Patient acceptability of the Tecnis® multifocal intraocular lens

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Abstract: Cataract surgery has evolved. The goal of the surgeon includes both restoration of vision and refinement of vision. Patients’ desire for spectacle independence has driven the market for presbyopia-correcting cataract surgery and development of novel intraocular lens (IOL) designs. The Tecnis® Multifocal Intraocular Lens incorporates an aspheric, modified anterior prolate IOL with a diffractive multifocal lens design. The design aims to minimize spherical aberration and improve range of focus. The purpose of this review is to assess patient acceptability of the Tecnis® multifocal intraocular lens.

Keywords: Tecnis®, intraocular lens, multifocal, presbyopia

Introduction

Presbyopia-correcting intraocular lenses are designed to provide freedom from glasses after cataract surgery. Monofocal intraocular lenses (IOL) are designed to provide excellent visual acuity at a single, fixed focal length; thus, if patients are corrected for distance, they require spectacle correction for reading vision.1 The importance of independence from glasses should not be undervalued. In one study, 10% of patients with presbyopia reported a willingness to trade 5% of their life expectancy to be rid of presbyopia.2 Thus restoration of both distance and near vision is a goal of the ophthalmologist. While medical treatments have failed to restore the accommodative abilities of the natural lens, modern cataract surgery with intraocular lens implantation is a specific time point where a surgical intervention to improve near vision is possible. However, replicating the optics of the young, accommodative lens remains a challenge.

Multifocal IOLs, developed in the last two decades, are a response to this challenge. Lenses are categorized as diffractive IOLs and refractive IOLs based on lens design. Comparison of multifocal and monofocal IOLs shows that multifocal IOLs improve near vision and lead to spectacle independence more often than monofocals.3–8 However, symptoms of decreased visual acuity and photic phenomena are a source of patient dissatisfaction with multifocal lenses and are reported with higher frequency.9

Many types of presbyopic-correcting lenses are available for implantation today. Currently in the United States, multifocal lens options include the ReZoom® lens (Abbott Medical Optics Inc, Santa Ana, CA), the ReSTOR® lens (SA60D3, Alcon Laboratories Inc, Fort Worth, TX), and the Tecnis® lens (ZM900, ZMA00, ZMB00, Abbott Medical Optics Inc, Santa Ana, CA). The alternative presbyopia-correcting lens is the Crystalens® (Eyeonics and 1CU, AlisoViego, CA; Human Optics, Erlangen, Germany).
Alternative lens designs, including fully accommodating intraocular lenses, are currently available outside of the United States or are in clinical trial. In a recent review, Lane et al discussed the ReZoom® and ReSTOR® lenses in detail. Briefly, the ReZoom® lens is a three-piece multifocal lens with multiple refractive optical zones. The annular rings (zones) provide focus at different distances and are proportioned to provide quality near, intermediate, and distance vision. The ReSTOR® lens is an apodized, diffractive one-piece lens. The diffractive grating is on the anterior surface of the lens. The Crystalens uses a hinged plate-optic design to allow anterior movement of the optic to provide a small range of accommodation. Multiple clinical trials and reviews of these lenses are available in the literature.

Evolution of Tecnis® lens design

The first generation of Tecnis® was a monofocal, aspheric, anterior-modified prolate lens (ZA9000 series). The Tecnis® lens was designed to minimize spherical aberrations and improve contrast sensitivity after cataract surgery with lens implantation. In younger patients, the negative spherical aberration of the crystalline lens and the positive spherical aberration of the cornea together create a nominal overall aberration. Spherical aberration increases with age as the lens gains positive aberration; this contributes to decreased visual function. Visual quality with intraocular lenses has been shown to be worse than the natural lens in age-matched controls. The Tecnis® lens was designed to add negative spherical aberration into the optical system, thus reducing the total spherical aberration. By reducing total aberration, the lens should reduce positive photic phenomena of glare and halos. Researchers reported that the Tecnis® lens provided improved subjective quality of vision, corrected visual acuity (CVA), and contrast sensitivity at various distances and in varied lighting conditions. The anterior-modified prolate design platform was used in the multifocal version of the Tecnis lens.

The multifocal Tecnis® lens diffraction pattern creates two major focal points that correspond to approximately 3.0 D on the spectacle plane. This design splits the light to be distributed among near and distant focus regardless of pupil size. The Tecnis® multifocal lens is a full diffractive optic versus an apodized diffractive optic of the ReSTOR® lens. Researchers have hypothesized that pupil size can affect the quality of vision; therefore, the full diffractive optic should make vision independent of pupil size. On the other hand, the apodized diffractive design (ReSTOR® lens) distributes light preferentially in the distance for large pupil sizes. These contrasting features are based on different theories of how lens design relates to visual quality. In addition, the diffraction pattern of this lens is on the posterior surface of the lens (as compared to the ReSTOR® lens on the anterior surface of the lens) and the multifocal lens has the aspheric prolate technology of the monofocal lens platform. In this article, we will discuss the design of the Tecnis® lens and outcome measures that determine patient acceptability and lens efficacy of the Tecnis® multifocal lens.

Initially, the Tecnis lens was available only as a three-piece silicone lens (ZM900); within the past two years, a three-piece acrylic diffractive lens (ZMA00) and a one-piece acrylic diffractive lens (ZMB00) have been approved by the FDA. The majority of the research in the literature was performed with the ZM900 lens model. Hutz et al performed a randomized trial to compare the visual outcomes in patients implanted with the diffractive silicone multifocal in one eye and the diffractive Tecnis® ZMA00 acrylic multifocal IOL in their fellow eye. Forty-two eyes of 21 cataract patients were randomized to either group and outcome measures were tested at six months and included uncorrected visual acuity (UDVA), best corrected distance visual acuity (CDVA) and corrected near visual acuity (CNVA), spherical equivalence, reading speed and acuity and photic phenomena. There were no significant differences between the two lens materials; both lenses provided excellent visual results.

Visual acuity

Outcomes based on visual acuity with multifocal lenses are divided into measurements of distance, intermediate, and near visual acuities. They are further subdivided into corrected and uncorrected (typically with spectacles) acuities. Near visual acuity is further subdivided into uncorrected, distance-corrected, or near-corrected visual acuities (UNVA, DCNVA, CNVA). While this may seem excessive, distance corrected visual acuities at distance and near can be used to determine if refractive surgery (for the distance prescription) would resolve postoperative complaints of blurred vision.

Comparison studies, retrospective reviews, and case series of the Tecnis® multifocal lens (ZM900) have shown promising results (Table 1). Goes performed a prospective case series of 59 eyes of 30 patients with the Tecnis® ZM900 (one eye was excluded secondary to a history of amblyopia). Ninety percent of patients achieved ≥20/30 UCVA (0.087 ± 0.085). All patients could read ≥J2 and 90% read J1 (0.133 ± 0.095). Near visual acuity also improved from one month to six months postoperatively. Fifteen eyes...
| Study                  | Year | Study type                        | Intraocular lens comparisons | Pts/no. of eyes | Length of follow up | Main outcomes                                                                 |
|-----------------------|------|-----------------------------------|-----------------------------|----------------|-------------------|-------------------------------------------------------------------------------|
| Goes                  | 2008 | Prospective case series           | Tecnis® ZM900               | 59 eyes of 30 patients | 6 months          | Examined distance, intermediate, and near vision after refractive lens exchange. Assessed overall satisfaction, photic phenomena, difficulty driving at night and spectacle independence. |
| Bautista et al        | 2009 | Prospective case series           | Tecnis® ZM900               | 250 eyes of 137 patients | 5 to 7 months     | Examined near vision, distance corrected near vision, uncorrected vision, best corrected vision. Assessed patient satisfaction, posterior capsule opacification and contrast sensitivity under photopic conditions. |
| Hutz et al            | 2006 | Prospective, randomized study     | Tecnis® ZM900 vs Array® SA40N vs SA60D3 | 120 eyes of 60 patients | 6 weeks           | Assessed reading ability (uncorrected, best distance corrected and best near corrected) under low and bright light. |
| Akaishi et al         | 2010 | Retrospective review              | Tecnis® ZM900               | 2500 eyes of 1558 patients | 3 months to 3 years | Examined distance and near vision (uncorrected and corrected). Assessed overall satisfaction, spectacle independence, and photic phenomena. |
| Hutz et al            | 2008 | Retrospective study               | Tecnis® ZM900 vs Array® SA40N vs SA60D3 | 60 eyes of 30 patients | 12 months         | Assessed intermediate vision (uncorrected and distance corrected) and reading speed under low and bright light. |
| Kaymak et al          | 2008 | Prospective non-randomized intra-individual comparative study | Tecnis® ZM900 vs ReSTOR®    | 32 eyes of 16 patients | 6 months          | Examined distance visual acuity, contrast sensitivity and near visual acuity under different contrast levels. |
| Cillino et al         | 2008 | Randomized prospective study      | Tecnis® ZM900 vs AR40 vs Array® SA40N vs ReZoom® | 124 eyes of 62 patients | 12 months         | Examined uncorrected and corrected distance, near, and intermediate visual acuity. Assessed defocusing curves, contrast sensitivity, and surveyed quality of life. |
| Palmer et al          | 2008 | Prospective, randomized control study | Tecnis® Z9000 vs Tecnis® ZM900 vs ReZoom® vs TwinSet® | 228 eyes of 114 patients | 3 months          | Examined distance visual acuity (uncorrected and corrected) at different contrast levels. Assessed contrast sensitivity at different spatial frequencies, pupil size and refraction. |
| Mester et al          | 2007 | Prospective comparative study     | Tecnis® ZM900 vs Array® SA40 | 100 eyes of 50 patients | 4 to 5 months     | Examined distance and near visual acuity (uncorrected and corrected). Assessed depth of focus, contrast sensitivity, reading speed, occurrence of photic phenomena, and spectacle independence. |
| Packer et al          | 2009 | Nonrandomized, multicenter, comparative study | Tecnis® ZM900 vs CeeOn® 911A | 489 eyes of 248 patients | 12 months         | Examined distance and near visual acuity (uncorrected and corrected). Assessed contrast sensitivity, reading speed, occurrence of photic phenomena, and spectacle independence. |
| Ngo et al             | 2010 | Retrospective study               | Tecnis® ZM900 vs ReSTOR® SA60D3 vs ReSTOR® SN60D3 | 108 eyes of 54 patients | 3 months          | Examined uncorrected and best corrected distance visual acuity as well as uncorrected and distance corrected near visual acuity. |
| Girek-Ciaciura et al  | 2009 | Prospective, nonrandomized, comparative study | Tecnis® ZM900 vs ReZoom® NXGI vs ReSTOR® SA60D3 | 60 eyes of 30 patients | 6 months          | Examined distance and near visual acuity (uncorrected and corrected). Assessed spectacle independence, photic phenomena, patient determination of quality of vision, and contrast sensitivity. |
(25%) required refractive surgery for residual refractive error or postoperative astigmatism. Bautista et al performed a prospective case series of 250 eyes of 137 patients with cataracts.21 Mean UCVA and BCVA were 0.144 ± 0.101 and 0.09 ± 0.03 logMAR (minimal angle of resolution) respectively, while 77.6% and 98.4% of eyes achieved ≥20/30. Uncorrected near visual acuity was ≥J2 in 96.8% and was ≥J1 in 83.2% of eyes. DCVA was ≥J1 in 95.6% of eyes. Similar to the other study, there was statistically significant improvement in visual acuity over time (attributed to neural adaptation).

In a recent retrospective review of 2500 eyes of 1558 patients implanted with the Tecnis® ZM900 (minimum of three months follow-up), 85% of patients achieved 20/30 BCVA at distance and 94% achieved J1 vision. Five percent of eyes required enhancement after initial surgery, but no eyes required lens exchange.22

The Tecnis® multifocal lens showed equivalency or slightly worse visual acuity compared to monofocal lenses for distance visual acuity. The Tecnis® lens is superior to monofocal lenses for near vision (uncorrected or distance corrected). In the FDA nonrandomized clinical trial, bilateral ZM900 lens implantation was compared to the monofocal CeeOn® 911A (CEMN, AMO Inc) with 489 eyes divided between groups.13 For distance vision, there was less than one Snellen line visual acuity difference for UCVA (7.54 ± 0.94 [20/22] versus 7.98 ± 1.06 [20/20]) and distance BCVA (8.35 ± 0.82 [20/18] versus 8.68 ± 0.78 [20/17]). Uncorrected UCVA and DCVA were significantly better in the Tecnis® group (P < 0.001) by four to five lines of near visual acuity. Palmer et al showed that the ZM900 resulted in slightly worse BCDVA compared to its monofocal counterpart (Z9000) (0.08 ± 0.05 logMAR versus 0.05 ± 0.05, respectively).23

Multiple trials compare the Tecnis® multifocal lens (ZM900) to other multifocal lenses including the RestOR® (SA60D3), the Array® SA40N (Advanced Medical Optics, Santa Ana, CA), the ReZoom® (AMO), and the TwinSet® (Acri. Tec, Zeiss, Germany).17,23–27 In all studies, there were no statistically significant difference between multifocal intraocular lenses for distance visual acuities (corrected or uncorrected). Mester et al compared 50 eyes with bilateral diffractive ZM900 to 50 eyes with bilateral refractive multifocal Array SA40 (AMO).17 Binocular uncorrected and corrected distance VA was not significantly different between the eyes; however, uncorrected and best-distance corrected near VA was significantly better in the Tecnis® group (P < 0.001). Hutz et al also compared the Tecnis® multifocal (ZM001, an older version of the ZM900) to the Array® SN40 and to the ReSTOR® SA60D3 to evaluate reading performance.28 At one year, they evaluated reading speed (distance corrected and uncorrected) in 30 pts (n = 10 per group) at 40 cm, 60 cm and 80 cm under low (6 cd/m²) and bright (100 cd/m²) light conditions. Under low light conditions, the Tecnis® lens had significantly better near visual acuity outcomes. Under bright light conditions, the difference between groups was less. Mean reading speed with UCVA and DCVA was significantly faster in the Tecnis® group.

Cillino et al compared visual acuity outcomes in multifocal IOLs (Tecnis® ZM900, Array® SA40N, ReZoom®) with a monofocal IOL (AR40) in a randomized prospective clinical trial looking at 62 consecutive patients.25 At twelve months postoperatively, the UCVA was ≥20/30 in all groups, and the BCVA was ≥20/20 in all groups without statistically significant differences. The Tecnis® group tended toward improved monocular UCVA and DCVA. The Tecnis® lens tended toward worse intermediate vision than either monofocal or refractive multifocal IOLs. Palmer et al also compared visual function in multifocal IOLs (Tecnis® ZM900, TwinSet®, ReZoom®) with a monofocal IOL (Tecnis® Z9000) in a prospective, randomized trial.22 At one and three months, binocular distance UCVA was similar in all groups; however, distance BCVA was better with the ReZoom® and monofocal Z9000 lens compared to both diffractive multifocal lenses. The lenses performed similarly for binocular NCVA. Not surprisingly, multifocal lenses performed better for distance corrected near VA than the monofocal lens. Other non-randomized trials support the conclusion that the Tecnis® ZM900, as compared to other multifocal diffractive or refractive lenses, provides equivalent or better visual acuity at distance and near, with or without correction.26,27

In summary, evidence from numerous studies supports the conclusion that the Tecnis® lens (ZM900) provides equivalent, if not improved, distance uncorrected visual acuity when compared to other multifocal lenses; it is controversial if the lens provides equivalent UCVA compared to monofocal lenses. Consistent with other diffractive lenses, the Tecnis® lens performed similarly or better at near when compared to refractive lenses. The significant advancement provided by this lens is the relative ‘pupil independence’ of the lens. Notably, diffractive lenses have previously been reported to provide worse intermediate visual acuity when compared to their refractive counterparts.29,30 Tecnis® has been shown in some studies to under perform its refractive counterparts and in others it has provided equivalent or better
intermediate visual acuity. Studies have also shown that this lens performs better in low light conditions compared with other multifocal lenses.

**Patient satisfaction and spectacle independence**

Patient acceptance of a presbyopic-correcting lens ultimately is determined by patient satisfaction and spectacle independence. Outcomes and optical features unique to each lens help guide discussions between the physician and patient regarding proper lens selection and realistic visual expectations. Proper preoperative counseling regarding expectations and limitations strongly influence patient selection and, ultimately, acceptance of the lens.

In the initial FDA nonrandomized clinical trial, Packer et al reported that 94.6% of patients would choose the Tecnis® ZM900 again versus 89.6% patients with the Cee-On® lens. Bautista et al reported on the patients’ subjective assessment of their vision. Thirty-nine percent of patients rated their vision as excellent, 51.2% rated their vision as good while 2.4% rated their vision as poor. Satisfaction was similar regarding near or distance vision and improved over the duration of the study (150–210 days). Similarly, Mester et al assessed patient acceptance at four to nine months after lens implantation with the Array® SA40 and the Tecnis® ZM900. Overall satisfaction was good with 88% of Tecnis® ZM900 patients and 78% of Array SA40 patients being very satisfied or satisfied. Forty-four percent of Tecnis® patients were very satisfied (versus 28% of Array® patients). No Tecnis® patients reported being unsatisfied. Goes et al reported spectacle independence in 92.8% of Tecnis® patients. Across studies, spectacle independence ranged from 77% to 92.8% in patients with the Tecnis® MIOL and 80% to 92% in patients with the Tecnis® ZM900.

**Photic phenomena**

Visual phenomena interfering with vision strongly influence patient satisfaction. When these phenomena interfere extensively with vision, a patient’s tolerance of the intraocular lens diminishes and an intraocular lens exchange may be required. Intraocular lenses can cause positive dysphotopsias (glare, halos, starbursts, etc) and negative dysphotopsias (shadows, dark crescents, etc). Multifocal lens design, with concentric rings of optical zones, creates positive dysphotopsias, also called photic phenomena, at higher rates than monofocal lenses. Reported complaints of photic phenomena vary across studies ranging from 22.4% to 81%. Variability in reporting and outcomes could be secondary to method for reporting symptoms (solicited questions versus patient-generated complaints), completeness of chart notes, or study type variations.

In a prospective, noncomparison study of the ZM900 lenses, Bautista found that halos and glare were reported in 22.4% of patients (20.4% with mild symptoms, 2% with moderate symptoms, 0% with severe symptoms). The symptoms improved (trend, not statistically significant) from initial postoperative visits to 150 to 210 days after surgery. Goes surveyed patients regarding occurrence of photic phenomena. Although individual question results were not reported, the most common complaint was photic phenomena (halos and glare). At six months, no patients reported severe glare, 7.2%
reported moderate glare, and 92.8% were asymptomatic. Between 3% and 4% of patients reported severe difficulty with night driving.

Studies that specifically asked patients about photic phenomena found significantly more frequent complaints. In the Akaishi et al study, severe glare and halos were reported in 6% and 2% of patients, respectively, and moderate glare and halos were reported in 26% and 16% of patients, respectively.22 Palmer et al reported that dysphotopsias occurred in 81% of ZM900 eyes, 47% of TwinSet® eyes, 53% of ReZoom® eyes, and 48% of monofocal patients.22 However, spontaneous, unprovoked patient complaints of dysphotopsias occurred in 16% to 19% of eyes with MIOLs versus 0% of eyes with monofocal lenses (P = 0.01).23 At one year, Packer et al surveyed patients about difficulty with their vision. They found the most frequently reported symptoms to be night glare in 15.5% (10.3% moderate and 2.6% severe) and halos in 22.4% (mild 12.1%, moderate 5.2% and severe 5.2%).13 The monofocal (Cee-on®) group reported glare and halos in 4.3% and 8.6% respectively. Photic phenomena are experienced by patients, but proper assessment of outcomes requires solicitation of symptoms by the physician.

**Contrast sensitivity**

Palmer et al compared contrast sensitivity of the Tecnis® ZM900, ReZoom®, TwinSet®, and Tecnis® monofocal Z9000 using the Functional Acuity Contrast Test (FACT) chart.23 (The FACT chart uses Gaussian sine-wave gratings to measure contrast sensitivity of varied spatial frequencies and contrast levels.) With BSCVA under mesopic (10 lux) and scotopic (1 lux) luminance levels, the monofocal Z9000 group had the best results that were statistically significant. Other comparisons of the Tecnis® multifocal to monofocal lenses show a trend toward worse contrast sensitivity with the multifocal lens.13 Similar to other multifocal lenses, the Tecnis® lens is not a perfect replica of the natural lens. Bautista et al found that the visual performance (under photopic conditions with BCVA) of the ZM900 lens underperformed compared to expected results from normal eyes on the Pelli–Robson test of contrast sensitivity.21,32 Inuoe et al designed model eyes with refractive and diffractive multifocal lenses to assess image quality for purposes of vitreoretinal surgery.33 Not surprisingly, the lenses behaved consistently with their design – images through the near zones of the ReZoom® lens were blurred, a slight defocus occurred centrally in both diffractive lenses, and significant blur occurred in the peripheral portion of the full-diffractive lens (Tecnis® ZM900).

In the Palmer study, there were no statistically significant differences between the multifocal lenses in scotopic or mesopic conditions.23 This result has been supported in other studies. Mester et al compared contrast sensitivity of the Tecnis® ZM900 to the Array lens using the FACT chart.17 Similar to the other study, there were no statistically significant differences under photopic conditions; however under mesopic conditions, the Tecnis® group had improved contrast sensitivity at the highest frequencies (P < 0.05) Gierek-Ciuciura et al compared contrast sensitivity of ReZoom®, ReSTOR®, and Tecnis® ZM900 and found no difference in contrast sensitivity amongst these multifocal lenses.26 Contrast sensitivity is a known potential drawback of multifocal lenses, and the Tecnis® lens is not an exception.

**Neural adaptation**

Tolerance to visual phenomena generated by multifocal lenses has been shown to improve over time. Researchers believe that the brain adapts to the altered visual input over time by a process called neural adaptation. Goes found significant near visual acuity improvement over six months even when refractive error remained stable (0.175 ± 0.122 logMAR to 0.127 ± 0.094 logMAR at one and six months, respectively (P = 0.005).18 During this time they reported that complaints of dysphotopsias decreased, although no statistical values were given. Bautista et al reported statistically significant improvement of distance and near visual acuity with the ZM900 lens between initial, 1- to 3-month, and 5- to 7-month postoperative visits.21 They reported that only a portion of patients improved over the course of the study.

Several studies hypothesize that neural adaptation plays a role in the visual outcomes of MIOLs.17,34,35 Although results of neural adaptation training are controversial, Kaymak et al examined how training affected visual performance with ReSTOR® and Tecnis® multifocal IOLs.36 Patients (eight bilateral ReSTOR and eight bilateral Tecnis® implantation) received computer-based visual training of one eye at six weeks after surgery. Although study numbers were small, there was a statistically significant improvement in distance and near visual acuity in the trained versus untrained eyes at six months (P < 0.01). No differences were noted between the two lenses. Thus, similar to other multifocal lenses, the Tecnis® lens is better tolerated over time.

**Conclusion**

In summary, evidence from numerous studies supports the conclusion that the Tecnis® lens (ZM900) provides
equivalent, if not improved, distance uncorrected visual acuity when compared to other multifocal lenses. The studies reviewed conclude that patients with Tecnis® multifocal lenses are more likely to be spectacle independent (compared to other multifocal lenses). Patients with Tecnis® lenses experience photic phenomena and have similar contrast sensitivity to patients with other multifocal lenses. The change to an acrylic platform (ZMA00 and ZMB00) did not affect visual outcomes when compared to the silicone model (ZM900) and provided the option of a one piece lens design (ZMB00). The Tecnis® multifocal lens gives surgeons a novel alternative, in both lens design and platform, to use in multifocal lens implantation.

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