



1960028
Memorandum

Date .SEP - 5 1997

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Allergan, Inc.
Model SA40N AMO® Array® Multifocal Ultraviolet-Absorbing Silicone Posterior
Chamber Intraocular Lens - ACTION

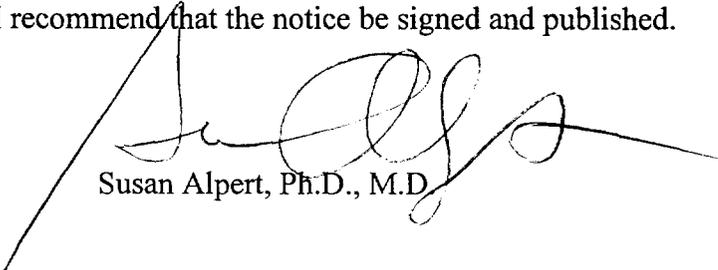
To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B);
and
- (2) the availability of a summary of safety and effectiveness data for the device
(Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.



Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ___ Disapproved ___ Date _____

Prepared by Ashley A. Boulware, CDRH, HFZ-460, August 4, 1997, 594-2053

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

Food and Drug Administration

[DOCKET NO. _____]

ALLERGAN, INC.; Premarket Approval of Model SA40N AMO[®]ARRAY[®]
Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber
Intraocular Lens

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Allergan, Inc., Irvine, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Model SA40N AMO[®]Array[®] Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 5, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Ms. Ashley A. Boulware,
Center for Devices and Radiological Health (HFZ-460),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-594-2053.

SUPPLEMENTARY INFORMATION: On September 3, 1996, Allergan, Inc., Irvine, CA 92612, submitted to CDRH an application for premarket approval of Model SA40N AMO®Array® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens. The device is a multifocal intraocular lens and is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed and who may benefit from useful near vision without reading add and increased spectacle independence across a range of distances where the potential visual effects associated with multifocality are acceptable. The lens is intended for placement in the capsular bag. The lens is available in powers of +16 to +24 diopters.

On July 10, 1997, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On September 5, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Marcia S. Yaross, Ph.D.
Director
Worldwide Regulatory Affairs
and Medical Compliance
Allergan Medical Optics
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92612-9534

SEP 5 1997

Re: P960028
Model SA40N AMO® Array® Multifocal Ultraviolet-Absorbing Silicone Posterior
Chamber Intraocular Lens (IOL)
Filed: September 3, 1996
Amended: October 9 and 28, 1996; December 2, 4, 10, and 23, 1996; January 30,
February 27, April 10, May 22, June 18, August 14 and 27, and
September 5, 1997

Dear Dr. Yaross:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Model SA40N AMO® Array® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens (IOL). This device is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed and who may benefit from useful near vision without reading add and increased spectacle independence across a range of distances where the potential visual effects associated with multifocality are acceptable. The lens is intended to be placed in the capsular bag. The lens is available in powers of +16 to +24 diopters. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH approval is subject to full compliance with the conditions described in the enclosure and the following:

- a. Registration of all patients receiving the above-referenced intraocular lens should be continued and the database should be maintained indefinitely, or until you are otherwise notified.
- b. A way of facilitating adverse reaction reporting, such as an 800 telephone number, should be maintained.
- c. Advertising and other printed materials prepared by your firm or its distributors should not include indications or claims not included in the FDA-approved labeling for the device, e.g., that the lens provides an improvement in intermediate vision or similar claims.

Expiration dating for this device has been established and approved at 5 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

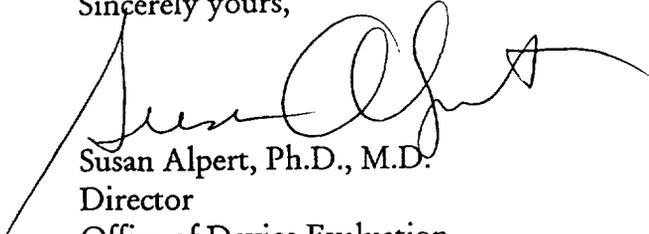
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact
Ms. Ashley A. Boulware at (301) 594-2053.

Sincerely yours,



Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
- (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
 - (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and
 - (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
 - (a) has not been addressed by the device's labeling or
 - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

- A. Generic Name of Device: Multifocal Posterior Chamber Intraocular Lens (IOL)
- B. Trade Names of Device: Model SA40N AMO® Array® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens
- C. Applicant's Name and Address:
Allergan, Inc.
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92731-9534
- D. Premarket Approval Application (PMA) Number: P960028
Date Filed: September 3, 1996
- E. Good Manufacturing Practice (GMP) Inspection Dates:
Date of Inspection (Irvine, CA Facility): August 26, 1997
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.
- F. Date of Ophthalmic Devices Panel Recommendation: July 10, 1997
- G. Date of Notice of Approval to Applicant: SEP - 5 1997

II. INDICATIONS

Model SA40N AMO® Array® Multifocal Silicone Posterior Chamber Intraocular Lens (IOL) (hereinafter called the Model SA40N) is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed and who may benefit from useful near vision without reading add and increased spectacle independence across a range of distances where the potential visual effects associated with multifocality are acceptable. This lens is intended to be placed in the capsular bag. The lens is available in powers of +16 to +24 diopters.

III. CONTRAINDICATIONS

None known.

IV. WARNINGS AND PRECAUTIONS

The following warnings and precautions are unique to Model SA40N. Additional warnings and precautions that apply to intraocular lenses can be found in the labeling (Attachment 1).

Warnings

1. Some visual effects may be expected because of the superposition of focused and unfocused multiple images. These include some perception of halos or radial lines around point sources of light under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. A very small percentage of patients (< 1% in the U.S. Clinical Study) may be dissatisfied to the point that they request explantation of the multifocal lens.
2. Under low contrast conditions, visual acuity is reduced with a multifocal lens when compared to a monofocal lens. Therefore, multifocal subjects 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 this IOL:**
 - The surgeon must target **emmetropia** as this lens is designed for optimum visual performance when emmetropia is achieved.
 - Patient selection and operative technique should be managed to ensure that the total postoperative corneal **astigmatism** does not exceed 1.5 diopters as effects of greater astigmatism on multifocal function are unknown.
 - Patients with **pupil sizes** less than 2.5 mm may not have any near benefit.
 - Care should be exercised to achieve **centration** of this IOL as visual performance may decrease with increasing decentration.
4. Although rarely observed during the clinical trial, the imaging quality and depth of field through this lens may potentially impact vitreoretinal surgery.

Precautions

1. Prior to surgery, the surgeon must provide prospective patients with a copy of the patient information brochure for this product and inform these patients of the possible risks and benefits associated with the use of this device.
2. The same degree of near benefit may not be achieved by all patients.
3. With regard to postoperative refraction, the +3.5 D add in the IOL plane corresponds, in most circumstances, to approximately +2.4 D to +2.8 D in the spectacle plane, depending on corneal power and anterior chamber depth. Note: autorefractors may not provide optimal postoperative refraction of multifocal patients. Manual refraction is strongly recommended.

4. Since the clinical study of the AMO® Array® multifocal IOL was conducted with the lens intended for implantation in the capsular bag, there are insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.
5. The safety and effectiveness of this lens have not been evaluated in patients with active ocular pathology or potential postoperative acuities worse than 20/30.

V. DEVICE DESCRIPTION

The Model SA40N multifocal intraocular lens has a biconvex optic with the multifocal lens geometry on the anterior surface. The lens has a 6 mm diameter ultraviolet-absorbing silicone (SLM-2) optic and extruded PMMA haptics in a modified-C configuration which provide an overall diameter of 13 mm. The multifocal area of the lens lies within a central 4.7 mm zone of the anterior surface. A series of annular zones of varying refractive power provide a continuous range of foci. For the range of apertures greater than 1.5 mm, the largest percentage of light energy is allocated to the distance image. The next significant portion of light energy is allocated to the near image region; the remaining light energy is distributed to intermediate foci. The lens is available in powers of +12 to +25 diopters in 0.5 diopter increments.

Model SA40N, the device approved in this PMA, is a Tier A modification of Model SSM-26NB, the model which was studied in the clinical trial. Model SA40N differs from Model SSM-26NB in the silicone optic material (SLM-2 versus SLM-1, both PMA-approved materials), the haptic material (PMMA versus polypropylene, both PMA-approved materials) and in its incorporation of a nearly constant center thickness design (the effective optic diameter varies with power to minimize variation in center thickness). Nonclinical testing demonstrates that these differences should not affect the mechanical or optical properties of the lens.

VI. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

A total of 456 Core patients were evaluated in a clinical trial to determine the safety of the AMO® Array® Multifocal Silicone Posterior Chamber Intraocular Lens. Of those, 400 Cohort patients were fully followed through the 12-14 month visit.

Secondary Surgical Interventions were reported as follows:

**Secondary Surgical Interventions
All Core Subjects (N=456)**

	Within One Year		After One Year*	
	n	%	n	%
Total Secondary Surgical Interventions	10 [†]	2.2	4	0.9
Repositioning of Lens	1	0.2	0	0.0
IOL Replacement for Improper Power Calculation	2	0.4	0	0.0
IOL Replacement for Optical/Visual Symptoms	1	0.2	2	0.4
IOL Replacement for Other Surgical Procedures (Enhanced Retinal Visualization)	1 [†]	0.2	0	0.0
Vitreotomy/Vitreolysis	3 [†]	0.6	0	0.0
Repair of Macular Hole/Vitreotomy	1	0.2	0	0.0
Argon Laser Retinopexy	1	0.2	0	0.0
Scleral Buckle Procedure	0	0.0	1	0.2
Cryotherapy to repair retinal tear	0	0.0	1 [‡]	0.2

* Includes patients experiencing Secondary Surgical Interventions after the final study visit as of May 10, 1996.

† Nine (9) subjects exhibited ten (10) interventions. One subject had two secondary surgical procedures, vitrectomy and IOL replacement.

‡ This patient was a participant in the Monofocal Fellow Eye Control Substudy (see Summary of Clinical Studies) and also underwent a scleral buckle procedure for the fellow eye implanted with an otherwise similar monofocal IOL.

Difficulty in maintaining stereopsis and fusion while performing an epiretinal membrane peel was reported in a single case. Additional effort to maintain fine focus was reported in a second epiretinal membrane peel. No other difficulty was reported in the other posterior segment procedures performed.

Potential secondary surgical interventions which have been associated with intraocular lenses, but did not occur in this clinical trial include: lens removal due to corneal touch, lens removal due to inflammation, corneal transplant, vitreous aspiration for pupillary block, iridectomy for pupillary block.

Contrast Acuity: Mean contrast acuities were lower in the multifocal eye than in the monofocal eye for the Monofocal Fellow Eye Control Subset (see Summary of Clinical Studies), with the mean differences between eyes ≤ 1.5 lines. The frequency of subjects with acuity in the multifocal eye > 2 lines less than the acuity in the monofocal eye increased with decreasing contrast and with the presence of glare to a maximum of 26.4% at 11% contrast with B.A.T. at low. (Testing was conducted using Regan acuity charts at 96%, 50%, 25% and 11% contrast for distance and C.A.T. charts at 100%, 50% 25% and 12.5% contrast for near acuities.)

Visual Symptoms: The most frequently occurring optical/visual symptoms were night flare/halos. The cumulative incidence of night flare/halos was 44.3% (177/400). The persistent incidence (at one year) of night flare/halos was 26.8% (107/400). The incidence of halos was significantly higher in multifocal eyes vs. monofocal eyes ($p < 0.001$). Statistically significant differences between multifocal and monofocal eyes were also observed for the mean degree of difficulty reported by subjects for glare/flare and blurred far vision.

**Difficulty with Visual Symptoms at One Year
Monofocal Fellow Eye Control Subset**

Question [†]	Difficulty	Multifocal Eye		Monofocal Eye	
		n	%	n	%
Halos	Moderate	23/98	23.5	22/98	22.4
	Severe	15/98	15.3	6/98	6.1
Glare/Flare	Moderate	35/95	36.8	30/95	31.6
	Severe	10/95	10.5	1/95	1.1
Blurred Far Vision	Moderate	11/96	11.5	9/96	9.4
	Severe	4/96	4.2	1/96	1.0
Distorted Near Vision	Moderate	15/99	15.2	11/99	11.1
	Severe	4/99	4.0	2/99	2.0
Distorted Far Vision	Moderate	7/98	7.1	7/98	7.1
	Severe	3/98	3.1	0/98	0.0
Night Vision	Moderate	27/95	28.4	27/95	28.4
	Severe	8/95	8.4	4/95	4.2
Blurred Near Vision	Moderate	14/97	14.4	18/97	18.6
	Severe	8/97	8.2	3/97	3.1
Diplopia One Eye	Moderate	11/99	11.1	9/99	9.1
	Severe	2/99	2.0	1/99	1.0
Diplopia Both Eyes	Moderate	8/99	8.1	8/99	8.1
	Severe	1/99	1.0	1/99	1.0
Depth Perception	Moderate	11/99	11.1	9/99	9.1
	Severe	1/99	1.0	1/99	1.0
Color Perception	Moderate	6/96	6.3	5/96	5.2
	Severe	0/96	0.0	0/96	0.0

[†] Patients were asked to indicate their degree of difficulty, if any, with each item.

Other complications: No incidence of hypopyon, intraocular infection or acute corneal decompensation was reported during the clinical study.

The complications experienced during the clinical trial of the AMO®Array® Multifocal Silicone Posterior Chamber Lenses include [clinical study rate vs. "FDA grid" rate (see Summary of Clinical Studies)]: macular edema (persistent) [0.8% vs. 0.8%], iritis (persistent) [0.3% vs. 1.0%], corneal edema (persistent) [0.0% vs. 0.6%], pupillary block (cumulative) [0.3% vs. 0.3%], secondary glaucoma (cumulative) [1.5% vs. N/A], and vitritis (cumulative) [0.5% vs. N/A]. Incidences of these complications were all comparable to or lower than those of the historical control ("FDA Grid") population.

Potential complications that did not occur in this clinical trial, but that may accompany cataract or implant surgery include, but are not limited to, the following: corneal endothelial damage, non-pigment precipitates, infection, retinal detachment, vitreous loss, iris prolapse, vitreous wick syndrome, uveitis and pupillary membrane.

VI. SUMMARY OF NONCLINICAL STUDIES

The applicant has performed nonclinical and clinical testing on this device in accordance with the FDA guidance document for testing intraocular lenses dated June 9, 1980 and the FDA guidance for multifocal intraocular lenses dated June 13, 1990. The applicant conducted a battery of in vivo and in vitro acute and chronic toxicity tests that establish the biocompatibility of the lens materials. These studies, combined with data from chemical and engineering analyses, demonstrate the suitability of the material and overall device design for use in an intraocular lens. The adequacy of the manufacturing processes, including sterilization, was established through review of the manufacturing information in the PMA as well as through on-site inspections. Nonclinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives.

VII. SUMMARY OF CLINICAL STUDIES

Objective and Study Design

The objective of the clinical study was to assess the safety and effectiveness of the AMO® Array® multifocal intraocular lens. Four hundred fifty-six (456) patients were enrolled in the Core study to achieve a final Cohort of 400 patients with complete follow-up. There were 14 investigational sites located in the U.S., 12 of which were represented in the Cohort population. Approximately 35 patients were enrolled at each U.S. site in order for each to contribute a minimum of 25 Cohort patients to the PMA. All patients were implanted with an AMO® Array® silicone multifocal IOL and followed for one year. A subset of these patients was enrolled as part of a Monofocal Fellow Eye Control Substudy. This substudy included 123 Core patients (103 Cohort), enrolled at five U.S. sites, who had a comparable monofocal IOL in their fellow eyes (implanted 4 to 8 weeks prior to the multifocal eye). The remaining 333 multifocal patients, not part of this substudy, had a fellow eye status of either multifocal (i.e., bilateral multifocal), monofocal (i.e., multifocal/ monofocal), cataractous or noncataractous.

Subject accountability for the 456 Core subjects enrolled was excellent, with 87.7% of subjects achieving Cohort status and only 1.8% of subjects lost-to-follow-up for the study. Comparison of Cohort and Noncohort subject demographics demonstrated the Cohort to be representative of the Core Study population.

Data were collected for preoperative, operative, and each of six postoperative reporting periods. In addition, a separate subject questionnaire was collected at the preoperative visit and at each of four postoperative visits. Among the 456 Core subjects, certain tests were required for all subjects whereas other tests were only required at specific sites. The tests required at specific sites are referred to as substudies of the entire study population and included: Contrast Sensitivity

(Acuity), Reproducibility for Contrast Sensitivity, Quality of Life, Fundus Photography, Visual Field, Defocus Curve, and Driving Simulation. For the majority of substudies, subjects were part of the 456 total. For the Driving Simulation and Quality of Life Substudies, additional bilateral monofocal subjects were included as well. Figure 1 (attached) provides detailed information of the make-up of the U.S. study and substudy populations.

Demographics

The population at risk for developing visually-disabling cataracts and needing cataract surgery is typically elderly; the elderly population has a slightly higher proportion of females to males. The average age of the cohort patients was 72.2 years at the time of surgery; 63.3% of the cohort patients were female and 36.8% were male. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology. The study population was 98.7% Caucasian, 1.0% African-American, and 0.3% Asian. In this study, which began in December 1993, all patients who met the inclusion criteria were included in the study.

In 1983 Stark et al. (Ophthalmology, 90(4): 311-317) published a grid of historical clinical data established from review of 45,543 eyes implanted with IOLs PMA-approved before 1982. FDA adopted the grid, which includes adverse reaction rates, sight-threatening complication rates and distance visual acuity results, for comparison to new lens models. Significantly more males in the AMO® Array® study (17.0%; 25/147) had cumulative sight-threatening complications compared to females (8.3%; 21/253). Although a significant difference was found between males and females, the incidence of cumulative sight-threatening complications was within the FDA grid values. Postoperative adverse reaction rates; uncorrected and best corrected distance visual acuities; uncorrected, distance-corrected and best corrected near visual acuities were not significantly different when compared by gender. The overall and best-case distance visual acuities were within grid values for both genders.

Data Analysis and Results

Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of Model SSM-26NB, in terms of best-corrected distance visual acuities, sight-threatening complications and adverse events, compares favorably with the grid of historical data. The visual acuities achieved by the Cohort subjects are tabulated below:

Distance Visual Acuity Cohort Patients (N = 400)			
	Uncorrected	With best correction	FDA Grid
20/20 or better	39.0% (156)	70.5% (282)	
20/40 or better	91.5% (366)	97.8% (391)	88.0%
20/41 - 20/80	7.5% (30)	1.5% (6)	
Worse than 20/80	1.0% (4)	0.8% (3)	

In the Monofocal Fellow Eye Control Subset, 85.3% (87/102) of multifocal eyes and 91.2% (91/102) of monofocal eyes achieved 20/40 or better uncorrected distance acuity. With best distance correction, 96.1% (98/102) of multifocal eyes and 99.0% (101/102) of monofocal eyes achieved 20/40 or better.

**Near Visual Acuity
Cohort Patients (N = 400)**

	Uncorrected*	With distance correction [†]	With additional add [†]
J1 or better	47.5% (189)	43.8% (173)	95.2% (376)
J3 or better	87.4% (348)	86.6% (342)	99.2% (392)
Worse than J3	12.6% (50)	13.4% (53)	0.8% (3)

* 2 subjects not reported

[†] 5 subjects not reported

In the Monofocal Fellow Eye Control Subset, 86.1% (87/101) of multifocal eyes and 48.5% (49/101) of monofocal eyes achieved J3 or better uncorrected near acuity (1 patient not reported). With distance correction, 82.0% (82/100) of multifocal eyes and 48.0% (48/100) of monofocal eyes achieved J3 or better (2 patients not reported). With distance correction and additional add, 99.0% (101/102) of both multifocal and monofocal eyes achieved J3 or better near acuity.

**Uncorrected Intermediate Visual Acuity
Monofocal Fellow Eye Control Subset (N = 102)**

	Multifocal Eye [†]	Monofocal Eye [†]
20/20 or better	2.0% (2)	2.0% (2)
20/40 or better	56.9% (58)	53.5% (54)
20/60 or better	74.3% (75)	70.3% (71)
Worse than 20/60	25.7% (26)	29.7% (30)

[†] 1 subject not reported

**Combined Distance and Near Visual Acuities
Cohort Patients (N = 400)**

	Uncorrected	With distance correction	With distance correction and additional add
20/40 or better/distance and J3 or better/near	82.2% (327)	86.3% (341)	97.7% (386)
Worse than 20/40 /distance and J3 or better/near	5.3% (21)	0.3% (1)	1.5% (6)
20/40 or better/distance and worse than J3/near	9.3% (37)	11.4% (45)	0.0% (0)
Worse than 20/40/distance and worse than J3/near	3.3% (13)	2.0% (8)	0.8% (3)

Clinical Substudies

The results of the contrast acuity substudy and reports of optical/visual symptoms have been discussed in the section above entitled “Potential Adverse Effects of the Device on Health.”

The **Spectacle Dependence and Use Substudy** results are reported for Cohort subjects in the tables below. Assessment of spectacle dependence and usage requires consideration of the bilateral status of a patient, as well as the binocular function of that patient. Although much of the data in this clinical study focused on monocular testing of unilateral cases; the data from the Cohort population has been stratified into bilateral multifocal, multifocal/monofocal or multifocal/other subgroups for analyses.

A significantly higher percentage of bilateral multifocal subjects (81.4%) reported they were able to function comfortably for near without spectacles compared to multifocal/monofocal subjects (56.4%; $p < 0.001$) and multifocal/other subjects (57.7%; $p < 0.001$). A significantly higher percentage of bilateral multifocal subjects reported that they did not wear spectacles for near (43.4%) or for distance (80.3%) compared to multifocal/monofocal (15.3% near, $p < 0.001$; 58.9%, distance, $p < 0.001$) and multifocal/other subjects (29.0% near, $p < 0.027$; 45.0% distance; $p < 0.001$). Further, a significantly higher percentage of bilateral multifocal subjects (45.4%) reported that they did not use visual aids compared to multifocal/monofocal (11.6%; $p < 0.001$) and multifocal/other (24.5%; $p < 0.001$) subjects.

**Percentage of Patients Able to Function Comfortably Without Glasses at One Year
(Directed Response*)
Cohort Patients (N=400)**

	Bilateral Multifocal N = 123	Multifocal/ Monofocal N = 177	Multifocal/ Other[†] N = 100
Near	81.4%	56.4%	57.7%
Intermediate	92.6%	85.8%	79.2%
Distance	93.4%	85.6%	77.4%

* Patient responses to prompted-choice questions from general patient questionnaire.

[†] Cataractous or non-cataractous phakic or aphakic fellow eye.

**Patients Reporting Spectacle Usage At One Year
(Directed Response*)
Cohort Subjects (N = 400)**

Use Of Visual Aid	Bilateral Multifocal N = 123		Multifocal/ Monofocal N = 177		Multifocal/ Other N = 100	
	n	%	n	%	n	%
None	54	45.4	20	11.6	24	24.5
For Reading	47	39.5	88	51.2	22	22.4
For Distance	2	1.7	5	2.9	5	5.1
For Reading + Distance	16	13.4	59	34.3	47	48.0
Total Reported	119 [†]	100.0	172 [‡]	100.0	98 [#]	100.0

* Subject responses to prompted-choice questions from general subject questionnaire.

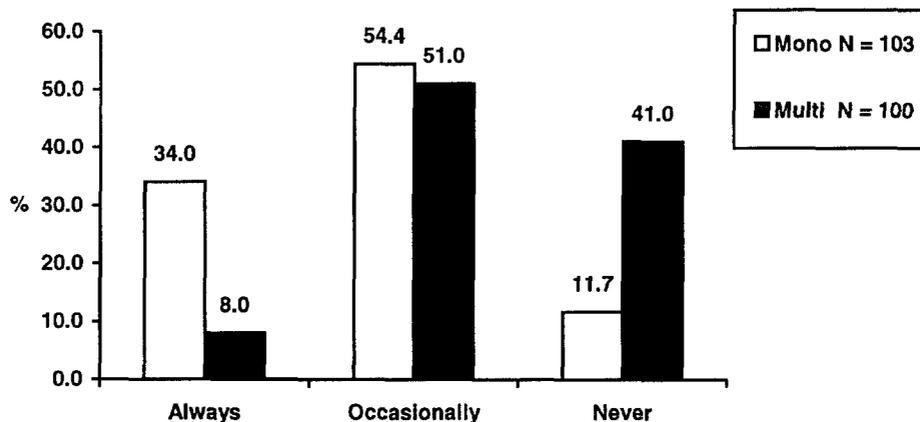
[†] 4 subjects not reported.

[‡] 5 subjects not reported.

[#] 2 subjects not reported.

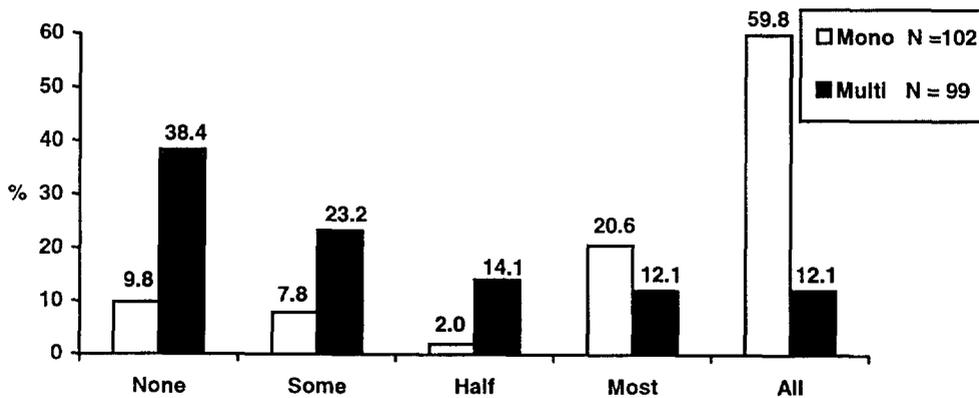
The **Quality of Life Substudy** was a parallel, non-randomized comparison of the functional status and quality of life of patients receiving bilateral AMO® Array® multifocal IOLs as compared to patients who received an otherwise similar monofocal IOL bilaterally. Questionnaires were administered to a total of 103 bilateral multifocal patients and 100 bilateral monofocal patients. Bilateral multifocal subjects reported significantly better function in most near vision and distance vision-related and social activities without spectacles vs. bilateral monofocal subjects. Significantly higher percentages ($p < 0.001$) of multifocal subjects reported that they did not wear spectacles vs. monofocal subjects in general (41.0% vs. 11.7%), for near vision (38.4% vs. 9.8%) or for distance vision (84.9% vs. 52.4%). Finally, multifocal subjects rated their overall binocular vision without spectacles to be significantly better than monofocal subjects (4.1 vs. 3.6; $p < 0.001$).

**Spectacle Wear
Quality Of Life Substudy
(Bilateral Multifocal vs. Bilateral Monofocal)**



Percent of subjects who always, occasionally, or never wear glasses. The difference among responses is statistically significant ($p < 0.001$).

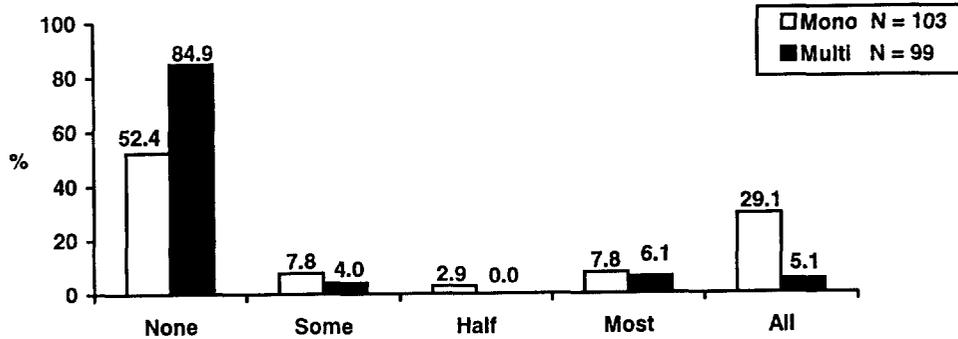
**Spectacle Wear For Near Vision
Quality Of Life Substudy
(Bilateral Multifocal vs. Bilateral Monofocal)**



Percent of subjects reporting use of glasses never, some of the time, half, most, or all of the time for near vision. The difference among responses is statistically significant ($p < 0.001$).

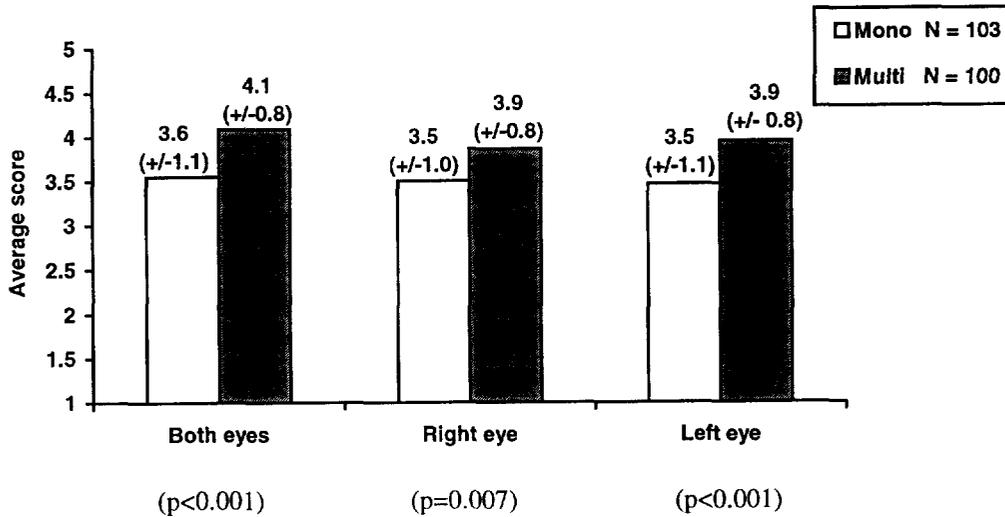
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**Spectacle Wear For Distance Vision
Quality Of Life Substudy
(Bilateral Multifocal vs. Bilateral Monofocal)**



Percent of subjects reporting use of glasses never, some of the time, half, most, or all of the time for distance vision. The difference among responses is statistically significant ($p < 0.001$).

**Average Vision Rating Without Glasses
Quality Of Life Substudy
(Bilateral Multifocal vs. Bilateral Monofocal)**



Average rating of vision without glasses in both eyes, right eye, and left eye between monofocal and multifocal groups.

Rating score: 1- poor, 2 - fair, 3 - good, 4 - very good, 5 - excellent

The **Fundus Photography Substudy** showed some differences in the quality of the photos for multifocal and monofocal patients. The photographic quality varied from slightly worse to slightly better in comparing the multifocal and monofocal fundus photographs, however the

results indicated that good photographs of the fundus can be achieved through the AMO® Array® multifocal optic.

During the clinical study, a vitreoretinal surgeon reported perceiving difficulties in maintaining stereopsis while performing a macular peel. In order to further evaluate the vitreoretinal surgeon's intraoperative view of the posterior ocular contents with an AMO® Array® IOL in situ, vitreoretinal surgery was conducted in New Zealand albino (NZA) and New Zealand/Dutch Belt pigmented (NZD) rabbit eyes that had been implanted with an AMO® Array® Multifocal Silicone IOL. This study was designed to evaluate the **adequacy of retinal visualization** while performing vitreoretinal surgery simulating a macular peel in NZA and NZD pigmented rabbit eyes implanted with an AMO® Array® IOL. Eight procedures were performed by two vitreoretinal surgeons to test the surgeon's ability to view and treat the retina both at the macula and at the retinal periphery. One of the two surgeons in the substudy reported that, while the view during surgery was equally good for the multifocal and monofocal IOLs, the image quality and depth of field did not appear as good through the multifocal IOL. A warning regarding this issue has been included in the labeling (see #4 in "Warnings," above).

The **Visual Field Substudy** was designed to evaluate differences in visual field performance between multifocal and monofocal eyes. In an evaluator-masked, paired-eye study, the visual fields from subjects implanted with the multifocal IOL in one eye and a monofocal IOL in the fellow eye were compared. Results between eyes were compared to determine if any visual field performance differences or systematic field defects were observed in multifocal eyes compared to monofocal eyes. Comparable visual field performance was demonstrated between multifocal and monofocal eyes.

The **Defocus Curve Substudy** showed that multifocal eyes demonstrated a significantly increased depth of focus at 20/40 visual acuity level compared to monofocal eyes within the medium pupil size range ($p=0.008$), with a mean depth of focus increase of 0.94 D. In this analysis, depth of focus was defined as the total range of defocus between distance and near where the visual acuity was 20/40 or better. The mean paired-eye, Regan line acuity difference, and the 95% confidence intervals, is provided in Figure 2. This figure demonstrates that the affect of the additional depth of focus is most pronounced at near, with nearly a three line visual acuity increase. The mean depth of focus curve obtained from testing a supplemental group of 15 patients is provided in Figure 3. Performance of patients with pupil sizes in the >2.5 and <4.0 mm group and the ≥ 4.0 mm group were generally similar. Insufficient data were available on patients with pupil sizes < 2.5 mm.

Figure 2
Depth of Focus
Mean Multifocal minus Monofocal Eye Acuity Line Difference
Pupil Size > 2.5 mm and < 4.00 mm
N = 10

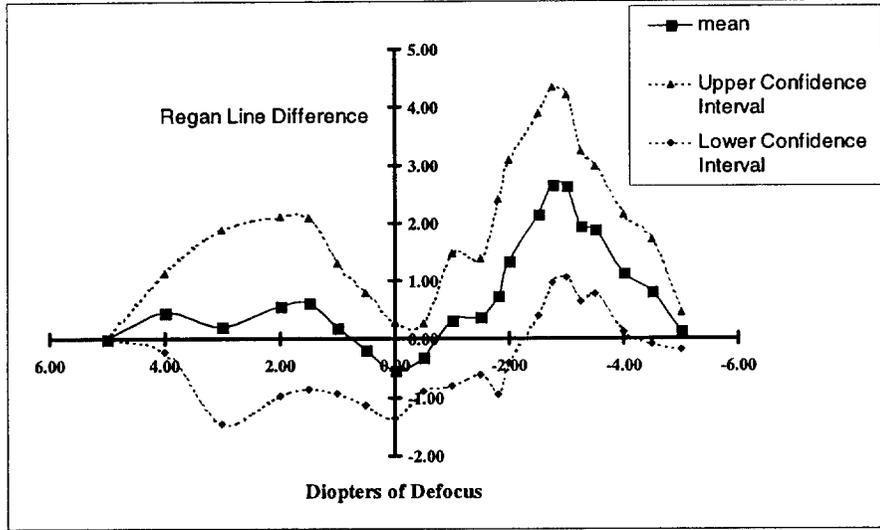
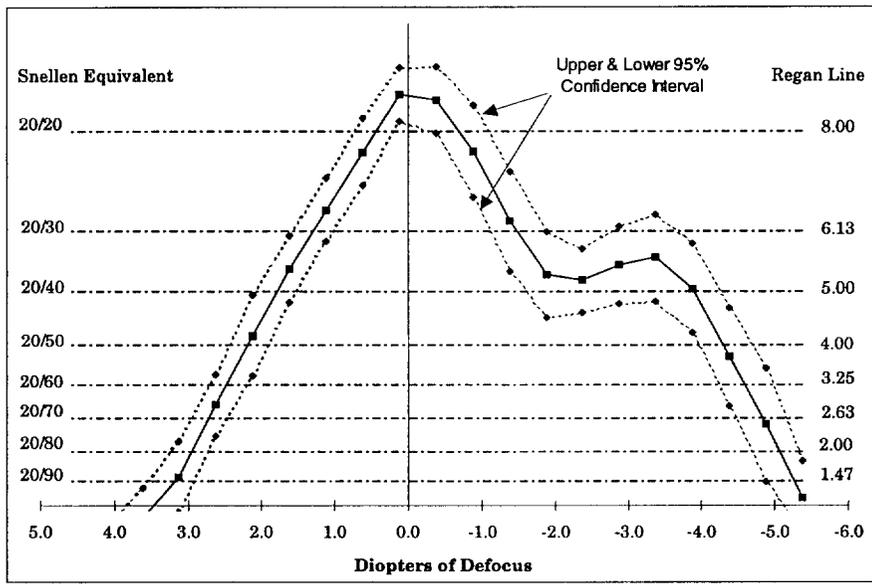


Figure 3
Mean Depth-of-Focus Curve
N = 15



The **Driving Simulation Substudy** was conducted to determine if the presence of the AMO[®] Array[®] Multifocal intraocular lens impacts driving performance and driving safety using a validated simulation of three different, visually challenging environmental conditions: nighttime in clear weather, nighttime with glare from an oncoming headlight, and fog. The driving

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simulator used in this substudy was validated against normal subjects driving in real-life conditions.

Sign recognition (rates and distances for 15 signs) and hazard detection and avoidance (rates, distances and avoidance scores for 4 objects) were evaluated for 33 bilateral multifocal patients and 33 bilateral monofocal patients.

A total of 30 measures of performance were evaluated. No significant difference in driving performance was found between mean performance of the groups for 26 of the measures; monofocal patients had significantly better performance for 4 measures. There was a trend toward better performance by the monofocal patients when an analysis was performed of those trials where one patient group had a greater detection rate and a greater detection distance.

Drivers with monofocal IOLs correctly identified warning signs at a significantly higher rate under one of nine conditions tested, clear nighttime. The greatest significant difference between groups was observed in the identification of the “Truck Crossing” sign under clear nighttime conditions; the sign was correctly identified by 79% of the monofocal patients, but only 49% of the multifocal patients. Of those patients who correctly identified the signs, no corresponding difference in sign recognition distances was found between the two lens groups for this condition. In fog conditions, drivers with multifocal IOLs generally had shorter guide and warning sign recognition distances (up to 26% shorter). As seen in the table below, under fog conditions, at average driving speeds, 7.7% more multifocal than monofocal patients were less than 2.25 seconds from the sign when it was identified. The minimum recommended time to recognize a sign is about 2.25 seconds.

**Percentage of patients less than 2.25 seconds from the sign when it was identified
(Average of 15 signs)**

Condition	Monofocal N=33	Multifocal N=33	Difference
Fog	26.6%	34.34%	-7.7%
Glare	37.78%	38.59%	-0.8%
Clear Night	43.43%	42.02%	+1.4%

However, the mean recognition distances of drivers with multifocal IOLs remained within safety guidelines (American Association of State Highway and Transportation Officials).

Among patients who were under 75 years old, drivers with monofocal IOLs detected certain roadway hazards at a significantly greater distance than those with multifocal IOLs. There was no such difference for these hazards in drivers greater than 75 years old. As seen below, for the most challenging simulated object, 21.7% more multifocal patients did not detect the hazard until closer than 100 feet. The distance of 100 feet was chosen for the analysis because at speeds of 30 mph or greater, a driver would not usually be able to stop safely within 100 feet.

Percentage of patients less than 100 feet from a hazard when it was detected

Condition		Monofocal		Multifocal		Difference
		N	%	N	%	
Fog	Ball	16/25	64.0%	15/20	75.0%	-11.0%
	Cone	1/20	5.0%	1/23	4.3%	+0.7%
	Suitcase	9/21	42.9%	14/23	60.9%	-18.0%
Glare	Ball	14/17	82.3%	22/23	95.6%	-13.3%
	Cone	3/22	13.6%	2/21	9.5%	+4.1%
	Suitcase	17/25	68.0%	16/19	84.2%	-16.2%
Clear Night	Ball	15/22	68.2%	16/24	66.7%	+1.5%
	Cone	0/24	0.0%	0/19	0.0%	0.0%
	Suitcase	9/20	45.0%	14/21	66.7%	-21.7%

When drivers could either maneuver around the hazard or stop to avoid a collision, there was no significant difference in hazard avoidance between drivers with multifocal vs. monofocal IOLs as seen in the table below.

Frequency of Collisions with Hazards

	Clear Night		With Glare		In Fog	
	Monofocal	Multifocal	Monofocal	Multifocal	Monofocal	Multifocal
Ball	59.1%	56.5%	93.8%	76.2%	56.0%	50.0%
Suitcase	55.0%	70.0%	95.7%	73.7%	75.0%	81.8%
Cone	29.2%	42.1%	50.0%	50.0%	50.0%	31.8%
Automobile	0.0%	0.0%	0.0%	3.0%	0.0%	0.0%

The Driving Simulation Substudy results indicate that multifocal patients should exercise caution when driving at night or in poor visibility conditions.

VIII. CONCLUSION

The Center for Devices and Radiological Health (CDRH) reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. At an advisory meeting held on July 10, 1997, the Ophthalmic Devices Panel recommended that Allergan, Inc.'s PMA for Model SA40N AMO®Array® Multifocal Silicone Posterior Chamber IOL be approved subject to submission to and approval by CDRH of labeling modifications as described by the Panel. CDRH concurred with the Panel's recommendation and issued a letter to Allergan, Inc. on August 8, 1997, advising that its PMA was approvable subject to the changes recommended by the Panel and required by FDA. In an amendment received by FDA on August 14, 1997, Allergan, Inc. submitted the revised labeling. CDRH approved this PMA in a letter to the PMA applicant dated SEP 5 1997 and signed by the Director, Office of Device Evaluation.

ATTACHMENT 3

**DRAFT PATIENT INFORMATION BROCHURE FOR THE AMO®ARRAY®
MULTIFOCAL UV-ABSORBING SILICONE POSTERIOR CHAMBER
INTRAOCULAR LENS**

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The AMO®Array® IOL Patient Information Brochure - Draft

This brochure is designed to help you and your surgeon decide on the right type of implant for you. **Please ask your surgeon about the risks and benefits of standard cataract surgery and intraocular lens (IOL) implantation.**

This brochure explains:

- What is a cataract
- How your surgeon will treat your cataract
- What implants there are to choose from
- Comparisons between the Monofocal and Multifocal implants
- What this means to you

What is a cataract

Inside your eye is a natural lens that helps to focus light from outside your eye. This creates images on the retina in the back of your eye (Figure 1). As people age, the lens can become less clear, even cloudy. This cloudiness in the lens is called a cataract. A cataract causes some of the light that enters your eye to be scattered across the back of your eye instead of forming an image. The cloudier the lens, the more light is scattered and the worse your vision becomes.

How your surgeon will treat your cataract

To improve your vision, your surgeon will remove your cloudy natural lens and replace it with an implant. This implant is an *intraocular lens*, or IOL for short. After your operation, your surgeon should give you a wallet card that identifies your implant. You should show this card to any eye doctor who treats you after your surgery.

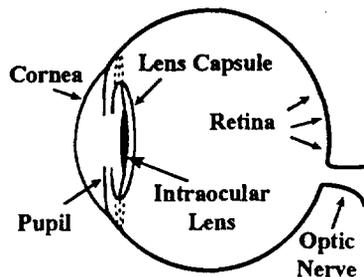


Figure 1. Diagram of eye with intraocular lens implant.

What implants there are to choose from

Your surgeon has a choice of IOLs that can be used successfully to improve your vision. One choice is between monofocal and multifocal IOLs.

The Monofocal IOL

This type of IOL was the first developed. It is designed to provide excellent vision at one set distance, usually far. This means that you should get good far vision, for example, when you look up at a distant mountain. However, you will most likely need glasses to perform activities such as reading or other near vision tasks.

The AMO®Array® Multifocal IOL

This new generation of IOL is different from monofocal IOLs. It is made of the same materials and basic design as many of Allergan's monofocal IOLs. But in addition to providing clear vision at far distances, it also provides good focus for a range of near distances. This means that you may see well for distance (far) activities such as watching television or children playing. In addition, you may see well for near activities, such as reading or crafts. You may therefore be less dependent on glasses for daily tasks.

As with many things, there is a trade off. This possible decrease in use of glasses may come at the cost of losing some of the sharpness of your vision. Even with glasses, this loss of sharpness may become worse under poor visibility conditions, for example in poor light or fog. There may also be some visual side effects, such as halos around lights at night.

Warnings

1. A very small percentage of patients (less than 1% in the U.S. Clinical Study) have been dissatisfied to the point of requesting removal of the multifocal lens.
2. In a driving simulation study, under one of nine low contrast conditions, 22% more multifocal patients than monofocal patients did not notice a hard-to-see object in the road until they were closer than 100 feet. The distance of 100 feet is important because at speeds of 30 mph or faster, a driver may not be able to stop safely within 100 feet. In the simulation, however, drivers could also drive around objects, and there was no difference in collisions with the objects.

Precautions

1. There is a chance (11%) that your vision may not be good enough to read small print without glasses with the multifocal IOL.
2. Please discuss with your physician whether this is the right lens for you. The following may affect your choice of IOL:
 - In rare instances, this lens may make some types of retinal surgery more difficult.

- AMO®Array® Multifocal Silicone Posterior Chamber IOL

- If the pupil of your eye is very small (less than 2.5 mm), the chances are greater that your near vision with a multifocal lens will not be better than with a monofocal lens.
- If the health of your eye makes it unlikely that your vision will be good after your cataract is removed, you may not get the full benefit of the multifocal IOL.

Comparisons between the Monofocal and Multifocal IOL

Both the monofocal and AMO®Array® multifocal IOLs have been thoroughly studied and are designed to replace the natural lens of the eye. The following table compares the other features of these two types of implants.

	Monofocal	The AMO®Array® Multifocal
DISTANCE VISION	This IOL generally gives good distance vision.	This IOL generally gives good distance vision, but it may not be quite as sharp as with a monofocal IOL.
INTERMEDIATE VISION (between 2 and 5 feet)	Intermediate vision is expected to be comparable between these two types of IOLs	
NEAR VISION	This IOL generally does not provide good near vision without glasses.	Most patients can expect near vision to be better than with a monofocal IOL, but there may still be some circumstances where you will need glasses for near work.
USE OF GLASSES	If you have this lens in both eyes, there is a 60% chance you will always wear your glasses for near work. There is a 34% chance you will wear your glasses all of the time (for any distance).	If you have this lens in both eyes, there is a 12% chance you will always wear your glasses for near work. There is a 8% chance you will wear your glasses all of the time (for any distance).
HALOS AND GLARE	With this IOL, there is a chance that you may have severe difficulty with halos around lights (6%) or with glare (1%).	With this IOL the chances of having severe difficulty with halos (15%) and glare (11%) are higher when compared to a monofocal IOL. You may grow accustomed to them or continue to notice them. In rare instances (less than 1%), patients have requested that the IOL be removed.

	Monofocal	The AMO®Array® Multifocal
LOW CONTRAST VISION (DRIVING)	Under poor visibility conditions, your vision may not be as sharp as in good light.	Under poor visibility conditions, your vision may be further reduced than it would be with a monofocal IOL. Under these conditions you may have more difficulty recognizing some traffic signs and hard-to-see objects in the road. Therefore, you may need to take extra care when driving, especially in poor light conditions.

What this means to you

Both monofocal and multifocal IOLs have their own advantages and disadvantages. Therefore, the choice of IOL will depend on how important you consider each of the factors described in the table above to be on your individual quality of life.

If your job or lifestyle requires you to do a lot of night driving, or very fine close work, then the multifocal may not be the IOL for you. Or if halos would be unacceptable to you, then you may be happier with a monofocal IOL.

If being less dependent on glasses after your operation would make your life better, then the AMO®Array® Multifocal IOL may be the right choice for you. For example, if being able to read a newspaper and also have clear distance vision is important to you, then the AMO®Array® IOL may let you do this without glasses. However, you should weigh the possible advantages with the possible disadvantages in deciding if this is the IOL for you.

The AMO®Array® IOL has been studied extensively in the USA, Europe, and Japan. In a survey of the U.S. study patients, 95% were satisfied with the results of their surgery in the eye implanted with the AMO®Array® IOL. Whichever IOL you choose, we hope that you are satisfied and have great pleasure in your improved vision.

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 Revised: 8/97

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ATTACHMENT 4

**DRAFT DIRECTIONS FOR USE FOR THE AMO®Array® MULTIFOCAL
UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS**

AMO®Array® Multifocal Silicone Posterior Chamber IOL

AMO®Array® Silicone Multifocal Posterior Chamber Intraocular Lenses
(SLM2/UV) - Draft

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

Description

Allergan AMO®Array® Multifocal Silicone Posterior Chamber Intraocular Lenses are available as biconvex optical lenses, with an anterior multifocal surface, designed to be implanted in the capsular bag. The optical portion has the capability of being folded prior to insertion, allowing the lens to be inserted through an incision of approximately 3.2 mm while preserving a full size lens body after implantation. Model SA40N is a Tier A (minor) modification of the clinically investigated parent Model SSM26NB.

When implanted, Silicone Posterior Chamber Intraocular Lenses replace the natural lens of the eye and function as a refracting medium in the correction of aphakia.

Indications for Use

Allergan AMO®Array® Multifocal Silicone Posterior Chamber Intraocular Lenses are indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed and who may benefit from useful near vision without reading add and increased spectacle independence across a range of distances where the potential visual effects associated with multifocality are acceptable.

These devices are intended to be placed in the capsular bag.

Warnings

1. Some visual effects may be expected because of the superposition of focused and unfocused multiple images. These include some perception of halos or radial lines around point sources of light under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. A very small percentage of patients (< 1% in the U.S. Clinical Study) may be dissatisfied to the point that they request explantation of the multifocal lens.
2. Under low contrast conditions, visual acuity is reduced with a multifocal lens when compared to a monofocal lens. Therefore, multifocal subjects 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 this IOL:**
 - The surgeon must target **emmetropia** as this lens is designed for optimum visual performance when emmetropia is achieved.
 - Patient selection and operative technique should be managed to ensure that the total postoperative corneal **astigmatism** does not exceed 1.5 diopters as effects of greater astigmatism on multifocal function are unknown.
 - Patients with **pupil sizes** less than 2.5 mm may not have any near benefit.

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- Care should be exercised to achieve **centration** of this IOL as visual performance may decrease with increasing decentration.
- 4. Although rarely observed during the clinical trial, the imaging quality and depth of field through this lens may potentially impact vitreoretinal surgery.
- 5. Do not resterilize this intraocular lens by any method. (See **Returned Lens Policy**.)
- 6. Do not store lenses at temperatures over 45°C (113°F).
- 7. The safety and effectiveness of this lens if placed in the anterior chamber have not been established. Implantation of posterior chamber lenses in the anterior chamber has been shown in some cases to be unsafe. Such implantation should take place only under an investigational protocol approved by FDA.

Precautions

1. Prior to surgery, the surgeon must provide prospective patients with a copy of the patient information brochure for this product and inform these patients of the possible risks and benefits associated with the use of this device.
2. The same degree of near benefit may not be achieved by all patients.
3. With regard to postoperative refraction, the +3.5 D add in the IOL plane corresponds, in most circumstances, to approximately +2.4 D to +2.8 D in the spectacle plane, depending on corneal power and anterior chamber depth. *Note: autorefractors may not provide optimal postoperative refraction of multifocal patients. Manual refraction is strongly recommended.*
4. Since the clinical study of the AMO®Array® multifocal IOL was conducted with the lens intended for implantation in the capsular bag, there are insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.
5. The safety and effectiveness of this lens have not been evaluated in patients with active ocular pathology or potential postoperative acuities worse than 20/30.
6. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition or may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight:
 - a. Congenital bilateral cataracts.
 - b. Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye.
 - c. Patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases.
 - d. Previous history of, or a predisposition to, retinal detachment.
 - e. Surgical difficulties at the time of intraocular lens implantation which might increase the potential for complications (e.g., persistent bleeding, significant vitreous prolapse or loss).
 - f. Patients with only one eye with potentially good vision.
 - g. Medically uncontrollable glaucoma.
 - h. Corneal endothelial dystrophy.
 - i. Proliferative diabetic retinopathy.

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7. The long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor implant patients postoperatively on a regular basis.
8. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively.
9. The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established.

Adverse Effects

A total of 456 Core subjects were evaluated in clinical trials to determine the safety of the AMO®Array® Model SSM26NB Multifocal Silicone Posterior Chamber Intraocular Lens.

Secondary Surgical Interventions were reported as follows:

**Secondary Surgical Interventions
 All Core Subjects (N=456)**

	WITHIN ONE YEAR		AFTER ONE YEAR*	
	n	%	n	%
TOTAL SECONDARY SURGICAL INTERVENTIONS	10 [†]	2.2	4	0.9
- Repositioning of Lens	1	0.2	0	0.0
- IOL Replacement for Improper Power Calculation	2	0.4	0	0.0
- IOL Replacement for Optical/Visual Symptoms	1	0.2	2	0.4
- IOL Replacement for Other Surgical Procedures (Enhanced Retinal Visualization)	1 [†]	0.2	0	0.0
- Vitrectomy/Vitreolysis	3 [†]	0.6	0	0.0
- Repair of Macular Hole/Vitrectomy	1	0.2	0	0.0
- Argon Laser Retinopexy	1	0.2	0	0.0
- Scleral Buckle Procedure	0	0.0	1	0.2
- Cryotherapy to repair retinal tear	0	0.0	1 [‡]	0.2

* Includes subjects experiencing Secondary Surgical Interventions after the final study visit as of May 10, 1996.

[†] Nine (9) subjects exhibited ten (10) interventions. One subject had two secondary surgical procedures, vitrectomy and IOL replacement.

[‡] This subject was a participant in the Monofocal Fellow Eye Control Substudy (see Clinical Study Results) and also underwent a scleral buckle procedure for the fellow eye implanted with an otherwise similar monofocal IOL.

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- AMO®Array® Multifocal Silicone Posterior Chamber IOL

Difficulty in maintaining stereopsis and fusion while performing an epiretinal membrane peel procedure was reported in a single case. Additional effort to maintain fine focus was reported in a second epiretinal membrane peel. No other difficulty was reported for the other posterior segment procedures performed.

Potential secondary surgical interventions that have been associated with intraocular lenses, but did not occur in this clinical trial include: lens removal due to corneal touch, lens removal due to inflammation, corneal transplant, vitreous aspiration for pupillary block, iridectomy for pupillary block. Other adverse events which have been associated with intraocular lenses, but did not occur in this clinical trial include: hypopyon, intraocular infection, acute corneal decompensation.

Contrast Acuity: Mean differences between eyes for the Monofocal Fellow Eye Control Subset (see Clinical Study Results), where significant, were generally within 1 to 1.5 lines. The frequency of subjects with paired-eye differences of > 2 lines increased with decreased contrast and with glare to a maximum of 26.4% at 11% contrast with the B.A.T. set at low. (Testing was conducted using Regan acuity charts at 96%, 50%, 25% and 11% contrast at distance and C.A.T. charts at 100%, 50%, 25% and 12.5% contrast at near.)

Visual Symptoms: Statistically significant differences were observed at one year for the mean degree of difficulty reported by subjects for **halos, glare/flare, and blurred far vision**. Subjects reported "severe" difficulty with these symptoms at the following rates (multifocal vs. monofocal eyes):

- halos (15.3 vs. 6.1%)
- glare/flare (10.5% vs. 1.1%),
- blurred far vision (4.2 vs. 1.0%)

Differences in mean difficulty scores at one year were not significant for the following symptoms (incidence of "severe" reports, multifocal vs. monofocal eyes): distorted near (4.0% vs. 2.0%) or far (3.1% vs. 0.0%) vision, difficulty with night vision (8.4% vs. 4.2%), blurred near vision (8.2% vs. 3.1%), monocular (2.0% vs. 1.0%) or binocular (1.0% vs. 1.0%) diplopia, depth perception (1.0% vs. 1.0%), and color perception (0.0% vs. 0.0%).

Other complications: No incidence of hypopyon, intraocular infection or acute corneal decompensation was reported during the clinical study.

The complications experienced during the clinical trial of the AMO®Array® Multifocal Silicone Posterior Chamber Lenses include (in order of frequency): [clinical study rate vs. "FDA grid" rate]: macular edema (persistent) [0.8 vs. 0.8%], iritis (persistent) [0.3 vs. 1.0%], corneal edema (persistent) [0.0% vs. 0.6%], pupillary block (cumulative) [0.3% vs. 0.3%], secondary glaucoma (cumulative) [1.5% vs. N/A], and vitritis (cumulative) [0.5% vs. N/A]. Incidences of these complications were all comparable to or lower than those of the historic control ("FDA grid") population.

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Potential complications which did not occur in this clinical trial, but which may accompany cataract or implant surgery include, but are not limited to, the following: corneal endothelial damage, non-pigment precipitates, infection, retinal detachment, vitreous loss, iris prolapse, vitreous wick syndrome, uveitis and pupillary membrane.

Clinical Study Results

The AMO®Array® Model SSM26NB multifocal silicone posterior chamber intraocular lens was evaluated in a prospective, nonrandomized study of 456 subjects followed for one year. Both historic and prospective controls were used, depending on substudy.

The 400 subject Cohort population in the clinical trial consisted of 63.3% females (253/400) and 36.8% males (147/400). 98.7% were Caucasian, 1.0% were Black and 0.3% were Asian. The mean age was 72.2 years. A total of 392 Cohort subjects did not have preoperative ocular pathology or postoperative macular degeneration (Best Case Cohort). Inclusion criteria required visual potential to be 20/30 or better in the operative eye.

The postoperative results demonstrated that the AMO®Array® Multifocal IOL provides distance and intermediate vision comparable to a monofocal IOL, with increased near vision. The distance and near acuities achieved by the best case cohort subjects (those with no preoperative pathology or postoperative macular degeneration) are described in the following tables:

Distance Visual Acuity		
Best Case Cohort Population (N = 392)		
	Uncorrected	With best correction
20/20 or better	39.8%	71.2%
20/40 or better	92.1%	98.5%
20/41 - 20/80	7.4%	1.0%
Worse than 20/80	0.5%	0.5%

Near Visual Acuity			
Best Case Cohort Population (N = 392)			
	Uncorrected	With distance correction	With additional add
J1 or better	48.0%	43.6%	95.8%
J3 or better	87.9%	87.3%	99.5%
Worse than J3	12.1%	12.7%	0.5%

**Combined Distance and Near Visual Acuities
Best Case Cohort Population (N = 392)**

	Uncorrected	With distance correction	With additional add
20/40 or better/distance and J3 or better/near	82.6%	87.1%	98.4%
Worse than 20/40 /distance and J3 or better/near	5.4%	0.3%	1.0%
20/40 or better/distance and worse than J3/near	9.5%	11.4%	0.0%
Worse than 20/40/distance and worse than J3/near	2.6%	1.3%	0.5%

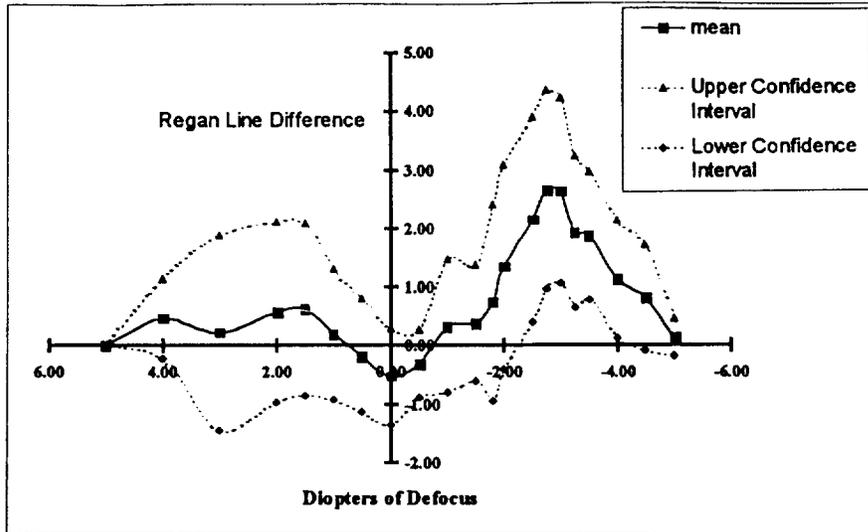
Test Results for Clinical Substudies: The Monofocal Fellow Eye Control Subset was comprised of 102 Cohort subjects with an otherwise comparable monofocal IOL in the contralateral eye.

The **Visual Field Substudy** showed comparable visual field performance between multifocal and monofocal eyes.

The **Defocus Curve Substudy** showed that multifocal eyes demonstrated a significantly increased depth of focus at 20/40 visual acuity level compared to monofocal eyes within the medium pupil size range ($p=0.008$), with a mean depth of focus increase of 0.94 D. In this analysis, depth of focus was defined as the total range of defocus between distance and near where the visual acuity was 20/40 or better. The mean paired-eye, Regan line acuity difference, and the 95% confidence intervals, is provided in **Figure 1**. This figure demonstrates that the effect of the additional depth of focus is most pronounced at near, with approximately a three line visual acuity increase. The mean depth of focus curve for all subjects in the Supplemental Defocus Curve Substudy is provided in **Figure 2**. Performance of subjects with pupil sizes in the >2.5 and <4.0 mm group and the ≥ 4.0 mm group were generally similar. Insufficient data were available to evaluate the performance of subjects with pupil sizes < 2.5 mm.

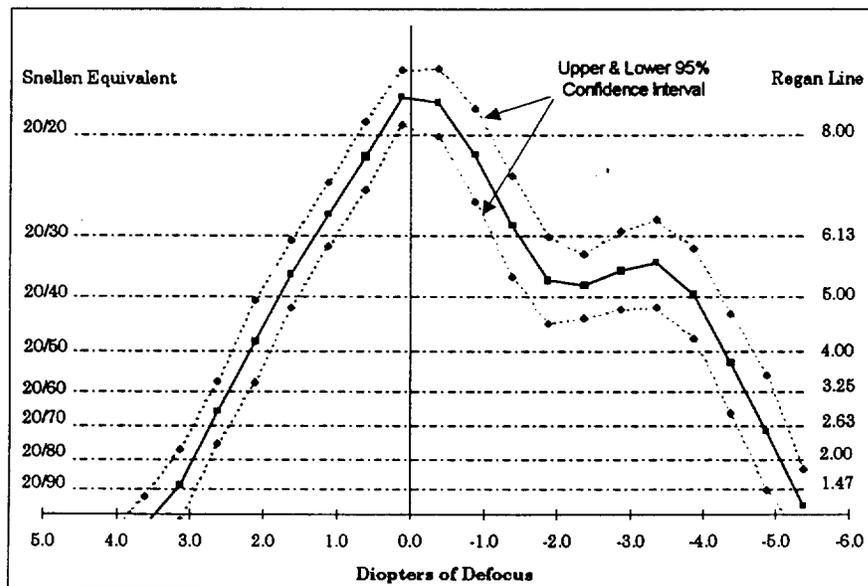
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Figure 1
Depth of Focus
Mean Multifocal minus Monofocal Eye Acuity Line Difference
Pupil Size > 2.5 mm and < 4.00 mm
N = 10



(See text for explanation)

Figure 2
Mean Depth-of-Focus Curve
N = 15



(See text for explanation)

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AMO®Array® Multifocal Silicone Posterior Chamber IOL

The **Fundus Photography Substudy** showed some differences in the quality of the photos for multifocal and monofocal subjects. The photographic quality varied from slightly worse to slightly better in comparing the multifocal and monofocal fundus photographs, however the results indicated that excellent photographs of the fundus can be achieved through the AMO®Array® multifocal optic.

The **Driving Simulation Substudy** was conducted to determine if the presence of the AMO®Array® Multifocal intraocular lens impacts driving performance and driving safety using a validated simulation of three different low contrast, visually challenging, environmental conditions: nighttime in clear weather, nighttime with glare from an oncoming headlight, and fog.

Sign recognition (rates and distances for 15 signs) and hazard detection and avoidance (rates, distances and avoidance scores for 4 objects) were evaluated for 33 bilateral multifocal subjects vs. 33 bilateral monofocal subjects.

A total of 30 measures of performance were evaluated. No significant difference in driving performance was found between groups for 26 of the measures; monofocal subjects had significantly better performance for 4 measures. There was a trend toward better performance by the monofocal subjects when an analysis was performed of those trials where one subject group had a greater detection rate and a greater detection distance.

Drivers with monofocal IOLs correctly identified warning signs at a significantly higher rate under one of nine conditions tested, clear nighttime. Of those subjects who correctly identified the signs, no corresponding difference in *sign recognition distances* was found between the two lens groups for this condition. In simulated fog conditions, drivers with multifocal IOLs generally had shorter guide and warning sign recognition distances (up to 26% shorter). **Under fog conditions, at average driving speeds, 7.7% more multifocal than monofocal patients were less than 2.25 seconds from the sign when it was identified. The minimum recommended time to recognize a sign is about 2.25 seconds.** However, the mean recognition distances of drivers with multifocal IOLs remained within safety guidelines (American Association of State Highway and Transportation Officials).

Among subjects who were under 75 years old, drivers with monofocal IOLs detected certain roadway hazards at a significantly greater distance than those with multifocal IOLs. There was no such difference for these hazards in drivers greater than 75 years old. **For the most challenging simulated object under nighttime conditions (one of nine trials), 21.7% more multifocal subjects did not detect the hazard until closer than 100 feet. The distance of 100 feet is significant because at speeds of 30 mph or greater, a driver would not usually be able to stop safely within 100 feet.** In the simulation, however, drivers could maneuver around hazards, and there was no significant difference in hazard avoidance (e.g., collisions) between drivers with multifocal vs. monofocal IOLs.

The Driving Simulation Substudy results indicate that multifocal subjects should exercise caution when driving at night or in poor visibility conditions.

Spectacle independence was reported for a range of distances from near through far, for AMO®Array® silicone posterior chamber intraocular lens Cohort subjects as shown below. The bilateral multifocal subjects were significantly more spectacle independent than the other two groups at near only.

**Percentage of Subjects Able to Function Comfortably Without Glasses at One Year
 (Directed Response*)**

All Cohort Subjects (N=400)

	BILATERAL MULTIFOCAL N = 123 %	MULTIFOCAL/ MONOFOCAL N = 177 %	MULTIFOCAL/ OTHER† N = 100 %
NEAR	81.4	56.4	57.7
INTERMEDIATE	92.6	85.8	79.2
DISTANCE	93.4	85.6	77.4

* Subject responses to prompted-choice questions from general subject questionnaire.

† Cataractous or non-cataractous phakic or aphakic fellow eye.

Frequency of spectacle wear was significantly different between bilateral multifocal and bilateral monofocal subjects ($p < 0.001$).

**Percentage of Subjects Who Always, Occasionally, or Never Wear Spectacles
 Quality of Life Substudy**

	BILATERAL MULTIFOCAL N = 100 %	BILATERAL MONOFOCAL N = 103 %
ALWAYS	8.0	34.0
OCCASIONALLY	51.0	54.4
NEVER	41.0	11.7

Detailed Device Description

The AMO®Array® is a multifocal intraocular lens. A multifocal IOL is designed to provide light to more than one focal plane.

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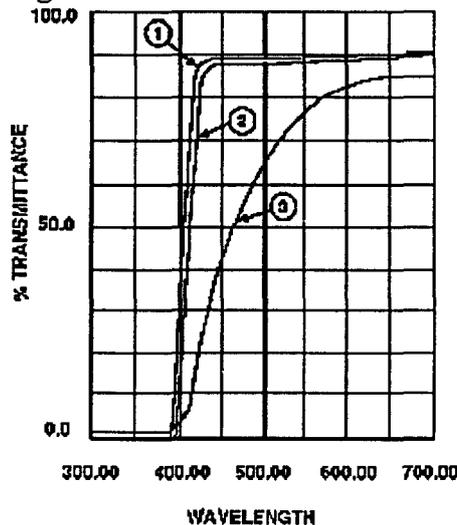
The physical properties of the lenses are:

Lens Optic

- Material: SLM2/UV
- Light transmittance: UV cut-offs at 10% T for a +16 diopter lens (thinnest) and a +24 diopter lens (thickest) are shown in Figure 3
- Specific gravity: 1.160 (25°C)
- Index of refraction: 1.460 (35°C)
- Diopter power: +16 to +24 diopters in 0.5 diopter increments
- +3.5 diopters of add power at the IOL plane (see Clinical Results)
- Refractive zonal-progressive IOL incorporating continuous range of foci (Figure 4)

Haptics

- Configuration: Modified C
- Material: Blue core polymethylmethacrylate (PMMA) monofilament

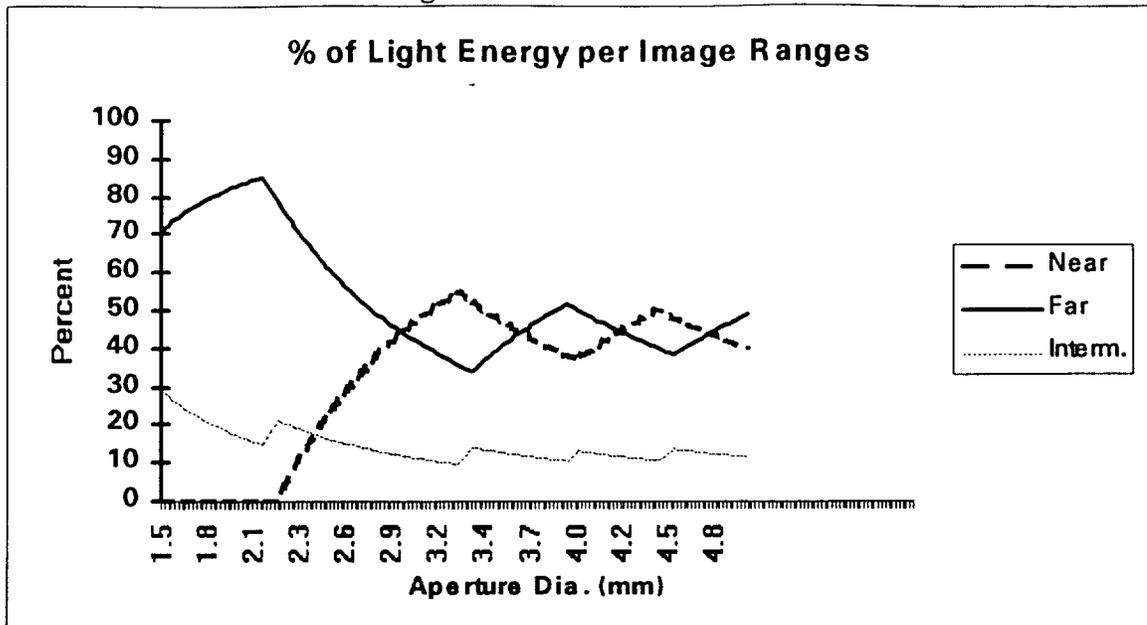
Figure 3**Legend:**

- Curve 1:** Spectral Transmittance (T) Curve Corresponding to the Central Region of the thinnest lens (+16 Diopter IOL).
- Curve 2:** Spectral Transmittance (T) Curve Corresponding to Central Region of the thickest lens (+24 Diopter IOL).
- Curve 3:** Spectral Transmittance (T) Curve* Corresponding to 53 year-old Phakic Eye.

Note: The spectral transmittance curves represent the range of transmittance values of IOLs made with this material.

* Boettner, E.A. and Wolter, J.R. 1962. Transmission of the ocular media. *Invest Ophthalmol.* 1:776-783

Figure 4



Directions For Use

1. Check the label on the lens package for proper lens model, dioptric power, and expiration date.
2. Open the package and verify the dioptric power of the lens.
3. Transfer the lens, using sterile technique to an appropriate loading device.
4. Various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
5. Handle the lens by the haptic portion. Do not grasp the optical area with forceps.
6. Refer to the specific instructions for use for proper use of the IOL insertion instruments.
7. The lens should be discarded if it remains folded in the IOL insertion instrument for longer than 5 minutes.

NOTE: ALLERGAN does not recommend the use of the Fine Folder or Fine Universal II forceps with this lens.

NOTE: The lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.

Calculation of Lens Power

The physician should determine preoperatively the power of the lens to be implanted.

Emmetropia should be targeted. The estimated A-constant for this lens is provided on the lens box. Lens power calculation methods are described in the following references:

- Hoffer, K.J., The Hoffer Q formula, A comparison of theoretical and regression formulas, J. Cataract Refract Surg, Vol 19, November 1993.

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- Retzlaff, J.A., et al. Development of the SRK/T intraocular lens implant power calculation formula, J. Cataract Refract Surg, Vol 16, May 1990.
- Holladay, J.T., et al. A Three Part System for Refining Intraocular Lens Power Calculations, J. Cataract Refract Surg, Vol 14, January 1988.

Physicians requiring additional information on lens power calculation may contact Allergan.

Patient Registration Instructions and Reporting

Registration

Each patient who receives an Allergan AMO®Array® Multifocal Silicone Posterior Chamber Lens must be registered with Allergan at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to Allergan. Patient registration is essential for Allergan's long-term patient follow-up program and will assist Allergan in responding to Adverse Reaction Reports and/or potentially sight-threatening complications.

An Implant Identification Card is supplied in the lens package. This card should be given to the patient with instructions to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

Reporting

Adverse Reactions and/or potentially sight-threatening complications 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 Allergan. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation, especially in younger patients.

Physicians must report these events in order to aid in identifying emerging or potential problems with Multifocal Silicone Posterior Chamber Lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with IOLs in general.

Physicians should use the following toll-free number when reporting adverse reactions or potentially sight threatening complications involving Allergan intraocular lenses. **National:** (800) 366-6554

How Supplied

The contents of the inner and outer peel pouches are sterile unless the packages are damaged or opened. The Intraocular Lenses are ethylene oxide sterilized and supplied in a lens case within a double aseptic transfer peel pouch. The contents of the inner and outer peel pouches are sterile unless the packages are damaged or opened.

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Expiration Date

Sterility is guaranteed unless the sterile pouch is damaged or opened. In addition, there is a sterility expiration date that is clearly indicated on the outside of the shelf-pack. The lens should not be used after the indicated date.

Returned Lens Policy

The lens may be returned to the manufacturer for credit within 30 days of purchase. After 30 days it can be replaced or exchanged at no charge.