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Legal and Ethical Considerations in the Development of New Dental Materials

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ABSTRACT
The development of new dental materials is crucial for advancing oral healthcare, offering improved durability, aesthetics, and biocompatibility. However, the innovation and commercialization of these materials raise significant legal and ethical concerns that must be carefully addressed to ensure patient safety and compliance with regulatory standards. The history of safety regulations for dental materials is deeply intertwined with the evolution of dental science, public health concerns, and advancements in materials technology. Over the centuries, as new materials were introduced into dental practice, it became evident that their safety and efficacy needed to be ensured through systematic regulation. From the early days of trial and error to the establishment of modern regulatory frameworks, the development of safety regulations for dental materials reflects growing scientific understanding and societal concerns about health and safety. The balance between innovation and patient safety remains a central concern, raising questions about how to manage potential risks while advancing dental technology. The aim of this review is to critically examine the legal and ethical considerations surrounding the development and implementation of new dental materials. It seeks to explore the regulatory frameworks governing dental material innovation, including approval processes, intellectual property rights, and liability issues. It aims also to explore the legal and ethical considerations surrounding the development and use of dental nanomaterials, with a focus on issues such as genotoxicity, carcinogenicity, cytotoxicity, biocompatibility, and biosafety. By examining these factors, we aim to provide a comprehensive framework for understanding the responsibilities of dental professionals, manufacturers, and regulators in ensuring the safe and ethical development of new dental materials. Additionally, the review aims to assess the ethical challenges through the lens of bioethics, focusing on principles such as patient safety, informed consent, and the balance between innovation and risk. The discussion concludes by emphasizing the role of dental practitioners, manufacturers, and regulatory bodies in maintaining a patient-centered approach to innovation, ensuring that legal and bioethical principles guide the future of dental material development.

Keywords: genotoxicity, carcinogenicity, cytotoxicity, biocompatibility, biosafety.

INTRODUCTION

The latest global statistics on dental diseases reveal a growing and concerning burden. As of 2024, about 3.5 billion people—almost half of the world's population—are affected by some form of oral disease. The most common oral health conditions include dental caries, severe gum disease, and oral cancers. The most widespread condition is the dental caries, affecting an estimated 2.5 billion people worldwide. Severe gum disease (periodontitis) that is affecting approximately 1 billion people, periodontitis can lead to tooth loss if untreated. Finally, around 380,000 new cases of oral cancers are diagnosed annually (Jain et al., 2024). The treatment of dental disorders mostly relies on the use of dental materials, such as crowns, prostheses, and restorations/fillings, as well as auxiliary instruments like impression materials. The development of new dental materials is a highly specialized field that intertwines clinical needs, patient safety, and scientific innovation. Researchers, manufacturers, and healthcare providers face several legal and ethical challenges throughout the process, from the inception of a new material to its market introduction and clinical use (Rathore et al., 2016). Dental materials have a unique feature in that many come from the industry partially completed, requiring

dentists to complete them. For example, resin paste is cured by mixing it with a separate catalyst paste or by using light curing units, and the cured material is then adjusted intraoral by grinding and polishing (Kowalska et al., 2021). Rules pertaining to patient safety, dental staff safety, and environmental protection are the goals of current safety rules for these products. Bioethics is a scientific concept that means the ability to monitor scientific progress with ethical awareness. While the term biosafety encompasses a range of measures intended to prevent, minimize, or eliminate risks associated with technological advancements that could jeopardize public health or the environment (Laith and Alnemri, 2007). Alongside scientific and technical hurdles, the development and implementation of new dental materials raise significant legal and ethical concerns that need to be addressed to ensure patient safety and the adherence to regulatory standards. This review intends to clarify the evolution of the legal and ethical standards that regulate the use of dental materials and to address the specific regulations for the development of new dental materials.

History of the development of safety regulations for new dental materials

The use of dental materials dates back thousands of years. Materials like gold, ivory, and seashells were used in rudimentary dental restorations. However, these materials were chosen largely based on availability and basic physical properties, with little understanding of their biological effects on human tissues (Marin, 2023). There were no formal safety regulations, and decisions were based on what worked in practice. The mid-19th century saw the formation of professional organizations such as the American Dental Association (ADA) in 1859. These organizations played a key role in advancing dental science, education, and ethics, but they also began addressing the need for standardization and safety in dental materials. The ADA's formation marked a turning point in the formalization of dental practice, although material safety was still largely left to professional judgment. One of the earliest formal attempts to establish standards came in the early 19th century when dentists in Europe and North America began using dental amalgam (a mixture of mercury, silver, tin, and other metals) as a filling material. The use of mercury raised safety concerns even at the time, and many dentists and physicians debated its potential toxicity. Despite these concerns, amalgam became widely used due to its durability and ease of use (Khangura et al., 2018). Another early study conducted by Fasoli regarding the reactions of dog teeth's dental pulp to the application of a filling substance (Fasoli, 1924). In the early 20th century, there was growing awareness of the importance of material safety due to increased public concern about health hazards from industrial materials. This period saw the creation of various national health agencies, which would later become instrumental in regulating medical and dental products. For example, the U.S. Food and Drug Administration (FDA) was established in 1906 (as the Bureau of Chemistry) to regulate the safety of food, drugs, and cosmetics. At the time, dental materials were not yet under direct regulatory oversight, but the groundwork was being laid for future regulation (Güven, 2017). Animal-based research on the safety of dental materials became more common in the 1950s and 1960s, and advances were made in histological methods and experimental evaluation procedures in the associated experiments. During the same period, the biological qualities of dental materials were initially tested using cell culture techniques, which subsequently became a key component of regulators' assessment of the biocompatibility of dental materials. A critical turning point in the regulation of dental materials came in the 1970s with growing public awareness of the potential risks associated with medical devices, including dental materials. In response to several high-profile cases of defective medical devices causing harm, the U.S. Congress passed the Medical Device Amendments in 1976, which gave the FDA authority to regulate medical devices, including dental materials(US FDA, 2019).

As globalization increased and dental materials were developed and marketed internationally, it became necessary to create harmonized safety standards that could apply across different countries. The term "medical device" was used but not defined in the previous regulation "Medical Device Amendments". Subsequently, the Medical Device Directive (MDD) defined a medical device as any tool, apparatus, appliance, substance, or other item that did not accomplish its primary intended function in or on the human body through the use of immunological, pharmacological or metabolic means (European Union 1993; European Union 2017). Dental materials are therefore categorized as medical device. It is interesting to note that the experiences gained from toxicity testing of materials used in dentistry in the United States were one of the main pillars for establishing this legislation. The most recent evolution in dental material regulation came with the European Union's Medical Devices Regulation (MDR), which came into effect in 2021. The MDR replaces the older Medical Devices Directive (MDD) and introduces stricter requirements for the safety, clinical evaluation, and post-market surveillance of medical devices, including dental materials. The MDR aims to improve patient safety by requiring more rigorous clinical testing and evidence of safety before devices can be marketed, increasing transparency in the approval process and ensuring that patients are fully informed about the materials used in their treatment, and strengthening post-market surveillance to detect and address safety issues as soon as they arise. The MDR also reflects growing public concern about the environmental impact of dental materials, including the disposal of hazardous materials like mercury. The International Organization for Standardization (ISO) established ISO 10993, a set of standards for the biological evaluation of medical devices, including dental materials. ISO 10993 introduced a comprehensive framework for assessing the biocompatibility of

materials**(ISO, 2014; ISO 2017)**, ensuring they did not cause harm when used in the human body. The standard requires that materials be tested for Cytotoxicity (potential to damage or kill cells), Sensitization (risk of causing allergic reactions, and Genotoxicity and Carcinogenicity (potential to cause genetic mutations or cancer) (Mateu-Sanz et al., 2023). The manufacturer is accountable for the safety of the medical device he brings to market and must demonstrate compliance ("Conformity") with the general safety and performance requirements outlined in the MDD or the MDR in order to be allowed to operate in the EU (Mohn and Zehnder, 2023). Future trends are moving towards the use of biocompatible and environmentally friendly materials. New materials, such as bioactive glass and polymers, are being developed to replace traditional materials like amalgam and metal alloys. These materials not only improve patient outcomes but also reduce the environmental impact of dental procedures.

Bioethics and biosafety in use of dental biomaterials

A significant number of teeth are lost annually as a result of periodontal diseases, dental caries, and trauma. Every dentist's dream is to regenerate lost teeth or their constituent parts. Compared to typical surgical methods, regenerative therapy has the advantage of restoring the original tissues rather than replacing them through reparative processes. Numerous biomaterials, including maxillofacial implants and different rehabilitative dental materials, have been employed on a regular basis for intensive oral rehabilitation. Biomaterial is described as any pharmacologically inert material that does not cause any adverse reactions when it interacting with a living organism, either at the implant site or throughout the organism (Eftekhar et al., 2021). However, the integration of these materials into clinical practice brings forth critical bioethical and biosafety considerations. Without accepted standards for biosafety, the use of biomaterials leads to ethical dilemmas because patients may receive treatment without being aware of the risks. Consequently, the dental professional's responsibilities have increased, and they now have to stay up to date on new techniques, materials, and research areas in addition to patient safety and ethical issues (Shilpa et al., 2020). Clinical studies are inherently subject to checks and balances pertaining to biosafety. Biomaterials come from a variety of origins, including human origin (decalcified freeze-dried bone allografts), animal origin (lyophilized bone grafts and bone morphogenetic protein), and synthetic origin (calcium sulfate and hydroxyapatite)(Tahmasebi et al., 2020). Biological processing is used to reduce the risks associated with the preparation of biomaterials. The biological risks to the patient rise if the professional uses biomaterials with doubtful origin or those that are obtained locally without hygienic precautions. Biosafety is a critical component of ethical dental practice, particularly when dealing with biomaterials that come into direct contact with tissues or are implanted in the body. Biomaterials, by their nature, interact with the biological environment, and their biocompatibility must be thoroughly assessed to ensure they do not provoke adverse reactions such as cytotoxicity, genotoxicity, inflammation, or hypersensitivity. Regulatory frameworks, such as those provided by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), require rigorous preclinical testing to evaluate these risks before biomaterials can be approved for use(Suhag, 2024).

Biocompatibility of new dental materials

Biocompatibility testing is a critical process in the evaluation of dental materials, ensuring that they are safe and appropriate for use in the human body. The primary goal of biocompatibility testing is to assess how a material interacts with biological tissues, including its potential to cause irritation, allergic reactions, toxicity, or other adverse effects. This testing is essential for materials that come into contact with tissues, such as those used in dental restorations, implants, adhesives, and prosthetics. Selecting a material for dental implants requires careful consideration of its impact on surrounding tissue. It must be strong enough to support the dental implant and durable enough to withstand wear over time. It must also be inert, meaning it cannot interact with the tissue in a way that would irritate or inflame it(Bandyopadhyay et al., 2023). The biocompatibility of a material can be assessed using several in vitro and in vivo techniques. Through a series of tests that assess cytotoxicity, sensitization, irritation, systemic toxicity, and long-term effects, researchers and manufacturers ensure that dental materials are safe for human use (Beauchamp, and Childress, 2019). Cytotoxicity tests that evaluates whether a material has the potential to cause cell damage or death. It is typically conducted in vitro (outside the body) using cultured cells. The material is exposed to these cells, and the effects on cell viability, growth, and morphology are measured. Cytotoxicity tests provide initial insight into the material's safety before more extensive testing in animals or humans is performed. Sensitization tests where dental materials are tested for their ability to provoke allergic responses. Sensitization tests, such as the Guinea Pig Maximization Test or the Murine Local Lymph Node Assay, are often used to evaluate the material's potential to cause allergic reactions. These tests measure immune responses to repeated exposure to the material. Irritation tests are designed to assess the potential of a material to cause localized irritation. For dental materials, irritation testing typically involves applying the material to mucous membranes, such as those in the mouth, and observing any inflammatory reactions. Skin irritation tests are also performed to assess possible reactions on the surface of the skin. Some dental materials may release substances that can enter the bloodstream and affect other parts of the

body. Systemic toxicity testing evaluates whether these materials can cause toxic effects in distant organs or tissues, such as the liver, kidneys, or central nervous system. Subchronic and chronic toxicity to evaluate the potential of dental materials, particularly used in long-term applications like implants or fillings, to cause adverse effects over an extended period. Mutagenicity and genotoxicity tests determine whether the material has the potential to cause genetic damage, which could lead to cancer or reproductive harm. Dental materials must be non-mutagenic to ensure they do not contribute to long-term health risks like cancer. Regulatory frameworks like ISO 10993 and FDA guidelines provide a robust structure for conducting these tests, ensuring that only biocompatible materials reach the market and are used in dental practice. Obtaining informed consent and minimizing harm to the patient are important ethical considerations when conducting biocompatibility tests. There is always the potential for people to suffer adverse effects from any type of medical test. This is especially true for tests that aim to measure an individual's reaction to an unfamiliar chemical, like a novel drug. The same applies to biocompatibility testing. Anyone can have an adverse reaction to the chemical being tested, and this can have serious health consequences. Therefore, before giving their consent to engage in biocompatibility testing, patients must be informed of the risks associated with the procedure. Informed consent is therefore a very important ethical consideration.

Regulatory Compliance

The legal framework governing the development of dental materials is grounded in strict regulations to safeguard public health. New materials are assigned to the various risk classes based on a detailed set of guidelines included in the MDD/MDR. The manufacturer declare compliance with the applicable regulation (MDD or MDR) and retains the technical documentation, which is used only in the event that a clinically overt adverse effect is observed following clinical use. These materials are classified based on their risk to patients. Class I, low risk, products like dental floss or examination gloves, requiring minimal regulation. Class II, moderate risk, products like dental fillings, bonding agents, or impression materials, which must meet certain performance standards and may require clinical testing. Class III, high risk, devices such as dental implants, which are subject to the highest level of scrutiny, including pre-market approval, due to their potential impact on human health (European Union, 1993). The manufacturer's quality management system is certified in accordance with ISO 13485 Medical Devices(ISO, 2016; Juuso, 2022). A suitable degree of third party involvement (referred to as a "notified body") is required for Class IIa, Class IIb, and Class III devices. The manufacturer of class II dental materials must complete the technical documentation and certify compliance with the applicable regulations. The relevant technical documentation is regularly reviewed by a notified body. Regulations for class III are often more restrictive. Producers of class III devices should compile main performance and safety aspects as well as the findings of the clinical evaluation into a document that is made available to the public(MDCG, 2020). In addition, the manufacturer needs to submit an application to the notified body in order to assess the technical documentation for the device before commercialization. REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is a European Union regulation enacted to better protect human health and the environment from the risks that chemicals used in dental materials (European Union, 2006). In the USA, similar legal regulations have been developed. The Food and Drug Administration (FDA) was given authority over the categorization and market clearance procedures while the Medical Device Amendments regulated the safety of dental materials. FDA's 510(k) Premarket Notification Process is one regulatory pathway that allows manufacturers to demonstrate that a new material is substantially equivalent to one already legally marketed. However, novel materials with no comparable existing product require more rigorous testing and approval(Santhosh and Kamaraj, 20118).

Clinical Research and Human Experimentation

In vitro studies has limits, because it cannot predict a material's behavior in the human body. Conversely, in vivo tests entail evaluating materials in animal models. These studies cost more money and take longer, but they yield more precise results regarding the way a substance will behave with human tissue**(Fini and Giardino, 2003)**. Thus, human testing is essential for evaluating the real-world safety and effectiveness of dental materials. However, this raises significant ethical issues, particularly concerning patient consent, risk exposure, and reporting of adverse effects. Maintaining professional ethics and protecting patient welfare and trust both depend on the following items.

- **Informed Consent:** Giving patients thorough information regarding novel procedures is necessary for informed consent, which is a fundamental component of moral dentistry practice. According to the Declaration of Helsinki, any participant in a clinical trial must give informed consent, fully understanding the risks and potential benefits of the experimental material. For example, a thorough discussion of the benefits and potential hazards of a novel orthodontic device in comparison to regular braces is necessary**(World Medical Association, 2003)**.

- **Ethical Standards**: Research ethics boards or institutional review boards (IRBs) must approve human trials to ensure they comply with Good Clinical Practice (GCP) guidelines, which protect the rights and welfare of patients**(Grady, 2015**). The ethical framework governing human trials in dentistry is built on several universally accepted principles derived from documents such as the Declaration of Helsinki, the Nuremberg Code, and Belmont Report**(Friesen et al., 2017)**. These principles include; respect for persons where this principle emphasizes respect for the autonomy of individuals, ensuring that participants enter research voluntarily and with adequate information; beneficence where researchers are obligated to minimize potential harm and maximize benefits for participants. This involves careful study design, ensuring that risks are minimized through proper planning, making sure that any potential benefits outweigh the risks, and avoiding unnecessary discomfort or harm to patients.

Ethical issues related to the environmental impact of new dental materials

The development of new dental materials has significantly advanced dental care, improving outcomes for patients through better restorations, adhesives, implants, and preventive treatments. However, alongside these innovations come ethical concerns related to human health, safety, and the environmental impact of both the materials themselves and the processes involved in their development and disposal. The ethical landscape of dental materials is shaped by a need to balance patient care, public health, and environmental sustainability(BDA, 2017). One of the most well-known environmental concerns in dentistry is the use of mercury in dental amalgam. Mercury is a hazardous substance, and its use raises ethical issues both in terms of patient health and environmental sustainability. Dental amalgam waste, if improperly disposed of, can lead to mercury contamination in water bodies, posing risks to wildlife and ecosystems(Martin et al., 2021). International efforts, such as the Minamata Convention on Mercury, have aimed to phase down the use of mercury in dentistry to reduce its environmental impact(Fisher et al., 2018). Dental materials like resin-based composites and sealants often contain Bisphenol A (BPA), a compound linked to endocrine disruption and other health concerns. The environmental impact of BPA leaching from dental materials into water systems is another ethical concern, as it can affect aquatic life and contribute to broader environmental pollution(Löfroth et al., 2019). The dental industry is heavily reliant on disposable materials or single-use plastics, such as gloves, suction tips, and plastic trays, many of which are not biodegradable. These materials contribute to environmental pollution, especially in landfills and oceans. Ethical concerns surround the sustainability of such practices, and there is a growing call for more environmentally friendly alternatives in dental practice, and for the use of biodegradable or reusable materials in the production of new dental materials where possible.Manufacturers of dental materials bear significant ethical responsibility for the environmental impact of their products throughout their lifecycle. There is a growing ethical imperative for researchers to consider the environmental impact of dental materials during the development phase(Shinkai et al., 2023). Innovations should focus not only on improving patient outcomes but also on reducing the environmental burden. For instance, developing biodegradable materials or those with a lower carbon footprint can help mitigate some of the negative impacts of current dental practices(Mittal et al., 2020). These regulatory guidelines include several considerations such as the use of eco-friendly materials that are biodegradable and recyclable with increased awareness of environmental sustainability. Materials such as bioactive glass and polylactic acid (PLA) are eco-friendly alternatives (Hussain et al., 2024).

Ethical and Legal Implications of using nanotechnology in dentistry

Nanotechnology has introduced groundbreaking possibilities in the field of dentistry, particularly in the development of advanced dental materials(Gavaskar et al., 2017; Prabakar, 2023). By manipulating matter at the nanoscale (one billionth of a meter), researchers can create materials with enhanced properties, such as improved strength, durability, antibacterial effects, and biocompatibility(Dipalma et al., 2024). While the benefits of nanotechnology in dentistry are promising, its application raises significant ethical and legal concerns that must be addressed to ensure the responsible development and use of these new materials. Nanotechnology-based dental materials often involve the use of nanoparticles, such as nanocomposites, nano-adhesives, or nano-fillers. While these materials offer improved properties, their small size also raises concerns about their long-term safety. For example, nanoparticles might penetrate deeper into tissues or organs, leading to systemic effects that are not fully understood. Inhaled nanoparticles have the ability to pass through cell membranes to enter the liver, spleen, bone marrow, and lymph nodes. Because nanomaterials are size-dependent, a non-toxic element at 100 nm can dramatically transform into a toxic element in its nanoform. Toxic nanoparticles can also be created when non-toxic nanomaterials degrade or combine(Karunakaran et al., 2024). Moreover, serious adverse reactions have been reported when human volunteers were exposed to a dose of nanomedicine lower than the documented hazardous limit in animal research. Therefore, participants need to

be aware of the degree of risk involved in working with new materials and data, as well as keep a close eye on any negative side effects and report them as soon as possible (Hester et al., 2015). Cosequently, regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), are faced with the challenge of evaluating the safety of nanomaterials, which may behave differently from conventional materials due to their nanoscale size(US FDA, 2014). Current regulatory frameworks may not be adequately equipped to assess the unique risks posed by nanotechnology, creating gaps in oversight. The legal responsibility falls on both manufacturers and regulators to develop more comprehensive guidelines that address these unique risks. Another ethical concern is ensuring that patients are fully informed about the potential risks and benefits of dental materials that incorporate nanotechnology. Nanotechnology-based dental materials are often more expensive to develop and manufacture due to the complexity of working at the nanoscale. This could result in these advanced materials being more costly for patients, potentially leading to disparities in access to the best available care. Wealthier patients may benefit from stronger, more durable materials, while those from lower socioeconomic backgrounds may have to rely on traditional materials. Ethically, this raises concerns about fairness and equity in dental care, as all patients should have access to the safest and most effective treatments. Nanotechnology-based dental materials may blur the lines between classifications of products, such as medical devices, drugs, or biologics. For instance, nanomaterials used for dental implants or restorative materials might exhibit both mechanical and biological properties(Sreenivasalu et al., 2020). Determining how to legally classify these materials is critical for regulatory approval, as different classifications may be subject to different levels of scrutiny and safety testing. When dentists are presented with a wide selection of materials, some with a long history of clinical use (like hybrid or microfilled composite resins) and others that are conceptually appealing and have short-term clinical studies supporting them (like nanofilled composite resins), they face an ethical dilemma due to the unpredictable nature of nanomaterials (Brey, 2012). In order to identify and address the ethical and societal implications through ethical analysis models, the concept of proactive ethics and governance has emerged to easily modify the ethics of nanotechnology towards an ethically acceptable outcome when the technology is still in its infancy. Therefore, while post-marketing studies on private companies' products are not mandatory, government agencies should support and encourage them in order to learn more about the long-term impacts of nanomaterials and notify legislative and regulatory bodies of any unfavorable side effects (AlKahtani, 2018).

Ethical Issues in the Sourcing of Dental Instruments and Materials

For many years, there has been several doubts about where medical equipment and supplies are sourced. Still, unsafe working conditions in the production of some medical items have lately come to light thanks to the efforts of the Medical Ethical and Fair Trade Group in collaboration with the British Medical Association's International Department(Bhutta and Roberts et al., 2009). This problem has not yet gained much traction in the dental industry. Ethical sourcing refers to the process of ensuring that the products, materials, and labor used in manufacturing meet defined standards of safety, fairness, environmental sustainability, and human rights. In dentistry, the ethical sourcing of dental instruments and materials is critical for ensuring patient safety, promoting environmental responsibility, and upholding social justice. Ethical sourcing requires dental companies to provide detailed information about where and how their materials are produced, ensuring that they comply with environmental regulations. This includes ensuring that suppliers meet sustainability standards for resource extraction and production, such as minimizing carbon emissions, reducing energy consumption, and responsibly managing waste(Duane et al., 2019). To ensure ethical sourcing, dental companies can seek third-party certifications that verify their compliance with ethical standards. Certifications such as Fair Trade, ISO (International Organization for Standardization), and environmental management standards (e.g., ISO 14001) provide assurance that companies are adhering to ethical practices in their sourcing of materials and manufacturing of dental instruments. For example, ISO 14001 certification focuses on effective environmental management systems, requiring companies to minimize their environmental footprint(ISO, 2015). Dentists and dental practices rely on manufacturers to provide ethically sourced products that meet safety and quality standards. If a product is found to be defective or harmful due to unethical sourcing practices, manufacturers could face legal consequences under consumer protection laws. Empirical data suggests that certain dental devices and products are manufactured under unethical conditions. Therefore, awareness should be raised among dentists about the conditions under which newly developed instruments and materials are manufactured. At every stage of the supply and purchasing chains, awareness-building efforts need to be made. Dentists would be well to investigate labor standards and try to find out where the tools and materials they use come from.

CONCLUSION

In conclusion, the development of new dental materials is a complex process that requires careful attention to both legal and ethical considerations. Legally, these materials must meet regulatory standards for safety, efficacy, and biocompatibility before they can be used in clinical practice. This ensures that patients are protected from harmful side effects or risks associated with untested products. Ethical considerations involve

ensuring patient safety, obtaining informed consent for experimental materials, and avoiding conflicts of interest in research and product endorsement. As advancements in dental material science continue, maintaining a balance between innovation with legal compliance and ethical responsibility is critical to fostering patients trust and ensuring the long-term success of these developments in the clinical practice. Ultimately, collaboration among researchers, dental professionals, and regulatory bodies is essential for the responsible evolution of dental materials.

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