American Dental Association

SCDI White Paper No. 1106

Dentistry — Overview of Artificial and Augmented Intelligence Uses in Dentistry

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AMERICAN DENTAL ASSOCIATION STANDARDS COMMITTEE ON DENTAL INFORMATICS WHITE PAPER NO. 1106 FOR DENTISTRY – OVERVIEW OF ARTIFICIAL AND AUGMENTED INTELLIGENCE USES IN DENTISTRY

The ADA Standards Committee on Dental Informatics (SCDI) has approved ADA SCDI White Paper No. 1106 for Dentistry – Overview of Artificial and Augmented Intelligence Uses in Dentistry. Working Groups of the ADA SCDI formulate this and other specifications and technical reports for the application of information technology and other electronic technologies to dentistry's clinical and administrative operations. The ADA SCDI has representation from appropriate interests in the United States in the standardization of information and electronic technologies used in dental practice. The ADA SCDI confirmed approval of ADA SCDI White Paper No. 1106 on December 30, 2022.

This ADA SCDI white paper was prepared by ADA SCDI Working Group 13.8 on Augmented Intelligence in Dentistry. The ADA SCDI thanks the members of Working Group 13.8 and the organizations with which they were affiliated at the time the white paper was developed:

Working Group 13.8 Voting Members
Robert Faiella (chairman), Individual Representative, Osterville, MA;
Brent Accurso, American Academy of Oral & Maxillofacial Pathology, Pontiac, MI;
Stephen Connelly, Individual Representative, San Francisco, CA;
Stephen Glenn, Individual Representative, Tulsa, OK;
Kimberly Harding, Monarch Innovation Partners, Rockville, MD;
Florian Hillen, VideaHealth, Inc., Boston, MA;
Wardah Inam, Overjet, Inc., Boston, MA;
Mark Jurkovich, Health Partners, Minneapolis, MN;
Jean Narcisi, American Dental Association, Chicago, IL;
Amrita Patel, New York University Langone Medical Center, Mount Vernon, NY;
Marie Schweinebraten, Georgia Reconstructive Dentistry, Duluth, GA;
Joel White, University of California San Francisco; and
Gregory Zeller, Individual Representative, Lutherville, MD.

ADA SCDI White Paper No. 1106 Subgroup Co-Chairs

Overview & Definitions

- Gary Guest, University of Texas San Antonio;
- Greg Zeller, Individual representative, Lutherville, MD.

Clinical Use

- Christopher Balaban, Overjet, Inc., Boston, MA;
- Joel White, University of California San Francisco.

Clinical Use Subsection Contributors

Prevention/Maintenance:

- Meredith Bailey, Boston University School of Dental Medicine, MA;

- Joseph Borg, NovoDynamics, Folsom, CA.

Oral Medicine/Pathology:

- Brent Accurso, American Academy of Oral & Maxillofacial Pathology, Pontiac, MI;
- Rohan Jagtap, University of Mississippi Medical Center, Jackson, MS;
- Stephen Thad Connelly, Individual Representative, San Francisco, CA;
- Suvendra Vijayan, University of Pittsburgh School of Dental Medicine, Pittsburgh, PA;
- Greg Zeller, Individual Representative, Lutherville, MD.

Caries Risk and Caries:

- Meredith Bailey, Boston University School of Dental Medicine, MA;
- Margaret Scarlett, SCI, Atlanta, GA;
- Callan White, Individual Representative, Asheville, NC;
- Greg Zeller, Individual Representative, Lutherville, MD.

Periodontics:

- Ryan Brandon, University of California San Francisco;
- Robert Faiella, Individual Representative, Osterville, MA;
- Guo-Hao Lin, University of California San Francisco;
- John Martin, Previser Corp., State College, PA;
- Chun-Teh Lee, University of Texas School of Dentistry, Houston.

Prosthodontics/Clinical-Technical Connection:

- Kyle Stanley, Pearl Dental, Laguna Beach, CA.

Oral Surgery:

- Eric Pulver, Denti.AI, Pulver Oral Surgery, Highland, IN;
- Larry Stigall, American Association of Oral and Maxillofacial Surgeons, Boone, NC;
- Sandy Guenther, American Association of Oral and Maxillofacial Surgeons, Rosemont, IL.

Endodontics:

- Reza Farshey, BubblesEndo LLC, North Bethesda, MD;
- Dr. Rohan Jagtap, University of Mississippi Medical Center, Jackson, MS;
- Dr. Roberta Pileggi, University of Florida College of Dentistry, Gainesville, FL;
- Dr. Indaiá Leibovitch, University of Florida College of Dentistry, Gainesville, FL.

Implants:

- Robert Faiella, Individual Representative, Osterville, MA;
- Alireza Nabavizadeh, NovoDynamics, Inc., Ann Arbor, MI.

Radiology and Diagnostic Images:

- Kim Harding, Monarch Innovation Partners, Rockville, MD;
- Rohan Jagtap, University of Mississippi Medical Center, Jackson, MS;
- Sanjay Mallya, UCLA School of Dentistry, Los Angeles, CA.

TMD/Pain Sleep Apnea:

- Amreesh Khanna, Midtown Dental, Calgary, Canada;
- William Harrell, Individual representative, Alex City, AL;
- Stephen Thad Connelly, Individual Representative, San Francisco, CA.

Oral Systemic Health:

- Gene Ranieri, Individual Representative, Highland, IN.
- Eric Pulver, Denti.AI, Pulver Oral Surgery, Highland, IN.

Orthodontics:

- William Harrell, Individual Representative, Alex City, AL;
- Stephen Thad Connelly, Individual Representative, San Francisco, CA.

Non-clinical Use

- Seung Baek, Guidance Dental, Buena Park, CA;
- David Rock, NovoDynamics, Inc., Ann Arbor, MI.

Regulatory-FDA

- Wardah Inam, Overjet, Inc., Boston, MA;
- Margaret Scarlett, SCI, Atlanta, GA.

Imaging-Algorithms

- Joel Karafin, XDR Radiology, Los Angeles, CA;
- George Kotsakis, University of Texas San Antonio.

Electronic Dental Record-Teledentistry-Dental Laboratories

- Chun-Teh Lee, University of Texas School of Dentistry, Houston;
- Kyle Stanley, Pearl Dental, Laguna Beach, CA.

Workflow – Future Benefits

- David Carsten, Oregon Health Sciences University, Vancouver, WA;
- Eric Pulver, Denti.AI, Pulver Oral Surgery, Highland, IN.

AMERICAN DENTAL ASSOCIATION STANDARDS COMMITTEE ON DENTAL INFORMATICS WHITE PAPER NO. 1106 FOR DENTISTRY – OVERVIEW OF ARTIFICIAL AND AUGMENTED INTELLIGENCE USES IN DENTISTRY

Foreword

(This Foreword does not form a part of the ADA SCDI White Paper No. 1106 for Dentistry – Overview of Artificial and Augmented Intelligence Uses in Dentistry).

Artificial Intelligence (AI) and Augmented Intelligence (AuI) has been used throughout industry for several years already. If anything, its use and adoption is increasing. This white paper is designed to provide the best available information on AI available (as of early 2022) in dental imaging and other areas of dentistry where imaging may impact the use of AI (or vice versa). Dentistry will likely see many more advancements in imaging and elsewhere quickly.

The reader may find some very pertinent and useful information on where and how AI/AuI in dental imaging is currently used and impacting our profession and where it may go in the foreseeable future. It is a first step by the ADA SCDI, with much more specific detail to follow.

AI/AuI in dental imaging remains a dynamic area with considerable change taking place. This paper includes several images from various AI/AuI dental imaging vendors. Please note that no acknowledgements are provided for specific images in the document. The Working Group that developed this paper believes that the variations available in visualizations, styles or key tools provided by the vendors will change over time. Additionally, different tools and visualizations may have greater utility for one practice than another.

It is strongly recommended that anyone interested in AI dental imaging review more than one vendor in order to identify the system that best suits their needs. Therefore, the Working Group elected to “deidentify” the vendor from the image in order to prevent the potential interpretation that this document endorses a specific vendor system or that any one vendor system is superior for a specific task or tasks over another. In full disclosure, some AI vendors were involved in the development of this paper and are listed in the authorship section and their involvement provided for more comprehensive insight. Several others provided important but more limited content.

Further, this has been a collaboration of many world class experts from academia, industry and the profession in the field of AI. It is due to their dedication and efforts that this paper was possible. They contributed far more than what this summary paper can include. Much of that knowledge and information will be used in further technical reports and standards that will follow and help guide the profession forward in this exciting addition to our patient care efforts. The ADA SCDI wishes to thank everyone who contributed.

This white paper was developed at the request of the ADA SCDI Subcommittee on Knowledge Management, Gary Guest, chairman. The ADA SCDI is grateful to Mark Jurkovich for his leadership role in the development of this document.

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Introduction

Artificial Intelligence (AI) *and* ***Augmented Intelligence (AuI)*** (defined below in definitions) are increasingly used as tools in dentistry in the area where computer science supports clinical and administrative tasks that aid dental care. AI and AuI both utilize algorithms extensively.

The *Merriam-Webster Online Dictionary* defines an algorithm as a finite sequence of well-defined instructions, typically used to solve a class of specific problems or to perform a computation.[1] Wikipedia states that, "Algorithms are used as specifications for performing calculations and data processing." Even algorithms programmed to "learn to perform a task using training data" are designed by humans to perform the designated task of decision support (defined below), thus making the AI and AuI computer system tools to support people. [Algorithms vs A.I: What's the Difference & What They Mean for Medicine (medicalfuturist.com)]

Everyday life offers many examples of AI/AuI in use such as Alexa, Siri, robotics, and gaming including chess matches featuring computers versus human chess masters. Automobiles implement AI/AuI in adaptive cruise control, parking assistance, and "self-driving" vehicles. Countless other examples of AI/AuI implementations exist in daily life including numerous systems that apply AI with imaging for facial recognition or for biometrics such as retinal scans and fingerprint scans.

At the core, AI/AuI systems comprise a computer science designed to mimic human intelligence. There are a number of approaches to AI/AuI systems, which include machine learning, deep learning, cognitive computing, computer vision, and natural language processing. Machine learning involves training computing systems to look for hidden patterns in data to build analytical models. Deep learning utilizes more complex neural networks of computing systems that loosely mimic the human brain to discover and analyze complicated patterns in very large "big data" databases. Cognitive computing refers to the use of computer systems to simulate human thought processes. Computer vision uses deep learning to recognize patterns in images and videos. Natural language processing (NLP) and intelligent document processing (IDP) use AI/AuI to recognize ideas in speech and written language and to capture these ideas as digital data elements as well as to communicate with system users in ordinary language.

Forbes stated in 2018 that the most important AI and AuI areas for healthcare would be administrative workflows, image analysis, robotic surgery, virtual assistants and clinical decision support.[1]] A 2018 report by Accenture mentioned the same areas and also included connected machines, dosage error reduction, and cybersecurity.[2] A 2019 report from McKinsey states important areas being connected are cognitive devices, targeted and personalized medicine, robotics-assisted surgery and electroceuticals.[3]

A recently published systematic review[4] states, "AI models have been used in detection and diagnosis of dental caries, vertical root fractures, apical lesions, salivary gland diseases, maxillary sinusitis, maxillofacial cysts, cervical lymph nodes metastasis, osteoporosis, cancerous lesions, diagnosis of dental caries, vertical root fractures, apical lesions, salivary gland diseases, maxillary sinusitis, maxillofacial cysts, cervical lymph nodes metastasis, osteoporosis, cancerous lesions, alveolar bone loss, predicting orthodontic extractions, need for orthodontic treatments, cephalometric analysis, age and gender determination."[4] The authors also state that these dental AI tools, "…mimic the precision and accuracy of trained specialists. In some studies it was found that these systems were even able to outmatch dental specialists in terms of performance and accuracy."[4]

The first robotic dental surgery system was cleared by the Food and Drug Administration for dental implant procedures in 2017. At the end of 2017, the world's first autonomous guided dental implant placement system was developed by Zhao and colleagues in China.[5]While dentistry has seen the increasing development of AI/AuI to support clinical care as well as administrative functions, electronic dental record systems (EDRs) used in many general dental practices have fallen far behind those used by our medical colleagues, in large part because they have less standardized "structured" information available for processing. Dentistry does not regularly record diagnostic codes, various patient observables, structured health history information, risk assessment tools filled out by patients, images with standardized metadata such as patient name, date of exposure, and type of image modality, and a host of other information data points that are now common within electronic medical record systems (EMRs).

In the EMR, using AI/AuI, the collected structured data is collated and compared across populations to provide medical clinicians with more information and "*decision support*" to assist the provider in determination of issues such as recommended tests, appropriate prescribing, and differential diagnosis. It is critical to note that, while AI/AuI systems can provide the clinician with great information on population health patterns, the clinician always must decide how this information applies to the individual patient. Human providers are always in control of care decisions and may receive support from AI/AuI systems in making those decisions. As dental systems improve and allow for greater structured documentation, increased computable decision support options will become available to the profession, including evidence-based guidelines to support defined standards of care.

As AI/AuI are incorporated into the EDR, additional considerations such as security, privacy, trust, quality, safety, and data standardization will ultimately determine the reliability and validity of AI/AuI tools applied to dentistry. In addition, consumers will, in the near future, expect access to their EDR digital data, including images, as required in the federal regulations surrounding information blocking included in the 21st Century Cures Act.

This white paper will introduce the use of Artificial Intelligence and Augmented Intelligence in clinical disciplines that include prevention, caries and periodontal disease, implants, oral and maxillofacial surgery, endodontics, prosthetics, dentomaxillofacial imaging, orthodontics, temporomandibular joint disorder and sleep disorders. Promising developments in teledentistry, electronic dental records, dental laboratory uses, and scanning are additional clinical topics. The clinical section concludes with a discussion of how AI and AuI related to dental imaging might impact clinical workflow and benefit the patient, both now and in the future.

Next, the white paper provides information on non-clinical areas with an initial focus on payor topics, such as claims processing, payment integrity, and quality assurance and on dental practice administrative issues involving claims preparation, including attachments. Additional non-clinical topics include a discussion of the regulatory environment, including the global framework and the U.S. regulatory landscape, with particular focus on the U.S. Food and Drug Administration.

In addition, the white paper includes two Appendices. Appendix 1 is “Imaging and Algorithms,” which discusses key principles of machine learning training and validation and which offers the reader key questions to consider about intended use and system performance. Appendix 2 is “FDA’s Ten Principles of Good AI/Machine Learning Practices,” which details present and potential future legislation and regulations related to AI.

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1 Scope

This document introduces the use of Artificial Intelligence (AI) and Augmented Intelligence (AuI) in clinical disciplines including prevention, caries and periodontal disease, implants, oral and maxillofacial surgery, endodontics, prosthetics, dentomaxillofacial imaging, orthodontics, temporomandibular joint disorder and sleep disorders. Promising developments in teledentistry, electronic dental records, dental laboratory uses and scanning also are included.

This paper further provides information on non-clinical areas, with a focus on payor topics, such as claims processing, payment integrity and quality assurance, and on dental practice administrative issues involving claims preparation, including attachments. The document also provides information on the current regulatory environment, including the U.S. Food and Drug Administration (FDA) and the global framework.

2 Terms and Definitions

In this document, the following definitions are applied to these specific terms:

Artificial Intelligence (AI) – Intelligence demonstrated by machines as opposed to natural intelligence displayed by humans. Some AI textbooks define the field as the study of any system that perceives its environment and takes actions that maximize the chance of achieving its goals.

Augmented Intelligence (AuI) – Sometimes referred to as intelligence amplification, AuI plays a similar role to AI except that it keeps human intelligence elements in its procedure. Rather than performing an assignment for a clinician like AI might do, AuI acts as a tool to assist the clinician in the task. One aspect of The American Medical Association House of Delegates' definition emphasizes that AuI's design *enhances* human intelligence rather than replacing it.

Clinical Decision Support (CDS) – Clinical decision support provides timely information, usually at the point of care, to help inform decisions about a patient's care. CDS tools and systems help clinical teams by taking over some routine tasks, warning of potential problems, or providing suggestions for the clinical team and patient to consider.

Machine Learning (ML) – IBM defines machine learning as a branch of AI and computer science which focuses on the use of data and algorithms to imitate the way that humans learn, gradually and automatically improving its accuracy.

Training Dataset – In dental imaging, the training dataset is typically a collection of dental images, such as intraoral radiographs. The samples in the dataset will provide examples of the kinds of finding the network is to detect. For instance, the sample radiographs might have a variety of already labeled class II lesions. It is then hoped the resulting network detects those lesions as effectively as the humans who originally identified them.

Validation Dataset – For a system to be validated, there must be a reference standard to which it's held. For a human clinician, that standard may be the opinion of teachers or of a review board. But for a software system, validation is typically achieved though testing against a validation dataset of test cases, which operates as a gold standard. And because the system cannot be interrogated as to its methods, the only way to evaluate the system is by its effectiveness in those test cases.

Testing Dataset – After an algorithm is created using the training dataset and validation dataset, the testing dataset (also known as a "holdout dataset" because it is a set of data never before seen by the algorithm) may be used to verify the algorithm's ability to perform on new data.

Ground Truth (also referred to as gold standard classification) – In machine learning, the term "ground truth" refers to the accuracy of the training set's classification for supervised learning techniques. This is used in statistical models to prove or disprove research hypotheses. It is critical for each validation test case that expected findings be correct and that the *ground truth* for each case is well established. In the case of dental imaging, analysis by oral and maxillofacial radiologists (OMR) to set this *ground truth* is highly regarded, but their participation in establishing this ground truth for any specific product or service is not guaranteed.

3 How is Artificial Intelligence (AI)/Augmented Intelligence (AuI) Being Used Clinically in Dentistry?

General Dental Anatomy Use

AI/AuI is used to identify anatomy and disease.

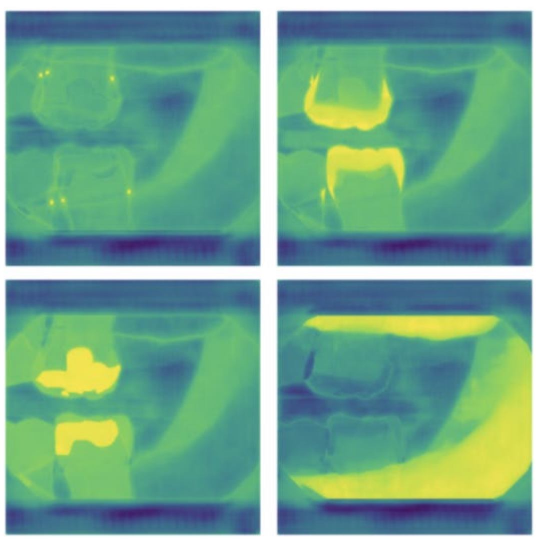

Figure 1 – Computer Vision Models Identifying Basic Oral Features
The panel illustrates images being processed by machine learning algorithms in order to detect and predict various findings of clinical importance highlighted in yellow.

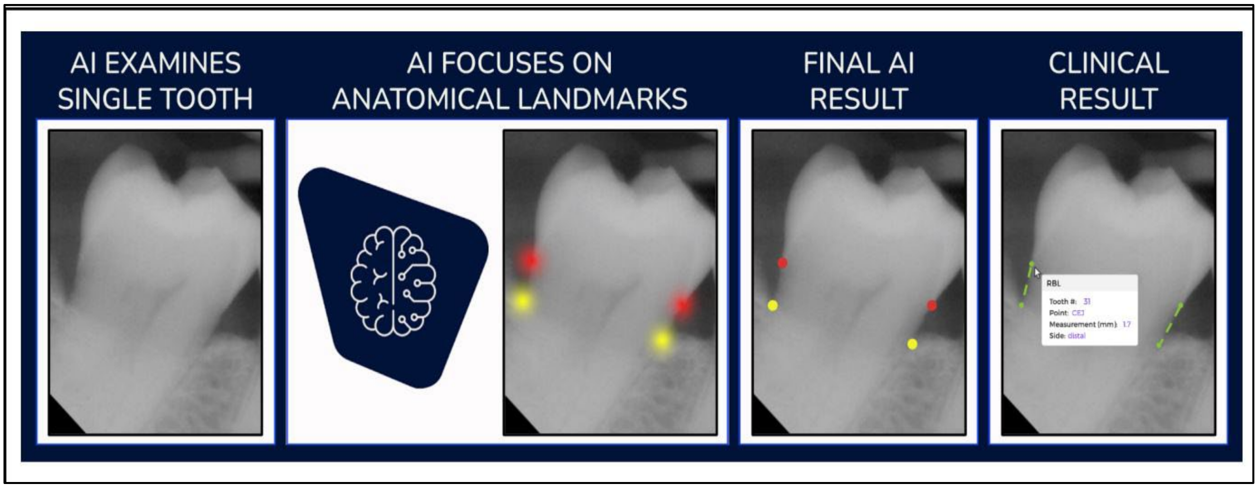

Figure 2 – Basic Example of How AI Provides a Clinical View from an Intraoral Image

Preventative and Maintenance Use

AI/AuI assisted diagnosis could allow for earlier intervention and preventative treatment with a diagnosis that can also be monitored. AI/AuI may assist dentists in many ways through continuous evaluation of their existing data. For example, periodontal disease is best treated through early intervention. Monitoring of existing data, including images, through AI/AuI will help identify changes and allow for preventative or early treatment.

AI/AuI assessment of images may also be incorporated into the treatment planning for certain preventative services, such as preventative resin restoration and space maintenance.

For the former, the decision to place a preventive resin restoration is based on clinical evaluations, patient dental history, and interpretation of diagnostic materials such as radiographic images. AI can detect and quantify the radiographic extent of caries. It could potentially generate treatment proposals, including assisting clinicians in determining the most effective and least invasive course of treatment.

For the latter, AI/AuI, using images, can aid in the detection of conditions that can lead to loss of space within a dental arch; ectopic eruption, ankylosis of a primary tooth; dental impaction, congenitally missing teeth, or other abnormal dental morphology.

Caries Detection Use

How dentists may best incorporate AI/AuI as a tool within their practices is ultimately the dentist's decision, but, as an aid to diagnosis, the technology has the potential to improve caries detection by clinicians.

Historically, caries detection was and still is achieved by clinical examination using a mirror and explorer in conjunction with a bitewing radiograph. Present use of digital imaging and scanners has improved detection, but AI/AuI has the potential to quantify and transform previous measures to improve patient treatment and outcomes.

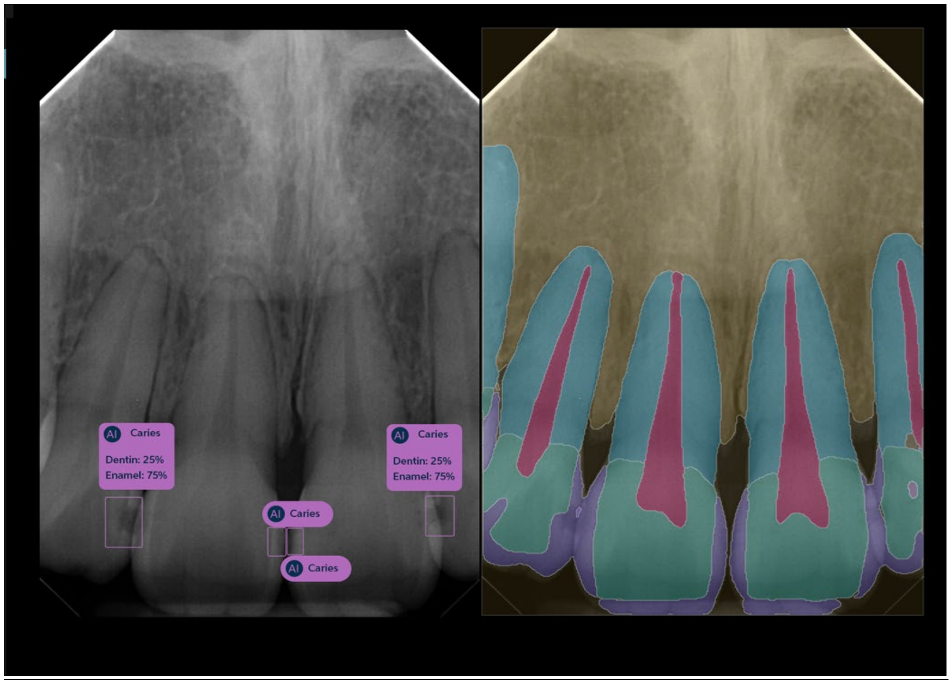

Figure 3 – AI-enabled Caries Detections and Tooth Part Segmentations, Provided by a Real-Time Chair-Side AI Radiology Interface

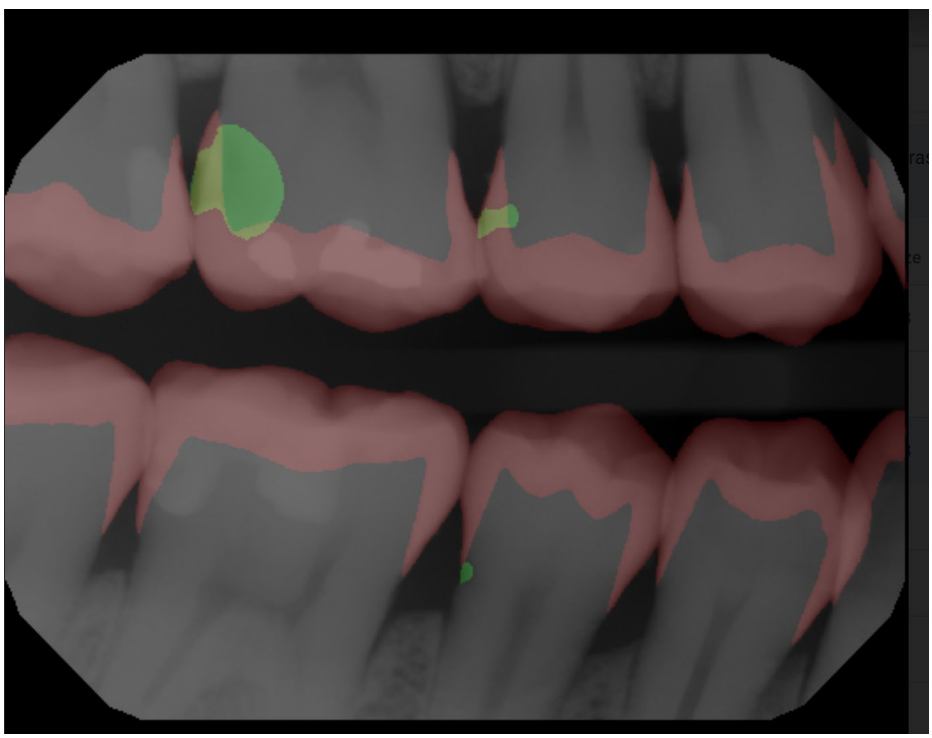

Figure 4 – AI-enhanced Image Which Shows Models Applied for Caries Identification and Quantification (Yellow) and Enamel (Red)

The ability to identify the DEJ allows for representation of carious lesion classification as well as progression or resolution in accordance with evidence-based literature.

Detection of early caries in enamel prior to formation of dentinal caries may enhance minimally invasive approaches to early caries. According to a study published in the Journal of Dentistry in December 2021, "The increase in sensitivity enabled by the use of AI was demonstrated in enamel caries, but not early or advanced dentin lesions."[7]

Currently, none of the existing dental imaging systems can differentiate active from arrested caries. One exciting opportunity for AI/AuI is to provide objective measures for baseline and follow-up for remineralization. The ability of AI/AuIto quantify the percentage of demineralization and assess trends could establish the validity of longitudinal data assessment over time as compared to a one-time, cross-sectional evaluation. AI/AuI has the capacity to "autocorrect" dental images and could not only assist in detection of active and arrested caries, but also in longitudinal patient database monitoring.

Periodontic Use

One purpose of a periodontal examination is to obtain data about clinical conditions. Common tools to obtain this data are a periodontal probe and various types of radiographic images. Several factors affect accuracy of the data using these tools.[8]

Data from a periodontal examination is required to determine diagnosis, risk, and prognosis as well as care choices. The appropriateness of the care choices is dependent on the comprehensiveness and measurement accuracy of clinical conditions assessed. Comprehensiveness and measurement accuracy are subject to clinician bias, skill, tools, and time. An inaccurate diagnosis, risk, or prognosis may occur because none are established using a standard method, set of clinical conditions, or weight for each clinical condition.[9]

Comprehensiveness and measurement accuracy of clinical conditions may be improved by AI/AuI applied to images by developing a method to automatically measure clinical conditions (Table 1).[9]

Accuracy of a diagnosis, risk, and prognosis may be improved by AI/AuI applied to images by developing a method that correlates a pattern in images to a similar pattern associated with a diagnosis, risk, or prognosis. This is important because gingival inflammation and loss of periodontal support can occur for reasons other than periodontitis. There are also many patterns of severity and distribution of clinical conditions that occur in periodontitis. Further, several categories of risk and prognosis are possible for a diagnosis of periodontitis.[10]

Using AI/AuI to assist in obtaining data about clinical conditions and establishing a diagnosis, risk and prognosis may be more efficient and accurate compared to current tools and techniques.

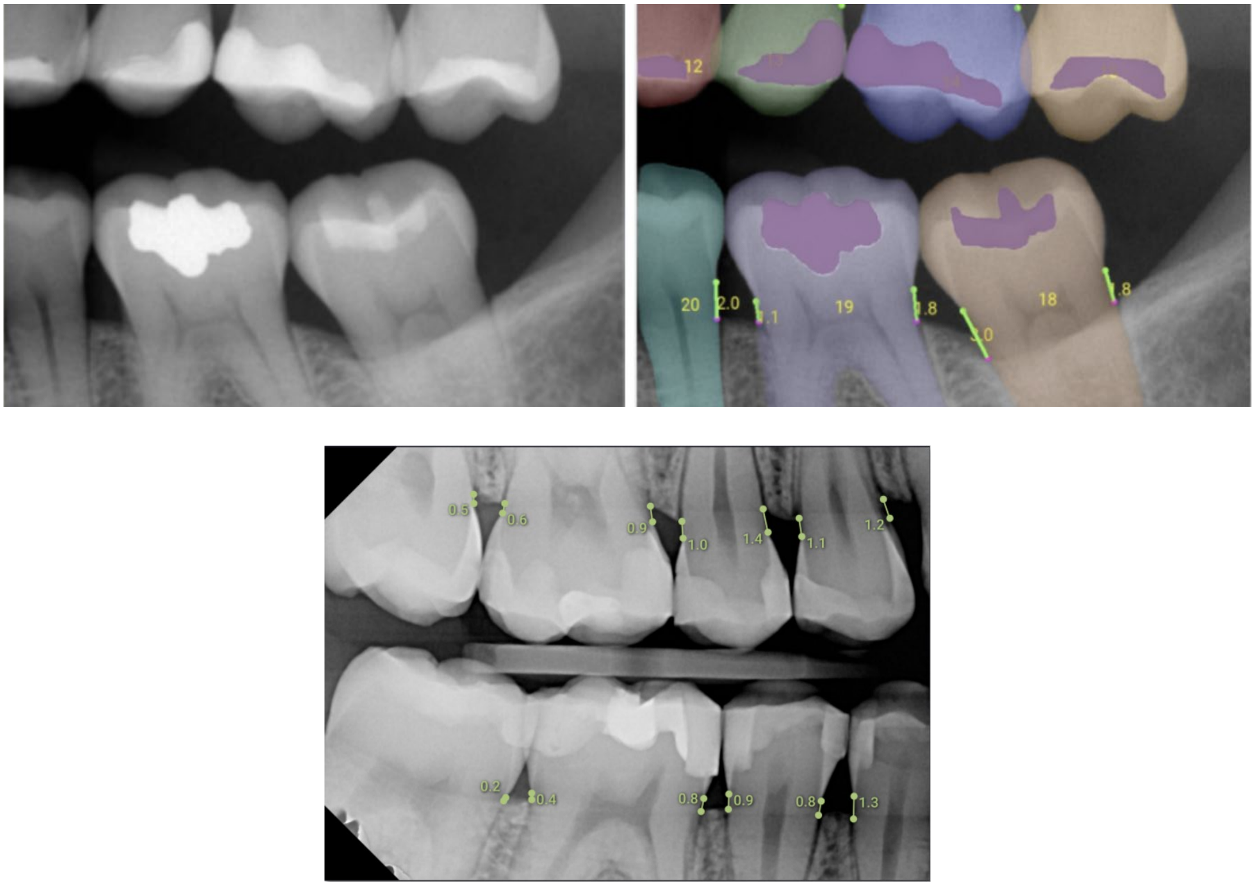

Figure 5 – Bitewing Radiograph Illustration Output
Bone level measured from CEJ to alveolar bone crest, without outputs displayed in millimeters. Additional models to detect tooth #, surface and associated restorations also visualized. Lower image indicates bone level loss with an estimated millimeter level.

Other evolutions of AI/AuI have been used to determine clinical attachment levels (CAL) and radiographic bone level. However, some challenges are encountered in evaluating dental bitewings and periapical radiographs due to the limited field-of-view of these images. A recent study using additional AI/AuI-related tools improved prediction of CAL from standard types of radiographs.

Determining radiographic bone level is important for making a periodontal diagnosis. We must also recognize that accurate interpretation of radiographic bone level is affected by individual experience and knowledge. Deep learning models, another AI/AuI tool, have been developed to assist clinicians in interpreting and measuring alveolar bone, allowing for a more accurate and reliable periodontal diagnosis. Studies have been published that describe measuring alveolar bone level on panoramic[11-13] or intraoral[14] radiographs using deep learning models. Specifically, one study demonstrated that a reliable periodontal diagnosis can be made based on interproximal bone level percentage and distance of each tooth measured by the deep learning model. Studies suggest the use of deep learning not only improves diagnosis accuracy but also significantly enhances clinical efficiency.[14]

These models require good image quality. Even with good quality, current radiographic images may lack the sensitivity necessary to capture the earliest stage of bone loss.

Additionally, many imaging capabilities are under investigation regarding the efficacy of monitoring and resolving inflammation. Future investigations are warranted to evaluate the application of AI/AuI imaging regarding measures and analyses used in the care for periodontitis (Table 1).

Table 1 – Examples of Measures, Calculations, and Analyses relevant for clinical care that may be obtained by AI applied to images

Measures	**Calculations**	**Analysis**
Severity and extent of inflammation	Rate of bone loss	Likelihood of a diagnosis of periodontitis
Pocket depth	Number of extracted teeth	Likelihood of risk for a periodontitis for its natural history
Clinical attachment level	Crown to root ratio	Likelihood of a prognosis for the natural history of periodontitis
Gingival margin from CEJ	Percent bone support	Effectiveness of treatment to prevent bone loss
Attached gingiva	Percent bone loss	Likelihood of proposed treatment to prevent bone loss
Gingival thickness	Surface area of bone support	

NOTE: Measures and calculations may apply to a tooth, sextant or other segment of a dentition, or to the entire dentition. A calculation may require images from different periods of time. Also, an analysis may require data regarding proposed or completed treatment.

Dental Implant Use

Dental implants have been broadly used to replace missing teeth since 1980. Challenges remain in design, performance monitoring and understanding of implant types and how well they work.

Various AI/AuI models have been developed to recognize the implant type in periapical and panoramic radiographs.[15-20] Similarly, AI models have been presented as reliable tools in determining the osteointegration success or implant prognosis[21-27] along with optimizing dental implant design [15-17]. In addition, a recent study showed the effectiveness of an AI/AuI model in identifying fractured dental implants using panoramic and radiographical images.[28]

The overall accuracy for AI/AuI models applied for implant type recognition ranges from 93.8 % to 98 % for prediction of osteointegration, while implant success varied between 62.4 % to 80.5 % among the related studies.

The future of implant dentistry could be focused on integration of radiographic implant images with cone beam computed tomography (CBCT) scans to enhance the accuracy of implant type recognitions. Moreover, standardization of dental imaging systems can provide a data set with higher quality for AI/AuI models, which could increase the accuracy of those models in identifying the implant type or predicting implant success.

Oral and Maxillofacial Surgery Use

Although the application of AI/AuIin oral and maxillofacial surgery is currently limited, the scope in the future may be vast. AI/AuI tools may assist Oral and Maxillofacial Surgeons (OMS) in diagnosing and planning treatment with the least possible errors.[29]

The ability to accurately classify individuals with cancer (true positives) among a pool of individuals in which a few have cancer is called sensitivity. The ability to accurately classify individuals without cancer (true negatives) is called specificity.

One study demonstrated that the use of AI/AuI tools was able to accurately predict the subgroups of internal derangements of the temporomandibular joint with very high specificity and sensitivity. The use of AI/AuI tools may help reduce the dilemma that dentists and surgeons have while diagnosing these conditions and help in the accurate prediction of treatment.[30]

Additional research has shown other promising results from the use of AI/AuI tools in the oral and maxillofacial specialty. Work has been done effectively by many researchers demonstrating that AI/AuI has great potential in simplifying the diagnosis and treatment of odontogenic cysts and tumors.[31, 32] AI/AuI tools have also been shown to aid in the early diagnosis of oral cancer detection. This can help to reduce the mortality associated with missed or late diagnosis. [31, 32] OMS are using AI technologies to assist them in precise diagnosis, the need of surgery, type of surgery, and postoperative outcomes following orthognathic surgery, with a high degree of accuracy and reproducibility.[33]

Additionally, Operation Smile and Microsoft are developing a tool that uses AI to improve outcomes after a cleft lip operation. This technology uses standardized pictures of the patient before and after the procedure to grade the result and inform the surgeon whether the outcome was satisfactory or not.[34]

The future applications of this technology can make oral and maxillofacial surgery potentially more efficient. Robotic assisted placement of implants is already a part of dental armamentarium. Trans-oral robotic surgery has gathered a lot of attention for oropharyngeal cancer surgery. Although currently no clinical trial has been done to compare the effectiveness of this technology, the initial results are very heartening.[35] With the right motivation and acceptance of new technology, the future of AI/AuI in oral and maxillofacial surgery appears bright.

Endodontic Use

AuI in endodontics is at a nascent stage [43, 44] however there are several areas where AI can support clinicians in endodontic treatment. Clinicians who do not have a strong background in interpreting radiographs will benefit immensely from these systems by helping them reach diagnostic accuracy potentially similar to that of specialists or experts.[43, 44] Dental specialists remain a critical part of not only developing AI/AuI further, but to provide sound patient outcomes in many complex cases.

In endodontics, imaging is of paramount importance as a diagnostic tool and as a modality to assess treatment outcomes. A clinician's ability to correctly interpret radiographic findings is central to the practice of endodontics. A significant issue facing dentists is the lack of consistency in interpreting radiographs among clinicians, sometimes due to the use of different imaging modalities.[36, 37]

Overall, extensive evidence shows that CBCT volumetric analysis is more accurate than periapical radiographs when detecting periapical lesions.[38-42] Dentistry is experiencing growth of the use and acceptance of CBCT.

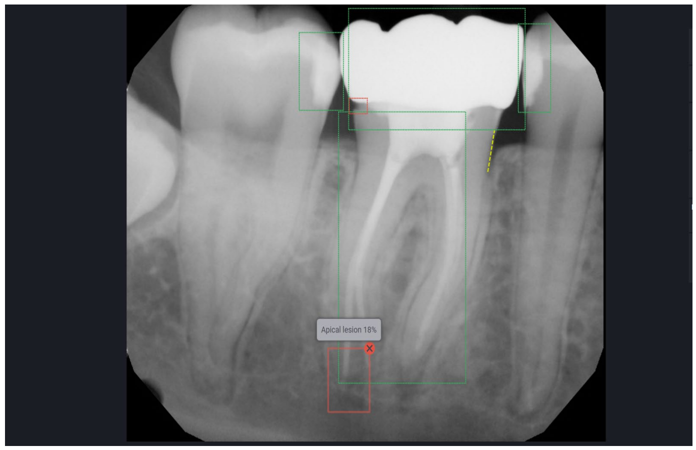

Figure 6 – Screen Shot of a Periapical Radiograph that Includes an Endodontically Treated Tooth and has been Analyzed by their AI Algorithms.

Current advances in the use of AI/AuI systems in endodontics appear to focus on the following areas:

1) Detection – A diagnostic support tool to aid clinicians in identifying periapical lesions, crown and root fractures, apical foramen determination, or assessing the quality of an existing root canal filling.

2) Pre-treatment planning – A tool to provide information such as working length determination, root and root canal system morphology such as the degree of canal curvature.

3) Prediction – AI is currently used in predicting outcome of endodontic retreatment and viability of stem cells.

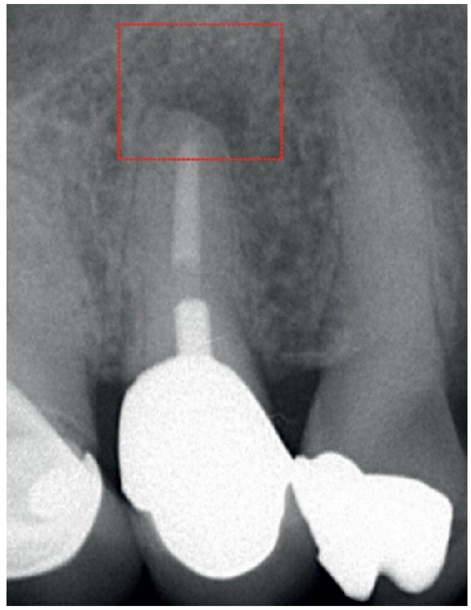

Figure 7 – Periapical Radiolucency on an Image without AI Definition

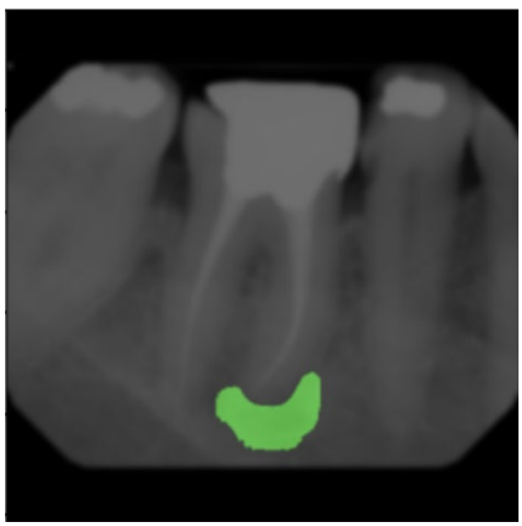

Figure 8 – Image using AI Visualization to Identify the Periapical Radiolucency (PARL)
Tracking progression or resolution of PARL's over time is a powerful tool for the clinician to have at their disposal.

AI/AuI has shown to be promising in identifying periapical pathologies. With CBCT as the imaging modality, an AI/AuI tool was successful in detecting 142 of a total of 153 periapical lesions and the reliability of correctly detecting a periapical lesion was 92.8%.[43]

Another area where AI/AuI has shown to help is in the detection of vertical root fractures (VRF). It is challenging to detect VRFs when looking at a two-dimensional radiograph without separation of the root fragments. However, there may be changes to the bone pattern suggestive of a VRF that can be identified by CBCT. Generally, CBCT is a better imaging modality for the detection of VRFs.

Using CBCT images, AI/AuI technology has demonstrated accurate diagnosis of VRFs in endodontically treated teeth, as well as intact teeth.[44]

Other areas include differentiating single vs. multiple roots in the distal root of a lower mandibular molar where one study showed high accuracy with the use of AI/AuI. [45]. Another study showed superior accuracy (96%) in locating the minor apical constriction, as compared to an endodontist (76%) using periapical radiographs.[46] For clinicians, it is very useful to obtain an accurate working length prior to endodontic treatment.

While the use of AI/AuI in endodontics is still in its infancy, the above examples show that incorporation into various aspects of endodontic care have the potential to improve accuracy in the information needed for the best care for their patients.

Dental Prosthetic Use

The laboratory side of dentistry has been a leader in technology and AI/AuI for the past 20+ years. This first started with the introduction of chairside scanning in conjunction with chairside design and milling. AI/AuI technology has been used in designing final restorations for decades. It is increasingly rare that laboratory technicians are doing traditional wax-ups for cases when a digital AI-based wax-up can be completed in seconds on most dental design software. The speed, reproducibility, and cost savings makes it efficient for the laboratory industry to incorporate these types of software into their ecosystem.

In addition, AI/AuI-based tools can assist in design of surgical guides and occlusal guards. With surgical guides being designed with only a few clicks on the intraoral scan, the dental team could place implants in an ideal position based on the restorative plan and ensure a proper fit on the digital patient model. With these digitally AI/AuI-designed surgical guides, practitioners could also utilize 3D printing in their practices to save cost and time on their implant cases.

The most recent AI/AuI-based technology to enter the laboratory space is case scoring, routing and automated margin marking. A big problem with large labs is routing their cases. A lab owner would want their best lab technician to get the most difficult cases and less experienced lab technicians to get more predictable cases that require very little guessing.

In addition, if a scan is of a minimum threshold, it can be automatically margin marked and sent to the AI/AuI-design phase without human intervention.

By utilizing AI/AuI algorithms throughout the lab process, the dental community can benefit from consistency, reproducibility, cost savings, and added intelligence to give patients the best restorations possible in the shortest amount of time.

Dental Radiology and Other Forms of Imaging Use

Applications of AI/AuI in radiology provide automatic recognition of complex patterns in imaging data and provide quantitative and qualitative radiographic assessment. The use of AI/AuI has shown very promising results in the field of oral and maxillofacial radiology.[47]

The potential clinical uses of AI/AuI in dentomaxillofacial radiologic imaging span a spectrum of end user applications. These include but are not limited to:

- Providing clinical data-driven decision trees to select the appropriate imaging examination.
- Identifying radiologic manifestations of disease. Examples: Coronal radiolucencies, periodontal bone loss, apical radiolucency, erosion of mandibular condyle.
- Interpreting radiologic findings. Examples: Caries lesions, marginal discrepancies, widened PDL's, calculus detection, periodontal bone loss, apical periodontal inflammation, TMJ pathology. Such automated interpretations may be based on radiologic image analysis alone, or may be combined information from historical, clinical, and laboratory findings.
- Applying radiomic information to predict therapeutic response and assess prognosis.
- Screening for potential disease. Examples: Osteoporosis.
- Annotating and/or segmenting anatomic structures. Examples: nerve canals, jaw bone segmentations, cephalometric analyses.
- Image enhancement and manipulation. Examples: Artifact reduction, low-dose imaging.
- Quality analysis and improvement. Example: Automated analysis of 2D- and 3D-image datasets to identify artifacts and technical errors.

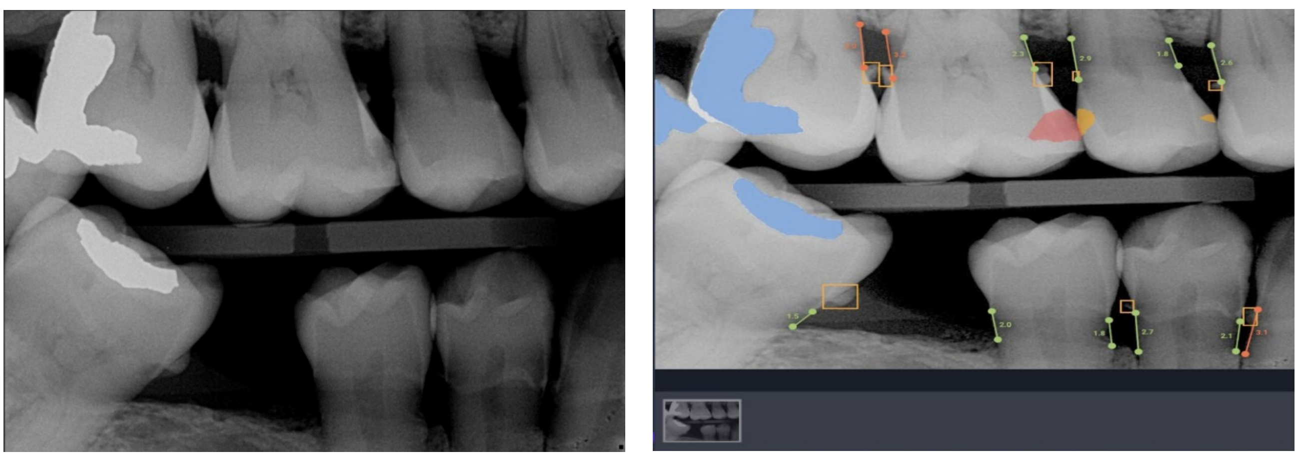

Figure 9 – Example of how AI Technology can Illuminate a Black, White and Grey Radiograph with Quantified, Precision Outputs for Doctor Communication and Patient Education

Key Questions to consider as you explore AI/AuI in dental imaging:

1) What tasks are claimed as part of the system's intended use?
2) How was it established that the validation dataset had enough images for each classification task claimed as part of intended use?
3) How was it established that the validation dataset had sufficient variety in gender, age, and ethnicity? And how was it established that there were enough images for each subpopulation?
4) Was the validation dataset sequestered from the training and testing processes?

5) If the system's intended use includes treatment planning, what rate of false positives should be expected?
6) If the system's intended use includes radiographic screening, what rate of false negatives should be expected?

Information describing how to evaluate systems using these questions can be found in Appendix 1. Additional questions for consideration can be found at the end of Appendix 1.

Future applications

Extending current techniques such as lesion detection and early lesion prediction may have major impacts on patient care.[48, 49] Image quality and quality analysis are poised for significant improvement.[50, 51] Patients may potentially see reductions in radiation exposure through application of some of these changes.[52]

Orthodontic Use

Orthodontic care has already seen significant impact from the application of various AI/AuI technologies. The dental community is well aware of the introduction and growing use of remote orthodontic care, both by those directly providing the care and by others using increasing levels of patient involvement and remote monitoring.

Growth assessment, an important element in identifying appropriate treatment has been an area of significant study in the orthodontic field. Currently, two of the most prevalent ways of growth assessment are cervical vertebrae maturation (CVM) on the lateral cephalometric image and the use of an additional x-ray, the hand-wrist radiograph. One current CVM analysis using AI/AuI algorithms reported a mean accuracy of 77.02%, which is considered very high.[53] Another AI study, using dental age, had an accuracy of over 90%, surpassing dental experts at age classification.[54]

The lateral cephalometric image is a sine qua non of a diagnostic orthodontic workup. Clinicians often spend several minutes tracing this image and variability can be high on certain radiographic landmarks, even among expert clinicians. A study on an AI/AuI-powered algorithm using convolusional neural network (CNN) showed tracing accuracy exceeding 90% and concluded that automated identification was more consistent than manual identification.[55] CNN is a network architecture for deep learning that learns directly from data. CNNs are particularly useful for finding patterns in images to recognize objects, classes, and categories.

This is just part of the story of AI/AuI use in orthodontics, however. Orthodontic care is increasingly using AI/AuI technologies for facial analysis, improving diagnostic accuracy, case design and treatment planning. Scans, model design and retainer construction are other areas where AI/AuI supported technologies are changing the care patterns and office treatment used in orthodontics.

Temporomandibular Joint Disorder (TMD) Use

We have already learned that oral and maxillofacial surgeons and others treating joint disorders can use AI/AuI-assisted imaging in accurately predicting internal derangements. Other areas of AI use in dentistry not directly associated with imaging may also assist clinicians in reaching both a proper diagnosis and best treatment plan.

Another area experiencing significant change is using AI/AuI-based nightguard design associated with intraoral scanning. These designs take into account the opposing occlusion to verify a proper bite for the patient when an appliance is worn. This AI/AuI-based design takes a very manual and challenging lab product and turns it into a highly scalable and repeatable procedure for all involved. If a patient were to lose their nightguard, or their dog decides to have a snack of plastic, the lab can simply reprint or mill the nightguard and have it shipped overnight for the patient to wear the next day.

Sleep Disorder Use

While it may not be intuitive that our various forms of imaging (radiographic, scans, visible, etc.) would be of use in addressing sleep disorders, increasingly the use of AI/AuI technologies are being investigated, along with imaging, to help clinicians and patients in this regard. Imaging helps identify the airways, obstructions, different designs, etc. As the amount and variety of imaging grows, identifying patterns through AI/AuI technologies will help in determining risk and identifying patients that would benefit from interventions.

Imaging coupled with various AI/AuI tools are already helping to do morphological analyses, classification of obstructive sleep apnea (OSA), screening and automation of landmark documentation. Future uses potentially include enhanced risk identification, remote monitoring and identification of the most effective treatment paths for patients.

Teledentistry Use

The use of both AI/AuI-based technologies paves the way for precision dentistry, focusing on providing tailored dental treatment plans and therapies for patients based on the integrated and analyzed information. Images, including radiographs, clinical photos and scanned models, are generally important for dental diagnosis, outcome evaluation and planned procedures. AI/AuI can interpret images and improve image quality to facilitate clinical decisions.

Although dental treatment cannot be remotely provided, teledentistry provides a newer approach to screen, diagnose oral diseases, and potentially help patients manage oral diseases when immediate dental care is not available. For some aspects of treatment, such as consultation and disease screening, teledentistry is comparable with face-to-face visits.[55-57]

When the data and information are collected during remote conversations or through online platforms in teledentistry, images are the most useful resources to evaluate the clinical conditions. AI can assist clinicians in interpreting these images to provide timely feedback. Additionally, many dental offices have digital records of their patients such as digital radiographs, intraoral scans, digital CBCT scans and intraoral and extraoral photographs. These existing images can aid the clinician and the AI in diagnosis and treatment planning in teledentistry.

Consultation, Triage and Diagnosis

During remote consultations, clinicians can make preliminary diagnoses and treatment plans based on the screening questionnaire, EHR/EDR and images. In addition to consultations, teledentistry can be used to triage patients who have active diseases or screen the patient's need for dental care. With the popularity of smartphones, patients can easily take clinical photos and share them with clinicians before or during teledentistry.

It is well known that radiographic images are essential to diagnose caries, periodontitis and other oral diseases. The literature has shown that radiographic images were used to triage patients who have maxillofacial trauma and decide whether these patients need surgery or other proper treatments.[58] The clinical photos taken by a smartphone were used to screen the dental conditions of children to make a preliminary diagnosis and suggest a treatment plan.[59, 60]

The clinical photos and scanned images can also be used for dental smile design.[61] These approaches are not only cost-effective but also have acceptable accuracy compared to the standard in-person screening and examination. Using AI/AuI-based technologies can further improve efficiency and efficacy in image processing and interpretation.

Monitoring

Teledentistry can also be used to monitor patient compliance and progress of treatment.[62, 63] During the COVID pandemic, clinicians used photos to remotely monitor surgically and non-surgically treated dental patients to decide whether they needed a clinical visit.[64] Photos were also used to monitor the oral hygiene of the patients who received orthodontic treatment.[65] AI/AuI can analyze and interpret these clinical photos in advance to help clinicians more efficiently screen these clinical pictures and make proper clinical suggestions, prepare their schedule and preplan for when orthodontic treatment isn't progressing as planned.

Electronic Dental Record (EDR) Use

In conjunction with reading radiographic imagery of patients and cross-referencing that output with data from the EDR/EHR, AI can help assist the dental team with understanding who has unscheduled treatment, potentially missed diagnoses and clinical opportunities to better serve their patients, based on complicated personal, medical, dental and behavioral information and the already established database in the electronic records system.

Data collection and repository

A large amount of high-quality data and a large number of images are required to develop AI/AuI-powered tools. The EDR/EHR is a great platform to store and integrate these data and images. To ensure quality and facilitate data sharing, a large and standardized database must be developed. BigMouth is an oral health database[66] populated from dental schools in the United States. It was developed from partially de-identified EDR/EHR data, including medical history, dental history, clinical findings, planned and received procedures. Radiographic images will be added in the future.

With this kind of effort, the shared data and images can be analyzed for quality management in clinical care and for research purposes, such as training and validating AI/AuI models.

Diagnosis, Treatment Planning, and Risk Assessment Based on EDR/EHR

Clinical diagnosis and treatment plans are the most important decisions that clinicians have to make based on available history, clinical findings and radiographic images. Sometimes, improper decisions might be made because of ignoring or misinterpreting information. A variety of data and images in the EDR system can be integrated to establish a knowledge network to facilitate clinical decision-making. All information can be comprehensively organized and analyzed by AI/AuI, then the reports can be provided to help clinicians make clinical decisions.

Several caries[67] and periodontal risk assessment tools[68-71] are available to assess the progression risk of caries and periodontal diseases. Similar to diagnosis and treatment planning, multiple medical, personal, and clinical characteristics have to be assessed to identify and stratify clinically distinct risk profiles. With the assistance of the EDR system, parameters included in the risk assessment models can be immediately analyzed to assign the risk profile to each patient. AI/AuI can analyze large clinical data sets and images over time to improve the clinical relevance of these identified risk factors and provide more personalized risk assessments for individuals.[72, 73]

Scanning Use

With the advance of digital dentistry, it is now common to scan teeth and tissues to replace traditional impressions. Digital scanning can reduce patient discomforts and improve clinical efficiency compared to traditional impressions. According to an American Dental Association Clinical Evaluators Panel survey in 2021, approximately half of dentists are using intraoral scanning in their practice.[74] AI/AuI is able to help the clinician identify potential errors on the scanned images, allowing them to correct possible mistakes.[72] AI/AuI can also identify anatomic structures on the scanned images to facilitate digital workflow for treatment planning and prosthetic, orthodontic and surgical device fabrication.[76- 77] In the future, facial scanning will be more widely used to plan treatment and evaluate outcomes with the assistance of AI/AuI. [78-80]

Limitations

Generally, teledentistry, EDR, and scanned images improve clinical efficiency and efficacy, but some clinicians with limited technical experience and knowledge may not be able to efficiently use these devices or software.[81, 82] In addition, some clinicians may feel AI/AuI is not more accurate than or comparable with clinicians in interpreting images and clinical information.

Quality of imagery is a major concern, as AI/AuI is based on specific data imagery. If imagery is taken by patients in their homes, the images of the extraoral and intraoral structures may be of poor quality, allowing for false-positive and false-negative results, which could be a hindrance to the dentist. It is because of this that doctors must understand the limitations of these AI/AuI systems and always know that they have the final say in the diagnosis.

In summary, the applications of AI/AuI in imaging in teledentistry, EDR and scanning are promising. Using AI/AuI technologies can improve clinical performance, efficiency and efficacy, but more studies and regulations are required to ensure its validity and reliability.

4 How Might AI/AuI Related to Dental Imaging Impact Workflow and Patient Benefits Now and Into the Future?

Workflow

Algorithms can be used to prepare, process and present digital images, including radiographs, impressions, occlusal/functional/facial analysis, periodontal charting, wear patterns and airway data to best support the provider as the final clinical decision maker. Treatment options using data and algorithmic analysis can be presented with the support of evidence-based decision making. Several examples have already been highlighted in previous sections.

Future

The use of AI/AuI can help support the creation of a real time, integrative, learning (oral systemic) healthcare system. It can provide predictive analytics based upon data collection that includes different levels of imaging and real time adaptive population health, leading to precision oral medicine. However, nonbiased algorithmic interpretation remains a challenge in all of healthcare, not just dentistry. Much still needs to be done in this area.

The generalized impact of AI/AuI could be abundant and widespread. It may lead to enhanced and timely payments for providers and an overall reduction in healthcare burden and cost for payors. A prevention model allows for identification, monitoring and early intervention. Subsequently, this can lead to a reduction of emergency room visits and costly procedures while allowing for improvement of systemic health.

Oral healthcare providers have the opportunity to be at the forefront of preventive care and offer insight into integrative health and wellness. AI/AuI algorithms will allow for digitally driven data analysis of our patient population, offering an expanded spectrum of care. This will be based upon current and past medical history, comparison of digital radiographs and impression files over time and other patient specific data. This may bring about improved outcomes based upon prevention and early intervention. AI/AuI will help aggregate and analyze a wide range of data focused upon enhanced diagnosis, treatment options, material selection, outcomes and monitoring directly benefiting patient care.

Patient Benefits

Benefits must be easily identified by patients. AI/AuI provides calibration between providers and patients. One example is creating uniformity between caries assessment scores impacting and influencing interpretation and communication between clinician and patient. Additionally, many of the firms offering AI/AuI imaging products advance the idea that it can improve patient understanding through better visualization. This may also lead to greater patient trust in the diagnostic process.

If properly and safely adopted, AI/AuI can lead to many efficiencies that should be clearly demonstrated as benefits to our patients.

5 AI/AuI in Dental Imaging and the Non-Clinical Dental Environment

An Augmented Intelligence system in dentistry is an Artificial Intelligence system designed to aid in the application of human expertise to dental-related tasks. Successful use of such AI/AuI systems results in the important tasks of dental payors, providers and clearinghouses being performed in more comprehensive, accurate and timely ways. Non-clinical uses are primarily carried out by third-party users such as payors and dental clearing houses.

The AI capabilities discussed below have been categorized as existing, commercially available capabilities, or capabilities that are in development and expected to be available in the next 3- 5 years.

Payor: Claim Processing

Currently, the primary use of AI/AuI systems is in the payor claim review process. AI can be used to validate the type and content of attachments submitted with claims and to screen radiographic images to determine whether proposed or completed treatments meet payor clinical guidelines.

Claims submitted by dental offices to payors may contain attachments. The type and content of attachments may vary based on individual payor claim submission requirements. When a claim is received by a payor, or prepared through a clearinghouse, a series of checks are performed to determine if the claim should be accepted, rejected, or returned for additional information. Part of this validation is to identify the type and content of each attachment.

Currently available products can utilize AI/AuI systems to determine whether an attachment is a radiographic image, a periodontal chart, photographs, copies of patient treatment records, or other types of correspondence. These AI/AuI products can perform the validation of submitted attachments to identify whether the required documents have been submitted, and whether the contents of the attachments include all necessary information.[83-86]

Dental offices are often required by payors to submit radiographs for select procedures. These images may be reviewed by the payor dental consultant staff. A claim may include a single radiograph or multiple radiographs (e.g., a full-mouth series).

Currently available AI/AuI products provide the ability to identify the type of radiograph, identify each tooth within a radiograph, and identify anatomic structures, existing restorations and pathologies.[87-89] AI/AuI can then detect whether the appropriate teeth and anatomic structures are present in the submitted image. If the correct information is not present in the radiograph, the claim may be returned to the dental office with a request for the correct radiographic image.

Most payors, as part of their claim review process, route a selection of claims to dental consultants for review to determine whether the service met the payor's clinical guidelines. The logistics and manpower required for such a review are such that, typically, only a small percentage of claims submitted undergo review by a dental consultant. AI/AuI systems provide the ability to perform an automated review of every radiographic image and associated attachments submitted with claims, not just a small subset.

Currently available AI/AuI products can make the review process more efficient by screening all radiographs submitted to identify those services that radiographically do not appear to meet the payor's clinical guidelines or are otherwise clinically inappropriate. The claims for those services are sent to a dental consultant for review. Claims that meet payor guidelines can complete the adjudication cycle without manual intervention. This type of prioritization of the review process significantly increases the effectiveness of the human reviewers as well as the efficiency of the overall review process.[90, 91]

Payment Integrity

Payors have an obligation as well as financial incentive to ensure appropriate use of premium dollars. This includes identifying and investigating potential acts of fraud, waste and abuse, which can include: (1) performing unnecessary services; (2) submitting a claim for a different service than was provided; (3) misrepresenting the clinical circumstance to justify payment; (4) falsifying documentation to justify payment; or (5) waiving co-payments.[83, 86]

As noted above, AI/AuI processing of radiographs, can accurately identify and segment teeth and their associated anatomy, existing restorations, and various pathologies in dental imagery. Additionally, computer vision provides the ability to create specialized representations of images, akin to a fingerprint, that can be compared to estimate the degree of similarity.[86]

These representations allow AI/AuI to compare submitted radiographs to those submitted previously in conjunction with other claims. And, importantly, using these digital fingerprints, similar images can be detected even when the images have been altered by cropping, resizing, contrast adjustment or other image manipulation techniques.[92] AI/AuI has the current capability to route any suspicious claims that have been submitted cross-patient, or under otherwise anomalous circumstances, to a dental consultant for appropriate investigation.

Payors may perform post-payment audits of claims, which may include reviews of treatment records, and associated images. An important capability now in development uses AI/AuI computer vision during post-payment reviews/audits to examine post-operative x-rays to determine if services were completed as billed and whether outcomes were within accepted practice standards.

Quality Assurance

Payors are subject to regulatory and contractual requirements to ensure consistent application of payor clinical guidelines by its professional review (dental consultant) staff.[93] A unique capability in development is the use of AI/AuI computer vision to monitor staff performance by comparing dental consultant decision making to their peers and to gold-standard AI/AuI models of performance. This can help identify training and retraining needs and help ensure consistent application of payer dental policy by its consultant staff.

Dental Practice

Claims prepared by dental offices and submitted to payors may contain attachments. The types and content of the attachments may vary based on individual payor claim submission requirements. A new capability now in development performs AI/AuI validation of claim packages at the dental office, prior to submission. Here, AI/AuI identifies whether all required documents have been included, and whether the contents of the attachments include all necessary information. Key to this comprehensive capability are AI/AuI subsystems that identify each tooth within a radiograph, the associated anatomic structures, and any existing restorations and pathologies.

Given this, AI/AuI can then determine whether the radiographic content appropriately supports the claim, or remedial steps are required before submission. The net effect of applying this capability within a dental practice is to streamline the claim adjudication process and shorten the revenue cycle.[93]

6 AI/AuI in Imaging and the Regulatory Environment

Perhaps one of the most important features to recognize about the use of AI/AuI in providing dental care is that it is *strictly a supplement to the clinician*. Dentists have the responsibility for diagnosis, prevention, care and treatment of oral diseases and conditions, under authority of state licensing agencies. Within their scope of practice, dentists use a variety of images, subjective and objective information and tools. AI/AuI provides a new tool to assist the dentist and dental team.

In addition to streamlining many routine front office and back office processes, new AI/AuI tools are emerging for the detection and monitoring of common oral diseases. Analyses of images from a variety of common dental devices is often used. These may include cameras, two-dimensional and three-dimensional radiographs, caries detection devices, and intraoral scanners. Longitudinal assessments, which can provide a glimpse into change over time, are now possible with AI/AuI, which, along with predictive data analytics, hold promise for improvements in individual, as well as population-based oral health outcomes.

The Global Regulatory Framework

There are several regulatory guideposts for future approvals, including privacy, consent for data use, equity, interoperability, transparency, validation and usability, according to the World Health Organization (WHO).[94]

In assessing AI/AuI, the practitioner must balance benefit and risks. While AI/AuI is an important and exciting decision support tool, responsibility for use, and benefits/risks for particular use, ultimately are dependent upon the decision authority of the dental professional using AI/AuI.

A global voluntary group, the International Medical Device Regulators Forum (IMDRF), provides guidance on medical device regulation. IMDRF develops internationally agreed upon guidance for medical devices. The Software as a Medical Device (SaMD) Working Group (WG) of the IMDRF supports specific guidance on innovation and timely access to safe and effective SaMD, globally. It is important to note that the recommendations of this group are strictly advisory.

The U.S. Regulatory Landscape (Jan 2022)

Food and Drug Administration (FDA) – According to the FDA, SaMD should include a validated clinical association between the outputs of the SaMD and the particular clinical conditions, as well as the data that is used for decision support with validated, private and secure technical and clinical data. This would exclude software within devices or used to run devices.

Table 2 – Clinical Evaluation Process

Clinical Evaluation		
Valid Clinical Association	Analytical Validation	Clinical Validation
Is there a valid clinical association between your SaMD output and your SaMD's targeted clinical condition?	Does your SaMD correctly process input data to generate accurate, reliable, and precise output data?	Does use of your SaMD's accurate, reliable, and precise output data achieve your intended purpose in your target population in the context of clinical care?

(Reference Diagram: https://www.fda.gov/media/100714/download)

FDA provides pre-market authorization of AI SaMD. Categorized by risk, FDA classifies use as Class I, Class II, and Class III, with Class I as the lowest risk.

FDA assesses patient safety, efficacy, use cases and risks (performance driven by use case/risk), and specifications. For example, the same tool used in the back office vs chair-side have different risk profiles, different safety and different performance measures. If a tool detects caries in the back office (for quality control), this is very different from a tool that detects caries chair-side (to aid diagnosis). The first use case has a low risk profile, while the second has a higher standard for risk and performance.[95]

Class I devices are perceived to be low or no risk. These may be exempt from FDA premarket notification (510k) and or current Good Manufacturing Practices (cGMP). Class II devices and Class III devices are subject to defined labeling, manufacturing and other requirements.

Additionally, the FDA has conducted workshops related to transparency in AI enabled medical devices and has created a list of principles for Good AI and Machine Learning practices. These can be found in Appendix 2.

7 Conclusion

This paper identifies many areas where AI/AuI have the potential for influencing the field of dentistry now and in the not too distant future. Dentistry is already beginning to see many changes including image analysis for caries and bone loss, robotic implant placement, and the many uses already implemented in prosthetic design and product construction. Many of the contributors to this paper would go further and suggest it will actually transform how dental care is delivered.

Appendix 1
Imaging and Algorithms

AI/AuI in Imaging – Algorithms and Key Questions

AI/AuI for dental image analysis is progressing rapidly. By understanding key principles of machine learning training and validation, and by asking key questions about intended use and system performance, clinicians can ensure the best patient care while reaping the benefits of an advancing technology.

AI/AuI Algorithms – The Classification Problem

Every day we are required to place a variety of situations into categories or classifications. Is the bread untoasted, under-toasted, just right, or burnt? By recognizing certain visual patterns associated with different levels of toastedness, we can classify a particular example into one of these categories. Of course, there are many kinds of patterns to notice, and many kinds of classifications to make. Is one's outfit suitable for sleep, exercise, play, or work? Is my child listless due to lack of sleep, dehydration, hunger, or emotional issues?

Because computer programs have proved capable of recognizing many kinds of patterns, they are also capable of handling a variety of classifications. By successfully recognizing features of chess positions, such a program is now the best chess player in the world. By successfully recognizing facial features, such programs now aid law enforcement in identifying suspects. And by recognizing features of the road, automobiles now warn drivers who drift out of their lane. Diagnosis can be viewed as such a recognition/classification problem. As a result, AI/AuI is well established in medicine, and has made some progress in dentistry.

The term Artificial Intelligence (AI) is often used for all these systems, but a distinction should be made. In the chess case, the system is acting independently. But in the latter cases the system acts only as an aid to the decision-maker. The term Augmented Intelligence (AuI) is often used to describe these latter cases.

Systems with Human Encoded Algorithms

One typically thinks of a computerized system as following the instructions of human programmers. So, of course one would expect that programmers could describe how the system arrives at a conclusion. For a system doing classification, one would expect programmers could describe how the system arrives at its classification findings. The terms AI/AuI have been applied to a variety of classification systems for which this is true.

One class of such systems encodes human expert knowledge into explicit rules. Called "Expert Systems," they rely on human expert knowledge. Such systems can stand alone within computers, or can be embedded into hardware systems that conduct measurements, e.g. heart monitors.

It is not always possible to reduce human expert knowledge into a set of rules. One approach for such a situation are K-Nearest Neighbor (KNN) systems. For each new sample to be classified, such a system tallies the various known samples that are most like the new one. The finding most prevalent in this tally is the finding suggested by the system.

Another approach is to reduce sets of known data to probabilities. For instance: The probability that a triangular shape is a lesion; the probability that a radiolucency is a lesion; and the probability that a particular position on the tooth has a lesion. Using Bayes Theorem, a Naïve Bayesian Classifier will mathematically combine those probabilities into a single probability, which it then uses to suggest a finding.

Systems with Machine Derived Algorithms

Humans are extremely good at recognizing human faces. But which of us can explain how we do it? And if we cannot explain our own process, a system designer must find a way to build a system without encoding any rules.

A revolution in AI/AuI began when developers began creating successful pattern recognition systems for which they could not provide a description of how the system did its classification. Most such systems are based on artificial neural networks (ANN). And although mathematics can provide an explanation of how these networks learn, and results can be measured for success, it is typically not possible to determine what patterns the network might be recognizing, or how the network uses those patterns to provide a finding.

Neural Network Learning

To the extent ANN's express intelligence, the intelligence is encoded in the details of each neuron's activation process and in the weight given to each neuron's activated output to later-layer neurons. Neural network training is a process of adjusting connection weights. Each input sample is tagged with a desired result and contributes to this training.

An intriguing aspect of machine learning is its ability to discover features in sample input. However, it is usually immensely difficult to determine what those features are. For example, one would not expect to be able to say, "The network discovered triangles in the input data, and those triangles are an important feature." This is part of a key issue with neural networks: It was the network's training process, rather than a designer that set the network weights; and it is generally not possible to know why network weights are as they are.

If training is fundamental to the performance of the network, then the training dataset of samples is also fundamental. In dental imaging, the training set is typically a collection of dental images, such as intraoral radiographs. The samples in the dataset will provide examples of the kinds of findings the network is to detect. For instance, the sample radiographs might have a variety of already-labeled class II lesions. It is then hoped the resulting network detects those lesions as effectively as the humans who originally identified them.

Human identification of findings in a dataset is called Data Labeling, Annotating or Tagging. Training to match the tagging is called Supervised Learning, which is the most common form of training for neural networks in dentistry. Since the point of such training is to mimic the behavior of the taggers, the network generally cannot improve on the taggers' expertise. Therefore, with supervised learning, one should not expect the network to detect findings the taggers could not. It is, however, possible that the network's consistency might improve upon the consistency of a tagger: Humans can tire or become distracted; neural networks do not.

A training dataset must have an adequate number and variety of samples, but generally, an increased quantity does not substitute for a lack of variety. If additional samples do not offer new views of intended findings, then the system has nothing to learn from them. A system should be expected to perform less well if its training set is less well tagged, even if the training set is larger.

System Validation

When a clinician's diagnostic ability is being evaluated, the evaluator can confirm that the clinician understands the diagnostic task, make sure that the clinician understands the features of the test case and question the clinician about the reasoning being used. In general, none of these are possible in evaluating a neural network. Though the network may report a test case as having a recognizable feature, it has no understanding of the diagnostic meaning of that feature. Though the network may encode features unnoticed by humans, we generally have no way to know what those features are or what they mean to the network's processing. And though a network may report a suggested finding, there is no practical way to question the network as to how it arrived at its conclusion. This makes objective validation of a neural network all the more important.
The Code of Federal Regulations (21 CFR 820) defines design validation as "…establishing by objective evidence that device specifications conform with user needs and intended use(s)." But what is the "intended use" of a machine learning system?

In managing the introduction of self-driving systems in cars, much attention is given as to whether a human driver must be present, whether the human must have hands on the wheel and whether the human or the system is being relied on for safe driving. These are issues of intended use. Is the driving system, like previous ones that warn of lane drift, merely an aid to the driver? Or is the system the responsible actor? Similarly, the provider of a machine learning system in dentistry should be clear and specific about the tasks included in the system's intended use; and should be clear and specific about where diagnostic responsibility lies. If human drivers are still responsible for driving safely, they must stay awake in the driver's seat, with their hands at the wheel. And if human clinicians are still responsible for diagnosis, they must be sure to treat a machine learning system merely as an instrument in their armamentarium.

Of course, a machine learning system is a complex and sophisticated instrument. So how will the clinician have confidence in what the system reports? Against what standard will the system be evaluated?

For a system to be validated, there must be a reference standard to which it's held. For a human clinician, that standard may be the opinion of teachers or of a review board. But for a software system, validation is typically achieved through testing against a Validation Dataset of test cases, which operates as a gold standard. And because the system cannot be interrogated as to its methods, the only way to evaluate the system is by its effectiveness at those test cases. Therefore, one's confidence in the system should be limited by one's confidence in the Validation Dataset.

It is therefore critical, for each validation test case, that the expected findings be correct; that the Ground Truth for each case be well established. It would be ideal to have, for each test image, conclusive determination of the disease status of the imaged area. Depending on the task for which the model is being developed, absolute "gold standard" measures such as histologic examination of Micro-CT is sometimes not feasible or practical. Post-treatment notes about cases may record actual findings, but they may be difficult to obtain. And, of course, not every accurate finding may involve treatment, and not every case requiring treatment may have had treatment and associated notes. Analysis by oral and maxillofacial radiologists is generally highly regarded, but their participation in tagging may be difficult to obtain. In practice, most validation image sets are tagged by dental clinicians, tagging which is easier to obtain but has less specificity.

The validation dataset must be sequestered from the system's training processes. Such sequestration is the only way to validate that the system's learning has been generalized beyond the specific samples encountered during training.

The Validation Dataset's scope must be adequate:

- To test for the various findings the system will be expected to detect, including findings of no disease.
- To test the system's ability to analyze images of poor quality, such as those with cone cuts or under-exposure.
- To test the system's performance among subpopulations, including patients of various age, gender and ethnicity.
- To test the system's reaction to novel images, such as images with electronic noise, images flipped from left to right, images of atypical restorations, or images that are not radiographs at all.

Ideally, all machine learning systems would be validated against the same validation dataset, allowing a direct comparison between systems. However, once the dataset became public, designers could train their networks to provide correct findings for just that data, ignoring the very large variety of real-world cases. It would be like allowing students to study from the test's answer book.

System Performance

As for many medical devices, a machine learning system's performance cannot be expressed as pass or fail. It is more useful to rate the system's performance for each of its claims. For example, how well does the system identify tooth numbers? How well does it identify a widened PDL space? How often will the system over-diagnose a lesion? How often will it under-diagnosis pulp involvement?

The needs of the user may be relevant to the questions to be asked.

- If the intended use of the system is to motivate an irreversible treatment, then the system's specificity may be most relevant: Is the rate of false positives very low?
- If the intended use for the system is radiographic screening, or clinician education, then the system's sensitivity may be most relevant: Is the rate of false negatives very low?
- If the intended use of the system is triage, then the system's accuracy (sometimes called test efficiency) may be most relevant: Is the overall percentage of correct findings high?

Machine learning systems can be sensitive to such considerations. Many can be tuned to minimize false positives, to minimize false negatives, or to achieve some combination which the designer considers optimal. In this way, a system can be tuned to meet goals related to maximizing patient care, to clinical productivity, or to business goals. Some designers even allow the user to make such adjustments, adapting the system for the task at hand.

Current Challenges for Machine Learning Systems

Establishment of Ground Truth – Most validation datasets rely on general clinicians to tag images, yet there is no consensus for credentials expected of taggers, for tagging procedures, or for required demographic information. Such consensus might improve comparability between machine learning systems.

Validation Scope and Quality – There is insufficient transparency in the quality and scope of the validation datasets currently being used. Research published in Academic Radiology (September, 2021) stated:

> "Just 9/118 reviewed AI/ML algorithms had a validation dataset sizes[sic] of over 1000 patients."
>
> "Presently, there is a lack of transparency and adequate evaluation datasets for most FDA-regulated AI/ML algorithms. The public facing FDA summaries lack information and/or data which could help estimate generalizability and robustness of several algorithms across imaging examinations performed in different geography, patient age, gender, race, socioeconomic status, equipment, acquisition, and reconstruction parameters."

Therefore, machine learning in dentistry would benefit from having a standard for the content of validation datasets, the processes by which samples are collected and the mechanisms for establishing ground truth. System designers, regulators, and users could then have appropriate confidence in the validated systems.

Responsibility – As long as clinicians are responsible for diagnosis and treatment planning, they must guard against becoming over-reliant on machine learning systems. For example:

- For a system intended merely to identify tooth numbers and automatically mount radiographs, false findings may not be significant.
- For a system intended to discover lesions, and having low false positives but high false negatives, the clinician might have high confidence in the identified lesions, but must still scan the entirety of each radiograph lest a finding be missed.
- For a system intended to discover lesions, and having high false positives but low false negatives, the clinician might have high confidence that all lesions have been identified, but must guard against the system over-diagnosing lesions.

On the validation of a machine learning system:

1. What tasks are claimed as part of the system's intended use?
2. How was it established that the validation dataset had enough images for each classification task claimed as part of its intended use?
3. How was it established that the validation dataset had sufficient variety in gender, age and ethnicity? And how was it established that there were enough images for each subpopulation?
4. Was the validation dataset sequestered from the training and testing processes?

On the clinical use of a machine learning system:

1. Is the system or the clinician responsible for diagnosis and treatment planning?

2. Are the system's findings compatible with the clinician's own?
3. Does the system report levels of confidence in its results?
4. Will the system fail catastrophically if novel input is encountered?

On the performance of a machine learning system:

1. If the system's intended use includes treatment planning, what rate of false positives should be expected?
2. If the system's intended use includes radiographic screening, what rate of false negatives should be expected?
3. To accommodate specific intended uses, can thresholds be configured to adjust these rates?

By understanding the principles underlying these questions, and pressing system providers to answer them, individual clinicians can help guide an advancing technology toward both better patient care and higher efficiencies.

Appendix 2

FDA's Ten Principles as "Good AI/Machine Learning Practices" [96]

1. The total product life cycle uses multidisciplinary expertise.
2. The model design is implemented with good software engineering and security practices.
3. Participants and data sets represent the intended patient population.
4. Training data sets are independent of test sets.
5. Selected reference data sets are based upon best available methods.
6. Model design is tailored to the available data and reflects intended device use.
7. Focus is placed on the performance of the human-AI team.
8. Testing demonstrates device performance during clinically relevant conditions.
9. Users are provided clear, essential information.
10. Deployed models are monitored for performance, and retraining risks are managed.

On October 14, 2021, a virtual public workshop was held by the FDA, "Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices (AI/ML) (FDA-2019-N-1185)," to discuss transparency of AI/ML enabled medical devices to patients, caregivers, and providers.[97]

Optimal labeling for users and essential information for certain stakeholders to build trust in these devices was discussed. The American College of Surgeons provided a comprehensive response to the FDA, outlining key parameters for transparency, including that they are clinically sound, integrated easily into workflow, cost, testing and validation, real time performance monitoring, post-market surveillance and special considerations for images and labeling.[98]

There is concern and effort being made to minimize racial and ethnic bias. The Agency for Healthcare Research and Quality (AHRQ) released a request for information about developing AI algorithms on this topic.[99]

Also in 2021, the Federal Trade Commission (FTC) issued an advisory to companies to not implement any AI tools which might result in bias and/or discrimination. AI companies are advised to periodically inventory, review and adjust algorithms to mitigate bias or discrimination and to communicate change in algorithms to users. Users should periodically monitor purchased products for any changes.[100]

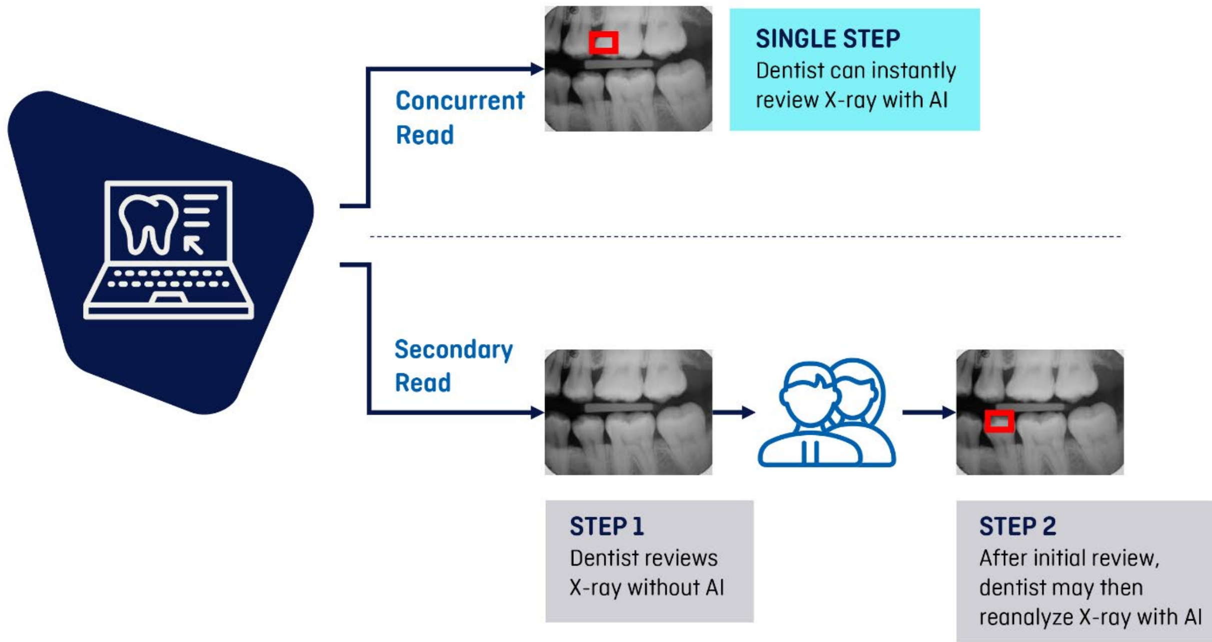

Figure A.1 – Two Methodologies used in Imaging AI

Federal Legislation that May Impact AI/AuI in Imaging

The 21st Century Cures Act Final Rule on Interoperability & Information Blocking (Cures Act) provides important information sharing requirements for exchanging information between health systems with Electronic Health Records. Under the Cures Act, patients would have immediate access to any imaging or tests used and this could include AI assessments of images.

Future Regulatory Considerations

Medical device labeling is any information associated with a device targeted to the patient or lay caregiver. It is intended to help assure that the device is used safely and effectively. Two general categories of information may be included in medical device patient labeling: (1) risk/benefit information; and (2) instructions for use (how to guide for the device). The label should provide information on intended user, intended population, indication for use, etc. Use the labeling to understand the following: 1) what is the device's intended use case; 2) understand when to use the device; 3) what population was the device tested on when selecting among similar devices; 4) understand how to operate and interpret the device outputs; 5) follow the manufacturer's directions carefully in using the device, such as understanding the basis for warnings, precautions, and contraindications.[101-103]

A simple label for all AI/AuI devices, as well as a more detailed labeling of AI/AuI devices, will be an important tool for proper use and assessment of risk. Labeling information about the AI/AuI products and services used within the dental setting should be clear to the dental practitioner.

Blueprint for Artificial Intelligence

In September 2022, the "Blueprint for an AI Bill Of Rights" was released in all sectors, including healthcare. The White House Office of Science and Technology Policy identified five principles to guide the design, use, and deployment of artificial intelligence to protect the American public. The Blueprint reinforces concepts to use technologies in ways that reinforce America's highest values.

Reference: https://www.whitehouse.gov/ostp/ai-bill-of-rights/

Considerations for Future Regulatory Action and Guidelines

As this field unfolds, consideration might given to these evolving technical requirements as adapted from WHO:[94]

- Clinical decisions are reserved for dental professionals.
- Standards for validity, safety, accuracy, and effectiveness occur within well-defined use cases.
- Transparency about how products are designed and function before they're used is provided by AI/AuI developers.
- Dental offices that rely on AI/AuI should ensure they are used under appropriate conditions by trained personnel.
- The best AI products promote equality and inclusiveness, and data sources for demographics are provided.

References

1. Marr B. How is AI used in healthcare—5 powerful real-world examples that show the latest advances. *Forbes;* 2018.
2. Kalis B, Collier M, Fu R. 10 promising AI applications in health care. *Harvard Business Review* 2018.
3. Singhal S, Carlton S. The era of exponential improvement in healthcare? *McKinsey Co Rev*.; 2019.
4. Khanager S, Al-Ehaideb A, et al. Developments, application and performance of artificial intelligence in dentistry – A systematic review. *J Dent Sci* 2021; Jan;16(1):508-522. doi: 10.1016/j.jds.2020.06.019. Epub 2020 Jun 30.
5. Wu Y, Wang F, Fan S et al. Robotics in Dental Impantology. *Oral Maxillofac Surg Clin North Am* 2019; Aug;31(3):513-518.
6. Information Blocking | HealthIT.gov, accessed November 30, 2021.
7. Mertens S, Krois J, et al. Artificial intelligence for caries detection: Randomized trial. *J Dent,* December 2021;115:103849.
8. Armitage GC, Svanberg GK, Loe H. Microscopic evaluation of clinical measurements of connective tissue attachment levels. *J Clin Periodontol* 1977;4:173-190.
9. Ahmed N, Abbasi MS, Zuberi F, et al. Artificial Intelligence Techniques: Analysis, Application, and Outcome in Dentistry-A Systematic Review. *Biomed Res Int* 2021;9:751-564.
10. Needleman I, Garcia R, Gkranias N, et al. Mean annual attachment, bone level, and tooth loss: A systematic review. *J Periodontol* 2018;89 Suppl 1:S120-S139.
11. Chang HJ, Lee SJ, Yong TH, et al. Deep Learning Hybrid Method to Automatically Diagnose Periodontal Bone Loss and Stage Periodontitis. *Sci Rep* 2020;10:7531.
12. Kim J, Lee HS, Song IS, Jung KH. DeNTNet: Deep Neural Transfer Network for the detection of periodontal bone loss using panoramic dental radiographs. *Sci Rep* 2019;9:17615.
13. Krois J, Ekert T, Meinhold L, et al. Deep Learning for the Radiographic Detection of Periodontal Bone Loss. *Sci Rep* 2019; 9:8495.
14. Lee CT, Kabir T, Nelson J, et al. Use of the deep learning approach to measure alveolar bone level. *J Clin Periodontol* 2021.
15. Lee, Jae-Hong, et al. "A performance comparison between automated deep learning and dental professionals in classification of dental implant systems from dental imaging: A multi-center study." *Diagnostics* 2020;10.11:910.
16. Lee, Jae-Hong, and Seong-Nyum Jeong. "Efficacy of deep convolutional neural network algorithm for the identification and classification of dental implant systems, using panoramic and periapical radiographs: A pilot study." *Medicine* 2020;99.26.
17. Hadj Saïd, Mehdi, et al. "Development of an Artificial Intelligence Model to Identify a Dental Implant from a Radiograph." *International Journal of Oral & Maxillofacial Implants* 2020;35.6.

18. Takahashi, Toshihito, et al. "Identification of dental implants using deep learning—pilot study." *International Journal of Implant Dentistry* 2020;6.1: 1-6.
19. Sukegawa, Shintaro, et al. "Deep neural networks for dental implant system classification." *Biomolecules* 2020;10.7:984.
20. Kim, Jong-Eun, et al. "Transfer learning via deep neural networks for implant fixture system classification using periapical radiographs." *Journal of clinical medicine* 2020;9.4:1117.
21. Oliveira, Adriano LI, Carolina Baldisserotto, and Julio Baldisserotto. "A comparative study on support vector machine and constructive RBF neural network for prediction of success of dental implants." Iberoamerican Congress on Pattern Recognition. Springer, Berlin, Heidelberg, 2005.
22. Oliveira, Adriano Lorena Inácio, Carolina Baldisserotto, and Julio Baldisserotto. "A comparative study on machine learning techniques for prediction of success of dental implants." Mexican International Conference on Artificial Intelligence. Springer, Berlin, Heidelberg, 2005.
23. Moayeri, Reyhaneh Sadat, Mehdi Khalili, and Mahsa Nazari. "A hybrid method to predict success of dental implants." RS Moayeri, M. Khalili, M. Nazari. *International Journal of Advanced Computer Science and Applications* 2016;7.5.
24. Ha, Seung-Ryong, et al. "A pilot study using machine learning methods about factors influencing prognosis of dental implants." *The journal of advanced prosthodontics* 2018; 10.6: 395-400.
25. Zhang, Hengguo, et al. "Trabeculae microstructure parameters serve as effective predictors for marginal bone loss of dental implant in the mandible." *Scientific reports* 2020;10.1:1-9.
26. Liu, Chia-Hui, et al. "Predicting the failure of dental implants using supervised learning techniques." *Applied Sciences* 2018;8.5:698.
27. Papantonopoulos, Georgios, et al. "Prediction of individual implant bone levels and the existence of implant "phenotypes" *Clinical oral implants research* 2017;28.7:823-832.
28. Lee, Dong-Woon, et al. "Artificial Intelligence in Fractured Dental Implant Detection and Classification: Evaluation Using Dataset from Two Dental Hospitals." *Diagnostics* 2012;11.2: 233.
29. Pereira KR, Sinha R. Welcome the "new kid on the block" into the family: artificial intelligence in oral and maxillofacial surgery. *British Journal of Oral and Maxillofacial Surgery* 2020;Jan 1;58(1):83–4.
30. Bas B, Ozgonenel O, Ozden B, Bekcioglu B, Bulut E, Kurt M. Use of artificial neural network in the differentiation of subgroups of temporomandibular internal derangements: A preliminary study. *Journal of Oral and Maxillofacial Surgery* 2012;Jan;70(1):51–9.
31. Frydenlund A, Eramian M, Daley T. Automated classification of four types of developmental odontogenic cysts. *Computerized Medical Imaging and Graphics* 2014;Apr;38(3):151–62.
32. Aubreville M, Knipfer C, Oetter N, Jaremenko C, Rodner E, Denzler J, et al. Automatic Classification of Cancerous Tissue in Laserendomicroscopy Images of the Oral Cavity using Deep Learning. *Scientific Reports* 2017;Dec1;7(1).

33. Artificial Intelligence in Medical Imaging. 2021; Available from: https://www.wjgnet.com/bpg/gerinfo/240
34. Ho V. https://news.microsoft.com/transform/operation-smile-dignity-children/.
35. Borumandi F, Cascarini L. Robotics in oral and maxillofacial surgery. *Annals of the Royal College of Surgeons of England* 2018;May 1;100:19–22.
36. Petersson A, Axelsson S, Davidson T, Frisk F, Hakeberg M, Kvist T, Norlund A, Mejàre I, Portenier I, Sandberg H, Tranæus S. Radiological diagnosis of periapical bone tissue lesions in endodontics: a systematic review. *Int Endo J.* 2012;45(9):783-801.
37. Tewary S, Luzzo J, Hartwell G. Endodontic radiography: who is reading the digital radiograph?. *J Endod.* 2011;37(7):919-21.
38. Estrela C, Bueno MR, Leles CR, Azevedo B, Azevedo JR. Accuracy of cone beam computed tomography and panoramic and periapical radiography for detection of apical periodontitis. *J Endod* 2008;34(3):273-9.
39. Lofthag-Hansen S, Huumonen S, Gröndahl K, Gröndahl HG. Limited cone-beam CT and intraoral radiography for the diagnosis of periapical pathology. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology* 2007;103(1):114-9.
40. Patel S, Dawood A, Mannocci F, Wilson R, Pitt Ford T. Detection of periapical bone defects in human jaws using cone beam computed tomography and intraoral radiography*. Int Endo J* 2009;42(6):507-15.
41. Torabinejad M, Rice DD, Maktabi O, Oyoyo U, Abramovitch K. Prevalence and size of periapical radiolucencies using cone-beam computed tomography in teeth without apparent intraoral radiographic lesions: a new periapical index with a clinical recommendation. *J Endod* 2018;Mar 1;44(3):389-94.
42. Tsai P, Torabinejad M, Rice D, Azevedo B. Accuracy of cone-beam computed tomography and periapical radiography in detecting small periapical lesions. *J Endod* 2012;38(7):965-70.
43. Orhan K, Bayrakdar IS, Ezhov M, Kravtsov A, Özyürek T. Evaluation of artificial intelligence for detecting periapical pathosis on cone-beam computed tomography scans*. Int Endod J* 2020;53(5):680-689.
44. Johari M, Esmaeili F, Andalib A, Garjani S, Saberkari H. Detection of vertical root fractures in intact and endodontically treated premolar teeth by designing a probabilistic neural network: an ex vivo study. *Dentomaxillofac Radiol* 2017;46(2):20160107.
45. Hiraiwa T, Ariji Y, Fukuda M, Kise Y, Nakata K, Katsumata A, Fujita H, Ariji E. A deep-learning artificial intelligence system for assessment of root morphology of the mandibular first molar on panoramic radiography. *Dentomaxillofac Radiol* 2019;48(3):20180218.
46. Saghiri MA, Asgar K, Boukani KK, Lotfi M, Aghili H, Delvarani A, Karamifar K, Saghiri AM, Mehrvarzfar P, Garcia-Godoy F. A new approach for locating the minor apical foramen using an artificial neural network. *Int Endod .* 2012;45(3):257-65.

47. Heo MS, Kim JE, Hwang JJ, Han SS, Kim JS, Yi WJ, Park IW. Artificial intelligence in oral and maxillofacial radiology: what is currently possible? *Dentomaxillofacial Radiology* 2021;50(3):20200375.

48. Hung K, Montalvao C, Tanaka R, Kawai T, Bornstein MM. The use and performance of artificial intelligence applications in dental and maxillofacial radiology: A systematic review. *Dentomaxillofacial Radiology* 2020;49(1):20190107.

49. Liew C. The future of radiology augmented with artificial intelligence: a strategy for success. *European journal of radiology* 2018;102:152-6.

50. Liew C. The future of radiology augmented with artificial intelligence: a strategy for success. *European journal of radiology* 2018;102:152-6.

51. Choy G, Khalilzadeh O, Michalski M, Do S, Samir AE, Pianykh OS, Geis JR, Pandharipande PV, Brink JA, Dreyer KJ. Current applications and future impact of machine learning in radiology. *Radiology* 2018;288(2):318-28.

52. Gyftopoulos S, Lin D, Knoll F, Doshi AM, Rodrigues TC, Recht MP. Artificial intelligence in musculoskeletal imaging: current status and future directions. *American journal of roentgenology* 2019;213(3):506.

53. Kök H, Acilar AM, İzgi MS. Usage and comparison of artificial intelligence algorithms for determination of growth and development by cervical vertebrae stages in orthodontics. *Progress in Orthodontics* 2019;20(1):1-10.

54. Guo Y-c, Han M, Chi Y, et al. Accurate age classification using manual method and deep convolutional neural network based on orthopantomogram images. *International Journal of Legal Medicine* 2021;135(4):1589-97.

55. Dobratulin K, Gaidel A, Kapishnikov A, et al. The efficiency of deep learning algorithms for detecting anatomical reference points on radiological images of the head profile. Paper presented at: 2020 International Conference on Information Technology and Nanotechnology (ITNT), 2020.

56. Estai, M., Kanagasingam, Y., Tennant, M. & Bunt, S. A systematic review of the research evidence for the benefits of teledentistry. *J Telemed Telecare* 2018;**24**, 147-156, doi:10.1177/1357633X16689433.

57. Alabdullah, J. H. & Daniel, S. J. A Systematic Review on the Validity of Teledentistry. *Telemed J E Health* 2018;**24**, 639-648, doi:10.1089/tmj.2017.0132.

58. Brucoli, M. *et al.* The use of teleradiology for triaging of maxillofacial trauma. *J Craniomaxillofac Surg* 2019;**47**, 1535-1541, doi:10.1016/j.jcms.2019.07.007.

59. Estai, M. *et al.* Teledentistry as a novel pathway to improve dental health in school children: a research protocol for a randomised controlled trial. *BMC Oral Health*, 2020;**20**, 11, doi:10.1186/s12903-019-0992-1.

60. Kopycka-Kedzierawski, D. T., McLaren, S. W. & Billings, R. J. Advancement of Teledentistry at the University of Rochester's Eastman Institute for Oral Health. *Health Aff (Millwood)* 2018;**37**, 1960-1966, doi:10.1377/hlthaff.2018.05102.

61. Gurel, G. In: *Esthetic Oral Rehabilitation with Veneers*. Cham: Springer; 2020: 235-263.
62. Estai, M., Kanagasingam, Y., Tennant, M. & Bunt, S. A systematic review of the research evidence for the benefits of teledentistry. *J Telemed Telecare* 2018;**24**, 147-156, doi:10.1177/1357633X16689433.
63. Ghai, S. Teledentistry during COVID-19 pandemic. *Diabetes Metab Syndr* 2020;**14**, 933-935, doi:10.1016/j.dsx.2020.06.029.
64. Giudice, A. *et al.* Can Teledentistry Improve the Monitoring of Patients during the Covid-19 Dissemination? A Descriptive Pilot Study. *Int J Environ Res Public Health* 2020;**17**, doi:10.3390/ijerph17103399.
65. Sangalli, L. *et al.* Effects of remote digital monitoring on oral hygiene of orthodontic patients: a prospective study. *BMC Oral Health* 2021;**21**, 435, doi:10.1186/s12903-021-01793-9.
66. Walji, M. F. *et al.* BigMouth: a multi-institutional dental data repository. *J Am Med Inform Assoc* 2014;**21**, 1136-1140, doi:10.1136/amiajnl-2013-002230.
67. Tellez, M., Gomez, J., Pretty, I., Ellwood, R. & Ismail, A. I. Evidence on existing caries risk assessment systems: are they predictive of future caries? *Community Dent Oral Epidemiol* 2013;**41**, 67-78, doi:10.1111/cdoe.12003.
68. Lang, N. P. & Tonetti, M. S. Periodontal risk assessment (PRA) for patients in supportive periodontal therapy (SPT). *Oral Health Prev Dent* 2003;**1**, 7-16.
69. Page, R. C., Krall, E. A., Martin, J., Mancl, L. & Garcia, R. I. Validity and accuracy of a risk calculator in predicting periodontal disease. *J Am Dent Assoc* 2002;**133**, 569-576, doi:10.14219/jada.archive.
70. Morelli, T. *et al.* Periodontal profile classes predict periodontal disease progression and tooth loss. *J Periodontol* 2018;**89**, 148-156, doi:10.1002/JPER.17-0427.
71. Mullins, J. M., Even, J. B. & White, J. M. Periodontal Management by Risk Assessment: A Pragmatic Approach. *J Evid Based Dent Pract* 2016;**16 Suppl**, 91-98, doi:10.1016/j.jebdp.2016.01.020.
72. Giordano, C. *et al.* Accessing Artificial Intelligence for Clinical Decision-Making. *Front Digit Health* 2021;**3**, 645232, doi:10.3389/fdgth.2021.645232.
73. Shimpi, N., McRoy, S., Zhao, H., Wu, M. & Acharya, A. Development of a periodontitis risk assessment model for primary care providers in an interdisciplinary setting. *Technol Health Care* 2020;**28**, 143-154, doi:10.3233/THC-191642.
74. Revilla-Leon, M. et al. Intraoral scanners: An American Dental Association Clinical Evaluators Panel survey. *J Am Dent Assoc* 2021;152, 669-670 e662, doi:10.1016/j.adaj.2021.05.018.
75. Chen, Y. W., Stanley, K. & Att, W. Artificial intelligence in dentistry: current applications and future perspectives. *Quintessence Int* 2020;**51**, 248-257, doi:10.3290/j.qi.a43952.
76. Hao, J. *et al.* Toward Clinically Applicable 3-Dimensional Tooth Segmentation via Deep Learning. *J Dent Res* 2021;220345211040459, doi:10.1177/00220345211040459.

77. Lian, C. *et al.* Deep multi-scale mesh feature learning for automated labeling of raw dental surfaces from 3D intraoral scanners. *IEEE transactions on medical imaging* 2020;**39**, 2440-2450.

78. Knoops, P. G. M. *et al.* A machine learning framework for automated diagnosis and computer-assisted planning in plastic and reconstructive surgery. *Sci Rep* 2019;**9**, 13597, doi:10.1038/s41598-019-49506-1.

79. Pellitteri, F., Brucculeri, L., Spedicato, G. A., Siciliani, G. & Lombardo, L. Comparison of the accuracy of digital face scans obtained by two different scanners. *Angle Orthod* 2021;**91**, 641-649, doi:10.2319/092720-823.1.

80. Revilla-Leon, M. *et al.* Facial scanning accuracy depending on the alignment algorithm and digitized surface area location: An in vitro study. *J Dent* 2021;**110**, 103680, doi:10.1016/j.jdent.2021.103680.

81. Estai, M., Kruger, E., Tennant, M., Bunt, S. & Kanagasingam, Y. Challenges in the uptake of telemedicine in dentistry. *Rural and remote health* 2016;**16**, 1-5.

82. Ben-Omran, M. O. *et al.* The use of teledentistry in facilitating oral health for older adults: A scoping review. *J Am Dent Assoc* 2021;**152**, 998-1011 e1017, doi:10.1016/j.adaj.2021.06.005.

83. Tabak, JA, Wilbert, AM, Alammar, M, Annigeri, RS, Carter, CN. Systems and Methods for Insurance Fraud Detection. Pearl Inc., US, 2021.

84. Tabak, JA, Wilbert, AM, Alammar, M, Annigeri, RS, Carter, CN, Tanz, O. Computer Vision-based Claims Processing. Pearl, Inc. US, 2021.

85. Brooks, M, Ei, D, McMillan, S, Rock, D, Schlosser, S. Methods and Systems for Periodontal Disease Screening. NovoDynamics, Inc. US, 2019.

86. Brooks, M, McMillan, S, Rock, D, Schlosser, S. Methods and Systems for Anomaly Detection in Dental Insurance Claim Submissions. NovoDynamics, Inc. US, 2019.

87. Bilgir, E, Bayrakdar, İŞ, Çelik, Ö, Orhan, K, Akkoca, et al. An artificial ıntelligence approach to automatic tooth detection and numbering in panoramic radiographs. *BMC Med Imaging* 2021;21:124.

88. Tuzoff, D, Krasnov, A, Kharchenko, M, Tuzova, L. Systems and Methods for Processing of Dental Images. Denti.AI Technology Inc. US, 2019.

89. Lee, J-H, Kim, D-H, Jeong, S-N, Choi, S-H. Detection and diagnosis of dental caries using a deep learning-based convolutional neural network algorithm. *Journal of Dentistry* 2018;77:106–111.

90. Chen, YW, Stanley, K, Att, W. Artificial intelligence in dentistry: current applications and future perspectives. *Quintessence Int* 2020;51:248–257.

91. Park, SH, Choi, J, Byeon, JS. Key Principles of Clinical Validation, Device Approval, and Insurance Coverage Decisions of Artificial Intelligence. *Korean J Radiol* 2021;22:442–453.

92. Zhou, P, Han, X, Morariu, I, Davis, LS. Learning Rich Features for Image Manipulation Detection. *IEEE/CVF Conference on Computer Vision and Pattern Recognition.* 2018:1053–1061.

93. Balaban, CM, Vidone, LS, Dufurrena, Q, Croley, D, Dosch, K, Inam, W, Puthussery, S. AI-Driven Transformation of Dental Benefits. *Compend Contin Educ Dent* 2021; 42(6).

94. World Health Organization (WHO). Ethics and Governance in Artificial Intelligence in Health. Geneva. 2021; https://www.who.int/publications/i/item/9789240029200

95. Food and Drug Administration. Overview of Device Regulation. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation

96. Food and Drug Administration. Good Machine Learning Practices for Medical Device Development: Guiding Principles. Washington: 2019; https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

97. Food and Drug Administration. https://www.ai.gov/event/fda-virtual-public-workshop-on-transparency-of-artificial-intelligence-machine-learning-enabled-medical-devices/

98. American College of Surgeons. Letter to the Food and Drug Administration. November 11, 2021 on FDA Workshop on Transparency of AI/ML -enabled medical devices, October 14, 2021; https://www.regulations.gov/comment/FDA-2019-N-1185-0143.

99. Agency for Healthcare Research and Quality. Request for Information on the Use of Clinical Algorithms That Have the Potential To Introduce Racial/Ethnic Bias Into Healthcare Delivery. March 5, 2021; https://www.federalregister.gov/documents/2021/03/05/2021-04509/request-for-information-on-the-use-of-clinical-algorithms-that-have-the-potential-to-introduce

100. Federal Trade Commission. Aiming for truth, fairness, and equity in your company's use of AI. https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai

101. Food and Drug Administration. Labeling Guidance. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/device-labeling-guidance-g91-1-blue-book-memo

102. Food and Drug Administration. https://www.fda.gov/media/71030/download

103. Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=801

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T 312.440.2500 F 312.440.7494 www.ada.org