

# Reasons for not performing surface ablation refractive surgery in Saudi population

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## Abstract:

**PURPOSE:** The primary goal of this study is to analyze the reasons why refractive surgery was not performed for candidates who requested the procedure among single eye-clinic visitors in Saudi Arabia. Secondly, we aimed to determine the corneal parameters that are characteristic of Saudi population and to figure out the relationship between the magnitude of central corneal thickness and the degree of myopia.

**METHODS:** A retrospective data was collected for all patients who presented to a single-surgeon eye clinic at King Abdul Aziz Medical City-National Guard, Saudi Arabia, seeking refractive surgery between January 2010 and December 2015.

**RESULTS:** Unstable refraction (21.78%) followed by amblyopia with unrealistic expectations (18.75%) and high myopia (15.62%) were the most common reasons not to proceed with refractive surgery in the included sample. The mean central corneal thickness for all patients included in this study was ( $538 \mu\text{m} \pm 32.6$ ). We found no significant relationship between central corneal thickness and the degree of myopia OD [ $r(178) = -0.017, P = 0.823$ ] and OS [ $r(182) = 0.016, P = 0.831$ ] for right and left eyes, respectively.

**CONCLUSION:** Unstable refraction followed by amblyopia with unrealistic expectations and high myopia were the leading causes not to perform refractive surgery in this study. No significant relationship can be figured out between central corneal thickness and the degree of myopia.

## Keywords:

Contraindications, just refractive surgery, myopia, Saudi Arabia

## INTRODUCTION

The advent of excimer laser-based procedures has made a major transition in the field of refractive surgeries. Being safe and effective, these options are gaining ground over the other refractive procedures.<sup>[1,2]</sup> However, refractive surgery is not totally risk-free.<sup>[3]</sup> Meticulous preoperative evaluation and careful patient selection should be considered for each individual patient to avoid incurring complications. Corneal ectatic disorders constitute the prime events of concern in this regard. However, less commonly, these surgeries can result in visual loss.<sup>[4]</sup>

Up to date, there are no widely-accepted guidelines to rule the process of selecting candidates for refractive surgery. The current

practice is based on a proposed set of criteria aimed to assess multiple corneal and visual parameters known to be altered by the surgery.<sup>[4]</sup> In addition, there is no clear consensus on the cut-off values for these parameters beyond which surgery should be withheld. In fact, a major challenge to reach such an agreement is the tremendous variation seen in these parameters across different populations and ethnic groups.<sup>[4]</sup>

The current study addresses the reasons for declining refractive surgery in Saudi candidates, along with exploring corneal parameters specific to this population. By reviewing the literature, we found no similar study conducted on the same population.

## METHODS

The conduct of this study was adherent to the tenets of declaration of Helsinki and the proposed

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methodology is Institutional Review Board (IRB)-approved by the ethics committee at King Abdullah international Medical research center (KAIMRC), Jeddah, Saudi Arabia.

### Study population

A retrospective chart review was conducted for all patients who requested refractive surgery at a single-surgeon Eye clinic in the National Guard Hospital, Jeddah, Saudi Arabia between Jan 2010 and Dec 2015.

### File selection

Two independent authors contributed to file extraction. To avoid selection bias, the process was repeated by another two individuals. Juxtapositioning of patients' names and file numbers was used to adjust for duplication. Disagreement between authors was resolved by consensus. By reading the clinical notes, and full file when necessary, all files were screened for eligibility to be selected. Incomplete data was a sufficient reason to discard a file.

### Variables

For each patient, we recorded the age, gender, uncorrected and best corrected visual acuity, manifest and cycloplegic refraction, tonometry, slit lamp examination, dilated fundus examination, Scheimpflug-based corneal tomography (Pentacam; Oculus, Inc, Lynnwood, WA). In addition, we specified the type of refractive surgery performed for each patient. In case the surgery was declined, we recorded the reason for which the procedure was not advised. All these variables were set before the review was started. No assumptions were made during the process of data collection and all collected variables were clearly stated in the original reports.

### Data extraction

These variables were extracted from included files by two independent authors and gathered into a predesigned sheet [index 1]. This sheet was pilot-tested on 15 included files and amended accordingly. Another two authors checked the extracted data and disagreement was resolved by referring to, and matching with, the original files. No contact with patients was conducted.

### Exclusion criteria and operational definitions

A given candidate would be considered unfit for undergoing refractive surgery if he/she is having one of the following: [Table 1].

Although not regarded as contraindication by itself, amblyopia of any degree if accompanied by unrealistic expectations was considered sufficient reason by the author to refrain from surgery.

### Surgical intervention

Although some authors prefer Laser-Assisted in-Situ Keratomileusis (LASIK) as compared to other surface ablating techniques,<sup>[2]</sup> we do not use it in our center to avoid the risk of flap-related complications. In this series, individuals who were fit for surgery underwent either Laser Assisted Keratomileusis (LASEK) or Epithelial Laser In-Situ Keratomileusis (Epi-

**Table 1: Exclusion criteria used to determine patients who are unfit for refractive surgery at our institution**

Criteria	Definition
Age	<18 Years
High myopia	< -8 D of sphere
High hyperopia	>+4 D of sphere
High astigmatism	>+6 D in myopia >+4 D in hyperopia
Insufficient central corneal thickness (CCT)	<480 $\mu$ m
Keratoconus	KCI>5%
Unstable refraction	>0.5 D change in sphere or cylinder over 1 year
Other corneal abnormality	
Other ocular disease patient with unrealistic expectations	

KCI=keratoconus index

Lasik). For both procedures, stromal ablation was performed using an excimer type of Light Amplification by Stimulated Emission of Radiation (LASER) device producing a beam with a frequency of 400 Hz designed by (Wavelight Allergretto Wave, Inc).

### Data analysis

All the data were pooled and analyzed using IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY, USA: IBM Corp. Two authors worked on collaboration for conducting the analysis. Categorical variables were expressed as frequencies and percentages. Quantitative variables were expressed as means and standard deviations. For inferential statistics, a t-test was used to compare numerical variables whereas Spearman's correlation test was used for comparisons among groups.  $P < 0.05$  were considered to indicate statistical significance.

## RESULTS

One hundred and thirty-seven female (68%) and sixty four male (32%) patients constituted the study population ( $n = 201$ ). Out of the total, one hundred and fifty-one patients (75.01%) were provided either Lasek or Epi-lasik procedure. Epi-Lasik was performed in 107 patients (53%) and Lasek was performed in 44 patients (22%). The mean central corneal thickness (CCT) for those underwent Lasek and Epi-Lasik surgery were ( $538.4 \mu\text{m} \pm 31.77$ ) and ( $546.6 \mu\text{m} \pm 36.69$ ), respectively.

In contrary, fifty patients (24.90%); 30 females and 20 males, did not undergo refractive surgery. Out of those 50 patients, 32 (15.92%) were found to have medical contraindications. The remaining 18 patients did not have surgery for non-medical reasons. Among the excluded group, unstable refraction (7/32, 21.78%) was the most frequent reason. Amblyopia with unrealistic expectations (6/32, 18.75%) and high myopia (5/32, 15.62%) respectively, were next in frequency (see Table 2). The mean CCT for those who did not have surgery is ( $533.9 \mu\text{m} \pm 36.45$ ).

Using spearman's analysis, we found no significant positive or negative relationship between the degree of myopia in diopters and central corneal thickness measured in micrometers. That is to say, in the left eyes of all myopic patients ( $n = 180$ ) the

test yielded that central corneal thickness is inversely related to degree of myopia with a correlation coefficient  $r = -0.017$ , ( $P = 0.83$ ). Whereas in the right eyes of the same patients, there was a positive linear relationship between the two variables with correlation coefficient  $r = 0.016$  ( $P = 0.82$ ).

Visual acuity examination done at 6 weeks postoperatively showed comparable results for both LASEK and EPI-LASIK procedures. Using independent t-test, no significant difference can be seen between both groups [Table 3].

## DISCUSSION

### Background and importance

This study is the first effort endeavored to address the contraindications for refractive surgery candidates in Saudi Arabia. The basis of this work stems from the current evidence showing that these contraindications would be notably different when compared across ethnically-unrelated populations.<sup>[3,4,6]</sup> This observed difference can sensibly be attributed to the wide variation in corneal parameters across different population groups.<sup>[4,6]</sup> For this fact, we also aimed to explore the pattern of corneal topographic and pachymetric characteristics in Saudi refractive surgery candidates.

Proper preoperative evaluation, along with a comprehensive explanation given to the patient during a transparent and an honest consenting session, are key to get the maximal patient satisfaction. This goal can be difficult to achieve in overly

anxious patients or those with unrealistic expectations. In addition, careful assessment of psychological and occupational status should also be part of the selection process.

### Rejection rate

In the current series, we found that 50/201 (24.90%) of the candidates were excluded from having refractive surgery. In comparison, the available data from multiple previous studies revealed a rejection rate ranging from 25.30 to 34.00 percent.<sup>[7]</sup> However, it was not clearly stated in all papers whether this exclusion was based on medical or non-medical reasons. In our study, after dropping out those who were excluded for non-medical reasons, the figure sinks down to 15.90%.

### The most common reasons not to perform laser vision correction in Saudi population

After analyzing the causes for the excluded group, we found that unstable refraction was the most frequent contraindication for refractive surgery. This would stand in a far contrary from the other reasons previously reported to be the most common, such as suboptimal corneal thickness,<sup>[4,6,7]</sup> high myopia<sup>[3,5]</sup> and abnormal corneal topography.<sup>[8]</sup> Unstable refraction is defined as a change in refractive power by  $>0.5$  diopter in sphere or cylinder over one year. This observation warrants further research. A possible explanation would be a subclinical corneal ectatic disorder that will deteriorate if refractive surgery performed.

Amblyopia with unrealistic expectations was the second most common contraindication in our series constituting 18.00% of those who were medically excluded. In contrast, the prevalence of amblyopia as a contraindication for refractive surgery in previously reported series ranged from only 0.7 to 3.0 percent.<sup>[3,6-8]</sup> This striking difference in the prevalence of amblyopia is another distinct feature we noticed about Saudi population; the first being unstable refraction. After all, having high proportion of amblyopic patients discovered incidentally in refractive clinic is clearly beyond usual. Further efforts should be directed to enhance and support effective strategies for a comprehensive national screening program.

Another reason to exclude candidates from having refractive surgery is the need for high refractive correction. Those patients require more stromal ablation and thus, elevating the risk of iatrogenic corneal ectasia.<sup>[3]</sup> High myopia was the most common contraindication for refractive surgery in multiple reported series<sup>[3,5]</sup> and remains among the leading causes in ours. The upper limit we adopted at our clinic was  $-8$  D of sphere. Beyond this, a given candidate would be excluded. The same cut-off value was recommended in previous studies,<sup>[9,10]</sup> though some authors believe that up to  $-12$  D can be treated with refractive surgery.<sup>[3]</sup> Up to date, this remains an issue of high controversy and no clear consensus is yet reached.<sup>[8]</sup> However, determining the degree of refractive correction should not be attempted without ensuring a sufficient corneal thickness in advance.<sup>[8]</sup> But how thick would be sufficient is another controversy. At our clinic, we avoid doing refractive surgery in patients with central corneal thickness less than

**Table 2: The reasons for not performing refractive surgery arranged in decreasing frequency**

Condition to exclude	Number*	Percentage
Unstable refraction	7	21.78
Amblyopia	6	18.75
High myopia	5	15.62
Keratoconus	4	12.5
High astigmatism	3	9.37
Thin cornea	1	3.12
High hyperopia	1	3.12
Keratoconus suspect	1	3.12
Cataract	1	3.12
Corneal scar	1	3.12
Retinal detachment	1	3.12
Retinitis pigmentosa	1	3.12
Abnormal corneal topography (steep cornea)	1	3.12

\*Note the total is 33 (not 32) as one patient was having both amblyopia and hyperopia and thus was considered twice to fit independently in each category

**Table 3: The follow up results of visual acuity examination done at 6 weeks postoperatively for the EPI-LASEK group compared to the LASEK group**

		n	Mean ± Std. Dev	P
VA6 OD	Lasek	43	6.14±0.55	0.264
	Epi-Lasik	103	6.35±1.17	
VA6 OS	Lasek	43	6.07±0.32	0.209
	Epi-Lasik	103	6.33±1.36	

VA6=visual acuity at 6 weeks postoperatively

480um even if the corneal topography was normal. Previous authors of similar studies also used the same point value to decide<sup>[4,5,8]</sup> while others preferred a more conservative approach and would counsel against surgery once the thickness fall below 500 um.<sup>[6,7]</sup> In addition to corneal thickness, prediction of residual stromal bed is another useful tool to help making the decision. By reviewing the literature, most of the available data suggest withholding refractive surgery if the residual stromal bed is below 250 um.<sup>[4-6]</sup> Others would refrain from doing such ablating procedures on corneas with estimated residual bed below 300 um.<sup>[7,8]</sup> Again, this also stands out as an unresolved controversial issue. However, a recent paper addressing the same issue proposed that the risk of ectasia is more related to the proportion (in percentage) of tissue ablated than the absolute values of corneal thickness or the estimated residual bed. In this paper, Santhiago *et al*, found that more than 40% of corneal tissue altered by the surgery is significantly related to the development of ectasia.<sup>[11]</sup> This novel finding was based on the anatomical fact that most of the tensile strength of the cornea relies on the anterior 40% of corneal stroma rather than the posterior 60 percent.<sup>[12]</sup>

### Central corneal thickness: A comparison among different population

The mean central corneal thickness for all patients included in this study was (538  $\mu\text{m} \pm 32.6$ ). A study conducted in Yemen, a geographically close population, found that the mean central corneal thickness for that cohort of patients is (521.67  $\mu\text{m} \pm 31.62$ ).<sup>[4]</sup> Though some ethnic ties might be present between the two populations, this data showed that Yemeni population clearly have thinner corneas. Data from India also demonstrate similar findings. Sharma *et al*, found that the most common contraindication for refractive surgery in suboptimal corneal thickness. In the excluded group, the mean central corneal thickness was (477.81  $\pm 22.65$ ).<sup>[6]</sup> In the bottom line, the current series shows that suboptimal corneal thickness is not a frequent finding in Saudi population as only one patient was excluded for that reason.

### The relationship between central corneal thickness and myopia

Analyzing the data using spearman's test revealed that the amount of stromal tissue as measured by central corneal thickness in micrometers has no significant effect on the degree of myopia. Similar finding was also reported in a previous study done in Taiwan.<sup>[13]</sup>

### Postoperative results

The outcome, in terms of uncorrected visual acuity, of patients we operated on this series was rewarding for both LASEK and EPI-LASIK groups. We noted no significant difference in the outcome between both groups.

### Limitation

An inherited source of bias in this study is the retrospective nature of the design and the small number of patients included. Larger series is needed to reach a more robust conclusion.

### Future direction

A follow up study on the same population conducted in a "prospective" manner would be useful to detect the change in patient attitude toward refractive surgery. This would also detect any change in the contraindications for refractive surgery as these factors are thought to be dynamic and subjected to change with time.<sup>[7]</sup> For instance, Bamashmus *et al*, conducted a similar study twice on the same population, but on different periods of time, looking for the reason why refractive surgery was not performed. Interestingly, he found changing results upon repeat.<sup>[4,5]</sup>

### CONCLUSION

A comprehensive knowledge about the characteristics of the population is of paramount importance for the conduct of vision-correcting surgeries, especially those parameters that are altered by the procedure. The Saudi population, as shown in this series, is clearly distinguished by the high prevalence of unstable refraction and amblyopia. While some populations are known for having suboptimal corneal thickness, this finding was not evident in our series. A complete preoperative assessment and careful patient selection is a prerequisite for good outcome and patient satisfaction.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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