A novel refractive nomogram for the Custom-Q laser-assisted in-situ keratomileusis treatment of myopia Ahmad Saeed

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Background

To describe a new refractive nomogram to be used during the Custom-Q myopic laser-assisted in-situ keratomileusis (LASIK) ablation that seeks to minimize the postoperative spherical aberration (SA). This nomogram aims to avoid postoperative changes in target refraction that usually occur with customization of the Q value. This was a prospective controlled interventional case series. **Materials and methods**

A total of 40 myopic patients (-1.00 \leq -8 D) were enrolled in this study. The right eyes of all patients were considered as the study group, where we targeted an ideal Q value of -0.45 during LASIK ablation. The corrected refractive error in the right eye was modified according to the new refractive nomogram to avoid the postoperative change in target refraction that occurs with the change in Q value. The left eyes of the same patients were considered as the control group with neither change in the Q value nor modification in the corrected refractive error. The classic outcome parameters such as visual acuity, cycloplegic refraction, as well as Q values and SAs were assessed and compared between the two groups preoperatively and at 1 month postoperatively. The LASIK machine involved in the treatment was The Allegretto Wave Eye-Q 400 Hz.

Results

There were no statistically significant differences (P>0.05) between the two groups regarding the postoperative visual acuity and refraction at 1 month. On the contrary, there were statistically highly significant differences (P<0.001) between the two groups regarding postoperative Q value and SA at 1 month postoperatively. **Conclusion**

The new refractive nomogram used with the Q factor customized myopic LASIK ablation, which targets an ideal Q value to minimize the SA as much as possible, appears to be efficient in avoiding postoperative changes in target refraction that occur with customization of the Q value.

Keywords:

LASIK, myopia, nomoogram Egypt J Cataract Refract 24:35–41 © 2019 The Egyptian Journal of Cataract and Refractive Surgery 1687-6997

Introduction

The most significant drawback of the standard myopic laser treatment is the decline in visual performance manifested by a decrease in night vision and contrast sensitivity, and this is mainly attributed to changes in corneal asphericity [1].

For every diopter of correction of myopia, there is a change in Q value toward corneal oblateness by 0.12–0.14 (with the Allegretto WaveLight and Visx, respectively), with less negative and more positive postoperative Q values [2].

There is a close relationship between the Q value and the induced spherical aberration (SA) such that as the Q value become more negative, or the lower it is, the more the total SA decreases or becomes negative and vice versa [3]. The normal human cornea has a slightly positive total SA, of the order of 0.12 µm [4]. A minimum of SA after refractive surgery would be obtained at a target Q-factor of \sim -0.4 to -0.5, but in fact modification of the *Q* value and minimization of SA will have its effect on ablation depth and hence postoperative refractive status [5].

The significance of customized adjustment of the Q factor in obtaining a minimal SA will lead to a clinical problem owing to the change in the final refraction that steadily go together with this adjustment (hypercorrection in myopic ablations and hypocorrection in hyperopic ablations). We can thus prevent hypercorrection or hypocorrection by modulating the amount of the spherical component

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to be corrected until the final ablation microns of the customized treatment match those of the standard treatment [6].

However, in our experience, this mathematical matching of the FACT treatment planning to the standard ablation depth always results in an undercorrection of the refractive error. In this study, we describe a new refractive nomogram for the Custom-Q laser-assisted in-situ keratomileusis (LASIK) treatment of myopia that target an ideal Q value and minimize the SA as much as possible without affection of the final refraction. To our knowledge, there is no definite nomogram for such adjustment.

Materials and methods

A total of 40 myopic patients seeking laser refractive surgery with manifest refractive spherical equivalent of -1.00 up to -8 D were enrolled in this study.

Inclusion criteria

Patients aged 18 years old or older, having stable refraction for at least 1 year, with myopia ranging between -1.00 and -8.00 D, and with up to -5 D astigmatism in both eyes were included.

Exclusion criteria

Patients who were pregnant, breast feeding, or were taking topical or systemic drugs that may delay healing or had systemic disease(s) that may delay healing were excluded from the study. Patients with corneal thickness less than $480 \,\mu$ m, or residual stromal bed less than $280 \,\mu$ m; patients with active ophthalmic disease, cataract, uveitis, glaucoma, corneal irregularity, keratoconus, and posterior segment abnormality; and patients who had any prior ophthalmic surgery were also excluded from the study.

The study was conducted between 2016 and 2017 at Al-Sharq vision correction center, Zagazig, Egypt.

The study protocol was approved by local ethics committee of Al-Sharq vision correction center.

This study is a prospective controlled study in which both eyes of each patient were treated with the Qfactor customized LASIK (FCAT profile).

After a complete ophthalmic examination and a thorough discussion of the risks and benefits of the surgery, the patients gave written informed consent.

Examinations

Complete preoperative examination consisted of cycloplegic refraction, manifest refraction, uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA), Pentacam tomography (OCULUS Pentacam HR, Wetzlar, Germany), wavefront analysis with pupils dilated to at least 6 mm in diameter (ZYWAVE 3; Technolas Perfect Vision, BAUSCH+LOMB, München, Germany), applanation tonometry, slit-lamp examination of the anterior segment of the eye, and fundus examination.

The right eyes of all patients were considered as the study group, where we are targeting an ideal Q value (-0.45) and adjusted the myopic correction according to the suggested nomogram during LASIK ablation, whereas the left eyes were considered as a control group with no change either in Q value or in the refractive error. We applied the following formula for the study group:

Correction (D)=manifest refraction+the (digits) of ΔQ (D).

 $\Delta Q = \text{Target } Q - \text{preoperative } Q$:

Target $Q = \text{refraction} \times 0.12 + \text{ideal } Q(-0.45).$

Target Q is applied in the operative treatment planning, taking in consideration two factors:

- (1) The ideal Q value of -0.45 which is required for aberration-free myopic ablation.
- (2) The change in the Q value that inherently occurs with the ablation for correcting the patient spherical error and must be compensated for, which equals 0.12 for each diopter (refraction×0.12).

For example, a patient has a manifest refraction of -4 D and preoperative Q value of -0.3, the target Q to be entered in the treatment plan is as follows:

Target $Q = \text{refraction} \times 0.12 + \text{ideal } Q(-0.45).$

Target $Q = (-4 \times 0.12) + (-0.45) = -0.93$.

 $\Delta Q = \text{Target } Q - \text{preoperative } Q$:

 $\Delta Q = -0.93 - (-0.3) = -0.63.$

Maximum change in ΔQ should not exceed one.

Correction (D)=manifest refraction+the (digits) of ΔQ (D).

Correction (D)=-4+(0.63)=-3.37 D.

So in this example, the treatment plan will be as follows:

The target *Q* is -0.93 (to achieve the ideal *Q* -0.45) and the correction to be entered is -3.37 D instead of -4 D.

The LASIK machine involved in the treatment was The Allegretto Wave Eye-Q 400 Hz (Wave-Light AG, Erlangen, Germany), and an automated microkeratome, Moria M2, (Moria, Antony, France) was used to create the corneal flap. All surgeries were LASIK with optical zone diameter of 6.5 mm and transition zone of 1.25 mm in both groups. The target refraction in both groups was emmetropia.

Postoperative follow-up visits were in days 1 and 3 and 1 month after surgery. On postoperative days 1 and 3, a slit-lamp inspection was performed, and UCVA was measured.

The classic outcome parameters such as visual acuity, cycloplegic refraction, as well as *Q* values and SAs were assessed and compared between the two groups preoperatively and 1 month postoperatively.

Preoperative and postoperative parameters were analyzed using the SPSS paired two-sided t-test. A P value less than 0.05 was considered statistically significant.

Statistical analysis

The collected data were computerized and statistically analyzed using statistical package for the social sciences program (SPSS) version 18.0 (IBM Co., New York, USA). Qualitative data were represented as frequencies and relative percentages. Quantitative data were expressed as mean±SD and range. Independent *t*-test was used to calculate difference between quantitative variables in the two groups in normally distributed data and Mann-Whitney test was used in not normally distributed data. Paired ttest was used to calculate difference between quantitative variables in the each group preoperatively and postoperatively in normally distributed data, and paired Wilcoxon was used in not normally distributed data. The significance level for all aforementioned statistical tests was done. The threshold of significance is fixed at 5% level (P value), where P value of more than 0.05 indicates nonsignificant results, P value of less than 0.05 indicates significant results, and P value of less than 0.01 indicates highly significant results.

Results

The mean age of the patients was 29.3 ± 8.40 years, ranging from 18 to 45 years, and there were 22 (55%) female patients and 18 (45%) male patients.

No significant differences were noted in patient demographics or preoperative clinical data. Patient's preoperative clinical data are summarized in Table 1.

There were no statistically significant differences (P>0.05) between right (0.93 ± 0.12) and left (0.95 ± 0.11) eyes regarding preoperative BCVA. There were no statistically significant differences (P>0.05) between right (0.93 ± 0.15) and left (0.96 ± 0.14) eyes regarding UCVA at 1 month postoperatively. In addition, there were no statistically significant differences (P>0.05) between preoperative BCVA and postoperative UCVA at 1 month in the two groups, as demonstrated in Fig. 1.

There were no statistically significant differences in the refraction between the right and left eyes whether preoperatively or at 1 month postoperatively, as shown in Table 2.

There were no statistically significant differences between right and left eyes regarding preoperative Qvalue (P=0.99) whereas there were statistically highly significant differences between right and left eyes regarding postoperative Q value at 1-month followup (P<0.001), and this is demonstrated in Table 3 and Fig. 2.

There were no statistically significant differences between the right and left eyes regarding preoperative SA (P=0.99), whereas there were statistically highly significant differences between the right and left eyes regarding postoperative SA at 1 month (P<0.001), and this is demonstrated in Table 4 and Fig 3.

	Table 1	Patients'	preoperative	clinical	data
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Variables	OD (n=40)	OS (n=40)	Test	Р		
Corneal thickness						
Mean±SD	552.48±39.79	554.82±39.4	t	0.79 (NS)		
Range	490–620	492–621	0.27			
K1						
Mean±SD	42.5±1.96	42.54±2.08	t	0.93 (NS)		
Range	39–45	39–46	0.08			
K2						
Mean±SD	43.68±1.97	43.95±2.27	t	0.56 (NS)		
Range	40–47	40–48	0.58			

OD, right; OS, left; NS, P>0.05.

At 1-month follow-up visit, there were statistically highly significant differences between the right and left eyes regarding the postoperative deviation of the Qvalue from the ideal level (-0.45), with the study group

Fig. 1



Preoperative [best-corrected visual acuity (BCVA)] and postoperative (BCVA) at 1 month.

Table 2 Preoperative and postoperative refraction					
Refraction	OD (<i>n</i> =40)	OS (n=40)	Р		
Preoperative s	pherical error				
Mean±SD	-3.21±2.04	-3.11±1.97	0.89 (NS)		
Range	-8.25 to -0.5	-7.5 to -0.25			
Preoperative of	ylindrical error				
Mean±SD	-1.03±1.25	-1.11±1.16	0.72 (NS)		
Range	-5 to 0	-4 to 0			
Postoperative	spherical error				
Mean±SD	-0.1±0.34	-0.08±0.29	0.92 (NS)		
Range	+0.25 to -0.5	+0.25 to -0.50			
Postoperative	cylindrical error				
Mean±SD	00±0.50	-0.25±0.5	0.88 (NS)		
Range	+0.25 to -0.50	+0.25 to -0.50			

OD, right; OS, left; NS, P>0.05.

Table 3 Preoperative and postoperative Q value

demonstrating a more close values to the ideal level; in addition, there were statistically highly significant differences between the right and left eyes regarding the postoperative deviation of the SA from the zero level with better results in the study group (P<0.001), and this is demonstrated in Table 5 and Figs 4 and 5.

Discussion

Many reports have shown the results of Custom-Q LASIK in myopic eyes with achieved target Q value more positive than that planned, in other words, with Q value less than that planned. None of them have taken in consideration that the myopic ablation itself changes the corneal asphericity from prolate to oblate (negative asphericity to positive asphericity) by 0.12 for every diopter correction of myopia [2].

The interplay between the effect of customization of the Q value on target refraction and the effect of





Preoperative and postoperative Q value at 1 month.

Variables	OD (<i>n</i> =40)	OS (<i>n</i> =40)	Test	Р	
Preoperative Q value					
Mean±SD	-0.32±0.17	-0.32±0.16	MW	0.99 (NS)	
Median (range)	-0.68 to -0.03	-0.68 to -0.03	-0.01		
Postoperative Q value					
Mean±SD	-0.19±0.19	0.05±0.29	MW	<0.001 (HS)	
Range	-0.45 to +0.29	-0.47 to +0.69	3.87		

HS, highly significant; MW, Mann–Whitney test; NS, P>0.05.

Table 4 Fleoperative	and postoperative spherical abo			
Variables	OD (<i>n</i> =40)	OS (<i>n</i> =40)	Test	Р
Preoperative spherical	aberration			
Mean±SD	0.06±0.17	0.06±0.16	MW	0.99 (NS)
Range	-0.3 to 0.35	-0.3 to 0.35	0.01	
Postoperative spherica	al aberration			
Mean±SD	0.19±0.20	0.43±0.29	MW	<0.001 (HS)
Range	-0.09 to +0.69	-0.10 to +1.07	3.77	

Table 4 Preoperative and postoperative spherical aberration

HS, highly significant; OD, right; OS, left; MW, Mann–Whitney test *P*, paired test; NS, *P*>0.05.

Fig. 3



Preoperative and postoperative spherical aberration.

myopic LASIK ablation on the target Q value had created a dilemma that needs a solution.

This is by far the first work in myopic Custom-Q LASIK that targets the postoperative Q value of -0.45, which has the least SA [7], taking in consideration to compensate for that opposite change in Q value that inherently occurs with myopic ablation and without affection of the target refraction.

So when planning for a Custom-QLASIK, it is not just enough to target a postoperative Q value of only -0.45, but we suggested applying the following formula.

Target Q = Refraction × 0.12 + -0.45. Example: -2 D myopic patient will have a target Q= (-2×0.12)-0.45=-0.24-0.45=-0.69.

So the target Q will be entered in the machine as -0.69 not the desired -0.45.

Moreover, it is known that achieving a postoperative target Q will affect the ablation depth and hence the postoperative refraction with hypercorrection in myopia and undercorrection in hypermetropia. One of the ways described to overcome such problem was to modulate the amount of the spherical component to be corrected until the final ablation microns of the customized treatment match those of the standard treatment [6].

However, in our hands, applying this way of modulation resulted in undercorrection of myopia especially with large ΔQ change despite removing the same tissue from the central ablation zone.

The explanation of this is that the tissue ablation involved in modification of Q value is removed from the mid-peripheral zone. This makes the effect of the amount of central ablation less effective in Custom-Q LASIK than an equal amount of central ablation in cases of standard platform. So it has to be modified again to overcome this minimized (central-mid periphery ratio) effect, which results in undercorrecting myopia, despite removing the same central depth as we mentioned.

We found that, for every 0.1 change in preoperative Q value toward a prolate cornea, there will be a myopic shift of ~0.1 D.

So we suggested this refractive nomogram to overcome this problem:

Correction (D)=Manifest refraction+the (digits) of ΔQ (D).

For example: a patient has a manifest refraction of -4 D and a ΔQ value (ΔQ) of -0.63.

Correction (D)=-4+(0.63)=-3.37 D.

We applied this nomogram, which in our hands achieved both a more predictable target Q value with less undercorrection found in the conventional way of dealing with customized FCAT.

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Variables	OD (<i>n</i> =40)	OS (<i>n</i> =40)	MW	Р
Difference in Q from it	deal level (-0.45)			
Mean±SD	-0.26±0.19	-0.50±0.27	4.09	<0.001 (HS)
Range	-0.74 to 0	-1.07 to -0.01		
Difference in spherical	aberration from zero level			
Mean±SD	-0.19±0.20	-0.43±0.29	3.77	<0.001 (HS)
Range	-0.69 to 0.09	-1.07 to 0.10		

Table 5 Mean difference in postoperative Q value from the ideal level (-0.45) and in spherical aberration from zero level among the studied aroun

OD, right; OS, left; HS, highly significant (P<0.01); MW, Mann-Whitney test.

Fig. 4



Regarding postoperative refraction, there was no statistically significant difference between the study group and the control group (P>0.05) with a mean postoperative spherical error of -0.1±0.34 and -0.08 ±0.29 in the study group and the control group, respectively, and a mean postoperative cylindrical error of 00±0.25 and -0.05±0.4 in the study group and the control group, respectively.

The nonexistence of statistically significant difference in refraction between the two groups suggests that our nomogram succeeded in avoiding overcorrection or undercorrection while adjusting for an ideal Q value. This is further supported by the absence of statistically significant difference in the postoperative UCVA between the two groups at 1 month postoperatively.

The mean postoperative Q value was -0.19 in the study group, whereas in the control eyes was +0.05, with highly significant difference between study and control group (P<0.001).

On the contrary, although the planned Q value (-0.45) was not achieved in all cases in the study group, the mean deviation from this level was less in the study group (-0.26 ± 0.19) than in the control group (-0.50)±0.27), with highly significant difference between them.









In a study done by Stojanovic et al. [7] to compare wavefront optimized versus Custom-Q treatments for myopic astigmatism, the postoperative Q value in the Custom-Q group ranged from -0.09 to -0.10 although the target Q value in their study was -0.5 to -0.6 in low and high myopia, respectively.

The difference in the achieved Q value between the study group in our study (-0.19) and the Custom-Q group in the study by Stojanovic (-0.09 to -0.10), despite that they had a lower target Q value (-0.5 to -0.6) than in our study (-0.45), may be explained by the fact that in the study by Stojanovic they did not compensate for the opposite change in Q value that inherently occurs with myopic ablation (Q value increased by +0.12 for every diopter correction of myopia).

In this study, there were statistically highly significant differences between the two groups regarding postoperative SA at 1 month (P < 0.001).

Koller *et al.* [8] in their study to compare the results of the Q-factor customized aspheric ablation profile with the wavefront-guided customized ablation pattern for the correction of myopic astigmatism found that corneal asphericity was less impaired by the Custom-Q treatment up to -5 D of myopia.

Stojanovic *et al.* [7] in their study to compare wavefront optimized versus Custom-Q treatments for myopic astigmatism reported no significant difference in postoperative SA between the two groups. Their explanation for this is that although postoperative oblate Q-shift was less in the Custom-Q group, the difference between groups was just marginally statistically significant (P=0.049) and did not result in any significant difference in postoperative SA.

Conclusion

The new refractive nomogram used with the Q-factor customized myopic LASIK ablation, which targets an ideal Q value to minimize the SA as much as possible, appears to be efficient in avoiding postoperative changes in target refraction that usually occurs with customization of the Q value.

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Conflicts of interest

There are no conflicts of interest.

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