British Journal of Medicine & Medical Research
12(10): 1-11, 2016, Article no.BJMMR.22098
ISSN: 2231-0614, NLM ID: 101570965

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Wavefront-guided Versus Standard Laser *in situ* Keratomileusis in Myopia Using a 213 nm Wavelength Solid-state Laser: Comparison of Higher-order Aberrations

Eleonore B. Iguban[1*], Archimedes L. D. Agahan[1,2] and Raymond P. Evangelista[2]

[1]Department of Ophthalmology and Visual Sciences, University of the Philippines Manila, Philippines.
[2]Refractive Surgery Section, Manila Vision Correction Center, Manila, Philippines.

Authors' contributions

This work was carried out in collaboration between all authors. Author EBI did the literature searches and wrote the manuscript. Author ALDA conceptualized the study and spearheaded the data analysis. Author RPE also contributed in the design of the study and data gathering. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/BJMMR/2016/22098
Editor(s):
(1) Pradeep Venkatesh, Professor, Ophthalmology, All India Institute of Medical Sciences, New Delhi, India.
(2) Ian Dooley, Limerick Regional Hospital, Republic of Ireland.
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(4) Tsung-Jen, Wang, Taipei Medical University, Taiwan.
Complete Peer review History: http://sciencedomain.org/review-history/12539

Original Research Article

Received 17th September 2015
Accepted 19th November 2015
Published 3rd December 2015

ABSTRACT

Purpose: To assess the accuracy, efficacy, stability and safety of laser in situ keratomileusis (LASIK) for myopia and compare the pre- and post-operative changes in higher-order aberrations after wavefront-guided (WF) and standard (STD) LASIK done using the Pulzar Z1, a 213-nm wavelength solid-state laser, and determine their effects on visual acuity and refractive outcomes.
Methods: This a retrospective case series composed of 80 eyes (40 patients) that had LASIK in an out-patient refractive surgery center in Manila, Philippines. Outcome measured were pre and post-operative manifest refraction spherical equivalent (MRSE), uncorrected distance visual acuity

**Corresponding author: E-mail: eleonore_i@yahoo.com;*

(UDVA), best-corrected distance visual acuity (CDVA), keratometry, root-mean-square (RMS) values, flap and ablation related complications.
Results: The mean UDVA improved from 20/400 pre-operatively to 20/25 post-operatively. Thirty six of the 40 eyes (90%) treated with STD LASIK and 39 of the 40 eyes (97.5%) treated with WF LASIK had UDVA of 20/30 or better at 1 year post-operatively. There was a significant decrease in spherical equivalent manifest refraction post-operatively in all patients. The average spherical equivalent at 1 year is -0.43D±0.64. After twelve months of follow-up, 85.5% (34 out of the 40 eyes) of those who underwent STD LASIK and 77.5% (31 out of 40 eyes) who underwent WF LASIK had postoperative manifest refractive spherical equivalent (MRSE) of -1.0 to +1.0D. The mean difference in the attempted versus achieved refraction was not significant between the 2 groups (p = 0.32). At 12 months post-operatively, seven eyes (17.5%) gained 1 line in the WF-guided LASIK, while the rest of the eyes either showed no change in CDVA or lost 1-2 Snellen lines. The total RMS generally increased postoperatively for WF LASIK while decreased for STD LASIK, but the mean RMS difference from the pre- and post-operative values between the 2 groups were not statistically significant. None of the eyes developed flap complications during the follow-up period.
Conclusion: Refractive surgery using the Pulzar Z1 213-nm wavelength solid-state laser is an effective and safe procedure in the treatment of myopia. Wavefront-guided LASIK offers no advantage over STD LASIK in improving higher-order aberrations and in achieving better visual and refractive outcomes.

Keywords: Higher-order aberrations; wavefront-guided LASIK; 213-nm solid-state laser; myopia.

1. INTRODUCTION

Laser *in situ* keratomileusis (LASIK) was first introduced in 1990s and since then, has reshaped the treatment landscape for correcting refractive errors, such as myopia, hyperopia, and astigmatism [1]. At present, LASIK remains one of the most commonly performed procedure in refractive surgery to correct myopia [2]. Myopia, also known as short-sightedness or near-sightedness, is an ocular condition in which the refractive power of the eye is greater than is required, resulting in light from distant objects being focused in front of the retina instead of directly on it [3].

Although conventional laser keratomileusis (LASIK) is accepted globally as an efficient and safe way in correcting sphero-cylindrical refractive errors, a decrement of visual performance after the surgery has been reported such as glare and halo under dim conditions, poor night vision and decrease of contrast sensitivity (CS) values, despite improvement in visual acuity [4]. Both contrast sensitivity and higher-order aberrations (HOA) after standard (STD) LASIK have also been shown to affect patient satisfaction and quality of vision post-operatively [5].

Wavefront-guided (WF) LASIK was introduced to address these notable decreases in vision quality after standard laser ablations by reducing or eliminating existing ocular aberrations [6]. Recent studies have concluded that wavefront guided customized corneal ablations are safe, effective, and predictable [7]. When compared with standard treatments, wavefront-guided ablations can reduce preexisting higher-order aberrations and lessen the occurrence of new higher-order aberrations which results in improved visual outcomes [7-8].

The solid-state Nd: YAG laser with an output wavelength of 213-nm is gaining popularity as a possible alternative to the long-established 193-nm excimer laser system because of environmental safety issues associated with the latter [9]. Studies have shown favorable cellular responses after ablation with 213-nm compared with 193-nm lasers as evident in the improved clinical course and corneal histo-pathological findings [10-11]. Solid state lasers, besides being cost effective and have a good safety profile, result in better wound healing, leading to a more reliable correction of refractive errors in both human and animal studies [10,12] They have been observed to have a smoother ablation surface because of the more accurate penetration of energy onto the corneal stroma, and its smaller spot size of 0.6 mm causes less mechanical stress on the cornea and less damage to the corneal structure [13]. The 213-nm laser also has greater transmissibility through water and balanced salt solution and is closer to the peak absorption of corneal collagen, which allows more selective energy absorption by corneal collagen and less energy absorption by the surrounding water [14]. Moreover, besides being able to correct primary refractive errors, the 213-nm solid-state laser has also been shown to be accurate, effective, and safe when used for photorefractive keratectomy with adjunctive use of Mitomycin for the correction of residual error of refraction after LASIK [14].

The purpose of this study is to assess the accuracy, efficacy, stability and safety of LASIK for myopia and compare the pre- and post-operative changes in higher-order aberration, using the root-mean-square (RMS) wavefront error, after WF and STD LASIK using the Pulzar Z1, a 213-nm wavelength solid-state laser.

2. MATERIALS AND METHODS

This is a retrospective case series involving 80 eyes of 40 patients with myopia who underwent standard LASIK using the Pulzar Z1 laser system in an out-patient refractive surgery center in Manila, Philippines. All patients with myopia who consulted at the center without any evidence of other ocular pathology that might affect the final visual and refractive outcomes were included. All patients submitted written informed consent and were able to complete at least one year of follow-up.

All patients underwent a complete ophthalmic evaluation. The preoperative and postoperative examinations included Uncorrected Distance Visual Acuity (UDVA), best Corrected Distance Visual Acuity (CDVA), subjective manifest refraction, wavefront refraction, and higher order aberrations measurements using Root-Mean-Square (RMS) wavefront error. Manifest Refractions (MR) were converted to Manifest Refractive Spherical Equivalent (MRSE). Patients with any of the following conditions were not eligible for surgery: Suspected ectasia or keratoconus, active ocular disease such as glaucoma and uveitis, significant cataract or retinal pathology, thin cornea (<500 μm) autoimmune disease, diabetes, or any other serious medical conditions. Patients who are engaged in sports and military activities, breastfeeding and pregnant women, and those who did not consent for the procedure were also excluded from the study. Other exclusion criteria are previous refractive and intraocular surgery and unrealistic expectations.

2.1 Surgical Technique

Two surgeons (A. L. D. Agahan, R. P. Evangelista) performed the laser procedures. Post-surgical emmetropia was intended in all cases. All 40 patients (16 males, 24 females) underwent LASIK. Twenty patients had wavefront-guided LASIK, while standard LASIK was done for the other 20 patients. Pre-operatively, all patients received 2-3 drops of topical Proparacaine and 1 drop of povidone-iodine 5% solution. A lid speculum was inserted to provide adequate exposure. The suction ring was applied to the limbus and a 8.5 mm corneal flap was created using the Hansatome microkeratome (Bausch and Lomb Surgical). The flap was reflected and dried with Weck-Cel sponge. The ablation was then carried out using the Pulzar Z1 213-nm wavelength solid-state laser (CustomVis) with centration based on the line of sight (line joining the point of fixation to the center of the pupil). The ablation profile had an annular shape with 6.0 mm optical zone and 8.0 mm treatment zone. After the ablation was completed, the corneal flap was repositioned and the edges were dried with Weck-Cel sponges. The retractor was removed and one drop of Prednisolone Acetate 1% was given. The patients were instructed to instill Moxifloxacin 0.3% 1 drop 4x/day, Prednisolone Acetate 1% 1 drop 4x/day, and Carboxymethylcellulose 1 drop 4x/day and were discontinued after 2 weeks. No intraoperative or postoperative complications were encountered.

Outcome measured were pre and post-operative manifest refraction (MRSE), uncorrected distance visual acuity (UDVA), best-corrected distance visual acuity (CDVA), keratometry, root-mean-square (RMS) values, flap and ablation related complications.

The UDVA, CDVA, and manifest refraction were taken 1, 3, 6 months, and 12 months postoperatively. Wavefront analysis to determine higher order aberrations were done using the Ray tracing aberrometer. The results were then evaluated using a CT-view (version 3.17, Sarver and Associates) software program for RMS comparison.

2.2 Calculation of the Wavefront-guided Ablation

Wavefront aberrations are measured and quantified in terms of Zernike polynomials wherein, up to 20 coefficients are measured showing the lower-order aberrations of the first- and second-order as well as the higher-order aberrations of the third to the fifth order. The RMS wavefront error is used to quantify the irregularity of the wavefront. It is expressed as the square root of the squared mean deviation of the higher-order aberrations. The higher the RMS value, the greater are the wavefront aberrations.

3. RESULTS AND DISCUSSION

3.1 Demographics

A total of 80 eyes of 40 patients underwent LASIK for myopia. Table 1 shows the baseline characteristics and demographics of all patients included in the study. All 40 patients (16 males, 24 females) had bilateral LASIK treatment. Twenty patients had WF LASIK, while STD LASIK was done for the other 20 patients. No intra- or postoperative complications occurred during the procedure. All eyes were seen at least 12 months postoperatively.

3.2 Visual Acuity

The mean visual acuity of the patients improved from a pre-operative UDVA of logMAR 1.40±0.61 (20/400) to post-operative UDVA of 0.06±0.09 (20/25) for WF LASIK group, and UDVA of 0.10±0.12 (20/25) for STD LASIK group. At one year post-operatively, 36 out of the 40 eyes (90%) who underwent WF LASIK, and 39 out of the 40 eyes (97.5%) who had STD LASIK done, had post-operative UDVA of 20/30 or better. All eyes (100%) had a vision of 20/50 or better postoperatively for both groups (Fig. 1).

3.3 Accuracy of Correction

After twelve months of follow-up, 85.5% (34 out of the 40 eyes) of those who underwent STD LASIK and 77.5%(31 out of 40 eyes) who underwent WF LASIK had postoperative manifest refractive spherical equivalent (MRSE) of -1.0 to +1.0D (Fig. 2). The average spherical equivalent at 1 year is -0.43 diopter ±0.64 (SD) (range: -2.31 to +1.50 diopters).

For the WF LASIK, the mean attempted refractive correction was -4.63D ±2.18, and the mean achieved refractive correction was -4.11±2.41. The linear regression analysis shows a very slight tendency towards under-correction (slope = 0.8973; intercept = 0.11) (Fig. 3). Coefficient of determination revealed a strong correlation between the attempted and the achieved correction (R^2= 0.92). For the STD LASIK group, the mean attempted refractive correction was -4.14D ±2.07, and the mean achieved refractive correction was -3.48±2.40. The linear regression analysis shows a very slight tendency towards under-correction (slope = 1.04; intercept = 0.83) as well (Fig. 4). One eye, however, was over-corrected by 2D. Coefficient of determination also revealed a strong correlation between the attempted and the achieved correction (R^2 = 0.81). The mean difference in the attempted versus achieved refraction was not significant between the 2 groups (p = 0.32).

3.4 Stability

The postoperative refraction of the eyes treated remained stable all throughout the 12-month follow-up period for both the WF and STD LASIK groups. Refractive stability was attained on the third postoperative month (Fig. 5) and the mean residual refractive error remained relatively stable at each follow-up visit.

Table 1. Demographics and baseline characteristics of patients

Parameter	Value
Patients: Eyes (N)	40 Patients: 80 Eyes
Male: Female (N)	16 Males: 24 Females
AGE (YRS)	
Mean ± SD	33.5 YRS ±7.41
Range	19-48
Pre-operative UDVA (LOGMAR)	
Mean ± SD	+1.40 (20/400)±0.61
Range	2.0-0.1
PRE-operative CDVA (LOGMAR)	
Mean ± SD	+0.02 (20/20)±0.09
Range	-0.12-0.7
Pre-operative MRSE (D)	
Mean ± SD	-3.54±2.2
Range	-9.0 - -4.12
Pre-operative astigmatism (D)	
Mean ± SD	-0.93±0.69
Range	-3.0 – 0.0
Attempted correction (D)	
Mean ± SD	-4.0±2.3
Range	-3.0 - -10.5
Follow-up (Months)	
Mean ± SD	12.38±1.03 Months
Range	12 -16 Months

CDVA: corrected distance visual acuity,
MRSE: manifest refraction spherical equivalent.
UDVA: uncorrected distance visual acuity

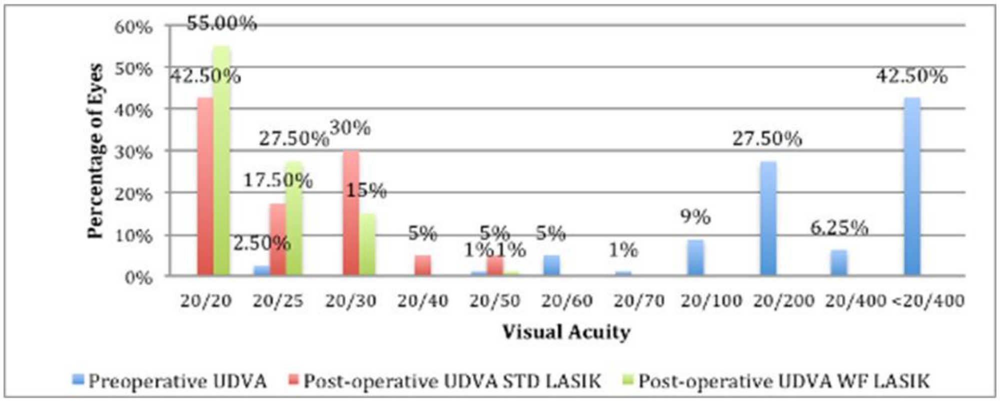

Fig. 1. Cumulative Uncorrected Distance Visual Acuity (UDVA) pre-LASIK and post-LASIK at 1 year

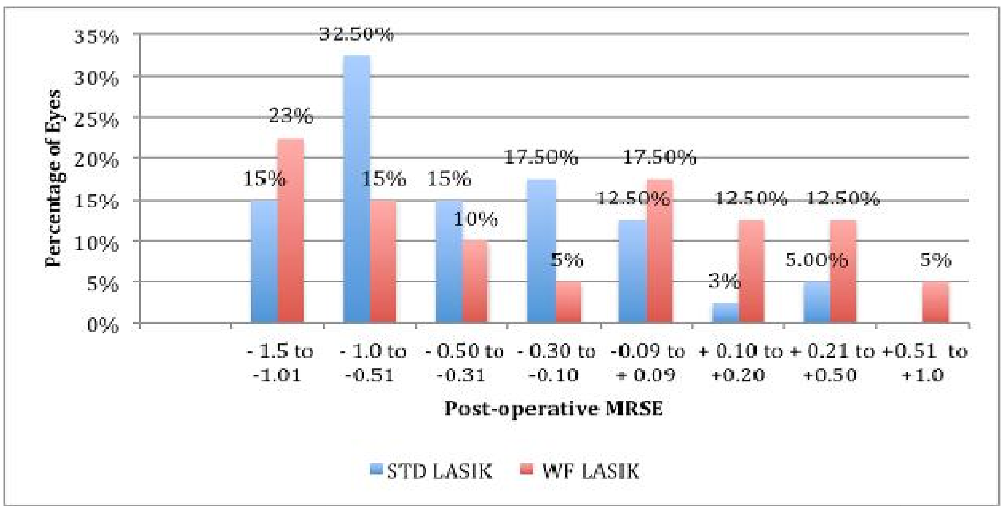

Fig. 2. Manifest Refractive Spherical Equivalent (MRSE) at one year post-LASIK

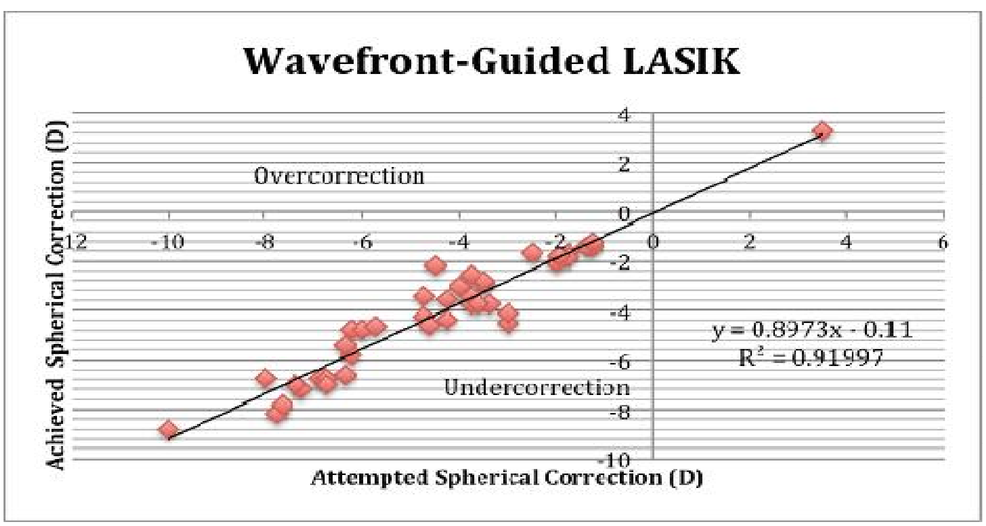

Fig. 3. Attempted v. achieved refractive results 1 year after Wavefront-Guided LASIK with Pulzar Z1

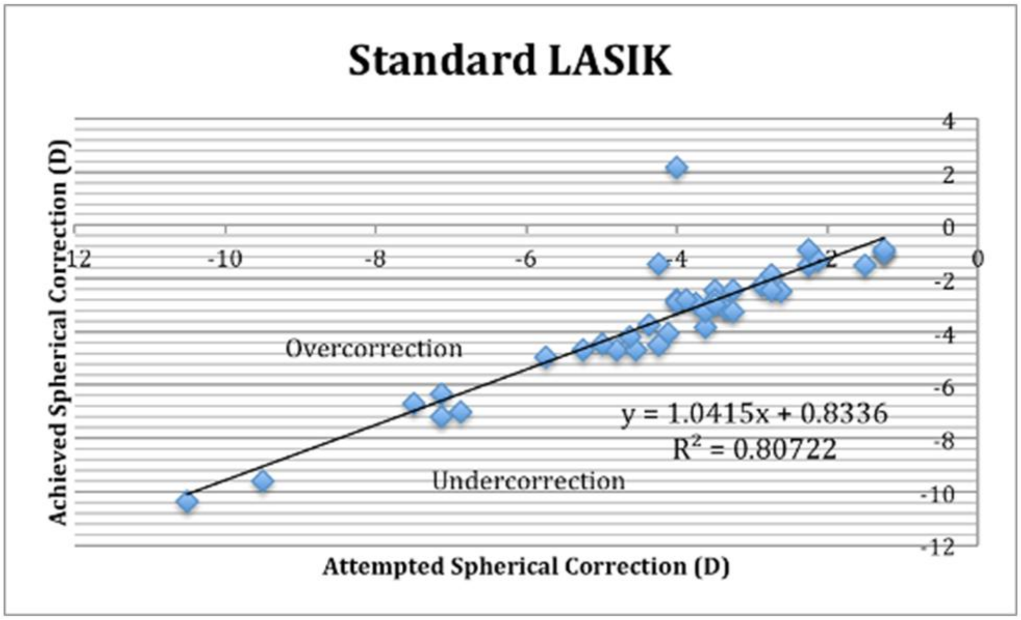

Fig. 4. Attempted v. achieved refractive results 1 year after Standard LASIK with Pulzar Z1

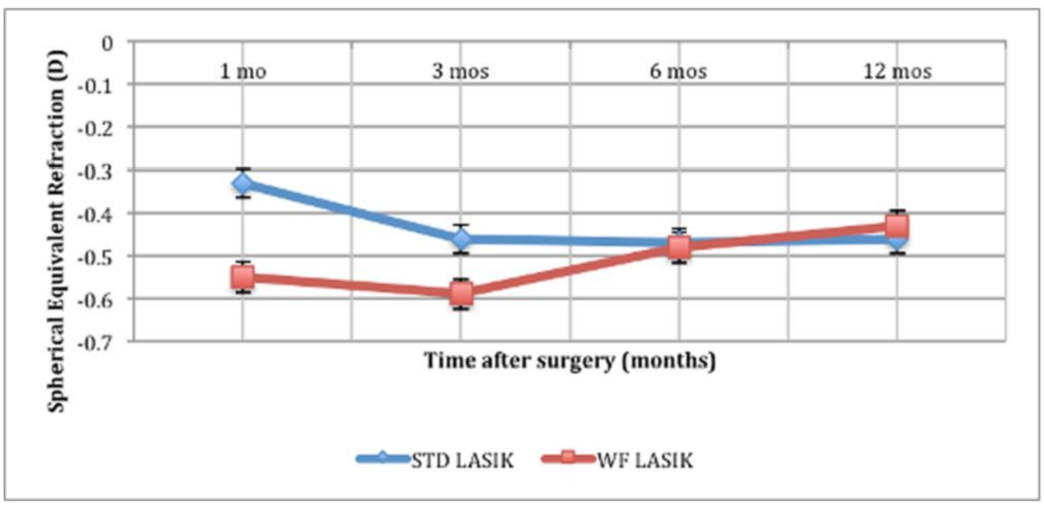

Fig. 5. Stability of refractive spherical equivalent at 1 year post-LASIK

3.5 Safety

At 12 months post-operatively, 67.5% (27 out of 40 eyes) in the STD LASIK group, and 62.5% (25 out of 40 eyes) in the WF LASIK group showed no change in their CDVA. Seven eyes (17.5%) gained 1 line in the WF LASIK group. On the other hand, eleven eyes (27.5%) in the STD LASIK group and 4 eyes (10%) from the WF LASIK group lost 1 line in their CDVA. (Fig. 6) No eyes lost 3 or more lines in their CDVA. None of the eyes developed haze of any degree during the 12-month follow-up period.

Fig. 7 shows the cumulative refractive astigmatism of patients before and after the LASIK procedure using the Pulzar Z1. The mean preoperative cylinder was -0.93D± 0.69, and the mean cylinder 12 months after the surgery was -0.68D±0.43 for the WF LASIK group and -0.64D±0.39 for the STD LASIK group. The mean change in cylinder power was −0.32D±0.84 and −0.22D±0.59 for the WF and STD LASIK, respectively. Majority of the patients (30%) who underwent WF and STD LASIK had post-operative astigmatism between -0.50 to -0.75 D (Fig. 7).

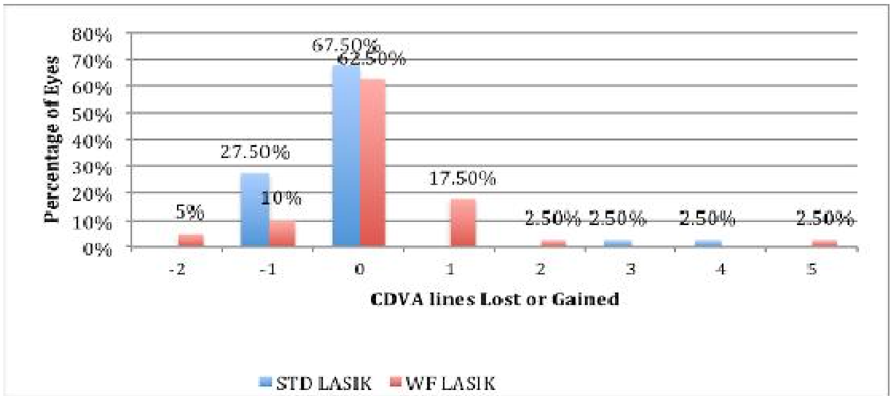

Fig. 6. Percentage of eyes that lost or gained lines of CDVA at 1 year post-LASIK

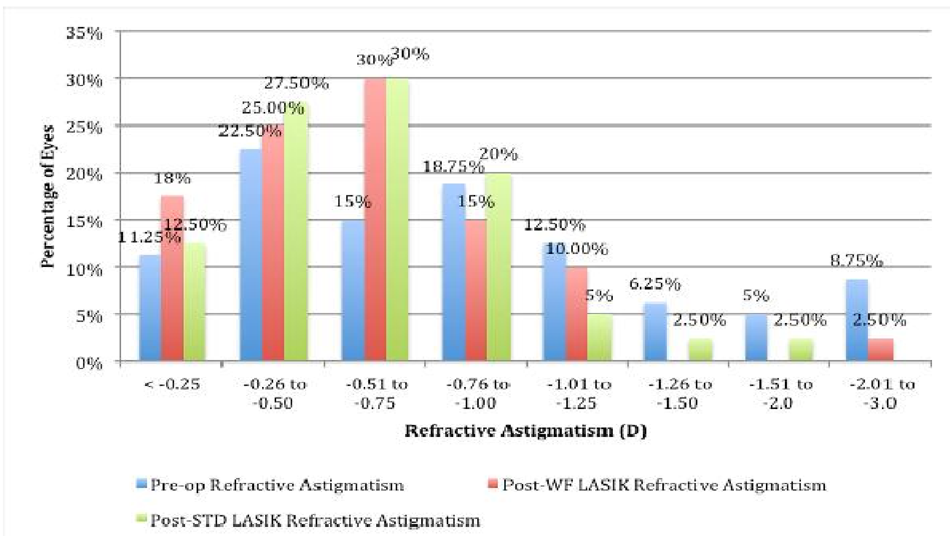

Fig. 7. Cumulative refractive astigmatism pre-LASIK and post-LASIK at 1 year

The mean keratometry (K) value was 45.12±1.70D preoperatively and 40.89±1.88D postoperatively. The mean difference between the preoperative and postoperative *K* value was 4.23D±0.18D. Based on the *K* values, the mean change in cylindrical power was 1.06D±0.50 D. No eye had any intraoperative, early, or late postoperative complications.

3.6 Higher-order Aberrations

Higher-order aberrations (RMS) generally increased postoperatively for WF LASIK while decreased for STD LASIK when compared with preoperative RMS values. The mean RMS difference from the pre- and post-operative values between the 2 groups was, however not statistically significant (p=0.32).

4. DISCUSSION

Laser-assisted in situ keratomileusis (LASIK) is a type of refractive surgery for the correction of refractive errors such as myopia, hypermetropia, and astigmatism [15]. The widespread use of excimer lasers in refractive surgery has been linked with safety issues in the clinical environment because of the use of the toxic gas, fluorine. Thus, a solid-state Nd: YAG laser with an output wavelength of 213-nm is gaining popularity as a possible alternative to the long-established 193-nm excimer laser system. They have increased reliability, robustness of design, safety and lower operating costs than gas or dye lasers. Several studies have also confirmed that corneal ablation rates of the solid state 213-nm lasers are comparable to those attained with excimer lasers for a similar pulse duration and repetition rates [16-17].

Table 2. Average Root Mean Square (RMS) in 40 eyes pre- and post-LASIK

Zernike coefficient (um)		Standard			Wavefront		
		Pre	Post	p	Pre	Post	p
3rd order							
Z3 -3	Trefoil w/base on x-axis	0.196125	0.156275	0.5566	0.129065	0.20135	0.1405
Z3 -1	coma along x-axis	0.2783	0.2669425	0.8952	0.124725	0.28365	0.0087
Z3 1	coma along y-axis	0.2263	0.190425	0.7579	0.112075	0.20245	0.0057
Z3 3	Trefoil w/base on y-axis	0.215825	0.152045	0.5755	0.92995	0.11655	0.1214
4th order							
Z4 -4	Quadrafoil	0.095075	0.092475	0.9369	0.06025	0.09065	0.0126
Z4 -2	2nd astig on y-axis	0.1579	0.071775	0.4019	0.06785	0.077025	0.5541
Z4 0	spherical aberration	0.1865	0.2795125	0.3054	0.134525	0.29617	0.0154
Z4 2	2nd astig on x-axis	0.07035	0.1008	0.1137	0.061	0.145775	0.0448
Z4 4	Quadrafoil	0.1435	0.08465	0.4996	0.059425	0.13585	0.1067
5th order							
Z5 -5	Pentafoil	0.096675	0.040875	0.3157	0.044625	0.073225	0.188
Z5 -3	2nd coma	0.076775	0.03978	0.2773	0.0502	0.082075	0.3269
Z5 -1	2nd coma	0.07925	0.079275	0.994	0.04245	0.1061	0.0779
Z5 1	2nd coma	0.07565	0.037475	0.4174	0.030875	0.045625	0.0426
Z5 3	2nd trefoil	0.07705	0.035275	0.3872	0.034025	0.0679	0.0743
Z5 5	Pentafoil	0.036775	0.04175	0.6754	0.03905	0.0447	0.5628

The Pulzar Z1 laser system, a 213-nm solid state laser, which was used in this study, has advantages that may be beneficial in producing effective results in refractive surgery, particularly in customized treatments. These advantages include a small spot size (0.6 mm diameter, 2.5 times smaller than a typical excimer laser spot), high pulse-to-pulse stability, uniform Gaussian intensity beam distribution, and ultra-fast tracking system. These promote a more accurate transfer of laser energy onto the corneal stroma, creating a smoother ablation surface. Moreover, the Pulzar Z1 laser system emits at a 213-nm wavelength, which is near to the absorption peak of corneal collagen [18]. The smaller spot size, on the other hand, causes less damage on the corneal structure and fewer cellular changes as a result of minimal mechanical stress during ablation [19]. It is also less affected by corneal hydration and environmental humidity, which are factors that may influence final outcomes of conventional excimer laser systems [18].

The results of this study showed that, in terms of visual outcomes, WF LASIK is safer in terms of number of Snellen lines gained in CDVA during the follow-up period. Eleven eyes (27.5%) in the STD LASIK group and 4 eyes (10%) from the WF LASIK group lost 1 line in their CDVA. Loss of lines in visual acuity might be either due to under-corrections/overcorrections or secondary to high corneal aberration induction and scattering resulting to reduction in image quality. Wavefront-guided LASIK is also more accurate in terms of post-operative UCVA with 97.5% of the eyes reaching 20/30 or better at 1 year post-operatively when compared to those who underwent STD LASIK. However, the mean difference in attempted versus achieved refraction was not significant between the 2 groups (p=0.32). These results were comparable to those achieved in a study using the excimer laser system wherein postoperative UCVA was 20/20 or better in 92% and 20/25 or better in 99% of eyes. [20] In terms of safety, the excimer laser system lost one line in CDVA in 6% of eyes and no eyes lost two or more lines [20]. In another study using the excimer laser system, all eyes treated had at least 20/50 UCVA and 91% of eyes either maintained or gained 1 line of CDVA [21].

In addition, LASIK using a 213-nm wavelength solid state laser in myopia increases overall higher-order aberrations for WF LASIK while it decreases overall higher-order aberrations in STD LASIK treatment. Wavefront-guided LASIK, moreover, offers no advantage over standard LASIK in improving higher-order aberrations (HOA) and in achieving better visual and refractive outcomes. This was observed despite the theoretical assumption that wave-front guided LASIK is able to identify higher order aberrations and formulate an ablation pattern to address them. When compared to other studies, our results were similar with the findings of Roces et al. [22] and Vongthongsri A, et al. [23] who concluded that LASIK in low to moderate myopia increases overall high-order aberrations, and the use of WF LASIK offered no advantage over conventional LASIK in decreasing high-order aberrations postoperatively and in achieving better visual and refractive outcomes. D'Arcy et al. [24] also observed that customized ablation was associated with a smaller but not statistically significant postoperative increase in HOA, better preservation of scotopic contrast sensitivity, quicker treatment time and removal of less corneal tissue. On the other hand, our results were in contrast with the findings of Urbano et al. [25] where WF LASIK produced better visual quality than STD LASIK in the retreatment of refractive errors after primary LASIK. The lack of significant difference between the outcomes of WF LASIK and STD LASIK for this study might be explained by significant unexpected aberrations that are induced by not just the corneal flap status and secondary effects of corneal tissue loss, but also by aberrations brought about by corneal tissue healing, reorganization, and remodelling after the surgical procedure among others. It must also be considered that any procedure circumferentially severing corneal lamellae produces a biomechanical response, which alters corneal dimensions in a manner that cannot be solely predicted with wavefront analysis.

The increase in corneal spherical aberration after WF LASIK may be due to the surgically induced changes in anterior corneal curvature where in the light rays emerging from the posterior surface strikes the lens in such a way that modified the lenticular aberrations and maintained the same level of internal aberrations compensation postoperatively as observed by Gatinel et al. [26] using ray tracing analysis. Moreover, in another study by McAliden, it was observed that corneal spherical aberration increased after LASIK with a subsequent corresponding increase in the internal spherical aberration [27]. This signifies an active compensatory mechanism of the internal optics of the eye to reduce the effect of the surgically-induced corneal higher order aberration. The exact mechanism of internal optics compensation following a refractive surgery procedure is still unclear, thus additional studies are warranted at this time.

Since this is a retrospective and non-randomized case series with a small sample size, another limitation would be the inability to extrapolate the findings of this study to a larger population. The absence of contrast testing, the wide variability in the amount of myopia, and the difference in the period of follow-up are also its major limitations. Other important parameters that should be taken into consideration are corneal topographic changes, patient satisfaction, and quality of vision post-operatively.

5. CONCLUSION

Refractive surgery using the Pulzar Z1 213-nm wavelength solid-state laser is an effective and safe procedure in the treatment of myopia. Wavefront-guided LASIK generally increased overall higher order aberrations while standard LASIK treatment showed decreased levels of higher order aberrations. Wavefront-guided LASIK offers no advantage over standard LASIK in improving higher-order aberrations and in achieving better visual and refractive outcomes. It is further recommended that future studies have a larger sample base and include patients with higher grades of myopia and astigmatism to validate the results of this study.

ETHICAL APPROVAL

The authors hereby declare that all procedures in this study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

None of the authors are consultants of the companies mentioned in this manuscript. They also have no financial interests in the results of this study.

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