The Crystalens HD™

Accommodating the future with vision and clarity

Reported highlights from sessions held during the 2009 XXVII ESCRS Congress in Barcelona, Spain
Crystalens outcomes:
A European perspective

The Crystalens HD™ is the fourth generation of the only FDA approved accommodating lens. Launched into Europe at the 2008 ESCRS congress in Berlin, its progress came under the spotlight at last year’s XXVII Congress of the ESCRS in Barcelona. A distinguished faculty of cataract surgeons presented their various experiences and findings including:

- Improvement of post-operative results in consecutive Crystalens IOL models
- Looking at outcomes in post-refractive surgery patients
- Six-month follow-up on the clinical performance of the newer generation Crystalens.

A sample of the information presented on these new generation accommodating IOLs is summarised in this supplement and has relevance to all cataract surgeons as they strive to deliver high quality surgery for visual correction of aphakia in adult patients with cataracts, providing them with improved near, intermediate and distance vision thereby reducing their dependency on glasses.

THE LENS
The Crystalens HD™ is a refractive IOL, with which cataract treatment and myopia or hyperopia correction can be performed at the same time. It is an accommodative IOL with an optic of the silicone material Biosil (Refractive Index 1.427) and haptics made of polyimide. This causes the IOL to grow together with the capsular bag, which is of course what’s required. The lens can also move forward and so enables pseudophakic accommodation. Unlike multifocal or diffractive IOL models, the Crystalens works only with one focus so the patient perceives objects at different distances as continuous vision.

THE SPECIFICATION
Available Powers
10 to 33 D in 0.50 D steps
18 to 22 D in 0.25 D steps

Diameter: 5.0 mm
Shape: Biconvex
Material: Biosil
A Constant: 118.8
Refractive Index: 1.427
ACD: 5.43 mm
Overall Length: HD520 — 10.00 to 16.5 D — 12.0 mm
HD500 — 17.0 to 33.0 D — 11.5 mm
This poster presentation evaluated three consecutive Crystalens models, which have undergone consecutive design changes: The AT-45, the Five-O and the Crystalens HD™.

The AT-45 involved modification of the lens optic to a ‘square’ rather than smooth edge in order to reduce the incidence of asymmetric capsular fibrosis, which could cause capsular contraction and IOL tilt. The Five-O was the second revision, which involved enlarging the lens optic to 5 mm, modifying the haptic plates to a squarer shape, for increased capsular support and increasing the arc length of the haptics for greater stability. In order to increase functional near vision with this lens, a third revision was made which adds a 1.5 mm diameter circle of -0.045 μm of spherical aberration to the optic’s central area. This helps with reading, especially when the pupil constricts, which is what happens with normal phakic accommodation.

In this case a total of 150 eyes of 75 patients were studied. In 2002-2003 50 eyes were implanted with the AT-45 Crystalens, in 2008 50 eyes were implanted with the Five-O and in 2009 50 eyes had the Crystalens HD™ implanted. Primary outcomes were recorded in a follow-up at 1 month and recorded average uncorrected visual acuity (UCVA 20/), monocular and binocular uncorrected near visual acuity (UCNVA) and spectacle independence for just the Crystalens HD™.

Key findings
Their results found that monocular uncorrected near vision (MUCN) was J1 or better in 12% of patients implanted with the AT-45 model, 17% with the Five-O model and 22% ifor those who received the Crystalens HD™. Binocular uncorrected near vision (BUCN) was J1 or better in 23% implanted with the AT-45, 33% with the Five-O and 42% with the HD model. Monocular uncorrected intermediate vision (MUCI) improved similarly in the consecutive models. J1 or better were 33%, 56% and 72% respectively (see Figure 1).

The results for spectacle independence for distance and reading for 38 patients implanted with the Crystalens HD™ lens were particularly favourable (see Figure 2).

The investigators’ conclusions were that the consecutive design modifications to the three Crystalens models had provided improved refractive outcomes for near, intermediate and distance visual acuity. Patient satisfaction was seen to be higher in those fitted with the Five-O and HD lenses. They also agreed that binocular implantation was mandatory.

![Figure 1](Image)

**Figure 1** % patients J1 or better: Crystalens AT45 vs 5-O vs HD

![Figure 2](Image)

**Figure 2** Spectacle Independence with HD Only

Highlights from a 2009 ESCRs free-paper session by Dr P. Schraepen and Dr E. Mertens, Belgium
"I was one of the first people in Europe to implant Crystalens HD™ and I can report a high level of satisfaction in those patients who have received it," commented Mr Sheraz Daya, of Centre for Sight in the UK. "The beauty of Crystalens HD™ is that it delivers excellent vision performance at all distances for my patients, and I can be confident that glare or halos will not cause a problem. Many of my patients no longer need to wear spectacles at all, which has given them more freedom than they thought possible."

Dr Daya is a consultant to Bausch & Lomb and is renowned as one of the leading experts on the Crystalens. This was a single surgeon study examining the visual outcomes of patients, selected to have the Crystalens HD™ or Five-O implanted. The subjects were either cataract or refractive lens exchange patients.

Cataract lens removal was conducted using the 1.8 mm C-MICS technique with the Stellaris™ system and subsequent lenses were implanted via an enlarged incision of 2.6 mm. Non-dominant eyes were targeted for -0.25 to -0.75 D. Distance, intermediate and near acuities were then measured for both monocular and binocular vision together with spectacle independence, complications and any requirements for retreatments.

Key findings
"At six months follow-up, monocular mean uncorrected distance vision was 20/27 with 78% of patients achieving 20/30 (Figure 3). 84% of the patients achieved 20/30 or better monocular uncorrected intermediate VA with 69% achieving 20/25 (Figure 4). For monocular near VA 74% achieved 20/30 or better and 42% 20/25 (Figure 5).

A staggering 72% of the patients reported ‘total’ spectacle independence and 94% indicated they did not require glasses for distance vision. The study found no complications and no adverse events.

“We concluded,” said Dr Daya, “that this data indicates the newer generation of Crystalenses all provide good distance, intermediate and near vision, all with a high degree of patient satisfaction.”

Highlights from a 2009 ESCRS free-paper session by Drs Sheraz Daya, Mayank Nanavaty and Carolina Prada, UK
The Italian experience

The early experience for this team was that after six months all 10 patients with a Crystalens HD™ implant had excellent visual acuity for distance, without and with correction.

The mean age was 70.5±9.8 years. The Rhexis diameter varied between 5 and 5.5 mm and all patients were examined 1 day, 1 week, 1 month and 6 months following surgery.

**Key findings**

- After 6 months the UCVA for distance was 0.12±0.08 logMAR.
- BCVA for distance was -0.08±0.06 logMAR, with +0.56±1.21 D as the mean refractive defect.
- Mean near UCVA was J3 at 40 cm in all of the study eyes, J2 in 4 eyes and J1 in 1 eye. Mean near VA with distance correction was J3 at 40 cm in all eyes, J2 in 7 eyes and J1 in 3 eyes. Binocular vision further improved the results, with 8 spectacle-free patients. The contrast sensitivity curve was found to be in normal values for pseudophakic eyes of the same age group.
- The near vision with distance correction results was acceptably good and indicates pseudoaccommodation. Eight patients out of the 10 reported complete satisfaction after 6 months.

The UK’s Crystalens learning curve

Implantation of the Crystalens HD™ should be performed by an experienced surgeon as born out by the experience of this study: “There is a slight learning curve when starting with the Crystalens that requires attention to patient selection, pre-operative and post-operative details and meticulous cortical clean-up,” said Dr Morris.

This prospective study examined 25 consecutive Crystalens patients (a total of 49 eyes) and no exclusion criteria were applied. Surgery consisted of a 2.7 mm superior limbal incision and a single 10 suture by a single surgeon, but in two surgical centres. All biometry measurements were therefore carried out by one of two biometrists and the most appropriate lens power calculation formula was selected, dependent upon the measurements. Outcomes measured included unaided monocular and binocular distance, intermediate and near VAs, YAG capsulotomy rates and visual aberrations.

**Key findings**

- 92% of eyes achieved monocular distance UCVA of 20/40 with 66% achieving 20/25 or better. Monocular intermediate UCVA results were 88% at 20/40 and 66% at 20/25. Near UCVA of 20/40 and 20/30 was achieved by 88% and 72% of eyes respectively. The mean uncorrected distance, intermediate and near results at 1 month were 20/23.5, 20/21.5 and 20/30.8. Five patients required early YAG laser capsulotomies within 3 months and one patient required unilateral LASIK for intolerable, but planned post-operative myopia in the dominant eye. “We believe,” said Dr Morris, “these results compare favourably with the data in the literature and will present 6 months follow-up data.”
- The study concluded that good distance, intermediate and near visual acuity can be achieved with the Crystalens. It also indicated that post-operative astigmatism correction should be performed to optimise final refractive outcomes.
Five patients (10 eyes) took part in this study and had been previously diagnosed with bilateral senile cataracts, which required cataract surgery. The inclusion criteria were:

- Best spectacle corrected visual acuity (BSCVA) < 0.5
- Bilateral senile cataract
- Age between 50-70 years old
- Corneal astigmatism < 1 D
- Absence of associated ocular pathology

Following phacoemulsification with clear cornea incision of 3 mm all received a Crystalens HD™ implantation (Figure 6).

Follow up took place after 24 hours, 1 week, 1 month, 3 months and 6 months and BUCVA and best spectacle corrected visual acuity (BSVA) was measured for distance, intermediate and near vision at all follow-ups.

**Key findings**
Mean BSVA pre-op was 0.26±0.19. Following surgery and implantation of the HD lens the mean distance BUCVA at 3 months was 0.96±0.15. The intermediate BUCVA at 3 months was 20/12.5 in 2 eyes, 20/16 in 3 eyes, 20/25 in 4 eyes and 20/20 in 1 eye. For near BUCVA (Figure 7) at 3 months 5 eyes reached J1, 2 eyes J2, 2 eyes J3 and 1 eye J5. The doctors did not observe any corneal oedema, inflammatory deposits in IOL or iritis. At 3 months follow-up the posterior capsule remained transparent in all cases.

Their conclusions were that the Crystalens accommodating IOL achieves good distance, intermediate and near VA results. However, longer-term follow-up is needed to confirm the successful expected VA outcomes.

**Figure 6** Surgical technique: Phacoemulsification with clear cornea incision 3mm

**Figure 7** Results for Best Uncorrected Visual Acuity 6 months follow-up

Highlights from a 2009 ESCRS free-paper session by Dr A. Arias-Puente, Dr O. Seijas-Leal and Dr E. Cobos-Garcia, Spain
Outcomes in post-refractive surgery patients

A small sub-group of 7 patients, with a mean age of 63 years, each received a Crystalens HD™ implantation following corneal refractive surgery and were then assessed in terms of refractive outcomes, spherical equivalent, astigmatic outcome, UCVA, BSCVA and post-operative enhancements. The refractive procedure included LASIK for 5 eyes, PRK for 3 eyes and radial keratotomy for 2 eyes. Six eyes had Crystalens HD™ implanted and 4 had Crystalens HD™ + limbal relaxing incision (LRI).

Key findings
One month follow-up found the mean spherical equivalent was -0.5 D±0.59 D and the mean post-op cylinder was -1.10 D±0.55 D. 60% of eyes were within 0.25 D of target refractive outcome.

Visual acuity for uncorrected distance was 20/40 in 100% of patients with 60% achieving 20/30 or better. For near UCNA 80% of patients achieved J5 or better and 60% were J3 or better. Best spectacle corrected visual acuity was 20/40 in 100% of patients.

Whilst a limited study, with a small sample size Dr Daya is confident that patients with prior refractive surgery can benefit from subsequent Crystalens implantation to provide improved depth of focus.

Outcomes in post-refractive surgery patients

The Crystalens is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia secondary to the removal of a cataractous lens in adult patients with and without presbyopia.

Careful pre-operative evaluation and sound clinical judgement should be used by surgeons to decide the risk/benefit ratio before implanting a lens in a patient.

The European experience of the Crystalens, to date, appears to offer cataract patients the ability to recover a wide range of high-quality vision while minimizing their dependence on spectacles.

As a selection of these studies show the technology has improved vastly from the original AT-45 to the new HD version. The modification to the optic has significantly increased the range of functional near vision without sacrificing contrast acuity or distance vision.

As with all surgery, managing the patient’s expectations pre-op is important. Patients should always receive a full, detailed explanation about the IOL, how it works and what the differences are compared to standard IOLS and standard cataract surgery.

That said, the mechanism of action and the design of the Crystalens is very promising. Working with only one focus makes it very convenient for the patient and it also means they experience very high comfort, which is the most convincing aspect for them and means potential strong referral opportunities for your practice.

Conclusions

Highlights from a 2009 ESCRS free-paper session by Dr S. Daya, Dr M. Nanavaty and C. Prada, UK

Outlook

The availability of the Crystalens HD™ lens is able to serve the growing demand for presbyopia solutions and Bausch & Lomb hopes it will provide more surgeons and their patients with more treatment options.