IOLs for Today's Cataract Surgery Patients

The AcrySof® IQ ReSTOR® family of lenses advances technology with the ACTIVEFOCUS™ design

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With a central portion 100% dedicated toward distance, the AcrySof® IQ ReSTOR® +2.5D IOL with ACTIVEFOCUS™ design moves refractive cataract surgery forward so that it can meet the vision needs of an increasing number of patients. Based on its optical design — an aspheric apodized diffractive surface with a distant-dominant refractive zone at the center — the lens provides a range of functional vision from distance to near and distance vision comparable to a monofocal.[1] These features make it suitable for both presbyopes and non-presbyopes who are motivated to reduce their dependence on eyeglasses and contact lenses.

In my practice, the ReSTOR® +2.5D IOL with the ACTIVEFOCUS™ optical design allows me to meet a fuller spectrum of patients' vision goals. Having it as a potential choice in addition to the AcrySof® IQ ReSTOR® +3.0D IOL enables fine-tuning of patient satisfaction.

Matching Patients' Goals With Solutions

Because of the uncompromised distance vision the lens provides, I'm very comfortable implanting it in the dominant eye of my athletic, active patients, many of whom are golfers, sailors, cyclists, or actors. Previously, I didn't consider a multifocal in the dominant eye to be an ideal choice due to the potential for glare and halo and/or reduction of contrast sensitivity. What I had been doing instead was placing a monofocal IOL for distance in the dominant eye, and if the patient wanted "social reading" ability, e.g., seeing the cell phone, or eating a meal without glasses, I'd place a multifocal in the non-dominant eye. While this was effective, the patient's range of vision wasn't necessarily maximized. Because the ReSTOR® +2.5D IOL with the ACTIVEFOCUS™ design is available, virtually taking away distance vision complaints I typically used to hear, it's a great choice for the dominant eye, which sets the stage for addressing each patient's personal priorities more optimally.

I most commonly use ReSTOR® +2.5D with the ACTIVEFOCUS™ design in the dominant eye with the AcrySof® IQ ReSTOR® +3.0D IOL in the fellow eye. I've found that it provides the best range of vision without distance vision complaints. Nuijts and colleagues[2] showed that, with this approach, there is no compromise of the distance vision defocus curve and patients also achieve good intermediate vision (at around 26 inches) and good reading vision (at 16 to 20 inches) (Figure 1).

I have also implanted ReSTOR® +2.5D IOLs with the ACTIVEFOCUS™ design bilaterally, targeted for plano, with good results. This approach is best when distance vision, or intermediate and distance vision, is the priority for a patient.

I recently implanted bilateral ReSTOR® +2.5D IOLs with the ACTIVEFOCUS™ design for a patient who is an actor but also spends all day using a computer because he's an engineer. He prefers not to have a refractive difference between his two eyes and he doesn't mind using reading glasses for closer tasks. He's very happy with his bilateral ReSTOR® +2.5D with ACTIVEFOCUS™, and is also a good example of how the lens has improved the intermediate vision that can be achieved with a multifocal. Good intermediate vision is an important consideration for many of today's cataract surgery patients, an insight drawn from the 2016 ASCRS Clinical Survey.[3] Respondents to the survey reported that "on average, presbyopia-correcting IOL patients were less satisfied with intermediate vision than near and distance vision." For individualized results for patients whose absolute priority is near vision, I recommend bilateral AcrySof® IQ ReSTOR® +3.0D IOLs.

Patient Selection Remains Important

Early in the era of presbyopia-correcting IOLs, it became clear that a thorough understanding of patients' personal postoperative vision goals was necessary for success. Both surgeon and patient had to understand what

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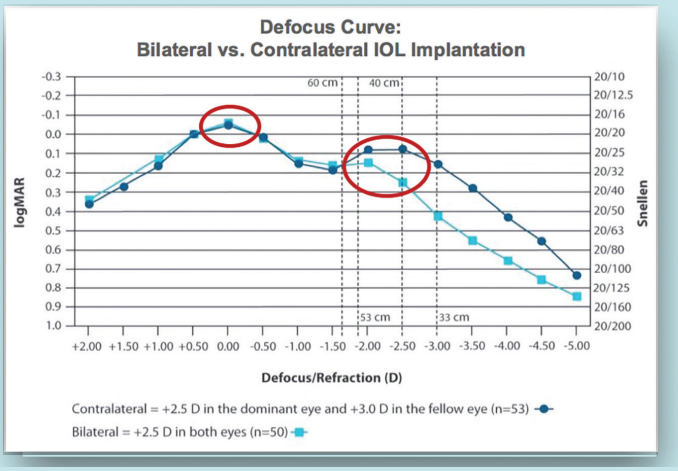
Blending ReSTOR® +2.5 and ReSTOR® +3.0 IOLs

- Bilateral ReSTOR® +2.5D IOL with ACTIVEFOCUS™ optical design provides functional visual acuity at distance through near
- ReSTOR® +2.5D IOL with ACTIVEFOCUS™ in dominant eye paired with ReSTOR® +3.0D IOL in fellow eye provides distance vision with approximately 2 additional lines of functional near vision



Study design: primary endpoint was non-inferiority of contralateral vs. bilateral implantation for corrected intermediate visual acuity. Secondary endpoint was non-inferiority of near vision.

1. Nuijts RM, Jonker SM, Kaufer RA, et al. Bilateral implantation of +2.5D multifocal intraocular lens and contralateral implantation of +2.5D and +3.0D multifocal intraocular lenses: Clinical outcomes. *J Cataract Refract Surg*. 2016;42(2):194-202.

was desired, what was obtainable, and what wasn't, and they had to consider the patient's lifestyle. Today, while the evolution in multifocal lens technology, such as the advanced ACTIVEFOCUS™ lens design, has provided more ways to individually tailor a case and reduce the incidence of post-op visual disturbances, patient education and expectation-setting still matter. It's something I happen to enjoy. I like discussing with patients what they want, analyzing the situation, and coming up with the best recommendation. By the time I leave the room, the patient and I have decided on the best refractive approach to their cataract surgery. I convey the quick summary to the surgery scheduler, and she goes over further details and dates. The time I spend with each patient has been key to the success of premium IOLs in my practice. Patients always understand what I can and can't deliver, so it's rare to have unexpected results, an unhappy patient, or an unexpected need for a secondary intervention.

While I'm discussing with a patient what he or she does for a living and with free time, I review the autorefraction data, particularly the automated keratometry values. Astigmatism is an important aspect of patient selection, as it always has been with presbyopia-correcting IOLs. It will be a variable much easier to address now that the AcrySof® IQ ReSTOR® Multifocal Toric IOLs — both +2.5D and +3.0D — have received FDA approval (more on that later). For nearly 100% of my ReSTOR® IOL patients, I use the VERION™ Image Guided System and the LensSx® laser (Alcon). Also, I don't recommend a presbyopia-correcting IOL to patients unless the health of their eye indicates a good prognosis, i.e., no corneal or macular pathology.

With Each Innovation, My Use of ReSTOR® IOLs Increases

Since I began using the ReSTOR® +2.5D IOL featuring the ACTIVEFOCUS™ design, the percentage of my patients receiving a ReSTOR® lens has increased by 5%. When the recently FDA-approved AcrySof® IQ ReSTOR® +3.0D Multifocal Toric and the AcrySof® IQ ReSTOR® +2.5D Multifocal Toric IOLs make their way into my practice, I expect my ReSTOR® volume to increase by an additional 10%.

IOLs with the ACTIVEFOCUS™ design deliver excellent distance vision, minimal to no vision disturbances, and a range of good vision for my patients, a combination of benefits that is ideally suited for the significant number of them who lead active lifestyles.

References

1. AcrySof® IQ ReSTOR® +2.5D Multifocal IOL Directions for Use.
2. Nuijts RM, Jonker SM, Kaufer RA, et al. Bilateral implantation of +2.5D multifocal intraocular lens and contralateral implantation of +2.5D and +3.0D multifocal intraocular lenses: Clinical outcomes. *J Cataract Refract Surg*. 2016;42(2):194-202.
3. American Society of Cataract and Refractive Surgery. ASCRS Clinical Survey. Available at: http://supplements.eyeworld.org/h/i/289602006-ascrs-clinical-survey-2016. Last accessed: March 30, 2017.

See Important Product Information about the AcrySof® ReSTOR® Multifocal IOLs on page 3

VERION® IMAGE GUIDED SYSTEM – IMPORTANT PRODUCT INFORMATION
VERION® REFERENCE UNIT AND VERION® DIGITAL MARKER

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INTENDED USES: The VERION® Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye. In addition, the VERION® Reference Unit provides pre-operative surgical planning functions to assist the surgeon with planning cataract surgical procedures. The VERION® Reference Unit also supports the export of the reference image, preoperative measurement data, and surgical plans for use with the VERION® Digital Marker and other compatible devices through the use of a USB memory stick. The VERION® Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, details from the VERION® Reference Unit surgical plan can be overlaid on a computer screen or the physician's microscope view.

CONTRAINDICATIONS: The following conditions may affect the accuracy of surgical plans prepared with the VERION® Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements. The following conditions may affect the proper functioning of the VERION® Digital Marker: changes in a patient's eye between pre-operative measurement and surgery, an irregular elliptic limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

WARNINGS:
Only properly trained personnel should operate the VERION® Reference Unit and VERION® Digital Marker. Use only the provided medical power supplies and data communication cable. Power supplies for the VERION® Reference Unit and the VERION® Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on. The VERION® Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

PRECAUTIONS: To ensure the accuracy of VERION® Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION® Digital Marker in conjunction with compatible surgical microscopes.

ATTENTION: Refer to the user manuals for the VERION® Reference Unit and the VERION® Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

LENSX® LASER IMPORTANT PRODUCT INFORMATION
FOR CATARACT TREATMENT

CAUTION: Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

INDICATION: The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

RESTRICTIONS:
- Patients must be able to lie flat and motionless in a supine position.
- Patient must be able to understand and give an informed consent.
- Patients must be able to tolerate local or topical anesthesia.
- Patients with elevated IOP should use topical steroids only under close medical supervision.

CONTRAINDICATIONS:
- Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetocele with impending corneal rupture
- Presence of blood or other material in the anterior chamber
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy
- Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
- Corneal thickness requirements that are beyond the range of the system
- Corneal opacity that would interfere with the laser beam
- Hypotony or the presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- History of lens or zonular instability
- Any contraindication to cataract or keratoplasty
- This device is not intended for use in pediatric surgery.

WARNINGS:
The LenSx® Laser System should only be operated by a physician trained in its use. The LenSx® Laser delivery system employs one sterile disposable Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.
The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

PRECAUTIONS:
- Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser.
- Discard used Patient Interfaces as medical waste.

COMPLICATIONS

- Capsulotomy, phacofragmentation, or cut or incision decentration
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tear
- Corneal abrasion or defect
- Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse
- Elevated pressure to the eye

ATTENTION
Refer to the LenSx® Laser Operator's Manual for a complete listing of indications, warnings and precautions.

ACRYSOF® IQ RESTOR® FAMILY OF MULTIFOCAL IOLS
IMPORTANT PRODUCT INFORMATION

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS: The AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Multifocal IOLs include AcrySof® IQ ReSTOR® and AcrySof® ReSTOR® Toric and are intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. In addition, the AcrySof® IQ ReSTOR® Toric IOL is intended to correct pre-existing astigmatism. The lenses are intended to be placed in the capsular bag.

WARNINGS AND PRECAUTIONS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling for each IOL. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery. The ReSTOR® Toric IOL should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. A reduction in contrast sensitivity may occur in low light conditions. Visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. Spectacle independence rates vary; some patients may need glasses when reading small print or looking at small objects. Posterior capsule opacification (PCO), when present, may develop earlier into clinically significant PCO with multifocal IOLs. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

ATTENTION: Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.

Alcon A Novartis Division