MALPRAXIS RISK MANAGEMENT IN IMPLANTOLOGY

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MALPRAXIS RISK MANAGEMENT IN IMPLANTOLOGY (Abstract): In present practice there is an increased demand from patients for prosthetic implant restoration solutions. At the same time one can notice a possible vulnerability regarding allegations of malpractice, as evidenced by the growing number of complaints of malpractice also maintained by negative reports, frequently incomplete or incorrectly documented from the press. This should require practitioners to have a professional attitude. Keywords: MALPRAXIS, IMPLANTO-PROSTHETIC, DENTAL PRAXIS, INFORMED CONSENT

The growing number of Romanian dentists on the medical market led to a reorientation of health services optics from providing optimal therapeutic solutions to focusing on patient satisfaction, for more profit. This led to a compromise in the application of therapeutic solutions along with a poor doctor-patient communication that has led to increased incidence of malpractice, which currently has strong media coverage. All this led to a loss of the patient’s confidence in the dentist and the quality of treatment. The patient’s reluctance towards the medical act is enhanced by continuously increasing rates of medical services so there will be much higher claims about the final result. His dissatisfaction may lead not only to the negative publicity attached but also to punitive professional claims, moral and material damages on grounds of malpractice.

The definition of malpraxis (lat. malus „bad” + gr. praxis „practice”) = malpractice is the professional error committed in the exercise of medical or medical-pharmaceutical act, generating damages on the patient, involving civil liability of medical personnel and medical products and services provider, healthcare and pharmaceuticals (according Law No. 95/2006 on healthcare reform).

Dentists must responsibly provide patient care according to the standards of competence and behavior that they have assumed when choosing this profession. The dentist needs to improve and promote the patient’s oral health so as to respect his dignity, autonomy rights. Also, the practice of the profession must take place effectively and with minimum risks for the physician. Knowledge and compliance with the legislation is, from this point of view, of the utmost importance and protects the doctor, giving him the opportunity to adopt an approved therapeutic behavior which reinforces his professional dignity.
Legal regulations directly concerning the practice and conduct of the physician in our country are:

- Law No. 95/2006 on healthcare reform, as modified - art. 649 et seq.
- Order No. 482/2007 of the Minister of Public Health - "Rules for the application of Title XV: civil liability of medical personnel and medical products and services provider, healthcare and pharmaceuticals" in Law no. 95/2006 on healthcare reform. Law no. 46/2003 of patient rights
- Deontological Code of the dentist.

These rules should consider the European standards and norms to which Romanian legislation must comply with.

A number of vulnerable aspects related to malpractice that stand out and that should be taken into account are strictly medical related: a standard guide of diagnosis and treatment, the patient's informed consent, confidentiality, patient access to their medical information, patient access to non-discriminatory treatment, access to media, the right to a second opinion, limiting to their own specialty. The minimal documentation necessary in a medical office at present is the sheet of treatment, the informed consent, the general status questionnaire, the registry of consultations and treatment, the laboratory sheet, various patient agreements, internal rules displayed, the job description for employees.

Prosthetics on implants involves particular issues compared to other types of treatment in practice. This is a new, modern therapeutic solution, expensive for the patient, requiring special training and equipment from the doctor.

A first step in therapeutic success is the suggestive phrase "know the patient and his limits." The clinician should professionally evaluate the patient's general condition, his clinical situation and decide whether the chosen therapeutic solution is up to the patient's expectations. This requires gathering information. Retrieving general patient data is an operation that takes time and can be performed even by the latter, using a standard form that the patient fills in the waiting room along with a questionnaire where the general condition will be checked, if he suffers from other diseases, if he is under a treatment that may interfere with dental therapy. General status questionnaire must be completed thoroughly, as some medical history are absolutely not suitable for surgery such as face bone radiotherapy, bisphosphonate treatment with immunosuppressives, recent myocardial infarction (MI), certain psychiatric disorders and drug abuse. Other conditions are considered negative factors for osseointegration of implants: some forms of diabetes, multiple allergies, cardiovascular risk, a general malaise, etc. Drinking and smoking are also included here. At this point the doctor will decide if the patient needs to obtain blood marker values that help to form a complete overview of his medical condition.

The patient's record is then completed along with the doctor with specialized data that should include the initial oral situation, diagnosis, prognosis, the description of each performed maneuvers, when it was performed, medical history, prognosis and initial costing, name and signature of the physician. After diagnosis and treatment plan development by the doctor, the patient must be explained to, as to a reasonable person, the treatment and outcomes proposed as well as the accidents and complications that may arise and provisionally
estimated costs. Subsequently, the patient must give his consent for the treatment by signing his informed consent, compulsory in writing.

*The patient’s informed consent is necessary for the application of the therapeutic solution.* It can take multiple forms: as a questionnaire with categories to be filled or checked or in the form of a declaration summarizing the risks and complications that may occur. It includes several parts: the patient’s personal data, that will be listed both in the treatment sheet, register of consultations and treatment and general status questionnaire; a part briefly describing the medical act, then the name and specialty of the medical team, another part stating that the patient has been explained the overall condition, diagnosis, prognosis, risks and complications that may occur after treatment and the cost estimates, risks that may occur if the patient does not follow the medical instructions. It will include information about: the legal representative for minors, or persons without discernment, consent for the collection, preservation and use of biological samples, the agreement for further investigation (dental records), information on the rules of the cabinet, the right to a second opinion. A section or important part is the answer to mental illnesses which the patient may present (for some conditions agreement becomes null), and then the name and signature for the agreement or disagreement of the patient or legal representative. Also the legal acts underlying the necessity of its conception and completion must be mentioned. The only situation where there is no need for the patient’s consent is life threatening situations, in which case an emergency report will be completed. In this report the circumstances, the initial state of the patient, the therapeutic emergency approach and general state after overcoming the emergency will be mentioned.

The patient’s correct information by the physician in order to obtain their consent for treatment requires communication skills from both sides. The explanation must be given by the use of a language specific for a 14 year old child, at a reasonable scientific level of patient comprehension. The patient is the only one able to decide what risks he is willing to take. In most dental offices informed consent forms are of a general nature. It is useful to develop this especially designed form for implant-prosthetic solution so as to eliminate the suspicion or the possibility that consent is considered to be formal(1, 2).

*Various types of agreement* are useful in practice such as: patient consent for the communication of medical data, patient agreement on the participation in higher education, agreement on communicating medical documents.

Rules of internal order are recommended for the patients to be displayed where several items are specified, such as: rules about conduct, scheduling patients, providing medical information, media access.

Medical offices, clinics, need to respect the confidentiality of patient data, here including the whole medical team: doctors, nurses, technicians. According to current laws, the physician may not disclose to any other person than the patient, data about its health. Information on the patient’s health, results of investigations, diagnosis, prognosis, treatment followed, and any information that could link the identity of a person of a certain medical information is strictly confidential, obligation of confidentiality continuing even after the patient’s death. The physician / medical staff
are not allowed to provide information on the nature of the above even to the family or friends of the patient, without its consent. In these circumstances, doctors are not allowed to communicate medical data about patients to third parties.

The principle of autonomy is reflected in the practices in the obligation to ensure patient access to personal health data. At the patient's request copies of sheet treatment and original dental scans will be made available to them (digital copies will be kept in the archive).

According to the law it is forbidden to discriminate between persons in similar circumstances on the basis of race, sex, age, ethnicity, social or national origin, and religion, political or personal dislike.

**Medical malpractice.** Relationship with the media is a controversial topic in the medical world, largely due to negative media campaign against Romanian medical activity and the perception of journalists by the medical world in an utterly unfavorable way. A Kompass Media report monitoring printed media revealed that during the 1 July 2007 - 17 September 2007 period, 97 articles were classified by the press as cases of "medical malpractice." All items monitored recounted discontents and complaints from patients, the tone used by publications being accusatory to the doctors, even without confirming the existence of a medical fault. According to legal regulations, no patient can be photographed or filmed in a medical facility without his express consent (without infringing the rules and regulations of the medical unit). The doctor may refuse or reschedule the meeting with the media, it is recommended to be retained in comments and treat everything with a detached tone and even positive if possible.

Of particular importance is the malpractice insurance that each of the medical staff has. It is advisable to negotiate the terms of the insurance coverage so as to obtain both material and moral damage, and cover more disputes over a longer period of time (3, 4).

The development of contracts between offices and suppliers of materials and equipment should also be considered, the certificate attesting that they have European compliance, the contracts between clinics and dental labs, in stating that prosthetic pieces have certificates of conformity and will also respect the confidentiality of patient data.

Of particular importance in supporting a correct diagnosis and optimal therapeutic option are intra and extra oral clinical examinations, followed by a series of paraclinical investigations. This can be achieved by making the initial extra oral photos that capture the smile line, the shape of the lips, and of the face, and intraoral that captures the initial dental status and the possible initial degree of dental hygiene. At the same time the dentist has to make a map of the periodontium, the periodontal probing, which is attached to the treatment sheet. Next the study designs should be made that record oral initial status and on which the mock-up of future dentures can be achieved. This mock up done in the lab is to help patients understand what the future prosthetic will be like. The physician should record the type of occlusion and the potential occlusal para functions.

Analogical or digital intra and extraoral dental X-rays, CBCT (cone bean computer tomography) are required for implant solutions. With digital radiological images processed using dedicated 3D software the volume and quality of jaw bone can be evaluated, also the distances to certain
anatomical landmarks, it can simulate various types and sizes of implant insertion axis and also determine the form of the surgery guide. Your doctor will decide if additional surgical maneuvers will be required for bone adjustment. Various makeovers will be recommended in order to establish an optimal pre implantation oral status. Digital prints together with intraoral scanners helps the doctor get a final prosthetic, close to that simulated on the computer and the mock-up. "Electronic" sheets and dedicated programs facilitate virtual presentation of the operating time and the final form of prosthetic reconstruction. It also helps in maintaining an accurate record of the patients and a close hospitalization. Hospitalization of patients should be made according to the needs of each patient so as to prevent any post therapeutic complications. Patients should understand the importance of these periodic checks, when the physician makes an assessment of oral and implant tissue, of the occlusal changes and a radiological examination of implant osseo integration (5).

Implantology is found at the intersection of two specializations: the dental alveolar surgery and prosthetic surgery. Hence, the need for the physician to achieve particular theoretical and surgical skills. Therefore, in the present practice in our country doctors are required to obtain a certificate of competence and a diploma in implantology, at which it is recommended the addition of certificates on various surgical skills. But of equal importance is the prosthetic stage, which, by unusual stress, can lead to loss of implants. Therefore, training in prosthetic rehabilitation is a very important issue, prosthetic on implants being different than on natural teeth.

To prevent potential disagreements with the patient, the doctor should mention that there are no guarantees of success and strength over time for certain maneuvers and dentures. Also it is necessary to consider the patient's expectations related to aesthetics, functionality, adaptation or resistance to various therapeutic solutions, those often going beyond the possibilities of achievement. Full preparation of the practitioner, choosing the therapeutic solution according to the particular clinical case, provides the premises for a successful treatment. Increased attention on a correct, sincere, disinterested communication, along with providing all the information from both sides, creating a partnership, may decrease the risk of conflict situations that have no relation to malpractice but that the patient perceives them as such.

REFERENCES