Cone-Beam CT

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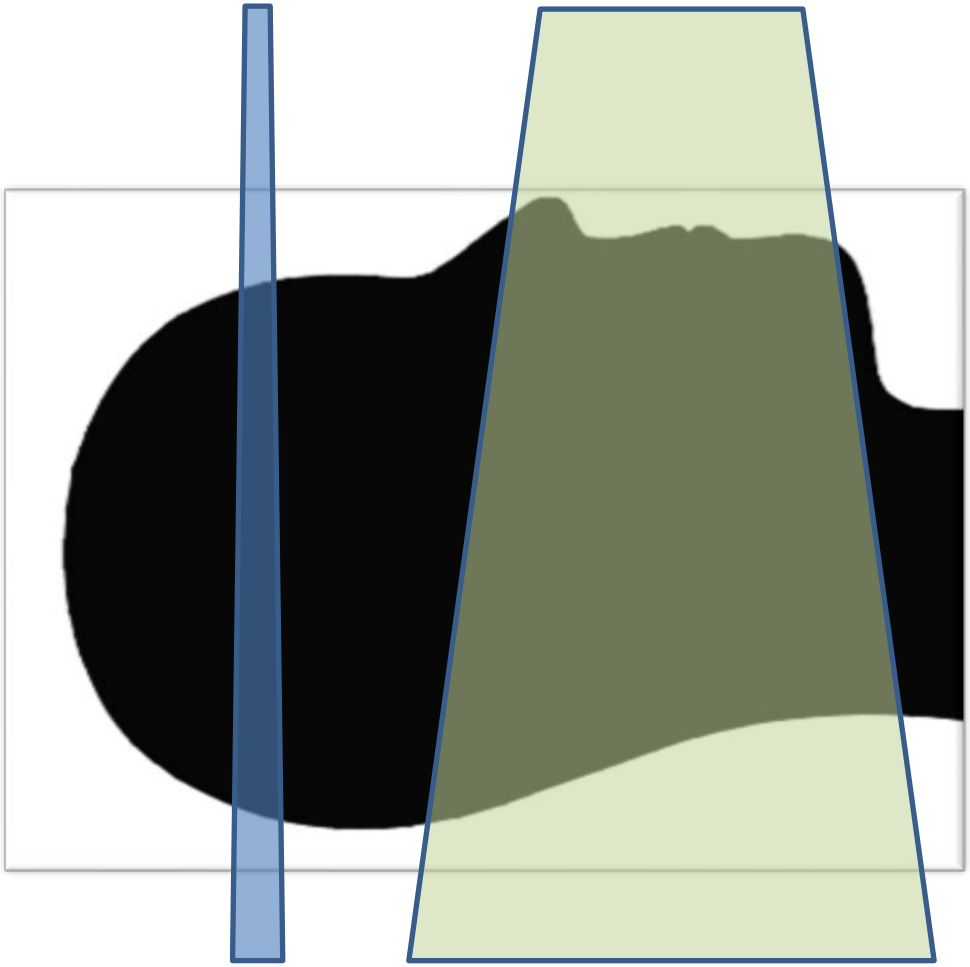
Progression toward CBCT:
Beam geometry: Narrow to cone-beam



What is Cone-beam CT?

From ICRP Publication 129, Cone Beam CT (CBCT) can be described as,

> *".. the use of a two-dimensional digital flat-panel detector to yield a three-dimensional volumetric image in one rotation."*

Benefits of CBCT vs. Conventional CT

CBCT can:

- Scan the imaged anatomy in a single rotation
- Provide very good spatial detail
- Provide sophisticated software-level features using recent software reconstruction improvements
- Provide patient radiation doses that are typically lower for similar types of imaging as compared to conventional CT

Clinical Applications of CBCT

- As a feature:
  - Fluoroscopic (e.g., C-arm) systems equipped with digital detectors and CBCT mode:
    - Radiation therapy
    - Interventional procedures
- As a dedicated CBCT device:
  - Dental and maxillofacial
  - ENT applications
  - Extremity imaging

Comparison of Dose
Dental CBCT vs. Conventional CT

Example: Head CT

Effective dose (mSv): Mean/SD*

- CBCT (large FOV): 0.21 / 0.21
- CT (brain + PF): 2.5 / 1.2

Data are from the following sources:

CBCT (large FOV): Ludlow JB, Timothy R, Walker C, Hunter R, Benavides E, Samuelson DB, et al. Effective dose of dental CBCT—a meta analysis of published data and additional data for nine CBCT units. Dentomaxillofac Radiol 2015; 44: 20140197.

CT (brain + PF): Conference of Radiation Control Program Directors. NEXT Tabulation and Graphical Summary of the 2005-06 survey of computed tomography. CRCPD publication E-15-3, 2015.

Organizations studying CBCT

- U.S.:
  - ADA: information and JADA publications
  - AAPM: Task Group-level activities
  - NCRP: Forthcoming dental report covers CBCT
- International:
  - ICRP: Publication 129 (2015)
  - SEDENTEXCT consortium (2011): Guidelines
  - HPA (UK): Guidance on CBCT (2010)
  - IAEA: Status of Computed Tomography Dosimetry for Wide Cone Beam Scanners (2011)

Applicable Standards

- FDA performance standard: 21 CFR 1020.33
- International consensus standards
  - IEC 60601-2-44: General safety and performance requirements for CT equipment: Applicable to Head and Body scanners
  - IEC 60601-2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray
  - IEC 61223-3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment

FDA concern: Characterizing Patient Dose

- Conventional dose parameter for CT: CTDI
  - Intended for narrow beam geometries < few cm and scanning acquisition with identifiable slice thickness
  - Alternative methods:
    - Kerma-Area Product: already displayed on some systems
    - Effective Dose: computationally involved; not intended for this purpose

FDA Concern: Applying Federal performance standards to CBCT

1020.33: CT Equipment:

- Defines CTDI and requires reporting of values to users
- Requires imaging performance information to users, e.g., noise, imaging performance
- Requires Quality Assurance program w/included QA phantom

– *Some aspects of 1020.33 are not applicable to CBCT*

Tracking Clinical Data: Radiation Dose Structured Report (RDSR)

- RDSR- collects and archives dose-related data as a DICOM object/actor
- DICOM- WG 28: charged to develop RDSR for CBCT equipment (2015)
- ICRP Report 129 (2015) recommendation:
  - *"Equipment used for both fluoroscopy and CBCT should provide aggregate dose indices for individual patients throughout the procedure through electronic display on the operator console* ***and a radiation dose structured report****."* [emphasis added]

Summary

- Federal performance standard- lacks specific coverage of CBCT devices
- Dose metric for CBCT- on-going effort by the professional community
- Scope of CBCT use continues to grow, e.g., pediatric use

Questions for TEPRSSC

- How does TEPRSSC recommend defining cone beam CT scanners in order for FDA to specify standards that apply to these devices?

Questions for TEPRSSC

- Should FDA develop standards that include the specification of image quality and dosimetry metrics specific to CBCT?
- If so, should FDA require their inclusion with device labeling as is done currently for conventional CT equipment in 21 CFR 1020.33? (Note: 21 CFR 1020.33 is currently applied to CBCT.)

Questions for TEPRSSC

- Are there specific pediatric safety concerns that should be included in standards for CBCT equipment?
- How does TEPRSSC recommend that FDA ensure that radiation dose structured reporting and other radiation safety features are available in *all* types of CT devices?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