LASIK in high hyperopia with WaveLight Allegretto Eye-Q excimer laser – One year results

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PURPOSE: To present one-year results after LASIK in high hyperopia with spherical equivalent (SEQ) of more than 3D using WaveLight Allegretto Wave 400Hz excimer laser and WaveLight Rondo microkeratome.

METHODS: Fifty-one eyes of 30 patients underwent LASIK to correct hyperopia. WaveLight Allegretto Wave 400 Hz excimer laser was used and flaps were created with WaveLight Rondo microkeratome. Mean preoperative SEQ was +4.16 ± 1.44 D (range: +3.25 to +8.00), and mean cylinder was -1.44 ± 1.52 D (range: 0 to -5.00). Mean preoperative UVA was 0.10 ± 0.12 (range: 0.01 to 0.40), while mean BSCVA was 0.69 ± 0.18 (range: 0.40 to 1.00). Uncorrected and best spectacle corrected visual acuities (UVA and BSCVA), as well as manifest refraction, were recorded at 1, 6 and 12 months after the treatment.

RESULTS: One month postoperatively UVA and BSCVA increased to 0.52 ± 0.23 (range: 0.3 to 0.8) and 0.66 +/- 0.19 (range 0.4 to 1.0) respectively and did not change statistically over 1-year interval (p=0.154 and p=0.196 respectively). One eye lost one line, 35 maintained, and 5 eyes gained one line of BSCVA. Manifest SEQ decreased to -0.35 ± 0.88 D (range: -2.00 to +1.00) at 1 month and stabilized at -0.41 ± 0.50 D (range: -2.00 to 0) at 1 month and did not change statistically over 1-year (p=0.500).

CONCLUSIONS: LASIK in high hyperopia using WaveLight Allegretto Wave provided predictable and stable results over the period of 1 year follow-up, comparable to the outcomes of low to moderate hyperopia. An initial overcorrection was planned to counteract a possible regression.

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The inclusion criteria were hyperopic sphere of at least +4.0 D, astigmatism of up to 5.0 D; with a minimal spherical equivalent of +3.0 D. Patients under 18 years old, those with history of previous corneal surgery, history to herpetic eye disease, corneal dystrophy, corneal scarring, keratoconus, severe dry eye, and collagen vascular diseases were excluded from this study.

Preoperative evaluation included uncorrected visual acuity (UCVA), refraction (manifest and cycloplegic), best spectacle corrected visual acuity (BSCVA), slit lamp examination, fundus evaluation, corneal tomography with the ALLEGRETTO WAVE Oculyzer™ (Oculus, Wetzlar, Germany), corneal topography with the ALLEGRETTO WAVE Topolyzer™ (Oculus, Wetzlar, Germany), and ultrasound corneal pachymetry with the Nidek US-1800 (Echoscan, Aichi, Japan).

All surgeries were performed by a single surgeon (MJ) in an outpatient refractive surgery clinic in Belgrade, Serbia. Measurements and data gathering were obtained by the surgeon and his staff.

The procedures were carried out under topical anaesthesia with a drop of proparacaine 1 % (Alcaine, Alcon, Fort Worth, Texas) instilled into patient’s eye just before the procedure. Eyelids were cleaned with povidone iodine antiseptic 10% (Betadine, Purdue Pharma L.P. CT) and the eye lashes were isolated with sterile plastic drapes (Tegaderm, 3M Health Care, St. Paul, Minnesota). The WaveLight Rondo microkeratome was used to cut the corneal flaps with a nasal hinge in all cases. The flaps were cut to expose a stromal bed of at least 9.0 mm in diameter to accommodate hyperopic (large diameter) ablations.

The ALLEGRETTO WAVE excimer laser (Alcon-WaveLight, Erlangen, Germany) was used to perform the ablations in all cases. These were all wavefront optimized (non-wavefront guided) ablations. We targeted to correct the cycloplegic refraction for emmetropia in all cases in this study. The ALLEGRETTO WAVE excimer laser is a flying spot laser system; it works with a 0.95 mm Gaussian spot and fires at a rate of 400 Hz. Eye tracking latency is 6 ms. Optical zone diameter 6.5 mm and together with the transition, the total ablation zone was 9.0 mm.

The spherical corrections were achieved by ablating an annular zone of tissue in the mid-peripheral cornea making the central cornea steeper. The cylindrical refractive error was corrected on a similar manner by ablating the mid-peripheral zone of the flat meridian.

Patients were examined half an hour after the surgeries to check for any flap irregularities or complications. Patients were seen at regular postoperative intervals at 1 day, 4 days, 1 month, 3 months, 6 months and at 12 months when the manifest refraction were repeated.

Paired student t-test was performed for statistical analysis, and the p values of <0.05 were regarded as statistically significant.

RESULTS

Forty-one eyes of 23 patients (80%) of the initial 51 eyes were available for follow up on the 12th month; seven patients (10 eyes) were lost to follow up.

There were no significant intra-operative complications noted in this limited group.

Pre and postoperative results can be found on Table 1. One month postoperatively UVA and BSCVA

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increased to \(0.52 \pm 0.23\) (range: 0.3 to 0.8) and 
\(0.66 \pm 0.19\) (range 0.4 to 1.0) respectively and did not 
change statistically over 1-year interval (p=0.154 and 
p=0.196 respectively).

One eye lost one line, 35 maintained, and 5 eyes 
gained one line of BSCVA.

Manifest SEQ decreased to \(-0.35 \pm 0.88\) D (range: 
\(-2.00\) to \(+1.00\)) at 1 month and stabilized at 
\(-0.16 \pm 0.65\) D (range: \(-0.75\) to \(+1.00\)) at 1-year fol-
low-up (p<0.05). Manifest cylinder decreased to 
\(-0.41 \pm 0.50\) D (range: \(-2.00\) to 0) at 1 month and did 
not change statistically over 1-year (p=0.500).

Seventy-six percent of the eyes after 1 month and 
71% after 1 year were within \(\pm 0.5\) D, while 90% of the 
eyes after 1 month and 93% after 1 year were within 
\(\pm 1.0\) D.

**DISCUSSION**

Broad beam scanning excimer lasers for correction 
of hyperopic refractive errors had been moderately satis-
factory\(^{10}\). Unlike in myopia where corneal flattening 
corrects the refractive error, in hyperopia and mixed 
astigmatism, central corneal steepening is needed to 
compensate for the refractive error. This can only be 
achieved by ablating corneal tissue mid-peripherally 
and leaving tissue centrally, which was a challenging 
task with broad beam excimer systems that were con-
trolled by aperture mechanisms. With the advent of 
flying spot lasers it may have become possible to over-
come this limitation. These lasers can accurately ablate 
the cornea into more complex shapes compared to the 
older scanning systems. Thus hyperopic and mixed 
astigmatism ablation patterns are theoretically more 
efficient with these lasers.

We have shown in this case series that indeed the 
ALLEGRETTO WAVE system can safely and effec-
tively perform hyperopic and hyperopic astigmatic cor-
rections, which is comparable to the results we obtain 
when doing myopic corrections.

At twelve months follow up our mean refraction 
manifest spherical equivalent was \(-0.16\) D (SD±0.65) 
and 71% of eyes were within \(0.5\) D of the intended 
post-operative refraction, which was slightly more 
overcorrection than in the USFDA trials at 6 months: 
mean SEQ +0.24 D (SD \(0.54\)) with 70% of eyes 
within 0.50 D of refractive target\(^{13}\). The reason for this 
difference may be the inclusion criteria of extreme 
hyperopia and high hyperopic astigmatism in our study 
compared to a low to moderate one in the USFDA 
trial, as well as our decision to correct the full cyclo-
plegic refraction rather than manifest one. If we con-
sider spherical error only, the values of +0.16 
(SD\(0.55\)) are comparable with the USFDA trial data.

Our results are also similar to those published with the 
laser system of the same manufacturer (14) or better than 
published results achieved with other similar systems for 
the correction of hyperopic refractive errors\(^{10-12,15-18}\).

Our results showed a mean regression of +0.37 
(SD\(0.21\)) over the first year follow up, most of which 
occurred in the first 6 months, while the SEQ main-
tained the stable value over 1 year follow-up period. In 
comparison, a mean +0.32 (SD\(0.02\)) D regression in 
the manifest refraction between the first month and 3\(^{rd}\) 
month and a smaller regression thereafter (not-signifi-
cant) has been described by Kanellopoulos et al with 
the older model (200 Hz) of the same laser\(^{14}\).

This laser system has been shown to have extreme 
stability for hyperopic treatments over the period of 
more than four years based on FDA and post FDA 
data\(^{13}\). Stability for 151 patients regarding the manifest 
refraction spherical equivalent within \(\pm 1.00\) D or less 
was seen in 119/127 (93.7%) eyes. Regression of effect of 
\(>1.00\) D was seen in 6/127 (4.7%) eyes and progres-
sion of effect was seen in 2/127 (1.6%) eyes\(^{13}\).

In comparison, evaluation of mean regression 
(increasing hyperopia) between 3 and 36 months post-
operatively in low hyperopia with SCHWIND ESIRIS 
laser (SCHWIND eye-tech-solutions, Kleinostheim, 
Germany) resulted in a Maloney index of 0.016 
D/month, or 0.2 D/year\(^{15}\).

There was a virtually no change of lines in the 
BSCVA, as expected in hyperopic treatments because 
correcting hyperopia in the cornea plane induces some 
«minification» effect as compared to the patient’s spe-
tacle correction. This is slightly different than with the 
results obtained in the FDA clinical trials, and study by 
Kanellopoulos et al where a marginal overall gain of 0.3 
to 0.4 lines was reported\(^{13,14}\).

Other systems showed slightly worse results in hyper-
opia over +3.00 D. Llovet et al performed hyperopic 
LASIK with MEL 80 excimer laser (Carl Zeiss Meditec, 
Jena, Germany), where 4.0% of the patients lost 2 or 
more lines and the enhancement rate was 18.4%\(^{16}\).

Waring et al. described that 63.1% (176/279) of 
eyes after hyperopic LASIK with NIDEK EC-5000 
excimer laser (Nidek Co. Ltd., Gamagori, Japan). 
achieved a SEQ within \(\pm 0.50\) D. Less than 2% (4/279) of 
eyes lost 2 lines of distance BCVA. Stability of 
refraction was demonstrated by 6 months, with a mean 
hyperopic shift of < 0.03 D from 3 to 6 months\(^{17}\).

Desai et al showed results of Visx Star S2 excimer 
laser (Abbott Laboratories Inc. Abbott Park, Illinois, 
USA) where a residual of +0.59±1.18 D was encoun-
tered after 3 years follow up in the high hyperopia 
group. The percentage of eyes within 1.00 D of 
emmetropia was 66.7%, and the hyperopic shift 
between 1 year and the last visit was +0.55 D\(^{18}\).

We theorize that good results with WaveLight 
ALLEGRETTO WAVE Eye-Q 400 Hz excimer laser 
system may be explained at least in part, by the fact that 
the system uses the wavefront optimized ablation
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Profile. This profile uses peripheral compensation for predicted energy loss due to corneal curvature, fluence decrease and reflection increase by increasing up to 35% more pulses in the periphery. Thus the excimer laser effectively treats hyperopia and cylinder close to the theoretical peripheral ring of 6.5 to 9.5 mm from the center of the visual axis. This principle along with the smooth stromal surface created by the microkeratome may contribute in the rapid visual recovery noted at day one in this limited case series.

Hyperopic LASIK utilizing the ALLEGRETTO WAVE excimer laser and the WaveLight Rondo microkeratome appears to be safe and effective in the correction of high hyperopia. The post-operative results at 1 year are notable for hyperopic and astigmatic refractive error correction, improvement in both UCVA and BSCVA, with minimal regression and need for enhancement. This study course through one year of follow up is considered short by the authors, as our previous clinical experience with other laser platforms has shown late hyperopic regression. Larger and longer follow up studies can elucidate on the safety, efficacy and stability of this surgical intervention.

REFERENCES


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