ARTICLE

Long-term follow-up and clinical evaluation of the light-adjustable intraocular lens implanted after cataract removal: 7-year results

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Purpose: To determine the long-term safety and effectiveness of a light-adjustable intraocular lens (LAL) over a period that is longer than reported in the literature at the time of the study.

Setting: University Eye Hospital, Bochum, Germany.

Design: Noninterventional observation.

Methods: In 445 patients, cataract surgery with LAL implantation was performed between April 2008 and December 2012. It was possible to contact 171 of these patients or their relatives through letter or telephone; 61 patients (103 eyes) agreed to participate in the long-term study and were examined.

Results: The mean time between the lock-in (final light treatment) and long-term visit was 7.2 years; 61 patients were included and examined. Corrected and uncorrected distance visual acuity was and remained good (n = 93). The refractive outcome was stable with minimal deviation. There were no significant changes in corneal thickness. In 2 patients, there were slight opacities of the IOL material without impact on visual acuity. Other eye diseases were within the normal range of the patients' age.

Conclusion: Seven years after implantation and refractive adjustment, eyes with an LAL had stable refraction, good visual acuity, and no IOL-associated pathologies. The findings suggest that LAL technology is a safe and efficient method to achieve good visual results without long-term complications.

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Cataract surgery has become increasingly safe and efficient over the past decades. Owing to elevated patient expectations, the achievement of the desired refraction has become a major challenge in modern cataract surgery.

Several trials have demonstrated that the target refraction is missed in a significant percentage of patients. In a multicenter data study with a high number of cases, Lundström et al.[1] reported that the biometry prediction error of ±0.5 D was only achieved in 72.7% of the cases. Similar results were measured by Simon et al.[2] in a retrospective study with 94% of the cases within ±1.0 D of the target refraction. Furthermore, many patients who have undergone corneal refractive surgery are now reaching the typical age for cataract surgery, with intraocular lens (IOL) power determination being particularly challenging in these eyes.[3] In addition to advanced preoperative biometry devices, IOL calculation formulas, and intraoperative aberrometry, IOL technologies that allow for postoperative adjustments of the refractive power have also been developed. Although in the past most of these adjustable technologies required an invasive procedure, the light-adjustable intraocular lens (LAL; RxSight, Inc.) uses profiled doses of ultraviolet (UV) light to adjust for residual refractive errors after cataract surgery. This technology received Conformité Européenne Mark approval in Europe in 2007 and U.S. Food and Drug Administration (FDA) approval in the United States in 2017. In a trial published by Hengerer et al.,[4] the deviation from the targeted refraction with the LAL was better than ±0.5 D in 98% of the cases 18 months postoperatively and in 91.8% of the cases 6 months postoperatively in the FDA-approved trial.[5] However, during the procedure, a significant amount of energy is sent through the eye and no long-term data are available in terms of refractive stability and safety. Our trial aimed at investigating the long-term safety and effectiveness of the LAL over a longer

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period than was reported in the literature at the time of this study.

METHODS

In this noninterventional observation trial, all patients who had been treated with an LAL at Ruhr University Eye Hospital in Bochum (Germany) between April 2008 and December 2012 were contacted. Through letter or telephone call, patients were invited to a follow-up examination, conducted in 2016 and 2017.

In total, 445 patients were contacted. Of these, 274 (62%) were not reached by phone and did not respond to the letter sent. In total, 171 patients or their relatives (38%) were reached, and 61 (14%) were able and willing to participate in the long-term trial, which consisted of 1 follow-up visit/examination. The trial received ethical committee approval from Ruhr University, and all aspects of the Declaration of Helsinki were observed. All patients signed an informed consent form.

Light-Adjustable Intraocular Lens

The LAL technology has been described in detail in earlier publications.[6-9] Briefly, it is a foldable, 3-piece, silicone IOL with an overall diameter of 13.0 mm; the optic is 6.0 mm in diameter. The IOL has squared posterior optic edges, round anterior edges, and blue poly(methyl methacrylate) modified-C haptics with a posterior optic–haptic 10-degree angulation. The IOL is manufactured in the range of +10.00 to +30.0 D, in 0.50 D increments from +16.00 to +24.0 D and in 1.00 D increments from +10.00 to +15.00 D and +25.00 to +30.0 D. The silicone contains macromers that are sensitive to UV light (365 nm). Two to 3 weeks after routine implantation of the IOL, the light delivery device is used to induce a controlled polymerization of the contained silicone macromers, which results in a predictable spherical and/or cylindrical power change. If further refinement of the refractive outcome is desired, the IOL power can be modified again, up to a total of 3 D of cylinder and 2 D of sphere. Owing to the distribution of the photosensitive silicone macromers, UV irradiation of the central segment of the LAL is performed in cases of hyperopic correction, whereas the periphery of the IOL is irradiated to treat residual postoperative myopia.[10] If the desired refractive state has been achieved, a final lock-in is then performed to permanently fix the refractive power of the IOL. This lock-in does not affect the final dioptric power of the IOL. Patients are required to wear special UV protective spectacles after LAL implantation until the final light treatment is completed to protect the eye from any unscheduled UV light exposure, which might severely influence the IOL power in a desirable way.

Surgical Technique

From 2008 to 2012, all included patients were operated on with the same surgical technique by two experienced surgeons (F.H.H. and H.B.D). In most cases, parabulbar anesthesia was administered by either injecting 2 mL to 6 mL of anesthetics (lidocaine hydrochloride 2% in combination with tetracaine hydrochloride at equal volumes), or applying topical anesthesia (oxybuprocaine hydrochloride eyedrops, Conjucain EDO 0.4%). After pharmacological mydriasis (0.5% tropicamide eyedrops, Mydriaticum; 5.0% phenylephrine eyedrops, Neo-Synephrine), a clear corneal incision at the 12 o'clock position using a 2.75 mm steel keratome (Alcon Laboratories, Inc.) was made. The side-port incisions were positioned at 3 o'clock and 9 o'clock. After instillation of the ophthalmic viscosurgical device (sodium hyaluronate 1.0%) into the anterior chamber, a continuous curvilinear anterior capsulorhexis between 4.5 mm and 5.5 mm was created. This was followed by phacoemulsification with the stop-and-chop technique (Stellaris; Bausch & Lomb, Inc.). The residual cortex was removed with irrigation/aspiration. The 3-piece silicone LAL was implanted directly in the capsular bag. After ophthalmic viscosurgical device removal, corneal wounds were closed with a balanced salt solution for watertightness, and antibiotic (ofloxacin, Floxal) and steroidal ointments (prednisolone, Ultracortenol) were applied.

Postoperative Treatment

Postoperative medication consisted of topical antibiotic (ofloxacin, Floxal) and steroid eyedrops (Dexa EDO), which were administered 4 times daily for the first week, after which the dosage was gradually tapered over 6 weeks. All patients were required to wear UV light–filtering spectacles during waking hours after cataract surgery until the final lock-in treatment was completed. All irradiation procedures were performed with the pupil fully dilated and the patient fixating on a flashing target light. The treatment exposures were delivered in a continuous dose. One to 2 days after the adjustment, the patient returned to the clinic for clinical examination. If the desired refraction had been achieved, the LAL was locked in. If further refinement of the residual refractive error was required, the IOL was adjusted again.

Long-Term Visit

In all cases, data from the original 1-year postoperative visit were available. This included subjective refraction (spherical equivalent [SE]) and uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) under photopic light conditions. Furthermore, preoperative and 1-year pachymetry data were available in 54 (52%) of 103 eyes.

During the long-term follow-up visit, subjective refraction, UDVA and CDVA under photopic light conditions, pachymetry, optical coherence tomography of the macula, and slitlamp examination of the anterior and posterior segment were performed by experienced investigators.

Statistics

The statistics were made using IBM SPSS Statistics for Windows software (version 19.0, IBM Corp.). A P value less than .05 was considered statistically significant.

RESULTS

This study enrolled 103 eyes of 61 patients. The mean age of the study group was 75 years ± 6.8 (SD) (range 54 to 88 years) with a sex ratio of 20 men (33%) and 41 women (67%). The median time between LAL implantation and the last follow-up was 7.2 years ±0.9 (SD). All planned measurements were performed successfully in all patients.

Ten eyes were excluded from the refraction and visual acuity analyses because of the following pathologies: 1 case of retinal detachment, 3 cases of epiretinal gliosis, and 1 case each of central retinal vein occlusion and branch arterial occlusion. Two eyes each developed wet age-related macular degeneration with anti–vascular endothelial growth factor therapy. One eye showed a decompensated Fuchs endothelial dystrophy and 1 eye developed vitreomacular traction.

The box plots in Figure 1 demonstrate the UDVA for the remaining 93 eyes. One year postoperatively, UDVA was 0.2 logarithm of the minimum angle of resolution (logMAR) (median ±0.2; range 1.2 to 0.1), and 7 years postoperatively, it was 0.28 logMAR (median ±0.21; range 1.2 to 0.2) (n = 93; P = .001). There was a minor change in CDVA from 0.07 logMAR (median ±0.12; range 0.6 to 0.1) 1 year postoperatively to 0.12 logMAR (median ±0.18; range 1

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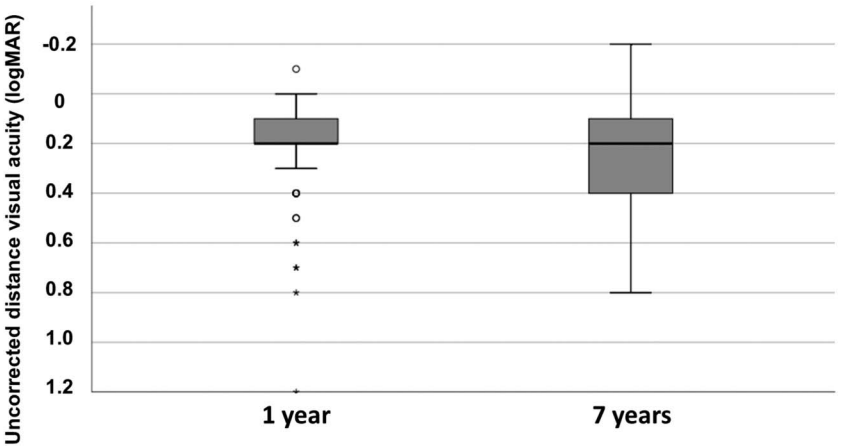

Figure 1. Uncorrected distance visual acuity after 1 year and 7 years (logMAR = logarithm of the minimum angle of resolution).

to −0.2) 7 years postoperatively (n = 93; *P* = .005) (Figure 2). Refraction was also stable (Figure 3). The refraction after 1 year was 0.04 D (median ±0.68; range −3.13 to 1.5) and 0.23 D (median ±0.73; range −3.13 to 1.88) after 7 years (n = 93; *P* = .005). The average central corneal thickness (CCT) remained unchanged from 550 µm (median ±29; range 485 to 612) preoperatively to 555 µm (median ±29; range 475 to 605) after 1 year (n = 53, *P* = .58) and 553 µm (median ±28; range 489 to 610) after 7 years (n = 54, *P* = .12) (Figure 4).

In 2 eyes, slight IOL opacities were found (after a history of chronic uveitis over years in 1 eye and multiple anti–vascular endothelial growth factor injections and a vitrectomy in the other). Both patients had a good visual acuity. They were asked whether they had photic phenomena. No photic phenomena were reported.

DISCUSSION

Refractive outcomes after cataract surgery are an important factor for determining the patient's satisfaction or, rather, disappointment after postoperative recovery and rehabilitation are completed. Residual refractive errors are common, even for the most experienced cataract surgeons. While treating these residual ametropias with corneal refractive procedures such as laser in situ keratomileusis or photorefractive keratectomy being a well-established approach, they may introduce new issues such as dry eye and other complications that can be avoided with an adjustable IOL.[11]

In addition, an increasing number of former refractive patients will undergo cataract surgery with remnants of earlier procedures on the eye's surface, potentially making further corneal procedures problematic.

A number of adjustable IOLs have been developed to address these shortcomings, described in a 2014 review by Ford et al.[10] Some of these technologies require a second invasive intervention, such as the multicomponent IOL, the mechanically adjustable IOL, and the repeatedly adjustable IOL. Other technologies allow for an external adjustment, such as the magnetically adjustable IOL and the liquid-crystal IOL with wireless control. These authors suggest that IOLs permitting noninvasive postoperative adjustment may become a mainstay of cataract treatment in the future.[10] The most clinically advanced of these is the LAL, first described by Schwartz in 2003.[6]

In our series, we have documented long-term results that confirm the refractive stability, good visual outcomes, and high safety profile of the LAL. Of the 445 operated patients, 274 (62%) were not reached by phone and did not respond to the letter sent. Most likely, the patients moved to a retirement home or are deceased. Similarly, 73.9% of the patients died 10 years after cataract surgery in the Blue Mountains Eye Study Cohort.[12] Therefore, the number of patients reached in our trial can be classified as valid. The results extend the observations published previously by Hengerer et al., which demonstrated favorable results after

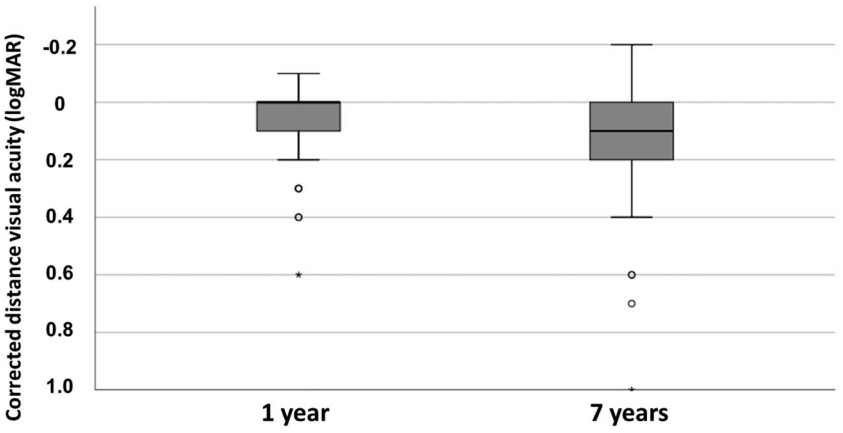

Figure 2. Corrected distance visual acuity after 1 year and 7 years (logMAR = logarithm of the minimum angle of resolution). (The bottom and top of the box are the 25th percentile and 75th percentile, respectively, and the bands near the center are the 50th percentile. The bars outside the box indicate the maximum and minimum of all data. A minor outlier (denoted by a small circle) is an observation 1.5 interquartile range outside the central box. An extreme outlier (denoted by an asterisk) is an observation 3 interquartile range outside the central box.)

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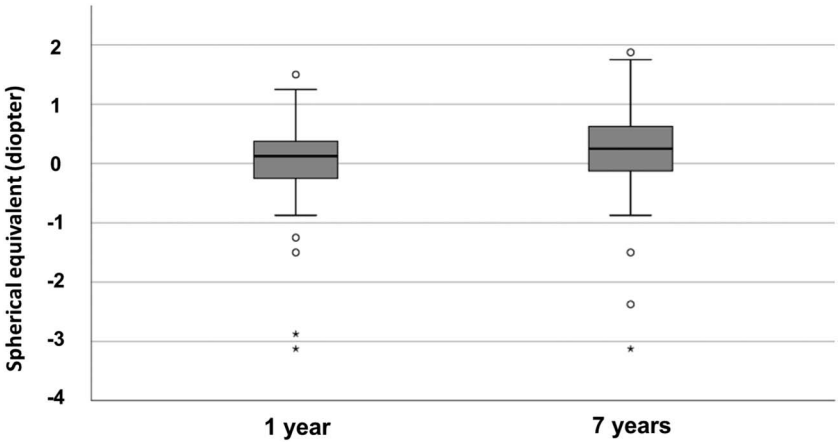

Figure 3. Subjective refraction preoperatively, after 1 and 7 years.

18-month follow-up.[4] That study included 122 eyes of 91 patients with residual postoperative refractive errors of +0.96 (±0.85) D of sphere and −0.98 (±0.50) D of cylinder. At the 18-month post–lock-in visit, the mean SE refraction was 0.03 ± 0.17 D with a mean residual sphere of 0.10 ± 0.22 D and a mean residual cylinder of −0.25 ± 0.22 D. In that study, 98% of eyes were within ±0.50 D of the targeted refractive outcome, 97% were within ±0.25 D, and 100% were within ±1.00 D of the intended outcome.[4] We also studied the technology in a group of 21 eyes with myopia because of an axial length of greater than 24.5 mm.[13] Twelve months postoperatively, 20 (96%) of the 21 eyes were within ±0.50 D of the intended refractive outcome and 17 (81%) were within ±0.25 D.[13] The efficacy of LAL technology had been demonstrated earlier in a number of pilot studies by Chayet et al.[7] on correcting postoperative myopia, hyperopia, and astigmatism. In the myopia study, for example, 14 eyes of 14 patients had residual refractive errors between −0.25 D and −1.50 D. Adjustment by irradiation was performed 10 to 21 days after implantation, followed by lock-in. After that, 93% of the eyes were within ±0.25 D of the intended refraction and 100% were within ±0.5 D. Refraction was stable for the 9-month follow-up, with a mean rate of change of 0.006 D per month, which was deemed to be about 6 times more stable than after corneal refractive procedures. The results in eyes with residual hyperopia and astigmatism were similar; in a small group of 5 eyes needing adjustment for astigmatism, all patients achieved a SE refraction within ±0.25 D of emmetropia and a UDVA of 20/25 or better at the 9-month follow-up.[8,14] The irradiation of the LAL may not only eliminate hyperopia, myopia, and astigmatism but may also—as Sandstedt et al.[15] have shown in vitro—have the potential to change the optical design of the IOL from monofocality to multifocality.

A retrospective trial by Brierley[3] focused on the performance of LAL technology in postrefractive ametropic pseudophakic patients, a group of patients that regularly pose problems in preoperative biometry and IOL calculation. The 34 eyes of 21 patients had a very precise refractive outcome: after the final lock-in, 74% of eyes were within ±0.25 D, 97% of eyes were within ±0.50 D, and 100% were within ±1.00 D of the target refraction. The mean absolute refractive error in the Brierley[3] cohort was 0.19 D. There are also a number of studies on the safety profile of LAL technology, following pioneering publications by Werner et al.[16] who demonstrated in an animal model that therapeutic dosages of UV light administered during lock-in do not cause corneal damage.

We therefore evaluated the potential effect of UV irradiation on the macula. Results showed that there was no significant difference in the mean macular thickness between preoperative and postoperative measurements. Preoperative mean center macular thickness measurements

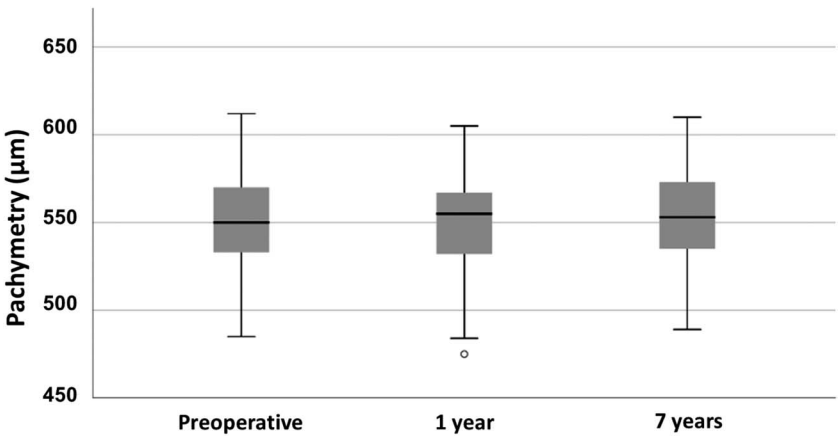

Figure 4. Corneal thickness preoperatively, and after 1 and 7 years.

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were 210 ± 21 μm (range 166 to 278 μm). Postoperatively, the mean central macular thickness was 209 ± 23 μm (range 171 to 320 μm) before adjustments, 210 ± 18 μm (range 170 to 265 μm) 1 week after adjustments, 212 ± 31 μm (range 171 to 271 μm) 1 month after lock-in, 218 ± 28 μm (range 171 to 274 μm) 3 months after lock-in, and 213 ± 17 μm (range 172 to 268 μm) at the 1-year follow-up visit. We therefore concluded that UV light exposure during LAL adjustments did not influence the incidence of postoperative macular edema and did not induce any changes in the macular layers.[17]

Werner et al.[18] conducted a trial in which no signs of retinal toxicity after near-UV light exposure up to 5 times the expected maximum treatment dosage used during adjustment and lock-in irradiation were evident. We have evaluated quantitative changes in endothelial cell loss and corneal thickness in 122 eyes with an LAL; the UV light exposure for adjustment and lock-in procedures did not add to the endothelial damage caused by cataract surgery. Two weeks postoperatively, before UV light exposure, the mean endothelial cell loss was 6.91% ± 3.66%, recovering to 6.57% ± 3.84% 12 months after the final lock-in. The decrease in the endothelial cell count was statistically significant from preoperatively to postoperatively before adjustment ($P < .05$) but not from postoperatively to 1 year after lock-in ($P > .05$). This indicates that endothelial cell loss was caused by cataract surgery, not the UV light exposure, because no additional cell loss was observed after the application of UV light for adjustments and lock-ins. These results were considerably better than the mean endothelial cell loss of 12.6% and 9.1% from preoperative values in 10 eyes 1 week postoperatively before the adjustment of the LAL and at 6 months, respectively, reported by Lichtinger et al.[19] The mean CCT increased from 548 ± 34 μm preoperatively to 563 ± 43 μm 2 weeks postoperatively before UV light exposure; at 12 months, the mean CCT was 544 ± 35 μm. These results suggest that UV light administered for adjustments and lock-ins is a safe and stable procedure for the human cornea.[20]

As mentioned previously, 10 eyes were excluded from the trial because of the development of ocular pathologies with major impact on visual acuity 7 years after IOL implantation; occurrence of these retinal conditions were consistent with the rate reported in the literature. One eye with an axial length of 25 mm developed rhegmatogenous retinal detachment (0.9%). As Gariano and Kim[21] described, the lifetime risk in this case is 1/300 (0.33%). Three patients (1%) had severe epiretinal membranes on both eyes. According to Fraser-Bell et al.,[22] the risk to develop epiretinal membranes after 5 years is 9.1%. Two patients (2%) were excluded because of wet macular degeneration. The lifetime risk was described as 1.6% by Klein et al.[23] In 1 eye (1%), a retinal artery occlusion occurred, which is described to have an incidence of 1/100 000.[24] One eye (1%) had a vitreomacular traction syndrome. The lifetime risk of this pathology is 1.5%.[25] Furthermore, 2 patients (4%) with Fuchs endothelial dystrophy were excluded. The risk of the development of Fuchs endothelial dystrophy in patients older than 40 years is 4%.[26] Our 7-year results add to the growing literature on LAL technology that demonstrates an excellent safety and effectiveness profile. It remains to be seen how this method will develop, now that it is FDA-approved and therefore increasingly used in the United States.

WHAT WAS KNOWN

- In cataract surgery, the refractive outcome can differ from the preoperatively calculated target refraction.
- In short-term trials, excellent postoperative refraction was reached with the light-adjustable intraocular lens (LAL).

WHAT THIS PAPER ADDS

- In this trial, for the first time to our knowledge, the long-term stability and safety of the LAL was investigated.
- Seven years after the implantation and adjustment of the LAL, stable refraction, good visual acuity, and no IOL-associated pathologies were measured.

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