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# Law Governing Cross-Border Disputes in Prosthetic Dentistry

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# Law Governing Cross-Border Disputes in Prosthetic Dentistry

Attia Suleiman Khalifa and Shahad Fadhil Bunyan

*Abstract*— **Medical tourism, including in the fields of prosthetic and maxillofacial dentistry, is a rapidly developing segment of the global healthcare industry. With the development of new technologies, such as 3D printing and dental implants, increasing numbers of patients are travelling abroad for dental treatment. This study demonstrates the complex legal consequences of medical errors in prosthetic dental treatment and clarifies the subtleties of professional fault according to the principles of law, and highlights the dual ergonomic and aesthetic aspects of prosthetic dentistry that differentiate it from direct therapeutic interventions and complicate both demonstration of harm and attribution of responsibility. It addresses the principles of private international law governing conflicts of law, and clarifies how the applicable law is determined when dentist and patient are from different countries, or when treatment has occurred abroad. It also provides a comparison of international regulations and legislation protecting patient rights, such the Oviedo Convention and the World Health Organization Declaration, and exposes the lack, in national laws, of any specific rules governing dental medical liability. The study concludes by stressing the need to increase dentists' understanding of the law, create new ways, such as mediation and arbitration, to settle disputes, and create a unified, global legal framework for medical responsibility in prosthetic dentistry.**

*Index Terms*—**Consumer Protection; International Law; Internationality; Jurisprudence; Legislation as Topic; Medical Liability; Patient Rights; Patient Safety; Prosthodontics.**

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## I. INTRODUCTION

As prosthetic dentistry continues to improve and new procedures and therapies are developed, a number of legal challenges have arisen around the issue of responsibility for medical malpractice in this specialised sector. Disagreements over prosthetic errors, whether the resulting impairment is aesthetic or functional, are a hot topic between patients and dentists, particularly with regard to who is at fault and the amount that should be compensated [1]. When an international dimension arises, such as treatment received abroad, this issue is further complicated [2].

Medical liability is the legal responsibility of a doctor or other healthcare practitioner for a job poorly executed that has caused harm to the patient [3]. Such responsibility is usually based on the three main tenets of civil liability: blame, harm, and causation. It refers to the practitioner's legal obligation to compensate the patient for harm resulting from a breach of technical, moral, or professional duties [4].

The extent of culpability varies by legal system (civil, criminal, or disciplinary) and by medical specialisation, particularly in fields that involve complex technological aspects, such as prosthetic dentistry [5]. Certain other aspects of this field, including its dual therapeutic and aesthetic focus, also set it apart from a legal standpoint. This adds complexity to the dentist's job, as patients have higher expectations: the aim is not just to restore oral functions such as eating and speaking, but also to achieve cosmetic outcomes [6].

Reliance on new technologies and materials, such as 3D printing and dental implants made from titanium or zirconia, increases the risk of complications caused by errors and treatment failures [7]. These risks are further compounded because, unlike other disciplines in which the interaction between practitioner and patient may involve just a single procedure, the therapeutic relationship between dentist and patient might last far longer, to

include treatment, maintenance, and modifications. The standards of legal liability thus become more nuanced in cosmetic and prosthetic practice, where both functional and aesthetic expectations must be met [8].

Whether or not the patient is aware of it, a contract exists between themselves and their prosthodontist. Dentists are obliged to provide care, but not to guarantee results. Nonetheless, if a dentist has made a clear promise, particularly with regard to cosmetic outcomes, they may be obliged to fulfil this. French civil law recognises two categories of professional obligation: the obligation of means and the obligation of results. Thus, if a patient is promised a specific result, the provider may be accountable. Furthermore, failure to reveal risks and possible complications is illegal and may result in civil liability [9].

The legal relationship between doctor and patient is based on informed consent, for which three crucial requirements must be met: the patient undergoes the work voluntarily; the patient is informed of and understands all of the facts related to the procedure; and the patient has the mental capacity to make the treatment decision [10].

The World Medical Association's Declaration of Helsinki states: "Medical intervention may not be done without the patient's informed consent, which means the patient fully understands the therapy and its risks" [11]. Article L1111-2 of the French Public Health Code states: "The patient has the right to clear and understandable information before any medical procedure, and consent must be informed, prior, and explicit" [12].

Nonetheless, the question remains as to which law applies when treatment is received abroad—that of the country where the treatment took place, that of the patient's county of origin, or a mutually-agreed international framework? What are the limits of patient protection under various legal systems? This study addresses the question of how international legal instruments and comparative law address prosthetic dentistry disputes while safeguarding patients' rights.

## II. LEGAL LIABILITY IN PROSTHETIC DENTISTRY: WHAT THE LAW SAYS ABOUT MEDICAL LIABILITY

*Duty of Care*

Breach of duty, causal link, and harm are the three elements of medical liability common to all legal systems. In the medical arena, however, and particularly in prosthetic dentistry, these words carry new weight due to the complexity of the field and high patient expectations. The duty of care compels the dentist to follow scientifically accepted methods while providing appropriate professional treatment. There is no need for a formal contract between the parties; the commencement of treatment establishes a legal relationship that includes this responsibility [13].

A doctor is obliged to comply with the principles of liability and to provide care that is consistent with established medical principles in his field; however, he is not obliged to guarantee a specific outcome [14]. The Egyptian Court of Cassation states: "The level of care that a careful peer in the same field would give is what defines the doctor's duty." (Ruling No. 13523 for the year 79, meeting on 10/12/2012) [15].

*Breaking the Law*

The law is broken when a dentist does not provide the required level of care, whether due to carelessness, being under-qualified, not following approved treatment standards, or utilising incorrect instruments or materials. Some examples of breach in prosthetic dentistry include placing prostheses without adequate examination of the mouth; poor instrument hygiene (which carries the risk of complications); or using a technique that is not scientifically proven. Breach occurs when a doctor acts in a way that differs from the way another, similarly qualified, doctor would have acted in the same situation [16].

*Causal Link*

It must be demonstrated that the provider’s breach of duty was the direct or most likely cause of the harm suffered by the patient. This can be very difficult to prove, particularly when the damage might

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have been caused by other factors, such as an allergic reaction to a substance, or poor patient compliance post-procedure. French law states that the link between cause and poor outcome must be "clear and directly relevant", while in American law, the “preponderance of evidence” test is employed, whereby the evidence must demonstrate the probability that the breach caused the injury [17].

*Damage*

Damage is the suffering incurred by the patient as a result of a medical error. This may include physical injury, including loss of ability to eat or permanent facial disfigurement, or psychological damage, such as emotional suffering or social shame due to prosthetic failure. Aesthetic harm is a significant element of disputes in prosthetic dentistry. The harm must be: real (not merely potential), direct, and legally relevant. In one example, the Paris Court of Appeal found a dentist liable for a faulty denture that permanently altered a patient's face, despite the dentist having followed all the rules, because the dentist had not explained the risks to the patient [18].

## III. LIABILITY IN PROSTHETIC DENTISTRY

Prosthetic dentistry is associated with a distinct set of technical and legal issues that affect the extent of medical culpability and set it apart from other medical fields. This is due to the nature of treatment, the instruments and materials utilised, and the fact that the outcome is expected, by provider and patient, to be both therapeutic and aesthetic [19].

Dental prostheses, including dentures, bridges, crowns, and implants, among others, are artificial devices designed to replace missing teeth or tissue. By their nature, they combine medical treatment and industrial technology. Thus, is the dentist or the manufacturer responsible for a design flaw? Is a material failure a medical error or a flaw in the product? [20].

Even if they did not make the device, the dentist may still be responsible if they did not adequately check the quality of the materials or inform the patient about other options. Furthermore, problems with prosthetics are not always immediately evident; they may take months or even years to appear, making it harder to establish when they occurred and who is to blame [21].

It can be difficult to demonstrate harm or treatment failure when the damage is indirect or not immediately evident. The patient could be unhappy for cosmetic reasons, due to pain that cannot be demonstrated via X-ray or other tests, or due to device failure caused by factors beyond his/her control, such as poor bone quality and/or inadequate after care [22].

This begs the question as to whether failure to achieve a predicted outcome constitutes a medical error. Is it the patient or the dentist who must prove their case? Because of the delicate nature of prosthetic work, evidence of damage in this field is often provided via expert reports and independent professional testimonies [23].

New technologies, including 3D printed tools, digital jaw scanning, and AI-tailored treatments, are changing the way dentists work, while also raising novel legal questions: Who is responsible for errors in a digital design? Is the dentist accountable for software failure? Should the patient be informed about a technology’s limitations? [24].

The European Medical Devices Regulation (EU MDR) states: "The dentist must make sure that the devices made for each patient meet safety and quality standards, even if they were made by someone else" (Article 745 of the EU). Thus, if treatment fails for technological reasons, both dentist and manufacturer may be responsible—as well as, possibly, the software supplier [25].

## IV. THE LAW GOVERNING MEDICAL DISPUTES

One of the most important, but difficult, legal challenges when medical disputes transcend national borders is establishing which law applies. This is particularly true in an age when medical tourism and cross-border treatment have become increasingly common, and more patients are receiving prosthetic dental care in countries other than their own. A conflict of laws exists when a medical dispute involves more than one

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jurisdictional connection, such as when patient and doctor are from different countries, when treatment occurs in one country but damage occurs in another, or when the medical contract is carried out in parts across more than one country [26]. In such situations, which law applies—the law where treatment was received, the law of the patient's home country, or legislation agreed upon by both parties in the treatment contract? [26].

When a legal relationship is connected to the laws of more than one state, choice-of-law rules must be applied to determine which law applies. Common connecting factors include *lex loci delicti* (the law of the place where the damage occurred), *lex nationalis* (law of the party's nationality), *lex domicilii* (law of the party's residence), and *lex locus contractus* (the law of the place where the contract was formed) [27, 2].

Some legal systems and courts use the "most favourable law" approach, particularly in medical matters, whereby they apply the law that gives most legal protection to the weaker party (the patient). This approach is based on humanitarian principles that protect patients and consumers, uphold the right of the injured party to fair justice and redress, and inform the state's responsibility to protect public health [28].

The French Court of Cassation states: "A foreign law chosen may be thrown out if it goes against the patient's basic rights or French public policy." This concept is flexible, but is not always supported by law. It is usually only applied when there is a conflict between a choice-of-law norm and public policy ideals [29].

Most national laws and international treaties allow the parties to mutually agree, ahead of time, the law that will govern the treatment contract, provided the decision is clear and unequivocal, does not contravene public policy, and does not harm any party, particularly the patient. According to Article 3 of the Rome I Regulation, "The people who sign a contract can choose the law that will apply to all or part of it." (Article 3 of Regulation (EC) No. 593/2008). While this provides some legal certainty, some states may also enforce restrictions to protect the weaker side, which is usually the patient [30].

As increasing numbers of patients look abroad for high-quality, economical dental procedures such as implantology, cosmetic restorations, and maxillofacial rehabilitation, the resulting, transjurisdictional, contractual relationships raise novel legal and ethical challenges related to patient rights, professional obligation, and standards of liability in different geographical jurisdictions.

In Europe, Directive 2011/24/EU (Patients' Rights in Cross-Border Healthcare) lays down the legal basis for the reimbursement of patients by their home systems for health care received in other EU states. It supports transparency, adequate provision of information, and quality control, instilling a sense of security for patients seeking treatment abroad. However, it does not establish pan-European criteria for medical malpractice liability; national laws would still prevail when establishing negligence or malpractice [31].

The Rome II Regulation (Reg. 864/2007) addresses non-contractual obligations and determines which country's law applies when harm occurs in the setting of cross-border healthcare—usually that of the nation where the harm was incurred. This implies that a patient who receives dental treatment in one EU nation but lives in another must frequently use the tort law of the country of treatment when making a malpractice claim. This can increase the difficulty of getting redress or compensation, due to variances in regulations governing processes, standards for evidence, and compensation amounts [32].

The Brussels I Recast Regulation (Reg. 1215/2012) clarifies the regulations as to where a patient may sue or be sued in civil or business proceedings. It stipulates that, in the context of medical tourism, parties may sue either in the nation where the provider is located or in their own home state, but only under specified circumstances. This serves to safeguard patients receiving treatment abroad, whilst emphasising the need for providers to uphold ethical and professional standards [33].

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The Services Directive (2006/123/EC) and the Professional Qualifications Directive (2005/36/EC as amended) are also relevant to medical tourism, albeit indirectly. They guarantee that providers working in EU countries are proficient and that their qualifications are internationally recognised. This obliges practitioners in the field of dental and prosthetic tourism to maintain the educational and professional requirements necessary to provide safe and proficient treatment to all patients [34].

National tort and medical malpractice laws are also relevant, with individual EU member states setting their own rules regarding professional negligence, statutes of limitation and compensatory limits, as well as criteria for expert evidence. These differences in national systems may leave both patients and doctors unsure of what to expect in the event of legal proceedings. For example, a maxillofacial prosthodontist treating international patients may encounter insurance regulations and liability limits vastly different from those of their home nation [35].

Another pertinent legal question arising from the increase in medical tourism is whether a foreign patient enjoys the same legal standing as a citizen, and to what extent the patient is aware of their rights under foreign laws [36,37].

Lunt & Mannion note: "Medical tourism gives rise to transnational medical disputes in the absence of clear legislation defining the legal duties and rights of foreign patients. In the absence of comprehensive international agreements, these disputes are left to national courts, leading to inconsistent and unpredictable outcomes " [38].

As lawsuits are generally filed in the country where the harm occurred, international patients can face serious practical obstacles, including cultural and language barriers; high litigation costs; and a poor grasp of their legal rights [39]. To address this, some countries have recently established medical arbitration systems to ensure faster, more professional resolution of disputes while upholding the principles of confidentiality. Nonetheless, arbitration remains optional and non-binding in many jurisdictions, and access for foreign patients is still limited [40].

Mediation is generally the more affordable and amicable option, but relies on the consent of both parties. Moreover, it is often unsuitable for cases involving severe harm or large compensation claims. The Council of Europe (2020) notes: "Alternative dispute resolution mechanisms in medical disputes represent a positive step, but they still lack unified legislative frameworks at the European level" [41].

In the absence of a comprehensive international treaty, some countries have enacted domestic laws to regulate the responsibility of healthcare providers with regard to foreign patients. Examples include:

*France:* Allows foreign patients to sue healthcare providers before French courts, treating them equally to citizens, subject to public order provisions [42].

*United Arab Emirates:* Requires private healthcare institutions to offer professional liability insurance for physicians and compensation for patients in the event of injury [43].

*Iraq:* Article 27 of Iraqi Civil Code No. 40 of 1951 establishes the principle that "non-contractual obligations are subject to the law of the state in which the event creating the obligation occurred." Accordingly, the Iraqi legislator has determined that liability arising from medical error is governed by the law of the state in which the error took place. The second paragraph of Article 27 states the following: "However, the provisions of the previous paragraph regarding obligations arising from an unlawful act shall not apply to events that occur abroad and are lawful in Iraq, even if they are unlawful in the country in which they occurred" [44].

This legal gap can result in injustice for patients or excessive protection for practitioners without proper accountability.

## V. COMPARISON OF INTERNATIONAL PATIENT PROTECTION LAWS

The last several decades has seen an increase in global initiatives to protect patients' rights. This is

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especially relevant with the globalisation of healthcare and the resulting rise in medical conflicts, including those around prosthetic dentistry. Different groups and professional organisations worldwide have published guidelines and protocols setting global standards for both patients' rights and doctors' legal obligations [45]. Some of the most important standards include:

- The Declaration on the Rights of the Patient, by the WHO and a number of countries, which lays out a basic set of patient rights to be followed by all healthcare systems. These include the right to clear and complete information concerning treatment, the right to provide informed consent, the right to privacy and confidentiality, the right to refuse treatment, and the right to file a complaint or seek legal action against a doctor or institution [46].
- The WHO Patients' Rights Framework (WHO, 2004) which states: "Policies about health care should be made to protect patients from carelessness and make it clear who is responsible." While not legally binding, this is generally perceived as a moral and legal guideline and has influenced legislation in numerous nations [47].
- The Oviedo Convention, signed in 1997, and the first international treaty to make human rights in medicine and biology legally binding. It was issued by the Council of Europe and is binding on the (mostly Western European) signatory states. Some of its key principles include respect for the dignity of all persons involved in healthcare activities, no treatment without free and informed consent, as well as the right of patients to access their medical records. According to Article 5, "Without the person's free and informed consent, no intervention in the health field can take place". The Convention also addresses biological and medical advances such as organ transplant and gene therapy, stipulating that legal action may be taken against healthcare professionals who violate patients' rights [48]. Non-signatory countries may also refer to this Convention as a model for patient protection laws [47].

For dentists in particular, the Fédération Dentaire Internationale (FDI) has established a Code of Ethics that includes both legal and ethical rules to be followed by all of its members. These include respect for patients, provision of adequate information, ensuring informed consent and privacy, competent use of tools and techniques, and avoiding assurances that cannot be guaranteed [48]. According to the FDI Code of Ethics (2018), "A dentist must not do anything that puts the patient at risk or damages the public's trust in dentistry." These principles are not binding; nonetheless, they serve as criteria in assessing professional conduct and legal responsibility [48].

## VI. CONCLUSION

From a medico-legal standpoint, the dual therapeutic and aesthetic goals of prosthetic dentistry complicate the attribution of liability and necessitate fully informed consent. The four elements of medical malpractice are the physician's duty to the patient; breach of that duty; causation between breach and injury; and damages. Of these, causation is often difficult to prove in dental prosthetics cases; most national laws do not provide clear regulations for the attribution of responsibility in this field, instead providing only vague, general rules. Regarding cross-border disputes, the various national systems follow different approaches under private international law to determine which law applies.

Thus, patient safety remains a challenging element of medical tourism. In the absence of an international treaty mandating cross-border medical accountability for signatory states, protection currently depends on soft law instruments such as the WHO declarations and the Oviedo Convention. Research is limited in this area due to the lack of uniform national and international legislation governing the practice of dental prosthetics. The laws of most jurisdictions do not specifically consider the dual medical and cosmetic nature of prosthetics, instead relying on general medical malpractice or consumer protection laws. Additionally, the multi-

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disciplinary aspect of this field, combining both clinical and technological expertise, adds to the difficulty in determining professional responsibility and establishing causation in malpractice cases. Furthermore, accurate comparison of the various legal systems is not possible, due to the varying legal interpretations of duty, breach, causation, and harm between different jurisdictions. Based on our findings, it would be reasonable for future studies to explore integrated legal frameworks and internationally comparative models that could enhance global patient protection and professional accountability.

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