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ORIGINAL RESEARCH

The Clareon Vs AcrySof PanOptix Trifocal IOL: A Comparative Study of Patient Satisfaction and Visual Performance

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Video abstract

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Purpose: To evaluate patient-reported outcomes of cataract surgery using the Clareon Panoptix and Panoptix Toric trifocal lenses and to compare these to the data collected previously for the AcrySof Panoptix and Panoptix Toric.

Patients and Methods: Prospective, open-label, multicenter analysis of satisfaction, spectacle independence, presence of unwanted side effects, and best-corrected visual acuity among patients undergoing cataract surgery who had been implanted at least 1 month previously with the Clareon PanOptix or PanOptix Toric trifocal IOL bilaterally. Results were compared to outcomes measured two years ago from a similar study with the AcrySof version of the same lens.

Results: No significant differences in patient satisfaction rates were reported between the two cohorts. Spectacle independence was similar with 88% of Clareon Panoptix and 83% of AcrySof Panoptix patients having no need for any corrective lenses. Quality of vision was not statistically different with 7% of Clareon vs 15% of AcrySof patients reporting "very much" or more of glare/halo severity. Significantly more AcrySof (66%) than Clareon (42%) patients achieved a spherical equivalent outcome within 0.25 D of target. Best corrected distance visual acuity differences were not statistically significant, and no safety concerns were reported.

Conclusion: The Clareon PanOptix trifocal lens provides similar satisfaction and spectacle independence and has a similar side effect profile and BCVA outcome to the identical lens made of the predecessor AcrySof lens.

Plain Language Summary: In this prospective, non-interventional, open-label, multicenter analysis evaluating patient-reported outcomes 1 month after scheduled cataract surgery, patients had similar satisfaction and spectacle independence with the Clareon PanOptix and PanOptix Toric trifocal lenses when results were compared to a previous study of the same lenses made of the predecessor AcrySof lens.

Keywords: cataract surgery, spectacle independence, glare, multifocal intraocular lens, lens material

Introduction

The demand for presbyopia-correcting lens implants in cataract surgery has continued to increase in recent years in the United States with 17% of cataract surgery patients selecting options that provide some degree of spectacle independence when they undergo surgery.[1] Indeed, patients undergoing this common procedure are no longer typically retirees who live sedentary lifestyles. Almost a quarter of those over age 65 are still employed and are actively using technology to navigate their lives.[2,3] Technology that provides a full range of vision from distance to intermediate to near is particularly desirable.[4,5] For years, multifocal lenses have provided an acceptable solution with less need for spectacle correction than monofocals.[6,7] However, these lenses can take a toll on visual quality, with glare, halos, and reduced contrast sensitivity, but some patients are willing to accept these side effects in exchange for greater spectacle independence.[8–13] Longevity

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of the implant is also important, as the average patient age at cataract surgery is 68, and the average life expectancy in the US is almost 78, implying that the typical patient will require clarity of his or her vision for over ten and sometimes many more years.[14,15]

In an effort to improve optical quality and longevity of its implants, Alcon, in 2022 introduced the Clareon hydrophobic acrylic lens material to the US market.[16–20] The purpose of this study was to evaluate patient-reported outcomes of cataract surgery using the Clareon Panoptix and Panoptix Toric trifocal and compare these results to similar data collected previously for the same lenses but made of the traditional AcrySof lens material.

Materials and Methods

This single-arm, non-randomized, non-interventional study conducted at three centers with the study authors as surgeons, prospectively evaluated patient reported outcomes among patients who had undergone cataract surgery at least one month previously in both eyes and received an Alcon Clareon PanOptix or Clareon PanOptix Toric trifocal IOL in each eye. We compared results to those collected two years previously on a group of patients who had received the predecessor lenses made of the AcrySof material with identical inclusion/exclusion criteria completing an identical questionnaire.[21] Calculation of sample size for this study followed the rationale for the prior study, assuming a 10% margin of error and 95% confidence interval with a response distribution of 80%. This yielded a 62 patient sample size. To limit the effect of residual refractive error on study results, patients were eligible for this study only if their refractive error at the time of the questionnaire was within 0.5 D of Plano for spherical equivalent and 0.75 D for cylinder.

Exclusion criteria included residual spherical refractive error of greater than 0.5 D or residual cylindrical refractive error of 0.75 or greater. Patients were also excluded if they had prior refractive surgery, complications like capsular tears, iris trauma, decentration of the IOL, cystoid macular edema, ocular disease that might affect their outcome, or posterior capsular opacity of grade 1 or greater. Surgery was performed by traditional phacoemulsification with or without assistance from a femtosecond laser. All cataract surgery was performed in both eyes on separate dates. Biometry was performed with a Zeiss IOLmaster 700 or Haag Streit LenStar 900. IOLs were selected for the lowest positive predicted spherical equivalent and lowest amount of predicted residual cylinder. The study was approved by WCG IRB (Puyallup, Washington) as protocol #20222354 and listed in ClinicalTrials.gov as NCT05346172. The protocol followed the principles of the Declaration of Helsinki, and patients completed an informed consent to participate. The corresponding author will honor reasonable requests for data for a period of 2 years following this study's publication date.

Enrolled patients completed a validated questionnaire to determine their outcome of surgery, including satisfaction and freedom from spectacles. This questionnaire is included in the Supplemental Information. Investigators also collected manifest refraction and best-corrected distance visual acuity as well as a slit lamp exam to evaluate exclusion criteria such as PCO.

PRO Questionnaire

The questionnaire administered (Research InSight LLC, Laguna Beach, CA, USA) had been created to evaluate patients receiving presbyopia-correcting IOLs as to their satisfaction and spectacle independence as well as the presence and severity of unwanted visual side effects. US Cataract surgeons have routinely used this software since 2014 as part of the MDbackline software suite, and the collective has been validated as well as published in number of studies.[22,23]

Results

Demographics

Sixty patients with a cataract diagnosis were enrolled with the Clareon PanOptix lens with mean age 67 ± 10.5 years (range 36–84), and 55% were females, compared to the 59 patients in the AcrySof PanOptix group who had average age of 69 ± 9.6 years (range 41–100) with 56% females (Table 1). These differences were not statistically significant. Femtosecond laser-assisted cataract surgery was performed in 78% of the Clareon and 88% of the AcrySof patients ($P > 0.14$, McNemar's Chi-Squared Test).

Table 1 Study Participants

	Clareon Panoptix	AcrySof Panoptix
N	60	59
Age (yrs)	67 ± 10.5 (range 36–84	69 ± 9.6 (range 41–100)
Age range	36–84	41–100
Females	55%	56%

A toric lens was used in both eyes in 31 (52%) Clareon and 29 (49%) AcrySof patients, in one eye of 11 (18%) of Clareon and 12 (20%) of AcrySof, and in neither eye in 18 (30%) Clareon and 18 (31%) AcrySof eyes.

Satisfaction

Differences in satisfaction reports did not show any statistical significance. Satisfaction was reported as "very satisfied" in 77% of Clareon and 85% of AcrySof Panoptix patients, "somewhat satisfied" by 22% and 12%, "neither satisfied nor dissatisfied" in 2% of each group, "somewhat dissatisfied" by 0 and 2%, and "very dissatisfied in no patient in either group (Figure 1).

Spectacle Freedom

Spectacle independence was high and not significantly different for both groups with 88% of Clareon Panoptix and 83% of AcrySof Panoptix patients reporting no need for corrective lenses for any activity ($P > 0.44$, McNemar Chi-squared test, Figure 2). The only activity where more than a single patient reported spectacle need was reading (including fine print), where 8% of Clareon and 17% of AcrySof patients reported a need for glasses ($P > 0.13$, Mcnemar's Chi-squared test). The frequency of needing glasses was similar between groups as shown in Figure 3.

Quality of Vision (Glare and Halos)

No significant differences were observed in reporting of "glare or haloes around lights in dim light situations" between the two lens materials (Figure 4). The bother reported from glare or halos were described as "very much", or "extremely"

Figure 1 Satisfaction with both Clareon and AcrySof IQ Panoptix lenses was high, with no significant differences between responses.

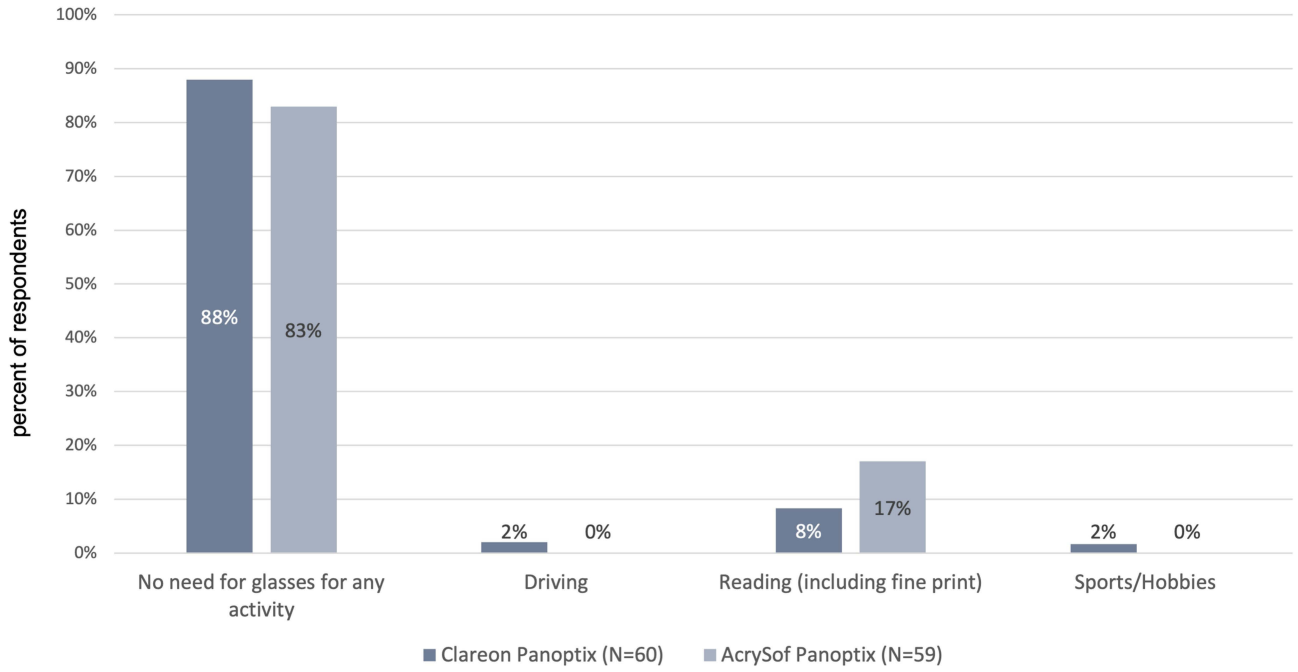

Figure 2 Spectacle need by activity was similar between Clareon and AcrySof IQ Panoptix lenses with no statistically significant differences.

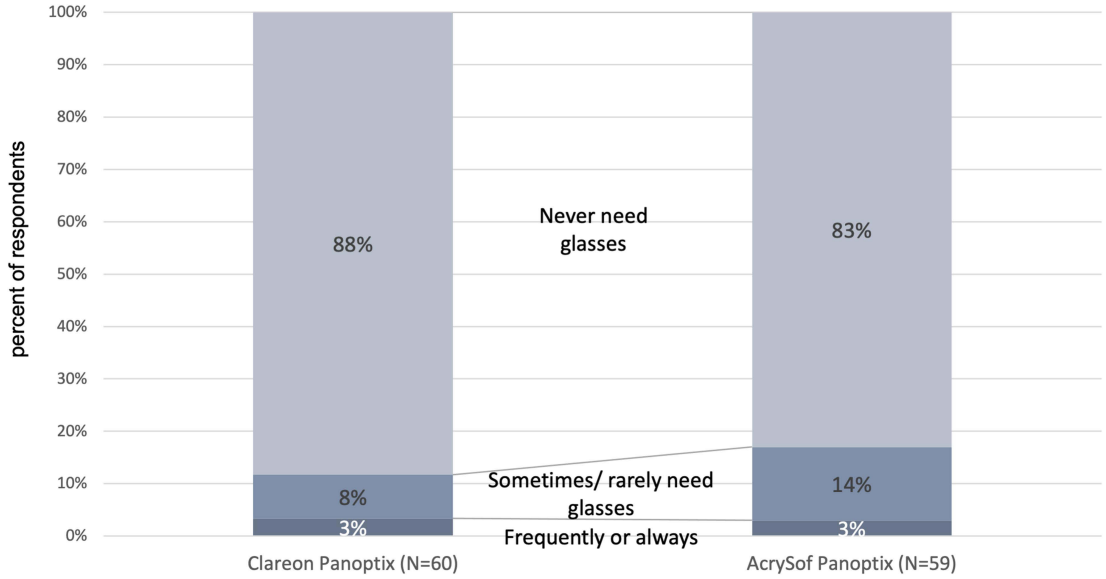

Figure 3 Frequency of needing spectacles was similar between the Clareon and AcrySof IQ Panoptix lenses.

for 7% of Clareon Panoptix and 15% of AcrySof Panoptix patients ($P > 0.16$, McNemar's Chi-squared test), and "not at all" or "just a little" was the response of 67% and 69%, respectively ($P > 0.30$).

Refractive Accuracy

Significant differences were noted between groups for spherical equivalent refractive accuracy. While all patients in both groups were within 0.5 D of Plano—an inclusion criterion for participation in this study–the proportion of patients within 0.25 D of Plano was 42% among patients with the newer Clareon material, which did not have a surgeon-individualized lens constant, and 66% for the AcrySof implants, where a surgeon-individualized lens constant was used. The proportion

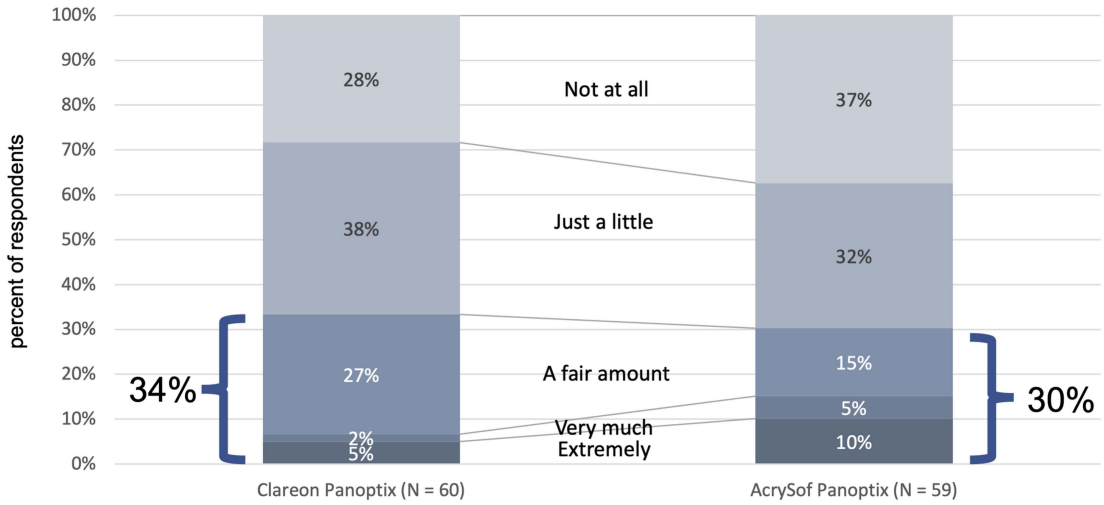

Figure 4 Severity of glare and halos were similar between the Clareon and AcrySof IQ Panoptix lenses.

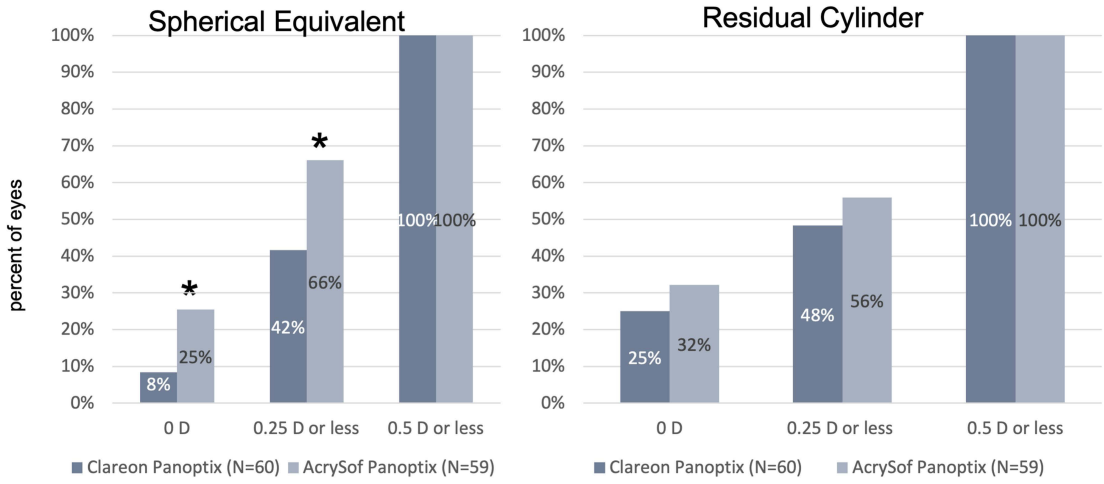

Figure 5 Refractive accuracy was similar for both lenses, but significant differences, noted with *Were noted for the proportion of eyes within 0 and 0.25 D of the target of Plano ($p< 0.01$, McNemar's Chi-Squared test).

with zero diopters of residual sphere was 8% of Clareon and 25% for AcrySof ($p< 0.01$, McNemar's Chi-Squared test for both comparisons). All other measures of refractive accuracy were similar between the two lens implants (Figure 5).

Best corrected distance visual acuity was very similar for both lenses, with 100% of patients achieving 20/30 or better 97% and 93% achieving 20/25 or better, and 75% and 76% achieving 20/20 or better acuity for the Clareon and AcrySof materials, respectively (Figure 6).

Discussion

AcrySof acrylic intraocular lenses were first introduced in 1990 and may be among the most widely implanted medical material in the developed world, given the rate of cataract procedures and this manufacturer's market share. Still, for many years, this lens material has been the subject of discussion on whether it develops "glistenings" that may degrade visual functioning, and the new Clareon material was developed to address these concerns.[24,25] The AcrySof IQ Panoptix trifocal lens was first introduced in Europe in 2015 and to the US in 2019.[21] To our knowledge, this is the first study that has directly examined patient satisfaction, comparing the new Clareon Panoptix and Clareon Panoptix Toric IOL to its predecessors made of the AcrySof material. The

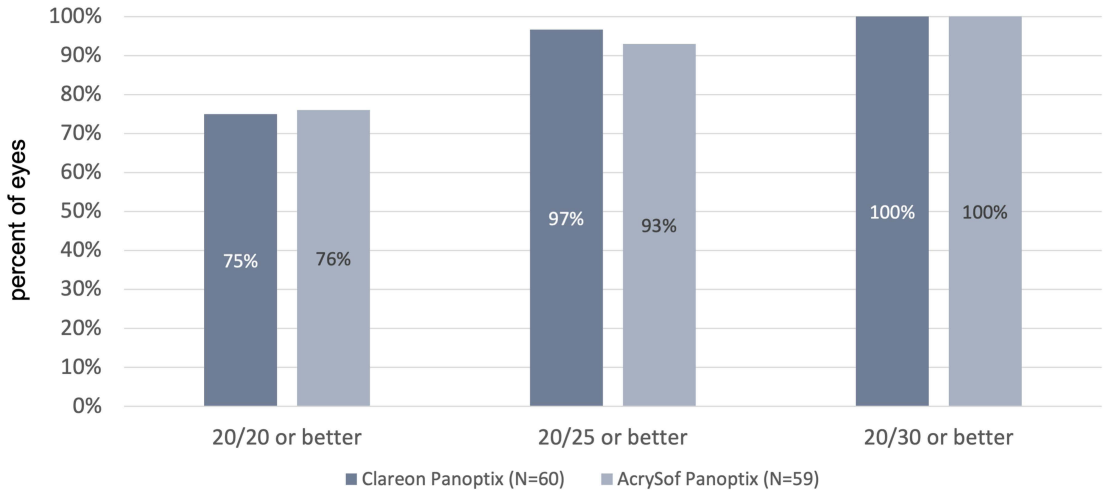

Figure 6 No differences in best corrected visual acuity were statistically significant (P>0.05, Chi squared test).

study showed no significant differences in patient satisfaction, spectacle independence, or complaints of problems with quality of vision.

Introducing a new lens material is a rare and important event for the eye care industry, for surgeons, and most of all for patients. Therefore, understanding the functional characteristics of this new material is important in cataract surgery.

Refractive accuracy is paramount to patient satisfaction in refractive cataract surgery. The inclusion criteria for this study required all patients to have 0.5 D or less of spherical refractive error and 0.75 D or less of cylindrical refractive error to be included. Among the two groups studied, a significant difference was found in the proportion of patients who had both $\leq$ 0.25 D and 0 diopters residual spherical error, with greater accuracy seen in the AcrySof group. We believe this difference occurred because the surgeons who enrolled patients had many years greater experience with the AcrySof lens material and were using individualized lens constants, which were not yet available for the Clareon lens material at the time of this study. Therefore, greater optimization of the AcrySof lens constants had occurred, and not surprisingly, greater accuracy was noted. The greater accuracy seen with AcrySof lenses may also explain the slightly greater (though not significant) reports of overall satisfaction among patients whose surgery had been performed with the older lens material. That the difference in overall satisfaction was not significant suggests that, even with significantly less accuracy for the finer points of refractive outcome, the new Clareon lens material performed comparably in the eyes of these patients.

This study is limited by the fact that the comparison groups underwent surgery at different times, with the AcrySof group undergoing surgery three years prior to the Clareon group. Despite the time difference, both groups had identical surgery performed by the same surgeons, were subjected to identical inclusion and exclusion criteria, completed identical tests in the same office settings, and both groups completed identical questionnaires. Nonetheless, small differences in the circumstances of the study could confound outcomes to some small degree. We do not believe a different study design to avoid this limitation would be realistic, given that the new lens material with its several benefits has become the standard implant used in the United States. Furthermore, the likelihood of a different outcome with contemporaneous patient enrollment is small.

Finally, this study evaluates outcomes one month after surgery. Certainly, this study does not attempt to report on long-term safety or outcomes, which will require many years of follow-up to determine. Still, this early measure of outcomes may provide additional confidence to surgeons considering working with this novel lens material.

Conclusion

The PanOptix multifocal IOL made of the Clareon hydrophobic acrylic performed similarly in terms of patient satisfaction and spectacle independence to the same lens in the predecessor AcrySof.

Acknowledgments

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Disclosure

Dr John Hovanesian reports grants, personal fees from Alcon, during the conduct of the study; personal fees from Alcon, outside the submitted work. Dr Michael Jones has nothing to disclose. Dr Quentin Allen reports Consultant from Alcon, during the conduct of the study.

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