Improved functional vision with a modified prolate intraocular lens

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Purpose: To evaluate whether the Tecnis Z9000 intraocular lens (IOL) (Pfizer) with a modified prolate anterior surface provides better quality of vision than a conventional spherical IOL.

Setting: Oregon Eye Institute, Eugene, Oregon, USA.

Methods: Patients presenting for cataract surgery who were randomly assigned to receive a Tecnis Z9000 IOL (Pfizer) or a Sensar® OptiEdge AR40e IOL (AMO) in 1 eye were followed for 3 months postoperatively. The patient could elect to have the same type of IOL implanted in the fellow eye. The results of sine-wave grating contrast sensitivity testing under mesopic and photopic conditions were compared interindividually.

Results: Monocular comparison was made between the 2 IOL groups, which comprised 15 patients each. The Tecnis IOL provided significantly better contrast sensitivity at 6 cycles per degree (cpd) under photopic conditions and at 1.5 and 3 cpd under mesopic conditions. Seven patients with a Tecnis IOL and 9 patients with an AR40e IOL had subsequent implantation in the fellow eye. In all eyes, including fellow eyes, having IOL implantation, the Tecnis provided significantly better contrast sensitivity at 3 and 6 cpd under photopic conditions and at 1.5, 3, and 6 cpd under mesopic conditions. The mean contrast sensitivity in fellow eyes showed that the Tecnis IOL produced significantly better results at some spatial frequencies.

Conclusions: Results show the Tecnis IOL with a modified prolate anterior surface may produce better contrast sensitivity than a standard spherical IOL under mesopic and photopic conditions. Because contrast sensitivity testing correlates well with functional vision, a goal of future research should be to evaluate patient performance using functional tests such as driving simulation.

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The term *functional vision* describes the effect of sight on quality of life. The ability to recognize faces and facial expressions, read the newspaper, drive at night, perform vocational tasks, and participate in recreational pursuits is related to functional vision. Functional vision is not reflected entirely in the measurement of visual acuity. For example, an individual with 20/20 visual acuity can have deficient functional vision while driving into the sun at dusk or dawn because changes in contrast sensitivity and the effect of glare can significantly impair detail discrimination.[1]

Conversely, studies demonstrate that contrast sensitivity is a robust indicator of functional vision.[2–4] The contrast sensitivity function, measured under varying conditions of luminance and glare, establishes the limits of visual perception across the spectrum of spatial frequencies. Contrast sensitivity testing determines the relationship between the optical efficiency of the eye (modulation transfer function) and the minimum retinal threshold for pattern detection (modulation threshold function).[5,6] Deficiencies in functional vision not detected by Snellen visual acuity measurements are identified with contrast sensitivity testing.[7]

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The correction of spherical and cylindrical refractive errors, whether by spectacles, contact lenses, or surgery, is important to intrinsic contrast sensitivity of the visual system because ametropias produce blur and hinder recognition of objects. However, higher-order optical aberrations, such as those observed with spherical aberration and coma, also have a significant impact on contrast sensitivity and functional vision.[8–16] The total effect of all monochromatic optical aberrations, measured by wavefront-sensing techniques and described by Zernike polynomials, represents an expression of the optical quality of the eye.[17,18] High optical quality is necessary for high contrast sensitivity. To test the limits of the visual system beyond the retina, we must first produce an image of the highest possible quality on the retina—the goal of lenticular and corneal surgery.

Contrast sensitivity deteriorates with advancing age even in the absence of ocular pathology such as cataract, glaucoma, and macular degeneration.[19] The pathogenesis of this decline in vision likely involves decreased retinal image quality caused by changes in the spherical aberration of the crystalline lens.[20,21] Spherical aberration, a property of all spherical lenses, occurs when the lens bends peripheral rays more strongly (positive spherical aberration) or less strongly (negative spherical aberration).

Spherical aberration is normally reduced in the human eye by 2 mechanisms.[1] The cornea, which is naturally prolate, has less refractive power peripherally. The flatter curve of the peripheral cornea refracts light less strongly than the steeper central curve. Therefore, the average cornea has less positive spherical aberration than a spherical lens. The cornea's spherical aberration remains positive, however, because peripheral rays come to a focal point anterior to paraxial rays.[1] The youthful crystalline lens has negative spherical aberration because its index of refraction is lower in the periphery than near the visual axis.[1] Both designs, the prolate cornea and the refractive gradient of the lens, reduce spherical aberration.

The positive spherical aberration of the cornea changes little with age.[22] The negative spherical aberration of the youthful lens compensates for the positive spherical aberration of the cornea, reducing total aberration in younger people. However, the internal gradient of the refractive index of the lens changes significantly with age, causing the total wavefront aberration of the eye to increase more than 3-fold between 20 and 70 years of age.[22] Thus, the lens loses its ability to compensate for aberration of the cornea, resulting in deterioration of optical quality in the aging eye.[19]

The Tecnis Z9000 (Pfizer) is a foldable polysiloxane posterior chamber intraocular lens (IOL) used for visual correction of aphakia after cataract surgery by phacoemulsification. The Tecnis IOL was designed to compensate for the spherical aberration of the average cornea.[23] Topographical measurement of the cornea and determination of average corneal spherical aberration in 71 patients presenting for cataract surgery[23] provided the basis for the shape of the Tecnis modified prolate anterior surface. In vitro studies have determined that the Tecnis IOL must be centered within 0.4 mm of the visual axis and tilted less than 7 degrees from the visual axis to provide better optical quality than a spherical IOL (personal communication, Sverker Norrby, PhD, Pfizer, Groningen, The Netherlands, January 12, 2003). The mean decentration and tilt reported for a silicone IOL 3 months postoperatively is 0.33 (mm) ± 0.18 (SD) and 2.44 ± 1.80 degrees, respectively, indicating that these tolerances also can be achieved with modern phacoemulsification techniques.[24] Proper implantation of the Tecnis IOL requires secure in-the-bag fixation with a continuous curvilinear capsulorhexis. The Tecnis IOL shares the basic design features of the CeeOn® Edge 911 IOL (Pfizer), including a 6.0 mm equiconvex square-edged silicone optic and angulated cap C polyvinylidene fluoride haptics.

To evaluate the potential functional vision improvement with this modified prolate lens technology, we compared the sine-wave grating contrast sensitivity in patients with a Tecnis Z9000 IOL with that in patients with a Sensar® OptiEdge AR40e IOL (AMO), a standard spherical acrylic IOL. The AR40e has a 6.0 mm equiconvex optic with a variable refractive optical zone, from 5.1 mm in powers above 25.0 diopters (D) to 6.0 mm in powers below 18.5 D. It has a sharp posterior edge and round anterior edge.

The initial findings of our study have been presented.[25] Based on those outcomes, the patient population was extended and the scope of our study expanded.

Patients and Methods

The study protocol and patient informed consent form were approved by the Institutional Review Board of the

Oregon Eye Surgery Center, Eugene, Oregon. Informed consent was obtained from all study participants. Candidates for unilateral cataract surgery were randomly assigned to receive a Tecnis or an AR40e IOL.

Patients aged 50 to 80 years with visually significant cataract, a potential Snellen visual acuity of 20/30 or better, and a mesopic pupil larger than 4.0 mm were eligible for inclusion in the study. Patients with ocular pathology other than cataract, neurologic or other disease known to affect contrast sensitivity, high hyperopia (>+6.0 D), high myopia (>−6.0 D), or keratometric cylinder greater than 1.5 D and patients using medication known to influence contrast sensitivity were excluded from enrollment. Also excluded were patients with an intraoperative or postoperative complication including the inability to achieve secure IOL fixation in the capsular bag.

All patients had a complete ophthalmologic examination including refraction, pupil evaluation, confrontational visual fields, extraocular motility, intraocular tension, and slitlamp and dilated fundoscopic evaluations. Preoperative testing included axial length measurement by partial coherence interferometry (IOLMaster, Carl Zeiss Meditec) or immersion ultrasonography (Axis II, Quantel) and computerized corneal topography (EyeSys, Tracey Technologies).

The surgical technique used for cataract extraction has been described.[26] Patients were treated postoperatively with ofloxacin (Ocuflox®), prednisolone acetate (Pred Forte®), and diclofenac sodium (Voltaren®) on a tapering schedule.

Postoperative evaluations were performed at 1 day, 2 weeks, and 3 months. Visual acuity, intraocular tension, and slitlamp examination were done at all visits. Approximately 3 months after surgery, refraction, computerized corneal topography, pupil size, contrast sensitivity, slitlamp, intraocular tension, and dilated fundoscopic examinations were performed in all patients. The tilt and decentration of the IOL were evaluated at each visit by aligning a hand light with the third and fourth Purkinje images.[27] Tilt was scored as none, mild (≤2 degrees), moderate (3 to 5 degrees), or severe (≥6 degrees). Decentration was recorded as 0.0 mm, >0 to 0.25 mm, >0.25 to 5.00 mm, >0.50 to 1.00 mm, or >1.00 mm; if decentration was >1.00 mm, the amount was specified as exactly as possible. Contrast sensitivity measurements were obtained using the Functional Acuity Contrast Test (FACT) chart (Vision Sciences Research) in the Stereo Optical VT1600 look-in viewer. The FACT chart uses Gaussian sine-wave gratings to measure contrast sensitivity at 5 standard spatial frequencies (1.5, 3, 6, 12 and 18 cycles per degree [cpd]) and contrast levels from 0.5% to 30.0%.

All measurements were obtained with best spectacle correction under mesopic (3 candelas/m^2 [cd/m^2]) and photopic (85 cd/m^2) luminance levels. The last patch on the FACT chart that each patient could correctly identify for each spatial frequency was assigned a contrast sensitivity value using a chart provided by Vision Sciences Research Corp. and converted to log scale to obtain the log contrast sensitivity value. The mean and standard deviation of the log contrast sensitivity values found in the 2 study populations were compared using a simple 2-tailed t test. A statistically significant difference was considered to exist when $P<.05$. A functionally significant difference in vision was considered to correspond to a 0.15 log unit or greater difference between tests. The region between 3 cpd and 6 cpd (peak contrast sensitivity) was considered to have the greatest correlation with functional vision (personal communication, Arthur Ginsburg, PhD, January 13, 2003).

After IOL implantation and follow-up of the study eye, patients were invited to participate in a study extension if visually significant cataract developed in the fellow eye. The same IOL was used in both eyes. Postoperative contrast sensitivity testing and all other examinations were performed according to the study protocol in the intent-to-treat population. Between-group comparisons in contrast sensitivity were made using (1) the mean value in each eye and (2) the mean value in each patient (ie, the mean measurement of 2 eyes).

Results

Monocular IOL Comparison

In all, 39 patients were randomized to receive a Tecnis or an AR40e IOL. Nine patients were excluded for the following reasons: keratometric cylinder greater than 1.5 D (n = 1); capsular tension ring placed during surgery (n = 2); posterior capsule tear (n = 1); cystoid macular edema (n = 2); lack of follow-up (n = 3). The resulting intent-to-treat population comprised 15 men and 15 women, with 8 men and 7 women in the Tecnis IOL group. In the Tecnis and AR40e groups, respectively, the mean age was 66.8 years and 70.3 years, the mean baseline Snellen best corrected visual acuity (BCVA) in the operative eye was 0.50 and 0.57, and the operative eye was dominant in 9 patients and 11 patients.

Three months after surgery, the mean Snellen BCVA improved to 1.02 (20/20) and 0.96 (20/21) in the Tecnis and AR40e groups, respectively. No postoperative IOL tilt or decentration was noted. The mean postoperative spherical equivalent refractive error was −0.06 ± 0.42 D in the Tecnis group and −0.01 ± 0.40 D in the AR40e group. Minimal difference was found between preoperative and postoperative corneal topographies, with a mean change of less than 0.5 D in either axis in all eyes with simulated keratometry at the 3.0 mm optical zone. Postoperative contrast sensitivity testing revealed significant differences ($P<.05$) between the treatment groups under both photopic and mesopic conditions: at 6 cpd under photopic conditions

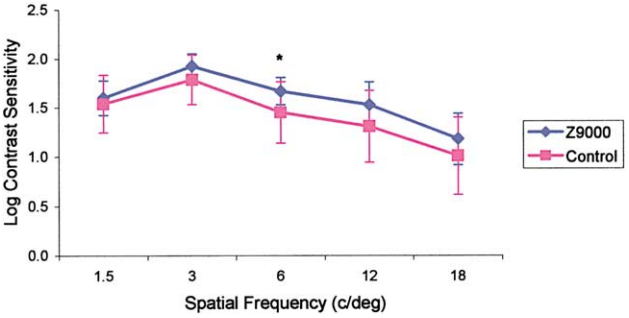

Figure 1. (Packer) Log contrast sensitivity by spatial frequency in eyes with a Tecnis Z9000 IOL (n = 15) and eyes with an AR40e IOL (control) (n = 15) measured under photopic conditions (85 cd/m^2). There was a statistically significant difference between the groups at 6 cpd ($P<.05$), corresponding to a 44.00% increase in contrast sensitivity (0.215 log unit difference).

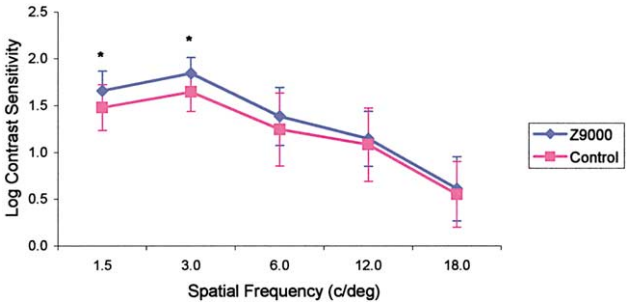

Figure 2. (Packer) Log contrast sensitivity by spatial frequency in eyes with a Tecnis Z9000 IOL (n = 15) and eyes with an AR40e IOL (control) (n = 15) measured under mesopic conditions (3 cd/m^2). There was a statistically significant difference between the groups at 1.5 and 3 cpd ($P<.05$), corresponding to increases in contrast sensitivity from 42.30% to 52.40% (0.18 to 0.19 log unit difference).

(Figure 1) and at 1.5 and 3 cpd under mesopic conditions (Figure 2).

Bilateral IOL Subgroup Comparison

Of the patients with a Tecnis IOL in 1 eye, 7 subsequently had cataract extraction and Tecnis IOL implantation in the fellow eye. Nine patients with an AR40e IOL in 1 eye later had implantation of an AR40e IOL in the fellow eye. Evaluation of this larger group of 22 eyes with a Tecnis IOL and 24 eyes with an AR40e IOL showed that eyes with a Tecnis IOL achieved a mean BCVA of 1.02 (20/20) and a mean postoperative spherical equivalent of −0.08 ± 0.32 D. Eyes with an AR40e IOL achieved 0.95 (20/21) and −0.02 ± 0.27 D, respectively. Again, the change in corneal topography was less than 0.5 D in any axis in all eyes.

When measurements in each eye were analyzed separately, the mean contrast sensitivity in the patients with a Tecnis IOL was significantly better at 3 and 6 cpd under photopic conditions (Figure 3) and at 1.5, 3, and 6 cpd under mesopic conditions (Figure 4). When the mean contrast sensitivity in both eyes was analyzed in patients having bilateral implantation, the Tecnis IOL produced significantly better results than the AR40e IOL at 3 cpd under photopic conditions (Figure 5) and at 1.5 and 6 cpd under mesopic conditions (Figure 6).

Discussion

The Tecnis Z9000 modified prolate IOL produced statistically and functionally significantly better contrast

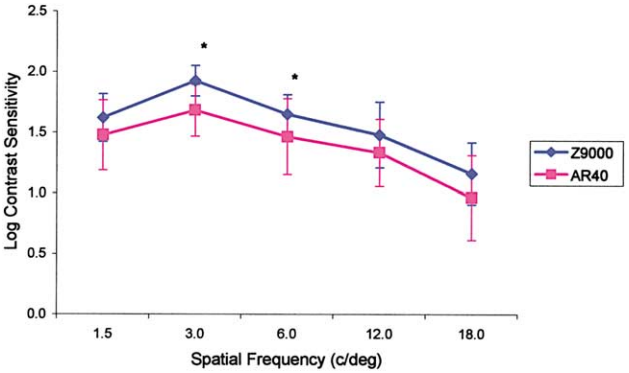

Figure 3. (Packer) Log photopic contrast sensitivity comparison in patients with bilateral implantation. In this analysis, each eye was taken as a separate data point. Statistically significant differences were found at 3 and 6 cpd ($P<.05$). The percentage increases in contrast sensitivity at all spatial frequencies ranged from 23.40% to 62.60% (0.14 to 0.24 log unit difference).

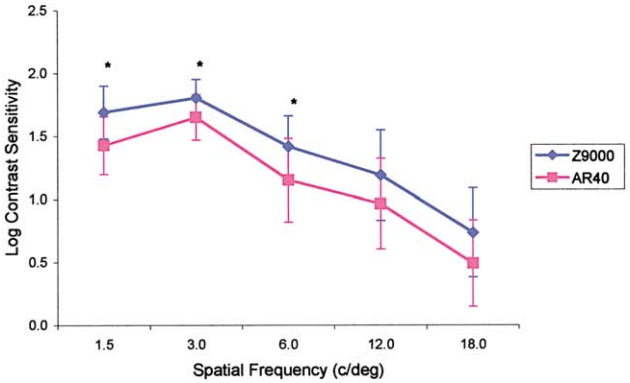

Figure 4. (Packer) Log mesopic contrast sensitivity comparison in patients with bilateral implantation. In this analysis each, eye was taken as a separate data point. The difference between the groups was statistically significant at 1.5, 3, and 6 cpd ($P<.05$). The percentage increase in contrast sensitivity ranged from 38.20% to 74.00% (0.15 to 0.27 log unit).

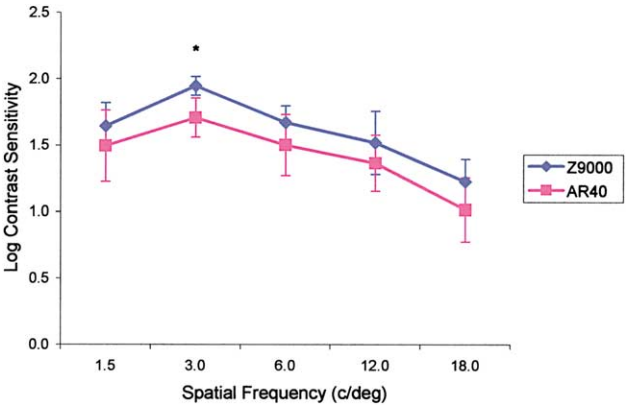

Figure 5. (Packer) Photopic log contrast sensitivity in all patients with bilateral implantation. In this analysis, the contrast sensitivity was taken to be the average contrast sensitivity measured in each patient's 2 eyes. Statistically significant improvement was found at 3 cpd ($P<.05$). The percentage increase in contrast sensitivity ranged from 33.90% to 66.50% across all spatial frequencies (0.15 to 0.24 log unit).

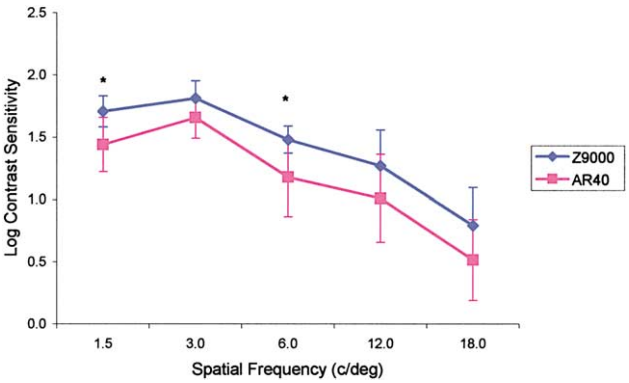

Figure 6. (Packer) Mesopic log contrast sensitivity in all patients with bilateral implantation. In this analysis, the contrast sensitivity was taken to be the average contrast sensitivity measured in each patient's 2 two eyes. Statistically significant improvement was found at 1.5 and 6 cpd ($P<.05$). The percentage increase in contrast sensitivity ranged from 39.80% to 70.10% across all spatial frequencies (0.16 to 0.30 log units).

sensitivity measurements than the AR40e IOL at some, but not all, spatial frequencies in patients with monocular and patients with binocular implantation. Improvements that suggest enhanced functional vision occurred under both mesopic and photopic conditions. Thus, the Tecnis IOL appears to provide an advantage over a standard spherical lens by correcting spherical aberration in the human eye. Additional research should be directed toward investigation of visual performance in which the conduct of functional tests may further demonstrate the advantages of improved optical correction.

The IOL used for comparison in the present study, the AR40e, has several design differences from the Tecnis Z9000 IOL independent of the spherical refractive surface. Therefore, it does not represent a pure control for the prolate modified surface. One interesting distinction is the size of the refractive optic zone, which varies in the AR40e IOL from 5.1 to 6.0 mm depending on the dioptric power of the lens. This smaller optical zone in eyes with an AR40e IOL with a power of 19.0 D or greater, coupled with a pupil larger than 5.0 mm and a particularly generous capsulorhexis, might represent a limiting factor for contrast sensitivity in some patients.

Although the AR40e is but 1 of many available IOLs, it has been shown to provide equal or better sine-wave grating contrast sensitivity than many other spherical IOLs. In a study comparing the visual outcome in 270 cataract patients who had implantation of an AR40e, Sensar AR40 (AMO), AcrySof® MA60BM (Alcon Laboratories, Inc.), 812 (Pfizer), or CeeOn 911A IOL, the AR40e led to significantly better contrast sensitivity than the 812 poly(methyl methacrylate) IOL at 12 and 18 cpd measured by the FACT chart. There were no other statistically significant differences between the lenses (J. Boberg-Ans, G. Boberg-Ans, "Subjective Glare and Contrast Vision [FACT Chart] Following Cataract Extraction Comparing 5 Different Intraocular Lens Designs of 3 Materials," presented at the XXth Congress of the European Society of Cataract & Refractive Surgeons, Nice, France, September 2002). In the present study, we used sine-wave grating contrast sensitivity as a test of functional vision; however, functional tests (eg, night driving simulation) may better demonstrate the advantages of improved optical correction.

The conclusions of the present study would have been strengthened by the performance of wavefront aberrometry, enabling the concurrent evaluation of the effect of the implanted IOLs on spherical aberration. The population study by Pfizer during the development of the Tecnis IOL suggests that at least 93% of eyes will achieve a significant reduction in spherical aberration (personal communication, Sverker Norrby, PhD, Pfizer, Groningen, The Netherlands, January 13, 2003). In a previous study that compared the quality of vision with the Tecnis IOL and a spherical silicone IOL (SI-40, AMO),[28] significantly less total spherical aberration (assessed with a Hartmann-Schack aberrometer) was found in eyes with a Tecnis IOL than in eyes with an SI-40

IOL. The authors also report significantly better mean photopic and mesopic contrast sensitivities at all spatial frequencies.

Another limitation to the present study was the rapid method used to determine IOL tilt and decentration. The method used gives a reasonable approximation but does not allow the degree of precision possible with Scheimpflug photography. Although Scheimpflug photography would have been more accurate, it is limited by distortion from the refractive media of the eye.[29] The presence of an aspheric IOL would have further complicated the mathematical correction necessary to obtain accurate information on decentration and tilt.

Using intraindividual comparisons rather than interindividual comparisons in the present study would have allowed the visual processing system of each patient to serve as a control. However, a drawback to this approach is patient dissatisfaction with vision in 1 eye if it is noticeably different from that in the fellow eye. In fact, 1 investigator recently reported that a patient who had IOL implantation as part of an intraindividual comparison trial requested replacement of the control IOL because the patient preferred the vision in the eye with the Tecnis IOL (L. Corydon, MD, "Tecnis Model Z9000 Compared with the Pharmacia CeeOn Edge Model 911," presented at the International Congress of Ophthalmology, Sydney, Australia, April 2002).

As advances in technology allow cataract and refractive surgeons to address higher-order optical aberrations, the measurement of functional vision becomes increasingly critical as a gauge of progress. Sine-wave grating contrast sensitivity testing is becoming increasingly useful for monitoring postsurgical outcomes and comparing treatment modalities. As further advances in technology allow correction of higher-order aberrations, accurate assessment of functional vision will play a key role in improving these techniques. This is reinforced by the results in our study, in which contrast sensitivity testing showed greater restoration of vision in patients with a Tecnis IOL than in patients with an AR40e IOL. The integration of wavefront technology and lens-based surgery demonstrated by the Tecnis IOL represents a step toward improving functional vision and quality of life for cataract patients.

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