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Dynamic Stimulation Aberrometry

Objectively Measured Accommodation and Pupil Dynamics after Phakic Iris-Fixated Intraocular Lens Implantation

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Purpose: Anterior iris-claw phakic intraocular lens (pIOL) implantation is a treatment option for refractive, ametropic patients. However, the postoperative accommodative ability has not been systematically researched. Dynamic stimulation aberrometry allows the objective and dynamical measurement of accommodation by observing ocular aberrations during the accommodation process. We investigated the dynamic accommodative ability after pIOL implantation compared with a healthy age- and gender-matched control group.

Design: Clinical, comparative case–control study.

Subjects: We included patients aged 18–50 years that either underwent pIOL implantation > 1 month ago or served as a healthy, phakic control group.

Methods: The accommodative ability and pupil dynamics of both groups were investigated using dynamic stimulation aberrometry. The method allows the analysis of dynamic parameters during accommodation, such as the accommodation speed. A 1:1 propensity score matching was conducted based on the patients' age and gender.

Main Outcome Measures: Parameters of objective accommodation, such as accommodative amplitude and pupil dynamic during accommodation.

Results: Fifty-eight healthy, phakic eyes < 50 years of age and 21 eyes after pIOL implantation to correct myopia (pIOL, Verisyse, AMO, Inc) were enrolled. Patients that underwent anterior pIOL implantation were examined on average 24 ± 18 months after surgery. After matching, the mean age of both groups was not significantly different (35 ± 8 vs. 34 ± 8 years). No significant difference in dynamic parameters of accommodation or the accommodative amplitude (2.8 ± 1.4 and 2.9 ± 1.4 diopters [D] for pIOL and control group, $P = 0.82$) were seen. Maximum and minimum pupil sizes were not significantly different. The change in pupil size during deaccommodation was significantly faster in patients after pIOL implantation ($P < 0.001$).

Conclusions: Dynamic stimulation aberrometry allowed the objective, dynamic, measurement of wavefronts in subjects with accommodative amplitudes up to 7 D. Phakic intraocular lens implantation does not impair the accommodative ability. It alters pupil dynamics during deaccommodation.

Financial Disclosure(s): Proprietary or commercial disclosure may be found after the references. *Ophthalmology Science 2024;4:100374 © 2023 by the American Academy of Ophthalmology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).*

Supplemental material available at www.ophthalmologyscience.org.

Alexander Duane first measured the monocular accommodation of his patients in the early 1900s. In 9 years, he measured a total of 4200 eyes and developed the well-known Duane plots.[1] As introduced by Helmholtz, accommodation consists of the near triad of convergence, myosis, and the ocular dioptric change in refraction in response to ciliary muscle contraction that allows the young distance-corrected eye to focus on near objects due to a change in refractive power of the crystalline lens due to its increased thickness and decreased equatorial diameter.[2–5] Duane himself applied a subjective method to measure a patient's accommodation using a modified accommodation line and Prince's rule[6] because it is still used in routine, refractive care.

However, various developments, such as accommodating intraocular lenses (IOLs) or the increased understanding of the role of accommodation in the pathophysiology of myopia, have brought up the need for objective measurements of accommodation. One way to objectively assess accommodation is by observing ocular aberrations and their changes during the process of accommodation.[7,8] The technique of dynamic stimulation aberrometry (DSA) makes use of this approach.[9,10] A DSA device is attached to an aberrometer. Figure 1 depicts the main elements of the DSA unit.

In short, using a periscope mirror system, a movable, near, real target or a distant, real target is projected into the measurement path of the aberrometer, allowing the

https://doi.org/10.1016/j.xops.2023.100374
ISSN 2666-9145/23

continuous wavefront measurement of the examined eye. Although 1 eye is measured at a time and is therefore aligned with the aberrometer measurement axis, both eyes can view the distant and near stimulus at all times inducing a more natural binocular accommodation stimulus. The accommodation stimulus can be varied between 3 diopters (D) and 7 D in steps of 0.25 D. A total of 300 aberration measurements are taken over 12 seconds and immediately evaluated after corrections based on the smallest pupil size during near accommodation. Two prior studies conducted by our group in 91 patients confirmed the potential of DSA as an alternative to optical coherence tomography, A-scan ultrasound, and infrared photorefraction, even possibly leading to more accurate results while at the same time allowing the accommodation stimulus to be presented to both eyes simultaneously.[9,10]

With an increase in highly myopic patients, treatment options to correct extreme refractive errors are needed.[11] Phakic intraocular lenses (pIOLs) are the main treatment for patients with high ametropia not suitable for laser refractive surgery. It is a safe and effective option with a low complication rate and good visual outcomes.[12–15] Phakic intraocular lenses can be divided into 2 groups based on the lens' location in the anterior or posterior chamber.[16] Because both groups do not require the extraction of the crystalline lens, the patient's natural accommodative ability should be preserved. Although 1 study researched the movement of the iris-fixated lens during the process of accommodation, there is very little evidence on accommodative amplitude after pIOL implantation. A recent systematic review[17] on this matter describes the current evidence as insufficient and calls for further research on accommodation in patients after pIOL implantation, because only few studies dealing with accommodation after posterior or angle-supported pIOL implantation were identified.[18–20]

In this study, we had 2 main objectives. First, we sought to further illuminate characteristics and implications of DSA in the field of accommodation research as well as myopia control and treatment. Second, to fill the knowledge gap around anterior iris-fixated phakic intraocular lenses and accommodation, we compared the accommodative ability and pupil dynamics of myopic patients that underwent anterior iris-claw pIOL implantation to healthy controls that were age- and gender-matched.

Methods

Patient Selection

In this study, we collected data from 2 groups of patients: healthy patients that underwent implantation of anterior iris-claw pIOLs to treat myopia in both eyes (Abbott Medical Optics) > 1 month after surgery, as well as a phakic control group. To be included in the phakic control group, the patients' spherical equivalent of the manifest refraction had to be between 3 and −3 D, the astigmatism < 2.5 D and the patient had to be aged < 50 years. We excluded patients with ocular diseases, especially retinal diseases or optical

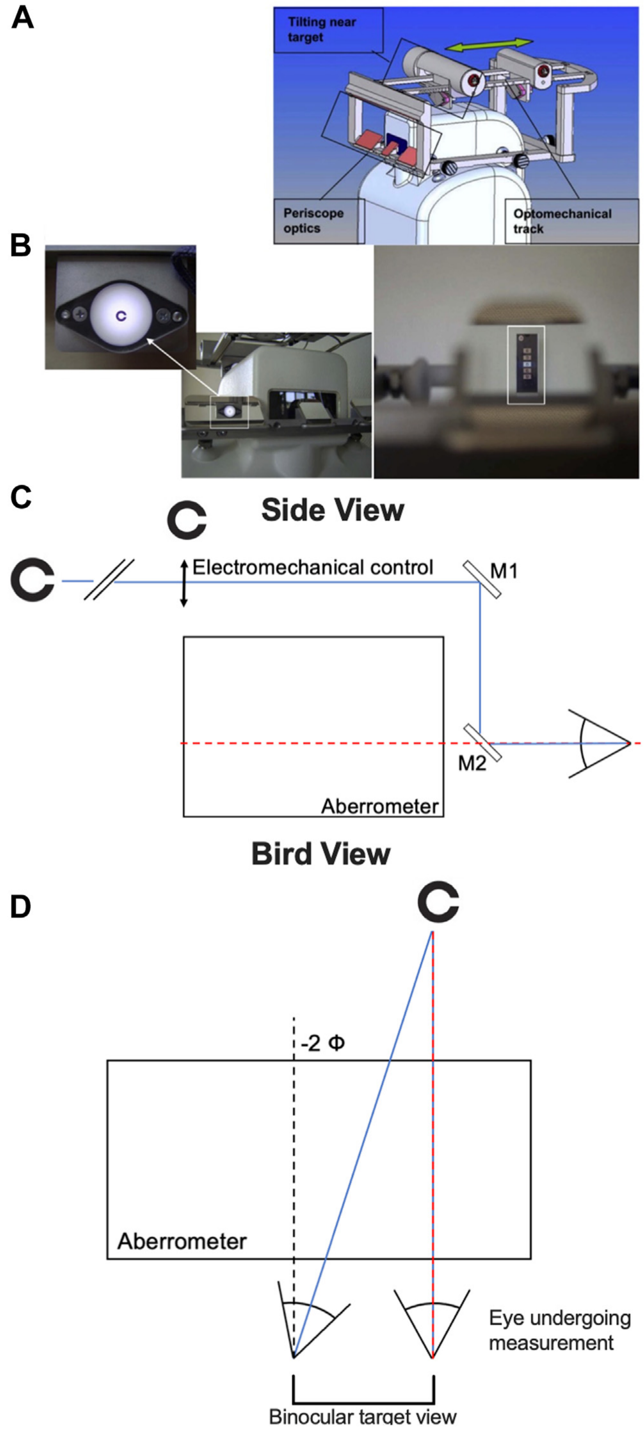

Figure 1. A, The dynamic stimulation aberrometry setup consists of an optomechanical track, a tilting near target as well as periscope optics to project a distance target. This figure is modified from Ehmer et al[9] and Hammer et al.[10] **B,** Subject view during measurement of the near target (left) and the distant target (right). **C,** Two periscope mirrors M1/M2 allow the target image to be aligned with the line of sight and the optical axis of the aberrometer. **D,** Bird view. In this example, the right eye undergoes measurement and is aligned with the optical axis of the aberrometer. Thus, the left eye converges.

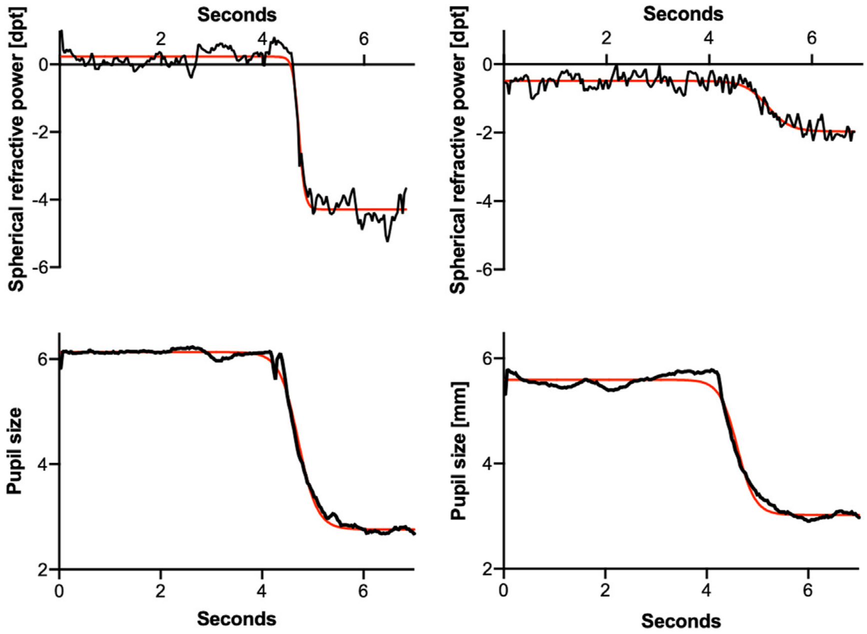

Figure 2. XY plots of one young and one older patient generated by dynamic stimulation aberrometry. The XY plots of the accommodative amplitude (black) of a 21-year-old patient (top left) and a 45-year-old patient (top right) and the corresponding, synchronized measurements of pupil size (bottom). Dynamic stimulation aberrometry allows the examination of accommodation and pupil motility dynamically in parallel. The red line depicts sigmoidal fitting used to quantify dynamic parameters. Maximum accommodation was defined as the span between the top and bottom part of the curve.

nerve diseases. Patients with systemic diseases, such as cancer or diabetes, decentration of the anterior chamber pIOL, or any irregular pupils and other iris defects were also excluded.

All patients gave written informed consent to participate in this study. This study was conducted in accordance with internationally recognized guidelines, including Good Clinical Practice (ICH-GCP) and the Declaration of Helsinki. It was approved by the ethics committee of the Medical Faculty of the University of Heidelberg (reference number: S-392/2011).

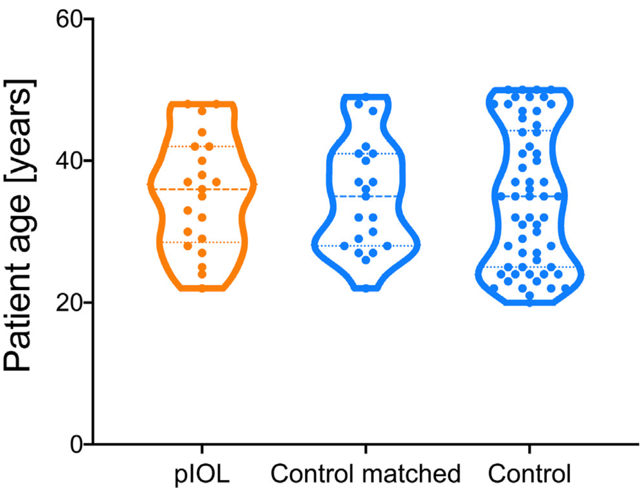

Figure 3. The age distribution of the phakic intraocular lens (pIOL) and the control group. Age is the most important predictor of one's accommodative amplitude. To better compare patients after pIOL implantation and controls, a propensity score matching based on age and gender was conducted. After matching, the newly formed control group and the pIOL group showed a very similar age distribution, as presented here.

DSA

The setup previously described by our group[9,10] was used throughout the study. In short, the DSA device (Optana GmbH) was connected to a WASCA aberrometer (Carl Zeiss Meditec AG). Three hundred measurements of the ocular wavefront were performed in 12 seconds. First, for 4 seconds the patient focused on the distant stimulus (100 measurements); after 4 seconds, the pivotable near target was presented. During the next 4 seconds the subject focused on the Landolt-rings on the near target (100 measurements). Subsequently, the subjects were told to focus on the distant stimulus for another 4 seconds, releasing the induced accommodation (100 measurements). Measurements were examined immediately after being performed. If the subject achieved the expected accommodation, the near stimulus was increased in the following measurement by 0.5 D. When maximum accommodation was reached, measurements were repeated 3 times to assure consistency of results. The maximum near stimulus that can be presented to a subject is 7 D. A central 2-mm pupil area was used throughout analysis for all patients. Although the stimulus is at all times presented to both eyes, the aberrometer can only measure 1 eye at a time. Thus, the entire procedure was then repeated for the other eye. For more details on the method, please see Hammer et al.[10]

Calculation of Dynamic Parameters of Accommodation and Pupil Dynamics

The accommodative amplitude as well as dynamic parameters, such as maximum pupillary speed, were based on sigmoidal curve fitting conducted in Prism 8 (GraphPad Inc.). Figure 2 showcases the changes of spherical refractive power and pupil size during the dynamic measurements for 2 exemplary cases.

Table 1. Refractive Errors on Group-Level

	Phakic IOL Group, n = 21		Phakic Control Group, n = 58
Refraction, D	Preoperative	Postoperative	
Sphere	−9.75 ± 3.03 (−15.00 to −3.50)	0.30 ± 0.58 (−1.00 to −1.50)	−0.25 ± 1.08 (−3.00 to −2.00)
Cylinder	−1.30 ± 0.77 (≤ −3.00)	−1.04 ± 0.67 (≤ −2.50)	−0.61 ± 0.56 (≤ −2.50)
Spheric equivalent	−10.37 ± 2.97	−0.2 ± 0.63	−0.49 ± 1.11

D = diopters; IOL = intraocular lens.
Data are presented as mean ± standard deviation (range).

The red line depicts the sigmoidal fit which was used. The following parameters were derived from the curve fitting: maximum accommodative amplitude, maximum accommodation speed during accommodation, maximum deaccommodation speed during deaccommodation as well as maximum pupil size, minimum pupil size, maximum pupil speed during accommodation, and maximum pupil speed during deaccommodation. More details on this matter are presented in Hammer et al.[10]

Propensity Score Matching

As patient age is the most important predictor of the accommodative amplitude, a propensity score matching based on the subject's age and gender was conducted to minimize bias. Matching was conducted in a 1:1 fashion using a caliper width of 0.1.

Propensity score matching was performed using Stata 17BE (StataCorp), as previously described in detail.[21−23]

Statistical Analysis

Distributions were tested for normality using the Kolmogorov−Smirnov test. *T* tests and Mann−Whitney *U* tests were used for comparison between groups. *P* values of < 0.05 were considered statistically significant. Only 1 eye per patient was used for analyses to reduce bias of different accommodation results between both eyes as well as possible bias due to 1 dominant eye leading accommodation. The analyzed eye was chosen at random. Statistical analyses were performed using Stata 17BE (StataCorp) and Prism 8 (GraphPad Inc.)

Power Analysis

Assuming a difference of 2 D between the pIOL- and control group, with a standard deviation of 1.5 D as clinically relevant and an allocation of 1:1, 21 patients per group were needed to achieve a power > 98% after propensity score matching. The power analysis was conducted with G*Power.[24,25]

Results

Study Cohort

A total of 79 eyes of 79 patients were included in the study: 21 eyes of 21 patients that previously underwent anterior chamber iris-claw IOL implantation and 58 phakic, healthy patients aged < 50 years that served as a control group. Although both eyes were measured, the eye included in the analysis was chosen at random to minimize bias by eye dominance. Due to the great impact of age on accommodation, the age distribution of both groups is showcased in Figure 3 before and after propensity score matching. Data on accommodation and pupil dynamics were normally distributed. The mean age was 35.4 ± 7.8 and 34.7 ± 9.8 years for the pIOL and unmatched control groups, respectively. The examination took place after a mean of 24 ± 18 months (7 weeks to 54 months) after pIOL implantation. The preoperative and postoperative refractive errors for pIOL group as well as for the control group are

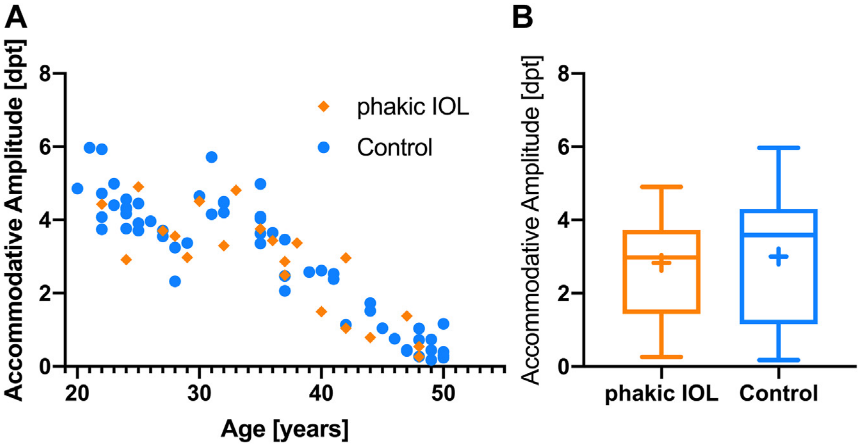

Figure 4. Unmatched analysis: the declining accommodative amplitude with age quantified with dynamic stimulation aberrometry. **A,** The 79 eyes of patients included in this study revealed the well-known near-linear decline of the accommodative amplitude with age. **B,** The mean accommodative amplitude of the phakic intraocular lens (pIOL) and the control group before matching. No significant difference can be seen.

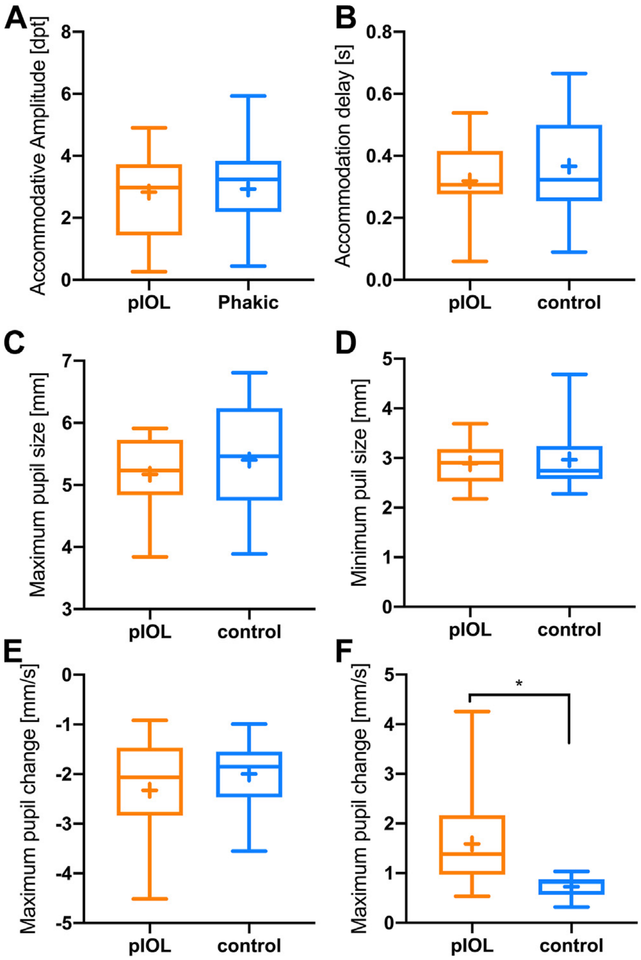

Figure 5. Matched analysis: accommodative amplitude, accommodation delay, and pupil dynamics. No significant difference was found in (**A**) the accommodative amplitude and (**B**) the accommodation delay (time after presentation of the near stimulus until accommodative refractive change is initiated by the subject, **B**). No significant difference was seen for the (**C**) maximum and minimum (**D**) pupil size as well as the maximum pupil change between groups. As presented in panels **E** (accommodation) and **F** (deaccommodation), the maximum pupil change during deaccommodation was significantly quicker after phakic intraocular lens (pIOL) implantation.

presented in Table 1. There was no significant difference in the spheric equivalent when comparing the postoperative values of the pIOL group with the control group (unpaired *t* test, $P = 0.15$).

Propensity Score Matching

All 21 pIOL patients were successfully matched with a healthy control patient based on age and gender. Table S2 (available at www.ophthalmologyscience.org) presents the standardized differences for age, gender, and accommodation stimulus, indicating a successful and effective matching. In the matched cohort, no significant difference in age or gender distribution was found (Table S2).

Feasibility of DSA Measurements

A maximum of 100 dynamic measurements is taken during the pre-accommodative phase (4 seconds) and the accommodative phase (4 seconds) during the DSA, respectively. We compared the number of successful measurements taken in each phase between the groups because they might influence results. The number of measurements did not significantly differ between groups during the preaccommodative phase (88.51 ± 0.73 vs. 88.48 ± 0.99; $P = 0.66$; Mann−Whitney *U* test for the pIOL and control groups, respectively) or during the accommodative phase (87.14 ± 1.58 vs. 87.63 ± 1.19; $P = 0.15$; unpaired *t* test for the pIOL and control groups, respectively).

Accommodation

Unmatched Analysis. The median accommodation achieved was 2.97 D (interquartile range [IQR], 1.44−3.73) for the pIOL group and 3.59 D (IQR, 1.16−4.31) for the control group. The accommodative ability did not differ between groups in this unmatched analysis ($P = 0.68$, unpaired *t* test). The presented accommodation stimulus was 4.93 ± 0.93 D and 5.01 ± 1.16 D for the pIOL group and the control group, respectively. Again, there was no statistically significant difference (unpaired *t* test, $P = 0.86$). Figure 4A depicts the accommodation measured by DSA for both groups as a scatter plot; Figure 4B shows group-level mean values and variance.

Matched Analysis. No significant difference in the accommodative amplitude ($P = 0.82$), the maximum accommodation speed ($P = 0.24$), or the maximum deaccommodation speed ($P = 0.45$) was found between groups. Again, no difference was found in the accommodation delay ($P = 0.32$), a measure of reaction time which was previously found to correlate with age,[10] further indicating a good patient matching (Fig 5).

Pupil Dynamics

Pupil dynamics were only analyzed in the matched cohort. No significant difference in maximum or minimum pupil size was found ($P = 0.32$ and $P = 0.62$, respectively). The maximum pupil speed during accommodation was not significantly different ($P = 0.25$); however, the pupil widened significantly quicker in patients in the pIOL group ($P < 0.001$; Fig 5).

Discussion

Summary

In this study, we used an innovative approach to observe the dynamic accommodation of patients after implantation of a phakic, anterior, iris-fixated intraocular lens and an age- and gender-matched control group. Dynamic stimulation aberrometry proved to be a clinically applicable objective technique to measure binocular accommodation in 79 patients. The accommodative ability was not significantly different between groups.

DSA as a Method to Objectively Measure Accommodation

Dynamic stimulation aberrometry is one of few methods to objectively measure one's accommodative ability. In 2008, our group first introduced this approach in a very small number of patients, including young, healthy, phakic patients, pseudophakic patients treated with varying IOL models including accommodating IOLs, as well as 1 patient that had undergone an anterior, iris-fixated pIOL. Recently, we formally introduced the method in a large cohort of 91 patients.[10] In this study, we included 21 patients after pIOL implantation. Dynamic stimulation aberrometry proved to be applicable without any changes to the measurement procedures.

Impact of Iris-Fixated Anterior Phakic IOLs on the Accommodative Ability

In this study, we did not see any changes of the accommodative function after phakic iris-claw implantation. In 2008, Stulting et al[26] presented the 3-year results of the Artisan/Veriseye phakic IOL, reporting excellent refractive results and very few complications. A recent systematic review by Hernández-Rodríguez et al[17] concluded that the current evidence on how pIOL implantation may affect accommodation is "poor" and has limited quality. No data on the impact of anterior pIOL implantation are available to this date. Only 2 articles studying posterior pIOL implantation were found. Both show a transient decrease of the accommodative ability after surgery that normalized approximately 1 year after surgery.[18,19] The authors attribute this decrease to a temporary dysfunction of the ciliary muscles induced by the pIOL fixation and may occur after the posterior pIOL implantation even if the crystalline lens remains untouched and intact. However, both used subjective methods to measure accommodation that rely on patients stating blurriness and may be influenced by other factors.

Accommodation is a process of the anterior segment of the eye. Morphological changes can provide information if iris-fixated lenses impair the process of accommodation. Previously, anterior segment optical coherence tomography revealed a combined forward movement of the IOL and the crystalline lens while still not damaging the endothelium during accommodation and under different lighting.[27,28] Our study further confirms no influence of iris-fixated IOLs on accommodation.

The Effect of Iris-Fixated IOLs on Pupil Dynamics

Pupil dynamics after iris-fixated IOL implantation were previously evaluated by exposing patients to different light conditions.[29−31] Two previous studies evaluated pupil size during accommodation in patients after pIOL implantation finding no difference in pupil diameter or the change of pupil size during various levels of near accommodation.[20,27] However, all previous studies did not investigate dynamic parameters such as the maximum change in pupil size during accommodation and deaccommodation. We found that patients after pIOL implantation show a greater speed during deaccommodation compared with healthy controls during accommodation. This could be related to tractional forces exhibited by the enclavation of the iris. However, further studies, possibly using dynamic imaging with anterior segment OCT, could investigate such changes in more detail.

Limitations

This study also has limitations. Patients that underwent anterior pIOL implantation were not all examined after a defined time point but after a time frame of several months to years after surgery. Also, in our study setting, because of the limited sensor range of the DSA device and the great refractive error prior surgery, we were not able to compare the accommodative ability of patients preoperatively versus postoperatively. As such, we therefore set a large and well-matched control group in place.

In conclusion, anterior pIOL implantation does not impair one's accommodative ability. Dynamic stimulation aberrometry proved to be a clinically relevant tool to objectively measure binocular accommodation using wavefront measurements.

Footnotes and Disclosures

Originally received: June 13, 2023.
Final revision: July 14, 2023.
Accepted: July 18, 2023.
Available online: July 24, 2023. Manuscript no. XOPS-D-23-00133R1.

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Disclosure(s):

All authors have completed and submitted the ICMJE disclosures form.

The author(s) have made the following disclosure(s):

G.U.A.: Grants − AMO/Johnson & Johnson, Alcon, Carl Zeiss Meditec, Hoya, Kowa, Oculentis/Teleon, Rayner, Santen, Sifi, Ursapharm, Biotech, Oculus, EyeYon, Acufocus, Conta-mac, Glaukos, Physiol, Rheacell, VSY; Consulting fees − Alcon, AMO/Johnson & Johnson, Carl Zeiss Meditec, Cristalens, EyeYon, Presbia, Rayner, SIFI, VSY; Personal fees/Honoraria − Acufocus, Alcon, AMO/Johnson & Johnson, Biotech, Carl Zeiss Meditec, Cristalens, Eyebright, Hoya, Kowa, Teleon, Oculus, Rayner, SIFI, Ursapharm, VSY; Support for attending meetings and/or travel − Alcon, AMO/Johnson & Johnson, Carl Zeiss Meditec, EyeYon, Hoya, Kowa, Teleon, Rayner, SIFI, Ursapharm.

The other authors have no proprietary or commercial interest in any materials discussed in this article.

This study was made possible through the support of the Klaus Tschira Foundation granted to G.U.A. The funding organization had no role in the design or conduct of this research.

HUMAN SUBJECTS: Human subjects were included in this study. This study was conducted in accordance with internationally recognized guidelines, including Good Clinical Practice (ICH-GCP) and the Declaration of Helsinki. It was approved by the ethics committee of the Medical Faculty of the University of Heidelberg (reference number: S-392/2011). All patients gave written informed consent to participate in this study.

No animal subjects were used in this study.

Author Contributions:

Conception and design: Hammer, Heggemann, Auffarth

Data collection: Hammer, Heggemann, Auffarth

Analysis and interpretation: Hammer, Auffarth

Obtained funding: Auffarth

Overall responsibility: Auffarth

Abbreviations and Acronyms:
D = diopters; **DSA** = dynamic stimulation aberrometry; **IQR** = interquartile range; **IOL** = intraocular lens; **pIOL** = phakic intraocular lens.

Keywords:
Aberrations, Dynamic wavefront measurement, Iris-claw lens, Objective accommodation, Phakic IOL.

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