PHYSICIAN LABELING
Alcon Laboratories, Inc.

ENGLISH

ACRYSof® IQ ReSTOR® MULTIFOCAL IOL

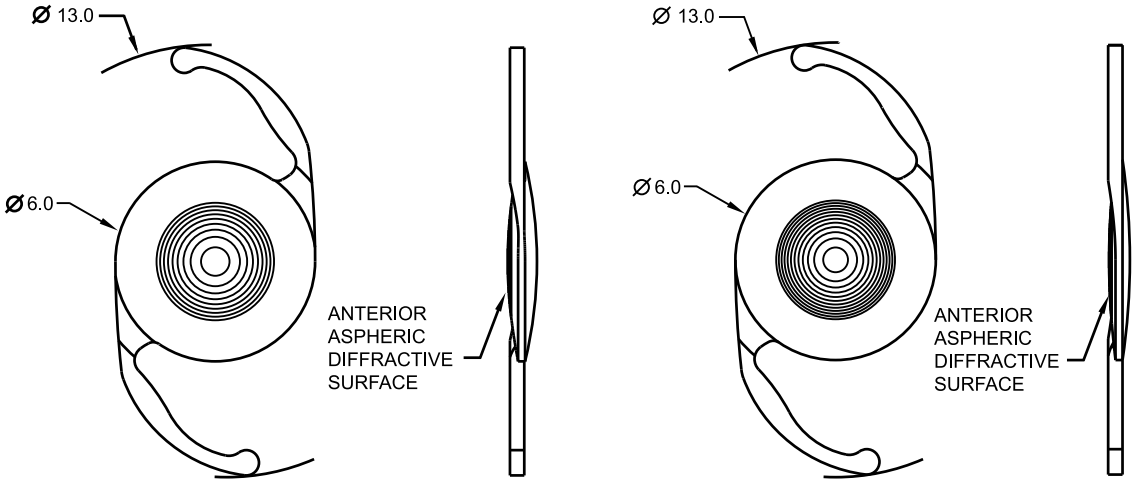
STERILE UV and Blue Light Filtering Acrylic Foldable
Apodized Diffractive Aspheric Posterior Chamber Intraocular Lenses

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

DESCRIPTION

The AcrySof® IQ ReSTOR® Apodized Diffractive Posterior Chamber Intraocular Lenses (IOLs) are ultraviolet and blue light filtering foldable multifocal intraocular lenses (IOLs). The optical portion consists of a high refractive index material with proprietary blue light filtering chromophore which filters light in a manner that approximates the human crystalline lens in the 400-475 nm blue light wavelength range (Boettner and Wolter, 1962). In addition to standard UV-light filtering, the blue-light filtering chromophore reduces transmittance of blue light wavelengths (see Table 2). The optical portion is symmetric biconvex and consists of a soft acrylic material capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance. The anterior surface of the AcrySof® IQ ReSTOR® IOL Models SN6AD1 and SN6AD3 are designed with negative spherical aberration to compensate for the positive spherical aberration of the cornea. The effect(s) of this aspheric design feature have not been clinically assessed.

Figure 1: Physical Characteristics, AcrySof® IQ ReSTOR® IOL
Models SN6AD1 (+3.0 D Add) and SN6AD3 (+4.0 D Add)
(all dimensions in millimeters)

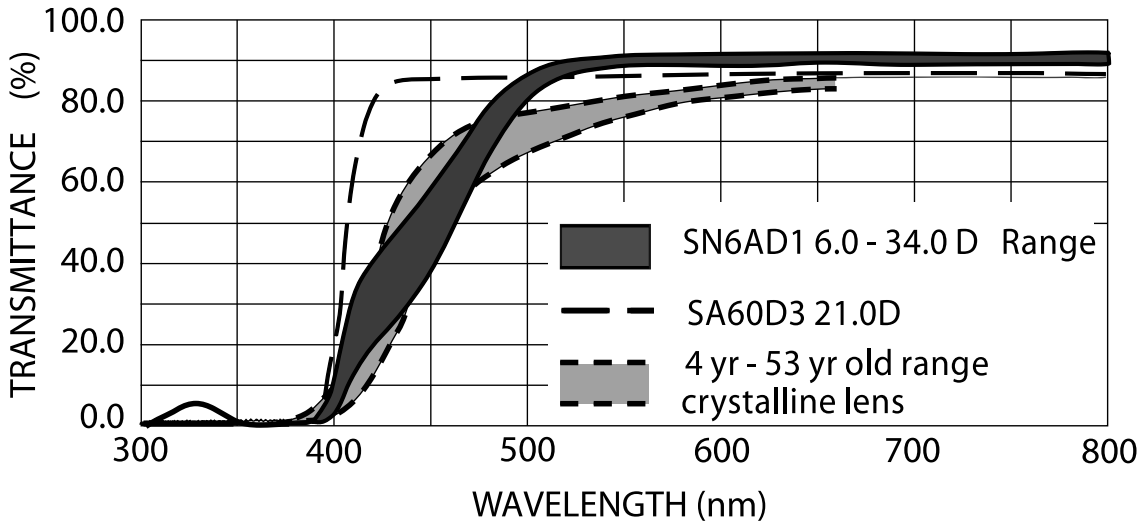


MODEL SN6AD1 MODEL SN6AD3

Table 1: Physical Characteristics of AcrySof® IQ ReSTOR® IOLs

	SN6AD1 (+ 3.0 diopters of add power for near vision)	**SN6AD3** (+ 4.0 diopters of add power for near vision)
Optic Type	Apodized Diffractive Aspheric	
Optics Material	Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer	
Optic Powers	For available base power range see ALCON® Product Guide	
Index Of Refraction	1.55	
Haptic Configuration	STABLEFORCE® Haptics	
Haptic Material	See optic material	
Haptic Color	Yellow	
Optic Diameter (mm)	6.0	
Overall Length (mm)	13.0	
Haptic Angle	0º	

Figure 2: Spectral Transmittance Curves (percentage of ultraviolet transmittance)



NOTES:

- The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values for models SN6AD1 and SN6AD3.
- The mid-power model SA60D3 IOL spectral transmittance curve is shown for comparison.
- Measurements were direct transmittance using actual lenses in the Diopter powers indicated.
- Human lens data from Boettner and Wolter (1962).

Table 2: Average Transmittance %T Comparison for 21.0 D Model SN6AD1, 20.5 D Model SN6AD3, and 21.0 D Models SA60D3

Model		**400 nm**	**425 nm**	**450 nm**	**475 nm**
SA60D3		23	84	86	86
SN6AD1		6	30	45	66
SN6AD3		7	32	47	68
Transmittance Difference	(SA60D3 –SN6AD1)	17	54	41	20
	(SA60D3 –SN6AD3)	16	52	39	18
Transmittance Reduction (% of SA60D3)	(SN6AD1)	74	64	48	23
	(SN6AD3)	70	62	45	21

MODE OF ACTION
AcrySof® IQ ReSTOR® IOLs are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. This IOL has a biconvex optic containing an apodized diffractive structure that provides increased depth of focus.
The aspheric symmetric biconvex optic of the AcrySof® IQ ReSTOR® IOLs are designed to compensate for the positive spherical aberration of the cornea. The effect(s) of this aspheric design feature have not been clinically assessed. The apodized diffractive optic structure provides increased depth of focus over a monofocal IOL. The available near add powers of +3.0 and +4.0 diopters provide surgeons the ability to select a treatment option with either a shorter (+4.0 D) or longer (+3.0 D) reading distance, depending on patient lifestyle and personal preference.

INDICATIONS
The AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lens (IOL) is 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. The lens is intended to be placed in the capsular bag.

WARNINGS
1. Some visual effects may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or radial lines around point sources of light under nighttime conditions.
2. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions. Therefore, multifocal patients should exercise caution when driving at night or in poor visibility conditions.
3. The physician should consider the following points that are unique to the use of the AcrySof® IQ ReSTOR® IOLs:
    - The surgeon must target emmetropia to achieve optimal visual performance.
    - Patients with significant preoperative (determined by keratometry) or expected postoperative astigmatism >1.0 D may not achieve optimal visual outcomes.
    - Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.

PRECAUTIONS
1. Prior to surgery, prospective patients must be provided with a copy of the Patient Information Brochure for this product and informed of the possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs.
2. Posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO with the AcrySof® ReSTOR® lenses as compared to the monofocal control.
3. The safety and effectiveness of the AcrySof® IQ ReSTOR® IOL have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions.

Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.

Before Surgery
- Significant irregular corneal aberration
- Retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or proliferative diabetic retinopathy, in which future treatment may be compromised by implanting this lens
- Amblyopia
- Clinically severe corneal dystrophy (e.g., Fuchs')
- Rubella, congenital, traumatic or complicated cataracts
- Extremely shallow anterior chamber, not due to swollen cataract
- Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye (e.g., iritis or uveitis)
- Aniridia
- Iris neovascularization
- Glaucoma (uncontrolled or controlled with medication)
- Microphthalmos or macrophthalmos
- Optic nerve atrophy
- Previous corneal transplant
- Pre-existing ocular conditions which may negatively impact stability of the implant
- Color vision deficiencies
  Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optical nerve diseases) has not been studied.

During Surgery
- Mechanical or surgical manipulation required to enlarge the pupil
- Vitreous loss (significant)
- Anterior chamber bleeding (significant)
- Uncontrollable positive intraocular pressure
- Complications in which the IOL stability could be compromised

4. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
5. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens

implantation before attempting to implant intraocular lenses.

6. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, and secondary surgical intervention. Secondary surgical interventions include, but are not limited to the following: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.
7. Care should be taken to remove viscoelastic from the eye at the close of surgery.
8. Do not resterilize these intraocular lenses by any method.
9. Do not store intraocular lenses at temperatures over 45°C (113°F).
10. Use only sterile intraocular irrigating solutions (such as **BSS®** or **BSS PLUS®** solution) to rinse and/or soak lenses.

CALCULATION OF LENS POWER

Accurate biometry is essential to successful visual outcomes. Preoperative calculation of required lens power for the AcrySof® IQ ReSTOR® IOLs should be determined by the surgeon's experience, preference, and intended lens placement. The suggested A-constant listed on the outer label is presented as a starting point for implant power calculations. Lens constants must be "personalized" to compensate for the differences in instrumentation, measurement technique, and IOL power calculation methods that exist between different clinical sites. To achieve optimal results with the apodized diffractive optic IOL, it is important to use a personalized lens constant. The provisional A-constant listed on the outer label has been estimated from lens design data.

Hoffer, K.J., The Hoffer Q formula: A comparison of theoretic and regression formulas. *J. Cataract Refract. Surg.* 19:700-712, 1993.

Holladay, J.T., *et al*., A three part system for refining intraocular lens power calculations. *J. Cataract Refract. Surg.* 14:17-24, 1988.

Holladay, J.T., *et al*., Standardizing constants for ultrasonic biometry, keratometry, and IOL power calculations. *J. Cataract Refract. Surg.* 23:1356-1370, 1997.

Retzlaff, J.A., Sanders, D.R., and Kraff, M. *Lens Implant Power Calculation*. 3rd ed., Slack, Inc., Thorofare, N.J., 1990.

DIRECTIONS FOR USE

Note: Targeting emmetropia, a +4 Add model should be chosen for multifocal patients who want their best uncorrected near acuity to be at ~33 cm, and a +3 Add model should be chosen for multifocal patients who want their best uncorrected near acuity to be at ~40 cm.

1. Examine the label on the unopened package for model, powers (base and add), proper configuration, and expiration date.
2. After opening the cardboard storage container, verify lens case information (e.g., model, power, and serial number) is consistent with information on outer package labeling.
3. This device is sterile until the inner pouch is opened. Inspect the pouch carefully for tears, cuts, punctures or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised (see RETURNED GOODS POLICY).
4. To remove the lens, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. To minimize the occurrence of marks on the lens due to handling, all instrumentation should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.
6. When removing the lens from the case, DO NOT grasp the optical area with forceps. The IOL should only be handled by the haptics. Handle lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.
7. Rinse the lens thoroughly using sterile intraocular irrigating solution such as **BSS®** or **BSS PLUS®** solutions. Prior to insertion, the lens should be carefully examined to ensure that particles have not adhered during handling.
8. Alcon recommends using an Alcon approved delivery system.
9. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Current techniques, appropriate instrumentation, and a list of their equivalents for delivery and implantation are available from Alcon. Surgeons should verify that appropriate instrumentation is available prior to surgery.
10. DO NOT reuse this IOL. This device is for single use only.

PATIENT REGISTRATION AND REPORTING

Each patient must be registered with Alcon Laboratories, Inc. immediately following implantation of one of these lenses. Registration is accomplished by completing the prepaid Implant Registration Card that is enclosed in the lens box and mailing it to Alcon Laboratories, Inc. Patient registration is essential for Alcon Laboratories, Inc. long-term patient follow-up program and will assist us in responding to adverse event reports. The Patient Identification Card included in the package is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye care practitioner the patient consults in the future.

Adverse events that may reasonably be regarded as lens-related and that were not previously expected in nature, severity, or degree of incidence should be reported to Alcon Laboratories, Inc. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation. Surgeons should use the following address and telephone number for reporting adverse events involving these intraocular lenses:

Alcon Laboratories, Inc.
Medical Safety (AB 2-6)
6201 South Freeway
Fort Worth, TX 76134-2099
Collect: (817) 551-4445

Overview of AcrySof® IOL CLINICAL STUDIES
The various clinical studies listed below have been conducted on AcrySof® Intraocular Lenses. In addition to data from the more recent clinical study of the AcrySof® IQ ReSTOR® IOL, the labeling from the original study of the AcrySof® ReSTOR® IOL is also included in order to provide data intended to help you make an informed decision as to whether or not to implant a multifocal or monofocal IOL (a monofocal IOL was used as a control in the original study).

1. AcrySof® ReSTOR® Apodized Diffractive Optic Posterior Chamber IOL (Models MA60D3 and SA60D3)
2. AcrySof® IQ ReSTOR® Posterior Chamber IOL (Models SN6AD3 and SN6AD1)
3. AcrySof® Natural Single-Piece IOL (Model SB30AL [color perception])

Clinical studies have not been conducted with the AcrySof® IQ ReSTOR® Apodized Diffractive IOL (Models SN6AD3/ SN6AD1 or MN6AD3/MN6AD1) to assess the effect of the added aspheric surface to the parent lens (Models MA60D3 and SA60D3) on spherical aberration, visual acuity and contrast sensitivity.

Summaries of each of the above clinical studies are provided below.

1. AcrySof® ReSTOR® APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL CLINICAL STUDIES

Summary of Clinical Studies (Models MA60D3 and SA60D3)
Multicenter clinical studies were conducted in the United States and Europe to establish the safety and effectiveness of the AcrySof® ReSTOR® Apodized Diffractive Optic IOL (Models MA60D3 and SA60D3). A total of 566 first-eye implanted ReSTOR® IOL (440 MA60D3 and 126 SA60D3) and 194 AcrySof® MA60BM Monofocal IOL Control patients comprise the All Implanted cohort. A Best Case cohort (no clinically significant preoperative ocular pathology or postoperative macular degeneration) consists of 391 MA60D3 and 109 SA60D3 ReSTOR® IOL patients and 172 Monofocal Control patients. Demographically, these studies consisted of 65.3% female and 34.7% male patients. Stratifying by race, there are 93.9% Caucasian, 2.6% Black, 0.9% Asian and 2.5% designated “Other” race. The mean age for the total population is 68.8 years.

Visual Acuity
ReSTOR® IOL subjects experienced a significant increase (≥ 2 lines) in uncorrected photopic and distance corrected photopic near vision as compared to monofocal control patients. The improvement in distance corrected near vision was greater under photopic than mesopic conditions. Mean spherical add power needed to achieve best corrected near visual acuity was higher under mesopic conditions (mean value of 2.5 D) than photopic conditions (range of mean values: 0.09 to 0.16 D). The average distance of best focus for near vision was approximately 2 cm closer than the predicted distance of 33 cm.
Results from a controlled clinical study revealed that maximum visual performance is achieved when implanted bilaterally. Binocularly implanted ReSTOR® IOL subjects achieved uncorrected and best corrected distance visual acuities similar to monofocal control subjects. When implanted monocularly, a statistically significant decrease (≤ 2 letters) in mean uncorrected and best corrected distance visual acuity was observed in subjects with ReSTOR® IOLs as compared to the monofocal controls. Older subjects implanted with the ReSTOR® lens (e.g., ≥ 80 years old), demonstrated a trend for poorer uncorrected distance visual acuity than the monofocal control patients.

Binocular Visual Acuity
The following is a summary of binocular visual acuity (VA) results for patients who completed the Form 4A (120-180 days after second eye implantation).

Figure 3-A:
Combined 20/40 or Better
Distance & Near Photopic Visual Acuity
Binocular, Best Case
6 Months Postoperative

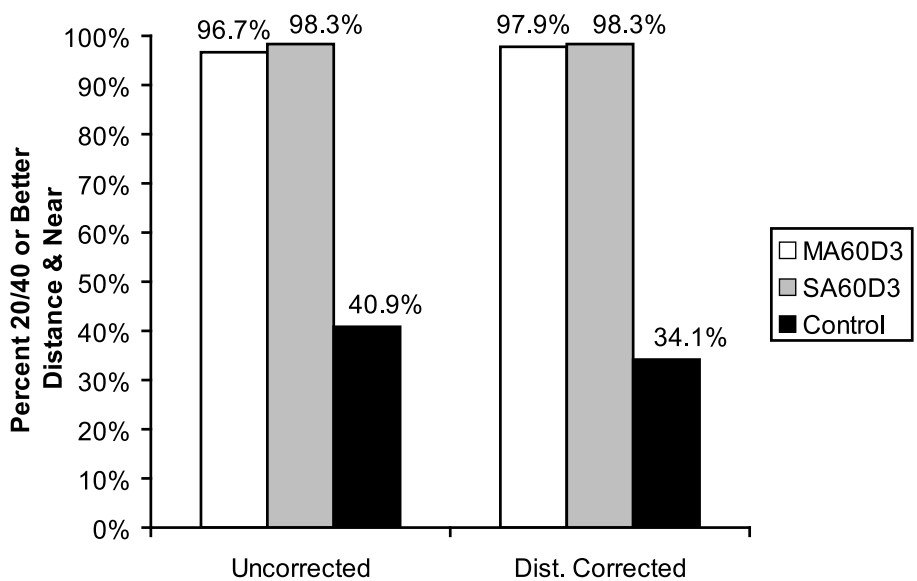


Figure 3-B:
Combined 20/25 or Better Distance
& 20/32 or Better Near Photopic Visual Acuity
Binocular, Best Case
6 Months Postoperative

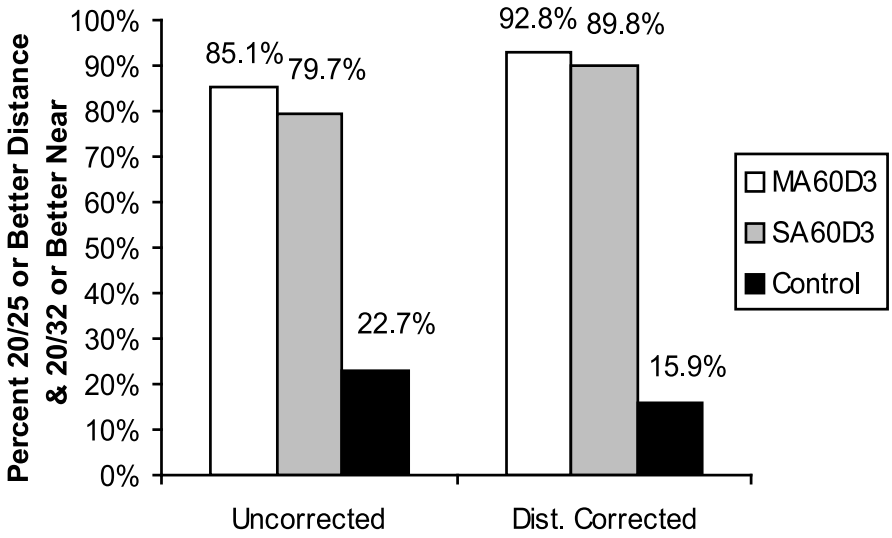


Table 3:
Cumulative Binocular Photopic Near Visual Acuity by Lens Model,
All Implanted, 6 Months Postoperative

		Sample size	20/20 (J0) or better	20/25 (J1) or better	20/32 (J2) or better	20/40 (J3) or better	Worse than 20/40 (J3)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	388	38.9	74.5	90.5	96.4	3.6
	SA60D3	69	46.4	69.6	87.0	98.6	1.4
	Monofocal	157	3.2	14.0	23.6	40.8	59.2
Uncorrected (Standard Distance)	MA60D3	388	36.9	69.1	87.9	95.9	4.1
	SA60D3	69	42.0	69.6	87.0	98.6	1.4
	Monofocal	157	0.6	2.5	8.9	26.1	73.9
Distance Corrected (Best Distance)	MA60D3	387	45.5	76.2	92.5	97.9	2.1
	SA60D3	69	43.5	76.8	88.4	97.1	2.9
	Monofocal	157	1.9	5.7	15.9	33.8	66.2
Distance Corrected (Standard Distance)	MA60D3	387	47.5	77.5	93.8	97.9	2.1
	SA60D3	69	44.9	76.8	89.9	98.6	1.4
	Monofocal	157	0.6	3.8	8.3	21.0	79.0
Best Corrected (Standard Distance)	MA60D3	387	54.3	85.0	96.4	98.4	1.6
	SA60D3	68	58.8	85.3	95.6	98.5	1.5
	Monofocal	157	52.9	79.6	94.3	96.8	3.2

Table 4:
Cumulative Binocular Photopic Distance Visual Acuity by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	388	64.2	88.1	95.1	99.2	0.8
	SA60D3	69	58.0	88.4	95.7	100.0	0.0
	Monofocal	157	70.7	91.7	94.9	97.5	2.5
Best Corrected	MA60D3	387	89.4	97.9	100.0	100.0	0.0
	SA60D3	69	88.4	100.0	100.0	100.0	0.0
	Monofocal	157	93.0	97.5	98.7	100.0	0.0

Monocular Visual Acuity
The following is a summary of monocular visual acuity (VA) results for patients who completed the Form 4 (120-180 days after first eye implantation), and Form 5 (330-420 days after first eye implantation) exams.

Table 5:
Cumulative Monocular Photopic Near Vision by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 (J0) or better	20/25 (J1) or better	20/32 (J2) or better	20/40 (J3) or better	Worse than 20/40 (J3)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	407	27.3	51.8	74.9	86.2	13.8
	SA60D3	110	28.2	53.6	79.1	90.0	10.0
	Monofocal	176	1.1	5.7	12.5	26.1	73.9
Uncorrected (Standard Distance)	MA60D3	407	19.2	42.5	67.6	84.5	15.5
	SA60D3	110	19.1	41.8	67.3	85.5	14.5
	Monofocal	176	0.0	0.6	6.8	11.9	88.1
Distance Corrected (Best Distance)	MA60D3	407	30.2	58.2	83.0	92.1	7.9
	SA60D3	110	30.9	63.6	86.4	94.5	5.5
	Monofocal	176	0.6	2.3	9.1	21.6	78.4
Distance Corrected (Standard Distance)	MA60D3	407	26.8	59.0	81.1	92.9	7.1
	SA60D3	110	30.0	64.5	80.9	96.4	3.6
	Monofocal	176	0.6	1.1	3.4	11.4	88.6
Best Corrected (Standard Distance)	MA60D3	406	35.5	70.7	88.4	95.6	4.4
	SA60D3	110	36.4	77.3	90.0	97.3	2.7
	Monofocal	176	34.7	67.0	85.2	94.9	5.1

Table 6:
Cumulative Monocular Photopic Distance Vision by Lens Model,
All Implanted, 6 Months Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	407	33.2	59.2*	77.1*	90.2	9.8
	SA60D3	110	29.1	53.6*	80.0*	92.7	7.3
	Monofocal	176	42.0	71.6	85.8	94.9	5.1
Best Corrected	MA60D3	407	73.5*	92.6	97.1	99.3	0.7
	SA60D3	110	77.3*	92.7	98.2	100.0	0.0
	Monofocal	176	84.7	96.0	98.3	99.4	0.6

*Statistically significant difference versus monofocal control

Table 7:
Cumulative Monocular Photopic Near Vision by Lens Model,
All Implanted, 1 Year Postoperative

		Sample size	20/20 (J0) or better	20/25 (J1) or better	20/32 (J2) or better	20/40 (J3) or better	Worse than 20/40 (J3)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	319	21.0	53.6	74.9	85.6	14.4
	Monofocal	89	3.4	4.5	11.2	19.1	80.9
Uncorrected (Standard Distance)	MA60D3	319	17.9	43.6	69.6	79.6	20.4
	Monofocal	89	0.0	0.0	2.2	12.4	87.6
Distance Corrected (Best Distance)	MA60D3	318	30.5	62.9	82.1	90.9	9.1
	Monofocal	89	0.0	1.1	3.4	14.6	85.4
Distance Corrected (Standard Distance)	MA60D3	319	29.5	60.5	80.6	90.3	9.7
	Monofocal	89	0.0	1.1	2.2	9.0	91.0
Best Corrected (Standard Distance)	MA60D3	319	36.4	70.2	89.3	94.7	5.3
	Monofocal	89	50.6	79.8	94.4	95.5	4.5

Table 8:
Cumulative Monocular Photopic Distance Vision by Lens Model,
All Implanted, 1 Year Postoperative

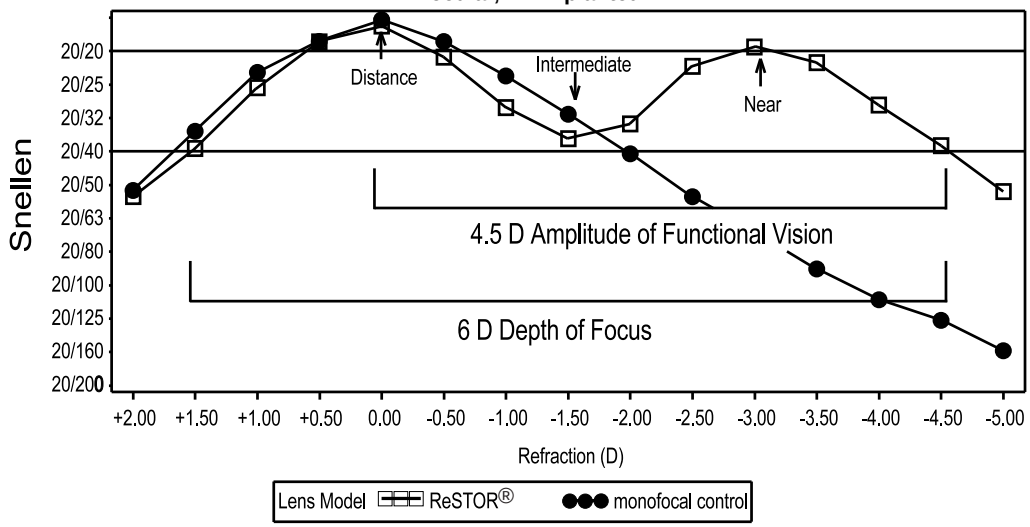
		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	319	30.1	58.9*	76.8*	90.0	10.0
	Monofocal	89	42.7	78.7	89.9	95.5	4.5
Best corrected	MA60D3	319	74.6*	93.4	97.8	99.1	0.9
	Monofocal	89	87.6	94.4	98.9	100.0	0.0

*Statistically significant difference versus monofocal control

Clinical Sub-studies

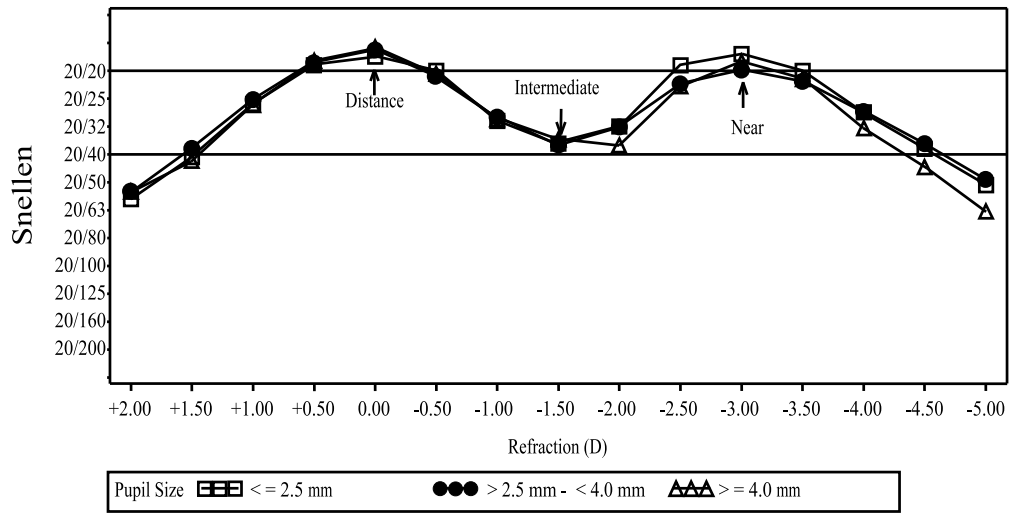
Defocus
A binocular refraction defocus curve from the United States Intermediate Vision Study (34 AcrySof® ReSTOR® IOL MA60D3 All Implanted patients) displays two peaks, with one at the zero baseline corresponding to the distance focal point of the lens and one near the –3.0 D of correction, which corresponds to the near focal point of the lens. The distance peak of this curve demonstrates that ReSTOR® IOL patients achieved a mean distance visual acuity of 20/20 or better, with an additional increased depth of focus from -2.0 D to -4.5 D as compared to monofocal control patients (N=27). This additional increased depth of focus translates to a mean intermediate visual acuity of 20/40 or better and is most pronounced at near, with up to a five-line visual acuity improvement for patients implanted with a ReSTOR® IOL versus the monofocal control (Figure 4).

Figure 4:
Mean Defocus Curves by Lens Model,
Binocular, All Implanted



These data demonstrate that the ReSTOR® IOL provides a 4.5 diopter amplitude of functional (20/40 or better) vision (from optical infinity to approximately 22 cm). Binocular performance of the ReSTOR® IOL was approximately 0.5 lines better for near vision and 1.5 lines better for intermediate vision than the monocular performance of the ReSTOR® IOL. Additionally, the defocus curves were within 1 line among groups when stratified by pupil size (Figure 5).

Figure 5:
Mean Defocus Curves by Pupil Size
Binocular, All Implanted (N=34)



Intermediate Vision
In addition to the clinical studies supporting the safety and effectiveness of AcrySof® ReSTOR® IOL Models MA60D3 and SA60D3, a parallel group (N=34), non-randomized, multi-center supplemental study was conducted in the U.S. to evaluate the performance of the AcrySof® ReSTOR® IOL Model MA60D3 for intermediate vision compared to the monofocal control, AcrySof® IOL Model MA60BM. At a distance of 70 cm, the percentage of eyes achieving 20/20 or better uncorrected vision and 20/25 or better distance corrected vision was significantly worse for the ReSTOR® IOL as compared to the monofocal control. No statistical differences were observed between the ReSTOR® IOL and the monofocal control lens for uncorrected and distance corrected vision 20/32 or better when tested at 50, 60 or 70 cm.

Table 9:
Intermediate Photopic Visual Acuity,
Binocular, All Implanted

			Percent 20/40 or better		
		Total Sample Size	50 cm	60 cm	70 cm
Uncorrected	ReSTOR®	34	82.4*	85.3	67.6
	Control	27	59.3	66.7	63.0
Distance Corrected	ReSTOR®	34	64.7	70.6	52.9
	Control	27	59.3	66.7	77.8

*=Statistically different from control at 0.05 level

Low Contrast Visual Acuity and Contrast Sensitivity
Contrast sensitivity and low contrast acuity under various lighting conditions was clinically equivalent between ReSTOR® IOL and monofocal control patients. While there was a tendency for reduced contrast sensitivity and low contrast acuity in ReSTOR® IOL patients in low lighting (mesopic) conditions when exposed to a glare source, no differences in contrast sensitivity from the monofocal control exceeded more than 0.3 log units, and no difference in low contrast acuity exceeded more than 2 Snellen lines.
Low contrast acuity results were comparable between ReSTOR® IOL and monofocal control groups measured with Regan contrast charts at all light sources and gray scales (100%, 25% and 9%). Functional vision (20/40 or better) was maintained under photopic conditions at all gray scales with and without glare and under mesopic conditions at 100% and 25% with and without glare.
A Vector Vision (CSV1000) contrast sensitivity chart that employs a full range of sine wave gratings at 9 contrast levels and 4 spatial frequencies (3, 6, 12, and 18 cpd) was used to assess contrast sensitivity under photopic (85 cd/m^2) and mesopic (2-5 cd/m^2) conditions, with and without a glare source. Statistical and descriptive comparisons of contrast sensitivity of the AcrySof® ReSTOR® IOL versus the monofocal control indicate that, while there are measurable differences between the two groups at higher spatial frequencies when tested under the same photopic and mesopic conditions with and without glare, none of these differences exceeded 0.3 log units. At certain spatial frequencies, the AcrySof® ReSTOR® IOL Model SA60D3 performed statistically significantly better than the AcrySof® ReSTOR® IOL Model MA60D3 by at least 0.128 log units under monocular mesopic with and without glare conditions and by 0.143 log units under binocular mesopic with glare conditions. Additionally, for monocular contrast sensitivity testing, there was no difference in the percentage of ReSTOR® IOL and monofocal IOL control patients who were not able to see any of the gratings. For binocular contrast sensitivity testing at least 85% of patients in both the ReSTOR® IOL and monofocal IOL control groups were able to see at least one grating, with the exception of mesopic with glare testing at 12 and 18 cycles per degree. At these spatial frequencies, the percentage of ReSTOR® IOL patients able to see at least one grating ranged from 85.9% - 75.0% as compared to 95.8% - 90.6% of monofocal control patients.

Table 10:
Mean Log Decrease in Contrast Sensitivity
ReSTOR® IOL Compared to Monofocal Control Under Photopic,
Mesopic and Glare Conditions, Monocular,
All Implanted, 6 Months Postoperative

		Spatial Frequency (c/d)			
Light Source (↓)	Model	A(3)	B(6)	C(12)	D(18)
Photopic w/o Glare	MA60D3	-0.02	-0.04	-0.09	-0.05
	SA60D3	0.01	-0.03	-0.12	-0.09
Photopic w/ Glare	MA60D3	-0.06	-0.15	-0.15	-0.15
	SA60D3	-0.05	-0.14	-0.18	-0.16
Mesopic w/o Glare	MA60D3	0.00	-0.12	-0.13	-0.09
	SA60D3	0.00	-0.02	0.00	-0.04
Mesopic w/ Glare	MA60D3	-0.08	-0.11	-0.12	-0.12
	SA60D3	-0.01	-0.04	-0.02	-0.06

Table 11:
Mean Log Decrease in Contrast Sensitivity
ReSTOR® IOL Compared to Monofocal Control Under Photopic,
Mesopic and Glare Conditions, Binocular,
All Implanted, 6 Months Postoperative

		Spatial Frequency (c/d)			
Light Source (↓)	Model	A(3)	B(6)	C(12)	D(18)
Photopic w/o Glare	MA60D3	-0.03	-0.11	-0.17	-0.12
	SA60D3	-0.06	-0.15	-0.21	-0.16
Photopic w/ Glare	MA60D3	-0.07	-0.23	-0.22	-0.17
	SA60D3	-0.10	-0.24	-0.23	-0.24
Mesopic w/o Glare	MA60D3	-0.06	-0.12	-0.26	-0.18
	SA60D3	-0.07	-0.17	-0.23	-0.19
Mesopic w/ Glare	MA60D3	-0.15	-0.24	-0.25	-0.19
	SA60D3	-0.07	-0.24	-0.23	-0.21

Summary of Driving Sub-study (Models MA60D3 and SA60D3)[1]
Night driving performance was tested using the NDS (Night Driving Simulator) developed and validated by Vision Sciences Research, Corp. in bilaterally implanted patients (23 ReSTOR® IOL Model MA60D3 Patients and 25 monofocal controls) were tested to determine visibility distances for the detection and identification of road warning signs, message signs and road hazards under various conditions (clear [normal], inclement weather [fog] and glare conditions). The simulated driving scenes using the NDS (Night Driving Simulator) were a city street at night with streetlights and a rural highway with low beam headlights.
It is important to realize that there are no absolute detection and identification distances for all targets to determine safety and efficacy. Actual visibility distances, excluding individual differences, will depend upon the target size, contrast (sign age, clean or dirty sign), background clutter (oncoming vehicle headlights, street and store lights) and vehicle headlight condition (low or high beams, clean or dirty lens). The NDS was designed to provide similar visibility distances to that of similar targets reported in the literature. One could use other targets in the real world and obtain other visibility distances; however, those distances would be relevant only for the conditions noted above, such as age and condition of the target, and would change over time. Therefore, safety and efficacy analysis can only be based on relative differences between the lenses, not absolute values. Visibility distance values could be biased to allow a very large difference between lenses to satisfy stopping distance requirements by making the simulator targets visible at very large distances or, conversely, visibility distance values could be biased to allow a very small difference between lenses to satisfy stopping distance requirements by making the simulator targets visible at very small distances. With this in mind, further analysis uses the actual target visibility distance examples first reported in the validation study literature for the NDS.
The ability of ReSTOR® IOL patients to detect and identify road signs and hazards at night was similar to the monofocal controls under normal visibility driving conditions.

Sign Identification

Rural Driving Conditions
The mean visibility distances, standard deviation and percentage difference of monofocal and ReSTOR® IOL subjects for sign identification under normal, fog and glare conditions in the rural scene are shown in Table 12.
Both fog and glare are seen to cause larger differences between the monofocal and ReSTOR® lens subject performance than the clear night condition. However, in all instances the mean differences were less than 15%.

Table 12:
Mean (± SD) Sign Identification Distances in Rural Scene

Identification Distance (feet)		Lens		Difference	% Loss over Control
		Control	ReSTOR®		
Visibility Condition	Targets				
Normal	Text	249 ± 57	230 ± 41	19	7.5 %
	Warning	523 ± 68	476 ± 81	47	8.9 %
Fog	Text	248 ± 42	215 ± 50	33	13.4 %
	Warning	512 ± 89	453 ± 88	60	11.6 %
Glare	Text	228 ± 56	195 ± 52	33	14.1 %
	Warning	512 ± 89	448 ± 83	64	12.5 %

1 This sub-study was conducted as part of the original AcrySof® ReSTOR® Apodized Diffractive Optic IOL clinical evaluations, not with the AcrySof® IQ ReSTOR® IOL models (SN6AD3 and SN6AD1).

City Driving Conditions
The mean visibility distances, standard deviation and percentage difference of monofocal and ReSTOR® IOL subjects for sign identification under normal, fog and glare conditions in the city scene are shown in Table 13.
Under glare conditions, the ability of the ReSTOR® lens subjects to identify the text sign is reduced on average by 28%, however there was only a small difference under these conditions for the warning sign.

Table 13:
Sign Identification Distances in City Scene

Identification Distance (feet)		Lens		Difference	% Loss Over Control
		Control	ReSTOR®		
Visibility Condition	Targets				
Normal	Text	160 ± 30	143 ± 31	17	10.8 %
	Warning	211 ± 26	201 ± 25	10	4.7 %
Fog	Text	159 ± 24	138 ± 34	21	13.2 %
	Warning	208 ± 23	184 ± 31	24	11.7 %
Glare	Text	142 ± 33	102 ± 46	40	28 %
	Warning	194 ± 26	170 ± 28	24	12.5 %

Detecting Hazards

Rural Conditions
The mean visibility distances, standard deviation and percentage difference of monofocals and ReSTOR® IOLs for hazard detection under normal, fog and glare conditions in the rural scene are shown in Table 14. In rural conditions, all differences for detecting hazards were less than 20%.

Table 14:
Hazard Detection Distances in Rural Scene

Detection Distance (feet)	Lens		Difference	% Loss Over Control
	Control	ReSTOR®		
Visibility Condition				
Normal	511 ± 80	474 ± 87	37	7.2 %
Fog	507 ± 92	465 ± 101	42	8.5 %
Glare	480 ± 98	386 ± 150	94	19.7 %

City Conditions
The mean hazard detection, standard deviation and percentage differences for control and ReSTOR® IOL subject groups for hazard detection under normal, fog and glare conditions in the city scene are shown in Table 15. For city conditions, in all instances the mean differences were less than 15%.

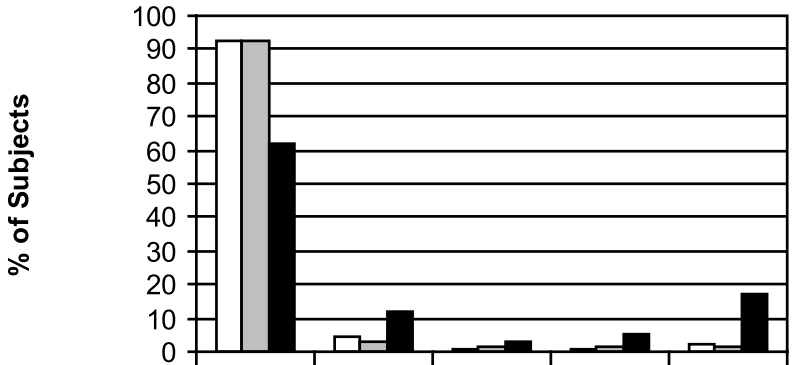
Table 15:
Hazard Detection Distances in City Scene

Detection Distance (feet)	Lens		Difference	% Loss Over Control
	Control	ReSTOR®		
Visibility Condition				
Normal	200 ± 52	183 ± 38	17	8.5 %
Fog	229 ± 66	211 ± 65	18	7.9 %
Glare	190 ± 67	166 ± 48	24	12.6 %

Retinal Detail
No difficulties in retinal treatment were encountered by any investigator in the study. However, one investigator had 20 reports of loss of retinal detail (i.e., the fundus appeared more anterior).

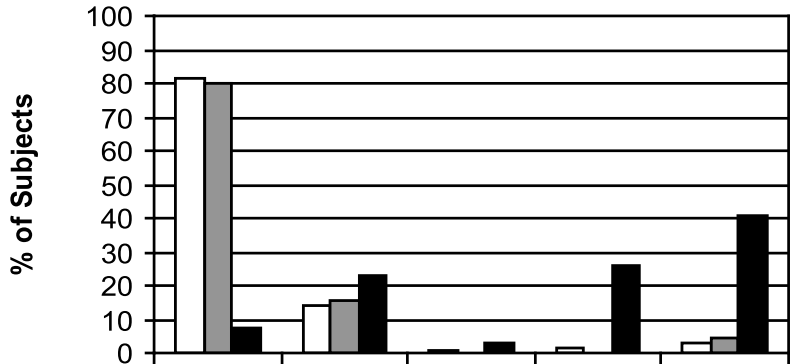
Quality of Life/Spectacle Independence
Patient reported spectacle independence was determined using the Cataract TyPE Specification instrument (Javitt, 1997). ReSTOR® IOL spectacle independence rates were statistically better ($p<0.0001$) than the control rates.

Figure 6:
Frequency of Spectacle Wear
Distance Vision, Bilateral Comparison



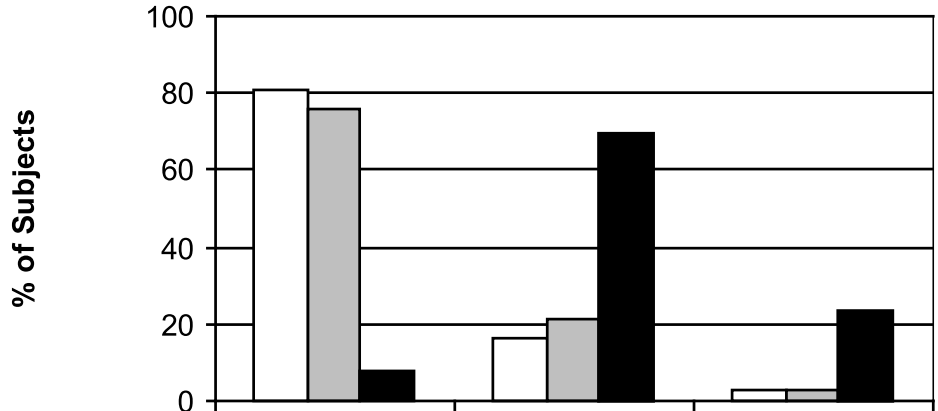
	None of the time	Some of the time	Half of the time	Most of the time	All of the time
MA60D3	92.5	4.5	0.4	0.8	1.9
SA60D3	92.9	2.9	1.4	1.4	1.4
Control	62.2	12.2	3.2	5.1	17.3

Figure 7:
Frequency of Spectacle Wear
Near Vision, Bilateral Comparison



	None of the time	Some of the time	Half of the time	Most of the time	All of the time
MA60D3	81.2	13.9	0.4	1.5	3
SA60D3	80	15.7	0	0	4.3
Control	7.7	23.2	2.6	25.8	40.6

Figure 8:
Overall Frequency of Spectacle Wear, Bilateral Comparison



	Never	Sometimes	Always
MA60D3	81	16	3
SA60D3	75.7	21.4	2.9
Control	7.7	69.2	23.1

Table 16:
Patient Satisfaction with Vision (without glasses)

		MA60D3	SA60D3	Control
Overall	Baseline	0.6 (N=311)	0.5 (N=126)	0.6 (N=193)
	Unilateral	2.6* (N=309)	2.5 (N=124)	2.4 (N=184)
	Bilateral	3.5** (N=268)	3.4** (N=69)	3.0 (N=155)
Day Vision	Baseline	0.9 (N=311)	0.7 (N=126)	0.8 (N=194)
	Unilateral	2.7* (N=309)	2.6 (N=123)	2.5 (N=185)
	Bilateral	3.5** (N=269)	3.4** (N=68)	3.0 (N=156)
Night Vision	Baseline	0.6 (N=311)	0.5 (N=126)	0.6 (N=193)
	Unilateral	2.4 (N=309)	2.5 (N=124)	2.4 (N=185)
	Bilateral	3.3** (N=269)	3.2* (N=69)	2.9 (N=156)

Satisfaction Scale (0-4): 0=not at all satisfied, 4=completely satisfied.
*=Significantly different from control at 0.05 level
**=Significantly different from control at 0.01 level

Table 17:
Self Rating of Vision (without glasses)

	MA60D3	SA60D3	Control
Baseline	4.2 (N=313)	4.1 (N=125)	4.1 (N=194)
Unilateral	7.1 (N=307)	7.1 (N=123)	6.9 (N=185)
Bilateral	8.7* (N=266)	8.9* (N=70)	7.9 (N=155)

Rating Scale (0-10): 0=worst possible vision, 10=best possible vision
*=Significantly different from control at 0.01 level

Adverse Events
The incidences of cumulative adverse events for the ReSTOR® IOL as compared to the FDA historical grid rates are provided in Table 18. A single occurrence of retinal detachment/repair, single occurrence of pupillary block, and surgical reinterventions exceeded the FDA Grid rate. No occurrences of persistent adverse events (adverse events in the FDA grid that are observed at the 12 month postoperative visit) were observed in any patients implanted with the ReSTOR® IOL.

Table 18:
ReSTOR® IOL versus FDA Historical Grid, First Eye – Safety

	ReSTOR® MA60D3 (N=440)		ReSTOR® SA60D3 (N=126)		FDA Grid rate*
	N	%	N	%	%
Cumulative Adverse Events					
Endophthalmitis	0	0.0	0	0.0	0.1
Macular Edema	12	2.7	1	0.8	3.0
Retinal Detachment/Repair	0	0.0	1	0.8	0.3
Hyphema	0	0.0	0	0.0	2.2
Pupillary block	1	0.2	0	0.0	0.1
Lens Dislocation	0	0.0	0	0.0	0.1
Surgical reintervention	10	2.3	2	1.6	0.8
IOL replacement for biometry error	2	0.5	0	0.0	NA
IOL replacement for incorrect power/ operating room error	2	0.5	0	0.0	NA
IOL replacement for visual disturbance	1	0.2	0	0.0	NA
IOL replacement for decentered IOL due to trauma	1	0.2	0	0.0	NA
IOL replacement due to patient dissatisfaction	0	0.0	1	0.8	NA
Laser treatment	3	0.7	1	0.8	NA
Fibrin removal	1	0.2	0	0.0	NA
Persistent Adverse Events:					
Macular Edema	0	0.0	0	0.0	0.5
Raised IOP Requiring Treatment	0	0.0	0	0.0	0.4
Corneal Edema	0	0.0	0	0.0	0.3
Iritis	0	0.0	0	0.0	0.3

*FDA draft guidance on Monofocal Intraocular Lenses, Annex B (October 14, 1999)

Visual Disturbances
With the exception of blurred near vision and problems with color perception, the monofocal control patients had a lower rate of severe observations than the ReSTOR® IOL patients (Table 19). Of the 440 subjects implanted with ReSTOR® IOL Model MA60D3 and 126 subjects implanted with Model SA60D3, one subject implanted with ReSTOR® IOL Model MA60D3 required lens explantation due to visual disturbances.

Table 19:
Visual Disturbances, 6 Months Postoperative
(Following second eye implantation)

Visual Disturbance	ReSTOR® Model MA60D3		ReSTOR® Model SA60D3		Monofocal Control	
	% Moderate	% Severe	% Moderate	% Severe	% Moderate	% Severe
Glare/Flare	20.1	4.9	23.2	4.3	7.1	1.9
Problems with Night Vision	8.5	4.1	10.1	2.9	3.8	1.9
Halos	18.0	4.4	23.2	7.2	1.9	1.3
Distorted Near Vision	0.8	0.8	0.0	0.0	0.6	0.0
Distorted Far Vision	1.0	0.3	0.0	0.0	0.6	0.0
Blurred Near Vision	5.9	0.8	7.2	0.0	12.8	3.8
Blurred Far Vision	5.9	1.0	5.8	0.0	3.2	0.6
Double Vision in both eyes	1.5	0.8	1.4	0.0	1.3	0.0
Problems with Color Perception	0.5	0.0	0.0	0.0	0.0	0.0

2. AcrySof® IQ ReSTOR® POSTERIOR CHAMBER IOLS

Summary of Clinical Study (Models SN6AD3 and SN6AD1)
A randomized, prospective, multicenter clinical study was conducted on cataractous subjects bilaterally implanted with either the AcrySof® IQ ReSTOR® IOL Model SN6AD3 or Model SN6AD1 to compare the clinical outcomes achieved with these IOLs which differ only in the amount of near add power (+4.0 D and +3.0 D, respectively). A total of 279 subjects were implanted in this clinical study with 270 and 272 subjects having completed the 3-month and 6-month follow-up examination, respectively. Demographically, the study consisted of 68.5% female and 31.5% male patients. Stratifying by race, there were 95.0% White, 2.5% Black, 0.7% Asian, 0.4% American Indian, and 2.5% designated “Other” race. The mean age for the study population was 69 ± 8 years.
Comparable clinical performance relative to near and distance visual acuity were observed for both Model SN6AD1 and SN6AD3, with better intermediate visual acuity noted for Model SN6AD1.
The study also identified that the average distance of best focus for near vision differed by approximately 6-7 cm. Compared to Model SN6AD3, Model SN6AD1 provides increased acuity at working distances farther than approximately 40 cm and reduced reading acuity at working distances closer than or equal to 33 cm. These clinical findings provide meaningful options, depending on patients’ lifestyle and personal preference.

Binocular Visual Acuity
The binocular photopic near and distance visual acuity measurements for the Model SN6AD1 are clinically and statistically equivalent to the control Model SN6AD3. Model SN6AD1 provides a one Snellen line or more improvement in mean distance corrected binocular intermediate visual acuity as compared to Model SN6AD3. Results are presented in Tables 20-23.
The near acuities listed were adjusted for the working distance and that the print size that can be read with Model SN6AD3 at ~33 cm is smaller than the print size that can be read with Model SN6AD1 at ~40 cm.

Table 20: Overall Comparison of AcrySof® IQ ReSTOR® IOLs
Mean Binocular Distance-Corrected Visual Acuity (logMAR)
6 Months Postoperative

Model	Near VA @ Best Distance	Intermediate VA @ 50cm	Distance VA
SN6AD1 (+3.0 D)	0.07 (20/25)	0.06 (20/25)	-0.05 (20/20)
SN6AD3 (+4.0 D)	0.10 (20/25)	0.28 (20/40)	-0.05 (20/20)

“Near” acuities were adjusted for the working distance – “20/20” letter font size is smaller for patients tested at a “near” distance of ~31-33 cm (patients implanted with Model SN6AD3) than it is for patients tested at a “near” distance of ~37-40 cm (patients implanted with Model SN6AD1). Patients implanted with the +4 add model will generally be able to read smaller font size at “near” than those implanted with the +3 add, due to the different working distance.

Table 21a: Binocular Visual Acuity Achieved at All of Three Testing Distances (Near VA @ Best Distance, Intermediate VA @ 50 cm, Distance VA @ 4 m), All Implanted at 6 Months Postoperative

	Model SN6AD3 (+4.0 D) N=134	
	n	%
20/20 or Better	10	7.5
20/25 or Better	30	22.4
20/32 or Better	60	44.8
20/40 or Better	88	65.7
Worse than 20/40	46	34.3

Average Near Best Distance = 31 cm
"Near" acuities were adjusted for the working distance – "20/20" letter font size is smaller for patients tested at a "near" distance of ~31-33 cm (patients implanted with Model SN6AD3) than it is for patients tested at a "near" distance of ~37-40 cm (patients implanted with Model SN6AD1). Patients implanted with the +4 add model will generally be able to read smaller font size at "near" than those implanted with the +3 add, due to the different working distance.

Table 21b: Binocular Visual Acuity Achieved at All of Three Testing Distances (Near VA @ Best Distance, Intermediate VA @ 50 cm, Distance VA @ 4 m), All Implanted at 6 Months Postoperative

	Model SN6AD1 (+3.0 D) N=138	
	n	%
20/20 or Better	53	38.4
20/25 or Better	92	66.7
20/32 or Better	126	91.3
20/40 or Better	132	95.7
Worse than 20/40	6	4.3

Average Near Best Distance = 37 cm
"Near" acuities were adjusted for the working distance – "20/20" letter font size is smaller for patients tested at a "near" distance of ~31-33 cm (patients implanted with Model SN6AD3) than it is for patients tested at a "near" distance of ~37-40 cm (patients implanted with Model SN6AD1). Patients implanted with the +4 add model will generally be able to read smaller font size at "near" than those implanted with the +3 add, due to the different working distance.

Table 22: Cumulative Binocular Photopic Near Visual Acuity of AcrySof® IQ ReSTOR® IOLs by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected (Best Distance*)	SN6AD1 (+3.0 D)	138	38.4	77.5	90.6	97.1	2.9
	SN6AD3 (+4.0 D)	134	29.9	66.4	85.8	96.3	3.7
Uncorrected (Standard Distance**)	SN6AD1 (+3.0 D)	138	45.7	74.6	92.0	94.9	5.1
	SN6AD3 (+4.0 D)	134	27.6	61.9	83.6	93.3	6.7
Distance Corrected (Best Distance)	SN6AD1 (+3.0 D)	138	44.9	75.4	92.8	95.7	4.3
	SN6AD3 (+4.0 D)	134	35.8	66.4	90.3	97.8	2.2
Distance Corrected (Standard Distance)	SN6AD1 (+3.0 D)	138	58.0	86.2	92.8	96.4	3.6
	SN6AD3 (+4.0 D)	134	41.8	74.6	91.0	98.5	1.5
Best Corrected (Standard Distance)	SN6AD1 (+3.0 D)	138	65.9	84.8	93.5	96.4	3.6
	SN6AD3 (+4.0 D)	134	50.0	79.9	94.8	97.8	2.2

*Best distance: The distance selected by the subject as the distance of best near vision
**Standard distance: 33 cm for Model SN6AD3 and 40 cm for Model SN6AD1
"Near" acuities were adjusted for the working distance – "20/20" letter font size is smaller for patients tested at a "near" distance of ~31-33 cm (patients implanted with Model SN6AD3) than it is for patients tested at a "near" distance of ~37-40 cm (patients implanted with Model SN6AD1). Patients implanted with the +4 add model will generally be able to read smaller font size at "near" than those implanted with the +3 add, due to the different working distance.

Table 23: Cumulative Binocular Photopic Distance Visual Acuity of AcrySof® IQ ReSTOR® IOLs by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	SN6AD1 (+3.0 D)	138	60.1	84.8	94.9	98.6	1.4
	SN6AD3 (+4.0 D)	134	67.9	86.6	95.5	97.8	2.2
Best Corrected	SN6AD1 (+3.0 D)	138	88.4	97.8	97.8	99.3	0.7
	SN6AD3 (+4.0 D)	134	89.6	98.5	99.3	100.0	0.0

"Near" acuities were adjusted for the working distance – "20/20" letter font size is smaller for patients tested at a "near" distance of ~31-33 cm (patients implanted with Model SN6AD3) than it is for patients tested at a "near" distance of ~37-40 cm (patients implanted with Model SN6AD1). Patients implanted with the +4 add model will generally be able to read smaller font size at "near" than those implanted with the +3 add, due to the different working distance.

Near Visual Acuity
The distance of best focus for near vision was also recorded for each patient. Patients receiving Model SN6AD3 (+4.0 D near add power) exhibited best near vision at an average distance of 31 cm while those receiving the Model SN6AD1 (+3.0 D near add power) exhibited best near vision at an average distance of 37 cm.

Defocus[2]
Depth of focus data were captured on Best Case (patients with no preoperative ocular pathology and no macular degeneration at any time) patients implanted binocularly with either Model SN6AD1 (116 patients) or Model SN6AD3 (114 patients).

2 Refer to Defocus section on page 8, the monofocal lens defocus curve from the previous clinical study.

A binocular defocus curve displays two peaks for each lens model, with one at the zero baseline corresponding to the distance focal point of the lens (infinity) and the other at the -2.5 D (SN6AD1) and –3.0 D (SN6AD3), respectively, which corresponds to the near focal point of the lens. The peaks of the distance and near curves of the Model SN6AD1 and SN6AD3 were similar in height and magnitude to each other. Patients achieved mean distance visual acuity of 20/20 and near visual acuities of 20/20 (SN6AD1) and 20/25 (SN6AD3), respectively.
As a result of the +3.0 D near add power in Model SN6AD1, the amplitude of functional vision was reduced by 0.75 D to 3.75 D as compared to the 4.5 D observed with Model SN6AD3 having a +4.0 D near add power.
On average, Model SN6AD1 patients achieved the following visual performance characteristics compared to Model SN6AD3 patients:

- A 20% increase (approximately 2.5 inches) in distance of best near visual acuity
- Visual acuity of 20/25 or better on average across a full range of near to intermediate distances (from 13 to 24 inches for activities such as reading and computer work) while maintaining comparable distance visual acuity to SN6AD3
- Twice the near to intermediate range of vision at 20/25 or better (range of approximately 11 inches versus 5 inches)
- Visual acuity of better than 20/32 from approximately 12 inches to infinity

Table 24 is based on a subgroup of patients (Best Case patients) implanted binocularly with either Model SN6AD1 (116 patients) or Model SN6AD3 (114 patients). Ranges were approximated based on interpolation between measured pointed on the defocus curve.

Table 24: Range of Vision at Various Acuity Levels

Average VA	SN6AD1 (+3.0)		SN6AD3 (+4.0)	
	Min. Near Distance	Max. Near Distance	Min. Near Distance	Max. Near Distance
20/25 or better	33 cm / 13 in	61 cm / 24 in	27 cm / 11 in	41 cm / 16 in
20/32 or better	30 cm / 12 in	Infinity	25 cm / 10 in	47 cm / 18 in
20/40 or better	26 cm / 10 in	Infinity	23 cm / 9 in	Infinity

Figure 9: Mean Defocus Curve for AcrySof® IQ ReSTOR® IOLs by Lens Model, Binocular, Best Case, 6 Months Postoperative

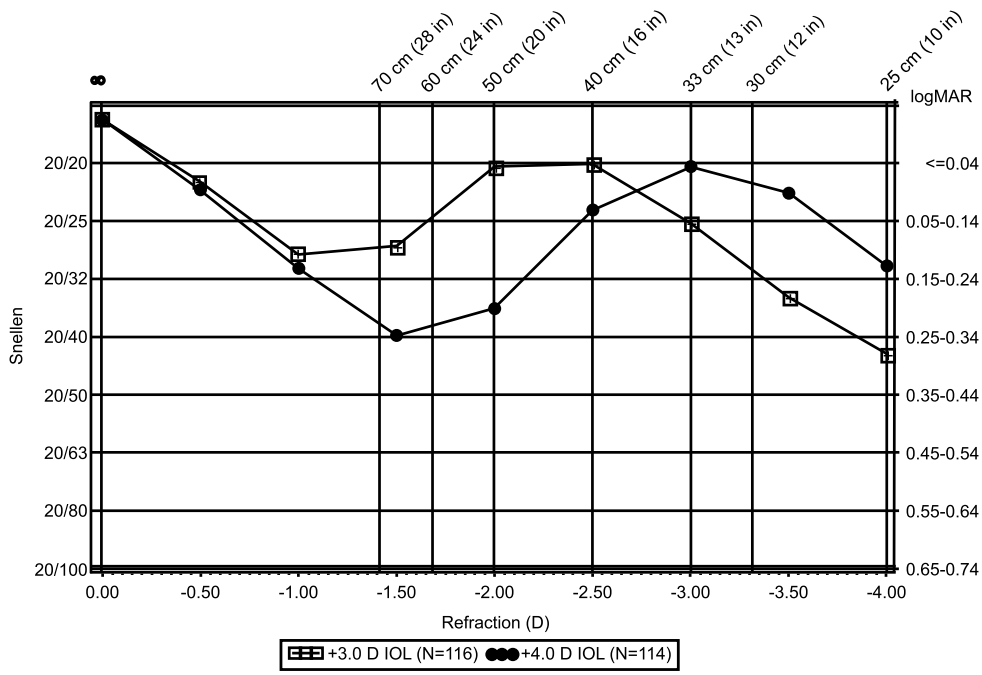


Figure 10: Mean Defocus Curves for AcrySof® IQ ReSTOR® IOLs by Pupil Size for Lens Model +3.0 D Add Power, Binocular, Best Case, 6 Months Postoperative

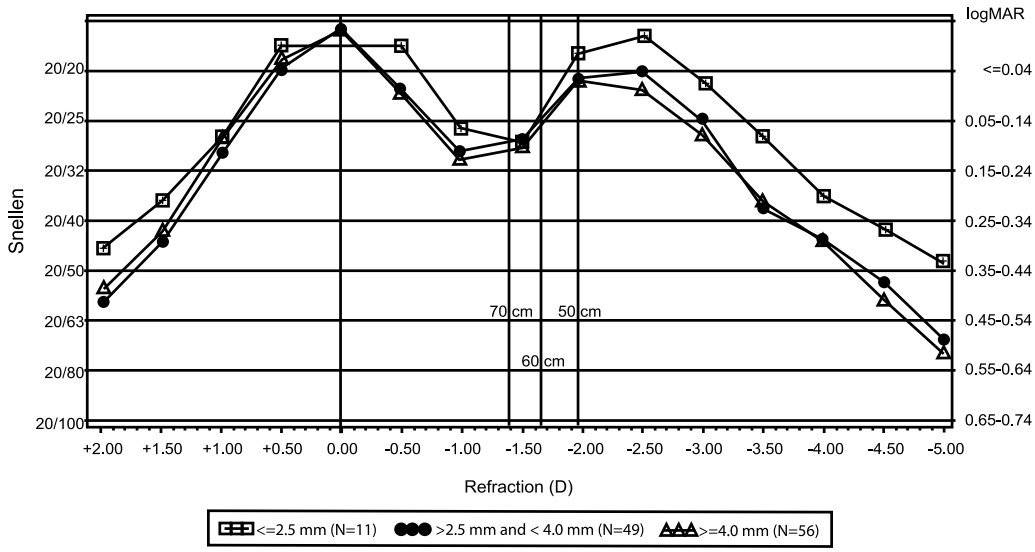
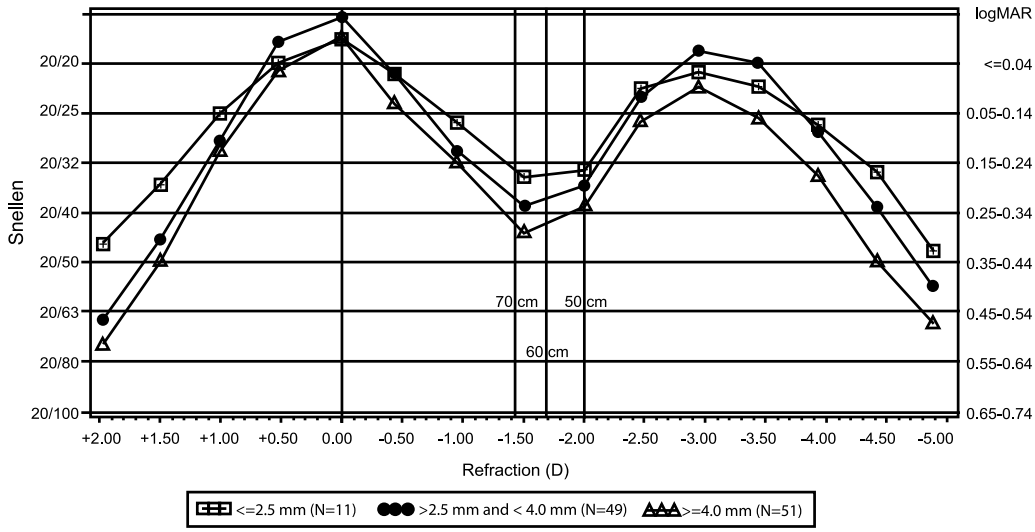


Figure 11: Mean Defocus Curves for AcrySof® IQ ReSTOR® IOLs by Pupil Size for Lens Model +4.0 D Add Power, Binocular, Best Case, 6 Months Postoperative



Intermediate Vision
The performance of Model SN6AD1 was compared to the control Model SN6AD3 for uncorrected and distance corrected intermediate vision at 50 cm, 60 cm, and 70 cm. As illustrated in Table 25 below, Model SN6AD1 demonstrated a clinically relevant increased improvement in uncorrected and distance corrected visual acuity and provides a one line or more improvement in binocular intermediate visual acuity as compared to Model SN6AD3.

Table 25: Intermediate Photopic Visual Acuity for AcrySof® IQ ReSTOR® IOLs, Binocular, All Implanted, 6-Months Postoperative

		Total Sample Size	Percent 20/25 or better			Percent 20/32 or better			Percent 20/40 or better		
			50 cm	60 cm	70 cm	50 cm	60 cm	70 cm	50 cm	60 cm	70 cm
Uncorrected	SN6AD1 (+3.0 D)	138	63.8	50.0	32.6	81.2	76.1	60.1	92.0	90.6	84.8
	SN6AD3 (+4.0 D)	134	20.1	23.9	20.9	46.3	38.8	36.6	70.1	63.4	59.0
Distance Corrected	SN6AD1 (+3.0 D)	138	81.9	66.7	30.4	94.2	85.5	64.5	96.4	94.2	85.5
	SN6AD3 (+4.0 D)	134	24.6	14.9	8.2	46.3	35.1	20.1	66.4	57.5	41.0

Statistical analyses of binocular distance corrected intermediate distance visual acuity demonstrate the superiority of Model SN6AD1 compared to Model SN6AD3 IOL. Mean distance corrected intermediate distance visual acuity was at least 1.5 logMAR lines greater for Model SN6AD1 at all three distances and remained statistically significant after adjustment for multiple testing. (Table 26)

Table 26: Mean LogMAR Distance Corrected Intermediate Visual Acuity, for AcrySof® IQ ReSTOR® IOLs, Binocular, All Implanted, 6-Months Postoperative

Intermediate VA	SN6AD1 (+3.0 D)	SN6AD3 (+4.0 D)	Difference	Adjusted P-values
50 cm	0.06	0.28	-0.22	<0.0001[1]
60 cm	0.11	0.32	-0.21	<0.0001[1]
70 cm	0.19	0.35	-0.16	<0.0001[1]

[1]Hommel's adjusted p-value for superiority following a test of non-inferiority

Contrast Sensitivity[3]

A Vector Vision (CSV1000) contrast sensitivity chart that employs a full range of sine wave gratings at 9 contrast levels and 5 spatial frequencies (1.5, 3, 6, 12, and 18 cpd) was used to assess contrast sensitivity under photopic (85 cd/m^2) and mesopic (3 cd/m^2) conditions, with and without a glare source.

Comparisons of contrast sensitivity measures demonstrated clinical equivalence between Model SN6AD1 and Model SN6AD3 under the lighting conditions and spatial frequencies tested. All differences in mean contrast sensitivity were less than 0.15 log units between lens models (Table 27).

For binocular contrast sensitivity testing, at least 76.3% of patients in both the Model SN6AD1 and Model SN6AD3 groups were able to see at least one grating, with the exception of mesopic with glare testing at 12 cycles per degree (cpd). At this spatial frequency and lighting condition, the percentage of Model SN6AD1 patients able to see at least one grating was 69.8% as compared to 70.2% of Model SN6AD3 patients.

Table 27: Mean Log Decrease in Contrast Sensitivity for AcrySof® IQ ReSTOR® IOLs, Model SN6AD1 Compared to Model SN6AD3, Under Photopic and Mesopic Glare Conditions, Binocular, All Implanted, 6 Months Postoperative

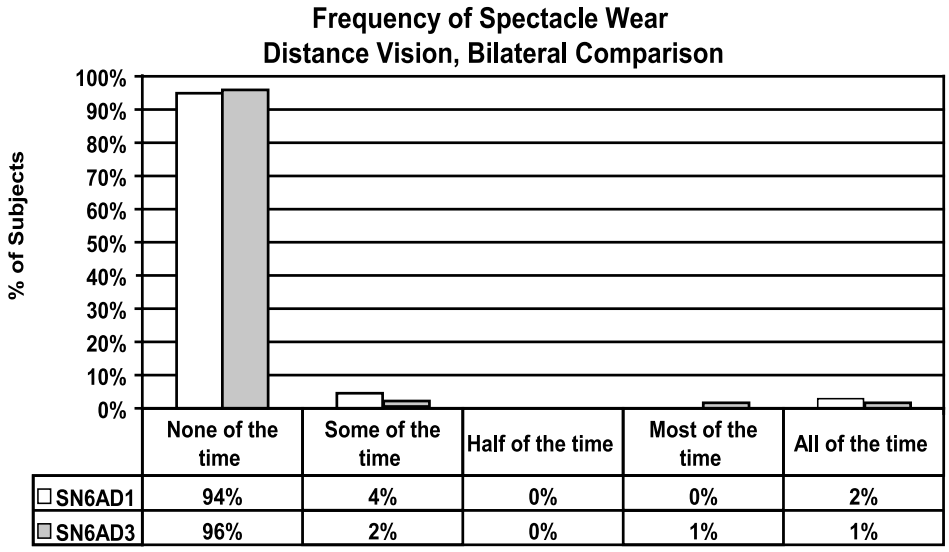
	Spatial Frequency (cpd)				
Light Source (↓)	E (1.5)	A (3)	B (6)	C (12)	D (18)
Photopic w/o Glare	-	-0.04	-0.03	0.01	-0.01
Photopic w/ Glare	-	-0.02	-0.02	-0.02	-0.04
Mesopic w/o Glare	0.00	-0.04	-0.08	-0.07	-
Mesopic w/ Glare	0.03	-0.04	-0.06	-0.07	-

Patient-Reported Outcomes/Spectacle Independence

Patient-reported spectacle independence was determined using the Cataract TyPE Specification instrument (Javitt, 1997). Spectacle independence rates between the Model SN6AD1 and Model SN6AD3 were similar, with better than 78% of patients in both groups reporting "never" having to use glasses at any time.

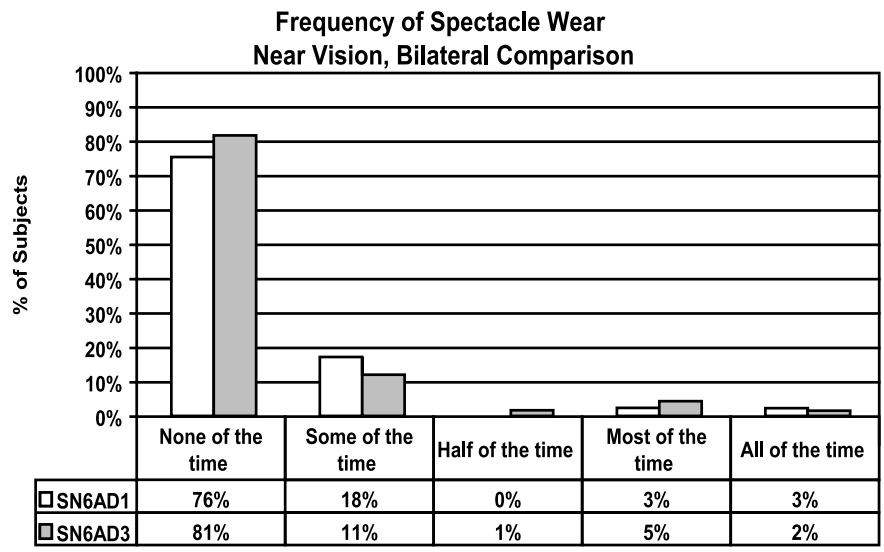
[3] Refer to Low Contrast Visual Acuity and Contrast Sensitivity section on page 10 for a comparison of multifocal to monofocal lenses from the previous clinical study.

Figure 12: Frequency of Spectacle Wear for AcrySof® IQ ReSTOR® IOLs, Distance Vision, Bilateral Comparison, 6 Months Postoperative



	None of the time	Some of the time	Half of the time	Most of the time	All of the time
SN6AD1	94%	4%	0%	0%	2%
SN6AD3	96%	2%	0%	1%	1%

Figure 13: Frequency of Spectacle Wear for AcrySof® IQ ReSTOR® IOLs, Near Vision, Bilateral Comparison, 6 Months Postoperative



	None of the time	Some of the time	Half of the time	Most of the time	All of the time
SN6AD1	76%	18%	0%	3%	3%
SN6AD3	81%	11%	1%	5%	2%

Figure 14: Overall Frequency of Spectacle Wear, for AcrySof® IQ ReSTOR® IOLs, Bilateral Comparison, 6 Months Postoperative

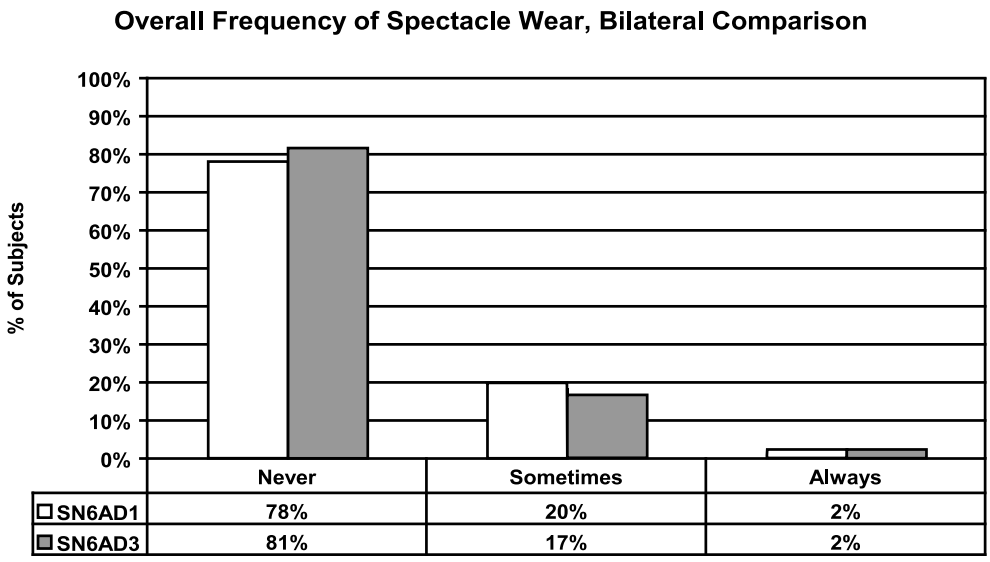


Table 28: Patient Satisfaction with Vision (without glasses), 6 Months Postoperative

		SN6AD1 (+3.0 D)	SN6AD3 (+4.0 D)
Overall	Baseline	0.5	0.5
	Bilateral	3.3	3.3
Day Vision	Baseline	0.7	0.7
	Bilateral	3.3	3.4
Night Vision	Baseline	0.6	0.5
	Bilateral	3.1	3.0

Scale: 0-4 (0=not at all satisfied; 4=completely satisfied)

Table 29: Self Rating of Vision (without glasses), 6 Months Postoperative

	SN6AD1 (+3.0 D)	SN6AD3 (+4.0 D)
Baseline	4.2	3.8
Bilateral	8.5	8.4

Scale: 0-10 (0=worst; 10=best)

Visual Disturbances[4]

There is no clinically relevant increase of severe visual disturbances when implanting Model SN6AD1 compared to the control Model SN6AD3 (Table 30a). In the patient satisfaction survey, the majority of patients implanted with Model SN6AD1 (93.5%) and the control Model SN6AD3 (92.0%) indicated that they would have the lenses implanted again. However, one patient with Model SN6AD1 underwent IOL replacement to resolve visual disturbances after the close of the study.

4 Refer to Visual Disturbances section on page 15 for a comparison of multifocal to monofocal lenses from the previous clinical study.

Table 30a: AcrySof® IQ ReSTOR® IOL Visual Disturbances, 6 Months Postoperative (following second eye implantation)

Visual Disturbance	Model SN6AD1 (+3.0 D)				Model SN6AD3 (+4.0 D)			
	N	None/ Mild	Mod	Severe	N	None/ Mild	Mod	Severe
		%	%	%		%	%	%
Glare/Flare	138	70.3	24.6	5.1	134	72.4	20.9	6.7
Halos	138	65.9	27.5	6.5	134	63.4	26.9	9.7
Distorted Near Vision	138	99.3	0.7	0.0	134	100.0	0.0	0.0
Distorted Far Vision	138	99.3	0.7	0.0	134	100.0	0.0	0.0
Blurred Near Vision	138	77.5	18.1	4.3	134	81.3	14.9	3.7
Blurred Far Vision	138	92.0	7.2	0.7	134	96.3	3.0	0.7
Problems with Night Vision	138	88.4	9.4	2.2	134	83.6	10.4	6.0
Double Vision with Both Eyes	138	97.1	2.9	0.0	134	97.8	2.2	0.0
Problems with Color Perception	138	97.8	1.4	0.7	134	98.5	1.5	0.0

None/Mild=0-2, Moderate=3-5, Severe=6-7

All mean visual disturbance ratings were within the None/Mild category (less than 3 on a scale of 0 to 7) for both the Model SN6AD1 and the control Model SN6AD3 (Table 30b).

Table 30b: AcrySof® IQ ReSTOR® IOL Visual Disturbance Mean Impact Ratings, 6 Months Postoperative (following second eye implantation)

Visual Disturbance	Model SN6AD1 (+3.0 D)			Model SN6AD3 (+4.0 D)		
	Mean	Std	N	Mean	Std	N
Glare/Flare	1.6	2.0	138	1.6	2.0	134
Halos	1.9	1.9	138	2.2	2.0	134
Distorted Near Vision	0.1	0.3	138	0.0	0.2	134
Distorted Far Vision	0.0	0.3	138	0.0	0.2	134
Blurred Near Vision	1.2	1.9	138	1.1	1.8	134
Blurred Far Vision	0.5	1.3	138	0.3	0.9	134
Problems with Night Vision	0.7	1.5	138	1.1	1.8	134
Double Vision with Both Eyes	0.1	0.6	138	0.1	0.6	134
Problems with Color Perception	0.1	0.7	138	0.1	0.4	134

None/Mild=0-2, Moderate=3-5, Severe=6-7

Adverse Events[5]

No unanticipated serious adverse device effects were observed in any patients implanted with Models SN6AD1 or SN6AD3. Adverse events shown in Table 31 were reported as unrelated to the IOL, except for one case (Model SN6AD1) with a lens replacement to resolve visual disturbances after the close of the study.

5 Refer to the Adverse Events section on page 15 for results from the full one year study to establish safety and effectiveness of the ALCON® ReSTOR® multifocal lens. This section includes a comparison of the multifocal results to those of the monofocal lens.

Table 31: AcrySof® IQ ReSTOR® IOLs (Models SN6AD1 and SN6AD3), First and Second Eye – Safety

	First Eye				Second Eye			
	SN6AD1 (+3.0 D) (N=153)		SN6AD3 (+4.0 D) (N=147)		SN6AD1 (+3.0 D) (N=151)		SN6AD3 (+4.0 D) (N=143)	
	N	%	N	%	N	%	N	%
Cumulative Adverse Events								
Hypopyon	1[a]	0.7	0	0	0	0	0	0
Endophthalmitis	1[a]	0.7	0	0	0	0	0	0
Macular Edema	4	2.6	2	1.4	0	0	1	0.7
Retinal Detachment/Repair	0	0	0	0	0	0	0	0
Hyphema	0	0	0	0	0	0	0	0
Pupillary block	0	0	0	0	0	0	0	0
Lens Dislocation	1[b]	0.7	0	0	0	0	0	0
Surgical reintervention	2	1.3	1	0.7	2	1.3	2	1.4
IOL repositioning	1[b]	0.7	0	0	0	0	0	0
IOL replacement for biometry error	0	0	0	0	0	0	0	0
IOL replacement for incorrect power / operating room error	0	0	0	0	0	0	1	0.7
IOL replacement for visual disturbance	0	0	0	0	1[f]	0.7	0	0
IOL replacement for decentered IOL due to trauma	0	0	0	0	0	0	0	0
IOL replacement due to patient dissatisfaction	0	0	0	0	0	0	0	0
Laser treatment	0	0	0	0	0	0	0	0
Fibrin removal	0	0	0	0	0	0	0	0
Other surgical reintervention	1[a]	0.7	1[c]	0.7	1[d]	0.7	1[e]	0.7
Other	0	0	0	0	0	0	0	0

[a]One patient with hypopyon and endophthalmitis underwent secondary surgical intervention for two vitrectomy procedures.
[b]One patient underwent three lens repositioning procedures.
[c]One patient underwent posterior lamellar keratoplasty due to Fuchs' dystrophy and later developed macular edema.
[d]One patient underwent vitrectomy to repair a macular hole.
[e]One patient underwent removal of residual crystalline lens cortex in the anterior chamber.
[f]One patient underwent a lens replacement to resolve visual disturbances after the close of the study.

3. AcrySof® NATURAL SINGLE-PIECE IOL

Summary of Clinical Study (Model SB30AL)
A clinical study was conducted on patients receiving the AcrySof® Natural Single Piece IOL as compared to the AcrySof® UV Single Piece IOL. The results achieved by the patients successfully followed for a minimum of one year postoperatively provided reasonable assurance of safety and effectiveness for the visual correction of aphakia. For information pertaining to the results obtained in this clinical study, please reference the corresponding Physicians Labeling or that provided with other AcrySof® Natural monofocal IOLs.

Summary of Color Perception Study
Color perception testing using the Farnsworth D-15 Panel Test was conducted at the 120 to 180 day postoperative period. Of the 109 subjects with normal color vision implanted with the AcrySof® Natural IOL in the first operative eye and examined at the 120-180 day postoperative visit, 107 (98.2%) passed the color perception test. Of the 102 subjects with normal color vision implanted with a AcrySof® UV IOL in the first operative eye and examined at the 120-180 day postoperative visit, 97 (95.1%) passed the color perception test. There were no statistically significant differences between AcrySof® Natural IOL and AcrySof® UV IOL for the percent of subjects that passed the color perception test at the 120 to 180 day postoperative visit. Therefore, the addition of the proprietary chromophore does not negatively affect color vision in patients with normal color vision.

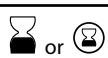
HOW SUPPLIED
The AcrySof® IQ ReSTOR® IOL is supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions (see DIRECTIONS FOR USE).

EXPIRATION DATE
Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to Alcon Laboratories, Inc. (see RETURNED GOODS POLICY).

RETURNED GOODS POLICY
In the United States, returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc. Returned Goods Number and be shipped via traceable means. A Returned Goods Number is obtained by contacting Alcon's Customer Service Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Sales or Customer Service Representative. Outside the United States, contact local Alcon offices or distributors regarding returned goods policy.

REFERENCES
Boettner, E.A. and Wolter, J.R. Transmission of the Ocular Media. *Invest. Ophthalmol*. 1:776-783, 1962.
Javitt, J, *et al*., Outcomes of Cataract Extraction with Multifocal Intraocular Lens Implantation. *Ophthalmol*. 104: 589-99, 1997.

Symbols Used on Labeling

SYMBOL	ENGLISH
IOL	Intraocular lens
PC	Posterior chamber
PCL	Posterior chamber lens
UV	Ultraviolet
D	Diopter
$Ø_B$	Body diameter (Optic diameter)
$Ø_T$	Overall diameter (Overall length)
	Do not reuse
	Use by (YYYY-MM: year-month)
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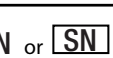	Serial Number
	Attention: See instructions for use
	Batch Code
	Manufacturer

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Fort Worth, Texas 76134-2099 USA

U.S. Pat. No's. 5,470,932; 5,699,142; 5,716,403; 7,879,089.