



June 15, 2023

HCAM Comments: Nursing Home and Long-Term-Care Unit (NH-HLTCU) Informal Workgroup - Final Report & Draft Language

Chair Falahee and Commissioners,

Thank you for the opportunity to provide public comment regarding the final report and draft language for the nursing home and long-term-care unit informal workgroup.

I also pass my thanks to Commissioner Haney for his leadership as chair of the informal workgroup, and the multiple department staff who were so responsive during and between the workgroup meetings.

Through collaborative efforts and discussions, workgroup participants and department staff were able to find consensus language for charges 1 through 7, and charge 10. Several charges were technical in nature; however, several also include substantive changes to the standards that have material impacts on providers and the department staff who implement the CON process. HCAM greatly appreciates the collaborative effort and the department's willingness to receive and incorporate stakeholder feedback that led to consensus support for the draft language for each of these charges.

While HCAM is supportive of the department's recommended draft language before you today, we urge the Commission to consider proposed language to charges 8 and 9.

Charge 8

Charge 8 tasked the workgroup with considering language taking into account the impact of a public health epidemic on the CON process. It is well documented that the COVID-19 pandemic – and the ensuing economic climate that has followed – has had a significant impact on Michigan's economy and long-term care providers. Following the unprecedented clinical challenges experienced by providers in 2020 and early 2021, historic inflation, workforce shortages, and supply chain interruptions disrupted the entire economy for the last several years – many of these challenges continue to this day.

The clinical challenges diverted facility resources to focus solely on resident care, and the economic challenges led to delays entirely out of providers' control. While it is true that the department may extend timelines to a limited degree under the current standards and administrative rules, HCAM members noted the significant administrative burden currently required under the CON process. Additionally, due to the unforeseeable challenges of the pandemic, the extensions – if they were granted – often were not sufficient, resulting in expiration of some approved projects.

Stakeholders offered language that would allow the department to take into consideration the extenuating circumstances outside of the providers control when considering extensions to project delivery requirements contained in Section 11 of the NH-HLTCU standards. The department expressed



concerns with the initially proposed language, emphasizing that the standards should offer greater discretion to the department. HCAM worked with other stakeholders to review and update proposed language to ensure discretion to the department.

The language presented for charge 8 in the final report from workgroup Chair Haney maintains this discretion, and is flexible enough to apply to the varying experiences of providers and potential future public health emergencies. This language allows for extensions if the department determines the evidence of delays caused by the emergency presented by the provider are sufficient to warrant an extension.

HCAM requests the consideration of the Commission to adopt the proposed language for Charge 8.

Charge 9

Charge 9 tasked the workgroup with reviewing the process of temporary closure to replace aging structures.

Updated, state-of-the-art facilities are a critical component of delivering quality care to nursing facility residents. Michigan providers are committed to investing in capital infrastructure – leading the nation in new builds and renovations of existing facilities. As the demand for long-term care continues to rise as Michigan ages, it is imperative that the state implement policies that continue to incentivize these investments.

The Michigan Department of Licensing and Regulatory Affairs (LARA) recognizes the need to permit and incentivize investments in new buildings and renovations through building program agreements. Such agreements allow facilities to maintain licensed beds while temporarily closing operations while construction is underway. Unfortunately, department interpretations of the NH-HLTCU standards do not offer the same flexibility.

Stakeholders offered language to make clear in the standards that under CON providers have the ability to temporarily halt the operation of licensed beds for the duration of construction. The department and stakeholders emphasized the need to address the rights of the residents who would be displaced during construction – HCAM appreciates the consideration of the residents in this process.

Language included in Chair Haney's final report seeks to address this concern, and explicitly details the rights of temporarily displaced residents and the responsibility on the provider to ensure those residents' rights are protected.

HCAM agrees with Commissioner Haney's assessment that the workgroup was trending towards consensus, and given more time to meet, the language could have been developed to address the concerns of all stakeholders.

HCAM requests the Commission include the language from Commissioner Haney's final report. If language is ultimately not adopted into the standards today, we urge the Commission to make Charge 9 the top priority at the next standards review, before 2025 if there is opportunity to do so.



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August 10, 2023

Mr. James Falahee, Chair
Certificate of Need Commission
Michigan Department of Health and Human Services
South Grand Building
333 S. Grand Avenue, 5th Floor
Lansing, Michigan 48933

Re: Exemption Request for CT Scanners

Dear Chairman Falahee,

I write to you today on behalf of the physician members of the **Michigan Otolaryngologic Society** to propose a change to the existing Certificate of Need ("CON") standards as they relate to Computed Tomography ("CT") scanners.

As you may be aware, **Michigan is one of only two states** that require a CON for low-dose, specialty-use CT scanners primarily used by ear, nose and throat physicians. These machines are made by prominent manufacturers such as Morita, Carestream, Mobius (owned by Stryker, a Michigan company) and Xoran Technologies, which is based in Ann Arbor, Michigan.

It is the combination of a lower acquisition cost and the on-demand, in-office use of these specialty CT scanners that sets these machines apart from traditional CT scanners. By allowing a limited use specialty CT scanner in ENT physician offices, patients and physicians have an opportunity to achieve better, faster and safer diagnostic imaging that is vital to a comprehensive treatment plan. Yet despite the promise of this technology and its availability in 48 other states without the requirements of a CON, Michigan maintains an outdated regulatory burden which effectively prohibits the use of this in-office specialty CT by our members.

Simply put, the requirement that all CT CON applicants, regardless of the type of equipment, demonstrate 7,500 equivalent CT scans in order to achieve CON approval, effectively prohibits any ENT physician and many small or more rural hospitals from acquiring a lower cost, low-dose specialty CT scanner.

This is not a new issue as various media outlets have reported on this situation dating back as far as 2007. Additionally, manufacturers of these machines have been requesting special consideration and review by the CON Commission and various work groups since 2008. Here we are fifteen years later and Michigan is still operating under an outdated regulatory standard and has made itself an outlier in the use of this technology.

Similar CT equipment used primarily by dentists was carved out of the CON regulations a few years ago and we are confident that the impact of this move is of great benefit to dentists and

their patients without undermining the intent of the regulations. This carve out was done without causing a detrimental effect to the healthcare system of our state and there are over 6,000 dentists in Michigan. This change has no doubt increased access to quality diagnostic testing at a lower cost to payers and patients alike.

In comparison, there are only between 120-150 ENT physicians in private practice, so a reasonable person could conclude that the impact on the current healthcare system and existing imaging centers would be nominal at best.

We believe the approach that 48 other states have taken towards exempting low-cost, low-dose specialty CT scanners is the most effective and least restrictive manner to achieving a balance of cost, quality and access when it comes to this diagnostic equipment.

We offer the following exemption language as a suggested option to consider;

Section 2. Definitions

(k) "CT Scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators used solely for treatment planning purposes in conjunction with an MRI unit, non-diagnostic, intraoperative guidance tomographic units, and dental CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate dental procedures by a licensed dentist under the practice of dentistry, **AND CONE-BEAN COMPUTED TOMOGRAPHY EQUIPMENT DESIGNED SPECIFICALLY FOR LIMITED-USE SPECIALTY IMAGING THAT IS FDA APPROVED AS A MEDICAL DIAGNOSTIC DEVICE AND USED EXCLUSIVELY BY AN INDIVIDUAL WHO IS LICENSED TO ENGAGE IN THE PRACTICE OF OTOLARYNGOLOGY.**

We believe that this change will remove CON regulations from low-dose, lower cost specialty CT scanners just as most of the nation has chosen to do, while still allowing Michigan to apply CON regulations to the healthcare additions that matter; large capital expenditures and procedure-intensive equipment. Michigan has already chosen to not regulate other lower cost medical equipment used in-office, most notably ultrasound, kidney dialysis equipment, and digital two-way x-ray machines.

Specialty CT scanners use in-office more closely align with the purpose and cost of these unregulated equipment and thus should be treated in the same manner in excluding them from CON regulations.

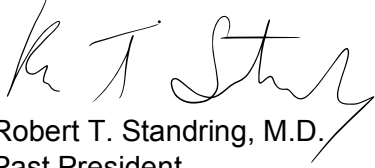
The benefits to allowing in-office CT scanning outside the CON process far outweigh any risks, and would improve the state's healthcare environment for physicians, patients, employees, and employers across the board. Additionally, other methods of controlling the proper use of CT scanners will remain, as CT scanners used in-office will still have to meet the requirements of the Michigan Radiation Safety Section, must still be approved by insurance companies via prior authorization for scans, must meet the accreditation requirements developed and rolled out nationally by both the American College of Radiology and the International Accreditation Commission.

The required CON for CT Scanners further limits access to care as many patients are fearful of entering hospitals for any reason, especially a quick radiologic study, and feel more comfortable going to their physician's office to obtain diagnostic testing that can deliver immediate results and lead to better treatment plans and outcomes.

We (again) urge the CON Commission to make this necessary change to the CON CT Standards and permit the use of in-office CT scanning by Michigan's ENT physicians.

Our members and patients thank you for your time and consideration of this important request.

Sincerely,

A handwritten signature in black ink, appearing to read "R T Standring". The signature is fluid and cursive, with the first name "R" and last name "Standring" being the most prominent parts.

Robert T. Standring, M.D.

Past President

Michigan Otolaryngologic Society



August 14, 2023

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Mr. James Falahee, Chair
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Simply put, the requirement that all CT CON applicants, regardless of the type of equipment, demonstrate 7,500 equivalent CT scans in order to achieve CON approval, effectively prohibits any ENT physician and many small or more rural hospitals from acquiring a lower cost, low-dose specialty CT scanner.

This is not a new issue as various media outlets have reported on this situation dating back as early as 2007. Additionally, manufacturers of these machines have been requesting special consideration and review by the CON Commission and various work groups since 2008. Here we are twelve years later and Michigan is still operating

under an outdated regulatory standard and has made itself an outlier in the use of this technology.

Similar CT equipment used primarily by dentists was carved out of the CON regulations in recent years and we are confident that the impact of this move is of great benefit to dentists and their patients without undermining the intent of the regulations and without causing a detrimental effect to the healthcare system of our state.

We believe the approach that 48 other states have taken towards exempting low-cost, low-dose specialty CT scanners is the most effective and least restrictive manner to achieving a balance of cost, quality and access when it comes to this diagnostic equipment.

We offer the following exemption language as a suggested option to consider;

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Joseph Seymour MD
President
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Our members and patients thank you for your time and consideration of this important request.

Sincerely,

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Jeffrey S. Weingarten, M.D.

Past President - Michigan Otolaryngologic Society
President - Ear, Nose and Throat Consultants

August 10, 2023

Michigan Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing, MI 48933
Submitted Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Re: CON Review Standards for Computed Tomography (CT) Scanner Services

Dear Certificate of Need Commission:

On behalf of the Michigan Association of Chiropractors, please accept this correspondence as written testimony regarding the following CON standards scheduled for review: Computed Tomography (CT) Scanner Services. Specifically, I would like to address cone beam CT (CBCT) scanners and proposed addition in Section 2(1)(ii), which reads:

ONLY. ANY OTHER USE OF CT SCANNERS (SUCH AS BUT NOT LIMITED TO CHIROPRACTIC UTILIZATION) THAT GENERATE A PEAK POWER OF 5 KILOWATTS OR LESS AS CERTIFIED BY THE MANUFACTURER WILL REQUIRE REVIEW AND APPROVAL AS A CT SCANNER SERVICE UNDER APPLICABLE SECTIONS OF THESE STANDARDS.

The Michigan Association of Chiropractors opposes the addition of this language to the definition of "CT scanner" in these rules and specifically finds the inclusion of "chiropractic utilization" particularly problematic, as singling out one physician-level health care profession seems discriminatory, arbitrary, and without basis. We furthermore urge the Commission to instead consider a certificate of need exemption for the chiropractic field, as was done for dental cone beam CT scanners in 2016. We urge the addition of language to Section 2(k) as follows:

"CT scanner" ... does not include ... and dental OR CHIROPRACTIC CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate dental procedures by a licensed dentist under the practice of dentistry OR CHIROPRACTIC PROCEDURES BY A LICENSED CHIROPRACTOR UNDER THE PRACTICE OF CHIROPRACTIC.

Cone Beam Computed Tomography has been used in chiropractic since 2011 and is being increasingly adopted throughout the profession, particularly among chiropractors whose work focuses on the upper cervical spine. The cranio-cervical junction is one of the most complex joints in the human body, given the region's bone morphology, biomechanics, neurology, ligamentous structures, and fluid dynamics, and it plays a major role in cervical spine stability.

By allowing the practitioner to see the cranio-cervical junction in three-dimensional images, cone beam CT has revolutionized the way upper cervical chiropractors examine and correct that region of the spine, providing the exact location and degree of misalignment and allowing for the extremely gentle and precise corrections performed by upper cervical chiropractors.

Advantages of Cone Beam CT

Three-dimensional Cone beam CT is vastly superior to two-dimensional X-ray when it comes to imaging and analyzing the upper cervical spine. Some of the reasons for this include:

Better Image Quality

Because the image is three dimensional and covers 360° (unlike x-ray, which is 2D), there is no image distortion or overlap of structures. Also, cone beam CT can distinguish between many types of tissues (bone, nerves, soft tissues), unlike traditional x-ray.

Lower Radiation Dose

It takes only one CBCT scan (as opposed to the typical three-six x-ray films needed) to gather the necessary information. A standard CBCT scan is 240 micro sieverts (equivalent to about 1/10 the radiation exposure of a standard 4-view cervical spine X-Ray series). The amount of radiation emitted by CBCT technology does not even require lead lining in the walls, just six feet of distance.

More Accurate Diagnoses and Precise Treatment Planning

Traditional 2D x-ray can sometimes result in misdiagnosis because of factors such as anatomical variations, asymmetry of structures, and positioning errors. CBCT allows for a wider variety of viewing angles and increased precision (more than 1,000 different angles of the spine vs. one view/angle per image), leading to better treatment outcomes. CBCT can also allow practitioners to visualize internal anatomy that cannot be diagnosed externally or by physical clinical examination.

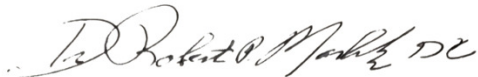
Conclusion

In conclusion, the chiropractic profession embraces this emerging technology, as it allows chiropractic physicians to analyze images that generate 3D clarity and better detail and resolution than traditional 2D x-ray is unable to provide. X-ray remains an incredible tool, but cone beam CT is the imaging technology of the future. Its use and emergence make it a vital addition to chiropractic radiographic analysis, especially regarding the upper cervical region of the spine. The enhanced images of CBCT increase the accuracy of the patient's diagnosis, make treatment planning more precise, and will lead to superior outcomes, all while emitting a safer dose of radiation than other diagnostic imaging studies. For these reasons, we believe that cone beam computed tomography is appropriate for use in chiropractic and across healthcare professions, not just dentistry.

We would also like to submit for your consideration the enclosed article from the May 23, 2023, edition of the *Journal of Contemporary Chiropractic*, "Cone Beam Computed Tomography: Technology Overview, Dose, and Utility Considerations for Chiropractors and Regulatory Bodies," which further clarifies and places these arguments into context.

Thank you for the opportunity to submit these comments and for your consideration. If you have any questions regarding these comments or if you would like any additional information, please contact MAC Executive Director Kristine Dowell at kris@chiromi.com.

Yours in Health,



Robert Markle, DC
President
Michigan Association of Chiropractors



CONE BEAM COMPUTED TOMOGRAPHY: TECHNOLOGY OVERVIEW, DOSE, AND UTILITY CONSIDERATIONS FOR CHIROPRACTORS AND REGULATORY BODIES

Jeffrey Scholten, BSc, PgCPain, DC, DCCJP, FCCJP, FICA¹; Arif Kos²; Matthew Richardson, DC, DACBR³; Karen Champion, DC, CCSP, FIAMA⁴

ABSTRACT

Introduction: As computed tomography (CT) applications progress through advances in X-ray capture and computer capabilities, evolutions in this technology have created confusion in differentiating different CT technologies. This underscores the need to develop a common understanding of these ionizing radiation-based imaging modalities by regulators and educational institutions in the chiropractic profession. This narrative review seeks to provide clarification and provides technological context addressing the physics and the clinical applications of CT.

Discussion: Computed tomography (CT) has various applications of cone vs planar X-ray beam and flat vs curve receivers. The evolution of greater-sized capture devices for X-ray has allowed CT to evolve to use lower-dose cone beam applications, allowing for cross-sectional CT imaging with lower dose and increased image clarity while reducing the imaging time required for patients.

Conclusion: This review provides a synopsis of CT technologies and offers an opportunity to understand similarities and critical differences between cone beam CT and multidetector CT. The benefits of information gained from cross sectional CBCT studies that is unavailable with conventional X-ray examinations to patient management are summarised. Utilizing CBCT in chiropractic practice is in the best interest of patients and clinicians from both an image quality and patient dose perspective and is an evolution to current technology as opposed to a new technology. (*J Contemporary Chiropr* 2023;6:92-99)

Key Indexing Terms: Chiropractic; Radiographic Imaging; Computed Tomography; Cone Beam Computed Tomography; Patient Dose; Patient Safety

INTRODUCTION

This narrative review, intended for chiropractors and their regulatory bodies, supplies a basic overview, comparison, and analysis of the technical workings of computed tomography (CT) (multidetector (MDCT) and cone beam (CBCT)) scanners. CBCT is an evolution in lower-dose computed tomographic imaging that is a variant of CT scanning rather than an entirely new technology.

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DISCUSSION

CBCT is a technological advancement in ionizing radiation-based studies that, like radiography and traditional CT, use X-ray radiation to produce diagnostic imaging studies for healthcare applications. The concept of use of the full cone beam was first introduced to the world of radiology soon after the development of the first CT scanners. (1,2) Its first utilization was mainly for angiography before being slowly introduced for other applications.

The most noticeable impact that cone beam scanners have had is their use in dentistry, which began in the 1990s. (2) Thanks to this evolution in CT scanners, the CBCT we see today has become ubiquitous in various dental applications such as orthodontics, implant planning, and endodontics. Slowly, more industries are beginning to see the usefulness of CBCT. In the last 3-5 years, CBCT use in chiropractic evaluation of the craniocervical junction has grown considerably and is providing chiropractors with high-quality 3D images of patient anatomy with lower effective dose of radiation than traditional CT. In most cases, the radiation dose absorbed by the patient is comparable to that of traditional chiropractic radiographic examinations of the head and neck. (1)

Review of Technology

X-ray tube: X-rays are generated in a tube containing an electrical circuit with 1 cathode and 1 anode separated by some distance in a vacuum. The cathode is generally made up of a tungsten filament which is heated when an electrical current is applied. (2) This in turn induces the release of electrons due to an effect commonly known as thermionic emission. Due to the high-voltage difference between the cathode and the anode, the electrons are then propelled towards the anode. These accelerated electrons collide with a focal spot made of high-density material [tungsten typically]. (2) As a result of these collisions, energy is created in the process and most is dissipated as heat. However, a small part of this energy is converted into X-rays via an effect known as Bremsstrahlung radiation. The X-rays form a beam as they exit the X-ray tube via a port, and the X-ray beam is controlled in size by collimation.

CT Scan: A difference between a conventional X-ray and a CT scan is that the X-ray tube and image receiver are fixed, whereas a CT scanner uses a motorized X-ray tube that circulates around the opening of a donut shaped ring, the gantry, which houses the radiation source. (3)

During a CT study, the patient will lie on a flat bed that slowly moves through the gantry while the X-ray tube rotates around the patient. The X-ray tube in the CT unit produces a narrow stream of fan-shaped X-rays directed at the body of the patient. (3) Some of the X-ray photons are absorbed by the patient and some pass through the patient's body and are received by digital detectors which are positioned directly opposite to the X-ray source. In a CBCT unit, the x-ray tube is fixed opposite the digital plate on a C-arm, which rotates as a unit around the patient.

Another key difference between MDCT and CBCT is the shape and size of the scanner itself. In its current form, a CBCT scanner looks like a small and condensed version of a MDCT scanner. Patient conveyance is not required with CBCT, though this does limit the area available to be imaged in a scan. The gantry and the FPD rotate simultaneously around the patient while shooting pulsed X-rays at the area of interest. The resulting X-rays strike the FPD on the opposite side of the source. (1) The digital plate collects the 2D data set and the computer applies the FDK algorithm to the acquired data allowing for the reconstruction of a fully 3D image of the area of interest.

Data collected by these detectors is in the form of voxels. A voxel is a combination of both "volume" and "pixel," which is a value on a regular grid in 3-dimensional space. The image made by the CT scanner consists of a square matrix of elements (the pixels) which also incorporates a depth measurement to become a voxel, or a volume element of the tissue of the patient.

Each time the X-ray source makes one full rotation, the CT's computer will create these voxels using mathematical techniques and construct a 1-dimensional

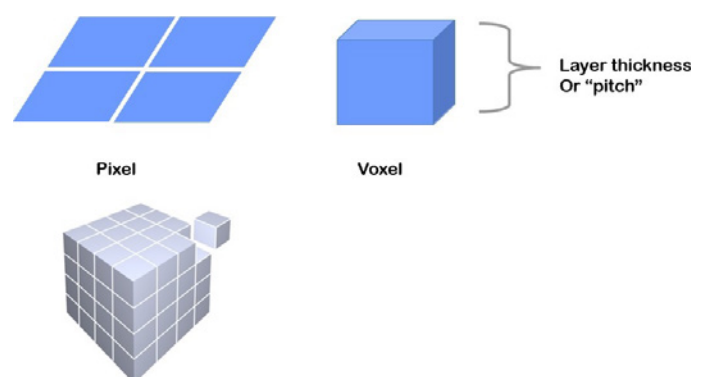


Figure 1. Depiction of the difference between a pixel and a voxel in a data acquisition sense (Used by permission of Johan Moed, PlanMed)

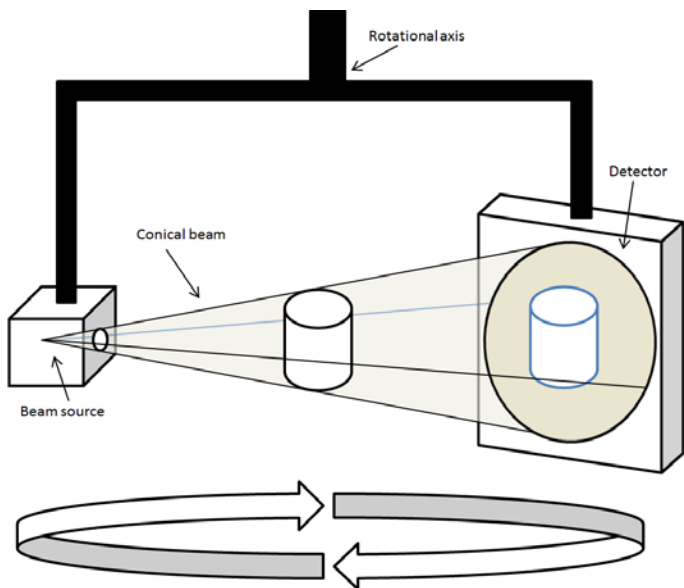


Figure 2. Principle of how a CBCT scanner works. (6)

X-ray image slice of the patient. (3) This process is then repeated to produce another image slice and continues until the desired number of slices is collected. These image slices are then either viewed singularly (2D) or stacked to form a 3D image of the patient that shows the skeleton, organs, and tissues as well as any abnormalities that the practitioner is trying to identify. (3) Helical CT accomplishes this data collection in a single spiralized collection as opposed to aggregate single slices. (Figure 1)

Technology Advancement

X-ray imaging devices (traditional radiography, MDCT, CBCT, fluoroscopy, etc.) use a common X-ray tube configuration to produce the beam. An X-ray tube used in CT scanners produces X-rays, which are then projected in a fan-shaped beam due to collimators in the machine. In MDCT, these fan-shaped beams strike a 1D detector, which interprets the values received and sends them to the computer to be interpreted, by which an image is then formed. Conversely, as the name suggests, CBCT scans use a cone shaped beam in which the X-rays come from the common X-ray tube configuration, only this time they strike a 2D flat-panel detector (FPD). (4)(Figure 2) These FPDs allow the CBCT to take multiple 2-dimensional X-ray images (basis projections) as opposed to the 1-dimensional X-ray images created by an MDCT scan. (5) For the 2D data from the FPD to be utilized properly by the CBCT,

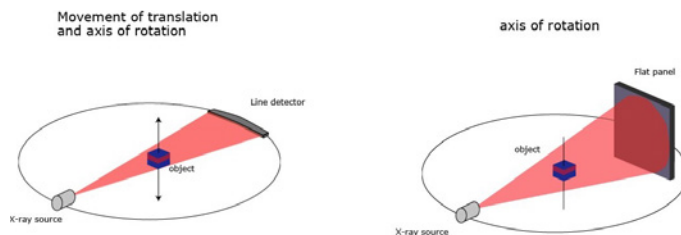


Figure 3. Depiction of CT acquisition geometries side by side for direct comparison. A: conventional MDCT. B: CBCT geometry (Used by permission of Johan Moed, PlanMed)

it is able to use the same mathematical techniques and computer programs as a MDCT. However, these algorithms must be updated and transformed slightly to allow for the interpretation of the newly created 2D data. For the computer to properly portray the new type of data, the algorithm may be transformed using a Feldkamp-type reconstruction algorithm [FDK]. (2) The FDK algorithm is a mathematical transformation of the original algorithm used to construct MDCT images, only it now considers 2D data rather than 1D data and is what ultimately allows the CBCT to create its 3D image. This shift in data acquisition allows for reduced dose to the patient. The MDCT X-ray beam is lower in energy to allow for more differential absorption; in contrast, the CBCT study uses a high-energy X-ray beam which decreases the number of photons absorbed by the patient.

It should be noted that with increasing numbers of rows in MDCT detector arrays, the acquisition geometry approximates a cone beam system because the incident X-ray photons fall on a 2D area of detectors just as they do with FPD. (4)(Figure 3)

CBCT – image quality and patient dose

When it comes to radiology and the ability of a chiropractor to diagnose a patient, a critically important factor is the quality of the image. Image quality is what allows the doctor to observe the study and make a diagnosis, whether that is looking for bone malalignment, broken bones, or foreign objects in the body. In many areas of healthcare today, diagnostic imaging is the gold standard in terms of diagnosis and assists in development of the treatment plan; this is precisely why the quality of the image makes all the difference in not only the doctor's role, but also in the quality of care received by the patient.



Figure 4. Lateral Cervical Radiographs (SS)

Pictured above is a neutral lateral radiograph (Figure 4) and sagittal slice of a CBCT image of the same patient (Figure 5)

It is important to keep in mind that chiropractors take multiple images of the same anatomic region when using traditional radiographs to obtain the necessary detail needed for proper treatment. As we begin to consider patient dose, the effective patient dose to obtain an image similar to that of Figure 4 (lateral cervical radiograph) is 0.02 mSv (20 μ Sv) and for an AP cervical spine radiograph is 0.12 mSv. (7).

The description above quoted effective dose. Due to the individual sensitivities that different tissues have to radiation, it is important to be clear about the kind of dose being described: absorbed, equivalent, or effective.

Absorbed dose "is the energy deposited in a small volume of matter (tissue) by the radiation beam passing through the matter divided by the mass of the matter". (8) This is measured in Gray (Gy) and "is equal to a joule of energy deposited in a kilogram of substance." (9)

Equivalent dose is a variation on absorbed dose that is focused on radiation-type based on its interaction with tissue. A change to units from Gray (Gy) to Seiverts (Sv) occurs after the absorbed dose is multiplied by a

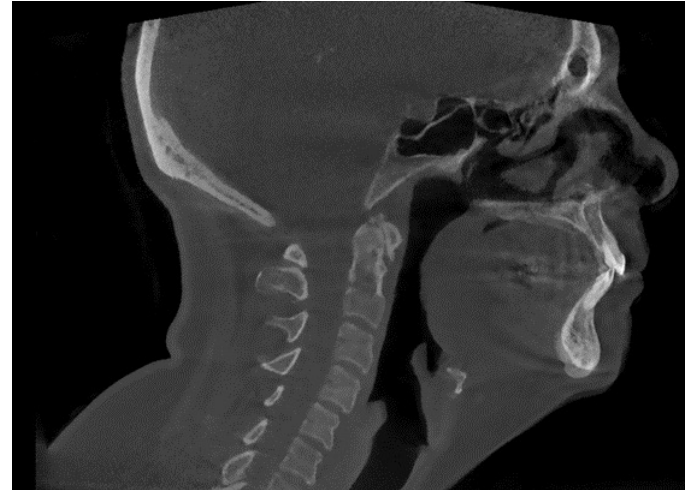


Figure 5. Midline sagittal reconstruction image -CBCT (SS)

radiation weighting factor. (8) This weighting factor is intended to allow for understanding of the amount of harm that is created by the various types of radiation (alpha, beta, gamma). (9) In X-ray, the radiation weighting factor is 1.0, so in effect the absorbed dose of 1 Gray (Gy) is equal to the equivalent dose in Seiverts (Sv). (8)

Effective dose multiplies the equivalent dose by a tissue weighting factor and is used to describe the effect of the radiation on the specific tissue that was exposed; effective dose is also described in Seiverts (Sv).

Understanding effective dose is necessary to evaluate the patient risk of having a diagnostic imaging study.

The effective dose obtained from Planmeca CBCT imaging supplies an effective dose range between 0.091 – 0.273 millisieverts (mSv) (91-273 microsieverts (μ Sv)) depending on patient size using standard settings at 30cm x 30 cm field of view, with effective dose reduced to .023-.068 mSv (23-68 μ Sv) with an ultra-low dose protocol. (Table 1) In contrast, the dose of a cervical spine x-ray examination has a total average effective dose of 0.2 mSv (200 μ Sv), and an MDCT has a total average effective dose of 3 mSv (3000 μ Sv) for the neck and 2 mSv (2000 μ Sv) for the head. (10)

As a result of this comparison between CBCT and X-ray imaging dose, CBCT supports doses being as low as reasonably achievable (ALARA) when considered against traditional X-ray examination, especially in cases in which extra views are recommended as in cases of trauma, radiculopathy, anatomic anomalies, and most chiropractic upper cervical techniques (UCTs). (11)

Table 1. Comparing patient size to voxel with exposure considerations.

VOXEL	XS			S			M			L			XL		
	kV	mAs	µSv	kV	mAs	µSv	kV	mAs	µSv	kV	mAs	µSv	kV	mAs	µSv
600	90	28	91	90	32	104	100	25	120	110	22	144	120	20	171
450	90	36	117	90	40	130	100	32	153	110	28	183	120	25	214
300	90	45	146	90	50	162	100	40	191	110	36	236	120	32	273
ULD															
600	90	7,1	23	90	8,0	26	100	6,3	30	110	6,3	41	120	6,3	54
450	90	9,0	29	90	10	32	100	8,0	38	110	7,1	46	120	6,3	54
300	90	11	36	90	12,5	40	100	10	48	110	9,0	59	120	8,0	68

(Planmeca VisoG7 Effective Dose Chart, D0011748, J Koivisto, University of Helsinki, Dept of Physics)

To understand health risks, it is helpful to understand what is allowed for people who work in occupations with regular radiation exposure. "The effective dose limits for a nuclear energy worker is set at 50 mSv in any one year and 100 mSv in five consecutive years. The dose limit for pregnant workers is 4 mSv from the time the pregnancy is declared to the end of the term." (9) For a frame of reference, the typical radiation an average individual in the USA can expect to encounter is 6.2 mSv (6200 µSv) (12,13) or from background radiation alone is 3 mSv (3000 µSv) annually. (10)



Figure 6. 3D reconstruction with threshold set to image bone surface using CBCT (SS)

Figure 6 depicts a 3D surface rendered reconstruction.

Figure 7 depicts a typical 3 view X-ray series; Figure 8 depicts multiplanar reconstruction (MPR) view using a single CBCT scan on the same patient.

Benefits of CBCT and 3D imaging

When considering chiropractic use of CBCT 3D imaging, there are several benefits available to the clinician, radiologist, and patient. These include less or equivalent radiation, better spatial resolution quality, wider variety of viewing angles, less time spent with image acquisition, easier patient positioning and improved patient experience, more precise treatment planning and protocol, reduction in electrical requirements, and reduced need for lead lined imaging suites.

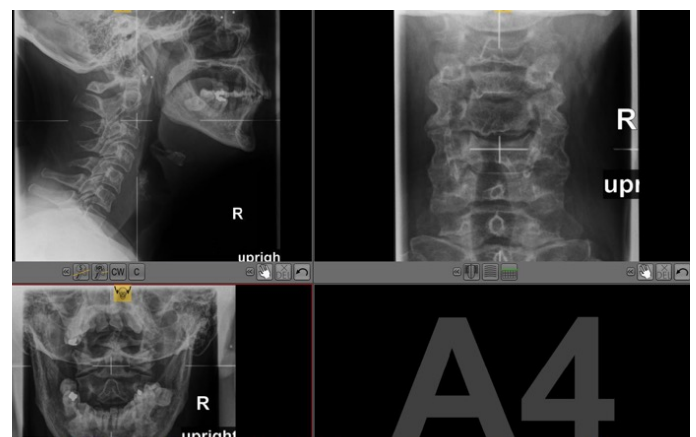


Figure 7. X-ray 3 view series (SS)

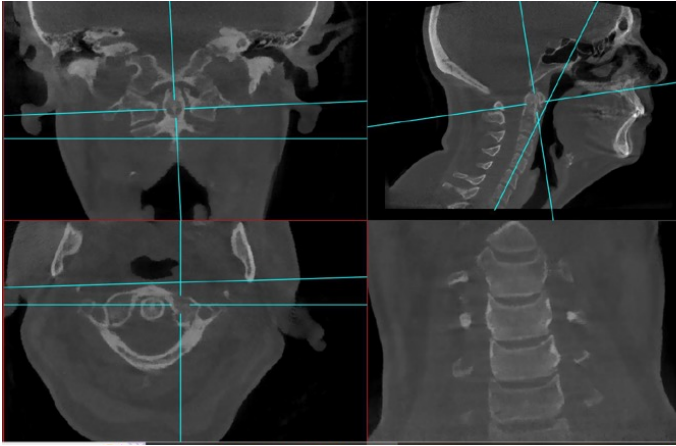


Figure 8. CBCT multiplanar image reconstructions

In general, CBCT imaging lasts around 40 seconds and may be taken while the patient is either seated or standing; this provides both versatility and accessibility given that standing is not always a viable option for many patients.

Use of CBCT instead of traditional x-ray also negates the UCT specialty images that might be required in the thorough evaluation of the spine by chiropractors, especially those of the craniocervical junction and cervical spine. The ability to manipulate the image angles and perspectives replaces the need for multiple X-ray views to assess vertebrae and joints from different vantage points; this eliminates the need for retake imaging as well as multiple exposures to adequately assess an area.

Image resolution and the ability to create multiplanar reconstructions, combined with the lack of magnification and distortion in the image, provides for a diagnostic imaging study free of technical limitations inherent to traditional X-ray. With the use of CBCT we see a clear reduction in the time required for image acquisition while simultaneously improving image quality.

CBCT provides the ability to visualize and accurately discern complicated segmentation anomalies of the craniocervical spine and enhances the ability to identify pathogenic proximity to other anatomy as compared to X-ray. Assessing severity of joint disease and other disease that is not able to be well studied with radiographs, is also enhanced with CBCT applications [i.e. fusions not evident on traditional X-ray, calcium pyrophosphate deposition disease (CPPD)/ pyrophosphate arthropathy involving the cruciate

ligament complex and other paraodontoid structures, Schmorl's nodes, and styloid process elongation (sometimes associated with Eagle Syndrome)]. The addition of CBCT in a chiropractic office not only improves the chiropractor's ability to provide care to their patients but does so while supporting ALARA guidelines.

Future Applications

After reviewing both MDCT scans and CBCT scans, CBCT is an evolution in existing computed tomography technology rather than a new technology. In both cases, X-rays are still produced in a similar fashion, with the only real changes occurring with image detection and computer programming. This progress is like the development of new imaging sequences, receptor development, or enhancing magnet strength in MR.

Although the data requisition in CBCT technology is 2D rather than 1D in MDCT, multiple detector arrays on regular MDCT scanners approximates the data collection of the CBCT's 2D surface. Essentially, this means that the special detectors used in MDCT are trying to recreate what the CBCT flat-panel detector already does during a scan. This mimicking of data acquisition is exactly what allows CBCT to essentially use the same algorithm that the MDCT scanner would use.

CBCT is seeing increased use in many different fields and is already used widely in dental imaging regarding the investigation of exact jaw pathologies such as tumours, inflammatory lesions, or for maxillofacial surgery. (14) The 3D cone beam also aims to address the limitations present in 2D imaging on mammography with high contrast between pathological and normal breast tissue. (15) CBCT is seeing advancements in both liver and lung imaging. (16,17) CBCT machines are being developed to evaluate the entire spine; the technology is advancing quickly, and in the coming decades it may replace conventional radiography in evaluating for many diseases of the spine. High-quality CBCT studies will provide chiropractors with improved detail resulting in more accurate identification of pathology and therefore improved quality of care for the patient.

CBCT and MDCT are both forms of CT with CBCT having significantly reduced effective radiation dose. The reduced dose provided by CBCT will allow it in many cases to replace traditional X-ray examinations. There is clear evidence to support the fact that CBCT is not something new entirely but rather an evolution of an existing technology that may be beneficial for both patients and chiropractors alike.

CONCLUSION

Although CBCT has been used extensively in the dental industry for more than 2 decades, the ability for a single CBCT scan to replace a full cervical X-ray series is a recent development due to increases in capture device size. Technological advancement will likely soon allow all skeletal regions to be imaged by CBCT. MDCT and CBCT machines share similarities in X-ray generation and data processing, and as a result CBCT is an evolution of established CT and X-ray technology. With no increase in effective dose rates, and improvement in cross-sectional imaging capability, CBCT should be available as chiropractors seek to follow informed patient care with mind to ALARA principles and is best regarded as inside the scope of chiropractic practice in which radiation-based diagnostic imaging is currently allowed. It is our opinion that CBCT is a valuable and safe dose radiation-based diagnostic imaging study appropriate for access and use across the healthcare professions.

AUTHOR CONTRIBUTIONS

The need for this paper was conceptualized by JS and designed by JS and AK. The manuscript was drafted by AK and JS and edited with contributions by MR and KC. Radiographic and CBCT imaging provided by JS with patient consent. All authors read and approved the final manuscript.

CONFLICT OF INTEREST

The authors declare no conflict of interest with this article.

ACKNOWLEDGEMENTS

We would like to acknowledge Kira Scholten, who provided technical editing feedback. Thanks to SS who permitted image use (CBCT from Barcelona) and to Dr. Kerry Johnson who provided images for consideration.

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