Over the past 2 1/2 years I have been a member of a joint committee comprising appointed representatives of the American Association of Orthodontists (AAO) and the American Academy of Oral and Maxillofacial Radiology (AAOMR). The committee has been tasked with developing a position statement providing selection criteria to assist practitioners in choosing appropriate radiologic imaging for patients presenting for orthodontic opinion and therapy, with particular reference to cone beam computed tomography (CBCT). The formation of this group coincided with the publication of a front-page article in The New York Times, which catapulted public awareness of the increased radiation dose and associated risks associated with CBCT, particularly in orthodontics. At the time of writing this editorial, the draft document has been submitted to the Executive Committee of the AAOMR and the Board of Trustees of the AAO. In developing this document, the committee members had many online discussions, as a result of which I have become aware of differing perceptions of the concept of radiation dose and risk assessment, especially as it pertains to low-dose diagnostic imaging and in particular maxillofacial radiology.

Recent reports have increased concerns over the potential association between radiation exposure and cancer and raised the use of ionizing radiation for diagnostic dental imaging as an important public health issue. Claus et al. published a case–control retrospective study in the prestigious journal Cancer describing a relationship between increased risk of intracranial meningioma and reported (by telephone interview) episodes of dental radiographic procedures performed in the past. Specifically, they found that patients with meningioma had twice the risk of reporting ever having a bite-wing x-ray compared with nondisease controls. They also stated that individuals who reported receiving bite-wing x-rays on a yearly or more frequent basis had an elevated risk as age increased. This study supports the findings of at least 2 previous independent research groups. However, these results are highly controversial because preliminary responses have highlighted limitations in the data collection and consistency of the study that may render the conclusions invalid.

What has become most apparent, through the committee’s dialog and recent published reports, is a need to clarify the risks associated with maxillofacial radiation dose.

RADIATION DAMAGE AND RISK ASSUMPTIONS

An excellent and concise update describing the biological effects of radiation, estimating risk estimation and radiation safety principles associated with the use of ionizing radiation in dentistry, was recently published. There are 2 broad, potentially harmful effects of the use of ionizing radiation in maxillofacial imaging. The direct death or malfunction of cells, referred to as deterministic effects, produces tissue-specific changes and requires a high dose over a short period of time (acute) and usually only presents clinically after a specific dose level or threshold has been reached. These levels are never reached in the diagnostic range encountered in oral and maxillofacial radiology. However, they can be seen in dental patients who undergo radiotherapy to the head and neck region for the treatment of cancer. One example of this is the presentation of radiation-induced oral mucositis. The second effect, called a stochastic effect, is the irreversible alteration of the cell, usually from damage to cellular DNA resulting in cancer, leukemia, and, occasionally, genetic damage. Stochastic effects (radiation-induced carcinogenesis and, to a lesser extent, heritable effects owing to mutation of reproductive cells), unlike deterministic effects, are the most important in dentistry. Stochastic effects result from low levels of radiation and may become apparent over an extended period of time—chronic exposure. Currently there is sufficient evidence demonstrating that there is a risk of tumors for individuals exposed to more than approximately 100 mGy. However, for dental radiography, including CBCT, dose exposures are far less than that at this level. What happens in the range below 100 mGy and, more specifically, what are the organ doses in the head from CBCT?

Consensus among radiation epidemiologists and radiobiologists internationally who focus on these issues is that stochastic risks should be considered linearly related to dose, all the way down to the lowest doses. This is known as the linear nonthreshold (LNT) hypothesis, which is the principle that is currently adopted by radiation protection organizations in the United States. However, some dispute the suggestion that there is really a risk at doses less than 100 mGy and that greater harm from misdiagnosis may occur to the patient by limiting diagnostic imaging based on such a flawed assumption. A position paper from the American Association of Physicists in Medicine states that...
“Predictions of hypothetical cancer incidence and deaths in patient populations exposed to such low doses are highly speculative and should be discouraged. These predictions are harmful because they lead to sensationalistic articles in the public media that cause some patients and parents to refuse medical imaging procedures, placing them at substantial risk by not receiving the clinical benefits of the prescribed procedures.”16 Others refute the evidence for the LNT hypothesis and describe cellular studies providing support for the beneficial and perhaps protective/adaptive mechanisms of low-dose radiation mitigating against cancer induction through DNA damage,17,18 a concept referred to as radiation hormesis.19 What these positions do confirm is that there is neither actual hard evidence for carcinogenesis at the level of dental exposures nor the absence of such damage. Acceptance of the LNT hypothesis does not mean that it is known that a risk exists at these levels, but rather that, in the absence of clear evidence of a threshold dose, it is prudent to assume that such a risk exists. This situation is unlikely to change in the foreseeable future. This implies that there is no safe limit or “safety zone” for ionizing radiation exposure in diagnostic imaging. Every exposure cumulatively increases the risk of cancer induction in direct proportionality.

WHOLE-BODY VERSUS ORGAN DOSE
Effective dose (E) is the currently accepted index used to measure the whole-body equivalent in terms of detriment—cancer and heritable effects.20 It allows comparison of partial-body exposures. E is calculated by multiplying average organ doses in specific susceptible tissues by “risk weighting factors” (which give each organ’s relative radiosensitivity to developing cancer) and adding up the total of all the numbers; the sum of the products is the “effective whole-body dose” or just “effective dose.”20 It is important to note that approximately two thirds of the weighted tissues that are included in the effective dose calculation are not found in the head and neck area and receive no or nominal doses from maxillofacial radiography imaging. This is an important factor in the low effective doses that are calculated for dental/maxillofacial examinations. As an example, the salivary gland dose imparted by a various scanning protocols of the ProMax 3D CBCT scanner (Planmeca, Helsinki, Finland) ranges from 0.56 mSv to around 5.5 mSv.21 The effective dose of this equipment ranges from 30 µSv and 306 µSv, respectively.21 These specific internal organ doses are very high, with the largest being comparable to that reported for medical computed tomography (CT) in the same article with a low-dose protocol (8.6 mSv).22 The estimated risk weighting factors for specific tissues and the inclusion of a number of additional tissues found in the head and neck region (most importantly the salivary glands, lymphatic nodes, muscle, and oral mucosa)9 resulted in substantial increases in radiation effective doses for specific maxillofacial radiographic procedures ranging from 32% to 422%.23 A recent retrospective cohort study by Pearce et al. provides more evidence of a link between exposure to radiation from medical CT and specific organ cancer risk in children.24 They found that radiation doses of about 50 mGy in children and young adults might almost triple the risk of leukemia and doses of about 60 mGy might triple the risk of brain cancer. For children younger than 15 years this is the equivalent of 5 to 10 CT scans of the head for bone marrow dose (range, 2-8 mGy per scan) and only 2 or 3 CT scans of the head for cumulative brain dose (range, 28-42 mGy per scan). At least 12 other groups are studying or planning to study national cohorts of children in relation to CT and cancer incidence.25 No such leukemia or brain cancer risks have been correlated with cumulative brain dose for CBCT; however, published data indicate most per-scan brain doses range from 0.27 to 0.9 mGy.22 Although this is low relative to medical CT, there should still be concern in maxillofacial imaging because some CBCT unit doses to the brain are as high as 9.2 mGy22 and CBCT examinations are still being proposed, by some, as substitutes for conventional imaging.

PEDIATRIC DOSE RISK
In their landmark paper, Brenner et al. reported that radiation doses from pediatric medical CT scans result in 3 to 5 times greater specific organ doses and, consequently, higher relative risk compared with adult medical CT examinations.26 For pediatric patients, the radiation risk to ionizing radiation is greater than that of adults for 4 reasons: (1) in the developing child, the relatively greater cellular growth rate and organ development are responsible for greater radiosensitivity of tissues than in adults; (2) younger patients have a longer expected lifetime for the effects of radiation exposure to manifest as cancer; (3) specific organ and effective doses are higher in children; and (4) unless specific pediatric exposure-reduction techniques are incorporated in imaging protocols, the radiation doses for small patients and children may exceed typical adult radiation levels. In relation to CBCT imaging for children, point (3) above has been confirmed experimentally by Theodorakou et al., who reported that head and neck organ doses, particularly for the salivary glands, are, on average, 30% higher than for adolescents with the same exposure.27 Therefore, it is generally considered that children may be 2 to 10 times more sensitive to radiation carcinogenesis than mature adults.26,28
When it comes to specific organ dose and radiation risk, children are not just small adults—modifications of exposure parameters should be considered obligatory. Unfortunately, not all currently available CBCT units are capable of implementing exposure-reduction techniques. Recently, the U.S. Food and Drug Administration announced that it is seeking public comment on a proposal recommending that manufacturers design new x-ray imaging devices with protocols and instructions that address use on pediatric patients. This proposal specifically includes dental CBCT devices. Furthermore, it proposes that manufacturers who do not adequately demonstrate that their new x-ray imaging devices are safe and effective in pediatric patients should include a label on their device that cautions against use for children.

COMPARING APPLES WITH APPLES
The previous discussion brings some doubt into my mind on the validity of continuing to compare radiation doses from oral and maxillofacial imaging procedures with background radiation simply because of the omission of considerations for the increased relative risk of children to radiation. To standardize comparison of radiation dose risk between various imaging procedures, the American College of Radiology, the sponsoring authority of medical radiology professionals in the United States, proposes the use of relative radiation level (RRL) designation. There are 6 RRL levels, designated 0 to ⭐⭐⭐⭐⭐⭐. The division between the fourth and fifth levels (⭐⭐⭐⭐ and ⭐⭐⭐⭐⭐) for adults is 10 mSv. This division is based on the estimate that approximately 1 in 1000 individuals will develop cancer from an exposure of 10 mSv. Reflective of the importance in considering the increased risks associated with exposing children to ionizing radiation at the same dose level, the RRL also incorporates pediatric, effective-dose estimate designations that are one-third of adult estimates. At the current time, this approach seems to be a meaningful method of reporting radiation dose risk, independent of a nonabsolute benchmark (e.g., variable panoramic effective dose), and incorporates considerations for pediatric patients.

CONCLUSIONS
In bringing these concepts to light and in view of the results of recent publications, there is little doubt that the risks from low-dose radiation, albeit low, are real. Effort at the professional level should now proceed not only toward comparing the radiation doses imparted by specific CBCT units, but also on relating this to increased risk in the pediatric population toward minimizing or eliminating unnecessary exposure in diagnostic imaging. The use of CBCT within dentistry has evolved to a stage where clinicians should heed professional direction establishing parameters for justification (that is, the development of selection criteria) and understand that dose optimization for the individual patient can only be accomplished by age- and task-specific imaging techniques.

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