Dental Cone-beam Computed Tomography

U.S. Food & Drug Administration

On this webpage, the FDA is providing:

- information about the use of cone-beam computed tomography in dentistry particularly in the pediatric population,
- information for patients, parents and health care providers to help reduce unnecessary radiation exposure from dental cone-beam computed tomography, and
- resources for manufacturers of dental cone-beam computed tomography devices.

Description

Cone-beam computed tomography systems (CBCT) are a variation of traditional computed tomography (CT) [1] systems. The CBCT systems used by dental professionals rotate around the patient, capturing data using a cone-shaped X-ray beam. These data are used to reconstruct a three-dimensional (3D) image of the following regions of the patient's anatomy: dental (teeth); oral and maxillofacial region (mouth, jaw, and neck); and ears, nose, and throat ("ENT").

Cone-beam computed tomography system.

Uses

Dental CBCT systems have been sold in the United States since the early 2000s and are increasingly used by radiologists and dental professionals for various clinical applications including dental implant planning, visualization of abnormal teeth, evaluation of the jaws and face, cleft palate assessment, diagnosis of dental caries (cavities), endodontic (root canal) diagnosis, and diagnosis of dental trauma.

Benefits/Risks

X-ray imaging, including dental CBCT, provides a fast, non-invasive way of answering a number of clinical questions. Dental CBCT images provide three-dimensional (3-D) information, rather than the two-dimensional (2-D) information provided by a conventional X-ray image. This may help with the diagnosis, treatment planning and evaluation of certain conditions.

Although the radiation doses from dental CBCT exams are generally lower than other CT exams, dental CBCT exams typically deliver more radiation than conventional dental X-ray exams. Concerns about radiation exposure are greater for younger patients because they are more sensitive to radiation (i.e., estimates of their lifetime risk for cancer incidence and mortality per unit dose of ionizing radiation are higher) and they have a longer lifetime for ill effects to develop.

The FDA has launched a pediatric X-ray imaging website [2] that provides specific recommendations for parents and health care providers to help reduce unnecessary radiation exposure to children. The FDA’s Center for Devices and Radiological Health defines the ages of the pediatric population as birth through 21 years.

Information for Patients and Parents

The American Dental Association (ADA) and the FDA recommend [3] that clinicians perform dental X-ray examinations, including dental CBCT, only when necessary for the diagnosis or treatment of disease. The clinical benefit of a medically appropriate X-ray imaging exam outweighs the small radiation risk. However, efforts should be made to help minimize this risk.

The FDA also recommends that for all X-ray imaging procedures, including dental CBCT, patients and parents of children should:

- Talk with their health care provider.
    - Review the benefits and risks of the procedure before it is performed.
    - Discuss if the imaging exam is necessary and if there are equally useful alternative exams that use no or less ionizing radiation.
    - Ask if the facility uses radiation reduction techniques such as size-based protocols for children.
- Keep a record of your family's medical-imaging histories.
    - The Image Wisely/FDA My Medical Imaging History [4] and Image Gently "My Child's Medical Imaging Record" [5] [6] cards provide a format for patients and parents to track all imaging exams as part of a discussion with the referring physician when a new exam is recommended.
- Resources for patients and parents about the benefits and risks of dental CBCT and other X-ray imaging include:
    - FDA Medical Imaging: Pediatric X-ray Imaging [7]
    - The Alliance for Radiation Safety in Pediatric Imaging in partnership with the American Academy of Oral and Maxillofacial Radiology: "What is Pediatric Dental Radiography?" [6] and "What Parents Should Know about the Safety of Dental Radiology" [8] [6]
    - The Radiological Society of North America's and the American College of Radiology's patient information webpage: RadiologyInfo: Dental Cone Beam CT [9]

Information for Dental Professionals

Dental CBCT should be performed only when necessary to provide clinical information that cannot be provided using other imaging modalities.

As stated in FDA's Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, the FDA recommends imaging professionals follow the principles of justification and optimization in the protection of patients undergoing radiological examinations. The FDA recommends that dental professionals:

- Discuss the rationale for the examination with the patient and/or parent to ensure a clear understanding of benefits and risks.
- Reduce the number of inappropriate referrals (i.e., justify X-ray imaging exams) by:
    - determining if the examination is needed to answer a clinical question,
    - considering alternate exams that use less or no radiation exposure, and
    - reviewing the patient's medical imaging history to avoid duplicate exams.
- Use exposure settings for dental CBCT exams that are optimized to provide the lowest radiation dose that yields an image quality adequate for

diagnosis (i.e., radiation doses should be "As Low as Reasonably Achievable"). The technique factors used should be chosen based on the clinical indication, patient size, and anatomical area scanned, and the equipment should be properly maintained and tested.

Additional information for health care providers on appropriate and safe use of dental X-ray imaging exams includes:

- The use of cone-beam computed tomography in dentistry: An advisory statement from the American Dental Association Council on Scientific Affairs (August 2012) [10] [6].
- The joint FDA and American Dental Association Guidelines for the Selection of Patients for Dental Radiographic Examinations-2004 [11] provides information on how to determine if X-rays are appropriate (justified) for a given patient. While these guidelines do not mention CBCT specifically, many of the general recommendations apply to dental CBCT.
- Recommendations specific to the use of dental CBCT can be found in the Joint Position Statement of the American Association of Endodontists and the American Academy of Oral and Maxillofacial Radiology USE OF CONE-BEAM COMPUTED TOMOGRAPHY IN ENDODONTICS [12] [6].
- Position statement of the American Academy of Oral and Maxillofacial Radiology on selection criteria for the use of radiology in dental implantology with emphasis on cone beam computed tomography (2012) [13]
- Based on data from many countries, including the U.S., the European Commission's SEDENTEXCT project has developed a training program [14] [6]and "Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology; Evidence Based Guidelines 2011". [15] [6]
- Academy of Dental Therapeutics and Stomatology's: A Clinician's Guide to Understanding Cone Beam Volumetric Imaging (CBVI) [16]
- The International Atomic Energy Agency (IAEA)’s Dental Radiology- X Rays [17] [6]contains information for health professionals to help protect patients from unnecessary radiation exposure in dental imaging including CBCT.
- The American Academy of Pediatric Dentistry (AAPD) Policy on Patient Safety [18] [6]gives general guidelines on safe use of dental imaging.
- FDA Medical Imaging: Pediatric X-ray Imaging [7]

Information for Industry

Dental CBCT systems are medical devices that are also radiation-emitting electronic products. The FDA regulates manufacturers of dental CBCT devices through the Electronic Product Radiation Control (EPRC) [19] and medical device provisions [20] of the Federal Food, Drug, and Cosmetic Act. Dental CBCT systems are classified under 21 CFR 892.1750.

For more information on bringing an X-ray imaging system to market and for post-market requirements see:

- Getting a Radiation Emitting Product to Market [21]
- Device Advice: Complementary Regulatory Assistance [22]
- Post-market Requirements (Devices) [23]

FDA's webpages on Computed Tomography [24] and Medical X-Rays [24] provide more detailed lists of industry resources relevant to dental CBCT systems.

On May 10, 2012, the FDA issued Draft Guidance: Pediatric Information for X-ray Imaging Device Premarket Notifications [25] to encourage manufacturers to consider the radiation safety of pediatric populations in the design of new X-ray imaging devices, including dental CBCT systems. On July 16, 2012, the FDA held a public workshop to discuss the draft guidance. Participants provided recommendations specific to dental cone-beam CT scanners. More information about the meeting (including archived webcast and presentation slides) are available on the workshop website, Device Improvements for Pediatric X-ray Imaging [26].

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[1] http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115317.htm
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[9] http://www.radiologyinfo.org/en/info.cfm?pg=dentalconect
[10] http://jada.ada.org/content/143/8/899.full
[11] http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm116504.htm
[12] http://www.aaomr.org/resource/resmgr/Docs/AAOMR-

AAE_postition_paper_CB.pdf
[13] http://www.ncbi.nlm.nih.gov/pubmed/22668710
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