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Comparison of higher-order aberrations after LASIK using disposable microkeratome 130 and 90 micron heads

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PURPOSE. *To analyze and compare higher-order aberrations (HOAs) in cases of laser in situ keratomileusis (LASIK) flaps made using the Moria M2 disposable 130-μm head with those made using the 90-μm head.*
METHODS. *Consecutive prospective comparative clinical trial. Ninety-four consecutive eyes of 48 patients were enrolled in this study. They were divided into two equal groups of 47 eyes that underwent wavefront-guided LASIK using VISX CustomVue (VISX, Santa Clara, CA) system. Corneal flap was created using the disposable Moria M2 130 μm in the first group and the 90 μm head in the second one. All patients were followed up for 6 months. Wavefront aberrations were measured at baseline, 1 month, and 6 months after surgery using the WaveScan (VISX Inc.) aberrometer. Root mean square (RMS) of HOAs, coma, and spherical aberration (SA) values were analyzed and compared in the two groups.*
RESULTS. *At 6 months, values of RMS of HOAs, coma, and SA obtained from the 130-μm head group were 0.32±0.10 μm, 0.20±0.11 μm, and 0.18±0.08 μm, respectively. Values of RMS of HOAs, coma, and SA obtained from 90-μm head group were 0.33±0.12 μm, 0.19±0.10 μm, and 0.15±0.08 μm, respectively. Analyzing the data obtained revealed no statistically significant differences between the two groups. In each group, there was a significant decay of higher-order RMS and coma values from 1 month to 6 months.*
CONCLUSIONS. *HOAs following use of Moria M2 disposable 90 μm head are similar to those arising following use of the 130 μm. (Eur J Ophthalmol 2008; 18: 332-7)*

KEY WORDS. *Higher-order aberrations, RMS, Coma, Spherical aberrations, Thin-flap LASIK*

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INTRODUCTION

Thin-flap laser in situ keratomileusis (LASIK) is a general term used to describe LASIK performed under intentionally created thin flaps of 130 μm thickness or less. Thin-flap LASIK has been proven to be a safe, effective, and predictable procedure for myopic refractive corrections (1-6). It has the potential advantage of preserving more posterior corneal tissue available for laser ablation and maximizing corneal mechanical stability, thus reducing the risk of iatrogenic keratectasia following conventional-flap LASIK (1, 7-8). In addition, thin-flap LASIK allows for rapid postoperative visual recovery (3), better flap thickness predictability (4), less risk of epithelial defects (5), and lower rate of enhancements (6). It has been proposed that ultrathin flaps (<100 μm) show better contrast sensitivity and less induction of higher-order aberrations (HOAs) when compared with thicker flaps (9), (Hachet E. Lepto-LASIK improves visual outcomes and safety of LASIK. Ocular SurgNews, August 15, 2004). The current study compares the root mean square (RMS) of HOAs, coma, and spherical aberration (SA) in LASIK corneal flaps created by the 130-μm with those fashioned by the 90-μm heads.

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PATIENTS AND METHODS

Study population

In this prospective interventional comparative clinical trial, 94 consecutive eyes of 48 patients (22 men and 26 women) were enrolled. All patients underwent wavefront-guided LASIK as a primary procedure to correct their myopia (with or without astigmatism). Patients were divided into two equal groups of 47 eyes (24 patients) each. The first group underwent LASIK using the disposable Moria M2 130 µm head while the second group had the same using the disposable Moria M2 90 µm head. Study inclusion criteria included a minimum age of 19 years, maximum age of 39 years, myopia of ≤–8.00 diopter (D) (with or without astigmatism of ≤–3.00 D), a visual acuity correctable to 20/20 or better, no history of previous refractive or intraocular surgery, a WaveScan-measured pupil of at least 6.00 mm in dim illumination, and a difference between manifest and WaveScan refractions (sphere and cylinder) between –0.50 D and +0.75 D. Preoperative soft contact lens wearers were instructed to stop their use for at least 2 weeks before surgery.

Exclusion criteria included cases with conditions that could affect ocular aberration, namely age ≥40 years, myopia higher than –8.00 D, astigmatism more than –3.00 D, keratometry values ≥45.0 D, patients with dry eyes, corneal or lenticular disease, and previous ocular surgery. Cases with the usual local and systemic contraindications to perform photorefractive corneal procedures were excluded as well.

Preoperative evaluation

Preoperative workup consisted of detailed medical and ophthalmic histories, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), subjective manifest and cycloplegic refractions, slit lamp biomicroscopy, applanation tonometry, and detailed funduscopy. Preoperative investigations included automated or manual keratometry, pupil size measurement, ultrasonic pachymetry, and corneal topography. In addition, a cluster of dilated WaveScan measurements was obtained for each patient using WaveScan System (VISX Inc., Santa Clara, CA). The surgical procedure, possible risks, and other visual rehabilitation options were discussed in detail with each patient, and an informed consent was obtained.

Surgical technique

After receiving topical anesthesia, the eyelids were prepared with povidone-iodine (Betadine®), and a drape was placed in the usual sterile fashion. The corneal periphery was marked using an ink marker to facilitate flap repositioning at the end of surgery. Corneal flap was created using Moria M2 microkeratome with the 130 µm single use head (Moria, France) in the first group of eyes, and with 90 µm single use head in the second group. In each patient, the same disposable head was used for operating both eyes. After creating the flap, a cyclodialysis spatula was used to elevate the flap and expose the stromal bed. Autocentration with the tracker system was selected followed by wavefront-guided ablation using VISX Star S4 CustomVue (VISX Inc.) system. After photoablation, the flap was repositioned and irrigation was performed under it. After surgery, all patients were prescribed a mixture of tobramycin and dexamethasone eyedrops (TobraDex®, Alcon Laboratories, Fort Worth, TX) to be applied 4 times daily for 7 days. Artificial tears were also prescribed to decrease postoperative irritation. Special sunglasses with ultraviolet filters were given to all the patients to be worn the first few days following surgery. Patients were instructed not to rub their eyes under any circumstances.

All eyes were targeted for emmetropia. The maximum optical zone was determined by the WaveScan software based on the relationship between sphere and cylinder and the ablation zone. The minimum optical zone was set at 6.0 mm, and the transition zone was 8.0 mm.

All patients were reviewed at 1 day, 1 week, and at 1, 3, and 6 months. Only 1-month and 6-month data are presented. In addition to subjective refraction and regular slit lamp examination, corneal topography was performed at each visit and WaveScan measurements were performed after 1 month and again after 6 months. Values of higher-order root mean square (RMS), coma, and spherical aberration in the two groups of patients were recorded and compared.

Statistical analysis of the results was performed using the SPSS/10.1 program for Windows. A normality test was applied to each sample of data before the statistical analysis. Results are expressed as mean ± standard deviation (SD). Statistically significant differences between data sample means were determined using paired-sample *t* test. p Values less than 0.05 were considered statistically significant.

RESULTS

Table I summarizes the demographic information and shows the visual acuity, refractive, and HOAs values obtained preoperatively. The two study groups were comparable to each other in all preoperative demographic, refractive, and HOA parameters with no preoperative statistically significant differences between them (p value > 0.05).

Postoperative higher-order RMS

Table II shows the higher-order RMS values obtained at 1 and 6 months postoperatively. Comparison of higher-order RMS values showed no statistically significant difference between the two study groups at both 1 month and 6 months postoperatively (p value > 0.05).
Within each group, higher-order RMS showed statistically significant decay from 1 month to 6 month values postoperatively (p value < 0.05) (Fig. 1).

Postoperative coma

Table III shows the coma values obtained at 1 and 6 months postoperatively. Data comparison of coma aberration showed no statistically significant difference between the two groups at both 1 month and 6 months postoperatively (p value > 0.05).
Within each group, coma showed statistically significant decay from 1 month to 6 month values postoperatively (p value < 0.05) (Fig. 2).

Postoperative spherical aberrations

Table IV shows the SA values obtained at 1 and 6 months postoperatively. Data showed no statistically significant difference between the two groups at both 1 and 6 months postoperatively (p value > 0.05).
Although there was a clinical tendency towards decrease of SA values from 1 month to 6 months (Fig. 3), the amount of decrease did not reach statistical significance (p value > 0.05) in both groups.

Postoperative visual and refractive data

Postoperative UCVA and BSCVA at 6 months are displayed in Table V. No eye lost one line or more of BSCVA. At 6 months, all eyes in both groups were within ±1.0 diopter of intended correction. The mean refraction spherical equivalent (MRSE) was –0.42±0.40 for the 130-µm group, and –0.49±0.37 for the 90-µm group.

TABLE I - SUMMARY OF PREOPERATIVE DATA

Parameter	Group A (130 µm)	Group B (90 µm)
No. of eyes	47	47
No. of patients	24	24
Age, yr, mean ± SD	28.3±4.2	27.0±4.5
Sex, n (%)		
Male	11 (45.8)	10 (41.7)
Female	13 (54.2)	14 (58.3)
BSCVA, n (%)		
≥20/20	47 (100)	47 (100)
>20/20	7 (14.9)	6 (12.8)
Refraction, mean ± SD		
Sphere	–4.03±2.1	–4.10±1.9
Cylinder	–0.82±0.6	–0.75±0.6
MRSE	–4.44±2.1	–4.46±1.9
HOAs, µm, mean ± SD		
RMS	0.29±0.10	0.30±0.12
Coma	0.16±0.11	0.17±0.11
SA	0.08±0.06	0.06±0.50

BSCVA = Best spectacle-corrected visual acuity; MRSE = Mean refraction spherical equivalent; HOAs = Higher-order aberrations; RMS = Root mean square; SA = Spherical aberration

TABLE II - POSTOPERATIVE HIGHER-ORDER RMS VALUES

Parameter	Group A (130 µm)	Group B (90 µm)	p value
1 month	0.36±0.12	0.37±0.14	0.635
6 months	0.32±0.10	0.33±0.12	0.896
p value	0.002	0.002	

Values are mean ± SD µm
RMS = Root mean square

TABLE III - POSTOPERATIVE COMA VALUES

Parameter	Group A (130 µm)	Group B (90 µm)	p value
1 month	0.34±0.21	0.31±0.21	0.388
6 months	0.20±0.11	0.19±0.10	0.858
p value	0.000	0.000	

Values are mean ± SD µm

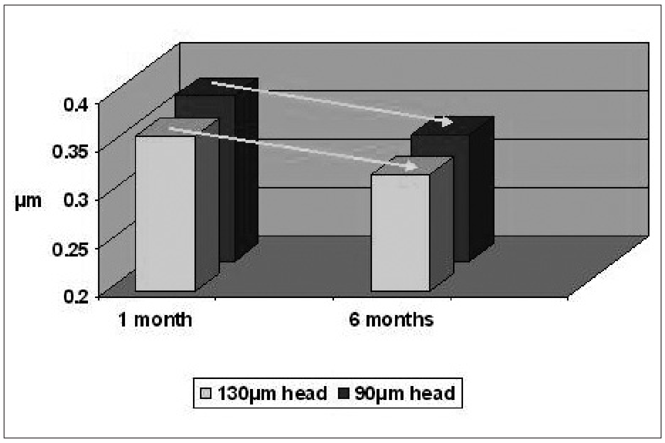

Fig. 1 - *Higher-order root mean square at 1 month and 6 months postoperatively.*

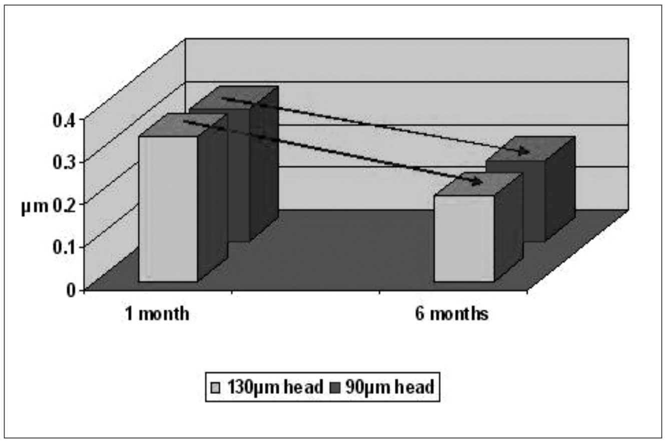

Fig. 2 - *Coma at 1 month and 6 months postoperatively.*

TABLE IV - POSTOPERATIVE SPHERICAL ABERRATIONS VALUES

Parameter	Group A (130 µm)	Group B (90 µm)	p value
1 month	0.21±0.14	0.16±0.14	0.161
6 months	0.18±0.08	0.15±0.08	0.110
p Value	0.075	0.604	

Values are mean ± SD µm

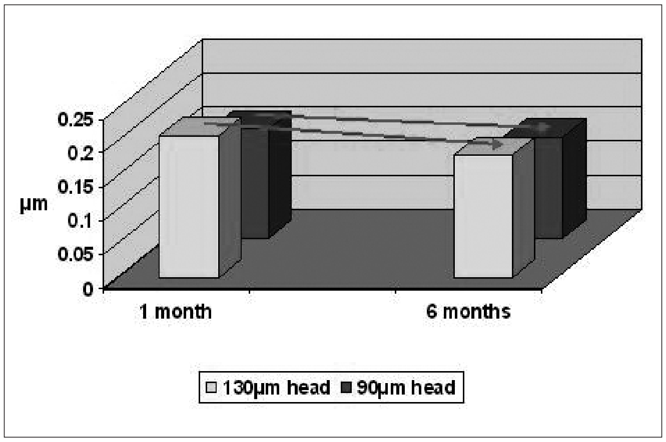

Fig. 3 - *Spherical aberrations at 1 month and 6 months postoperatively.*

TABLE V - POSTOPERATIVE UCVA AND BSCVA AT 6 MONTHS

Parameter	Group A (130 µm)	Group B (90 µm)
UCVA		
≥20/20	43 (91.4)	44 (93.6)
≥20/40	45 (95.7)	46 (97.8)
BSCVA		
≥20/20	46 (97.8)	46 (97.8)
≥20/40	47 (100)	47 (100)

Values are n (%).
UCVA = Uncorrected visual acuity; BSCVA = Best spectacle-corrected visual acuity.

Complications

No intraoperative or postoperative complications were reported in the study.

DISCUSSION

LASIK is currently the most common form of refractive surgical procedure performed in patients with low to moderate refractive errors (10). Conventional LASIK entails the formation of a relatively thick corneal flap at a depth of 160–180 µm. Therefore it has the potential risk of compromising the corneal biomechanical stability that predisposes, in some cases, to the most notorious complication of LASIK, namely corneal ectasia or iatrogenic keratoconus (11, 12). Several techniques have been proposed to get over this problem especially in patients at risk of excessive thinning of the residual corneal bed such as those with thinner corneas (central pachymetry measures less than 550 μm) and high myopic refractive errors. Thin-flap LASIK, laser-assisted subepithelial keratectomy (LASEK), and epithelial laser in situ keratomileusis (epi-LASIK) are relatively recent superficial photoablative techniques that aim at maximizing the amount of residual posterior corneal stroma following laser ablation. Efficacy and safety of these procedures compare favorably with those of LASIK (4-7, 13-16). Thin-flap LASIK allows for faster and more comfortable visual recovery relative to LASEK and epi-LASIK which have the disadvantages of pain and blurred vision for several days postoperatively (17, 18).

Classically, visual acuity outcomes, contrast sensitivity, and wavefront aberrations are the criteria used for functional assessment of quality of vision following different photoablative techniques. The creation of a conventional LASIK flap (160–180 μm) induces second order as well as higher-order aberrations (19, 20). It has been suggested that HOAs are less significant in thinner flap and more superficial LASIK procedures due to the fact that the stromal structural stability and biomechanical function of the cornea are less compromised (Hachet E. Lepto-LASIK improves visual outcomes and safety of LASIK. Ocular SurgNews, August 15, 2004).

Few studies have aimed at direct comparison between HOAs following different superficial photoablative techniques and those after conventional flap LASIK. A recent study showed significantly higher RMS wavefront error of HOAs for a scotopic pupil in wavefront-guided LASEK when compared to wavefront-guided LASIK during the first postoperative month (21). In a study evaluating the early clinical outcomes of epi-LASIK for myopia, Dai et al (22) found that HOAs increased significantly while contrast sensitivity decreased 1 month postoperatively and was restored to preoperative levels in eyes with preoperative spherical equivalent refraction <–10.0 D. Chalita had no significant differences in HOAs between wavefront-guided LASIK using 110m Moria M2 microkeratome and Intralase femtosecond laser flaps (Chalita MR. Comparison of custom LASIK outcomes with femtosecond laser and conventional microkeratome. Presentation at American Society of Cataract and Refractive Surgery/American Society of Ophthalmic Administrators (ASCRS/ASOA) Annual Meeting; April 2005; Washington, DC).

Recent studies showed better visual acuity and contrast sensitivity results in patients with ultrathin-flap (<100 μm) compared with medium (100–129 μm) and thick (>130 μm) flaps with no statistical difference in the complication and retreatment rates (6, 9).

The current study revealed no statistical difference in higher-order RMS, coma, and SA between customized LASIK cases done with 130 μm and those performed with 90 μm microkeratome heads on 1 month and 6 month follow-ups. Of note, both groups have shown the same characteristic decay of the initial postoperative rise of HOAs. By 6 months, higher-order RMS and coma values were significantly less than those obtained at 1 month postoperatively. SA values showed less pronounced decrease of the initial postoperative rise, yet values did not reach the level of statistical significance in both groups.

This study had the limitation of not reporting the intraoperative pachymetry of the corneal flap to document the achieved flap thickness with either microkeratome. This would have better demonstrated the impact of flap thickness on the HOAs. However, several previous studies have measured the actual thickness range of the flaps created with both microkeratome heads. In addition, they have demonstrated the accuracy and reproducibility of Moria M2 microkeratomes. The mean flap thickness that is achieved using the 130 μm head range between 145 μm and 153 μm (24, 25), while the mean postoperative flap thickness using the 90 μm head is between 109 μm and 115.4 μm (26, 27). Based on the previous reports, we assumed that the 130 μm head produced thicker mean flap thickness than that obtained by the 90 μm head.

Analysis of postoperative HOAs is one of the objective ways to evaluate the functional outcome following different LASIK techniques. We recommend that further comparative studies be conducted to elucidate the outcome of HOAs following different superficial LASIK procedures. These studies should include larger numbers of patients who have higher mean myopic refractive errors and are followed up over longer periods of time.

The authors have no financial interest in any of the issues discussed in this article and have no proprietary interest in the development or marketing of the products or medical equipment used in this study.

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