Initial Clinical Results of a New Telescopic IOL Implanted in Patients With Dry Age-Related Macular Degeneration

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ABSTRACT

PURPOSE: To evaluate the safety and efficacy of the iolAMD technology (London Eye Hospital Pharma, London, UK), which includes two injectable, hydrophobic acrylic intraocular lenses (IOLs) in a pilot study of patients diagnosed as having cataract and dry age-related macular degeneration.

METHODS: The cataract surgery and IOL implantation were performed after a preoperative evaluation using the iolAMD simulator in eyes with bilateral intermediate dry age-related macular degeneration. Outcomes were intraoperative and postoperative complications, subjective and objective visual acuity improvement, visual field changes, and postoperative diplopia.

RESULTS: Three eyes of 2 patients were evaluated. The surgeries were uneventful. All eyes gained monocular reading vision at the 1-week postoperative visit. One patient with monocular implantation recognized diplopia for distance vision. Preoperative corrected distance visual acuity ranged from 20/800 to 20/125 and corrected near visual acuity was 20/800 or less. Two months after surgery, corrected distance visual acuity increased to levels between 20/40 and 20/25 (uncorrected distance visual acuity was 20/60 to 20/32; uncorrected near visual acuity was 20/200 to 20/25).

CONCLUSIONS: These early results showed that the iolAMD simulator is a promising technology improving near and distance visual acuity in eyes with intermediate dry macular degeneration. The prismatic IOL effect did not lead to diplopia when implanted bilaterally. The surgery was safely performed.

rior surface that had been implanted in three eyes. Other technologies use combinations of intraocular implants with different powers to aim a telescopic effect for magnifying. The iolAMD technology (London Eye Hospital Pharma, London, UK) is a new approach of two injectable, small-incision, hydrophobic acrylic IOLs. IOL 2 is a high-power minus lens placed into the capsular bag, whereas the IOL 1 is a high-power plus lens implanted into the sulcus. After implantation they both act as a telescope, allowing a magnification of the image and distribution of the retinal picture 3° apart from the fovea due to the slight intended decentration of sulcus implanted IOL 1 (0.85 mm). The purpose of our study was to implant this IOL technology in 3 eyes of 2 patients with intermediate dry AMD after cataract removal and to evaluate the efficacy and safety.

**PATIENTS AND METHODS**

The case series was reviewed by the local ethics committee of Goethe-University Frankfurt and approval was not needed due to the number of eyes and an implant with CE mark approval, respectively. All tenets of the Declaration of Helsinki were observed. Both patients had a visually significant cataract and intermediate dry macular degeneration with drusen and volunteered for the study, providing signed informed consent. The exclusion criteria were pathologies that might be aggravated by the IOL or make it ineffective, other pathologies of the retina or cornea, glaucoma, pseudoexfoliation, zonular loss, or a history of uveitis.

Preoperatively, all enrolled patients underwent a full clinical examination including manifest refraction, Snellen corrected distance and near visual acuity, noncontact partial coherence laser interferometry (IOL Master; Carl Zeiss Meditec, Jena, Germany), and anterior segment imaging (Pentacam HR; Oculus Optikgeräte GmbH, Wetzlar, Germany). A fundus photography (Figure A, available in the online version of this article) and optical coherence tomography (Figures B-D, available in the online version of this article) examination of the macula was performed. Furthermore, the iolAMD simulator was used for determination of the lens orientation.

The iolAMD lens system received CE mark approval in 2014 and is based on a Galileian telescope using two lenses of differing power in minus and plus. Both lenses are manufactured from a hydrophobic acrylic material and can be injected with a standard soft tip cartridge and injector system for 3.0-mm incision size. The capsular bag positioned IOL (IOL 2) is a high-minus-power lens (-49 diopters [D]) with a 4.0-mm optic and an overall length of 11.0 mm. The plate haptic is symmetrical and vaulted posteriorly approximately 15°. The sulcus-positioned IOL (IOL 1) is a high-plus-power lens (+63 D) and the 5.0-mm hyper-aspheric-optic is slightly decentered on the plate haptic. The overall diameter is 11.75 to 12.0 mm and the haptic is bent anteriorly to enhance the recommended distance between the optics of 2 mm after implantation. Both lenses have a refractive index of 1.525 and, in combination, the remaining refractive power of 21 D. The A-constant is estimated at 119.4. Magnification is provided up to $\times1.25$.  

All eyes underwent small-incision phacoemulsification using topical anesthesia. The two-step clear cornea main incision was placed at the 12-o’clock position using a 2.2-mm metal keratome (Slit Knife 2.2 angled; Alcon Laboratories, Inc., Fort Worth, TX). The single-plane sideport incisions were placed at the 9- and 3-o’clock positions and made with a 1.2-mm metal keratome (Sideport Knife, dual bevel; Alcon Laboratories, Inc.). After instillation of Healon 1% (Abbott Medical Optics, Inc., Santa Ana, CA) into the anterior chamber to protect the endothelium, the continuous curvilinear capsulorrhexis of an intended diameter of 5.0 mm was performed using Utrata capsulorrhexis forceps (Zeidler, Heidelberg, Germany) through the main incision. Cataract surgery was performed using the Stellaris phacoemulsification machine (Bausch & Lomb, Aliso Viejo, CA) in all eyes. After flipping half the nucleus, further chopping under continuous phacoaspiration was performed. For removal of the remaining cortex, bimanual irrigation and aspiration through the nasal and temporal incisions were performed following by polishing of the posterior capsule. After enlarging the corneal tunnel to 3.2 mm with a 3.2-mm metal keratome (Slit Knife, dual bevel; Alcon Laboratories, Inc.) and a second instillation of ophtalmic viscosurgical device, the single-piece AMD 1 lens was implanted in the posterior chamber using an injector system. Afterward, the single-piece AMD 2 lens was also injected and positioned in the sulcus. According to the asymmetric haptic design, the optic of this lens was decentered toward the leading haptic and was aligned according to the preoperative evaluated axis. After carefully removing the ophthalmic viscosurgical device, all eyes were covered with a patch. Standard topical ofloxacin and dexamethasone eye drops were administered four times daily for the first week, then the dosage gradually decreased over a period of 4 weeks. All surgeries were performed by the same surgeon (FHH) in July 2014.

The following endpoints were evaluated: (1) manifest refraction; (2) corrected and uncorrected distance visual acuity; (3) corrected and uncorrected near visual acuity; (4) Snellen corrected distance and near visual acuity; (5) corrected and uncorrected distance and near visual acuity; (6) refraction; (7) visual acuity; (8) intraocular pressure; (9) postoperative complications; and (10) retreatment.
RESULTS
The result of the preoperatively predicted near visual acuity was 20/200. All 3 eyes gained near visual acuity of 20/100 at 1 day after cataract surgery. During the 3-month follow-up, distance and near visual acuity increased. In 1 eye there was an increase of corrected near visual acuity of 20/32 and corrected distance visual acuity of 20/25. All detailed information is presented in Table 1.

Table 1. Preoperative and Postoperative Visual Results, Simulated Expected Visual Acuity, and Subjective Refraction

<table>
<thead>
<tr>
<th>Patient (Eye)</th>
<th>Preoperative</th>
<th>Postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CDVA</td>
<td>CNVA</td>
</tr>
<tr>
<td>1 (left)</td>
<td>20/800</td>
<td></td>
</tr>
<tr>
<td>2 (left)</td>
<td>20/125</td>
<td></td>
</tr>
<tr>
<td>2 (right)</td>
<td>20/125</td>
<td></td>
</tr>
</tbody>
</table>

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

Statistical Analysis
For statistical analysis, the logMAR value of visual acuity was converted in decimal notation and vice versa, as described by Westheimer. 10

Figure 1. Scheimpflug image of the two component intraocular lenses (IOL) 1 month after surgery.

Figure 2. Postoperative subjective refraction was +1.5 D (patient 2) at 3 months. For near visual acuity testing, we added +3.0 D of sphere.

Figure E (available in the online version of this article) presents the IOLs position photographed by slit lamp and the Pentacam analysis of the effective lens position at the 1-month follow-up examination of the left eye (patient 2). The patient with bilateral implantation perceived no double vision because the decentration axis in both eyes was vertical. The other patient with singular implantation recognized an increase in visual acuity but complained about diplopia in reverse events.
a vertical direction. Orthoptic examination revealed a visual field deviation of 3°, which could be solved by prismatic spectacle correction for distance and near glasses. Furthermore, the visual acuity of the second eye with a monofocal single IOL was two lines above the eye with the telescopic implant.

**Complications**

All surgeries were without complication and the postoperative course of visual recovery was comparable with regular cataract surgery and implantation of only a single IOL in the capsular bag. There was no rise in intraocular pressure or iris-related problems such as shaving of pigment or pupillary block. The anterior chamber remained stable and the gap between both lenses provided the telescopic effect in all three eyes.

**Discussion**

This study was designed as a pilot study and 3 eyes with intermediate dry AMD were included. Although the iolAMD simulator was used preoperatively for prediction of the postoperative near visual acuity, it showed predicted worse than 20/100 and all results obtained here were 20/40 to 20/25 (corrected distance visual acuity) after 3 months. This underestimation of the possible visual acuity may be related to the senile cataract lowering visual acuity by itself preoperatively. Furthermore, the iolAMD simulator is useful to predict the effective implantation axis prior to surgery. In our study, all lenses had been placed in a vertical axis and the IOL implantations could be obtained safely and were stable during the 3-month follow-up. No postoperative rotation was necessary. The possibility to rotate the sulcus IOL later in life could be an option to reestablish visual acuity, because the macular pathology is not a stable parameter. In case of further progress along this primary direction, the surgeon is able to simulate visual field rotation again if another direction of the implantation axis can improve the previous effect and then rotate the sulcus lens according to this new location.

Other approaches currently under evaluation are lenses using a Fresnel prism on the posterior surface to relocate the field of retinal perception. This concept has shown to be effective in a recent pilot trial that contained eyes with late stage AMD.

Until now, iolAMD lenses were designed hyper-aspheric to provide a large depth of focus. The combination of a high-power minus 49-D lens placed in the capsular bag and a high-power plus 63-D lens arranged in the sulcus results optically in a Galileian telescope. Furthermore, the decentration of the plus lens allows a shift of the retinal focus of 5° along the axis. This item is important because there are no other power ranges available, limiting this technology to eyes with an axial length of 21 to 23 mm with a resulting power of 21 D. The IOL power cannot be adapted perfectly to patient anatomy right now.

Bilateral implantation can be recommended according to the underlying macular pathology to prevent diplopia in daily life situations. Proof of concept has been done with the patient receiving the iolAMD in 1 eye, because the other eye was pseudophakic. As a result of centering the gained visual field, double vision was conspicuous and could be solved by prism correction.

**Figure 2.** Postoperative intraocular lens position of the (A) left eye of patient 1 and (B) right eye of patient 2 one month after surgery.
The first implantations in this pilot study remained safe and showed restoration of both distance and reading visual acuity after cataract removal for 3 months of follow-up in patients with intermediate dry AMD. Further studies with more patients with dry AMD and long-term follow-up are currently under design to report on potential side effects over time in the future. Currently, only one IOL power is available and a fixed angle of deviation of the visual field can be obtained. There is important scope for individual optimization according to all patients with AMD and pseudophakic eyes, respectively. Other macular pathologies could also be potential options for implantation of this technology.

**AUTHOR CONTRIBUTIONS**

Study concept and design (FHH, PA); data collection (IC-H); analysis and interpretation of data (FHH, TK, IC-H); drafting of the manuscript (IC-H); critical revision of the manuscript (FHH, PA, TK); statistical expertise (IC-H)

**REFERENCES**

Figure A. Preoperative fundus photography of the (A) left and (B) right eye of patient 2.

Figure B. Preoperative optical coherence tomography of the left eye of patient 1.
Figure C. Preoperative optical coherence tomography of the right eye of patient 2.

Figure D. Preoperative optical coherence tomography of the left eye of patient 2.

Figure E. Postoperative image of the left eye of patient 1 one month after surgery.
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