

Refractive Surgery: Considerations in Forensic and Occupational Medicine

Salducci Mauro¹

¹Department of Sense Organs, Faculty of Medicine and Dentistry, Medical Legal Ophthalmology, Sapienza University of Rome, Italy

ABSTRACT

In this brief communication, we will assess what issues are most forensic inherent in refractive surgery, devoting also to the general aspects of the problem, but without going into the specifics of individual cases or individual techniques. The current practice of a pre-printed signature below, often couched in general terms or formulated in an endless list of possible complications, serves more to define this event as bureaucratic and therefore as a consensus "documented" rather than "informed". Especially when this form is signed just before surgery, with the patient ready to be operated, is constantly interpreted by the judge as an act devoid of the meaning of information that enables the patient freedom of choice, which is seen instead as a safe conduct for the surgeon to protect against future challenges.

Key Words: Refractive surgery, forensic medicine, PRK, LASIK.

How to Cite this Article: Mauro S. Refractive Surgery: Considerations in Forensic and Occupational Medicine. Pak J Ophthalmol. 2022, **38 (4)**: 296-298.

Doi: 10.36351/pjo.v38i4.1469

*Correspondence: Mauro Salducci
Department of Sense Organs
Sapienza University of Rome, Italy
Email: mauro.salducci@uniroma1.it*

*Received: July 08, 2022
Accepted: August, 31, 2022*

INTRODUCTION

Refractive surgery was born about a century ago (the first mention is in 1746, when Boerhaave proposed removal of transparent lens in high myopia) and passing through various stages came to Radial Keratotomy and finally to the excimer laser in 1990.¹ It started in our country during the last two decades, from a few ten procedures the agreement year to thousands nowadays. With an increase in the number of interventions, there is also a parallel increase in the number of medical-legal issues related to the intervention. Thus shifting the category of ophthalmologists in the group of professions at greatest risk of denunciation, together with anesthesiologists, orthopedists, obstetricians-gynecologists and of course plastic surgeons.

DISCUSSION

We shall start with a basic question: Does refractive surgery or cosmetic surgery appear to be functional? In fact, initially, the Third Civil Chamber of the Supreme Court rejected any distinction between ordinary surgery and cosmetic surgery by establishing the principle according to which both were subject to the same rules of law. The work of a professional was similar to that of a good father and was not callable for damages in case of failure, provided that he acted with integrity and adequacy of resources.²

In 1982, however, upsetting the principles mentioned above, a new judging of Section III appeared in Civil Supreme Court according to which: a) verification of the consent of the patient was essential to the legitimacy of a surgical procedure that has aesthetic purposes, b) whether intervention conformed to the request or the consent was taken after being adequately informed by the surgeon about the effective scope of intervention, in relation to its gravity, achievable outcomes, inevitable difficulties and complications.³ A more recent interpretation dates back to August 5, 1985, when the Second Civil Chamber of the Court of Cassation has partly reduced

this sharp dichotomy between obligation of means and obligation of results between the two types of surgery, thereby returning the doctor the obligations of diligence and not the attainment of the result.⁴ Nevertheless, the above care must be objectively aimed at the achievement of the expected results. The Court states that the relationship between client and therapist in general (surgeon or doctor) and the surgeon practicing cosmetic surgery is different; in the first case, the recovery from a disease or at least, the reduction of related events is pursued, in the other case, an improvement in physical appearance to improve the social life is required. However, influential lawyers and medical examiners claimed that refractive surgery addresses a visual defect that causes a disability in social life, forcing the use of glasses and still preventing a correct view in various fields of work or activities, nevertheless representing a real pathology. In addition, this intervention to eliminate the refractive error cannot and should not be considered for aesthetic purposes and therefore it should be considered as a contract aimed at improving the state of the patient and not a guarantee of results.⁵ Nevertheless, in every medical treatment it is necessary that there is a constant relationship of proportionality between the medical examiner foreseeable benefits and the predictable damage that the healthcare provider should always evaluate from time to time based on the parameters offered by the best medical science and experience of the moment. The damage caused by actions not justified by a previous medical condition (aesthetic intervention, correction of myopia, etc.), are always evaluated according to the highest standards. Therefore, it is not possible to offer a definitive answer to the question.

The consent is certainly a very thorny issue in general medical practice and especially in the branch of refractive eye surgery that is, considered to be halfway between the traditional surgery and aesthetics. The term “informed consent” which we see today, is considered as a responsibility of a cosmetic surgeon to conveniently inform the customer in a clear and certain manner regarding the actual outcome of that surgery. This information finds its most rigorous application in the field of cosmetic surgery, or in that of refractive surgery, in which there is a benefit in the strict sense for the health, or, at least if there is, it has a rather vague value and it is not characterized by a therapeutic purpose or by a necessity. Therefore, in this field, the patient must be absolutely adequately

informed about the minimal risks he must take, even though they are statistically very low. If the risk, low is not accepted by the patient, in the event of its occurrence, it always remains borne by the doctor as a professional responsibility.⁶

Especially in the field of refractive surgery, it is extremely important that the information is given well in advance compared to the intervention. The surgeon talks to the patient to convince him to undergo surgery and, at the same time, tries to understand what the real expectations he (the patient, who must always be at the center of all our professional attention) has from the intervention itself. A personal discussion with some patients may even propose the withdrawal from the intervention in some cases.

A recent publication of Ophthalmology contains some statistical data on professional liability cases involving eye surgeons who practiced the LASIK or PRK technique as defined in the United States, during a given period. The data were collected by dall’ OMIC (Ophthalmic Mutual Insurance Company) between 2933 refractive surgeons insured for 100 cases of complaints between 1996 and 2002.^{7,8} The highest percentage of cases refer to the surgeons who performed 300 to 1000 refractive surgeries (29.4%), compared to those who performed 100 to 300 surgeries. The percentage of male surgeons was higher than that of women. Through various means of advertising their activities of refractive surgeons, individuals with strong commercial impact were more persecuted than the ones who were less visible, spending more time explaining or having a conversation with their customers before surgery (median 73 minutes versus 55 minutes). Finally, the percentage of disputes being less for those who run their own patient than those who share the management of collaborator assistants in ophthalmology.⁸

In forensic, reports often state that the intervention offered was simple and safe, that the patient was promised that he would “finally remove his glasses”. Our suggestion is that surgeons should take a little time to establish a real relationship with the patient. They should also be aware that to sign consent does not constitute a waiver for whatever happens during surgery. They should not ignore that a patient who believes, rightly or wrongly, that he did not have the desired result, can miraculously make it “disappear” from their professional life. The orientation of the problem in the field of refractive surgery is soaring,

mainly driven by promises of sensational results that are some way, suggested by some stakeholders. The formula “reliable results with easy to perform surgery” is the most dangerous for a surgeon, especially an ophthalmologist. Two consequences implicitly derive from it: the first is that you establish a contract with a guarantee of results, the second is that in the event of a dispute it always reverses the burden of proof.

If the surgeon performed a surgery that was not difficult to perform and the result was deteriorated by the initial conditions of the patient, it would be up to the surgeon to demonstrate that his actions did not lead to the unforeseeable complications. What should always be argued is that interventions such as cataract extraction or refractive surgery interventions are a “standardized” method for instrumentation and execution time. However, that cannot and should not be regarded as routine or easy to perform. These should always be considered as HIGH SURGERY INTERVENTIONS. This certainly do not help us in our work of conviction when we hear what is being said or promised to patients who are possible subjects to surgery by some of our less wiser colleagues, who, afterwards, are paying the consequences in the courtroom.⁹

One final note is with respect to wave-front technology. In forensic practice, it is currently used to detect disturbances in vision that cannot be justified in the face of a good visual acuity or even after full surgical correction of ametropia. However, in our opinion, considering that the wave front will by its very nature evaluate the aberrations of the whole eye, it makes no sense to bring proof of damage caused by surgery without documenting what the situation was before surgery. In fact, the surgeon having made the surgery alone on the corneal surface will be made responsible for the worse of the total aberrometry framework. It would be like trying to assess the loss of vision in one eye, without knowing the starting point of visual acuity. Introducing an expert in the activity, and also new methods that allowed us to better understand the situation of an eye and well-being of even more sophisticated ones anatomically and functionally, turned out to be nothing but an ailment for legal medical purposes only.¹⁰

CONCLUSION

With this brief view, we have absolutely not exhausted all the legal physician’s problems on the issue. We

should not forget that the knowledge, techniques and tools in ophthalmology are always in constant change and evolution and therefore, forensic issues are revisited in each case in the light of the period in which the issue arises.

Conflict of Interest: Authors declared no conflict of interest.

REFERENCES

1. **McAlinden C.** Corneal refractive surgery: past to present. *Clin Exp Optom.* 2012; **95 (4):** 386-398. doi: 10.1111/j.1444-0938.2012.00761.x.
2. **Traina F.** Medical malpractice: the experience in Italy. *Clin Orthop Relat Res.* 2009; **467 (2):** 434-442. doi: 10.1007/s11999-008-0582-z.
3. **Salducci M, Pacella F, Malvasi M, Messineo D, Comberati AM, Pacella E.** Medico legal considerations on refractive surgery. *Clin Ter.* 2020 Nov-Dec; **171 (6):** e476-e480. doi: 10.7417/CT.2020.2260.
4. **Gioia G, Salducci M.** Optical coherence tomography angiography versus fluorescein or indocyanine green angiography: legal implications for ophthalmologists. *New Front Ophthalmol.* 2019; 5. doi: 10.15761/NFO.1000232.
5. **Anbar M, Mohamed Mostafa E, Elhawary AM, Awny I, Farouk MM, Mounir A.** Evaluation of Corneal Higher-Order Aberrations by Scheimpflug-Placido Topography in Patients with Different Refractive Errors: A Retrospective Observational Study. *J Ophthalmol.* 2019; **2019:** 5640356. doi: 10.1155/2019/5640356.
6. **Medical Negligence – Laser Eye Surgery Complications – Medico Legal Issues | Carter Anhold Solicitors".** Carteranhold.Ie, 2022. <https://www.carteranhold.ie/medical-negligence-laser-eye-surgery-complications-medico-legal-issues/>. Accessed 22 July 2022.
7. **Insuring Refractive Surgery: Liability Risks – OMIC ".** Omic.Com, 2022, <https://www.omic.com/insuring-refractive-surgery-liability-risks/>. Accessed 22 July 2022.
8. **Liability Risks Associated With PRK And The Excimer Laser – OMIC ".** Omic.Com, 2022, <https://www.omic.com/liability-risks-associated-with-prk-and-the-excimer-laser/>. Accessed 22 July 2022.
9. **Shahbaz R, Salducci M.** Law and order of modern ophthalmology: Teleophthalmology, smartphones legal and ethics. *Eur J Ophthalmol.* 2021; **31 (1):** 13-21. doi: 10.1177/1120672120934405.
10. **Avoiding Malpractice in Refractive Surgery".** Medscape, 2022, <https://www.medscape.com/viewarticle/885915>. Accessed 22 July 2022.