Crystalens HD 9-Month Results

For most patients, optimal results are achieved by 4 to 6 weeks after implantation.

BY MARK TOMALLA, MD

The Crystalens HD (Bausch + Lomb, Rochester, New York; Figure 1) works with only one focal point, unlike multifocal zonal or diffractive IOL models that function with several foci using various rings or optical zones. Due to Crystalens HD's novel design, the patient perceives objects at different distances (near, intermediate, and distance) as continuous vision. In January 2009, we began implanting the Crystalens HD in a prospective, open, uncontrolled observational study now including 74 eyes. This article reviews 9-month postoperative results in 20 eyes.

Patients with cataract, presbyopia, myopia, hyperopia, or astigmatism up to 0.75 D were enrolled in the study. Eyes with very wide pupil, with a ciliary body or a capsular bag that was not intact, and patients who had undergone previous surgery were excluded. Follow-up examinations were performed immediately postoperatively and at 1, 3, 6, 9 and 12 months. We examined visual acuity with Jaeger charts for near vision and Sloan charts for intermediate vision. Both UCVA and BCVA were determined for distance vision. We also recorded patient satisfaction by means of a questionnaire (Table 1).

IOL PARAMETERS

With the Crystalens HD, we can perform cataract surgery and simultaneously correct myopia, hyperopia, and mild astigmatism (ie, up to 0.75 D). The central thickness of the IOL is 3 µm greater than that of the previous model, the Crystalens 5.0, shortening the spherical radius and adding negative spherical aberration to the mid-peripheral zone of the lens. The negative spherical aberration influences the correction of presbyopia.

The 5-mm optic of the Crystalens HD is made of the silicone material Biosil (refractive index 1.427; Bausch + Lomb). The rigid polyimide haptics are designed so that the IOL grows together with the capsular bag. The Crystalens HD is available in a range from 10.00 to 35.00 D, with 0.25 D increments between 18.00 and 22.00 D.

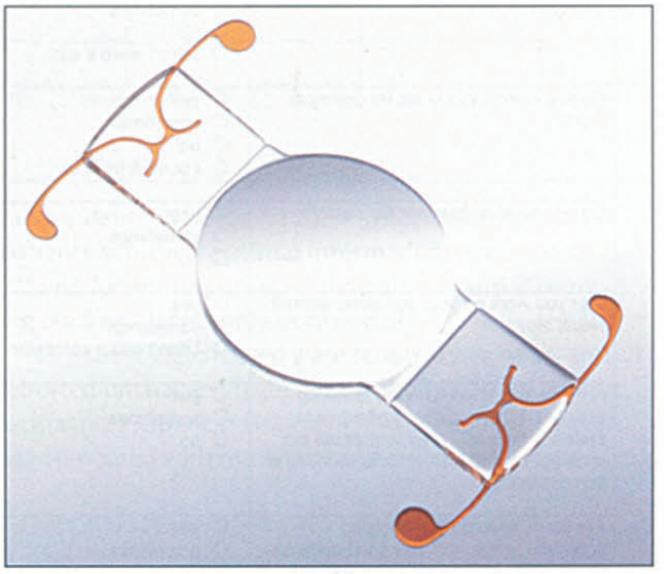

Figure 1. The principles behind the Crystalens HD provide patients with continuous vision at different distances.

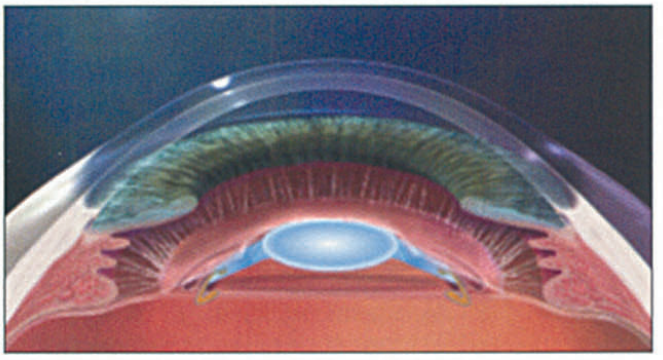

Figure 2. Forward movement of the Crystalens HD has been confirmed in several studies.

IMPLANTATION

Only an experienced surgeon should implant the Crystalens HD, because the surgical procedure is different from standard cataract surgery. Following are some pearls for the operative technique:

- When placing the Crystalens HD into the injector,

TABLE 1. PATIENT QUESTIONNAIRE: CRYSTALENS HD

Patient ID

Time Postop: ○ 1 day ○ 1 ○ 3 ○ 6 ○ 9 ○ 12 months

Activities:	
What are you able to read without visual aid?	○ magazine/journal headlines ○ menu ○ SMS ○ newspaper ○ package information sheet for medicine ○ price tag ○ nothing
Do you need a visual aid for driving during the day?	○ yes ○ sometimes ○ no ○ I don't drive a car
Do you need a visual aid for driving at night?	○ yes ○ sometimes ○ no ○ I don't drive a car
Do you need a visual aid for watching tv?	○ yes ○ sometimes ○ no
Can you work on your computer without visual aid?	○ yes ○ sometimes ○ I don't use a computer
Are you able to perform the following activities, where normally **good near vision** is necessary, without visual aid: cooking, sewing, use of tools, working at home, crafting	○ yes ○ sometimes ○ no
Are you able to do the following activities, where normally good distance vision is necessary, without visual aid: cinema, theater, sports	○ yes ○ sometimes ○ no

General well being:	
Are you satisfied with the treatment result?	○ yes ○ no
Does the treatment result fulfill your expectations?	○ yes ○ no
If given the choice, would you select the same treatment again?	○ yes ○ no
Would you recommend the treatment to a friend or a relative?	○ yes ○ no
Did your visual acuity improve after the treatment?	○ yes ○ equal ○ no
How is your visual acuity at night?	○ better ○ equal ○ worse
Is there an activity that you can no longer do?	○ no ○ yes

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 IOL must be implanted in the capsular bag, whereby the natural movement of the ciliary muscle can be used later for focusing;
- The capsulorrhexis must be larger than the optic of the IOL, (ie, a 6-mm capsulorrhexis must be created for an IOL optic of 5 mm. The anterior capsular bag must be clearly outside the optic;
- Because the silicone optic is soft and the polyimide haptics are rigid and inflexible, the Crystalens HD is difficult to position in the capsular bag, especially in patients with narrow pupils. The surgeon should position the injector in the middle of the pupil, place it in the capsular bag, and then inject the IOL slowly;
- The IOL must be rotated until it fits perfectly. Afterward, the cortex and the ophthalmic viscosurgical device must be thoroughly removed from behind the optic; and
- The IOL must be pushed backward until there is complete contact with the posterior capsular bag and should not move forward from that position; and
- Immediately after surgery, the pupil is dilated with a single dose of atropine to create an accommodation block lasting 10 to 14 days. Patients will experience severe glare and will not be able to read. It is the surgeon's duty to inform patients of these side effects prior to surgery.

PRINCIPLE OF ACTION

The forward movement of the Crystalens HD enables pseudophakic accommodation, which has now been confirmed in numerous studies using objective and subjective methods (Figure 2).[1-4] 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, securing the haptic ends onto

TABLE 2. BINOCULAR VS MONOCULAR PATIENT RESULTS

UCVA for binocular patients (n=6)			
	1.00	**0.80**	**0.67**
Distance vision*	65%	100%	
Intermediate	100%		
Near	82%		100%
UCVA for monocular patients (n=14)			
	1.00	**0.67**	**0.50**
Distance vision*	11%	82%	
Intermediate	100%		
Near	23%		100%

** Optimal biometry analysis was not available during the first implantations. Therefore, the first distance values are worse than average. This will be corrected when more cases can be analyzed.*

the capsular bag. If the patient does not avoid accommodation during this time, the refocus capacity of the IOL upon accommodation will not be guaranteed.

All patient data in our study are reported to SurgiVision Consultants, Inc., an independent organization that performs statistical data assessment. Our experience has shown that optimal postoperative results are achieved after 4 to 6 weeks. We perform Nd:YAG capsulotomy for posterior capsular opacification as early as 8 to 10 weeks postoperatively to improve the mobility of the Crystalens HD and to prevent induced astigmatism. If astigmatism is present postoperatively, 90° ellipsoid gaps should be created behind the optic-haptic junction, in the direction of the haptics, to reduce tension on the capsular bag and on the IOL.

POSTOPERATIVE RESULTS

At 9 months, binocularly operated patients have better results than monocularly operated patients (Table 2). Intermediate and near vision were 1.0 in 100% and 0.5 in 100% of eyes, respectively. All patients were spectacle independent for distance vision. Likewise, all patients achieved optimal intermediate vision, with 71% no longer requiring reading glasses and 29% needing reading glasses only occasionally.

No patient experienced glare sensitivity or halos, and all reported unchanged night vision. The subjective patient satisfaction with near vision (95%) was higher than average compared with multifocal and diffractive IOLs.

CONCLUSION

After implantation of the Crystalens HD, patients achieved convincing postoperative clinical results for both distance and near vision. The values for intermediate vision were particularly impressive. The principle of action of this accommodating IOL, which works with only one focus, results in higher-than-average subjective patient satisfaction. ■

TAKE-HOME MESSAGE

- With the Crystalens HD, patients perceive objects in focus at near, intermediate, and distance.
- The surgical procedure is different from standard cataract surgery, and the capsulorrhexis must be larger than the optic of the lens.
- The patient must avoid accommodation for 10 days postoperatively to guarantee full refocus capacity.

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