Myopic Astigmatism and Presbyopia Trial

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• PURPOSE: No prospective double-masked study has evaluated whether low astigmatism benefits or harms patients with presbyopia, whose intermediate and near vision might theoretically benefit from enhanced depth of focus provided by astigmatism. The purpose of the first Myopic Astigmatism and Presbyopia (MAP I) study was to determine whether low myopic astigmatism enhances or harms the visual acuity, stereopsis, or quality of life in patients with presbyopia.
• DESIGN: Prospective, randomized, double-masked, crossover design clinical trial.
• METHODS: Fifteen patients with presbyopia aged 45 to 68 years were recruited from an academic center population. These patients were given a baseline eye examination, including manifest refraction, Early Treatment of Diabetic Retinopathy Study (ETDRS) logarithm of minimal angle of resolution (logMAR) visual acuity at distance, intermediate, and near, accommodative amplitudes, and stereo vision. Each patient was then cycled in random order through three masked pairs of soft contact lenses. The power of each contact lens pair was calculated by the subtraction method to maintain a spherical equivalent of −0.5 diopters, while providing either no astigmatism (spherical arm, SPH), 1 diopter of with-the-rule (WTR) astigmatism, or 1 diopter of against-the-rule (ATR) astigmatism. Actual refractive errors produced were measured by masked examiner. Outcomes measured at the end of 1 week of usage of each contact lens arm were binocular (ETDRS) logMAR visual acuity at three distances (far [4 m], intermediate [1 m], and near [33cm]); near stereoacuity, using the quantitative Titmus Stereotest; and quality of life, measured using the Refractive Status and Vision Profile (RSVP), a standardized questionnaire.
• RESULTS: Visual acuity results across the three arms were similar. However, 1-m logMAR visual acuity was better for the spherical arm than either astigmatic arm (−0.06 SPH, +0.01 WTR, +0.02 ATR). Near (33 cm) and distance (4 m) acuities were similar across arms. Stereoacuity was better in ATR than WTR (50 vs 102 seconds, $P = .01$). Subjects preferred SPH slightly over the WTR astigmatic arm by the RSVP quality-of-life survey instrument (101 vs 104, $P = .05$). Other intergroup comparisons showed no difference in RSVP scores.
• CONCLUSIONS: This study has demonstrated that intermediate distance acuity and refractive quality of life are slightly better with spherical low myopic refractive error vs either astigmatic arm. Near and far distance acuity were unaffected by low myopic astigmatism compared with spherical low myopia. Near stereopsis was best in the ATR arms, but this did not produce better near visual acuity or RSVP quality of life. (Am J Ophthalmol 2003;135:628–632. © 2003 by Elsevier Inc. All rights reserved.)

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Modern cataract and refractive surgery techniques have greatly enhanced the ophthalmic surgeon's ability to plan and control the amount of astigmatism remaining after surgery. During cataract surgery, limbal relaxing incisions, "on-axis surgery," and toric intraocular lenses can virtually eliminate postoperative astigmatism. Excimer lasers are now universally approved for correction of myopic astigmatism. The ability to control astigmatism has, in fact, surpassed the clinical evidence about how astigmatism impacts on quality of vision and quality of life after cataract or refractive surgery. Conventional wisdom holds that astigmatism, in general, should be minimized or eliminated. Few prospective investigations exist in the literature to validate this widely held belief. One retrospective analysis of pseudophakic patients with postoperative myopic against-the-rule (ATR) astigmatism had better near vision than those with myopic with-the-rule (WTR) astigmatism and similar spherical equivalents.[1]

Sawusch and Guyton[2] proposed that myopic astigmatism might enhance the near vision of patients with presbyopia by placing one astigmatic focal line near the retina in distance viewing, and the other focal line would fall near the retina while patients viewed an intermediate or near target. They calculated the optimal amount of astigmatism for each level of myopia using computer modeling of the cross section of the conoid of Sturm.

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However the visual performance of the "idealized" refractions produced by the computer model was not compared with that of spherical low myopia or other refractive errors. Huber[3] showed that pseudophakic patients with simple myopic astigmatism of −0.79 diopters (spherical equivalent) ±0.6 diopters were able to see better than 20/50 from far to near. He did not suggest an orientation to this optimal amount of astigmatism, however. A computerized review of the literature, using MEDLINE from 1966 to the present, failed to identify a single prospective double-masked study designed to evaluate whether low astigmatism benefits or harms the patient with presbyopia, whose intermediate and near vision might theoretically benefit from enhanced depth of focus provided by astigmatism.

The purpose of the Myopic Astigmatism and Presbyopia (MAP) study was to determine whether low myopic astigmatism enhances or harms the visual acuity, stereopsis, or quality of life in patients with presbyopia. Three different refractive errors were induced sequentially in patients with presbyopia with toric contact lenses to determine whether spherical low myopia, low myopic WTR, or low myopic ATR astigmatism provides the best visual function at various distances.

DESIGN

THE MAP STUDY WAS A SINGLE-CENTER, PROSPECTIVE, double-masked, nonrandomized comparative trial. Institutional review board approval was obtained from George Washington University before patient enrollment.

METHODS

TWENTY CONSECUTIVE PATIENTS MEETING ENTRY CRITERIA who signed the informed consent were enrolled in the study. They were selected from the Comprehensive and Contact Lens Services at the George Washington University Hospital Department of Ophthalmology according to the following criteria (Table 1: Entry and Exclusion Criteria).

At the first study visit, patients were refracted by noncycloplegic retinoscopy and "push-plus" subjective enhancement. From the spectacle plane refraction, a cornea plane power-cross was constructed for each eye by correcting each meridian for the vertex distance. Ideal contact lens power was calculated, and the actual contact lens for each arm selected was that commercially available Bausch and Lomb (Rochester, New York, USA) toric or spherical lens that came closest to producing the desired "error lens." Error lenses that were not a perfect match were within 0.25-diopter of the spherical equivalent and astigmatic amplitude. When two possibilities were equidistant from the ideal lens, the lens that produced less than 1 diopter of astigmatism was always chosen. Target corneal plane refractive error arms are listed in Table 2.

TABLE 1. Entry and Exclusion Criteria for the Myopic Astigmatism and Prebyopia Trial

Entry criteria
1. Age ≥45 years
2. Myopia (spherical equivalent >2 diopters)
3. Patients with regular astigmatism, having an axis within 15 degrees of 90 or 180.
Exclusion criteria
1. Best-corrected distance vision worse than 20/30 in either eye
2. Intolerance to contacts: GPC, severe dry eye, conjunctivitis
3. Any prior incisional ocular surgery or laser refractive surgery within 12 months
4. Prior radial keratotomy, keratoconus, or irregular astigmatism
5. Allergy to any component of lenses or solutions
6. Inability to insert or remove lens daily
7. Pupil size <2.0 mm in ambient lighting

GPC = giant papillary conjunctivitis.

TABLE 2. Experimental Arms and Target Corneal-plane Refractive Errors

Spherical low myopia	−0.50 diopter spherical
Low myopic with-the-rule astigmatism	−1.00 + 1.00 × 090
Low myopic against-the-rule astigmatism	−1.00 + 1.00 × 180

TABLE 3. Outcome Variables Measured for Each Arm of Study

1. Masked logMAR ETDRS visual acuity at far distance (4 m)
2. Masked logMAR ETDRS intermediate acuity (1 m)
3. Masked logMAR ETDRS near acuity card (33 cm)
4. Quantitative near stereopsis with Randot circles
5. Refractive status and vision profile, a validated survey instrument

ETDRS = Early Treatment of Diabetic Retinopathy Study; logMAR = logarithm of minimal angle of resolution.

Patients were then cycled through three contact lens pairs, in random order, each of which was selected to produce a specific and identical refractive error in both eyes. In this study, each patient serves as his or her own control by virtue of serial measurements in the different arms. Contact lens pairs were calculated by the vector subtraction method to purposefully undercorrect the patients' manifest refraction by a spherical equivalent of −0.50 diopters in each arm. In the spherical arm, the

TABLE 4. Accuracy of Mean Refractive Error Created by Study Contact Lens Arms

Refractive Variables	Spherical Group	WTR Group	ATR Group	F Value	*P* Value
Spherical equivalent	−0.27 D	−0.28 D	−0.20 D	0.12	.89
Astigmatic amplitude	0.37 D	0.83 D	0.82 D	6.49	.0039
Astigmatic axis	23	84	3	26.55	<.0001

ATR = against-the-rule; D = diopter; WTR = with-the-rule.

target-induced refractive error was −0.50 diopters spherical. In the WTR arm, the target-induced refractive error was −1.00 + 1.00 axis 090. Similarly, in the ATR arm, the target was −1.00 + 1.00 axis 180. The spherical equivalent targets are identical so that any acuity or quality-of-life (QOL) differences between experimental groups would be strictly the result of the astigmatism amplitude and axis.

The order that each patient cycled through the three arms was randomized by the study coordinator to avoid learning curve bias. This was done because many of the patients were novice contact lens wearers, and we thought this might lead patients to favor the last lens pair over the first pair simply on the basis of increasing familiarity with contact lens use. Lens pairs were distributed to the study participants to wear 1 week at a time. After contact lens care and handling instructions were provided to each participant, each pair of contact lenses was assessed for proper fit. After 20 to 30 minutes wearing the new lens pair, the patient was overrefracted by an examiner masked to the lens arm assignment. The result was recorded and sealed. That examiner was thereafter considered "unmasked" and was specifically excluded from participating in the subsequent visual acuity assessments for that patient. An over-the-counter reading spectacle was recommended for each patient based on "age-appropriate" accommodative requirements, above the −0.5 spherical equivalent. These were not provided. Patients returned to clinic each week for visual acuity assessment at far (4 m), intermediate (1 m), and near (33 cm) distances. Quantitative stereoacuity was also tested using Randot circles, and a QOL survey, the Refractive Status and Vision Profile (RSVP),[4] was completed (Table 3). At the end of this visit, this pair of study lenses was discarded, and the next arm of contact lenses was given to each participant for fitting assessment and overrefraction. This was repeated until the patient had tried each of three arms or dropped out of the study.

RESULTS

• **PATIENTS:** Twenty patients were recruited for this study, of whom 15 completed all three arms of the study. Age ranged from 47 to 68 years, with an average 54.7 (SD, 6.6) years of age.

TABLE 5. Representative Average Refraction by Group

Spherical	−0.46 + 0.37 × 023
With-the-rule	−0.70 + 0.83 × 084
Against-the-rule	−0.61 + 0.82 × 003

• **ACCURACY OF INTENTIONAL REFRACTIVE ERROR PRODUCED WITH CONTACT LENSES:** This study created intentional refractive errors with Bausch and Lomb toric soft contact lenses by careful power-cross vertex correction of spectacle plane refractions. The success of this technique was assessed by masked retinoscopic overrefraction of each contact lens arm after a 20-minute settling period. Success of the model required equal spherical equivalent in each arm and achievement of the distinct astigmatic amplitudes and axes for each arm. The mean spherical equivalent refractive error created in each arm of the study was identical by analysis of variance, as shown in Table 4. The result was the same for right eyes and left eyes alike. The mean astigmatism axis and amplitudes created in the three study arms were close to intended targets and differed significantly between groups ($P = .0039$ for astigmatic amplitude, $P < .0001$ for astigmatic axis). The spherical group had a mean of 0.37-diopter axis 23 degrees. The WTR group had a mean 0.83-diopter axis 84 degrees, and the ATR group mean was 0.82-diopter axis 3 degrees. Pairwise comparisons confirmed that the differences in astigmatic amplitude between either astigmatic group and the SPH group were significant and that the mean astigmatic axes differed significantly between the two astigmatic groups, and the SPH and WTR groups, but not the SPH and ATR groups. A representative average refraction is shown for each group (Table 5).

• **REFRACTIVE QUALITY OF LIFE: RSVP SCORES:** Self-reported refractive QOL scores, measured by the RSVP questionnaire, were similar across the three groups (Table 6). Subjects preferred spherical low myopia slightly over both astigmatic groups: QOL scores for spherical low myopia SPH vs ATR differed by more than five points, a difference that is clinically but not statistically significant ($P = .33$). Subjects recorded a smaller but more consistent QOL preference for SPH over WTR, which approached

TABLE 6. Refractive Status and Vision Profile Quality-of-life Scores by Group

Spherical	101.2
With-the-rule	104.0
Against-the-rule	106.6

A lower score indicates better visual functioning and quality of life.

significance (101 vs 104; P = . 051). None met the Bonferroni adjusted alpha level 0.0128.

• **BINOCULAR EARLY TREATMENT DIABETIC RETINOPATHY STUDY logMAR VISUAL ACUITY AT VARIOUS DISTANCES:** Binocular Early Treatment Diabetic Retinopathy Study (ETDRS) logMAR visual acuity was best for the spherical low myopia group at the intermediate (1-m) testing distance (Snellen equivalent, 20/15-2). The visual acuity advantage of the spherical over the ATR group was small but consistent (SPH vs ATR: −0.06 vs +0.01; P = .0128). The advantage of SPH over WTR was similar but did not reach significance (−0.06 vs +0.02; P = .167). With-the-rule and ATR performed identically at the intermediate distance (+0.02 vs +0.01; P = .899).

For the far (4-m) distance visual acuity, a nonsignificant trend, approximately 1 line Snellen equivalent, favored SPH over ATR (−0.07 vs +0.01; P = .09). All three groups performed similarly in distance binocular ETDRS logMAR acuity.

Compared with 1- and 4-m acuities, the binocular near ETDRS logMAR acuity (33 cm) was poorer, roughly 20/30 or Jaeger 2, in these patients with presbyopia for all three study arms. No differences in acuity were present between groups.

We calculated a summary statistic, overall binocular ETDRS logMAR acuity, which is the mean of the binocular acuity scores at all three working distances. The overall score was best for spherical low myopia, and the difference approached significance comparing SPH with ATR (+0.04 vs +0.08; P = .026). A nonsignificant difference was found between SPH and WTR (+0.04 vs +0.08; P = .19).

• **NEAR STEREOPSIS ACUITY:** The ATR group performed dramatically better than the WTR group (50 vs 102.7 arc seconds; P = .0143). Against-the-rule did only slightly better than SPH (50 vs 75 arc seconds; P = .067). The stereopsis advantage of SPH over WTR was not significant (75 vs 102.7 liters; P = .083).

• **SECONDARY ASSOCIATIONS:** Linear regression analysis revealed that age is inversely associated with intermediate acuity (Pearson correlation coefficient, −0.523; P = .045) and near acuity (−0.661; P = .0061). Far acuity was not associated with age in this population (0.38; P = .159).

DISCUSSION

THIS NONRANDOMIZED COMPARATIVE INTERVENTIONAL study tested the impact of small amounts of regular astigmatism on visual acuity, stereopsis, and visual quality of life in 15 subjects with presbyopia aged 45 to 68 years (mean, 54.7 years). This was accomplished by cycling each participant through three sets of toric soft contact lenses chosen to create specific refractive errors.

Analysis of the masked overrefraction produced in each arm showed that on average patients were slightly less myopic than the target for each arm. This resulted from the fact that the stock toric lenses used in the study were available in only 0.5-diopter spherical increments and three astigmatic powers (0.75, 1.25, and 1.75). We created arbitrary guidelines to select lenses when the precise prescription lens dictated by our calculations was not available, to avoid unwitting creation of differences in spherical equivalent or other bias. The rule was: Choose the lens that created slightly less, rather than slightly more, myopia and astigmatism. This probably accounts for the mean spherical equivalent in each arm, −0.25 diopters, not −0.5, and why both astigmatic groups had 0.8, rather than 1.0, diopter of astigmatism. Ultimately, this antibias safeguard reduced the difference in refractive error and perhaps also reduced the visual acuity and QOL difference between groups. Fortunately, mean spherical equivalent was identical for each arm of the study, ensuring that any difference in vision, stereopsis, or quality of life was the result of astigmatic not spherical equivalent differences.

Visual quality of life, measured by the RSVP,[4] was the primary end point for the MAP I study. The study had an 80% power to identify a five-point difference in quality of life between groups. While trends toward improved quality of life favored the spherical group, these did not meet the predetermined minimum clinically significant difference of five points nor the Bonferroni adjusted alpha level of 0.0128. This suggests, for patients with presbyopia with a spherical equivalent of approximately −0.25 diopters, that the presence of 0.8-diopter of astigmatism in each eye, whether WTR or ATR, does not significantly improve nor hamper the visual quality of life measured by RSVP. The RSVP was developed to study the impact of refractive surgery on quality of life. Among the 13 RSVP questions that ask about tasks that are distance specific, such as driving (far) and reading (near), 9 asked about far-distance–dominated activities, 2 asked about intermediate activities, and 2 asked about near activities. Thus, this instrument may be somewhat biased toward refractive conditions that optimize distance acuity. It is possible that a survey instrument geared more toward near vision would have had a different outcome.

Secondary endpoints were binocular logMAR visual acuities rigorously measured by backlit ETDRS charts at 4 m, 1 m, and 33 cm. No group achieved a 2-line advantage, typically considered a clinically significant difference. However, the logMAR acuities consistently favored the spherical over one or both astigmatic groups by approximately 1 Snellen line of vision at the 1-m, 4-m, and the overall visual acuity score. The near vision was identical and poor in all three groups. This was expected because of presbyopia, because the mean age was 54.7 years, and the spherical equivalent was −0.25 in each arm.

Intriguingly, the stereopsis scores were significantly better for the ATR group than the spherical and especially the WTR astigmatic group. The near stereopsis test uses polarizing filters and double-printed images to separate horizontally identical images to each eye. The brain interprets the horizontally separated images as elevation above the page. Apparently, the eyes with ATR astigmatism, the vertical back focal line of which is optically closest to the retina during near vision, had an advantage in perceiving the artificial horizontal position disparity of the stereopsis test. Those with spherical refractive error had intermediate, and those with WTR astigmatism, whose vertical front focal line is located farthest from the retina, in the vitreous, during near work, had the worst near stereopsis perception. The reason that the ATR group had better near stereopsis but equally poor logMAR acuity compared with the spherical and WTR groups was not obvious. Trindade and associates[1] showed that patients with myopic astigmatism after cataract surgery have better near reading with ATR than WTR astigmatism. They theorized that the predominance of vertical strokes over horizontal strokes in the Roman alphabet might favor ATR over WTR for near work and WTR over ATR for far work, two situations in which the vertical focal line is nearest the retina. However, this particular study was neither masked nor randomized, and acuities were not measured with ETDRS charts. It is possible that near letter recognition, as tested, is simply less different than the stereotest, which relies strictly on perception of a horizontal separation.

This study has shown that low ATR astigmatism enhances near stereopsis over WTR and SPH, at the cost of slightly worse visual acuity at distance and intermediate distances and slightly worse quality of life as measured by the RSVP refractive survey. This may have implications for preoperative planning of intraocular lens implantation, as well as other types of refractive surgeries. Future research could better define what the optimal postoperative refractive error should be after cataract and refractive surgery. Before wavefront and higher-order aberrometry measurement is incorporated into surgical planning for refractive surgery, it would be beneficial to investigate more fully the impact of astigmatism on postoperative visual function and quality of life.

REFERENCES

1. Trindade F, Oliveira A, Frasso M. Benefit of against-the-rule astigmatism to uncorrected near acuity. J Cataract Refract Surg 1997;23:82–85.
2. Sawusch MR, Guyton DL. Optimal astigmatism to enhance depth of focus after cataract surgery. Ophthalmology 1991;98: 1025–1029.
3. Huber C. Planned myopic astigmatism as a substitute for accommodation in pseudophakia. Am Intra-Ocular Implant Soc J 1981;7:244–249.
4. Vitale S, Schein OD, Meinert CL, Steinberg EP. The refractive status and vision profile: a questionnaire to measure vision-related quality of life in persons with refractive error. Ophthalmology 2000;107:1529–1539.
5. Early Treatment Diabetic Retinopathy Study Research Group. Grading diabetic retinopathy from stereoscopic color fundus photographs—an extension of the modified Airlie House classification. ETDRS report number 10. Early Treatment Diabetic Retinopathy Study Research Group. Ophthalmology 1991;98(5 Suppl):786–806.