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Quality of Vision after Bilateral Multifocal Intraocular Lens Implantation

A Randomized Trial – AT LISA 809M versus AcrySof ReSTOR SN6AD1

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Purpose: To compare postoperative visual symptoms and spectacle freedom after bilateral implantation of the AT LISA 809M (Carl Zeiss Meditec, Jena, Germany) versus the AcrySof ReSTOR SN6AD1 (Alcon Laboratories, Irvine, CA) multifocal intraocular lens (IOL).

Design: Double-masked, prospective, randomized, controlled clinical trial.

Participants: A total of 188 patients undergoing bilateral sequential cataract surgery or bilateral refractive lens exchange.

Methods: Patients were preoperatively randomized (allocation ratio 1:1) to bilateral implantation with the AT LISA 809M IOL or ReSTOR SN6AD1 IOL. Postoperative outcomes were assessed 4 to 8 months after second eye surgery.

Main Outcome Measures: The primary outcome was visual symptoms evaluated with the Quality of Vision (QoV) questionnaire. Secondary outcomes included other questionnaire data (CatQuest-9SF, spectacle independence, vision satisfaction, and dysphotopsia) and visual function measures (near, intermediate, and distance visual acuity, binocular reading speed [International Reading Speed Texts], contrast sensitivity, and forward light scatter). Adverse events, including intraoperative and postoperative complications, also were evaluated.

Results: There was no significant difference between IOL groups in Rasch-adjusted QoV scores for frequency ($P = 0.95$), severity ($P = 0.56$), and bothersomeness ($P = 0.34$) of visual symptoms; median (interquartile) scores for these QoV subscales were 29 (15–37), 22 (13–27), and 14 (0–29) for the AT LISA 809M IOL group, respectively, and 32 (15–37), 22 (13–30), and 14 (0–29) for the ReSTOR SN6AD1 IOL group, respectively. Halo was the most prominent dysphotopsia symptom, with 6% in both IOL groups reporting halo symptoms as very bothersome. Complete spectacle independence was achieved in 69 of 84 (82.1%) AT LISA 809M recipients and 66 of 85 (77.6%) ReSTOR SN6AD1 recipients ($P = 0.57$). Preferred reading distance was slightly nearer for the AT LISA 809M IOL. There were no statistically significant differences in any of the other secondary outcome measures.

Conclusions: Visual symptoms were similar after bilateral implantation of the AT LISA 809M and ReSTOR SN6AD1 IOLs. Both these diffractive bifocal IOLs produce high levels of spectacle independence and patient satisfaction. However, a small but clinically significant minority of patients remained symptomatic and dissatisfied with visual results 4 to 8 months after surgery. *Ophthalmology 2015;■:1–11 © 2015 by the American Academy of Ophthalmology.*

Spectacle independence is a central aim in modern cataract surgery. Although bilateral monofocal intraocular lens (IOL) implantation leads to high levels of patient satisfaction, most patients still require spectacles for at least some activities after surgery.[1,2] Flexible haptic monofocal IOLs have delivered only limited gains in near vision over conventional monofocal IOLs, and these diminish with time.[3] Multifocal IOLs with diffractive or refractive optics designed to deliver more than 1 point of optimum focus have been more successful, delivering unaided distance vision at the same level as monofocal IOLs with significantly better unaided near vision and complete spectacle independence in a high proportion of patients,[2,4,5] but the tradeoff between gains in spectacle freedom and optical side effects for multifocal IOLs is widely recognized.[4,5]

Research has focused on optic design improvements aiming to optimize spectacle freedom while minimizing visual symptoms. Designs based on diffractive optics have produced superior near vision and greater spectacle independence than refractive multifocal IOLs, with similar levels of visual symptoms.[6,7] A reduced near focus addition[8] and, more recently, trifocal optics[6,9,10] have been introduced to

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Table 1. Inclusion and Exclusion Criteria

Inclusion criteria	Sequential bilateral cataract surgery or refractive lens exchange
	Motivation for spectacle independence
	Age ≥21 yrs
Exclusion criteria	Ocular comorbidity (amblyopia, retina, or optic nerve pathology) that may reduce postoperative CDVA
	Reduced zonular/capsular stability
	Corneal astigmatism >1.50 D
	IOLMaster (Carl Zeiss Meditec, Jena, Germany) biometry not possible
	IOL power <10 or >30 D
	Professional night drivers, pilots, and other occupations for which induced dysphotopsia could threaten career
	Vulnerable groups, including patients in residential care or with learning difficulties or severe psychiatric disorders
	Poor mobility
	Poor comprehension of written English

CDVA = corrected distance visual acuity; D = diopters; IOL = intraocular lens.

enhance the intermediate range. Further optical modifications, including variations in asphericity and diffractive step profile variations, have been developed to improve the quality of vision. We compare 2 market-leading diffractive bifocal IOLs, the AT LISA 809M (Carl Zeiss Meditec, Jena, Germany) and the AcrySof ReSTOR SN6AD1 (Alcon Laboratories, Irvine, CA), each featuring diffractive step profile variations designed to minimize visual symptoms after implantation,[6,8,9,11–13] in a double-masked, prospective, randomized, controlled trial using a validated dysphotopsia questionnaire[14] as the main outcome measure.

Methods

Study Design

This study was conducted at 5 sites in 2 hospitals: Moorfields Eye Hospital, London (4 sites), and King's College Hospital, London (1 site). The protocol was approved by the U.K. Collaborative Research Ethics Committee. The principles of Good Clinical Practice were adhered to throughout in accordance with the Declaration of Helsinki. The study was a prospective, randomized, controlled clinical trial, registered at www.controlled-trials.com/ISRCTN64155646.

Enrollment of Participants

This trial included patients undergoing sequential bilateral cataract surgery or refractive lens exchange. Inclusion and exclusion criteria are detailed in Table 1. Eligible patients were identified by participating surgeons at their preoperative assessment, given an explanation of the trial and its aims, and sent home with detailed trial information designed to be readily comprehensible to a nonexpert reader. After a minimum cooling-off period of 24 hours, provisional consent to participate in the trial was obtained by telephone after further counseling with trial coordinators. Confirmation of willingness to participate in the trial was obtained 5 to 10 days before surgery. Participants were then registered in the trial and received a randomization number. Written confirmation of consent to participate in the trial was obtained by participating surgeons upon admission for first eye surgery.

Randomization and Treatment Allocation

Study patients were randomized by a medical statistician to bilateral implantation of the AT LISA 809M or the ReSTOR SN6AD1 multifocal IOL using a 1:1 treatment allocation ratio. Minimization was used to help distribute this 1:1 allocation ratio evenly throughout participating sites and recruitment settings (National Health Service or private practice). Minim software (http://www-users.york.ac.uk/~mb55/guide/minim.htm) was used for randomization sequence generation, allocation concealment, treatment allocation, and minimization.

Trial Intraocular Lenses

The AT LISA 809M (near addition +3.75 diopters [D]) and the ReSTOR SN6AD1 (near addition +3.00 D) are both bifocal diffractive IOLs. Both have modifications to the diffractive step profile designed to increase light distribution to the distance focus and reduce light scatter, aiming to improve subjective visual quality while preserving good unaided near visual function.

The ReSTOR SN6AD1 IOL is distance dominant but pupil size dependent, with a graded reduction of diffractive step height (apodization) toward the periphery of the central diffractive zone. Discounting scattered light, the ReSTOR SN6AD1 IOL has a 50/50 distance to near focus light distribution in the central 2 mm of the optic, which transitions to 100% distribution to the distance focus outside the 3.6-mm-diameter diffractive zone.

The AT LISA 809M IOL has a wider-angle step transition with alternate refractive and diffractive zones across the full width of the optic. A 65/35 distance-to-near focus light distribution ratio is maintained at all pupil diameters.

Treatment and Surgical Technique

IOLMaster (Carl Zeiss Meditec) optical biometry was used throughout. Intraocular lens dioptric power was selected targeting emmetropia, using the IOL power corresponding to the negative (myopic) predicted refractive outcome closest to zero. Biometry printouts were configured using optimized calculation constants published by the User Group for Laser Interferometric Biometry (http://www.augenklinik.uni-wuerzburg.de/ulib/c1.htm). The SRKT biometry formula was used in IOL power calculations for all eyes with an axial length ≥22 mm. The Hoffer Q biometry formula was used for all other eyes.

Phacoemulsification and IOL implantation were performed by 12 consultant ophthalmic surgeons in the Moorfields IOL Study Group through a 2.4-mm limbal or clear corneal incision. Limbal relaxing incisions (http://www.lricalculator.com) were used in eyes with 1.00- to 1.50-D keratometric astigmatism (all eyes had a ≤1.50-D keratometric astigmatism) (Table 1). The IOLs were implanted in the capsular bag using the manufacturers' recommended IOL loading and injection technique. The interval between the first and second eye surgery was 1 to 4 weeks. Remedial laser refractive surgery was offered to all patients with symptomatic refractive errors after completion of the trial assessment.