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Perfecting Vision & Enhancing Life

EyeWorld reports live from Bali, Indonesia ...

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Special report on the inaugural Asia-Pacific Crystalens Forum

Refractive surgery was once the field of choice for specialization in anterior segment ophthalmic surgery. "Nobody cared about cataract surgery at that point," said **Gregg Feinerman, MD**, associate clinical professor, Department of Ophthalmology, University of California, CA, USA. "It just wasn't that interesting."

Advancements in IOL technologies and designs, however, have turned the tables, rejuvenating the field of cataract surgery. "Cataract surgery has now become involved with the premium market," Dr. Feinerman said.

An interesting recent development in that "premium" market is the approval by the US Food and Drug Administration (FDA) of the Crystalens accommodating IOL (Bauch & Lomb Surgical, Aliso Viejo, CA, USA).

The Crystalens quickly grew in popularity among surgeons in North America. "Since its launch in the US last July, it has become the number one presbyopic lens in the US," said Anthony Pui, director of marketing, Bausch & Lomb.

Some surgeons, however, may be hesitant to adopt the new technology, at least in part due to reluctance with the need to optimize implantation techniques to fulfill the lens's promise of uncompromised vision with the ability to accommodate.

"In order to achieve the best possible outcomes from this lens, we at Bausch & Lomb have developed a set of specific guidelines in fitting techniques that will ensure predictability and good outcomes," said Pui.

Bausch & Lomb conducted the first Asia-Pacific Crystalens Forum on 14 May 2009 in Bali, Indonesia, to share those guidelines in preparation for the lens's approaching release in the region.

Crystalens: Development and mechanisms

The idea of an accommodating lens is often met with roughly equal parts skepticism and excitement. Until recently, evidence from research had been largely equivocal.

However, some years ago, Stuart Cumming, MD, Laguna Beach, CA, USA, and colleagues noted that some patients still seemed to accommodate with plate haptic IOLs even after eliminating pseudoaccommodative factors such as residual myopia, with-the-rule astigmatism, and small pupils, said Dr. Feinerman.

More studies have since provided evidence that the restoration of accommodation is very much a possibility with artificial replacement of the natural crystalline lens.

It is possible, but not simple. It took Bausch & Lomb six iterations of the Crystalens before the lens was fit for FDA approval. The seventh, the AT-45, was the first model to be approved.

"The Crystalens was developed to try to mimic the accommodative mechanism of the natural lens," Dr. Feinerman said. He described two such mechanisms by which the lens achieves accommodation: forward axial movement and accommodative arching.

> *"[The Crystalens HD] is a much more predictable lens due to greater surface area contact between the plates and the anterior capsule, and the design of the haptics provided better centration"*
>
> **Gregg Feinerman, MD**

The Crystalens is placed in the capsular bag and vaulted posteriorly; the lens has a hinged design that allows the optic to move forward.

The capsular bag contracts around the lens, trapping it in the posterior position. With accommodation, the ciliary bodies contract, displacing the vitreous mass. Pressure from the vitreous then pushes the lens forward into the anterior position. "But there must be something else because we're getting more accommodation than what would be expected from that small amount of movement of the lens," said Dr. Feinerman. This secondary mechanism, he said, is accommodative arching.

"There's a similar situation going on," Dr. Feinerman said, comparing the wavefront iTrace maps (Tracey Technologies, Houston, TX, USA) of a young phakic patient with those of a patient with the Crystalens implant. "There's a greater change in the center of the lens, a greater power change in the center and less in the periphery."

In addition, in both cases there is an increase in negative spherical aberration and an increase in coma, he said, all indicating that some degree of accommodative arching does in fact occur with the Crystalens.

These mechanisms, according to the findings of several studies, including one by Dr. Feinerman himself, result in about a 3D accommodative amplitude.

Since the AT-45, the Crystalens has undergone further enhancements to produce the Crystalens 5-O and, most recently, the Crystalens HD.

The change from the AT-45 to the 5-O, said Dr. Feinerman, is the most radical Crystalens upgrade so far: a 5-mm optic (the AT-45 has a 4.5-mm optic) and rectangular haptics (the AT-45 haptics are trapezoidal).

The 5-O changes were aimed at increasing the optic diameter and increasing accommodation by allowing greater plate motion through the creation of a more uniform pocket in the capsular bag, even if the capsular bag has fibrosed, he said.

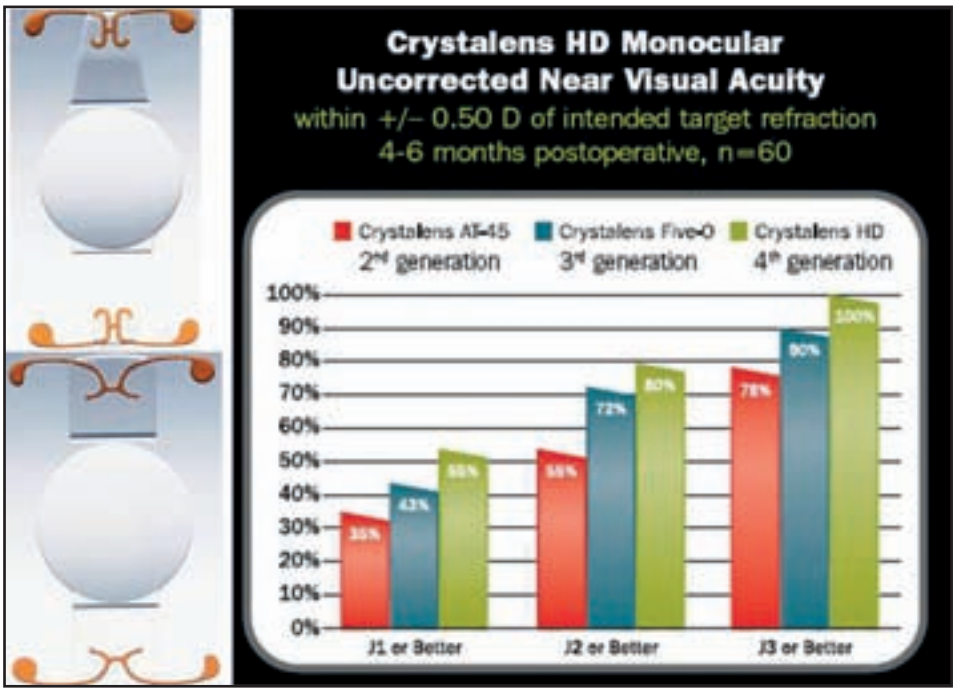
"It is also a much more predictable lens due to greater surface area contact between the plates and the anterior capsule, and the design of the haptics provided better centration," said Dr. Feinerman.

The design creates 70% more surface area contact while the improved haptic design provides 27% more support.

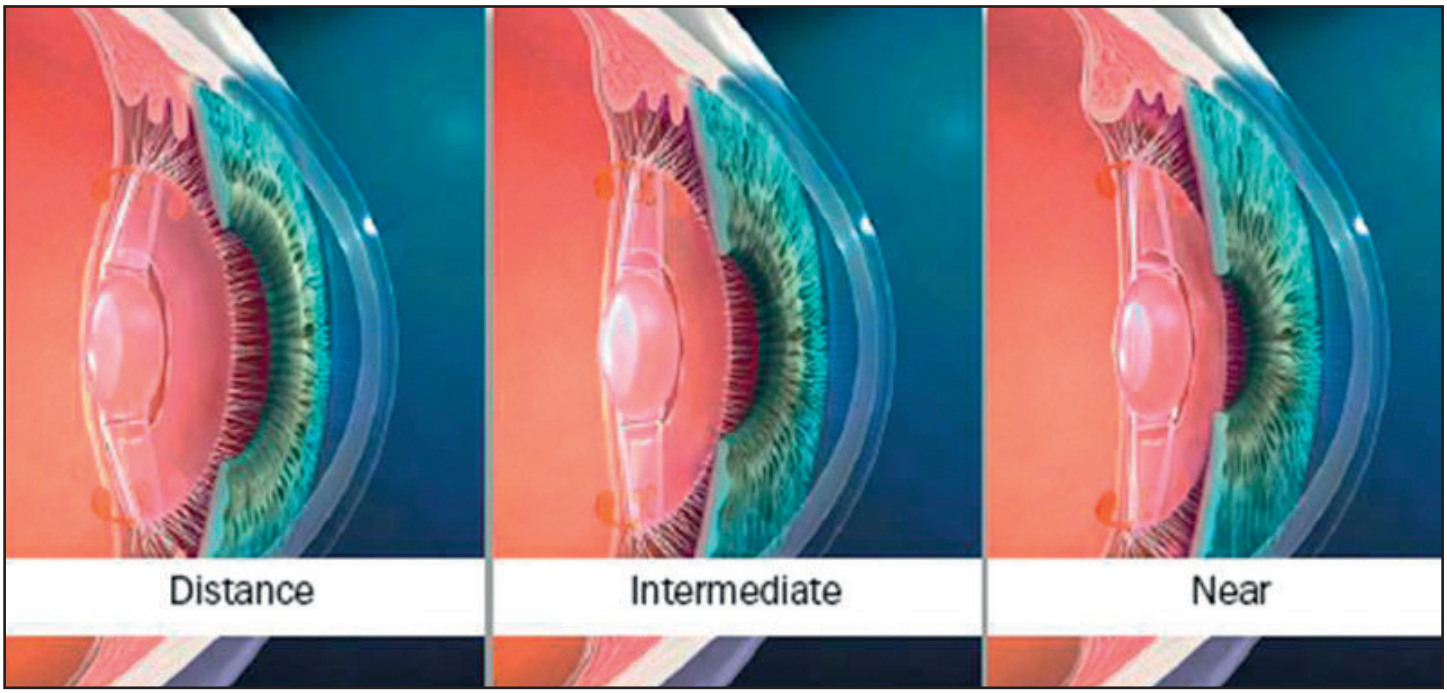
Finally, the Crystalens 5-O is less dependent on a perfect capsulorhexis than the AT-45 and is more "injector-friendly," said Dr. Feinerman. The haptics are designed to fold toward the optic, making it easier for the lens to pass through the injector.

Dr. Feinerman presented the results of a study comparing the 5-O with the ReZoom (Abbott Medical Optics, AMO, Santa Ana, CA, USA) and the current iterations of the ReSTOR multifocal IOL (Alcon Laboratories, Fort Worth, TX, USA).

Comparing monocular, uncorrected distance vision, the 5-O "did better than all the others and on every level," he said. For monocular, uncorrected



The Crystalens HD has a bigger optic size compared to the AT-45 and has a wider haptic profile to ensure stability in the eye. Performance of the Crystalens HD is improved as compared to the previous models



The hinges on the Crystalens allow pressure changes during accommodation to vault the optic forward to induce refractive changes

near vision, the 5-O performed better than the ReSTOR at J3 and J2 and did almost as well at J1.

With the HD upgrades, Bausch & Lomb sought to create a lens "that gives high definition distance vision, high definition intermediate vision, and improved near vision," Dr. Feinerman said.

The Crystalens HD has a prolate optic—a bispheric lens, with different curvatures at the center and at the edge. The design augments the effect of accommodative arching.

The change does not make the lens a multifocal lens, Dr. Feinerman said. Unlike multifocal lenses, the Crystalens HD retains a single point of focus on the retina. Unlike the multiple optical zones of multifocal IOLs, the Crystalens is not prone to visual disturbances like glare and halos. In addition, the increased central thickness of the HD's optic enhances depth of focus and improves contrast sensitivity.

According to Dr. Feinerman, the HD performed statistically significantly better than the ReSTOR, with 100% of patients receiving the HD having J3 or better vision, 80% J2 or better, and 50% J1 or better.

Furthermore, the lens performed well independent of pupil size or lighting conditions. In contrast, Dr. Feinerman has had to provide halogen flashlights to help his multifocal IOL patients read in low-light conditions. His patients with multifocal IOLs simply could not read in dim light.

Dr. Feinerman implants the lens through a 2.75-mm clear corneal incision. He uses a 5.5- to 6.0-mm capsulorhexis, i.e., a rhexis just a little larger than the Crystalens optic.

A watertight wound seal is essential to ensure that the lens is vaulted posteriorly, so he routinely hydrates the incision and puts in a single stitch to ensure that the wound lips remain apposed, he said.

Crystalens results

The surgeon's technique for implanting the Crystalens "is very important. I slow down when we're doing this," said **Karl Stonecipher, MD**, director, TLC Laser Eye Centers, Greensboro, NC, USA.

Dr. Stonecipher said that while it is now possible to do entire cataract surgeries in three to five minutes, a perfect capsulorhexis is vital to the Crystalens. If there is a tear or any problem with the rhexis, "you might as well just forget about this lens," he said.

Implanted properly, however, the Crystalens provides excellent results. Dr. Stonecipher presented data from DataLink, an online tracking system provided by Bausch & Lomb to help surgeons monitor their outcomes and compare them with those of other surgeons around the world.

According to his own dataset from DataLink, the Crystalens "gives the best intermediate vision of all the IOLs possible," Dr. Stonecipher said. It may be that patients implanted with the Crystalens will need a thin pair of reading glasses, but he finds this an "easier sell" than having patients who need adequate lighting all the time, as with Dr. Feinerman's multifocal lens patients and their halogen flashlights.

Dr. Stonecipher made this conclusion based on his older data from

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> *Karl Stonecipher, MD*

before recommendations for refractive targets with the various versions of the Crystalens were optimized—in this older dataset, his patients' outcomes were an average of 20/32 for distance, 20/22 for intermediate, and 20/30 for near.

In order to achieve the best results, he said, surgeons should keep in mind the updated targeting recommendations for each type of Crystalens; each lens requires a different refractive target that depends on the refractive shift expected to occur with wound healing. Specifically, with the 5-O, Dr. Stonecipher said, surgeons should target a slight myopia; with the HD, on the other hand, surgeons should target a slight hyperopia.

These new targets allow surgeons to "get better outcomes than we've ever seen with any other platform," he said.

Simply by adjusting the procedure to these new targets, Dr. Stonecipher now achieves average outcomes of 20/20 for distance with the 5-O, 20/17 for intermediate, and 20/25 for near.

The refractive predictability demonstrated by the consistency of outcomes following these adjustments appears to extend well beyond the immediate post-op period. Despite some users claiming that the Crystalens exhibits some changes in refractive predictability over time, the 5-O and the HD, in Dr. Stonecipher's experience, "all seem to stay stable," with the HD having 25% less refractive shift than the 5-O, and 79% of implanted HDs having no change at all in stability.

This, however, does not preclude the need for touch ups post-op. Any residual refractive error needs to be corrected. "Typically we want to do that after a YAG," Dr. Stonecipher said. "I usually will not YAG a patient for three months, and then I like to make sure that there's refractive stability.

"I put that concept into patients' head before I even start. I tell them that they may be coming back for an enhancement," he said. "But on the same side of the coin if they're 20/20 and happy, I'm not going to touch them."

The Crystalens provides good intermediate vision, and this, said Dr. Stonecipher, seems to be a key point in making patients 20/20 and happy.

"We're in a PDA world, so everyone's using their little phones," he said. "They're working on their computers so I think intermediate vision is much more important these days."

Unlike multifocal lenses, the Crystalens uses 100% of the incident light at all distances, so the quality of vision is maintained at distance, intermediate, and near.

Despite these qualities, success with the Crystalens still requires a constant review of outcomes, Dr. Stonecipher said. This means reviewing outcomes not just between cases but within the same case, between the first and second eyes of the same patient.

He recommended that surgeons perform their first 50 Crystalens implantations on cases that require bilateral IOL implantation, choosing patients carefully and taking only those who have realistic expectations.

"I usually wait a week or two between eyes," Dr. Stonecipher said. "I will look at the patient and say, 'Ms. Johnson, are you happy? If you're happy, I'll do the same thing.' If she says, 'Well, I'd really like to get a little more near,' then I'll target a slight minus, not to exceed that first minus in the second eye. Then, I'll analyze my data."

DataLink is a vital part of the Crystalens program not only because it allows surgeons to monitor their own progress, but also because it allows them to learn from each other.

Dr. Stonecipher recommends that beginning surgeons input the entire dataset of their first 50 patients into DataLink; they should include their worst as well as their best outcomes.

Furthermore, through DataLink Bausch & Lomb is constantly looking at the data and outcomes of surgeons around the world. The company is always prepared to send technical support to clinics and surgeons whose outcomes are "not quite in line with what everyone else is getting."

Dr. Stonecipher, for one, is more than happy to help surgeons through the transition to using the Crystalens because he believes it is "a great lens," worthy of its place as the number one presbyopic lens in the US.

Tips, tricks, and clinical pearls: How to maximize Crystalens benefits for your patients

The Crystalens has yet to achieve the same status in the Asia-Pacific; the lens was released in Singapore at the end of 2008 and experience in the region has thus far been limited. Bausch & Lomb plans on rolling the lens out to a few more markets in the region later this year.

Raymond Loh, MD, consultant, cornea service, Singapore National Eye Centre, is one of the few surgeons in the region who have had experience with the lens.

"I think the first step in any cataract refractive practice is to make sure that you set the expectations of your patients correctly," Dr. Loh said. "That prevents a lot of unhappy patients later on."

The emphasis, he said, is on delivering functional distance, intermediate, and near vision. He said that good stereopsis and minimal visual disturbances are also goals that go with high quality uncorrected visual acuity to produce the 20/20, happy patient.

Dr. Loh first recommends that surgeons avoid post-refractive cases, at least initially.

Patients should have good ocular health with the potential for good vision; corneal astigmatism should be less than 1 D.

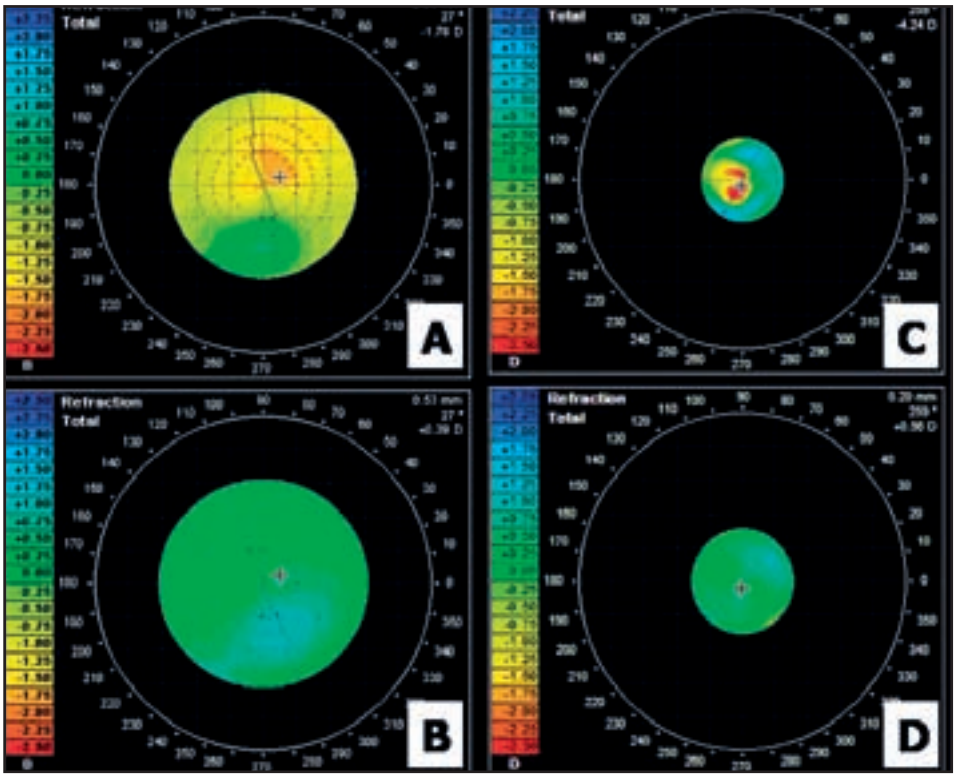
Psychologically, said Dr. Loh, the ideal patient should not be too demanding ("type A-minus or less," he said) and should have reasonable expectations.

In terms of visual demands, the "sweet spot patients," said Dr. Loh, are those who are –1 to –3.5 D pre-op. Dr. Loh said that these myopes are used to good near vision so more care should be used in setting expectations.

In or out of that sweet spot, "refractive accuracy is very important. I think you want to obtain consistent high quality measurements," Dr. Loh said. "If it's available, the non-contact IOLMaster [Carl Zeiss Meditec, Dublin, CA, USA] is what I recommend."

He suggests immersion ultrasonography if an IOLMaster is not available, but he doesn't recommend contact biometry.

Accuracy, he said, is key. "If you're not sure, repeat your measurements."



Wavefront comparison between a phakic patient (A&B) and a Crystalens patient (C&D). Wavefront changes are apparent in the non-accommodative state (B&D) versus the accommodated state (A&C)

According to Dr. Loh, Bausch & Lomb recommends using the SRK/T or Holladay 2 formulas, depending on axial length. For instance, surgeons should use the Holladay 2 for flatter or steeper Ks, Dr. Loh said.

Dr. Loh recommends targeting plano for the first eye and adjusting targets for the second eye depending on the result of the first.

"I look at this kind of surgery as refractive surgery, so everything slows down: rhexis, wound construction, everything," Dr. Loh said.

As with any other procedure, good wound construction, clear corneas, and freedom from complications are essential. Thorough capsular polishing—both anterior and posterior—and a regular capsulorhexis are particularly important for the Crystalens.

Dr. Loh suggests using a 5- or 6-mm corneal marker as a guide for making the capsulorhexis for those just starting out.

Dr. Loh demonstrated the use of the Crystalsert, which he said is similar to the Softport AO injector (both manufactured by Bausch & Lomb). He injects viscoelastic into the loading bay, then places the IOL on the dock and slides the dock closed. He engages the injector and slowly advances the IOL until it reaches the first stop.

The haptics can be seen bending backward as the IOL is advanced; this indicates that the IOL is advancing evenly, Dr. Loh said.

Dr. Loh uses a two-handed technique, with a second instrument—usually a Sinskey hook—to ensure that all the haptics are in the capsular bag.

The lens, he said, should be in a posterior vaulted position, haptics placed in the 6 to 12 o'clock meridian. The capsule should be smooth with no striae.

Like Dr. Feinerman, Dr. Loh hydrates the wound before removing the viscoelastic; the viscoelastic

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>
> *Raymond Loh, MD*

should then be thoroughly removed.

Astigmatism, Dr. Loh said, needs to be addressed, or the outcomes will not be as good as they could be. He uses Nichamin's nomogram and corrects the astigmatism either before surgery or during IOL insertion.

"LASIK and PRK can be done after lens implant, PRK as soon as six weeks, and LASIK at about three months," he said.

After surgery, Dr. Loh said he gives patients +1.50 D readers when a cycloplegic agent is used. He said that distance vision usually stabilizes after a week while near vision begins to stabilize at two weeks.

In order to closely monitor surgical outcomes, especially for beginners, Dr. Loh suggests several steps at day 10 to 14 post-op: check keratometry; check corrected and uncorrected visual acuities; perform a controlled maximum plus refraction; check distance and near visual acuity through distance correction, if any; perform a gradual push-up of the plus add; and cycloplegic refraction, "if you're not getting good visual acuity for distance, just to make sure the patient isn't accommodating while you are refracting."

Steroids and nonsteroidal medication should be given from seven to eight weeks, and nonsteroidals should be given for the duration of steroid therapy.

Capsulotomy, said Dr. Loh, should be performed when PCO, fibrosis or later stage myopia develop. He would not do YAG capsulotomy until about three months post-op.

"The main thing is to tell patients not to force their reading during the first 10 to 14 days, so we normally give them +1.50 add for the first two weeks," Dr. Loh said. "After that I think you need to challenge their near vision. No matter how much they complain that their near vision is not quite as good as they had hoped, tell them to continue trying to read without the reading glasses. You can give them exercise booklets, which may help in patients with slow accommodation. Always consider the refractive state of the fellow eye."

If the procedure is done correctly, said Dr. Loh, the goal of delivering good distance, intermediate, and near vision can easily be met and even exceeded by the Crystalens.

Accommodation vs. multifocality: Which technology will patients benefit from the most?

In his practice, Dr. Stonecipher uses the toric aspheric, the ReSTOR in a limited quantity, and the Crystalens 5-O and HD; he has thus used both multifocals and accommodating lenses. Comparing these two types of "premium" lenses, Dr. Stonecipher's first advice is for surgeons to avoid mixing and matching technologies.

He once had a patient insist on having a multifocal put in her second eye after having an accommodating lens implanted in her first eye. The difference in vision between her eyes emphasizes the limitations of the multifocal IOL: lower distance and intermediate visual acuity, near vision that requires a specific point of focus and good lighting, and "a color difference that's very distinct," the patient said. "I've learned not to notice it when both eyes are open, but when I go from eye to eye, it's an amber cast to everything white."

Electron microscopy done on the Crystalens HD (A&B) showing the on-edge (A) and en face profile (B) of the IOL to compare it to the non-HD surface of the Crystalens 5-0 (C)

The Crystalens, in her experience, provides "overall better vision," the patient said.

"When I talk about accommodating versus multifocal IOLs, I try to stick with whatever technology I'm going to do," Dr. Stonecipher said.

Dr. Stonecipher still gets patients who specifically request a multifocal, he said. In such cases, he may try to discourage the patient but will implant the lens if the patient continues to insist, cautioning that he or she will have to "deal with the postoperative issues as need be."

With the ReSTOR +3.0, Dr. Stonecipher said, patients are "getting a little bit more intermediate, or a better range of vision compared to the +4.0. But we still have the issue of multifocality, which is reduced vision in dim light."

For Dr. Stonecipher, even more disturbing than this drop in vision with dim light is the way these lenses induce visual disturbances. "We're still seeing halos and glare with multifocals," Dr. Stonecipher said.

Because of the reduced vision in dim light and the visual disturbances, driving at night is a common point of contention with multifocal IOLs. While some surgeons use it as an argument against multifocal IOLs, others say that it doesn't really matter given that most of their patients don't drive anyway.

Dr. Stonecipher, however, thinks that argument misses the point. "I know there are a lot of people who don't drive at night, such as a lot of our elderly population. But I think that the majority of people still do things at night. It's not like when the sun goes down we all go home."

It may be that 96% of patients who receive the ReSTOR would want the same lens again, but the remaining percentage of unsatisfied patients, said Dr. Stonecipher, "can just wear you out. It goes to that old adage that one happy patient may send you 20 patients, but one really unhappy patient will keep 50 out of your door."

The Crystalens doesn't have the limitations of multifocal lenses—no loss in contrast sensitivity, no drop in vision in low-light conditions, and no visual disturbances.

It is "a true accommodating lens," said Dr. Stonecipher, with at least one of his patients getting as much as 4.8 D of accommodation. "That's an exception to the rule, but some of these people can really move the lens based on what their accommodative amplitude is," he said.

Dr. Stonecipher consistently sees a range of between 2 to 2.5 D of accommodation in his Crystalens patients.

Where multifocal lenses like the ReSTOR and ReZoom shine, said Dr. Stonecipher, is in terms of near visual acuity, at J1 or better.

"But we're still getting good numbers with the Crystalens HD," he said. The numbers at J1 are "a little bit better with ReSTOR [but] equal at the J2 level."

Significantly, said Dr. Stonecipher, while multifocal patients may be on target refractively, they may still be unhappy. With the Crystalens HD, unlike with multifocal lenses, contrast sensitivity and mesopic vision results are very good and very stable over time, and this seems to make quite a difference in terms of the patient's subjective experience.

In addition, "I think it creates excellent depth of focus," said Dr. Stonecipher. "I think that it's much better than a multifocal IOL."

Because of the quality of vision the Crystalens offers, being on target refractively isn't always necessary to make patients happy. "You have to have a low threshold for enhancing those patients, but at the same time, if you've got a happy patient, leave him alone," Dr. Stonecipher said. "You don't need to fix it if it's not a problem with the patient. A lot of people have the mentality that they don't mind wearing glasses.

"I try to make them glasses-free," he said. "At the same time I don't hesi-

Ray tracing to compare the different presbyopia correcting lenses shows a single point of focus for the Crystalens as compared to multiple points of focus for the different types of multifocal IOLs

> ***"With the Crystalens HD, contrast sensitivity and mesopic vision results are good and stable over time, and this seems to make quite a difference in terms of the patient's subjective experience"***
>
> ***Karl Stonecipher, MD***

tate to tell them, post-op, they may need a thin pair of reading glasses."

Dr. Stonecipher believes that current technology is excellent, but this is not the end. He foresees further advancements, such as in the application of femtosecond lasers in cataract surgery, in performing capsulotomies, incisions, and the like.

"I think that we're only going to keep getting better, and the Crystalens HD is a step in the right direction."

Incorporating Crystalens into your practice

No one foresaw that cataract surgery, not LASIK, would emerge as the premium market in anterior segment ophthalmic surgery. "When you look at the LASIK market, that is definitely not the premium market," Dr. Feinerman said. "LASIK volume fluctuates with consumer confidence, and it's a difficult market to get into as a surgeon because it's less predictable."

The population of patients over 60, he said, "is your premium market. Those are the people who have put away money for years and saved, and they are much less likely to fluctuate with the economy.

"I think the ideal Crystalens patient is age 50 and up, with a cataract starting to compromise vision. These patients value an active lifestyle and they're concerned about their appearance and quality of life. They don't want to get old, and they're spending billions of dollars on lifestyle enhancing procedures."

Cost is an issue, of course, but Dr. Feinerman believes the Crystalens gives good value for the money.

"Value-based pricing is what we're talking about, and the Crystalens procedure is worth it to your patients," he said. "Patients over the age of 50 will pay a bit more for a premium lens.

"In the US, people are spending money on LASIK, blepharoplasty, liposuction, facelifts, Botox, collagen, dental implants. They're doing the same here to a different degree, but they're still doing it. In the US, they're even sending their dogs for cataract surgery for US$2,500. So if you don't think you have the kind of patients who would pay US$3,000 per eye for an upgraded lens, that's a wrong assumption."

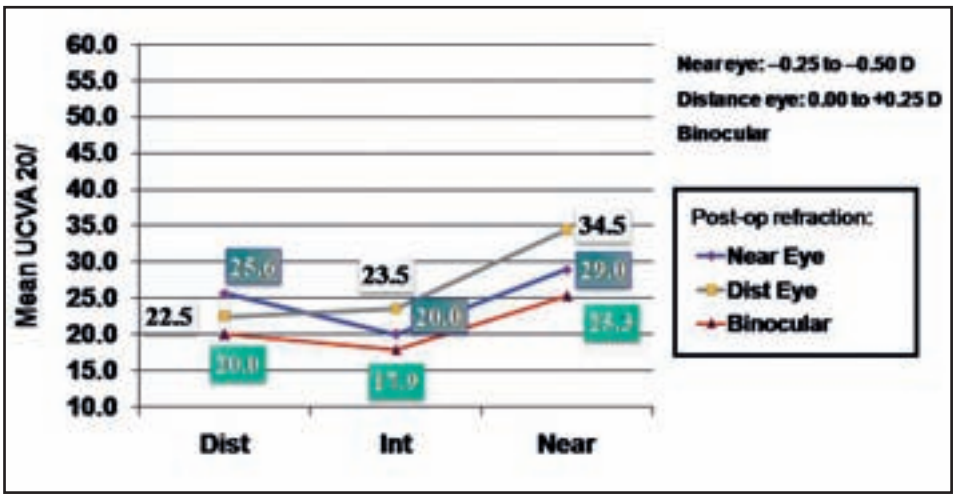
Incorporating the Crystalens into an existing practice, said Dr. Feinerman, is a matter of "resetting your mind and the way you think about cataract surgery," something he sees going on everywhere as the premium IOL market establishes itself around the world.

"You have those patients in your practice," he said. "Current market demographics show that all of the cataract eyes and about a third of the LASIK eyes are Crystalens candidates. That's half of your current database, so Crystalens patients are already in your waiting room."

Earlier in his practice, Dr. Feinerman performed about 1,000 multifocal IOL implantations, with less than satisfying results.

When the Crystalens was released, many surgeons in North America were resistant, mainly because of the results of studies conducted in Europe "where [the Crystalens] was given out to surgeons without a lot of technical assistance," Dr. Feinerman said. "They had some issues with the AT-45 before it was FDA approved in the US."

Dr. Feinerman discussed the lens with colleagues prior to FDA approval. "There were a lot of concerns about whether this was really the right technology to go with," he said. "It took me a while and a lot of discussion with colleagues to implant the lens."



Visual outcomes of the Crystalens HD (Near conversion: 20/40 = J3, 20/32 = J2, 20/25 = J1)

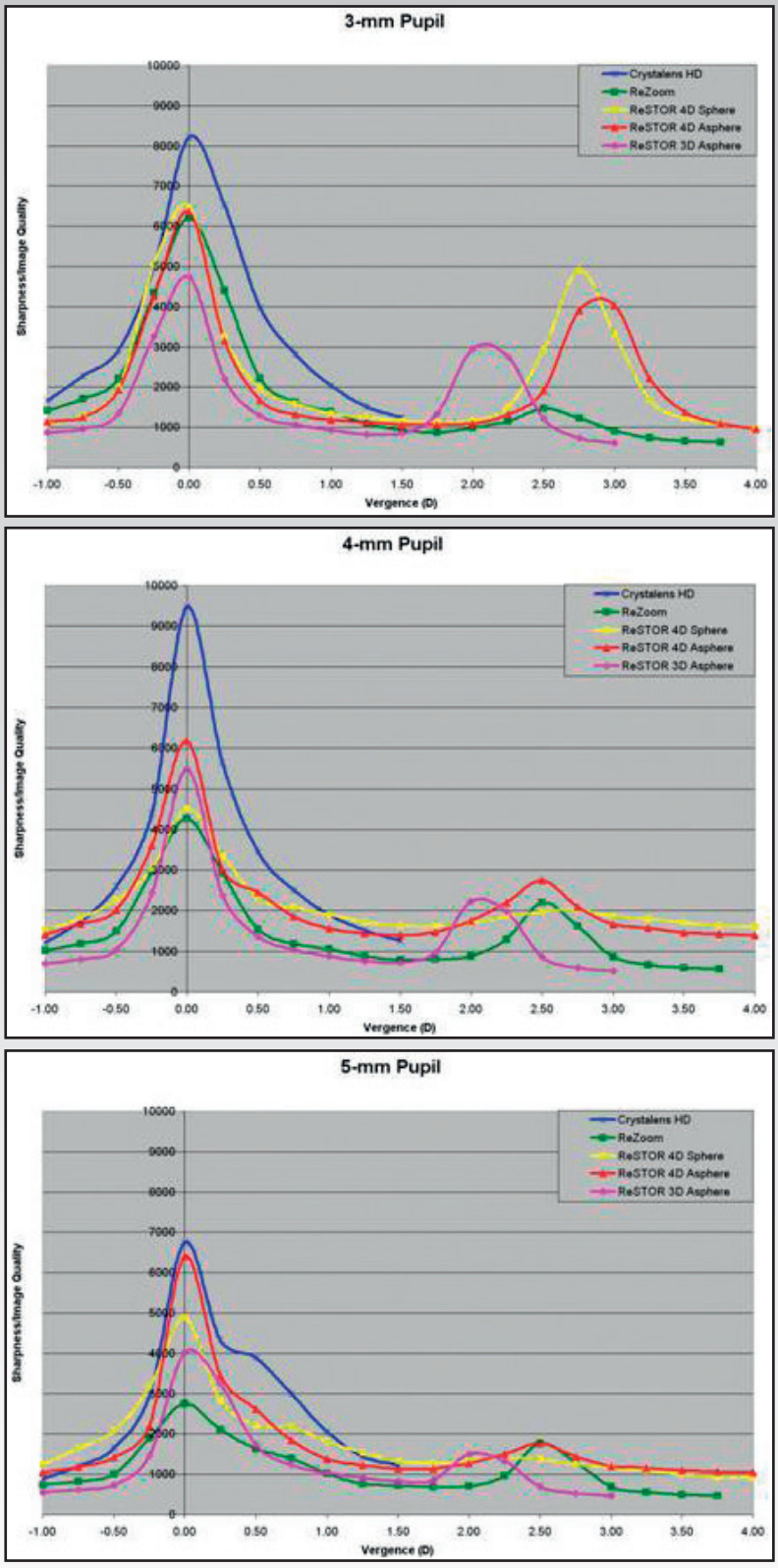


Image resolution of the Crystalens HD across different pupil sizes compared to multifocal lenses

After FDA approval, Dr. Feinerman went on to perform the first Crystalens implantation in Southern California. "I decided to give it a try and was extremely satisfied with the results."

It proved a smart decision on more than one level. Apart from the satisfaction his patients felt with the vision the Crystalens provided, being the first to implant the Crystalens meant that Dr. Feinerman's clinic made the news—free advertising for the practice.

This, he said, is one way to circumvent advertising restrictions that may exist in some countries. "I know in Singapore at least, you can't do advertising for your product," Dr. Feinerman said. "What you might consider, if you have restrictions where you live, is to simply send a press release to your local news station and find a way to get yourself in front of the camera talking about a new premium intraocular lens."

In addition to the boost his practice received from the media, Dr. Feinerman's marketing strategy includes "newsletters that we send to the patients, a DVD in the waiting room explaining the procedure, brochures, and a bulletin board with letters from patients and testimonials."

It doesn't hurt that the Crystalens HD itself provides the best kind of advertising: great outcomes that patients clearly enjoy, which makes them more than willing to share their experiences with potential patients.

In the FDA study, 100% of patients implanted with the Crystalens could read J3 or better. "I don't like to use this for patients, but it is nice to keep in the back of my mind as a surgeon because I think that's overpromising; I'd rather underpromise and overdeliver."

The Crystalens, in Dr. Feinerman's view, is "phenomenal," and has been an overall good investment for his practice. "The HD has worked out really well for us."

Ultimately, said Dr. Feinerman, incorporating the Crystalens into any

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>
> *Gregg Feinerman, MD*

practice begins with the surgeon. "The new technology starts with you. From diagnosing and treating eye disease to offering advanced vision correction procedures, the patient counts on your guidance and expertise," he said. "Your word is so valuable to them. They want quality vision and if we don't give them that, it's going to bite us.

"I would encourage you to change your mindset and promote premium IOLs, and expect a broader range of vision without sacrificing the visual quality for your patients."

Evolution of a presbyopic lens practice from a non-refractive cataract mindset

Contrary to the trend in anterior segment ophthalmic surgery noted by Dr. Feinerman during his training, **Terence Devine, MD**, chief ophthalmologist, Guthrie Clinic, PA, USA, and associate professor of ophthalmology, State University of New York, NY, USA, never liked doing refractive surgery. In 1996, Dr. Devine said he performed 500 PRKs and didn't enjoy doing them.

"I didn't have any disasters, every patient was 20/40 or better, but I really didn't like doing refractive surgery," he said. "I didn't like the selling to the patients. It was more like a commodity that they were shopping for, and after awhile I gave that up."

When he encountered the Crystalens, he had three concerns: what he called the "unhappy patient," the patient who had reasonable expectations that the procedure failed to meet; the "angry patient," who, despite a successful operation with good outcomes from the surgeon's point of view, did not have reasonable expectations to begin with and could probably never have been satisfied; and the "unhappy, angry patient."

"I was reluctant to get into doing anything refractively," Dr. Devine said. He didn't even have a LASIK setup in his practice and so could not perform any touch ups that might be necessary post-op.

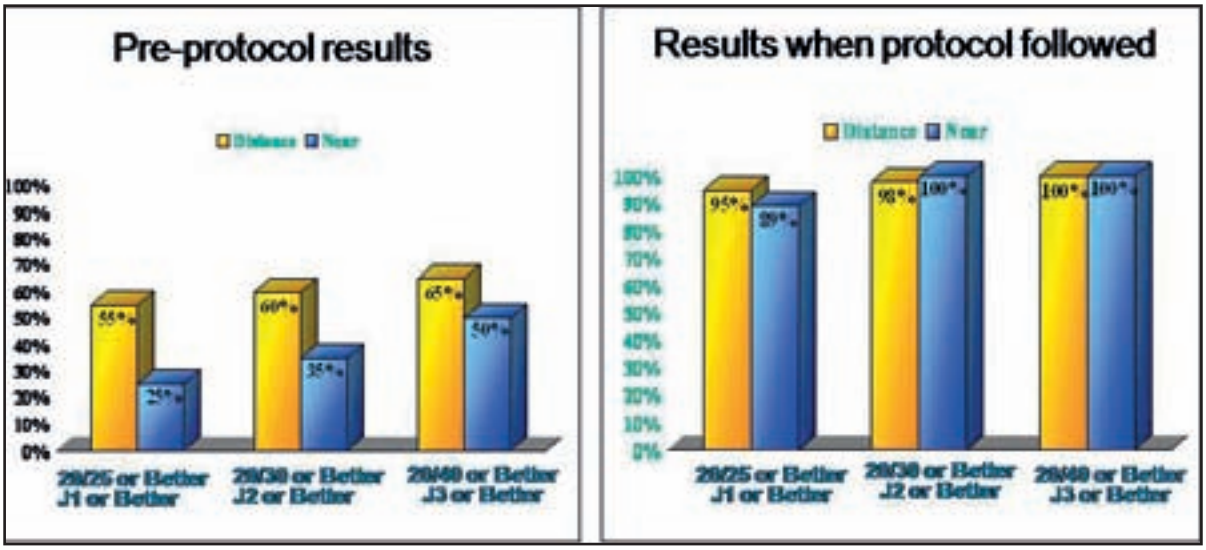
In addition, he was concerned about the extra time it would take to implant the lens. Like many cataract surgeons, he has a busy enough practice just removing cataracts without having to "spend a great deal of extra time on patient education, managing their expectations pre-op, and talking to them post-op."

But "most significant of all was the negative experience that I had dealing with patients from other surgeons who had put in multifocals."

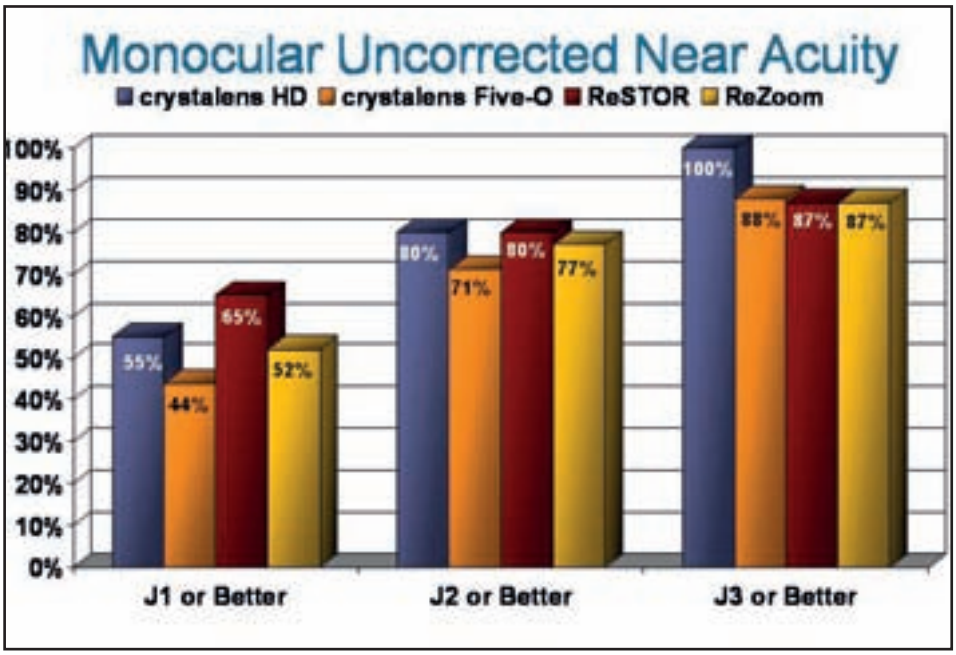
Not surprisingly, then, the first thing that caught Dr. Devine's attention was that the Crystalens was not a multifocal IOL. "That really got my interest," he said.

Dr. Devine was impressed by a video showing a patient accommodate with the Crystalens after losing the iris in a car accident.

"There's a lot of evidence that supports this," he said. "When you do simultaneous wavefront comparison you can actually see that it is increasing and decreasing as the lens moves. So this isn't pseudoaccommodation where this would be a static phenomenon."



Refractive results improved dramatically when biometry protocols were followed



This graph compares the monocular uncorrected near VA of the Crystalens HD with that of the third-generation IOL Crystalens AT-50, Alcon ReSTOR, and AMO ReZoom with the HD IOL showing favorable results

It helped to think that, in the worst case scenario, "If it didn't give that accommodation, all I had done was put in a monofocal IOL," Dr. Devine said. "I didn't have a patient who was unable to drive at night or lost best-corrected acuity, or had a yellowish, waxy kind of vision."

The litigious environment in the US also prompted Dr. Devine to try the Crystalens.

"Back when IOLs were relatively new and not so popular in the early 80s, a lot of cataract surgeons were doing phaco and not putting implants in—they were fitting the patients with contact lenses," he said. "In the United States, there were actually some lawsuits at that time, patients who had successful surgery but were angry because they weren't offered the implant."

At any rate, Dr. Devine went ahead and implanted the Crystalens in 10 patients, carefully selecting patients with realistic expectations and making sure to underpromise. "I told all the patients that they might need glasses," he said. "I told patients that there was no guarantee of anything. I told them there is a high likelihood that they would be able to drive without glasses, but they might need them for driving at night in the rain; that they could read a newspaper without glasses, but they might need them for reading fine print.

"As long as they understood and accepted that, I felt the odds were extremely good I could deliver and probably exceed their expectations."

After 10 patients—five with the 5-O and five with the HD—Dr. Devine temporarily stopped implanting the Crystalens to see how they would turn out.

One thing Dr. Devine noticed that had not been mentioned by the refractive cataract surgeons was the effect of dry eye on outcomes. "I learned early that some of the patients with dry eye had a little more fluctuation in their vision and when I treated the dry eye, they did very well."

Those outcomes made a difference for Dr. Devine; for one thing, it made him look at the marketing of the lens in a different light. "I found that it was very different from selling a LASIK or PRK," he said. "The only thing that you're doing is helping them choose the implant. It wasn't like I was selling a commodity anymore. I was much more comfortable because all I had to do was educate them. At this point, I feel almost a moral obligation to offer this to patients."

He also quickly learned that cost was not as much of an obstacle as he'd expected. "To my surprise, there are a lot of people who want this lens," Dr. Devine said. "When you think about it as a lifetime investment, you can easily spend $2,500 or $4,000 on cigarettes, cosmetics, or one vacation."

That said, the first thing Dr. Devine wants his patients to understand is that they have a choice. "I don't want them to feel that if they don't have the money, or if they just don't feel like they want this, that they're going to get a second-rate lens," he said. "The quality of vision, by which I mean sharpness, color, and brightness, is going to be just as good with the monofocal lens as with the more expensive Crystalens.

"Patients often ask what I would want, and I tell them that I would want the Crystalens. If there was no cost to this lens, it's the lens I would put in everyone."

Dr. Devine needs to take some extra time to educate his patients on the Crystalens; for this reason, he developed his own 12-page patient education booklet. He walks his patients quickly through the booklet and lets them take a copy home for them to think over.

If they decide on a monofocal lens, he tells his patients that everything they need for the procedure is already in the clinic. If they decide on the Crystalens, he asks them to come back for some additional measurements. On their return visit, Dr. Devine checks their topographies and talks to

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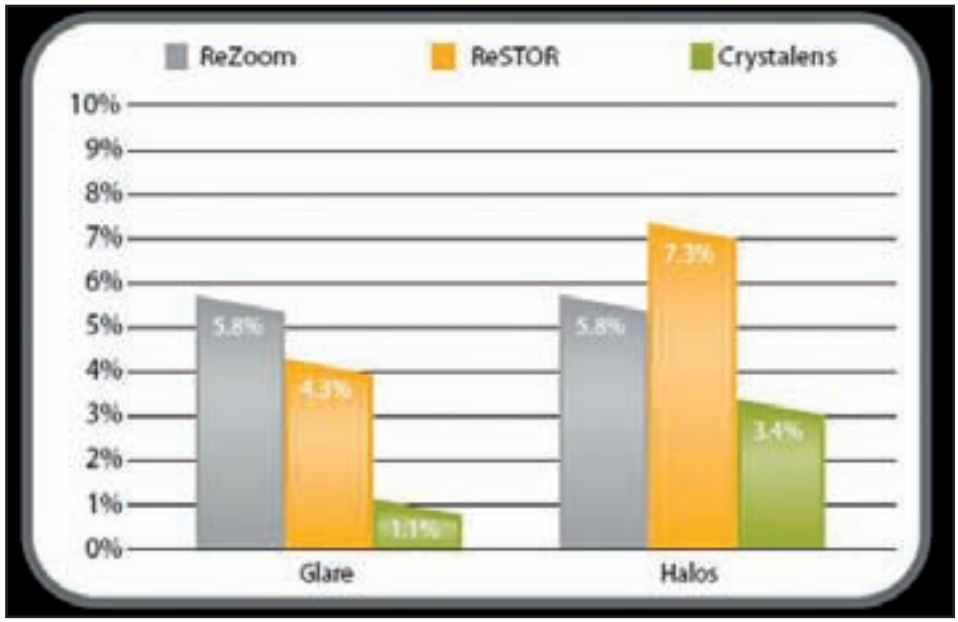

The Crystalens HD has significantly lower rates for dysphotopsias as compared to multifocal lenses

them again to make sure there are no misunderstandings.

Pre-op, Dr. Devine conducts a Schirmer's test on his patients to make sure they don't have dry eye. Otherwise, he goes through more or less the same steps as Drs. Feinerman, Loh, and Stonecipher in preparation for surgery.

For the surgical procedure itself, Dr. Devine says, "you can do anything you want." He personally operates on cataracts exclusively through 1.8-mm C-MICS; in order to insert the lens, he extends the incision to 2.85 mm.

"You can get it in smaller, but I don't see any real advantage to squeezing this in and stretching the incision."

At the time of the Bausch & Lomb forum, Dr. Devine had performed a total of 42 Crystalens implantations, with data on hand for 40 out of the 42 patients. Visual outcomes were generally excellent; the worst outcome was with one patient in his first five patients who had excellent distance and intermediate vision but had J5 near vision at one month. Fortunately, her near vision improved to J3 at six months.

"Some of these patients are going to be 20/20 and J1 on day one; we got some of those, more than I ever expected," Dr. Devine said. "More likely, you're going to have the 20/25 and 20/30 patient and J3, but if you've got good distance vision, if you're on refractively, some of these patients will take longer to develop that reading ability."

None of the 40 patients have asked for the lens to be removed, and this includes a post-LASIK patient and one with rosacea. Dr. Devine also had a patient whose capsulorhexis was less than perfect; he implanted the Crystalens anyway, despite the warnings of Drs. Feinerman, Loh, and Stonecipher. She was 20/25 and J1 on day one, and has been since.

Although that one case doesn't prove anything, it does demonstrate that there is still a lot to learn about the lens and the way the eye accommodates. Dr. Feinerman, for instance, said that he has used the Crystalens in vitrectomized patients; even these patients seem able to accommodate with the lens.

"It truly is the lens I would want in my eye if I were having cataract surgery," said Dr. Devine. "These are the happiest patients I've had. I look forward to seeing these patients post-op."

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