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Association of Surgeon Experience with Outcomes of Femtosecond LASIK

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Abstract

Purpose—To determine effect of surgeon experience on outcomes of LASIK.

Methods—Retrospective case series of myopic femtosecond LASIK performed by residents and fellows compared to an attending, with mean follow-up of 6.6 months.

Results—Seventy-two eyes (38 patients) had LASIK performed by a trainee and 157 eyes (83 patients) by an attending. There were no statistically significant preoperative differences. The attending surgeon had lower mean flap thickness ($p=0.0001$), but ablation depth and residual stromal bed were similar. Postoperative uncorrected distance visual acuity was significantly better in the experienced surgeon group on the first postoperative day ($p=0.0203$). Postoperative findings of microstriae ($p<0.0001$) and interface debris ($p=0.0034$) were more common with trainee-performed LASIK.

Conclusions—Visual outcomes are excellent after femtosecond LASIK performed by trainees and experienced surgeons. Early postoperative complications are more common in trainee-performed LASIK, but are not visually significant. Resident and fellow LASIK surgical training with a comprehensive refractive curriculum under the guidance of an experienced surgeon is safe and appropriate.

INTRODUCTION

With more than a million refractive surgeries performed each year, laser-assisted in situ keratomileusis (LASIK) is one of the most common surgical procedures performed in the United States.¹ As such, it is critical that ophthalmology residency programs incorporate refractive surgery education, including both didactic instruction in the fundamental concepts of refractive surgery and practical hands-on experience with refractive procedures. Several recent publications,^{2–4} as well as the recently released Accreditation Council for Graduate Medical Education (ACGME) guidelines support this sentiment.⁵

The new 2010 ACGME guidelines mandate that residents perform or assist in at least six refractive surgery cases during their training. Kwon et al. reported that only 55% of programs surveyed in 2005–6 had resident-performed LASIK surgery.² This was more than double the 26% of trainees performing LASIK reported in 2000 by Aaron and Aaberg.³ Despite this significant increase in resident training, approximately 9% of programs did not provide any refractive training for residents in the more recent survey.² The American

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Academy of Ophthalmology, the International Society of Refractive Surgery, and the American Society of Cataract and Refractive Surgery all support refractive surgery experience as a necessary element in ophthalmology training; however, there has been considerable debate about how to best incorporate refractive surgery training.^{2-4, 6-8}

One of the main considerations in surgical training is maintaining patient safety while providing a supportive environment for learning new techniques. Few previous studies have been performed to assess whether trainee-performed LASIK surgery is associated with increased risks. One study of outcomes of initial experience with LASIK cases by 19 surgeons using a microkeratome suggested comparable results to those reported by experienced surgeons.⁹ Another study compared the first 50 cases performed by each of 10 anterior segment fellows using a microkeratome with cases of experienced faculty members and reported similar visual acuity outcomes with slightly higher, but acceptable, complication rates for the fellows.¹⁰ In another study, outcomes of 44 cases of 22 patients who underwent LASIK performed by residents using a microkeratome were assessed and LASIK surgery performed by residents was found to be safe and effective.¹¹ Another recent report of resident-performed refractive surgery found excellent visual outcomes.¹²

Our study directly compares outcomes of initial experience of femtosecond laser LASIK surgeries performed by trainees in our residency and cornea fellowship programs to the surgical outcomes of an experienced refractive surgeon.

MATERIALS AND METHODS

After approval by the University of Michigan Institutional Review Board, a retrospective review of the records of all myopic LASIK surgeries with a femtosecond laser for flap creation performed by residents and fellows in the refractive surgery service at the W.K. Kellogg Eye Center from 2003 to 2009 was performed. Consecutive eyes undergoing myopic LASIK by a surgeon-in-training were included. Inclusion criteria for patients included a minimum age of 21 years, a normal ophthalmic examination except for refractive error, stable refraction for at least 6 months, and a minimum calculated residual corneal stromal bed thickness greater than 275 microns. Patients with irregular contour on corneal topography were excluded. Based on the new ACGME guidelines of assisting or performing six refractive cases in residency, we chose to include up to the first six LASIK cases performed by each trainee in our analysis. Of note, some trainees did perform more than six surgeries during the course of their training, but these were not included in this analysis. A total of 72 eyes of 38 patients were included in the trainee group; 34 eyes of 19 patients had surgery performed by 18 senior residents, and 38 surgeries on 19 patients were performed by 8 corneal fellows. These were compared to a control group of 157 eyes of 83 consecutive patients (from 2008–2009) who underwent myopic LASIK performed by an experienced refractive surgeon (SIM).

Preoperative clinical characteristics, treatment parameters, visual acuities, intraoperative and postoperative complications of the trainee-performed cases were recorded. DLK was graded clinically as previously described by Linebarger et al.¹³ Stage 1: white granular cells located in flap periphery; Stage 2: white cells migrate toward flap center; Stage 3: white cells more densely clumped, often with relative peripheral clearing; Stage 4: stromal melting, scarring, bullae formation, and stromal volume loss. Even very mild flap interface inflammation was noted as Stage 1 DLK.

The preoperative screening process, surgical technique, and postoperative regimen were similar for all patients. LASIK surgeries were performed using the IntraLase femtosecond laser (Abbott Medical Optics, Irvine, CA) for flap creation and an excimer laser (Technolas

217, Bausch & Lomb, Rochester, NY) for stromal ablation. The postoperative treatment protocol was the same for all patients, using prednisolone acetate 1% and a fourth generation fluoroquinolone eye drop every 2 hours for the first 24 hours after the procedure, followed by four times a day for the first postoperative week. Routine follow-up included visits at 1 day, 1 week, 1, 3, 6, and 12 months after surgery.

All prospective LASIK patients were given the option of having LASIK performed by a resident or fellow at a discounted price. Residents and fellows took part in a 4 hour didactic curriculum on refractive surgery, 1 hour wet lab experience, and acted as clinical assistant on at least 5 procedures prior to performing their first surgery. The trainees were all closely supervised through the process of case selection, surgical decision-making, the procedure, and postoperative care by the same experienced refractive surgeon (SIM).

Statistical analysis was performed using SAS 9.3 software (SAS Institute, Cary, North Carolina). Comparisons between the groups were made using t-test for continuous subject-based variables and linear mixed regression models (to adjust for inter-eye dependency) for continuous eye-based variables; categorical comparisons were made using chi-square and Fisher's exact tests. Logistic regression models, using generalized estimating equations to correct for inter-eye correlation, were used to assess differences in rates of postoperative complications. P-values less than .05 were considered statistically significant.

RESULTS

Preoperative

Seventy-two eyes of 38 patients operated on by residents or fellows and 157 eyes of 83 patients operated on by one attending faculty surgeon were included. The mean age of the 16 male and 22 female trainee patients was 38.3 ± 11.3 years and the mean age of the 37 male and 46 female in the attending group was 37.8 ± 9.8 years. The mean follow-up of the trainee and attending patients was 6.3 ± 5.0 months (1 day to 1 year) and 6.7 ± 4.8 months (1 day to 1 year), respectively. There were no differences in preoperative characteristics between the attending and trainee groups (Table 1).

Intraoperative

Mean LASIK flap thickness was greater in the trainee cases when compared to the attending cases ($p < .0001$). There were no other differences in intra-operative parameters between the two groups (Table 2).

Visual Acuity Outcomes

Uncorrected distance visual acuity (UDVA) was better in the attending-operated patients ($\log\text{MAR} = .02 \pm .14$) than in the trainee patients ($\log\text{MAR} = .08 \pm .15$) on the first postoperative day ($p = .0203$). UDVA was similar in both groups at all subsequent time points (Figure 1). Corrected distance visual acuity (CDVA) was similar between the two groups at all postoperative time points, although there was a trend ($p = .0762$) towards better CDVA in the attending group on the first postoperative day. No eyes lost any lines of CDVA in this study.

Complications

There were no major surgical or postoperative complications in any patients in this study. Postoperative flap microstriae and interface debris were more common in trainee-performed LASIK when compared to cases performed by the attending surgeon (Table 3). Over the course of follow-up, microstriae were observed postoperatively in 9 (12.5%) of the trainee patients and 3 (1.9%) of the attending patients ($p < .0001$). The presence of microstriae was

correlated with decreased UDVA and CDVA at the 1 week postoperative time point ($p < .001$). LASIK interface debris was present in 12 (16.7%) patients in the trainee group and 5 (3.2%) patients in the attending group ($p = .0034$). These postoperative complications were observed only in the early postoperative period, and did not have a significant effect on long-term outcomes.

Diffuse lamellar keratitis (DLK), defined as any inflammation present in the flap interface, developed in 13 (18.1%) of the trainee operated patients and 28 (17.8%) of the attending operated patients. The majority of cases of DLK were very mild without long-term sequelae. There was no difference in the incidence or severity of DLK between the two groups (Table 3). There was a similar rate of enhancement procedures in the two groups, with two re-treatments performed in each ($p = .5903$).

DISCUSSION

Refractive surgery is increasingly being incorporated into residency training programs; however, the outcomes and complications of trainee performed LASIK have not been carefully examined. Our study suggests that outcomes are comparable after femtosecond LASIK performed by trainees when compared to an attending surgeon, without significant additional patient risks. Although minor early postoperative complications, including microstriae and interface debris, were more common in trainee-performed LASIK, visual outcomes in both groups of patients were similar after the first postoperative day. There were no severe complications and no postoperative microbial infections in either study cohort. This suggests that resident and fellow LASIK surgical training under the guidance of an experienced surgeon is safe and appropriate, and should continue to be incorporated into ophthalmology training programs.

This is the first study to report trainee outcomes in LASIK exclusively using a femtosecond laser for flap creation. Previous studies investigating outcomes of trainee-performed LASIK utilize a microkeratome,^{9,10,12} and report slightly higher complication rates than in our current study. Femtosecond LASIK has been shown to be more predictable, reliable, and safer than LASIK using a mechanical microkeratome.^{14,15} Advantages of the femtosecond laser include greater accuracy and reproducibility in flap creation, fewer flap complications, stronger flap adherence, and less epithelial ingrowth.¹⁶ The primary disadvantage of the femtosecond laser is the higher associated cost. However, the improved safety and predictability of the femtosecond laser makes it attractive for use in training residents and fellows.

The only significant difference identified in the pre- or intra-operative comparisons of the patient cohort in our study was flap thickness. The trainee group had significantly thicker flaps as compared to the attending group ($p < .0001$). We suspect this finding is due to a trend towards thinner LASIK flaps over time since the trainee cases in this retrospective study were collected over a longer period of time (2003–2009) than the attending cases (2008–2009).

UDVA was the same in both groups at all time points evaluated, except for the first postoperative day ($p = .0203$). This difference may be due to the increased rate of minor early postoperative complications of microstriae and flap debris in the trainee-performed surgeries.¹⁷ Despite the increased rate of minor complications, none of the trainee patients had vision threatening complications and UDVA between the two groups was similar after the first postoperative day. CDVA was not significantly different between the groups at any measured time point.

Retrospective studies have potential shortcomings that must be taken into account when interpreting the findings. The trainee-operated patients in this study chose to have their surgery performed by a trainee, rather than a more experienced surgeon, for a reduced surgical fee. Although this could introduce bias into our analysis, our preoperative evaluations (Table 1) indicate that the groups were similar in all measured parameters. Further, this reduced-cost option provides a model by which training programs can encourage patients to participate in trainee-performed refractive surgery. Ideally, a prospective study in which refractive surgery patients agree to be randomized to either a trainee or attending surgeon for their procedure may be performed. Extended follow-up evaluations for assessment of long term complications between the two groups would also be of interest.

Although this study spans several years, there were no significant changes in surgical techniques or equipment used in our facility over this time period, although there were changes in the femtosecond laser settings over time. Our unique comparison of femtosecond LASIK surgeries performed by a single experienced attending compared to trainee-performed cases all of which were overseen by the same supervising faculty member provides a fairly controlled environment to allow for reasonable comparisons.

This study provides compelling data with regards to safety of trainee performance of femtosecond LASIK procedures with appropriate supervision and training. All trainees in this study were required to participate in an extensive four hour didactic and one hour wetlab exposure prior to performing any LASIK procedures. In addition, all trainees assisted the attending surgeon in a minimum of five cases prior to their first procedure. Further, the attending was involved in every step of the patient evaluation and postoperative care to ensure patient safety and a well-rounded understanding of refractive surgery by the trainees. We suggest that a LASIK surgical training curriculum for residents and fellows under the guidance of an experienced surgeon, with complete disclosure to patients, is safe and appropriate.

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Figure 1. LogMAR Uncorrected Visual Acuity

Comparison of uncorrected visual acuity (UCVA) of trainee and attending LASIK groups reveals a statistically significant difference (*) on the first postoperative day ($p=.0203$). At all other time points, there was no difference in UCVA between the groups. Pre- and post-operative UCVA was significantly improved after LASIK surgery at all time points ($p<.0001$).

Table 1**Preoperative Characteristics**

	Trainee	Attending	P-value
Total patients	38	83	-
Total Eyes	72	157	-
	Mean (SD)	Mean (SD)	P-value
Age (years)	38.3 (11.3)	37.8 (9.8)	.7499
Spherical Equivalent (D)	-3.7 (2.0)	-3.5 (1.8)	.5810
Astigmatism (D)	-0.6 (0.7)	-0.7 (0.9)	.1126
logMAR UCVA	1.4 (.6)	1.4 (.6)	.8347
logMAR BCVA	-.07 (.07)	-.07 (.08)	.7679
Corneal Thickness (μm)	558.7 (26.6)	560.8 (28.9)	.6004
	Total (%)	Total (%)	P-value
Gender			
Female	43 (59.7)	87 (55.4)	0.5412
Male	29 (40.3)	70 (44.6)	
Eye			
Right	36 (50)	79 (50.3)	0.9643
Left	36 (50)	78 (49.7)	

Abbreviations: D=diopeters

P values from t-test for continuous subject-based variables and linear mixed regression models (to adjust for inter-eye dependency) for continuous eye-based variables, and Chi-square for categorical variables.

Table 2

Surgical characteristics

	Trainee (n = 72)	Attending (n= 153)	P-value
Flap Thickness (μm)	120.99 ± 3.84	116.69 ± 8.87	<.0001
Residual Stromal Bed (μm)	354.29 ± 43.26	361.14 ± 41.42	.2752
Flap Diameter (mm)	8.76 ± .26	8.82 ± .21	.0928
Optical Zone (mm)	6.54 ± .39	6.64 ± .32	.0640
Treated Spherical Equivalent (D)	-3.68 ± 2.0	-3.52 ± 1.79	.5810
Ablation Depth (μm)	83.35 ± 38.49	84.83 ± 37.46	.7897

Abbreviations: D=diopeters

P values from linear mixed regression models (to adjust for inter-eye dependency) for continuous eye-based variables

Table 3

Odds ratio of developing postoperative complications in attending-operated eyes as compared to trainee-operated eyes.

	OR (95%CI)	P-value
DLK	1.07 (0.43,2.68)	.8811
DLK grade	0.22 (0.02,2.79)	.2411
Interface debris	0.17 (0.05,0.56)	.0034
Flap microstriae	0.08 (0.03,0.28)	<.0001

Abbreviations: OR=odds ratio, CI=confidence interval, DLK=diffuse lamellar keratitis P values from logistic regression models, using generalized estimating equations to correct for inter-eye correlation