Extended use of LASIK procedure – possible medical error? 
Ethical and forensic case assessment

Catalina Corbu1, Raluca Moisescu2, Raluca Iancu1,3, Cristina Nicula4,*, Mihai Marinescu5

Abstract: Excimer laser in situ keratomileusis (LASIK) is a relatively new surgical procedure that can be used to correct refractive errors of the eye, such as myopia. Since the 90’s, many patients have experienced the benefits of this technique and LASIK has become a frequent practice among ophthalmologists, who used it to correct high myopia. By experiencing a series of postoperative complications, surgeons became aware of the fundamental importance of establishing the limitations of the procedure in order to accurately advise and select patients.

We present the case of a young female with a history of bilateral refractive surgery (LASIK) for high myopia, which developed unilateral corneal ectasia 11 years after the procedure. All of the inclusion criteria valid at the time she underwent surgery were followed, although they are no longer applicable in present. Corneal ectasia in this case is an iatrogenic complication of LASIK and was successfully treated using corneal collagen cross-linking.

After an evaluation of both forensic and ethical issues generated by this case, we concluded that performing LASIK on this patient was not a medical error at that time, but that the late postoperative complications that may occur are an indication of the importance of establishing the right inclusion criteria, as well as the possible medico-legal consequences of criteria changing over time.

Key Words: Laser in-situ keratomileusis, myopia, corneal ectasia, medical error, inclusion criteria, forensic assessment, ethical issues.

The basis for all modern techniques which apply laser beams in order to correct myopia and to avoid long-term wear of glasses is credited to Igancio Barraquer in the late 1940s, followed by studies performed on rabbit eyes, which led to Pallikaris investigation of the laser on human eyes in 1991 [1]. LASIK (Laser-Assisted in situ Keratomileusis) is the most common type of refractive surgery, involving the fewest complications. Between 1990 and 2000, this procedure was used on a large scale without anticipating the complications that followed.

More than 20 years later, an online survey dated May 2010 shows that 98% of Europeans would have LASIK again, 69% think it is a safe and well-established procedure, 17% are concerned about side effects and only 11% wouldn't consider it [2]. Currently, LASIK is performed on hundreds of thousands of people with myopia or other refractive errors worldwide [1].

1) "Carol Davila" University of Medicine and Pharmacy, Dept. of Ophthalmology, Bucharest, Romania
2) Emergency Eye Hospital Bucharest, Romania
3) Emergency University Hospital Bucharest, Romania
4) "Iuliu Hatieganu" University of Medicine and Pharmacy, Dept. of Ophthalmology, Cluj-Napoca, Romania
* Corresponding author: MD, PhD, Associate Professor, 38 Axente Sever Street, Cluj-Napoca, Cluj County, Romania, Tel.: 0040722849575, E-mail: niculacristina65@yahoo.com
5) "Carol Davila" University of Medicine and Pharmacy, Department of Legal Medicine, Bucharest, Romania
There are a series of investigations and measurements which must be performed when evaluating a patient with myopia as a possible candidate for refractive surgery. First of all, refraction must be determined and it must be stable for at least 1 year before attempting surgery [3-5]. The predicted postoperative corneal thickness (measured using corneal pachymetry) should not be less than 410-430 μm, with a residual stromal bed of at least 250 μm, regardless of the amount of myopia targeted [6, 7].

Corneal curvature (measured and quantified using corneal topography as well as keratometry) is a useful screening tool to prospective evaluation of refractive surgery candidates and as a diagnostic aid in assessing refractive surgery patients with poor outcomes [8, 9]. According to the newest guidelines, it is preferable to obtain a postoperative curvature no flatter than 40.00 to 41.00 D when correcting myopia [7]. Corneal biomechanics determined using the Ocular Response Analyzer (ORA, Reichert Inc., Depew, NY) are useful when suspecting any change in corneal resistance [10]. In addition, if the preoperative endothelial cell count is less than 2000 cells/mm² an alternative solution to corneal refractive surgery must be considered [7].

Medical indications for treating myopia using excimer laser are defined individually for each patient but the inclusion criteria have changed significantly over the years, mostly concerning the highest value of myopia to be corrected. For example, in the period 1998-2002, the recommended range of application included higher values of myopia (up to -12 D) [1, 5]. In 2002, one of the pre-established criteria for surgical contraindication was myopia over 12 D [5]. Unfortunately, the postoperative follow-up revealed a series of complications over the following years, which determined surgeons to reconsider using LASIK outside the 8.00 D limit [11-17].

One of the most important late postoperative complications of laser eye surgery is corneal ectasia. It is characterized by poor vision and topographic findings resembling that of keratoconus, the patient, usually a young adult with an active social life and a rising career, being often forced to consider changing his workplace [3]. Screening measurements taken before surgery are usually performed postoperatively also if there is any suspicion of such complication. Scientists agree that reevaluating the patient's parameters allows early diagnosis and successful treatment for most postoperative complications of LASIK surgery [15, 16].

Over the years, surgeons have concluded that all LASIK candidates must fulfill the following inclusion criteria: at least 18 years old with stable refraction of at least 1 year duration, absence of associated ocular disease (infection, cataract, glaucoma, progressive myopia) or any general pathology [18]. Currently the recommended range of application for LASIK is correction of myopia up to -8.00 D. Some refractive and anatomical considerations serve since 2010 as guidelines in all European countries for practical purposes [7, 13].

**CASE REPORT**

A 37-year-old woman was referred to us in May 2011 complaining of decreased vision in the right eye, progressing over the last 12 months. In February 2000 she had undergone a bilateral LASIK procedure at the age of 26 for high myopia of -10.00 diopters (D) in the right eye (OD) and -9.00 D in the left eye (OS). Preoperative keratometry results obtained from patient's medical records are shown in Table 1 and postoperative pachymetry measurements were 412 μm OD and 416 μm OS (normal values range between 520-540 μm). The postoperative documented refraction was + 0.25 D OD and -0.25 D OS. The surgeon stated that best uncorrected visual acuity (BUVA) was 20/30 OD and 20/20 OS, which was stable for the following years. Unfortunately, 10 years later the patient developed unilateral keratectasia.

In May 2011 we determined her BSCVA 20/40 OD with -2.00x100 and BUVA 20/20 OS, with a refraction of -4.00x166 OD and -0.50x113 OS. Keratometry measurements are shown in Table 1. Corneal pachymetry was 401 micrometers OD and 415 micrometers OS. Corneal topography (Optopol Technology) showed asymmetric bow-tie pattern OD (Figure 1), consistent with unilateral keratectasia. The ORA measurements performed in May 2011 showed modified corneal resistance, typical for a patient who underwent corneal refractive surgery, with a mild to moderate suspicion index for corneal ectasia in the right eye.

Corneal collagen cross linking is a modern technique which uses UV light and a photosensitizer in order to strengthen chemical bonds in the cornea. The goal of the treatment is to halt progressive and irregular changes in corneal shape [19]. In the case presented, corneal collagen cross-linking (CXL) with riboflavin was successfully performed in June 2011 without any intraoperative complications. In December 2012, the patient's BCVA was 20/30 OD with -2.00x100 and corneal pachymetry was 402 micrometers OD and 414 micrometers OS. Keratometry measurements (Table 1) and corneal topography (Figure 2) showed a 1.13 D reduction in Kmax OD, consistent with the diagnosis of stationary keratectasia.

**Table 1. Central keratometry measurements**

<table>
<thead>
<tr>
<th>Date</th>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb 2000</td>
<td>42.50 D x 166 / 43.00 D x 66°</td>
<td>44.70 D x 90° / 45.50 D x 180°</td>
</tr>
<tr>
<td>May 2011</td>
<td>31.50 D x 156° / 35.50 D x 80°</td>
<td>35.25 D x 88° / 35.75 D x 178°</td>
</tr>
<tr>
<td>December 2012</td>
<td>31.25 D x 153° / 34.25 D x 73°</td>
<td>35.25 D x 82° / 35.75 D x 172°</td>
</tr>
</tbody>
</table>

OD- right eye; OS – left eye
DISCUSSION

The above-presented case raises both an ethical and a legal medicine issue, generated by the initial enthusiasm for the benefits of the LASIK procedure, combined with the changes of the inclusion criteria over time.

The ethical issue on discussion is the existence of an ethical dilemma regarding the correction of myopia using LASIK. On one hand, benefits are clear: by performing this procedure the patient's need of...
optical external correction (glasses or contact lenses) is eliminated (often with significant improvement in quality of life, especially for high levels of myopia). On the other hand, this procedure comports certain risks and complications (both immediate and late) that could sometimes outweigh the benefits of LASIK. Therefore, the ethical discussion here may be centered on the interpretation of the four fundamental principles of
bioethics: beneficence, non-maleficence, autonomy and justice [20, 21]. Medical ethics philosophy can be regarded from various perspectives, such as principle-based approaches, utilitarian approaches, virtue ethics approaches or deontological approaches [22], of which the principle-based perspective has gained more and more ground in contemporary bioethics [23]. The principle is not subject to discussion because the informed consent is mandatory but the principles of justice (the procedure is expensive) and the balance between risks and benefits asks for a a careful evaluation of beneficence and non-maleficence.

If we look at the ethical issue from the consequentialist point of view, the consequences of an action are the determining criteria for its rightness [24]. Thus, from a consequentialist standpoint, a morally right act is one that will produce a good outcome, which, in our case is a significant improvement in patient's uncorrected visual acuity. The problem of this approach is that the principle of non-maleficence becomes of secondary importance and this contravenes to the principle-based approach, in which all the fundamental principles of bioethics should be of equal importance and normally present.

The medico-legal issue is related to possible malpractice litigation due to the occurrence of postoperative complications such as corneal ectasia. When assessing cases of alleged medical care deficiencies (the forensic term used to refer to “malpractice” claims), the judiciary (medico-legal or forensic) expertise shall be directed to certain aspects based on which the forensic expert will conclude whether the claims are medically founded [25, 26]. The medico-legal expert must confirm and objectify a medical error, an actual detriment or prejudice of the patient and an eventual causal link between the medical error and the patient's detriment (in other words, the prejudice must occur as a result of the medical error). In this respect, the abovementioned case may present itself as a rather paradoxical situation:

- if the patient had met all the inclusion criteria in use at the time of the LASIK procedure, then the unfavorable outcome may be either:
  - the result of a possible medical error in the surgical treatment or postoperative surgical managing the patient;
  - a surgical incident predictable/unpredictable, attributable/ attributable to the medical team;
  - insufficient knowledge or poor science knowledge regarding inclusion criteria;
- if the patient did not meet the inclusion criteria, any postoperative complications are regarded as:
  - a result of inappropriate selection of the patient, hence imputable to the medical team, even though the procedure itself was properly executed because the surgery did not meet the medical indication at that time.

In this particular type of cases, the inclusion criteria have changed over time precisely because of the frequent occurrence of complications in patients with high values of myopia (between -8.00 D and -12.00 D). Therefore, when assessing such cases, from a malpractice claim, the legal medicine expert must take into consideration both the inclusion criteria in use at the time of the procedure (accordingly, the medical team cannot be held responsible for improper selection of the patients) as well as the probable cause for the occurrence of the complication (high level of myopia) which also cannot be assimilated to a medical error. The expert must base his conclusions on objective ground and this are the inclusion criteria by the time when the surgery was performed. The deontology rules in this case Kantian laws when assessing the good will and the full respect for the duty to perform in action [27] if all normative procedures are to be fulfilled.

Considering the above, the case presented may comport a possible malpractice discussion related to the appropriateness of the intervention considering the possible severe long-term complications on one hand, as well as the existence of other surgical methods (clear lens replacement surgery) on the other hand. Thus, the medical error in this case can be confirmed only if the inclusion criteria for LASIK were not met. However, the expert must refer the assessment to the criteria applicable at the time of surgery (2000), rather than the current criteria. If we refer to the current criteria, the procedure in 2000 was a medical error; consequently the patient's detriment is imputable to the surgeon. If, on the contrary, we refer to the criteria applicable in 2000, then the procedure was a success according to the guidelines used by surgeons at that time, hence the malpractice accusation is not confirmed.

However, although the malpractice claims in this case cannot be sustained by objective scientific criteria, this shows that despite the fact that inclusion criteria were met at the time of surgery, these criteria may change over time so that a certain procedure might always be subjected to accusations of malpractice.

**CONCLUSION**

Although it is not considered a medical error judging by the criteria applied in 2000, the refractive procedure was performed in a borderline case and the requirements used at that time proved later to be extensive for the real number of possible complications. Nowadays, the recommended range of application for LASIK became narrower in order to prevent such complications as this one. Also, the active role of forensic system and the practical applicability of medical ethics in cases such as the one presented can result in beneficial changes of the Good Practice Guides, ultimately for the benefit of patients.
References