

Multifocal intraocular lenses in cataract surgery

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Multifocal Intraocular Lenses in Cataract Surgery

Niels Erik de Vries

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General introduction

Aims and outline of the thesis

GENERAL INTRODUCTION

The crystalline lens is part of the optical system of the eye that focusses rays of light on the retina. In subjects with an emmetropic refractive state, parallel rays emerging from a distant object are focussed on the fovea with the different parts of the optic system in their natural state. In ametropic subjects, the power of the optical system needs to be adjusted (with spectacles, contact lenses, or refractive surgery) in order to reach this desired situation.

Apart from contributing to the optical power of the eye as a whole, the crystalline lens is able to dynamically change the optical power of the system by the process of accommodation. Light rays emerging from objects at near distance rather than at infinity are entering the eye at an angle rather than parallel. The optical power of the lens must therefore be increased in order to let the light rays converge at the retina. According to the theory pioneered by Helmholtz, contraction of the ciliary muscle decreases tension on the zonular fibers, resulting in a change in shape and therefore optical power of the crystalline lens. The dynamic optical power of the system contributes to the ability of the subject to visualize objects at a range of distances. During life the ability of the crystalline lens to change in shape decreases, leading to presbyopia.

Removal of the crystalline lens followed by implantation of an artificial intraocular lens (IOL) in the capsular bag of the eye, as practiced in cataract surgery, offers an opportunity to address refractive anomalies in patients who are ametropic. Advances in preoperative calculations of the optical power of the IOL necessary for a desired refractive result, smaller incision sizes at the time of cataract surgery and the introduction of IOLs with a wide range of spherical and cylindrical optical powers in small increments have contributed to the current state where cataract surgery is not just a treatment for a vision-threatening disease, but should additionally be considered as a refractive surgery procedure.

Despite these advances, implantation of an IOL with a fixed focal point (a non-accommodative monofocal IOL) will theoretically render a patient at best emmetropic for a single fixed working distance only, leading to a postoperative result comparable to presbyopia in an emmetropic subject. Although more complex optical phenomena such as certain higher order aberrations, corneal shape and pseudoaccommodation can play a role in increasing the depth of field, spectacle independence for a range of working distances is not to be expected after implantation of a monofocal IOL. Multifocal IOLs on the other hand are designed to have two or more fixed focal points, thus facilitating a sharp retinal image of objects at multiple working distances resulting in increased spectacle independence.

AIMS AND OUTLINE OF THE THESIS

The current thesis aims to evaluate the advantages and disadvantages of implantation of multifocal intraocular lenses after removal of the natural crystalline lens in cataract surgery. Diffractive versus refractive designs, aspheric versus spherical designs, and low reading addition versus high reading addition designs are compared in clinical studies and a literature review. Finally, cases of dissatisfaction after implantation of a multifocal intraocular lens are investigated. The goal of this thesis is to contribute to the understanding of the use of multifocal IOLs in patients with a desire to become spectacle independent following cataract surgery.

Chapter 1 is a short introduction into the subject of multifocal IOLs and their use in cataract surgery.

Chapter 2 is a literature review describing the results of currently available studies on the use of multifocal IOLs in cataract surgery in the peer-reviewed literature.

Chapter 3 presents the results of a clinical study analyzing visual acuity, spectacle independence and patient satisfaction after implantation of a multifocal intraocular lens with a three-year follow-up.

Chapter 4 describes the results of a study comparing levels of intraocular straylight between patients with a monofocal and a multifocal intraocular lens. Due to the multiple points of focus of a multifocal intraocular lens and the scattering of light in diffractive optics, multifocal intraocular lenses may be associated with an undesirable increase in intraocular straylight.

Chapter 5 discusses a study comparing two diffractive multifocal intraocular lenses, one with a spherical design and one with an aspheric design. From a theoretical point of view aspheric designs result in a superior retinal image quality compared to spherical designs. The third study investigates whether this results in clinical differences as well.

Chapter 6 presents a study comparing two aspheric diffractive multifocal intraocular lenses, one with a lower (3.0 D) and one with a higher (4.0 D) reading addition. From a theoretical point of view a lower near addition results in a superior performance at intermediate working distances compared to a higher near addition, but might result in inferior performance at reading distances. The fourth study investigates clinical differences between low-add and high-add multifocal intraocular lenses.

Chapter 7 presents the results of an observational study describing the symptoms, perceived etiology and treatment of patients dissatisfied with their visual function following implantation of a multifocal intraocular lens.

Chapter 8 is a general discussion of the obtained results and a correlation with clinical practice. Finally, chapter 9 is a summary of the current thesis.



Literature review

Multifocal Intraocular Lenses in Cataract Surgery: Literature Review of Benefits and Side-effects

Niels E. de Vries, MD, Rudy MMA Nuijts, MD, PhD

Submitted

INTRODUCTION

Accommodation is the ability of the eye to dynamically change its optical power in order to create a sharp image on the retina of distant, intermediate and near objects.¹ Von Helmholtz pioneered the theory that accommodation is the result of changes in optical power of the crystalline lens, as a result of changes in shape and position of the crystalline lens due to changes in tensile strength of the zonular fibers after relaxation or contraction of the ciliary muscle.² During life, the ability to accommodate decreases, resulting in presbyopia.³ This is thought to be the result of changes in elasticity of the crystalline lens^{4, 5} and of changes in the contractility of the ciliary muscle.^{6, 7} Thus, even emmetropic subjects who were spectacle independent beforehand will eventually become dependent on spectacles for near vision once they have become presbyopic.

Apart from age-related changes in the crystalline lens which lead to presbyopia, age-related changes in the crystalline lens may lead to cataract formation.⁸ Cataract surgery with implantation of an artificial intraocular lens (IOL) has the potential not only to increase visual acuity, but also to change the patient's refractive state. Ideally, an IOL would allow the presbyopic patient to regain his or her ability to accommodate. Although refilling the capsular bag with a clear, but elastic substance, would theoretically lead to the desirable result, experiments in this field have been unsuccessful so far.⁹ Similarly, a change in position of the IOL or parts thereof within the optical system would change the optical power of the optical system as a whole, thus providing the patient with the ability to accommodate.¹⁰ Ultrasound studies have shown changes in position of accommodative IOLs within the optical system in response to physiological or pharmaceutical stimuli¹¹, although others did not find significant movement of these IOLs.^{12,13} In clinical practice, movement of these accommodative IOLs has been shown to be insufficient to result in large changes in power of the optical system.^{10,14}

Apart from strategies to provide IOLs with a dynamic optical power or position within the optical system, IOLs can be designed to provide two or more fixed optical powers. So-called multifocal IOLs have been designed to result in two or more coexisting retinal images where only the image corresponding to either the distance or near focal point is sharp. This concept is known as "simultaneous vision",¹⁵ although "simultaneous imaging" would be a more appropriate term. Multifocal IOLs have two or more fixed rather than one adapting focal point and are therefore pseudo-accommodative rather than truly accommodative. The earliest multifocal IOLs were introduced in the late 1980s.^{16, 17} As presented in **table 1**, multifocal IOLs have been developed using refractive, diffractive and combinations of both optical principles. Refraction is based on a change in direction of the light ray due to a change in opti-

cal density encountered by the light ray. Diffraction is based on the observation that light that encounters a discontinuity or edge in the material where it travels in, scatters in numerous different directions. Light energy arriving at an edge or discontinuity can thus be divided over two or more focal points, similar to refractive lenses. Both effects were described by Fresnel in the 1820s when working on lenses for lighthouses, and can be used to design IOLs with multiple focal points.¹⁵ More recently, so-called “aspheric” multifocal IOLs have been introduced. In these IOLs, optical properties of the IOL have been altered to decrease higher order aberrations of the total optical system, mainly by compensating for the increased spherical aberration of the cornea in older subjects.^{18,19} In monofocal IOLs, implantation of aspherical IOLs resulted in superior visual performance compared to their spherical counterparts, especially with respect to mesopic visual acuity and contrast sensitivity.^{20,21} In multifocal IOLs, implantation of aspheric IOLs has been found to result in superior²² or equal²³ visual performance compared to their spherical counterparts. Apart from refractive versus diffractive and spherical versus aspheric designs, multifocal IOL designs can be described as either pupil dependent or pupil independent. In zonal refractive designs and designs with a central diffractive structure, the division of the light energy is depending on pupil size. IOL designs with a similar peripheral and central optical zone are pupil independent. The differences between different designs of multifocal IOLs are best illustrated in ray-tracing studies²⁴ and optomechanical eye model studies.²⁵ The current paper describes different available designs, as well as results and side-effects of the implantation of multifocal IOLs following cataract surgery.

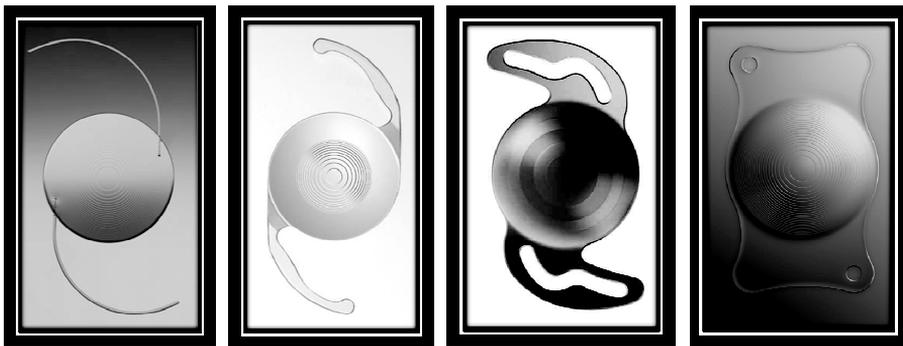


Figure 1. Examples of multifocal intraocular lenses, including the multifocal Tecnis ZM900 by AMO (upper left), ReSTOR SA60D3 by Alcon (upper right), M-flex by Rayner (lower left) and Acri.LISA 366D by Zeiss Meditec (lower right). (all images courtesy of their respective manufacturers).

Table 1. Examples of multifocal intraocular lenses (IOLs).

	Array (SA40N, SA40NB)	ReZoom	Acri.LISA (366D, 376D, 536D)	Acri.LISA (466TD)
Company	Abbott Medical Optics	Abbott Medical Optics	Carl Zeiss Meditec	Carl Zeiss Meditec
Design	refractive	refractive	diffractive + refractive	diffractive + refractive
Pupil	dependent	dependent	independent	independent
Near add	+3.50	+3.50	+3.75	+3.75
Toric	no	no	no	yes
Aspheric	no	no	yes	yes
	ReSTOR (SA60D3, SN60D3, MN60D3)	ReSTOR (SN6AD3, SN6AD1)	ReSTOR (SND1-T2/3/4/5)	Tecnis ZM900
Company	Alcon Laboratories	Alcon Laboratories	Alcon Laboratories	Abbott Medical Optics
Design	diffractive + refractive	diffractive + refractive	diffractive + refractive	diffractive
Pupil	dependent	dependent	dependent	independent
Near add	+4.00	+4.00, +3.00	+3.00	+4.00
Toric	no	no	yes	no
Aspheric	no	yes	yes	Yes
	Lentis Mplus (LS-312MF, LS-313MF)	Lentis Mplus Toric	M-flex (630F, 580F)	M-flex T (630F, 580F)
Company	Oculentis GmbH.	Oculentis GmbH.	Rayner Ltd.	Rayner Ltd.
Design	refractive, sector-shaped near zone	refractive, sector-shaped near zone	refractive	refractive
Pupil	independent	independent	dependent	dependent
Near add	+3.00	+3.00	+3.00, +4.00	+3.00, +4.00
Toric	yes	no	no	yes
Aspheric	yes	yes	yes	yes
	CeeOn 811E*	PA 154N*	TrueVista 68STUV*	Acri.Twin 733+737*
Company	Pharmacia	Allergan	Storz	Acri.Tech/ Carl Zeiss Meditec
Design	diffractive	refractive	refractive	diffractive
Pupil	independent	dependent	dependent	independent
Near add	+4.0	+3.50	+4.0	+4.0
Toric	no	no	no	no
Aspheric	no	no	no	yes

* = no longer available

MATERIALS AND METHODS

Bibliographic research was performed in Pubmed/Medline and most recently updated February 1st, 2011. Keywords used were “multifocal intraocular lens” as well as the respective brand names presented in **table 1**. Articles were included if they reported on clinical trials, adult patients with cataract, bilateral surgery with a single type of multifocal IOL, absence of co-existing ocular pathology such as amblyopia, and absence of previous or subsequent corneal refractive procedures such as limbal relaxing incisions or laser refractive surgery. Papers were classified either as randomized controlled trials (RCTs) or non-randomized case series, either with or without a control group. RCTs were included regardless of the date of publication, case series were included if published after December 31st, 2008. Data analysis focused on uncorrected distance visual acuity (defined as visual acuity measured at 4–6 meters), uncorrected intermediate visual acuity (defined as 60–100 centimetres) and uncorrected near visual acuity (defined as 30–50 centimetres, either standardized for all subjects within the study or at the working distance preferred by the individual patient). Mean visual acuities are reported in the current paper as Log-MAR units \pm standard deviation, if necessary after conversion of reported alternative visual acuity units. A secondary outcome parameter noted was spectacle independence, defined as not using spectacles for distance, intermediate and near vision tasks. Photoc phenomena, such as glare, flare and halos, and contrast sensitivity were not used as outcome parameters given the lack of uniformity in reporting these findings in the available papers, as described later in this paper.

RESULTS

Bibliographic research and data-analysis

The search for RCTs reporting on the results of implantation of multifocal IOLs following phacoemulsification of the crystalline lens identified a total of fourteen papers. One paper was excluded from the current review since it reported the results of implantation of multifocal IOLs in refractive lens exchange rather than in cataract surgery²⁶ and one paper was excluded since it reported on the results of unilateral implantation of multifocal IOLs.²⁷ The search for non-randomized case series, either with or without control groups, published after December 31st, 2008 reporting on the results of multifocal IOLs returned 96 papers. Seventy were excluded for reasons presented in **table 2**, the 26 remaining studies were included in the current literature review.

Table 2. Reasons for exclusion of the 70 studies excluded from the current literature review.

Reason for exclusion	Number of studies
Outcome parameters other than visual acuity and spectacle independence used (stereopsis, perimetry, electroretinography, effects of simulated astigmatism, pupillometry, contrast sensitivity, intraocular straylight, wavefront aberrometry)	12
In-vitro study	11
Descriptions of postoperative complications (posterior capsular opacification, endophthalmitis, interference with intraoperative view during vitrectomy, autorefraction and optical coherence tomography, occurrence of dysphotopsia and other reasons for patient dissatisfaction)	10
Multifocal IOL combined with laser refractive surgery	8
Refractive lens exchange study population	6
Previously published results	5
Unilateral and/or pediatric study population	4
Alternative techniques (scleral fixation of the multifocal IOL, cyclosporine as adjuvant therapy)	2
Description of national practice patterns	2
Description of questionnaire for spectacle dependence	2
Monovision strategies	2
Cost-benefit analysis	1
IOL of non-multifocal design	1
Reporting visual acuities as median value only	1
Reporting visual acuities as percentages of patients only	1
Different types of multifocal IOLs implanted in contralateral eyes	1
Amblyopic cases	1

Table 3. Randomized controlled trials comparing results of implantation of different types of multifocal intraocular lenses.

Study*	Year	IOL type (number of eyes)	UNVA (logMar)	UDVA (logMar)	complete SI (% of patients)
Alfonso ⁶⁶	2010	ReSTOR SN60D3 (20)	0.03 ± 0.05 [§]	-0.04 ± 0.10 [§]	-
		ReSTOR SN6AD3 (20)	-0.05 ± 0.06 [§]	-0.08 ± 0.10 [§]	-
		ReSTOR SN6AD1 (20)	-0.08 ± 0.04 [§]	-0.06 ± 0.05 [§]	-
		Acri.LISA 366D (20)	-0.02 ± 0.08 [§]	-0.08 ± 0.08 [§]	-
Santhiago ⁶⁷	2010	ReSTOR SN6AD3 (32)	0.03 ± 0.08 [§]	0.02 ± 0.07 [§]	-
		ReSTOR SN6AD1 (32)	0.02 ± 0.08 [§]	0.03 ± 0.07 [§]	-
Maxwell ⁶⁸	2009	ReSTOR SN6AD3 (228)	0.12 [§]	0.02 [§]	81.2%
		ReSTOR SN6AD1 (232)	0.10 [§]	0.02 [§]	78.3%
Martínez-Palmer ⁶⁹	2008	Tecnis ZM900 (52)	0.06 ± 0.09 [†]	0.18 ± 0.10	77.0%
		ReZoom (64)	0.22 ± 0.14 [†]	0.14 ± 0.12	44%
		Acri.Twin (64)	0.11 ± 0.12 [†]	0.16 ± 0.12	87.5%
Cillino ³⁴	2008	Array SA40N (32)	0.20 ± 0.06	0.06 ± 0.10	43.7%
		ReZoom (30)	0.21 ± 0.10	0.07 ± 0.14	53.3%
		Tecnis ZM900 (32)	0.14 ± 0.11	0.16 ± 0.10	87.5%
Hütz ⁵²	2008	Array SA40N (20)	0.43 ± 0.14	-	-
		ReSTOR SA60D3 (20)	0.28 ± 0.15	-	-
		Tecnis ZM001 (20)	0.16 ± 0.11	-	-
Gunenc ⁵⁴	2008	Array SA40N (20)	20 % ≥ J1 [§] 40 % ≥ J2 [§]	90 % ≥ 20/25	60%
		CeeOn 811E (20)	90 % ≥ J1 [§] 100 % ≥ J2 [§]	80 % ≥ 20/25	60%
Chiam ⁷⁰	2007	ReSTOR SA60D3 (100)	0.11	0.06	86%
		ReZoom (100)	0.23	0.02	70%
Mester ⁵⁰	2007	Array SA40 (50)	~0.40	~0.08 [§]	33.3%
		Tecnis ZM900 (50)	~0.22	~0.08 [§]	82.6%
Hütz ⁷¹	2006	Array SA40N (20)	69 words/min [§]	-	-
		Tecnis ZM001 (20)	166 words/min [§]	-	-
		ReSTOR SA60D3 (20)	138 words/min [§]	-	-
Leyland ⁷²	2002	Array SA40NB (58)	0.43 ± 0.16	0.06 ± 0.10	28%
		TrueVista (30)	0.46 ± 0.21	0.10 ± 0.15	33%
Liekfeld ⁷³	1998	CeeOn 811E (26)	0.04 ± 0.05	0.09 ± 0.12	-
		PA 154N (24)	0.32 ± 0.24	0.12 ± 0.10	-

* = first author, [§] = binocular, [†] = binocular with distance correction, J = Jaeger optotype, SI = spectacle independence, UDVA = uncorrected distance visual acuity, UNVA = uncorrected near visual acuity.

Visual acuity and spectacle independence

The results of the papers reporting on RCTs are presented in **table 3**. The results of the papers reporting on case-series either comparing the results of different types of multifocal IOIs or reporting on the results of a single type of multifocal IOL are presented in **table 4**.

Table 4. Non-randomized studies reporting results of implantation of different types of multifocal intraocular lenses.

IOL type	Study*	Patient Type (number of eyes)	UNVA	UDVA	SI
Array	Fujimoto ⁷⁴	cataract (72)	0.24	0.06	34.7%
	Ito ³³	cataract (44)	0.19 ± 0.12 [§]	-0.10 ± 0.00 [§]	-
ReZoom	Chang ⁷⁵	cataract (30)	0.17 [§]	-0.01 [§]	50%
	Forte ⁷⁶	cataract (55)	J2.3 ± 0.7	0.05 ± 0.09	-
	Gierek-Ciaciura ⁷⁷	cataract (20)	0.20 ± 0.04	0.11 ± 0.01	70%
	Zelichowska ⁷⁸	cataract (46)	-	0.03 ± 0.06	-
Acri.LISA 366D	Alfonso ²²	cataract (40)	-0.05 ± 0.07 [§]	0.01 ± 0.18 [§]	-
	Alió ⁷⁹	cataract (40)	0.12 ± 0.12	0.10 ± 0.12	-
	Castillo-Gómez ⁸⁰	cataract (20)	0.06	0.15	-
	Fernández-Vega ⁸¹	cataract (170)	0.00 ± 0.02 0.00 ± 0.03	0.07 ± 0.02 0.10 ± 0.16	-
ReSTOR SA60D3, SN60D3, SN6AD3	Alfonso ²²	cataract (36)	-0.04 ± 0.18 [§]	0.02 ± 0.13 [§]	-
	Alió ⁷⁹	cataract (40)	0.19 ± 0.12	0.19 ± 0.18	-
	Blaylock ⁵⁶	cataract (74)	0.06 [§]	0.00 [§]	-
	Chang ⁷⁵	cataract (30)	0.07 [§]	0.08 [§]	72.7%
	Cionni ⁸²	cataract (190)	0.11	0.05	80.6%
	Gierek-Ciaciura ⁷⁷	cataract (20)	0.11 ± 0.01	0.17 ± 0.02	80.0%
	Hayashi ⁸³	cataract (63)	0.1 [†]	0.1 [†]	-
	Hida ⁸⁴	cataract (40)	85% > J2	0.03 ± 0.05	-
	Mester ⁸⁵	cataract (40)	0.24 ± 0.18 [†]	0.17 ± 0.22	-
	de Vries ⁸⁶	cataract (46)	-0.01 ± 0.05 [§]	0.05 ± 0.12 [§]	-
ReSTOR SN6AD1	Zelichowska ⁷⁸	cataract (46)	-	0.03 ± 0.05	-
	Alfonso ⁸⁷	cataract (40)	-0.04 ± 0.06 [§]	0.00 ± 0.10 [§]	-
	Hayashi ⁸⁸	cataract (64)	0.21	0.08	-
	Kohnen ⁸⁹	cataract (186)	-0.01 ± 0.11 [§]	-0.03 ± 0.13 [§]	88%
	Mester ⁸⁵	cataract (40)	0.17 ± 0.14 [†]	0.14 ± 0.14 [†]	-
	de Vries ⁸⁶	cataract (68)	0.04 ± 0.12	0.04 ± 0.14	-
Tecnis ZM900	Akaishi ⁹⁰	cataract (2500)	0.00 ± 0.00	0.06 ± 0.09	97.9 %
	Castillo-Gómez ⁸⁰	cataract (20)	0.11	0.08	-
	Gierek-Ciaciura ⁷⁷	cataract (20)	0.12 ± 0.03	0.14 ± 0.02	80 %
	Packer ⁹¹	cataract (244)	0.16	0.04	84.8%
	Palomina ⁹²	cataract (250)	0.22 ± 0.08	0.14 ± 0.10	88.4%
Lentis Mplus LS312	Alió ⁹³	cataract (24)	0.30 ± 0.21	0.25 ± 0.33	-
M-flex 630F	Aslam ⁹⁴	cataract (20)	65% ≥ J6	0.18 ± 0.20	-
	Cezón-Prieto ⁸⁵	cataract (32)	0.28 ± 0.11	0.09 ± 0.09	70 % near, 80 % intermedi- ate, 90 % distance

* = first author, § = binocular, † = binocular with distance correction, ‡ = derived from figure, J = Jaeger optotype, RLE = refractive lens exchange, SI = spectacle independence, UDVA = uncorrected distance visual acuity, UNVA = uncorrected near visual acuity.

DISCUSSION

Implantation of a multifocal IOL is aimed at providing patients with good uncorrected visual acuity for both distance and near visual tasks. Patients with a monofocal IOL can have both good uncorrected distance and near visual acuity resulting from favourable corneal astigmatism,^{28,29} favourable corneal wavefront aberrations,^{30,31} or myopic undercorrection in one eye resulting in pseudophakic monovision.^{32,33} Randomized controlled trials^{34–40} and meta-analyses of randomized-controlled trials^{41,42} comparing the results of multifocal IOL implantation with the results of monofocal IOL implantation concluded that uncorrected near vision is improved by implantation of a multifocal IOL, resulting in lower levels of spectacle dependence for near tasks, without compromising distance visual acuity. The results of the current bibliographic search for papers in the peer-reviewed literature reporting on the results of bilateral implantation of multifocal IOLs in cataract surgery demonstrate that implantation of both refractive, hybrid refractive-diffractive, and diffractive multifocal IOLs result in high levels of uncorrected distance and near visual acuity. Uncorrected near visual acuity appears to be better for diffractive and hybrid diffractive-refractive IOLs compared to refractive IOLs, and uncorrected distance visual acuity appears to be comparable for all types of multifocal IOLs. Spectacle dependency tended to be lower in diffractive and hybrid diffractive-refractive IOLs compared to refractive multifocal IOLs.

Despite their benefits with regard to uncorrected visual acuity at multiple distances, multifocal IOLs are also associated with more photic phenomena and a decreased contrast sensitivity function compared to monofocal IOLs, as well as with a decreased visual acuity at intermediate rather than far and near distances. Halos and glare are more often reported by individuals with a multifocal IOL compared to patients with a monofocal IOL.^{43,44} Refractive multifocal IOLs appear to be associated with more photic phenomena compared to diffractive multifocal IOLs.³⁴ Photic phenomena are among the most frequent reasons for patient dissatisfaction following implantation of multifocal IOLs.^{45,46} Likewise, multifocal IOLs are associated with lower contrast sensitivity compared to monofocal IOLs.³⁴ Especially in mesopic circumstances,⁴⁷ or in patients with decreased contrast sensitivity due to ocular pathology, such as macular degeneration or corneal dystrophies, this can become clinically relevant.^{48,49} The reason for the lower contrast sensitivity could be that multifocal IOLs result in coexisting images, one sharp and one out of focus, with the light from the latter reducing the detectability of the former image due to the reduced contrast difference between target image and its surrounding secondary image. Additionally, contrast sensitivity is lower in multifocal IOLs than in monofocal IOLs since only part of the light energy originating from the object viewed is used for imaging of the object, since the light energy is diminished as it is divided over two or

more focal points in multifocal IOLs and partly lost due to scatter in diffractive IOLs. Diffractive multifocal IOLs appear to be either equal or superior to refractive multifocal IOLs with respect to contrast sensitivity.⁴⁸⁻⁵⁰ Although contrast sensitivity in individuals with multifocal IOLs is diminished compared to individuals with monofocal IOLs⁵¹, it is within the normal range compared to age-matched phakic individuals.^{47,51} Multifocal IOLs, unlike accommodative IOLs, depend on two fixed focal points which each represent two fixed working distances (far and near) at which they deliver a sharp image to the retina (surrounded by a blurred retinal image or images resulting from the other focal point or points). Working distances between these “sweet spots” are associated with suboptimal visual acuity, potentially resulting in difficulties with computer work and similar activities.⁵² Traditionally, refractive multifocal IOLs performed better at intermediate than near distance.⁵³ For that reason, refractive multifocal IOLs were therefore implanted bilaterally in patients with strong intermediate vision demands, combined with a diffractive multifocal IOLs in the non-dominant eye or combined with mini-monovision strategies leaving the non-dominant eye slightly myopic to increase visual function at near distances.⁵³⁻⁵⁵ Similarly, diffractive multifocal IOLs have been combined with mini-monovision strategies to increase visual function at intermediate distances.⁵⁶ The introduction of diffractive multifocal IOLs with lower near adds however, has increased visual acuity at intermediate distance without decreasing near and distance visual acuity.

Despite the large number of published papers on the performance of single or multiple types of multifocal IOLs as presented above, comparing the performance of different types of multifocal IOLs is currently hampered for several reasons. First, despite work to develop instruments to measure subjective quality of vision⁵⁷, there is no consensus on which test or questionnaire to use for the measurement of the subjective quality of vision including the occurrence and severity of photic symptoms, resulting in many different questionnaires and grading systems being used in different papers. Since photic phenomena such as glare and halos seem to wear with time⁵⁸, a standardized follow-up time would also be essential to compare results of different IOLs from different studies. Secondly, there is no standardized test for near visual acuity. Some studies use single character reading charts, such as Snellen³⁴ and ETRDS⁸⁵ near visual acuity charts. Other studies use function-based tests such as the MNread chart, Radner chart⁷¹ and variations thereof³³, measuring reading speed, number of mistakes and critical character size when reading sentences rather than single characters. Thirdly, there is no consensus whether visual acuity measurements should be reported either binocular or monocular. Binocular visual acuity is generally higher, which might be the result of slight refractive differences between both eyes (resulting in an pseudophakic mini-monovision) or of more complex and less understood neurological processes. In clinical practice, bin-

ocular implantation has indeed been shown to be preferable to monocular implantation.⁵⁹ Fourthly, contrast sensitivity measurements are currently not standardized, with the CSV-1000,^{75,86} Functional Acuity Test Chart,^{69,87} Ginsburg box,^{49,85} and the CAT-2000⁸⁸ systems being used. Discussion exists what levels of contrast sensitivity should be considered normal, given the large standard deviation of contrast sensitivity in normal subjects, and whether multifocal IOLs should be compared to age-matched phakic subjects or age-matched subjects with a monofocal IOL. Finally, multifocal IOLs have been associated with higher levels of higher order aberrations compared to monofocal IOLs.⁶⁰ The role of these aberrations, however, is not clear. Not only is their value for the depth of focus disputed,^{30,31} but also the ability of wavefront analyzers to correctly measure aberrations in the subjects with a multifocal IOL has both been clarified.^{61,62} Lower levels of higher order aberrations in so-called "aspheric optics" have been shown to be beneficial in monofocal IOLs²¹, but this is less evident for multifocal IOLs.^{23,63} Thus, comparing different types of multifocal IOLs with regard to aberrometric findings is currently impossible, too. Given the lack of consensus on any of these five items, a direct comparison between different types of multifocal IOLs in order to decide which IOL leads to the most desirable results is still difficult.

In general, multifocal IOLs are able to provide patients with excellent uncorrected distance and near visual acuity resulting in high levels of spectacle independence. Although superior from a theoretical point of view, currently available accommodative IOLs are unable to offer the same level of near visual acuity.⁶⁴ Pseudo-accommodative multifocal IOLs are either based on diffractive or refractive designs. Diffractive designs appear to deliver equal or superior results compared to refractive designs with respect to near visual acuity, occurrence of photic phenomena and possibly with respect to contrast sensitivity. Dissatisfaction following implantation of multifocal IOLs is rare, and is often amenable for treatment (e.g. by treating posterior capsule opacification with laser capsulotomy, or treating a residual refractive error with spectacles or laser refractive surgery).^{45,46} Other cases of dissatisfaction are due to the occurrence of phenomena inherent to the design of multifocal IOLs (such as glare and halos) and are therefore more difficult to treat.^{45,46} This demonstrates the importance of preoperative patient education, careful patient selection and individualized weighing of benefits and side-effects of multifocal IOLs.^{39,65} If these principles are respected, multifocal IOLs can lead to excellent results and high levels of patient satisfaction.

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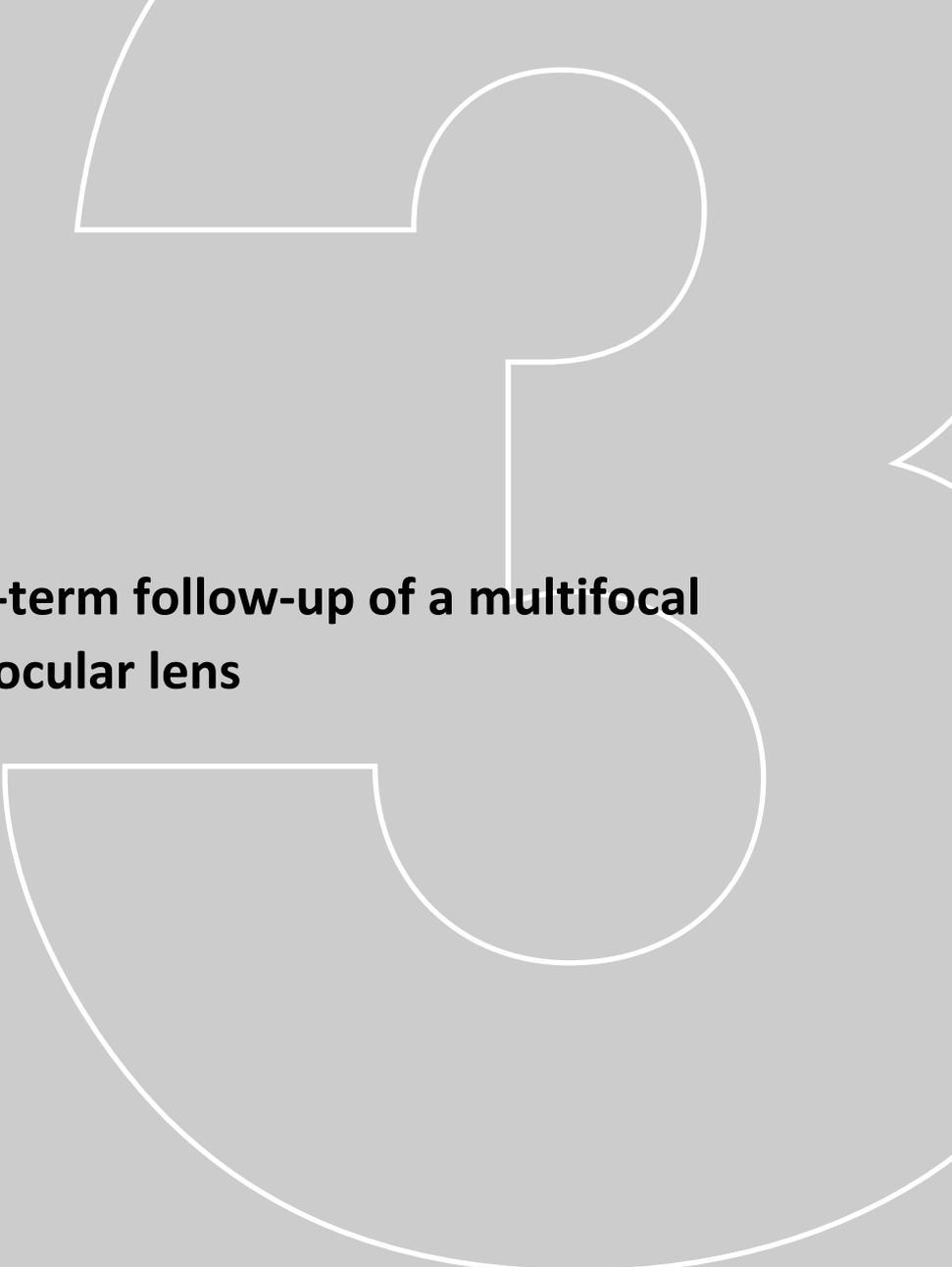
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Long-term follow-up of a multifocal intraocular lens

Long-term follow-up of a multifocal apodized diffractive intraocular lens after cataract surgery

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ABSTRACT

PURPOSE: To report the long-term performance of the AcrySof ReSTOR SA60D3 intraocular lens (IOL) after cataract surgery.

SETTING: University Hospital Maastricht, Maastricht, the Netherlands.

METHODS: This prospective clinical trial comprised 44 eyes (22 consecutive patients) having cataract surgery with implantation of the ReSTOR IOL. Monocular and binocular uncorrected distance visual acuity, best corrected distance visual acuity, uncorrected near visual acuity, best distance-corrected near visual acuity, spectacle dependence, undesired visual symptoms, patient satisfaction, and incidence of posterior capsule opacification were analyzed 6 months and 3 years postoperatively.

RESULTS: The mean uncorrected distance acuity (logMAR) was 0.046 ± 0.099 at 6 months and 0.115 ± 0.173 at 3 years and the mean best corrected distance acuity, -0.040 ± 0.075 and -0.018 ± 0.093 , respectively. Binocular uncorrected and best-corrected near acuities (logMAR) were 0.009 ± 0.029 at 6 months and 0.014 ± 0.035 at 3 years. All patients achieved a binocular uncorrected and best distance-corrected near acuity of 20/25 or better at 6 months and 3 years. On a quality-of-life questionnaire, patients reported good distance, intermediate, and near acuity without complaints of severe glare or halos. Complete spectacle independence for distance and near acuity was achieved by 83.7% and 81.9% of patients, respectively, at 6 months and 85.0% and 75.0% of patients, respectively, at 3 years. Four eyes (9.1%) required neodymium:YAG capsulotomy.

CONCLUSIONS: Cataract surgery with the AcrySof ReSTOR SA60D3 IOL provided good, stable distance and near visual acuities over a 3-year follow-up, leading to low spectacle independence and high patient satisfaction.

INTRODUCTION

The visual performance of patients after cataract extraction is greatly dependent on the choice of intraocular lens (IOL). Although monofocal IOLs provide excellent visual function, for many patients the limited depth of focus does not allow clear vision at both distance and near. Pseudoaccommodating IOLs were developed to offer pseudophakic patients the possibility of satisfactory distance and near vision and independence from spectacles.^{1,2} Multifocal IOLs, which use refraction³⁻⁵ or diffraction⁶⁻⁹, and accommodative¹⁰ IOLs were developed to provide patients with spectacle independence. The AcrySof ReSTOR SA60D3 IOL (Alcon Laboratories) incorporates a hybrid diffractive–refractive concept that has been shown to result in good visual outcomes after cataract¹¹⁻²⁰, clear lens²¹, or piggyback IOL²² surgery. Previous studies have examined the visual outcomes over a short period (1.5 to 12.0 months); however, to our knowledge, no long-term studies of this type of IOL are available. The purpose of this study was to assess the visual performance 3 years after cataract surgery with bilateral implantation of the AcrySof ReSTOR SA60D3 IOL.

PATIENTS AND METHODS

Study Design

This prospective study comprised 44 eyes of 22 consecutive patients who had cataract surgery and bilateral implantation of the AcrySof ReSTOR SA60D3 multifocal IOL at the University Hospital Maastricht, The Netherlands, between December 2003 and November 2004. The tenets of the Declaration of Helsinki were followed, and full ethical approval was obtained from the University Hospital Maastricht. Informed consent was obtained from all patients after a full explanation of the nature and possible consequences of the study and surgery was given. Patients were considered for participation if they were between 43 years and 85 years of age, required binocular IOL implantation, and were motivated to achieve spectacle independence. Exclusion criteria included preoperative astigmatism greater than 2.00 diopters (D), occupational night driving, history of glaucoma or retinal detachment, corneal disease or previous corneal or intraocular surgery, abnormal iris or pupil deformation, macular degeneration or retinopathy, neuro-ophthalmic disease, and a history of ocular inflammation.

Intraocular Lens Characteristics

The AcrySof ReSTOR SA60D3 multifocal IOL uses apodization, diffraction, and refraction. The apodized diffractive region of the IOL, situated within the central 3.6 mm optic zone, comprises 12 concentric steps of gradually decreasing (1.3 to 0.2 mm) height, creating multifocality from distance to near (2 foci). The refractive part of the optic surrounds the apodized diffractive region. This area directs light to a distance focal point for larger pupil diameters and is dedicated to distance vision. The overall diameter of the IOL is 13.0 mm, and the optic diameter is 6.0 mm. The IOL power used in this study ranged from +17.00 to +25.00 D and incorporated a +4.00 D near addition power at the IOL plane, or about +3.25 D at the corneal plane.¹²

Preoperative Examination

Before cataract surgery, patients had a full ophthalmologic examination including manifest refraction, keratometry, slitlamp biomicroscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy through a dilated pupil. Axial length and anterior segment size were measured using the IOLMaster (Carl Zeiss). The SRK/T formula was used for IOL power calculation, and the targeted refraction was emmetropia.

Surgical Technique

All surgeries were performed by the same surgeon using phacoemulsification with the Legacy coaxial phaco machine (Alcon Laboratories), topical anesthesia, and a 3.0 mm clear corneal incision along the steep corneal meridian. Phacoemulsification was followed by irrigation and aspiration of the cortex and IOL implantation in the capsular bag.

Parameters

LogMAR visual acuity charts were used for vision testing. For uncorrected distance visual acuity and best corrected distance visual acuity, patients were tested using the 100% contrast Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Precision Vision) under photopic lighting conditions. Uncorrected near visual acuity and best distance-corrected near visual acuity measurements were obtained using a handheld near logMAR chart at a standard distance of 33 cm. Binocular intermediate distance-corrected visual acuity was tested at 60 cm. Contrast sensitivity function was determined using the CSV-1000 system (Vector Vision, Inc.). This instrument consists of a translucent chart with background illumination calibrated at 85 cd/m², thereby providing independence from room illumination. Examinations were performed unilaterally with best spectacle refractive correction in place, if applica-

ble, and with an undilated pupil. Absolute values of log contrast sensitivity function were obtained for each combination of eye and spatial frequency, and means and standard deviations were calculated. Results were compared with population norms from a 50-year to 75-year age group.²³ In addition, absolute values were normalized for each spatial frequency by dividing the mean log contrast sensitivity function through the mean log contrast sensitivity function from the population norm, as described previously.²⁴ Intraocular lens decentration was determined by measuring the distances between the center of the diffractive structure and the center of the pupil on the vertical and horizontal axes using a slitlamp (Haag-Streit). A difference of 0.5mm or more between the 2 distances on 1 axis was considered to represent significant IOL decentration. An assessment of patient satisfaction, visual phenomena, and spectacle dependency was performed at the 6-month and 3-year postoperative visits. Patients rated the quality of vision without spectacles for distance, near, and intermediate vision on the following scale: 1 = excellent; 2 = good; 3 = satisfactory; 4 = not so good; 5 = bad. Items related to intermediate vision tasks were the capability to perform fine handiwork, games, or cooking, which patients rated on the following scale: 1 = no problem; 2 = a little difficult; 3 = quite difficult; 4 = very hard; 5 = impossible. Patients rated visual disturbances (e.g., glare and halos) on the following scale: 1 = severe; 2 = moderate; 3 = mild; 4 = none. To assess spectacle dependency, patients were asked about their requirement for spectacle wear at distance and near vision on the following scale: 1 = always; 2 = most of the time; 3 = quite often; 4 = some of the time; 5 = never. Postoperative assessments were routinely performed at 1 week, 1, 3, and 6 months, and 3 years after the surgery. The 6-month and 3-year examinations were performed by the same ophthalmic technician, who was unaware of the objective of the study.

Statistical Analysis

Data analysis was performed using SPSS for Windows (version 14.0, SPSS, Inc.). Normality was checked by the Shapiro-Wilk test, and the t test was performed to compare outcomes at 6 months and 3 years. Differences were considered to be statistically significant when the P value was less than 0.01.

RESULTS

The mean age of the 22 patients was 74.2 years \pm 8.7 (SD) (range 43 to 85 years). **Table 1** shows the patients' demographics. All patients completed the 3-year follow-up.

Table 1. Demographic characteristics of patients.

Characteristic	Value
Eyes (n)	44
Age (y)	
Mean \pm SD	74.2 \pm 8.7
Range	43 to 85
Sex (M/F)	8/14
Keratometry (D)	
Mean \pm SD	
K1	44.37 \pm 1.86
K2	43.55 \pm 1.94
Range	40 to 48
IOL power (D)	
Mean \pm SD	21.70 \pm 2.17
Range	17 to 25
Axial Length (mm)	
Mean \pm SD	22.99 \pm 0.88
Range	21.26 to 24.53

IOL = intraocular lens

Visual Outcomes

Table 2 shows the mean and distance and near visual acuities 6 months and 3 years after surgery. At 3 years, all patients had a binocular best corrected distance acuity of 20/40 or better and 95%, of 20/25 or better. No statistically significant differences were found between the 6-month and 3-year visits in monocular and binocular uncorrected distance acuity and best corrected distance acuity ($P > .01$) (**Table 2**). At 3 years, all patients had monocular best distance-corrected near acuity and binocular uncorrected and best distance corrected near acuity of 20/25 (**Table 2**). No statistically significant differences were found between the 6-month and 3-year visits in near acuity under monocular and binocular conditions ($P > .01$). Binocular distance-corrected intermediate vision was 0.357 at 3 years.

Table 2. Visual acuity results 6 months and 3 years after IOL implantation.

Parameter	Acuity at 6 Monts			Acuity at 3 Years			P value
	Mean	Number (%)		Mean	Number (%)		
		20/40 or better	20/25 or better		20/40 or better	20/25 or better	
Distance (6 m) acuity (logMAR)							
Monocular uncorrected	0.128 ± 0.130	42/44 (95.5)	23/44 (52.3)	0.197 ± 0.185	34/44 (77.3)	21/44 (47.7)	.021
Monocular best distance-corrected	0.012 ± 0.086	44/44 (100.0)	41/44 (93.2)	0.052 ± 0.110	44/44 (100.0)	35/44 (79.5)	.027
Binocular uncorrected	0.046 ± 0.099	22/22 (100.0)	19/22 (86.4)	0.115 ± 0.173	20/22 (90.9)	18/22 (81.8)	.056
Binocular best-distance corrected	-0.040 ± 0.075	22/22 (100.0)	22/22 (100.0)	-0.018 ± 0.093	22/22 (100.0)	21/22 (95.5)	.199
Near (33 cm) acuity (logMAR)							
Monocular uncorrected	0.020 ± 0.109	43/44 (97.7)	42/44 (95.5)	0.058 ± 0.081	43/44 (97.7)	42/44 (95.5)	.032
Monocular best distance-corrected	0.034 ± 0.060	44/44 (100.0)	43/44 (97.7)	0.065 ± 0.087	44/44 (100.0)	44/44 (100.0)	.027
Binocular uncorrected	0.009 ± 0.029	22/22 (100.0)	22/22 (100.0)	0.014 ± 0.035	22/22 (100.0)	22/22 (100.0)	.332
Binocular best-distance corrected	0.009 ± 0.029	22/22 (100.0)	22/22 (100.0)	0.014 ± 0.035	22/22 (100.0)	22/22 (100.0)	.332

Refractive Changes

Table 3 shows the postoperative refractive results. There was no statistically significant difference between the 6-month and 3-year results ($P > .1$). The spherical equivalent (SE) was 0.14 ± 0.34 D at 6 months and 0.09 ± 0.37 D at 3 years ($P = .22$). Emmetropia was achieved in 43.2% of eyes at 6 months and 45.5% at 3 years. At 3 years, 90.9% of eyes were within ± 0.50 D and all eyes were within ± 1.00 D.

Table 3. Differences in refraction between 6 months and 3 years postoperatively.

Parameter	6 Months	3 Years	P value
Mean SE (D) ± SD	0.14 ± 0.34	0.09 ± 0.37	.22
Sphere (D)			
Mean ± SD	0.53 ± 0.54	0.52 ± 0.56	.46
Range	-0.50 to +2.00	-0.25 to +2.00	
Cylinder (D)			
Mean ± SD	-0.79 ± 0.66	-0.88 ± 0.67	.12
Range	0.00 to 2.50	0.00 to 2.75	
% SE ± 0.5 (D)	84.1	90.9	-
% SE ± 1.0 (D)	100.0	100.0	-

SE = spherical equivalent

Contrast Sensitivity

Six months postoperatively, the mean postoperative monocular best-corrected contrast sensitivity was 1.62 ± 0.26 log units at 3 cycles per degree (cpd), 1.76 ± 0.41 log units at 6 cpd, 1.32 ± 0.37 log units at 12n cpd, and 0.91 ± 0.29 log units at 18 cpd. The mean normalized contrast sensitivity was 1.04, 0.98, 0.88, and 0.98 at 3 cpd, 6 cpd, 12 cpd, and 18 cpd, respectively. Three years postoperatively, the mean postoperative monocular best corrected contrast sensitivity was 1.57 ± 0.25 log units at 3 cpd, 1.63 ± 0.20 log units at 6 cpd, 1.12 ± 0.37 log units at 12 cpd, and 0.65 ± 0.30 log units at 18 cpd. The mean normalized contrast sensitivity was 1.01, 0.91, 0.75, and 0.70 at 3 cpd, 6 cpd, 12 cpd, and 18 cpd, respectively.

Self-Reported Quality of Vision, Visual Disturbances, and Spectacle Dependency

The mean self-reported quality of vision rating without spectacles for distance vision was 1.84 ± 0.69 at 6 months and 2.11 ± 1.15 at 3 years. For near vision, the mean rating was 1.78 ± 0.67 and 2.22 ± 1.17 , respectively. No statistically significant differences were found between values at 6 months and 3 years for distance, near, or intermediate vision ($P > .01$). **Table 4** shows the results of the quality-of-life questionnaire detailing the capability of conducting handiwork, games, or cooking. The mean patient-reported visual disturbance ratio for glare was 3.80 ± 0.41 at 6 months and 3.75 ± 0.55 at 3 years. The mean patient-reported visual disturbance ratio for halos was 3.95 ± 0.22 and 3.80 ± 0.52 , respectively. No patient reported severe visual disturbances (e.g., halos and glare) at either time point. **Table 5** shows patient-reported spectacle dependence for distance and near vision. At 6 months, 83.7% of patients reported that they never wore spectacles for distance vision compared with 85.0% at 3 years. Full spectacle independence at near was recorded by 81.9% of patients at 6 months and 75.0% at 3 years.

Table 4. Self-reported quality-of-life questionnaire results 6 months and 3 years postoperatively.

Activity	Mean Score ^a ± SD		P value
	6 Months	3 Years	
Handiwork	1.30 ± 0.67	1.30 ± 0.67	1.000
Games	2.13 ± 2.80	1.25 ± 0.71	0.422
Cooking	1.67 ± 0.58	1.00 ± 0.00	0.339

^a 1 = no problem; 2 = a little difficult; 3 = quite difficult; 4 = very hard; 5 = impossible

Table 5. Spectacle dependence at distance and near 6 months and 3 years postoperatively.

How Often Do you Wear Glasses for Seeing Objects at. . . .	Percentage	
	6 Months	3 Years
Distance		
Always	14.3	15.0
Most of the time	0	0
Quite often	0	0
Some of the time	0	0
Never	83.7	85.0
Near		
Always	9.1	10.0
Most of the time	0	10.0
Quite often	4.5	0
Some of the time	4.5	5.0
Never	81.9	75.0

Complications, Capsulotomies, and Intraocular Lens Centration

No intraoperative complications or potentially sight-threatening postoperative complications (eg, persistent corneal edema, pupillary block, retinal detachment, endophthalmitis) occurred. No additional interventions (eg, corneal refractive surgery or residual astigmatism) were required. Four eyes (9.1%) required neodymium:YAG (Nd:YAG) capsulotomy for posterior capsule opacification (PCO). Two capsulotomies were performed within the first year after surgery; the mean time between IOL implantation and capsulotomy was 15 ± 12.7 months. Visual acuity was 20/40 or better in all eyes having an Nd:YAG capsulotomy. No IOL decentration was noted during the follow-up period.

DISCUSSION

Postoperative follow-up of patients is the main difficulty when conducting longitudinal studies. However, such analysis in patients with multifocal IOLs is necessary to assess the long-term performance and possible changes that can occur in visual acuity over time. To our knowledge, the only other longitudinal study of multifocal IOL performance was by Slagvold,²⁵ who evaluated the visual performance of the 3M diffractive multifocal IOL 8 years after implantation. The purpose of the present study was to analyze the long-term (3 years) changes in visual performance in patients who had bilateral implantation of the AcrySof ReSTOR SA60D3 IOL. In this prospective study, no serious surgical events occurred and no IOL was explanted. The study was of patients with low degrees of astigmatism, a regular corneal shape on corneal topography, and preexisting hyperopia (36.4%), emmetropia (9.1%), or myopia (54.5%). At the 6-month postoperative visit, both distance and near visual

acuties were good and compared favorably with those reported in other studies of cataract patients with this IOL.^{12,19,20} The binocular mean uncorrected distance acuity and best corrected distance acuity was 0.046 logMAR and -0.040 logMAR, respectively. Kohnen et al.¹² report mean values of 0.04 logMAR and -0.05 logMAR, respectively, in 127 patients. Alfonso et al.¹⁹ found similar values (0.060 logMAR and 0.034 logMAR, respectively) in 325 patients, as did Vingolo et al.²⁰ (0.06 logMAR and 0.05 logMAR, respectively) in 100 patients. For near vision, uncorrected acuity and best distance-corrected acuity were 0.009 logMAR in our study. Kohnen et al.¹² found mean values of 0.09 logMAR and 0.05 logMAR, respectively; Alfonso et al.¹⁹ of 0.013 logMAR and 0.011 logMAR, respectively; and Vingolo et al.²⁰ of 0.10 logMAR and 0.07 logMAR, respectively. In our study, all patients achieved binocular best corrected distance acuity and best distance-corrected near acuity of 20/25 or better. Similar percentages were found by Kohnen et al.¹² (97.5% and 83.9%, respectively), Alfonso et al.¹⁹ (92% and 98.5%, respectively), and Vingolo et al.²⁰ (98% and 98%, respectively). Three years after surgery, both distance and near visual acuities remained good and did not differ significantly from those reported at the 6-month visit. The mean monocular and binocular uncorrected distance acuities were 20/25 and 20/20, respectively, and the mean monocular and binocular uncorrected near acuities, 20/20 and 20/20, respectively. The mean monocular and binocular best distance-corrected near acuity and best corrected distance acuity value was 20/20. All patients achieved binocular best distance-corrected near acuity and best corrected distance acuity of 20/25 or better. No comparison with previous studies can be made due to the lack of available long-term data on this type of IOL. No statistically significant refractive changes were observed between the 6-month and 3-year postoperative visits. The SE was less than 0.25 D at both examinations. At 6 months and 3 years, 43.2% and 45.5% of eyes, respectively, were emmetropic and all eyes were within ± 1.00 D of the intended correction. This provides further information on the accuracy of the IOL power selection and stability of the IOL in the capsular bag after implantation. These results agree with those of Fernandez-Vega et al.²¹ at 6 months (SE <0.25 D; 100% of eyes within ± 1.00 D). In our study, the mean contrast sensitivity function was comparable to normal values at the 2 lower spatial frequencies. At 3 cpd and 6 cpd, the mean log contrast sensitivity function was within ± 1 SD of the mean normal log contrast sensitivity function. At 12 cpd and 18 cpd, the differences in mean log contrast sensitivity function between our cohort and normal values were larger. Souza et al.¹⁴ found a lower mean log contrast sensitivity function in patients with the AcrySof ReSTOR IOL than in patients with a monofocal AcrySof SA60AT IOL (Alcon Laboratories), although the difference between the 2 types of IOLs was only significant in the monocular assessment and not in the binocular assessment. Vingolo et al.²⁰ also found a lower mean log contrast sensitivity function between the 2 types of IOLs. The difference, however, was only significant when measured using the static rather than the dynamic program of the device. A

more pronounced loss of contrast sensitivity function after implantation of zonal progressive multifocal IOLs has been reported.^{26,27} Previous quality-of-vision studies^{12,14,19,20} report a high level of satisfaction in patients with the AcrySof ReSTOR SA60D3 IOL over a 6-month follow-up. In our study, patients with this IOL achieved good visual acuity for distance and near vision at 6 months and 3 years. The self-reported quality-of-life questionnaire showed that the AcrySof ReSTOR SA60D3 IOL offers good distance, intermediate, and near visual acuity. The task that scored the lowest at 6 months was the ability to play games, with a score of 2 (a little difficulty); this improved at the 3-year visit to a score of 1 (no problem). In general, the ability to perform the 3 visual tasks was good, without reported problems at 6 months or 3 years. Patients were asked to rate visual disturbances (glare or halos), and none of them classified these as being severe at the 6-month or 3-year visit. One could argue that the apodized (step-height blending) diffractive optic of the AcrySof ReSTOR SA60D3 IOL plays a role in minimizing these phenomena by distributing the amount of energy traveling to the distance and near focal points according to pupil size, thus minimizing visual disturbances such as glare or halos under lower lighting levels. Other studies found high percentages of patients with complaints of halos and glare. Souza et al.¹⁴ report that 40% of patients had mild to moderate glare complaints and 50% mentioned nighttime halos. In a study by Chiam et al.¹⁶, 21.3% of patients had moderate glare complaints and 16.3% and 3.8% reported moderate halos and severe halos, respectively. Kohnen et al.¹² found that 24.6% and 8.5% of patients reported moderate glare and severe glare, respectively, while 16.1% and 4.2% reported moderate halos and severe halos, respectively. Thus, a high percentage of patients have mild or moderate complaints of halos and glare, but severe complaints are rare. As Kohnen et al.¹² point out, the complaints diminish with time, probably due to neural adaptation. This might be the explanation for the lower ratios of glare and halos in the current study. In addition, a recent study showed that implantation of the AcrySof ReSTOR IOL results in decreased intraocular straylight compared with the level in an age-matched non-cataractous population.²⁸ At 6 months, spectacle independence for distance vision and near vision was 83.7% and 81.9%, respectively. Kohnen et al.¹² found similar percentages (88% for distance; 84.6% for near). Vingolo et al.²⁰ reported a higher percentage of total spectacle independence (92%). At 3 years, 85% of patients reported spectacle independence for distance activities and 75% for near activities. Posterior capsule opacification is the most common complication of modern cataract surgery, with an incidence up to 50% at 2 years.²⁹ It has been speculated that as multifocal IOLs distribute light to 2 foci, even minor PCO might create symptoms. With the 3M posterior concave IOL, the Elschnig pearl-type of PCO occurred more frequently than the fibrotic type.²⁵ The Elschnig type necessitates an Nd:YAG capsulotomy at an earlier time than the fibrotic type. Slagsvold²⁵ reports that there was no difficulty focusing on the capsule after implantation of the 3M IOL; however, laser pits on the optic of

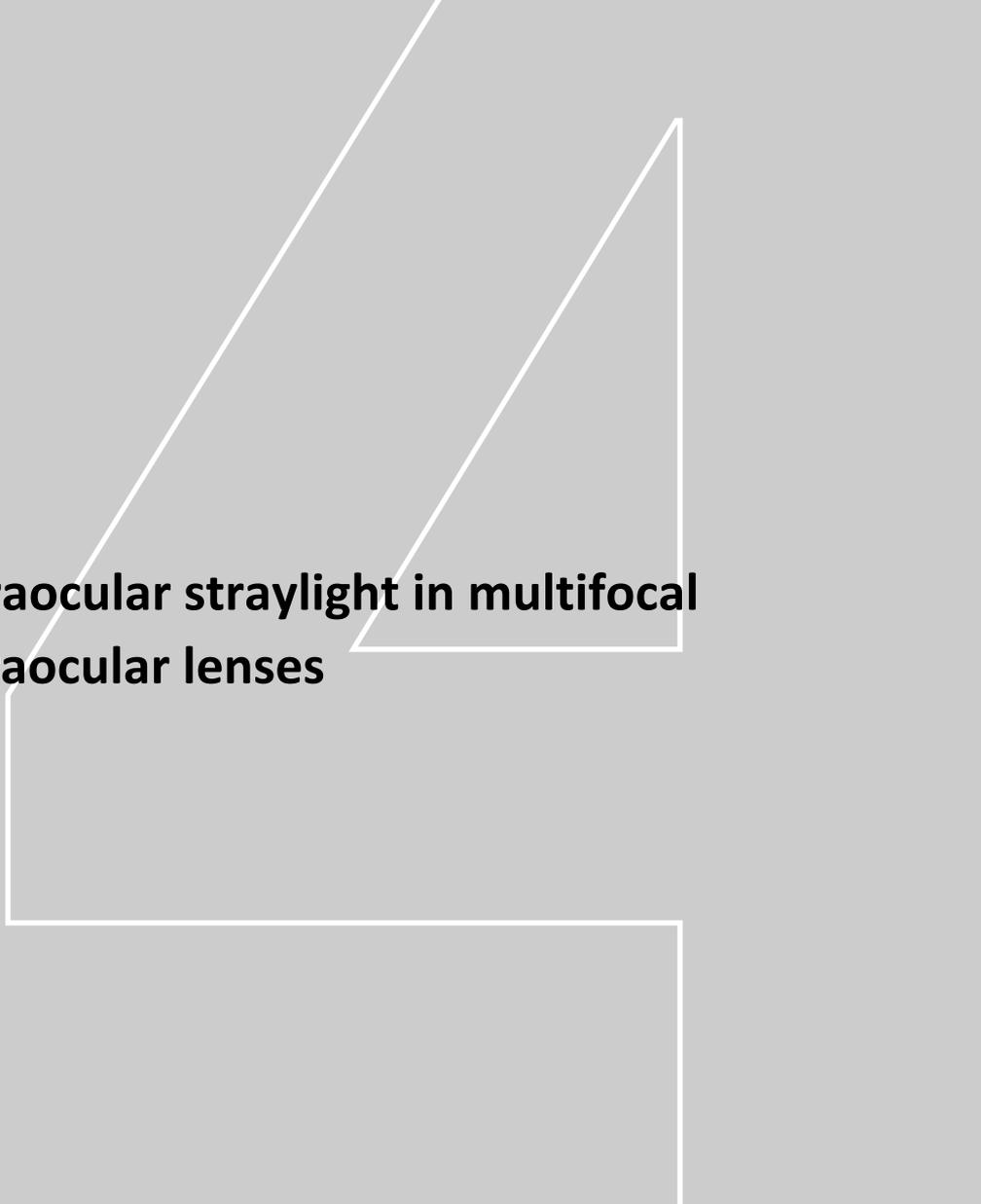
this injection-molded IOL were somewhat more distinct and irregular than those on other types of poly(methyl methacrylate) (PMMA) IOLs. Data from the U.S. Food and Drug Administration study⁶ showed the occurrence of Nd:YAG capsulotomy in eyes with the 3M IOLs was 10% at 4 to 6 months.⁶ Slagsvold²⁵ reported that 50% of eyes were treated during the 8-year follow-up; at the time of capsulotomy, 2 of 3 eyes had a visual acuity of 20/40 or better. Slagsvold concluded that patients with the 3M IOL do not require earlier capsulotomies than patients receiving monofocal PMMA IOLs. In our study, 4 eyes (9.1%) required Nd:YAG capsulotomy during the 3-year follow-up, 2 eyes at 6 months and 2 eyes at 24 months postoperatively. Given our results, the use of Nd:YAG capsulotomy for the treatment of PCO after AcrySof ReSTOR SA60D3 IOL implantation is a relatively safe, non-invasive method to improve visual acuity. Accurate IOL centration is vital for the success of all IOL implantations, and the necessity of accurate IOL centration increases when using multifocal designs. With its ring structure, the degree of decentration with the AcrySof ReSTOR SA60D3 IOL was easy to assess and in all cases, the IOL was well centered.

In conclusion, our study showed that the AcrySof ReSTOR SA60D3 IOL provided our patients with a satisfactory full range of vision and a low incidence of visual disturbances and PCO during the 3-year follow-up. The frequency of spectacle wear was reduced for both distance and near, and the IOL provided enhanced quality of life when implanted bilaterally.

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Intraocular straylight in multifocal intraocular lenses

Intraocular straylight after implantation of the multifocal AcrySof ReSTOR SA60D3 diffractive intraocular lens

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ABSTRACT

PURPOSE: To measure intraocular straylight (as a measure of glare) after cataract surgery and implantation of an AcrySof ReSTOR SA60D3 multifocal or AcrySof SA60AT monofocal intraocular lens(IOL) (both Alcon Laboratories).

SETTING: University Hospital Maastricht, Maastricht; Isala Clinics, Zwolle; Netherlands Institute for Neurosciences, Amsterdam, the Netherlands.

METHODS: In a prospective open observational case series, a newly developed straylight meter was used to objectively measure straylight 6 months postoperatively in 66 eyes with a diffractive AcrySof ReSTOR SA60D3 IOL (multifocal group) and 40 eyes with a monofocal AcrySof SA60AT IOL (monofocal group). A comparison of straylight levels in an age-matched population without cataract (control group) was performed.

RESULTS: The straylight level was $1.20 \log \text{ units} \pm 0.16 \text{ (SD)}$ in the multifocal group and $1.10 \pm 0.19 \log \text{ units}$ in the monofocal group. When the difference in mean level of straylight was adjusted for age, mean straylight levels were 0.078 log units lower in the monofocal group than in the multifocal group ($P = .026$). Straylight levels in both pseudophakic groups were lower than in the control group without cataract ($P < .0001$).

CONCLUSIONS: Levels of intraocular straylight log(s) were significantly lower for both types of IOL than in age-matched subjects from the normal population. The mean level of intraocular straylight 6 months postoperatively was higher in patients with an AcrySof ReSTOR SA60D3 IOL than in patients with a monofocal AcrySof SA60AT IOL. Implantation of the former IOL would therefore result in a smaller gain in contrast sensitivity and a smaller reduction in glare and halos than implantation of the latter IOL.

INTRODUCTION

Intraocular straylight is the result of scattering of light entering the human eye secondary to imperfections of the optical media.¹ The resulting diffuse illumination of the retina reduces the amount of contrast between the perceived image of an object and the surrounding retina. Therefore, intraocular straylight can be described as a veil of light that decreases the quality of vision.¹ The amount of straylight in an eye is expressed as log (straylight parameter), or log(s). Higher values indicate more straylight and more sensitivity to glare.² The phenomenon of straylight is usually measured at scattering angles of more than 1 degree. In contrast, the deflection of light rays due to refractive effects, such as plain defocus and aberrations in multifocal intraocular lenses (IOLs), are classically limited to angles less than 1 degree. Within the normal eye, 4 major sources contribute to the amount of intraocular straylight: the cornea, lens, iris and sclera, and retinal fundus.³ Although corneal light scatter remains more or less constant with age, light scattering caused by the lens increases markedly with age.⁴ Intraocular straylight caused by light shimmering through the not perfectly opaque iris and sclera depends on the level of pigmentation, as is the case for the amount of light reflected backward from the retinal fundus. In the normal population, straylight has a strong correlation with age and increases rapidly after the age of 50 years (**Figure 1**).⁵ An increased level of intraocular straylight can lead to glare complaints, even without clear loss of visual acuity.¹ Factors that can lead to increased levels of straylight are the presence of cataract⁴; corneal changes after refractive surgery such as radial keratotomy,⁶ photorefractive keratectomy,^{7,8} or laser in situ keratomileusis^{9,10}; retinitis pigmentosa¹¹; corneal edema¹²; and contact lens wear.¹³ Cataract surgery may significantly decrease the levels of straylight.¹⁴ Implantation of an IOL after cataract surgery can lead to subjective complaints resulting from defocus, such as halos and glare. This has been reported with refractive¹⁵⁻¹⁹ and diffractive^{20,21} multifocal IOLs as well as with monofocal IOLs.^{16,22} With the earlier model of the zonal refractive Array SA40N multifocal IOL (Advanced Medical Optics), moderate to severe halos and glare were reported in up to 64.2% and 14.0% of eyes, respectively.²³ In a multicenter trial of the results of implantation of the diffractive AcrySof ReSTOR SA30D3 multifocal IOL (Alcon Laboratories), severe halos and glare were reported by 4.2% and 8.5% of patients, respectively²⁰. Apodization of the surface of the AcrySof ReSTOR SA30D3 IOL, which consists of gradual tapering of the diffractive steps from the center to the outside edge of the surface of the IOL, was introduced to decrease the severity of halos and glare. The additional role of the light deflected due to diffraction from a multifocal IOL in the occurrence of subjective complaints such as halos and glare is currently unknown. No objective test exists to measure subjective glare complaints in patients with a multifocal IOL. The goal of the current study was to objectively measure the levels of intraocular straylight in patients with an apodized diffractive multi-

focal IOL (AcrySof ReSTOR SA60D3) or a monofocal IOL (AcrySof SA60AT, Alcon Laboratories) and to compare these values with those in non-cataractous age-matched subjects.

PATIENTS AND METHODS

A straylight meter (Oculus C-Quant, Oculus GmbH) based on the compensation comparison method was used to determine the level of intraocular straylight. The meter measures the level of intraocular straylight by compensating for the amount of straylight (induced by a peripheral light source) on a test field, with counterphase flickering of the test field of variable intensity. The level of intensity of the counterphase flickering required to compensate for the induced flickering by the straylight is a measure of the level of intraocular straylight. The test field is divided into 2 half fields: 1 with and 1 without counterphase compensation light. The patient's task is a forced-choice comparison between the 2 half fields to decide which half flickers more strongly. This method is known as compensation comparison.^{24,25} In this prospective study, straylight levels were measured 6 months after bilateral implantation of monofocal AcrySof SA60AT IOLs or AcrySof ReSTOR SA60D3 IOLs. The monofocal AcrySof SA60AT is a hydrophobic acrylic refractive IOL. The multifocal AcrySof ReSTOR SA60D3 consists of an outer refractive zone and a separate central zone with an apodized diffractive surface. The latter structure divides light energy over 2 separate foci.²⁶ Therefore, the IOL has 2 powers, 1 of which is used for distance vision and the other, for near vision. A nearby object will be focused by the central diffractive structure while the peripheral zone simultaneously depicts the nearby object of interest as very defocused and faint.²⁰ Distance objects are depicted by the periphery and the central structure of the IOL. Apart from the diffractive structure in the center of the AcrySof ReSTOR SA60D3 IOL, it is similar to the monofocal AcrySof SA60AT IOL. Cataract surgery consisted of a no-stitch, 2.8 mm posterior limbal incision, phacoemulsification with implantation of a multifocal AcrySof ReSTOR SA60D3 or monofocal AcrySof SA60AT IOL. Sixty eyes of 32 patients received a multifocal AcrySof ReSTOR SA60D3 IOL (multifocal group) and 44 eyes of 23 patients received a monofocal AcrySof SA60AT IOL (monofocal group). No patient had characteristics that would be expected to lead to an increased level of intraocular straylight postoperatively. All patients signed an informed consent form before testing. Levels of straylight were compared between the 2 IOL groups and between the IOL groups and age-matched subjects without cataract or glare complaints (control group). These normal values were obtained from a previously developed database of levels of intraocular straylight in healthy non-cataractous volunteers.¹⁴ The mean of the scores in both eyes of the patients had to be less than Lens Opacities Classification System III grade 1.5 for the patient to be considered non-cataractous. First, a

comparison was made between patients in both IOL cohorts and their age-matched phakic controls. The measured log(s) in each patient was subtracted from the log(s) in the age-matched normal subject, derived from the previously mentioned database of levels of intraocular straylight in healthy volunteers.¹⁴ A Student t test was used to determine statistical significance between the 2 pseudophakic cohorts and age-matched normal subjects. Second, the results in the multifocal group and the monofocal group were compared by multivariate linear regression analysis to calculate the correlation between the measured level of straylight and the patient's age and IOL type.

RESULTS

Straylight measurements were performed a mean of 202 days \pm 15 (SD) and 187 \pm 10 days after cataract surgery in the multifocal group and monofocal group, respectively. Patient data are shown in **Figures 1** and **2**. Both IOL groups had statistically significantly lower levels of straylight than the control group ($P < .0001$, both IOL groups) (**Figure 1** and **Table 1**). The mean difference in measured log(s) between the control group and the 2 IOL groups was -0.158 ± 0.209 for the monofocal group and -0.121 ± 0.171 for the multifocal group (**Table 1**). When stratified according to age at the time of surgery, only patients 70 years or older had significantly lower levels of straylight than their age-matched non-cataractous counterparts (**Table 1**). The mean level of straylight ($P = .0059$) and the mean patient age ($P = .0381$) were statistically significantly higher in the multifocal group than in the monofocal group (**Table 2**). Thus, a factor in the different mean straylight levels could be the higher mean age rather than the different IOL types. Multiple linear regression analyses with log(s) as the dependent variable found age and IOL type influenced the amount of straylight (**Figure 2**). The log(s) increased 0.006 units for every year of age ($\beta = 0.006$, adjusted $r^2 = 0.100$, $P = .001$). The mean log(s) in the monofocal group was 0.078 units less than in the multifocal group ($\beta = 0.078$, adjusted $r^2 = 0.043$, $P = .026$).

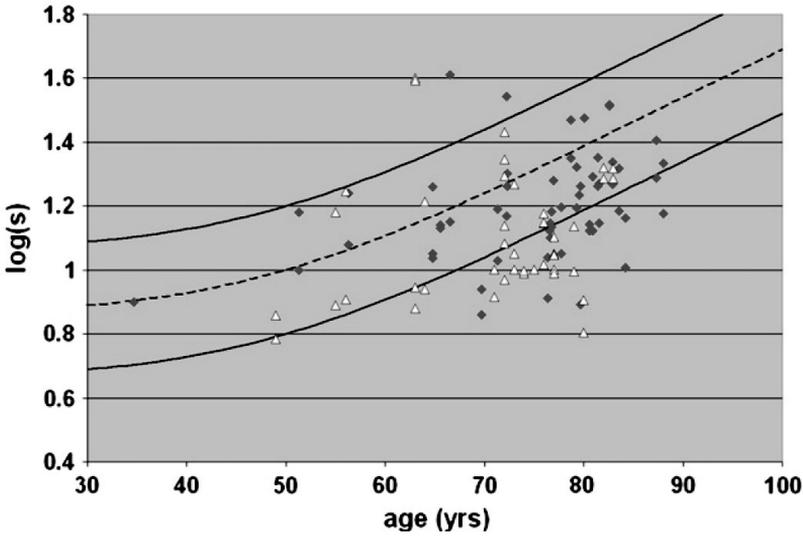


Figure 1. Levels of straylight in patients 6 months after cataract surgery compared with mean levels of straylight in non-cataractous subjects. The diamonds represent cases in the multifocal group. The triangles represent cases in the monofocal group. The lines represent mean levels of straylight in non-cataractous subjects ± 2 SD, the data for which were derived from a previously developed database (adapted from van den Berg et al.¹⁴).

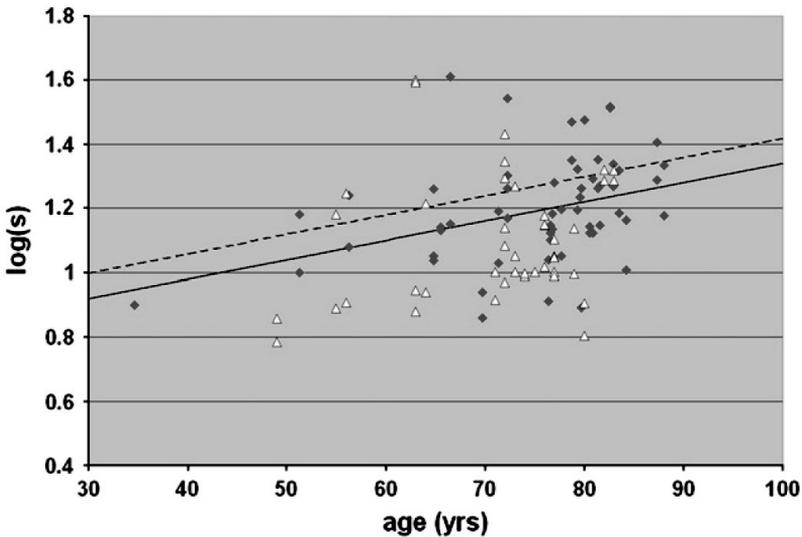


Figure 2. Linear regression analysis (equations in Table 2) of measured levels of straylight in the monofocal group (triangles) and multifocal group (diamonds). The dotted line represents the regression line for the multifocal group. The continuous line represents the regression line for the monofocal group.

Table 1. Comparison of pseudophakic patients and non-cataractous age-matched controls.

Parameter	Monofocal Group	Multifocal Group
All ages		
Number	44	60
Mean log(s) study group ± SD	1.103 ± 0.192	1.202 ± 0.164
Mean log(s) age-matched controls ± SD	1.262 ± 0.120	1.322 ± 0.131
Mean difference* ± SD	-0.158 ± 0.209	-0.121 ± 0.171
P value	< .0001	< .0001
Younger than 70 y		
Number	12	14
Mean log(s) study group ± SD	1.087 ± 0.281	1.113 ± 0.187
Mean log(s) age-matched controls ± SD	1.092 ± 0.064	1.129 ± 0.101
Mean difference* ± SD	-0.0044 ± 0.258	-0.016 ± 0.200
P value	.954	.799
70 y and older		
Number	32	46
Mean log(s) study group ± SD	1.109 ± 0.152	1.229 ± 0.150
Mean log(s) age-matched controls ± SD	1.325 ± 0.055	1.381 ± 0.066
Mean difference* ± SD	-0.216 ± 0.157	-0.152 ± 0.150
P value	< .0001	< .0001

* = log(s) in study group – log(s) in age-matched controls

Table 2. Comparison of the monofocal and multifocal group.

Variable	Monofocal Group (n=44)	Multifocal Group (n=60)	P value
Measured log(s)			
Mean ± SD	1.103 ± 0.192	1.202 ± 0.164	.0059
Range	0.784 – 1.601	0.860 – 1.610	
Age (y)			
Mean ± SD	71.0 ± 8.9	75.0 ± 10.0	.0381
Range	49.0 – 83.0	35.0 – 88.0	
Multiple linear regression	Log(s) = 0.818 + age x 0.006	Log(s) = 0.740 + age x 0.006	0.026

DISCUSSION

The natural human crystalline lens is a source of light scattering.³ If the lens is replaced with an artificial IOL during cataract surgery, the new lens may become a source of light scatter and the scatter can differ from that of the original crystalline lens. Assuming an IOL is made of perfectly clear material, one could expect a monofocal IOL to have no scattering effect. In the current study, pseudophakic patients with a monofocal or multifocal IOL had lower levels of straylight than their non-cataractous peers. However, from the current data it is not possible to deduct whether a monofocal IOL has no scattering effect. In a larger study comparing pa-

tients with monofocal IOLs and a phakic population, 44% of patients with an IOL had less straylight than their non-cataractous counterparts of the same age.¹⁴ Multifocal IOLs such as the AcrySof ReSTOR SA60D3 divide the amount of light energy over 2 focal points to simultaneously provide focused images of near and far objects.²⁶ The coexisting images on the retina lead to a situation somewhat similar to the aforementioned veil of light that occurs due to straylight. The occurrence of glare and halos in some patients with multifocal IOLs, such as the Array^{15,16} and AcrySof ReSTOR,^{15,20,21} has been well documented. In addition, the AcrySof ReSTOR SA60D3 IOL is based on the principle of diffraction rather than refraction to accomplish its multifocality. In any diffractive optical system, a percentage of light energy is directed toward higher diffractive orders rather than to 1 of the 2 foci,²⁶ which may also lead to higher levels of intraocular straylight. The present study looked at light deflection over larger angles (>1 degree), named straylight, which is identical to disability glare according to the definition of the Commission Internationale de l'Eclairage. On the other hand, the deflection of light rays due to refractive effects, such as plain defocus and aberrations in multifocal IOLs, are classically limited to angles less than 1 degree. Although glare and halo were originally used to describe scattering over angles greater than 1 degree in the natural eye,² both terms are also now being used to describe subjective visual complaints in patients with multifocal IOLs. Although the terms often remain without definition, it can be assumed that halo refers to the light from the secondary focus deflected at angles much smaller than 1 degree. Pupil size has been found to be of little importance in measurements of intraocular straylight.²⁷ Therefore, no pharmacological means were used to control the pupil diameter to represent a situation comparable to the natural state of the eye on a day-to-day basis. As a result, variance in pupil diameter in patients would be expected to account for little of the variance in straylight levels. In this study, patients in both IOL groups had lower levels of intraocular straylight than their age-matched non-cataractous controls ($P < .0001$). When the data were stratified by age groups, the difference in straylight level between pseudophakic and non-cataractous age-matched subjects was statistically significant in the group that was 70 years or older at the time of surgery. This might be caused by the rapid increase in straylight past the age of 70 years in non-cataractous subjects, enabling a higher rate of decrease of straylight levels by IOL implantation. The clinical relevance of this finding is that cataract surgery with implantation of a monofocal AcrySof SA60AT IOL or multifocal AcrySof ReSTOR SA60D3 IOL lowers the amount of intraocular straylight compared with that in phakic eyes that have not had surgery. Lower levels of intraocular straylight could be expected to result in fewer complaints of glare and halos and less loss of contrast sensitivity in surroundings in which sources of straylight are present. This might lead to higher levels of visual acuity and a higher subjective quality of vision in conditions encountered on a daily basis. When comparing the 2 IOL groups, the mean level of intraocular straylight

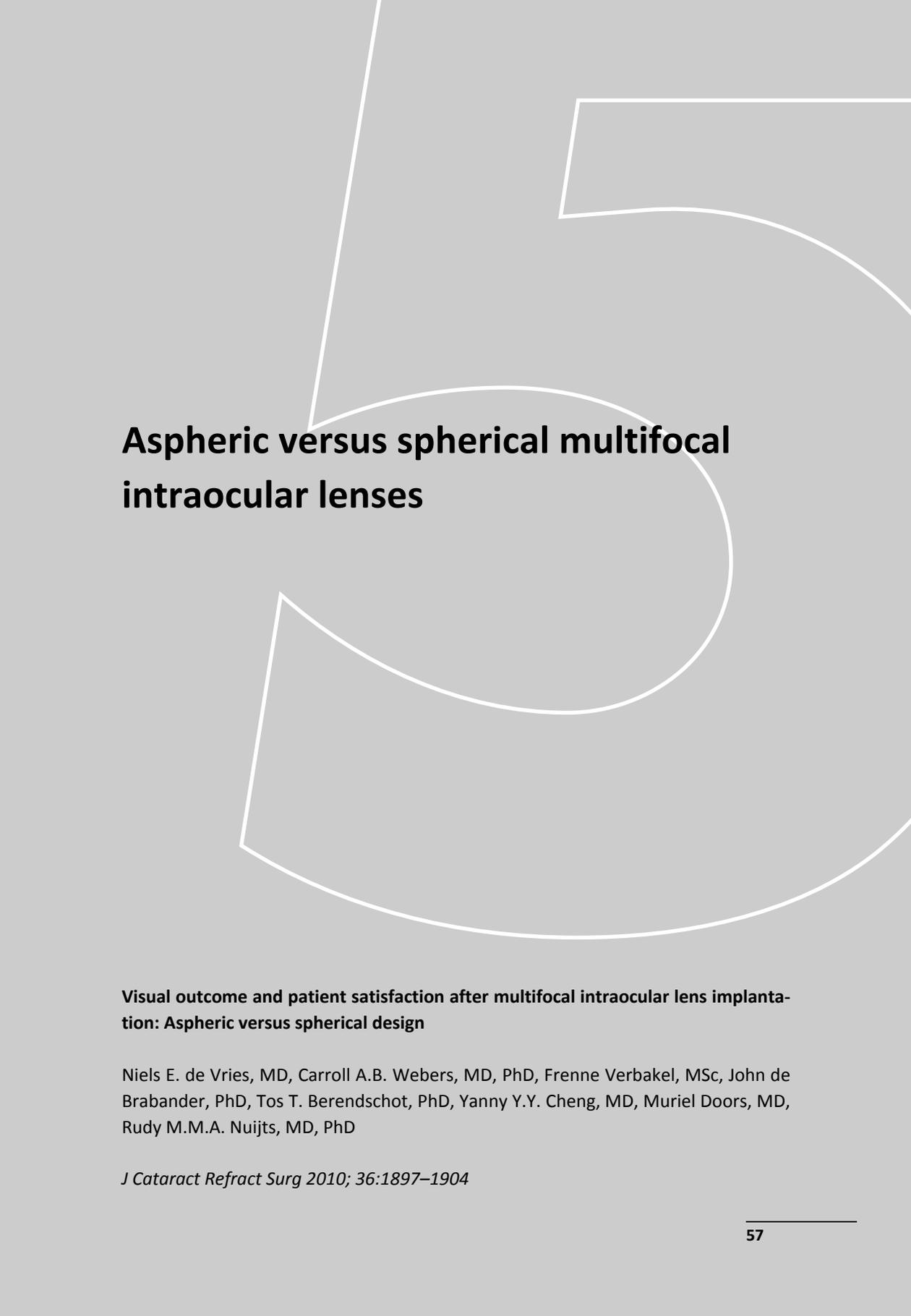
was lower in the monofocal group than in the multifocal group. The difference between the 2 groups might be partially explained by the significantly higher mean age in the multifocal group. Because of the significant influence of age on the expected amount of straylight,⁵ adjustment for age is essential when comparing other factors that influence the level of intraocular straylight in phakic persons. However, even though the increase in straylight levels in aging is presumed to be dominated by the crystalline lens, other parts of the eye might play a part. It has been found that pseudophakic patients also have a small increase in straylight levels with age.¹⁴ This suggests that even if a person has had an IOL implanted, age can be expected to affect the level of straylight. Therefore, a correction for age was applied in the comparison of the 2 pseudophakic groups. To adjust for the difference in mean age between the 2 IOL types, multivariate linear regression analysis was performed. The analysis showed a significantly lower straylight level in the monofocal group than in the multifocal group ($P = .027$). Posterior capsule opacification (PCO) can be expected to occur at the same rate in eyes with either type of IOL based on the similar material and design of the IOLs (apart from the diffractive structure in the central part of the AcrySof ReSTOR). Furthermore, before we measured straylight, we ruled out the presence of PCO in this cohort and no patient had a neodymium: YAG laser capsulotomy. Therefore, the difference in straylight levels of 0.078 log units (comparable to a difference of 20%) between the 2 IOL groups seems to be the result of the diffractive component of the multifocal IOL. Alternatively, if the mean level of log(s) in the monofocal group were to be translated using the age-versus-log(s) graph in a non-cataractous population (**Figure 1**), the mean straylight level would be comparable to that at age 59.7 years. Taking into account the 0.078 log(s) age-corrected difference between the monofocal and multifocal groups, the multifocal group would have an equivalent age of 65.7 years, a difference of 6.0 years. The clinical relevance of these findings is in implanting a multifocal AcrySof ReSTOR SA60D3 IOL rather than a monofocal AcrySof SA60AT IOL, the potential to lower the amount of intraocular straylight is partially sacrificed to gain multifocality. This might be reflected in slightly more complaints of glare and halos as well as slightly lower contrast sensitivity in situations in which sources of straylight are present. Indeed, clinical experience with the AcrySof ReSTOR IOL seems to be in line with these expected findings. Additional studies correlating levels of intraocular straylight with levels of subjective complaints and contrast sensitivity are necessary to determine with certainty whether the difference between the 2 IOLs used in our study is of clinical value with respect to complaints of glare and halos and a noticeable loss in contrast sensitivity in daily life. The recently introduced aspherical version of the multifocal AcrySof ReSTOR IOL (AcrySof SN6AD3, Alcon Laboratories) will possibly result in lower levels of intraocular straylight.

In conclusion, this study shows that cataract surgery with implantation of the AcrySof SA60AT or AcrySof ReSTOR SA60D3 IOL lowers the mean level of intraocular straylight compared with the level in age-matched non-cataractous subjects, as determined by the C-Quant straylight meter. After compensation for differences in mean age, mean levels of intraocular straylight were slightly lower in the monofocal group than in the multifocal group. The full clinical relevance of this finding remains unclear until further clinical studies determine the effect of specific levels of intraocular straylight on the occurrence of visual disturbances and the level of contrast sensitivity in patients with multifocal IOLs.

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Aspheric versus spherical multifocal intraocular lenses

Visual outcome and patient satisfaction after multifocal intraocular lens implantation: Aspheric versus spherical design

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ABSTRACT

PURPOSE: To evaluate visual outcomes and patient satisfaction after implantation of an aspheric apodized diffractive intraocular lens (IOL) or a spherical apodized diffractive IOL in cataract surgery.

SETTING: Maastricht University Medical Center, the Netherlands.

DESIGN: Nonrandomized clinical trial.

METHODS: This prospective nonrandomized study with a 6-month follow-up compared the results of cataract surgery with implantation of an aspheric AcrySof ReSTOR SN6AD3 IOL and a spherical AcrySof ReSTOR SN60D3 IOL. Main outcome measures were uncorrected (UDVA) and corrected (CDVA) distance visual acuities, uncorrected (UNVA) and distance-corrected (DCNVA) near visual acuities, straylight levels, incidence of glare and halos, and contrast sensitivity levels.

RESULTS: The mean UDVA was 0.14 ± 0.15 logMAR in the aspheric group (47 eyes) and 0.14 logMAR ± 0.17 (SD) in the spherical group (45 eyes) and the mean CDVA, -0.01 ± 0.06 logMAR and 0.02 ± 0.10 logMAR, respectively. The mean UNVA was Jaeger (J) 1 in 83.0% of patients in the aspheric group and 55.5% of patients in the spherical IOL group ($P = .003$). The DCNVA was J1 in 95.7% and 71.1%, respectively ($P = .001$). There were no significant differences between the 2 groups in contrast sensitivity levels, intraocular straylight levels, incidence of night-vision symptoms, or subjective rating of vision.

CONCLUSIONS: Patients with the aspheric multifocal IOL had significantly better near vision than patients with the multifocal spherical IOL. The UDVA, CDVA, intraocular straylight, night-vision symptoms, and contrast sensitivity were similar between the 2 groups.

INTRODUCTION

Presbyopia-correcting intraocular lenses (IOLs), including accommodating and multifocal models, were developed to provide satisfactory distance and near vision without the need for spectacles.¹⁻³ Multifocal IOL technology has incorporated refractive^{4,5} and diffractive^{6,7} principles. Of monofocal IOLs, aspheric models perform better than their spherical counterparts in clinical and laboratory studies.⁸⁻¹² Other studies^{13,14} found no significant differences in visual acuity and contrast sensitivity between aspheric monofocal IOLs and spherical monofocal IOLs.

The purpose of the current study was to compare the clinical performance of an aspheric multifocal IOL and spherical multifocal IOL. Near and distance visual acuity, straylight levels, contrast sensitivity, and the incidence of night-vision symptoms were evaluated after implantation of the IOLs during cataract surgery.

PATIENTS AND METHODS

Study Group and Protocol

In a prospective study, patients were enrolled in a 6-month comparative nonrandomized clinical trial. Patients were divided into 2 groups and had implantation of an aspheric multifocal IOL or spherical multifocal IOL. The tenets of the Declaration of Helsinki were followed, and full ethical approval was obtained from Maastricht University Medical Center. All patients provided informed consent after receiving a full explanation of the nature and possible consequences of the study and the surgery. Patients were considered for participation if they were between 40 years and 85 years of age, had senile cataract, and were motivated for spectacle independence. Exclusion criteria included preoperative (non-manageable) astigmatism of more than 2.00 diopters (D), occupational night driving, a history of glaucoma or retinal detachment, corneal disease or previous corneal or intraocular surgery, abnormal iris or pupil deformation, macular degeneration or retinopathy, neurophthalmic disease, and a history of ocular inflammation. Before surgery, patients had a full ophthalmologic examination. The evaluation included manifest refraction, corneal topography, slitlamp biomicroscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy.

Intraocular Lenses

The aspheric IOL in this study was the AcrySof ReSTOR SN6AD3 and the spherical IOL, the AcrySof ReSTOR SN60D3 (both Alcon, Inc.). Both IOLs consist of an outer

refractive zone and a separate central zone with an apodized diffractive surface. The apodized diffractive region is located in the central 3.6 mm optic zone of the IOL. This area comprises concentric steps of gradually decreasing (1.3 mm to 0.2 mm) height, creating multifocality from distance to near (2 foci). The diffractive structure serves as a +4.00 D near addition power at the IOL plane, corresponding to +3.25 D at the corneal plane. The refractive part of the optic surrounds the apodized diffractive region. This area directs light to a distance focal point for larger pupil diameters and is dedicated to distance vision. The overall diameter of the IOL is 13.0 mm and the optic diameter, 6.0 mm. In the aspheric model, the anterior surface is modified to produce negative spherical aberration to compensate for the positive spherical aberration of the cornea. The posterior surface is convex and does not add to the aspheric nature of the IOL. Otherwise, the design and the material of the aspheric IOL are similar to those of the spherical IOL.

Surgical Technique

The same surgeon (R.N.) performed all phacoemulsification and IOL implantation procedures. Phacoemulsification was performed using a standard technique (Infinity, Alcon, Inc.) through a 2.8 mm clear corneal superior incision. A well-centered 4.5 to 5.0 mm capsulorhexis was created and the IOL implanted in the capsular bag. If necessary, additional laser-assisted subepithelial keratectomy (LASEK) was subsequently performed to correct residual astigmatism.

Postoperative Follow-up

Patients were examined 1 week and 1, 3, and 6 months postoperatively.

Visual Acuity

Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were determined monocularly using a 100% contrast Early Treatment Diabetic Retinopathy Study chart (Precision Vision) under photopic lighting. Uncorrected near visual acuity (UNVA) and distance-corrected near visual acuity (DCNVA) measurements were obtained using a handheld near reading chart (de Nederlanders, Medical Workshop, and Parinaud, Van Hopplynus). Near vision was expressed by local units, which were subsequently transformed into Jaeger (J) values as described previously.⁵

Contrast Sensitivity, Pupil Size, and Intraocular Straylight

Contrast sensitivity was measured monocularly with distance correction under photopic conditions (luminance level 85 candelas/m²) using CSV-1000 contrast sensitivity charts (VectorVision). Pupillometry was performed using a P2000 SA pupillometer (Procyon Instruments Ltd.), which is a digital infrared device that takes binocular simultaneous measurements of the pupil diameter at 3 levels of luminance (scotopic [0.04 lux], mesopic low [0.4 lux], and mesopic high [4.0 lux]). The mean and standard deviation (SD) and the range of scotopic, mesopic-low, and mesopic-high pupil diameters were assessed by the software and displayed as a diagram. Intraocular straylight levels were measured monocularly using a C-Quant straylight meter (Oculus Optikgeräte GmbH) as described previously.^{15,16}

Visual Quality, Night-Vision Symptoms, and Spectacle Dependency

Patient satisfaction, visual phenomena, and spectacle dependency were assessed using a validated questionnaire at the 6-month visit.⁵ Patients rated satisfaction with quality of vision without spectacles on a scale from 1 to 5 (1 = excellent; 2 = good; 3 = satisfactory; 4 = not so good; 5 = bad) for distance vision and near vision. Patients rated visual disturbances (glare and halos) on the following scale: 1 = severe; 2 = moderate; 3 = mild; 4 = minimal; 5 = none. To assess spectacle dependency, patients were asked about their requirement for spectacle wear at distance and at near on the following scale: 1 = always; 2 = most of the time; 3 = quite often; 4 = rarely; and 5 = never.

Power Calculation and Statistical Analysis

Sample sizes were calculated based on previously published data on contrast sensitivity for the aspheric IOL⁷ or spherical IOL.¹⁷⁻¹⁹ In addition, published data on contrast sensitivity from studies comparing aspheric and spherical versions of the monofocal IOL on which the ReSTOR IOL is based were consulted.^{8,12} Based on an assumed mean contrast sensitivity level at 3 cycles per degrees (cpd) of 1.7 for the aspheric group and 1.5 for the spherical group, a standard deviation of 0.3 for both groups, $\alpha = 0.05$, and $\beta = 0.1$, the required number of patients would be 48 for both groups based on a previously published method of calculation.²⁰ All examinations used for statistical analysis were performed 6 months postoperatively. Data analysis was performed using SPSS for Windows software (version 14.0, SPSS, Inc.). Statistical comparisons of the 2 study groups were calculated using the Student t test for numerical data and the Mann-Whitney U test for categorical data. Differences were considered statistically significant when the P value was less than 0.05.

RESULTS

The aspheric group comprised 47 eyes of 24 patients and the spherical group, 45 eyes of 23 patients. Bilateral cases (23 patients in aspheric group; 22 patients in spherical group) received the same IOL model in both eyes. **Table 1** shows the patients' demographics by group. There was a statistically significant difference between the 2 groups in preoperative axial length, power of the implanted IOL, and spherical equivalent (SE).

Table 1. Patient demographics by group.

Variable	Mean \pm SD		P value
	Aspheric IOL Group (n = 47 eyes)	Spherical IOL Group (n = 45 eyes)	
Age (y)	65.3 \pm 9.7	68.4 \pm 10.7	.142
Axial length (mm)	23.79 \pm 1.27	23.06 \pm 0.78	.01*
Implanted IOL power (D)	19.52 \pm 4.12	21.69 \pm 2.23	.02*
Preoperative data			
SE (D)	-1.38 \pm 3.02	0.61 \pm 3.02	.01*
Astigmatism (D)			
Refractive	-0.87 \pm 0.67	-0.70 \pm 0.71	.255
Topographic	0.92 \pm 0.64	0.94 \pm 0.60	.867
Postoperative data			
SE (D)	0.11 \pm 0.43	0.09 \pm 0.33	.745
Astigmatism (D)			
Refractive	-0.69 \pm 0.51	-0.68 \pm 0.60	.943
Topographic	-0.79 \pm 0.52	-1.08 \pm 0.58	.016*

IOL = intraocular lens, SE = spherical equivalent

* = statistically significant

Refraction and Visual Acuity

Table 1 shows the mean postoperative values for SE, refractive cylinder, and topographic cylinder by group. The only statistically significant difference between the aspherical group and the spherical group was in topographic cylinder ($P = .016$). Laser-assisted subepithelial keratectomy was performed to correct residual astigmatism in 3 eyes of 2 patients in the aspheric group and in no eye in the spherical group ($P = .085$). The preoperative topographic astigmatism in the 3 eyes having LASEK was 1.25 D, 2.10 D, and 3.20 D, respectively. Postoperative topographic astigmatism in these 3 eyes was 1.47 D, 2.50 D, and 2.13 D, respectively, resulting in surgically induced astigmatism of 0.36 D, 0.27 D, and 1.10 D, respectively. Laser-assisted subepithelial keratectomy was performed 2.5 months, 5.2 months, and 5.4 months, respectively, after cataract surgery. **Table 2** shows the mean postoperative UDVA and CDVA by group; there was no statistically significant difference between

the 2 groups. **Figure 1** shows the UNVA and DCNVA by group. The UNVA was Jaeger (J) 1 in 83.0% of patients in the aspheric group and 55.5% of patients in the spherical IOL group and the DCNVA, J1 in 95.7% and 71.1%, respectively; the differences between the 2 groups were statistically significant in favor of the aspheric group ($P = .003$ and $P = .001$, respectively).

Table 2. Postoperative distance visual acuity.

LogMAR acuity	Mean \pm SD		P value
	Aspheric IOL Group	Spherical IOL Group	
UDVA	0.14 \pm 0.15	0.14 \pm 0.17	.852
CDVA	-0.01 \pm 0.06	0.02 \pm 0.10	.079

CDVA = best-corrected distance visual acuity, IOL = intraocular lens, UDVA = uncorrected distance visual acuity

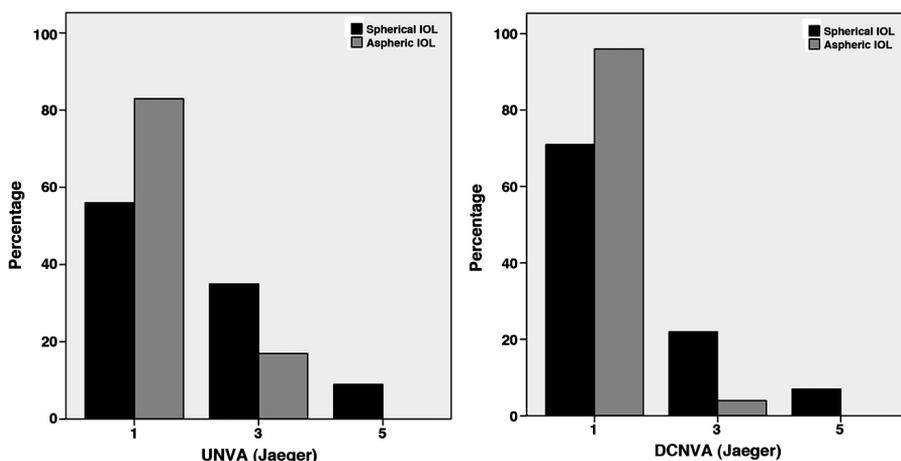


Figure 1. Postoperative UNVA and DCNVA by IOL group (DCNVA = distance-corrected near visual acuity; UNVA = uncorrected near visual acuity).

Contrast Sensitivity, Pupil Size, and Intraocular Straylight

Figure 2 shows the mean contrast sensitivity. There was no statistically significant difference in contrast sensitivity between the aspheric and the spherical group at any spatial frequency (3 cpd, $P = .194$; 6 cpd, $P = .877$; 12 cpd, $P = .259$; 18 cpd, $P = .122$). The mean pupil size in the aspheric group was 5.08 ± 0.95 mm under scotopic conditions, 4.39 ± 0.96 mm under mesopic-low conditions, and 3.52 ± 0.71 mm under mesopic-high conditions. The mean pupil size in the spherical group was 4.89 ± 1.11 mm under scotopic conditions, 4.02 ± 0.83 mm under mesopic-low conditions, and 3.10 ± 0.51 mm under mesopic-high conditions. The mean pupil size under mesopic-low conditions was statistically significantly larger in the aspheric group

($P = .011$); there were no other significant difference between groups. There was no statistically significant difference in contrast sensitivity at 3 cpd, 6 cpd, 12 cpd, or 18 cpd between eyes in the 2 groups with a postoperative scotopic pupil diameter of 5.0 mm or larger ($P = .784$, $P = .467$, $P = .848$, and $P = .909$, respectively). Linear regression analysis found no statistically significant correlation between pupil diameter and contrast sensitivity level in either group (**Figure 3**). The mean straylight level was 1.19 ± 0.19 in the aspheric group and 1.16 ± 0.16 in the spherical group; the difference between groups was not statistically significant ($P = .337$).

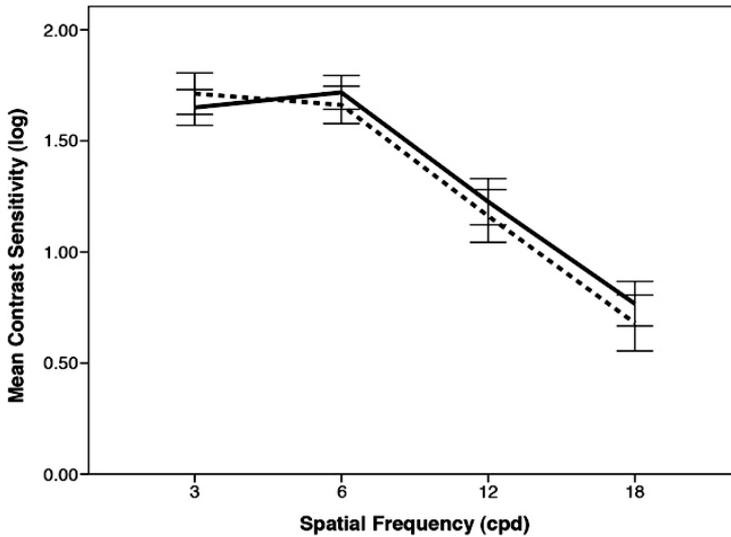


Figure 2. Contrast sensitivity under photopic conditions in the spherical group (solid line) and aspheric group (dotted line). The error bars represent the 95% confidence interval (cpd = cycles per degree), near vision ($P = .147$), occurrence of glare ($P = .480$), or occurrence of halos ($P = .096$).

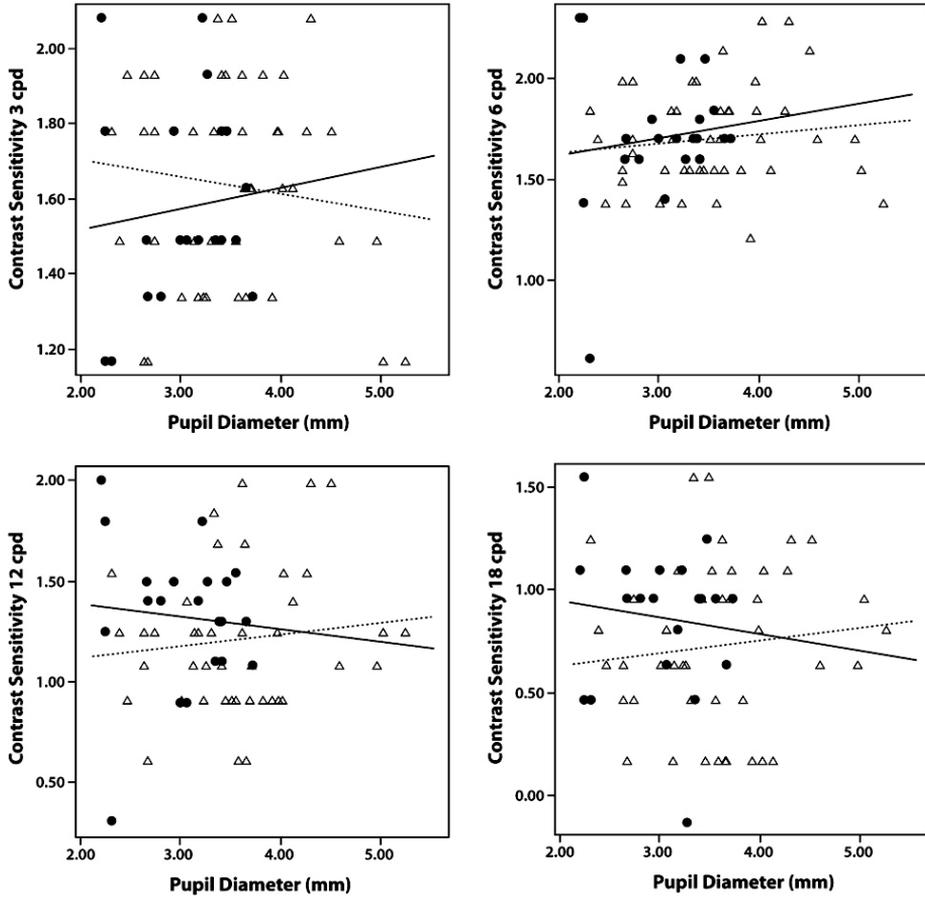


Figure 3. Linear regression analysis of contrast sensitivity at different spatial frequencies as a function of postoperative mesopic-high pupil diameter. The solid circles and line represent the spherical cases and regression line, respectively. The open triangles and dotted line represent the aspheric cases and regression line, respectively (cpd = cycles per degree).

Patient-Reported Parameters

Twenty-three patients (95.8%) in the aspheric group and 22 patients (95.7%) in the spherical group completed the questionnaires. **Figure 4** shows the results of the questionnaires. There were no statistically significant differences between the 2 groups in subjective quality of distance vision ($P = .335$), subjective quality of near vision ($P = .946$), spectacle independence for distance vision ($P = .710$), spectacle independence for near vision ($P = .147$), occurrence of glare ($P = .480$), or occurrence of halos ($P = 0.096$).

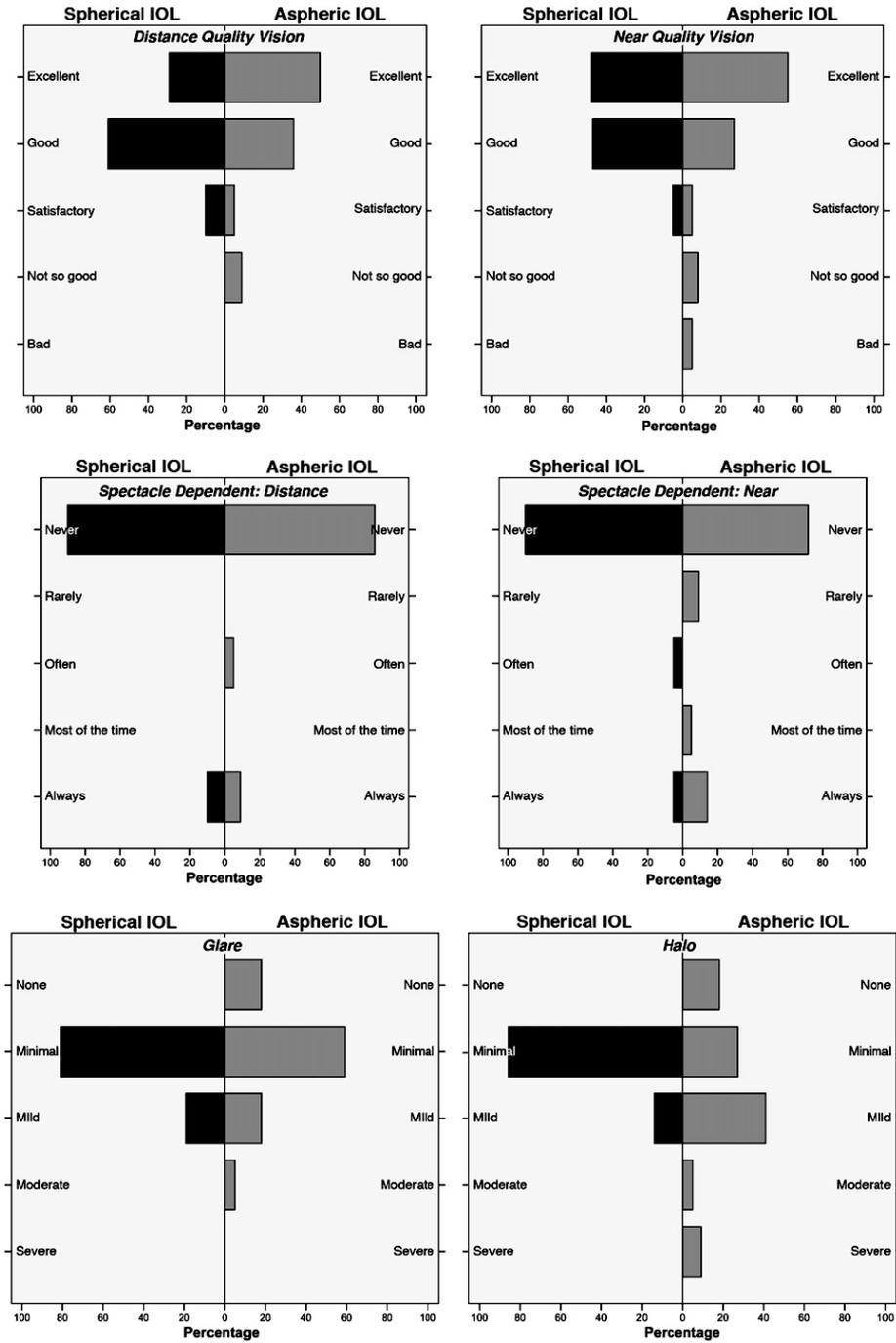


Figure 4. Results of the questionnaire as a function of type of implanted intraocular lens (IOL = intraocular lens).

DISCUSSION

In the current study, we compared the objective and subjective results of implantation of the spherical AcrySof ReSTOR SN60D3 IOL and the aspheric Acry-Sof ReSTOR SN6AD3 IOL. The spherical model was introduced in 2003 in Europe and in 2005 in the United States. Studies have found that implantation of the spherical IOL gives good clinical outcomes in cataract surgery,^{6,17,21,22} refractive lens exchange,²³ and piggyback implantation.²⁴ Recently, the aspheric model was introduced. Apart from the modified anterior lens surface, the aspheric IOL is similar in design and material to its spherical predecessor. In our study, there were significant differences in near vision between the aspheric group and the spherical group. A higher percentage in the aspheric group than in the spherical group were able to read J1 uncorrected and with distance correction. The better near vision may be the result of the better quality retinal image conferred by the lower levels of spherical aberration with aspheric IOL; however, it may also be the result of differences in refractive outcomes between the 2 groups. Although postoperative refractive astigmatism and SE were comparable in the 2 groups, topographic astigmatism was significantly higher in the spherical group than in the aspheric group. Even though against-the-rule astigmatism can be beneficial to a patient's reading ability,²⁵ we assume that the lower levels of corneal astigmatism in the aspheric group resulted in the better near vision. There was no significant difference in preoperative topographic astigmatism between the 2 groups; thus, the difference in postoperative topographic astigmatism may be because the decreased thickness of the aspheric IOL results in less wound stress.

Except for differences in near vision, our study found no significant differences between the aspheric group and the spherical group. Laboratory studies²⁶ found better image quality with aspheric monofocal IOLs than with spherical monofocal IOLs. Clinical studies of monofocal IOLs⁸⁻¹² report higher levels of mesopic contrast sensitivity with aspheric designs than with spherical designs, although other clinical studies^{13,14} found no significant differences in contrast sensitivity.

Aspheric multifocal IOLs have been shown to result in better image quality than spherical multifocal IOLs in laboratory studies.^{27,28} Spherical multifocal IOLs are associated with higher straylight levels,²¹ lower contrast sensitivity levels,²⁹ and higher levels of night-vision symptoms³⁰ than spherical monofocal IOLs. Multifocal IOLs with an aspheric optics may perform better than previous-generation multifocal IOLs. However, in our clinical study, distance visual acuities were similar in the aspheric group and the spherical group. In addition, there were no significant differences in contrast sensitivity or intraocular straylight and similar percentages of patients reported glare and halos. A possible explanation for this finding could be that

the mean pupil size in eyes with senile cataract tends to be small, thereby limiting the potential positive effect of asphericity on spherical aberrations.^{29,31} Another possible explanation is that aspheric IOLs do not solve the problem of chromatic aberration, which is mainly dependent on the material of the IOL rather than its shape.^{32,33} A third possible explanation is that the change in design (from a spherical optic to an aspheric optic) addresses spherical aberrations only and not the possible negative or positive effects of higher-order aberrations (HOAs).³⁴ Coma-like aberrations, for example, are associated with increased reading ability in patients with a monofocal IOL.³⁵ A fourth possible explanation is that contrast sensitivity levels and night-vision symptoms result from the distribution of light energy between 2 distinct images and the loss of light energy into higher diffraction orders inherent to the design of any diffractive multifocal IOL, whether of spherical or aspheric design.³⁶ Results in our study indicate that the design modifications to the diffractive multifocal IOL that were intended to reduce spherical aberrations did not lead to clinically significant improvements in distance vision, night vision symptoms, or contrast sensitivity.

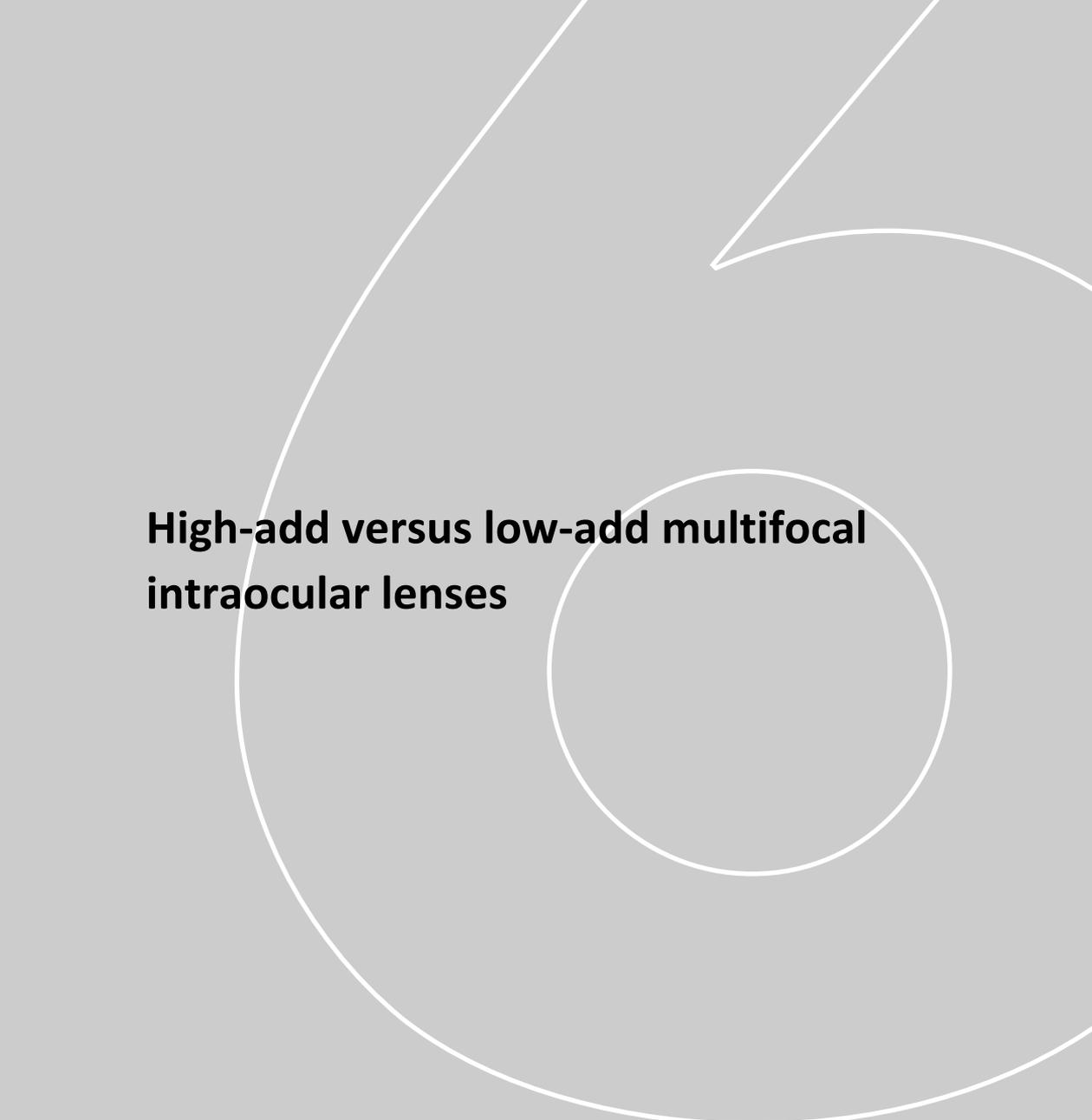
It is possible that a subset of patients with larger pupil diameters could benefit more from an aspheric IOL than patients in the general cataract population. Larger pupils are associated with higher levels of HOAs in pseudophakic patients with monofocal or multifocal IOLs.³¹ A clinical study comparing monofocal IOLs³¹ found a significant difference in the reduction of 4th-order and primary spherical aberrations in eyes with aspheric IOLs than in eyes with spherical IOLs, especially when the pupil was at least 5.0 mm; differences in total HOAs were found with pupil sizes of at least 6.0 mm. Higher levels of HOAs can result in lower levels of contrast sensitivity, as reported in phakic eyes after photorefractive keratectomy³⁷ or after cataract surgery with implantation of a monofocal IOL¹⁵ or multifocal IOL.³⁸ These findings indicate that patients with larger pupils might benefit more from aspheric IOLs than patients with smaller pupils. In our study, however, there were no significant differences in contrast sensitivity between the aspheric group and the spherical group, even in the subset of patients with a scotopic pupil diameter of 5.0 mm or larger. Selecting patients for an aspheric IOL rather than a spherical IOL based on preoperative pupil size may prove difficult in a clinical setting because the preoperative pupil size does not adequately predict the postoperative pupil size.³⁹

In conclusion, the aspheric AcrySof ReSTOR SN6AD3 IOL, when implanted bilaterally during cataract surgery, provided patients with higher levels of UNVA and DCNVA than the spherical AcrySof ReSTOR SN60D3 IOL. However, the 2 groups had similar levels of distance visual acuity, contrast sensitivity, intraocular straylight levels, and of night vision symptoms.

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High-add versus low-add multifocal intraocular lenses

Visual outcomes after cataract surgery with implantation of a + 3.00 D or + 4.00 D aspheric diffractive multifocal intraocular lens: Comparative study

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ABSTRACT

PURPOSE: To compare the visual performance after cataract surgery with implantation of + 3.00 diopter (D) or + 4.00 D aspheric multifocal intraocular lenses (IOLs).

SETTING: Department of Ophthalmology, Maastricht University Medical Center, the Netherlands.

METHODS: This prospective study compared the results of bilateral cataract surgery with implantation

of a + 3.00 D AcrySof ReSTOR SN6AD1 IOL or a + 4.00 D AcrySof ReSTOR SN6AD3 IOL. The main outcome measures were binocular uncorrected (UDVA) and corrected distance visual acuities, binocular uncorrected (UNVA) and corrected near visual acuities, binocular uncorrected (UIVA) and corrected intermediate visual acuities, preferred working distance, straylight and contrast sensitivity levels, and wavefront aberrometry measurements.

RESULTS: The + 3.00 D IOL was implanted in 68 eyes and the + 4.00 D IOL, in 46 eyes. The UIVA was significantly better in the + 3.00 D IOL group than in the + 4.00 D IOL group at 40, 50, 60, and 70 cm. The preferred working distance for near tasks was significantly lower in the + 3.00 D IOL group (38.9 cm) than in the + 4.00 D IOL group (31.0 cm). The UDVA was better in the + 3.00 D IOL group; the UNVA at the preferred working distance was similar in the 2 groups. Contrast sensitivity and intraocular straylight levels were also similar. The mean levels of higher-order and spherical aberrations were lower in the + 3.00 D IOL group.

CONCLUSION: Cataract surgery with the + 3.00 D IOL resulted in better intermediate vision than with the + 4.00 D model without compromising distance and near visual acuity.

INTRODUCTION

Presbyopia-correcting intraocular lenses (IOLs), including accommodating and multifocal models, were developed to provide satisfactory distance and near vision without the need for spectacles.^{1–3} Multifocal IOL technology currently uses refractive^{4–8} and hybrid principles.^{9–11} The spherical AcrySof ReSTOR SN60D3 IOL (Alcon, Inc.), introduced in 2003, incorporated an apodized hybrid diffractive–refractive structure to create an IOL with 2 focal points. Implantation of this IOL has resulted in good clinical outcomes after cataract surgery,^{9–11} refractive lens exchange,^{12–15} and piggy-back IOL implantation.¹⁶ At present, 2 aspheric successors of this multifocal IOL are available: the AcrySof ReSTOR SN6AD3 IOL with a near addition (add) of + 4.00 diopters (D) (equivalent to approximately 3.20D at the spectacle plane) and the AcrySof ReSTOR SN6AD1 IOL with a near add of + 3.00 D (equivalent to approximately 2.40 D at the spectacle plane). The + 3.00 D model was designed to provide better intermediate vision without compromising near or distance visual acuity. Evaluation of the + 3.00 D model^{17,18} and the + 4.00 D model^{19–21} found good visual performance at different distances. A recent study²² compares the + 3.00 D model and the + 4.00 D model with respect to visual acuity and patient satisfaction. However, to our knowledge, no study has directly compared the contrast sensitivity, straylight, and wavefront aberration measurements of the 2 models. The purpose of the current study was to assess near, intermediate, and distance visual acuities; straylight levels; contrast sensitivity levels; and wavefront aberrometry findings after bilateral implantation of the + 3.00 D or + 4.00 D aspheric diffractive multifocal IOL after cataract surgery.

PATIENTS AND METHODS

Study Group and Protocol

In this prospective study, patients were enrolled in a 6-month comparative nonrandomized clinical trial. Patients were divided into 2 groups and had cataract surgery and bilateral implantation of the + 3.00 D model or the + 4.00 D model. The tenets of the Declaration of Helsinki were followed, and full ethical approval was obtained from Maastricht University Medical Center. After receiving a full explanation of the nature and possible consequences of the study and surgery, all patients provided informed consent. Patients were considered for participation if they were between 40 years and 85 years of age, had senile cataract, and were motivated for spectacle independence. Exclusion criteria included preoperative (unmanageable) astigmatism greater than 2.00 D, occupational night driving, a history of glaucoma or retinal detachment, corneal disease or previous corneal or intraocular surgery, abnormal

iris or pupil deformation, macular degeneration or retinopathy, neuroophthalmic disease, and a history of ocular inflammation. Before surgery, patients had a full ophthalmologic examination including manifest refraction, corneal topography, slitlamp biomicroscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy.

Intraocular Lenses

The + 3.00 D and + 4.00 D aspheric diffractive multifocal IOL models consist of an outer refractive zone and an additional central zone with an apodized diffractive surface. The apodized diffractive region is situated in the central 3.6 mm optic zone of the IOL. This area comprises concentric steps of gradually decreasing height, creating multifocality (2 foci). The diffractive structure of the + 3.00 D model consists of 9 steps, which serve as a + 3.00 D near add power at the IOL plane. The diffractive structure of the + 4.00 D models consists of 12 steps, which serve as a + 4.00 D near add power at the IOL plane. The refractive part of the optic surrounds the apodized diffractive region. This area directs light to a distance focal point for larger pupil diameters and is dedicated to distance vision. The overall diameter of both IOL models is 13.0 mm and the optic diameter, 6.0 mm. The anterior surface is modified to produce negative spherical aberration to compensate for the positive spherical aberration of the cornea. Apart from the central diffractive structure, the design and material of the 2 IOL models are similar.

Surgical Technique

The same surgeon (R.N.) performed all phacoemulsification and IOL implantation procedures using a standard technique. Phacoemulsification was performed through a 2.6 mm clear corneal superior incision using an Infinity phaco unit (Alcon, Inc.). A well-centered capsulorhexis of 4.5 mm to 5.0 mm was created, after which a + 3.00 D IOL or a + 4.00 D IOL was implanted in the capsular bag.

Visual Outcome Measurements

Postoperative assessments were routinely performed at 1 week and at 1, 3, and 6 months. Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were determined using the 100% contrast Early Treatment Diabetic Retinopathy Study chart (ETDRS Chart, Precision Vision) under photopic conditions. Uncorrected near visual acuity (UNVA) and distance-corrected near visual acuity (DCNVA) were measured binocularly using a handheld ETDRS near reading chart (Precision Vision) under photopic conditions at the working distance preferred by the patient. Uncorrected intermediate visual acuity (UIVA) and distance-corrected

intermediate visual acuity (DCIVA) were measured binocularly at 40, 50, 60, and 70 cm working distance using the aforementioned ETDRS near reading chart. Intermediate visual acuity measurements were corrected for their respective working distance using the following formula:

$$\text{Standardized VA} = -\log \left[\frac{\text{working distance}}{0.4 \times 10^{\text{measured VA}}} \right]$$

where VA is visual acuity. A defocus curve was constructed by monocular distance visual acuity measurements using the ETDRS chart at 4 m with spectacle correction in 0.50 D increments from -5.00 to +2.00 D from the patient's manifest refraction.

Contrast Sensitivity, Pupil Size, and Intraocular Straylight

Contrast sensitivity was measured monocularly with distance correction under photopic conditions (luminance level 85 candelas/m²) using a CSV-1000 contrast sensitivity chart (VectorVision). Pupillometry was performed using a Procyon P2000 SA pupillometer (Procyon Instruments Ltd.). The pupillometer is a digital infrared device for taking binocular simultaneous measurements of pupil diameter at 3 levels of luminance (scotopic, mesopic low, and mesopic high). The mean, standard deviation, and range of scotopic, mesopic low, and mesopic high pupil diameters were assessed by the software and displayed as a diagram. Distance visual acuity was also determined using 10% and 25% contrast ETDRS charts (Precision Vision) as a measure of contrast sensitivity. Intraocular straylight levels were measured monocularly using a C-Quant straylight meter (Oculus Optikgeräte GmbH) as described previously.^{23–25}

Wavefront Aberrometry

Wavefront aberrometry was performed using an Imagine Eyes aberrometer (Ziemer Group). The maps were analyzed with a 5.0 mm pupil diameter and up to the 10th order of Zernike coefficients.

Analysis

All examinations were performed 6 months postoperatively. Data analysis was performed using SPSS for Windows software (version 14.0, SPSS, Inc.). Statistical comparisons between the + 3.00 D IOL group and the + 4.00 D IOL group were calculated using the Student t test for numerical data and Pearson chi-square for categorical data. Differences were considered statistically significant when the P value was less than 0.05.

RESULTS

Demographics

The + 3.00 D IOL group consisted of 68 eyes, and the + 4.00 D IOL group consisted of 46 eyes. **Table 1** shows the preoperative patient characteristics. Although there was not a statistically significant difference between the 2 groups in age, the axial length was statistically significantly longer in the + 4.00 D IOL Group ($P = .027$).

Visual and Refractive Outcomes

Table 1 also shows the postoperative spherical equivalent (SE), astigmatism, scotopic and mesopic pupil sizes, and intraocular straylight. There were no statistically significant differences between the + 3.00 D IOL group and the + 4.00 D IOL group in any of these parameters. One eye in the + 3.00 D group required postoperative laser-assisted subepithelial keratectomy (LASEK). Because the LASEK was performed after the postoperative data were collected, this patient was included in the current analysis. No eye in the + 4.00 D group required postoperative LASEK.

Table 1. Patient demographics by IOL group.

Variable	Mean \pm SD		P value
	+ 3.00 D Group (n = 68 eyes)	+ 4.00 D Group (n = 46 eyes)	
Age (y)	63.5 \pm 8.7	65.8 \pm 9.1	.172
Axial length (mm)	23.36 \pm 0.99	23.84 \pm 1.24	.027*
Postoperative data			
SE (D)	0.06 \pm 0.49	0.12 \pm 0.43	.571
Astigmatism (D)	-0.57 \pm 0.40	-0.70 \pm 0.50	.110
Pupil size (mm)			
Scotopic	5.26 \pm 0.65	5.07 \pm 0.96	.223
Mesopic low	4.61 \pm 0.67	4.39 \pm 0.97	.187
Mesopic high	3.57 \pm 0.63	3.51 \pm 0.72	.630
Intraocular straylight (log)	1.27 \pm 0.61	1.19 \pm 0.19	.443

IOL = intraocular lens, SE = spherical equivalent

* = statistically significant

Table 2 shows the postoperative distance, intermediate, and near visual acuities by group. There were statistically significant postoperative differences between the + 3.00 D IOL group and the + 4.00 D IOL Group in mean monocular and binocular UDVA ($P = .004$ and $P = .006$, respectively); mean preferred working distance for binocular UNVA ($P < .001$); binocular UIVA at 40 cm, 50 cm, 60 cm, and 70 cm ($P = .004$, $P = .001$, $P = .001$, and $P = .007$, respectively); mean preferred working distance for binocular DCNVA ($P < .001$); and mean binocular DCIVA at 50 cm, 60 cm,

and 70 cm ($P = .009$, $P = .001$, and $P = .012$, respectively). **Table 3** shows the postoperative binocular CDVA with 10% contrast and 25% contrast ETDRS charts measured under photopic and mesopic conditions. **Figure 1** shows the defocus curve in both IOL groups.

Table 2. Postoperative distance, intermediate, and near visual acuities.

Variable	Mean \pm SD		P value
	+ 3.00 D Group	+ 4.00 D Group	
Monocular			
UDVA (logMAR)	0.04 \pm 0.14	0.14 \pm 0.15	.004*
CDVA (logMAR)	-0.04 \pm 0.09	-0.01 \pm 0.06	.145
Binocular			
UDVA (logMAR)	-0.03 \pm 0.10	0.05 \pm 0.12	0.008*
CDVA (logMAR)	-0.06 \pm 0.12	-0.05 \pm 0.07	.782
Preferred WD (cm), binocular UNVA	38.9 \pm 4.0	31.0 \pm 4.2	<.001*
UNVA (logMAR) at preferred WD	0.04 \pm 0.12	-0.01 \pm 0.05	.069
UIVA			
At 40 cm	0.10 \pm 0.11	0.22 \pm 0.10	.004*
At 50 cm	0.09 \pm 0.13	0.28 \pm 0.16	.001*
At 60 cm	0.09 \pm 0.11	0.24 \pm 0.15	.001*
At 70 cm	0.15 \pm 0.14	0.29 \pm 0.13	.007*
Preferred WD (cm), binocular DCNVA	38.4 \pm 4.7	30.6 \pm 3.7	<.001*
DCNVA (logMAR) at preferred WD	0.03 \pm 0.12	-0.01 \pm 0.05	.160
DCIVA			
At 40 cm	0.08 \pm 0.11	0.14 \pm 0.11	.131
At 50 cm	0.07 \pm 0.12	0.20 \pm 0.13	.009*
At 60 cm	0.16 \pm 0.14	0.33 \pm 0.10	.001*
At 70 cm	0.19 \pm 0.12	0.31 \pm 0.13	.012*

CDVA = best-corrected distance visual acuity, DCIVA = distance-corrected intermediate visual acuity, DCNVA = distance-corrected near visual acuity, UDVA = uncorrected distance visual acuity, UIVA = uncorrected intermediate visual acuity, UNVA = uncorrected near visual acuity, WD = working distance

* = statistically significant

Table 3. Postoperative binocular CDVA at 10% contrast and 25% contrast on ETDRS charts measured under photopic and mesopic conditions.

CDVA	Mean \pm SD		P value
	+ 3.00 D Group	+ 4.00 D Group	
Binocular 10% contrast			
Photopic	0.10 \pm 0.13	0.16 \pm 0.08	.167
Mesopic	0.24 \pm 0.15	0.28 \pm 0.12	.377
Binocular 25% contrast			
Photopic	\pm 0.09	0.07 \pm 0.05	.030*
Mesopic	0.15 \pm 0.13	0.18 \pm 0.10	.469

CDVA = corrected distance visual acuity

* = statistically significant

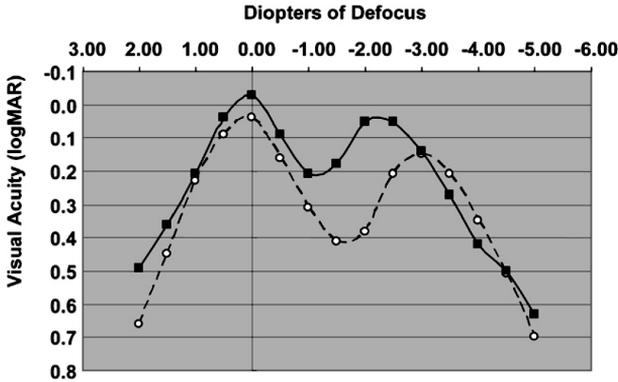


Figure 1. Mean high-contrast monocular visual acuity with best correction for distance vision as a function of the chart vergence in the +3.00 D IOL group (solid line) and the +4.00 D IOL group (dotted line).

Contrast Sensitivity, Pupil Size, and Intraocular Straylight

Figure 2 shows the contrast sensitivity under photopic conditions by IOL group. There was no statistically significant difference between the 2 groups at any spatial frequency. The mean contrast sensitivity levels in the + 3.00 D IOL group and the + 4.00 D IOL group were, respectively, 1.72 ± 0.30 and 1.70 ± 0.25 at 3 cycles per degree (cpd) ($P = .707$), 1.69 ± 0.32 and 1.67 ± 0.29 at 6 cpd ($P = .771$), 1.13 ± 0.36 and 1.17 ± 0.40 at 12 cpd ($P = .524$), and 0.65 ± 0.33 and 0.69 ± 0.43 at 18 cpd ($P = .596$). There was no statistically significant difference between the 2 IOL groups in mean pupil size under scotopic, mesopic low, or mesopic high conditions ($P = .223$, $P = .187$, and $P = .630$, respectively). There was also no statistically significant difference between groups in the mean straylight levels ($P = .443$).

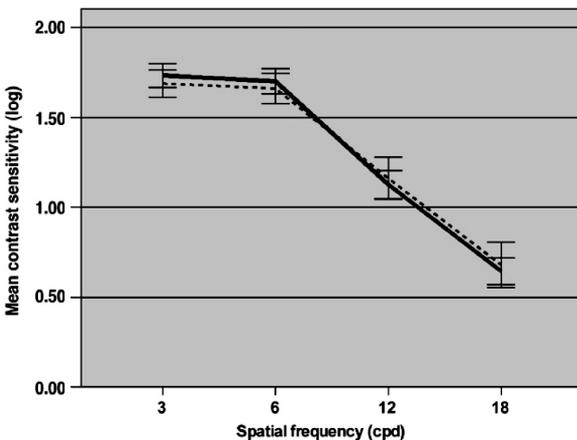


Figure 2. Contrast sensitivity under photopic conditions in the + 3.00 D IOL group (solid line) and the + 4.0 D IOL group (dotted line). The error bars represent the 95% confidence interval (cpd = cycles per degree).

Wavefront Aberrometry

Table 4 shows the postoperative aberrometry results by group. The mean levels of higher-order, coma, and spherical aberrations were statistically significantly lower in the + 3.00 D IOL group than in the + 4.00 D IOL group.

Table 4. Postoperative wavefront aberrometry (5.0 mm pupil).

Aberration	Mean RMS (μm) \pm SD		P value
	+ 3.00 D Group	+ 4.00 D Group	
Higher order	0.27 \pm 0.13	0.42 \pm 0.15	<.001*
Coma	0.16 \pm 0.09	0.23 \pm 0.19	.014*
Trefoil	0.19 \pm 0.12	0.24 \pm 0.14	.026*
Spherical	0.03 \pm 0.06	0.08 \pm 0.12	.004*

RMS = root mean square; * = statistically significant

DISCUSSION

In the current study, results of bilateral implantation of the + 3.00 D AcrySof ReSTOR SN6AD1 IOL were compared with results of bilateral implantation of the + 4.00 D AcrySof ReSTOR SN6AD3 IOL. The results could help when advising patients in choosing which model would best suit their needs. First, the + 3.00 D IOL group had significantly better postoperative UIVA than the + 4.00 D IOL group at 40, 50, 60, and 70 cm working distances. Second, the + 3.00 D IOL group had a significantly larger optimum working distance than the + 4.00 D IOL group. Third, intraocular straylight and contrast sensitivity levels were similar in the 2 groups; thus, these 2 metrics of visual performance should not influence the choice for either model. Finally, wavefront aberrometry showed significantly lower levels of HOA, coma, and spherical aberrations in the + 3.00 D IOL group than in the + 4.00 D IOL group.

Multifocal IOLs are reported to result in good distance and near visual acuity. Because of their design, objects at intermediate distance produce images of lesser quality than objects located at infinity or the optimum near point, as shown in optical bench testing.²⁶ Even though on questionnaires patients report few difficulties performing tasks at intermediate distance,¹¹ the difference between visual acuity at intermediate and visual acuity at near and infinity is readily apparent in the defocus curve of patients with multifocal IOLs.¹⁷⁻²⁰ For patients conducting tasks at intermediate distance (eg, computer work) rather than at short distances, a smaller depth of focus and a near point at close distance might negatively influence patient satisfaction. In the current study, the + 3.00 D IOL had a near point at a more adequate distance for these tasks (mean preferred working distance 38.9 cm versus 31.0 cm for UNVA measured with a handheld reading chart). Similarly, in the defocus curve,

this difference is seen as the difference in diopters of defocus associated with the second peak in visual acuity. Similarly, the depth of focus, determined by the amplitude of functional vision (0.3 logMAR or better), was larger on the defocus curve for the + 3.00 D IOL than on the curve for the + 4.00 D IOL. This would be expected to result in higher patient satisfaction with performing tasks at intermediate distance. In the defocus curve, the height of the peak associated with the UNVA in the + 4.00 D IOL group was lower than in the + 3.00 D IOL group. Maxwell et al.²² compared the + 3.00 D model and the + 4.00 D model using defocus curves and also found a slightly lower near peak with the + 4.00 D model. A direct comparison between the 2 defocus curves is not possible because the current defocus curve is based on monocular rather than binocular visual acuities. A reason for the difference between the 2 models could be the higher mean age in the + 4.00 D group than in the + 3.00 D group (65.8 years versus 61.9 years), which may have resulted in slightly worse macular function in the older eyes. Measurements of distance, intermediate, and near visual acuities with the ETDRS charts agree with those previously reported for the + 3.00 D IOL model^{17,18,22} and the + 4.00 D IOL model.^{19–22} Near visual acuity at this preferred working distance was better with the + 4.00 D model, although the difference did not reach statistical significance. The UDVA was better with the + 3.00 D model. This might have been caused by small differences in refractive error (although differences in SE and astigmatism did not reach statistical significance) because the CDVA was similar in the 2 groups.

Multifocal IOLs are associated with higher straylight levels^{23–25} and lower contrast sensitivity⁵ than monofocal IOLs. In the current study, 2 multifocal IOLs were compared and no significant differences in contrast sensitivity or in intraocular straylight were noted between them. Apparently, the differences in design between the + 3.00 D model and the + 4.00 D model are not associated with significant changes in these 2 parameters and therefore should not influence the selection of 1 model over the other for an individual patient. Pupil size is associated with contrast sensitivity as well as with straylight^{27,28} and was similar in the 2 IOL groups, thereby enabling comparison of the 2 models. Hartmann-Shack aberrometry measures objective characteristics of the optical system formed by the human eye that are associated with the quality of the retinal image. The complexity of using data from Hartmann-Shack sensors in diffractive IOLs has been described.^{29,30} Doubt exists about what any aberrometer truly measures when a patient has a diffractive IOL because the IOL has 2 powers and hence produces 2 wavefronts, resulting in ambiguity about whether the distance or near wavefront is being measured. However, considering that the diffractive efficiency is low at the infrared wavelength used for measurement, we believe that the distance aberration was likely recorded. This correlates with previous values obtained with the original + 4.00 D spherical AcrySof ReSTOR IOL model.¹³ Lower spherical aberration values are expected with the aspheric

models than with the spherical model considering the reduction in corneal spherical aberration after IOL implantation with the former. This match between cornea and IOL asphericity in monofocal IOLs has been given much attention recently (see Monte's-Mico' et al.³¹ for a review). In our study, we found differences in aberrations between the 2 IOL models, specifically in the spherical aberration, even though both models have the same asphericity design. However, the + 3.00 D aspheric IOL has 1.00 D less add. In addition, differences in the diffractive zones (9 with + 3.00 D IOL and 12 with + 4.00 D IOL) and the central zone diameter of each model (0.856 mm versus 0.742 mm) may play a role in the different wavefront aberration outcomes we found. In our study, the mean absolute levels of higher-order aberrations (HOAs) were significantly lower in the + 3.00 D IOL group. Although theoretically this could lead to a better retinal image with the + 3.00 D IOL, there was no significant difference in visual acuity or in contrast sensitivity between the 2 groups in our study. Cataract surgery itself induces consistent and significant changes in several aberrations, notably trefoil and tetrafoil.³² Because the surgical technique in our study was the same in the 2 IOL groups, the differences in wavefront aberrometry findings are probably related to the difference in the design of the central structure of the IOLs.

In conclusion, the + 3.00 D AcrySof ReSTOR SN6AD1 IOL, when implanted bilaterally following cataract surgery, gave better results than the + 4.00 D AcrySof ReSTOR SN6AD3 IOL in intermediate vision without compromising near and distance visual acuity, contrast sensitivity, or straylight. The + 3.00 D model was also associated with significantly lower levels of HOAs and spherical aberrations and a higher preferred working distance. Therefore, except for patients with a strong preference for a shorter working distance, the + 3.00 D seems the ReSTOR model of choice at this time.

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Dissatisfaction in patients with a multifocal intraocular lens

Dissatisfaction after implantation of multifocal intraocular lenses

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ABSTRACT

PURPOSE: To analyze the symptoms, etiology, and treatment of patient dissatisfaction after multi-focal intraocular lens (IOL) implantation.

SETTING: Department of Ophthalmology, Maastricht University Medical Center, the Netherlands.

DESIGN: Case series.

METHODS: In this retrospective chart review, the main outcome measures were type of complaints, uncorrected and corrected distance visual acuities, uncorrected and distance-corrected near visual acuities, refractive state, pupil diameter and wavefront aberrometry measurements, and type of treatment.

RESULTS: Seventy-six eyes of 49 patients were included. Blurred vision (with or without photic phenomena) was reported in 72 eyes (94.7%) and photic phenomena (with or without blurred vision) in 29 eyes (38.2%). Both symptoms were present in 25 eyes (32.9%). Residual ametropia and astigmatism, posterior capsule opacification, and a large pupil were the 3 most significant etiologies. Sixty-four eyes (84.2%) were amenable to therapy, with refractive surgery, spectacles, and laser capsulotomy the most frequent treatment modalities. Intraocular lens exchange was performed in 3 cases (4.0%).

CONCLUSION: The cause of dissatisfaction after implantation of a multifocal IOL can be identified and effective treatment measures taken in most cases.

INTRODUCTION

Multifocal intraocular lenses (IOLs) were developed to provide patients with an IOL with more than 1 focal point, enabling good visual acuity at more than 1 distance. Ideally, multifocal IOLs would provide excellent distance and near visual acuity without compromising characteristics of visual function, such as contrast sensitivity, intermediate visual acuity, positive dysphotopsia (glare and halos), and negative dysphotopsia (a dark crescent in the temporal field of vision). Many recent studies report excellent results in most cases after implantation of a multifocal IOL, be it a diffractive,¹⁻⁴ refractive,^{2,3,5-7} or hybrid diffractive-refractive^{5,8-12} design. Other studies show that multifocal IOLs also have weaknesses, such as unsatisfactory visual acuity at specific working distances,^{6,13-15} increased dysphotopsia (compared with monofocal IOLs),¹⁶⁻²⁰ decreased contrast sensitivity,^{17,18,21,22} and increased intraocular straylight.^{19,23} This prompted some authors²⁴⁻²⁶ to state that the potential trade-offs of multifocal IOLs should be weighed against the potential benefits on an individual basis. Despite high levels of general patient satisfaction after multifocal IOL implantation, some patients will be dissatisfied, even to a point where the multifocal IOL must be explanted.^{27,28} The current study focused on the symptoms, etiology of complaints, and treatment of patients with multifocal IOLs.

PATIENTS AND METHODS

Study Design

In this retrospective study, the charts of patients referred for dissatisfaction with their visual performance after implantation of a multifocal IOL were reviewed. The study was performed at a tertiary referral hospital. The following data were recorded: age, sex, time between IOL implantation and referral, preoperative manifest refraction, axial length, IOL type, nature of complaints, postoperative visual acuity, manifest refraction, aberrometry, pupillometry, corneal topography, biomicroscopy, and fundoscopy. Visual acuity was determined using Snellen charts, and means and standard deviations (SD) were calculated using logMAR data. Wavefront aberrometry was performed using the ImagineEyes aberrometer (Ziemer AG) with a 5.0 mm pupil diameter. Pupillometry was performed using the P2000 SA pupillometer (Procyon Instruments, Ltd.). The pupillometer is a digital infrared device that takes simultaneous binocular pupil diameter measurements at 3 levels of luminance (scotopic, mesopic low, mesopic high). The mean \pm SD and range of scotopic, mesopic-low, and mesopic-high pupil diameters were assessed by the software and displayed as a diagram. Corneal topography was performed using the Pentacam Scheimpflug camera (Oculus GmbH).

Intraocular Lenses

The multifocal IOLs implanted were the + 4.00 D Restor (SA60D3, SN60D3, SN6AD3, Alcon Laboratories, Inc.), + 3.00 D Restor (SN6AD1, Alcon Laboratories, Inc.), Tecnis ZMA00 (Abbott Medical Optics, Inc.), and Rezoom (Abbott Medical Optics, Inc.). Both the +3.00 D and +4.00 D Restor IOLs consist of an outer refractive zone and an additional central zone with an anterior apodized diffractive surface. The diffractive structure consists of 9 steps serving as a +3.00 diopter (D) near addition (add) power at the IOL plane or 12 steps serving as a +4.00 D near add power at the IOL plane. Both models are hydrophobic acrylic and have an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. The Tecnis ZMA00 is a purely diffractive IOL with the diffractive structure located at the posterior surface. It consists of 32 concentric steps and covers the full surface of the IOL. It has a near add of +4.00 D at the IOL plane. The hydrophobic acrylic IOL has an overall diameter of 13.0 mm, an optic diameter of 6.0 mm, and poly(methyl methacrylate) (PMMA) haptics. The Rezoom is a purely refractive multifocal acrylic IOL with PMMA haptics. Five concentric rings cover the full surface of the IOL, with zones 1, 3, and 5 being distance dominant and zones 2 and 4 being near dominant. It has a +3.50 D near add power at the IOL plane. The overall diameter is 13.0 mm and the optic diameter, 6.0 mm.

Statistical Analysis

Data analysis was performed using SPSS for Windows software (version 15.0, SPSS Inc.). Statistical comparisons of patient groups were performed using the Student t test for numerical data and the Fisher exact test for categorical data. Differences were considered statistically significant when the P value was less than 0.05, taking multiple comparisons into account.

RESULTS

The study evaluated 76 eyes of 47 patients. **Table 1** shows the patients' demographics at the time of presentation.

Table 1. Demographic characteristics of patients at presentation.

Characteristic	Value
Mean age (y)	59.2 ± 12.3
Mean AL (mm)	23.97 ± 1.45
Mean manifest refraction (D)	
Sphere	-1.07 ± 4.23
Cylinder	-0.99 ± 0.80
SE	-1.56 ± 4.40
Mean time, surgery to presentation (d)	187 ± 178
Sex, n (%)	
Male	39 (51.3)
Female	37 (48.7)
Complaints, n (%)	
Bilateral	54 (71.1)
Unilateral, unilateral IOL	9 (11.8)
Unilateral, bilateral IOLs	13 (17.1)

Means ± SD

AL = axial length, IOL = intraocular lens, n = number of eyes, SE = spherical equivalent

Intraocular Lens Type

Of the eyes, 69 (90.8%) had a +4.00 D Restor IOL, 4 (5.3%) had a +3.00 Restor IOL, 2 (2.6%) had a Tecnis IOL, and 1 (1.3%) had a Rezoom IOL. One Tecnis IOL and the Rezoom IOL were implanted in the same patient as a mix-and-match strategy.

Visual Acuity and Refraction

At the time of presentation, the mean uncorrected distance visual acuity (UDVA) was 0.28 ± 0.20 logMAR (SD) (range 1.30 to .08 logMAR) and the mean corrected visual acuity (CDVA) was 0.01 ± 0.10 logMAR (range 0.30 to -0.10 logMAR). The mean refractive sphere was 0.68 ± 0.55 D (range -0.50 to 2.25 D), the mean refractive cylinder was -0.95 ± 0.69 D (range -3.00 to 0.00 D), and the mean refractive spherical equivalent (SE) was 0.20 ± 0.61 D (range -2.13 to 1.63 D).

Presenting Symptoms

Table 2 shows the presenting symptoms. Unsatisfactory visual acuity was reported in 72 eyes (94.7%). Of the 72 eyes, 25 had coexisting photic phenomena and 47 had solely symptoms of unsatisfactory visual acuity. Photic phenomena were reported in 29 eyes (38.2%). Of the 29 eyes, few eyes ($n = 4$) had satisfactory visual acuity in the presence of debilitating photic phenomena whereas 25 eyes had coexisting visual acuity complaints.

Table 2. Presenting symptoms.

Symptom	Eyes, n (%)
Blurred vision	
Distance only	28 (36.8)
Near only	12 (15.8)
Distance and near	32 (42.1)
Photic phenomena	29 (38.2)
Blurred vision and photic phenomena	25 (32.9)

Etiology of Complaints and Clinical Findings

Table 3 shows findings thought to have contributed to the patients' symptoms. **Table 4** shows the occurrence of specific findings at presentation based on the nature of the presenting symptoms (blurred vision or photic complaints). **Table 5** shows the pupil diameters in the general study population, in patients with and without photic complaints, and in patients with and without reading complaints under mesopic circumstances. There were no statistically significant differences in the mean pupil diameter at any of the 3 illumination levels between patients with and patients without photic complaints or between patients with and patients without reading complaints under mesopic conditions. Aberrometry was performed in all patients when the complaints were not alleviated by treatment of observed ametropia; reliable measurements with a minimum pupil diameter of 5.0 mm were available for 19 eyes. **Table 6** shows the aberrometry results in these eyes. The mean levels of total aberrations, higher-order aberrations, defocus, astigmatism, coma, trefoil, and spherical aberration were not significantly different between patients with and patients without photic complaints or between patients with and patients without clinical IOL decentration.

Table 3. Prevalence of clinical findings in patients and perceived etiology of complaints (n = 76 eyes).

Clinical finding/perceived etiology	Eyes, n (%)
Ametropia/astigmatism	49 (64.5)
Wavefront anomalies	9 (11.8)
Large pupil size	11 (14.5)
Decentration of IOL	7 (9.2)
Posterior capsule opacification	12 (15.8)
Dry eye	3 (4.0)
Other findings	22 (28.9)
Map-dot-fingerprint corneal dystrophy	3 (4.0)
Fuchs corneal endothelium dystrophy	2 (2.6)
Irregular corneal astigmatism	2 (2.6)
Capsulorhexis too small	2 (2.6)
Vitreous floaters	4 (5.3)
Epiretinal membrane	1 (1.3)
Macular edema in diabetes	2 (2.6)
Negative dysphotopsia	2 (2.6)
Diminished mesopic contrast sensitivity	3 (4.0)
Wrong IOL power implanted	1 (1.3)
Unexplained etiology	2 (2.6)
Single contributing finding	43 (56.6)
Multiple contributing findings	31 (40.8)

IOL = intraocular lens

Table 4. Symptoms reported by patients and perceived etiology of complaints.

Clinical finding/perceived etiology	Complaint, number of eyes (%)			
	Blurred vision (n = 72)	Photopic complaints (n = 29)	Blurred vision + photopic complaints (n = 25)	Mesopic reading (n = 6)
Ametropia/astigmatism	46 (63.9)	10 (34.5)	7 (28.0)	5 (83.3)
Wavefront anomalies	9 (12.5)	6 (20.7)	6 (24.0)	0
Large pupil size	11 (15.3)	7 (24.1)	7 (28.0)	1 (16.7)
Decentration of IOL	7 (9.7)	5 (17.2)	5 (20.0)	0
Posterior capsule opacification	12 (16.7)	3 (10.4)	3 (12.0)	3 (50.0)
Dry eye	3 (4.2)	0	0	0
Other etiology	18 (25.0)	13 (44.8)	9 (36.0)	4 (66.7)
Unexplained etiology	2 (2.8)	2 (6.9)	2 (8.0)	0

IOL = intraocular lens

Table 5. Mean pupil size under 3 illumination levels related to type of complaints in eyes with available pupillometry measurements.

Group	Mean pupil size (mm) \pm SD		
	Scotopic	Mesopic low	Mesopic high
All eyes (n = 56)	5.77 \pm 0.96	4.91 \pm .88	3.81 \pm 0.68
Photoc complaints			
Yes (n = 19)	5.52 \pm 1.02	4.62 \pm 0.68	3.69 \pm 0.50
No (n = 37)	5.90 \pm 0.91	5.06 \pm 0.94	3.87 \pm 0.75
P value	.155	.075	.334
Reading complaints in mesopic conditions			
Yes (n = 19)	6.48 \pm 1.04	5.18 \pm 1.00	3.91 \pm 0.59
No (n = 37)	5.68 \pm 0.92	4.87 \pm 0.87	3.80 \pm 0.69
P value	.054	.430	.699

Table 6. Aberometry findings related to types of complaint and clinical findings in eyes with available aberrometry measurements.

Group	Mean aberration (μ m) \pm SD						
	Total	HOA	Defocus	Astigmatism	Coma	Trefoil	SA
All eyes (n = 19)	0.90 \pm 0.47	0.40 \pm 0.17	0.48 \pm 0.50	0.51 \pm 0.35	0.20 \pm 0.12	0.27 \pm 0.17	0.06 \pm 0.04
Photoc complaints							
Yes (n = 8)	0.67 \pm 0.25	0.39 \pm 0.21	0.27 \pm 0.21	0.40 \pm 0.23	0.19 \pm 0.14	0.27 \pm 0.22	0.04 \pm 0.03
No (n = 11)	1.07 \pm 0.52	0.40 \pm 0.15	0.59 \pm 0.61	0.59 \pm 0.41	0.22 \pm 0.12	0.27 \pm 0.14	0.08 \pm 0.05
P value	.063	.984	.168	.254	.607	.972	.057
IOL decentration							
Yes (n = 3)	0.64 \pm 0.21	0.32 \pm 0.06	0.38 \pm 0.17	0.40 \pm 0.16	0.21 \pm 0.13	0.18 \pm 0.08	0.02 \pm 0.01
No (n = 16)	0.95 \pm 0.49	0.41 \pm 0.19	0.47 \pm 0.54	0.53 \pm 0.38	0.20 \pm 0.13	0.28 \pm 0.18	0.07 \pm 0.04
P value	.307	.452	.794	.570	.874	.357	.063

HOA = higher order aberrations, IOL = intraocular lens, SA = spherical aberration

Treatment and Results

Table 7 shows the type of treatments performed and their prevalence. Of all study eyes, 64 (84.2%) were amenable to therapy; 22 eyes (28.9%) were treated with a combination of 2 or more modalities. Ametropia and astigmatism were treated with spectacles or refractive surgery in cases in which subjective refraction using trial frames increased distance visual acuity. The most frequent treatment was photorefractive keratectomy (PRK). In eyes having PRK, the mean sphere was 0.91 ± 0.53 D; the mean cylinder, 1.28 ± 0.76 D; and the mean SE, 0.25 ± 0.76 D. **Figure 1** shows the preoperative and postoperative UDVA and CDVA. The uncorrected near visual acuity (UNVA) before PRK was reported in 28 eyes; it was Jaeger (J) 1 in 10 eyes (35.7%) and J3 or better in 24 eyes (85.7%). After PRK, it was J1 in 16 eyes (57.1%) and J3 or better in 27 eyes (96.4%). In eyes that received spectacles for treatment, the mean sphere was 0.66 ± 0.42 D; the mean cylinder, 0.86 ± 0.76 D; and the mean

SE, 0.23 ± 0.37 D. The mean UDVA was 0.24 ± 0.15 logMAR and the mean CDVA was 0.02 ± 0.06 logMAR; 80% of patients were able to read J3 or better. Eyes with large pupils were treated with brimonidine 0.2%. In these eyes, the mean scotopic, mesopic-low, and mesopic-high pupil diameters were 5.83 ± 0.92 mm, 5.07 ± 0.64 mm, and 4.09 ± 0.34 mm, respectively. The treatment resulted in subjective improvement in photic complaints in 9 eyes (81.8%). Difficulties with reading, specifically under mesopic conditions, were treated with a combination of treatment modalities in 3 of 4 patients with this complaint. In 1 patient, reading spectacles combined with brimonidine drops were prescribed for both eyes, resulting in an increase in reading ability (J3 binocular UNVA, J1 binocular corrected near visual acuity [CNVA]). Another patient (1 eye) had unsatisfactory results after brimonidine treatment and had coexisting photic complaints; the multifocal IOL was exchanged for a monofocal IOL. A third patient was treated for coexisting ametropia with PRK, resulting in monocular UNVA of J1 bilaterally. Another patient (1 eye) reported difficulties reading under mesopic circumstances; reading spectacles were prescribed and a neodymium:YAG (Nd:YAG) capsulotomy was performed, resulting in a CNVA of J5.

Table 7. Treatment of complaints (n = 76 eyes).

Treatment	Eyes, n (%)
PRK	37 (48.7)
Spectacles	14 (18.4)
Nd:YAG capsulotomy	12 (15.8)
Artificial tears, punctum plugs	3 (4.0)
Brimonidine	11 (14.5)
Other	5 (6.6)
Reoperation	6 (7.9)
Capsulorhexis enlarged	2 (2.6)
IOL repositioned	1 (1.3)
IOL exchanged	3 (4.0)
None	12 (15.8)
Single modality	42 (55.3)
Multiple modalities	22 (28.9)

IOL = intraocular lens, Nd:YAG = neodymium:YAG, PRK = photorefractive keratectomy

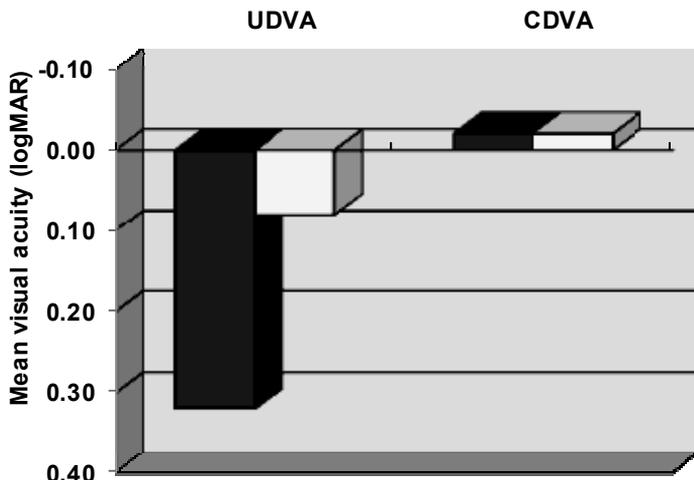


Figure 1. Visual acuity before (dark grey) and after (light grey) refractive surgery. CDVA = corrected distance visual acuity, UDVA = uncorrected distance visual acuity

The multifocal IOL was explanted in 3 eyes. One patient had a unilateral Tecnis IOL and reported blurred vision and halos. Even though UDVA improved from 0.40 logMAR uncorrected to 0.00 logMAR with spectacles, the patient preferred exchange for a monofocal IOL to refractive surgery given the coexisting photic phenomena. The other 2 eyes (1 in a patient with bilateral IOLs and 1 in a patient with a unilateral IOL) had a +4.00 D Restor IOL. The former patient reported blurred vision for distance and near that was caused by ametropia after IOL implantation (refractive astigmatism, 0.75 D; SE, +1.25 D). Given the short time since implantation (9 days), IOL exchange for a Restor IOL of a different power was performed. The latter patient reported blurred distance visual acuity, difficulty reading under mesopic circumstances, and halos at night. Because spectacle correction resulted in limited improvement (UDVA 0.40 logMAR versus CDVA 0.30 logMAR) and the pupil was large (mesopic low, 6.68 mm), the multifocal IOL was explanted and exchanged for a monofocal IOL. After IOL exchange, the UDVA was 0.0 logMAR or better with resolution of blurred vision in all eyes and photic phenomena resolved in 2 eyes.

DISCUSSION

The current study evaluated the presenting symptoms, etiology of complaints, and treatment of those complaints in 76 eyes of 49 patients who were dissatisfied after multifocal IOL implantation. The most common presenting symptom, blurred vision, occurred in 94.7% of eyes despite a mean UDVA of 0.28 ± 0.20 logMAR. This agrees with a previous observation by Galor et al.²⁸ that subjective complaints often do not

mirror the measured visual acuity; the authors also stressed the importance of contrast sensitivity function, wavefront disturbances, and visual function under mesopic conditions in the subjective rating of quality of vision. Ametropia and/or astigmatism was the main cause of blurred vision in our study, as indicated by the mean refractive sphere of 0.68 D and the mean refractive cylinder of -0.95 D as well as by the percentage of patients treated with refractive surgery (48.7% of all eyes) or spectacles (18.4% of all eyes). In a study by Woodward et al.²⁷ of 43 eyes of 32 patients dissatisfied after multifocal IOL implantation, blurred vision was reported in 95.4% of eyes, similar to the percentage in our study. In that study, however, the blurred vision was more often caused by posterior capsule opacification (PCO) than by ametropia and astigmatism, although astigmatism was also an important cause of blurred vision; the refractive astigmatism was greater than 0.75 D in 28% of cases. This is reflected by the higher percentage of eyes treated with Nd:YAG capsulotomy (34.9% of all eyes) and the lower percentage of eyes treated with refractive surgery (16.3% of all eyes) or spectacles (16.3% of all eyes) in the study by Woodward et al. than in the current study.

In the current study, 38.2% of eyes had photic symptoms with or without coexisting visual acuity complaints. Even though complaints of glare can be caused by the IOL itself, as shown in previous studies of the prevalence of glare and halos,¹⁶⁻²⁰ other causes should be ruled out. Intraocular lens decentration in particular is an important cause of photic complaints in multifocal IOL patients, with a reported incidence as high as 11%.²⁷ Also, decentered multifocal IOLs were found to be a main indication for IOL exchange.²⁹ In the current series, decentered multifocal IOLs did not result in specific changes in wavefront aberrometry, although coma, astigmatism, and third-order aberrations have been suggested as markers of tilt and decentration of multifocal IOLs.³⁰ More specifically, no statistically significant differences were found in any aberrometry value between patients with IOL decentration and those without IOL decentration. This may be caused by the lack of accuracy of wave-front aberrometry in eyes with multifocal IOLs, as previously described.^{31,32} The value of wavefront aberrometry in eyes with a diffractive or refractive multifocal IOL is controversial because the wavefront of the IOL is the result of 2 distinct superimposed wavefronts.^{31,32} Apart from IOL decentration, which was noted in 17.2% of the 29 eyes with photic complaints, a large pupil (24.1% of eyes with photic complaints) and PCO (10.4% of eyes with photic complaints) were also thought to contribute to the photic complaints in the current study. In the study by Woodward et al.,²⁷ photic complaints were reported in 41.9% of eyes. In contrast to findings in the current study, PCO was the main cause for this complaint, with 12 of 18 eyes (66.7% of eyes with photic complaints) having PCO. Pupil size was considered to be the cause of photic complaints in 4 eyes (22.2%) with photic complaints in the study by Woodward et al. In that study, 2 of the 4 eyes had a small pupil and a diffractive IOL and

were being treated with cyclopentolate to increase pupil size. In contrast, in the current study, 11 eyes with a large pupil and a diffractive IOL were treated with brimonidine to decrease pupil size. The effect of brimonidine drops on photic complaints is hard to establish given the subjective nature of the complaints and the combination of the treatment with other treatment modalities.

A third type of complaint after implantation of a multifocal IOL, difficulty reading under mesopic conditions, was reported by 4 patients (6 eyes). No significant differences in mean pupil size were observed between patients with this complaint and those without it, although there was a trend toward eyes with complaints to have a larger pupil. In individual cases, however, a large pupil was presumed to be the cause for this complaint. In these patients, given the pupil-dependent design of the Restor IOL, a higher percentage of light energy might be directed to the distance focal point rather than to the near focal point while reading under mesopic circumstances. Although pupil size is subject to changes caused by cataract surgery,³³ pupil size might have to be considered before deciding to implant a pupil-dependent multifocal IOL. Because the dissatisfaction of patients with larger pupils may be multifactorial, treatment in these cases consisted of a combination of reading spectacles, Nd:YAG capsulotomy, PRK, and brimonidine drops.

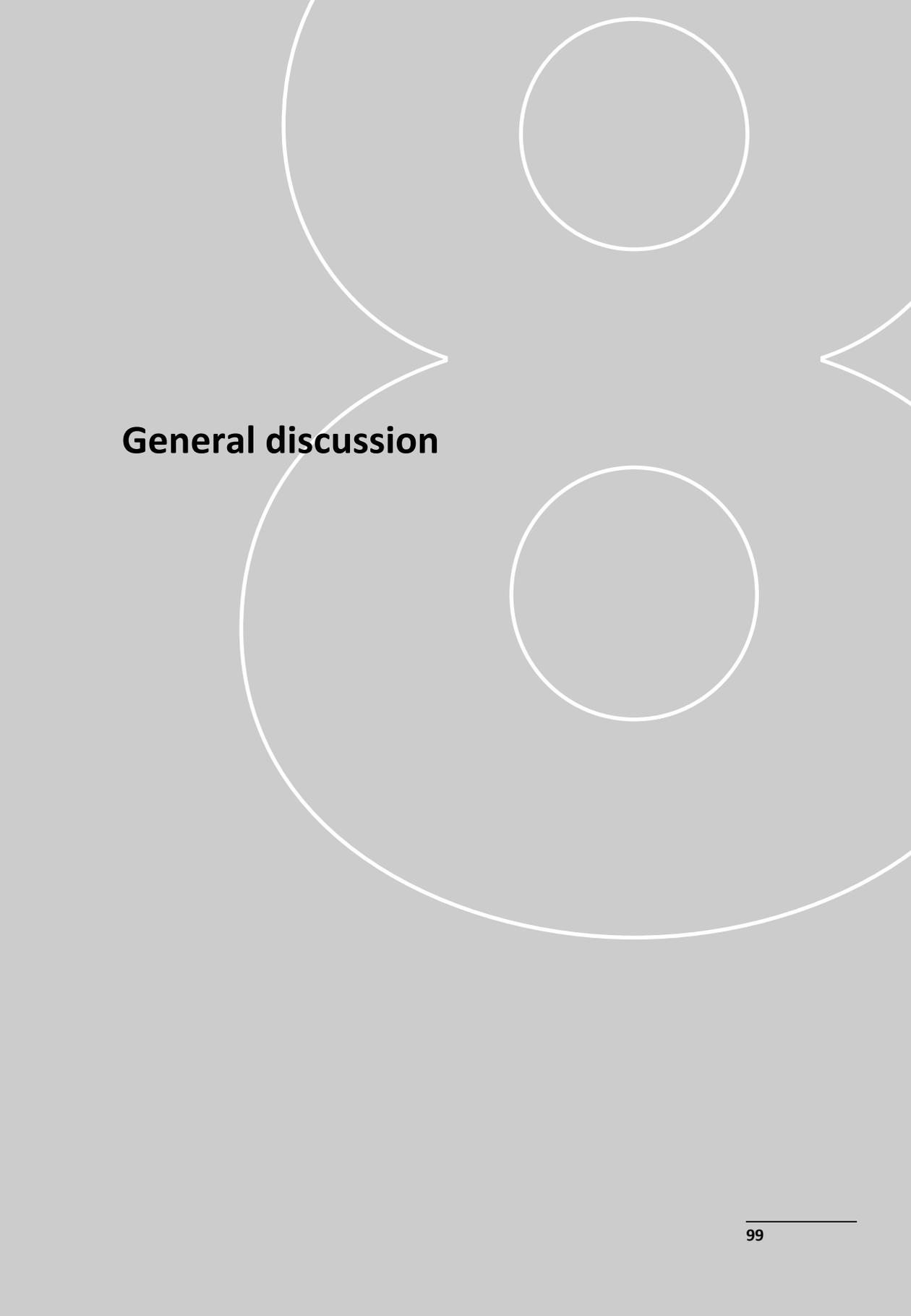
Apart from ametropia, PCO, IOL decentration, large pupils, aberrometry characteristics, and factors relating to the IOL design, coexisting ocular pathology can result in dissatisfaction after implantation of multifocal IOLs. Corneal dystrophies were noted in 5 patients in the current study, and these can lead to decreased visual acuity, decreased contrast sensitivity, and increased glare,³⁴⁻³⁶ thereby augmenting the same effects associated with multifocal IOLs. Therefore, coexisting or even mild ocular pathology expected to increase over time (e.g., early age-related macular changes) should be critically evaluated before multifocal IOL implantation is scheduled. The exact pattern of complaints and the conditions influencing the type and severity of complaints may be influenced by the design of the IOL used. The IOLs in the current study mainly consisted of diffractive multifocal models (98.7% of eyes) and of the +4.00 D Restor model (90.8% of eyes). Therefore, the current study did not allow a comparison between types of IOLs.

In conclusion, despite extensive positive experiences with multifocal IOLs, some patients are dissatisfied postoperatively. Presenting symptoms can be classified as complaints about visual acuity, complaints associated with photic phenomena, or a combination. There are many causes of these complaints, including residual ametropia, PCO, pupil size, and coexisting ocular pathology. However, most causes of dissatisfaction can be treated successfully and explantation of the multifocal IOL appears to be rare.

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The background features a light gray color with several white geometric shapes. A large white circle is partially visible on the left side. In the upper right and lower right areas, there are smaller white circles. A white line with a pointed end extends from the left towards the center, and another similar line extends from the right towards the center, creating a central space where the text is located.

General discussion

GENERAL DISCUSSION

Removing the cataractous lens from the eye including the capsular bag, as first practiced by Daviel in 1747,¹ could be considered the first stage in cataract surgery as it is being practiced today. Rapidly, options to treat the resulting aphakia by implantation of an IOL were considered, heralding the second stage in cataract surgery. Casanova describes a conversation on the subject of IOLs in the year 1764 in his memoirs.² Casanova passed the idea on to Casaamata, who first attempted to implant a glass IOL following a cataract extraction in Dresden in 1795. Ridley implanted a polymethylmethacrylate IOL in the capsular bag of a patient in 1949, after observing fragments of the same material in eyes of Royal Air Force pilots originating from shattered airplane canopies doing no harm as long as they remained stationary in the eye.³ Smaller incision sizes, made possible by the introduction of phacoemulsification of the crystalline lens and the introduction of foldable IOLs decreased the amount of surgically induced astigmatism. Better formulas for IOL power calculations and better ways to measure axial length decreased postoperative spherical ametropia. Due to better control of the spherical and the cylindrical postoperative refractive state, cataract surgery became a procedure not only aimed at providing better visual acuity, but also aimed at providing patients with a desirable postoperative refractive state. In this third stage, cataract surgery has therefore become, at least in part, a refractive surgery procedure. However, non-accommodative monofocal IOLs can provide emmetropia and therefore spectacle independence for one working distance only, as they can not mimic the changing optical power of the pre-presbyopic crystalline lens as described by Helmholtz.⁴ Currently, multifocal IOLs are increasingly implanted to surpass this shortcoming of non-accommodative monofocal IOLs.

This thesis demonstrates the ability of multifocal IOLs to provide patients with an uncorrected distance and near visual acuity of 20/25 or better in the majority of cases, resulting in complete spectacle independence in around 80% of patients. Aspheric designs were found to result in a significant increase in uncorrected near visual acuity compared to spherical designs in multifocal IOLs. Similarly, multifocal IOLs with lower near additions were found to result in a significantly better intermediate visual acuity compared to multifocal IOLs with higher near additions. In general, however, monofocal IOLs are superior to multifocal IOLs with respect to levels of intraocular straylight, contrast sensitivity and occurrence of glare and halos. If patient dissatisfaction with their multifocal visual function occurs this can be treated effectively in around 85% of cases.

Suggestions for future research would include studies focussing on changes in design of multifocal IOLs in order to improve the aforementioned drawbacks, notably

photic complaints and loss of contrast sensitivity. Ideally, future IOLs should be designed as truly accommodative IOLs, since these would be best fitted to mimic the pre-presbyopic natural crystalline lens. As long as conceptual problems with the latter have not been cleared, aspherical diffractive and diffractive-refractive multifocal IOLs with low additions seem to be the best alternative to provide patients with optimized visual acuity at more than one distance.

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Summary

Samenvatting

SUMMARY

Chapter 1 describes the aim of the current thesis as a study on the results of multifocal intraocular lenses implanted in the capsular bag in cataract surgery, aimed at providing patients with optimized uncorrected visual acuity at near, intermediate and distant working distances.

Chapter 2 gives an overview of currently available papers in the peer-reviewed literature on the pros and cons of multifocal intraocular lenses. Case-series and randomized controlled trials show that multifocal IOLs are successful in providing patients with levels of uncorrected near visual acuity unmatched by monofocal IOLs. However, multifocal IOLs have been associated with decreased contrast sensitivity, increased levels of subjective complaints such as glare and halos compared to monofocal IOLs, and lower intermediate visual acuity compared to near and distance visual acuity. Diffractive and combined refractive-diffractive multifocal IOLs seem to be superior compared to purely refractive multifocal IOLs with regard to near visual acuity levels, occurrence of glare and halos, and postoperative spectacle independence.

Chapter 3 addresses clinical results of a widely-used spherical, refractive-diffractive multifocal IOL (ReSTOR SA60D3) over a period of three years in a cohort of 44 eyes following cataract surgery. All patients achieved a binocular uncorrected and best distance-corrected near acuity of 20/25 or better at 6 months and 3 years. On a quality-of-life questionnaire, patients reported good distance, intermediate, and near acuity without complaints of severe glare or halos. Complete spectacle independence for distance and near acuity was achieved by 83.7% and 81.9% of patients, respectively, at 6 months and 85.0% and 75.0% of patients, respectively, at 3 years.

Chapter 4 describes the results of a study undertaken to objectively measure intraocular straylight, a physical phenomenon arising from light scatter in the eye influencing quality of vision, in subjects with either a monofocal or a multifocal IOL. The monofocal IOL (AcrySof SA60AT, 40 eyes) and multifocal IOL (ReSTOR SA60D3, 66 eyes) are completely similar apart from the central diffractive structure only present in the multifocal IOL. A comparison of straylight levels in an age-matched population without cataract (control group) demonstrated significantly lower straylight levels in both the multifocal and monofocal group compared to phakic subjects. A comparison of straylight levels between multifocal and monofocal subjects demonstrated significantly lower straylight levels in the monofocal group compared to the multifocal group. This finding could contribute to the decreased contrast

sensitivity and increased levels of glare complaints observed in multifocal IOLs compared to monofocal IOLs.

Chapter 5 describes the results of a study undertaken to compare the clinical performance after cataract surgery of either spherical or aspheric multifocal IOLs. From a theoretical point of view, as well as from literature on monofocal IOLs, an aspheric design could be superior with respect to visual acuity and contrast sensitivity to a spherical design. The aspheric IOL (ReSTOR SN6AD3, 47 eyes) and spherical IOL (ReSTOR SN60D3, 45 eyes) are completely similar apart from the modifications to the anterior surface of the former IOL to reduce levels of spherical aberration. Uncorrected near visual acuity was significantly better in the aspheric group, but there were no differences with regards to mean uncorrected distance visual acuity, contrast sensitivity levels, intraocular straylight levels, incidence of night-vision symptoms, and subjective rating of vision.

Chapter 6 describes the results of a study undertaken to compare the clinical performance after cataract surgery of either low-add or high-add multifocal IOLs. Multifocal IOLs with a lower near addition were introduced to increase visual acuity at intermediate working distances. The low-add multifocal IOL (ReSTOR SN6AD1, 68 eyes) and high-add multifocal IOL (ReSTOR SN6AD3, 46 eyes) are completely similar apart from the design of the central diffractive structure delivering a + 3.00 diopter (D) or + 4.00 D reading addition, respectively. The uncorrected visual acuity was significantly better in the + 3.00 D IOL group than in the + 4.00 D IOL group at 40, 50, 60, and 70 cm. Uncorrected distance visual acuity was better in the + 3.00 D IOL group; the uncorrected near visual acuity at the preferred working distance was similar in the 2 groups. Contrast sensitivity and intraocular straylight levels were also similar. The mean levels of higher-order and spherical aberrations were lower in the + 3.00 D IOL group. In this prospective study, the + 3.00 D IOL resulted in better intermediate vision than with the + 4.00 D model without compromising distance and near visual acuity, contrast sensitivity levels and intraocular straylight levels.

Chapter 7 describes a study on dissatisfaction in patients following cataract surgery with implantation of a multifocal IOL. Symptoms, etiology, and treatment are described in a case series consisting of 76 eyes. Blurred vision was the main complaint, followed by a combination of blurred vision and photic complaints. Residual ametropia and astigmatism, posterior capsule opacification, and a large pupil were the 3 most significant etiologies. More than 80% were amenable to therapy, with refractive surgery, spectacles, and laser capsulotomy being the most frequently used treatment modalities. This study demonstrates that the cause of dissatisfaction

after implantation of a multifocal IOL can be identified and effective treatment measures taken in the majority of cases.

Chapter 8 features a general discussion on the use of multifocal IOLs in cataract surgery as described in the previous chapters, and suggestions for future research.

SAMENVATTING

Hoofdstuk 1 beschrijft de doelstellingen van dit proefschrift als een studie naar de klinische resultaten van implantatie van een multifocale intraoculaire lens na cataract chirurgie. Deze techniek is erop gericht een optimale ongecorrigeerde leesvisus, intermediaire visus en afstandsvisus te verkrijgen, zodat de postoperatieve brilafhankelijkheid wordt geminimaliseerd.

Hoofdstuk 2 geeft een overzicht van de beschikbare studies in de wetenschappelijke literatuur met multifocale implantlenzen als onderwerp. Case-series en randomized controlled trials tonen aan dat multifocale implantlenzen bij gebruik in geselecteerde patiënten geassocieerd zijn met een betere leesvisus dan monofocale implantlenzen, zonder nadelige gevolgen voor de afstandsvisus. Multifocale implantlenzen zijn echter ook geassocieerd met een verminderde contrastsensitiviteit en toegenomen klachten van glare en halo's t.o.v. monofocale implantlenzen, en een verminderde ongecorrigeerde visus op intermediaire afstanden t.o.v. de ongecorrigeerde visus nabij en veraf. Diffractieve en hybride diffractieve-refractieve multifocale implantlenzen lijken superieur aan refractieve multifocale implantlenzen t.a.v. ongecorrigeerde leesvisus, incidentie van glare en halo's en postoperative brilafhankelijkheid.

Hoofdstuk 3 beschrijft een studie naar de klinische resultaten van een veelgebruikte sferische, hybride diffractieve-refractieve multifocale implantlens (ReSTOR SA60D3) na cataractchirurgie, met een follow-up periode van drie jaar. Alle patiënten bereikten een ongecorrigeerde binoculaire afstandsvisus van afstands-gecorrigeerde leesvisus van 20/25 of beter, zowel na 6 maanden en 3 jaar. Patiënten rapporteerden een hoge mate van tevredenheid over hun afstands-, lees- en intermediaire visus, en een afwezigheid van als "ernstig" geclassificeerde glare en halo's. Volledige brilafhankelijkheid voor afstands- en leesvisus werd gerapporteerd voor 83.7% en 81.9% van de populatie op 6 maanden, en 85.0% en 75.0% van de populatie na drie jaar.

Hoofdstuk 4 beschrijft de resultaten van een studie waarbij met behulp van objectieve meetmethoden intraoculair stroolicht metingen werden verricht in patiënten met ofwel een monofocale, danwel een multifocale implantlens. Intraoculair stroolicht betreft een fysisch fenomeen veroorzaakt door lichtverstrooiing in het oog dat de kwaliteit van zien beïnvloedt. De monofocale implantlens (AcrySof SA60AT, 40 ogen) en de multifocal implantlens (ReSTOR SA60D3, 66 ogen) zijn identiek afgezien van de centrale diffractieve structuur die alleen in de multifocale lens aanwezig is om een secundair brandpunt aan de implantlens te verkrijgen. Bij een vergelijking t.a.v. het strooichtniveau tussen een controlegroep zonder cataract en bovenge-

noemde pseudofake groepen bleek dat zowel de groep met een multifocale implantlens als de groep met een monofocale implantlens een lager gemiddeld strooiligheidsniveau kent in vergelijking tot de fake controlegroep. Bij een vergelijking t.a.v. het strooiligheidsniveau tussen een groep met een multifocale implantlens en de groep met een monofocale implantlens bleek het gemiddelde strooiligheidsniveau in de groep met een monofocale implantlens significant lager te zijn t.o.v. de groep met een multifocale implantlens. Deze bevinding zou een gedeeltelijke verklaring kunnen zijn voor de verminderde contrastgevoeligheid en toegenomen incidentie van glare klachten in patiënten met een multifocale implantlens t.o.v. patiënten met een monofocale implantlens.

Hoofdstuk 5 beschrijft de resultaten van een studie welke de klinische resultaten van cataractchirurgie met implantatie van sferische multifocale implantlenzen vergelijkt met cataractchirurgie met implantatie van asfere multifocale implantlenzen. Op grond van theoretische voordelen en op grond van klinische studies naar implantatie van monofocale asfere implantlenzen zou een asfere multifocale implantlens geassocieerd kunnen zijn met superieure resultaten t.o.v. een sferische multifocale implantlens t.a.v. visus en contrast sensitiviteit. De asfere multifocale implantlens (ReSTOR SN6AD3, 47 ogen) en de sferische multifocale implantlens (ReSTOR SN60D3, 45 ogen) zijn identiek afgezien van de modificaties aan de anterieure zijde van de eerstgenoemde welke de sferische aberraties van het gehele optische systeem verminderen. De ongecorrigeerde leesvisus was significant beter in de groep met een asfere multifocale implantlens t.o.v. de groep met een sferische multifocale implantlens, maar er waren geen significante verschillen t.a.v. afstandvisus, contrastgevoeligheid, intraoculair strooiligheidsniveau, incidentie van glare en halo's, en subjectieve kwaliteit van zien.

Hoofdstuk 6 beschrijft de resultaten van een studie welke de klinische resultaten van cataractchirurgie met implantatie van multifocale implantlenzen met een lage leesadditie vergelijkt met cataractchirurgie met implantatie van multifocale implantlenzen met een hoge leesadditie. De eerstgenoemde implantlenzen werden geïntroduceerd met als doel de intermediaire ongecorrigeerde visus te verbeteren. De multifocale implantlens met een lage additie (ReSTOR SN6AD1, 68 ogen) en de multifocale implantlens met een hoge additie (ReSTOR SN6AD3, 46 ogen) zijn identiek afgezien van het ontwerp van de centrale diffractieve structuur welke respectievelijk een + 3.00 dioptrie (D) of + 4.00 D leesadditie geven. De ongecorrigeerde leesvisus was significant beter in de + 3.00 D IOL groep t.o.v. de + 4.00 D IOL groep bij een werkafstand van 40, 50, 60 en 70 cm. De ongecorrigeerde afstandvisus was beter in de + 3.00 D IOL groep, de ongecorrigeerde leesvisus op de werkafstand zoals deze geprefereerd werd door de individuele patiënt was vergelijkbaar in de twee groepen. Contrastsensitiviteit en intraoculair strooiligheidsniveau waren eveneens vergelijkbaar

tussen de twee groepen. De gemiddelde hogere orde aberraties en sferische aberraties waren lager in de + 3.00 D groep. In deze prospectieve studie was het + 3.00 D model implantlens in vergelijking met het + 4.00 D model implantlens geassocieerd met een betere intermediaire visus. Implantatie van het +3.00 D model implantlens resulteerde in een gelijkwaardige lees- en afstandsvisus, contrastsensitiviteit en intraocular strooilicht niveau in vergelijking met het + 4.00 D model implantlens.

Hoofdstuk 7 heeft betrekking op een studie naar ontevredenheid over de resultaten onder patiënten na cataract chirurgie met implantatie van een multifocale implantlens. Symptomen, etiologie, en behandeling hiervan worden geïnventariseerd in een serie bestaande uit 76 ogen. Tegenvallende gezichtsscherpte was de meestgenoemde klacht, gevolgd door een combinatie van tegenvallende visus met fotopische klachten zoals glare en halo's. Postoperatieve ametropie en astigmatisme, nastaar en een bovengemiddeld grote pupildiameter waren de drie meest voorkomende oorzaken van klachten. In meer dan 80% van de gevallen was een therapie of combinatie van therapiën mogelijk, met refractiechirurgie, brilcorrectie en Nd:YAG-capsulotomie als meest frequent gebruikte behandelingsmodaliteiten. De studie toont aan dat in het merendeel van de gevallen van subjectieve klachten na implantatie van een multifocale lens een oorzaak te traceren is, en een behandeling mogelijk is.

Hoofdstuk 8 bestaat uit een algehele discussie t.a.v. de eerdere hoofdstukken over de toepassing van multifocale implantlenzen in de cataractchirurgie en suggesties voor toekomstig onderzoek.

Dankwoord

DANKWOORD

De totstandkoming van dit proefschrift kwam tot stand met medewerling van velen. Enkelen wil ik in het bijzonder noemen.

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Curriculum vitae

Publications

CURRICULUM VITAE

Niels Erik de Vries was born on June 22nd, 1979 in Erlangen (Germany). His secondary school certificate was obtained at Coenecoop College, Waddinxveen (the Netherlands) where he also served as a member and president of the student council. Between 1997 and 2003 he studied medicine at the Erasmus University in Rotterdam (the Netherlands). During this period, he pursued a visiting clerkship in ophthalmology at the University Hospital Hannover (Germany) with professor Winter, a research internship at the Rotterdam Eye Hospital with Dr. Martinez and a Summer Program in European studies at the University of Vienna (Austria).

Between 2004 and 2009, the author was a resident in ophthalmology at the University Hospital Maastricht (the Netherlands) directed by professor Hendrikse. During this period, he commenced the research which led to the current thesis and presented the results of his research projects at congresses of the American Society of Cataract and Refractive Surgeons (2007, 2009, 2010), congresses of the European Society of Cataract and Refractive Surgeons (2006 - 2008, 2010) and numerous national meetings. In the same period, he took part in the Summer Program at the National Diplomatic Academy in Vienna (Austria), and became a Fellow of the European Board of Ophthalmology in Paris (France). In the summer of 2011 he spent five weeks at the oculoplastic department of the Ludwig Maximilians University Hospital with professor Hintschich and at the Herzog Carl Theodor Eye Hospital with professor Riedel, both in Munich (Germany).

The author currently works as an ophthalmologist and ophthalmic surgeon at the University Hospital Maastricht, the Regional Hospital in Brunssum (the Netherlands) and the private clinic Dr. Budo in St. Truiden (Belgium). His main professional interests are anterior segment surgery and oculoplastic surgery.

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