex were aspirated and the foldable AIOL was implanted into the capsular bag after reintroduction of viscoelasticum.

2.3. Statistical Analysis

GraphPad Prism (Macintosh Version 9.3.1 GraphPad Software, Inc., La Jolla, CA, USA) was used to perform the statistical analyses. We used a paired and unpaired two-tailed t test for comparison of two groups and ordinary one-way ANOVA with Tukey's multiple comparison test to compare more than two study groups. The level of significance was defined as $p < 0.05$. Exact p-values are reported unless $p < 0.001$. All data are presented as absolute values or as the mean ± standard deviation (±SD).

3. Results

The lens reported here was implanted in 119 eyes of a total of 65 patients with a mean age of 73.5 ± 8.9 years. Patient demographics are shown in Table 1. No intraoperative complications occurred in any of the surgeries. The pre- and postoperative results are shown in Table 2. Preoperatively, a CDVA of 0.413 ± 0.17 logMAR was measured. At 3 months postoperatively (postOP 1), the mean UNVA, CNVA, UDVA, and CDVA were 0.086 ± 0.08; 0.010 ± 0.04; 0.064 ± 0.07; and 0.027 ± 0.06 logMAR, respectively. The mean values of the last follow-up between 2020-2021 (postOP 2) for the UNVA, CNVA, UDVA, and CDVA were 0.107 ± 0.10; 0.039 ± 0.08; 0.097 ± 0.11; and 0.040 ± 0.09 logMAR, respectively. All cases showed significant improvement ($p < 0.001$) between preoperative and postoperative visual acuity. We found no significant difference between the UNVA or CNVA and the UDVA or CDVA, neither within postOP 1 nor within postOP 2 (Figure 2(a) and Figure 2(b)). However, comparing the visual outcomes between postOP 1 and postOP 2, there is a significant difference between the postOP 1 and 2 CNVA, as well as between the postOP 1 and 2 UDVA (Figure 2(c) and Figure 2(d)). In postOP 1, 75% of patients achieved an UNVA of at least 0.1 logMAR and approximately 83% achieved an UDVA of at least 0.1 logMAR. In postOP 2, approximately 71% of patients achieved an UNVA of at least 0.1 logMAR and approximately 73% achieved an UDVA of at least 0.1 logMAR. Mean UNVA and mean UDVA decreased to an average of 0.1 logMAR within the first two postoperative years but then remained at this level for up to 10 years (Figure 3(a)). No difference in visual acuity between men and women could be found postoperatively. However, a significant difference in visual

Table 1. Demographic overview of the patients including mean time since surgery.

Characteristics	Value
***Sex, n* (%)**	
male	24 (37)
female	41 (63)
total	65 (100)
***Age* (yr)**	
mean ± SD	73.5 ± 8.9
***Eyes, n* (%)**	
right	59 (49.6)
left	60 (50.4)
total	119 (100)
Time since surgery	
mean (yr)	5.3

yr = years.

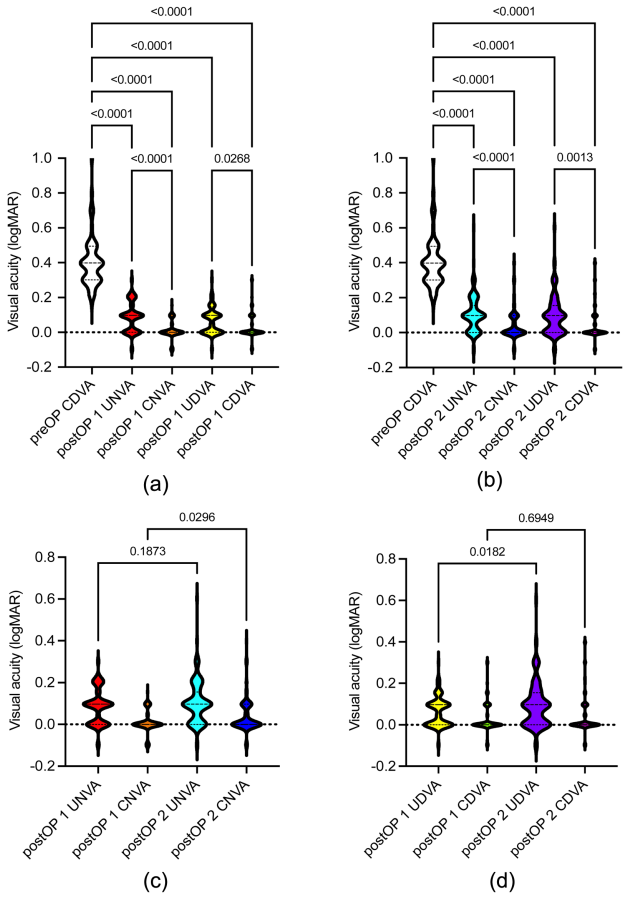

Figure 2. Comparison of pre- and postoperative visual acuity (VA). Ordinary one-way ANOVA with Tukey's multiple comparison test was performed to compare the groups. (a) Comparison of preoperative corrected distance visual acuity (CDVA) with mean VA results at 3 months postoperatively (postOP 1). (b) Comparison of preoperative CDVA with mean VA results at last follow-up (postOP 2). (c) Comparison of corrected and uncorrected distance VA (CDVA and UDVA) between postOP 1 and postOP 2. (d) Comparison of corrected and uncorrected distance VA (CDVA and UDVA) between postOP 1 and postOP 2.

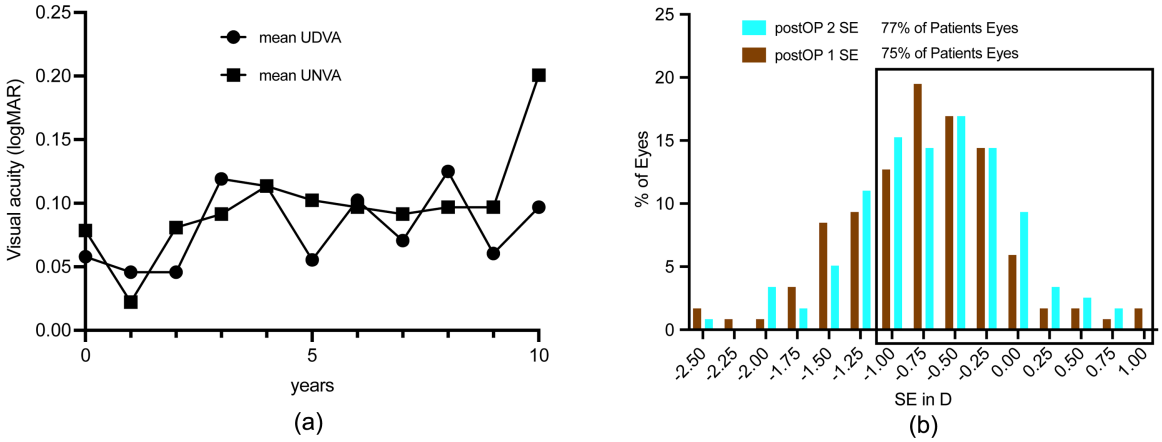

Figure 3. Overview of changes in visual acuity over time and the spherical equivalent (SE) in postOP 1 and postOP 2. (a) Changes in mean UNVA and UDVA from early postoperatively up to 10 years after cataract surgery. (b) The rectangle shows the area around ±1 D of SE, where 75% of the postOP 1 and 77% of the postOP 2 are located.

Table 2. Visual acuity preoperative and postoperative after 3 months (postOP 1) and in follow-up from 2020-2021 (postOP 2).

Characteristics	preOP	postOP 1	postOP 2
UNVA (logMAR)			
mean (±SD)	-	0.086 (±0.08)	0.107 (±0.10)
CNVA (logMAR)			
mean (±SD)	-	0.010 (±0.04)	0.039 (±0.08)
UDVA (logMAR)			
mean (±SD)	-	0.064 (±0.07)	0.097 (±0.11)
CDVA (logMAR)			
mean (±SD)	0.413 (±0.17)	0.027 (±0.06)	0.040 (±0.09)
Gauge (Dpt.)			
mean (±SD)	1.35 (±3.41)	−0.28 (±0.69)	−0.13 (±0.72)
Astigmatism (Dpt.)			
mean (±SD)	−1.20 (±1.36)	−1.04 (±0.83)	−1.14 (±0.90)

UNVA = uncorrected near visual acuity; CNVA = corrected near visual acuity; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity.

outcomes was found in relation to patient age at last follow-up. Younger patients (mean age of 70 years) showed better CNVA and CDVA than older patients (mean age of 75 years).

To validate our findings, we compared the monocular postOP 2 results of 6 patients (3 right and 3 left eyes with AIOL) with the visual acuity of the respective other pseudophagic eye in which a foreign monofocal IOL had been implanted previously. It was possible to determine the implantation date of the foreign lens, which was on average 7.8 years before the postOP 2 controls. In comparison, the mean time between AIOL implantation and postOP 2 was 5 years. Statistical analysis confirmed a significantly better CNVA, UDVA and CDVA ($p < 0.05$) of the AIOL eyes. We found no significant difference between the UNVA of the two groups.

Upon verbal questioning during the postOP 2 follow-up, almost 70% of the patients answered that they were not dependent on spectacles since lens implantation, neither for near vision, nor for driving, computer work, or distance vision. In the remaining 30% who depended on glasses for daily life, we found significantly lower UNVA and UDVA at both postoperative controls. Furthermore, the occurrence of disturbing optical phenomena (e.g. halo or glare) was questioned and denied by all patients.

The postoperative spherical equivalent (SE) was significantly improved compared to the preoperative SE. Thus, a high refractive accuracy is demonstrated with approximately 75% of patients from postOP 1 and approximately 77% of patients from postOP 2 within ±1 D of postoperative refractive error (**Figure**

3(b)). We could not find any evidence of deterioration of astigmatism. Due to posterior capsule opacification, a Nd: YAG capsulotomy was performed in 84% of the patients by the time of the last follow-up. In all cases, this procedure proved to be successful and there were no further complications or treatment interventions. No further evidence was found to indicate complications from cataract surgery.

4. Discussion

We report in this study the (long-term) results after implantation of a new AIOL in 119 eyes. Postoperatively, two follow-up examinations were performed on each patient (postOP 1 and 2), in which notably good results were obtained. On average, 5.3 years after lens implantation, the mean CNVA was 0.039 ± 0.08 logMAR and the mean CDVA was 0.040 ± 0.09 logMAR. To ensure accommodation by the lens, its structure is based on the principle of the so-called "optic shift". Therefore, the haptics of the lens have a 5˚ posterior angulation. The literature reports that a lens movement of 1 mm equals a change in refractive power of about 2 D [4] and further that AIOLs can effectively transfer the force of the ciliary body to the lens [11]. However, the eye is affected by age-related degeneration processes, therefore the power transmission to the lens decreases with time [12]. We suspect that these age-related degenerative processes cause a decrease in visual acuity within the first two postoperative years. To the best of our knowledge it is unique in the literature so far, that visual loss with an AIOL stagnated two years postoperatively and settled at a mean visual acuity of 0.1 logMAR. Several studies demonstrated that the optic shift principle allows only partial or no accommodation and does not improve near vision [5] [6]. However, in our study UNVA showed significantly less variation over the maximum postoperative duration of 10 years than UDVA. Even though we found significantly worse CNVA and UDVA in the postOP 2 control, UNVA decreased below a visual acuity of 0.1 logMAR in just 4% of patients between postOP 1 and postOP 2. As further evidence of age-related degeneration processes, we demonstrated significantly worse postoperative visual acuity in older patients (mean age 75 years). Younger patients showed a better visual outcome, which was also confirmed in the literature [13] [14]. It could be assumed that the lens implantation should not be performed too late to maximize the visual results. We also investigated the influence of gender on visual outcome, but could not find any significant differences.

There are reports in the literature that lens placement in the sulcus improves visual outcome [15], thus representing the better location for lens placement than the capsular bag [13] [16] [17]. However, this aspect is controversial [16], as sulcus placement may cause a potential outflow obstruction [18]. For this reason, no routinely implantation into the sulcus was performed in this study. Since the visual outcome of the lens is notably good, the theory of improved visual outcome with implantation into the sulcus should be critically considered.

For comparison with the (long-term) results of other AIOLs, some of those described as "most commonly used" by Zvorničanin *et al.* [19] were used. This comparison is shown in Supplementary **Table S1** and demonstrates that the presented lens was able to achieve the best visual results. Furthermore, we were able to demonstrate with our control group that the AIOL achieves better results than other conventional monofocal IOLs. We assume that the significant differences between the AIOL group and the foreign lens group would probably not change with a larger cohort, or with the exact same length of a control period. The rather unsatisfactory reports of other AIOLs [4] are probably the reason why only few scientific articles on this topic have been published recently. In addition, patient satisfaction after implantation of AIOLs seems to be highly variable, which could be another reason for the neglect of AIOL studies in the literature [20]. The long-term results of AIOLs can be promising, so the overall goal should still be to fully establish physiologic accommodation in pseudophagic eyes [21].

The majority of current literature refers to trifocal lenses, which are designed to provide sharp vision in all three optic planes [22]. Especially the intermediate visual acuity becomes increasingly important due to the growing use of computers and tablets [3] [23]. Despite the missing determination of the intermediate visual acuity, we assume similar good results due to the accommodative properties of the lens presented here. The literature also reports a particularly good distance visual acuity of the trifocal lenses, whereas the near visual acuity usually shows the worst results within the three optic planes. Thus, near visual acuity of greater than 0.1 logMAR [24] [25] [26] [27] is frequently reported, in some cases even greater than 0.2 logMAR [28] [29]. Hence, trifocal lenses only partially fulfill their actual purpose (*i.e.* sharp vision in all three optical planes) and achieve a visual outcome similar or worse than some of the AIOLs. In addition, however, optical phenomena (e.g. halo or glare) occur frequently with trifocal lenses. Fernández *et al.* [28] reported disturbing optical phenomena in 32% of the cases, McNeely *et al.* [26] in more than 40% and Brito *et al.* [27] even in 50% of the cases. Although the literature reports the occurrence of optical phenomena with monofocal lenses [30], they do not occur that often. The appearance of such optical phenomena negatively influences patient satisfaction [31] [32]. In our cohort, all patients denied subjective perception of optical phenomena. Therefore, we assume that patient satisfaction should be better compared to trifocal lenses. In addition, dependence on spectacles may also reduce patient satisfaction [29]. Regardless of reports in the literature about insufficient spectacle independence of AIOLs, almost 70% of patients in our cohort were completely independent of spectacles at the time of postOP 2 follow-up. This fact should also have positively influenced patient satisfaction. Reportedly, at least 0.4 logMAR UNVA is needed to read a newspaper, with better UNVA allowing even smoother reading [33]. We found significantly worse UNVA and UDVA in patients who required glasses, which is also confirmed by Kim *et al.* [34] who reported worse UNVA in spectacle-dependent patients within their study.

The aim of cataract surgery is to restore emmetropia, but after lens implantation refractive errors may still be present and influence the visual outcome [29]. In our cohort we demonstrated a high refractive accuracy with approximately 75% of patients (postOP 1) and 77% (postOP 2) within ±1 D of postoperative refractive error. In a few cases, dislocation of the lens haptics occurred over time, which may have induced astigmatism. Nevertheless, in these cases enough vision remained for daily life and therefore there was no indication for re-surgery. Patients with amblyopia were excluded from the study cohort, as no representative postoperative visual acuity was measurable here. However, their visual acuity and thus also their quality of life improved due to lens implantation. We expect to achieve even better visual outcomes as surgical methods are further adapted and improved. In this cohort 84% of patients received Nd: YAG capsulotomy due to PCO. A mean time to capsulotomy of 44 months has been reported in the literature [28]. Additionally, rates of capsulotomy in other studies (e.g. 60% or 70%) [13] [28] are comparable to our rate.

The circumstance that the participation rate in the follow-up controls is rather low is limitation and strength at the same time. As the number of participants increases, the data become more representative. The reason for the low participation in the follow-up examinations could be a high patient satisfaction, as well as a sufficiently good visual performance, so that the follow-up examinations were not considered necessary by the patients. Furthermore our study is limited by a lack of evidence of the accommodative properties of the lens, therefore additional investigations should be performed.

5. Conclusion

In conclusion, this new accommodative intraocular lens (AIOL) achieved UNVA, CNVA, UDVA and CDVA of 0.107 ± 0.10; 0.039 ± 0.08; 0.097 ± 0.11 and 0.040 ± 0.09 logMAR after a mean of 5.3 years postoperatively. Thereby, the (long-term) results for accommodative intraocular lenses are particularly promising, especially since the positive visual results did not deteriorate further after the first two postoperative years. However, a precise proof of the (pseudo-) accommodative ability of this lens remains and is subject to further investigations.

Authors' Contribution

All authors contributed to the study conception and design. Material preparation and data collection were performed by Jacob Ritter, Justus Petrick, and Violeta Doci. Data analysis was performed by Jacob Ritter, Justus Petrick, Anna-Lena Kloberdanz and Charlotte Rammler. The first draft of the manuscript was written by Jacob Ritter and Justus Petrick and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Conflicts of Interest

All authors declare that they have no conflict of interest.

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Supplementary

Table S1. Outline of visual acuities at 3 months postoperative, from alternative accommodative intraocular lenses.

	UNVA	CNVA	UDVA	CDVA
Crystalens HD (Bausch Lomb) [35]	0.42 (±0.15)	0.07 (±0.06)	0.26 (±0.45)	0.04 (±0.08)
1 CU Lens (Human optics) [36]	0.55 (±0.11)	0.47 (±0.14)	0.02 (±0.10)	0.00 (±0.09)
Tetraflex (Lenstec Inc.) [37]	0.49 (±0.16)	0.05 (±0.05)	0.12 (±0.15)	−0.01 (±0.05)
Synchrony (Abbott) [38]	0.16 (±0.19)	-	0.23 (±0.28)	0.00 (±0.04)
Tek-Clear (Tekia, Inc.) [37]	0.38 (±0.17)	0.04 (±0.05)	0.30 (±0.20)	0.00 (±0.05)
WIOL-CI (Medicem) [39]	0.27 (±0.19)	-	0.10 (±0.09)	0.05 (±0.06)

UNVA = uncorrected near visual acuity; CNVA = corrected near visual acuity; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity. Reporting of visual acuity in logMAR (±SD).