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MEDICAL LEGAL CONSIDERATIONS ON REFRACTIVE SURGERY

CONSIDERAZIONI MEDICO LEGALI SULLA CHIRURGIA REFRATTIVA

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Abstract

This study is a summary of legal occurred over time in Italy concerning the valuation 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.

Riassunto

Il presente studio rappresenta una sintesi dell’evoluzione giuridica avvenuta nel tempo in Italia in tema di valutazione della responsabilità professionale sanitaria del danno da chirurgia refrattiva, alla luce altresì degli elementi diagnostici ottenibili dalle nuove tecniche relative agli accertamenti diagnostici preoperatori per la correzione chirurgica delle principali ametropie.

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), the keratomileusis Barraquer (1980) and finally to the excimer laser in 1990, and at the same time to be included for the purpose refractive IOL in the posterior chamber of the eye still with crystal (1).

It is then passed in our country in the last two decades from a few tens of events per year, tens of thousands today. With the number of interventions, however, is 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 to and of course to plastic surgeons.

We will try to objectively assess what issues are most forensic 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 years of professional activity ultraspecialistic expert on these subjects (2).

Objectives and Methods

The first place to start was and is the basic question: Refractive surgery appears to be a functional or cosmetic surgery? Recall that the difference is not trivial. In fact, the functional surgery, the contract established between doctor and patient and regulated by art. 2230 and following of the Civil Code imposes on the health operator only an obligation of means, but not results, while cosmetic surgery would seem to pose a constant instead of mandatory results (11). 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.

In 1982, however, upsetting the principles mentioned above comes a new judgtion of Section III. 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) about 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, to the effects achievable, to inevitable difficulties and complicates any foreseeable risks involving the probability of a negative outcome, so that you can decide between the advisability of intervention, because then the reasonable expectatative of success and the need to omit in the absence of expected benefits, except in each case by the certainty of outcomes ominous or permanent. "

A more recent interpretation in merite dates back to August 5, 1985 do 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. Nevertheless you 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, says the Court, different is the relationship between client and therapist in general (surgeon or doctor who) and surgeon practicing cosmetic surgery: is pursued in the first case, the recovery from a nursing disasters or, at least, the reduction of related events; another, a improvement in physical appearance, in a view to improving the social life and true professional, the latter also characterized by the type of activity, hence the corresponding diversify 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 cosmetic surgeon regarding the obtainable a actual improvement in physical appearance that has a positive effect on the professional life and social life (4).

Influential Lawyers and Medical Examiners claimed therefore 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 own and that the ametropia prevents however to carry out in a satisfactory manner, nevertheless represents a real pathology. Therefore an intervention to eliminate the alteration can not and should not be considered for aesthetic purposes, however, and therefore to be considered as contract aimed at improving the state front and not a guarantee of results (5).

It is judged therefore necessary that in every medical treatment there is a constant relationship of proportionality between the medical examiner foreseeable benefits and predictable damage that the healthcare provider should always evaluate from time to time on the basis of 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.

So it really is not possible to give a definitive answer to the question, which is certainly not left unresolved, but defined by another element that should help to clarify any situation and any dispute, that the informed consent health (6). Consent it 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 is considered to be halfway between the traditional surgery and aesthetics. The first time in the recent history of medicine in which appears the term "informed consent", which is the one that we see today, is a judgment of the Supreme Court in 1985 that considered a cosmetic surgeon responsible for not having "informed" conveniently the customer in a clear and certain, the actual outcome of that.

It 'still a requirement always necessary for the permissibility of medical treatment, in order that the doctor may substitute its own will to the will of the person entitled in respect of personal rights such as the freedom and integrity of health (7).

The consensus understood as duty of information finds its most rigorous application in the field of cosmetic surgery, or in that as the refractive surgery where there is a benefit in the strict sense for the health, or at least if there is has a value rather vague , and is not characterized by a therapeutic purpose or by a necessity, nor never presents the characters urgency.

In this field, therefore, the patient must be absolutely adequately informed of even minimal risks to which must match, even though they represent a statistically very low, because if the risk albeit low is not accepted by the patient, in the event of its occurrence then always remains borne by the doctor as a professional responsibility (8). However, there is an added problem of the formalization of such informed consent, as that is also able to demonstrate judicially by health professionals that they have fulfilled this duty adequately. The current practice of a pre-printed signature below, often couched in general terms and / or synthetic, or formulated in a sometimes redundant with an endless list of possible complications, which in some cases bordering on psychological terrorism, 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 (9).

Especially in the field of refractive surgery is extremely important that the information is given well in advance compared to the intervention, the surgeon you talk to the patient to convince him to undergo surgery, but rather to understand what the real expectations that he (the patient, who must always be at the center of all our professional attention) put in the intervention itself. A personal discussion with some patients may even propose to withdraw from the medical intervention in some cases (10).

Results

A recent publication of Ophthalmology contains some statistical data on professional liability cases involving eye surgeons who had practiced the technique LASIK or PRK as defined in the United States, in a given period of time. The data were collected dall'OMIC (Ophthalmic Mutual Insurance Company) between 2933 refractive surgeons insured for 100 cases of complaints between 1996 and 2002 (3).

Table 1

Cataract Surgery		Refractive Surgery		Vitreoretinal Surgery		Other Surgery	
2001	2002	2001	2002	2001	2002	2001	2002
50%	51%	31%	37%	3%	5%	16%	8%

If we analyze the points individually, we find that the highest percentage of cases is the responsibility of surgeons performing between 300 and 1000 refractive surgery (29.4%) compared to those who make between 100 and 300 (19, 6), the percentage of surgeons males is higher than that of women, the percentage of surgeons with previous cases is higher as claims for compensation had in the past, individuals with strong commercial impact through various means of advertising their activities refractive surgeon are more persecuted than their less visible, those who spend more time before surgery (median 73 minutes) in explanation or in a conversation with their customer disputes are less than those who spend less (55 minutes) and finally, the percentage of disputes is less for those who run their own patient than those who share in the management of a collaborator assistants in ophthalmology.

This publication therefore does nothing but confirm those figures assumed that repeat for a long time on the basis of our own experience in the topic.

The patient complains unhappy fact in classrooms Judicial always been treated by the surgeon as an object placed in an assembly, that the day was made there were so many people before and after him, and then his speech it could not be customized. Reports often and also that the intervention was offered as a simple and safe, which has been promised that he would "finally removed his glasses," the consensus was that the sign just before entering the operating room, which in days after surgery, compared with its complaints about pain or visual impairment, the surgeon made a visit to his assistant and often do not want to see him more, that he had addressed the specific surgeon just because he had seen on television or who had seen the magnificence of newspapers and magazines and then thought it was the best ever, etc.. These complaints often expressed in simple terms, sometimes childish, they have all the common factors which are precisely the raise expectations too high, take a little time to establish a real relationship with the patient, believing that to sign a consent constitutes a waiver for TOTAL whatever happens, believe that not seeing a patient who believes, rightly or wrongly, did not have the desired result can miraculously make it "disappear" from their professional life, etc.

The table set out above, published on information gleaned from the Italian Society of Ophthalmology and having as its object the causes for professional responsibility in Italy and referred to the years 2001 and 2002, indicated that the percentage divided by type of intervention.

We can therefore say that the orientation of the problem coroner in the field of refractive surgery is soaring, driven mainly by promises of sensational results that are in some way suggested by some stakeholders. The formula "reliable results with easy to perform surgery" is the most dangerous we could be in for a forensic surgeon especially ophthalmologist. From it are derived implicitly two consequences: the first is that you establish a contract with a guarantee of results, and that's something we have already discussed, the second is that in the event of a dispute is 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 skill, involves the solution of technical problems new or particularly complex 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, and the result is deteriorated by the initial conditions of the patient, this fulfills the charge against him trying only that the operation was easy to perform and the result was a pejorative result, having to assume the inadequacy and diligent execution of professional services by the surgeon, with the result that it is in this case the trader to prove the contrary, that the performance had been performed properly and that the outcome

pejorative was caused by the occurrence of an unexpected event, unpredictable, or the pre-existing of a particular physical condition of the patient, can not be assessed with the criterion commonly ordinary professional care. It 'so obvious the explosive force of the judgment against the attitude of the traditional surgeon waiting for recognition of his professional liability that the patient believed damaged try somehow his fault. If he instead performed a surgery "is not difficult to perform and the result is deteriorated by the initial conditions of the patient," it will be up to the surgeon in action to demonstrate that its actions are occurring complications unforeseen and unforeseeable. The will minimize at all costs possible complications of surgery, wanting to make it trivial to cause the patient to undergo surgery, implicitly implies that it is "easy running" fore and therefore the burden of proof. Always argue that interventions such as cataract extraction or refractive surgery interventions are "standardized" method for instrumentation, execution time ", but that can not and should not be regarded as routine or easy to perform even must always be considered as INTERVENTIONS HIGH SURGERY, but certainly not helped us in our work of conviction when we hear what is being said or promised to patients possible subjects to be made by some of our little wiser colleagues, who then are to pay the consequences in the courtroom (13, 14).

One final note always a medical office in respect of a technical semeiologic that, just as a result of refractive surgery, is also on the increase and is spreading in clinical practice, ie the wavefront currently really necessary, as It is also apparent from the medico-legal considerations in this field expressed in numerous technical consultancy office, prepared on behalf of the Ordinary Court of Rome.

In forensic practice, it is currently used to detect these disturbances in vision that can not be justified in the face of a pretty good visual acuity or even full after surgical correction of ametropia.

Increasingly this survey is required as part of a 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 (16).

At this point shows that the majority of cases does not consider the expert witness evidence or documentary evidence and can not be ordered in order to acquire the Acts of the evidence that the parties have the burden of providing (Cass . civ. 18.12.1970 n.2713, Cass.civ. 09.06.1972 n.1811, Cass.civ. 25.07.1972 n.2534, Cass.civ. 15.03.1975 n.1008, Cass.civ. 05.04.1976 n.1184, Cass.civ. 945 of 08.03.1977, Cass.civ. 15.09.1986 n.5607, Cass.civ. 17.10.1988 n.5645) In our opinion, however, 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 an alteration wavefront after surgery without documenting what the situation was before the wavefront on the case concrete. Only in this case, in fact, having acted surgery alone on the corneal surface, will be charged to it a change for the worse of the framework aberrometric total of examining (13). Otherwise it would be like trying to assess the loss of vision in one eye, without knowing the visual acuity of departure. Then introduce expert in the activity also new methods that allow us to better understand the situation anatomical and functional of an eye and well-being of even more sophisticated ones, but availment for medical purposes legal only when they can actually take the test value (12).

Conclusions

Obviously you do not think you have absolutely exhausted all the problems coroner on the issue with these short emphases, in fact the only purpose was to propose the topics on which we will be forced to think in the future in an ever more frequent, not forgetting, however, that never any consideration coroner we do today about the past, however, this must be reported to the knowledge and clinical practice of the period to which we refer (14), 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 (15).

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