Clinical Evaluation of the OptiVis™ Multifocal Intraocular Lens

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ABSTRACT

Introduction: The purpose of this study was to evaluate the efficacy of the OptiVis™ Multifocal Intraocular Lens (IOL) in patients undergoing bilateral crystalline lens replacement following extracapsular extraction by phacoemulsification.

Methods: This was a prospective 6-month, open-label, nonrandomized clinical trial of subjects undergoing bilateral implantation with the OptiVis Multifocal IOL. Of the 121 eyes enrolled, 88 eyes of 44 subjects completed the entire 6-month trial. **Results:** After 6 months, the majority of eyes had a distance best-corrected visual acuity of 20/20 or better, with 89.8% achieving that outcome, and 100% with 20/32 or better. At an intermediate distance, most eyes (90.9%) had a distance corrected intermediate visual acuity of 20/40 or better, and 53.4% had an acuity of 20/32 or better. At a near distance, most eyes (95.5%) had a distance corrected near visual acuity of 20/40 or better by month 6. The

most commonly reported adverse event was mild-to-moderate halos ($n=30$, 36%) and mild-to-moderate glare ($n=15$, 18%). In addition, there was one case of cystoid macular edema, one posterior capsular opacification, and one case of severe corneal edema. Postoperative contrast sensitivity was comparable with normal phakic subjects ≥ 60 years of age. **Conclusion:** The OptiVis Multifocal IOL provided satisfactory visual acuity at distance, near, and intermediate with no apparent reduction in contrast sensitivity. Additional, longer-term follow-up studies are planned.

Keywords: bilateral crystalline lens replacement; extracapsular extraction; OptiVis Multifocal Intraocular Lens; phacoemulsification

INTRODUCTION

A cataract is an opacity or cloudiness of the crystalline lens which may prevent a clear image from forming in the cornea, and is the leading cause of blindness worldwide.¹ Age-related cataracts are responsible for 48% of world blindness, or about 18 million people.² In the United States, about 300,000–400,000 new visually-disabling cataracts occur annually.³

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With the recent introduction of multifocal intraocular lenses (IOLs), patients undergoing cataract surgery have more treatment options than ever before. Multifocal IOLs generate different foci in an attempt to overcome the visual limitation at near and intermediate distances that is associated with conventional monofocal IOLs.⁴ The aim of these multifocal IOLs, therefore, is to allow patients to achieve spectacle independence. These lenses, however, are not without limitations, with some patients reporting problems with halos, glare, and loss of contrast sensitivity.^{5,6}

The OptiVis™ Multifocal IOL (Aaren Scientific, Inc, Ontario, CA, USA) is a relatively new entry to the multifocal IOL market and offers several advantages over those currently available. The lens is distance dominant and has a diffractive zone that allows for far and near vision for a full range of pupil sizes. The progressive power refractive zone allows for far and intermediate vision, and the apodized diffractive design is intended to minimize light loss outside far and near foci in order to reduce halo. Additionally, the bi-sign aspherization is designed to improve image contrast at large pupils for different corneal asphericities, and even with lens tilt and/or decentration. The lens is made from hydrophilic, acrylic material with UV-absorber, and has a refractive index of 1.46. It is a one-piece design and has earned CE-approval status. Specifically, the OptiVis IOL has a posterior multifocal surface that consists of three zones: central zone (zone 1) is a progressive refractive power for far and intermediate distances, within central 1.5 mm diameter. The annular zone, within 1.5 mm–3.8 mm diameters (zone 2), is the apodized diffractive zone for far and 2.5 diopter (D) effective (40 cm for near distance) for near. The peripheral refractive zone (zone 3) is shaped for bi-sign aspherization. The lens drawing in Figure 1 demonstrates the three optical zones.

Figure 1. The OptiVis lens.

For the OptiVis lens, the zone 1 power profile starts at the intermediate power at the center of the lens, with the power profile designed to extend the focus range from far to intermediate distances. The power profile of the negative slope of zone 1, and part of the base surface of the diffractive zone 2, is intended to expand the depth of focus from far to intermediate distances. The unique refractive zone of the OptiVis lens has the advantage of using 100% of the available light sent to the retina for imaging which, together with unique apodization of zone 2, reduce the overall light loss versus any other diffractive optic. Ultimately, the design of the OptiVis lens allows for a predictable intermediate zone lacking in other multifocal lenses, while still providing similar vision at far and near.

The purpose of this study was to evaluate the efficacy of the OptiVis Multifocal IOL in patients undergoing bilateral phacoemulsification.

METHODS

This study was a 6 month, open-label, nonrandomized clinical trial of 121 enrolled eyes expected to undergo bilateral implantation with the OptiVis multifocal IOL, with the second surgery at least 1 week, and no more than 4 weeks, after the first surgery. For each subject, the decision for which eye to operate on first was at the discretion of the physician. After each surgery, each subject was examined

7–14 days postoperatively and at 30 days, 90 days, and 180 days following the second surgery. All subjects were treated with the normal standard of care for cataract surgery, in addition to the specific trial requirements. Of the 121 eyes enrolled, 108 eyes were examined at 1 month, 94 eyes at 3 months, and 88 eyes of 44 subjects were tested at 6 months.

The mean age of implanted patients was 70.43 ± 6.33 years with a visual potential of 20/30 or better in each eye after cataract removal and IOL implantation, and a preoperative best corrected distance visual acuity (BCDVA) worse than Snellen 20/40 (or worse than 20/30 in the presence of glare as measured using a Snellen chart with Brightness Acuity Tester [BAT] at medium). Patients were required to have a naturally dilated pupil size (in dim light) ≥ 4.0 mm (with no dilation medications) for both eyes, a preoperative corneal astigmatism of no more than 1.0 D, a clear intraocular media other than cataract, and the availability, willingness, and sufficient cognitive awareness to comply with examination procedures.

Patients were excluded for concurrent participation or participation during the last 30 days in any other clinical trial, or use of systemic or ocular medications that may affect vision (the use of any miotic agent was specifically contraindicated). Patients with acute or chronic disease, or illness that would increase the operative risk or confound the outcome(s) of the study (eg, diabetes mellitus, immunocompromized, connective tissue disease, etc), were excluded. Subjects with diabetes mellitus, or a history of uncontrolled systemic or ocular disease (eg, uncontrolled ocular hypertension or glaucomatous changes in the retina) were also excluded, as were those with a history of ocular trauma, prior ocular surgery, amblyopia, strabismus, corneal abnormalities such as stromal, epithelial, or endothelial

dystrophies, intraocular inflammation, or a recurrent ocular inflammatory condition. Moreover, subjects with a known pathology that may affect visual acuity, particularly retinal changes that affect vision (macular degeneration, cystoid macular edema, proliferative diabetic retinopathy, etc) were not permitted to enroll, nor were patients diagnosed with degenerative visual disorders (eg, macular degeneration, or other retinal disorders) that were predicted to cause future acuity losses to a level of 20/30 or worse. Those subjects with pupil abnormalities (nonreactive, tonic pupils, abnormally shaped pupils, or pupils that do not dilate at least 4.0 mm under mesopic/scotopic conditions), or those presented with a capsule or zonule abnormality that may affect postoperative IOL centration or tilt; including pseudoexfoliation, trauma, or surgical complications (eg, zonular rupture, eccentric anterior capsulorhexis) were not permitted to enroll.

Each investigator used a standard small-incision, phacoemulsification cataract extraction surgical technique. Lenses were folded for implantation and inserted through a suggested 2.5 mm incision size, as per the physician's standard technique when using the implantation system. The incisions were either clear corneal or scleral tunnel, at the discretion of the physician. The anterior capsulotomy was a continuous curvilinear capsulorhexis, approximately 5.0 mm–5.5 mm in diameter, and the lens was to be placed in the capsular bag using the recommended insertion device (the commercially available Naviject 2.2 1P system [Medicel AG, Wolfhalden, Switzerland]). Wound closure was left to the surgeon's discretion, and preoperative and intraoperative medications, and viscoelastic materials, were used as customary for each physician.

Physicians were to manage the surgical outcome to ensure that the total postoperative

refractive astigmatism was as minimal as possible, with the total postoperative astigmatism (including any surgically-induced astigmatism) no greater than 1.0 D, regardless of axis. Postoperative astigmatism was permitted to be managed by incision site placement and no additional refractive procedures were to be performed during the 6-month postoperative study period.

The rights, safety, and wellbeing of the participating patients were protected consistent with the ethical principles laid down in the Declaration of Helsinki.

Outcome measures included monocular uncorrected distance visual acuity (UCDVA) and BCDVA under photopic conditions, monocular distance corrected intermediate visual acuity (at 70 cm) under photopic conditions, and monocular distance corrected near visual acuity (at 40 cm) under photopic conditions at both a fixed distance and the subject's preferred distance. Contrast sensitivity was measured in a subset of 28 patients using the Optec® Functional Visual Analyzer™ (Stereo Optical Co., Inc., Chicago, IL, USA).

RESULTS

Eighty-eight eyes of 44 patients completed the 6-month clinical trials at two clinical sites; in France and in Italy.

Demographics

The mean age of implanted patients (121 eyes) was 70.43 ± 6.33 years.

Baseline Acuity

The mean preoperative BCDVA (121 eyes) was 20/50 and the mean preoperative UCDVA (121 eyes) was 20/80.

Monocular Visual Acuity

BCDVA

The majority of eyes (89.8%) achieved a BCDVA of 20/20 or better at month 6, and 100% achieved 20/32 or better (Figure 2).

UCDVA

More than half of the eyes (55.7%) achieved a UCDVA of 20/20 or better at month 6, and 96.6% achieved 20/40 or better (Figure 3).

Figure 2. Distance best-corrected visual acuity.

Figure 3. Uncorrected distance visual acuity.

Distance-Corrected Intermediate Visual Acuity (DCIVA)

The majority of eyes (90.9%) had a DCIVA of 20/40 or better at month 6 (Figure 4), and 34.1% had an acuity of 20/25 by month 6.

Figure 4. Distance-corrected intermediate visual acuity.

Uncorrected Intermediate Visual Acuity

Most eyes (78.4%) had an uncorrected intermediate visual acuity of 20/40 or better at month 6, and 44.3% had an acuity of 20/32 (Figure 5).

Figure 5. Uncorrected intermediate visual acuity.

Distance-Corrected Near Visual Acuity

Nearly one third (33.0%) of eyes had a distance-corrected near visual acuity of 20/25 or better by month 6, and 95.5% had an acuity of 20/40 or better by month 6 (Figure 6).

Figure 6. Distance-corrected near visual acuity.

Uncorrected Near Visual Acuity

Most eyes (88.6%) had an uncorrected near visual acuity of 20/40 or better by month 6, and 26.1% had an acuity of 20/25 (Figure 7).

Figure 7. Uncorrected near visual acuity.

Contrast Sensitivity

Twenty-eight patients underwent monocular contrast sensitivity testing and the results are displayed in Figures 8 to 10.

Monocular Contrast Sensitivity, Daytime Conditions (85 cd/m^2)

The mean contrast sensitivity of 28 patients during daytime conditions, as tested on the

Figure 8. Monocular contrast sensitivity testing (28 patients), Functional Visual Analyzer Test, daytime conditions (85 cd/m^2).

Figure 9. Monocular contrast sensitivity testing (28 patients), Functional Visual Analyzer Test, nighttime conditions (3 cd/m^2), without glare.

Functional Visual Analyzer™ (Stereo Optical Co., Inc, Chicago, USA) was 1.67 at 1.5 cycles per degree (cpd), 1.88 at 3 cpd, 1.79 at 6 cpd, 1.21 at 12 cpd, and 0.21 at 18 cpd.

Monocular Contrast Sensitivity, Nighttime Conditions (3 cd/m^2), With No Glare

The mean contrast sensitivity of 28 patients during nighttime conditions with no glare, as tested on the Functional Visual Analyzer, was 1.76 at 1.5 cpd, 1.85 at 3 cpd, 1.53 at 6 cpd, 0.60 at 12 cpd, and 0.20 at 18 cpd.

Monocular Contrast Sensitivity, Nighttime Conditions (3 cd/m^2), With Glare

The mean contrast sensitivity of 28 patients during nighttime conditions with glare, as tested on the Functional Visual Analyzer, was 1.60 at 1.5 cpd, 1.68 at 3 cpd, 1.40 at 6 cpd, 0.54 at 12 cpd, and 0.14 at 18 cpd.

Patient Satisfaction

Overall, patients were very satisfied with the visual outcomes after undergoing implantation

Figure 10. Monocular contrast sensitivity testing (28 patients), Functional Visual Analyzer Test, nighttime conditions, (3 cd/m^2), with glare.

with the OptiVis lens. At the month 6 visit, 88.9% of patients reported never wearing spectacles and 11.1% reported wearing them only sometimes. One-hundred percent of patients were either completely (64.6%) or mostly (35.4%) satisfied with the postoperative vision without glasses during the day. At night, 40.9% were completely satisfied with the postoperative vision and 50% were mostly satisfied.

Adverse Events

The overall incidence of adverse events was mild-to-moderate halos at 36% ($n=30/84$ eyes), with 22 reported as mild and eight reported as severe. Moreover, there was an incidence of 18% of mild-to-moderate glare ($n=15/84$ eyes), with only one of those patients reporting moderate glare, and the remaining 14 reporting only mild glare. In addition, there was one case of cystoid macular edema, one posterior capsular opacification, and one case of severe corneal edema.

DISCUSSION

The findings of the present study demonstrate the efficacy and safety of the OptiVis™ multifocal IOL. Patients had satisfactory visual outcomes at all distances, with the majority of eyes achieving 20/40 or better at distance, intermediate, and near.

The introduction of multifocal IOLs into the practice of clinical ophthalmology has enabled surgeons to provide patients with an effective modality for improving the near and intermediate vision, and reducing (or eliminating) dependence on spectacles for reading. However, some multifocal models have been associated with a reduction in visual quality due to glare and halos. Those side effects can limit visual function and reduce patient quality of life.⁷ In some models, the incidence of glare and halo have been reported to

range from 6% to 40% for glare, and from 11% to 44% for halo.^{8–11} Although, in recent years, the newest multifocal IOLs are typically associated with lower incidence of these phenomenon,^{12–13} a recent study of 2500 patients reported that 6.1% of patients treated with Tecnis™ (Abbott Medical Optics Inc., Santa Ana, CA, USA) multifocal IOLs experience glare and 2.1% experience halo.¹⁴ In the present study, the incidence of glare and halo was considerably lower than many previous reports, with a combined incidence of only 6.7%, and no severe incidence reported.

Patients in the present study also did not appear to have a reduction in contrast sensitivity after implantation of the OptiVis Multifocal IOL. These results were comparable to a previously published report by Hohberger and associates who evaluated contrast sensitivity in normal subjects in an age cohort similar to the patients in this study (>60 years of age).¹⁵

The finding that the majority of patients had optimal visual outcomes, not only at distance and near, but also intermediate, may prove to be an advantage of the OptiVis lens relative to other multifocal IOL models. Trattler and associates¹⁶ recently presented the results of an analysis of a patient registry with more than 8000 records that suggests that many of these lenses provide excellent outcomes at distance, but worse outcomes at near and intermediate. For example, those authors found that, although mean distance acuity was excellent across the lenses evaluated, the mean acuities worsened for both near and distance. In a recent study by Udaondo et al., 126 eyes of 63 patients with bilateral cataracts received either OptiVis or ReStor +3™ (Alcon Inc., Hunenberg, Switzerland) IOLs bilaterally. Although there were no differences in neither near, nor intermediate, visual acuity, OptiVis patients had significantly better intermediate vision, with a preferred working

distance of 48.8 cm, compared with a ReStor +3.00 preferred working distance of 39.6 cm (Data on file, Aaren Scientific).

This OptiVis study has some limitations. It is an open-label evaluation of a single product and there exists the potential for investigator bias. In addition, the study is relatively small and of short-term duration. Despite these limitations, this trial provides data that demonstrates the efficacy and safety of a new multifocal IOL and may allow clinicians an additional choice for patients undergoing cataract surgery.

CONCLUSION

In conclusion, the OptiVis™ Multifocal IOL provided excellent visual acuity at distance, near, and intermediate. Additional, longer-term follow-up studies are planned.

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