

## Medico legal considerations on refractive surgery

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### Abstract

This study is a summary of legal issues that occurred over time in Italy, concerning the evaluation of the professional responsibility of the health damage caused by refractive surgery, also in the light of the diagnostic elements obtained from the new techniques relating to diagnostic tests for preoperative surgical correction of the main ametropia. *Clin Ter 2020; 171 (6):e476-480. doi: 10.7417/CT.2020.2260*

**Key words:** forensic medicine, refractive surgery, laser excimer, compliance patients, corneal haze, malpractice

### Background

Refractive surgery was born about a century ago (but the first mention is in 1746, when Boerhaave proposed the removal of the lens transparent to high myopia) and passing through various stages (Fukala 1890, Sato 1955), came to the Radial Keratotomy of Fyodorov (since the 70s of the last century) (1-3), the keratomileusis Barraquer (1980) and finally to the excimer laser in 1990(4,5), and at the same time to be included for the purpose refractive IOL in the posterior chamber of the eye phakic (6,7).

It has been passed in our country in the last two decades, from a few tens of events per year, to tens of thousands today(8-12). However, with the number of interventions, it has also increased in parallel with the number of medical-legal issues related to the interventions themselves, 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 (13).

We will try to objectively assess what issues are the most forensically inherent in this type of surgery, devoting also to the general aspects of the problem, but without going into the specifics of individual cases or individual techniques, extrapolating from them exactly what we

found in common in the years of professional activity as ultra-specialist expert on these subjects (14).

### Objectives and Methods

The first place to start was and is the basic question: Does refractive surgery or cosmetic surgery appear to be functional? Recall that the difference is not trivial. In fact, the functional surgery, the contract established between the doctor and the patient and regulated by art. 2230 and following the Civil Code, imposes only an obligation of means, but not results on the health operator, while cosmetic surgery would seem to pose a constant instead of mandatory results (15). At this point, it is worth recalling some guidelines of the Supreme Court of Cassation. 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 if both were subject to the same rules of law, in which the work of the professional was similar to that of a good father family is not callable for damages in case of failure, provided that he acted with integrity and adequacy of resources, finding it to be a consequence of this obligation, however, to ensure a result (16-18).

In 1982, however, upsetting the principles mentioned above, a new judging of Section III appeared. Civil Supreme Court according to which: a) verification of the consent of the patient is essential to the legitimacy of a surgical procedure that has aesthetic purposes. b) what is essential to the accurate distinction between aesthetic surgery or intervention performed purposes, functional in order to determine whether the operation performed in practice is directed to one or other type of intervention, conforms to the request, if, in either case, this has consented after being adequately informed by the surgeon of the effective scope intervention, in relation to its gravity (19), A more recent merit of 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

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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. Nevertheless, the above care must be objectively aimed at the achievement of the result hoped. Possible variations should also be covered - in the case of surgery performed for aesthetic purposes within a correct and detailed information because, the Court states, the relationship between client and therapist in general (surgeon or doctor who) and the surgeon practicing cosmetic surgery is different: in the first case, the recovery from a nursing disasters or, at least, the reduction of related events is pursued. Another one is an improvement in physical appearance, in a view to improve the social life and true professional, and the latter, also characterized by the type of activity, hence correspondingly diversifying the duty of information, usually limited to the therapist, to possible risks and effects of treatments or interventions suggested, surgical interventions proposed (as such, in fact, to be placed in serious danger to the life or safety the patient) and instead imposed on the cosmetic surgeon regarding the obtaining of an actual improvement in physical appearance, that has a positive effect on the professional life and social life (17,19)

Therefore, 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 that constitute a good individual's self and that, however, the ametropia prevents their carrying out in a satisfactory manner, nevertheless representing a real pathology (20-22). In addition, an intervention to eliminate the alteration cannot and should not be considered for aesthetic purposes, however, and therefore be considered as a contract aimed at improving the state front and not a guarantee of results (23).

Nevertheless, in every medical treatment it is judged 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. Therefore, 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 (20).

Therefore, it is not possible to offer a definitive answer to the question, which is certainly not left unresolved, but defined by another element that should help clarifying any situation and any dispute that the health informed consent refers to (8). Consent is certainly a very thorny issue in general medical practice and especially in the branch of refractive eye surgery that is, as we have already seen, considered to be halfway between the traditional surgery and aesthetics. The first time in the recent history of medicine the term "informed consent" appears, which is the one that we see today, is a judgment of the Supreme Court, from 1985, which considered a cosmetic surgeon responsible for not having conveniently "informed" the customer in a clear and certain manner regarding the actual outcome of that surgery (17).

It is still a requirement that is always necessary for the permissibility of the medical treatment, so that that the doctor may substitute its own will to the will of the person entitled with respect to personal rights such as the freedom and integrity of health (24).

The consensus understood as duty of 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, nor never presents the characters' urgency (25).

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, because, if the risk albeit low is not accepted by the patient, in the event of its occurrence, it always remains borne by the doctor as a professional responsibility. However, there is an added problem of the formalization of such informed consent, as health professionals are also able to judicially demonstrate that they have fulfilled this duty adequately (19). The current practice of a pre-printed signature below, often couched in general terms and/ or synthetic, or formulated in a sometimes-redundant way, with an endless list of possible complications, which, in some cases, is bordering the psychological terrorism, serves more to define this event as bureaucratic and therefore as a "documented" consensus rather than an "informed" one (26). Especially when this form is signed just before surgery, with the patient ready to be operated, it is constantly interpreted by the judge as an act devoid of the meaning of information that enables the patient to have freedom of choice, which is seen instead as a safe conduct for the surgeon to be protected against future challenges.

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 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 medical intervention in some cases (28,28).

## Results

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 (29).

If we analyzed the points individually, we would find that the highest percentage of cases refer to the responsibility of surgeons who perform between 300 and 1000 refractive surgeries (29.4%), compared to those who perform between 100 and 300 (30). The percentage of male

surgeons was higher than that of women; the percentage of surgeons with previous cases was higher compared to claims for compensation in the past. Through various means of advertising their activities of refractive surgeons, individuals with strong commercial impact are more persecuted than the ones who are less visible, spending more time explaining or having a conversation with their customers before surgery (median 73 minutes), disputes being less frequent than in those who spend less time (55 minutes) and 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 (31).

Therefore, this report does nothing but confirm those assumed figures that repeat for a long time based on our own experience in the topic.

The patient complains unhappy the fact that in classrooms the surgeon has always treated the judicial aspect as an object placed in an assembly, that there were so many people before and after him, and his speech could not be customized. Reports often state that the intervention offered was simple and safe, that the patient was promised that he would “finally remove his glasses”, the consensus being the signature just before entering the operating room, which in days after surgery, compared with his complaints about pain or visual impairment, the surgeon making a visit to his assistant and often refusing to see him more (30). The patient addressed the specific surgeon just because he had been seen on television and he had the magnificence of newspapers and magazines, that being the reason why the patient thought the surgeon was the best ever, etc. These complaints often expressed in simple terms, sometimes childish, all have the common factors that precisely raise expectations. 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. 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 table published on information gleaned from the Italian Society of Ophthalmology and having the causes for professional responsibility in Italy as its object and referring to the years 2001 and 2002, indicated that the percentage divided by the type of intervention. Therefore, we can state that 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 (32). The formula “reliable results with easy to perform surgery” is the most dangerous for a forensic 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.

Quote verbatim the provisions of the Supreme Court (Judgment of 16.11.1988 n.16220): when the intervention is difficult to perform (because it requires considerable skills, involves the solution of new or particularly complex technical problems and involves a large degree of risk), the patient should try to ascertain the responsibility of the surgeon, precise and specific modes of operation of the performance and post-operative, otherwise for an intervention not difficult to perform, the result being

deteriorated by the initial conditions of the patient, this fulfilling the charge against him, trying only to prove that the operation was easy to perform and the result was a pejorative one, having to assume the inadequacy and diligent execution of the professional services by the surgeon, with the result that in this case the trader proves the contrary, that the performance has been performed properly and that the pejorative outcome was caused by the occurrence of an unexpected and unpredictable event, or the pre-existence of a particular physical condition of the patient, that cannot be assessed with the criterion commonly ordinary professional care. The explosive force of the judgment against the attitude of the traditional surgeon waiting for recognition of his professional liability is so obvious that the patient believed that the damage is somehow his fault. If he instead performed a surgery “that is not difficult to perform and the result was deteriorated by the initial conditions of the patient”, it will be up to the surgeon in action to demonstrate that his actions did not lead to unforeseen and unforeseeable complications. This will minimize all the costs for possible complications of surgery, attempting to influence the patient to undergo surgery, implicitly implying that the burden of proof is fore and therefore “easy running”. 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, but that cannot and should not be regarded as routine or easy to perform; they should always be considered as HIGH SURGERY INTERVENTIONS, but they 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 (33).

One final note is with respect to a technical semiology in a medical office, just as the result of refractive surgery, which is also increasing and spreading in clinical practice, i.e. the wavefront currently really necessary, as it is also apparent from the medico-legal considerations in this field expressed in numerous technical consultancy offices, prepared on behalf of the Ordinary Court of Rome (34,35).

In forensic practice, it is currently used to detect these disturbances in vision that cannot be justified in the face of a good visual acuity or even full after surgical correction of ametropia. Increasingly, this survey is required as part of an official technical consultancy to highlight any remnants of hangover or brought to trial by expert witnesses in order to emphasize an aspect of the damage to be assessed for reaching an additional compensation (30,36,37).

However, in our opinion, considering that the wavefront will by its very nature evaluate the aberrations of the whole eye diopter, it makes no sense to bring proof of damage of an alteration wavefront after surgery without documenting what the situation was before the wavefront on the case was concrete. In fact, only in this case, having made the surgery alone on the corneal surface will have charged it, a change for the worse of the total aberrometry framework of examination (10,38). Otherwise, it would be like trying to assess the loss of vision in one eye, without knowing the starting point of visual acuity.

Then, 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, when they could have actually just taken the test value (20,39).

## Conclusions

Obviously, you do not think you have absolutely exhausted all the coroner's problems on the issue with these short emphases, in fact the only purpose was to propose the topics to which we will be forced to think in the future, not forgetting, however, that never any coroner shall take into consideration that what we do today is about the past, but, this must be reported to the knowledge and clinical practice of the period to which we refer (7), that the knowledge and techniques as tools in medicine, particularly 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 crimes occurred under budget forensic (16,33).

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