Original Article

Study of change in contrast sensitivity in relation to depth of ablation after wavefront optimized myopic laser-assisted *in situ* keratomileusis

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Purpose: The aim of this work was to study the change in contrast sensitivity (CS) in relation to depth of stromal ablation after wavefront-optimized (WFO) myopic laser *in situ* keratomileusis (LASIK). **Methods:** This was as prospective, longitudinal, comparative study. The study participants were divided into two groups: Group 1 ≤50 μ ablation depth; 60 eyes and group 2 >50 μ ablation depth; 60 eyes. All underwent WFO LASIK. Uncorrected and corrected distance visual acuity (UDVA and CDVA) and CS were measured preoperatively and postoperatively at 1 week, 2 weeks, and 2 and 6 months. Two-way repeated-measures analysis of variance (ANOVA), Unpaired *t* test and one-way repeated measures ANOVA were used to test differences across time periods within each treatment group. A value of $P < 0.05$ was considered as statistically significant. **Results:** The mean ablation depths in groups 1 and 2 were 39.30 μ ± 7.22 μ and 69.90 μ ± 12.09 μ, respectively; the maximum depth was 94.62 μ. In group 1, the preoperative mean CS was 1.91 ± 0.07, which improved postoperatively at 1 week (1.93 ± 0.06) and remained stable in subsequent follow-ups (1.94 ± 0.05). In group 2, the mean CS preoperatively was 1.87 ± 0.12, which postoperatively at 1 week and 6 months were 1.93 ± 0.07 and 1.94 ± 0.03, respectively ($P < 0.05$). Between the groups, preoperative CS was significantly different ($P = 0.04$), but the change in CS post-LASIK was insignificant ($P > 0.05$). **Conclusion:** There was a significant improvement in CS after WFO myopic LASIK in all patients irrespective of ablation depth (up to 94.62 μ).

Key words: Contrast sensitivity, LASIK, WFO

Laser *in situ* keratomileusis (LASIK) is currently the most common refractive surgical procedure performed for the correction of myopia, hyperopia, and astigmatism.[1] Standard ablation profiles in conventional LASIK proved to be effective in compensating for refractive error, with excellent postoperative uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) but the quality of vision deteriorated significantly;[2] hence, visual acuity measurements using standard clinical tests are useful but give an incomplete description of visual ability. To assess subtle changes in visual performance, other aspects of vision such as contrast sensitivity (CS) should be measured.[3] The incidence of visual complaints by patients even after a successful refractive surgery ranges from 3 to 40%.[4] These problems have been attributed to an increase in higher order aberrations (HOAs) due to change in the corneal shape towards a more oblate pattern.[4] New aspheric non-individualized algorithms were thus designed to compensate for the spherical aberration induced, which led to improved visual outcomes.[5] The wavelight allegretto excimer laser (Wavelight Technologies, Erlangen) has a proprietary ablation algorithm that has a population-averaged spherical aberration correction built into it, and is referred to as "wavefront-optimized (WFO) treatment."[6] WFO ablation has

an aspheric profile designed to limit the induction of a positive spherical aberration by removing more tissue in the periphery than in the classic ablation profile, by sending an increased number of laser pulses to the corneal periphery rather than the center, and thus maintaining the cornea's prolate shape postoperatively.[6,7] Several studies[8-11] have demonstrated that myopic LASIK based on standard ablation profile induces a significant decrease in postoperative CS test values, which is directly related to the degree of refractive error and the amount of corneal tissue ablated. This improves and usually returns to preoperative levels during a variable time of recovery, which ranges from 3 to 12 months.[12]

Hori-Komai *et al*.[13] compared aspherical ablation profiles with conventional ablation profiles and reported that the former are associated with less induction of spherical aberration, better low-contrast UDVA, and better CS. Similarly, Khalifa *et al*.[14] reported improvement in CS postoperatively in WFO and WFG (wavefront guided) LASIK. There are no previous studies on correlation of depth of stromal ablation with improvement in CS in WFO aspherical ablation profile. On the contrary, Padmanabhan *et al*.[15] showed a generalized decrease in CS in

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WFO group. In light of these equivocal findings, we evaluated the change in CS after WFO Myopic LASIK and its correlation with depth of stromal ablation over 6 months.

Methods

This prospective, interventional, comparative, longitudinal study was carried out at a tertiary care eye hospital in South India between August 2016 and June 2018. The study was approved by the institutional review board and adhered to all the principles mentioned in the Declaration of Helsinki 2000. Based on previous literature on outcome variable for CS with a minimum difference of 0.15 log units in Peli Robson CS chart for 90% statistical power, 5% level of type 1 error and 95% confidence interval (CI) and at 5% level of significance, the estimated sample size was 96 eyes. A total of 120 eyes (60 eyes in each group) were considered based on the follow-up period and number of LASIK surgeries per year. The inclusion criteria of the study were patient aged >18 years with stable refractive error,–0.50 to–6.00 diopters (D) of spherical myopia: According to our own protocol we prefer surface ablation or phakic intraocular lenses for myopia >6.00D because high-power spectacles are known to induce significant aberrations that can degrade the threshold measurements of CS,[16] astigmatism between 0.00D to–3.00D, maximum manifest spherical equivalent (SE) of–6.00D and patients who came for all follow-up visits. Exclusion criteria were amblyopia, presence of significant dry eye, anterior segment abnormalities (corneal opacities, corneal epithelial basement membrane dystrophy, cataract), macular or retinal pathologies, estimated postoperative residual stromal bed (RSB) thickness < 300 μ, mesopic pupil diameter >6 mm, established or forme fruste keratoconus, autoimmune disease, collagen vascular disease, diabetes mellitus, pregnancy, lactation. After satisfying the inclusion and exclusion criteria, written informed consent was taken from every patient enrolled in the study. Soft contact lens users were asked to discontinue lenses 2 weeks before preoperative evaluation. The preoperative examination for each patient included the following: unaided visual acuity for distance and near using standard Snellen eye chart, CDVA with spectacles, manifest refraction, automated keratometry (AK), intraocular pressure measurements, corneal tomography (Sirius, CSO), pupil diameter under photopic, mesopic and scotopic conditions using Sirius tomographer (CSO), and CS with CDVA was evaluated using the Pelli Robson Test with the patient seated at 1-m distance under photopic condition. The chart has large Sloan letters that occupy approximately one cycle per degree of vision. The letters are arranged in triplets, which decrease in contrast by 0.15 log units for each triplet. The contrast tested ranges from 100% to 0.56% (log CS 0.00–2.25). Pelli Robson scoring sheets were used to determine the CS. The "letter-by-letter" scoring system was used, where by each letter correctly identified was scored as 0.05 log units (except for the first triplet, where contrast is 100%). Test ended when the patient missed two of three letters in a triplet. Test was performed for each eye separately. Slit-lamp biomicroscopy of the anterior segment, cycloplegic refraction with cyclopentolate hydrochloride 1.0% (Cyclogyl, INTAS pharmaceutical) and dilated fundus evaluation by indirect ophthalmoscopy with 20 D lens were performed. All eligible patients were scheduled for WFO LASIK for myopia and myopic astigmatism. The correction target was based on manifest refraction with emmetropia being the target in all patients. Stromal ablation depth was calculated before the procedure by Wavelight Allegretto excimer laser machine (Wavelight Technolgie, Erlangen). Based on stromal ablation depth patients were divided into two groups, group 1 with stromal ablation depth of ≤50 μ and group 2 with >50 μ. Postoperatively patients were examined on day 1, 1 week, 2 weeks, 2 months, and 6 months. All postoperative visits included evaluation of AK, UDVA, CDVA, corneal tomography and CS evaluation.

Surgical technique

One drop of proparacaine 0.5% (paracaine) was instilled in each eye 5 min and just before the procedure. This was followed by a povidone-iodine (Betadine) preparation of the eyelids. Eyelashes were separated by a drape, and a speculum was placed in the operative eye. The microkeratome settings (suction ring, flap, and stop) were chosen according to the steepest keratometry (manufacturer's nomogram). The Moria M2 90 μ single-use head was used to obtain desired 90 μ flap thickness and a nasal hinge. One single-use head was used in both eyes for each patient (the right eye was always done first). Aspheric spherocylindrical refractive ablations (WFO) were generated using manifest refraction values entered manually. Ablation zone was kept at 6.5 mm and ablation depth was calculated by the machine. After the microkeratome pass, the flap was lifted and wavefront optimized photoablation was done using the Wavelight Allegretto 400 excimer laser system. Flap was floated back into position and the stomal bed was irrigated with a balanced salt solution. All patients were examined 60 minutes after surgery to check for flap adherence, Findings were noted. Postoperative medications included topical moxifloxacin 0.5% with dexamethasone 0.1% eye drops (Milflodex, SUN pharmaceuticals) four times daily for 1 week then tapered weekly for 1 month and lubricating eyedrops (eyemist gel , Sun pharmaceutical) six times a day for 2 months.

Statistical analysis

Sample size was calculated using the following formula:

$$N = \frac{(Z\alpha)^2 \times \sigma^2}{e^2}$$

Where N is sample size, Z_α = 1.96 for 5% level of significance, and σ and e are pooled standard deviation and difference of means of two groups. CS was considered as primary outcome variables. Study group 1 and 2 (≤50 μ vs. >50 μ) were the primary independent variables and time of assessment (Preoperative, 1 week, 2 weeks, 2 months, and 6 months) was the other independent variable.

Two-way repeated-measures analysis of variance (ANOVA) was performed to assess the interaction between treatment group and time. Since there was significant interaction, the simple main effects were analyzed to check whether there is any difference in CS (dependent variable) between treatment groups at different time periods (vice versa). Unpaired t test was used for testing differences between two treatment groups and one-way repeated measures ANOVA was used to test differences across time periods within each treatment group. All the effect sizes were presented as mean difference and 95% CI. *Post hoc* Bonferroni corrected *P* values were used

to adjust for all multiple comparisons. A value of *P* < 0.05 was considered as statistically significant. IBM SPSS statistical software version 23 was used for data analysis.

Results

This comparative study included 120 eyes of 66 patients (33 patients in groups 1 and 2 each), with the mean age of 24.7 ± 3.8 years in group 1 and 24.4 ± 3.8 years in group 2 (ranged from 18 years to 37 years). There were 15 male and 18 female patients in group 1, while 14 male and 19 female patients in group 2. Twenty-seven patients underwent bilateral while six underwent unilateral treatment in each group. All patients attended 6-month follow-up visit. Preoperative mean flat keratometry (K1) and steep keratometry (K2) in group 1 were 43.87 ± 2.4, 44.31 ± 2.5 while in group 2, they were 43.65 ± 2.6 and 44.30 ± 2.6, respectively. At last follow-up, keratometry values had significantly flattened in both groups (group 1: 41.78 ± 2.5, 42.15 ± 2.5; group 2: 39.96 ± 2.4, 40.30 ± 2.6, respectively, *P* < 0.001). In groups 1 and 2, the mean preoperative corneal thickness was 527 μ (484–592 μ) and 533 μ (490–603 μ), respectively. The mean ablation depth in group 1 was 39.30 μ and in group 2, 69.90 μ. However, the minimum and maximum ablation depths were 27 μ (group 1) and 94.62 μ (group 2), respectively. Table 1 shows the preoperative and postoperative CS in both groups. In group 1, the postoperative CS improved (1.93 ± 0.06, *P* > 0.05) but it was not statistically significant. In Group 2, there was a significant gain in CS at 1 week (1.93 ± 0.07, *P* = 0.009) of follow-up period, it remained almost the same in second month and sixth month follow-up visits (*P* < 0.05). On comparing CS between groups 1 and 2, preoperative CS was significantly different between the groups (1.91 ± 0.07 versus 1.87 ± 0.12; *P* = 0.004). Postoperatively, there was gain in CS in both the groups but there was no statistically significant difference between the groups (1.94 ± 0.03 vs 1.94 ± 0.03, *P* > 0.05). Table 2 shows a comparison of preoperative and postoperative CS between the groups. Preoperatively, in groups 1 and 2, the mean SE were –2.13 ± 1.19 D (range –1 to –3.0 D) and –4.12 ± 1.71 D (range –3.0 to –6.0 D), respectively. Fig. 1 shows postoperative efficacy (UDVA) of WFO LASIK in groups 1 (A) and 2 (B) postoperatively at 6 months. The difference between the groups in terms of efficacy was not statistically significant (*P* = 0.783). Fig. 1c and d shows postoperative accuracy of SE to intended correction at 6 months; the differences between the groups were not statistically significant (*P* > 0.05). Fig. 2 shows postoperative safety of WFO LASIK in groups 1 (A) and 2 (B)

at 6 months. No patient in either group lost lines of CDVA. There were no intraoperative or postoperative flap related complications. Regarding stability, there were no statistically significant changes in the measured manifest refraction at 2 weeks, 2 months and 6 months follow-up visits in both groups [Fig. 2c and d].

Discussion

This study was performed with the aim of comparing the change in CS in relation to the depth of ablation after WFO LASIK in Myopic patients. Standard ablation profiles create oblate cornea leading to induction of HOA most notably spherical aberration[4] in conventional LASIK. These in turn have been shown to correlate with a loss in low-contrast visual acuity, CS and with night vision problems.[3,11,17,18] Chan *et al.*[3] and several others[8-11] have demonstrated that myopic LASIK based on standard ablation profile induced a significant decrease in postoperative CS test values. This improves and usually returns to preoperative levels during a variable time of recovery, which ranges from 3 to 12 months later.[12] In standard ablation profiles, worsening of CS was in direct correlation with degree of refractive error and the amount of corneal tissue ablated.[12] The ALLEGRETTO WFO ablation maintains a more natural corneal shape by adjusting for the asphericity of the cornea based on the anterior curvature readings. The system compensates for the slope in the cornea by delivering a larger number of pulses to the periphery, minimizing the amount of spherical aberration induced during surgery as compared to traditional laser systems.[19] WFO ablation offers distinct advantage over standard ablation profiles in terms of excellent visual quality, improved CS, safety and reduced induction of HOA.[13] Khalifa *et al.*[14] reported nonsignificant improvement postoperatively in CS at all spatial frequencies in WFO and WFG groups. Ozulken *et al.*[6] compared WFO ablation with topography-guided ablation (TGA) protocols and showed statistically similar improvement in CS in both groups. In our study, group 1 with SE ranging from –1 D to –3.00 D with stromal depth of ablation ≤50 μ and group 2 with SE ranging from –3.00 D to –6.00 D with stromal ablation depth >50 μ were evaluated for CS. We found an increase in CS at 1 week postoperative period in both the groups, which was not statistically significant in group 1 whereas in group 2 it was statistically significant. This however remained stable in subsequent follow-ups. Preoperatively group 1 patients (low to moderate myopia) had near normal CS (mean CS = 1.91 ± 0.09),

Table 1: Preoperative versus Postoperative Contrast Sensitivity in groups 1 and 2

Group	Time period	Mean±SD	Mean difference	95% of mean difference	*P*
Group one	Pre op	1.91±0.09	Baseline		
	1 week	1.93±0.06	0.018	0.022-0.057	1.000
	2 weeks	1.94±0.05	0.023	0.015-0.060	0.832
	2 months	1.94±0.03	0.030	0.003-0.063	0.093
	6 months	1.94±0.03	0.030	0.003-0.063	0.093
Group two	Pre op	1.87±0.12	Baseline		
	1 week	1.93±0.07	0.060	0.010-0.110	0.009
	2 weeks	1.93±0.07	0.060	0.010-0.110	0.009
	2 months	1.94±0.04	0.070	0.027-0.113	<0.001
	6 months	1.94±0.03	0.075	0.034-0.116	<0.001

Pre op: Pre operative, SD: Standard deviation

Table 2: Comparison of preoperative and postoperative contrast sensitivity between groups 1 and 2

| Time period	Group	Mean±SD	Mean difference	95% of mean difference	P
Baseline	Group 1	1.91±0.09	0.045	0.002-0.081	0.017
	Group 2	1.87±0.12			
1 week	Group 1	1.93±0.06	0.002	-0.020-0.025	0.827
	Group 2	1.93±0.07			
2 weeks	Group 1	1.94±0.05	0.007	-0.014-0.029	0.497
	Group 2	1.93±0.07			
2 months	Group 1	1.94±0.03	0.005	-0.008-0.018	0.468
	Group 2	1.94±0.04			
6 months	Group 1	1.94±0.03	0.00	-0.011-0.011	1.000
	Group 2	1.94±0.03			

SD: Standard deviation
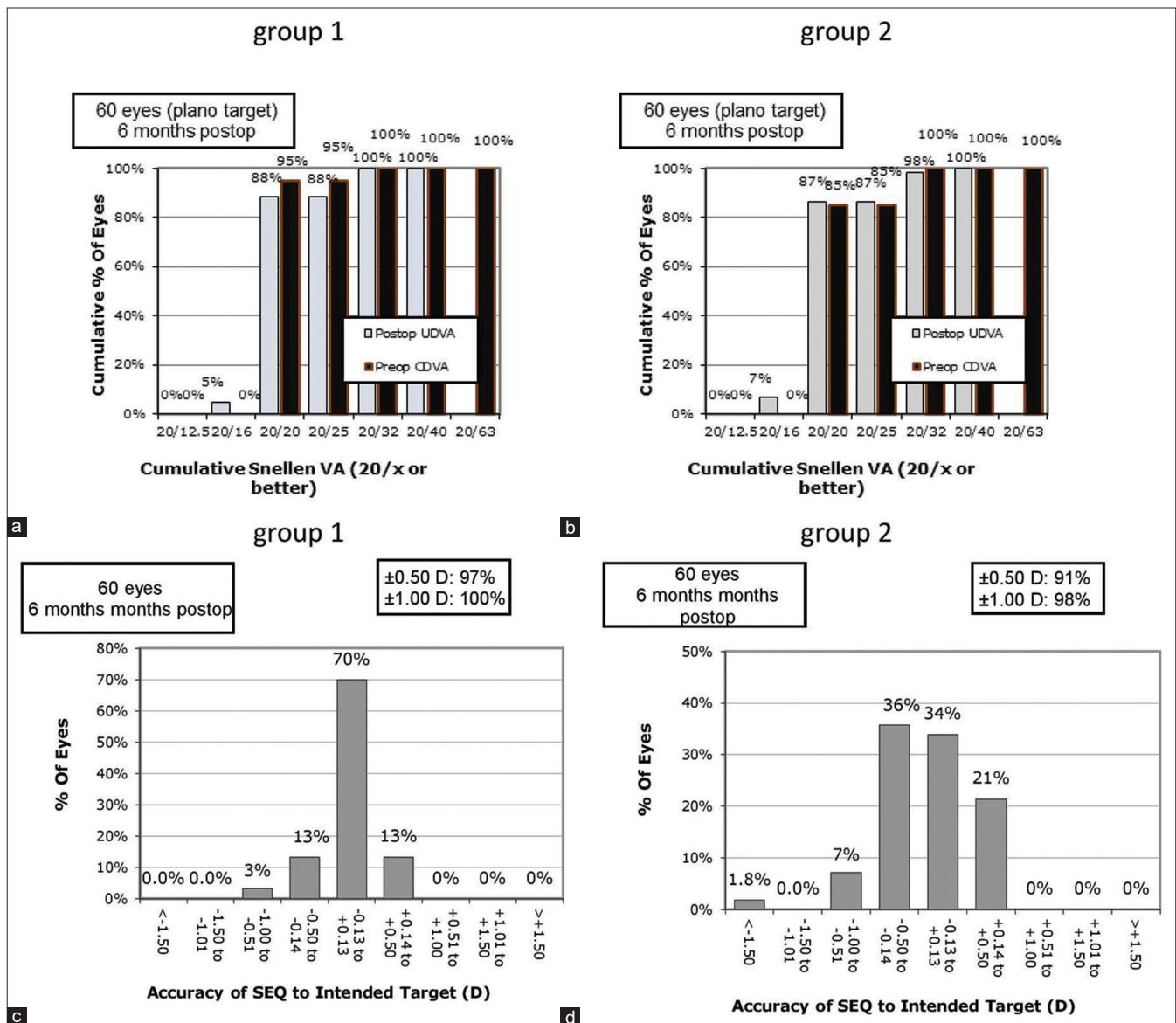
Figure 1: Postoperative efficacy (UDVA) of wave front optimized LASIK in groups 1 (a) and 2 (b) postoperatively at 6 months. Postoperative accuracy of spherical equivalent (SEQ) to intended correction at 6 months postoperatively in groups 1 (c) and 2 (d)

whereas group 2 patients (high myopia) had mean CS of 1.87 ± 0.12. Possible explanation for low preoperative CS in group 2 could be due to increased HOAs, increased forward light scattering, and early retinal dysfunction.[20,21] We found
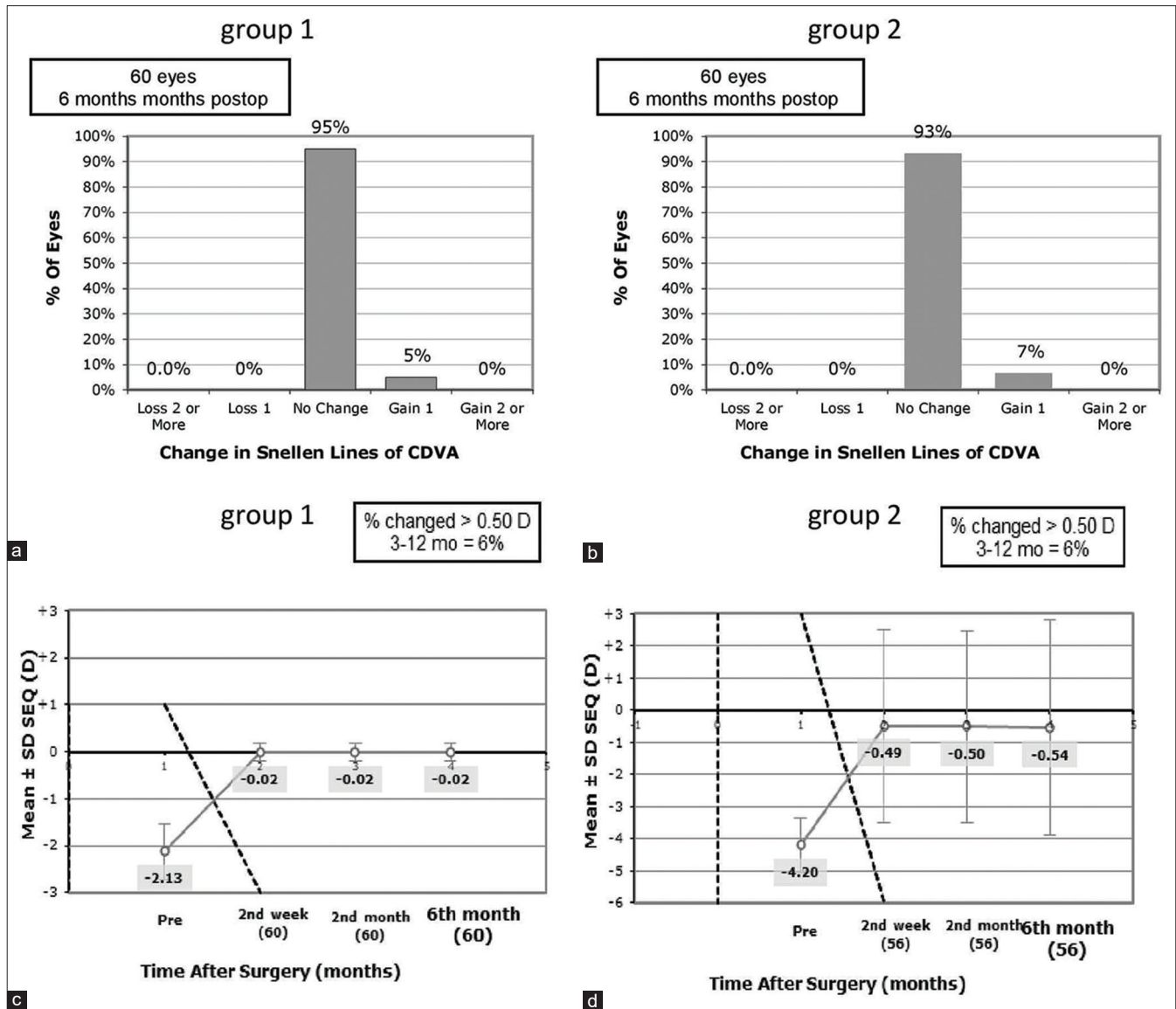
Figure 2: Postoperative safety of wave front optimized LASIK in groups 1 (a) and 2 (b) at 6 months. Postoperative stability up to 6 months in groups 1 (c) and 2 (d)

there was no significant difference in CS post-WFO ablation between the groups based on the ablation depth. Our results differ from that found by Padmanabhan *et al*.[15] who reported that CS values decreased postoperatively in WFO group while there was no significant change in CS in WFG group. On the contrary, Hassan *et al*.[7] compared wavefront guided with wavefront optimized ablation and both groups showed a statistically significant improvement in the mean CS values at 6 months postoperatively compared with preoperative values. Similarly, several other studies,[6,7,14,19,22,23] also reported comparable efficacy, predictability, visual and refractory outcomes of WFO ablation profile with WFG and TGA profiles. Stonceipher *et al*.[19] reported that in cases of significant preoperative RMS HOAs ≥ 0.35 μ, WFG ablations may offer superior results in terms of reduced spherical aberration postoperatively but have no advantage over WFO treatments in patients who have preoperative RMS HOAs <0.3 μ which constituted 83% of their study population.[19]

In our study maximum stromal ablation was 94.62 μ and there was a significant improvement in CS postoperatively, which was not in correlation to depth of ablation. This shows that even in higher depth of ablation, WFO profile maintains the cornea as prolate as possible. To the best of our knowledge, there are no studies available to report the correlation of CS in WFO ablation based on depth of stromal ablation.

This study has limitations: The sample size was relatively small, shorter follow-up duration, CS under mesopic conditions was not evaluated, Pelli Robson chart used in our study is easy to use but the results obtained may be influenced by illumination, reflections from the chart and the chart per se can get faded over a period of time and lastly correlation of induced spherical aberration with CS was not analyzed, although Stonceipher *et al*. reported no correlation between induction of HOA and CS postoperatively.[19]

Conclusion

There was a significant improvement in CS after WFO myopic LASIK in all patients irrespective of ablation depth (up to 94.62 µ). There was no significant difference in change in CS post-LASIK between ≤50 µ and >50 µ ablation depth groups. Our study shows even with stromal ablation up to 94.62 µ, there was a significant improvement in contrast sensitivity after WFO myopic LASIK.

Conflicts of interest

There are no conflicts of interest.

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