Comparison of Dexis CariVu to Traditional Bitewing Radiography for Diagnosis of Interproximal Caries

BY

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THESIS

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This thesis is dedicated to my daughter, Kayla Helen Horn. You spent the first year of your life watching your mom work hard to achieve her goals. May you be inspired to do what you love and achieve all your own goals.

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LIST OF ABBREVIATIONS

ALARA	As Low As Reasonably Achievable
CCD	Charge Coupled Devices
DEJ	Dentin-Enamel Junction
DiFOTI	Digital Image Fiber Optic Trans Illumination
DR	Digital Radiography
EOS	Electro-Optical Sciences
FOTI	Fiber Optic Trans Illumination
PI	Primary Investigator
QLF	Quantitative Light-induced Fluorescence
UIC	University of Illinois at Chicago

SUMMARY

A study was conducted to assess the DEXIS CariVu device for the detection of interproximal carious lesions on primary teeth. Bitewing radiographs and CariVu images of interproximal surfaces were obtained from mixed dentition patients. An expert committee agreed upon 90 images and rated them as no caries, incipient caries not touching the dento-enamel junction (DEJ), and caries touching the DEJ and into dentin. A questionnaire was distributed to 24 residents and faculty members at the University of Illinois at Chicago (UIC) Department of Pediatric Dentistry. Raters scored both sets of images for the depth of the carious lesion on the same scoring system as the expert committee.

The bitewings showed a high accuracy for detecting caries and CariVu showed a low accuracy. Accuracy was lowest for CariVu for incipient lesions at 23%. For these incipient caries images, there was a nearly even divide between under-scoring and over-scoring. Sensitivity and specificity ranges were 0.92-0.99 and 0.87-0.93 for bitewings and 0.68-0.82 and 0.53-0.72 for CariVu. There was no difference in inter-rater reliability for either bitewings or CariVu by rater status (1st year residents versus 2nd year residents versus faculty). There was a difference in inter-rater reliability between bitewings and CariVu, with bitewings being more accurate.

Increased training to improve both capturing and interpreting CariVu images may at least partially improve the accuracy. At this time, CariVu may be used as an adjunct method to help verify caries detected by bitewings.

1. INTRODUCTION

1.1 Background

Bitewing radiographs are currently the gold standard method of assessing teeth for presence and depth of interproximal carious lesions. However, there is a potential negative health impact from any radiographic exposure. Therefore, every effort should be made to minimize the number of x-rays and employ the As Low As Reasonably Achievable (ALARA) principle of limiting the radiographic dose in the practice of dentistry. Additionally, radiograph sensors are often uncomfortable for children, making it difficult to obtain diagnostic radiographs and increasing the risk of multiple re-takes. Alternative and adjunct methods in diagnosing interproximal caries should therefore be identified and explored scientifically.

DEXIS CariVu is a device that has been introduced in dental practice as an alternative method for interproximal caries detection using light only, thereby having the potential to eliminate a child's radiation exposure completely. It is therefore a worthwhile area of scientific exploration.

1.2 Purpose Of The Study

The aim of this study is to evaluate the ability of the DEXIS CariVu device to accurately diagnose interproximal carious lesions by comparing it with the standard bite-wing radiography. Tooth surfaces were scored for presence and depth of carious lesions by using images of both DEXIS CariVu and dental radiographs. Scores of same tooth surfaces were directly compared. Statistical evaluation of the sensitivity and specificity of the DEXIS CariVu method was completed to determine suitability of this method for correct diagnosis of interproximal caries. A questionnaire, where various DEXIS CariVu images and dental radiographs of same tooth surfaces was evaluated by a number of pediatric dental residents and faculty, was used to establish consistency of scoring by multiple users.

Objectives:

To evaluate the sensibility and specificity of DEXIS CariVu device as a method of interproximal caries detection compared to standard bite-wing radiography.

To evaluate the inter-rater reliability of the DEXIS CariVu device.

1.3 Hypotheses

The DEXIS CariVu method has the same sensitivity and specificity in detecting interproximal caries as the standard bitewing radiography.

The DEXIS CariVu method has the same inter-rater reliability as the standard bitewing radiography.

2. REVIEW OF THE LITERATURE

2.1 Dental Caries

Dental caries, is “the localized destruction of susceptible dental hard tissue by acidic by-products from bacterial fermentation of dietary carbohydrates” (Longbottom et al., 2009). It has also been described as a diet-bacteria induced disease with relatively slow progression over time (Hume, 1996). Cariogenic plaque consists of highly organized colonies of microorganisms which metabolize the dietary carbohydrates into weak acids, responsible for the demineralization of the hard tooth structures and the advancement of the process. In addition to the process of demineralization, remineralization can also occur. The ratio of these two processes depends on many specific factors including calcium and phosphate ions, food, drink, and microbiota of the mouth (Abou Neel et al., 2016).

Dental caries is a dynamic process. Multiple cycles of de- and remineralization can occur in early carious lesions. If, ultimately, the net demineralization prevails its clinical manifestation is lesion cavitation. While a structural defect in the hard tissues resulting from the carious process requires operative intervention, successful identification if initial lesions and instigation of preventive strategies can interfere with the disease progression.

The tooth is comprised of three layers: enamel, dentin, and pulp. Caries is the disease process whereby bacteria breaks down the layers of the tooth and causes tooth decay. While deep caries that extend far into the dentin or pulp are in clear need of treatment, smaller carious lesions can be harder to identify and define. These lesions, known as incipient lesions, present a difficult treatment planning decision for the practitioner. Specifically, when lesions penetrate the enamel and approach the dentin-enamel junction (DEJ), there is not a strong correlation between depth of lesion on a radiograph and cavitation status (Nascimento et al. 2010). These incipient caries therefore fall into a questionable treatment category where some practitioners would choose to treat the lesion and others would choose to monitor the lesion for progression.

2.2 Caries Detection Methods

The aim of early caries detection is to introduce preventive measures and modify the cariogenic factors to stop the progression of the disease at a stage where operative treatment will not be necessary.

The biggest concern with the traditionally used methods of detection is that a large proportion of non-cavitated lesions remain undetected, while if appropriately diagnosed the process at that stage can be reversed by effective remineralization therapies.
Pitts (2001) describes the depth of caries with a metaphor of an iceberg (see Figure 1), where lesions that extend into dentin or far enough into enamel can be detected clinically or radiographically but outer layer enamel caries may not be detectable.

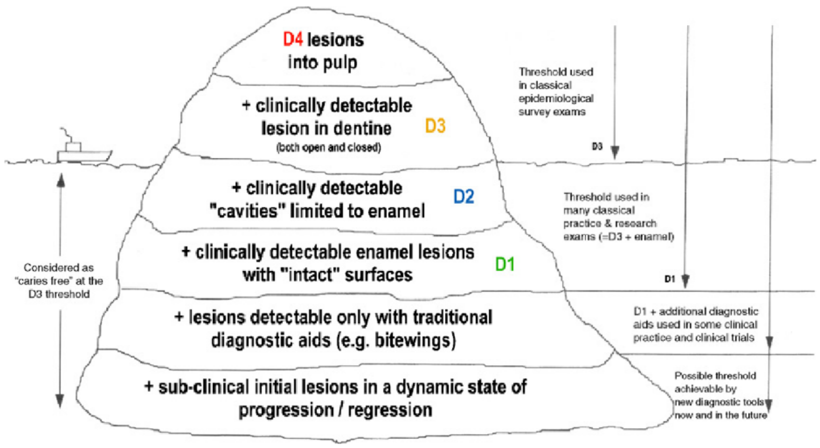


Fig. 1 Depth of carious lesions and their detection (modified from Pitts, 2001)

The ideal caries detection method should be accurate, precise, easy to use, and applicable for every surface of the tooth (Zandona et al., 2006). The methods can be characterized by their specificity, sensitivity, and correlation with the truth. The reliability and reproducibility of a test can be evaluated by intra-class correlation or kappa coefficients (Pretty and Maupome, 2004).

Sensitivity measures the proportion of actual positives, which are correctly identified as such. Detection method or device is more sensitive if it allows for more lesions to be identified. Specificity measures the proportion of negatives, which are correctly detected. A detection method is more specific if it is capable of truly identifying that a lesion is not present i.e. that the surface is free of caries (Pretty, 2006).

Caries detection methods rely on a specific physical principle (summarized in Table I and Figure 2).

TABLE I

PHYSICAL PRINCIPLES USED IN CARIES DETECTION METHODS[a]

Physical principle	Method of detection
Visual	Examiner sight, dry tooth
Tactile	Probe
Radiographs	Digital substraction radiography Digital image enhancement
Visible light	Fiber-optic trans illumination (FOTI) Digital image fiber-optic trans illumination (DiFOTI) Quantitative light induced fluorescence (QLF)
Laser light	Laser fluorescence measurement (DIAGNODent)
Electrical current	Electrical conductance measurement Electrical impedance measurement
Ultrasound	Ultrasonic caries detector

[a] Modified from Pretty et al., 2006

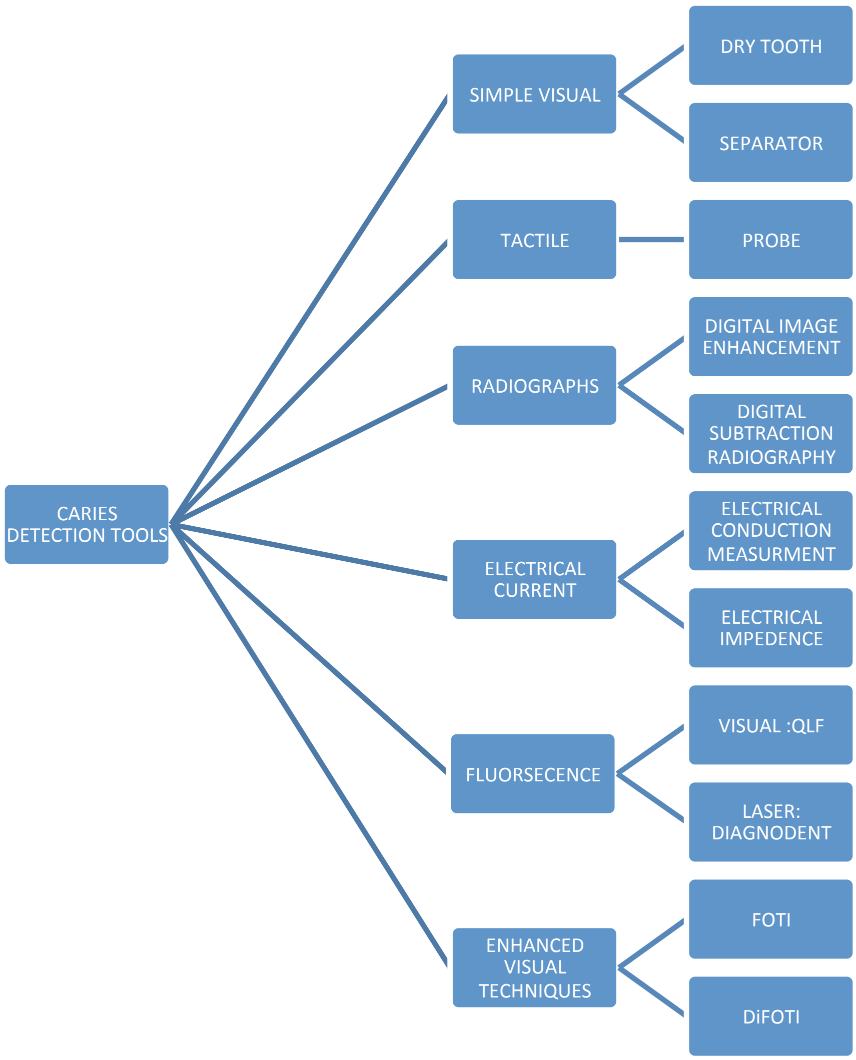


Figure 2. Classification of common caries detection methods

2.2.1 Visual Detection

Visual detection is the most common method that every clinician uses at all times. Its disadvantage is that it is subjective, depends on the dentist's experience and ability. It also relies on examining qualitative features as color and texture, while quantitative evaluation is more difficult and unreliable (Maupome and Pretty, 2004). For adequate visual examination the clinician should have a well cleaned tooth, dry surface (5 sec. under the air jet), good overhead light, and good vision. A sound enamel structure is almost transparent due to the densely packed hydroxylapatite crystals and has refractive index of 1.62 (Thylstrup and Fejerskov, 1978). If the structure is demineralised the voids between the crystals decrease the refraction index and the penetrating photons of light are scattered leading to the appearance of a white spot. While the voids are filled with water the refraction index is 1.33, but when the tooth surface is well dried it reduces the index to 1 (same as the air index), (Thylstrup and Fejerskov, 1978).

Bader et al., (2001) did a systematic review evaluating the evidence of the different caries detection methods. They identified 20 studies evaluating the performance of the visual detection of the occlusal caries and only one study for proximal lesions. They concluded that the strength of the evidence is poor due to the small number of studies with appropriate design. The results showed that median range sensitivity between 0.25-0.66 and specificity 0.69-0.91.

2.2.2 Tactile Detection

The tactile assessment is performed with dental probe on a clean dry tooth. It is recommended that a ball ended explorer is used as a sharp one can damage the enamel surface of an early lesion, does not add any benefit to the accuracy of detection, and also may lead to false positive results (Ekstrand et al., 2009). Many authors warn about possibility of transferring cariogenic bacteria between tooth surfaces while probing and creating irreversible traumatic defects in the fissures. Yassin, (1995) demonstrated that a white spot lesion can be easily cavitated during probing. This method is also subjective as clinicians may interpret ‘stickiness’ of the fissure differently (Kidd, 1998). Bader et al. identified 9 studies evaluating this method of detection and found that it is more specific (median range of 0.94-0.99) than sensitive (median range of 0.19-0.32) which highlights the risk of false negative diagnoses.

2.2.3 Radiographic Detection

Radiographs are routinely exposed in the dental practice for detection of caries. This method has a sensitivity range of 0.54-0.66 and specificity of 0.83-0.95 for dentinal caries, but is less reliable for detection of enamel caries with sensitivity range of 0.3-0.41 and specificity of 0.76-0.78 (Bader et al., 2001). The same review found over 35 studies evaluating the performance of the radiographic detection in dentinal caries against only 6 studies dealing with enamel caries. The conclusion was that the quality of evidence is poor and that x-ray method is less sensitive and more specific meaning that it has a tendency to produce false positive results.

Many authors advocate the use of this method for interproximal surfaces. Pitts, (1996) stated that clinical examination alone can detect just over 50% of the proximal lesions, in comparison to radiographic examination which can identify over 90% of the interproximal decay. Espelid and Tveit (1986) also confirmed that bite-wing radiographs can increase the detection of proximal lesions by a factor of two.

Digital radiography (DR) has the benefit of lower dose radiographic exposure compared to conventional film radiography. It also allows for the images to be easily archived and replicated. The disadvantage of this technique is the lower diagnostic yield compared to the conventional x-rays and lower sensitivity and specificity for small interproximal lesions.

Although DR has only 255 shades of grey compare to the millions of the conventional radiograph, the image can be software enhanced for better diagnostic performance (Pretty, 2006).

Clinical examination and visual inspection is often sufficient to detect and diagnose occlusal caries. However, interproximal caries that have not extended to the occlusal, facial, or lingual surface have traditionally been detected via bite wing radiography.

In a study assessing 5,676 restorations, the most frequent diagnostic combination used for posterior interproximal lesions was clinical assessment plus radiographs at a rate of 47% (Rindal et al., 2015).

Abesi et al., 2012 assessed radiographic imaging techniques for detection of proximal caries on permanent teeth using a gold standard of teeth that were sectioned for histological analysis. They looked specifically at charge coupled devices (CCD) for digital radiography and at E-speed films for conventional radiography. For the detection of enamel caries, the sensitivity and specificity of film were 38% and 98% and of CCD were 15% and 96 %, respectively. For the detection of both dentin and enamel caries, the sensitivity and specificity of film were 55% and 100% and of CCD were 45% and 100%, respectively.

Wenzel et al., 2013 assessed cone beam CT, solid-state sensors, and photostimulable phosphor plates for detection of proximal caries on permanent molars and premolars. For the solid-state digital radiographic sensors using the Digora Toto, Soredex system they found the mean percentage (range) for sensitivity to be 19 (3-24) and for specificity to be 99 (99-100). The gold standard comparison employed for this study was visual inspection of the teeth mounted in tooth blocks, using the naked eye under strong light.

2.2.4 Fiber Optic Transillumination

Fiber optic transillumination (FOTI) is a device that uses high intensity white light shown through a tip of a hand piece. When pointed at a tooth structure the white light scatters and presents defects as shadows. It shows the absorption of light photons in carious tooth structure. Therefore, carious lesions appear dark under this transillumination.

FOTI has the advantage that can be used on all tooth surfaces and can detect very early lesions. It is also quick and easy to apply, inexpensive, non invasive and can be used in areas with difficult access. However, it has a limited value when used around restorations and it is an operator subjective method that cannot quantify and record data. It produces very low sensitivity (median range of 0.4-0.21) and high specificity (median range of 0.88-1) (Astvaldsdottir et al., 2012).

Cortes et al., 2003 reported that FOTI correlated well to the caries histology but has limited ability in distinguishing between lesions with different depth. It is equally accurate for detecting caries on the occlusal surface as the visual detection. A digital imaging FOTI (DiFOTI) has been introduced with the advantage that it can record images by incorporated grey camera with different heads for occlusal and interproximal surfaces. Yet, the method remains subjective as there is no quantification of the results (Pretty, 2006).

2.2.5 Visible Light Fluorescence

Quantitative light-induced fluorescence (QLF) is a light box unit with hand piece on a liquid light guide and intraoral camera. Fluorescence is a phenomenon where the reflected light is of different colour and wavelength than the initially illuminated. The image is detected in the blue-green light range, recorded, and analyzed by software using pixel values of the sound enamel and then subtracting those pixels which are considered to be lesion. The method enables for longitudinal assessment by a video repositioning system that allows the exact position of the original image to be replicated on subsequent visits. QLF is objective method that offers the advantage for very early lesion detection, quantification, and storage of the images. This benefits its use in research and patient motivation programs. The systematic review by Bader et al. identified only 2 studies evaluating this method, but the specificity and sensitivity are very high, both over 0.8, therefore the method is promising. The current concerns with QLF are that the method may not be able to distinguish between carious and non-carious lesions (Pretty, 2006).

2.2.6 Laser Fluorescence

DIAGNOdent is a device that has been developed for caries detection using laser fluorescence to illuminate the surface of occlusal lesions. A tip is used to produce a red light and collect the reflected fluorescence. The fluorescence emitted from the surface of the tooth is then measured and analyzed (Kucukyilmaz et al., 2015). An advantage of this system is that it does not detect artificial lesions and it has been described to measure the degree of bacterial activity. An *in vitro* study reviewed the DIAGNO-Dent's performance and found a high correlation with the histological examination, also the reported sensitivity is 0.75 and specificity is 0.96 (Shi et al., 2001). Although studies have shown that its reliability is high, in around 0.9 (Lussi et al., 1999), the device has downside including false positive results in presence of plaque, calculus and staining. Therefore, a strict requirement is adequate cleaning of the teeth before examination with the device. The systematic review of Bader et al., (2001) found an overall very good and promising performance of DIAGNOdent, however only *in vitro* trials were included. The fact that there is not a clinical study conducted to date makes the recommendation for its use in the dental practice difficult (Pretty, 2006).

In a study comparing three different caries detection methods on 200 primary molars, it was found that DIAGNOdent showed high levels of reproducibility for detection of caries at the dentin level. The authors therefore concluded that DIAGNOdent can increase the rate of identification of occlusal caries and is a good adjunct tool for caries detection (Kucukyilmaz et al., 2015).

2.2.7 Electrical Current

The methods of caries detection using electrical current rely on the fact that every material has different conductance. A demineralized lesion in the dental hard tissues has fewer minerals; more voids between crystals and more water content compare to a caries free structure, therefore the electrical conductance between the two differs. This fact is used in caries detection by measuring the conductivity difference and analyzing the results.

Electronic caries monitor is a device emitting single, fixed-frequency alternating current which measures the 'bulk resistance' of the tooth surface where it is applied (Longbottom and Huysmans, 2004). The hard surface being examined has to be covered with conducting medium and the contact should be constant for the cycle duration. This method has been reported to have high sensitivity (0.75) and specificity (0.87), although most of the available trials are *in vitro* performed and the only one clinical study has been done on root caries (Huysmans et al., 2000). It is easy to use and well accepted from patients, however results can be influenced by the tooth temperature, dehydration, and staining.

Electrical Impedance Spectroscopy is another application that uses a range of electrical frequencies and provides information on capacitance and impendence. This method is yet to be developed for clinical practice, but promises more accurate analysis on the tooth structure including presence and extends of caries (Pretty, 2006).

2.2.8 Ultrasound

The rationale behind the use of ultrasound for caries detection is based on the fact that sound passes through different structures and the reflected waves can be collected to produce an image of these structures. The research into the use of ultrasound for caries detection has been very limited. Only few studies are available although the reported results show promise. For example Bab et al. (1999) used Ultrasonic Caries Detector (UCD) for identifying proximal lesions and reported that this technique is superior to conventional radiography.

2.2.9 DEXIS CariVu

DEXIS, a digital dental imaging company, was founded in 1993. They first launched the DEXIS Digital x-ray in 1995 in Germany (DEXIS, 2016). Since that time, it has been gaining popularity worldwide.

DiFOTI (Digital Image fiber optic transillumination) was first introduced in 2001 by Electro-Optical Sciences (EOS). While FOTI only allows for practitioner viewing of the transillumination intraorally, DiFOTI overcomes this barrier by capturing a digital image (Astvaldsdottir et al., 2012).

On December 11, 2006, EOS announced an exclusive licensing agreement with KaVo Dental GmbH, a German company. At that time KaVo earned all rights to the DiFOTI technology and renamed it DIAGNOcam. In 2014, DEXIS introduced an enhanced DiFOTI System under the name CariVu. CariVu is a hand-held device that utilizes near-infrared light with transillumination technology (Figure 3). This FDA approved device is safe and uses non-ionizing radiation (DEXIS, 2016). The level of energy used in this application poses no risk to the patient and offers potential benefits. Unlike DIAGNOdent which is used for detection of occlusal caries, CariVu can be used for detection of interproximal caries.

Figure 3: DEXIS CariVu handheld caries detection device

On a CariVu image, healthy enamel appears white whereas carious lesions appear dark (Figure 4). The increased porosity of the structure, characteristic for the process of demineralization, enables absorption of the light, while sound hard tissues reflect it in full. The images are therefore easy for practitioners to read since they mimic the dark caries color seen on traditional radiographs.

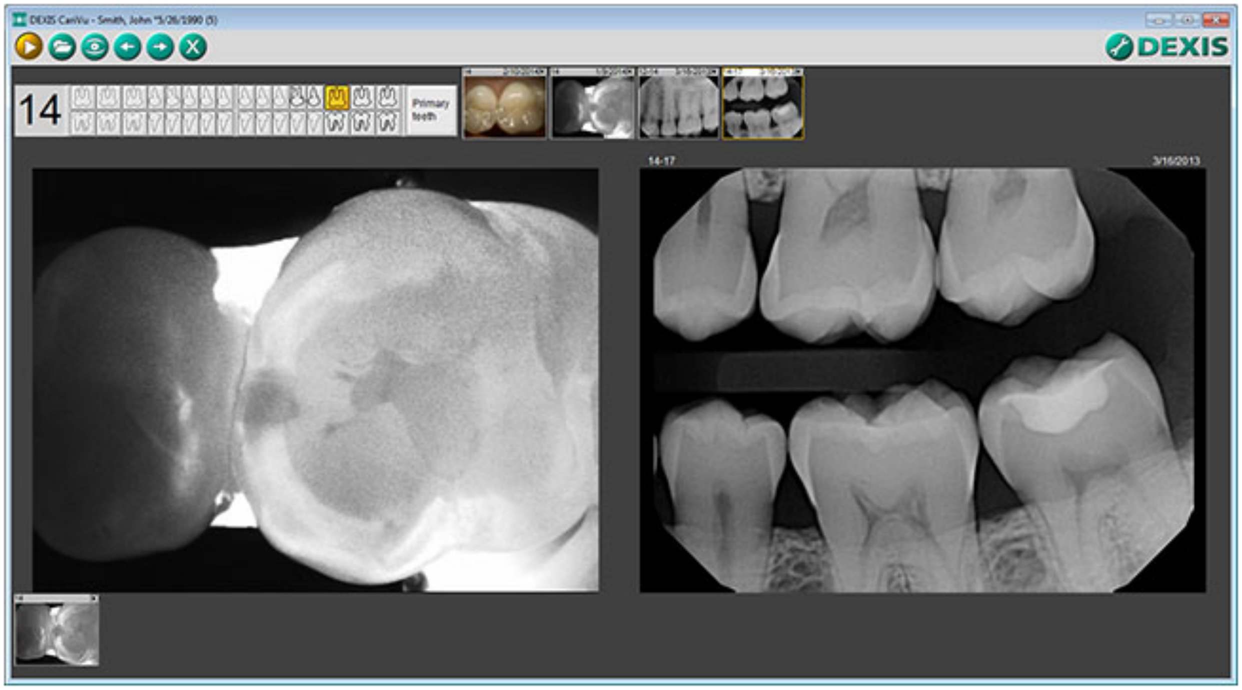


Figure 4: A depiction of a CariVu image (left) alongside a traditional bitewing image (right) of the same tooth surfaces (DEXIS, 2016).

In order to obtain a CariVu image, the sensor is placed into the mouth and is held over the tooth of interest. The light is shined on the tooth so the image can be visualized before it is captured. Two rubber pieces contact the tooth surface on the buccal and the lingual in order to stabilize the device over the area of interest (Figure 5). The image is then captured by either clicking a button on the device itself or on the computer monitor. This image capture is similar to a traditional photograph in that nothing is being emitted during the image taking process. Rather, the device is simply capturing what can already be viewed. Images are stored digitally in the patient’s electronic health record, similar to the storage of radiographic images.

Figure 5: Tip of DEXIS CariVu device that is positioned over the tooth surface so that it hugs the tooth and the light shines on either side of the tooth.

The search for novel caries detection methods that are non-invasive, inexpensive and practical while at the same time poses excellent reliability and validity is continuous.

The DEXIS CariVu device allegedly offers quick and efficient detection of interproximal carious lesions and can be used for very young patients that lack sufficient cooperation for other traditional methods for caries assessment. However, to date there is no literature available evaluating the DEXIS CariVu device as a method of detection of interproximal carious lesions on primary teeth.

Astvaldsdottir et al., (2012) evaluated the accuracy of DiFOTI for interproximal caries detection as compared to that of film and digital radiography. After analyzing 112 proximal surfaces and comparing to a reference of histological sections, they found that DiFOTI had higher diagnostic accuracy for interproximal enamel lesions than film or digital radiography, while the diagnostic accuracy for interproximal dentin lesions was the same across all three methods (Astvaldsdottir et al., 2012).

In 2013 Kuhnisch et al., published a study assessing the ability of DIAGNOcam to detect non-cavitated interproximal lesions on permanent teeth. They found accuracy ratings of 2% for visual examination, 96% for bitewing radiographs, and 99% for DIAGNOcam, as compared to *in vivo* examination after excavating the caries intra-orally (Kuhnisch et al., 2013).

There are no studies to date on the DEXIS CariVu model of the DiFOTI technology. Moreover, there are no published studies in the literature that assess the use of DiFOTI technology on primary teeth.

Good quality studies are needed to investigate how this new technology compares to traditionally used techniques of caries detection and to evaluate its sensitivity and specificity. The current study is designed to address this gap in the literature.

2.3 Sensitivity and Specificity

In healthcare literature, a “gold standard” refers to the most accurate test available to date for diagnosing a certain disease under reasonable conditions. Other tests will therefore be compared to this gold standard to determine whether they are useful (Parikh, 2008).

Sensitivity measures the ability of any test to accurately diagnose someone as having the disease. It is measured by calculating all those individuals with the disease who tested positive for the disease divided by the total number of individuals who possess the disease. The calculation is: Sensitivity = A / A+C = A (true positives) / A+C (true positives + false negatives) = probability of testing positive for a disease when the disease is truly present (Parikh, 2008) (Table II).

Specificity measures the ability of any test to accurately diagnose someone as being disease free. It is measured by calculating all those individuals without the disease who tested negative for the disease divided by the total number of individuals who do not possess the disease. The calculation is: Specificity = D / B+D = D (true negatives) / B+D (false positives + true negatives) = probability of testing negative for a disease when the disease is absent (Parikh, 2008).

TABLE II

DEFINING SENSITIVITY AND SPECIFICITY

	Disease Present	Disease Absent
Test Positive	A	B
Test Negative	C	D
	Sensitivity = A / A+C	Specificity = D / B+D

3. METHODOLOGY

3.1 Image Collection

Approval of the study was obtained from the University of Illinois at Chicago Institutional Review Board (Appendix A).

Young patients in the UIC Pediatric Dental Clinic were assessed first clinically and, where deemed necessary, digital bitewing radiography was utilized for comprehensive evaluation of the interproximal surfaces (as per the recommendations of the American Academy of Pediatric Dentistry, 2014 updated Guideline, Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents, see Figure 6). The Kavo FOCUS™ X-ray machine with Anti-Drift mechanism was used to generate high-frequency intraoral exposure. Either DEXIS Platinum sensor or Gendex GXS-700 digital intraoral sensors were used for image capture depending on the size of the patient's mouth. SNAP-A-RAY® DS by Dentsply Rinn universal sensor holder or adhesive foam bite tabs were used for sensor placement, depending on patient comfort.

Furthermore, certain patients were examined with the DEXIS CariVu device. Both image types (radiograph and CariVu) were captured by residents or dental assistants in the UIC Department of Pediatric Dentistry. The radiographic and DEXIS CariVu images were stored in the patient's electronic health record in the Axium system.

Risk Category	Diagnostics	Interventions: Fluoride	Interventions: Diet	Interventions: Sealants [λ]	Restorative
Low risk	– Recall every six to12 months – Radiographs every 12 to 24 months	– Twice daily brushing with fluoridated toothpaste [μ]	No	Yes	– Surveillance [χ]
Moderate risk patient/parent engaged	– Recall every six months – Radiographs every six to 12 months	– Twice daily brushing with fluoridated toothpaste [μ] – Fluoride supplements [δ] – Professional topical treatment every six months	– Counseling	Yes	– Active surveillance [ε] of incipient lesions – Restoration of cavitated or enlarging lesions
Moderate risk patient/parent not engaged	– Recall every six months – Radiographs every six to 12 months	– Twice daily brushing with toothpaste [μ] – Professional topical treatment every six months	– Counseling, with limited expectations	Yes	– Active surveillance [ε] of incipient lesions – Restoration of cavitated or enlarging lesions
High risk patient/parent engaged	– Recall every three months – Radiographs every six months	– Brushing with 0.5 percent fluoride – Fluoride supplements [δ] – Professional topical treatment every three months	– Counseling – Xylitol	Yes	– Active surveillance [ε] of incipient lesions – Restoration of cavitated or enlarging lesions
High risk patient/parent not engaged	– Recall every three months – Radiographs every six months	– Brushing with 0.5 percent fluoride – Professional topical treatment every three months	– Counseling, with limited expectations – Xylitol	Yes	– Restore incipient, cavitated, or enlarging lesions

Figure 6. AAPD Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents, Latest Revision 2014, Table 6

For the purposes of this study, the PI identified, by a search in Axium, a total of 22 patients that had both bitewing x-rays and DEXIS CariVu images documented. The PI reviewed the corresponding charts. They represented only healthy children aged 6-11 years old with mixed dentition. This was intended to allow for analysis of the images on both types of teeth.

From these 22 patients, a total of 221 paired image surfaces of primary molars and permanent first molars were collected by the PI. An image pair consisted of a digital bitewing and a CariVu image of the same tooth surface on the same patient. Each tooth had the potential to general two image surfaces, except for permanent first molars, which only generated mesial surfaces. Each patient chart had the potential to generate 20 paired image surfaces to utilize in the questionnaire. There are 20 interproximal posterior surfaces in the mouth of a full mixed-dentition patient as shown in Figure 7.

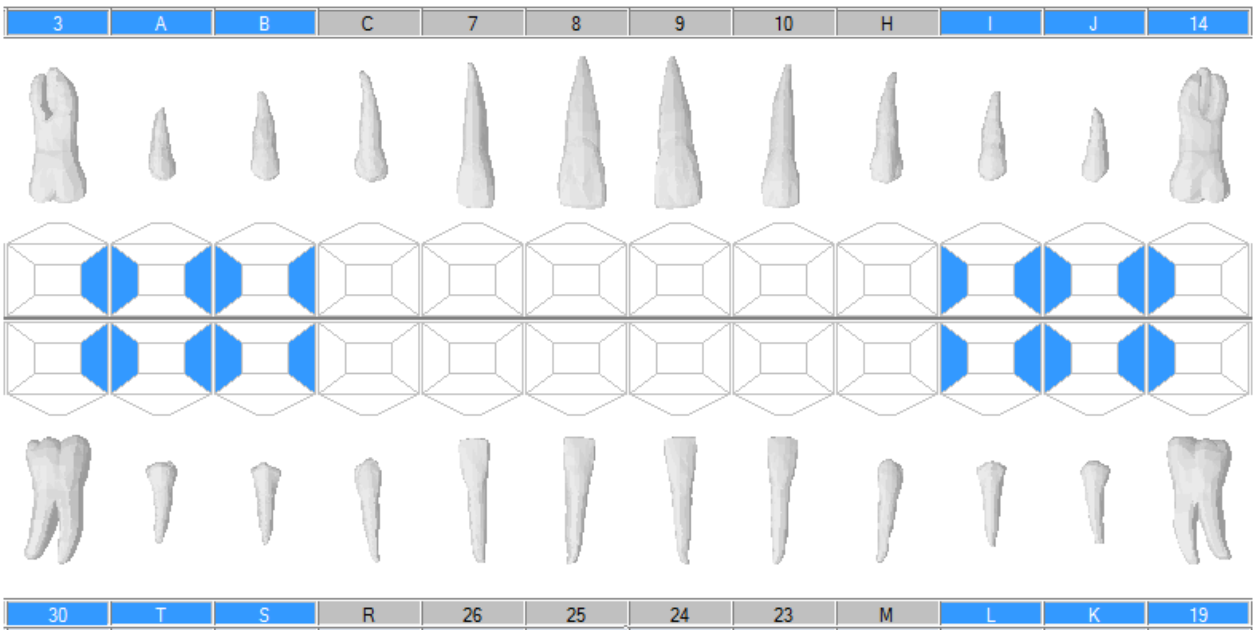


Figure. 7: Depiction of the 20 interproximal tooth surfaces that can be generated from one mixed-dentition patient.

Images were only included if both the bitewing and CariVu image of the same tooth was considered diagnostic by the PI. If there was an overlap between surfaces, poor illumination, or otherwise non-diagnostic images, then the image pair was excluded from the study.

All images were exported from DEXIS and stored in a Microsoft Powerpoint file. Patient identifiers were not included with the images but the images were labeled so that the pairs could be matched later.

3.2 Image Compilation

For the purposes of this study a simple scoring system was implemented to describe the depth of the carious lesion (Figure 8).

Score	Explanation
1	No caries
2	Incipient caries not touching the DEJ
3	Caries touching the DEJ and into dentin

Figure 8. Scoring system implemented for the purposes of the study

An expert committee assessed all of the paired radiographic and CariVu images provided by the PI. The committee was comprised of two faculty members: Dr. Sahar Alrayyes (primary research advisor and pediatric dentist) and Dr. Evelina Kratunova (research committee member and pediatric dentist).

Both expert committee members were trained and calibrated prior the start of the study. The training included studying the DEXIS CariVu manufacturer's video tutorial and official instructions of use. The examiners then assessed all 221 radiographic and corresponding CariVu images collected for the study.

Each of the two experts scored both the bitewing and CariVu images. They scored the images independently from one another. They gave separate bitewing and CariVu scores; these scores did not have to match. They scored each image according to the designated system (Figure 8) or chose to exclude the image altogether if they deemed it non-diagnostic.

Images were only included in the final questionnaire if the bitewing score for both expert raters was the same. After excluding all non-matching bitewing scores and excluding all images deemed non-diagnostic by the experts, 90 image pairs were agreed upon and included. All included images were of primary molars. Of these 90 images, the expert committee rated 33 as no caries, 26 as incipient caries not touching the DEJ, and 31 as caries touching the DEJ and into dentin. These categories will henceforth be referred to as no caries, incipient caries, and dentinal caries.

The paired bitewing and CariVu images were separated into two image sets: bitewing and CariVu. Each of these image sets was independently randomized using the randomization tool on Microsoft Excel to generate a set of randomized numbers 1-90. Based on this randomization, the image sets were manually re-ordered. The questionnaire was created by ordering the 90 randomized bitewing images followed by the 90 independently randomized CariVu images. The finalized questionnaire is included in Appendix B.

3.3 Choice of Gold Standard

For the purposes of this study, radiographs were selected as the gold standard for caries diagnosis. The expert committee generated ratings for all of the radiographic images and these ratings were then deemed to be the “correct” diagnosis.

3.4 Subject Enrollment

All pediatric dental residents and faculty members at the Department of Pediatric Dentistry, UIC, were invited to participate as subjects in the study and to serve as raters. The PI and the two faculty committee members were excluded. Previously, a 45 minute session had been conducted at the UIC Department of Pediatric Dentistry. This session was conducted by a representative from DEXIS and was meant to instruct the members of the department on DEXIS CariVu utilization.

Raters were recruited verbally. No advertising was utilized. Raters were asked to participate by completing the questionnaire. Raters were given the option to opt out and not complete the questionnaire, or to decide not to participate after they had begun completing the questionnaire. Raters were informed that the questionnaire would take up to 30 minutes to complete. Raters were not aware of which patients the images were taken from, and were not aware of how the CariVu and radiographic images matched.

The questionnaire included a cover letter (Appendix C), which contained the elements of informed consent. Raters were given a sample of different CariVu images which were taken from the DEXIS CariVu user manual (Appendix D). They were permitted to reference this chart as they rated the images. Raters were informed that the first 90 images were bitewings and the second set of 90 images were CariVu. Raters were instructed to announce their scoring for each image audibly. The PI recorded the ratings into a Microsoft Excel workbook.

The PI answered questions about image orientation or which surface was meant to be scored. Beyond this, the PI did not provide any information to the raters during the ratings.

3.5 Statistical Analysis

Statistical analysis was performed using Vassar Stats, a website for statistical computation (Lowry 2017), and IBM SPSS Statistics software package (IBM Corp. 2015).

4. RESULTS

4.1 Number of Raters and Response Rate

The ratings occurred over a period of four weeks in February and March of 2017. Raters' response times ranged from 5 to 30 minutes. On occasion, ratings were interrupted to allow for patient management in the clinic. When this occurred, rating was resumed at the next available break in the day.

All pediatric dentists and pediatric dental residents of the UIC Department of Pediatric Dentistry were asked to participate in the study. This consisted of 18 residents and 10 faculty members. One resident and two faculty members were excluded from participating due to their involvement in compiling the images or their presence on the expert committee. There were therefore 25 individuals eligible for participation. One faculty member did not participate due to lack of availability during the administration period. Therefore, there were 24 raters in all.

4.2 Demographics

In regards to demographic data, raters were only asked to answer one question, "Are you a first year resident, a second year resident, or a faculty member?" Nine were first year residents, eight were second year residents, and seven were faculty members.

4.3 Determination of observations for data analysis

Sensitivity and specificity are evaluated by comparing each observation with a gold standard. We had a choice of averaging the observations by image, or by counting each observation as if it were unique, despite the fact that there were multiple observers of the same image. Averaging observations by image would result in a sample size of 90 (the number of images sampled). Counting each observation as independent resulted in a sample size of 90 images times 24 raters, or 2160 observations. The second method was considerably easier to calculate. We calculated sensitivity by both methods with virtually identical results, so the rest of the calculations were done using the sample size of 2160.

4.4 Accuracy of Image Scoring by Image Type

Tables III and IV demonstrate the overall accuracy of ratings of bitewings and of CariVu, respectively. Rater scoring were then compared to the expert scoring. Images were grouped by image types (no caries, incipient caries, dentinal caries). The expert committee rated the 90 images as follows: 33 as no caries, 26 as incipient caries not touching the DEJ, and 31 as caries touching the DEJ and into dentin. The 90 image pairs were then assessed by 24 raters, resulting in a total of 2160 observations each for CariVu and bitewings. This yielded 33 x 24 = 792 observations of images of no caries, 26 x 24 = 624 observations of images of incipient caries, and 31 x 24 = 744 observations of images of dentinal caries.

TABLE III

ACCURACY OF IMAGE SCORING FOR BITEWINGS[a]

		No Caries	Incipient Caries	Dentinal Caries	Total
Incorrect	Count	105	193	51	349
	% within expert rating	13%	31%	7%	16%
Correct	Count	687	431	693	1811
	% within expert rating	87%	69%	93%	84%
Total		792	624	744	2160

[a] Pearson Chi-Square = 153, 2 df, p = 0.000

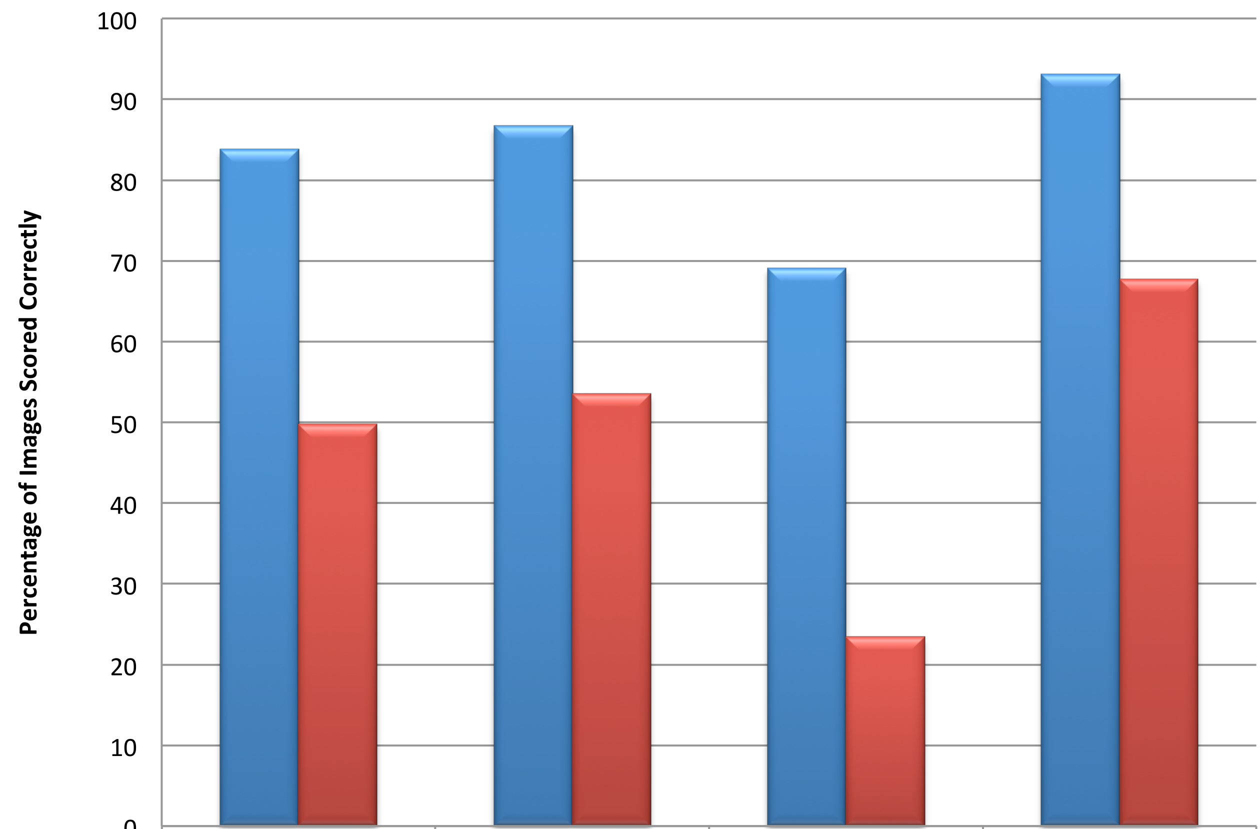
TABLE IV

ACCURACY OF IMAGE SCORING FOR CARIVU[a]

		No Caries	Incipient Caries	Dentinal Caries	Total
Incorrect	Count	368	478	240	1086
	% within expert rating	47%	77%	32%	50%
Correct	Count	424	146	504	1074
	% within expert rating	54%	23%	68%	50%
Total		792	624	744	2160

[a] Pearson Chi-Square = 274, 2 df, p = 0.000

These results are depicted graphically for the percent correct for both bitewings and CariVu in Figure 9.



	Overall	No Caries	Incipient Caries	Caries into Dentin
Bitewing	83.8	86.7	69.1	93.1
CariVu	49.7	53.5	23.4	67.7

Figure 9. Accuracy of Image Scoring for Bitewings and CariVu, Percent Correct

4.5 Sensitivity and Specificity

Sensitivity and specificity for both bitewings and CariVu were calculated using three comparisons.

4.5.1 No Caries versus Caries

Expert committee ratings on the bitewing images were used as a reference for the correct score in all tables. Sensitivity and specificity were calculated for no caries versus caries. To accomplish this, the expert ratings of incipient caries and dentinal caries were grouped. This allowed for a categorization of [no caries] versus [incipient caries + dentinal caries]. This was then compared to the ratings, which were categorized in the same way. Sensitivity and specificity were then calculated with a 95% confidence interval (Table V) using the Vassar Stats website for that purpose (Lowry 2017).

TABLE V

SENSITIVITY AND SPECIFICITY OF BITEWING RADIOGRAPHS COMPARED TO CARIVU IMAGES, GROUPED AS CARIES VS NO CARIES [a]

		Value	**95% Confidence Interval**
Bitewings	Sensitivity	0.92	0.90-0.93
	Specificity	0.87	0.84-0.89
CariVu	Sensitivity	0.72	0.69-0.74
	Specificity	0.54	0.50-0.57

[a] Calculations were made grouping all carious lesions into a Caries category and comparing them to the No Caries category, with the expert raters used as the gold standard. Calculations were made through the Vassar Stats website (Lowry 2017). N=2160.

4.5.2 No Caries versus Dentinal Caries

Sensitivity and specificity were calculated for no caries versus dentinal caries. To accomplish this, images rated by the experts as no caries and dentinal caries were used, omitting the incipient caries images. This allowed for a categorization of [no caries] versus [dentinal caries]. This was then compared to the raters. Ratings of incipient caries and dentinal caries were grouped: [no caries] versus [incipient caries + dentinal caries]. Sensitivity and specificity were then calculated with a 95% confidence interval (Table VI), again using the Vassar Statistics website (Lowry 2017).

TABLE VI

SENSITIVITY AND SPECIFICITY OF BITEWING RADIOGRAPHS COMPARED TO CARIVU IMAGES, GROUPED AS NO CARIES VS DENTINAL CARIES [a]

		Value	**95% Confidence Interval**
Bitewings	Sensitivity	0.99	0.98-0.99
	Specificity	0.87	0.84-0.89
CariVu	Sensitivity	0.82	0.79-0.84
	Specificity	0.53	0.50-0.57

[a] Calculations were made comparing No Caries to the Dentinal Caries category, with the expert raters used as the gold standard. Expert rated images of Incipient Caries were eliminated from the calculation. Calculations were made through the Vassar Stats website (Lowry 2017). N=1536.

4.5.3 Dentinal Caries versus Other Categories

Sensitivity and specificity were calculated for dentinal caries compared to the other two categories. To accomplish this, the expert ratings of no caries and incipient caries were grouped. This allowed for a categorization of [no caries + incipient caries] versus [dentinal caries]. This was then compared to the raters which were categorized in the same way. Namely, [no caries + incipient caries] versus [dentinal caries]. Sensitivity and specificity were then calculated with a 95% confidence interval (Table VII).

TABLE VII

SENSITIVITY AND SPECIFICITY OF BITEWING RADIOGRAPHS COMPARED TO CARIVU IMAGES, GROUPED AS DENTINAL CARIES VS OTHER CATEGORIES [a]

		Value	**95% Confidence Interval**
Bitewings	Sensitivity	0.93	0.91-0.95
	Specificity	0.93	0.91-0.94
CariVu	Sensitivity	0.68	0.64-0.71
	Specificity	0.72	0.69-0.74

[a] Calculations were made grouping No Caries and Incipient Caries into an "Other" category and comparing them to the Dentinal Caries category, with the expert raters used as the gold standard. Calculations were made through the Vassar Stats website (Lowry 2017). N=2160.

4.6 Distribution of Scoring

The distribution of incorrect scoring by the raters was analyzed for both bitewings and CariVu.

For the images scored as no caries by the expert committee (33 images x 24 raters = 792 images total), the bitewings were scored by the raters as 687 (87%) having no caries, 83 (11%) having incipient caries, and 22 (3%) having dentinal caries. The CariVu were scored by the raters as 424 (55%) having no caries, 195 (25%) having incipient caries, and 173 (22%) having dentinal caries (McNemar-Bowker Test = 199, 3 df, p = 0.00) (see Figure 10). This analysis controlled for multiple viewers rating the same image.

For the images scored as incipient caries by the expert committee (26 images x 24 raters = 624 images total), the bitewings were scored by the raters as 105 (17%) having no caries, 431 (69%) having incipient caries, and 88 (14%) having dentinal caries. The CariVu were scored by the raters as 248 (40%) having no caries, 146 (23%) having incipient caries, and 230 (37%) having dentinal caries (McNemar-Bowker Test = 210, 3 df, p = 0.00) (see Figure 11). This analysis controlled for multiple viewers rating the same image.

For the images scored as dentinal caries by the expert committee (31 images x 24 raters = 744 images total), the bitewings were scored by the raters as 8 (1%) having no caries, 43 (6%) having incipient caries, and 693 (93%) having dentinal caries. The CariVu were scored by the raters as 136 (18%) having no caries, 104 (14%) having incipient caries, and 504 (68%) having dentinal caries (McNemar-Bowker Test = 158, 3 df, p = 0.00) (see Figure 12). This analysis controlled for multiple viewers rating the same image.

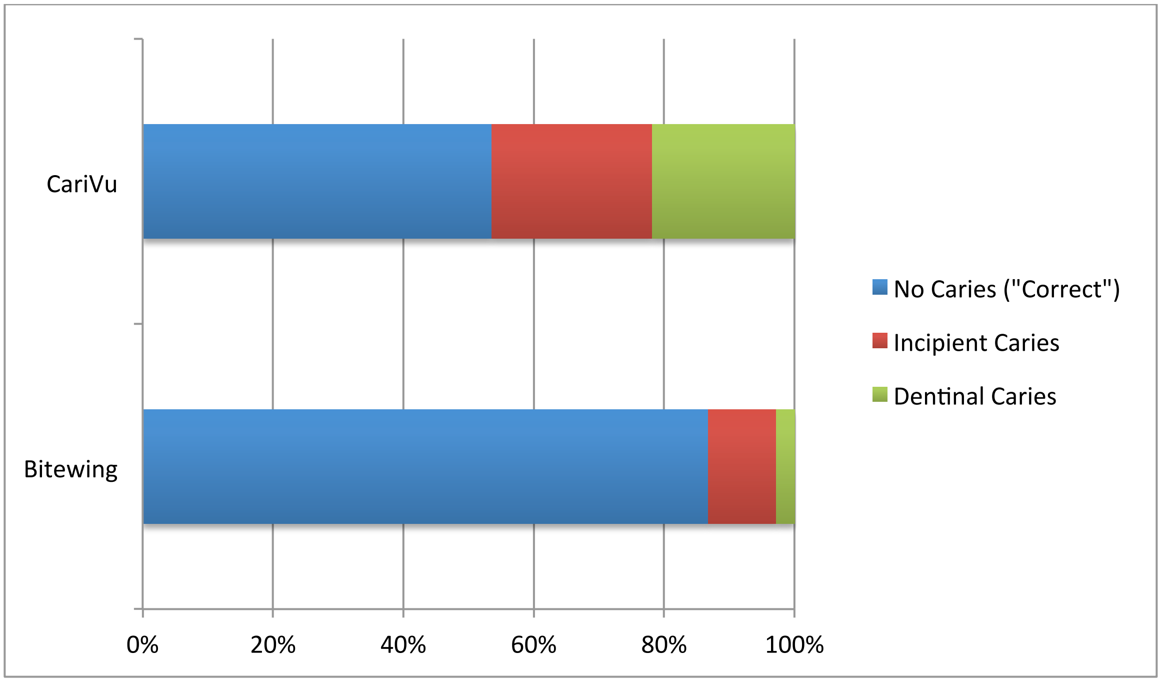


Figure 10. Images scored as “No Caries” by expert committee; Distribution of rater scoring

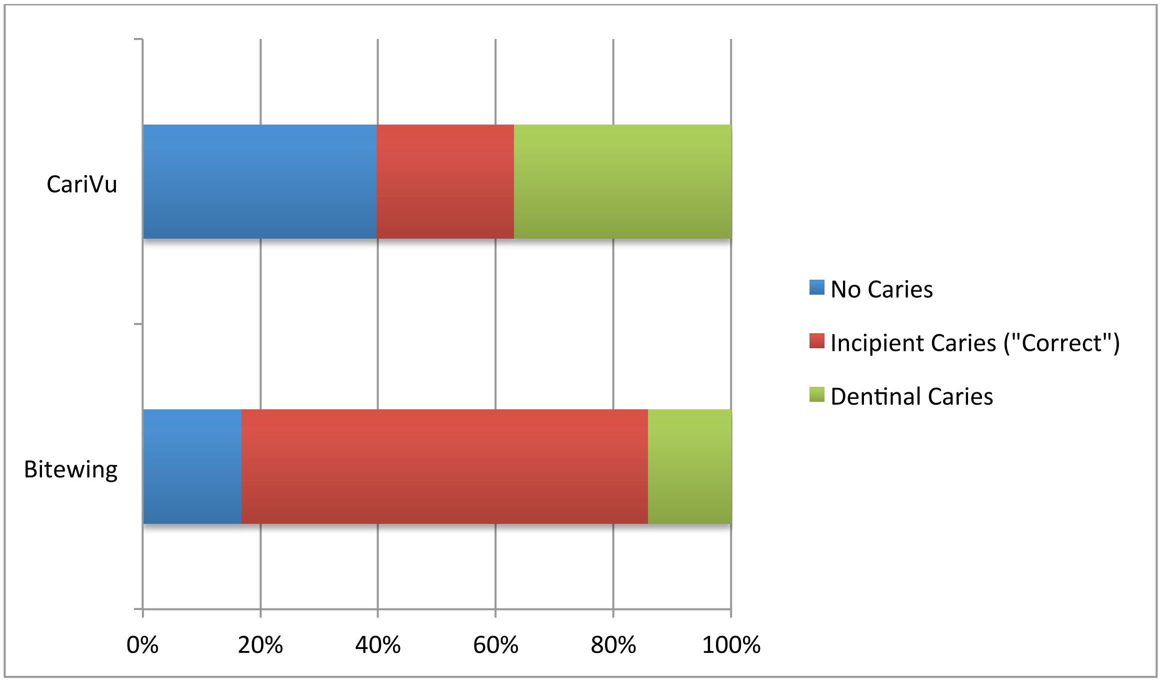


Figure 11. Images scored as “Incipient Caries” by expert committee; Distribution of rater scoring

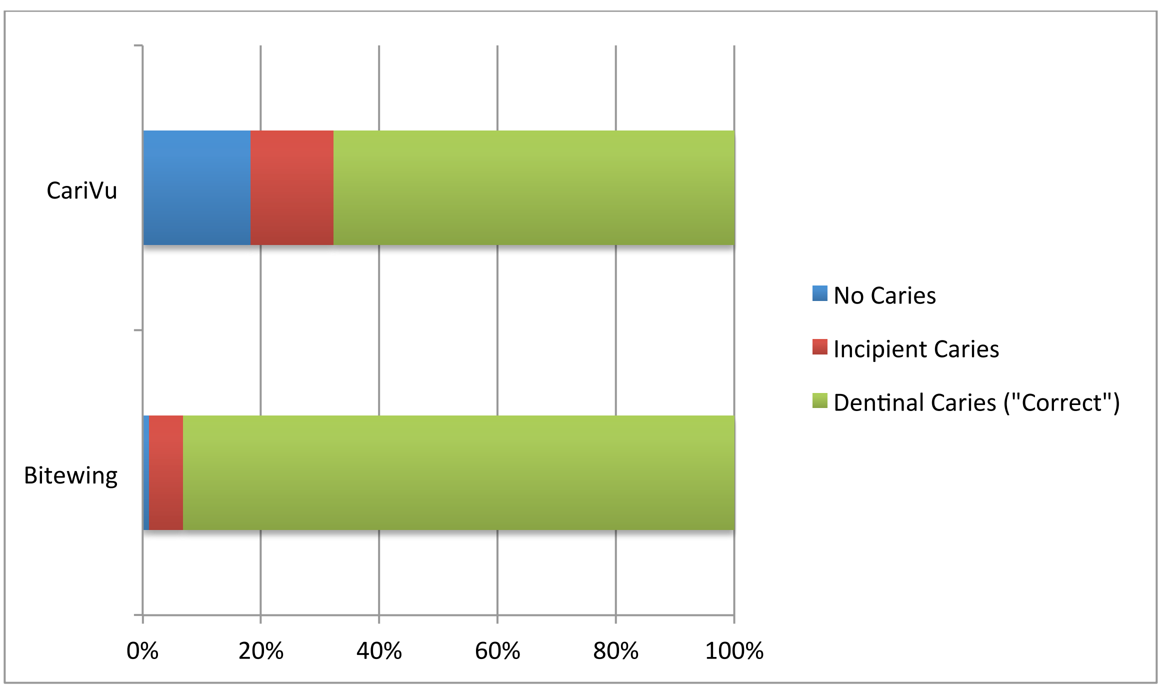


Figure 12. Images scored as “Dentinal Caries” by expert committee; Distribution of rater scoring

4.7 Inter-rater Reliability

Inter-rater reliability was calculated for both bitewings and CariVu. Kendall's Tau b was calculated for each of the 24 raters. Each rater's Kendall's Tau b was calculated compared to each of the other 23 raters, and the correlations were then averaged. This was used to generate a mean inter-rater reliability for radiographs (M=0.78, CI=0.77-0.79, N=24) with the lowest rater's Kendall's Tau b being 0.71 and the highest being 0.82. A mean inter-rater reliability was also generated for CariVu (M=0.48, CI=0.46-0.50, N=24) with the lowest rater's Kendall's Tau b being 0.33 and the highest being 0.56.

A paired samples T-test was conducted to compare overall Kendall's Tau b between radiographs and CariVu for each rater. The mean inter-rater reliability was significantly higher for radiographs than for CariVu (Paired T = 24.9, 23 df, $p<0.001$).

A comparison by rater status of each rater's mean inter-rater reliability was performed. Rater status was defined as first year resident versus second year resident versus faculty member. There was no difference in the inter-rater reliability for either bitewings (ANOVA F=0.123, 2 df, p=0.9) or CariVu (ANOVA F=1.225, 2 df, p=0.3) by rater status.

5. DISCUSSION

5.1 Strengths and Limitations of the Study

5.1.1 First Investigation of DEXIS CariVu

This study is the first investigation of the DEXIS CariVu device. While previous studies have assessed DiFOTI (Astvaldsdottir et al., 2012) and DIAGNOcam (Kuhnisch 2013), none have studied the more recent DEXIS CariVu. Moreover, this is the first investigation of any type of DiFOTI technology for its application on primary teeth.

5.1.2 Use of Bitewings as a Gold Standard

One feature of this study was the use of bitewing radiographs as a gold standard for comparison, deeming bitewings as the “correct” diagnosis. This methodology conforms with numerous other studies which implemented similar designs (Bizhang et al., 2016; Huth et al., 2010; Lussi et al., 2006). Moreover, Pitts explained that x-ray examination can increase interproximal caries detection rates from 50% based on clinical examination alone up to 90% when conventional x-ray examination is used (Pitts 1996). This provides validation of radiographs as an excellent diagnostic tool. However, since radiographs are a diagnostic tool and not a true measure of caries status, using them as a gold standard confers limitations on this study design. For the purposes of this pilot study on DEXIS CariVu for primary teeth, radiographs served as a suitable comparison.

Previous studies have demonstrated alternative modes of comparison. Astvaldsdottir et al. evaluated the accuracy of DiFOTI for interproximal caries detection using a reference of histological sections (Astvaldsdottir et al., 2012). Kuhnisch et al. assessed the ability of DIAGNOcam to detect non-cavitated interproximal lesions by comparing to *in vivo* examination after excavating the caries intra-orally (Kuhnisch et al., 2013). Wenzel et al. utilized visual inspection of mounted teeth as a gold standard (Wenzel et al., 2013). These methods of histological sections, *in vivo* examination of the excavated tooth, and visual inspection (either of extracted teeth or by orthodontic separation *in vivo*) may be superior to the use of bitewings as a comparison as they more accurately assess the true caries status of the tooth.

In this trial, the results provided by the expert committee were considered to be the correct evaluation of the images or the "true" assessment of the tooth surfaces. A bias is introduced with this assumption as it is possible the expert committee scores are in error. However, the high level of professional experience of the two committee members provides assurance that the evaluation provided from them in agreement is the most objective possible, considering the limitations of the diagnostic methods studied here. In addition, the raters agreed with the experts to a high degree, thus validating our gold standard.

The use of radiographs as the gold standard for caries diagnosis lead to another limitation of the study. Only radiographic images that were agreed upon by both members of the expert committee were included in the questionnaire. As a result, the radiographs included here were clearer than would be found in a typical diagnostic setting. It would have been more reflective of a true clinical scenario to have include all radiographic captured images, but this would have made it impossible to have a gold standard for comparison.

5.1.3 Inclusion of Teeth with Large Cavitation

Analogous to radiographs, CariVu images portray caries as a darker region on the image. This is presented as a benefit of the CariVu system, as it allows practitioners to interpret CariVu images in the same way as radiographs without needing additional training (Kachalia, 2015). However, unlike radiographs, CariVu images are influenced by the distance of the sensor tip from the tooth. When the sensor is too far, it cannot capture an image and the image will appear white (no caries). In this study, teeth with large cavitations were included. On bitewings, these lesions would easily be identified as dentinal caries. On CariVu though, since the sensor tip would be far from the base of the lesion, the lesion might actually have appeared white rather than dark. Not knowing how to interpret these white areas, raters may have incorrectly rated them as either no caries or incipient caries. A clinical user of the device will typically have more information from clinical examination and would therefore be less susceptible to this sort of mistake.

One way of avoiding this issue in future studies would be to not include any teeth with cavitations clinically visible from the occlusal surface. Another method would be to include an intraoral photograph of the tooth alongside each CariVu image so that subjects could corroborate with information they would typically obtain from a clinical examination. This might result in a more accurate reading of caries presences (fewer false negative readings), but it would not improve the false positive rate.

5.1.4 Inexperience of Users

All users of CariVu in this study were new and inexperienced. They all have had only minimal theoretical training and none of them had used the system in their practice.

Images were captured by both residents and dental assistants in the UIC Department of Pediatric Dentistry. These personnel had ample experience and training in capturing bitewing radiographs. However, they had only minimal training and little experience in capturing CariVu images. Thus, the diagnostic quality of the CariVu images utilized in this study may be less than ideal.

5.2 Accuracy of Image Scoring by Image Type

There was a difference in accuracy of caries detection between bitewings and CariVu images, with bitewings being more accurate. This held true for all types of lesions. The difference was largest for incipient caries. These results indicate that while overall, CariVu is an inferior tool for assessing interproximal caries as compared to bitewings, this is especially true for incipient lesions.

Menem et al. reported 0.78 and 0.81 accuracy of digital bitewing radiography in detecting proximal caries lesions, for cavitated and non-cavitated lesions, respectively (Menem et al., 2017). The cavitated lesions reported there are comparable to our dentinal lesions and the non-cavitated lesions reported there are comparable to our incipient lesions.

The present study found accuracies of 69% and 93% for digital bitewing radiography for incipient and dentinal lesions, respectively. An explanation for the lower accuracy for incipient caries and higher accuracy for dentinal caries in the present study is the use of primary teeth. Due to a difference in anatomy, caries in primary teeth can be difficult to discern in the thinner enamel layer but then progress more rapidly once in dentin. This would result in lower accuracy for detecting enamel caries but larger, and therefore easier to diagnose, dentinal caries.

5.3 Sensitivity and Specificity

The images for this study were chosen for the clarity of the radiographic images. This would suggest that the sensitivity and specificity found in this study for bitewings should be artificially high. This proved true for the sensitivities calculated in this study. In the present study, rater responses were being compared to the expert committee ratings on the radiographs. Thus, rather than truly measuring whether the radiographs were sensitive for detecting caries, we were measuring whether the raters were sensitive for detecting caries that the experts had already judged as being present. The higher sensitivities reported here indicate that the raters were successful in identifying caries on radiographs that the experts had already determined were visible on those same radiographic images.

The sensitivities generated in the present study were 0.92, 0.99, and 0.93, listed in the order described above (no caries versus caries, no caries versus dentinal caries, and non-dentinal caries versus dentinal caries). Previous studies assessing bitewing radiography have reported sensitivities ranging from 0.15-0.66. This is much lower than the sensitivities for digital bitewings detected for any of the methods used in this study.

The specificities reported in previous studies range from 0.76-0.99 (Abesi et al, 2012; Bader et al., 2001; Wenzel et al., 2013). The specificities generated in the present study were 0.87, 0.87, and 0.93, reported in the order listed above. These specificities fall within the range of those detected in previous studies. This indicates that the specificities calculated in this study are equivalent to those found in previous studies, which indicates that the methods used here are reliable for producing consistent results.

Sensitivity and specificity are defined as disease present versus disease absent. The ratios are calculated using a two by two comparison of data. Our analysis ranking three levels of disease, doesn't easily lend itself to such analysis. We grouped the disease levels in order to address the questions: Can raters distinguish caries from no caries? Can raters distinguish caries from no caries if they are only looking at clear dentinal caries? And can raters distinguish dentinal caries from the other two groups?

For the first two calculation methods (no caries versus caries and no caries versus dentinal caries), the sensitivities were higher than the specificities. This means that for these analyses, both the bitewings and the CariVu were good for detecting caries and poorer for ruling out no caries. The exception to this was the specificity for non-dentinal caries versus dentinal caries. For this, bitewings showed a high sensitivity (0.93) and specificity (0.93) and CariVu showed a lower sensitivity (0.68) and higher specificity (0.72). This higher specificity relative to the sensitivity indicates that raters were able to rule out dentinal caries when compared to both incipient caries and no caries on CariVu images.

5.4 Distribution of Scoring

The distribution of image scoring was assessed for all three image types. This was done to better understand rating errors. Clinically, this has important ramifications. If an image is scored as more diseased than its true status then practitioners will over-diagnose and therefore over-treat. If an image is scored as less diseased than its true status, then practitioners will under-diagnose and therefor under-treat.

Warren et al., (2006) conducted a longitudinal studying monitoring progression of non-cavitated carious lesions in primary teeth. Overall, they found that after monitoring smooth surface lesions for four years, 5% had been filled by a dentist and 0% presented with frank caries (Warren et al., 2006). This can be interpreted to mean that only 5% of lesions had progressed to frank caries and all of those that had progressed had been treated by a dentist and restored. With such a low level of disease progression, it would be more harmful to overtreat than to undertreat. Unnecessary treatment subjects patients to local anesthetic, potentially painful dental procedures, and the psychological stress of having excessive dental work performed.

For images scored as 'no caries' by the experts, raters mistakenly diagnosed bitewing images as 'incipient' (11%) more often than as 'dentinal' (3%). However, raters were equally likely to rate the 'no caries' CariVu images as having either incipient caries (25%) or dentinal caries (22%). This even distribution of mistakes for CariVu as opposed to the gradient distribution of mistakes for radiographs shows a tendency toward possible guessing on CariVu images on the questionnaire. Additionally, this means that with CariVu, the over-diagnosis mistakes made are likely to be more serious than with radiographs.

For images scored as incipient caries by the experts, raters were equally likely to diagnose the bitewing images as no caries (17%) than as dentinal (14%). Similarly, raters were equally likely to rate the CariVu images as having no caries (40%) as having dentinal caries (37%). These errors would lead to an equal likelihood of over-diagnosing and hence over-treating as under-diagnosing and hence under-treating for both radiographs and CariVu.

For images scored as dentinal caries by the experts, raters were more likely to diagnose the bitewing images as incipient (6%) than as no caries (1%). Raters were equally likely to rate the CariVu images as having incipient caries (14%) as having no caries (18%). Again, CariVu rater errors appear to be almost random and show a tendency toward possible guessing. And again, rater errors with CariVu tend to be more severe.

Both the no caries images and the dentinal caries images showed a trend for CariVu. For Bitewings, when raters scored the images incorrectly, they tended to select the score that was closest to the correct score. For CariVu, when raters scored the images incorrectly, they did so in a manner that was not predictable which way their responses would go, because their incorrect responses were evenly spread among the incorrect response choices.

One possible explanation for this trend is the lack of experience of the raters with regard to CariVu. For inexperienced users, the images may have been difficult to interpret. Therefore, when they scored the images incorrectly, it was not a matter of deciding the depth of the carious lesion. Rather, raters may have be randomly guessing between the three possible answer choices. This would result in an even distribution among incorrect answer choices, as was seen with all three image types for CariVu.

5.5 Inter-Rater Reliability

The Kendall's Tau b generated for radiographs was M=0.78 which as an acceptable inter-rater reliability. This indicates that clinically, practitioners can reliably use radiographs to diagnose caries. Conversely, the Kendall's Tau b generated for CariVu was M=0.48 which is a poor inter-rater reliability. This indicates a lack of inter-rater reliability for CariVu. Clinically, poor reliability of a method indicates that different users will interpret images differently. One practitioner may diagnose a lesion as being present while another would diagnose it as being absent based on the same CariVu image. The lack of consistency is undesirable for a clinical diagnostic method.

When comparing the overall Kendall's Tau b for radiographs versus CariVu, the inter-rater reliability was better for radiographs. However, some of this superiority is due to the prior selection of radiographs for their diagnostic clarity.

Rater status did not affect inter-rater reliability for either radiographs or CariVu. This was somewhat surprising. One possible theory for why individual raters may not have been successful in scoring images in the same way as the expert committee was lack of experience. If this theory was true, then there would have been lowest reliability for 1st year residents who possess the least experience and highest reliability for faculty who possess the most experience. However, this did not prove true for either diagnostic tool. Therefore, lack of experience with the device cannot be used as an explanation for poor accuracy.

5.6 Implications for Care

For the no caries images and the dentinal caries images, the implications for care are clear. Images diagnosed as no caries would result in no treatment being performed. Images diagnosed as dentinal caries would result in restorative dental treatment being performed.

For the incipient caries images though, the implications for care are much more complicated. According to the Updated 2014 AAPD Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents, incipient carious lesions may or may not require treatment, depending on the type of patient being treated. This guideline divides patients into low risk, moderate risk, and high risk groups (AAPD 2015).

For children age six years and older, low risk factors include receiving optimally fluoridated drinking water, brushing teeth daily with fluoridated toothpaste, receiving topical fluoride from a health professional, having additional home measures (such as xylitol, MI paste, and antimicrobial products), and having a dental home/ regular dental care. Moderate risk factors include having special health care needs, being a recent immigrant, having defective restorations, and wearing intraoral appliances. High risk factors include being of low socioeconomic status, having greater than three between meal sugar-containing snacks or beverages per day, having one or more interproximal lesions, having active white spot lesions or enamel defects, and having low salivary flow.

According to the guideline, if a patient age six years or older is a low risk patient then the restorative treatment of choice would be "surveillance." If the patient is a moderate risk patient then the restorative treatment of choice would be "active surveillance of incipient lesions and restoration of cavitated or enlarging lesions." If the patient is a high risk patient then the restorative treatment of choice would be to "restore incipient, cavitated, or enlarging lesions." (AAPD 2015).

Incipient carious lesions are indicated for monitoring in both low and moderate risk patients. The CariVu device would be a desirable method for monitoring these lesions due to its lack of radiation exposure for the patient. However, this is precisely the area where the CariVu shows the lowest accuracy. It is therefore highly problematic to use the CariVu for monitoring incipient lesions. Kachalia advocates for the use of CariVu and states that "there is a valid argument to be made that CariVu may be all that is needed in certain cases" (Kachalia, 2015). Based on the findings in this study, CariVu does not have sufficient accuracy, sensitivity, or specificity to be used alone as a diagnostic device. It may, however, be used as an adjunct device to help verify caries detected by bitewings.

5.7 Future Studies

This study utilized bitewings as a reference for true caries status in the tooth. Future studies should assess the DEXIS CariVu device for detection of interproximal lesions on primary teeth, but should utilize a superior comparison for true caries status. Histological sections, *in vivo* examination of excavated teeth, and visual inspection would both serve as possible comparisons.

As previously discussed, lesions with large occlusal cavitations may have resulted in CariVu images which were difficult to interpret. This is because lesions may have appeared white, rather than dark as they typically should. This could be avoided in future studies by not including any images with obvious occlusal cavitation. Additionally, intraoral photographs to accompany the CariVu images would help raters corroborate what they are seeing with clinical information.

The subjects in this study were residents and faculty of the UIC Department of Pediatric Dentistry. At the time of the study, CariVu was a relatively recently added diagnostic tool and was not being widely utilized by most residents and faculty in the clinic. There was one 45 minute session during which residents and faculty were trained in CariVu by a representative from DEXIS. Compared to their experience with radiographs, the raters' prior experience with CariVu was limited. Perhaps with more time and experience capturing and interpreting CariVu images, both image quality and interpretation could improve. Future studies should test the DEXIS CariVu device on practitioners with more extensive CariVu experience.

6. CONCLUSIONS

1. There is a difference in accuracy of caries detection between bitewings and CariVu images, with bitewings being more accurate. This held true for all lesion types and the difference was greatest for incipient caries.
2. When scored incorrectly, CariVu images displayed an even distribution between incorrect response options.
3. There is no difference in inter-rater reliability by rater status.

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APPENDICES

APPENDIX A

Exemption Granted

September 29, 2016

Allison L. Horn, DDS
Pediatric Dentistry
801 S. Paulina
M/C 850
Chicago, IL 60612
Phone: (312) 996-7532 / Fax: (312) 413-8006

RE: Research Protocol # 2016-0899
"Comparison of Dexis CariVu caries detection device to traditional bite wing radiography for diagnosis of interproximal caries in primary and young permanent teeth"

Sponsors: None

Dear Dr. Horn:

Your Claim of Exemption was reviewed on September 29, 2016 and it was determined that your research meets the criteria for exemption. You may now begin your research.

<u>Exemption Period:</u> **September 29, 2016 – September 29, 2019**
Performance Site: UIC

Subject Population: 1) Adult (18+ years) subjects (UIC Dentistry Residents and Faculty)

2) De-identified data from patients that had both bite-wing x-rays and Dexis CariVu images prior to August 30, 2016.

Number of Subjects: 1) 40 UIC Pediatric Dentistry Residents and Faculty
2) 50 Patients that had both bite-wing x-rays and Dexis CariVu images prior to August 30, 2016.
3) Total = 90 Subjects

The specific exemption categories under 45 CFR 46.101(b) are:
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; and

APPENDIX A (continued)

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

HIPAA Waiver:
The Board determined that this research meets the regulatory requirements for waiver of authorization as permitted at 45CFR164.512(i)(1)(i)(A). Specifically, that the use or disclosure of protected health information (PHI) meets the waiver criteria under 45CFR164.512(i)(2)(ii); the research involves no more than a minimal risk to the privacy of the individuals; the research could not practicably be conducted without the waiver; and the research could not practicably be conducted without access to and use of the PHI.

The type of protected health information (PHI) to be used in the research includes:
Retrospective image data collection: There is a pool of pediatric dental patients that have both bite-wing radiographs and Dexis CariVu images of the same tooth surfaces. These images and radiographs are available in the electronic dental health record system Axium used in the UIC Pediatric Dental Clinic. For the purposes of this study, the PI will identify, by a search in Axium, a maximum of 50 patients that have had both bite-wing x-rays and Dexis CariVu images documented. The report generated from the search will include the personal patient dental record number (in Axium) for patients aged 6-11 years old, who have bite wing radiographs and CariVu images. The search will be based on the patients' age and the billing codes of the bite wing radiograph and CariVu images. The PI will review the charts where images will be drawn from only healthy children aged 6-11 years old with mixed dentition. This means that the patients will have a combination of primary (baby) teeth and permanent (adult) teeth in their mouths. This will allow for analysis of the images on both types of teeth.

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
09/06/2016	Initial Review	Exempt	09/15/2016	Modifications Required
09/20/2016	Response to Modifications	Exempt	09/29/2016	Approved

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:

1. Amendments You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.

APPENDIX A (continued)

2. Record Keeping You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.

3. Final Report When you have completed work on your research protocol, you should submit a final report to the Office for Protection of Research Subjects (OPRS).

4. Information for Human Subjects UIC Policy requires investigators to provide information about the research to subjects and to obtain their permission prior to their participating in the research. The information about the research should be presented to subjects as detailed in the research protocol and application utilizing the approved recruitment and consent process and document(s).

Please be sure to use your research protocol number (2016-0899) on any documents or correspondence with the IRB concerning your research protocol.

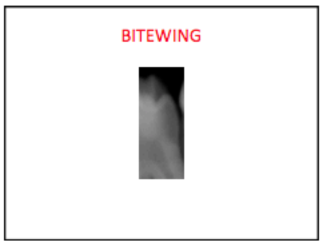
We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS office at (312) 996-1711 or me at (312) 355-2908.

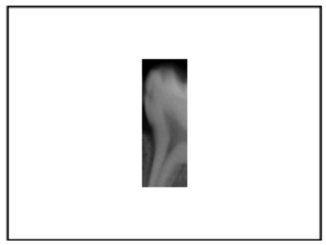
Sincerely,
Charles W. Hoehne
Assistant Director, IRB #7
Office for the Protection of Research Subjects

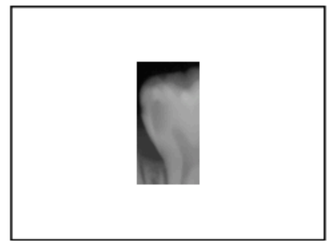
cc: Marcio Da. Fonseca, Pediatric Dentistry, M/C 850
Sahar Alrayyes, Pediatric Dentistry, M/C 850
Privacy Office, Health Information Management Department, M/C 772

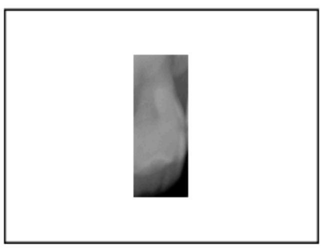
APPENDIX B

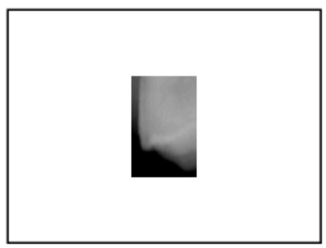
Images 1-9

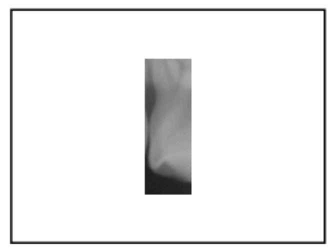


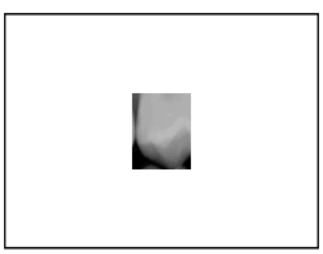


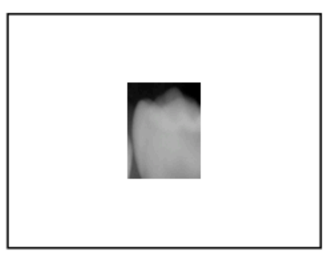


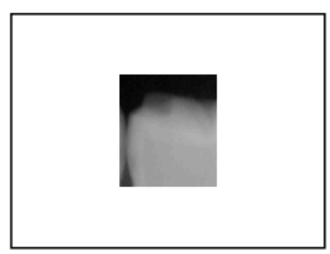






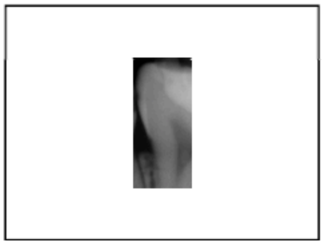
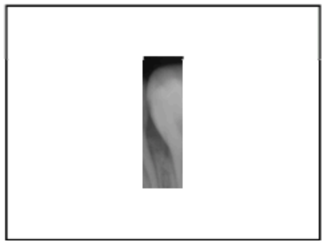
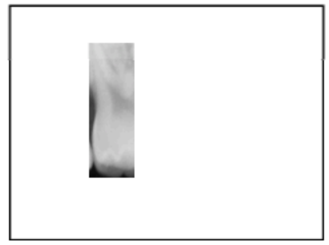


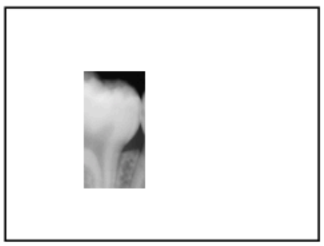
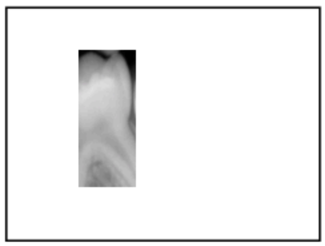
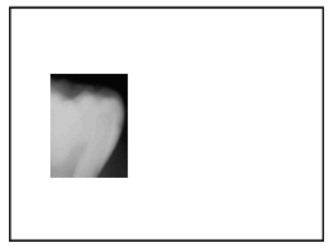


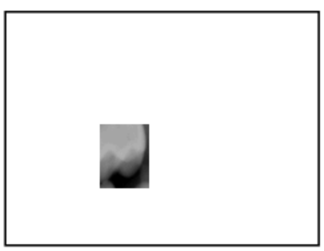
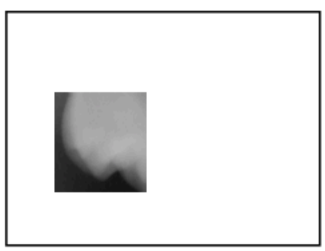
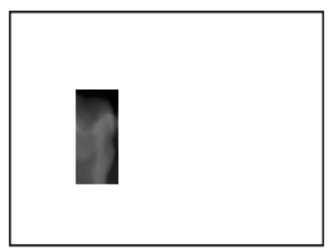


APPENDIX B (continued)

Images 10-18

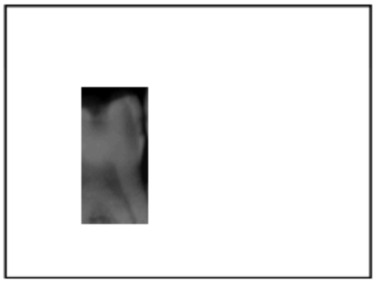
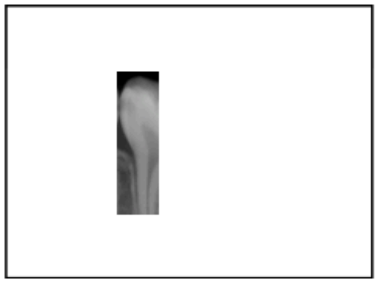
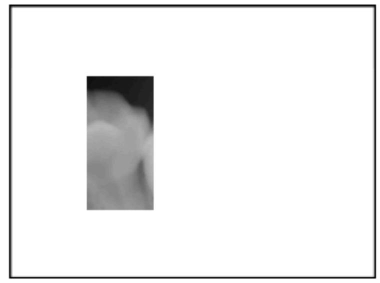
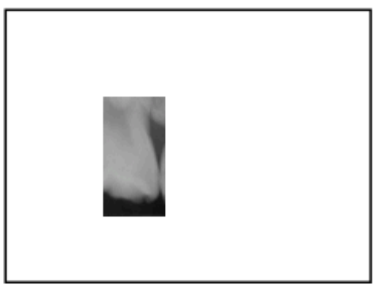




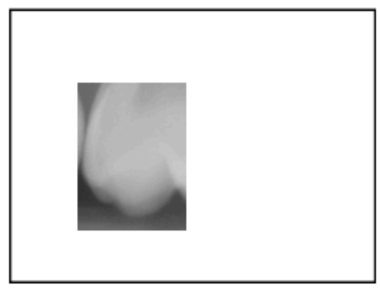
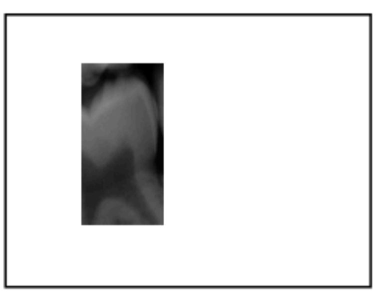
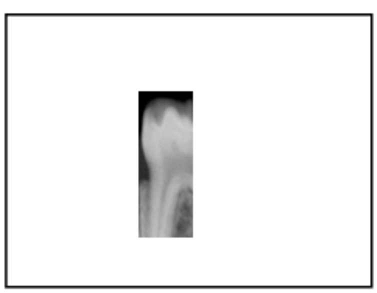
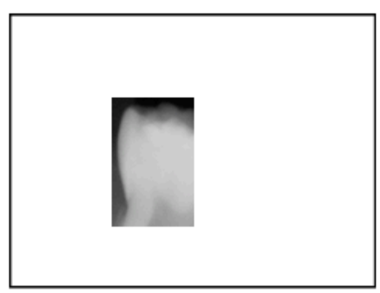




APPENDIX B (continued)

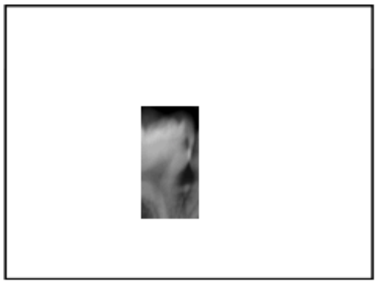
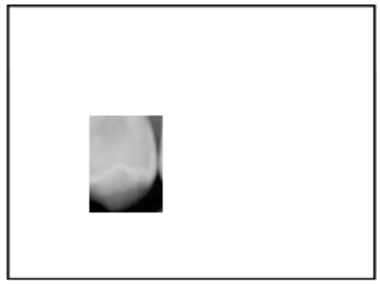
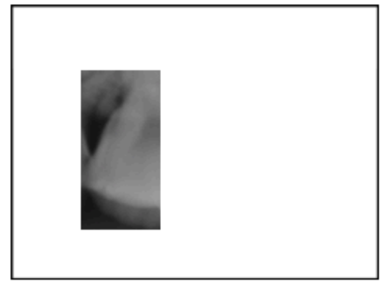
Images 19-27

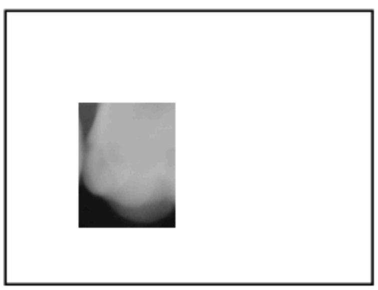
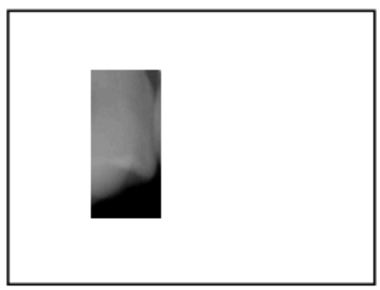
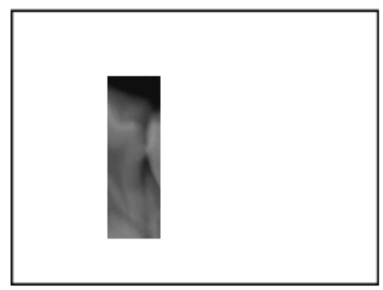





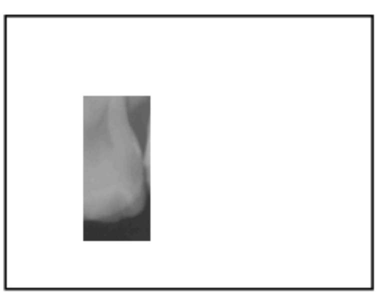
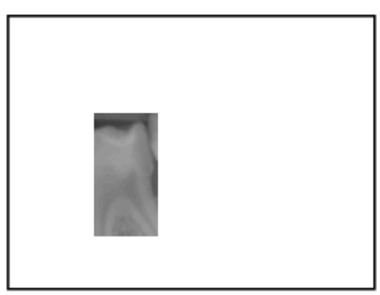
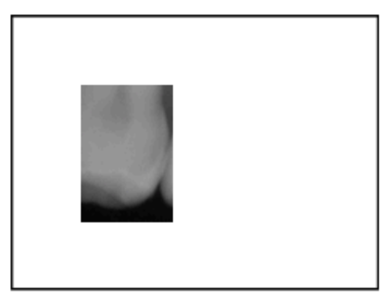





APPENDIX B (continued)

Images 28-36

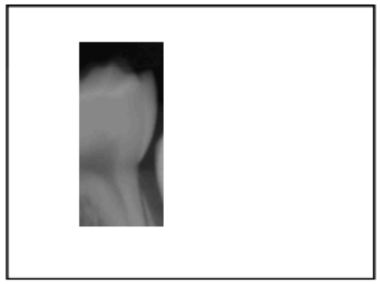
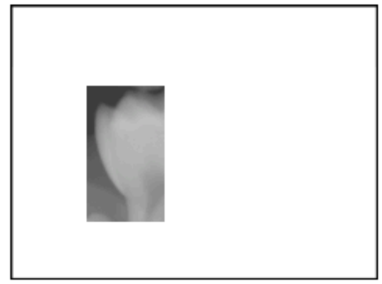




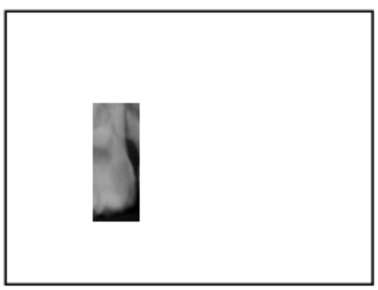
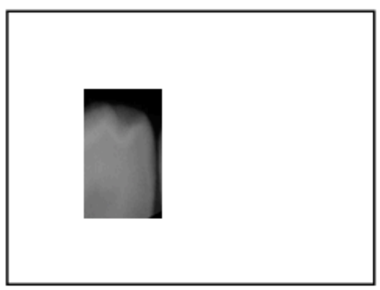
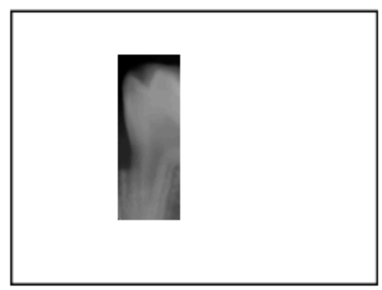




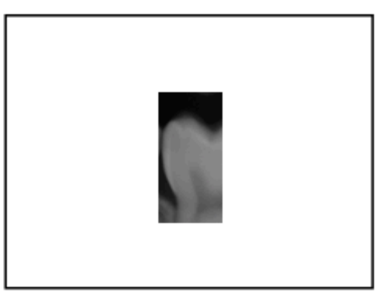
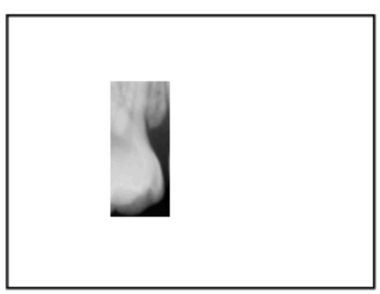
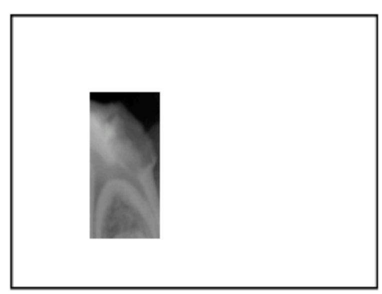




APPENDIX B (continued)

Images 37-45

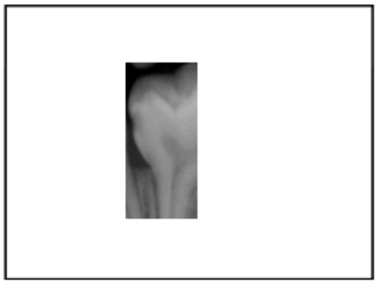
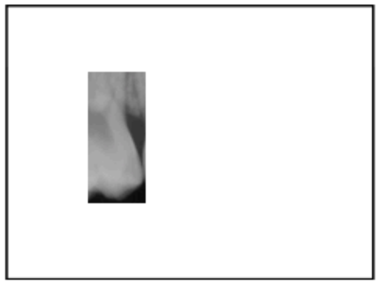
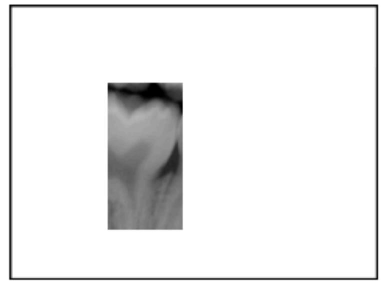
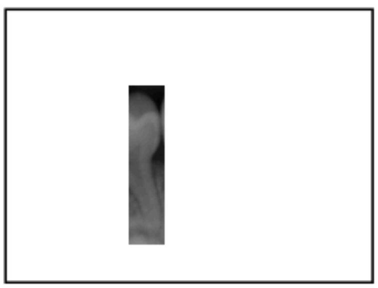
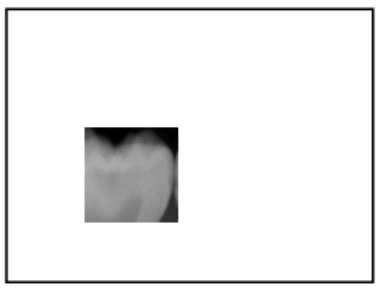
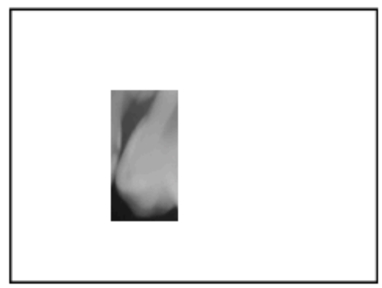
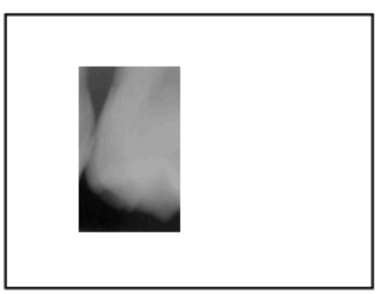




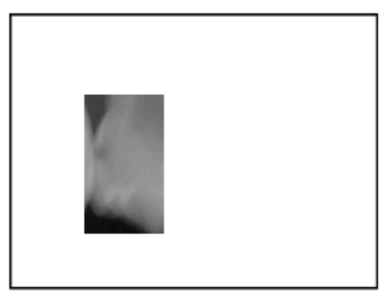




APPENDIX B (continued)

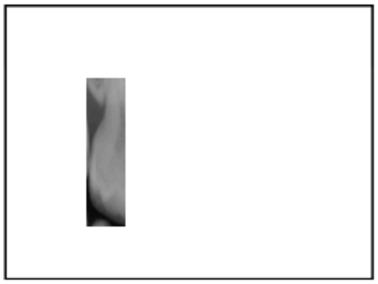
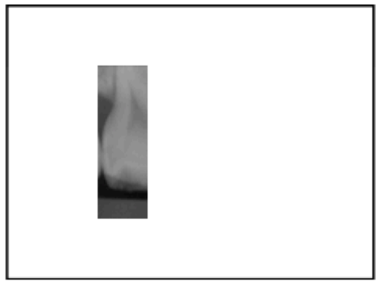
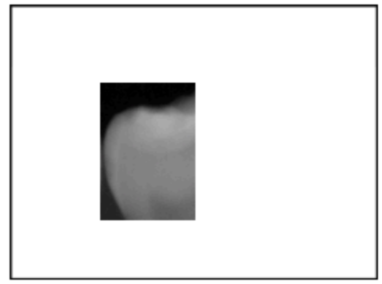
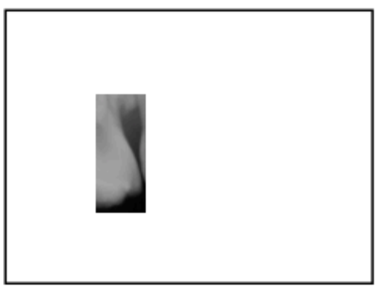
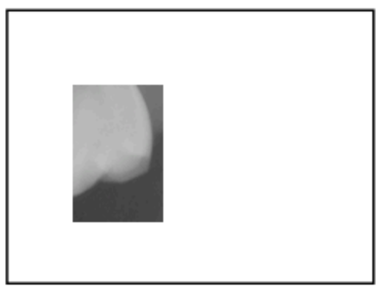
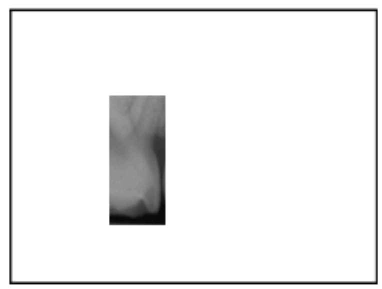
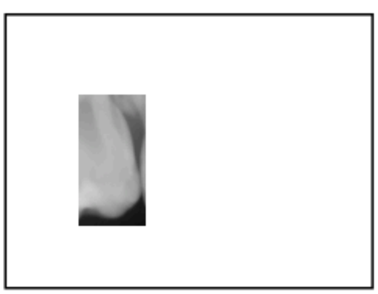
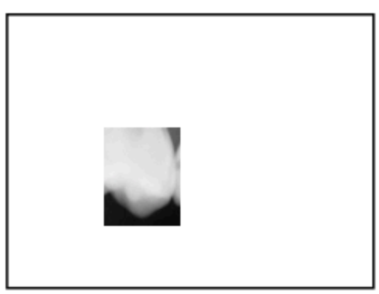
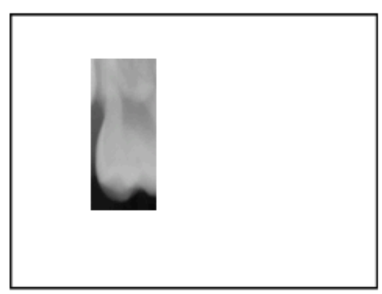
Images 46-54



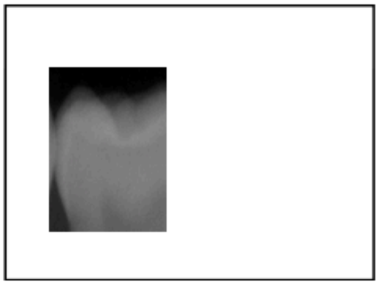
APPENDIX B (continued)

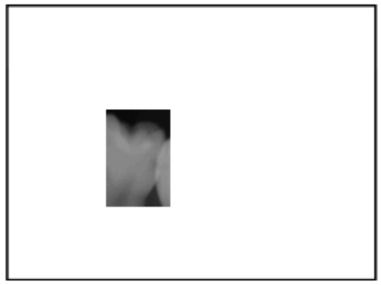
Images 55-63

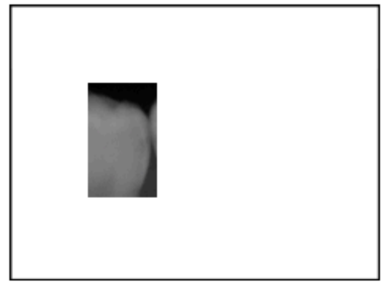










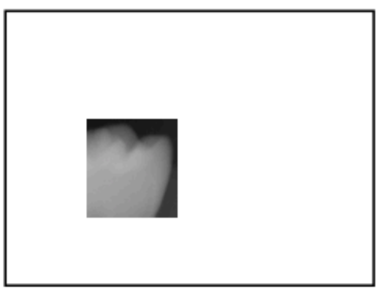
APPENDIX B (continued)

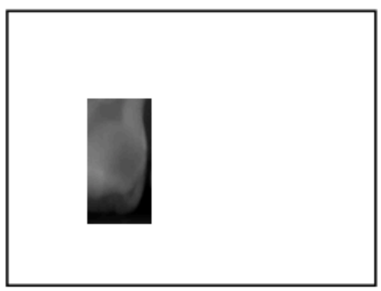
Images 64-72

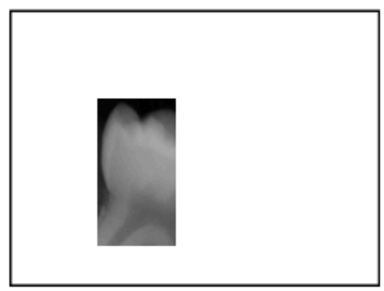


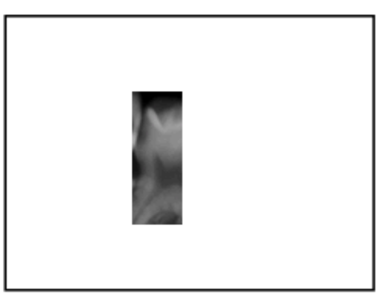


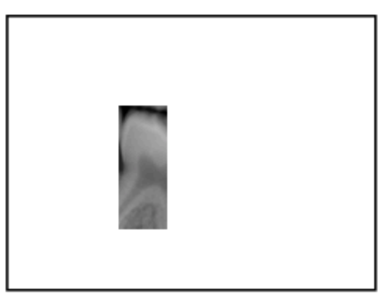


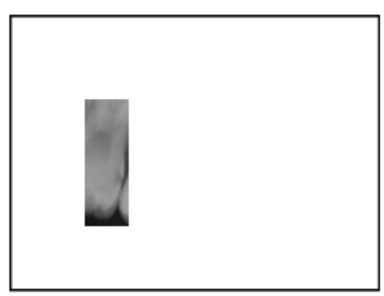






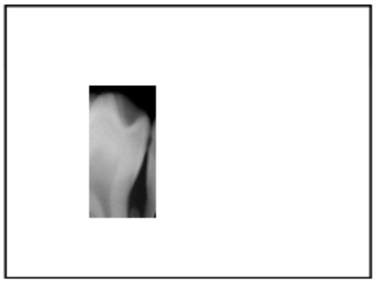
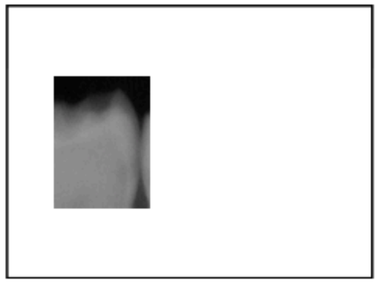
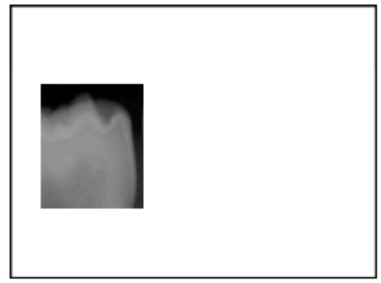
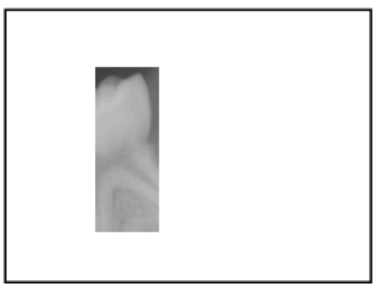
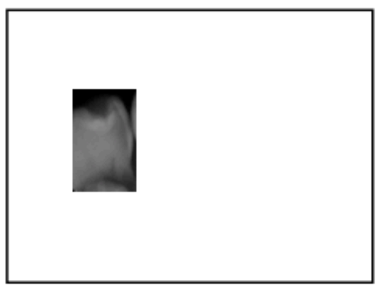
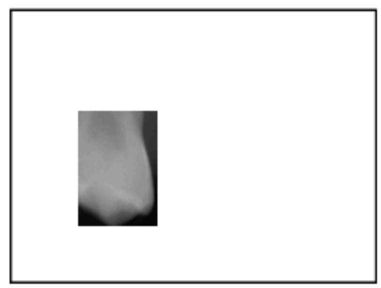
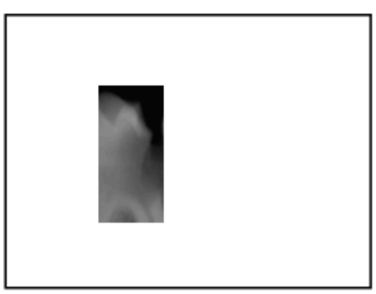


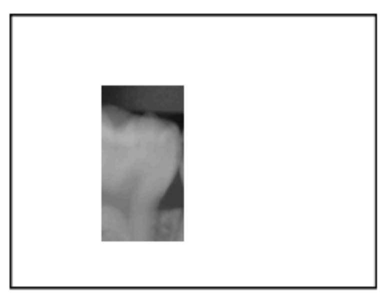




APPENDIX B (continued)

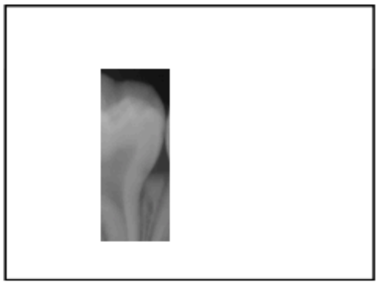
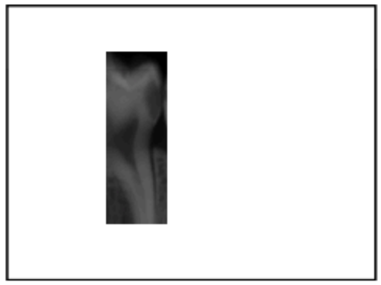
Images 73-81

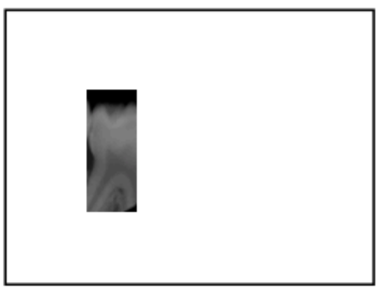








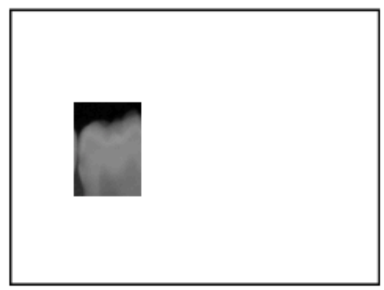
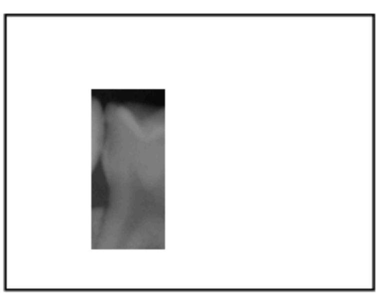
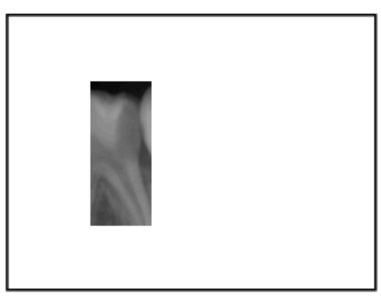
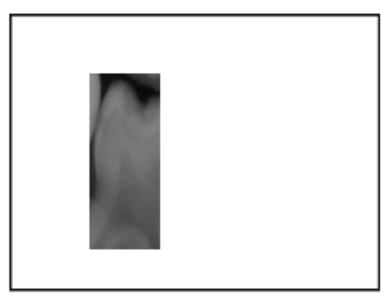


APPENDIX B (continued)

Images 82-90

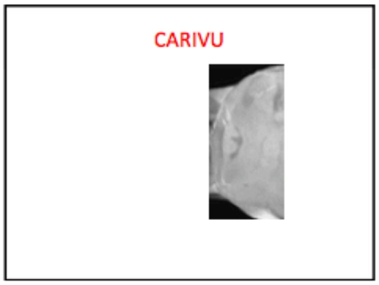



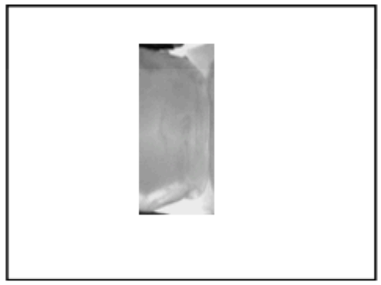


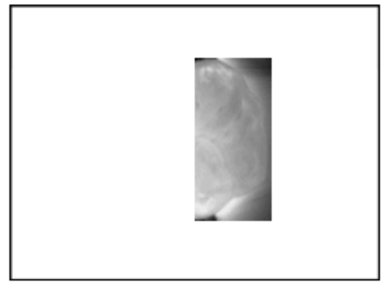





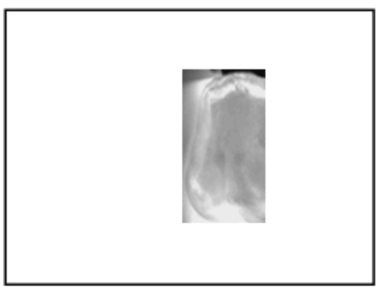
APPENDIX B (continued)

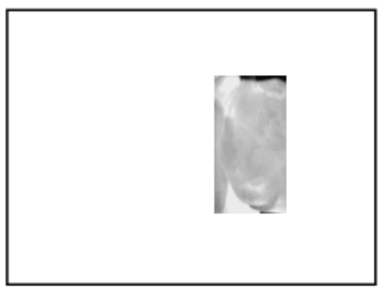
Images 91-99

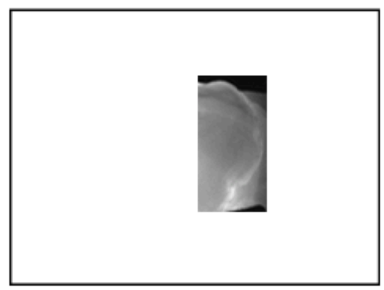


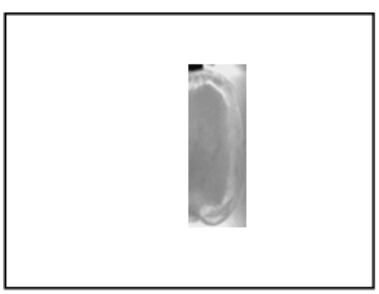


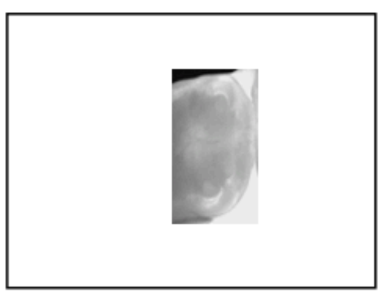


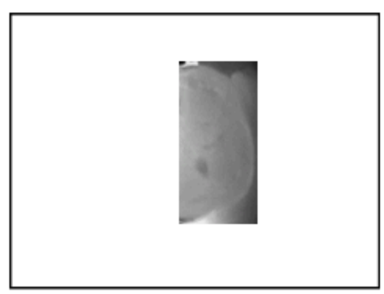






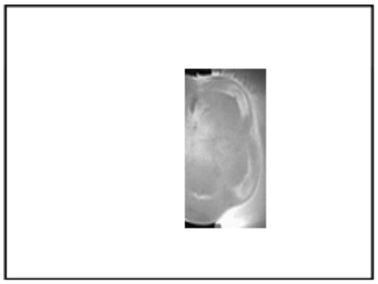
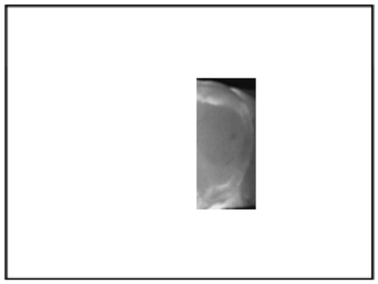
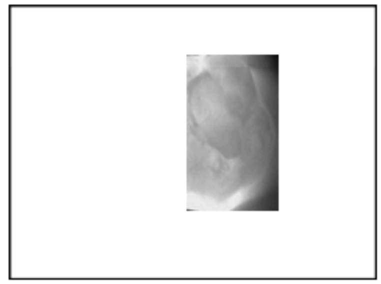
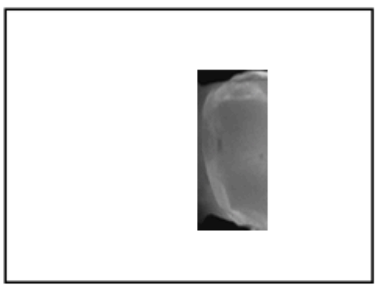
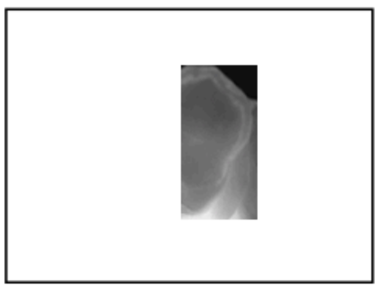
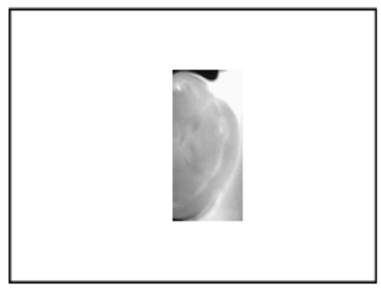


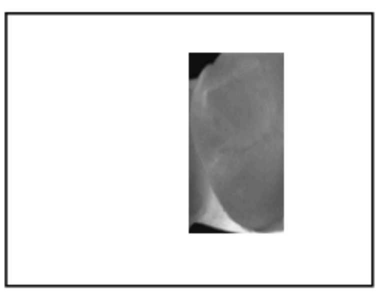
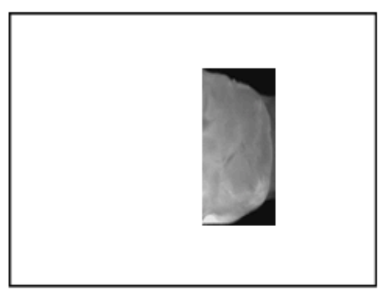




APPENDIX B (continued)

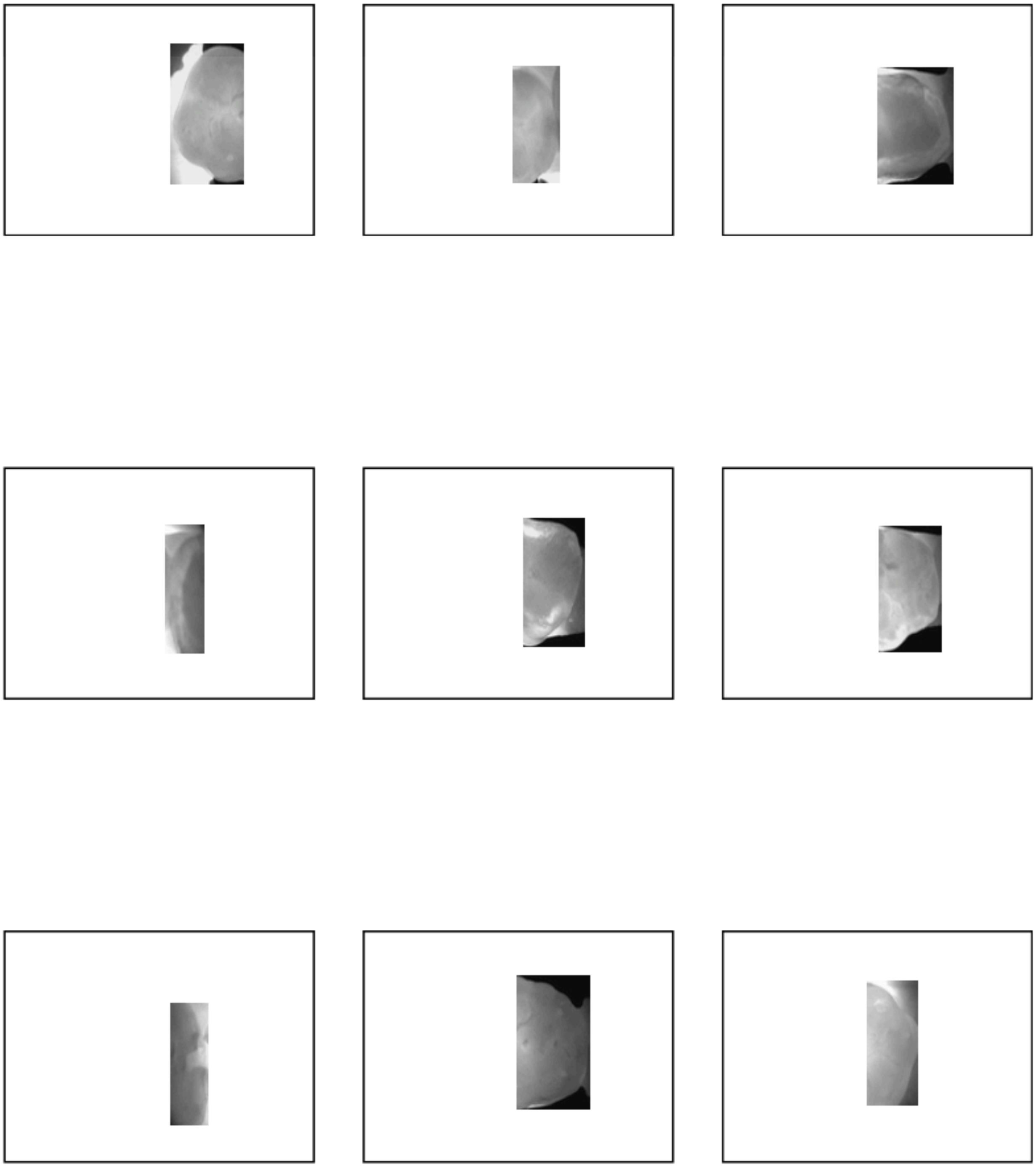
Images 100-108

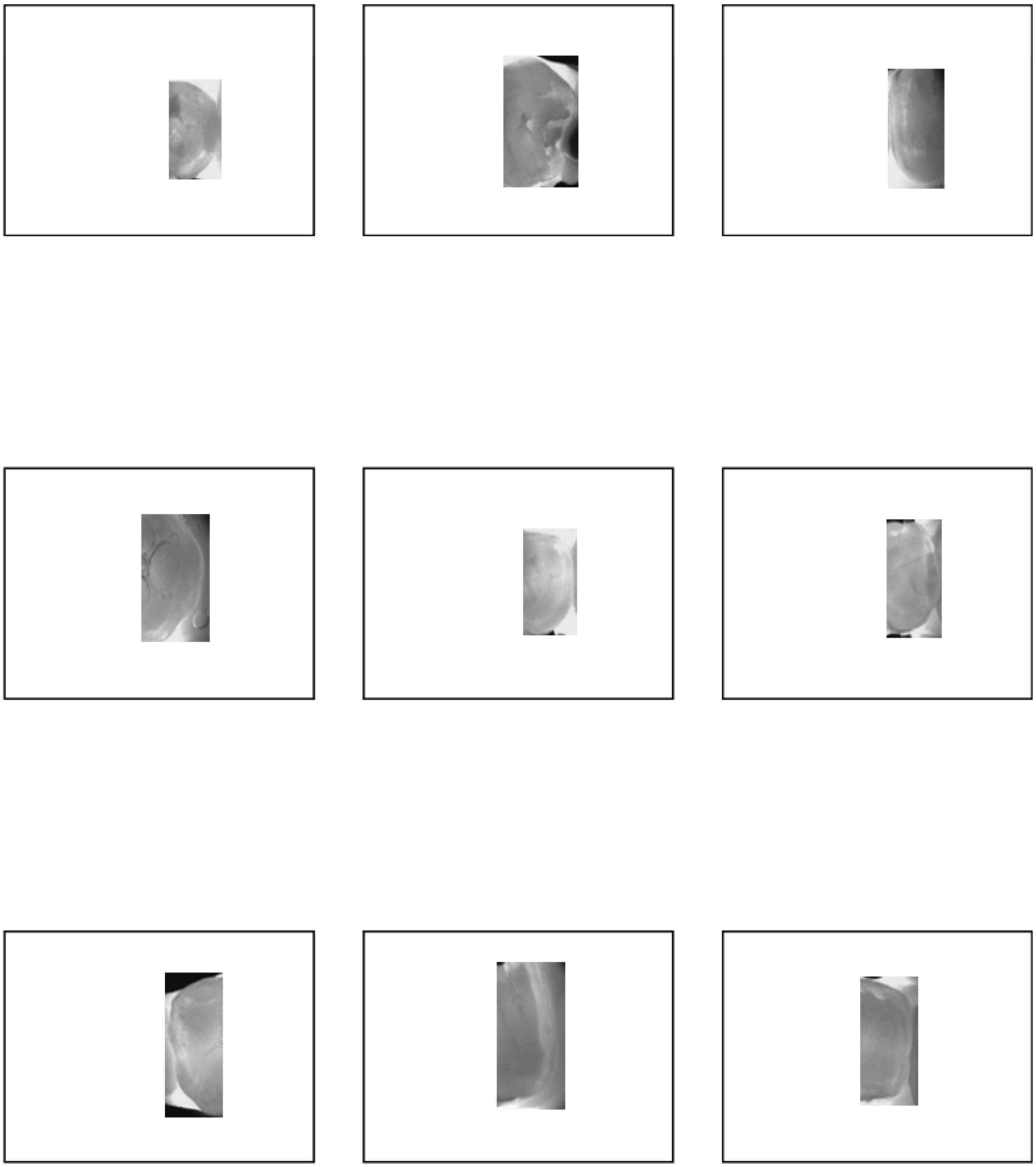
APPENDIX B (continued)

Images 109-117



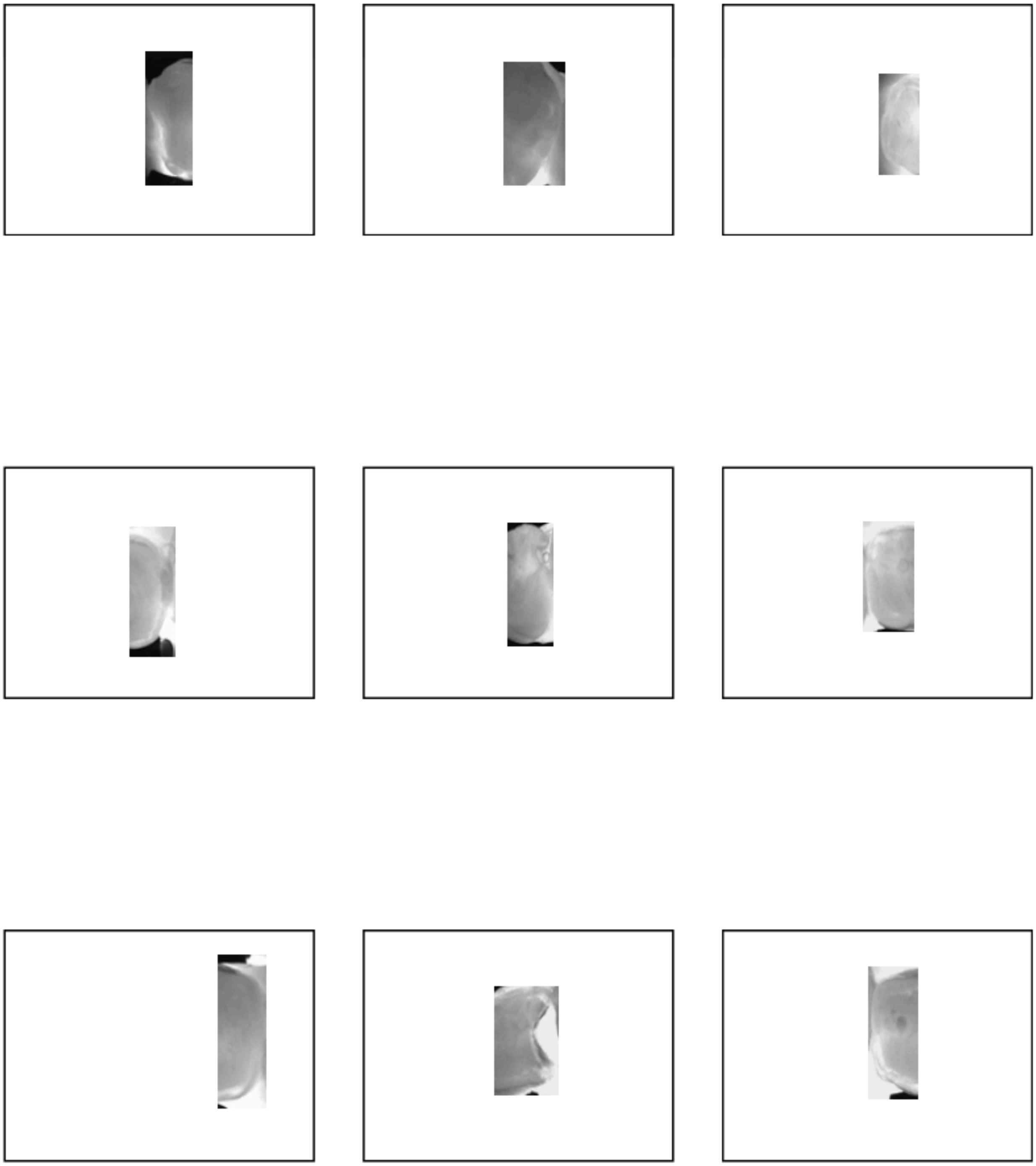
APPENDIX B (continued)

Images 118-126



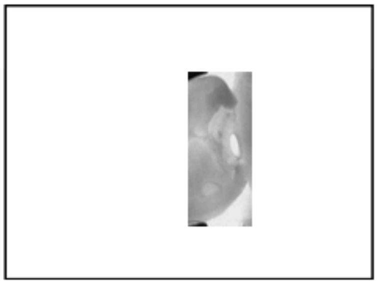
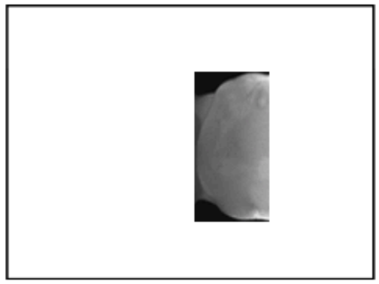
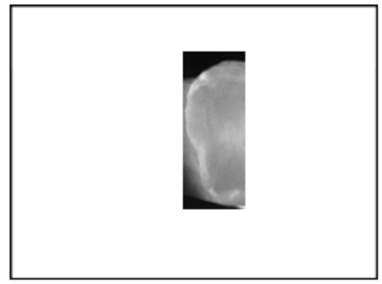
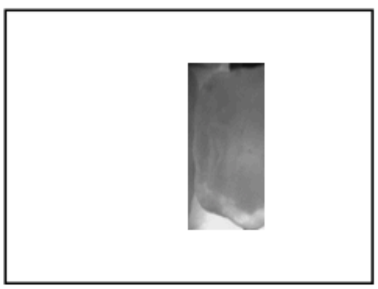
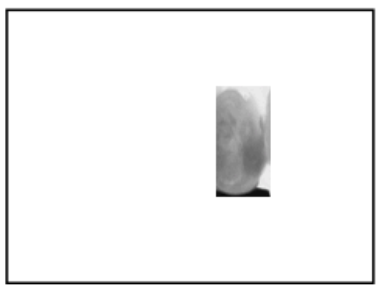
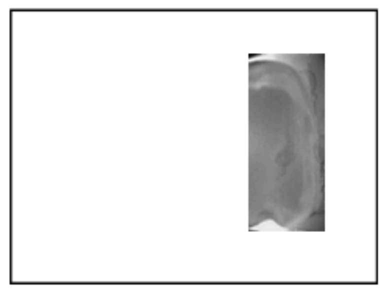
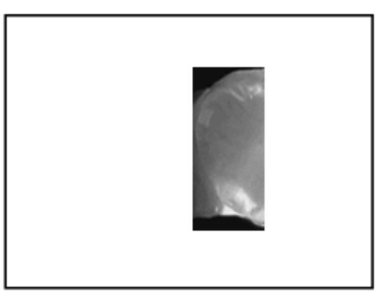
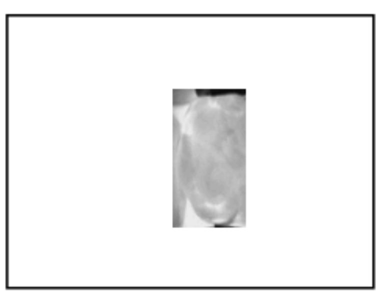
APPENDIX B (continued)

Images 127-135



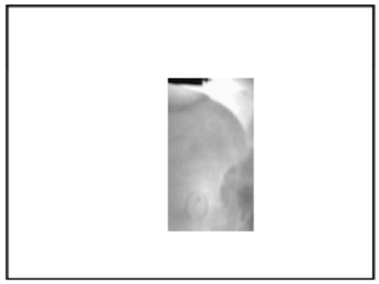
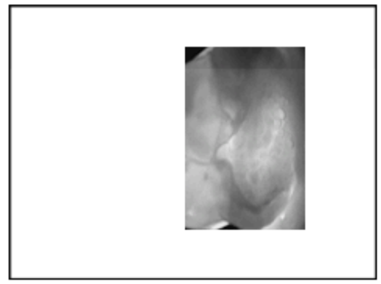
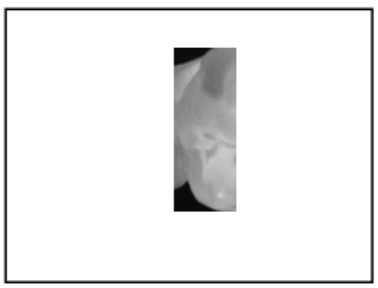
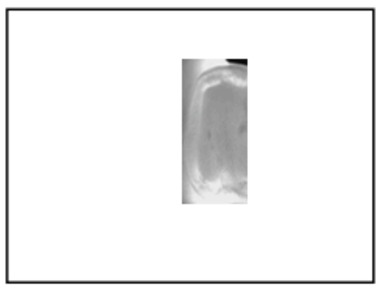
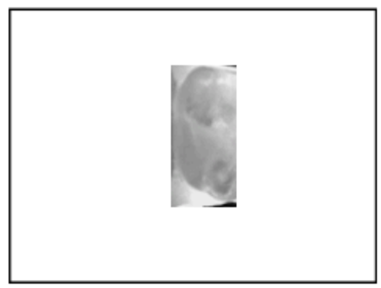
APPENDIX B (continued)

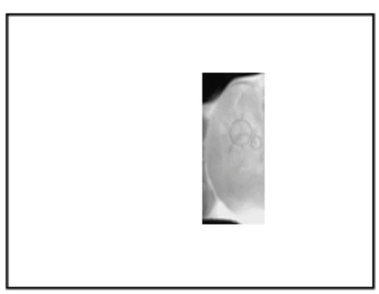
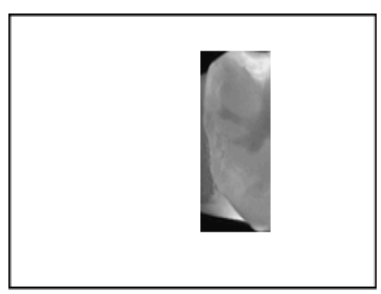
Images 136-144


APPENDIX B (continued)

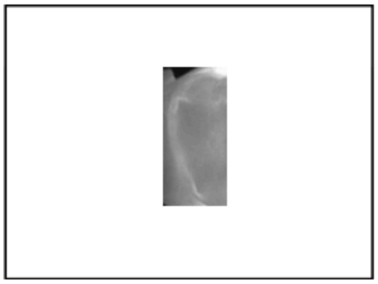
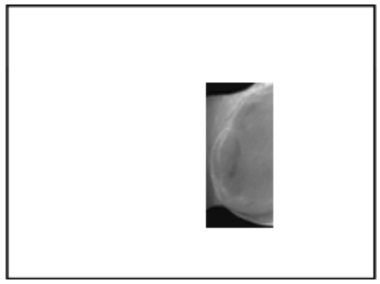
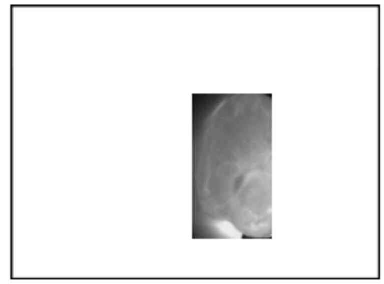
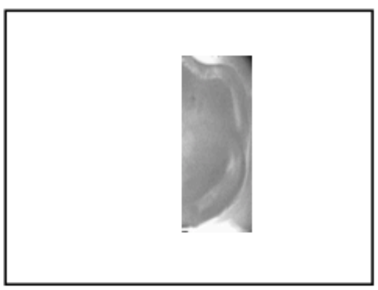
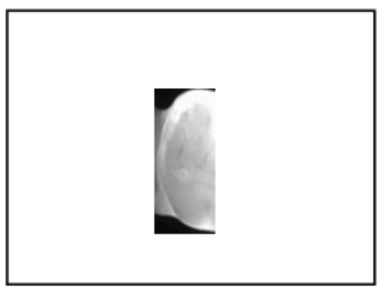
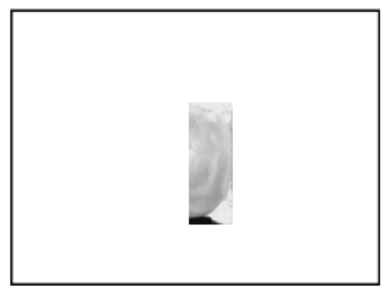
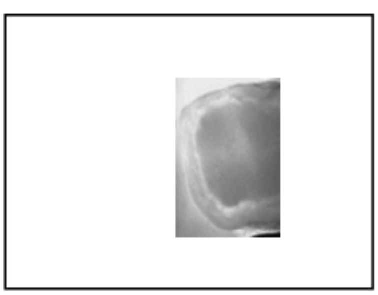
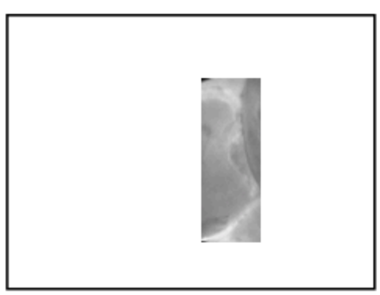
Images 145-153

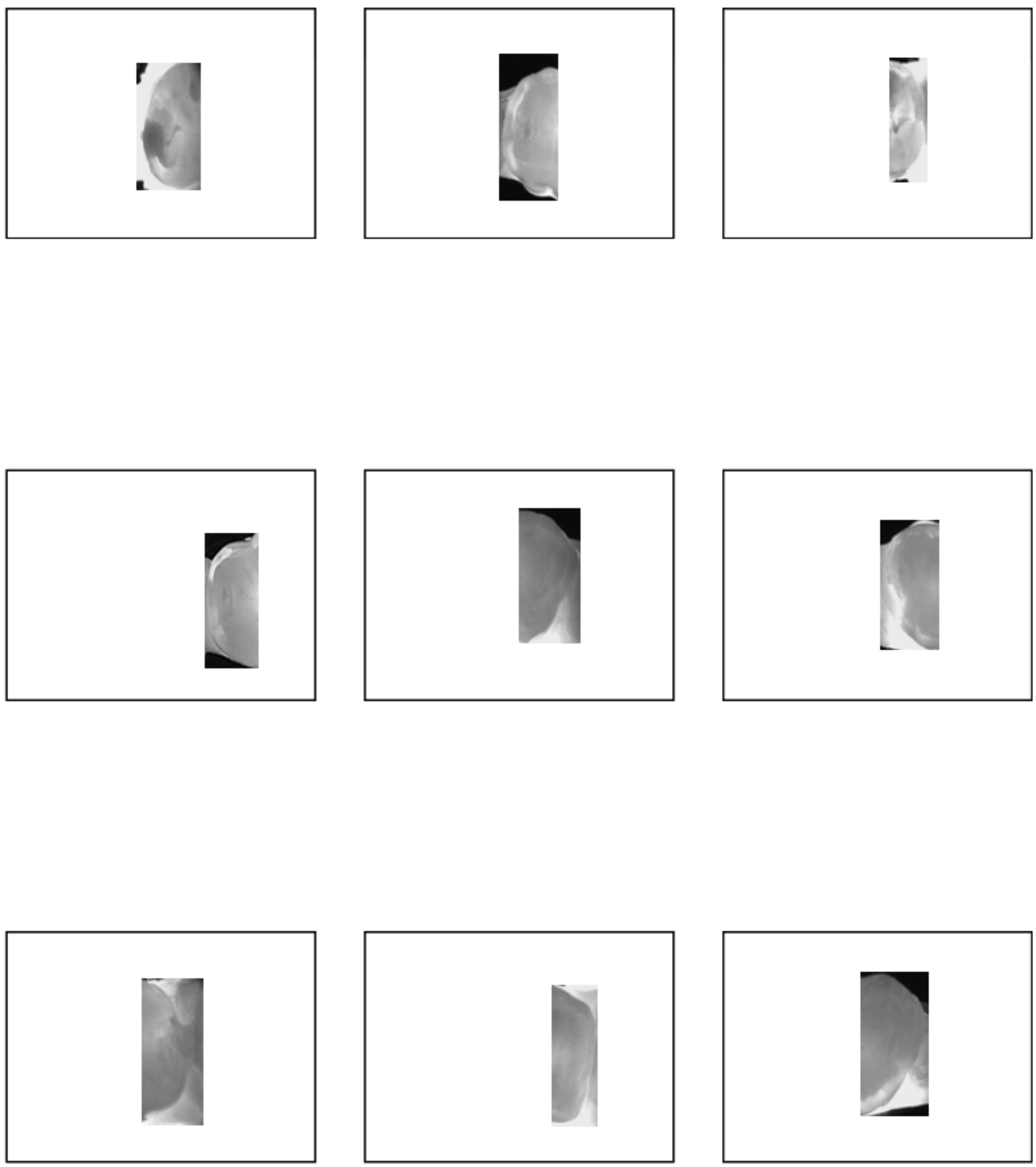
APPENDIX B (continued)

Images 154-162

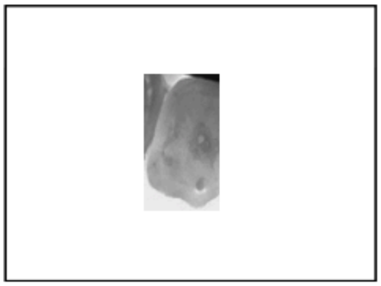
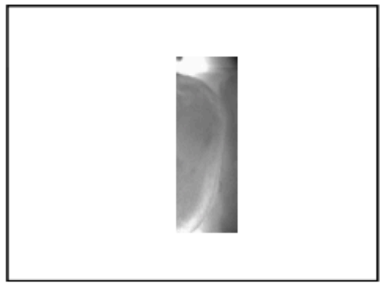

APPENDIX B (continued)

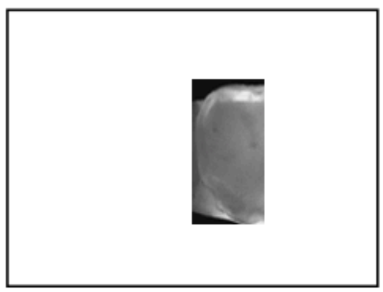
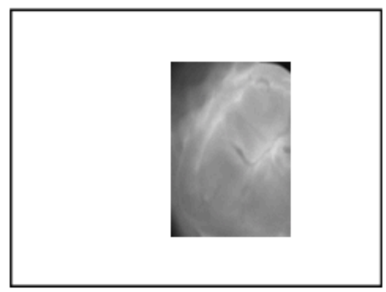
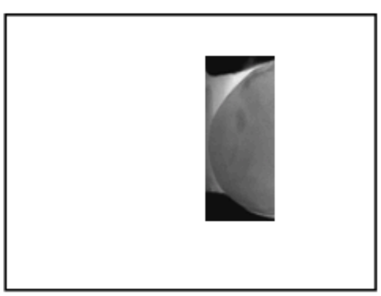
Images 163-171



APPENDIX B (continued)

Images 172-180

APPENDIX C

Dear Prospective Participant,

We are attempting to ascertain how different diagnostic images are viewed and interpreted by practitioners. This study is strictly voluntary and you can withdraw at any time. Every effort will be made to keep your participation confidential. Your decision whether or not to participate will not impact your relationship with UIC or the Department and will not impact your standing.

There will be no risks involved in completing the questionnaire. The questionnaire will take you no longer than 30 minutes to complete. You will see a series of images. Some of these are traditional bite wing images. Some of these are CariVu images which were captured from the occlusal view of the tooth. You will be asked to classify each image as:

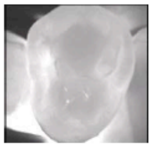
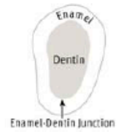
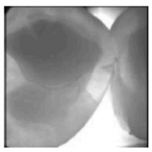
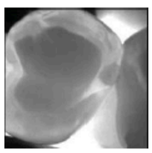
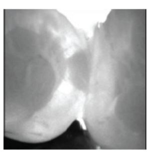
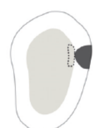
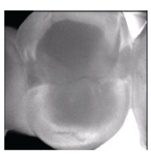
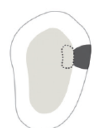
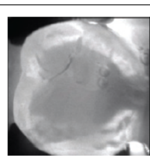
1) No Caries
2) Incipient caries not touching the DEJ
3) Caries touching the DEJ and into dentin

For questions, you may contact the Primary Investigator, Allison Horn, DDS, at ahorn8@uic.edu.

If you have any questions about rights as a research subject, please contact the office of protection of research subjects of the University of Illinois at Chicago at (312) 996-1711.

APPENDIX D

Proximal Caries Detection Classification

	CariVu	Description	Clinical Representation	Treatment Options
0		Sound surface		• Monitoring • Preventive intervention
1		First detectable signs of an enamel caries lesion		• Caries monitoring • Preventive intervention
2		Established enamel caries lesion		• Caries monitoring • Preventive intervention
3		Established enamel caries lesion which reached the enamel dentin junction at a single point		• Caries monitoring • Preventive intervention
4		Dentin caries due to an established enamel caries lesion with an extended involvement of the enamel-dentin junction		• (Minimal) Invasive operative treatment*
5		Established dentin caries		• Invasive operative treatment*

* A parallel bitewing might be indicated to predict the dentine caries extension in relation to the pulp.
Preventive Intervention: Plaque control, fluoride application, caries infiltration etc.

Adapted from DEXIS CariVu Operator Manual

VITA
Allison Horn, DDS

EDUCATION:

University of Illinois at Chicago, Chicago, Illinois — 2015- 2017
Certificate in Pediatric Dentistry
Master of Oral Sciences

New York University, College of Dentistry, New York, New York — 2011 - 2015
Doctor of Dental Surgery
Pediatric Dentistry Honors Program

University of Michigan, Ann Arbor, Michigan — 2006 –2009
Bachelor of Arts
Psychology Major
Phi Beta Kappa
Magna Cum Laude

EMPLOYMENT:

Project Renewal, Inc., New York, New York — 2010 - 2011
Next Step Counselor,
Case worker, Employment Counselor, GED Intructor

LICENSURE:

Commission on Dental Competency Assessments (previously NERB), Board Certified — Feb, 2015
Illinois State Dental License — July, 2016

PROFESSIONAL MEMBERSHIP:

American Academy of Pediatric Dentistry — 2014 - current
Illinois Society of Pediatric Dentists — 2015 - current