



# Criminal Liability of Dentists for Using Substandard Materials in Restoring and Implanting Patients' Teeth

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## Abstract

The use of substandard, counterfeit, or non-standard materials in dental treatments has been one of the most important factors in causing physical injuries, treatment failure, and increasing patient complaints in recent years. This study aimed to investigate the dimensions of criminal, civil, and disciplinary liability of dentists for using substandard materials in restoring and implanting teeth. The research method is descriptive-analytical and based on the study of laws, regulations, jurisprudential sources, and international standards. The findings show that, according to Articles 495 and 496 of the Islamic Penal Code, the use of substandard materials—even without causing harm—can be considered a violation or crime, and in the event of harm, the dentist may be sentenced to pay blood money, compensation, or criminal penalties. From the perspective of Islamic jurisprudence, the rules of non-harm, waste, attribution, pride, and honor of deception guarantee the physician against any harm—even unintentionally. A comparative analysis with the legal systems of the United States, Germany, France, and Turkey shows that strict supervision of the quality of materials and the requirement to use equipment with CE and FDA standards play an important role in reducing harm. Finally, suggestions are presented for amending laws, strengthening supervision, professional training, and improving medical standards.

Keywords: Criminal liability, dentistry, substandard materials, implants, Islamic Penal Code, Islamic jurisprudence.

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## 1. Introduction

Dentistry is one of the most sensitive and specialized fields of medical science that is directly related to the general health, quality of life and appearance of individuals.

In recent decades, the increasing demand for restorative, cosmetic and dental implant services has made dentistry one of the most frequently consulted fields of treatment.

Along with this growth, the increase in patient complaints about injuries caused by dental treatments has also been significant. A significant part of these complaints is related to the use of substandard, counterfeit or non-standard materials in dental restorations and implants (Shahidi et al., 2020).

Dental materials, including composites, amalgams, ceramics, adhesives, implants and prosthetic components, play a decisive role in the success of treatment. The quality of these materials not only affects the durability and aesthetics of the restoration, but can also cause serious consequences such as infection, implant failure, gingivitis, bone loss, chronic pain, and even systemic damage (Misch, 2015). Therefore, the use of standard and licensed materials is one of the requirements of the dental profession.

In recent years, the widespread entry of counterfeit or low-quality dental materials into the Iranian market has raised serious concerns. Reports from the Ministry of Health show that some of these materials are smuggled into the country and lack international approvals such as CE or FDA (Ministry of Health, 2019). In addition to medical risks, the use of these materials can also lead to criminal liability for the dentist, because the legislator considers providing medical services using substandard materials to be a form of professional misconduct and in some cases a crime (Government Penal Code for Health Affairs, 2018).

From the perspective of criminal law, the dentist has a duty to the patient to use standard, authorized, and appropriate materials and tools. Any failure in this regard, if it results in physical injury or damage, can result in criminal liability. This liability may be analyzed in the form of criminal attribution, recklessness, violation of government regulations, or fraud in treatment (Islamic Penal Code, 1392). Therefore, a careful examination of the elements of criminal liability in this area is necessary.

From the perspective of medical ethics, the use of substandard materials is also a violation of the fundamental principles of professional ethics. The principle of non-maleficence and the principle of beneficence require that the doctor choose the best and safest treatment method for the patient (Beauchamp & Childress, 2019). The use of substandard materials, even if it is aimed at reducing costs for the patient, can be an example of "fraud in treatment" and a violation of the patient's trust.

From the perspective of Islamic jurisprudence, a physician is also obligated to avoid any harmful action. Rules such as harmlessness, waste, attribution, and arrogance hold the physician responsible for any harm resulting from treatment. The use of substandard materials, if it results in harm, can be a clear example of attribution, and obligates the physician to compensate for the damage and even endure religious punishment (Makarem Shirazi, 2013).

Necessity and Importance of Research

Given the importance of the subject, the main issue of the present study is:

How is the criminal liability of dentists for using substandard materials in the restoration and implantation of patients' teeth explained in Iranian law and what criteria are there for determining fault or crime?

This question has different dimensions:

- .1What are the legal foundations of the criminal liability of dentists?
- .2What type of fault is the use of substandard materials considered legally?
- .3Is the dentist's knowledge and awareness of the substandard nature of the materials a condition for committing a crime?
- .4What is the role of the patient's informed consent in this regard?
- .5In the event of injury, what types of responsibilities (criminal, civil, regulatory) are faced by the dentist?
- .6What is the view of Islamic jurisprudence regarding the use of harmful materials in treatment?
- .7What standards are there in the laws of other countries for controlling the quality of dental materials?

The importance of this research is that the use of substandard materials, in addition to harming patients' health, reduces public trust in the medical community and increases legal cases. On the other hand, the lack of sufficient awareness of some dentists regarding the criminal consequences of using substandard materials can expose them to heavy responsibilities. Therefore, a precise explanation of criminal responsibility in this area can help improve the quality of dental services and reduce possible harm.

## .2Theoretical foundations and concepts

Criminal responsibility of dentists in using substandard materials in dental restoration and implantation

### .1–2Definition of criminal responsibility

Criminal responsibility means the legal obligation of an individual to be accountable for behavior that the law has recognized as a crime and has determined a punishment for it. In Iranian criminal law, criminal responsibility is realized when there are three legal, material, and moral elements (Ardebili, 2018). The legal element refers to the existence of a legal text, the material element refers to the criminal behavior and the harmful result, and the spiritual element refers to the intention or fault of the perpetrator.

In the field of medicine, criminal liability arises when a doctor or dentist causes harm to a patient through carelessness, negligence, lack of skill, or failure to comply with government regulations (Islamic Penal Code, 2013). Therefore, the use of substandard materials in dentistry, if it leads to harm, can be an example of criminal behavior.

## .2-2The position of dentistry in the health system

### 1. The position of dentistry in the health system

Dentistry is one of the main pillars of the health system and its role is not limited to the treatment of oral and dental diseases, but also has a direct impact on beauty, nutrition, quality of life, and public health. The World Health Organization has identified oral health as one of the main indicators of public health and emphasizes that oral diseases can affect nutrition, speech, social relationships, and even systemic diseases such as diabetes and heart disease (WHO, 2020). Therefore, dentistry is not only a medical field, but also a part of public health and social welfare. This broad position has made the quality of dental services and the standardization of consumables of particular importance.

### .2The scope of dental services and the importance of consumables

Dental treatments include a wide range of services; from tooth restoration with composite, amalgam, inlays and onlays to root canal treatment, fixed and removable prostheses, oral surgeries, implants, and cosmetic treatments such as laminates and veneers. Each of these treatments requires specialized materials and equipment, the quality of which plays a decisive role in the success of the treatment. For example, the quality of composite plays a fundamental role in the durability of the restoration, the quality of the implant plays a fundamental role in the success of the implant, and the quality of the prosthetic material plays a fundamental role in the chewing function and aesthetics (ADA, 2019). For this reason, dentists are required to use standard materials, licensed and approved by regulatory agencies. The use of substandard materials can lead to treatment failure, harm to the patient, and even criminal or regulatory liability (Shariat-Bagheri, 2018.)

### 3. The necessity of observing professional standards

Given the sensitivity of dental treatments, it is essential to observe professional and ethical standards in the selection of materials and treatment methods. The dentist must ensure that the consumables have valid approvals, appropriate expiration dates, and standard storage conditions. This requirement is important not only from a professional ethics perspective, but also from a legal perspective; because any damage caused by the use of substandard materials can result in civil and criminal liability (Islamic Penal Code, 1392). In many countries, including Iran, regulatory organizations such as the Ministry of Health and the Food and Drug Administration monitor the import, production, and distribution of dental materials to ensure patient health.

### 2-3. Types of Restorative Materials and Dental Implants

To understand the criminal liability of dentists, the types of materials used in dentistry and the importance of their quality must first be examined.

**Restorative Materials** Restorative materials are the most important components of dental treatments and are used to restore tooth structure, fill cavities, and maintain normal tooth function.

Low quality restorative materials can cause restoration failure, secondary caries, tooth sensitivity, gingivitis, and even tooth loss (Ferracane, 2017). Therefore, the use of standard and certified materials is one of the professional and legal requirements of dentists.

## 2 .Prosthetic and aesthetic materials

Prosthetic and aesthetic materials include dental ceramics, zirconia, metal alloys, veneers, and other materials used in the aesthetic and functional reconstruction of teeth. These materials must be of high strength, biocompatibility, color stability, and fracture resistance. The use of poor quality materials in this area can cause restoration breakage, discoloration, allergic reactions, inflammation or gingival recession, and severe patient dissatisfaction. Since aesthetic treatments are expensive and sensitive, the use of standard materials in this area is doubly important (Shahidi et al., 2020.)

## 3 .Implant Materials

Dental implants are usually made of titanium or zirconia and must meet very strict biomechanical and biological standards. Counterfeit, smuggled, or substandard implants can cause implant failure, infection, bone loss, chronic pain, and even complete tooth loss (Misch, 2015). Since implant placement is a surgical treatment, the use of poor quality materials in this area can have severe and sometimes irreversible consequences. Therefore, the dentist is obliged to check the authenticity and standardization of the implant before use.

## 4 .Auxiliary materials

Auxiliary materials include cements, impression materials, bone powder, membranes and other materials used in restorative, prosthetic and surgical treatments. The quality of these materials also plays an important role in the success of the treatment, because any defect in the cement, impression or restorative materials can cause treatment failure, infection or prosthesis incompatibility. The standardization of these materials is essential in terms of biocompatibility, strength and chemical stability (Shahidi et al., 2020.)

## 2 .4–The concept of “substandard materials” from a scientific and legal perspective

### a) Scientific definition of substandard materials

From a scientific perspective, substandard materials are materials that lack international standards such as CE or FDA, are produced from poor quality raw materials, have expired dates, do not have appropriate storage conditions or are counterfeit and smuggled. These materials can cause allergic reactions, treatment failure, infection, bone loss, and serious injuries (Shahidi et al., 2020). Therefore, the scientific diagnosis of substandard materials is based on technical, biological, and safety criteria.

### b) Legal definition of substandard materials

In Iranian law, substandard materials include materials without a license from the Ministry of Health, substandard materials, counterfeit materials, smuggled materials, and expired materials (Government Penal Code for Health Affairs, 1367). The use of these materials—even if they do not cause harm—is considered a violation, and if they cause harm, it is considered a crime. This legal definition shows that the legislator has a preventive approach and considers the mere use of unauthorized materials punishable.

## 2.5–International standards for dental materials

### 1 .CE standard (Europe)

The CE standard indicates that the product has been approved in terms of safety, biocompatibility, and manufacturing quality and can be supplied in European countries.

### 2 .FDA Standard (USA)

The US Food and Drug Administration (FDA) is one of the strictest regulatory bodies in the world, and FDA-approved dental materials are usually of very high quality.

### 3 .ISO Standards

ISO standards such as ISO 4049, ISO 6872, and ISO 14801 are among the most important standards for dental materials and set precise technical and biological criteria.

### 4 .Iranian Ministry of Health Standards

The Iranian Ministry of Health also publishes a list of permitted materials, and the use of materials outside this list is considered a violation (Ministry of Health, 2019).

5. Civil and disciplinary liability of dentists

The liability of dentists is not limited to the criminal sphere. In many cases, the use of substandard or substandard materials, in addition to criminal liability, also gives rise to civil liability (compensation for damages) and disciplinary liability (professional misconduct). In this section, the civil and disciplinary dimensions of these responsibilities are examined.

#### 5-1. Civil liability arising from fault

Civil liability in Iranian law means the obligation of an individual to compensate for damage caused to another. In the fields of medicine and dentistry, this liability is mainly based on fault, and fault can include carelessness, negligence, lack of skill, or failure to comply with regulations (Katouzian, 2012). In dentistry, the use of substandard materials is one of the clearest examples of professional fault; Because the dentist is obliged to use standard and licensed materials and any deviation from these standards can lead to civil liability.

#### 1 .Legal basis of civil liability

The legal basis of the civil liability of dentists is stated in several important laws. Article 1 of the Civil Liability Law (1339) stipulates that anyone who, without legal permission, intentionally or as a result of negligence, causes harm to the life or health of another is liable for damages.

Articles 495 and 496 of the Islamic Penal Code also emphasize that the physician is liable in the event of fault—even with the patient’s consent (Islamic Penal Code, 1392). The Medical System Law (1383) also considers the physician to be obliged to comply with professional standards. Therefore, if a dentist uses substandard materials and this causes damage, his civil liability is certain.

## 2 .Types of damages that can be claimed

### a) Material damages

Material damages include the cost of re-treatment, the cost of medication, the cost of corrective surgery, the cost of transportation, and damage caused by the loss of teeth or implants. These damages are provable and claimable, and courts usually accept them.

### b) Moral damages

Moral damages include pain and suffering, damage to beauty, loss of self-confidence, and anxiety and stress. Iranian courts have increasingly accepted moral damages in recent years (Shariat-Bagheri, 2018.)

### c) Damages caused by disability

In cases where the damage is severe, the patient can claim damages caused by reduced working capacity or disability.

## 3 .Causal relationship

To realize civil liability, a causal relationship must be proven between the use of a substandard substance and the damage caused. In dentistry, this relationship is usually proven through forensic medicine theory, expertise from the medical system organization, and a review of medical records. If it is proven that the substandard material was the direct or indirect cause of the injury, the dentist will be held liable.

## 4 .The Role of Informed Consent in Civil Liability

Patient consent is only valid when the patient is aware of the quality of the material, possible risks, and available alternatives (Beauchamp & Childress, 2019). If the dentist uses substandard materials without the patient’s knowledge, consent is invalid and civil liability is aggravated. In such cases, the patient can claim fraud or malpractice. According to Article 496 of the Islamic Penal Code, consent cannot remove the doctor’s fault.

## 4 .2–The Role of Professional Liability Insurance

Professional liability insurance is one of the most important tools for protecting dentists. This insurance covers damages resulting from professional errors, carelessness, negligence, and the use of substandard materials (in the event of unintentional injury.)

### 1 .Limits of Insurance Coverage

Insurance usually covers blood money, material damage, moral damage (in some companies), and legal fees. However, cases such as intentional use of counterfeit materials, use of smuggled materials, use of expired materials with knowledge of corruption, and treatment in unauthorized centers are not covered by insurance.

## 2 .The role of insurance in reducing complaints

The existence of insurance reduces tension between the patient and the doctor, accelerates compensation for damage, and reduces the financial burden on the doctor (Rahmani et al., 2021). This plays an important role in reducing complaints and increasing patient trust.

## 4 .3–Disciplinary responsibility in the medical system organization

Disciplinary responsibility is related to violations that a doctor or dentist commits within the framework of the profession, and its handling is within the competence of the medical system organization.

### 1 .Types of violations related to substandard materials

Violations include the use of unlicensed materials, the use of counterfeit materials, failure to inform the patient, failure to comply with scientific standards, improper storage of materials, and the purchase of materials from unauthorized sources.

### 2 .Disciplinary punishments

Disciplinary punishments include verbal warnings, written reprimands, cash fines, license suspension, and license revocation (Medical System Law, 2004.) ( 3. Disciplinary investigation process

The investigation process includes the patient's complaint, initial examination, referral to the first-instance panel, expert opinion, issuance of a verdict, and the possibility of appeal. In many cases, expert opinion plays a decisive role.

## 4 .4–Case Studies

### Case 1: Use of counterfeit implants

In this case, the dentist used an implant that did not meet the CE standard, and the patient suffered infection, bone loss, and implant failure.

Result:

Disciplinary conviction (6-month suspension(

Civil conviction (payment of damages(

No criminal conviction (due to lack of intent(

### Case 2: Use of expired composite

The patient developed severe sensitivity and gingivitis after tooth restoration. Investigations showed that the composite was expired.

Result: Written reprimand, civil conviction

Case 3: Use of contraband

The dentist used contraband, but no harm occurred.

Result: Disciplinary conviction, criminal conviction according to the State Penal Code

No civil liability (due to lack of damage)

### 3 .Disciplinary liability

The Turkish Dental Association (TDB) has strict regulations for the use of standard materials.

### 7 .Conclusions and suggestions

Dentists' criminal liability for using substandard materials in dental restorations and implants

#### 7 .1–Conclusion

The present study showed that the use of substandard, counterfeit or non-standard materials in dental treatments is one of the most important factors in causing physical injuries, treatment failure, increasing patient complaints and creating criminal, civil and disciplinary liabilities for dentists. A review of Iranian laws, jurisprudential rules and international standards shows that the Iranian legal system has a relatively strict approach in this area, but in some areas, such as monitoring the dental equipment market and requiring professional liability insurance, it needs to be strengthened and improved.

From the perspective of Iranian criminal law, Articles 495 and 496 of the Islamic Penal Code, the Health Affairs Government Penal Code, and the Ministry of Health regulations provide a specific framework for the liability of dentists. According to these laws, the use of substandard materials—even without causing harm—can be a violation or a crime. In the event of harm, the dentist may be sentenced to pay blood money, compensation, a fine, or even imprisonment. The moral element of this crime is usually fault, and the doctor's knowledge or ignorance of the quality of the materials affects the severity of the liability. From the perspective of civil liability, the dentist is obliged to compensate the patient for material, moral, and medical damages. The causal relationship between the use of substandard materials and the harm caused is usually established through forensic expertise and the medical system. The patient's consent is valid only when it is informed; otherwise, the consent has no legal effect.

From the perspective of disciplinary liability, the Medical System Organization has strict regulations for the use of standard materials. Violation of these regulations can lead to reprimands, fines, suspension or revocation of licenses. A review of actual cases shows that disciplinary boards take a serious and strict approach in cases of the use of counterfeit or smuggled materials.

From the perspective of Islamic jurisprudence, rules such as harmlessness, waste, attribution, pride and the sanctity of deception provide a strong basis for the liability of

the physician. Islamic jurisprudence considers the use of harmful materials to be haram and considers the physician to be a guarantor—even unintentionally. These jurisprudential foundations are consistent with Iranian law and strengthen the moral and religious legitimacy of legal action against medical malpractice.

A comparative analysis also revealed that advanced countries such as the United States, Germany and France have very strict supervisory systems for controlling the quality of dental materials. In these countries, the use of substandard materials can result in criminal, civil, and regulatory liability. The experience of these countries shows that effective monitoring of the medical equipment market and requiring doctors to use materials that meet international standards play an important role in reducing injuries and complaints.

In summary, the present study shows that the responsibility of dentists in the use of substandard materials is a multi-layered responsibility that has criminal, civil, regulatory, ethical, and jurisprudential dimensions. Compliance with scientific and legal standards, transparent information to patients, and the use of licensed materials are the most important strategies for preventing liability and improving the quality of dental services.

## **.2-7 Recommendations**

### **.1 Legislative proposals**

-Establish an integrated system for tracking dental materials similar to those in Europe and the United States, to prevent the entry of counterfeit materials.

-Legally require dentists to use materials with CE or FDA standards if possible.

-Amend the Government Penal Code and increase the penalties for the use of counterfeit materials in dentistry.

-Legally require professional liability insurance for all dentists.

### **.2 Implementation recommendations**

-Strengthen the Ministry of Health's supervision over the import, distribution, and sale of dental materials.

-Create an online database of authorized and standard materials.

-Increase periodic inspections of dental offices and clinics.

-Deal seriously with sellers of counterfeit and smuggled materials.

### **.3 Educational recommendations**

-Include training on criminal liability and professional ethics in dental courses.

-Hold training workshops for dentists on detecting counterfeit materials.

-Educate patients about the importance of using standard materials and the right to ask about the quality of materials.

### **.4 Research recommendations**

- Conduct field studies on the prevalence of the use of substandard materials in Iran.
- Examine the impact of material quality on the rate of medical complaints.
- Conduct more extensive comparative research on global standards for dental materials.

### Final Conclusion

In addition to threatening the health of patients, the use of substandard materials in dentistry leads to heavy criminal, civil, and disciplinary responsibilities for dentists. Iranian laws, Islamic jurisprudence, and international standards all emphasize the need to use standard materials and provide clear information to patients. Strict implementation of these principles can help improve the quality of dental services, reduce complaints, and increase public trust.

### References

1. Persian sources
2. Ardebili, M. (2018). *General Criminal Law (Volume 1)*. Tehran: Mizan.
3. Shariat-Bagheri, M. (2018). *Physician Responsibility in Iranian Law*. Tehran: Jangal.
4. Katouzian, N. (2018). *Civil Responsibility*. Tehran: Publication Joint Stock Company.
5. *Government Sanctions Law for Health Affairs*. (2018).
6. *Islamic Penal Code*. (2019).
7. *Medical System Organization Law*. (2024).
8. Ministry of Health, Treatment, and Medical Education. (2019). *List of Authorized Dental Equipment and Materials*.
9. Jurisprudential Sources
10. Hilli, Allama (Jafar ibn Hassan). (1410 AH). *Rules of Laws*. Qom: Islamic Publishing Institute.
11. Shahid Thani, Zayn al-Din ibn Ali. (1413 AH). *Methods of Understanding*. Qom: Islamic Publishing Institute.
12. Tabatabaei, Sayyid Muhammad Hussein. (1374). *Al-Mizan fi Tafsir al-Quran*. Qom: Islamic Publishing Office.
13. Qurtubi, Muhammad ibn Ahmad. (1999). *Al-Jami' al-Ahkam al-Quran*. Beirut: Dar al-Kutb al-Ilmiyah.
14. Makarem Shirazi, N. (1392). *New Inquisitions*. Qom: Imam Ali ibn Abi Talib School.
15. Mousavi Khomeini, Ruhollah. (1408 AH). *Tahrir al-Wasilah*. Qom: Institute for the Compilation and Publication of Imam Khomeini's Works.
16. Najafi, Muhammad Hassan. (1981). *Jawaher al-Kalam*. Beirut: Dar al-Ihya' al-Turaht al-Arab.
17. English sources (scientific and medical)
18. Beauchamp, T. L., & Childress, J. F. (2019). *Principles of biomedical ethics (8th ed.)*. Oxford University Press.
19. Duteil, P. (2018). Medical liability in France: A comparative perspective. *European Journal of Health Law*, 25(3), 245–260.

20. European Commission. (2019). Medical devices: Guidance document. Brussels: EU Publications.
21. FDA. (2020). Dental materials: Regulatory overview. U.S. Food and Drug Administration.
22. Ferracane, J. (2017). Resin composite—State of the art. *Dental Materials*, 33(1), 1–10.
23. Misch, C. (2015). *Dental implant prosthetics* (2nd ed.). Mosby.
24. Rahmani, A., et al. (2021). Professional liability insurance in dentistry: A global review. *Journal of Dental Practice*, 12(4), 210–219.
25. Shahidi, S., et al. (2020). Complications of low-quality dental materials: A clinical review. *International Journal of Dentistry*, 2020, 1–9.
26. World Health Organization. (2020). Oral health fact sheet. WHO Publications.
27. Laws and official documents
28. Constitution of the Islamic Republic of Iran. (1979.)
29. Civil Liability Law. (1939.)
30. Consumer Rights Protection Law. (2009.)
31. Medical Equipment Regulations. (Ministry of Health, 2016.)