Wavefront-optimized Surface Ablation With the Allegretto Wave Eye-Q Excimer Laser Platform: 12-month Visual and Refractive Results

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ABSTRACT

PURPOSE: To evaluate the wavefront-optimized algorithm of the Allegretto Wave Eye-Q (Wavelight AG) 400-Hz excimer laser platform.

METHODS: Three hundred three eyes of 303 patients treated with advanced surface ablation were evaluated prospectively. Topical mitomycin C (MMC) was used when ablation was ⩾80 μm. Efficacy, safety, and predictability at 12 months were quantified with subjective refraction, visual acuity (logMAR), and slit-lamp examination.

RESULTS: Mean postoperative uncorrected distance visual acuity (UDVA) was 20/20.5 (0.01±0.05 logMAR). Postoperative UDVA was equal or better than preoperative corrected distance visual acuity (CDVA) in 94.7% of eyes. Efficacy index was 1.05. Corrected distance visual acuity was maintained (93.7%) or improved (5.9%) in 99.6% of treated eyes. No patient lost ⩾2 lines. Safety index was 1.05. Haze at 12 months was grade ⩽0.5 in 98% of treated eyes and grade ⩽1 in 100% of treated eyes. Mean postoperative manifest refraction spherical equivalent (MRSE) was −0.03±0.15 diopters (D). Postoperative MRSE was within ±0.50 D in 99% of eyes. Overcorrection was documented in 0.66% and undercorrection in 0.33% of eyes.

CONCLUSIONS: The wavefront-optimized algorithm of the Allegretto Wave Eye-Q excimer laser platform showed good efficacy, safety, and predictability in advanced surface ablation, with or without MMC intraoperative use. [*J Refract Surg.* 2011;27(11):792-795.]

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The wavefront-optimized algorithm of the Allegretto Wave Eye-Q 400-Hz excimer laser platform (Wavelight AG, Erlangen, Germany) is conceived to offset 4th order aberrations induced by excimer laser ablation by taking some eye variables into account and using pre-planned ablation profiles based on a large population analysis.[1] This nomogram is conceived to preserve the natural aspheric shape of the cornea. This nomogram increases ablation depth in the midperiphery of the optical zone, compensating for the loss of energy caused by the angle of the laser beam.[2] The aim of this study was to validate (quantifying efficacy, safety, and predictability results) the wavefront-optimized algorithm for advanced surface ablation, with or without the intraoperative application of topical mitomycin C (MMC) according to ablation depth.

PATIENTS AND METHODS

All patients included in this study were targeted for emmetropia and had 12-month follow-up. Patients with unstable refraction, anterior or posterior uveitis, corneal scarring, excessive dry eyes, blepharitis, or systemic disease likely to affect epithelial healing were excluded. Patients with keratoconus, corneal dystrophy or degeneration, glaucoma, retinal diseases, history of severe ocular trauma, or previous ocular surgery were also excluded.

Preoperative measures included manifest and cycloplegic subjective refraction, slit-lamp evaluation, applanation tonometry, Schirmer I test, indirect fundus ophthalmoscopy, orthoptic examination, pupillometry, corneal topography, and corneal confocal microscopy. Visual acuity was measured with Snellen charts and converted to logMAR equiva-

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lents for statistical analysis. Corneal topography was performed with the Allegretto Oculyzer (WaveLight AG), which is based on the technology of the Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany), using a rotating Scheimpflug camera to image the anterior segment of the eye.

A detailed explanation of the treatment was given to all patients, and informed consent was obtained before any procedure. This protocol was approved by the institutional review boards of the involved institutions. All patients were treated using the wavefront-optimized algorithm of the Allegretto Wave Eye-Q excimer laser with a 400-Hz active eye-tracker and 0.95-mm Gaussian laser beam.

A topical anesthetic (oxybuprocaine 0.4% drops, Novesina; Novartis Farma, Milan, Italy) was used before surgery. Chemical epithelial removal was performed with a 20% ethanol balanced salt solution. Epithelium was removed with a sponge and excimer laser treatment was applied. Immediately after treatment, patients with ⩾80-µm planned ablation received a single topical application of MMC 0.02% administered by placing a soaked sponge over the ablated stroma for 2 minutes, according to a previous protocol.[3] The corneal surface and entire conjunctival fornix were thoroughly irrigated with 20 cc of balanced salt solution. At the end of the procedure, levofloxacin (Oftaquix; Tubilux Pharma, Pomezia, Italy) was administered in all treated eyes. Levofloxacin eye drops were used four times a day until complete corneal reepithelialization. All eyes were treated with artificial tears (carboxymethylcellulose sodium 0.5%, Optive; Allergan, Westport, Ireland) three times a day for 3 months and topical dexamethasone (Etacortilen; SIFI, Catania, Italy) four times a day for 1 month. Patients were observed at 1 week and 6 and 12 months. During follow-up, corneal topography and confocal microscopy were performed at 6 and 12 months.

Mean outcome measures concerned efficacy, safety, and predictability at 12 months. Efficacy was evaluated by comparing each patient's postoperative uncorrected distance visual acuity (UDVA) to preoperative corrected distance visual acuity (CDVA). Efficacy index was calculated as the ratio between mean postoperative UDVA and mean preoperative CDVA. Safety assessment included comparison between post- and preoperative CDVA, safety index (mean postoperative CDVA/mean preoperative CDVA), and grade of corneal haze. Corneal haze was graded according to the haze grading system reported by Fantes et al.[4] Predictability outcomes were postoperative manifest refraction spherical equivalent (MRSE) within ±0.50 diopters (D) and percentages of over- and undercorrection. All statistical analyses were performed with SAS 9.2 software (SAS Institute Inc, Cary, North Carolina). Only right eyes were considered for statistics. To verify the significance of surgical treatment result in terms of efficacy and safety between postoperative UDVA and preoperative CDVA and between postoperative CDVA and preoperative CDVA, respectively, *t* test was performed. For predictability assessment, linear regression analysis of achieved MRSE versus attempted MRSE was performed.

TABLE

Preoperative Parameters of 303 Eyes That Underwent Advanced Surface Ablation With the Allegretto Wave Eye-Q Excimer Laser Platform

Population	N (%)
Female	200 (66)
Male	103 (34)
Myopia	111 (36.63)
Simple myopic astigmatism	4 (1.32)
Compound myopic astigmatism	188 (62.05)
Parameter	**Mean±SD (Range)**
Age at surgery (y)	34.2±6.7 (20 to 54)
CDVA (logMAR)	0.024±0.043 (−0.040 to 0.220)
Pachymetry (µm)	552.40±31.91 (438.0 to 670.0)
Sphere (D)	−4.12±2.01 (−10.25 to −0.50)
Cylinder (D)	0.67±0.77 (3.50 to 0.25)
MRSE (D)	−4.45±2.00 (−11.00 to −1.00)
K1 (D)	43.07±1.43 (38.80 to 46.70)
K2 (D)	44.05±1.38 (40.30 to 48.30)

CDVA = corrected distance visual acuity, MRSE = manifest refraction spherical equivalent, K1 = flat meridian curvature (simK), K2 = steep meridian curvature (simK)

RESULTS

Three hundred three consecutive patients received advanced surface ablation. Patient demographics are listed in the Table. Intraoperative MMC was administered in 42.6% of treated eyes. At 12 months, mean postoperative UDVA was 20/20.5 (0.01±0.05 logMAR; range: 0.3 to −0.04 logMAR). In 94.7% (287/303) of eyes, postoperative UDVA was equal or better than

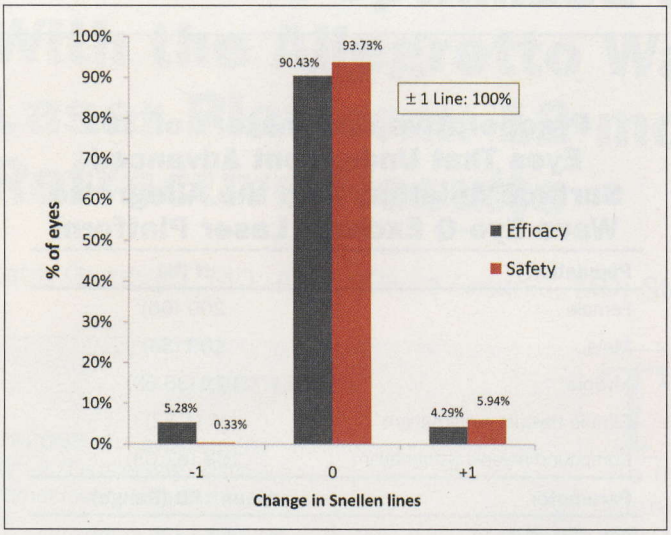

Figure 1. Visual results at 12 months. Efficacy is reported as difference in Snellen lines between postoperative corrected distance visual acuity (CDVA) and preoperative uncorrected distance visual acuity. Safety is reported as the difference in Snellen lines between postoperative and preoperative CDVA.

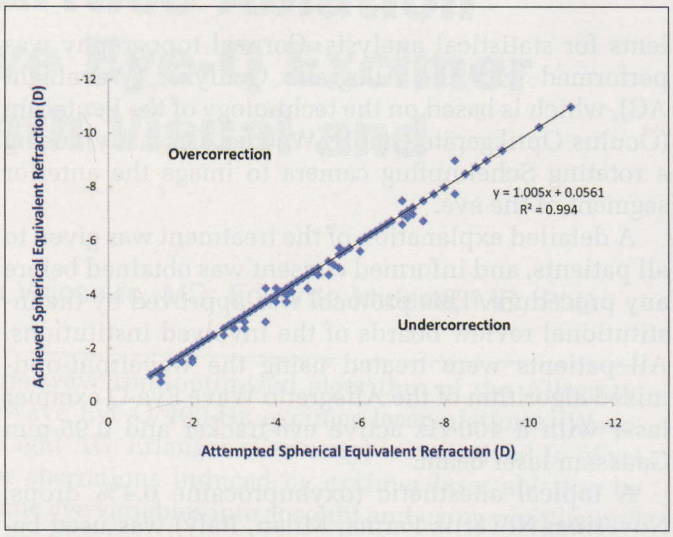

Figure 2. Scatterplot of accuracy at 12 months. Difference between measured and intended postoperative manifest refraction spherical equivalent.

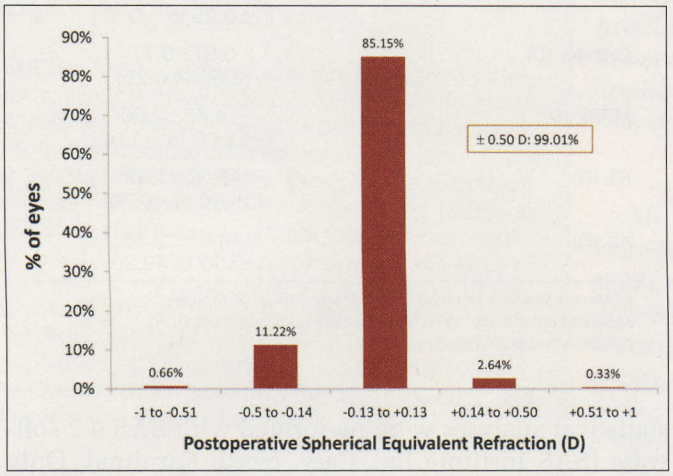

Figure 3. Spherical equivalent refraction predictability at 12 months. Distribution of postoperative manifest refraction spherical equivalent.

preoperative CDVA ($P<.001$). Safety index and efficacy index at 12 months were both 1.05 (Fig 1). Haze was grade ≤0.5 in 98% of eyes and grade ≤1 in 100% of eyes. Mean postoperative MRSE was −0.03±0.15 D (range: −0.75 to 0.75 D), and postoperative MRSE was within ±0.50 D in 99% of eyes (Figs 2 and 3).

DISCUSSION

In this study, the wavefront-optimized algorithm of the Allegretto Wave Eye-Q 400-Hz excimer laser platform showed good efficacy, safety, and predictability in advanced surface ablation. Wavefront-optimized correction demonstrated a high safety profile, with no eye losing 2 or more lines of CDVA and a low incidence of haze. The intraoperative use of topical MMC, whose long-term safety profile has been reported recently,[5] also contributed to these findings.

Current reports on aspheric and customized algorithms (topography-guided, wavefront-guided, and custom-Q) show that postoperative results are similar independent of the laser platform used.[6-17] In previous studies, the wavefront-optimized algorithm of the Allegretto Wave 200-Hz excimer laser platform was used and eyes were treated with LASIK.[1,14-21] Studies regarding wavefront-optimized correction using the Allegretto Wave Eye-Q 400-Hz excimer laser platform and advanced surface ablation are limited.[17,18,20,21]

Previous studies using the Allegretto 200-Hz excimer laser platform in LASIK report 20/20 or better postoperative UDVA in 70.5% to 93% of treated eyes and accuracy within ±0.50 D in 81.9% to 89%, with follow-up ranging from 3 to 6 months.[1,14,16,18,19] Studies concerning the same excimer laser platform in advanced surface ablation show 20/20 or better postoperative UDVA in 80% to 100% of treated eyes.[18,20,21] Randleman et al[18] compared results of LASIK and advanced surface ablation using the Allegretto 200-Hz platform and concluded that advanced surface ablation is an effective alternative to LASIK. Kymionis et al[20] evaluated the Allegretto 200-Hz and 400-Hz platforms and found comparable results in surface treatments. Using the 400-Hz platform, postoperative UDVA was 20/20 or better in 83% of eyes and postoperative MRSE was within ±1.00 D in 96.9% of eyes. Maerza et al,[17] who evaluated LASIK results with the Allegretto 400-Hz platform, reported mean postoperative UDVA of

0.96±0.22 (decimal) and postoperative MRSE within ±0.50 D in 86% of eyes.

The major limitation of the current study is the lack of more detailed subjective evaluation of the quality of vision, including patient satisfaction. Moreover, an aberrometric evaluation may also be useful, as the wavefront-optimized algorithm has been specifically designed to minimize the induction of higher order aberrations, which may result in poor postoperative subjective quality of vision. The specific evaluation of these functions is ongoing in a new protocol.

The wavefront-optimized algorithm of the Allegretto Wave Eye-Q 400-Hz excimer laser platform showed good visual and refractive results, confirming advanced surface ablation, with MMC when necessary, as an effective and safe option for excimer laser corneal refractive surgery. Refractive surgery techniques and protocols are continuously improving to achieve better results with faster and painless visual recovery. Further improvements in the understanding of corneal biomechanical changes and in controlling corneal wound-healing responses could enhance excimer laser surgery outcomes to higher levels of efficacy, safety, and predictability.

AUTHOR CONTRIBUTIONS

Study concept and design (C.G., A.G.C., S.V., E.M.); data collection (A.G.C.); analysis and interpretation of data (C.G., A.G.C., S.V., E.M.); drafting of the manuscript (A.G.C.); critical revision of the manuscript (C.G., S.V., E.M.); supervision (E.M.)

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