

Accuracy of the LaserArcs Femtosecond Cataract Surgery Arcuate Incision Nomogram in Patients Undergoing Cataract Surgery and Astigmatism Reduction

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Purpose: The purpose of this study is to evaluate the efficacy and safety of the laserarcs.com nomogram in reducing astigmatism among cataract patients that underwent astigmatism reduction with laser arcuate incisions.

Methods: In this retrospective study, 50 patients who underwent uncomplicated cataract surgery with laser arc incisions for the reduction of astigmatism with a single surgeon between the dates of January 23, 2021 and February 10, 2022 were evaluated in a single eye. Preoperative astigmatism was determined on the basis of keratometry from biometry (IOLmaster, Carl Zeiss Meditec or LenStar LS900, Haag-Streit, Bern, Switzerland) and was compared to the postoperative manifest astigmatism. The percent change in the absolute magnitude of astigmatism was calculated along with the percent of patients with various levels of postoperative astigmatism.

Results: Mean cylinder was 0.97 ± 0.49 D pre-op and 0.21 ± 0.28 D postop. Mean reduction in cylinder was $81.4 \pm 47.7\%$ ($P < 0.00001$, one-sample *t*-test compared to a hypothetical 60% reduction in cylinder). Residual cylinder was ≤ 0.5 D in 90%, 0.25 D in 72%, and 0 D in 58%. Postoperative uncorrected visual acuity was 20/30 or better in 92% and 20/20 or better in 40%. Subgroup analysis showed that residual astigmatism was not affected by patient age, magnitude of preoperative astigmatism, preoperative spherical equivalent, or corneal curvature. No adverse events related to the laser arcuate incisions were noted.

Conclusion: Use of the LaserArcs nomogram yielded a significant reduction in preoperative astigmatism. Postoperative uncorrected visual acuity was substantially similar to best-corrected visual acuity, suggesting that many patients undergoing treatment will function without correction for distance tasks.

Keywords: nomogram, LaserArcs, astigmatism, cataract surgery, femtosecond laser, keratotomy

Introduction

Femtosecond lasers allow the precise placement of arcuate keratotomy incisions in patients undergoing cataract surgery. Though these surgical devices have been available for several years, most current nomograms designed to reduce astigmatism with these incisions are derived from those developed for manual arcuate keratotomy.¹⁻⁵ Anecdotal reports from surgeons indicate that the previous nomograms have limited accuracy in the setting of femtosecond laser surgery.

LaserArcs.com is an online arcuate incision nomogram calculator initially developed on the basis of 12 months of data tabulation of patients undergoing femtosecond surgery with arcuate incisions. Since that time, its user base has grown significantly, and currently over 3500 calculations are performed each month on this platform.

Previous research has shown that preexisting astigmatism of ≥ 1 diopter may be present in up to 47% of cataract eyes, affecting approximately 12 million Americans today.^{6,7} Treating astigmatism in combination with cataract surgery increases visual acuity and patient satisfaction, making accurate, effective astigmatism correction techniques an important consideration.⁸ Femtosecond laser-assisted astigmatic keratotomy (FSAK) allows surgeons to achieve highly consistent

results with comparable or superior accuracy to traditional manual techniques.^{9,10} Additionally, FSAK procedures improve significantly in both consistency and efficacy when informed by well-designed nomograms.¹¹ One such nomogram, LaserArcs.com, is the subject of this study.

The purpose of this study is to evaluate the efficacy and safety of the LaserArcs.com nomogram in reducing astigmatism among cataract patients who underwent astigmatism reduction with laser arcuate incisions.

Materials and Methods

This was a single-surgeon, retrospective study of patients undergoing femtosecond laser-assisted cataract surgery with arcuate incisions for the reduction of astigmatism. Arcuate incision anatomy was calculated using the LaserArcs online nomogram. The primary endpoint of this study was the percent reduction in absolute magnitude of astigmatism in the subject population based upon the absolute difference of postoperative manifest refraction. Postoperative manifest cylinder was the exploratory endpoint.

All patients had undergone a preoperative manifest refraction, and keratometry was determined using an IOLmaster V (Carl Zeiss Meditec, Oberkochen, Germany) with software version 5.2.1 to 5.4 or a LenStar LS900 (Haag-Streit, Bern, Switzerland) version 4.2.1 to 4.4.0, which are comparable instruments for the purposes of corneal power measurement.¹² Posterior corneal astigmatism and central topography were both included in these calculations. Biometry data was manually uploaded to the online LaserArcs software for calculation, and a graphical printout (Figure 1) was generated for use in surgery.

All arcuate incisions were made to an 8.0 mm diameter at a depth 80% of the corneal thickness as measured by the OCT corneal depth measurement of the LenSx (Alcon, Ft Worth) femtosecond laser. Laser arcuate incisions were not further manipulated or opened by the surgeon. The femtosecond laser was also used to create an anterior capsulotomy of 5.5 mm and for lens fragmentation. No other incisions were made with the femtosecond laser. No toric lens implants were used in study eyes, and an attempt was made to include about 30% of patients receiving multifocal implants with preoperative cylinder less than 0.7 D, so the study could evaluate the common scenario of correcting astigmatism with a multifocal implant where a sufficiently low toric power is not available. All postoperative refraction data was collected one month after surgery.

A sample size estimation was performed using results from an independent data set of 400 eyes and determined that 50 unilateral eyes would provide >90% statistical power to demonstrate a clinically meaningful percent reduction of astigmatism with a target reduction of 60%. All enrolled subjects were required to be 22 years of age or older and had cataracts but otherwise healthy eyes, not exhibiting any significant ocular morbidity that would be expected to influence outcome measures. All patients had preoperative keratometric astigmatism greater than 0.25 D and were implanted with a non-toric IOL, and all patients' laser astigmatic keratotomy was planned using the LaserArcs nomogram. Patients with visually significant co-morbidities that could affect their visual outcome after surgery, like corneal, retinal, or optic nerve disease, were excluded, and all patients had a preoperative corneal topography screening for ectasia, higher-order aberrations, or other abnormalities and would be excluded from treatment if significant corneal pathology were identified. Patients with surgical complications either during or after surgery (capsule tears, iris trauma, decentered IOL, cystoid macular edema, etc.) that would, in the judgment of the investigator, influence the outcome measures of the study, and patients with previous refractive surgery prior to cataract surgery were also excluded.

Prior to collection of retrospective data, this study was registered on ClinicalTrials.gov as NCT 05278442. It was also approved by WCG IRB (Puyallup, Washington) as protocol 20220599 and adhered to both the Declaration of Helsinki and good clinical practices as defined by the U.S. Food and Drug Administration. A waiver of written informed consent was provided by the IRB. Reasonable requests for de-identified patient data relating to the study findings will be available through the corresponding author for 5 years following the publication date.

Results

Fifty eyes of fifty patients underwent femtosecond cataract surgery with arcuate incisions and placement of a non-toric IOL between January 23, 2021 and March 24, 2022 were enrolled in the study. Average age was 69.0 ± 11.2 years (range 47–86). Of the patients enrolled, 30 (60%) were females and 33 (66%) had their right eye evaluated. Mean preoperative manifest spherical equivalent refraction was 0.34 ± 2.72 D (range –9.25 to +6.63), and mean preoperative manifest cylinder was 1.1 ± 0.64 D (range 0 to +2.50). Mean preoperative keratometric cylinder was 0.97 ± 0.49 D (Range 0.26 to

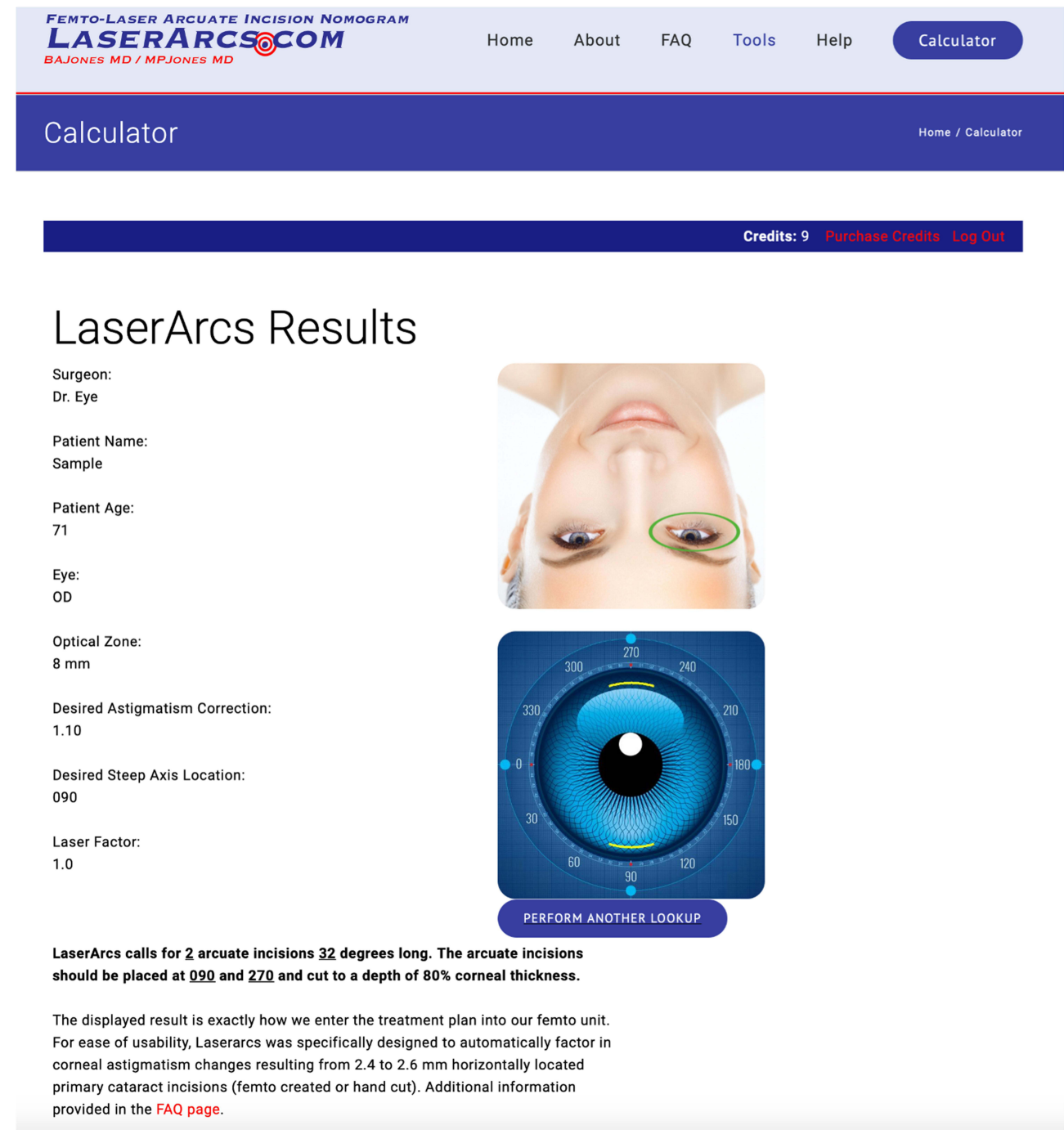


Figure 1 The LaserArcs software graphical output. Reprinted with permission from LaserArcs.

2.48). The mean arcuate incision length dictated by the nomogram was $29.1^\circ \pm 9.9^\circ$ (range 15° to 62°), and all incisions were made to a depth of 80% of the measured corneal thickness at an 8.0 mm diameter.

Among the IOLs used in these patients, none were toric. Monofocal lenses were used in 33 (66%), 16 (32%) received a trifocal, and 1 patient received a non-diffractive multifocal lens. Subgroup analysis revealed no significant difference between IOL groups for patient age or preoperative keratometric cylinder.

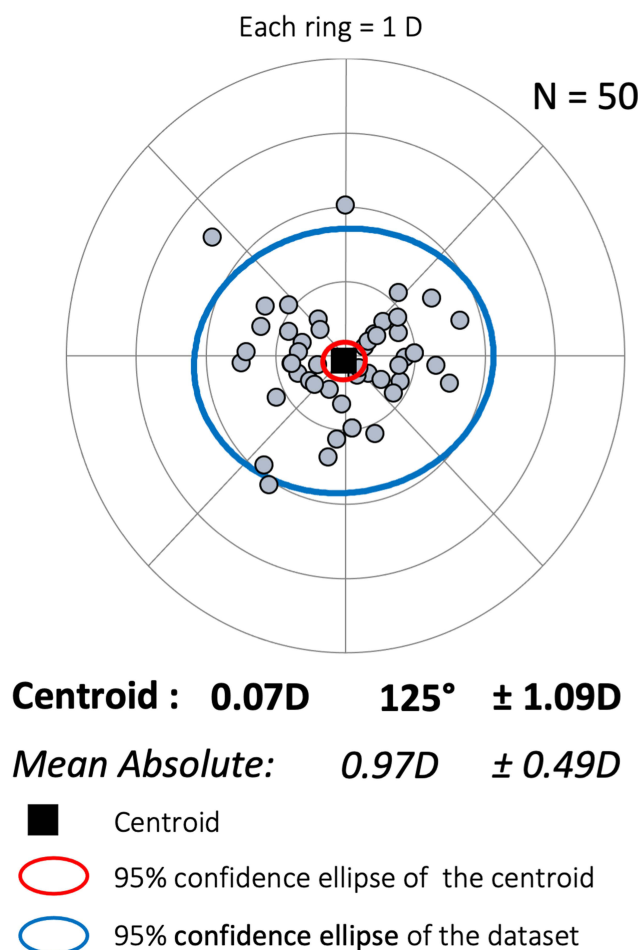


Figure 2 Preoperative keratometric cylinder.

Abbreviation: D, diopters.

Primary Outcome Measure

The mean reduction of astigmatism was $81.4 \pm 47.7\%$ (95% confidence interval range 67.7%–94.3%, $P < 0.00001$, one sample *T*-test vs hypothetical 60% reduction in cylinder). Mean postoperative manifest cylinder was 0.21 ± 0.28 D (range 0 to 1.0 D). Double angle plots of preoperative keratometric cylinder and postoperative manifest cylinder are shown in [Figures 2 and 3](#). A reduction in cylinder was noted in 48 (96%) of eyes with a mean decrease of 0.93 ± 0.47 D. Two eyes (4%) showed an increase in cylinder—one of these had preoperative keratometric cylinder of 0.26 D and increased by 0.49 D at the same axis as preoperative cylinder. The other had preoperative keratometric cylinder of 0.3 D and had a 0.45 D increase, also at a similar axis. Further discussion of eyes with preoperative astigmatism less than 0.5 is included below.

Other Outcome Measures

Of all postoperative patients, 90% were within 0.5 D of the target of zero astigmatism, and 72% were within 0.25 D ([Figure 4](#)). Uncorrected vision of 20/20 was achieved by 20 (40%) patients, 20/25 by 37 (74%), 20/30 by 46 (92%), and 20/80 by 100% of patients. No significant relationship was identified between postoperative residual astigmatism and patient age ([Figure 5](#)), preoperative level of astigmatism ([Figure 6](#)), preoperative spherical equivalent ([Figure 7](#)), or overall preoperative corneal curvature ([Figure 8](#)).

Postoperative uncorrected distance acuity (UCDVA) was the same or better than best distance corrected visual acuity (BDCVA) in 24 (48%) eyes, within one line of BDCVA in 43 (86%), and within two lines in 48 (96%). No adverse

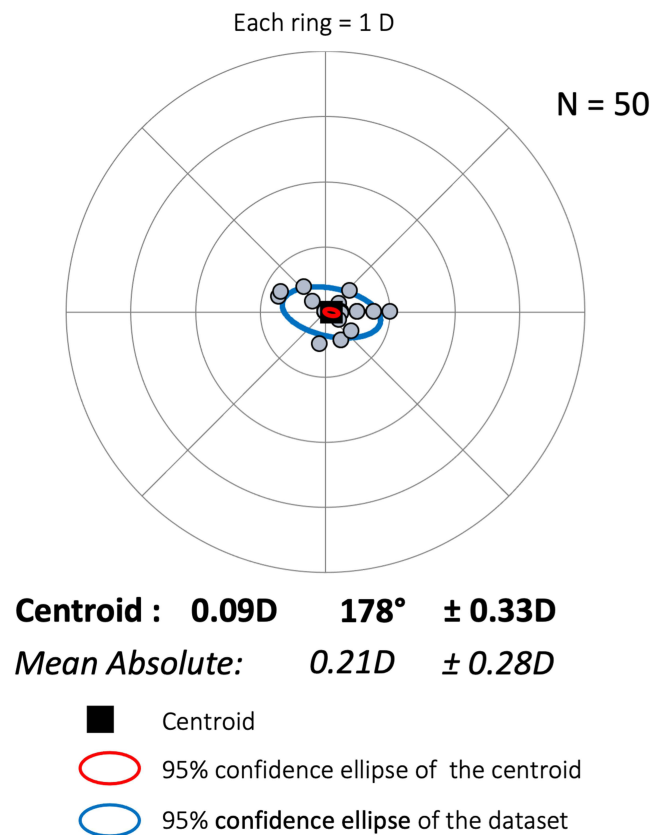


Figure 3 Postoperative refractive astigmatism at the spectacle plane.

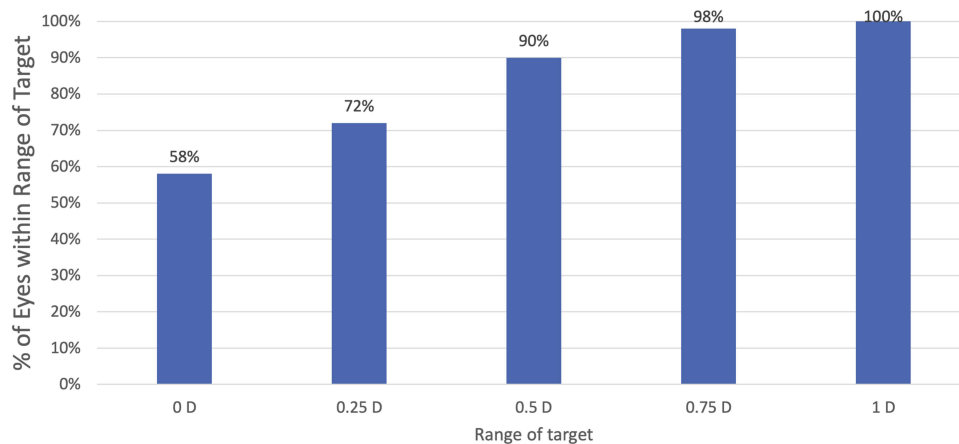


Figure 4 Residual manifest astigmatism. 90% of eyes were within 0.5 D of target and 72% within 0.25 D (N=50).

events related to the laser arcuate incisions were reported for any patient in the study. Specifically, no penetrating incisions, wound leaks, or delayed epithelial healing were reported.

Subgroup analysis was performed on six eyes that had preoperative keratometric cylinder of less than 0.5 D. All received a single arcuate incision of arc length 17° to 22°. Two of the six, described above, had a postoperative increase of manifest cylinder to 0.75 D at the same axis as the preoperative keratometry in both eyes. The other four had no postoperative manifest cylinder. All six eyes had uncorrected postoperative acuity of 20/20.

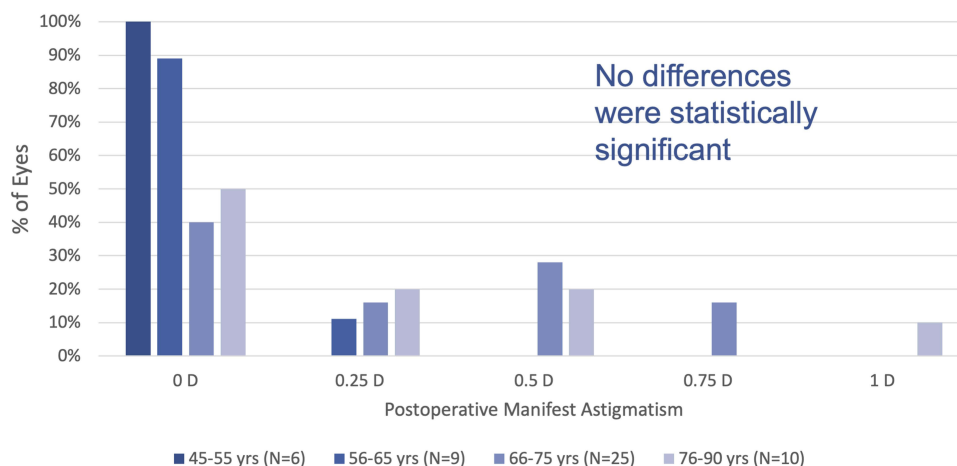


Figure 5 The age of patients did not significantly affect residual astigmatism.

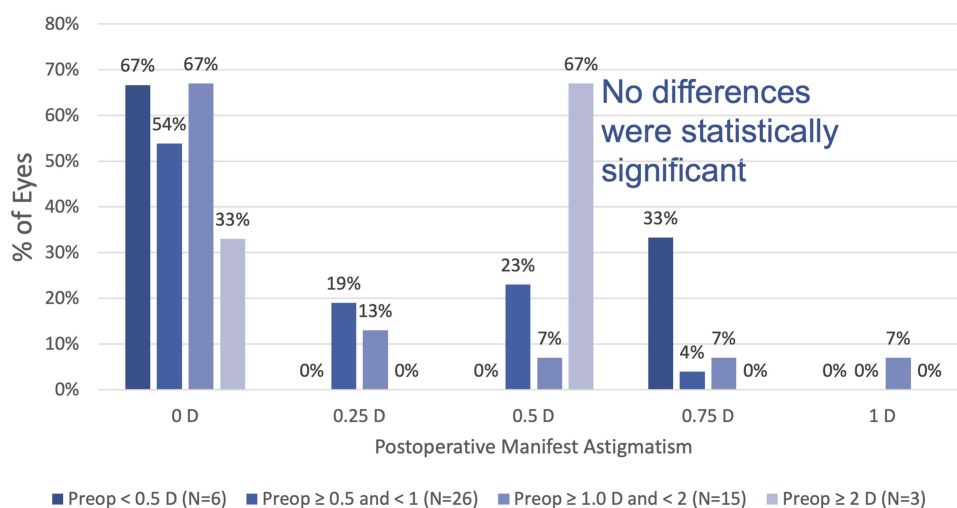


Figure 6 The magnitude of preoperative keratometric astigmatism did not significantly influence residual astigmatism.

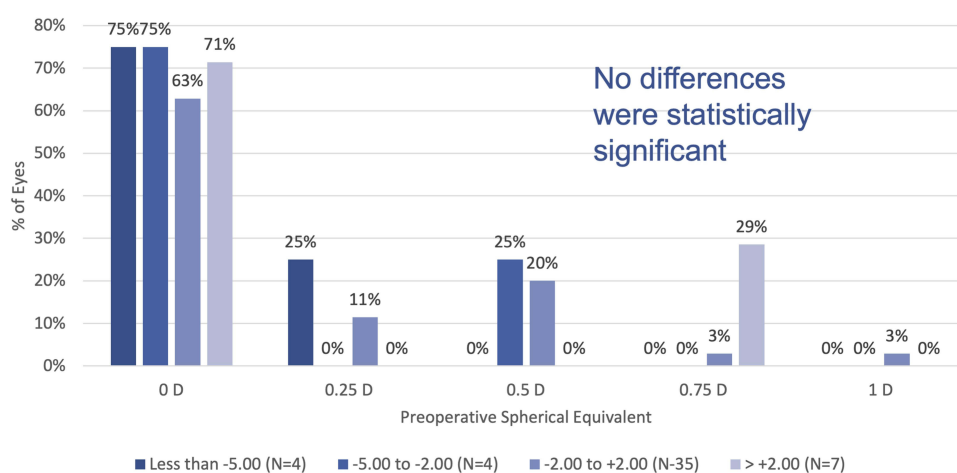


Figure 7 Preoperative spherical equivalent did not significantly influence residual astigmatism.

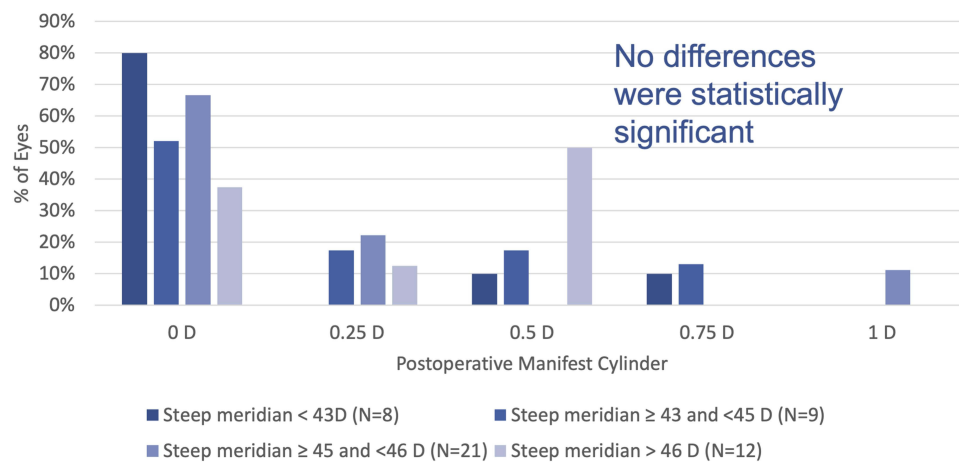


Figure 8 Preoperative corneal curvature did not significantly influence residual astigmatism.

Discussion

To our knowledge, this is the first formal study of refractive outcomes of patients undergoing arcuate keratotomy guided by the LaserArcs nomogram. This nomogram, which was developed specifically for use with the femtosecond laser, was based on linear regression analysis of an initial 1500 patients who had undergone laser arcuate keratotomy with known pre- and postoperative outcomes. The nomogram has been used for over 200,000 procedures since it was made publicly available in October of 2012.

The results show that the LaserArcs nomogram significantly reduced preoperative astigmatism with a mean reduction of preoperative astigmatism of 81%. Postoperative uncorrected visual acuity was substantially similar to best-corrected visual acuity, suggesting that many patients undergoing LaserArcs treatment should be able to function postoperatively without correction, at least during distance vision tasks. Moreover, the accuracy of the correction was not significantly affected by variations in patient age, corneal power, magnitude of preoperative keratometric astigmatism, or preoperative spherical equivalent.

These results, with a mean postoperative manifest cylinder of 0.21 ± 0.28 D compare favorably with previously published literature on outcomes of femtosecond arcuate incisions. One study of 23 patients by Yoo¹³ with 1.0 to 3.0 D of preoperative astigmatism reported postoperative cylinder of 0.79 ± 0.11 D at one month. Another study by Wendelstein treating patients with preoperative corneal astigmatism of 0.75 to 2.5 D in 43 patients showed postoperative mean cylinder of 0.39 ± 0.25 D at one month.¹⁴

This analysis is also different from previous studies because it includes six eyes which underwent arcuate keratomies for preoperative corneal astigmatism of less than 0.5D. These low-astigmatism eyes are generally not included in studies of arcuate keratotomy because accurate determination of axis may be difficult and, in any case, some might debate the benefit of surgically correcting such low levels of astigmatism. Nonetheless, four of these six low-astigmatism patients who received arcuate incisions achieved zero astigmatism postoperatively, and those two which had an increase in postoperative astigmatism still achieved uncorrected acuity of 20/20. While these patients are too few for statistical analysis, the trend suggests that arcuate incisions were at least not harmful among the eyes examined, in this study, which had lower preoperative astigmatism than normally is evaluated in such studies.

Also, retrospectively identifying subjects for this study required reviewing charts of patients operated over a 14-month time period. This extended time period was necessary because one of the goals of the study was to include about one-third of patients with preoperative cylinder less than 0.7 D who received a multifocal implant and where astigmatism correction was desirable, but a sufficiently low power toric implant was not available in the US.

No safety issues were noted with the LaserArcs procedures in this study.

However, this study is not without limitations. It was performed at a single center with 50 eyes only. Among the LaserArcs-treated patients, greater refractive accuracy was found in younger vs older patients, those with lower vs higher

degrees of astigmatism, and those with flatter corneas. While these differences were not statistically significant, a study with larger numbers might reach statistical significance and help identify refinements to the nomogram. This study also did not include patients with prior refractive surgery. This exclusion was made to avoid variables that could confound the results. Future studies validating this nomogram may well include previously operated eyes to validate these techniques in that special patient population.

In a prospective study, it is standard to evaluate the astigmatic effect of incisional procedures by comparing preoperative to postoperative keratometric cylinder. In this retrospective study, the available data were limited to what was collected as part of standard clinical care, which postoperatively includes only a manifest refraction. Thus, the data analysis follows the guidance of Reinstein and others to evaluate postoperative manifest cylinder in light of preoperative corneal cylinder.¹⁵

In addition, as this study's goal was only to examine the LaserArcs nomogram's effectiveness, this study did not evaluate the full breadth of astigmatism surgery outcome metrics that a study assessing arcuate incisions as a surgical technique might have.

Long-term stability of surgical results is also not addressed in this one-month study. However, previous studies of arcuate keratotomy have reported stability 5 and 12 months postoperatively using similar surgical techniques.^{13,14} While more prolonged follow-up in this study could have demonstrated the stability of its refractive results, there is no reason to suspect any less stability than was demonstrated in these earlier publications.

These limitations are more than offset by the strengths of the study, which is the first to report on the widely used LaserArcs program's efficacy for the improvement of arcuate keratometry reduction of astigmatism.

Data Availability Statement

Reasonable requests for de-identified patient data relating to the study findings, including any outcome measures, will be available through the corresponding author, John A. Hovanesian, MD, for 5 years following the publication date.

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Disclosure

Dr Michael Jones is a co-owner of and the lead designer of the website for LaserArcs. In addition, Dr Michael Jones has a patent 9,480,603 B2 issued; and Dr Jones is a paid consultant for Alcon. Dr John A Hovanesian is a stockholder of and reports grants and personal fees from Alcon, during the conduct of the study. The authors report no other conflicts of interest in this work.

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