Clinical outcomes of a new extended range of vision intraocular lens: International Multicenter Concerto Study

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PURPOSE: To analyze the clinical outcomes after implantation of an extended range of vision intraocular lens (IOL), the Tecnis Symfony, in a routine clinical setting.

SETTING: Forty clinical sites in Finland, France, Germany, Norway, Spain, Sweden, and the United Kingdom.

DESIGN: Prospective case series.

METHODS: The study comprised 411 patients who had bilateral implantation of the extended range of vision IOL, with intended micro-monovision in 1 group (monovision group) and intended emmetropia in the other group (non-monovision group). Visual acuity, spectacle independence, patient and surgeon satisfaction, and photic phenomena were analyzed during the 4- to 6-month follow-up.

RESULTS: The monovision group comprised 112 patients and the non-monovision group, 299 patients. The mean decimal uncorrected distance (UDVA), intermediate (UIVA), and near (UNVA) visual acuities were 0.95, 0.81, and 0.69, respectively, 4 to 6 months postoperatively. Significantly better UIVA ($P = .003$) and UNVA ($P = .011$) were found in the monovision group than in the non-monovision group. Spectacle independence was high, with 14.4% of eyes requiring reading spectacles frequently. More than 90% of patients reported no or mild halos, glare, starbursts, or other photic phenomena. Patient satisfaction scores (median) for distance, intermediate, and near vision were 9.0, 10.0, and 8.0, respectively. The satisfaction score for near vision increased to 9.0 in the monovision group. More than 91% of patients said they would recommend the same procedure to their friends and family.

CONCLUSION: The extended range of vision IOL provided successful visual restoration across all distances after cataract surgery, with a minimal level of disturbing photic phenomena and high levels of patient satisfaction.

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A new-concept intraocular lens (IOL), the extended range of vision IOL, is based on new optical technology and is now commercially available. This technology uses a proprietary achromatic diffractive echelette design that corrects the corneal chromatic aberration for enhanced contrast sensitivity and generates an extended range of vision.[A]

The average eye has approximately 2.0 diopters (D) of chromatic aberration for wavelengths between 400 nm and 700 nm and 0.8 D for wavelengths between

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500 nm and 640 nm.[1] Significant levels of chromatic aberration have also been found in pseudophakic eyes with different types of IOLs.[2–5] Indeed, most pseudophakic longitudinal chromatic aberration arises from the chromatic dispersion of IOLs rather than from the cornea or other ocular media.[5] Ocular chromatic aberration causes blur and reductions in contrast vision.[3,6] The correction of this type of aberration using an achromatic IOL has been shown to improve the overall optical quality in eyes having cataract surgery.[7–10] Furthermore, the combination of this chromatic aberration correction with the correction of spherical aberration provides improved simulated retinal image quality over spherical and aspheric IOLs without sacrificing depth of field or tolerance to decentration.[7]

The aim of the current multicenter study was to evaluate the outcomes obtained with the extended range of vision Tecnis Symfony IOL (Abbott Medical Optics, Inc.) in terms of visual performance, spectacle independence, photic phenomena, and patient satisfaction. It is not possible to measure chromatic aberration in the daily routine of an ophthalmologic practice, and this parameter was not considered in the study.

PATIENTS AND METHODS

Patients

The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee of each participating study site. All included patients signed a consent form. The Concerto is a prospective international multicenter study to evaluate the visual performance and patient satisfaction after cataract surgery with bilateral implantation of the Tecnis Symfony IOL. This study included patients from 40 active study sites in Finland, France, Germany, Norway, Spain, Sweden, and the United Kingdom.

Inclusion criteria were visually significant bilateral cataract surgery with implantation of the new extended range of vision IOL, age of 18 years or older, postoperative corneal astigmatism of 0.75 D or less, and availability to attend the follow-up visits. Patients were excluded from the study when the following conditions were present: potential visual acuity worse than 0.6 decimal (0.2 logMAR) in each eye caused by ocular pathological processes, systemic or ocular medication that could affect vision, chronic or acute pathology that could alter the result, previous ocular surgery, amblyopia, strabismus, forme fruste or clinical keratoconus, pupil abnormalities, capsule or zonular fiber abnormalities with the potential of inducing IOL decentration or tilting, and participation in another clinical study.

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Clinical Protocol

This study was performed as a retrospective and prospective study. Patients were enrolled consecutively after bilateral implantation of the new extended range of vision IOL. The last preoperative patient visit and the surgery were documented retrospectively, and the 4- to 8-week and 4- to 6-month follow-up visits were documented prospectively. Surgery and follow-up examinations followed the routine procedures in each clinic in this observational study.

A complete preoperative ophthalmologic examination was documented in all cases and included measurement of uncorrected (UDVA) and corrected (CDVA) distance visual acuity, manifest refraction, Goldmann tonometry, slitlamp anterior segment examination, optical biometry, keratometry, and retina evaluation under pupil dilation. At the 2 postoperative visits, the following parameters were evaluated: binocular UDVA and CDVA, binocular uncorrected near visual acuity (UNVA) measured at 40 cm, and binocular uncorrected intermediate visual acuity (UIVA) measured at 70 cm.

Also, patients were asked about their spectacle use after surgery; that is, How often do you need spectacles to see at far/intermediate/near distances? The answer was categorized by 0%, 25%, 50%, 75%, and 100% of time. With regard to photic phenomena, patients were asked the undirected question, Do you experience any problems with your vision? The patient responses were categorized by glare, halos, starburst, and other phenomena, which had to be specified. Each category was graded as mild, moderate, or severe. Patients were also asked about their satisfaction with the outcome as follows: How satisfied are you with your spectacle-free vision at far/intermediate/near distance? The answer choices ranged from 0 (not at all satisfied) to 10 (very satisfied). They were also asked 2 yes or no questions: Would you choose the same lens again? and Would you recommend this lens to your relatives and friends?

Finally, surgeons were asked to assess their level of overall satisfaction with the surgical procedure and outcomes as well as their satisfaction with the IOL implantation procedure, achievement of target refraction, and visual performance provided.

Surgical Technique

All cataract surgeries were performed by experienced surgeons from the Concerto Study Group using a standard phacoemulsification technique or a femtosecond laser–assisted technique. The IOLs were implanted in the capsular bag through the main incision using the Unfolder Platinum 1 series screw-style inserter (Abbott Laboratories, Inc.). The study sites used their routine protocols for postoperative care.

Extended Range of Vision Intraocular Lens

The Tecnis Symfony is an extended range of vision IOL based on diffractive achromatic technology (Figure 1). The IOL has an achromatic diffractive pattern that elongates the focus and compensates for the chromatic aberration of the cornea. With multifocal IOLs, 1 image is in focus while the out-of-focus image is suppressed (simultaneous vision), and this out-of-focus image generates halos.[11] According to the manufacturer, halos are not expected with this IOL because it provides an elongated focal area rather than 1 or various individual focal points.