Cone-Beam CT

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Technical Electronic Product Radiation Safety Standards Committee Meeting, October 25-26, 2016
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:

Organizations studying CBCT

• U.S.:
  – ADA: information and JADA publications
  – AAPM: Task Group-level activities
  – NCRP: Forthcoming dental report covers CBCT

• International:
  – 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?