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Original Research

Ethical challenges and Medicolegal issues of Cone Beam CT usage in pediatric patients

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ABSTRACT:
Objectives: The following article review addresses the ethical and medicolegal challenges surrounding using CBCT in pediatric patients. **Data Review:** Data collection was done through previously published papers for the literature review. The following databases were used to collect the already published articlesfrom GoogleScholar and Pubmed. **Conclusion:** There is a widespread use of CBCT in pediatric patients for diagnostic and treatment modalities however, the use of CBCT technology involves potential liabilitiesand risks associated with it.
Keywords: CBCT, radiation, diagnosis, dose, pediatric, ethical, informed consent.

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INTRODUCTION

Dental radiography is an essential diagnostic modality in dental practice and the most frequent radiographic diagnostic procedure in medicine.[5] As oral health providers, our maingoal is to safeguard the therapeutic outcome, health, and quality of life of our patients, and to achieve this purpose, dentomaxillofacial radiology is often used in pediatric dentistry.[8]

One type of radiography is Cone beam computed tomography (CBCT), which has a vast range of dentomaxillofacial applications[6], including for children and young adults.[3] Cone beam computed tomography (CBCT) provides high-quality three-dimensional images of the maxillofacial area[2] and it obtains real measurements of the maxillofacial region in theaxial, sagittal, coronal planes and from different angles.[4] Although the use of cone beam CTis rising, it comes with a lot of ethical dilemmas, like Johan Hartshorne[20] states in his reviewarticle: cone beam CT is a fundamental diagnostic tool for clinical assessment and treatment planning and has revolutionized implant practice. However, CBCT comes with pitfalls, liabilities, and risks.[20]

Cone Beam CT is often requested before orthodontic treatment, maxillofacial surgery, placement of dental implants and to evaluate benign and malignant tumors, bone disease, orother pathological conditions.[4] In addition, it is frequently used in pediatric patients requiring corrective or reconstructive surgery, such as cleft palate and orthognathic patients.[5] CBCT has several advantages compared to two-dimensional (2D) radiographs but also has some disadvantages, the most concerning is that radiation doses are higher[1], and in pediatric patients can be a sensitive issue.[6] This issue is an important challenge, according to Ioana Maria Colceriu-Șimon et al[1], the use of CBCT in the field of orthodontics and dentofacial orthopedics is increasing and some orthodontists are replacing two-dimensional radiographic images with 3D ones. The main concern is that children have a greater susceptibility to radiation damage than adults, due to immature anatomical and biological structures.[4] Therefore, the dose of CBCT has become a major concern, as ionizing radiation is a known carcinogen.[14]

Whenever dentists require radiographs, they must provide their patients with justifiable diagnostic options, carrying out the risk-benefit analysis before

prescribing CBCT.[14] An important patient safety issue is understanding the radiation dose imparted by CBCT and the potential biological risks to the patient. Therefore, appropriate selection criteria must be used with the minimum radiation exposures that result in images of acceptable diagnostic qualities.[20] Radiation dose is measured as the quantity which is absorbed by someone exposed to X-rays. The measurable doses from the radiological procedures are expressed as diagnostic reference levels.

- CBCT procedures (based on median values from literature): 50 μSvor below for small- or medium-sized scanning volumes, and 100 μSv for large volumes.

It can be emphasized that the CBCT effective dose is comparatively higher than the conventional radiographic techniques.[21]

This study emphasizes the ethical challenges or dilemmas that face with the use ofCBCT in pediatric populations

EFFECTIVENESS

The precise role that CBCT plays in all fields of dentistry is still in a state of flux. However, it is used across all disciplines, more for some than for others, and certainly in orthodontics.[17]

CBCT, nowadays, is part of an important place in the diagnosis and the planning of treatments.[14] For example, it has wide use in pediatric patients, such as diagnostic and therapeutic management of impacted and supplementary teeth are considered a prime and justified indication for cone-beam CT in pediatric dentistry.[6]

Traumatic injuries in children are very common, affecting mostly the dentoalveolar complex, the dental and bone fractures are the most frequent early complications associatedwith trauma.[6] CBCT can lead to very high diagnostic accuracies for root fracture. Furthermore, these levels of accuracy are higher than when using periapical radiographs.[3] For example, a systematic review by Fernanda Cristina Sales Salineiro et al[15], demonstrates that CBCT imaging rendered a higher sensitivity and diagnostic odds ratio values for root fractures than periapical radiographs. However, the presence of metallic posts or endodontic fillings could slightly affect the diagnosis accuracy of root fractures in CBCT images.[15]

For developmental disorders in children, such as cleft lip and palate (CLP), the use ofCBCT is widely used.[3] It determines the cleft's shape, size, and volume. Also, CBCT monitors the development and eruption of adjacent teeth and analyses the involvement of the nasal cavity. These data are required to plan surgical procedures (bone graft and orthognathic surgery) and orthodontic approaches.[6]

The possibilities of CBCT application for orthodontic reasons range from impacted teeth to TMJ morphology.[13] CBCT is widely used in orthodontics, because it has several advantages over 2D imaging, such as increased image quality, a short exposure time, and a lower radiation dose compared to traditional computed tomography.[1]

The evidence regarding the diagnostic value of CBCT for resorption of teeth was weighted towards that associated with unerupted maxillary canine teeth. It is probably the most common pediatric use of CBCT and may be relevant to pediatric dentists working withtheir orthodontic colleagues.[3]

RISKS

Now a days, there are guidelines published related to the clinical use of CBCT including referral guidelines, also known as "appropriateness criteria" and "selection criteria, but very little is found specifically on pediatric use of CBCT.[3] This is a huge concern becausechildren and young adults are three to five times more sensitive than adults to radiation- induced carcinogenesis and have many remaining years of life for cancer to develop.[5] The pediatric population, consisting of patients under 18 years, shows increased radio sensitivitycompared to adults due to the higher rates of cell growth and organ development. Children's susceptibility to mutagenic factors is increased due to differences in assimilation, metabolism, and excretion. In addition, children have a longer lifespan to express the radiation-induced effects.[1]

The pediatric population is more susceptible to the risks of ionizing radiation. This heightened susceptibility has multiple reasons. Under-aged patients present with a higher mitotic activity which inherently leads to the higher radiation sensitivity of tissues that are less developed and contain more undifferentiated cells.[8] Furthermore, young patients are more susceptible to ionizing radiation (IR) because of the increased number of young cells that are strongly affected at the level of the DNA and cell division. This problem raises the need to investigate the effects of low-dose IR, such as CBCT exposure, especially because of the increased proportion of children in the orthodontic practice.[1] The routine use of CBCT for all orthodontic patients is currently not supported by strong evidence, leading to an intense debate in the scientific literature. Some practitioners advocate its routine use for all orthodontic patients, while others are more reluctant because of the increased radiation burden on pediatric patients.[1] Therefore, as many orthodontic patients are children and young adults, with many years of life left, during which time latent untoward effects of radiation could progress to life-threatening diseases.[14] As a result, orthodontists need to justify CBCT scans for their patients and limit radiation exposure.[14] According to the European commission's guideline[16] the radiation doses involved, the largely pediatric age group of patients and the daily use of this X-ray as a routine tool for orthodontic practice has become controversial and requires very critical consideration.[16]

ETHICAL DILEMMAS

The principles of ethics from the American Code

explain five principles that need tobe involved in the dentist's behavior and how a professional dentist conducts toward their patients.

The five principles are:[18]

- *Autonomy:* professionals must treat the patient according to the patient's desires, within the bounds of an accepted treatment, and protect the patient'sconfidentiality.
- *Non-Maleficence*: professionals must protect the patient from harm.
- *Beneficence*: professionals must act for the benefit of others.
- *Justice*: professionals must be fair in their dealings with patients, colleagues, and society.
- *Veracity*: professionals have a duty, to be honest, and trustworthy in their dealings with people.

Therefore, it is important to understand the applications of cone beam CT and if it can be used routinely in some dental specialties without transgressing ethical principles. For example, all CBCT examinations must be justified on an individual basis by demonstrating that the potential benefits to the patients outweigh the potential risks.[16] Furthermore, adequate information should be provided to the patients to make them understand the risks associated with radiation[14], especially when the patients are children or young adults, which as we explained are more susceptible to risks.

As a result, it is compulsory that dentists extend an informed consent to every patient before CBCT prescription and when these patients are children and adolescents, their assent also be taken along with informed consent from parents/guardians.[14] Also, when referring apatient for a CBCT examination, the referring dentist must supply sufficient clinical information (patient history and results of examination) to allow the CBCT practitioner to perform the Justification process.[16]

The clinician performing or interpreting CBCT scans for implant dentistry should take into consideration current radiologic guidelines for the safe and effective use ofCBCT.[20]

Several mandates need to be accomplished in the presence of a CBCT, for example, CBCT radiography must not be carried out unless history and clinical examination have been performed and must be justified for each patient to demonstrate that the benefits outweigh the risks (Justification). CBCT must use the smallest volume size (FOV) that is compatible with the clinical situation and a quality assurance program must be established and implemented for each CBCT facility, including equipment, techniques, and quality control procedures (Optimization). CBCT equipment should be installed in a protected enclosure anddesignated as a controlled area. In addition, the provision of personal monitoring must be considered (Staff Protection). Finally, staff members involved with CBCT must have received adequate theoretical and practical training.[20]

DISCUSSION

The CBCT geometry has widespread use in diagnostic CT and interventional radiology. Conventional tomography was a technique that was used to take radiographs in only specific cases such as severe anomalies. However, conventional tomography was very expensive and concurrently exposed the subjects to excessive radiation. The diagnostic capacity was better with the CBCT as it uses volumetric tomography. IOPAR and OPG wereused as diagnostic imaging techniques in the past as the radiation exposure was considered low, however, these techniques produced 2D representation of the images which posed problems in the treatment planning.[9] CBCT has higher radiation exposure however the dosereduction seems to be less and between 96% and 51% as compared with conventional CT. CBCT technology causes excess radiation exposure. This excessive radiation exposure can be hazardous for children because the rate of tissue growth is higher in children and there isa high risk of DNA damage as a result of the excessive radiation.[3] There is a variation in the technical efficiency of CBCT machines. The diagnostic efficacy of one CBCT machine may differ from the other high-quality CBCT machines. Some CBCT machines may produce low-quality radiographs which may not be helpful for diagnostic purposes.[9] Overall, CBCT affects the treatment planning and analysis of the treatment plan. CBCT is very helpful across all diagnostic modalities. It is particularly helpful in assessing ectopic teeth, cysts, and supplemental teeth. CBCT has been a useful diagnostic tool for pediatric dentists as it aids in assessing the closeness to adjacent local structures concerning the treatment. Therefore, it makes the surgical approach convenient. Furthermore, CBCT has improved the treatment plans for pediatric dentists. One of the most important applications of CBCT is in the assessment of trauma-related cases. CBCT can delineate resorption and fractures which may be easily missed in 2D imaging techniques. In some cases, CBCT rejected certain findings which were in question in the 2D images. In general, pediatric dentists are conservative when it comes to ordering CBCT for pediatric patients. As compared to adults the radiation risks are higher in pediatric patients. However, the most important use of CBCT is in orthodontics. It is mostly utilized to assess the developing dentition.[10] CBCT has a large application in dentomaxillofacial imaging, especially in children. However, it does pose some risks to pediatric dental patients. CBCT utilizes ionizing radiation which can cause damage to DNA. In children, the risk of carcinogenesis is of particular concern because of high tissue radiosensitivity.[11] The effective radiation dose should be kept into consideration. Therefore, the practitioners need to follow principles of radiation protection to protect the children from stochastic biological damage.

The three principles of radiation protection include

justification, limitation, and optimization. Justification means that a radiograph must only be taken if there is no other way to obtain necessary information. Limitation suggests that the practitioners must try to keep the radiation dose appropriate i.e. As low as reasonably achievable (ALARA). The third principle suggests that the practitioner should try to achieve accurate and good-quality radiographs utilizing the previous two principles.[12]

Ethical principles can be involved when a dentist or another health professional uses a cone beam CT. For example, the principle of ***autonomy*** must be respected by allowing patients to make their own informed choices for treatment. Therefore, on the issue of CBCT, autonomy refers to respect for a person's choice of diagnostic modality.[14]

Furthermore, the autonomy principle involves informed consent, and this legal document should be obtained from every patient before taking CBCT, and the risk associated with stochastic effects of radiation should be disclosed in the information sheet provided to the patients in a simple, understandable manner. Moreover, in cases where patients cannot give informed consent, consent can be obtained from parents or guardians.[14]

When a practitioner is considering using a CBCT, he/she always looks for the patient's best interest, by maximizing benefits and minimizing harm. Consequently, the principles of **beneficence** and ***non-maleficence*** are involved, because the dental professional has to weigh the net benefit from the CBCT scan against the radiation risks.[14]

Clinicians should treat their patients fairly, providing them with informed and justifiable diagnostic options. Therefore, the ***justice*** principle could be implied in the use of CBCT. For example, for patients with cleft lip and palate, the use of CBCT is justified over the use of CT images because of less radiation and low cost.[14]

ETHICAL AND MEDICOLEGAL CHALLENGES OF USING CBCT TECHNOLOGY

With the advancement of CBCT technology, clinicians must be aware of the risks and liabilities associated with its use. Dentists with inappropriate training must not perform the interpretation of the extended field of view diagnostic imaging studies using CBCT. The American Association of Oral and Maxillofacial Surgery does not exclude non-radiologist dentists from reading the CBCT radiographs, however, they are of the view that these dentists must acquire the proper training to be able to read the radiographs correctly. Dentists are held responsible for the standard of care and therefore, must be able to receive additional training for CBCT interpretation. The most common error regarding the use of CBCT is either a large FOV or a very small FOV. A larger FOV leads to an image that does not provide enough details and also provides a greater radiation dose. This raises potential liability concerns as the scan may not provide a correct image for diagnostic modality and also exposes the patient to excessive radiation. Clinicians who do not possess adequate training in reading the CBCT radiograph must refer the scan to a specialist such as an Oral and Maxillofacial radiologist for review. Clinicians are morally and ethically obligated to weigh the benefits and risks associated with CBCT usage. It should be used for better treatment planning and diagnostic modality. At the same time, it is important to obtain informed consent regarding the use of CBCT technology. With the use of CBCT, the clinician can better explain the diagnostic and treatment planning to the patient. However, if the patient refuses treatment after being made aware of the risks and benefits of the treatment, it should be documented as well as part of the CBCT radiography protocol. The use of CBCT carries the risks of medicolegal risks and the clinicians must be aware of those risks. If a clinician owns a CBCT machine and is taking scans of his/her patients but also taking the scans of patients being referred from outside, in that case, the dentist must make sure that they do not lack malpractice coverage in case of a lawsuit situation for a misdiagnosis. It is also legally important to read the entire scan and not a part of the scan. CBCT also provides the important information that may be required for insurance reimbursement. The significance of CBCT for implant treatment planning cannot be denied. In some cases, implant failure can happen despite an exceptional standard of care. CBCT documentation helps in this regard in case a question arises the dentist can provide detailed information to prevent litigation. Therefore, it is of paramount importance that clinicians receive proper training in reading the scans. They must ensure that they meet the requirements of licensing and malpractice liability coverage from insurance carriers.[20]

CONCLUSION

Ionizing radiation is a known human carcinogenic factor and its biological effects are more important in young patients because of their higher radio sensitivity.

The indications for the use of CBCT in pediatric dentistry have not been properly addressed. Multiple international organizations have tried to review the available literature and offer guidelines for judicious use of CBCT in the orthodontics field. However, the three basic principles of radiation protection (justification, limitation, and optimization) should suffice.

On the other hand, CBCT is an excellent and essential tool for dentists if they want to know specifically if a tooth is fractured or not, also it aids in the detection of periapical lesions or tumors. Many orthodontists are using this type of x-ray in their daily practice, however, a large volume of CBCT should not be used routinely for orthodontic diagnosis. As stated in the study of Maret et al (19), CBCT is not a panacea and should not be used in every case. From a public health

perspective, there is no need for all dentists to have a CBCTdevice in their practices.

It is mandatory that CBCT guidelines are incorporated into the dental education curriculum and that dentists or practitioners undergo certification in CBCT protocols and guidelines. Additionally, all the staff members who manipulate the cone beam CT must receive appropriate training and continuing education particularly when new CBCT equipment or techniques are adopted.

REFERENCES

1. Colceriu-Şimon IM, Băciuţ M, Ştiufiuc RI, Aghiorghiesei A, Ţărmure V, Lenghel M, et al. Clinical indications and radiation doses of cone beam computed tomography in orthodontics. MEDICINE AND PHARMACY REPORTS. 2019;94(4):346–51.
2. Gümrü B, Guldali M, Tarcin B, Idman E, Sertac Peker M. Evaluation of cone beam computed tomography referral profile: Retrospective study in a Turkish pediatric subpopulation. 2021;22:66–70.
3. Horner K · Barry. S · Dave. M · Dixon. C · Littlewood. A · Pang. C. L· Sengupta. A Srinivasan. V. Diagnostic efficacy of cone beam computed tomography in pediatric dentistry: a systematic review. Eur Arch Paediatr Dent. 2020;21:407–26.
4. İşman Ö, Yılmaz HH, Aktan AM, Yilmaz B. Indications for cone beam computed tomography in children and young patients in a Turkish subpopulation. Int J Paediatr Dent. 2017 May;27(3):183-190.
5. Jacobs R., Pauwels R., Scarfe W.C., De Cock C., Dula. K., Willem. G et al. Pediatric cleft palate patients show a 3- to 5-fold increase in cumulative radiation exposure from dental radiology compared with an age- and gender-matched population: a retrospective cohort study. Clin Oral Invest. 2018;22:1783–1793.
6. Opening AC, Jacobs R, Pauwels R, Stratis A, Hedesiu M, Salmon B, DIMITRA Research Group. Cone-beam CT in pediatric dentistry: DIMITRA project position statement. Pediatr Radiol. 2018;48(3):308–16.
7. Sheikh K, Liu D, Li H, Acharya S, Ladra MM, Hrinivich WT. Dosimetric evaluation of cone-beam CT-based synthetic CTs in pediatric patients undergoing intensity-modulated proton therapy. J Appl Clin Med Phys [Internet]. 2022 Apr 12; Available from:http://dx.doi.org/10.1002/acm2.13604
8. Van Acker, J.W.G., Pauwels, N.S., Cauwels, R.G.E.C. et al. Outcomes of different radioprotective precautions in children undergoing dental radiography: a systematic review. Eur Arch Paediatr Dent 21, 463–508 (2020). https://doi.org/10.1007/s40368-020-00544-8
9. Bhardwaj SS, Alghamdi S, Almulhim B, Alassaf A, Almalki A, Bhardwaj A, et al. CBCT in Pediatric Dentistry: Awareness and Knowledge of Its Correct Use in Saudi Arabia. Applied Sciences 2021;12:335. https://doi.org/10.3390/app12010335.
10. Gallichan N, Albadri S, Dixon C, Jorgenson K. Trends in CBCT current practice within three UK Paediatric Dental Departments - European Archives of Paediatric Dentistry [Internet]. SpringerLink. Springer Berlin Heidelberg; 2020 [cited 2022May31]. Available from: https://link.springer.com/article/10.1007/s40368-020-00526-w
11. De Felice F;Di Carlo G;Saccucci M;Tombolini V;Polimeni A; Dental cone beam computed tomography in children: Clinical effectiveness and cancer risk due to radiation exposure [Internet]. Oncology. U.S. National Library of Medicine; [cited 2022May31]. Available from: https://pubmed.ncbi.nlm.nih.gov/30836369/
12. Aps, J. K. M. (2013, April 6). Cone Beam Computed Tomography in pediatric dentistry: Overview of recent Springer Link. RetrievedMay 31, 2022, fromliterature - European archives of pediatric dentistry. https://link.springer.com/article/10.1007/s40368-013-0029-4 s
13. De Grauwe A, Ayaz I, Shujaat S, Dimitrov S, Gbadegbegnon L, Vande Vannet B, Jacobs R. CBCT in orthodontics: a systematic review on the justification of CBCT in a pediatric population before orthodontic treatment. Eur J Orthod. 2019 Aug 8;41(4):381-389. doi: 10.1093/job/cjy066. PMID: 30351398; PMCID: PMC6686083.
14. Parveen S, Kulkarni U, Mascarenhas R, Shetty R. Awareness and Practice of Ethics and Guidelines with Cone-Beam Computed Tomography Prescription in Orthodontics. Journal of Indian Orthodontic Society. 2019;53(1):49-56. doi:10.4103/jios.jios_134_18
15. Salineiro FCS, Kobayashi-Velasco S, Braga MM, Cavalcanti MGP. Radiographic diagnosis of root fractures: a systematic review, meta-analyses and sources ofheterogeneity. Dentomaxillofac Radiol. 2017 Dec;46(8):20170400. doi: 10.1259/dmfr.20170400. Epub 2017 Nov 2. PMID: 28749700; PMCID: PMC5965946.
16. European Commission. Cone Beam CT for Dental and Maxillofacial Radiology: Evidence-Based Guidelines. Luxembourg: SEDENTEXCT; 2012. Available from: http://www. sedentexct.eu/content/guidelines-cbct-dental-and-maxillofacialradiology. [Last accessed on 2022 Jul 15].
17. Friedland, B., Scarfe, W.C. (2018). Ethical and Medicolegal Issues Related to CBCT. In: Scarfe, W., Angelopoulos, C. (eds) Maxillofacial Cone Beam Computed Tomography. Springer, Cham. https://doi.org/10.1007/978-3-319-62061-9_6
18. American Dental Association American Dental Association principles of ethics and code of professional conduct, with official advisory opinions, revised to November2020. https://www.ada.org/
19. Maret D, Vergnes JN, Peters OA, Peters C, Nasr K, Monsarrat P. Recent Advances in Cone-beam CT in Oral Medicine. Curr Med Imaging. 2020;16(5):553-564. doi: 10.2174/1573405615666190114152003. PMID: 32484089.
20. Hartshorne J. Essential guidelines for using cone beam computed tomography (CBCT) in implant dentistry. Part 3: Radiation dose, risks, safety, ethical and medico-legal considerations. 26 INTERNATIONAL DENTISTRY -AFRICAN EDITION [Internet]. [cited 2022 Aug 11];8(5). Available from: http://www.moderndentistrymedia.com/oct_nov2018/hartshorne_part3.pd
21. Radiation doses in dental radiology [Internet]. IAEA. IAEA; 2017 [cited 2022Aug16]. Available from: https://www.iaea.org/resources/rpop/health-professionals/dentistry/radiation-doses