Results Nine Months After Implantation of Crystalens HD

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Abstract

The Crystalens HD is – according to our experience – a bifocal intraocular lens (IOL). In addition to treating cataracts, the Crystalens HD can be used to correct myopia, hyperopia, slight astigmatism and presbyopia. In this article we present our first results nine months post-operatively from an open, uncontrolled, prospective, observational study. The surgical procedure used differs considerably from standard cataract operations. Posterior capsule opacification was treated early – eight to 10 weeks post-operatively – using a specific YAG-capsulotomy. We have implanted over 70 IOLs and nine-month results are available for 30 eyes. Uncorrected visual acuity for distance vision was 0.67 in 82%, for intermediate vision 0.8 in 100% and for near vision 0.5 in 100%. Sixty-eight per cent of the patients no longer need reading glasses and 100% have no blinding sensitivity/halos and unchanged nightvision. After Crystalens HD implantation, the long-term post-operative clinical results were convincing. Subjective patient satisfaction was above average.

Keywords

Crystalens HD, bifocal intraocular lens (IOL), refractive IOL, premium IOL, cataract, treatment and correction of presbyopia, myopia, hyperopia, slight astigmatism

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The Crystalens HD (Bausch & Lomb, Rochester) is a new bifocal intraocular lens (IOL). It is a fourth-generation refractive IOL (see *Table 1*). Concerning this IOL-type, one can see a continuous improvement and further development concerning the design and refractive possibilities. In addition to treating cataracts, the Crystalens HD can be used to correct myopia, hyperopia and slight astigmatism up to 0.75D. The Crystalens HD is 3µm thicker in the middle of the optic than at the periphery. This additional thickness shortens the spherical radius and adds negative spherical aberration to the mid-peripheral zone of the optic. The negative spherical aberration influences the correction of presbyopia. The 5mm optic of the Crystalens HD is made of silicone, with a refractive index (RI) of 1.427 (see *Figure 1*). The rigid haptics are made of polyimide. The Crystalens HD is available in the range of 10.0–30.0D in 0.5D steps. Between 18.0 and 22.0D – the major diopters – it is available in 0.25D steps. Because it is a refractive IOL, the surgeon can offer the best possible correction with this range.

Patient Selection

The Crystalens HD can be implanted in eyes with cataract, presbyopia, myopia, hyperopia or astigmatism up to 0.75D. Implantation of this IOL type is not recommended in eyes with very wide pupils or with a ciliary body or capsular bag that is not intact, and in eyes that have undergone previous operations.

Implantation

The surgery/implantation differs clearly from standard cataract surgery:

- When placing the Crystalens HD into the injector, attention must be paid to the correct direction of implantation of the IOL. This can be verified by noting the different ends of the haptics.
- The round right haptic, which is a little bit larger, must be positioned accurately when placing the IOL into the injector.
- The IOL must be implanted in the capsular bag. During surgery, it is important to ensure that the zonula fibres remain intact.
- The capsulorhexis must always be larger than the optic of the IOL; that is, a 6mm capsulorhexis must be created for a 5mm IOL optic. The anterior capsular bag must be placed clearly outside the optic (see *Figure 2*).
- The silicone optic is very soft and the polyimide haptics are rigid and inflexible, so the Crystalens HD is difficult to position in the capsular bag, especially in eyes with narrow pupils. It is recommended to position the injector with the IOL through the middle of the pupil into the capsular bag and then inject it slowly.
- The IOL must be rotated at least 180° until it fits perfectly. Afterwards, the cortex and the ophthalmic viscosurgical device must be thoroughly removed from behind the optic (see *Figure 3*).

Mechanism of Action of the 'Accommodative' Crystalens HD

According to the literature, the natural movement of the ciliary muscle is used for accommodation. The ability of the Crystalens HD to move forwards enables pseudophakic accommodation; this has been confirmed in several scientific studies using objective and subjective methods (see *Figure 4*).[1–4]

Also according to the literature, the polyimide material of the haptics causes the IOL to grow quickly and firmly together with the capsular bag. For undisturbed and complete growth, it is important that the patient does not accommodate during the first 10 days after implantation. This allows enough time for fibrosis to occur, which will

Table 1: Crystalens Generations

Year of FDA Approval	Model	Major Improvements
2003	Crystalens AT-45	'Accommodating' intraocular lens
2005	Crystalens AT-45 SE	Square edge 360 degree Major diopters 0,25 steps
2006	Crystalens Five-0 SE	Optic 5mm Greater haptic surface
2008	Crystalens HD 500	Optic: central anterior portion enhanced, thicker

FDA = US Food and Drug Administration.

secure the haptic ends onto the capsular bag. If accommodation is not avoided during this time, the refocus capacity of the IOL, which is essential for accommodation, will not be able to develop properly. During this period, the patient will suffer from increased blinding sensitivity and will not be able to read. The patient must be made aware of this prior to surgery.

In the light of our experience and own measurements we are not able to confirm the above-described movement of the IOL. We think that the Crystalens HD works as a bifocal IOL and our patient data and results – very good distance vision and excellent intermediate vision – seems to support this hypothesis.

Post-operative Determination of Refraction

Immediately post-operatively, it may be that accommodation occurs very slowly during the change from distance vision to near vision. If a Crystalens HD has been implanted, the procedure for post-operative determination of refraction differs from that used for a monofocal IOL. The process should be carried out as though treating a young, myopic patient.

Immediately before the follow-up examination, the Crystalens HD patient must not read to avoid an accommodation spasm. All measurements for distance vision should be performed first, before intermediate and near vision are measured and controlled.

The treated individual needs to be patient concerning near vision, which must be trained. The patient must wait 10–14 days after surgery before starting to train his or her eyesight for reading. After that, the patient can start training by reading without reading glasses; their near vision will improve over time.

Results Nine Months Post-operatively

In January 2009, we began implanting the Crystalens HD in a prospective, open, uncontrolled observational study that now includes 79 eyes. This article reviews the results up to nine months post-operatively in 30 eyes.

In our experience, optimal post-operative results are achieved four to six weeks after surgery. Concerning our results, it is important to note that we were not able to perform optimal biometric measurements during our first implantations; as a result, our first values for distance vision are worse than average. We think these values will improve with a greater number of implantations.

Follow-up examinations were performed immediately post-operatively and at one, three, six and nine months. Additional follow-up is planned at 12 months. We examined visual acuity using Jaeger charts for near

Figure 1: Crystalens HD Fourth Generation

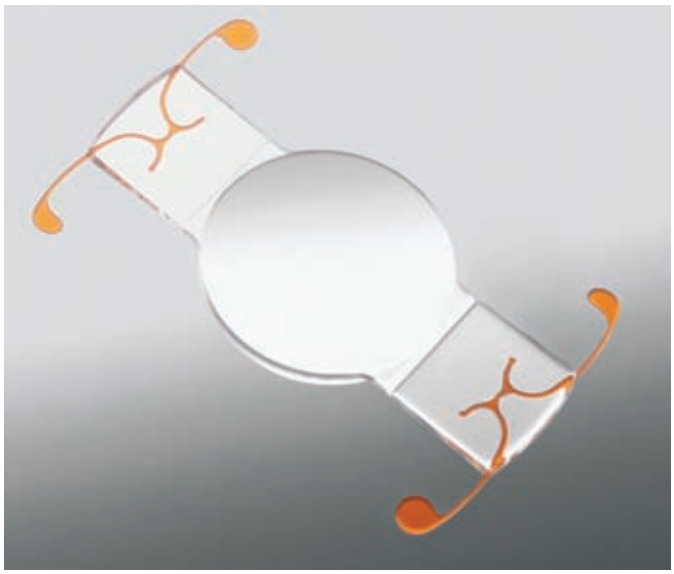

Photo: copyright B&L.

Figure 2: The Optic and the Optic–Haptic Conjunctions Must Remain Free

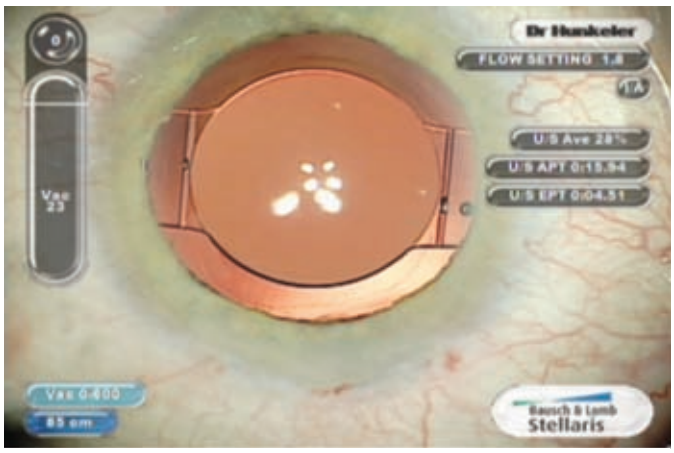

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Figure 3: The Intraocular Lens (IOL) Must Be Rotated at Least 180º and the Viscoelastic Substance Must Be Removed Behind the IOL Optic

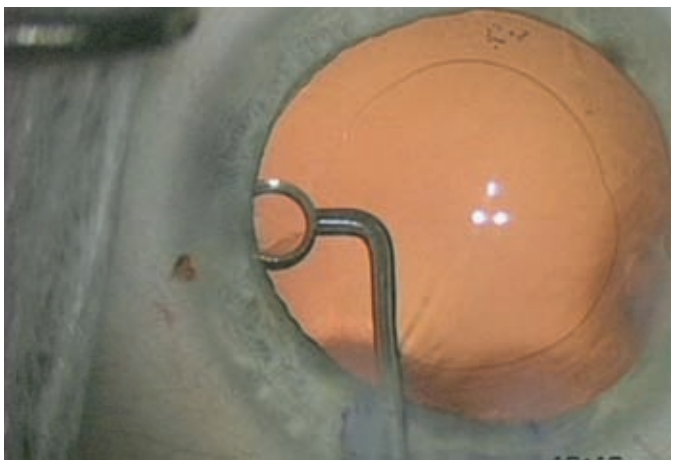

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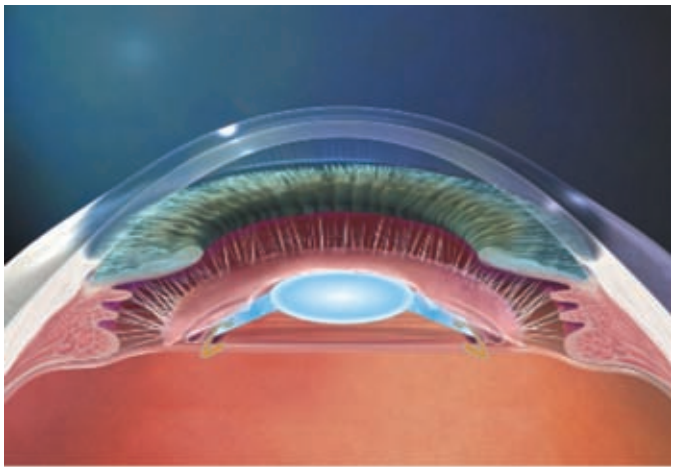
Figure 4: Crystalens HD in the Capsular Bag



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vision and Sloan charts for intermediate vision. Uncorrected visual acuity (UCVA) was determined for distance vision. We also recorded patient satisfaction by means of a questionnaire.

At nine months post-operatively (n=30), binocular-operated patients showed considerably better values than monocular-operated patients. UCVA for binocular patients (n=8) was:

- distance vision 1.00 = 73%, 0.80 = 100%;
- intermediate vision 1.00 = 100%; and
- near vision 1.00 = 87 %, 0.67 = 100%.

UCVA for monocular patients (n=22) was:

- distance vision 1.00 = 20%, 0.67 = 82%;
- intermediate vision 1.00 = 70%, 0.80 = 100%; and
- near vision 1.00 = 39%, 0.50 = 100%.

At nine months post-operatively:

- 93% of the patients showed optimal intermediate vision;
- 68% of the patients no longer needed reading glasses and 32% of the patients only occasionally needed reading glasses; and
- 100% of the operated patients had no blinding sensitivity or halos and unchanged night vision.

Posterior Capsule Opacification

Posterior capsule opacification is treated early in all patients, eight to 10 weeks after IOL implantation. We performed a specific YAG-capsulotomy. First, we created a central 3mm gap Then, if astigmatism had developed, we created ellipsoid 90° gaps behind the optic–haptic conjunctions in the direction of the haptics to reduce the tension exerted on the capsular bag and on the IOL.

An anterior YAG capsulotomy with low energy should be performed if capsulorhexis has been created too small and capsulorhexis and optic overlap. In this case, the patient suffers from poor post-operative near vision. Also it can be performed if unilateral overlapping occurred. This can cause the IOL to tilt causing lens-induced astigmatism.

This specific YAG capsulotomy counteracts a possible surgically induced astigmatism. Independent of the grade of PCO, we perform this YAG capsulotomy in 100% of our Crystalens HD patients after eight to 10 weeks.

The Economic Importance of the Crystalens HD

The Crystalens HD belongs in the refractive-surgical treatment spectrum of a modern eye clinic or practice. Treatment possibilities are expanded when this IOL model can be offered to patients. The Crystalens HD is an IOL with added value. In addition to presbyopia correction, the IOL is offered in 0.25 steps in the major diopters. The surgeon can correct only minimal astigmatism values, but post-operatively further LASIK or intrastromal refractive correction with the femtosecond laser can be performed. This IOL can be offered to self-paying patients as an IOL with vision comfort (premium treatment). In Germany, patients covered by public health insurance can be offered the Crystalens HD as an 'Individuelle Gesundheitsleistung' (IGeL, individual health service), which they have to pay for themselves.

Conclusion

After implantation of the Crystalens HD, patients achieved good post-operative clinical results for both distance and near vision. The values for intermediate vision were particularly convincing. The subjective patients statisfaction with this IOL is higher than average. ■

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