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The effect of procedure room temperature and humidity on LASIK outcomes

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Abstract

Objective—To determine if procedure room temperature and humidity during LASIK affects refractive outcomes in a very large patient sample.

Design—Retrospective cohort study.

Participants—202,394 eyes of 105,712 patients aged 18 to 75 years old who underwent LASIK at an Optical Express, Inc. location in their United Kingdom and Ireland centers from January 1, 2008 to June 30, 2011 who met inclusion criteria.

Methods—Patient age, gender, pre- and one month post-LASIK manifest refraction and flap creation technique were recorded as well as the ambient temperature and humidity during LASIK. Effect size determination, in addition to univariate and multivariate analysis was performed to characterize the relationships between LASIK procedure room temperature and humidity and post-operative refractive outcome.

Main Outcome Measures—One month post-LASIK manifest refraction.

Results—No clinically significant effect of procedure room temperature or humidity was found on LASIK refractive outcomes. When considering all eyes in our population, an increase of one degree Celsius during LASIK was associated with a 0.003 diopter more hyperopic refraction one month post-operatively and an increase in one percent humidity was associated with a 0.0004 more myopic refraction. These effect sizes were the same or similar when considering only myopic eyes, only hyperopic eyes and subgroups of eyes stratified by age and pre-operative refractive error.

Conclusions—Procedure room temperature or humidity during LASIK was found to have no clinically significant relationship with post-operative manifest refraction in our population.

It is unclear whether ambient temperature or humidity during the laser in-situ keratomileusis (LASIK) procedure affects refractive outcomes. In LASIK, the excimer laser is used to precisely remove a lenticule of tissue by ablating the corneal stomae, resulting in a change in refraction. Unlike the femtosecond laser which has an interface in direct contact with the

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cornea, the excimer applies laser energy to the cornea which travels through room air. It is therefore possible that changes in ambient temperature or humidity in the procedure room may affect the energy profile at the corneal surface, presumably by altering the absorption or light scattering properties of the air between the laser source and the cornea. It has been observed that excimer ablation rates in hydrogel buttons[1], ex-vivo bovine corneas[2] and human corneas[3] seem to be affected by their degree of hydration, suggesting that environmental factors which affect the level of corneal stromal hydration may change the response of corneal tissue to the excimer laser in clinical practice.

Limited in-vitro experimental data have not demonstrated that the ablation properties of the excimer laser are affected by ambient temperature[4]. However, a few reports from moderately sized patient populations have suggested that ambient temperature or humidity may indeed have a clinically significant effect on refractive outcome following LASIK[3, 5].

The primary aim of the present study was to determine in a very large patient cohort if procedure room temperature or humidity during LASIK has a clinically significant effect on the refractive outcome.

Methods

This study was deemed exempt from full review by the Committee on Human Research at the University of California, San Francisco because it used only de-identified patient data. This work is compliant with the Health Insurance Portability and Accountability Act of 1996 and adhered to the tenets of the Declaration of Helsinki.

Our study group included all patients aged 18 to 75 years old who underwent LASIK in their United Kingdom and Ireland centers from January 1, 2008 to June 30, 2011 who met inclusion criteria. All patients underwent a complete dilated ophthalmologic examination pre-operatively when considering eligibility for LASIK. This examination included an assessment of the tear film, which must be considered normal in order to proceed, as well as a slit lamp examination of the lids, lashes and cornea, with and without fluorescein staining, and measurement of the tear break-up time. Eyes were included if their pre-operative spherical equivalent manifest refraction was between −12.00 and +4.00 diopters (inclusive), emmetropia was the goal of LASIK (eyes with a target of ametropia for monovision were excluded), data was recorded for ambient temperature and humidity during LASIK and in which a manifest refraction was recorded one month following surgery. Manifest refraction was performed using a resolution-based technique in which the endpoint is the least amount of minus sphere that results in the best visual acuity ("push plus"). Cycloplegic refraction was also performed pre-operatively (thirty minutes following the instillation of two drops of 1% tropicamide) but was not performed post-operatively and therefore was not used for this study. The following data are also routinely recorded for all patients undergoing LASIK at Optical Express, Inc., and were gathered and analyzed for this study: patient gender and age, LASIK flap creation method (femtosecond vs. microkeratome) and pre-operative manifest refraction. Temperature and relative humidity were recorded immediately preceding each LASIK procedure (Cable Free ThermoHygrometer, Model# EMR963HG, Oregon Scientific, Portland, OR).

Operative Technique

No attempt was made to control temperature or humidity in the operating suite. The excimer laser nomograms used at Optical Express, Inc. were not based on ambient temperature or humidity, hence no adjustments were made for these factors. LASIK surgery was performed by one of 23 surgeons working at Optical Express centers. The Moria ONE Use-Plus automated microkeratome (Moria S.A., Antony, France) was used with a 130-μm standard head (or a Large-Cut head for some hyperopic eyes) and a suction ring with adjustable stops chosen by the surgeon on the basis of the keratometry readings, to create nasally hinged flaps. The IntraLase FS-60 laser (Abbott Medical Optics, Abbott Park, IL) created femtosecond flaps with diameter ranging from 8.2 to 9.2 mm and programmed depth from 100 to 120 μm. All femtosecond flaps were created with the hinge placed superiorly. Patient and surgeon preference determined the choice of procedure. Excimer laser was performed on a VISX Star S4 IR platform (Abbott Medical Optics, Santa Ana, CA). For LASIK flaps created by the femtosecond laser, the flap was lifted in a dry technique with no sponge being applied to the stromal bed before excimer laser treatment. For flaps created by the mechanical keratome, the flap was lifted and a semi-moist sponge was wiped across the stromal bed to ensure a uniform hydration. The excimer laser treatment was then immediately applied. After excimer laser application, the stromal bed was irrigated and the flap repositioned. Postoperatively, patients were prescribed a third-generation fluoroquinolone and 1% prednisolone acetate, each 4 times a day for 1 week, and instructed to use an artificial tear solution 4 times a day for a month.

Statistical Analysis

Univariate descriptive statistics were reported for pre- and post-operative spherical equivalent, and for humidity and temperature. Kernel density smoothing was used to assess the distribution of each variable. We conducted linear mixed effects regression using one month postoperative spherical equivalent manifest refraction as the outcome, and baseline spherical equivalent manifest refraction, temperature and humidity as predictors. This analysis accounts for statistical dependence of the two eyes from within an individual patient. Additional analysis included Optical Express, Inc. store location as a crossed random effect. Analyses were stratified by age categories and pre-operative refractive error; such stratification was feasible due to the large sample size. Continuous variables were compared using the Student’s t-Test. Due to the large sample size, application of classical frequentist approaches to the entire data set may yield statistical significance for effects of negligible quantitative importance. Before analysis, an effect size of 0.5 diopters was considered to be clinically significant.

Results

The distribution of preoperative spherical equivalent was bimodal, with a larger peak for myopic individuals. Post-operative spherical equivalent, and procedure room temperature and relative humidity were evaluated and found to be unimodally and normally distributed.

In all 202,394 eyes of 105,712 patients were included for analysis. The demographics of included patients are listed in Table 1. There were more females than males. The mean procedure room temperature during LASIK was 21.0 degrees Celsius (69.8 degrees Fahrenheit) range 15.0-30.0 degrees, standard deviation 1.43 degrees. The mean humidity was 40.8% range 20.0-80.0%, standard deviation 6.30%. In all, 142,349 eyes (69.4%) underwent flap creation by the femtosecond laser and 60,045 (29.7%) by the automated microkeratome.

When evaluating all eyes in the population together, procedure room temperature and humidity did not show a clinically significant relationship with post-operative manifest refraction, although as expected the relationships were very statistically significant ($P=0.0094$ for temperature and $P<0.0001$ for humidity). When considering all eyes, an increase of one degree Celsius during LASIK was associated with a 0.003 diopter more hyperopic manifest refraction one month following the procedure and an increase in one percent humidity was associated with a 0.0004 more myopic manifest refraction one month following the procedure. For perspective regarding the lack of clinical relevance of these effects, the refractive change predicted to occur between the lowest and highest temperature in our sample (15 degrees) would be 0.045 diopters and between the lowest and highest humidity (60%), 0.024 diopters. These results were the same when including flap technique and Optical Express Inc. geographical surgery location in a multivariate analysis.

When considering only eyes that underwent myopic LASIK, an increase of one degree Celsius during LASIK was associated with a 0.003 diopter more hyperopic manifest refraction one month following the procedure, whereas an increase of one percent humidity was associated with a 0.0008 diopter more myopic manifest refractionWhen considering only eyes that underwent hyperopic LASIK, an increase of one degree Celsius during LASIK was associated with a 0.006 diopter more myopic manifest refraction one month following the procedure and an increase of one percent humidity was associated with a 0.0008 diopters more myopic manifest refraction. None of these effects were considered clinically significant. The effect of procedure room temperature and humidity on post-operative manifest refraction following LASIK remained clinically insignificant when flap creation technique, location of surgery and gender were included in a multivariate analysis.

Table 2 shows all subgroups of eyes stratified by age and pre-operative refractive error, and the number of eyes in each group. It reveals that most patients were between 18 and 50 years old with mild to moderate myopia. Only two patients were found to be both very highly myopic and above 60 years of age and this small group was excluded from subgroup analysis.

Tables 3 and 4 list the effect sizes of changes in one degree Celsius or one percent humidity on post-operative refractive error in each subgroup. In general, Table 3 reveals that the largest effect of temperature was seen in eyes that were more hyperopic pre-operatively. This was most pronounced in the subgroup with pre-operative refractive error of +2.00 to +4.00 diopters and aged 18-30 years. In this subgroup, an increase in one degree Celsius during LASIK was associated with a decrease in one month post-operative refractive error (more correction) of 0.048 diopters. This effect was considered not to be clinically significant and all other age and refractive error groups experienced smaller effects from changes in procedure room temperature. These analyses were repeated with only male and only female eyes and the same results were found.

The effect of procedure room humidity during LASIK on post-operative refractive error was exceedingly small in every subgroup. Table 4 reveals that the largest effect was seen again in hyperopes, specifically those with a pre-operative refractive error between +2.00 to +4.00 diopters aged 60-75 years. This effect of a 0.0086 diopter increase per percent relative humidity increase is extremely small and clinically insignificant. Indeed, procedure room relative humidity would need to change by an absolute value of 58.4 points (percent) to affect a 0.5 diopter change in post-operative refractive error in this subgroup. This analysis was repeated including only male and only female eyes and the same results were found.

Discussion

Overall, our data showed no clinically significant effect of procedure room temperature or humidity on refractive outcomes in LASIK. These findings were also robust despite flap technique or location of surgery and within individual subgroups based on age, refractive error and gender. To our knowledge this study represents the largest dataset used to evaluate these relationships.

No significant effect of temperature was found in most subgroups based on age and pre-operative refractive error (Table 3). A small effect of increased correction with increasing temperature was found in hyperopic eyes aged 18-40 and 60-75 years (Table 3). The reason for this is unclear, but may have to do with increased excimer treatment durations in hyperopic compared to myopic patients. Regardless, the effect is small with procedure room temperature needing to change by 10.4 degrees Celsius (18 degrees Fahrenheit) in order to result in a 0.5 diopter predicted change in post-operative refractive error in this subgroup. Conversely, no clinically significant effect of humidity was found in all subgroups. Excimer laser treatment duration was not measured in this study but is presumed to be directly related to the magnitude of the pre-operative refractive error, which showed no relationship with temperature or humidity.

Two smaller clinical studies have suggested that ambient temperature and humidity may affect LASIK outcomes more significantly than what is reflected by our data. Based on an analysis of retreatment rates rather than measured residual refractive error, Walter et al[3] found both procedure room humidity and temperature to correlate significantly with the amount of post-LASIK ametropia in the 368 eyes evaluated in their series. Interestingly, that study found outdoor temperature and humidity to correlate even more strongly with LASIK outcomes than the procedure room environment. These authors proposed that outdoor humidity might change corneal hydration status and thus the corneal stromal response to the excimer laser.[3] In another report, De Souza et al evaluated 237 eyes that had underwent LASIK and suggested that the temperature and relative humidity of air in their LASIK procedure room may have affected their refractive outcomes.[5]

The results of the present study differ from those aforementioned. An extremely small effect of ambient temperature, and virtually no effect of ambient humidity was found on LASIK outcomes in our very large population. These differences in study findings may not be surprising. Indeed, smaller samples of data are inherently more susceptible to findings that are a result of chance. Our study sample includes approximately 500 times more eyes than those in the previous reports. Indeed, most of the individual subgroups analyzed in this study include a number of eyes that exceeds that included in aforementioned studies combined.

One limitation of the present study was that only one month post-operative refractive error was measured. It is possible that different results regarding the effects of temperature and humidity on LASIK outcomes might be seen in our population if more follow-up were available. However, an explanation for procedure room temperature or humidity affecting post-operative LASIK outcomes only beyond one month post-operative would have to invoke some process involving a differential healing pattern as opposed to a difference in laser ablation efficiency at the time of treatment.

The VISX Star S4 IR excimer laser was used for all eyes in this series. The manufacturer recommends it be operated with ambient temperature between 15-27 degrees Celsius (60-80 degrees Farenheit) and with 35%-65% relative humidity.[6] In our population, no eyes were treated at ambient temperatures of 15 degrees Celsius or less, although 414 eyes were treated at 27 degrees Celsius or more. In addition, 42,657 eyes were treated at 35% or less relative humidity and 320 were treated with 65% or more relative humidity. We independently evaluated the groups of eyes that were treated outside the manufacturer’s recommendations and found no clinically significant effect of temperature or humidity on post-operative refractive error in those groups. In our study, procedures were performed within a temperature range of 15 and 30 degrees Celsius and 20 to 80% relative humidity, confirming the predictability of laser ablation rates within this range. Our data cannot comment on a possible effect of ambient temperature and humidity on LASIK outcomes outside of these ranges.

Our series of over 200,000 eyes reveals that there is likely no clinically significant effect of procedure room ambient temperature and humidity (within the ranges we evaluated) on refractive outcomes in LASIK. Small effects of temperature on refractive outcome were found in a few subgroups of patients, but these effects were not clinically significant. Procedure room humidity was found to have no effect on refractive outcome.

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Table 1

Patient Demographics

Age	Mean (SD) years
All patients	39.1 (11.9)
Men	39.5 (12.1)
Women	38.9 (11.8)
Eye	n (% of total)
Right	100,240 (49.5%)
Left	102,154 (50.5%)
Male	90243 (44.9%)
Female	110628 (55.1%)
Myopic	155,865 (77%)
Hyperopic	46,529 (23.2%)
Mixed astigmatism with spherical equivalent of zero	1,527 (0.75%)
Preoperative refraction	Mean (SD) diopters
Sphere	−1.92 (2.55)
Cylinder	+0.76 (0.76)
Spherical equivalent	−1.54 (2.58)

SD = standard deviation

Table 2

Number of eyes in age/pre-operative refraction subgroups

	Age (years)				
Pre-operative spherical equivalent (diopters)	**18-29.9**	**30-39.9**	**40-49.9**	**50-59.9**	**60-74.9**
$-12 \le \times < -9$	71	82	54	25	2
$-9 \le \times < -6$	2398	2376	1829	695	122
$-6 \le \times < -3$	14612	14485	10634	4420	684
$-3 \le \times < 0$	33752	35005	23992	9124	1503
$0 \le \times < +2$	2355	3869	4851	6870	2300
$+2 \le \times \le +4$	760	1207	4866	9901	5835

Table 3

Effect of procedure room temperature during LASIK on refractive outcome, subgroup analysis
Each cell = effect of increase of one degree centigrade on one month post-operative spherical equivalent (diopters), listed as mean (standard deviation).

Age (years)					
Pre-operative spherical equivalent (diopters)	**18-30**	**30-40**	**40-50**	**50-60**	**60-75**
$-12 \le \times < -9$	0.00752 (0.00824)	0.00727 (0.00811)	0.0126 (0.0108)	0.0209 (0.0175)	Not applicable[a]
$-9 \le \times < -6$	0.00483 (0.00229)	0.00195 (0.00234)	0.00748 (0.00334)	0.00213 (0.00591)	0.0253 (0.0152)
$-6 \le \times < -3$	0.00303 (0.00114)	0.00207 (0.00116)	0.00403 (0.0015)	0.0113 (0.00299)	−0.00013 (0.00763)
$-3 \le \times < 0$	0.00237 (0.00512)	−0.00354 (0.00381)	−0.00241 (0.00424)	−0.00169 (0.00416)	−0.00104 (0.0075)
$0 \le \times < +2$	−0.0135 (0.0123)	0.00712 (0.00992)	−0.00905 (0.00651)	−0.00385 (0.00452)	−0.00788 (0.00598)
$+2 \le \times \le +4$	−0.048 (0.0231)	−0.0375 (0.0214)	−0.00739 (0.0166)	0.000347 (0.0147)	−0.0406 (0.0224)

[a]Too few patients in group for meaningful analysis

Table 4

Effect of procedure room humidity during LASIK on refractive outcome, subgroup analysis
Each cell = effect of increase of one percent relative humidity on one month post-operative spherical equivalent (diopters), listed as mean (standard deviation).

	Age (years)				
Pre-operative spherical equivalent (diopters)	**18-30**	**30-40**	**40-50**	**50-60**	**60-75**
−12 ≤ × < −9	−0.00328 (0.00189)	−0.000454 (0.0019)	−0.00437 (0.00244)	−0.00457 (0.00396)	Not applicable[a]
−9 ≤ × < −6	−0.000938 (0.000517)	−0.000577 (0.000534)	−0.00101 (0.00076)	−0.000842 (0.00136)	−0.00487 (0.00381)
−6 ≤ × < −3	−0.000655 (0.000259)	−0.000906 (0.000265)	−0.000815 (0.000347)	−0.0014 (0.000675)	0.000845 (0.00185)
−3 ≤ × < 0	−0.000968 (0.00117)	−0.00167 (0.000891)	0.000525 (0.00098)	−0.00225 (0.000961)	−0.00109 (0.00183)
0 ≤ × < +2	0.00193 (0.00319)	0.00433 (0.00233)	−0.000688 (0.00148)	−0.000192 (0.00106)	−0.000113 (0.00143)
+2 ≤ × ≤ +4	0.0047 (0.00571)	0.00416 (0.0051)	−0.00234 (0.0036)	−0.000262 (0.00357)	0.00856 (0.0056)

[a]Too few patients in group for meaningful analysis