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Wavefront-optimized laser in situ keratomileusis with the Allegretto Wave Eye-Q excimer laser and the FEMTO LDV Crystal Line femtosecond laser: 6 month visual and refractive results

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ABSTRACT

Purpose: To present the first reported series of patients undergoing myopic LASIK with the FEMTO LDV Crystal Line femtosecond laser and the WaveLight Allegretto Eye-Q excimer laser. We report the uncorrected and corrected distance visual acuity (UDVA and CDVA), refractive predictability, efficacy and safety of laser in situ keratomileusis (LASIK) performed with the above laser platforms.
Methods: This prospective interventional case series study evaluated consecutive eyes with low to moderate myopic astigmatism that underwent LASIK with the FEMTO LDV Crystal Line femtosecond laser and the WaveLight Allegretto Eye-Q 400 Hz excimer laser. Visual and refractive changes as well as complications were evaluated after wavefront-optimized laser treatment.
Results: Four hundred and forty four patients (887 eyes) reached the 6-month time gate. Mean age at time of procedure was 31 years (range: 20–59). Mean pre-op spherical-equivalent (SE) was −3.44 diopters (D) ± 1.34 D (range: −0.50 to −7.00) whilst the postoperative spherical equivalent decreased to −0.08 ± 0.31 D (range −2.25 to 1.00). At 6-month follow up, 96.9% of patients had monocular uncorrected distance visual acuity of 20/20 or better with 95.2% of patients within ±0.5 D of intended refractive outcome. All patients achieved 20/20 binocular distance uncorrected visual acuity. No significant intraoperative or postoperative complications were encountered during the 6-month follow-up period.
Conclusions: The combination of the above laser platforms provides safe, effective and predictable results in correcting compound myopic astigmatism with excellent visual outcomes.

1. Introduction

Laser in situ keratomileusis (LASIK) is currently the most common refractive surgical procedure performed for the correction of myopia, hyperopia, and astigmatism [1]. The advantages of LASIK include rapid postoperative improvement of visual acuity, negligible postoperative discomfort, and the possibility of further enhancement [1,2]. The effectiveness, safety, and stability of LASIK for the correction of refractive errors have been well documented, with advancements in technology further improving clinical outcomes over the past decade [3].

The introduction of femtosecond laser flap creation has significantly reduced flap-related complications whilst the next generation of excimer laser machines have contributed to further enhanced refractive results of LASIK [4]. As new lasers emerge in the market, it is important to assess and compare their results with existing reports of clinical outcomes in the peer reviewed literature.

The aim of the current study was to evaluate the visual and refractive outcomes of LASIK for the correction of low to moderate myopic astigmatism using the FEMTO LDV Crystal Line femtosecond laser (Ziemer Ophthalmic Systems, Switzerland) and the WaveLight Allegretto Eye-Q 400 Hz (Alcon Laboratories, Inc., Fort Worth, TX). To the best of our knowledge, this is the first reported series of patients undergoing myopic LASIK with the above mentioned laser platforms.

1.1. Patients and methods

This prospective study included consecutive eyes with low to moderate amounts of myopic astigmatism that had LASIK. All patients provided written informed consent in accordance with the tenets of the Declaration of Helsinki.

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Inclusion criteria for the study were low to moderate myopia (−0.50 to −6.00 D sphere and 0 to −3.50 D cylinder) and age between 20 and 59 years. Exclusion criteria were topographic corneal irregularity consistent with any degree of keratoconus, estimated residual stromal thickness of less than 300 μm after laser ablation, unstable refraction, nonrealistic expectations, history of previous refractive surgery, previous intraocular surgery or a history of ocular pathology. Patients discontinued soft contact lens wear at least 1 week prior and rigid gas-permeable contact lenses at least 1 month prior to the preoperative examination.

1.2. Preoperative examination

The preoperative ophthalmologic examination included uncorrected (UDVA) and corrected (CDVA) distance visual acuities, manifest refraction, slit lamp biomicroscopy, Goldmann applanation tonometry, corneal topography (Pentacam, Oculus, Optikgeräte, GmbH, Germany), ocular wavefront aberrometry (OPD scanner, NIDEK, Gamagori, Japan) and fundoscopy.

1.3. Surgical technique

All surgeries were performed by either A.M. or D.A. Two drops of proxymetacaine were administered immediately prior to surgery. Initially a 110 μm flap with a superior hinge and a 9.0 mm or 9.5 mm diameter (depending on pre-op K readings) was created using the FEMTO LDV femtosecond laser. Thereafter the flap was elevated and stromal ablation was performed with the Allegretto Wave 400 Hz excimer laser, preserving the flap edges and hinge. All eyes received wavefront-optimized treatment and emmetropia was targeted making nomogram adjustments as per the manufacturer recommendations.

After excimer ablation, the flap was replaced and the interface thoroughly irrigated to eliminate any residual epithelial cells, meibomian gland material, and debris. Postoperatively, Predforte (Allergan, Irvine, USA) was used 2 hourly for the first 2 days, then four times a day for a further 5 days. In addition, Ofloxacin 0.3% (Allergan, Irvine, USA) was used four times a day for the first week and Celluvisc 1.0% (Allergan, Irvine, USA) was used 2 hourly for the first week, then as required thereafter.

1.4. Postoperative follow-up

Patients were seen at day 1, week 1, month 1, month 3 and month 6 post-operatively. Outcome measures were uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), refractive error and proximity to target refraction at the 6-month time gate. The efficacy index was calculated as the ratio between mean postoperative UDVA and mean preoperative CDVA whilst the safety index was calculated as the ratio between mean postoperative CDVA and mean preoperative CDVA. Complications and loss of CDVA were also recorded.

1.5. Statistical analysis

Statistical analysis was performed with the SPSS for Windows software (version 15.0, SPSS, Inc., Chicago). Snellen visual acuity was transformed into logMAR units for statistical analysis. The Student *t* test for paired data was used for comparison between the parametric preoperative and postoperative data. Statistical significance was considered at $P < 0.05$.

2. Results

The study included 887 consecutive eyes of 444 patients. The mean age of patients at the time of procedure was 31 years

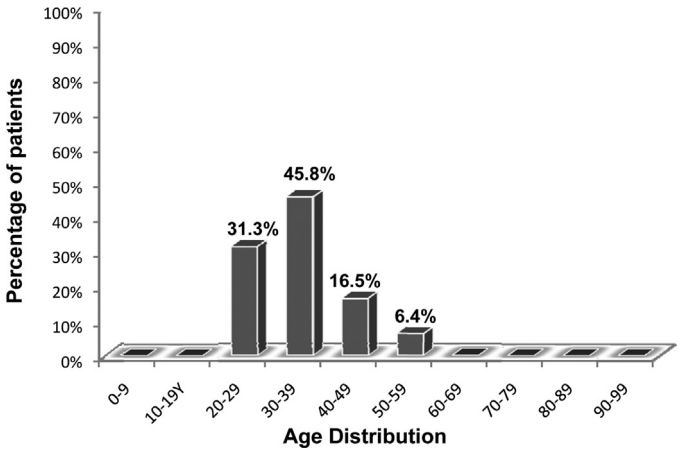

Fig. 1. Preoperative CDVA versus postoperative UDVA at 6 months (CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity).

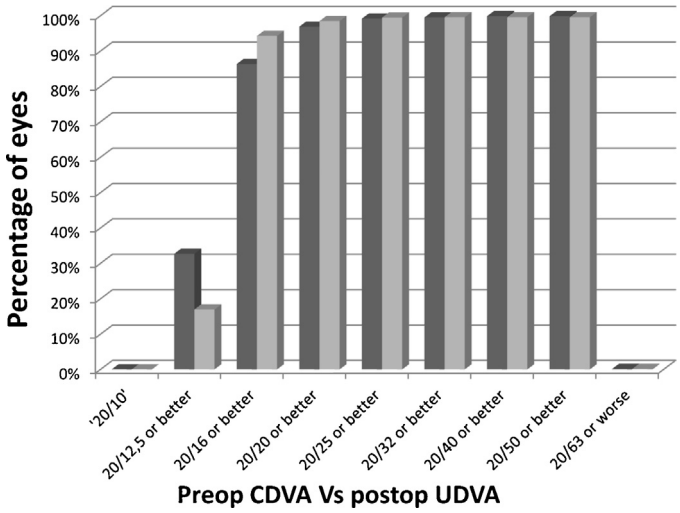

Fig. 2. Postoperative binocular UDVA (UDVA = uncorrected distance visual acuity).

(Fig. 1). The preoperative and postoperative refractive outcomes are demonstrated in Table 1. The mean preoperative spherical equivalent (SE) decreased significantly 6 months postoperatively ($P < 0.01$, paired *t* test). At the 6-month follow-up visit, 1.2% of patients who had not achieved 20/20 UDVA underwent monocular LASIK enhancement. All patients undergoing enhancement achieved 20/20 or better UDVA after 3 months of retreatment.

2.1. Efficacy

All eyes had 20/50 or worse UDVA preoperatively. At the 6-month follow-up visit, the UDVA was 20/20 or better in 860 eyes (96.9%) and 20/32 or better 883 eyes (99.5%) (Fig. 2). All patients achieved 20/20 or better binocularly (100%). The efficacy index (ratio of mean postoperative UDVA to mean preoperative CDVA) was 1.13.

2.2. Safety

At the 6-month follow-up visit, 505 eyes (56.9%) had no change in CDVA, 319 eyes (35.9%) gained one line or more whilst 54 eyes (6.0%) lost one line (Fig. 3). The safety index (ratio of mean postoperative CDVA to mean preoperative CDVA) was 1.08.

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