ABOUT CAO

The California Association of Orthodontists (CAO) is the California component of the American Association of Orthodontists (AAO)—the largest and oldest dental specialty organization.

The CAO represents nearly 1,500 orthodontic members who practice in California. CAO members are specialists who have completed dental school and then successfully completed 2–3 years of additional training at an accredited orthodontic residency program. Our members are experts in diagnosing and treating all orthodontic problems in patients of all ages—from child to adult. CAO is engaged in legislative advocacy to protect patient health and improve access to care.

MISSION

CAO's mission is to:

- Support its members in their pursuit of excellence during their practice of orthodontics
- Promote the values of ethical practice as defined by the American Association of Orthodontists
- Advocate for its members in issues related to professional governance and regulation
- Provide continuing education opportunities for members
- Encourage the public to seek an orthodontic specialist when considering comprehensive orthodontic treatment

SUPPORTED LEGISLATION

1. **AB 1629** (Asm. Haney): Dental Insurance Network Transparency & Assignment of Benefits.

2. **AB 2029** (Asm. Sharp-Collins): Dental Insurance Provider Portal Transparency.
3. **SB 1311** (Sen. Wahab): Infection Control Certification Options for Dental Assistants.
4. **AB 1717** (Asm. Castillo): Medi-Cal Reimbursement for Dental Visits to Care Facilities.
5. **AJR 25** (Asm. Bonta): Federal Affordable Care Act Premium Tax Credits.
6. **SB 1137** (Sen. Valladares): Medical and Dental Expense Tax Deduction Expansion.
7. **SR 82** (Sen. Pérez): Children's Dental Health Month Resolution.

KEY CONTACTS

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GET TO KNOW

Orthodontists in the State of California

Who we are:

- Orthodontists rooted in and licensed to practice in the state of California.
- Dental specialists and health care providers who diagnose, prevent, intercept and treat dental and facial irregularities.
- **Small business owners and job creators with an economic impact on communities throughout California.**
- Civically engaged, working to make the communities we serve better.
- Dedicated to improving the health of the public by promoting quality orthodontic care, the importance of overall oral healthcare and ***advocating for patient health and safety***.

We support laws that:

Acknowledge the importance of an **in-person examination** and appropriate radiographic imaging prior to orthodontic treatment, based on reliable scientific evidence.

Require those dentists who are providing teledentistry services to **disclose their information to patients**, including their name, license number, telephone number, practice address and education credentials.

Support dental boards having **increased investigative and enforcement authority over non-licensees** involved in administering or providing teledentistry services to California patients.

Support efforts to utilize technology that provides **affordable treatment options** and broadens **access to care**, while keeping patient health and safety the priority.

CAO CALIFORNIA ASSOCIATION of ORTHODONTISTS

AAO American Association of Orthodontists

Fast Facts:

CAO is the California component of the American Association of Orthodontists.

Number of AAO members in California: **1912**

Average amount of post-secondary education per member: **10-11 years**

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More facts!

OrthoFacts.org

RADIOGRAPHIC IMAGING

Radiographic imaging (x-rays and other types) is an essential component of the evaluation and diagnosis that must occur prior to beginning orthodontic treatment.

CALIFORNIA ASSOCIATION of ORTHODONTISTS

American Association of Orthodontists®

orthofacts.org

For some companies offering orthodontic treatment "direct-to-consumer," or through clear aligners mailed directly to the patient, x-rays or other radiographic images of the patient's teeth are not taken by the company or the dentist/orthodontist providing treatment.

A 3D digital scan of the patient's teeth does not provide the same information as radiographic images, because digital scanners cannot view below the surface of the gums.

Radiographic images provide crucial information for the safety and success of the patient's treatment, and includes essential components that simply cannot be replicated by reviewing only digital scans or other photographs. Moreover, the minimal risks of taking x-rays are far outweighed by their clear value for orthodontic treatment.

In order to best protect patients, laws should require radiographic imaging (x-rays) before orthodontic treatment begins.

Moving teeth is a complex biological process. Teeth are moved by the pressure exerted by an orthodontic appliance, like clear aligners or braces.[1] This pressure causes necrosis (death) of the vascular tissue around the tooth, allowing the tooth to move within its alveolus (bone socket); and bone then reforms around the tooth.[2,3]

Moving teeth is not just a cosmetic procedure. The pressure from clear aligners or other orthodontic appliances causes "minor reversible injury" to the tooth-supporting structures.[4] Moving teeth must take into consideration not just the final appearance of the teeth, but also impact on tooth and jaw function.[5]

The complexity of the process of moving teeth **requires that a trained expert (dentist or orthodontist) have all necessary information** at their disposal (which can only be gained through an in-person examination) before starting treatment.

Radiographic images are an essential component of the evaluation and diagnosis that must occur prior to the start of orthodontic treatment.

It is "widely considered beneath the standard of care to initiate orthodontic care without first acquiring proper diagnostic information. A clinician who begins orthodontic treatment without appropriate radiographs necessary for creating an adequate and appropriate diagnosis and treatment plan **may be breaching the standard of care.**" [6]

"Diagnosis and treatment planning for the correction of misaligned teeth **should not be performed without a thorough review of baseline radiographs** by a skilled orthodontist or radiologist." [7]

Radiographic images are "**an important part of the clinical examination**" and a **require[d], ... integral part of treatment planning.**" [8]

Radiographic images are "an **essential part of the diagnostic process in orthodontics**" and "**a crucial step in the initial diagnostic process.**" [9]

[1] Wise, G.E. and King, G.J. (2008) Mechanisms of tooth eruption and orthodontic tooth movement. J Dent Res, 87, 414-434 at 414.
[2] Wise & King (2008) at 415.
[3] Antoun, J.S., Mei, L., Gibbs, K. and Farella, M. (2017) Effect of orthodontic treatment on the periodontal tissues. Periodontol 2000 74, 140-157 at 141.
[4] Wise & King (2008) at 414.
[5] Gkantidis, N., Christou, P. and Topouzelis, N. (2010) The orthodontic-periodontic interrelationship in integrated treatment challenges: a systematic review. J Oral Rehabil, 37, 377-390 at 377.
[6] Abdelkarim, Al. and Jerrold, L. (2018) Clinical considerations and potential liability associated with use of ionizing radiation in orthodontics. Am J Orthod Dentofacial Orthop, 154, 15-25 at 16 (emphasis added).
[7] Park, J.H. (2020) A licensed orthodontist versus do-it-yourself orthodontics. Am J Orthod Dentofacial Orthop, 157, 591-92 at 591 (emphasis added).
[8] Taylor, N.G. and Jones, A.G. (1995) Are anterior occlusal radiographs indicated to supplement panoramic radiography during an orthodontic assessment? British Dental Journal 179 at 10 (emphasis added).
[9] Sameshima, G.T. and Asgarifar, K.O. (2001) Assessment of root resorption and root shape: periapical vs. panoramic films. Angle Orthodontist 71, 185-89 at 185 (emphasis added).
[10] Witcher, P.T., Brand, S., Gwiliiam, J.R., and McDonald, F. (2010) Assessment of the anterior maxilla in orthodontic patients using upper anterior occlusal radiographs and dental panoramic tomography: a comparison. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 109:765-74 at 765; Michelogiannakis, D., Vastardis, H., Malkopoulos, I., Papathanasopoulou, C., and Tosios, K.I. (2018) The challenge of managing patients with generalized short root anomaly: A case report. Quintessence Int, 49, 673-79 at 677.
[11] Witcher et al. (2010) at 770-71.
[12] Park (2020) at 592.
[13] McCollough, C.H., Bushberg, J.T., Fletcher, J.G., and Eckel, L.J. (2015) Answers to common questions about the use and safety of CT scans. Mayo Clin Proc, 90, 1380-92 at 1380 (emphasis added).
[14] Abdelkarim and Jerrold (2018) at 17-18.

RADIOGRAPHIC IMAGING

Radiographic imaging (x-rays and other types) is an essential component of the evaluation and diagnosis that must occur prior to beginning orthodontic treatment.

Radiographic images are indispensable for evaluation of the patient's oral health prior to beginning orthodontic treatment.

Digital scanning (such as the iTero® scanners) create a 3D image that can be used in place of traditional alginate impressions. *They are not a substitute for radiographic imaging because they cannot view below the surface of the gums*—that is, they do not show the tooth roots, or anything else that cannot be seen with the naked eye.

Radiographs are required to assess short root anomaly (abnormally short tooth roots), which is a *significant risk factor for root resorption (the loss of tooth roots)* during orthodontic treatment.[10]

"Intraoral radiographs are likely to be needed if a full and reliable assessment is to be made, especially to assess root morphology."[11]

One researcher sums up the risks of failing to perform radiographic imaging succinctly in stating,

"What if there is a supernumerary tooth in the path of the tooth movement that might result in root resorption? What if there are other pathologic lesions or findings that need attention before the initiation of tooth movement such as dentigerous cysts, periapical disease, periodontal bone loss, interproximal or secondary caries [decay], or bony lesions such as ameloblastoma? Consider if the patient has an undiagnosed temporomandibular disorder, devitalization of teeth, or current crown or bridgework."[12]

There are countless conditions that can profoundly affect orthodontic treatment and can only be diagnosed through the use of radiographic images.

In nearly all orthodontic cases, the minimal risk associated with radiographic images is far outweighed by their clear value for orthodontic diagnosis and treatment.

Radiographic images used in the orthodontic context pose a minimal, nearly statistically insignificant risk to the patient, with technology continuously evolving to reduce the risk even further.

"Although there is a perception among some physicians and patients that the dose of ionizing radiation from medical imaging examinations, particularly CT, poses a substantial cancer risk to patients, **this perception is not consistent** with data from high-quality studies, nor with current consensus opinions of radiation protection organizations."[13]

The effective doses for some commonly-utilized orthodontic radiographic images (measured in microsieverts (μSv)) are as follows:

RADIOGRAPHIC IMAGING TECHNIQUE	EFFECTIVE DOSE OF RADIATION
• Digital panoramic radiography	• 6-38 μSv
• Digital cephalometric radiography	• 2-10 μSv
• CBCT	• 20-1025 μSv

For reference, the average effective dose of radiation in the United States from naturally occurring, ubiquitous background radiation (that is, unavoidable radiation exposures from sources such as radon gas and cosmic rays) is approximately 3000 μSv per year.[14]

In other words, the typical effective dose from the most common orthodontic radiographs (digital panoramic and cephalometric) is but a very small fraction of the dose of radiation most individuals are exposed to environmentally each year in the United States.

Statutes and regulations governing teledentistry should include that radiographic images (x-rays) be taken before any orthodontic treatment that will lead to irreversible changes to the dentition, in order to best protect the patient's health and well-being.

For more information, visit orthofacts.org

QUESTIONS TO ASK ABOUT THE SAFETY OF DTC ORTHODONTICS

CALIFORNIA ASSOCIATION of ORTHODONTISTS

Orthodontic treatment is a complex process which could lead to potentially irreversible and expensive damage such as tooth and gum loss, changed bites, and other issues if not done correctly. Patients' health and safety depend upon a proper assessment prior to beginning treatment and access to a trained professional during the course of treatment to address any issues that may arise.

Ask companies using the DTC model the following questions to help determine how safe the company's treatment model is.

1. **How many individuals purchased an aligner system from your company in California last year?**
2. **Of those, how many were seen in person for an exam prior to beginning treatment?**
3. **Were they seen in person by an orthodontist licensed to practice in California?**
4. **How many orthodontists licensed to practice in California do you employ?**
5. **Of those that weren't seen in person, how was it determined that they were a suitable candidate for aligner treatment?**
6. **How does an individual contact the treating orthodontist if they have a question or problem during treatment?**
7. **How many refund requests did you receive from patients in California last year?**
8. **How many patients were required to sign a non-disclosure agreement to receive a refund?**

Moving teeth is not a cosmetic process like teeth whitening. Marketing and selling an orthodontic appliance as a stand alone product without appropriate doctor involvement poses significant risk to patient health and safety.

DIY ORTHODONTICS LEGISLATOR FAQ

Things to consider when making policy decisions related to direct-to-consumer orthodontics

ACCESS TO CARE | COST OF TREATMENT

Q: DTC companies claim that they've helped patients save thousands of dollars. They say their service is about $2,000. Is their service cheaper than going to an orthodontist?

A: The direct-to-consumer models do not account for the range of treatment plans and options offered by traditional orthodontists. Their cost claims appear to be made using a "standard cost" for orthodontic treatment, however in reality treatment costs vary based on the unique needs of each patient. For simple cases like the ones DIY aligner treatment is designed to address, the cost of treatment from an orthodontist may be only marginally more, be covered by insurance and includes the oversight of an orthodontist who monitors treatment to ensure treatment progresses as intended.

Consider:

- The direct-to-consumer models do not offer access to care, so much as access to a product.
- DTC companies often charge exorbitant interest rates (up to 22.92% in CA) to finance treatment.
- Aligners are very common in an orthodontic office and offered as a treatment option to patients for whom such treatment is deemed safe and effective.
- Many orthodontists also utilize degrees of remote monitoring where they feel it is appropriate.
- Often the mild to moderate cases that can be treated with direct-to-consumer models would be a comparable cost at a traditional orthodontist.
- If someone has insurance, they can use that with an orthodontist.

PATIENT SAFETY | IN-PERSON VISITS

Q: DTC companies say that patients can go to one of their stores to get scans or do them at home with an impression kit to get a 3D image of their teeth. Isn't getting an in-person scan sufficient to ensure treatment is safe and effective?

A: Photos and a scan do not replace radiographs, a physical examination and probing depths completed by the orthodontist needed to safely diagnose the proper use of an aligner. Many direct-to-consumer orthodontic treatments are initiated using at-home impressions, taken by the customer. There is no value placed on pre-treatment X-rays, or diagnosis of gum disease, cavities and other factors that may make treatment unsafe for a patient.

Consider:

- Who are the people taking scans? Are they under the supervision of licensed orthodontist?
- Who is the dentist/orthodontist overseeing treatment? Are they licensed in California?
- Does the patient have a way to contact the doctor if they have questions or problems?
- An orthodontist completes 2-3 years of specialized training after completing dental school to fully understand the complexities involved with safely moving teeth.

COMPLAINTS

Q: If there are so many issues with this service, why do we not see complaints with the Dental Board?

A: Because direct-to-consumer orthodontic treatment is marketed as an aligner to address cosmetic concerns rather than a medical device that will affect not only tooth position but also facial structure, jaw position and bite composition, consumers often view their treatment as a commodity/product rather than a healthcare service. As a result, it is not commonly understood that complaints should be made to the Dental Board of California.

Consider:

- Aligners are a medical device requiring proper diagnosis to ensure safe use.
- There is no contact between the patient and the clinician who approved the case.
- Unlike orthodontists, who are required by law to make clear the process for filing a complaint if a patient is dissatisfied with their results, these emerging business models do not clearly disclose the process for making a complaint. Thousands of patients have filed complaints with the Better Business Bureau rather than the Dental Board.
- Unhappy customers are instead often required to sign nondisclosure agreements as a condition of receiving a refund.
- Patients seeking retreatment at a CAO member office are encouraged to file complaints with the Dental Board of California, however they may not follow through.
- While AB 1519 does provide basic patient safety parameters for companies utilizing telehealth models to provide orthodontic treatment, the language is not specific enough to hold companies accountable for failure to comply.

REFUNDS & RETREATMENT

Q: DTC orthodontics is a business. Can't customers contact them to have problems resolved or just get their money back if there's an issue?

A: If the patient is able to determine who the treating orthodontist is on their case, they generally do not have a way to contact them directly if they experience problems or have questions during treatment. There is not an orthodontist present in the physical locations that patients visit, and the person listed as the treating orthodontist may not even reside in the state. In some instances patients can get their money back, but there can be lasting damage to the teeth that results from improper diagnosis and/or unsupervised treatment.

Consider:

- Improper diagnosis/oversight can result in problems that are worse than the condition a patient sought treatment for in the first place.
- While a patient may be able to see a licensed orthodontist for retreatment to correct problems caused by direct-to-consumer providers, they can experience lasting/irreparable harm.

ABOUT CAO

CAO CALIFORNIA ASSOCIATION of ORTHODONTISTS

www.caortho.org

The California Association of Orthodontists (CAO) is the Californian component of the American Association of Orthodontists (AAO). The CAO represents nearly 1,500 member orthodontists who practice in California. CAO members are specialists who have completed dental school and then successfully completed 2–3 years of additional training at an accredited orthodontic residency program to fully understand the complexities involved with the safe movement of teeth. CAO is engaged in legislative advocacy to protect patient health and improve access to care.

THE TELEDENTISTRY CATCH-22 TRAP

CALIFORNIA ASSOCIATION of ORTHODONTISTS

American Association of Orthodontists

How Mail-Order Orthodontic Companies are Hoping to Play State Legislatures and Dental Boards to Avoid Meeting the Standard of Care for Teledentistry that will Help to Better Protect Patients

Dental boards and state legislatures throughout the United States have expressed concern that patients who elect to receive orthodontic treatment through mail-order are not being adequately protected.

The scientific evidence overwhelmingly demonstrates that an in-person examination and x-rays prior to orthodontic treatment are essential to the standard of care for safe and effective treatment.

Yet, mail-order orthodontic companies are using a catch-22 hoping to prevent legislators and dental boards from codifying, in statute or regulation, a standard of care that would protect these patients. How is this happening?

Mail-order Companies to Lawmakers:

"You can't legislate a standard of care. You can't include that in a statute; you have to leave standard of care to the dental board."

Mail-order Companies to Dental Boards:

"The statute doesn't mention a specific standard of care, so you have no authority to put it into regulation; and you'll get sued if you do."

A "catch-22" is defined as a **paradoxical situation from which an individual cannot escape because of contradictory rules or limitations**. This is precisely what mail-order orthodontic companies are doing to avoid meeting the standard of care that will help better protect patients.

Mail-order companies want legislators to believe that they must defer to dental board members on determining the standard of care; and **dental board members** are told by mail-order orthodontic companies they will be sued if they set the standard of care in a rule without specific language in a statute establishing that standard of care.

The AAO strongly supports the authority of both legislatures and dental boards to codify specific elements of a standard of care they reasonably believe necessary to protect patients. For more information on the scientific evidence that supports elements of the standard of care necessary to protect patients receiving mail-order orthodontic treatment, please visit www.orthofacts.org.

More facts!

OrthoFacts.org

CALIFORNIA ASSOCIATION of ORTHODONTISTS

STANDARD OF CARE: DIAGNOSTIC RECORDS FOR ORTHODONTIC TREATMENT

With the broad array of treatment options available, making orthodontic decisions for you and your family can be difficult. Adding to the confusion is direct advertising by appliance manufacturers as well as provider companies. CAO member orthodontists consider many factors to determine which treatment option(s) will be safe and effective for each patient, but the process begins with gathering basic but critical information about the patient's oral health.

In an effort to assist potential patients in knowing that they are being well assessed before treatment, this document outlines the information that should be obtained before any treatment is undertaken. This recommendation represents the bare minimum of records that are needed to protect the health and safety of patients and to uphold the most basic standard of care.

In many cases additional records are necessary before beginning treatment—such as a 3-D image or x-rays of individual teeth to more fully assess and address a patient's orthodontic needs. Additionally, and especially for adults, a periodontal evaluation by a dentist or periodontist may also be needed.

While these records can be gathered by a licensed technician at the direction of your treating doctor, the California Association of Orthodontists feels that an in-person examination by your treating doctor assures that you have been adequately evaluated before beginning treatment.

This standard of care recommendation for the baseline of records needed prior to beginning orthodontic treatment was developed in consultation with the heads of the University-based orthodontic departments in California and is consistent with the *Clinical Practice Guidelines for Orthodontic and Dental Facial Orthopedics* published by the American Association of Orthodontists and the AAO's position paper: *Legal, Ethical and Clinical Concerns with Common Components of a Direct-To-Consumer Orthodontic Treatment Model*.

RECORDS NEEDED FOR ORTHODONTIC TREATMENT

The California Association of Orthodontists recommends the following diagnostic records, at a minimum, be obtained before beginning orthodontic treatment:

Phase I Treatment
- Lateral Cephalometric radiograph*, Panorex*, 3 Facial and 5 intraoral photographs* (ABO Standard), Models (either physical or digital)

Single Phase or Phase II Treatment
- Lateral Cephalometric radiograph*, Panorex*, 3 Facial and 5 intraoral photographs* (ABO Standard), Models (either physical or digital)

Adult Treatment
- Lateral Cephalometric radiograph*, Panorex*, 3 Facial and 5 intraoral photographs* (ABO Standard), Models (either physical or digital)

Combined Orthodontic & Surgical Treatment
- Lateral Cephalometric radiograph*, Panorex*, 3 Facial and 5 intraoral photographs* (ABO Standard), Models (either physical or digital)

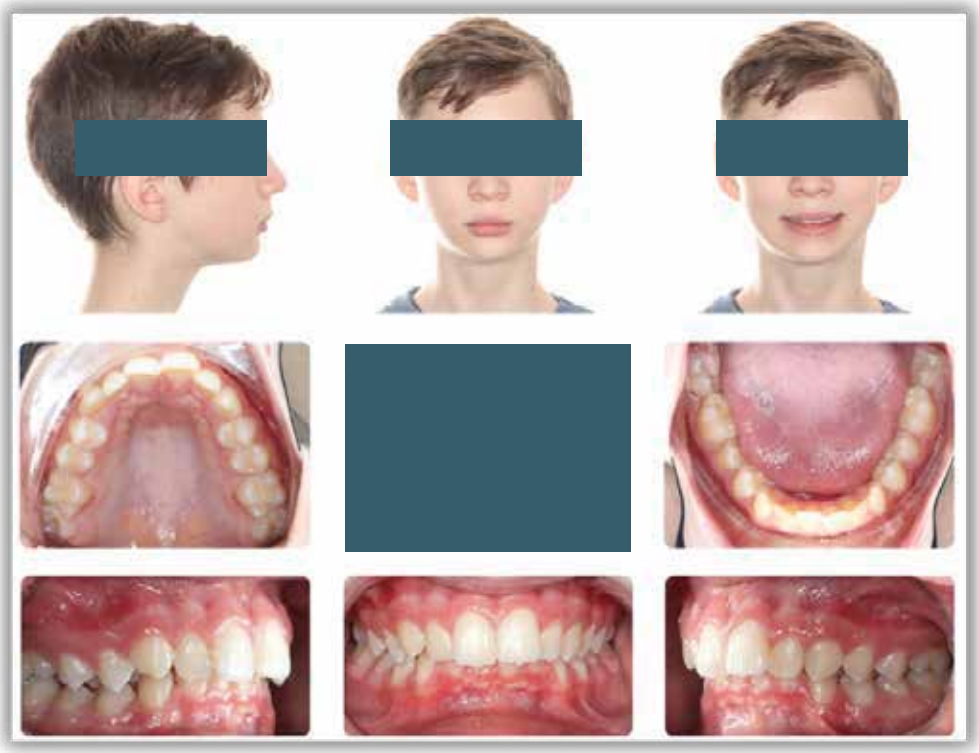
Limited Tooth Movement for Pre-prosthetic Reasons
(i.e. molar uprighting or single tooth extrusion etc.)
- Panorex*, 3 Facial and 5 intraoral photographs* (ABO Standard), Models (either physical or digital)

*CBCT Scan is acceptable instead of lateral cephalometric radiograph and panorex when the field is sufficient that these radiographs can be generated from it. Intraoral photo can be replaced with a full-color intraoral scan.

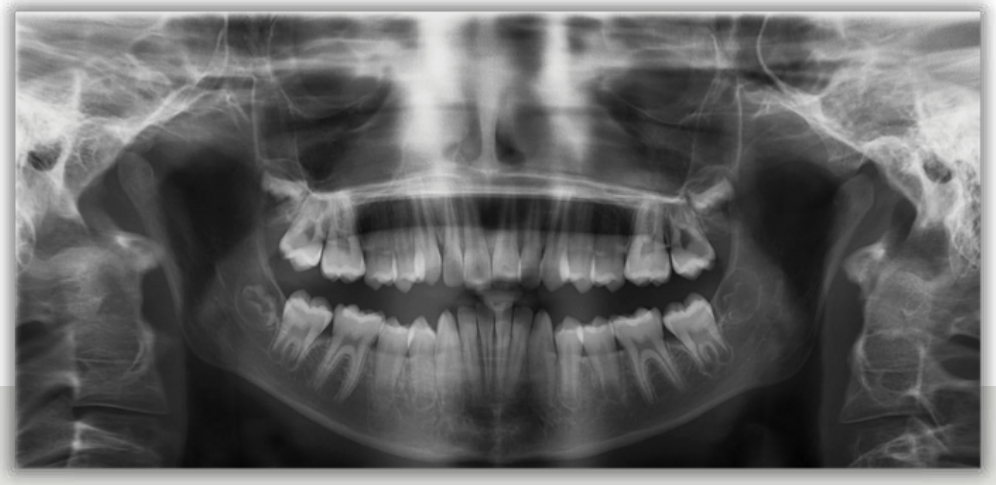
EXAMPLES OF RECOMMENDED RECORDS

To assist you in understanding if the appropriate records have been obtained, the following examples illustrate what each record looks like.

Frontal and Side Photos & Intraoral Photos

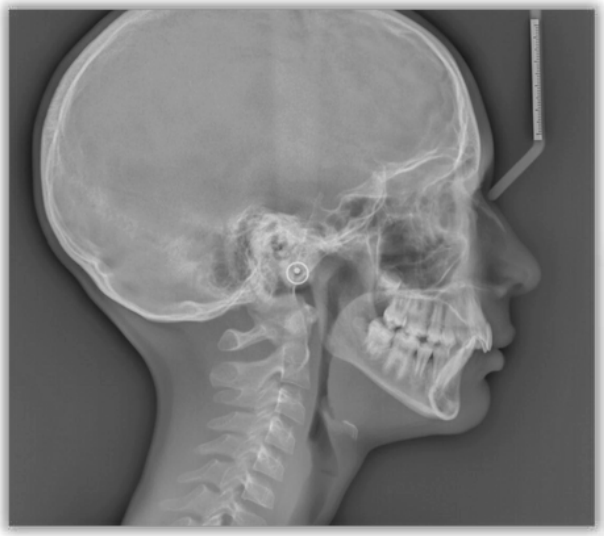


Panoramic Radiograph

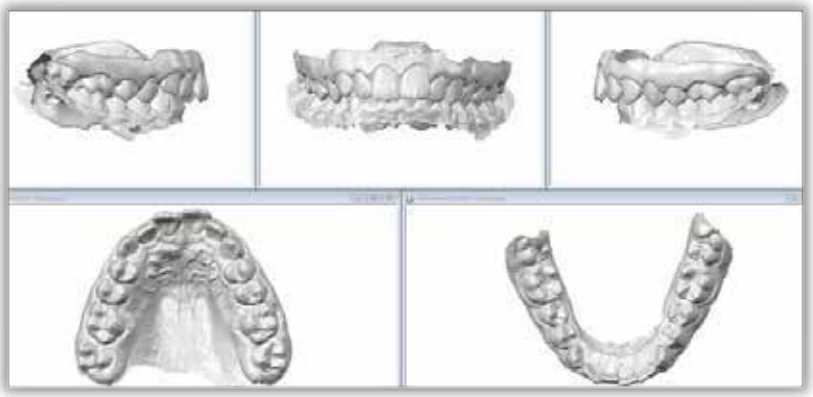


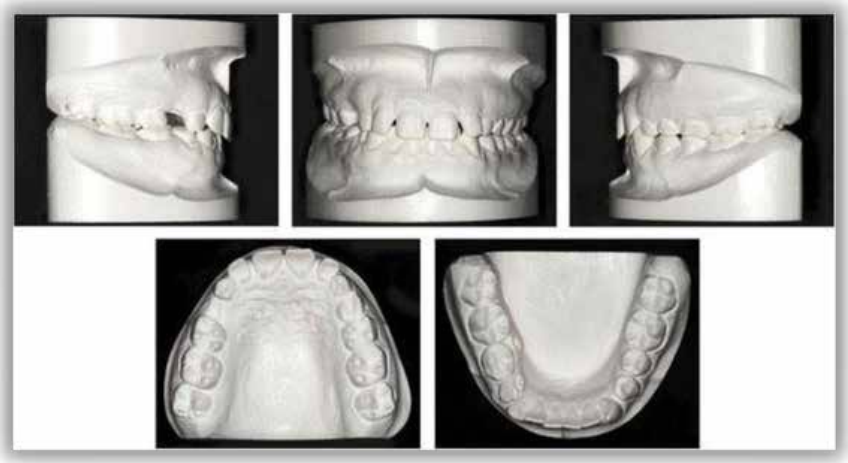
EXAMPLES OF RECOMMENDED RECORDS

Lateral Head Film commonly called a Cephalometric Radiograph



Digital or Physical Models of Your Teeth





This document is offered with the goal of providing guidance and facilitating increased access to care while ensuring that the minimum information needed for safe and effective treatment has been gathered prior to beginning orthodontic treatment.

CAO CALIFORNIA ASSOCIATION of ORTHODONTISTS

www.caortho.org

RESPONSIBLE INTEGRATION OF ARTIFICIAL INTELLIGENCE IN ORTHODONTIC CLINICAL PRACTICE

A Position Paper of the American Association of Orthodontists

Current as of November 10, 2025

Foreword

The AAO extends gratitude to its Task Force on Artificial Intelligence (AI) in Orthodontics whose efforts were expertly led by Dr. Heather Stone Hopkins. The Task Force was comprised of Dr. Heather Stone Hopkins, Dr. Jonas Bianchi, Dr. Lucia Cevidanes, Dr. Jae Park, Dr. Anthony Puntillo, Dr. Mario Tai, Ryan Goy, Frank Hemm, and Zelko Relic, and overseen by the AAO Committee on Technology Chair, Dr. Lisa Alvetro. We would like to acknowledge the assistance of Dawn M. Bielawski, PhD with editing. The following paper sets out the scientific evidence upon which the AAO bases its position for the safe, responsible, and clinically appropriate integration of artificial intelligence in orthodontic care.

Table of Contents

I. Objectives

This paper, authored by the AAO Task Force on Artificial Intelligence (AI) in Orthodontics, provides professional guidance for the responsible development, implementation, and oversight of AI technologies in orthodontic clinical care. While not regulatory in nature, it establishes a framework to support ethical adoption, patient safety, and professional accountability in the integration of AI systems.

This position paper has the following objectives:

1. Preserve professional authority
Ensure that the orthodontist remains the well-informed, educated final decision maker in patient care.

2. Promote transparency in AI development
Emphasize the essential role of developers and vendors in designing, validating, and monitoring AI technologies with transparency, data integrity, and ongoing lifecycle accountability to ensure their trustworthiness in clinical care.

3. Protect patient safety
Establish clear, risk-based recommendations for the responsible clinical integration of AI tools.

4. Establish a principles-based framework
Define an AI governance framework for orthodontics that identifies the orthodontist as the Human-in-Command (HIC) at the point of care and aligns clinical, educational, and regulatory responsibilities across the profession.

These objectives are operationalized through six core principles that collectively guide the responsible integration of AI in clinical orthodontics:

1. AI Governance and the Human-in-Command (HIC)
2. Regulatory Alignment and Risk-Based Oversight
3. Trustworthiness and Transparency Across the Lifecycle
4. Patient Autonomy
5. Education and Clinical AI Competency
6. Operational Integration and Data Privacy

II. Introduction

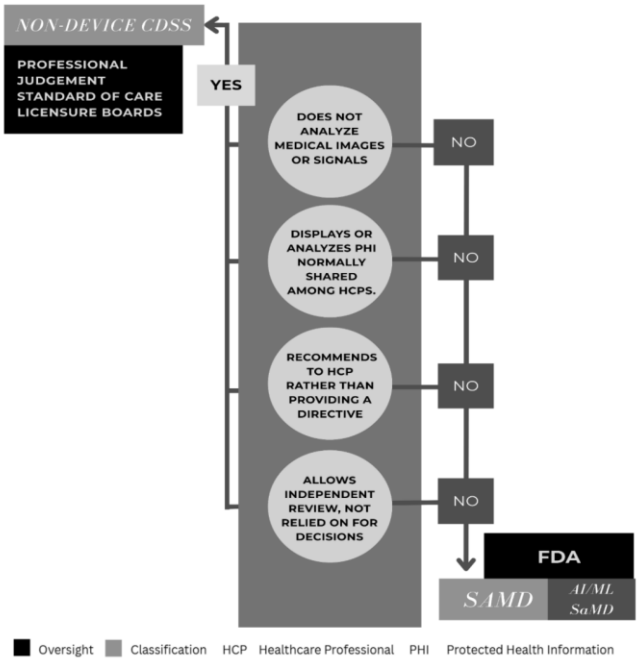
Artificial intelligence (AI) has been integral to the digital transformation of orthodontics, supporting diagnostic and treatment-planning applications across multiple dental specialties.[1,2] Fixed-logic systems, such as *if–then* rules, decision trees, and clinical scoring algorithms, have long assisted clinical decision-making in orthodontics.[3] These rule-based systems produce consistent outputs from identical inputs and do not learn or adapt over time. Historically, oversight for such tools has been determined by their context of use (COU) and the level of risk they pose to patient safety rather than by the type of AI employed.[4-6] The AAO Task Force on AI in Orthodontics was formed not because AI is new to orthodontics, but because adaptive AI systems introduce a fundamental shift in clinical risk. The ability of these technologies to evolve introduces new challenges in validation, reliability, and safety and redistributes responsibility for patient care across the development, deployment, and clinical use lifecycle.[7,8] With the rise of generative and other adaptive systems, the potential for AI to influence clinical decision-making is increasingly evident.[9-11]

Rather than focusing on the underlying architecture or type of AI system, the guidance in this position paper is grounded in COU, level of clinical risk, and the necessity of professional judgment by a licensed orthodontist.[4-6,12-14]

As illustrated in Figure 1, regulatory classification depends on the software's function, which is determined by the four exemption criteria established under the 21st Century Cures Act.[12] Utilizing these criteria, systems that support clinician judgment are classified as Clinical Decision Support Software (CDSS), while those that direct or drive clinical action without independent review fall under FDA oversight as Software as a Medical Device (SaMD).[5,15]

The dynamic nature of adaptive systems necessitates clear governance structures that define where oversight resides and how accountability is distributed.[13,16] When a supportive AI tool is classified as CDSS, oversight of its COU falls to the licensed orthodontist, who is held to the professional standard of care and accountable to state licensure boards. Because CDSS functions within the scope of professional judgment rather than federal device regulation, orthodontists must be equipped to evaluate, interpret, and implement these tools responsibly in practice.[5,7,12,13,17,18]

Figure 1 – *Decision pathway for determining whether clinical decision support software (CDSS) qualifies as a non-device under the 21st Century Cures Act.*



Conversely, when an AI system directly informs or drives treatment decisions, it is classified as SaMD or the subcategory AI/ML SaMD and regulated by the FDA, which maintains oversight across all stages of the product lifecycle, including design, development, and post-deployment use. This places responsibility on developers to design AI systems with patient safety, clinical relevance, and long-term performance in mind.[8,19] This includes ensuring transparency in how the tool operates, establishing mechanisms for human oversight, and maintaining accountability for performance over time.[20-22]

The central issue addressed by this paper is not the presence of AI in orthodontics, but the manner in which its use reshapes the orthodontist's role in clinical decision-making. Oversight is determined not by the technical architecture of the AI system, but by the function it performs and the degree of influence it exerts in patient care.

To support this goal, the American Association of Orthodontists (AAO) has developed six core principles to guide the responsible development and use of AI technologies in clinical orthodontics. A profession-defined framework is essential to ensure that AI tools are designed, deployed, and monitored in ways that uphold the specialty's standards of care, protect patient safety, and preserve the orthodontist's role as the primary decision maker in treatment.

What is Artificial Intelligence (AI)?

The FDA defines AI as *"a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments"*.[19]

The International Organization for Standardization (ISO) defines an AI system as a *"system that is capable of perceiving its environment and taking actions to maximize its chances of achieving its goals"*.[23]

Regulatory status is not determined by how AI is defined or by its technical architecture. Classification and oversight depend on the software's intended use and the ability of a licensed professional to independently review the basis for its output, so oversight follows COU and patient risk rather than model type.[4-6,12]

Together, these definitions characterize AI as a system that can process inputs, detect patterns, and generate outputs to achieve specific goals. In clinical settings, AI technologies may be used to support data analysis, enhance diagnostic accuracy, and generate recommendations based on complex information inputs.[9,10,13]

Clinical Decision Support Software (CDSS)

CDSS refers to software designed to assist healthcare professionals in clinical decision-making by analyzing or displaying medical information and providing recommendations that inform, but do not replace, professional judgment.[3,5]

Under the 21st Century Cures Act, Section 520(o)(1)(E) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), certain types of CDSS are excluded from the definition of a medical device. This exemption depends on the tool's intended use, its level of clinical risk, and whether the healthcare professional retains the ability to independently assess the basis for any recommendations.[5,12] This classification is determined by how the software is used, not by whether it incorporates AI or another type of technology.[5]

Even when not subject to FDA regulation, CDSS tools remain part of clinical care and must be used in accordance with the standard of care, professional licensure, and applicable state oversight.[6,7,13,24]

Software as a Medical Device (SaMD)

The International Medical Device Regulators Forum (IMDRF) defines Software as a Medical Device (SaMD) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.".[4] Under the FD&C Act, SaMD is classified as a medical device and is subject to regulatory requirements based on its intended use and level of patient risk.[15] These requirements may include premarket review, quality system regulations, and postmarket surveillance to ensure safety, effectiveness, and ongoing compliance.[5,22]

AI/ML SaMD

AI or machine learning (ML) capabilities are increasingly being integrated into SaMD. When software that meets the definition of SaMD incorporates AI or ML functions, it is referred to as AI/ML SaMD. These tools remain regulated as medical devices under the Federal FD&C Act, consistent with their intended medical purpose.[5]

ML refers to the capacity of systems to learn from problem-specific training data to automate analytical model building and solve associated tasks.[25] AI/ML SaMD differs from traditional, rule-based SaMD because it uses ML algorithms to analyze complex datasets and generate predictive, data-driven outputs that inform clinical decision-making.[4,5]

Some AI/ML systems incorporate adaptive or continuous learning capabilities, meaning they can update performance or outputs as new data are collected through real-world use. This adaptive behavior introduces additional regulatory considerations, including the need for mechanisms that ensure the system remains safe, effective, and transparent as it evolves.[13,22]

To address these challenges, the FDA applies a Total Product Lifecycle (TPLC) approach that includes premarket assessment, postmarket performance monitoring, and the use of Predetermined Change Control Plans (PCCPs) to manage algorithm updates in a predictable and controlled manner.[19,22] These oversight mechanisms ensure that modifications do not compromise clinical performance, introduce new risks, or reduce transparency.

The level of regulatory scrutiny applied to AI/ML-based SaMD depends on the product's intended use, associated patient risk, transparency, and the degree to which its performance may change after deployment.[13,22]

Examples in Orthodontics

CDSS in Orthodontics

A common example of CDSS in orthodontics is digital cephalometric analysis software that calculates standard angular and linear measurements (e.g., SNA, SNB, ANB) based on user-identified landmarks. This type of software does not independently detect anatomical features, interpret findings, or make clinical recommendations. It performs standardized calculations using static logic and user-provided inputs.[26]

SaMD in Orthodontics

An example of SaMD in orthodontics is digital bonding software that enables the simulation of bracket placement and generates a treatment-specific appliance, such as a custom transfer tray. The orthodontist may adjust bracket positions during the planning phase, but once finalized, the software autonomously designs the tray used for clinical delivery. Because the software's output directly determines how the brackets will be positioned and delivered to the patient, and because it is relied upon to perform a medical function within the treatment workflow, it qualifies as SaMD under the definition established by the IMDRF.[4] The system is regulated by the FDA as a Class II medical device and is subject to premarket review, performance validation, and postmarket controls.[5]

This type of software does not meet the exemption criteria under Section 520(o)(1)(E) of the FD&C Act, as the clinician cannot independently review the underlying logic or data that generate the final output.[5,15] Its classification is determined by its intended use, associated clinical risk, and the extent to which its outputs are used in treatment without further human interpretation or modification.[4,5]

AI/ML SaMD in Orthodontics

An example of AI/ML-based SaMD in orthodontics is an FDA-authorized dental image analyzer used for remote treatment monitoring. These systems analyze intraoral photographs captured by patients or clinicians through imaging applications and connected hardware. ML algorithms autonomously detect and quantify clinical features such as aligner fit, attachment loss, soft-tissue conditions, occlusal relationships, and alignment progress.

This type of software qualifies as AI/ML SaMD under the FD&C Act because it performs a medical function independently of hardware and uses AI to interpret patient images. Clinicians rely on its outputs to guide treatment decisions without independently recalculating or reproducing the underlying analysis, which disqualifies it from the Clinical Decision Support Software (CDSS) exemption in Section 520(o)(1)(E).[15,19]

It specifically qualifies as AI/ML SaMD because it performs its medical function using ML algorithms trained on clinical data to identify and analyze features relevant to orthodontic treatment. Unlike traditional rule-based SaMD, which relies on fixed, preprogrammed logic, AI/ML SaMD employs statistical models that learn from data to generate analytical or predictive outputs, such as detecting tooth movement, attachment loss, or soft-tissue changes. The distinction lies in the software's computational method and its reliance on learned patterns rather than deterministic rules, which introduces additional regulatory considerations for continuous validation, transparency, and lifecycle oversight.[5,13,22,24]

To manage adaptive risk, the FDA applies a TPLC regulatory framework that includes Predetermined Change Control Plans (PCCPs) and continuous postmarket performance monitoring to ensure that algorithmic updates remain safe and effective.[16,22] These tools are regulated as Class II dental image analyzers (Product Code SBC, 21 CFR 872.1770) and are subject to general and special controls, including validation, labeling, and ongoing performance testing.[16,22]

Current and emerging AI applications across diagnostics, treatment planning, appliance design, and remote monitoring are summarized in Tables A1-A4 in the Appendix, which organize key capabilities, functions, benefits, limitations, and supporting evidence for each category.

III. Core Principle 1: AI Governance and the Human-in-Command (HIC)

In clinical practice, AI systems must function as supportive tools that enhance, but never replace, the expertise of a licensed professional. Regardless of type or regulatory classification, all AI technologies that support or influence diagnosis, treatment planning, or patient care must operate within an AI governance framework that preserves professional accountability and patient safety.

AI Governance

AI governance encompasses the system-level responsibilities of identifying, evaluating, and approving appropriate technologies; validating their intended use; integrating them into organizational workflows; and monitoring their performance across the practice or entity.[4,13,16] Governance establishes the structures, policies, and accountability mechanisms that ensure AI systems are safe, effective, and aligned with patient care standards.

It establishes who is responsible for decisions about how AI systems are developed, approved, and used, and ensures that these technologies operate safely, transparently, and in alignment with professional, legal, and societal values. In private practice, governance is carried out directly by the owner orthodontist. In small group practices, governance functions may be shared among partners. In large group practices and dental service organizations (DSOs), governance functions such as procurement, contracting, and enterprise-level policy occur at the corporate level.[7]

Human-in-Command Oversight

The Human-in-Command (HIC) concept, adapted from global AI governance literature*, is defined here as the licensed professional of record.[13,24,27] The HIC exercises comprehensive oversight at the point of care, extending beyond clinical decision-making or output validation. This role encompasses the authorization, supervision, and accountable use of AI technologies in clinical practice. The HIC determines when, how, and by whom approved AI systems are applied within clinical workflows and ensures that every use of AI occurs within the boundaries of licensure and the professional standard of care.[18,28]

HIC oversight begins with assessing whether the selected AI tools meet a quantifiable clinical need and verifying that they have been validated for their intended purpose. Delegation of AI-related tasks must account for the level of patient risk associated with each AI function, as defined by regulatory bodies such as the FDA and must respect the duties legally permitted for staff under state dental practice acts.[6,13,22,27] Oversight must be implemented and monitored at the practice level by the HIC to ensure compliance with regulatory guidance, protect patient safety, and uphold the standard of care.[13,16,24,27,29]

**The concept of Human-in-Command (HIC) originates in technology governance and appears in international health policy literature. In this paper, it is applied specifically to orthodontics, where the HIC is defined as the licensed orthodontist of record, consistent with American Dental Association (ADA) policy and global expectations that accountability rests with qualified clinicians.*

Relationship Between Governance and Oversight

The separation between organizational governance and clinician oversight is essential. Governance establishes what AI systems are approved for use and defines the conditions under which they may be deployed.[7] Oversight ensures that, in every clinical encounter, the licensed orthodontist retains authority over how those systems are applied to patient care.[24] By clearly distinguishing these roles, the framework preserves accountability, prevents inappropriate delegation of clinical authority, and maintains patient protection.[27]

Risks of Absent AI Governance and HIC Oversight

Without structured AI governance and HIC oversight, orthodontic practices face operational, legal, and ethical vulnerabilities. Without clear, enforceable oversight by a licensed orthodontist in the role of HIC, AI tools may be used in ways that violate scope-of-practice laws, compromise patient safety, and erode trust in the profession. The absence of well-defined AI governance allows clinical decision-making to drift outside the bounds of licensure and regulation, exposing patients, providers, and the profession to avoidable harm.[7,13,16,24] The key risks include:

1. Use Beyond Validated Context of Use
Without a licensed clinician overseeing how AI tools are selected, integrated, and supervised, systems may be deployed outside their validated context. This increases the likelihood of diagnostic inaccuracies, unsupervised treatment planning, or prescription errors based on unverified or non-clinically validated outputs.[30]

2. Inappropriate or Unaccountable Delegation
Orthodontists are always responsible for the delegation of duties to staff. Without proper oversight, AI may enable tasks that extend beyond legally permitted duties under state dental practice acts. This can lead to unauthorized delegation of diagnostic or treatment-related decisions, bypassing the orthodontist's required judgment.[16,27]

3. Absence of Lifecycle Monitoring and Feedback Loops
When governance structures are not in place, AI systems may be deployed without mechanisms for continuous monitoring, validation, and detection of model drift. This disconnect between intended use and real-world performance violates both FDA and IMDRF expectations for post-deployment surveillance and safe lifecycle management.[20,22]

4. Breakdown of Legal and Ethical Accountability Between Clinicians and Developers
When responsibility for tool selection, validation, and use is not clearly defined, accountability becomes fragmented, and liability may fall inconsistently between clinicians and developers. While the orthodontist, as the licensed professional, ultimately holds legal responsibility for patient care, the growing influence of AI systems on clinical outcomes means that inadequate governance can shift additional, often unrecognized, liability to the provider.[7,31-33]

5. Breakdown of Legal and Ethical Accountability Between Clinicians and Organizations
In larger practices or corporate governance models, AI systems are often selected, validated, or deployed at the enterprise level without the orthodontist's direct involvement. Even so, the licensed clinician remains legally responsible for how those systems are used in patient care.

Without clearly defined governance structures and HIC oversight, orthodontists may unknowingly assume greater liability than intended, bearing responsibility for clinical outcomes influenced by decisions made at the organizational or corporate level. Clear alignment between enterprise governance, HIC oversight, and clinical application is essential to ensure patient safety and protect both clinicians and organizations from unmanaged risk.[7,16,27]

6. Erosion of Public Trust
Patients expect orthodontists to be the final decision-makers in their care. If AI tools are used without clear oversight, or if decisions appear automated or unaccountable, trust in both the technology and the clinician is diminished.

7. Undermining Licensure-Based Practice
Licensure defines who is legally authorized to diagnose, plan, and deliver orthodontic care. If AI tools direct patient care without orthodontist oversight as the HIC, it undermines licensure and risks normalizing "provider-less" decision-making, eroding one of the profession's core safeguards for patient safety.

8. Increased Patient-Safety Risks
Patient safety is the ultimate casualty when AI governance and HIC oversight are absent or poorly defined. Without governance to validate systems, monitor performance, and set boundaries for use, and without HIC oversight to ensure appropriate application in patient care, the safeguards that anchor clinical safety collapse.

Errors in diagnosis, treatment planning, or appliance design may go undetected when clinicians rely on AI tools that have not been properly vetted or are applied outside their validated context. When governance and HIC roles are unclear, the feedback loop between system performance and clinical outcomes breaks down, removing the critical human judgment needed to protect patients from algorithmic errors, bias, and inappropriate recommendations.[7,13,16]

Call to Action

To protect patient safety, ensure ethical care, and preserve trust in AI-integrated orthodontic practice, licensed orthodontists must retain final authority over all clinical decisions involving AI technologies. This authority should be exercised through an AI governance framework in which the HIC role is filled by the licensed professional at the point of care. The HIC is accountable for the AI tools used in patient care and for how those tools are applied to support or direct clinical decisions within the bounds of licensure and the standard of care.

Without clearly defined governance structures and professional accountability, AI systems may be used outside their intended purpose or without adequate clinical oversight. Such gaps can lead to inappropriate delegation of clinical authority, erosion of accountability, and potential harm to patients.[7,34,35]

Leading global frameworks affirm that qualified professionals must remain accountable for the deployment and oversight of AI in healthcare. While terminology may vary, the shared principle is consistent: the use of AI in clinical care must remain under the authority and direction of a licensed professional.[13,24,28,36]

The AAO calls on developers, industry vendors, and regulatory bodies to:

1. Establish Well-Defined AI Governance Frameworks
Every orthodontic practice or organization implementing AI in a clinical setting must maintain a clearly defined governance framework that outlines the selection of AI tools, their validation for clinical use, and the conditions under which they may be deployed. Governance frameworks must define the role each AI system will play in clinical workflows, ensure transparency in how decisions are made, and preserve clinician autonomy in determining when and how AI tools are used in patient care, particularly when their outputs influence patient-care decisions.

2. Require Human-in-Command (HIC) Oversight at the Point of Care
All AI tools used in orthodontic patient care must operate under the oversight of a licensed orthodontist serving as the HIC. The HIC is accountable for how AI tools are used to support or direct patient-care decisions and must ensure that their application aligns with licensure requirements, regulatory expectations, and the standard of care. Oversight must be active, documented, and proportionate to patient risk, ensuring that clinical authority, ethical responsibility, and liability remain with the licensed professional at every point of care.

3. Establish Clear Delegation Frameworks Based on Risk and Context of Use
The AI governance framework should clearly define how delegation is structured based on state dental practice acts and allowable duties for staff. Oversight requirements must be proportionate to the AI tool's intended clinical function, risk to the patient, and regulatory classification. HIC oversight at the point of care determines appropriate delegation based on the tool's authorized COU and the level of risk associated with it.

For lower-risk tools, tasks may be delegated to trained staff, provided they fall within the scope of duties permitted under applicable regulations and remain under the orthodontist's supervision. Regardless of delegation, the licensed orthodontist retains responsibility for ensuring each tool is used in accordance with its authorized COU and the standard of care. This risk-based approach aligns with oversight principles outlined by the FDA, IMDRF, WHO (World Health Organization), and NIST (National Institute of Standards and Technology).[6,13,16,24]

4. Prohibit Direct-to-Consumer AI That Bypasses Licensure
State dental laws should explicitly prohibit the use of AI technologies to diagnose, prescribe, or manage orthodontic treatment outside the supervision of a licensed provider. Direct-to-consumer (DTC) AI models that deliver clinical recommendations or treatment decisions without orthodontist oversight violate scope-of-practice laws and undermine patient protection. These systems bypass established safeguards of licensure, professional accountability, and HIC oversight, presenting significant risks to patient safety and public trust in the profession.

5. Align AI Use With State-Level Delegation Rules
AI systems should be regulated using the same principles that govern delegation to human auxiliaries. Just as clinical tasks may only be assigned to staff based on training, competency, and licensure, AI clinical tools must not be used to perform or influence decisions that exceed the legal authority of the licensed provider. Orthodontists must remain responsible for how AI-supported tasks are assigned, validated, and supervised within clinical workflows.[27,28]

IV. Core Principle 2: Regulatory Alignment and Risk-Based Oversight

AI tools used in orthodontic care must align with the highest regulatory standards based on COU, clinical risk, and lifecycle oversight. Global regulatory bodies, including the FDA, IMDRF, WHO, and ISO, have endorsed a risk-tiered regulatory approach for AI/ML SaMD. These frameworks require oversight to be proportionate to the system's intended use and potential for harm, rather than applying uniform regulation across all tools.[13,20,22,24]

Adherence to Global AI/ML SaMD Guidance and Standards

Building on the governance framework established in Core Principle 1, Core Principle 2 defines how regulatory alignment and risk-based oversight ensure accountability across the AI lifecycle. AI technologies intended for patient care must conform to global frameworks that govern how systems are designed, validated, classified, and monitored.

AI developers and industry vendors are responsible for meeting regulatory and quality-management standards, maintaining transparency, and marketing AI tools only within the boundaries of their approved COU.[20,22,24] Following the AI governance framework laid out in Core Principle 1, the HIC is responsible for oversight at the point of care, verifying that any AI tool used in practice has been developed in accordance with applicable standards and is used within its authorized scope.

U.S. FDA

The FDA applies its TPLC framework to AI/ML SaMD, outlining expectations for premarket validation, postmarket surveillance, and the use of Predetermined Change Control Plans (PCCPs) to manage adaptive algorithm changes.[5,19,22,37]

International Medical Device Regulators Forum (IMDRF)

IMDRF guidance defines SaMD and establishes the risk-based oversight principles adopted by global regulators to classify and govern such software, including AI-enabled tools.[8,24,38]

ISO 13485

This international standard specifies quality management system requirements for the design, development, and production of medical devices, including software-based tools.[20]

Risks from Inappropriate Oversight for AI Tools

1. Overregulation That Discourages Innovation
Subjecting low-risk assistive AI tools, such as those used for administrative, educational, or visualization purposes, to the same regulatory requirements as higher-risk medical devices can inflate development costs and delay clinical access.[22,24,39] Evidence suggests that disproportionate regulation may discourage innovation, particularly among startups and academic developers, without corresponding gains in patient safety.[1,13] Proportional, risk-based oversight is therefore essential to safeguard both patient protection and technological progress.

2. Clinical Harm from Off-Label Use and Misclassification
Marketing or deploying AI tools outside their authorized COU can introduce significant clinical risk.[15] When systems are promoted or utilized for functions they were not cleared to perform, particularly diagnostic or treatment planning tasks, they bypass required validation and quality management processes mandated under U.S. and international device regulations.[5,22,39] This increases the likelihood of automation bias, misdiagnosis, and irreversible treatment errors.[40] Off label deployment also deprives the clinician of cleared labeling and performance evidence needed to assess whether an AI output is accurate or appropriate, thereby undermining professional judgment and exposing patients to harm.[41]

Together, these risks underscore the need for a unified regulatory approach that protects patients while enabling responsible innovation.[13,22,24,39] Oversight must remain clinically grounded, proportionally enforced, and anchored in professional accountability. The following Call to Action outlines the steps necessary to ensure that AI/ML based SaMD in orthodontics are governed by both human expertise and regulatory rigor.

Call to Action

To ensure that AI technologies used in orthodontic care are safe, clinically appropriate, and ethically deployed, regulators, developers, and clinicians must share responsibility for aligning tool development and use with the highest global standards.

The AAO calls on developers, industry vendors, and regulatory bodies to:

1. Define and Validate Context of Use at the Point of Development
All AI tools intended for use in patient care must include a clearly defined and validated COU. This definition must inform the tool's regulatory classification, risk assessment, and lifecycle monitoring requirements.

2. Comply with Risk-Based Regulatory Frameworks Across the Full Product Lifecycle
Developers must adhere to regulatory standards such as the FDA's TPLC framework, IMDRF SaMD guidance, and ISO 13485, which collectively define premarket validation, postmarket surveillance, change-control mechanisms, and, where applicable, Predetermined Change Control Plans (PCCPs) for adaptive systems.[20,22,24]

3. Market Tools Only Within Their Authorized Use
AI technologies must not be promoted or deployed for functions outside their approved regulatory scope. Off-label marketing increases risk to patients, undermines clinician trust, and may trigger legal or regulatory consequences.

4. Support Regulatory Harmonization and Transparency
To foster both innovation and public trust, regulators should work toward consistent international standards that define expectations for classification, explainability, performance monitoring, and ethical deployment.

5. Enable Proportionate Oversight to Promote Responsible Innovation
Low-risk AI tools that do not inform clinical judgment should not be subjected to full regulatory requirements. Regulators should continue to support scalable oversight models that reduce barriers to innovation while maintaining safety.

By ensuring that AI tools are accurately classified, transparently developed, and deployed only within their approved context, the orthodontic profession can accelerate access to responsible innovation while protecting patient safety and professional accountability.

Together, Core Principles 1 and 2 reinforce the dual obligation of clinicians and developers: to maintain human authority in clinical care and to align tool development with global regulatory expectations.

V. Core Principle 3: Trustworthiness and Transparency Across the Lifecycle

AI tools must be reliable, explainable, and consistent from development through deployment and postmarket use.[6,22,28] For clinicians to use these tools safely, they must have visibility into how models are trained, validated, updated, and monitored over time.[19,24,40,42]

Trust is not earned by performance claims alone. It requires transparency across the full product lifecycle, clear documentation of training data sources, validation procedures, update history, and mechanisms for ongoing risk monitoring. Clinicians are not responsible for auditing algorithms or inspecting code, but they must be able to verify that any AI tool adopted into practice is supported by trustworthy development practices and vendor accountability.[5,22,24,43]

This expectation is reinforced in the American Dental Association's (ADA's) Standards Committee on Dental Informatics (SCDI) White Paper No. 1106[27], the American Medical Association's (AMA's) *Principles for Augmented Intelligence in Health Care*[36], ISO/IEC (International Organization for Standardization/International Electrotechnical Commission)[28], and guidance from the WHO[29] and the U.S. Department of Health and Human Services[44]. These frameworks emphasize that trust in clinical AI must be built on evidence, transparency, explainability, and postmarket accountability, not assumptions or proprietary opacity.

To operationalize trust and transparency, AI tools must be developed, validated, and maintained in accordance with five foundational pillars. These pillars establish the developer's obligations across the product lifecycle and define the verification responsibilities of the licensed orthodontist serving as the HIC at the point of care.

Five Pillars of Trustworthiness in AI Development

1. Dataset quality and bias mitigation

2. Rigorous clinical validation

3. Explainability and auditability

4. Continuous monitoring and risk management

5. Transparency and vendor accountability

A summary of these pillars and of trustworthy AI development, outlining the corresponding responsibilities of developers and the verification requirements for orthodontists acting as the HIC can be found in Table 1.

Table 1. Five pillars of trustworthy AI/ML SaMD development and corresponding roles of developers and orthodontists (HIC)[a]

Pillar	Focus	Developer Responsibilities	Orthodontist (HIC) Verification
1. Dataset Quality and Bias Mitigation	Use of reliable and representative data	● Build models with diverse, well-documented datasets. ● Test for and reduce demographic or data bias.	● Review vendor reports showing dataset sources, diversity, and bias testing.

Pillar	Focus	Developer Responsibilities	Orthodontist (HIC) Verification
		• Keep clear records of how data were collected and prepared.	• Confirm the data reflect the tool's intended clinical use.
2. Rigorous Clinical Validation	Proof of safety and performance	• Validate tools using real clinical data and risk-based testing. • Report key metrics such as accuracy, sensitivity, and specificity. • Recheck performance regularly after release.	• Confirm the tool has been independently validated and cleared for its intended use. • Review performance metrics and regulatory classification.
3. Explainability and Auditability	Understanding and tracing AI outputs	• Design tools that show how results are generated (e.g., heatmaps, confidence scores). • Keep logs linking each output to its model version and dataset.	• Ensure outputs are interpretable and confidence levels are visible. • Retain the ability to review and override AI-generated results.
4. Continuous Monitoring and Risk Management	Ensuring safety over time	• Monitor model performance and update when data or standards change. • Document updates, known issues, and retraining results. • Alert users to any performance changes or risks.	• Check that monitoring systems and update logs are available. • Confirm version histories and alerts are communicated clearly by the vendor.
5. Transparency and Vendor Accountability	Openness and responsibility	• Provide clear labeling, documentation, and contact pathways.	• Require access to documentation before adopting the tool.

Pillar	Focus	Developer Responsibilities	Orthodontist (HIC) Verification
		• Disclose training methods, limitations, and known risks. • Respond to clinician reports and maintain traceable records.	• Keep records of vendor communications, updates, and issue reports.

[a] *Sources: ISO[22], NIST[6], WHO[28], IMDRF[24], FDA[5,29]*

Risks to Patient Care and Clinical Adoption if Trustworthiness Is Not Upheld

AI tools used in orthodontics, independent of their regulatory classification, must meet foundational standards for trustworthiness.[6,22,28,29] When these safeguards are absent, tools may produce unreliable, biased, or opaque outputs that compromise clinical decision-making and expose patients and providers to harm.[24,40,43] The following risks illustrate what can occur when AI systems are adopted without sufficient transparency, validation, and ongoing oversight[5,8,13,22]

1. Patient Harm from Inaccurate or Unvalidated AI Outputs
Poorly validated models, or those trained on low-quality or non-representative data, can produce inaccurate outputs, including false positives and false negatives, that directly lead to misdiagnosis or unsafe treatment decisions. In orthodontics, this may result in overlooked pathology, mistimed interventions, or inappropriate treatment recommendations, compromising patient safety.[6,13,22,45]

2. Health Inequities from Inequitable or Biased AI Tools
When AI tools are not intentionally designed and tested for fairness, they often generalize poorly to underrepresented populations.[6,45] This can lead to unequal diagnostic accuracy, inappropriate treatment recommendations, and the amplification of existing health disparities.[13,43] Rather than closing care gaps, biased AI may widen them, producing outcomes that contradict professional and ethical obligations to fairness, equity, and inclusion.[13,46]

3. Poor Generalizability in Real-World Clinical Settings
AI models developed and tested in controlled research environments may perform inconsistently when deployed in real-world orthodontic practice.[22,45] Without demonstrated generalizability across patient populations, imaging conditions, and clinical workflows, these systems may yield unreliable or non-reproducible outputs, reducing clinical effectiveness and increasing the potential for patient harm.[6,13]

4. Reduced Access to AI Tools for Marginalized Populations
When bias is not proactively identified and addressed during development, AI tools may underperform for marginalized or underserved groups.[22,45] As a result, these systems often cannot be safely deployed for those populations, effectively excluding them from access to AI-enabled diagnostics and treatment planning technologies.[13,29,43] This lack of equitable design and validation perpetuates existing disparities in care, even as AI adoption expands.[39]

5. Clinical Risk from Unexplainable or Opaque AI Outputs
When AI models do not provide interpretable reasoning behind their outputs, orthodontists cannot meaningfully evaluate or challenge recommendations.[47,48] This lack of explainability undermines clinical oversight, making it difficult to detect errors, assess appropriateness, or justify treatment decisions.[6,13] Opaque models therefore pose direct risks to patients, since unsafe or inappropriate outputs may go undetected, leading to errors in diagnosis, treatment planning, or care delivery.[22,43]

6. Patient Harm from Unmonitored Performance Drift
Adaptive AI models are not static. Over time, they may degrade or behave unpredictably in response to changes in input data, clinical practices, or environmental conditions.[6,10] Without continuous monitoring, validation, and drift detection, these performance shifts can go unnoticed and result in silent failures that erode clinical confidence and place patients at risk.[19,24]

7. Accumulation of Hidden Bias Over Time
Dynamic or continuously learning AI systems may acquire new biases after deployment if not proactively managed.[6,45] Without routine fairness audits and demographic performance evaluations, these models can gradually develop patterns that disadvantage certain groups.[24,43] This slow drift in fairness may go undetected, compounding inequities in care and undermining patient trust over time.[13]

8. Reinforcement of Outdated or Biased Clinical Norms
When AI models are trained on historical data that reflect outdated or biased clinical practices, such as overtreatment trends, racial disparities, or gender bias, they risk amplifying past harms rather than correcting them.[45,49] Without intentional bias mitigation and dataset review, AI can codify and perpetuate these inequities under the appearance of "evidence-based care."[6,13]

9. Undermining the Orthodontist's Role as Human-in-Command
The orthodontist's authority as the HIC relies on a baseline level of transparency and trustworthiness within AI tools.[24,28] Without clear insight into how systems generate and update their outputs, orthodontists cannot effectively validate recommendations, exercise oversight, or fulfill their professional responsibility for patient care.[13,21,22]

10. Undisclosed Algorithm or Dataset Changes
When vendors modify algorithms or retrain models under a PCCP, those changes may be reported to regulators but not communicated to clinicians.[19,22] Without clear and timely disclosure to end users, orthodontists may unknowingly rely on systems that no longer behave as originally validated or expected.[6,24] This loss of transparency compromises the orthodontist's ability to maintain oversight, verify appropriateness of use, and protect patient safety.[6,19,22]

11. Breakdown in Trust and Innovation Adoption
Untrustworthy AI systems do not just fail individually; they erode confidence in the broader use of AI within orthodontics and medicine.[6,13] A single unethical or unsafe deployment can stall adoption, dissuade clinicians from integrating AI into practice, and set back innovation across the field.[13,46]

12. Legal and Ethical Exposure
Using unvalidated, biased, or opaque AI systems violates established ethical principles and exposes orthodontists, vendors, and institutions to significant legal risk, particularly when patient harm occurs and oversight of a licensed professional is insufficient.[13,22,50,51]

Call to Action

The AAO calls on developers to[†]:

1. Innovate Responsibly

a. To protect patients and ensure equitable care, developers must commit to building transparent, validated, and accountable AI tools from the start. The orthodontic community depends on vendors to uphold trustworthiness through ethical design, documentation, and continuous collaboration with clinicians.

2. Use Quality, Diverse, Clinically Verified Data

a. Train and validate models using authentic, high-fidelity clinical data - synthetic or low-quality datasets should only be used if equivalence is validated.[20,22]

b. Ensure broad demographic representation across age, ethnicity, gender, and geography to prevent performance disparities.[13,43,45]

c. Maintain dataset documentation that includes source provenance, labeling protocols, preprocessing steps, and version history to ensure auditability.[6,28]

d. Conduct regular bias audits and fairness testing throughout the AI lifecycle, reporting demographic performance differences and mitigation steps.[6,13,43,45]

3.Validate According to Risk Tier

a. Follow risk-based validation standards consistent with FDA and global guidance for SaMD, ensuring that the level of evidence is proportional to clinical risk.[4,22,24,29,51]

b. Use graded validation strategies proportional to risk, such as multi-site or randomized studies for high-risk AI models, and require independent external validation datasets that reflect the intended population.[6,22,24,29]

c. Publish key performance metrics (e.g., accuracy, sensitivity, specificity, F1-score) and detailed validation methodologies to enable peer and clinician evaluation.[6,22,24]

d. Include postmarket validation and re-verification schedules with continuous monitoring and drift detection to confirm ongoing safety and accuracy over time.[6,19,24]

4. Enable Full Explainability and Transparency

a. Integrate explainable AI features such as heatmaps, overlays, feature attribution, and confidence scores, so that clinicians can understand model reasoning and uncertainty.[6,47,48]

b. Provide clear, accessible documentation of intended use, known limitations, and interpretability safeguards to support safe clinical use and informed oversight.[22,28,29]

c. Ensure clinicians can meaningfully review, interpret, and override AI-generated outputs at the point of care, preserving HIC responsibility.[13,22.47,52]

d. Include traceability that links each output to model version, dataset lineage, and update history to enable audit and accountability across the lifecycle.[6,22,24,28]

5. Implement Continuous Monitoring and Update Protocols

a. Employ real-time drift detection, error tracking, and performance alerts accessible to both vendors and clinicians to maintain transparency and safety.[6,19,24]

b. Establish and follow clearly defined Algorithm Change Protocols (ACPs) and PCCPs to govern updates in adaptive AI models, documenting all retraining and validation processes.[22,24]

c. Provide postmarket performance dashboards to regulators and clinicians that report drift, retraining events, and update outcomes in an accessible and auditable format.[6,19,28]

d. Collaborate with orthodontists and professional organizations to integrate clinician feedback into model updates, ensuring real-world alignment, accountability, and shared oversight.[6,28,29]

6. Disclose Limitations and Maintain Documentation

a. Publicly release Post-Validation Reports (PVRs) summarizing data sources, validation results, and risk-mitigation strategies to promote transparency and accountability.[22,24,28]

b. Clearly disclose known limitations and failure conditions, identifying scenarios where the system may underperform or require manual oversight.[13,22]

c. Notify clinicians of any algorithm or dataset change that could affect model performance, not only those reported to regulators, to maintain real-world safety and trust.[6,19,22,29]

d. Maintain traceability logs, structured labeling, and accessible documentation in compliance with ISO/IEC 42001:2023 and related governance standards.[6,24,28]

e. Communicate proactively and clearly with clinicians, ensuring orthodontists have the information needed to uphold HIC oversight and patient safety.[13,21]

[†]*For a detailed outline of these developer responsibilities, including standardized reporting templates and communication requirements, see the AAO's forthcoming supplemental guidance on AI Transparency, Fairness, and Vendor Accountability.*

The AAO calls on regulatory bodies to:

Protect the Public Trust

1. Regulators should ensure that all AI/ML SaMD tools used in clinical orthodontics are appropriately classified, registered, validated, and regulated under medical device standards consistent with FDA guidance and the IMDRF SaMD framework, with clear boundaries from CDSS exemptions.[4,22,24,52]

2. Regulators should expect developers to maintain regulator-reviewable documentation of dataset sources, demographic composition, labeling, and preprocessing, and to conduct fairness audits with stratified performance analysis during both premarket and postmarket phases.[6,28,29,39]

3. Regulators should require explainability and practical transparency for high-risk applications. Models are expected to provide interpretable outputs, such as confidence scores or visual saliency maps, sufficient for clinician oversight, consistent with the FDA AI/ML Action Plan and Good Machine Learning Practice principles.[5,6,13,22,37]

4. Regulators should support continuous oversight and real-world surveillance by promoting TPLC models that include real-time performance monitoring, drift detection, error reporting, and re-verification after updates.[6,19,22,24]

5. Regulators should establish clear accountability mechanisms for vendors whose tools underperform due to undisclosed updates, performance drift, bias, or inadequate validation. PCCPs and ACPs should include provisions for communicating clinically relevant updates and release notes to clinicians.[19,22,50,51,53]

6. Regulators should enforce risk-tiered clinical validation expectations by setting performance requirements appropriate to the device's clinical risk classification, requiring independent external validation representative of the intended population, and preventing deployment absent sufficient evidence.[6,20,22,24,29]

7. Regulators should require lifecycle transparency and traceability by ensuring that clinician- and regulator-accessible documentation includes data sources, intended use, training methods, version history, update protocols, retraining triggers, and monitoring practices. Public summaries should be encouraged where feasible without breaching privacy or intellectual-property protections.[6,22,24,28,29]

The AAO calls on orthodontists to:

Govern with Oversight

As licensed healthcare professionals, orthodontists should remain the final decision-makers in all AI-assisted care. The licensed professional is expected to protect patient safety, uphold clinical integrity, and ensure the ethical implementation of AI/ML SaMD systems.[13,21,22,24]

1. Orthodontists should request documentation on dataset diversity, authenticity, and clinical validation before implementing any AI tool.[22,29] Confirm that models were trained on representative, real-world orthodontic data encompassing varied ages, ethnicities, and geographies.[22,43,45] Avoid tools built on low-fidelity or unverified data sources.[6,45]

2. Orthodontists should adopt only AI tools that demonstrate performance appropriate to their clinical-risk classification and provide evidence of independent, external validation before clinical use.[22,24,29] Thresholds reported in the literature for high-risk diagnostic applications often exceed 90% for accuracy or similar metrics, but these figures are illustrative, not prescriptive. Regulators evaluate adequacy of performance evidence relative to risk classification, intended use, and validation context.[22,24,29,41,54]

3. Orthodontists should require sufficient explainability for every AI-generated recommendation to ensure safe and informed clinical use.[13,22] Use only systems that provide interpretable outputs, such as confidence scores, visual saliency maps, or feature attribution tools, and confirm that these explanations are accessible and understandable to the clinician.[6,48] Orthodontists should be able to interpret, question, and override results as the HIC, maintaining final accountability for clinical decisions.[24,47,52]

4. Orthodontists should review AI-assisted decisions periodically to detect performance drift or unsafe outputs and remain informed about software updates or retraining events that could affect clinical behavior.[22,24] Any deviations or unexpected outcomes should be documented, and concerns reported to vendors or regulators to support continuous postmarket surveillance and system improvement.[6,19]

5. Orthodontists should request PVRs, update histories, and documentation of known system limitations to verify that AI tools remain transparent, validated, and regulatory-compliant.[22,29] Clinicians should decline or discontinue use of tools that lack adequate transparency, fail to demonstrate safety or regulatory compliance, or do not provide sufficient evidence of validation.[22,28] Providing structured feedback to vendors when performance or risk diverges from clinical expectations supports accountability and continuous improvement across the AI lifecycle.[24,29]

6. Orthodontists should participate in continuing education (CE) that focuses on the ethical use, explainability, and regulatory oversight of AI/ML SaMD to ensure competent and responsible implementation in clinical practice.[1,6,13,41] All team members should understand system functions, limitations, and escalation protocols to maintain safe, informed integration of AI technologies into patient care.[21,41]

VI. Core Principle 4: Patient Autonomy

Respect for patient autonomy requires full transparency about both the use of AI in clinical care and the use of patient data in AI development, validation, or retraining.[13,39,45,55] Patients have the right to know when AI tools are involved in their diagnosis or treatment and when their data, whether identifiable or de-identified, contribute to AI system improvement.[13,22,39,56] Clinicians and developers should ensure that data governance and auditability standards are in place to document dataset provenance, composition, and secondary use consistent with ethical and technical best practices.[28]

AI algorithms rely on large volumes of clinical data to learn, predict, and assist in decision-making. In orthodontics, these datasets are often privately owned and not subject to external review, raising concerns about data provenance, diversity, and consent for secondary use.[45,55] The unregulated collection and reuse of patient data for model training can erode public trust, amplify bias, and compromise data integrity.[13,56,57]

Orthodontists should disclose when AI tools meaningfully contribute to patient care and ensure that patients are informed if their de-identified data are used to improve or retrain algorithms.[13,30,39] Communication should be clear, concise, and patient-friendly, emphasizing the supportive, not substitutive, role of AI in clinical decision-making.[13,58]

Risks to Patient Care from Lack of Disclosure and Transparency

Failure to establish clear disclosure and transparency standards for the use of AI and patient data in orthodontic care may result in:

1. Erosion of patient trust and diminished public confidence in orthodontic providers and emerging technologies when AI use or data handling is not openly disclosed[13,41,58]

2. Legal and ethical exposure for clinicians if patients are unaware that AI contributed to their care or that their data were used for algorithm development or retraining.[22,39,53]

3. Compromised clinical accountability and oversight when AI-generated recommendations are applied without sufficient human verification or without disclosing their use to patients.[24,29,30]

4. Propagation of bias and inequity, as undisclosed algorithmic limitations and non-representative datasets may produce variable accuracy across patient populations, exacerbating healthcare disparities.[43,45,55,57]

5. Loss of patient autonomy and recourse, as lack of transparency limits patient understanding, informed participation, or the ability to question or refuse AI-supported recommendations.[13,39,58]

Call to Action

The AAO urges state dental boards and legislatures to take immediate action by recommending that:

1. Clinicians document in patient records when AI or AI-enabled tools meaningfully contribute to diagnosis, treatment planning, or care delivery, and when patient data, whether identifiable or de-identified, are used to support AI system development, validation, or retraining.

2. Communication standards should be established to ensure patients receive clear, patient-friendly explanations of how AI supports their care and how their data may be used, including the technology's capabilities and limitations, and the orthodontist's ongoing oversight.

3. State-level policies and guidance align with national and international AI governance frameworks to safeguard patient rights, ensure data privacy, and uphold ethical standards for transparency and accountability.

4. Education and professional training initiatives should be supported to equip dental professionals with the knowledge and skills to use AI responsibly, communicate transparently with patients, and uphold robust data governance and cybersecurity practices.

VII. Core Principle 5: Education and Clinical AI Competency

As licensed healthcare professionals, orthodontists carry both an ethical obligation to patients and legal accountability for the technologies they integrate into care. Education in AI must therefore extend beyond basic literacy to encompass the knowledge and judgment required to evaluate, implement, and manage these tools responsibly. Orthodontists serve as the HIC at the point of care, exercising comprehensive oversight that includes selecting appropriate AI systems, verifying their clinical validity, ensuring their use aligns with licensure, and maintaining accountability for every AI-supported decision. Through structured education and deliberate competency development, orthodontists can ensure that AI strengthens professional judgment rather than replaces it.

Understanding how AI tools are developed, how their training data are sourced and validated, and how these models evolve through continuous learning is essential to protecting patient safety and professional integrity. Because AI systems are dynamic and may change over time, orthodontists must verify that each tool remains clinically validated, used within its intended context, and subject to ongoing human oversight.

Continuous, standardized education across all stages of training and professional practice is critical to fulfilling this responsibility. By advancing AI literacy throughout the profession, orthodontists can safeguard patient welfare, uphold clinical accountability, and lead in the responsible and ethical integration of emerging technologies.

AI Education Framework: Three-Tier Competency Model

1. Foundational AI Literacy

Orthodontists working directly or indirectly with AI tools should develop a basic understanding of AI principles, including ML fundamentals, data bias awareness, and AI's role in orthodontics. To ensure responsible implementation, continuous human oversight, clinical agency, and ongoing validation are essential.[1] There is a strong need to provide CE for clinicians, along with recommendations for orthodontic programs to incorporate AI literacy into their curricula. AI tools are increasingly being integrated into dental and orthodontic training programs, enriching professional development through simulations, diagnostic tools, and virtual patient models. These technologies enhance diagnostic and treatment planning capabilities while equipping clinicians with modern tools to improve care, efficiency, and precision.[45,59] It is imperative that the end user understands the limitations of an AI system as well as who bears the responsibility in patient care.[60]

A core curriculum should outline essential knowledge that dental professionals must possess regarding AI. This curriculum must emphasize basic definitions, ML types, the role of training-validation-testing splits, and the concept of dynamic versus static AI systems. It should also underscore the importance of understanding AI explainability, reference tests, and the black box nature of most models—skills vital for building foundational AI literacy among clinicians.[2] While AI applications show significant promise, manual supervision is still required to mitigate errors and variability. Continuous education for orthodontists is crucial, as it equips them with the ability to critically assess AI outputs, understand the underlying algorithms, and recognize their limitations. This ongoing education reinforces the importance of human expertise in validating AI-driven decisions and encourages the responsible use of these technologies in clinical practice.

Preclinical & Residency Programs

AI competencies should be integrated across undergraduate and postgraduate levels through a domain-based structure: understanding AI foundations, identifying dental-specific use cases, evaluating AI technologies, and addressing ethical or governance issues. This structure encourages the development of case-based learning, AI simulations, and outcome-based instruction, aligning well with the needs of orthodontic training programs aiming to blend AI into clinical learning environments..[55]

Integrate AI literacy, diagnostic simulations, and case-based virtual learning modules into orthodontic education to prepare future clinicians with foundational and applied AI competencies. Examples are as follows:

a. Simulation of Clinical Environments - AI-driven simulations can be used for training on orthodontic procedures and patient management.

b. Virtual Patients and Case-Based Learning - Implementation of virtual patients with AI-driven decision-making to simulate real-life cases .[61] Generative AI tools can be used to enhance automated feedback systems, providing immediate, personalized feedback on residents' clinical performance and treatment planning while fostering critical thinking and decision-making; and

c. Personalized Learning Paths AI-Powered Diagnostic Tools - Integration of AI in teaching students to interpret diagnostic data and its metrics.[62]

2. AI Training for Clinical Readiness

Orthodontists should receive hands-on training using AI-powered tools for cephalometric analysis, treatment simulations, appliance design, etc. Training should include interpreting confidence scores, identifying uncertainty, assessing bias, and understanding AI-generated outcomes.[27,41] Integrating AI into dental education and training presents both opportunities and responsibilities. As Kim et al.[63] emphasize, AI tools should augment clinical decision-making, not replace it. One key challenge is addressing inherent biases within AI algorithms, which may exacerbate health disparities if left unchecked.

Ethical AI education must help clinicians understand AI’s limitations, critically assess its outputs, and navigate concerns such as data privacy, security, and regulatory compliance. A stepwise integration approach is recommended, allowing orthodontists to build competency and confidence progressively as they adopt AI technologies into clinical practice.

Furthermore, it is essential to have hands-on experience with the typical architecture of AI tools, including backend algorithms, cloud-based inference systems, and model modularity. The curriculum also teaches learners how to evaluate AI systems using performance metrics such as accuracy, sensitivity, specificity, and Dice scores, enabling orthodontists to effectively assess AI outputs. These structured training elements equip clinicians to critically interpret diagnostic models and recognize how biases or low generalizability can impact treatment quality.[55]

3. Continuous Learning

Current and future applications of AI in orthodontics necessitate that licensed professionals continuously update their knowledge and skills. Ongoing education ensures that orthodontists can make informed, ethical decisions when selecting, validating, and supervising AI tools for clinical use. Continuous learning should highlight both the opportunities AI presents to improve accuracy, efficiency, and personalization of care, and the ethical challenges it introduces related to bias, accountability, and data governance.

The curriculum for AI education in orthodontics must be adaptable and evolve continuously, keeping pace with AI advancements and changing regulations. As part of their ongoing professional development, orthodontists should stay current on emerging concepts such as algorithmic explainability, risk-based regulation, and interdisciplinary oversight. This will enable them to responsibly adapt their clinical use of AI tools as these technologies progress.[55]

Risks to Patient Care from Lack of AI Training

Untrained clinicians may misunderstand AI's performance metrics, apply models beyond their intended use, or assume unjustified confidence in AI-generated outcomes. Challenges related to AI use, such as lack of generalizability, dataset bias, and over-reliance on opaque black box systems, can all compromise patient safety if clinicians are not adequately trained to supervise AI outputs critically.[55] The following are risks to patient care related to lack of clinicians' AI training:

1. Misinterpretation of AI Outputs Leading to Treatment Errors
Orthodontists without proper training may misinterpret AI-generated recommendations, increasing the risk of diagnostic errors and poor treatment planning.[10,13,18,41]

2. Over-Reliance on AI Without Critical Evaluation
There is a risk that residents and clinicians may become overly reliant on AI and neglect to develop critical thinking and problem-solving skills.[64] First, unquestioning acceptance of AI-generated outputs can lead to misdiagnosis or delayed diagnosis if errors or algorithmic biases go undetected. Second, complex or atypical cases often fall outside the scope of AI training datasets. Patients with rare conditions or unique variations may require adaptive reasoning and clinicians who have not developed strong problem-solving skills may struggle to manage such cases. Third, over-reliance on AI risks an erosion of clinical judgment and patient-centered care. Effective orthodontic treatment extends beyond technical outputs; it requires weighing psychosocial, ethical, and contextual factors. A clinician dependent on AI may undervalue these dimensions, reducing patient trust and satisfaction. Finally, a lack of critical evaluation skills may prevent clinicians from recognizing biases in AI systems. If training data are not representative of diverse patient populations, AI outputs may disproportionately misguide treatment in underserved groups, leading to inequities in care delivery.

3. Ethical and Regulatory Non-Compliance
Lack of training on AI ethics, transparency, and evolving regulations can lead to violations of scope-of-practice laws or device misuse, resulting in legal liability and disciplinary action.[50,51,53] Patients may be exposed to unvalidated or improperly supervised AI tools, increasing the likelihood of harm from inappropriate treatment recommendations or device failures. Regulatory non-compliance can also undermine patient safety safeguards built into healthcare oversight systems, leaving patients vulnerable to unsafe technologies.

4. Erosion of Clinical Authority
If clinicians are not equipped to oversee AI tools, there is a risk that critical decision-making shifts from providers to software, thereby undermining the orthodontist's central role in patient care.[30,53,65] When AI assumes an unchecked role in decision-making, patients may receive care that is technically consistent with algorithmic outputs but misaligned with their individual needs, values, or preferences.

5. Delayed Adoption and Innovation Fatigue
Without targeted training and support, clinicians may feel overwhelmed or skeptical of AI, slowing adoption and widening gaps between clinical practice and innovation.[18,30,64,66] Delayed adoption of validated AI tools can slow access to innovations that improve diagnostic accuracy, efficiency, and personalization of care. Conversely, clinician burnout from poorly supported implementation may reduce the quality of patient interactions and overall care delivery. Patients are therefore indirectly affected when clinicians lack the training and resources to adopt AI responsibly.

Call to Action: Implementing AI Training in Orthodontic Education

To prevent avoidable patient harm and professional liability, the orthodontic profession must act now to close the AI training gap.

The AAO calls for the following from orthodontists, vendors, and institutions:

1. Integrate AI coursework into preclinical and residency programs
To ensure that future orthodontists are equipped to interpret, supervise, and responsibly use AI in clinical care, AI coursework should be integrated into both preclinical and residency-level education. This integration must go beyond general exposure and include basic structured instruction in core concepts such as ML fundamentals, training-validation-testing models, performance metrics, and AI explainability.

Clinical modules should introduce practical applications of AI, including its supporting role in diagnostic simulations, cephalometric analysis, treatment planning, and appliance design. The curriculum should also emphasize ethical use, regulatory awareness, and the clinician's ultimate accountability when employing AI-assisted tools.[54,55,67]

2. Establish AAO-led continuing education courses
To ensure consistent, safe, and ethical integration of AI in orthodontic practice, we call on the AAO to develop continuing education (CE) courses. These courses should offer CE that prioritizes clinical oversight, ethical application, and regulatory compliance. CE courses should clearly define the orthodontist's role as the supervising authority over AI-assisted diagnostics and treatment planning particularly for tools categorized as SaMD and tools implemented in electronic health systems.

The CE should include training on critical topics such as interpreting AI performance metrics (e.g., sensitivity, specificity, Dice scores), managing uncertainty and bias in AI outputs, understanding FDA and IMDRF classifications of AI tools, and applying principles of human oversight and autonomy as outlined in international guidelines. This approach will not only standardize clinician readiness but will also support legal and ethical accountability.[55,68]

3. Stimulate vendor-sponsored training programs
Vendors who develop and distribute AI tools for orthodontic applications must play an active role in clinician education. We recommend requiring that all AI systems introduced into patient care be accompanied by structured, vendor-sponsored training.

This training should clearly explain the tool's intended use, functional scope, data limitations, and necessary safeguards for safe implementation. It should also include practical demonstrations of how the system processes information, interprets clinical inputs, and generates outputs. By formalizing vendor responsibility in the education pipeline, we strengthen accountability, reduce misuse, and promote a culture of shared responsibility between developers and clinicians for patient outcomes.[69]

4. Promote Faculty Development in AI Education
To successfully integrate AI into dental education, faculty members must be provided with sufficient AI training. This is essential due to current studies indicating that a considerable number of dental educators possess limited AI literacy.

This lack of knowledge can obstruct the effective adoption of AI technologies in dental education. Therefore, comprehensive training programs that concentrate on AI applications in dentistry should be provided to faculty members by the school administrators. This will allow them to confidently incorporate AI technologies into their curricula, ultimately improving the standard of dental education.

VIII. Core Principle 6: Operational Integration and Data Privacy

Operational integration and data privacy are foundational to the responsible use of AI in orthodontics. Without secure, interoperable systems that protect patient information and function reliably within clinical workflows, even the most advanced AI tool cannot deliver safe or effective care. Fragmented data infrastructures, inconsistent interoperability standards, and variable vendor accountability create tangible risks to safety, efficiency, and public trust.[6,7,22,28,29] As AI tools become increasingly embedded in diagnostic and treatment processes, their reliability and safety depend not only on algorithmic performance but also on the integrity of the data infrastructure, interoperability of connected systems, and clearly defined professional accountability for their use.[6,14,22,28,29]

Risks to Patient Care from Interoperability and Data Standardization Challenges

Seamless integration of AI tools into practice management software, imaging platforms, and electronic health records presents ongoing challenges that can jeopardize efficiency, accuracy, and patient safety if not properly addressed.

1. Lack of Data Standardization and Interoperability

Without consistent data standards, AI systems in orthodontics risk misreading or corrupting patient information as data move between platforms.[6,28] Even minor mismatches in file formats or communication protocols can cause loss of critical health data or introduce diagnostic and treatment errors that compromise patient safety.[21,70]

2. Limited AI Adoption Due to Interoperability Barriers

Failure to establish consistent interoperability standards across AI systems and clinical platforms can hinder adoption, reducing efficiency and delaying access to advanced diagnostic and treatment technologies.[6,21,22,28]

3. Inequitable Access Due to Inadequate Interoperability

When interoperability standards are fragmented or inconsistently adopted, smaller or resource-limited orthodontic practices face disproportionate barriers to implementing AI technologies. These disparities slow adoption, limit access to advanced diagnostic and treatment tools, and risk widening gaps in care quality across patient populations.[14,29]

Data Privacy and Ethical AI Use

The responsible integration of AI clinical tools into orthodontic practice requires a consistent focus on safety, interoperability, and patient data protection across all stages of use.[6,14,22,28,29]

AI systems that manage patient data must comply with privacy and security regulations, maintaining encryption, access control, and secure storage to prevent unauthorized access or misuse.[6,20,22] Ethical governance of these systems ensures that AI-supported recommendations preserve patient autonomy, transparency, and clinician oversight, reinforcing the orthodontist's responsibility for protecting patient trust and information integrity.[13,14,29]

AI systems that handle patient data must comply with privacy and security regulations to prevent unauthorized access, misuse, or data breaches. Compliance with the U.S. Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act, together codified at 42 U.S.C. Chapter 6A, Subchapter XXVIII, and related provisions of Chapter 156, as well as with international and technical standards such as ISO/IEC 42001 and 27001, ensures that patient information is protected through secure design, encryption, and controlled access.[6,20,28,29,71,72]

Risks When Data Privacy Is Not Upheld in AI-Enabled Orthodontics

1*. Patient Data Breaches and Unauthorized Access*

Weak encryption, inadequate access controls, or insecure data sharing expose sensitive health records to cyberattacks, theft, and misuse, violating HIPAA and eroding patient trust.[6,20,71,72]

2. *Corruption or Loss of Clinical Data*

Poor governance or inconsistent data standards can cause information loss or corruption during storage or transfer, resulting in diagnostic errors, disrupted treatment continuity, and compromised patient safety.[6,22,28]

3. *Unauthorized Secondary Use or Re-identification of Patient Data*

Inadequate de-identification and lack of transparency allow vendors or AI developers to repurpose clinical data for algorithm training or commercial use without consent, breaching ethical and legal standards.[5,13,14]

4. *Regulatory Non-Compliance and Legal Liability*

Failure to meet HIPAA, HITECH, or ISO standards exposes orthodontists and vendors to regulatory fines, breach-notification obligations, and potential litigation for patient harm or data misuse.[28,29,71,72]

Call to Action: Strengthening Operational Integration and Data Privacy in Orthodontic AI

1. *Adopt and enforce standardized data-exchange protocols* such as HL7 FHIR (Health Level 7 Fast Healthcare Interoperability Resources) and DICOM (Digital Imaging and Communications in Medicine) across orthodontic systems to prevent data loss and diagnostic error.[6,28]

2. *Mandate compliance with HIPAA, the HITECH Act, and ISO/IEC security frameworks* to ensure robust encryption, access control, and breach-response capabilities.[6,20,71,72]

3. *Require vendor transparency and data-use governance,* including disclosure of how patient information is collected, stored, and used for algorithm development.[5,13,14]

4. *Provide equitable support for practice modernization,* offering technical guidance or funding mechanisms to help smaller practices meet interoperability and security standards.[14,29]

5. *Institutionalize continuous education on AI data ethics and cybersecurity,* ensuring clinicians and staff remain competent stewards of digital health information.[13,14,28]

Call to Action: Framework for Evaluating and Implementing AI Tools in Orthodontics[‡]

As AI continues to shape orthodontic diagnostics, treatment planning, and workflow design, orthodontists must adopt a structured, evidence-based approach to evaluation and implementation. A three-phase model consisting of Evaluate, Implement, and Monitor provides a foundation for the responsible integration of AI clinical tools in orthodontics.

Evaluate

Orthodontists should identify specific clinical needs, verify that AI tools are validated on diverse, high-quality datasets, and confirm that each system complies with applicable regulatory and technical standards, including FDA, IMDRF, ISO, HIPAA, and HITECH requirements. Careful assessment of workflow compatibility and vendor transparency ensures that AI adoption enhances precision, safety, and efficiency rather than introducing new risks.

Implement

Pilot AI tools on a limited number of clinical cases before full deployment, ensuring performance aligns with clinician benchmarks and established quality measures. Staff must be trained to validate AI outputs, recognize system limitations, and maintain transparency with patients regarding the role of AI in their care. Integration should align with state licensure requirements and uphold the orthodontist's HIC responsibility.

Monitor and Educate Continuously

Clinicians must conduct regular audits to monitor accuracy, bias, and real-world reliability, while maintaining ongoing education in AI ethics, cybersecurity, and data governance. Collaboration with vendors and professional organizations ensures continuous improvement and regulatory compliance.

[‡]*A detailed version of this framework, including step-by-step guidance, case examples, and performance benchmarks, is available as a supplemental guide: Framework for Evaluating and Implementing AI/ML SaMD in Orthodontics.*

IX. Conclusion

The framework and Core Principles outlined in this document provide a roadmap for the safe, equitable, and effective adoption of AI in clinical orthodontics. They emphasize that orthodontists remain accountable for technology selection, validation, and oversight; that developers share responsibility for the ethical design, transparency, and secure deployment of AI tools; that data integrity and patient privacy must never be compromised; and that continuous education is essential to sustain clinical readiness in a rapidly evolving digital landscape.

As AI systems become increasingly integrated into diagnostic and treatment workflows, they hold the potential to usher in a new era of precision orthodontics, where diagnostic accuracy, treatment planning, and patient monitoring are tailored to individual characteristics, mirroring the progress achieved in precision medicine. To realize this promise, the orthodontic profession must lead in defining the standards for responsible AI use. This leadership requires collaboration among clinicians, educators, vendors, and regulators to uphold transparency, protect patients, and preserve public trust.

The American Association of Orthodontists envisions a future in which AI integration strengthens both the science and the art of orthodontics, advancing innovation while preserving humanity in care. By prioritizing patient safety, ethical governance, and clinician oversight, orthodontists can ensure that AI becomes not a replacement for expertise but a reflection of it, a tool that amplifies the profession's enduring commitment to excellence and the well-being of every patient.

X. Appendix

Table A1: Diagnostics

AI Capability	AI Functionality	Benefits	Limitations	Referenced Studies
Cephalometric Analysis	Automates landmark detection with high accuracy	Reduces variability, increases efficiency	Requires validation against diverse datasets	Schwendicke et al.[1]; Lin et al.[18]; Nordblom et al.[41]; Kim et al.[73]; Mohammad-Rahimi et al.[74]; Strunga et al. [75]
CBCT Segmentation	Automates craniofacial structure segmentation	Enhances detection of skeletal discrepancies	Accuracy depends on imaging quality	Wang[76]; Scarfe et al[77]; Gillot et al.[78]
TMJ Diagnostics	Analyzes imaging, clinical, and biomarkers for early TMJ OA detection	Allows early intervention and prevention	Limited by dataset diversity	Bianchi et al.[79]
Orthognathic Surgery Planning	Integrates cephalometric data for precise treatment planning predictions	Improves surgical outcomes and planning	May require extensive model validation	De Oliveira et al.[80]

Table A2: Treatment Planning

AI Capability	AI Functionality	Benefits	Limitations	Referenced Studies
Simulating Treatment Outcomes	Generates visual treatment progress simulations	Enhances patient education and engagement	Does not account for biological variability	Kazimierczak et al.[81]
Models that Simulate Predictive Treatment Outcome Models	Uses deep learning to forecast patient-specific tooth movement	May potentially improve precision in treatment adjustments	Subject to deviations due to bone remodeling	Volovic et al.[82]; Wang et al.[83]

AI Capability	AI Functionality	Benefits	Limitations	Referenced Studies
Optimizing Aligner Therapy	Enhances sequencing and attachment placement based on ML analysis	Improves treatment planning predictability and efficiency	Depends on real-time compliance tracking	Khanagar et al.[17]; Castroflorio et al.[84]
Simulation of Predicting Tooth Movement	AI models analyze biomechanical patterns and real-world cases to refine tooth movement simulations predictions	Enhances virtual tooth movement simulation accuracy and force application strategies	Requires real-time monitoring to validate simulation's predictions	Wang et al.[83]; Hasegawa et al.[85]; Barone et al.[86]; Hansa et al.[87,88]
Simulating Surgical Outcomes	AI simulates/predicts post-operative facial changes in orthognathic surgery and palatal expansions	Improves treatment planning accuracy, anatomical identification, and patient visualization	Requires large datasets and extensive clinical validation	Kato et al.[89]; Ma et al.[90]; Almarhoumi[91]

Table A3: Appliance Design

AI Capability	AI Functionality	Benefits	Limitations	Referenced Studies
Custom Brackets and Aligners	AI-driven CAD/CAM optimizes appliance fit and force application	Improves treatment efficiency and personalization	Requires accurate digital impressions	Tsolakis et al.[92]; Farook et al.[93]
Custom Appliance Fabrication	AI automates tooth segmentation, collision detection, and treatment adaptation for 3D modeling	Enhances aligner and bracket customization, optimizing tooth movement efficiency	Dependent on high-quality scans and material precision	Bichu et al.[92]; Tsolakis et al.[93]; Farook et al.[94]

AI Capability	AI Functionality	Benefits	Limitations	Referenced Studies
AI-Optimized 3D Printing	Reduces production errors and optimizes material use in appliance fabrication	Ensures precision, reproducibility, and faster appliance delivery	Requires robust quality control and material validation	Tsolakis et al.[92]
Virtual Testing of Appliances	Simulates appliance behavior pre-fabrication	Reduces chairside adjustments and remakes	Needs validation with real-world cases	Hasegawa, et al.[85]; Hansa et al.[88]
Integration of CAD/CAM and 3D Printing	Automates AI-driven appliance design and fabrication workflows	Reduces manual modifications, improves efficiency, and expedites fabrication	May require additional clinical validation for widespread adoption	Tsolakis et al.[92]; Impellizzeri, et al.[95]; Hou, et al.[96]

Table A4: Remote Monitoring

AI Capability	AI Functionality	Benefits	Limitations	Referenced Studies
Remote Monitoring Systems	Analyzes intraoral images for treatment compliance	Reduces in-office visits, enhances oversight	May not replace direct clinical evaluation	Hansa et al.[87,88]
Real-Time Alerts for Deviations	AI-generated alerts for treatment inconsistencies	Allows early intervention, prevents delays	Relies on patient adherence to monitoring	Strunga et al.[75]
Improving Compliance	ML-based tracking and reminders for aligner wear	Enhances adherence and patient engagement	May require integration with patient apps	Caruso et al.[97]

XI. Abbreviations, Acronyms and Glossary

Abbreviation or Acronym	Term
3D	three-dimensional
ACP	algorithm change protocol
ADA	American Dental Association
AI	artificial intelligence
AMA	American Medical Association
AAO	American Association of Orthodontists
CAD/CAM	computer-aided design/computer aided manufacturing
CBCT	cone beam computed tomography
CDSS	Clinical Decision Support Software
CE	continuing education
COU	context of use
DICOM	Digital Imaging and Communications in Medicine
DTC	direct-to-consumer
FD&C Act	Food, Drug, and Cosmetic Act
HIC	Human-in-Command
HIPAA	Health Insurance Portability and Accountability Act
HL7 FHIR	Health Level 7 Fast Healthcare Interoperability Resources
IEC	International Electrotechnical Commission In context of ISO/IEC
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
ML	machine learning
NIST	National Institute of Standards and Technology
PCCP	Predetermined Change Control Plan
PVRs	post-validation reports
SaMD	Software as a Medical Device
SCDI	Standard Committee on Dental Informatics (with ADA)
TMJ OA	temporomandibular joint osteoarthritis
TPLC	Total Product Lifecycle
U.S.	United States
WHO	World Health Organization

Glossary

Term	Definition
AI literacy	A basic understanding of AI principles, including machine learning fundamentals and data bias awareness.
Artificial Intelligence (AI)	The FDA defines AI as "a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments." The International Organization for

	Standardization (ISO) defines an AI system as a "system that is capable of perceiving its environment and taking actions to maximize its chances of achieving its goals" (ISO 2023 6).
Artificial intelligence/machine learning Software as a Medical Device (AI/ML SaMD)	When software that meets the definition of SaMD also incorporates AI or ML, it is classified by the FDA as AI/ML-based SaMD. Due to its dynamic nature, AI/ML SaMD requires a Total Product Lifecycle (TPLC) regulatory approach
Assistive AI	Per the FDA, this refers to AI-enabled products designed to support human decision-making by providing suggestions, data, or analysis to help clinicians make more informed choices. The orthodontist remains the final decision-maker.
Clinical Decision Support Software (CDSS)	This type of software is intended to assist healthcare professionals in making clinical decisions. Digital cephalometric analysis software is an example of this in orthodontics.
Context of use (COU)	Defines the specific role, scope, and environment in which the system is intended to be used. Must be explicitly specified to ensure appropriate regulatory evaluation and oversight. The COU directly informs risk classification and determines the appropriate level of oversight needed to ensure safe, accountable use.
Digital bonding software	This software enables the simulation of bracket placement and generates a treatment-specific appliance. This is an example of Software as a Medical Device (SaMD) because the software's output directly determines how the brackets will be positioned and delivered to the patient, and because it is relied upon to perform a medical function within the treatment workflow.
Digital cephalometric analysis software	This software calculates standard angular and linear measurements (e.g., SNA, SNB, ANB) using user-identified landmarks and is an example of Clinical Decision Support Software (CDSS).
Human-in-Command (HIC)	The concept of Human-in-Command (HIC) originates in technology governance and appears in international health policy literature. In this paper, it is applied specifically to orthodontics, where the HIC is defined as the licensed orthodontist of record, consistent with American Dental Association (ADA) policy and global expectations that accountability rests with qualified clinicians. A licensed clinician retains *ultimate authority* over how AI systems are used in clinical care—including control over deployment, interpretation, and decision-making. HIC reinforces clinician accountability across all risk tiers.
Post-Validation Reports (PVRs)	Summaries of performance testing results, known limitations, and validation outcomes.
Predetermined Change Control Plan (PCCP)	A structured framework that allows for anticipated, controlled updates to AI/ML software functions post-deployment.

Software as a Medical Device (SaMD)	The International Medical Device Regulators Forum (IMDRF) defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device" (IMDRF, 2013). Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), SaMD is classified as a medical device and is subject to regulatory requirements based on its intended use and level of patient risk.
Total Product Lifecycle (TPLC)	Expanded regulatory requirements to ensure AI/ML SaMD is safe during the design, development, and deployment stages, needed due to the software's potential to adapt and change over time. This approach emphasizes both premarket validation and postmarket surveillance to prevent unsafe or biased AI tools from impacting clinical care.

XII. **References**

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