A COMPARISON OF INTRAORAL IMAGE QUALITY, ERROR RATES, OPERATOR AND PATIENT DOSIMETRY BETWEEN A HAND-HELD DEVICE AND WALL-MOUNTED X-RAY SOURCES

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A thesis submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in Oral Maxillofacial Radiology, School of Dentistry.

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ABSTRACT

Billy James Phillips: A Comparison of Intraoral Image Quality, Error Rates, Operator and Patient Dosimetry between a Hand-Held Device and Wall-Mounted X-Ray Sources
(Under the direction of Enrique Platin)

Objectives: To compare handheld and wall-mounted x-ray sources during Full Mouth Examination (FMX).

Methods: One operator simulated exposure of 10 FMX on a RANDO phantom for each of seven studies: three handheld and four wall-mounted. Optical Stimulated Luminescence (OSL) dosimetry was utilized to record dose. Effective dose was calculated using 2007 International Commission on Radiologic Protection (ICRP) tissue weights. Differences due to technique were evaluated using Analysis of Variance (ANOVA). A cohort of 75 dental students exposed one FMX utilizing each device. Observers were calibrated and blinded to assess technique errors and Line Pair (LP) resolution.

Results: Mean FMX dose was significantly less for handheld 36µSv than for wall-mounted devices 98µSv ($p=0.0217$). Mean operator exposures were indistinguishable from ambient background levels (<2 µGy/study). Mean total technique error was not different between devices ($p = 0.29$). Mean LP resolution was significantly higher for the handheld device, ($p < 0.01$).

Conclusion: Operator, patient dose, and mean sum of total errors were not different. LP resolution was significantly higher for the handheld device during FMX simulation.

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LIST OF ABBREVIATIONS

ALARA	As Low As Reasonably Achievable
ANOVA	Analysis of Variance
ASE	Agreement Standard Error
CBCT	Cone Beam Computed Tomography
cc	Cone Cut
cm	Centimeter
CT	Computerized Tomography
DDS	Doctor of Dental Surgery
DPI	Dots per Inch
DXTTR	Dental X-Ray Trainer
EPR	Electronic Patient Record
E_{US}	Effective Dose per individual, United States of America population
FDA	Food and Drug Administration
FMX	Full Mouth Survey examinations
ha	Horizontal Angulation
ICRP	International Commission on Radiologic Protection
id	Image Distortion
JAD-RAD™	Dental X-ray Shield
kVp	Kilovoltage
LP	Line Pair
mA	Milliamperage
mSv	Millisieverts

mR	Millirads
NCRP	National Council of Radiation Protection and Measurement
OSL	Optical Stimulated Luminescence
PA	Periapical
PID	Positioning Indicating Device
pp	Packet Placement
PSP	Photostimuable Plates
SAS	Statistical Analysis System
UNC	University of North Carolina at Chapel Hill
µSv	Micro Sieverts
XCP	Extension Cone Paralleling

INTRODUCTION:

There has been no independent research concerning the use of handheld x-ray devices in academic dental curriculums. Furthermore, there is widely varied state regulation of their use in the private practice of dentistry. The North Carolina Department of Health and Human Services, Protection Section, mandates facilities planning to utilize handheld dental x-ray units to receive an approval for rule exemptions from the Radiation Protection Section prior to use of the unit. "Exemptions will not be granted for routine dental x-rays where permanently installed units are a viable option." Applicable rules for exemption are outlined in The North Carolina Regulations for Protection against Radiation (*15A NCAC 11*).

Similar, restrictions on the use of handheld devices apply with the military Dental Corps. Department of the Navy policy 6600 Ser M3C/AT – 17215, 09/22/2008: Appropriate Use of Hand-Held X-Ray Units for Oral and Maxillofacial Radiography restricts the use of handheld x-ray devices forensic, combat, humanitarian, and emergency operations where access to traditional fixed x-ray sources are not available.

Such restriction and policy while well intentioned by state regulatory radiation protection agencies and the military are not evidence based. Such restriction and policy decisions require current research into the occupational and patient risk to exposure to ionizing radiation from handheld x-ray devices.

The safety of the handheld x-ray device is not the only question current research must investigate. Even if proven safe the diagnostic quality of intraoral images acquired by these devices must also be evaluated. The As Low As Reasonably Achievable (ALARA) principle recommends that the diagnostic task be matched to the imaging modality selected by the practitioner and that patient benefit outweigh any risk to exposure to ionizing radiation. It does not matter if the handheld x-ray device is safe if image quality is not adequate diagnostically.

The primary aim of this study was to evaluate the utility of a handheld x-ray device within a Dental School environment. Study null hypotheses include: 1) There was no statistical difference in image quality error between the Aribex, Nomad Pro and the Planmeca Intra wall-mounted sources. 2) There was no statistical difference in recorded personnel dosimetry between the Aribex, Nomad Pro and Planmeca devices.

This study was the first independent research to compare operator and patient dosimetry, image quality, and technique error rates in a Dental School curriculum between the Aribex, Nomad Pro® (Aribex, Orem, UT) and Planmeca Intra® (Planmeca USA Inc., Roselle, IL). The research protocol was designed to simulate a worst-case clinical scenario to evaluate the research questions. A cohort of 2nd year dental students without prior clinical radiology training was identified. The operators utilized no lead apron shielding during image acquisition with the handheld x-ray source. The integrated internal and external shielding of the handheld device provided the only operator shielding to scatter radiation. Operators were required to complete an online training module on the use of the Nomad Pro and, successfully complete a test. Round open cone collimation 6 cm diameter was utilized for the handheld and wall- mounted device.

REVIEW OF LITERATURE:

The history of dentistry and the use and efficacy of diagnostic imaging are well documented. The dynamic history and technology associated with the clinical practice of dentistry is ever evolving and spans advancements in restorative materials, armamentarium, and the diagnostic sciences. The potential for risk to the clinical practitioner and patient is always present and mandates continued extensive investigation to evaluate the risk to benefit ratio in treatment planning and clinical decision-making. There is specific biological risk in diagnostic imaging and exposure to ionizing radiation.

The risk, diagnostic efficacy, and benefits associated with the materials and equipment utilized to acquire diagnostic imaging is well documented in the published literature. Richards evaluated occupational exposure and compared patient exposure reported in the published literature with then current techniques and rightly acknowledges risk will never reach zero.[1-8] Our knowledge of the biological risk, deterministic and stochastic effects, of exposure to ionizing radiation is presented in additional research by Wall[9], and White[10]. Radiation protection recommendations and guidelines are outlined by the 2007 Recommendations of the International Commission of Radiological Protection[11] and the National Research Council[12].

In 2006, Americans were exposed to more than seven times as much ionizing radiation from diagnostic imaging compared to recorded figures from the early 1980s, and diagnostic imaging constituted nearly half the total radiation exposure of the U.S. population from all sources. The average effective dose per individual in the U.S. population (E_{US}) from all sources has increased by a factor of 1.7 to 6.2 mSv as a result of the growth in utilization of x-ray diagnostic imaging and radionuclides[13].

Computerized Tomography (CT) first introduced in 1972 has become integral in medical diagnostic imaging. The expanding clinical application of CT alone has directly led to an annual 10% increase in CT procedures over the past twenty years. In 2006, 62 million procedures were reported that is, 207 CT examinations per 1000 population, with an average dose per examination of 7 mSv. Currently, medical CT represents 50% of all medical exposure and 24% of the exposure from natural and man-made sources combined[13]. In addition, approximately 18 million nuclear medicine procedures were reported in the US in 2006 or, 60 per 1000 population, double the procedures reported in the early 1980s. CT, fluoroscopy and nuclear medicine procedures contributed 2.7 mSv to E_{US} in 2006, accounting for 90% of all medical diagnostic imaging procedures[13].

The documented explosion of E_{US} directly attributed to diagnostic imaging stands in stark contrast to the significant historical reduction in exposure to ionizing radiation in dental intraoral radiography. To address this growth in high dose medical and dental imaging clinicians must consider all factors: risk benefit ratios, appropriate selection criteria, imaging techniques, specific diagnostic task, and the impact of ordered diagnostic imaging on treatment planning and patient outcomes. Along with clinical justification for diagnostic imaging considerations must also be given to occupational risk to personnel from exposure to ionizing radiation. NCRP Report No. 160 documents diagnostic exposure is an integral and growing piece of total exposure E_{US}, and should be considered in any radiology quality assurance program[13].

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INTRODUCTION:

Since the first dental x-ray taken by Otto Walkoff of himself (Fig 1) in 1896, exposure to x-rays from diagnostic dental radiographic procedures has been of great concern. The dental profession has historically sought through technological advancement to reduce both occupational and patient exposure to ionizing radiation. Richards[1] evaluated occupational exposure and reported environmental controls and operator protections to reduce dose based on techniques and equipment available in the 1960's. A subsequent study by Richards[2] in 1981 compared patient exposure to dose reported in the published literature with then current techniques.[3-7] Nolan[3] had demonstrated a range of total exposure with 25 films per full-mouth examination at 35 to 315 R, averaging 12.6 R/film. By 1974 Alcox[8] reported an average patient exposure of 271 mR/film. In 1981 in a comparison study, Richards[2] reported patient exposure of 170 mR/film and 143 mR/film respectively with and without backscatter. Richards[2] dramatically illustrated the significant historical reduction in patient exposure with the development of increasingly faster film sensitivities. He reported a reduction in patient dose, by a factor of 0.02 with the introduction of Ektaspeed film when compared to the very slow Regular film available in the 1920's. All of these studies document the dental professions repeated success in reducing both occupational and patient exposure to ionizing radiation through improved technique, armamentarium, and environmental controls.

Fig 1: First dental x-ray. © Google: https://www.google.com/search?q=first+dental+x+ray.

Further reduction may yet be achieved with continued advances in technology. In his conclusions, Richards[2] acknowledged the risk will never reach zero but that the risk involved in dental diagnostic imaging was acceptable. Such advances will always require rigorous evaluation to achieve the principle of ALARA.

While the impetus for the development of handheld devices may not have been dose reduction it could be one of the currently available tools to further reduce patient exposure to ionizing radiation during intraoral diagnostic imaging. The utility of handheld x-ray units for intraoral radiography has been demonstrated in field, forensic, humanitarian, and surgical applications. The safety of this technology has been reported in controlled experiments as well as in the context of general dental practice. [9, 10] Within the United States, the NOMAD® Pro is

cleared for sale by the Food and Drug Administration (FDA). The state of North Carolina currently requires an exemption for use of handheld devices, and is contemplating the approval of handheld devices within general dental practice. The current policy of the United States Navy on the use of handheld x-ray devices in the practice of military dentistry restricts their use as a substitute when traditional wall-mounted units are available; citing fixed unit advantages: higher operating potentials, beam quality, shorter exposure times, higher operation tempo, rigid mounting, remote activation, and reduced operator exposure. Navy policy delegates the appropriate use of handheld x-ray devices to emergency and forensic use outside the dental clinic, deployment, and humanitarian operations. [11]

This study was the first independent study to evaluate the safety and efficacy of handheld devices in a cohort of students within an educational environment. The potential patient and operator dose impact of substituting handheld devices in an educational institutional setting has not been reported. The objective of this study was to compare image quality, error rates, operator and patient dosimetry during Full Mouth Survey examinations (FMX) between the Nomad Pro® (Aribex, Orem, UT) handheld device and the Planmeca Intra® (Planmeca USA Inc., Roselle, IL) wall-mounted x-ray source, Fig 2.

Fig 2. Left: Nomad Pro® (Aribex, Orem, UT) handheld device. Right: Planmeca Intra® (Planmeca USA Inc., Roselle, IL) wall-mounted x-ray source.

MATERIALS & METHODS:

One operator exposed seven imaging studies, a total of 180 images per study, simulating 10 FMX's on a RANDO phantom (The Phantom Laboratory, Salem, NY). Three studies were completed using the handheld device and four were completed using the wall-mounted x-ray source. Photostimuable Phosphor Plates (PSP) receptor settings for an average adult were used. The wall-mounted source and the hand-held device each incorporated a 6 cm diameter open cone. Technical specifications for the handheld and wall mounted x-ray device are presented in Table 1. Optical Stimulated Luminescence (OSL) dosimetry was utilized to record operator and phantom dose (Nanodot, Landauer Inc., Glenwood, IL). Three dosimeters per area were attached to thyroid, waist and trigger hand areas of the operator prior to each study. Dosimeters were placed within the phantom in twenty-four predetermined anatomic locations (Ludlow et al 2008). Dosimeters were read with a MicroStar reader (Landauer Inc., Glenwood, IL). Effective dose was derived using the 2007 ICRP calculation.

A cohort study of seventy-five 2nd year dental students at the University of North Carolina School of Dentistry DDS program was assigned to pre-clinical radiology to acquire intraoral images. The use of the Aribex, Nomad® Pro handheld device was integrated as part of their preclinical laboratory curriculum. Each student completed a standard 18 image FMX examination (14 periapicals and 4 horizontal bitewings) using the Aribex, Nomad Pro® (Aribex, Orem, UT) handheld device and an additional FMX series using the Planmeca Intra® (Planmeca USA Inc., Roselle, IL) wall mounted x-ray source. A training module was viewed by each student prior to the use of the handheld device. A test over this material was taken following training. Test scores were recorded. A pass rate of 100% was required. Exam questions were indexed to the training material for easy reference by the student if there was an incorrect response to a training question.

Radiographic training mannequins (DXTTR, Rinn Corp) were used for patient simulation. Five DXTTR's were selected and labeled for sole use throughout the duration of the study. Each DXTTR was examined and refurbished prior to the beginning of the study with complete mounted maxillary and mandibular adult dentitions, including third molars. The same DXTTR was used by the student for both handheld and wall mounted image acquisition. Images produced with the Aribex, Nomad® Pro handheld device and wall mounted x-ray source utilized the Rinn Extension Cone Paralleling (XCP) receptor-holding device (Rinn, corporation). PSP receptors were used for image acquisition (Gendex Dental Systems, Des Plaines, IL). The images were scanned with a Scanora unit at 300 dots per inch and processed for viewing utilizing VixWin software (Gendex Dental Systems, Hatfield, PA). The original FMX examinations were placed in a digital mount within each student Electronic Patient Record (EPR).

Following completion of each FMX sequence, students acquired two additional images of an LP test phantom held in a jig utilizing each x-ray device. The jig consisted of a 16-group Line pair per millimeter (LP) test tool with a range of resolutions from 5 to 20 line pairs per millimeter (Model 07-555, Nuclear Associates, Division of Victoreen, Carle Place, NY), and a JAD-RAD^{TM} collimator attachment (JADRAD Dental Diagnostics, Farmington, CT). The test tool and JAD-RAD^{TM} were secured to a positioning platform. The jig was placed on a tripod allowing easy transport and positioning between imaging stations. Users were instructed to align and center the central ray with the JAD-RAD^{TM} face of the jig. Receptors were positioned in the apparatus parallel to the LP tool plane at a distance of 3cm from the LP tool and imaged. The jig is designed with a Plexiglas holder to standardize the position of the receptor from the LP tool. Images were viewed in a randomized order by three masked observers to determine the number of line pairs resolved. In order to move FMX and LP images from the student EPR account into a research module and de-identify the images, the FMX and LP images were exported and re-labeled utilizing a random number generator in groups of 10 FMX and LP images to 15 shadow charts.

Optimal exposure and exposure latitude for PSP receptors was evaluated for each device by assessing step-wedge images, Fig 3. Three OSL dosimeters were exposed at each exposure time and the mean absorbed dose was calculated. Based on mean absorbed dose a cofactor was derived to normalize dose for the beam energy for each device, Fig 4. Normalized effective dose was compared between handheld and wall mounted x-ray exposure settings.

Three experienced observers (A, B, and C) were calibrated per the UNC, Division of Radiology Clinical handbook. The observers were masked to x-ray device and student. Each

FMX and LP was scored for the presence of imaging technique errors to include: receptor placement, vertical angulation, horizontal angulation, image distortion, presence of a cone cut, double image, the number of line pairs resolved, and required image re-takes utilizing the clinical Radiographic Analysis Form of the University of North Carolina, School of Dentistry. Following a two week wash-out period, the observers re-evaluated a randomly selected sample (10%) of the original 150 FMX and LP images. A questionnaire was designed to evaluate the student's perceived ease of use for the Aribex, Nomad® Pro handheld device and wall mounted x-ray sources. Students completed the forms at the end of each imaging sequence.

Statistical analysis was completed utilizing SAS 9.2 (SAS Institute, Cary, NC). Operator exposures and phantom doses were evaluated separately using ANOVA. A paired t-test analysis of wall-mounted and hand-held data was used for the outcome variable mean sum total error rate. Mean LP resolution was assessed using ANOVA. A linear mixed model was used for each of the outcome variables, x-ray source, receptor position, and observer as modeled factors. Kappa and McNemar intra and inter-observer agreement and discordance were calculated. Survey data was scored using a Likert scale response and analyzed with descriptive statistics.

A general linear model with correlated errors (Diggle et al. 2002) was fit to the triple repeated design where each student used both devices and took x-rays of the anterior, posterior, and bitewing locations using each device. The covariance matrix was assumed to be of direct product form (Galecki, 1994) with unstructured covariance matrices specified for device, location, and observer. Pairwise interactions were included in the initial model and removed if not statistically significant using the Wald statistic. The Kenward-Roger degrees-of-freedom adjustment was used to test the primary (null) hypothesis of no differences between devices and

no differences between locations. P-values <0.05 are considered statistically significant. This is the first step to evaluate and introduce handheld x-ray devices within a Dental School curriculum.

Table 1. Technical specifications for the handheld and wall mounted x-ray devices.

	Nomad Pro	**Wall Mounted**
Kilovoltage (kVp)	60 (constant potential)	70 (constant potential)
mA	2.5	8
Clinical exposure time sec: PSP		
Anterior PA	0.16	0.20
Posterior PA	0.19	0.32
Bitewing	0.20	0.32
PID diameter (cm)	6	6
Source-to-skin distance (cm)	20	30
Focal spot size (mm)	0.4	0.7
Exposure activation	On unit	Remote

Fig 3 A. PSP exposure latitude wall mounted x-ray device.

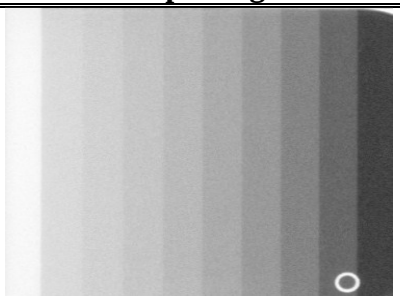
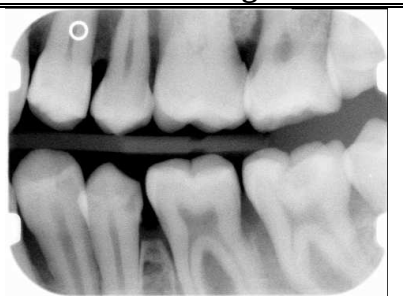
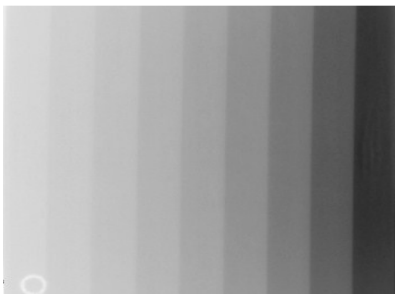
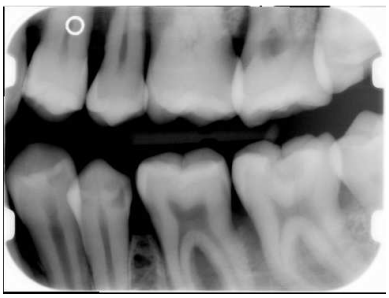
	Step-wedge	**Bitewing**
Lowest 0.025s		
Highest 0.5s		

Figure 3B. PSP latitude handheld x-ray device.

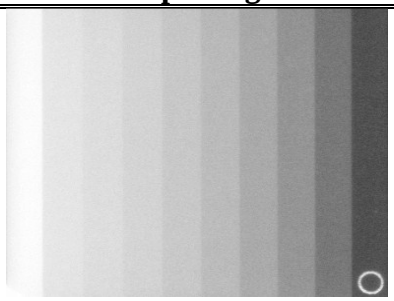
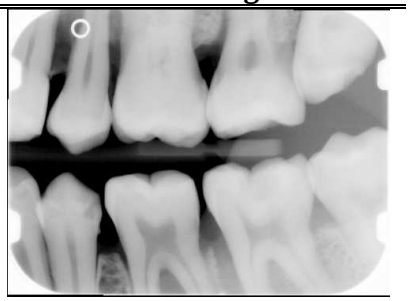
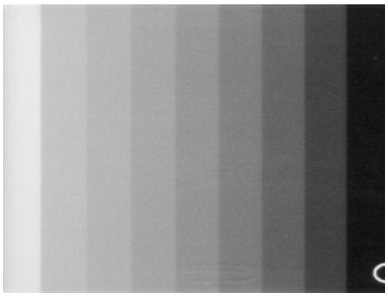
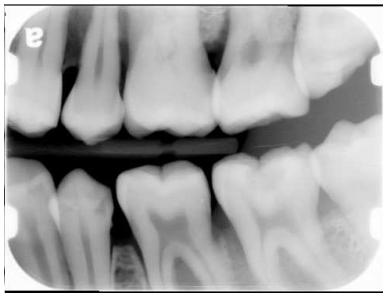
	Step-wedge	Bitewing
Lowest 0.025s		
Highest 0.5s		

Figure 3 C. Normalized and optimal exposures (Sec) for wall mounted and handheld x-ray devices.

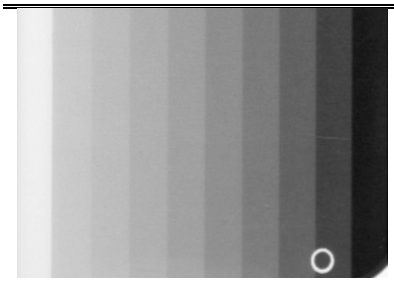
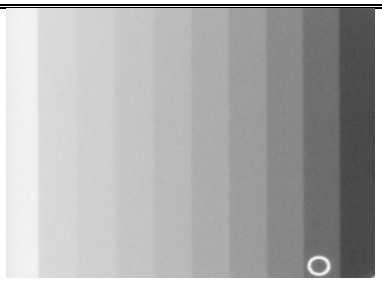
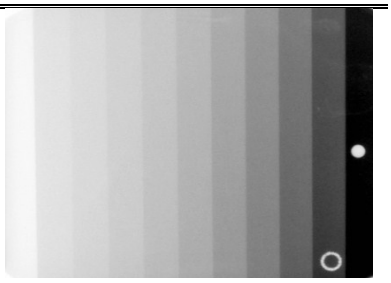
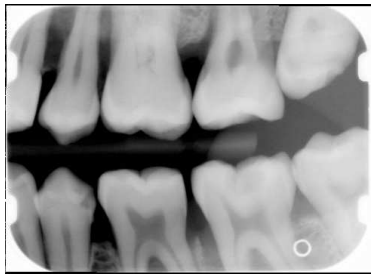
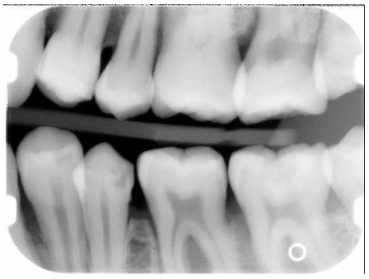
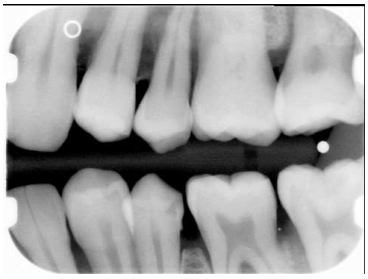
Wall Mount 0.32s	Normalized Wall Mount 0.125s	Nomad Pro 0.19s
		
		

Figure 4A. Hand-held device LP resolution.

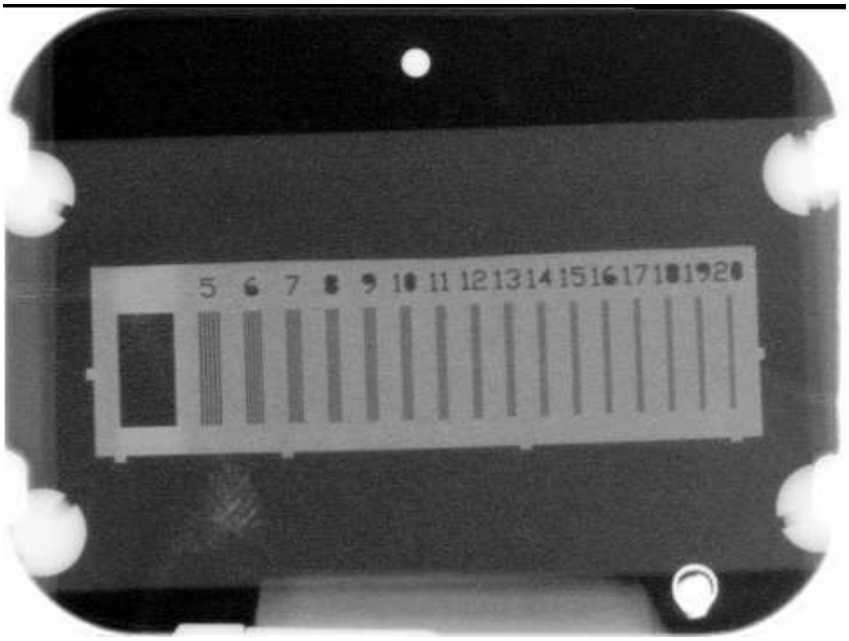


Figure 4B. Wall-mounted device LP resolution.

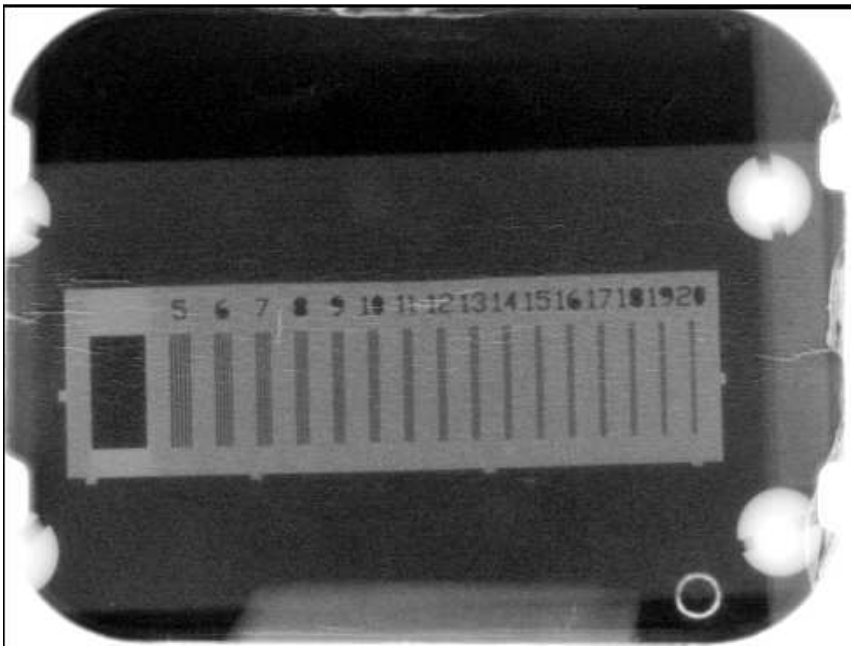
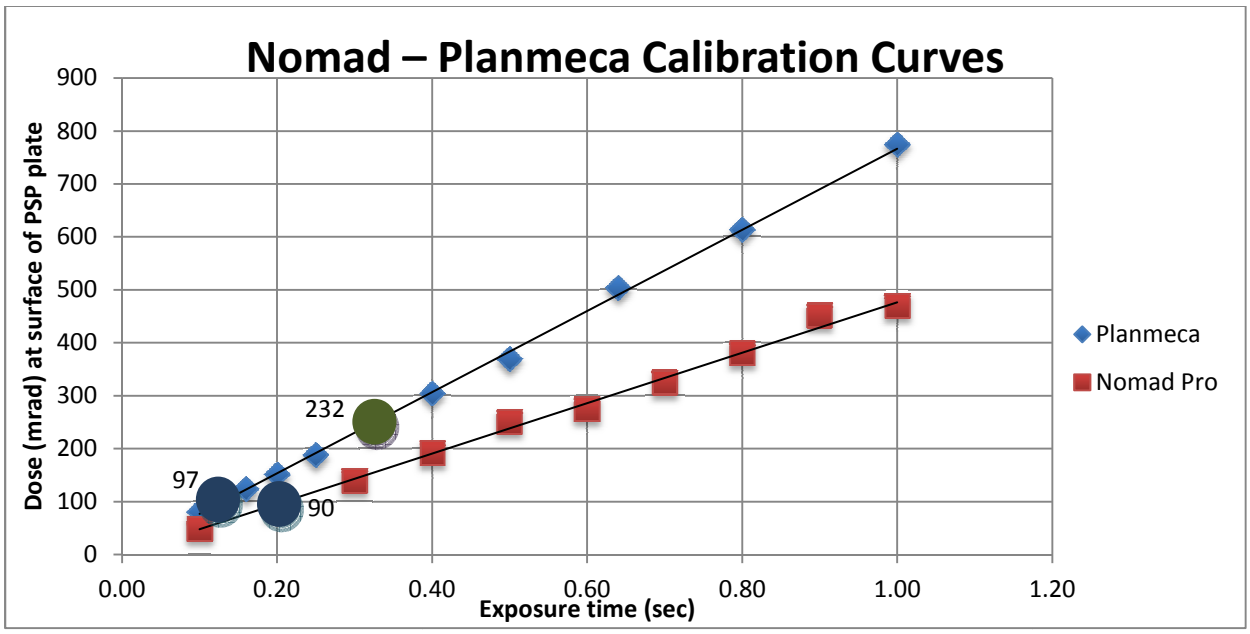


Figure 5. Mean dose per exposure (Sec) mrad.



Nomad programmed setting and Planmeca technique chart settings for PBW

Nomad programmed setting and Planmeca adjusted for equivalent exposure

RESULTS:

ANOVA indicated a statistical significant difference among wall mounted and handheld device effective dose (µSv), ($p < 0.01$). Tukey HSD tests indicated statistical significant differences between the wall mounted and handheld doses, the wall mounted and normalized wall-mounted doses. Tukey HSD test indicated no statistical significant difference between normalized wall mounted and handheld doses. Mean (SD) FMX effective dose was significantly less for the Nomad Pro 36µSv (8.4) than for wall-mount 98µSv (14.3) ($p=0.0217$). The normalized dose for the wall-mounted source was 41µSv, Table 2. Mean operator exposures were indistinguishable from ambient background levels (<2 µGy/study) and were not different for handheld and wall mounted sources ($p=0.2624$) or dosimeter location ($p=0.6815$) during FMX imaging simulation, Table 3. Total effective patient dose was reduced 12% with the

handheld device during FMX simulation. A comparison of tissue equivalent dose is presented, Fig 5.

For image analysis a linear mixed model was separately used for each outcome. Unstructured covariance structure was assumed for the six repeated measurements. Pairwise interaction between device and observer was included in the model, and removed if not statistically significant. The least squared means were then calculated from each final model. Significant level was $p = 0.05$.

ANOVA indicated no statistical significant difference in mean (SD) total technique error between devices adjusting for observers, ($p = 0.29$). A statistical significant interaction between device and observer, ($p < 0.01$) was observed. Mean sum total error rate by location: posterior periapical, anterior periapical, and bitewing are presented in, Table 5.

For mean LP resolution, there was not statistically significant interaction between observer and device indicating that the pattern of responses for the observers was similar for the two devices ($P>.05$). There was a statistically significant difference among observer mean LP resolution adjusting for device ($p < 0.01$) as well as a significant difference between devices adjusting for observer ($p < 0.01$), Table 4. Higher LP resolution favoring the handheld x-ray source was demonstrated, Table 5.

Weighted Kappa using sum total error and mean LP resolution was utilized to evaluate inter-observer reliability. The weighting scheme was linear with no proportionality. Inter-observer weighted Kappa values were moderate in evaluation of packet placement (pp) and horizontal angulation (ha) errors between observer A and B. The weighted Kappa value for

line pair LP resolution was substantial between observer A and C. Between all observers weighted Kappa values range fair to substantial in cone cut (cc) errors, and image distortion (id) errors, Table 6. Intra-observer theoretically in almost all previous research is better than inter-observer reliability. Given the experience level of observers and that there was no expectation of learning during the wash-out period it was elected not to pursue intra-observer agreement.

Operator satisfaction with the handheld device during FMX simulation was favorable. Considering ease of use of the handheld device 97% of the operators were satisfied compared to only 50% satisfied with the wall mounted device. 87% of the operators would recommend the handheld device to colleagues and 99% of the operators were satisfied with their overall experience with the handheld device, Table 7.

Table 2. Effective Dose ANOVA Table and Tukey Test

Source	**df**	**F Ratio**	**Prob > F**
Device	2	34.1298	0.0005*

Level	**Groups**		**Least squared means**
Wall Mount	A		98.3
Adjusted Wall Mount		B	41.0
Nomad Pro		B	36.0

Table 3. ANOVA Full Model

Source	**Nparm**	**df**	**Sum of Squares**	**F Ratio**	**Prob > F**
Device	1	1	0.3112963	1.2815	0.2624
Study	3	3	1.0980815	1.5068	0.2227
Location	2	2	0.1875651	0.3861	0.6815

Figure 6. Tissue specific equivalent dose comparisons

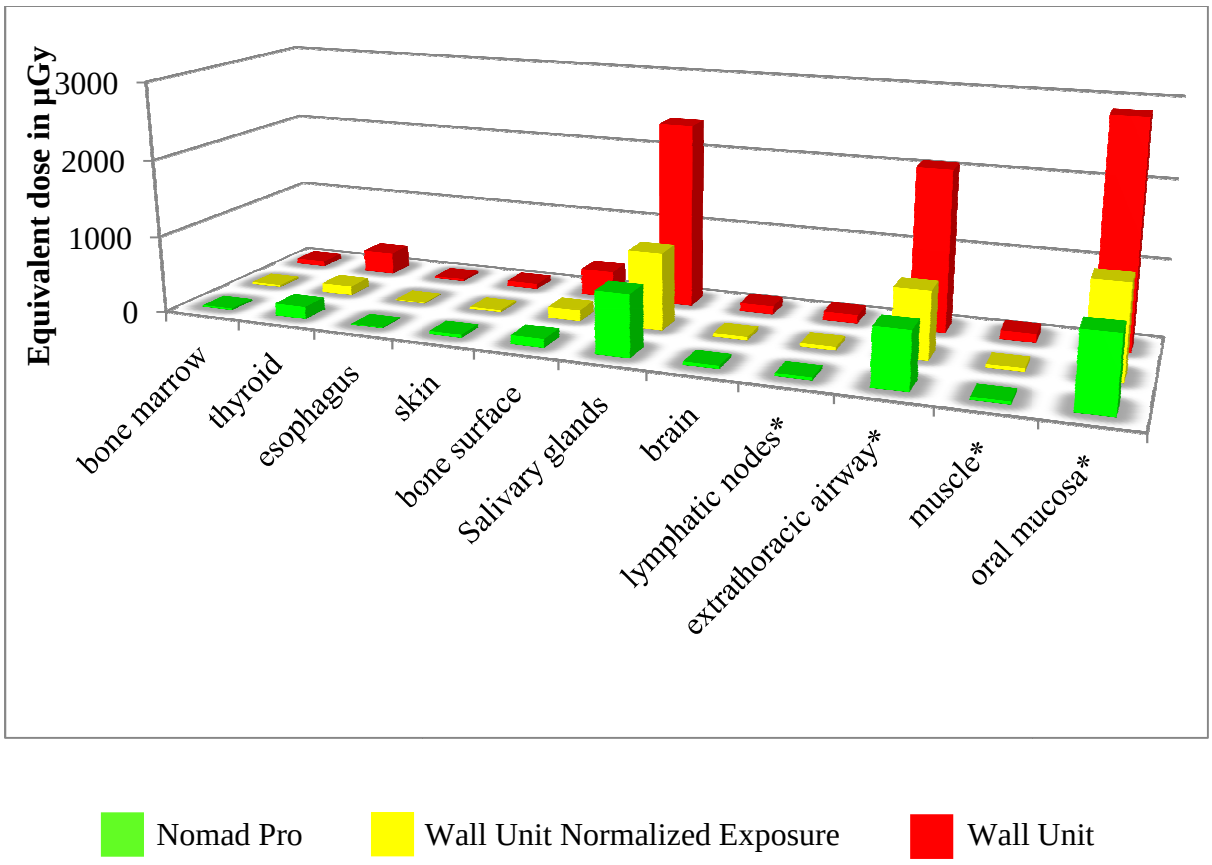


Table 4. Linear mixed model.

Outcome	Factor	DF	F	P
err	device	1 / 74	1.10	0.2977
	observer	2 / 74	37.96	<.0001
	device*observer	2 / 74	5.66	0.0052
err_bw	device	1 / 74	1.52	0.2221
	observer	2 / 74	20.27	<.0001
	device*observer		(removed)	
LP	device	1 / 74	35.12	<.0001
	observer	2 / 74	58.45	<.0001
	device*observer		(removed)	

Figure 7. Mean error per FMX.

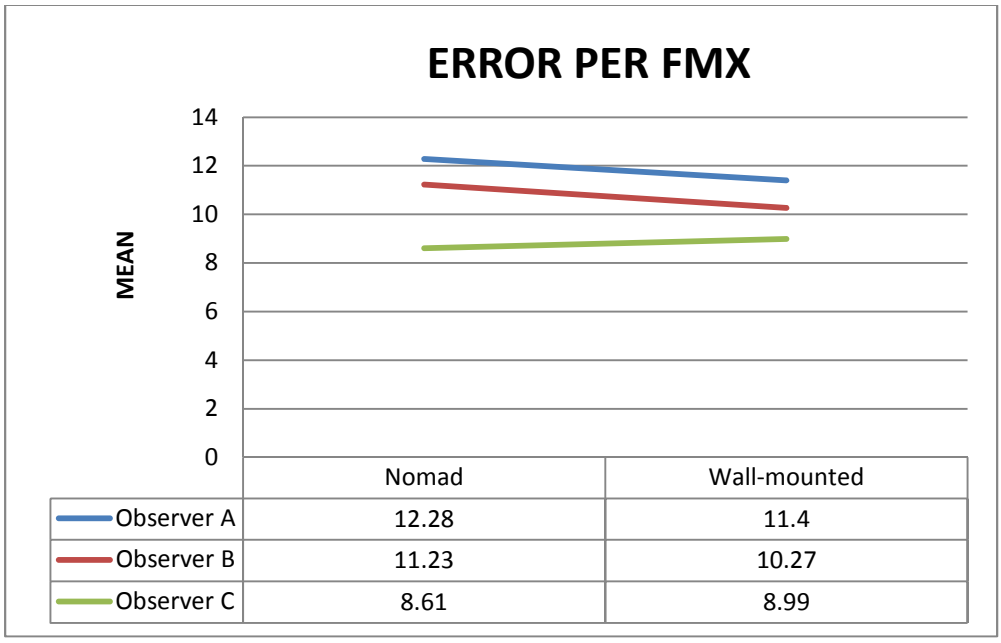


Figure 8. Mean LP resolution.

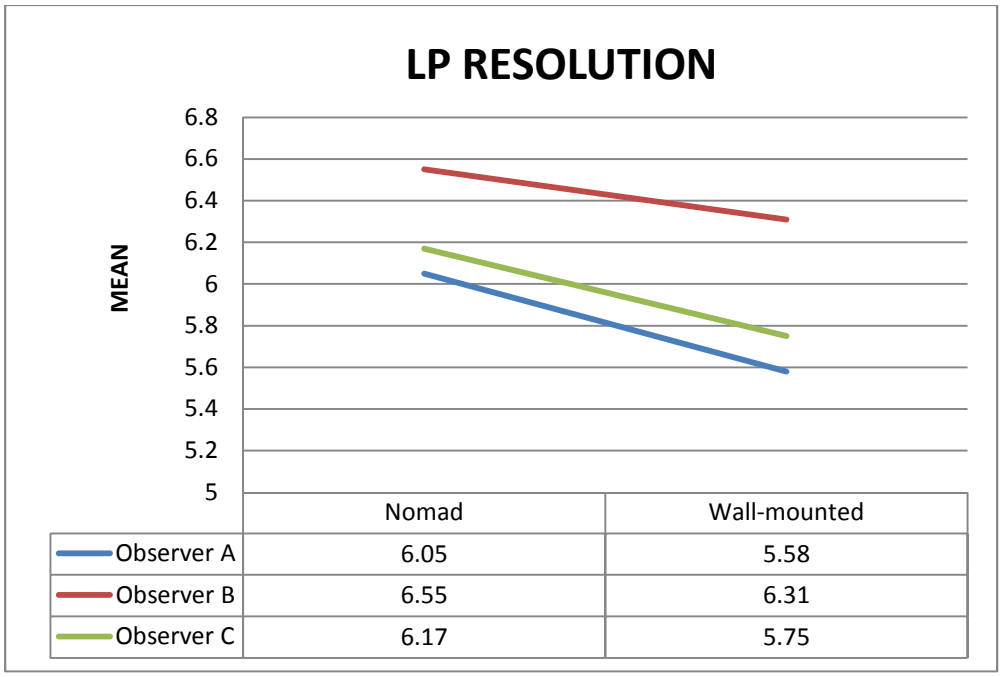


Table 5. Descriptive statistics.

Variable	Label	device	observer	N	Missing	Q1	Median	Q3	Mean	Std
err	sum of (err1-err18)	Nomad	A	75	0	8	13	16	12.28	5.45
			B	75	0	7	11	16	11.23	5.60
			C	75	0	6	8	11	8.61	3.86
		Wall Mounted	A	75	0	9	12	14	11.40	4.51
			B	75	0	8	10	12	10.27	3.86
			C	75	0	7	9	11	8.99	3.42
err_ant	anterior - sum of technique errors	Nomad	A	75	0	2	3	5	3.40	2.19
			B	75	0	0	2	4	2.40	2.30
			C	75	0	1	2	3	2.24	1.79
		Wall Mounted	A	75	0	2	3	4	2.93	1.92
			B	75	0	0	2	2	1.53	1.67
			C	75	0	0	1	2	1.56	1.51
err_post	posterior - sum of technique errors	Nomad	A	75	0	4	6	8	5.99	3.19
			B	75	0	3	6	9	5.92	3.39
			C	75	0	3	4	6	4.37	2.22
		Wall Mounted	A	75	0	5	6	8	6.08	2.93
			B	75	0	4	6	8	6.21	2.52
			C	75	0	4	5	7	5.47	2.53
err_bw	bitewing - sum of technique errors	Nomad	A	75	0	2	3	4	2.89	1.78
			B	75	0	2	2	4	2.91	1.87
			C	75	0	1	2	3	2.00	1.46
		Wall Mounted	A	75	0	1	2	3	2.39	1.56
			B	75	0	1	2	4	2.52	1.87
			C	75	0	1	2	3	1.96	1.44
LP	line pair resolution	Nomad	A	75	0	6	6	6	6.05	0.82
			B	75	0	6	7	7	6.55	0.81
			C	75	0	6	6	7	6.17	0.55
		Wall Mounted	A	74	1	5	6	6	5.58	0.60
			B	75	0	6	6	7	6.31	0.49
			C	75	0	5	6	6	5.75	0.55

Table 6. Inter-observer Kappa values.

Observer		pp (Packet placement)		ha (Horizontal angulation)		va (Vertical angulation)		id (Image Distortion)		LP (line pair resolution)	
		Weighted Kappa	ASE	Weighted Kappa	ASE	Weighted Kappa	ASE	Weighted Kappa	ASE	Weighted Kappa	ASE
A	**B**	0.51	0.14	0.44	0.14	0	0	0.61	0.18	0.23	0.19
A	**C**	0.03	0.09	0.56	0.13	0	0	0.35	0.20	0.69	0.19
B	**C**	0.14	0.09	0.21	0.09	0.35	0.16	0.37	0.19	0.18	0.16

Table 7. Operator satisfaction

Variable	Label	Category*	Freq	Pct (%)
Q1	Aribex, Nomad® Pro handheld device is easy to use.	1	1	1
		3	1	1
		4	23	30
		5	51	67
Q2	Conventional wall-mounted x-ray source is easy to use.	1	1	1
		2	8	11
		3	29	38
		4	31	41
		5	7	9
Q3	Aribex, Nomad® Pro handheld device is much better than conventional wall-mounted x-ray source.	1	1	1
		2	8	11
		3	16	21
		4	31	41
		5	20	26
Q4	I would use the Aribex, Nomad® Pro handheld device in the future.	1	1	1
		3	3	4
		4	34	45
		5	38	50
Q5	I would purchase the Aribex, Nomad® Pro handheld device for my practice.	0	1	1
		1	1	1
		2	3	4
		3	19	25
		4	26	34
		5	26	34
Q6	I would recommend the Aribex, Nomad® Pro handheld device to colleagues.	1	1	1
		3	9	12
		4	40	53
		5	26	34
Q7	The CD/ROM on-line training module adequately prepared me to complete the clinical procedure.	missing	1	1
		0	2	3
		1	1	1
		3	4	5
		4	42	55
		5	26	34
Q8	Overall, how satisfied are you with your experience with the Aribex, Nomad® Pro handheld device.	3	1	1
		4	35	46
		5	40	53

*Likert scale: (0) not applicable, (1) strongly disagree, (2) disagree, (3) neutral, (4) agree, (5) strongly agree.

DISCUSSION:

The significant differences noted in patient effective dose and LP resolution between devices were primarily due to unit technical specifications and technique protocols: kVp, mA, exposure, and focal spot size. The calculated mAs was 0.5 and 2.56 for the handheld and wall-mounted devices respectively. Dose reduction was attributed to the optimization of exposure factors while LP resolution was primarily due to smaller focal spot size with the handheld unit. A limitation within the methodology however is noted with scanning acquired images at 300 dots per inch (DPI). At the lower 300 DPI scanner setting, versus 600 DPI, mean average LP resolution observed approaches the theoretical threshold for resolution. Scan setting at 600 DPI may demonstrate different LP resolution results. Further research in image quality with the Nomad Pro is needed to fully evaluate actual threshold for LP resolution with a handheld device.

More rigorous observer calibration may be beneficial in future comparison image quality studies assessing handheld and wall mounted x-ray sources. For sum total technique error, Observer A reported the highest number of average errors and Observer C the lowest for both devices. Both Observer A and B reported slightly lower average sum total errors for the wall-mounted x-ray source while Observer C noted no difference, Observer difference does not follow the same pattern with each device, Figure 7. Observers B mean LP resolution is higher over devices than mean LP resolution for observer A and C. Observer difference follows the same pattern with each device, Figure 8. A consensus model of agreement where observer differences were noted would have been more beneficial; however, time and scheduling

constraints for observers to achieve consensus in our study of one hundred and 150, 18 image, FMX's for six technique errors and LP resolution was not feasible.

Dental student performance is well documented in the literature. Mourshed[12] in a study of FMX's made by dental students reported a technical error rate of 47 and 48 percent with periapical and bitewing radiographs utilizing bisecting the angle technique. The most frequent error reported was packet placement. The average total error rate per FMX was 7.8. Ilkay[13] evaluated periapical radiography utilizing bisecting the angle technique. Approximately 64 percent of the radiographs were deemed unacceptable and the two most frequent technique errors were incorrect angulation 35 percent and incorrect packet placement 34 percent. Crandell[14] reported average errors per FMX for dental hygiene students, senior, and junior dental students of 0.53, 1.48, and 1.73 respectively. Studies[15-18] utilizing positioning devices in intraoral radiography noted technique errors due to cone cut decreased while packet placement errors increased.

In our study second year dental students were evaluated and utilized paralleling techniques with a positioning device with round cones. Mean error rate per FMX was 12.28 (5.45) for the handheld device and 11.4 for the wall-mounted device. By anatomic location the highest mean error was noted in posterior periapical imaging with mean error per FMX of 5.99 and 6.08 for the handheld and wall-mounted device respectively. The mean error per FMX in the anterior region was 2.93 for the handheld device and 1.56 for the wall-mounted device. Bitewing imaging demonstrated a mean error per FMX of 2.89 and 2.39 for the handheld and wall-mounted device respectively. Dental student performance reported in our study cannot be directly compared to previous studies due to differing methodology: intraoral radiographic

technique, positioning devices, collimation, and student experience. For our cohort of second year dental students this exercise was their first pre-clinical radiology experience. Sum total technique error per FMX may be substantially different in a more clinically experienced dental student population.

In conclusion, the Nomad Pro is as safe to use for operators and safer to use for patients when comparing equivalent dose with conventional wall-mounted sources using round-cones. Patient dose reduction is attributable to optimization of exposure factors. Technique charts at the University of North Carolina, School of Dentistry recommended exposure for molar projections was 0.32 seconds. While recommended exposure was in the upper limit of the demonstrated latitude this was appropriate given the dental student cohort. Optimized exposure factors may not be appropriate for dental school environments. In an institutional setting transitioning from wall-mounted x-ray sources to the Nomad Pro handheld device, a reduction in patient exposure most likely will take place. Technique error rates equivalent between handheld and wall mounted x-ray devices. LP resolution favors the hand-held device. Finally, overall operator satisfaction with the handheld device is favorable.

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