A COMPARISON OF THE CLINICAL AXIAL EXTENSION OF CLASS II CARIOUS LESIONS WITH DIFFERENT DIAGNOSTIC IMAGES

Mohammed S. H. Bin-Shuwaish, B.D.S.

A thesis submitted in partial fulfillment of the requirements
for the degree of Master of Science in Restorative Dentistry

Horace H. Rackham School of Graduate Studies
The University of Michigan
Ann Arbor, Michigan
2006

Thesis Committee Members:

Joseph B. Dennison, D.D.S., M.S. (Chairman)
Peter Yaman, D.D.S., M.S.
Sharon L. Brooks, D.D.S., M.S.
Gisele Neiva, D.D.S., M.S.

DEDICATION

No endeavor is completed without the influence and encouragement of family.

To my mother,
Whose prayers, support and unconditional love guided me to strive toward the highest of
goals.

And to the memory of my father,
Who raised me to be the person I am today.

To my brothers and sisters,
You have been with me every step of the way, through good times and bad and you have
always given me the guidance, and support.

And especially to my brother, Hussain,
Who always encouraged me to set higher goals for my self in life and provided the model by
which I could achieve my goals.

ACKNOWLEDGEMENTS

TABLE OF CONTENTS

Chapter 1

Chapter 2

LIST OF FIGURES

LIST OF TABLES

Chapter 1

A Comparison of the Clinical Axial Extension of Class II Carious Lesions with Different Diagnostic Images

1.1 BACKGROUND AND SIGNIFICANCE:

The correct estimation of the interproximal caries extension for posterior teeth continues to be a tough clinical task even for experienced clinicians due to the limitations of direct examination and evaluation of the interproximal surfaces of these teeth. Different diagnostic tools are being used to help giving a more accurate and reliable diagnosis. Examples of these diagnostic tools are: bitewing radiography (conventional and digital radiography), fiber-optic transillumination (FOTI), digital imaging fiber-optic transillumination (DIFOTI ™), in addition to the other newly developed technologies.

Since 1895, when x-rays were discovered, the use of radiographs as a diagnostic tool has become an integral part of clinical dentistry. Conventional bitewing radiography has been an indispensable tool in detecting interproximal lesions in posterior teeth since the 1920s. Eastman Kodak Company has been the predominant dental film manufacturer worldwide for the last 80 years and has developed several generations of increasingly faster and better films [1].

D-speed (Kodak Ultra-speed) film has been manufactured since the 1940s. It became the "gold standard" to which all subsequent films and digital technology has been compared. Two generations of the Ektaspeed films were introduced over the last 20 years with a decrease in the radiation exposure by several folds. Kodak stopped manufacturing Ektaspeed films in 2001 after they started marketing the new Insight (F-speed) films in

the spring of 2000. These films are faster than previous versions of intra-oral films (60% faster than D-speed films and 20% faster than E-speed films), but their diagnostic quality has been questioned. As a result, D-speed films are still considered the "gold standard" for bitewing radiographic caries diagnosis and many practitioners still use these films in their offices.

Since digital radiography was introduced to the market more than two decades ago, more clinicians are replacing conventional radiographs with digital radiography [2].

Intraoral digital radiography offers several advantages over conventional radiography, as was shown by several studies. These advantages include: low radiation exposure, elimination of film developing, immediate availability of the generated image for evaluation on the computer screen and digital manipulation to enhance viewing. The actual amount of exposure reduction is dependent on a number of factors including film speed, sensor area, collimation, and retakes. The primary disadvantages of the digital systems include the rigidity and thickness of some sensors, decreased resolution, higher initial system cost, unknown sensor lifespan, difficulties in maintaining infection control with the sensor and the cable to prevent cross-contamination [3].

In digital radiography, the image is constructed using pixels or small light sensitive elements. These pixels can be a range of shades of grey depending on the exposure, and are arranged in grids and rows on the sensor [4]. The digital image can be acquired directly, semi-directly or indirectly. Indirect digital radiographic image can be produced by scanning conventional radiographs using a flatbed scanner and a transparency adaptor, or by using a charged coupled device (CCD) camera instead of the flatbed scanner. Direct digital sensors use either a CCD chip, a solid-state detector composed of an array of X-ray or light sensitive pixels on a pure silicon chip and the sensor communicates with the

computer through an electrical cable, or complementary metal oxide semiconductor active pixel sensor (CMOS-APS). The CMOS-APS is the latest development in solid state direct digital sensor technology which has several advantages including design integration, low power requirements, manufacturability, and low cost [5]. However, CMOS sensors have more fixed pattern noise and a smaller active area for image acquisition [3]. In the semi-direct image systems, a phosphor storage plate (PSP), also referred to as "photo-stimulable phosphor plate", is used which stores energy after exposure to radiation and emits light when scanned by a laser scanner that stimulates the phosphor plate and stores a record of the number of light photons detected [4].

In the 1980s, Trophy Corporation introduced the first CCD based dental digital radiography system to the market. The system was called Radiovisiography (RVG). Since then various companies have introduced many more CCD based systems offering a variety of options. In 1994, Digora introduced the PSP technology to the dental digital radiography market. More recently Schick Technologies, Inc. introduced the CMOS digital radiographic detectors to be used in the dental profession.

With the rapid development in digital technology, digital radiographic systems are more commonly used by dental practitioners. The RVG sensors, as one example (Trophy Radiologie, Croissy Beaubourg, France [now Trophy, a Kodak Company, Rochester, N.Y]) has been developed over the past 25 years until Eastman Kodak Company recently launched their new digital sensor RVG-6000 with true resolution of more than 20 lp/mm and using the new super CMOS technology with Optical fiber.

Several studies have been conducted to compare the diagnostic efficacy of CCD to, PSP, CMOS, and/or conventional radiographs to detect the proximal carious lesions. Lots of the studies found these systems to perform similarly [6-10]. However, most of these

studies were conducted based on *in-vitro* testing. One clinical study found that CCD based direct digital radiography was not as accurate as conventional film images (D and E-speed films) for the purpose of diagnosing proximal caries in the mixed dentition [11].

With advances in computer technology, dentists are able to use computer-based software to aid detection of interproximal carious lesions. In the early 1980s the idea of using the computer to interpret radiographic films was considered a new development in the field of oral radiology. In 1984 Pitts and others were able to test one of the early computer based image analysis systems applied to automatically examine the presence of the interproximal carious lesion. Although these studies found this system able to produce a consistent reading for the carious lesion, it was found to be less specific than the human observer [12, 13]. These systems were then improved to perform as well as human observers to support the decision for restoring interproximal carious lesions and therefore, were potentially useful in diagnosing these lesions [14-17]. However, the programs developed and evaluated in theses studies have not resulted in support systems available for the general dentist [18].

The Logicon Caries Detector (Logicon Advanced Technology, Los Angeles, CA, USA) is FDA approved software that was introduced a few years ago to aid in the diagnosis of interproximal carious lesions in conjunction with digital intraoral radiographic images. Eastman Kodak Company started to include this software with their newly developed RVG sensors as an adjunct to diagnosing interproximal carious lesions. Few studies have been conducted to evaluate the quality of this software; however, most of these studies were conducted *in-vitro*. Therefore, comparing the performance of this software to human observers to diagnose the interproximal carious lesions using *in-situ* validation method will help the general clinician in his decision to restore a carious tooth.

Illuminating teeth to determine the presence of demineralization or caries is a novel method to detect and monitor dental caries. The Digital Imaging Fiber-Optic Transillumination (DIFOTI) system (Electro-Optical Sciences, Irvington, NY; USA), has made this technology accessible for dental practitioners. The principle behind transilluminating teeth is that demineralized areas of enamel or dentin scatter light (in this case a high intensity white light) more than sound areas [19].

DIFOTI technology uses light, a charge-coupled device (CCD) camera, and computer-controlled image acquisition. The advantages of DIFOTI over radiography include: no ionizing radiation, no film, real-time diagnosis, and higher sensitivity in detection of early lesions not apparent to X-ray, as demonstrated *in-vitro* [20]. A single fiber-optic cable in the patented mouthpiece delivers light to one of the tooth's smooth surfaces. As this light travels through layers of enamel and dentin, it scatters in all directions toward the non-illuminated surfaces. The light is then directed through the mouthpiece to a miniature electronic CCD camera in the hand-piece. The camera digitally images the light emerging from the various surfaces of the teeth. These images are displayed on a computer monitor in real time and stored on the hard drive for easy retrieval. Carious lesions are visualized as darkened shadows due to the difference in light refraction between healthy and demineralized tissues [21].

Only one recent *in-vitro* study has compared the interproximal caries depth on images taken with DIFOTI, and F-speed films to the actual histological depth of the lesion and found that DIFOTI was able to detect surface demineralization at an early stage, but is not able to measure the depth of an approximal lesion [22]. Once again, this study compared the different images *in-vitro* and used the histological depth as the validation method to determine the carious lesion extension.

Most of the *in-vivo* studies conducted comparing the radiographic and clinical appearance of class II carious lesions have focused on the cavitation status of the proximal surface, not the actual *depth* of the lesions. In fact, there were no clinical studies found that attempted to measure the *in-situ* depth of class II carious lesions clinically and correlate the findings with that of digital, Ultraspeed radiographs, and DIFOTI.

Since digital radiography provides less radiographic exposure than conventional films, as documented in the literature, an investigation of the clinical performance of the digital systems to determine the depth of interproximal lesions and compare this performance to the most commonly accepted bitewing radiograph, Ultraspeed film, and the new radiation-free diagnostic method, DIFOTI, will provide important information to clinicians to help them make more accurate diagnostic decision when restoring class II carious lesions.

This research project uses an *in-situ* validation method for determining the true clinical extension of proximal carious lesions and compares the findings to the data gained from Ultraspeed bitewing radiographs, digital, and DIFOTI images.

1.2 PURPOSE AND HYPOTHESES:

1.2.1 Purpose:

The purpose of this study is to compare the axial extension of class II carious lesions in different diagnostic images (utilizing D-speed film, and RVG-6000 size 2 DDR sensor) to the true clinical extension.

Secondary objectives included:

(1) Compare the diagnostic findings of the D-speed films to the RVG-6000 size 2 direct digital radiographic images.

(2) Compare the findings of the two radiographic images to the results of visual and the DIFOTI examinations.

(3) Evaluate the patient's discomfort while taking the radiographs with two different radiographic sensors (using the D-speed film and the RVG-6000 DDR sensor).

1.2.2 Hypotheses:

Three hypotheses were tested in this study:

1.2.2a Primary Hypothesis:

$H0_1$: Axial extension of class II carious lesions determined by clinical dissection is not significantly different from a diagnostic estimate using: D-speed bitewing radiographs or RVG-6000 images.

Ha_1: Axial extension of class II carious lesions determined by clinical dissection is significantly different from a diagnostic estimate using: D-speed bitewing radiographs or RVG-6000 images.

1.2.2b Secondary Hypothesis:

H0₂: There is no significant difference in the diagnostic ability between the D-speed bitewing radiographs and the RVG-6000 images in estimating the axial extension of the class II carious lesions.

Ha₂: There is a significant difference in the diagnostic between the D-speed bitewing radiographs and the RVG-6000 images in estimating the axial extension of the class II carious lesions.

1.2.2c Third Hypothesis:

H0₃: The use of DIFOTI in conjunction with either the RVG-6000 digital radiographic images or the D-speed images does not improve the diagnostic ability of these diagnostic methods.

Ha₃: The use of DIFOTI in conjunction with either the RVG-6000 digital radiographic images or the D-speed images improves the diagnostic ability of these diagnostic methods.

1.2.3 Specific aims:

1. To measure the true clinical extension of class II carious lesions using sequential intra-oral photographs and a novel measurement reference device during operative dissection.

2. To correlate the radiographic and DIFOTI diagnoses of class II carious lesions with the true clinical findings.

3. To evaluate if there is any diagnostic difference between the direct digital radiography (RVG-6000) and D-speed films.

4. To compare the results of visual, and DIFOTI examination to the radiographic and clinical findings.

5. To evaluate the differences between the RVG-6000 size 2 sensor and D-speed films in terms of patient's discomfort.

1.3 REVIEW OF LITERATURE:

1.3.1 Interproximal caries depth: actual vs. radiographic:

The detection of interproximal dental caries is often dependent upon radiographic images as an adjunct to clinical examination. It has been found that conventional films reveal twice as many approximal caries lesions extending into the dentin of the posterior teeth as can be discovered clinically [23-26]. Histological studies of extracted teeth using D-speed and E-speed films have mostly shown that caries extension *in-situ* is usually further than it appears to be radiographically [27].

Comparing the actual depth of the interproximal caries to the radiographical extension of the lesions has been conducted in multiple laboratory studies. The radiographic depth of the lesion, in most studies, was correlated to the caries status of the proximal surface, with caries status being described as sound, decalcified, cavitated, non-cavitated, etc. However, some studies used categorical rating scales to describe the caries extension such as: the extension of the decay from the mesial to distal using 0.5 mm scale, or using the dentino-enamel junction (DEJ) as a reference for the measurement. Validation of depth in these studies has been accomplished in different ways. One method involves sectioning of the experimental teeth followed by histological examination. This technique is usually used, *in-vitro*, with extracted teeth and cannot be used for teeth *in-situ*. Hence, another method has been used, *in-vivo*, that involved the clinical observation and classification of the lesion at the time of operative treatment. Once the lesion is accessed operatively, observations are made of the cross-section of the lesion in the floor of the preparation as it is dissected apically in a step wise manner.

Most studies utilized a validation method based on direct visualization, when checking for cavitation of the proximal surface, and histological sectioning or clinical observation during cavity preparation when measuring axial depth of caries progression. Some studies, however, used direct visualization, sometimes with the aid of a probe, as the validation method to determine the "true" caries status of the proximal surface.

In 1970 Marthaler and Germann compared the radiographic extension of the interproximal carious lesions to the visualized appearances of proximal surfaces of 15 extracted teeth [28]. Following 15 minutes of drying, the interproximal surfaces of the teeth were examined and scored according to the following severity scale: 1. no lesion, 2. subsurface lesion (surfaces intact but demineralized with white or brown spots), and, 3. cavitated lesion (any break of the surface integrity). The teeth were then radiographed from the facial aspect in a manner simulating bitewing technique without the use of a soft tissue simulator. The radiographs were then evaluated at 2X magnification, and once again the teeth were scored. Radiographic categories included: R0 = no radiolucency; Rl = radiolucency limited to the outer half of the enamel; R2 = radiolucency penetrating into the inner half of the total enamel thickness; and R3 = radiolucency visible in the enamel and outer half of the dentin. Radiographs were scored by one of the two investigators. Results showed that 42% of all radiolucencies confined to the enamel (up to the DEJ) were cavitated. Likewise, 84% of lesions that showed radiographic penetration into the outer half of dentin were cavitated. This study has just correlated the "presence" or "absence" of the cavitation to the appearance of the lesion radiographically, but did not measure "the depth" of the lesions. Therefore, the validation method in this study was the merit visualization of the lesion on the proximal surface.

Rugg-Gunn AJ conducted another study to compare the clinical appearance of posterior proximal surfaces to the radiographic appearance [29]. A total of 370 interproximal surfaces in 463 13-year-old children were examined and radiographed. Proximal surfaces of permanent molars and premolars in which the adjacent tooth had recently exfoliated were examined and scored using the following 5-point clinical scale: 1. sound, 2. white spot with shiny surface, 3. white spot with dull surface, 4. cavity less than or equal to 0.5 mm in diameter, and 5. cavity greater than 0.5 mm in diameter . Recent exfoliation of the adjacent tooth allowed direct visual inspection of the carious surface *in-situ*. D-speed bitewing radiographs were made and scored using the following 5-point radiographic scale: 1. sound, 2. radiolucency confined to enamel, 3. radiolucency in enamel and up to the DEJ, 4. radiolucency extending into the outer half of dentin, and 5. radiolucency extending into the inner half of dentin. An interproximal surface was considered "visible" and eligible for direct examination if a 3-mm ball-ended burnisher could pass through the interproximal space. Results showed that most of the surfaces that displayed caries activity were more advanced clinically than radiographically. Surfaces that were scored as having radiographic lesions in enamel short of the DEJ displayed clinical involvement ranging from sound (31%), shiny white spot (22%), dull white spot (26%), and small cavity less than 0.5 mm in diameter (21%). In regard to cavitation, 27% of lesions in enamel and 100% of lesions extending into dentin were cavitated. As with the previous study, this study correlated the cavitation status of the proximal surfaces to their radiographic appearance. There was no attempt to compare the depth of carious involvement from a clinical standpoint. In this study the experimental teeth had no adjacent contacts and that does not represent the real clinical situation for most of the cases. Only 12 of 370 (3%) surfaces examined in this study fell into this radiographic

category (penetrating the DEJ), firm conclusions probably should not be made on this small number of cases. The author concluded that the results of the study made it difficult for either the research worker or clinician to place a high level of validity on the findings of bitewing radiographs. Once again, the validation method for the analysis was the direct clinical visualization.

In 1982, Bille and Thylstrup conducted a clinical investigation to compare the radiographic extension to the clinical appearance of proximal lesions in posterior teeth [30]. They used clinical scoring for the lesions during cavity preparation. In this study, 158 interproximal lesions in permanent molars and premolars of Danish children aged 8-15 years were the study sample. The lesions used in the study were diagnosed as needing restoration by one of seven dentists, and were graded according to a 5-point radiographic scale which was related to the depth of the lesion in the axial direction. The radiographic changes were graded by the two primary investigators. Clinical grading was performed by one of seven different restorative dentists after stopping the drilling procedure when the maximal axial extent of the lesion appeared in the gingival wall, cervical to the interproximal contact area. The clinical grading scale categorized hard tissue changes in the cross-section of the lesion and included visible changes in enamel and dentin, the presence and depth of cavitation of the proximal surface, the degree of dentinal discoloration, and the hardness of dentin to an explorer tip. This study focused primarily on the cavitation status of the proximal surfaces in regard to their radiographic appearances. Results showed that 66% of the 158 lesions were graded as being without macroscopic cavitation. Further evaluation of the data showed that 13% of the lesions were confined to enamel and 20% of lesions that just involved the DEJ were cavitated. Lesions "approximately halfway through dentin" on the radiograph were cavitated 52%

13

of the time, and all the lesions greater than halfway through dentin were cavitated. There was no significant difference in the cavitation status according to radiographic depth of the lesions when comparing tooth type (molar versus premolar). In general, the majority of the lesions were found to be further extended clinically than radiographically. However, because the radiographic and clinical scales had slightly different scoring categories, direct correlations are difficult to establish. Although this study focused primarily on cavitation status of the proximal surface, and not caries extension, the results provided useful information. For instance, 46% of lesions radiographically confined to enamel showed clinical extension into dentin. Alternatively, 34% of lesions radiographically involving the DEJ were confined to enamel clinically. This type of information is valuable since many practitioners consider caries involvement in dentin the threshold for restorative treatment. The authors advocated macroscopic cavitation as the restorative threshold. Interestingly, 48% of the lesions halfway through dentin radiographically showed no signs of clinical cavitation. Thus, this report raised some difficult theoretical treatment dilemmas, such as how to handle lesions well into dentin that have intact proximal surfaces. The authors did not specify the type of film used and the amount of time between the radiographs and restorations. Also nothing was mentioned regarding the examiners calibration and standardization. It was, however, the first clinical study in which there was an attempt to measure the depth of proximal caries versus simply categorizing the proximal surface in terms of cavitation.

Three years later an article was published by Mejare et al who conducted a clinical study of a different nature [31]. They examined the proximal surfaces of 598 posterior permanent teeth in 63 teenagers (mean age =14 years 11 months) having teeth removed for orthodontic purposes. The proximal surfaces of the extracted premolars, as well as the

adjacent surfaces of the neighboring teeth that remained in the mouth, were directly inspected after extraction. Clinical scoring of the directly visualized surfaces was recorded via a joint decision by the three investigators. The categories included intact surface, incipient caries (white or brown spot), and cavity formation (surface breakdown). Radiographic grading was done using D-speed, pre-extraction bitewing films, and the surfaces were scored as: 1. sound, 2. radiolucency in enamel less than or equal to two-thirds of the enamel thickness, 3. radiolucency in enamel greater than two-thirds the enamel thickness, or 4. radiolucency in dentin. The radiographs were examined simultaneously by three investigators. Results showed that 52% of surfaces scored as sound radiographically showed caries clinically, with most of these lesions being of the incipient, non-cavitated variety. Lesions radiographically scored as being in the outer two-thirds of enamel demonstrated incipient caries clinically 80% of the time, while the rest were intact (9%) or cavitated (11%). None of the radiolucencies reaching the inner third of enamel were sound. In this group, lesions were incipient 69% of the time and cavitated 31% of the time. Finally, all radiolucencies into dentin showed clinical cavitation. In general the study was well done and yielded similar results to the Rugg-Gunn study.

In 1986, Espelid and Tveit compared the radiographic diagnosis of interproximal carious lesions with both direct visualization/probing of the intact proximal surface and from within prepared class II cavities [32]. One hundred and fifty one (151) Extracted molar and premolar carious teeth were utilized. All proximal surfaces were examined directly both visually and with an explorer and scored using a 5-point scale. This was the first of two validation procedures performed by the primary investigators. The scoring categories included: 1. sound, 2. discolored lesion without cavitation, 3. small cavitation,

4. lesion showing both discoloration and small cavity, and 5. lesion present showing both discoloration and large cavity (>1.5 mm). The teeth were then radiographed, using D-speed film placed tangentially to their proximal surfaces and scored independently by 7 experienced clinicians using a 6-point scale. Radiographic categories included: Rl = no lesion; R2 = lesion not more than halfway into enamel; R3 = lesion up to the DEJ; R4 = lesion into the outer third of dentin; R5 = lesion extending between outer third and half of dentin; and R6 = lesion more than halfway into dentin. The score used for each surface was the average value of the 7 clinicians. Finally, modified class II preparations into the pulp were made into the proximal surfaces of the teeth and the lesions once again graded on a 6-point visual scale that corresponded to the radiographic scale. This procedure was considered a second validation method of true caries extent and was based on a joint decision by the primary investigators. The results showed that 73% of lesions radiographically scored as "not more than halfway into enamel" were found to be cavitated when directly visualized. Radiographic diagnoses of "up to the dentinoenamel junction" were found to be cavitated 88% of the time, 49% of which were observed to extend into the outer third of dentin or deeper. Radiographic lesions into the outer third of dentin were truly into dentin 84% of the time, and 93% of these lesions were cavitated. Interestingly, 12.5% of the deepest lesions clinically (into the inner half of dentin) were diagnosed as sound on the radiographs. It was shown that 61.3% of carious lesions without cavitation were also diagnosed as sound from the radiographs. Although a soft tissue simulator was used, such *in-vitro* conditions do not necessarily mimic the *in-vivo* situation. In general, this study showed higher rates of surface cavitation in enamel lesions up to the DEJ than other studies, especially those conducted *in-vivo*.

Another study conducted in 1986 by Mejare and Malmgren also used clinical

16

observation during cavity preparation as the validation method [33]. They compared the clinical and radiographic appearance of proximal carious lesions at the time of operative treatment in young permanent teeth. In this study, 60 primary lesions, 20 in premolars and 40 in molars, were examined in 43 Swedish children aged 7 to 18 years. The carious lesions, ranging in depth from the inner half of enamel to the outer half of dentin, were scored from recent radiographs (< 3 months) and then again clinically at the time of operative treatment. The radiographs were scored by the two investigators simultaneously and a joint decision was made. All of the lesions fell into one of two categories, "radiolucencies limited to the inner half of enamel with no involvement of the dentin", and "radiolucencies from the DEJ to halfway through dentin." Dental tissue changes evident during drilling were photographed and the lesions were scored according to caries extension and presence of cavitation using a 6-point scale. In this study a cavity was defined as a visible surface breakdown extending more than one-fifth of the enamel thickness and was noted during the drilling procedure. Lesions were "dissected" from the occlusal direction and photographs made at multiple stages to document the lesions at their deepest extent in the axial direction. Results showed that 28 of the lesions were radiographically scored as being confined to the enamel and 32 as being into dentin. Of the lesions radiographically confined to the enamel, 61% were found to be cavitated. Lesions that showed dentinal involvement were cavitated 78% of the time. There was no statistical difference in the percentage of teeth with cavitation present between molars and premolars given the same radiographic appearance. In regard to caries extension, as detected by visual color changes in enamel and dentin, different clinical presentations were found for lesions demonstrating similar radiographic presentations. For instance, of the 28 teeth radiographically scored as having caries confined to enamel, validation found

4 lesions to be confined to enamel without cavitation, 5 lesions confined to enamel with cavitation, and 19 lesions extending into dentin, 12 of which were cavitated. Hence, 19 of 28 (68%) of those lesions deemed to be confined to enamel on the radiograph had clinically progressed into dentin. Significantly, two-thirds of these lesions (into dentin) were cavitated, an important factor in terms of the decision to restore. This study was limited to young adult teeth in children who regularly attended a public dental health service, so the sample is obviously not representative of the general population. In addition, radiographic film type and developing were not specified, information which would be useful for comparison with other results. However, important information was gained through this study.

Pitts and Rimmer performed a clinical study in 211 children between the ages of 5 and 15 years to compare the status of 1,468 permanent and 756 primary posterior approximal surfaces on the basis of their appearance on posterior bite-wing radiographs and the findings of a direct *in-vivo* visual examination [34]. Kodak Ultra-speed (D-speed) films were used. All bitewing films were evaluated by the one observer, and surfaces scored as: 1. sound, 2. radiolucency up to half-way through enamel, 3. into the inner half of enamel, 4. into the outer half of dentin, or into the inner half of dentin. Following temporary tooth separation for a week using elastomeric bands, direct visualization of the proximal surfaces was possible and scoring categories included sound, white-spot lesion, brown-spot lesion, cavitation into enamel, cavitation into dentin, and cavitation reaching the pulp. Results showed that, for permanent teeth, none of the proximal surfaces with radiolucencies confined to the outer half of enamel were cavitated. The percentages of surfaces cavitated for radiolucencies to the inner half of enamel, outer half of dentin, and inner half of dentin were 10.5%, 40.9%, and 100%, respectively. Primary teeth showed a

18

slightly lower cavitation rate, with 2.9%, 28.4%, and 95.5% of teeth in the same categories affected. This study only looked at cavitation status of surfaces relative to radiographic appearance, but not the depth of carious extension. In regard to cavitation status, only one investigator examined and recorded the values for each surface. The authors mentioned that assessment of the reproducibility of scoring the temporarily separated proximal surfaces was precluded by the general design and logistics of the study. In general, the cavitation rates for the different radiographic categories used were lower than those reported in other studies. One possible explanation would be that assessment of the surface may not be as accurate when only approximately 1 mm of space exists between the teeth, as opposed to extracted teeth (pre-orthodontic treatment) on the bench-top or situations where the adjacent tooth has recently exfoliated and larger spaces are present.

In 1992, De Araujo FB et al compared the accuracy of clinical examination with bitewing radiographs when direct visualization following temporary tooth separation, using elastomeric bands, was used as the validation method [35]. Bitewing radiographs with D-speed films of 168 high school students in Brazil were reviewed specifically for interproximal caries by three examiners, and 77 surfaces were found to have proximal radiolucencies. These 77 surfaces were included in the study and scored radiographically, clinically, and again clinically following temporary tooth separation. Radiographic scoring categories included: 1. less than or equal to two-thirds the enamel thickness, 2. greater than two-thirds of the enamel thickness and to the DEJ, and 3. into dentin. The first clinical examination was completed by the three examiners using mirror and explorer and a consensus agreement reached, with categories being "healthy surface", "white-spot lesion", and "carious cavitation". Temporary tooth separation using elastic

bands for 24 hours was followed by a second clinical examination. The space created by the tooth separation provided for direct visualization and tactile exploration of the surfaces, and the findings of this examination were considered the validation method for the radiographic and conventional clinical examination (without separation). Results showed that 51% of the radiolucent lesions diagnosed radiographically were judged as healthy, normal enamel on conventional clinical examination. Validation after separation revealed 64% of the lesions to be of the white-spot variety and 36% to be cavitated. There were no false positive radiographic diagnoses. Radiographically, 87% of the lesions extended less than two thirds of the way through enamel were white spots and 13% were cavitated. Lesions greater than two-thirds of the way through the enamel up to the DEJ were 74% white spots and 26% cavitated lesions. Radiographic dentinal lesions were 10% white spots and 90% cavitated. In regard to conventional clinical examination, 79% of the surfaces scored as sound were white spots, and 21% cavitated. Surfaces diagnosed as white spots were just that in 67% of the cases, but were cavitated in 33%. All of the surfaces scored as cavitated by the conventional clinical examination proved to be cavitated following separation. There were no false positive diagnoses made using the radiographs. Since the only surfaces used in the study were those deemed to have radiolucencies, there may have been some bias when the clinical examinations (both before and after separation) were performed, though over half of the surfaces were scored as sound clinically. The main outcome of interest in this study was cavitation status. Results of this study are similar to others in reported rates of cavitation for respective radiographic involvement.

In 1996, Akpata et al conducted *in-vivo* study in Saudi Arabia which utilized another method of gaining direct visualization of the interproximal surface of interest [36]. The

20

purpose of the study was to determine the influence of age, past caries experience, and tooth type on the probability of clinical cavitation at radiolucent areas on proximal surfaces of posterior teeth. In this study, 62 premolars and 46 molars in patients aged 17-48 years demonstrating primary caries on contiguous (back to back) proximal surfaces of premolars and molars were selected. Bitewing radiographs using E-speed film were made and scored by a dental radiologist. Radiographic scoring groups included: 1. radiolucency in the outer half of enamel, 2. inner half of enamel up to the DEJ, 3. outer half of dentin, and 4. inner half of dentin. Following preparation of the deeper of the two lesions in each case, the contiguous proximal surface was examined by direct visualization for the presence of macroscopic cavitation, and a consensus reached as to its status. The data obtained were subjected to logistic regression analysis with cavitation as the dependent variable, while age, tooth type and past caries experience were independent variables. Past caries experience was measured as DMFT (decayed, missing, filled teeth) and DFS (decayed, filled surfaces). Results of this study showed that when the proximal radiolucency was confined to the outer half of enamel, there was no clinical cavitation, but when it extended to the inner half of enamel, outer half of dentin, and inner half of dentin, clinical cavitation was observed in 19.3, 79.1, and 100% of the cases, respectively. Logistic regression analysis showed that there was a statistically significant relationship between age and the probability of clinical cavitation when the radiolucency extended to the inner half of the enamel. There was no significant relationship between age and probability of cavitation when the radiolucency reached the dentin. There was only a weak association between tooth type and the probability of cavitation, and caries experience had no influence on the probability of cavitation.

This study is one of very few that tried to correlate probability of cavitation with

21

other factors such as age and past caries experience. The results seemed to indicate that when the radiolucency extends to the DEJ, the probability of cavitation increases with age, it showed that 50% chance of cavitation was associated with age 39. The authors suggested that in younger patients with inner-enamel lesions, a preventive approach would be warranted, whereas with patients over 39 years of age, the tendency should be towards restorative intervention. However, this study did not quantify the depth of carious lesions. Instead, the presence or absence of cavitation alone was noted and correlated to radiographic appearance.

K Gungor et al (2005) assessed the approximal carious lesion depth with Insight and Ultraspeed films [37]. Eighty extracted teeth (40 molars and 40 premolars), with and without proximal carious lesions, were used in this study. The teeth were embedded in sticky wax and mounted in dental stone simulating anatomical contacts of two premolars and two molars. The teeth blocks were imaged with Ultraspeed and Insight films in the presence of 1 cm acrylic block used to simulate the soft tissue. The mesial surfaces of the teeth were rated according to the following five-point scale: 1. caries definitely not present, 2. caries probably not present, 3. unsure, 4. caries probably present , and 5. caries definitely present as determined by three oral and maxillofacial radiologists. When a score of four or five was made, the radiographic depth of caries was rated according to the following five point scale 1- radiolucency in the outer half of enamel, 2- radiolucency in the inner half of enamel, 3- radiolucency in the external one third of dentin, 4- radiolucency in the middle one third of dentin, 5- radiolucency in the internal one third of dentin approaching the pulp. The true caries extents were evaluated histologically using a stereomicroscope and data was analyzed using SPSS statistical package program. Out of 77 surfaces, 21 were found to be caries free (score 0), 46 had lesions localized at enamel

22

and dentin (scores 1, 2, 3, 4) and 10 had lesions in the inner half of dentin approaching the pulp. Observer scores for each surface were evaluated to find the degree of agreement. The results showed a positive correlation between the observers and the agreement level which was almost perfect for both films. A high-positive intra-observer correlation level between true approximal caries depth diagnosis was also found between Ultraspeed and Insight (Gamma values ranged between 0.825-0.990 for Ultraspeed and 0.9- 0.931 for Insight at $p<0.001$). The correct depth diagnosis for Ultraspeed film was 55.8 and 54.9% Insight film at $p<0.001$. It was found that 26.8% of the Ultraspeed film and 27.7% of the Insight film underestimated the lesion depth. The results and validation method for this study was similar to some the other studies that used the histological presentation of the carious extension as the validation method.

The relationship between histological and radiographic caries lesion depth measured in images from four digital radiography systems was evaluated, in an *in-vitro* study, by Jacobsen JH et al [38]. The study sample consisted of 177 extracted teeth which were mounted in blocks of silicone, 3 in each block with 2 non-test teeth, 1 at each end of the row of test teeth. A 12-mm acrylic plate was placed between the tube and the teeth to simulate soft tissue. Images were then obtained with two solid-state sensors: Dixi (Planmeca), and Sidexis (Sirona), and with two photostimulable phosphor plate systems: Digora (Soredex) and DenOptix (Gendex). After radiographic exposures, each tooth was sectioned mesiodistally to be examined under the microscope by two experienced observers to select the section in which the caries lesion was deepest. A direct digital photograph was taken of that section. Caries was defined to be present when a demineralization was observed in an area predisposed to caries. Four observers, 2 dental students with little experience with digital radiographs (observers 1 and 2) and 2

radiologists with many years of experience in digital radiographic caries diagnosis (observers 3 and 4), independently measured the lesion depth in all histological sections. The images could be enhanced by the individual observer with regard to contrast, brightness, gamma curve function and image size. Eventually, 64 lesions were included in the study, which could be seen by all 4 observers in all four types of radiographs. To measure the individual lesion depth in the digital images of the histological section and the radiographs, the computer program "Pordios" was used. The mean histological lesion depth for each observer and a correlation between the observers' lesion depth measurements were calculated. The 'gold standard', or true lesion depth, was defined as the mean of the 4 observers' measurements on the histological sections. Analysis of variance was performed first with the difference between the histological and radiographic measurement as the statistical test variable and thereafter using the regression coefficient as the test variable. The results showed that observer 1 generally underestimated the depth of the lesions in all four digital systems. There was a statistically significant difference between the radiographic depths compared to the gold standard: Sidexis (underestimation 51%), Dixi (underestimation 40%), and DenOptix (underestimation 32%). Observer 2 also underestimated the depth of the lesions in all four digital systems. In DenOptix and Sidexis images lesions were highly underestimated (37 and 31%, respectively) and in Dixi and Digora images less (20 and 17%, respectively). Observer 3 underestimated significantly the lesion depth in DenOptix images (17%), while there was no significant difference between the radiographic measurements and the gold standard in the remaining systems. Observer 4 underestimated significantly the depth of the lesions in Sidexis images (23%), while in the other three systems no significant difference was observed between the histological

24

and radiographic measurements. Digora possessed the overall smallest underestimation, followed by Dixi, DenOptix and Sidexis. As with most of the *in-vitro* studies the validation method in this study was the histological presentation of the caries. However, the authors used a computer program to measure the actual depth. Using observers with different experiences (dental students and radiologists) could affect the interexaminer reliability and the agreement between the observers would be difficult to achieve.

1.3.2 Evaluation of the digital RadioVisioGraphy (RVG) systems:

The first digital x-ray sensors for use in dentistry was introduced to the dental profession in the mid-1980s by Francis Mouyen (RVG, Trophy Radiologie, Croissy Beaubourg, France [now Trophy, a Kodak Company, Rochester, N.Y.]). Shortly thereafter, another system was developed by Per Nevig and colleagues (Sens-A-Ray, Regam Medical System, Sundsvall, Sweden), and within a decade many more manufacturers entered the market [39].

Multiple studies have been conducted to evaluate the accuracy of different intraoral digital radiographic systems to detect interproximal carious lesions.

In 1980s, Francis Mouyen et al conducted *in-vitro* study to evaluate the physical properties of the RVG system and compared that with the Ultraspeed film [40]. A head phantom consisted of six Plexiglas slabs (15x15x1.6 cm^3) representing soft tissue, and two aluminum slabs (15x15 x 0.5 cm^3), representing the teeth and bone, was used to measure the integral absorbed dose. The authors also tested the blackening dose relation, perceptibility, and modulation transfer function for periapical D-speed film and RVG sensor. The x-ray generator used was operated at 70 kV, 8Ma. Trimax 2 and 4 rare-earth screens were evaluated for the RVG system. To measure the blackened dosed, films and

RVG sensor were placed on either side of ion chamber x-ray monitor and were exposed simultaneously. The oscilloscope reading provided RVG's grey level without enhancement and with maximal enhancement. For measuring the integral absorbed dose, the exposure of the phantom was normalized for net optical density 1 (10% translucency) of the film and for an RVG video signal at 10% whiteness level without enhancement and with maximal enhancement. A relative integral dose index was computed as the sum of absorbed doses in each slab (conversion factors 0.93 for tissue, 4 for bone) multiplied by the irradiated volume. With films, a circular radiation field 6 cm in diameter was used; with the RVG sensor, a 4 cm diameter was used. To evaluate RVG's capacity to visualize small details, a contrast detail test was carried out. Films and RVG images, taken with increasing exposure times, were viewed by 10 persons. Each person had 10 seconds to reduce the number of perceptible details on each radiograph. For evaluating the modulation transfer function, a comparison of the resolution of film and RVG was carried out. The authors concluded that RVG system was able to produce radiographic images immediately after exposure and at considerably lower dose levels than are necessary for films. The resolution of the RVG was lower than the resolution of conventional periapical films. They also found that conventional films offer their best resolution when viewed with a magnifying glass, while the RVG system already provides the necessary magnification. Although the authors did not display their results in numbers, this study explained some of the characteristics of the original RVG system and how it was working.

In 1993 M. Russel and N.B Pitts conducted a preliminary study to compare the sensitivity, specificity, predictive value positive (the predictive value of a positive test refers to the probability that the disease is present given that the test result is positive)

and diagnostic accuracy of video prints from the Mark 2 RVG (the improved RVG model) in basic mode to the conventional bitewing radiographs using D- and E-speed films [41]. The histological appearance of hemisected teeth was used as the validating method. To perform the study, 120 extracted teeth mounted in silicone blocks were used. Teeth were mounted in sets of 4 (2 premolars and 2 molars in contact), and 2 blocks were held, using a "jig", in a relationship similar to opposing upper and lower dental arches. Tissue equivalent material of 20 mm thickness was placed between the teeth and the x-ray beam. Teeth blocks were then radiographed using 15 D-speed films, 15 Ektaspeed films and 15 RVG exposures. The x-ray unit was operated at 70 kVp and 8 mA. The examiners were not formally calibrated to determine their diagnostic performance when using the new method in their own way. The prints were examined under normal overhead fluorescent lighting using the following rating scale: R0 = sound, Rl = outer half enamel lesion, R2 =inner half enamel lesion, R3 ± (0) = outer half dentin lesion, and R4± (0) =inner half dentin lesion, (suffix 0 where surface enamel overlapped provided that radiolucency in dentin is distinct). Subsequently the teeth were hemisected mesiodistally and examined independently by each examiner under a microscopic magnification of x 10. The lesions were rated using the following analogous criteria 0= no caries apparent, 1= carious lesion(s) in outer half of enamel only, 2= carious lesion(s) into inner half of enamel but not into dentin (up to and including the DEJ), 3= carious lesion(s) through enamel and into outer half of dentin, 4= carious lesion(s) through enamel and into the inner half of dentin. In order to confirm the histological ratings, the teeth were serially sectioned giving a minimum of 8 slices per tooth. The diagnostic accuracy in this study was defined as the percentage of correct diagnoses (true-positives and true-negatives) implies equal weighting for positive and negative errors. The results

27

showed that 3-5 RVG exposures are approximately equivalent to 1 conventional E speed film, bitewing exposure. This finding was in contrast to those of other studies [Mouyen et al., 1989 and others], who were in agreement that the dose of RVG was 40% of that for E speed film. However, the RVG system that the authors used here was not the same old model as the Trophy Company had improved the system over those years. Interexaminer reliability for D and E speed bitewing films, and RVG measured by means of Cohen's x was 0.3; thus the examiners achieved a 'fair' agreement according to the 6-point scale. The authors concluded that the difference between the three methods were not statistically significant for the diagnosis of caries *in-vitro*. This was a good descriptive study that was able to define some of the characteristic features of the RVG compared to conventional films.

A. Wenzel et al used 116 extracted human premolars and molars mounted three in a line with approximal contacts to assess four digital systems (Digora, RVG, Sens-A-Ray, and Visualix) for the detection of approximal and occlusal caries [42]. A 12-mm thick acrylic plate was used to stimulate soft tissue. The x-ray unit was operated at 70 kV and 8 mA. Exposure time was selected individually for each system. Sixteen randomly chosen images from each of the four systems were compressed using the JPEG (Joint Photographic Experts Group) and were displayed to 6 radiologists, in a random order, without altering the brightness or contrast controls. The observers were asked to write their scores for the occlusal and the "left" and "right" approximal surface of each tooth in "scoring fields" on the monitor in relation to the displayed image. The following 5-point confidence scale was used to score caries: 1 = definitely present, 2= probably present, 3= unsure, 4= probably not present, 5= definitely not present. The program automatically stored the observers' scores for each surface. The teeth were then removed from the

plaster of Paris and were serially cut mesiodistally into sections of 700 micrometer. The sections were examined under the stereomicroscope (x25). Two observers independently scored the three surfaces of each tooth as: 0=sound surface, 1= caries in enamel, 2 = caries in dentin. The diagnostic performance of each observer and system was compared with the true diagnosis (histology) by calculating true positive (TP) and false positive (FP) values. An average receiver-operating characteristic (ROC) curve for each system was obtained. Differences between the areas under the curves were then tested by a univariate Z-score test. For approximal surfaces, results showed that ROC areas ranged from 0.425 to 0.702. However, these differences were not significant. For occlusal surfaces, RVG tended to be the most accurate system, followed by DIG. The results also showed that RVG and DIG detected about half the lesions with about 5% false positive scores, while SAR detected 43% and VIX 38% with 2% false positives. When comparing ROC curve areas, the differences between the systems were not significant for approximal surfaces (DIG/SAR $p = 0.84$; DIG/VIX $p = 0.85$; DIG/RVG $p - 0.65$; SAR/VIX $p = 0.98$; SAR/VIX $p = 0.76$; VIX/RVG $p = 0.75$). The differences between the compressed and the uncompressed images were not significant ($p= 0.89$ for occlusal and 0.84 for approximal surfaces). The authors concluded that the four tested digital systems performed almost equally well for detection of occlusal and proximal carious lesions. On the other hand, images compressed to 8% of their original storage requirements were not less accurate than their originals.

In a similar study, E. Gotfredsen et al evaluated observers' use of image-enhancement facilities and time consumption in assessing caries in radiographs taken with four digital systems: Digora (DIG), Radiovisiography (RVG), Sens-A-Ray (SAR) and Visualix (VIX) [43]. In this study, 131 extracted premolars and molars were mounted in sets of three.

29

Radiographs were taken of the teeth using the four digital radiography systems. The x-ray unit operated at 70 kV and 8 mA. A 12 mm thick acrylic plate was used as soft tissue scatter. The digital images were exported in TIF format. To assess the effect of compression, 16 images were randomly chosen from each of the four digital systems and compressed by JPEG. A total of 588 images were thus available for evaluation. A mouse-controlled program was used to enhance the images and store the observers' scores. The program had three options (gamma, brightness and contrast) for digital image enhancement. The following information on the performance of the six observers was automatically stored by the program for each surface of each tooth: caries score, gamma curve value at recording, brightness value at recording, and contrast value at recording. Observers could manipulate the images to optimize their quality before making their diagnosis. Differences between the four systems with respect to the original image histogram, observers' use of image enhancement, and time spent recording were evaluated statistically together with differences between the compressed and uncompressed images. The results showed that the mean value of the original image brightness of the DIG and VIX images were lighter $(x > 127)$ than the RVG and SAR images $(x < 127)$. All image histograms were on the light side of the available range of grey shades. The extent to which image enhancement was used, i.e. the changes in gamma (G), brightness (B) and contrast (C) were calculated. In total, G was changed in 96% of the images, B in 36% and C in 19%. Less than 1% of the images were not manipulated at all. The VIX images were enhanced most often $(x = 5.13)$ followed by SAR (4.58), DIG (4.32), and RVG (3.90). There were significant differences in the number of manipulations performed between all systems. On average, less time was spent with the DIG images (23 s), while the other systems needed more time (25 s). The

differences between the DIG and the images from the three other systems were highly significant (p < 0.001). There were no significant differences between the CCD-based systems (p < 0.2). There was, however, a difference between time spent scoring the compressed images (x = 22.5 s) and the original images (x = 23.7 s). In conclusion, compressed images were manipulated more often than uncompressed. The authors stated that since there was no direct relationship between the time spent and the number of manipulations performed, the latter is not the sole factor determining the time observers need to reach a diagnosis.

In Japan, K Araki et al conducted a study to compare the sensitometric properties and resolution of four digital intra-oral radiographic systems [44]. Three of these systems were CCD based digital systems: RVG-4 (Trophy), CDR (Schick), and Dixel (Morita) and the fourth one was a PSP system: Digora (Soredex). The dental x-ray unit used for the RVG-4, CDR and Digora was a HI-EMIX 90 and for the Dixel, a MAX-FM with two different focal lengths. Both x-ray units were operated at 60 kV. The pixel size along with the sensitometric properties and resolutions were measured using a 2 mm wide slit placed on each detector and exposed perpendicularly 100 cm from the focal spot. The number of pixels in the image was counted on the Image PC. The detector was uniformly covered by the x-ray beam, and exposed to obtain the gray level values for each system. The exposure time was increased in successive steps to obtain the sensitometric data. Five images were obtained at each exposure for all the systems. The region of interest (ROI) was set at the center of the image and the mean gray value of each ROI calculated. To measure the resolution, a specially fabricated test object made of 2 mm thick heavy alloy containing a 10 mm-wide slit, placed in close contact with the detector at an angle of 10^0 to the long and short axes of the detector, was used. The results showed that, in all cases,

the measured pixel size was almost the same as that given by the manufacturers. The CCD based systems showed a linear relationship between exposure and gray level. RVG-4 had the highest resolution with the narrowest latitude, whereas Digora had the wider latitude but the lowest resolution. However, authors concluded that each system has its own specific properties. In this study, two different x-ray units were used with different focal distances. Using different machines with different systems may affect the accuracy of the end results.

A comparison of 18 different x-ray detectors currently used in dentistry was performed in a recent study by AG Farman et al [45]. In this study, spatial resolution, contrast perceptibility, and relative exposure latitudes of 18 current dental x-ray detectors including solid-state systems (CCD and CMOS), photostimulable phosphor plates, and a conventional film were evaluated. The detectors studied were the following: CMOS devices including CDR wired and wireless systems (Schick Technologies, Inc,), RVG 6000 and RVG 5000 (Eastman Kodak); CCD-devices including CygnusRay MPS (Cygnus Technologies), Dexis (Provision Dental Supplies), Dixi v3 (Planmeca Oy), DSX 730 USB and DSX 730 Evolution (Owandy/Julie RadioVision), Sigma (GE/Instrumentarium Imaging), Sidexis (Sirona), RSV (Visiodent); RVG-ui (Formerly Trophy Radiology, now Kodak), ViperRay (Integra Medical), and Visualix (Gendex); photostimulable phosphor systems including DenOptix (Gendex), and ScanX (Air Techniques Inc.); and Insight film (Eastman Kodak). The x-ray unit used was operated at 70 kVp, 8 mA. Film radiographs were evaluated in a darkened room using a viewbox. The digital radiographic images were displayed on a 17-inch CRT screen in the same darkened room. Four evaluators worked independently to evaluate the images and outcomes were decided by consensus when there were discrepancies in ratings. Spatial

resolution (image sharpness) was measured by using a test grid phantom. An aluminum perceptibility test device was manufactured and an optical bench was used to assure reproducible projection geometry and to accommodate human tooth specimens and the various x-ray detectors. Seventeen mm of acrylic was placed to simulate soft tissue, without variations in focal distance or filtration. The exposure latitude was determined by expert consensus using clear discrimination of the DEJ as the criterion for the minimum acceptable exposure. Results of this study showed that the highest spatial resolution was found with Insight film, RVG-ui (CCD), and RVG 6000 (CMOS) detectors, each of which achieved 20 lp/mm, followed by Dixi2 v3 at ≥16 lp/mm. Contrast resolution was almost similar for all 18 detectors. The greatest exposure ranges were found with photostimulable phosphors and the Kodak RVG 6000 and RVG 5000 detectors. Authors concluded from this technical trial that most current x-ray detectors generally perform well in terms of spatial and contrast resolutions, and in terms of exposure latitude. They recommended that dental x-ray generators should be modified to provide lower exposure options when using digital x-ray detection systems for dentistry.

1.3.3 Evaluation of Ultraspeed (D-speed) radiograph:

1.3.3a Comparative studies:

When Kodak produced its current version of D-speed film (Ultra-speed) in 1955, it became the "gold standard" to which most subsequent films and, recently, digital technology has been compared.

In 1981, Kodak introduced Ektaspeed film (E-speed film), with reduced radiation exposure to patients by 50% compared to Ultra-speed film, but these films gained limited clinical acceptance because of their poor image quality [46]. Kodak refined their technology and launched Ektaspeed Plus film to replace Ektaspeed in 1994. Ektaspeed Plus

introduced a new T-Mat film emulsion, which uses light-sensitive silver halide grains that are flat rather than pebble-shaped and oriented to face the x-ray beam in a perpendicular fashion. T-Mat technology also increased the light-gathering ability, or speed, of Ektaspeed Plus [47].

In the summer of 2000, Eastman Kodak introduced Insight (F-speed) film which builds on the existing emulsion technology used for Ektaspeed Plus film, as the same T-grain emulsion is refined with an optimum amount and size of silver grains so as not to degrade image sharpness [1]. The manufacturer claims that this new film requires 60% less exposure time than Ultra-speed film and 20% less than Ektaspeed Plus.

In 2001, Kodak discontinued the production of Ektaspeed Plus film to be completely replaced by the new F-speed films.

Many studies have been conducted comparing diagnostic capabilities of the D-speed film to E-speed, F-speed, and/or digital radiographs.

Some investigational studies reported superior image quality of the D-speed films over Ektaspeed film in terms of contrast and image sharpness, one of these studies was conducted by Thunthy and Weinberg who compared the sensitometric properties of D and Ektaspeed films [48]. The study showed that E-speed film was approximately twice as fast as D-speed film. Both films had almost the same useful density range, but D-speed film had higher average film contrast and lower latitude than Ektaspeed film.

Hintze H et al compared the diagnostic accuracy of Ultraspeed Kodak film to Ektaspeed, Ektaspeed Plus, and Agfa M2 Comfort films for caries detection [49]. A total of 103 occlusal and 224 proximal surfaces were examined independently by three observers. A histological examination served as the validation method for lesion depth. Receiver operating characteristic (ROC) curve areas were calculated to express the diagnostic

accuracy of the tested films. In the proximal surfaces the ROC curve areas ranged from 0.550 (in Ultraspeed films) to 0.696 (in Ektaspeed Plus films). The results of this study showed no statistically significant differences between the different film types.

Ardakani FE et al evaluated the diagnostic advantage of D- and E-speed films for detecting interproximal caries [50]. In this study, 80 extracted maxillary premolar teeth were used. The teeth were approximated in pairs by embedding them in soft wax to simulate the natural position of teeth in the mandibular arch. The teeth were then divided into 4 groups of ten pairs each and cavities of 0.5, 1, 1.5, and 2 mm depths were prepared in proximal surfaces of the teeth in each group. Each pair of teeth was radiographed once using D-speed film then again using E-speed film with a standardized exposure time of 0.16 s, at 60 kVp and 8mA settings. The examiners measured the cavity depth from mesial to distal using a probe with 0.5 mm scales. Each of the four examiners completed a personal table for all radiographs. The examiners measurements and the true depths were then analyzed statistically. The diagnostic quality of D-speed was compared to that of E-speed films regarding the percentage of error in diagnosing cavity depth. The results showed no significant difference between the true depth and diagnostic depth of proximal caries in D-speed film. In addition, the differences between true depth and diagnostic depths in similar depths are more apparent (between depths 0.5 and 1.0 mm or depths 1.5 and 2.0 mm); therefore, D-speed film was said to have a good sensitivity for diagnosing caries. E-speed films showed a small, although significant difference between the true depth and diagnostic depth. However, the authors stated that, because of the limitations of the study, the small statistical difference between the true depth and diagnostic depth in E-speed film can be ignored.

In 2000, A. Wong et al conducted a comparative in-vitro study between the Kodak Ultraspeed and Ektaspeed Plus x-ray films for detection of dental caries [51]. Forty extracted premolar and molar teeth were used, 10 non-carious teeth were included to function as controls, and arranged to simulate a bitewing examination. The teeth were radiographed using Ultraspeed and Ektaspeed Plus dental x-ray films. Three different exposure times were used for each film. For E-speed film 0.20, 0.12 and 0.05 seconds were used while for D-speed 0.40, 0.25, and 0.10 seconds were used. A 20 mm thick block of wax was used to simulate the soft tissue. Following a double-blinded procedure, all radiographs were examined by six general dentists to determine the presence and depth of the decay in the proximal surfaces. Decisions on the depth of decay were rated on a six level confidence scale: 1=less than halfway through enamel; 2=greater than halfway through enamel; 3= to the DEJ; 4=beyond the DEJ; 5= no lesion; 6= unsure if a lesion is present. The actual extent of the decay in the teeth was determined by sectioning the teeth and examining them under a microscope. The results showed no significant difference between the two films for the mean correct diagnosis with the overall means being 61.6 % and 61.4 % for D speed and E-Plus, respectively. However, there was a significant difference between the means for the three exposures for D speed. Underexposed film had a mean correct diagnosis of 57.4 %, which was significantly less than the means of 63.3 % and 64 % for optimum and overexposed film, respectively. The respective means for E-Plus were 60 % (underexposed), 61.9 % (optimum) and 62.3 % (overexposed). However, the practitioners used were not consistent in their ability to make a correct diagnosis, or for the film for which they got the highest correct diagnosis.

J. R. Tamburus and M. A. Lavrador compared the radiographic contrast of Ultraspeed film to Ektaspeed and Ektaspeed Plus films [52]. An aluminum stepwedge was

radiographed for the objective assessment and a dried human mandibular segment including the teeth was used for the subjective evaluation. In the objective assessment, contrast was evaluated from the measured optic densities and the results were analyzed statistically. Subjective evaluation was performed by 12 dentists with a range of clinical experience and scores were assigned to five dental and bony structures. In the objective evaluation there was no significant difference in contrast obtained with the Ultra-speed and Ektaspeed Plus films, both had significantly better contrast than Ektaspeed film. The subjective assessment revealed that the majority of the dentists preferred either Ultra-speed or Ektaspeed Plus films for contrast.

To compare the densitometric properties and perceived image quality of Insight (F-speed) and Ultra-Speed (D-speed) film radiographs processed with rapid chemistry, Bernstein DI et al conducted a study similar to the one performed by Tamburus and Lavrador [53]. The effects of density, contrast, and film speed on perceived image quality were also studied. In this experiment, human mandible encased in tissue-equivalent acrylic with an attached aluminum step-wedge was used. Standardized images were made with F- and D-speed films using an x-ray unit operated at 65 kVp and 7 mA. A 2 mm thickness of aluminum-equivalent filtration was used with a nominal focal spot size of 0.25 mm^2 and the target-to-film distance of 23 cm. Processed radiographs were measured for background density (including base plus fog) in regions corresponding to airspaces. Density measurements were made with an X-Rite 331 densitometer in 5 separate regions of each film by using an aperture setting of 2.0 mm, and the mean density was recorded. Contrast was determined for each image by using an 8-step aluminum wedge. The 7-mm-thick and 1-mm-thick steps were measured for density in 2 separate regions, and the difference between their means was reported as a measure of image contrast. Three

groups of processed radiographs arranged by density were created after determining the exposure times for both D- and F-speed films that were necessary to achieve approximate background densities of 1.5, 2.0, and 3.0. Appropriate exposure times were established by irradiation of both D- and F-speed films to each of the x-ray generator's factory preset time intervals. Four D-speed and four F-speed films were exposed at 21 time intervals, ranging from 0.020 second to 2.0 seconds, and the mean density of the four films (for each speed and time interval) was then calculated. Out of 96 radiographs, 4 radiographs were randomly selected from each density group and film type. This set of 24 D- and F-speed radiographs, including all 3 different desired densities, were displayed to 5 endodontic residents from the University of Louisville without magnification. Observers were asked to rate radiographs as unsatisfactory, satisfactory, or superior in terms of the ability to demonstrate the following: (1) root canal obturation, (2) periodontal ligament space at the apex of the mandibular first molar distal root, (3) the mandibular second molar mesial DEJ, (4) the mandibular second molar mesial crestal interproximal bone level, and (5) the perceived overall quality of the entire image. Observations were then analyzed and statistical tests were conducted. Contrast was grouped into 3 categories (<0.45; 0.45-0.55; and >0.55) and analyzed by analysis of variance to determine the effect on perceived image quality. The results showed no difference in perceived quality between D- and F-speed films. Significant differences between density groups were present irrespective of film speed. A higher density was associated with a higher perceived quality ranking for the 5 quality determinations. For all 5 measures of quality, observers preferred radiographs from the 3.0 background density group to those from the 2.0 and 1.5 density groups. Contrast increase was directly proportional to increased density. Higher image density was significantly associated with higher quality rankings

for all 5 areas studied. Higher contrast also resulted in higher quality ratings for all 5 radiographic sites. When density and contrast were controlled, film speed had no significant effect on the rankings of the 5 sites in terms of image quality.

Sheaffer JC et al evaluated the effects of direct exposure x-ray film speed and background density on observer assessment of endodontic working lengths and on perceived radiographic image quality [54]. A human cadaver maxilla section with surrounding soft tissues was used for the study. The canal length to the radiographic apex was determined on 4 canals in maxillary posterior teeth by using Trophy RVG images and 5 observers assessed the distance from the file tip to the radiographic apex on radiographs made with Kodak D-, E-, and F-speed and Flow D- and E-speed direct exposure x-ray films that were exposed to produce background densities of 1.5, 2.0, and 3.0. Subjective appraisal of radiographic quality was also assessed. Results showed no statistically significant difference among Kodak Ektaspeed Plus (E-speed), Kodak Ultra-Speed (D-speed), and Flow D. Films with a background optical density of 3.0 received 98% favorable ratings; radiographs with a background optical density of 2.0 received 77% favorable ratings; and those with background optical density of 1.5 received only 18% favorable ratings at the 95% confidence level. Flow D film received the most favorable ratings, but there was no statistically significant difference among other film types at the 95% confidence level.

In a recent study, Schiff T and Solomon BE performed a subjective evaluation for the diagnostic quality of the D-speed films and compared that to the F-speed films [55]. In this study, 12 full mouth sets (FMS) of radiographs were taken by radiology technicians. Ten were taken using Ultra-Speed films on the left side of the patient and Insight films on the right side of the patient. The remaining two sets of films were taken using Insight films

on both sides of the patient to act as a control. Each film was exposed using 15 mA, 80 KVp, and the appropriate exposure time for the film speed (12 impulses for anterior films and 18 impulses for posterior films when using Insight film (F-speed), or 24 impulses anterior films and 36 impulses for posterior films when using Ultra-Speed film (D-speed.). Ten general dentists evaluated the FMS looking for differences in diagnostic quality of the films, and asked only to compare the right side of the FMS to the left side and select which side of the FMS they preferred, if any. Results showed that 65.7% of the practitioners preferred the images that were taken using the Insight films, the remaining 34.3% of the practitioners showed a preference for the images that were taken using Ultra-speed films. However, this *in-vitro* study did not specify the characteristics used to evaluate the good quality radiograph since the "preference" is very subjective evaluation. Furthermore, if the same side of jaw with the same angulation was used to evaluate the two types of films, the results would be more reliable.

Thunthy and Ireland conducted a study to compare the visibility of caries on F- and D-speed films [1]. They used three extracted teeth, each with a small visually recognizable proximal carious lesion, which were placed in a mounting jig and exposed using a constant x-ray source-to-film distance of 14 inches. Exposures were made for both films with exposure times ranging from 3 to 24 impulses, resulting in 11 exposures for each film type. All films were processed under standardized processing solutions. This procedure was used for each of the three sample teeth. Three blinded examiners, two operative dentistry professors and one oral and maxillofacial radiologist, examined the randomized radiographs with a magnifying glass under idealized viewing conditions. The three examiners were in consensus and chose the Ultra-speed radiographs made at 10 impulses and the Insight radiographs made at 4 impulses for clarity of the carious lesions

and acceptable film densities. The investigators found that caries detection for both films was comparable, though the Insight film showed a slight amount of "mottling" under magnification due to the low exposure times. This experiment was not designed for technical analyses, as conceded by the authors, but "for the benefit of general dental practitioners". However, films made under such conditions do not necessarily represent the clinical situation. For instance, there was no soft tissue present (or soft-tissue simulator employed), the teeth were not in normal proximal anatomic position, and the examiners were not truly blind in that they knew there was a lesion present. In effect, the examiners were simply comparing the films. These results may or may not be indicative of the clinical situation of diagnosing lesions on posterior teeth.

Farman and Farman compared the radiographic quality of F-speed film to that of Ultra-speed, Ektaspeed, Ektaspeed Plus and Agfa M2 Comfort films [56]. The study further evaluated the effects of six processing solutions most widely available in either the USA or Europe. The x-ray generator was operated at 90 kVp and 50 mA, and exposure times ranged from 1/120 to 5 seconds. Characteristic curves were established and film density, speed, contrast, and spatial resolution were all evaluated. Results showed that choice of processing solutions had an important impact on the quality of the resulting radiograph, even when all the manufacturer's recommendations were followed precisely. The investigators found no significant difference in contrast, latitudes, or spatial resolution among the films tested. This study compared films using standard technical analyses, and within the parameters of the study no significant differences could be found. The subtle changes seen in proximal caries, however, may not correlate well to such technical analyses, and these results should not be translated directly to the clinical situation.

Ludlow et al conducted a study to compare film speed, contrast, and exposure

latitude of Insight (F-speed) to Ultra-speed (D-speed) and Ektaspeed Plus (E-speed) films [57]. Technical analysis was made for film density, with characteristic curves plotted for each film type and processing condition. Speed determined according to ISO guidelines and film response to conditions of processor solution depletion was assessed. Resolution was evaluated using line-pair tests; exposure latitude was compared using step-wedge images; and subjective assessments of film quality were made by nine observers with advanced training in dental radiography. Results showed that the three films were classified appropriately in regard to speed. Response to processing solution depletion showed that on day one, Ultra-speed films displayed a greater gradient than Ektaspeed Plus and Insight films, but by day five, Ultra-speed films provided the least contrast, whereas Ektaspeed Plus and Insight films were essentially tied for the greatest contrast. There was no statistically significant difference in resolution between the tested films.

Price C had also compared Insight to Ektaspeed Plus and Ultra-speed films [58]. In his study, the three types of films were exposed and processed under standardized conditions. Values of base plus fog, speed, and contrast were derived. Resolution was compared by a line-pair plate. All unexposed films, of each type, gave base plus fog densities which agreed to within 0.01. The mean base plus fog density values (and standard deviations) were 0.177 (0.005), 0.208, (0.004) and 0.215 (0.005) for Ultra-speed, Ektaspeed Plus, and F-speed respectively. There was little difference in density values between the top and bottom films in each packet. The bottom films gave lower values because of attenuation by the upper films. Ultra-speed contrast was a little greater at densities below 1.00, then falls behind the values for the other two emulsions. All contrast responses are very favorable, and the minor differences between them are unlikely to have any clinical relevance. Radiographs were selected with exposure times of 0.8 s for the Ultraspeed, 0.4

s for Ektaspeed Plus, and 0.32 s for the F-speed emulsions. The corresponding density values were: Ultra-speed: 0.48, Ektaspeed Plus: 0.48, F- speed: 0.51. In conclusion, this study showed similar contrast between the three different films. Ultra-speed film demonstrated slightly better resolution than Insight and Ektaspeed Plus, which were similar to each other.

Ludlow et al compared Insight (F-speed), Ektaspeed Plus (E-speed), and Ultra-speed (D-speed) films in regard to their abilities to detect proximal caries [59]. Extracted molars and premolars, 21 of each, were mounted in normal anatomic relationships in sets of 3 with non-experimental teeth on each end to ensure all experimental surfaces had proximal contacts. Eighty four proximal surfaces were available for radiographic and histological evaluation. Single film packets of no. 2 size Insight, Ektaspeed Plus, and Ultra-speed film were used to image the teeth using an x-ray unit operating at 70 kVp and 8 mA, with 1 cm. thickness of tissue equivalent material. Exposure times were selected which produced a density in dentin of approximately 1.0 measured with a densitometer. Three oral and maxillofacial radiologists and three general dentists served as observers in the study, each viewing one film type at 3 sessions spaced a week apart. The films were displayed one at a time in random sequence on a conventional masked viewbox, using 2X magnification when appropriate. Observers scored the presence or absence of caries using the following scale; 1 = lesion definitely absent, 2 = lesion probably absent, 3 = uncertain if lesion present or absent, 4 = lesion probably present, 5 = lesion definitely present. Any sign of decalcification was to be considered caries, regardless of size, degree of penetration into enamel or dentin, or treatment strategies. Following radiographic imaging, each tooth was sectioned longitudinally in 0.4 mm thick slices and examined under a dissecting microscope for the presence of caries. Histological sections were

reviewed by two examiners, and a forced consensus was reached, with surfaces classified as carious if any degree of decalcification was present. Receiver operating characteristic (ROC) analysis was used to assess each observer's performance in detecting caries using each of the three film types. Histological results showed that 37.5% of the surfaces were non-carious, 32.5% had lesions confined to enamel, and 16.3% had lesions in dentin. Area under ROC curves showed Ultra-speed to have the highest mean score (0.88), followed by Ektaspeed Plus (0.85) and Insight (0.84). It must be emphasized that this study compared the films for the presence of caries and not the extent of caries. Very slight density differences, like those typical of dentinal caries, may result in differences in the ability to measure extent of decay from the radiographs using the different films. Considering histological validation was being used, it would have been interesting to include carious extension measurement as part of the study.

1.3.3b Survey studies:

Few survey studies have been conducted to evaluate practitioner's preferences in different areas for using different radiographic films.

Button TM et al conducted one of these surveys in New York, USA. A total of 77 facilities and 186 intraoral units were evaluated from December 1994 through March 1996 [60]. No predetermined criteria were used in the selection of facilities, and it was assumed that the data represent a random sample. The surveys were conducted in accordance with the requirements of the New York State Department of Health, with measurement of kVp added to the usual required tests. The collected data were stored and analyzed by means of Microsoft Excel. Results of this study showed that the factors contributing to increased exposure, listed from most frequent to least frequent, were as follows: improper processing, kilovoltage miscalibration, use of D-speed techniques with

E-speed film, use of newly installed units with default timer settings that were too high, exposure timer failure, and insufficient half-value layer. Only 18% of the facilities surveyed reported using E-speed film.

In 2002 Ilguy D et al conducted another survey in Turkey [61]. The survey was based on 636 dentists who attended the 11th International Congress organized by the Turkish Dental Association. A questionnaire which included 32 questions was given to the dentists who participated in the study. The sections of the questionnaire were (1) demographic characteristics of dentists, (2) radiographic equipment (3) radiographic techniques and processing, and (4) radiation protection. Forty respondents out of 636 who participated in the study were excluded due to respondent's errors while filling out the questionnaire. In total, 596 questionnaires were analyzed. The dentists in the study group practiced in either private practice (76.7%) or clinics and hospitals (23.3%). Only 69 (11.7%) respondents reported using film holders for the paralleling technique. It was observed that 65.8% of the dentists did not have any knowledge about speed of film they used. Of the rest, D-speed film was the most preferred with 21.7%, followed by E-speed (10.2%) and F-speed (2.3%). No statistically significant difference was found between the speed of film and the dentists' working situation.

Svenson B et al investigated the attitudes of Swedish dentists to the choice of dental x-ray films [62]. A questionnaire was sent to 2000 randomly selected general dental practitioners to assess their use of different types of dental x-ray films and collimators, and their attitudes and knowledge on methods of dose reduction. Logistic regression analysis was used to analyze the effects of postgraduate courses, gender, age, working alone, and working in the Public Dental Health Service (PDHS) or private practice on the type of film and collimator used. The response rate was 69.3%. D-speed film was used by

52% of the respondents while 47% of them use E-speed film.

Salti L and Whaites EJ performed a radiographic survey of private dental clinics in Damascus, Syria using a postal questionnaire to produce recommendations for improving the quality of dental radiographic services and education in Syria [63]. Three hundred private dental clinics in Damascus were surveyed. The questionnaire contained 27 questions on demographic information, equipment, techniques, selection criteria, frequency of examinations, and undergraduate/ postgraduate education. Results showed that 202 (67%) dentists responded of which 95% graduated in Syria. Seventy three percent used D-speed films, 57% did not use film holders and beam aiming devices, 25% did not use a viewing box.

In England and Wales, Tugnait A et al conducted a survey in 2002 that aimed to determine the self-reported use of panoramic radiography, D- and E-speed film, rectangular collimation, film holders, equipment fitted with a long spacer cone (>200 mm) and the bisecting angle and paralleling techniques by general dental practitioners and to see if use was related to the dentists' age and postgraduate qualifications [64]. Three mailings of a self-completion questionnaire were circulated to 800 general dental practitioners working in the National Health General Dental Service in England and Wales. A response rate of 74% was achieved. Sixty-one percent of general dental practitioners reported use of panoramic equipment. Fifty percent of dentists always used E-speed film and 18% always used rectangular collimation. Sixty-eight percent of dentists always used bitewing film holders though fewer (37%) used periapical film holders.

1.3.4 Conventional films vs. Digital Radiography:

1.3.4a Diagnosis of interproximal carious lesions:

A number of studies compared the diagnostic performance of different digital radiographic systems, including RVG, to conventional films in detecting interproximal carious lesions. The diagnostic accuracy of the recent digital radiographic systems has been shown to vary from system to system, with some systems being just as accurate as conventional films [8, 9, 41, 65, 66]. However, a few studies found that some digital systems were less accurate in detecting proximal carious lesions than conventional films [10, 11, 67, 68]. It is worth noting that the majority of these studies have evaluated diagnostic performance in the laboratory setting, but few clinical studies have been conducted to determine whether the clinical efficacy approximates laboratory findings [3].

One of the early studies (1994) was conducted by H. Hintz et al compared D-, E-speed films, RVG, and Visualix digital systems for the detection of enamel approximal and dentinal occlusal caries lesions [8]. The study material consisted of 66 extracted premolars and permanent molars with no visible approximal decay. Varying degrees of demineralization appearing as chalky white or discolored spots or areas were present. The teeth were embedded 3 in a line in plaster of Paris contained in wax moulds. The teeth were radiographed by conventional radiography with D- and E-speed films using an x-ray unit operated at 70 kVp and 10 mA. An acrylic block, 10 mm thick, was placed adjacent to the teeth to simulate soft-tissue. Digital images of the teeth were recorded by the RVG and the Visualix systems (first generations). The approximal surfaces of the teeth were assessed independently by three observers with the four graphic methods. The occlusal surfaces were assessed independently by two observers. Decisions on the presence of caries were rated using a five point scale: 1 = definitely present; 2 = probably present, 3 = unsure, 4 = probably not present, and 5 = definitely not present. After assessment, the teeth were removed from the plasters and sectioned in planes orientated mesiodistally.

47

The diagnostic performance of each observer with the different diagnostic methods was compared with the true diagnosis (histology), true-positive (TP) values (sensitivity) and false-positive (FP) values were calculated. The results showed that, for the approximal surfaces, the area under the receiver operating characteristic (ROC) curve ranged from 0.53 (Visualix) to 0.70 (Ektaspeed film). The average diagnostic accuracy with D- and E-speed films was equal. No statistically significant differences between the four radiographic methods were found. The mean values for the three observers readings as plotted under ROC were: 0.54 (Visualix), 0.59 (RVG), and 0.61 (E-speed and D-speed films). The authors concluded that conventional films and digital radiography did perform equally well in detecting interproximal carious lesions in enamel.

A similar study was conducted by Nair M.K. and Nair U.P. compared the diagnostic efficacy of Kodak Ektaspeed Plus film, Kodak Insight film and Schick CMOS-APS digital sensor with respect to caries detection in 92 proximal surfaces of extracted unrestored teeth, 51 of which were carious [9]. The true depth was evaluated histologically and the lesions classified as enamel or dentinal. Eight observers scored the radiographs using a five-point confidence rating scale. Analyses using receiver operating characteristic curves revealed the diagnostic accuracy of the tested films and digital system (Ektaspeed Plus - 0.760, Insight - 0.778 and CMOS-APS sensor - 0.732). ANOVA revealed significant differences with respect to caries depth ($p<0.031$) and observers ($p<0.0001$). The results suggest that none of the imaging modalities evaluated in this study differed in their diagnostic capabilities with respect to proximal decay detection.

In 1996, SC White and DC Yoon conducted a study at UCLA School of dentistry, LA, California to evaluate the performance of a digital CCD system (Shick technologies, Inc.)

for detecting proximal surface caries compared with E-speed film [67]. In this study, three hundred and twenty extracted teeth (mounted in groups of three or four in a line) were imaged with the CCD digital system and the E-speed film using an x-ray unit operated at 70 kVp. A total of 16 experienced dentists scored the proximal surfaces of these teeth for the extent of enamel and dentin lesions using the following scoring scale: 1. caries definitely present, 2. probably caries, 3. cannot tell, 4. probably no caries, 5. definitely no caries. The CCD images were displayed on a 14 inch SVGA monitor and were allowed to magnify the image and adjust the density and contrast. The teeth were subsequently sectioned to determine the actual caries depth. Results showed that sensitivity of the CCD system (43.6 for definitely caries score) was consistently lower than film (49.6 for definitely caries score) while the specificity of the CCD system was consistently higher (97.6 for definitely caries score), compared to the E-speed film (97.1 for definitely caries score). The accuracy of CCD and film images was not significantly different, either when sensitivity and specificity were averaged or when accuracy was weighted to reflect caries prevalence of 2, 5 or 10%. Authors concluded that dentists using a direct digital CCD system performed as well in interpreting proximal surface caries as with E-speed film. In this study variables like image size, contrast and density in comparing the CCD to the E-speed film were not controlled which may affect the end result. However, the advantage of manipulating the image to achieve a quality diagnosis should be considered when comparing these systems to the conventional images. The interexaminer reliability between a large number of examiners (16 examiners) would be difficult to achieve which may affect the accuracy of the results.

K Syriopoulos et al at the Academic Center for Dentistry Amsterdam, Netherlands, compared the diagnostic accuracy for the detection of approximal caries of two dental X-

ray films, two CCD-based digital systems and two storage phosphor (PSP) digital systems [10]. Sixty unrestored extracted premolars were used. The teeth were mounted in groups of five. Three teeth in the middle of each block were used in the study with the teeth at either end creating natural contact points. In total, 20 plaster blocks were constructed. For each radiograph two blocks were used simulating a bitewing radiograph. The x-ray unit was operating at 60 kVp and 7mA. A 12 mm thick soft tissue equivalent material was placed between the cone and blocks. Two dental films (Agfa Dentus M2 and Kodak Ektaspeed Plus), two CCD systems: (Gendex Visualix II and Sirona Sidexis), and two PSP systems: (Soredex Digora and Gendex) were used to radiograph the teeth blocks. The digital images were displayed on a SVGA 17 inch monitor. Eight observers (4 General practitioners, and 4 radiologists) scored the images using the following four point scale: 0=no caries; 1=lesion restricted to the enamel; 2=lesion reaching the DEJ; 3=lesion extending into the dentin. The radiographic scorings were compared with histological depth of the lesions. The final materials consisted of 56 proximal surfaces (14 sounds, 11 with enamel caries, 8 with caries reaching DEJ, and 23 dentinal caries). To calculate the estimation errors, the values for depth of caries determined from the histological examination were subtracted from the values recorded by the eight observers. If, for example, the histological examination revealed a sound surface (score 0) and the diagnosis of the observer was enamel lesion (score 1), subtraction resulted in an estimation error score of 1 (absolute error) or +1 (net bias). Estimation error of 0 indicated that the observers' diagnosis was the same as the outcome of the histological examination. The results showed significant difference in accuracy (estimation error) with the seven imaging modalities. The order of the systems, from the most accurate to the least was Sidexis, Dentus M2, Digora, DenOptix (600 dpi), Visualix, and DenOptix

(300 dpi). The difference in accuracy between Sidexis (the first-rated system) and DenOptix 600 dpi (the last-rated) was 0.17. No significant differences were found between the first four imaging modalities, Sidexis (CCD), Dentus M2 film, Ektaspeed Plus film and Digora (SP). Results also showed that the performance of the observers was significantly affected by the depth of the lesion. In conclusion, the results showed no significant difference in diagnostic accuracy between the two dental films and the Sidexis and Digora systems. However, The DenOptix (300 d.p.i) system was significantly inferior to the dental films. The diagnosis of the radiologists was significantly closer to the actual lesion depth than that of the general practitioners, independent of the imaging modality used.

In 1998, Uprichard KK et al conducted an *in-vitro* study at the school of dentistry, Medical College of Georgia, Augusta, Georgia; to compare the performance of a CCD based direct digital radiography and traditional dental radiography for the detection of proximal surface dental caries in the mixed dentition [11]. Fifteen quadrants of extracted teeth, arranged from the primary canine to permanent first molar, were imaged using direct digital (Schick Technologies) and conventional films (D-speed and E-speed Plus), the x-ray unit operated at 65 kVp and 15 mA. Five pediatric dentists viewed the images and scored the 270 proximal surfaces for presence of caries on a 5 point scale. Examiners were not allowed to adjust the contrast or density of the image. The teeth were sectioned and viewed microscopically to determine the gold standard. Receiver operating characteristic (ROC) analysis and ANOVA were used to evaluate the viewer's performance for detecting proximal caries using the 3 different image receptor types. Results showed that examiners were significantly more accurate in diagnosis of proximal surface caries using either D-speed or E-speed Plus films than they were using the direct

digital receptor. The mean areas under the ROC curve for the viewers were 0.7595 for D-speed film, 0.7557 for E-speed Plus film, and 0.5928 for the direct digital receptor. The results also indicated that selected viewers' accuracy increased when viewing the direct digital images a second time. This study did not mention if the digital images were viewed in the enhanced or un-enhanced mode. The authors stated that when establishing the gold standard, only carious lesions that initiated at the outer enamel surface corresponding to the proximal contact area were scored as carious, and because of this, several proximal surfaces may have been erroneously scored as carious by the viewers, due to cervical caries or caries initiating on the occlusal surface and involving the dentin adjacent to the proximal surface. This may have affected the results in regard to the presence of the caries.

In 2000, Haak R et al conducted an investigation at University of Cologne, Germany, to compare the accuracy of treatment decisions in proximal sites using three intra-oral radiographic systems [65]. Sixty extracted premolars and molars were divided into six groups (42 sound, 21 with visible evidence of caries, and 21 showed macroscopic cavitation between 0.5 and 1.5 mm in diameter) and radiographed with conventional film images (Ultraspeed), a storage phosphor plate (Digora) and a CCD system (Dexis) using an x-ray unit operated at 70 kVp and 7 mA. Dental wax, 12 mm thick, was used to simulate the soft tissue. Ten observers assessed the 84 surfaces on the bitewing radiographs for their requirement of restorative treatment using 6-rank confidence scale. The restorative treatment threshold was defined as presence of macroscopic cavitation, which was confirmed by direct clinical examination. The results showed no significant differences between the groups. Ratios for positive test results were: 5.29 (Ultraspeed), 8.14 (Digora), 9.67 (Dexis) and 11.37 (enhanced Dexis). The accuracy of restorative

treatment decisions based on digital and conventional radiographs was comparable. This study used the clinical examination (macroscopic presentation of caries) as the validation method for the presence of the decay.

In a recent study conducted by Elaine DA et al in Brazil, the accuracy of the proximal caries detection was evaluated using Sidexes CCD digital system (enhanced and un-enhanced images), Ektaspeed Plus and insight films [68]. Fifty-two extracted premolars were imaged under identical standardized geometric and exposure conditions. Four observers (two radiologists and two general practitioners), using five points confidence scale, rated 104 approximal surfaces for the presence or absence of carious lesions. The true diagnosis of the presence and depth of carious lesions was validated histologically. The results showed that the mean ROC curve areas for approximal surfaces were 0.865 (E speed), 0.856 (F speed), 0.816 (un-enhanced Sidexis) and 0.776 (observer enhance Sidexis). There were no significant differences between un-enhanced digital Sidexis and films. Observer enhanced Sidexis images exhibited a statistically significant lower diagnostic accuracy than the film images for two of the observers. However, this could be explained, as the authors stated, by the difference in the experience between the observers.

In 2005, Erten H et al used 80 approximal surfaces of 40 mounted extracted molars and premolars to evaluate the efficiency of Ultraspeed, Ektaspeed Plus, Insight radiographic films, and RVG digital system in detecting approximal carious lesions [66]. The mounted teeth were radiographed with the above mentioned films and digital system. The presence or absence of approximal caries was evaluated by three observers according to a five-point confidence scale. The actual status of each surface was validated histologically determined from the teeth sections. Sensitivity, specificity, positive and negative predictive values, and likelihood ratios of the imaging modalities were

calculated, and observer responses were assessed. The results showed that sensitivity values for Ultraspeed, Ektaspeed Plus, Insight, and RVG were 0.39, 0.48, 0.45, and 0.49, respectively, while the specificity values were 0.91, 0.88, 0.84, and 0.90, respectively. The difference in detecting approximal carious lesions between the systems was not statistically significant.

1.3.4b Patient acceptance:

One major disadvantage of the digital intraoral radiographic modalities, especially the solid state based systems, is the increase in the size, rigidity, and thickness of the digital sensors. This problem varies from one system to another according to the geometrical criteria of the sensor, and may cause patient's discomfort while taking the radiographic image. Patient's discomfort may lead to some errors in the image or increase the number of retakes which subsequently increases the radiation exposure to the patient. However, little has been published so far to evaluate the patient's discomfort to the digital receptors and compare that with different conventional films.

Wenzel A et al in one of his studies compared a CCD based sensor and a storage phosphor plate with respect to patient comfort and the efficacy of a simple cross-infection control procedure in connection with a posterior bitewing examination [69]. One posterior bitewing radiograph was taken of the left and right side both with the Digora storage phosphor plate, 35×45 min external measures and with RVG XL sensor, 32×45×7.5 min external measures. The RVG sensor was wrapped in a rubber tube and fixed to a film holder. The Digora phosphor plate was packed in the plastic envelope that goes with the system and positioned in the film holder. After both exposures, the enveloped plates were disinfected with an alcohol tissue before they were cut open. Rubber gloves were worn during the full exposure procedure. After the examination with both systems had been

completed, the patient assessed his/her feeling of discomfort when examined with each system on 100-mm Visual Analog Scales (VAS). The difference between VAS scores for the two systems was tested by the Wilcoxon's signed ranks test. Microbiological samples were taken from 14 patients (two per day at randomly chosen days) throughout the study period. For the RVG, samples were taken from the disinfected sensor and cord close to the sensor before it was wrapped in rubber, from the outside of the rubber tube before entering the oral cavity as well as just after exposures, and from the sensor and cord after removal of the rubber tube, and again, after disinfection. For the Digora, samples were taken from the phosphor plate before packing, from the outside of the envelope before entering the oral cavity, from the outside of the envelope after exposure and after disinfection, and from the edge of the plate after cutting open the envelope. The results showed that 58% of the patients preferred the Digora plate, 30% the RVG sensor, and 12% had no preference. Median VAS score for discomfort with the Digora was 20 mm (range 0–82) and 32 mm with the RVG (range 0–99). The difference was statistically significant ($P<0.001$). Only the coated RVG sensor and the enveloped Digora plates retained large numbers of oral bacteria immediately after exposure. Although the RVG sensor with the rubber tube mounted was exposed twice before samples were taken, while each of the enveloped Digora plates was exposed only once, the large difference in bacterial counts for these samples indicate that the rubber tube retained more bacteria than the envelope. The vast majority of the relatively small number of cultivable bacteria in all other samples was catalase-positive, Gram-positive cocci and Gram-positive rods. The authors concluded that the phosphor plate was less unpleasant than the CCD sensor for the majority of the patients and cross-contamination posed a minor problem for both systems when simple hygiene procedures were followed. In this study the authors

compared the CCD system to PSP but no conventional films were included in the comparison. However, nothing was mentioned about the source of discomfort when taking each radiograph.

Bahrami G et al conducted a study at University of Aarhus, Denmark to evaluate recording errors and patient's discomfort during bitewing examinations using four digital receptors [70]. In this study, 58 females and 20 males; ranging in age from17 to 65 years were referred to the radiology department for radiographic bitewing examination. Two bitewings were recorded on each side of the mouth using four digital receptors, two CCD sensors (Trophy and Planmeca), and two PSP systems (Digora and DenOptix). The x-ray unit was operated at 65 kV, 10 mA. The DenOptix phosphor plate was placed in its prefabricated plastic envelope which is soft with rounded edges. The Digora phosphor plate was placed in its prefabricated plastic envelope which has relatively sharp edges. Each CCD sensor was placed in a rubber tube covering the receptor, the receptor holder and the cord. The radiographs were all captured, stored and viewed in a dimmed room. A predetermined rotation model was performed to ensure that all receptors were used in all positions an equal number of times and that the two sensors and the two phosphor plates were never used on the same side of the mouth. A conventional film was placed in the same position as the Digora phosphor plate to evaluate the patient's discomfort but was not exposed. After each exposure with a particular system the patient was asked to score his/her feeling of discomfort on a 100 mm visual analogue scale (VAS). The scores on the VAS were subsequently measured to the nearest 0.5 mm. Three observers individually examined each bitewing image. Receptor positioning errors in the sagittal plane were determined from the tooth surfaces present on each image and positioning errors in the vertical plane were determined from the presence of the alveolar bone crest. The teeth and

surfaces were abbreviated as follows: 3=canines, 4=1st premolars, 5=2nd premolars, etc. The mesial surface=m, the distal surface=d and the occlusal surface=o. Cone positioning errors were determined from cone cuts. Wilcoxon's signed ranks test was used to evaluate differences in discomfort between the four systems. The results showed significant differences ($P<0.05$) for the posteriorly positioned bitewings between the Digora and the other systems for surfaces 7d and 7o in the upper jaw. In the lower jaw, surface 7o was displayed on significantly fewer Digora images than on Planmeca and DenOptix images ($P<0.05$). No differences were found between the other systems. The third molar was present in too few patients to be included in the calculation. Cone cuts occurred in 19% of DenOptix images resulting in a total of 18 missing surfaces, in 9% of Digora images resulting in 17 missing surfaces, and in one Planmeca image (one missing surface). There were no cone cuts in Trophy images. There was no statistically significant difference between the DenOptix plate and conventional film, which were scored as the most comfortable receptors compared with the other three ($P<0.05$). The other three systems followed in this order: Planmeca, Digora and Trophy, with the differences between them all being statistically significant ($P<0.05$). In conclusion, CCD sensors most often could not be positioned anteriorly enough to display the canine and 1st premolar in a bitewing examination, while distal surfaces of the most posterior molars were often missing on Digora images. DenOptix PSP plates were the most comfortable for the patients. The authors tried to use the different tested sensors in a rotational model to ensure that each sensor was used once in each place. However, the order of using these sensors may have affected the patients' response as the patient may be more exhausted with the last sensor used in his/her mouth and this would probably have a negative affect on the patient's response.

Versteeg CH et al compared CCD-image receptor (Sidexis) with conventional films. They used fifty teeth as the study sample [71]. Radiographs from all areas of the jaws were exposed by three radiologists using either size 1 or size 2 films and the Sidexis direct digital dental radiography system with the appropriate film holders. Image quality was assessed by two radiologists using the following nine individual criteria: (1) correct horizontal placement, (2) crown of tooth completely visible, (3) 4 mm area of bone around apex, (4) Parallel with occlusal surface, (5) correct horizontal angulation, (6) tooth upright, (7) correct vertical angulation, (8) no cone cutting, (9) remaining factors: no film bending, superimposition of anatomical structures or unsharpness, correct processing and no other errors of image quality. Each radiograph was also given an overall rating as: 1. excellent (no errors present), 2. acceptable (errors present which did not detract from the diagnostic quality), 3. unacceptable (errors present which made the radiograph diagnostically unacceptable). MANOVA statistics were based on the mean of the nine criteria for each exposure. The exposures were divided into three time periods: exposures 1 to 17, exposures 18 to 34 and exposures 35 to 50. The variables for MANOVA were: imaging technique (film or sensor), image sequence (film-sensor or sensor-film), period, technician and radiologist. Results showed a significant difference between film and sensor exposures ($P < 0.014$). Six percent of dental films required retakes compared with 28% with the sensor. The authors concluded that periapical radiography with a CCD sensor leads to more errors and thus more retakes than conventional films.

1.3.5 Digital imaging fiber-optic transillumination (DIFOTI):

Digital imaging fiberoptic transillumination (DIFOTI) was developed by Schneiderman A.H. et al who conducted a study at University of Medicine and Dentistry of New Jersey, Newark, USA to explain and assess this new diagnostic method [20]. Fifty extracted teeth (16 incisors, 8 canines, 12 premolars and 14 molars), with and without caries, were used to evaluate this diagnostic tool. Each tooth was subjected to visual inspection by 2 experts, under x4 magnification, explorer and histological sections. The caries types included incipient and frank caries near approximal, smooth, occlusal and root surfaces. DIFOTI images of the 50 teeth were acquired systematically; six images were taken for each incisor and canine, obtained with different controlled, repeatable camera/illuminator viewing geometries. With respect to the tooth, the CCD camera was diametrically opposite to the illuminator fiber and coaxial with it, three angles of incidence were used, each with facial and lingual illumination. An additional (seventh) image was acquired of the transilluminated occlusal surface of each premolar and molar, with illuminator fiber directed at the lingual-cervical area. For comparison, conventional radiographs (with Ektaspeed plus films) of the same 50 teeth were produced using an x-ray unit operated at 70 kVp, 7 mA, at 16 impulses. Five expert clinicians read the radiological film images, four of them were trained to read DIFOTI images in a 2-hour session on the principles of the method. The dentist's diagnostic performance, using DIFOTI and radiological images was scored against the gold standard (the expert clinicians scoring) to determine sensitivity and specificity. Readers were asked to determine the presence (or absence) and location of caries relative to tooth surfaces. They were not asked to diagnose the caries (e.g., frank, incipient) or depth of penetration. The results showed that for approximal caries, the sensitivity of DIFOTI was more than twice

(0.69) as high as for conventional radiographs (0.31), while the specificity was 10% lower (0.73 for the DIFOTI and 0.88 for the conventional film). For occlusal caries, the sensitivity of DIFOTI was over 3 times higher, while the specificity was gain 10% lower. For facial and lingual surfaces, the DIFOTI sensitivity was more than that of conventional radiography by more than 10 times. For root caries, the sensitivities of the two techniques were similar.

Another *in-vitro* study was conducted by Sunguk Keem and Marek Elbaum at the Department of Electrical Engineering, Columbia University, to develop a method for quantitatively monitoring changes in light transmission that can be associated with clinically significant biological changes in tooth tissue [72]. They examined the relative merit, for DIFOTI images, the wavelet-coefficient domain and the spatial domain, for segmentation of the tooth of interest (TOI) within the field of view (FOV), for estimation of position and rotation of the TOI, and for quantitative determination of changes in light transmission patterns over the TOI. The same fifty extracted teeth that were used in the previous study were imaged with the DIFOTI at five different levels of light intensity. Authors concluded that The DIFOTI system provides a new imaging modality produced by fiber optical transillumination of a tooth imaged on a CCD camera and digitized for further quantitative analysis. The monitoring capability of DIFOTI was demonstrated *in-vitro* by controlling and testing the repeatability of several of the imaging parameters used to acquire the images. The intensity of the illumination light source, which had to be adjusted for each tooth individually, was identified as the parameter that is most difficult to repeat, and that is most significant for reproducibility of the transillumination image. The lesion segmentation in the wavelet representation is repeatable if done at the same resolution level (scale) on DIFOTI images of the same tooth. The wavelet representation

of the DIFOTI images achieves high sensitivity to simulated small changes introduced in the segmented lesion, while the robustness of pattern matching with respect to intensity variation is maintained.

A recent study conducted by Young DA and Featherstone JDB at University of the Pacific, School of Dentistry compared the DIFOTI to F-speed film and depth of approximal lesions [22]. Seven extracted teeth (canines and premolars) were used. The proximal surfaces of these teeth were visibly free of caries (no cavitations, white- or brown- spot lesions or any signs of demineralization or remineralization). A dental curette was used to create approximately 1mm scratches on mesial and distal surfaces of each tooth, creating 14 small "windows". These surfaces were then treated with a demineralization solution that simulates the *in-vivo* demineralization process that occurs in the mouth (the solution consisted of calcium phosphate, in an acetate buffer). Teeth were subjected to the demineralization solution for 14 weeks at 37 $^\circ$C. Every two weeks, the demineralization process was interrupted to take DIFOTI images (two images, one with the same radiograph angle and one with 45-degree angle) and bitewing radiographs (with F-speed films) using an x-ray unit set at 15 mA and 5 impulses. The radiographs were scanned manually at a high resolution (1,200 dots per inch) and evaluated using data analysis software to measure the depth of the lesion. At the 14-week period of controlled demineralization, thin longitudinal sections were made through the center of the lesion in each sample. The thin specimens were histologically analyzed using the gold standard polarized light microscopy (PLM). The PLM images were then entered into the computer and magnified to measure the depth of the lesion using the data analysis software. After the samples had been demineralized for 14 weeks the authors were not able to identify the depth of a lesion on any of the samples using DIFOTI at the bitewing-

like angle. At 45-degrees, however, DIFOTI images did successfully identify surface demineralization. The lesions were identified on 12 of the 14 samples using F-speed radiographic film. No signs of surface cavitation were detected on the lesions using visual magnification and tactile methods. An analysis of variance indicated that significant differences existed among the means for the DIFOTI, F-speed radiographic film and PLM groups at the $P < .0001$ significance level. The Tukey test showed that the DIFOTI group mean was significantly different from those of the F-speed radiographic film group and the PLM group ($P < .001$), but the radiographic film group mean and the PLM group mean were not significantly different from one another ($P > .05$). The mean depth determined by PLM was approximately 30 % higher than that determined by the radiographs. The authors concluded that DIFOTI is able detect surface demineralization at an early stage, but is not able to measure the depth of approximal lesion. Therefore, DIFOTI should not be used for assessing the depth of approximal lesions in the same manner as a clinical bitewing radiograph. This *in-vitro* study is the only one, among very few studies, that evaluated the performance of the DIFOTI in determining the depth of the approximal lesions. However, the sample size was very small (seven teeth) and the lesions were created to simulate the clinical demineralization. If more teeth were included with and without carious lesions to control the study, the results would be more reliable. Furthermore, all of the lesions, as assessed by F-speed radiography, were in the enamel only; none of the lesions penetrated the DEJ, and none of the samples were cavitated. Including deeper lesions, beyond the DEJ, would have probably added more value to the results of the study.

Clearly there is a need to determine how to interpret lesion depth using DIFOTI (if at all possible) and studies needed to determine whether DIFOTI can monitor the progress

of demineralization successfully over time [73]. However, no studies have been reported comparing DIFOTI to D-speed and digital radiography to determine the depth of class II carious lesions.

1.3.6 Logicon Caries Detector (LCD):

Logicon Caries Detector or LCD (Logicon Advanced Technology, Los Angeles, CA, USA) is newly developed software that was recently introduced to the market in conjunction with Kodak RVG sensors and its purpose is to assist the dentist in diagnosing proximal caries. Since 1984, different computerized image analysis systems were evaluated for use in caries diagnosis. However, none of these systems was available to the general dentist [18]. Pitts developed a computer-aided, software-driven, TV-based system that incorporates an image memory, recursive filtration, and 256 gray-level resolution, to detect and measure approximal enamel radiolucencies produced by natural carious lesions [12]. Few studies were conducted *in-vitro* to evaluate reproducibility of this computer-aided image analysis method [13-17]. In one of these studies, three series of radiographs depicting natural caries lesions were employed [13]. Films of 11-12-year-old schoolchildren, dental students from Hong Kong and extracted teeth were used. Each surface was "searched" three times resulting in data from 450, 600 and 180 searches, respectively. Results showed consistency in lesion detection for all but two of the 1230 searches with significant difference between the reproducibility of the two clinical series, with measurements of the Hounslow lesions being more consistent.

Heaven et al used the proximal surfaces of 13 extracted molars and premolars which were classified directly and radiographically as sound or decayed [15]. Eleven faculty dentists examined bitewing radiographs of the teeth and responded on a 5-point certainty scale, whether caries was present. Ten other faculty dentists used a computer-based

program to examine the radiographs. The sensitivity for the computer-assisted faculty was significantly ($p < 0.05$) superior or equal to the unassisted faculty group.

Wenzel A. was among the first researchers to conduct a study to evaluate the newly developed Logicon Caries Detector Program [18]. Fifty-four approximal surfaces for 130 patients (63 males and 67 females) were used. Teeth were scored by the author as: 24 surfaces (9 molars and 15 premolars) were sound, 16 surfaces (9 in molars and 7 in premolars) were scored as carious in enamel, and 14 surfaces (9 in molars and 5 in premolars) were scored as carious in dentin. All surfaces were non-restored, but 15 were adjacent to a restored occlusal surface. For each patient, one posterior bitewing was taken of the left and right side with the RVG XL sensor (Trophy Radiologie Inc). An experienced radiographer was trained in positioning the sensor for bitewing examination. The author was trained to use the program and he instructed 5 observers in the use of the program. All observers were dentists who were working or had worked in general dental practice, 1 of which had experience with digital radiography. To assess the consistency of the diagnostic outcome of the LCD program, the analysis was repeated ten times for each surface. If the program gave a warning or suggested a repeat of the analysis, this was done until the program accepted the analysis. Since there are no guidelines of where exactly to place the mouse when starting the analysis, or how wide the wedge should be as long as the borders of the enclosed approximal surface are respected, the position of the cursor was apt to vary to some degree for the ten analyses. The probability of a caries lesion was expressed in percent of the full pixel height. The two most diverging lesion probabilities (Lp_{min} and Lp_{max}) from the ten analyses were saved for enamel and dentin separately. For overlapping surfaces the manual mode analysis was selected. The 5 observers scored the 54 surfaces individually. Each surface was scored before and after

the use of LCD on a 0-3 scale (0 = sound, 1 = caries in enamel, 2 = caries in dentin less or equal than half way to pulp, 3 = caries in dentin less than or equal half way to pulp). Before the use of LCD the image could be enhanced by changing contrast, brightness and image size with the Trophy software. The lesion probability provided by LCD for each surface by each observer (Lp_{obs}) was measured in pixels and recorded in percent for enamel and dentin, the same procedure as for the consistency analysis. To quantify the variation in carious lesion probability, the difference between the two most diverging probabilities for a carious lesion (Lp_{max} - Lp_{min}) was calculated for each tooth surface in enamel and dentin separately. The difference was then calculated in pixels. It was calculated in how many of the surfaces, the difference between Lp_{min} and Lp_{max} resulted in a change by the program from an indication that caries was not present to an indication that caries was present in enamel and dentin, respectively. It tested whether there were differences between the consistency of the program for molars and premolars for overlapping and non-overlapping surfaces and for surfaces adjacent to an occlusal surface with a filling and with no filling. Observer agreement in caries diagnosis was also calculated. Results showed no statistically significant differences in consistency of the program in regards to tooth type, overlapping, surface or the presence or absence of the filling. The mean difference in center cursor position was 10 pixels. The difference in lesion probability (Lp_{max} - Lp_{min}) did not correlate to the difference in cursor position at Lp_{max} and Lp_{min}. The 5 observers changed their caries score after the use of LCD in a total of 31 surfaces. Kappa values for inter-observer agreement for caries scores before the use of LCD (Caries 1) ranged between 0.39 and 0.61 (mean = 0.47) and after the use of LCD (Caries2) between 0.37 and 0.69 (mean = 0.48). The author concluded that the LCD program

was not very consistent and the inter-observer agreement in caries diagnosis did not improve using the program.

In 2002, Wenzel A. et al conducted another *in-vitro* study to compare the diagnostic accuracy for detection of approximal caries lesions between the LCD program and human observers' assessments of the same images [74]. A total of 190 extracted were mounted in blocks with three test teeth and two non-test teeth in each block. The non-test teeth were placed at each end of the block to simulate a row of teeth in the dental arch. Each test tooth was radiographed with the RVG: an older, but widely sold sensor from 1994 "RVG_{old}" and a more recent sensor from 2000, which has a higher resolution "RVG_{new}". A 12-mm acrylic plate was placed between the tube and the tooth block to simulate soft tissue. Before starting the study, the guideline manual for how to operate Logicon was thoroughly studied by four observers. Each approximal surface was scored on the RVG_{old} and RVG_{new} images by the four observers individually. A disease severity scale of three steps was used to match the scale used in the LCD program (0=sound, 1=caries in enamel, 2=caries into dentin). The digital images were displayed on a 15-inch screen and could be enhanced by changing gamma curve, contrast, brightness, and image size. At a separate session some weeks later, the observers were asked to run the LCD program both on RVG_{old} and RVG_{new} images. For validation of the true status of caries, the teeth were serially sectioned and examined under a microscope (x12.5–16.0 magnification). Caries was defined to be present if a demineralization (opaque-white to dark brown color change) was observed in an area predisposed to caries. The histological assessment was performed using the same disease scale used for the radiographic images. Sensitivities, specificities, positive and negative predictive values were thereafter calculated for two disease thresholds: disease=caries in enamel and dentin (scores 1+2)

and disease=caries only in dentin (score 2). Differences between sensitivities and specificities were tested using McNamara's x2 test and the predictive values using x2 test with correction for continuity. A total of 363 approximal surfaces were evaluated. Some observers were, in a few cases, unable to analyze a premolar surface with LCD because the program failed to detect the border between enamel and dentin and thus refused the analysis. Results showed that specificities were lower for all observers using LCD on both types of RVG images than when the observers themselves assessed the RVG images. The differences were statistically significant for three of the observers on either one or both types of RVG images. The authors concluded that the LCD caries detection program is less accurate than human observers' assessments of caries in approximal surfaces on the same radiographs. The results of this study were discussed by Gakenheimer, one of the LCD inventors, and he claimed that the authors did not follow the manufacturer's instructions in some steps when they used the program which raised questions about the value of the authors' laboratory study to practicing dentists [75].

Gakenheimer evaluated the program on Trophy's RVG-4 sensor in a clinical study [76]. Eighteen general practitioners from throughout the eastern and western United States, including dentists in private practice and dentists in the faculty group practice at UCLA (LA, California) were trained by the author to participate in the study. Ninety patients (with 175 surfaces) ranging in age from 10 to 79 years and from different racial groups participated in the study. Cases included incipient caries (caries penetrating less than halfway into the enamel) and moderate to advanced caries (penetrating up to halfway through the dentin). The obvious (severe) cases of caries where the lesion was readily seen radiographically to penetrate more than halfway through the dentin were excluded. Qualifying surfaces with lesions were identified by each participating dentist as test

surfaces. The dentists were asked to include, whenever possible, a control surface with the test surface. These were surfaces that initially were interpreted (before being analyzed with LCD) to be caries-free and that would be exposed to direct visual and physical examination. Generally, the control surfaces were the surfaces adjacent to the test surfaces. Each dentist performed an initial evaluation of test and control surfaces without the LCD program. This included a visual evaluation of the radiographs for the presence of a lesion in the enamel and dentin and an initial judgment regarding treating or not treating the lesion. The dentists then applied the LCD to the radiographic images of both test and control surfaces and performed a second evaluation of these surfaces and treatment was based on this second evaluation. If a surface was not treated, then that surface and the associated control surface were not included in the study. If a test surface was treated, then the dentist determined its true lesion status during cavity preparation by recording the lesion's percentage of penetration into the enamel and its depth, in millimeters, of penetration into the dentin. For validation purposes, the dentists took intraoral camera images of all prepared and exposed surfaces. Each dentist looked at roughly 10 surfaces. Sensitivity, specificity and accuracy for dentin caries diagnosed by each dentist both before and after using the LCD were analyzed. The mean sensitivity among all the dentists before they used LCD was 70.3 % and 90.5% after they used the program. An unweighted paired *t* test was performed to control the dentist variability and the Wilcoxon test. Results showed significant improvement in sensitivity associated with the use of the LCD program. Specificity for all dentists before using the LCD was 88.6 % and after using it was 88.3 %, with a difference of -0.3 %. The mean accuracy for all dentists before using the LCD was 75.6 % and 88.3% after using it with a difference of 12.7 %. The author concluded that there is improvement in diagnostic accuracy

associated with the use of the LCD program and this improvement is due entirely to the improvement in sensitivity. In this clinical investigation, 18 practitioners performed the study. This may raise question in regard to the possibility to achieve inter-examiner reliability. The validation method used here was the clinical measurement of the caries extension. However, no details were presented about the procedure and way of measuring the caries extension.

Kang B-C et al evaluated the performance of the LCD using RVG-4 and RVG-ui sensors by comparing results of each detector to the results of clinical and histological examinations [77]. Thirty six extracted teeth (3 incisors, 3 canines, 18 premolars and 12 molars) were mounted 2 in a block of plaster to form 18 blocks. The clinical appearance of the proximal surfaces ranged from sound to opaque white or brown discoloration with or without a cavity. A plaster mold was made to accommodate and reposition the RVG-4 (also known as RVG-XL for the sensor size used) or RVG-ui size #2 sensors. The sensor was set on an optical bench and held in the plaster mold. A 1 cm thick acrylic plate was placed between the cone and the block to simulate soft tissue scatter. X-ray was operated at 70 kVp and 8 mA. Images were obtained with both sensors (8-bit for the RVG-4 and 12-bit for the RVG-ui). The exposure time ranged from 0.05-0.12 seconds for the RVG-ui sensor and 0.12-0.23 seconds for RVG-4 sensor. The proximal surfaces of each image were analyzed 3 times both with manual and automatic modes for proximal caries detection utilizing the LCD program, which resulted in a total of 12 analyses per proximal surface. LCD analysis was performed by an experienced examiner trained by the manufacturer of the system. The teeth were then separated from the plaster blocks. Using a no. 5 explorer under a 500 g load, the depths of the white or discolored and cavitated carious lesions were measured. Lesions were classified clinically as follows: 0

= sound proximal tooth surface, 1 = non-cavitated, white opaque, or brownish discolored caries, 2 = minimally cavitated carious lesion with measured depths exceeding 0.1 mm but not reaching 0.2 mm, 3 = cavitated caries with depths of 0.2 mm or greater depth (up to 1.6 mm). To validate the depth of the lesions histologically, the teeth were sectioned mesiodistally and examined under 15 x magnification. Carious demineralization, defined as opaque or brownish discolorations, was scored on a scale from 0 to 2, where 0 = sound, 1 = caries restricted to enamel, 2 = caries extending into dentin. The histological presentation of the caries in enamel and dentin was compared to the LCD analysis-aided decision and sensitivities and specificities derived were compared using the Chi-square test. The histological treatment decision criteria for dentin extension were compared with clinical treatment decision criteria of cavitation in terms of sensitivity and specificity. For the presence or absence of the caries the overall proximal caries diagnostic sensitivity ranges were 0.50-0.80. Overall specificity ranges were 0.35-0.88. The sensitivities and specificities for manual and the automatic modes of analysis with LCD for the RVG -4 or RVG-ui images were not significantly different ($p< 0.05$). The sensitivity of the LCD to detect caries penetration in dentin ranged from 0.43-0.79. The specificity range was 0.51-0.81. Comparing manual and the automatic modes of analysis and RVG-4 versus RVG-ui images, the sensitivity differences for LCD were not significantly different ($p< 0.05$). The specificity with the automatic mode of the LCD analysis of RVG-ui images was significantly greater than that for the LCD manual analysis of RVG-ui images ($p< 0.05$). However, the specificity of the LCD automatic analysis of RVG-ui images was not significantly greater than that determined for either manual or automatic analysis of RVG-4 images ($p< 0.05$). The authors concluded that the overall sensitivities and specificities regarding both caries diagnosis and the treatment decision showed no

difference in diagnostic performance between RVG- and RVG-ui sensors for the LCD and that Logicon Caries Detector should be used merely as an adjunct to traditional diagnostic methods to identify proximal carious lesions and to determine the appropriate treatment.

1.4 REFERENCES:

1. Thuthy KH, Ireland EJ. A comparison of the visibility of caries on Kodak F-speed (Insight) and D-speed (Ultra-speed) films. LDA J 2001; 60(2):31-2.

2. Chong MJ, Seow WK, Purdie DM. Visual-tactile examination compared with conventional radiography, digital radiography, and diagnodent in diagnosis of occlusal occult caries in extracted premolars. Pediatric Dent 2003; 25(4):341-9.

3. Parks ET, Williamson GF. Digital radiography: An overview. J Contemp Dent Pract 2002; 3(4):23-39.

4. Brennan J. An introduction to digital radiography in dentistry. Journal of Orthodontics 2003; 29(1):66-9.

5. Sanderink GC, Miles DA. Intraoral detectors. CCD, CMOS, TFT, and other devices. Dent Clin North Am 2000; 44(2):249-55, v.

6. Tyndall DA, Ludlow JB, Platin E, Nair M. A comparison of Kodak Ektaspeed Plus film and the Siemens Sidexis digital imaging system for caries detection using receiver operating characteristic analysis. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1998; 85(1):113-8.

7. Wenzel A. Digital imaging for dental caries. Dent Clin North Am 2000; 44(2):319-38, vi.

8. Hintze H, Wenzel A, Jones C. In-vitro comparison of D- and E-speed film radiography, RVG, and Visualix digital radiography for the detection of enamel approximal and dentinal occlusal caries lesions. Caries Res 1994; 28(5):363-7.

9. Nair MK, Nair UP. An in-vitro evaluation of Kodak Insight and Ektaspeed Plus film with a CMOS detector for natural proximal caries: ROC analysis. Caries Res 2001; 35(5):354-9.

10. Syriopoulos K, Sanderink GC, Velders XL, Van Der Stelt PF. Radiographic detection of approximal caries: a comparison of dental films and digital imaging systems. Dentomaxillofacial Radiol 2000; 29(5):312-8.

11. Uprichard KK, Potter BJ, Russell CM, Schafer TE, Adair S, Weller RN. Comparison of direct digital and conventional radiography for the detection of proximal surface caries in the mixed dentition. Pediatric Dent 2000; 22(1):9-15.

12. Pitts NB. Detection and measurement of approximal radiolucencies by computer aided image analysis. Oral Surg Oral Med Oral Pathol 1984; 58(3):358-66.

13. Pitts NB, Renson CE. Reproducibility of computer-aided image-analysis- derived estimates of the depth and area of radiolucencies in approximal enamel. J Dent Res 1985; 64(10):1221-4.

14. Heaven TJ, Firestone AR, Feagin FF. Computer-based image analysis of natural approximal caries on radiographic films. J Dent Res 1992; 71:846-9.

15. Heaven TJ, Weems RA, Firestone AR. The use of a computer-based image analysis program for the diagnosis of approximal caries from bitewing radiographs. Caries Res 1994; 28:55-8.

16. Firestone AR, Sema D, Heaven TJ, Weems RA. The effect of a knowledge- based, image analysis and clinical decision support system on observer performance in the diagnosis of approximal caries from radiographic images. Caries Res 1998; 32:127-34.

17. Duncan RC, Heaven T, Weems RA, Firestone AR, Greer DF, Patel JR . Using computers to diagnose and plan treatment of approximal caries detected in radiographs. J Am Dent Assoc 1995; 126(7):873-82.

18. Wenzel A. Computer-automated caries detection in digital bitewings: consistency of a program and its influence on observer agreement. Caries Res 2001; 35(1):12-20.

19. Pretty IA, Maupome G. A closer look at diagnosis in clinical dental practice: Part 5. Emerging technologies for caries detection and diagnosis. J Can Dent Assoc 2004; 70(8): 540, 540a-540i.

20. Schneiderman A, Elbaum M, Shultz T, Keem S, Greenebaum M, Driller J. Assessment of dental caries with digital imaging fiber-optic transillumination (DIFOTI): In-vitro study. Caries Res 1997; 31:103-10.

21. Friedman J, Marcus MI. Transillumination of the oral cavity with use of the fiber optics. J Amer Dent Assoc 1970; 80:801-9.

22. Young DA, Featherstone JDB. Digital fiber-optic trans-illumination, F-speed radiographic film and depth of approximal lesions. J Amer Dent Assoc 2005; 136:1682-7.

23. Kidd EAM, Pitts NB. A reappraisal of the value of the bitewing radiograph in the diagnosis of posterior approximal caries. Br Dent J 1990; 169:195-200.

24. Mann J, Pettigrew JC, Revach A, Arwas JR, Kochavi D. Assessment of the DMF-S index with the use of bitewing radiographs. Oral Surg Oral Med Oral Pathol 1989; 68(5):661-5.

25. De Vries HC, Ruiken HM, Konig KG, Van 't Hof MA. Radiographic versus clinical diagnosis of approximal carious lesions. Caries Res 1990; 24(5):364-70.

26. Hintze H. Screening with conventional and digital bite-wing radiography compared to clinical examination alone for caries detection in low-risk children. Caries Res 1993; 27(6):499-504.

27. Jessee SA, Makins SR, Bretz WA. Accuracy of proximal caries depth determination using two intraoral film speeds. Gen Dent 1999; 47(1):88-93.

28. Marthaler TM, Germann M. Radiographic and visual appearance of small smooth surface carious lesions studied on extracted teeth. Caries Res 1970; 4:224-42.

29. Rugg-Gunn AJ. Approximal carious lesions: a comparison of the radiological and clinical appearances. Br Dent J 1972; 133:481-4.

30. Bille J, Thylstrup A. Radiographic diagnosis and clinical tissue changes in relation to treatment of approximal carious lesions. Caries Res 1982; 16: l-6.

31. Mejare I, Grondah, H, Carlstedt K, Grever A, Ottosson E. Accuracy at radiography and probing for the diagnosis of proximal caries. Scand J Dent Res 1985; 93:178-84.

32. Espelid I, Tveit AB. Clinical and radiographic assessment of approximal carious lesions. Acta Odontol Scand 1986; 44:31-7.

33. Mejare I, Malmgren B. Clinical and radiographic appearance of proximal carious lesions at the time of operative treatment in young permanent teeth. Scand J Dent Res I986; 94:19-26.

34. Pitts NB, Rimmer PA. An *in-vivo* comparison of radiographic and directly assessed clinical caries status of posterior approximal surfaces in primary and permanent teeth. Caries Res 1992; 26:146-52.

35. De Araujo FB, Rosito DB, Toigo E, Dos Santos CK. Diagnosis of approximal caries: radiographic versus clinical examination using tooth separation. Am J Dent 1992; 5:245-8.

36. Akpata ES, Farid MR, Al-Saif K, Roberts EAU. Cavitation at radiolucent areas on proximal surfaces of posterior teeth. Caries Res 1996; 30:313-6.

37. Gungor K, Erten H, Akarslan ZZ, Celik I, Semiz M. Approximal carious lesion depth assessment with insight and ultraspeed films. Oper Dent 2005; 30(1):58-62.

38. Jacobsen JH, Hansen B, Wenzel A, Hintze H. Relationship between histological and radiographic caries lesion depth measured in images from four digital radiography systems. Caries Res 2004; 38:34–8.

39. Van Der Stelt PF. Filmless imaging, the uses of digital radiography in dental practice. J Amer Dent Assoc 2005; 136:1379-87.

40. Mouyen F, Benz C, Sonnabend E, Lodter JP. Presentation and physical evaluation of RadioVisioGraphy. Oral Surg Oral Med Oral Pathol 1989; 68(2):238-42.

41. Russel M, Pitts NB. Radiovisiographic diagnosis of dental caries: initial comparison of basic mode videoprints with bitewing radiography. Caries Res 1993; 27(1):65-70.

42. Wenzel A, Borg E, Hintze H, Grndahl H-G. Accuracy of caries diagnosis in digital images from charge-coupled device and storage phosphor systems: an *in-vitro* study. Dentomaxillofacial Radiol 1995; 24: 250-4.

43. Gotfredsen E, Wenzel A, Grondahl HG. Observers' use of image enhancement in assessing caries in radiographs taken by four intra-oral digital systems. Dentomaxillofacial Radiol 1996, 25(1): 34-8.

44. Araki K, Endo1 A, Okano T. An objective comparison of four digital intra-oral radiographic systems: sensitometric properties and resolution. Dentomaxillofacial Radiol 2000; 29: 76-80.

45. Farman AG, Farman TT. A comparison of 18 different x-ray detectors currently used in dentistry. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2005; 99(4): 485-9.

46. Matt GD, McClanahan SB. Dental Imaging - advances in conventional and digital radiography. Clinical updates National Naval Dental Center J 2003; 25 (4): 7-8.

47. Tjelmeland EM, Moore WS, Hermesch CB, Buikema DJ. A perceptibility curve comparison of Ultra-speed and Ektaspeed Plus films. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1998; 85(4):485-8.

48. Thunthy KH, Weinberg R. Sensitometric comparison of Kodak Ektaspeed Plus, Ektaspeed, and Ultra-speed Dental Films. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1995; 79(1):114-6.

49. Hintze H, Christoffersen L, Wenzel A. In-vitro comparison of Kodak Ultra-speed, Ektaspeed, and Ektaspeed Plus, and Agfa M2 Comfort dental x-ray films for the detection of caries. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1996; 81(2):240-4.

50. Ardakani FE, Davari A, Goodarzipour D, Goodarzipour K, Fallahzadeh H. Evaluation of the diagnostic advantage of intraoral D and E film for detecting interproximal caries. J Contemp Dent Pract 2004; 5(4):58-70

51. Wong A. Monsour PA, Moule AJ, Basford KE. A comparison of Kodak Ultraspeed and Ektaspeed plus dental X-ray films for the detection of dental caries. Aust Dent J 2002; 47(1):27-9.

52. Tamburus JR, Lavrador MA. Radiographic contrast. A comparative study of three dental X-ray films. Dentomaxillofacial Radiol 1997; 26(4):201-5.

53. Bernstein DI, Clark SJ, Scheetz JP, Farman AG, Rosenson B. Perceived quality of radiographic images after rapid processing of D- and F-speed direct-exposure intraoral x-ray films. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2003; 96(4):486-91.

54. Sheaffer JC, Eleazer PD, Scheetz JP, Clark SJ, Farman AG. Endodontic measurement accuracy and perceived radiograph quality: effects of film speed and density. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2003; 96(4):441-8.

55. Schiff T, Solomon BE. An in-vivo evaluation of the diagnostic quality Ultra-speed versus Insight intraoral dental film. J Contemp Dent Pract 2004; 5(4):50-7.

56. Farman TT, Farman AG. Evaluation of a new F speed dental x-ray film. The effect of processing solutions and a comparison with D and E speed films. Dentomaxillofacial Radiol 2000; 29(1):41-5.

57. Ludlow JB, Platin E, Mol A. Characteristics of Kodak Insight, an F-speed intraoral film. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2001; 91(1):120-9.

58. Price C. Sensitometric evaluation of a new F-speed dental radiographic film. Dentomaxillofacial Radiol. 2001; 30(1):29-34.

59. Ludlow JB, Abreau Jr M, Mol A. Performance of a new F-speed film for caries detection. Dentomaxillofacial Radiol 2001; 30(2):110-3.

60. Button TM, Moore WC, Goren AD. Causes of excessive bitewing exposure: results of a survey regarding radiographic equipment in New York. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1999; 87(4):513-7.

61. Ilguy D, Ilguy M, Dincer S, Bayirli G. Survey of dental radiological practice in Turkey. Dentomaxillofacial Radiol 2005; 34(4):222-7.

62. Svenson B, Soderfeldt B, Grondahl HG. Attitudes of Swedish dentists to the choice of dental X-ray film and collimator for oral radiology. Dentomaxillofacial Radiol 1996; 25(3):157-61.

63. Salti L, Whaites EJ. Survey of dental radiographic services in private dental clinics in Damascus, Syria. Dentomaxillofacial Radiol 2002; 31(2):100-5.

64. Tugnait A, Clerehugh V, Hirschmann PN. Radiographic equipment and techniques used in general dental practice. A survey of general dental practitioners in England and Wales. J Dent 2003; 31(3):197-203.

65. Haak R, Wicht MJ, Noack MJ. Conventional, digital and contrast-enhanced bitewing radiographs in the decision to restore approximal carious lesions. Caries Res 2001; 35(3):193-9.

66. Erten H, Akarslan ZZ, Topuz O. The efficiency of three different films and radiovisiography in detecting approximal carious lesions. Quintessence Int 2005; 36(1):65-70.

67. White SC, Yoon DC. Comparative performance of digital and conventional images for detecting proximal surface caries. Dentomaxillofacial Radiol 1997; 26(1):32-8.

68. De Araujo EA, Castilho JC, Medici Filho E, De Moraes ME. Comparison of direct digital and conventional imaging with Ekta speed Plus and Insight films for the detection of approximal caries. Am J Dent 2005; 18(4):241-4.

69. Wenzel A, Frandsen E, Hintze H. Patient's discomfort and cross-infection control in bitewing examination with a storage phosphor plate and a CCD-based sensor. J Dent 1999; 27(3):243-6.

70. Bahrami G, Hagstrom C, Wenzel A. Bitewing examination with four digital receptors. Dentomaxillofacial Radiol 2003; 32:317-21.

71. Versteeg CH, Sanderink GC, van Ginkel FC, van der Stelt PF. An evaluation of periapical radiography with a charge-coupled device. Dentomaxillofacial Radiol 1998; 27(2):97-101.

72. Keem S, Elbaum M. Wavelet representations for monitoring changes in teeth imaged with digital imaging fiber-optic transillumination. IEEE Trans Med Imaging 1997; 16(5):653-63.

73. Young D.A. New caries detection technologies and modern caries management: Merging the strategies. Gen Dent 2002; 50:320-31.

74. Wenzel A, Hintze H, Kold LM, Kold S. Accuracy of computer-automated caries detection in digital radiographs compared with human observers. Eur J Oral Sci 2002; 110:199–203.

75. Gakenheimer DC. Computer-automated caries detection tools: A big payoff is possible when user judgment is combined with the tool. Letter to the editor. Eur J Oral Sci 2003; 111:179–81.

76. Gakenheimer DC. The efficacy of a computerized caries detector in intraoral digital radiography. J Amer Dent Assoc 2002; 883-90.

77. Kang B-C, Scheetz JP, Farman AG. Computer-aided proximal caries diagnosis: Correlation with clinical examination and histology. Korean J Oral Maxillofac Radiol 2002; 32:187-94.

Chapter 2

A Comparison of the Clinical Axial Extension of Class II Carious Lesions with Different Diagnostic Images

2.1 ABSTRACT:

Statement of problem: Multiple laboratory studies had shown that bitewing radiographs tend to underestimate the actual extension of interproximal carious lesions. However, very few clinical studies have been performed to evaluate the newly introduced digital diagnostic imaging systems [direct digital radiography (DDR) and digital imaging fiber-optic transillumination (DIFOTI)] to estimate the extension of class II carious lesions.

Purpose: The purpose of this study was to compare the axial extension of class II carious lesions in different diagnostic images (D-speed film, and RVG-6000 DDR sensor) with the true clinical extension and correlate the findings of the two radiographic images to the results of the DIFOTI examination. This study also evaluated the patient's discomfort during the radiographic bitewing examination with two different radiographic sensors (D-speed film and RVG-6000 size 2 sensor).

Materials and methods: Fifty one interproximal carious lesions in posterior teeth were utilized. Each carious lesion was examined visually and with the DIFOTI, then the tooth was exposed to the Ultraspeed (D-speed) and the complementary metal oxide silicone (CMOS) based digital sensor (Kodak RVG-6000 size 2 DDR sensor). The true caries depth was validated clinically from intra operative photographs that captured the cross-sectional views of the lesion at its deepest point during the step wise dissection of the lesion. During the operative procedures the cavitation status was recorded. A 3-mm segment sectioned from the tip of a periodontal probe was placed on the occlusal surface of the decayed tooth or the adjacent tooth to act as a reference instrument before exposing the teeth to the radiographs and during the operative procedure. Two clinicians scored the radiographic images. DIFOTI images were scored using a 4-point categorical scale. The carious lesion extension from the dentino-enamel junction (DEJ) was measured from each radiograph in mm and the results were compared to the true clinical depth using the one way ANOVA, Tukey test, and simple linear regression analyses.

Results: It was found that both radiographic sets underestimated the clinical depth (p<0.0001) with the RVG-6000 images being significantly closer to the actual depth of the lesion than the D-speed (p=0.0031). DIFOTI significantly improved the estimation of the size of the lesion when used in conjunction with D-speed (p=0.0039) and RVG-6000 (p=0.0024) images. Fifteen lesions (35%) were cavitated with clinical depth ranging from 1.1 to 2 mm from the DEJ.

Conclusions: Both radiographs underestimated the true carious depth with the RVG-6000 images being more accurate in estimating the caries extension especially in small lesions. DIFOTI helps to improve the diagnosis of small lesions especially when used in conjunction with bitewing radiography. D-speed film was less unpleasant than RVG-6000 size 2 sensor.

2.2 INTRODUCTION:

The correct estimation of the interproximal caries extension for posterior teeth continues to be a difficult clinical task even for experienced clinicians due to the limitations of direct examination and evaluation of the interproximal surfaces of these teeth. For more than 80 years, conventional bitewing radiography has been considered to be an indispensable tool in detecting interproximal lesions in posterior teeth. It has been found that conventional films reveal twice as many approximal caries lesions as can be discovered clinically [1-4]. D-speed (Kodak Ultra-speed) film has been manufactured since the 1940s. Because of its superior diagnostic quality D-speed films became the "gold standard" for bitewing radiographs to which all subsequent radiographs have been compared [5].

Since digital radiography was introduced to the market more than two decades ago, more clinicians are replacing conventional radiographs with digital radiography [6]. Intraoral digital radiography offers several advantages over conventional radiography, as was shown by several studies. Theses advantages include: low radiation exposure, elimination of film developing, immediate availability of the generated image for evaluation on the computer screen and digital manipulation to enhance viewing. However, the primary disadvantages of the digital systems include the rigidity and thickness of the sensors, the high initial system cost and unknown sensor lifespan [7].

The first digital x-ray sensor for use in dentistry was introduced to the dental profession in the mid-1980s by Francis Mouyen (RVG, Trophy Radiologie, Croissy Beaubourg, France [now Trophy, a Kodak Company, Rochester, N.Y.]). With the rapid development in digital technology, digital radiographic systems are more commonly used

by dental practitioners. The RVG sensors have been developed over the past 25 years until Eastman Kodak Company recently launched their new digital sensor RVG-6000 with true resolution of more than 20 line pairs/mm (lp/mm) and using the new super complementary metal oxide silicone (CMOS) technology with optical fiber.

Several studies have been conducted to compare the diagnostic efficacy of different digital radiographic systems [charged couple device (CCD), CMOS based solid state sensors and/or phosphor storage plate (PSP) based sensors] with conventional radiographs to detect the proximal carious lesions. The majority of the studies found these systems to perform similarly [8-12]. However, most of these studies were conducted based on *in-vitro* testing. Comparing the actual depth of the interproximal caries to the radiographical extension of the lesions has been performed in multiple laboratory studies.

Illuminating teeth to determine the presence of demineralization or caries is a novel method to detect and monitor dental caries. The digital imaging fiber-optic transillumination (DIFOTI) system (Electro-Optical Sciences, Irvington, NY; USA), has digitized this technology which received the FDA approval in 1999. The principle behind transilluminating teeth is that demineralized areas of enamel or dentin scatter light (in this case a high intensity white light) more than sound areas [13]. DIFOTI technology uses light, CCD camera, and computer-controlled image acquisition. The advantages of DIFOTI over radiography include: no ionizing radiation, no film and higher sensitivity in detection of early lesions not apparent to x-ray, as demonstrated *in-vitro* [14]. Only one recent *in-vitro* study has compared the interproximal caries depth on images taken with DIFOTI, and F-speed films to the actual histological depth of the lesion and found that DIFOTI was able to detect surface demineralization at an early stage, but was not able to measure the depth of an approximal lesion [15].

Most of the *in-vivo* studies conducted comparing the radiographic and clinical appearance of class II carious lesions have focused on the cavitation status of the proximal surface, not the actual *depth* of the lesion. In fact, there were no clinical studies found that attempted to measure the *in-situ* depth of class II carious lesions clinically and correlate the findings with that of digital, Ultraspeed radiographs, and DIFOTI.

Since digital radiography provides less radiographic exposure than conventional films, as documented in the literature, an investigation of the clinical performance of the digital systems to determine the depth of interproximal lesions and compare that with the most commonly accepted bitewing radiograph, Ultraspeed film, and the new radiation-free diagnostic method, DIFOTI, will provide important information to clinicians to help them make more accurate diagnostic decision when restoring class II carious lesions.

The **Objectives** of this study were:

1. To compare the axial extension of class II carious lesions in different diagnostic images (D-speed film, and RVG-6000 size 2 DDR sensor) to the true clinical extension and correlate the findings of the two radiographic images to the results of the DIFOTI examination.

2. To evaluate the patient's discomfort while exposing the two different radiographic sensors (D-speed film and the RVG-6000 direct digital sensor).

2.3 MATERIALS AND METHODS:

2.3.1 Study Subjects:

Fifty three class II carious lesions were included in this study. Approval for the project from the local institutional review board (I.R.B.) was obtained. Each patient was asked to sign a consent and HIPAA forms to participate in the study after explaining the scope of the study to him/her. A full medical and dental history was reviewed at the screening visit. Patients who had one or more class II carious lesion(s) that had been treatment planned for restoration(s) were recruited for the project. The participating patients received the proper restorative treatment at the University Of Michigan School Of Dentistry at no charge.

2.3.2 Inclusion Criteria:

When selecting the patients to participate in the study, specific inclusion criteria were: 1. Dental caries should have progressed to a point that it must be restored (at or beyond the DEJ); 2. The surface in which the caries was found must be in contact with the proximal surface of the adjacent tooth. Primary teeth, teeth with frank cavitation, pulpal symptoms or severe rotation were excluded.

2.3.3 Clinical Examination:

The intra-oral clinical examination included visual, and DIFOTI examinations. These procedures were performed by the primary investigator and the results were recorded in the patient's data form.

2.3.3a Visual Examination:

The tooth with a proximal carious lesion was cleaned using prophy paste and rubber cup and then carefully cleaned with cotton pellets and dental floss. After drying the tooth

with stream of air, the area of each lesion was evaluated from the buccal, lingual, and occlusal aspects under direct and reflected light using a standard dental mirror and operatory light. The appearance of a dark shadow or opaque "halo" under the enamel of the marginal ridge or in the area of the proximal contact was considered indicative of presence of caries. Findings from the visual examination were recorded on the patient's data form as halo "present" or "absent".

2.3.3b DIFOTI Examination:

DIFOTI examination was performed after the visual examination and with the dental operatory light turned off. The tooth was dried and isolated with cotton rolls. Then DIFOTI system (Electro-Optical Sciences, Inc., Irvington, NY, USA) was used according to the manufacturer's instructions (Fig 1). The proximal mouthpiece was mounted on the handpiece. One side of the mouth piece has a relay image mirror that sends the transmitted light to the CCD camera in the handpiece, while the other side is the source of the fiber-optic light. The mouth piece was placed over the tooth with the proximal lesion allowing light to shine from the buccal surface in the proximal contact, through the tooth, and captured on the lingual surface and then another image was taken from the lingual surface (Fig 2). The image appeared instantly in real time on the computer monitor and the images were saved on the patient record.
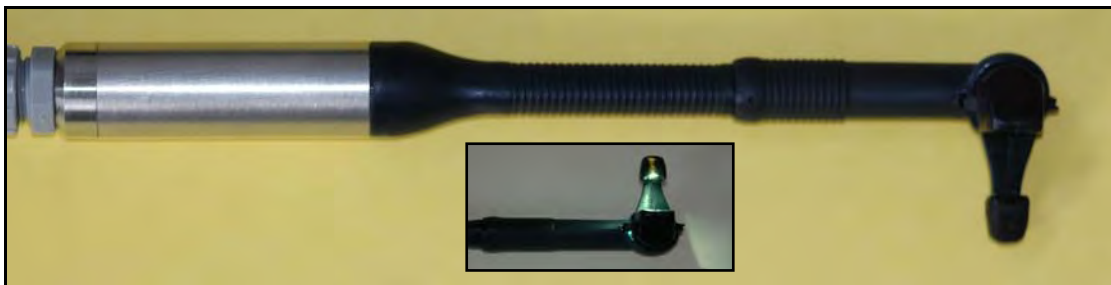
Fig 1. DIFOTI ™ system with the interproximal tip mounted on the handpiece.
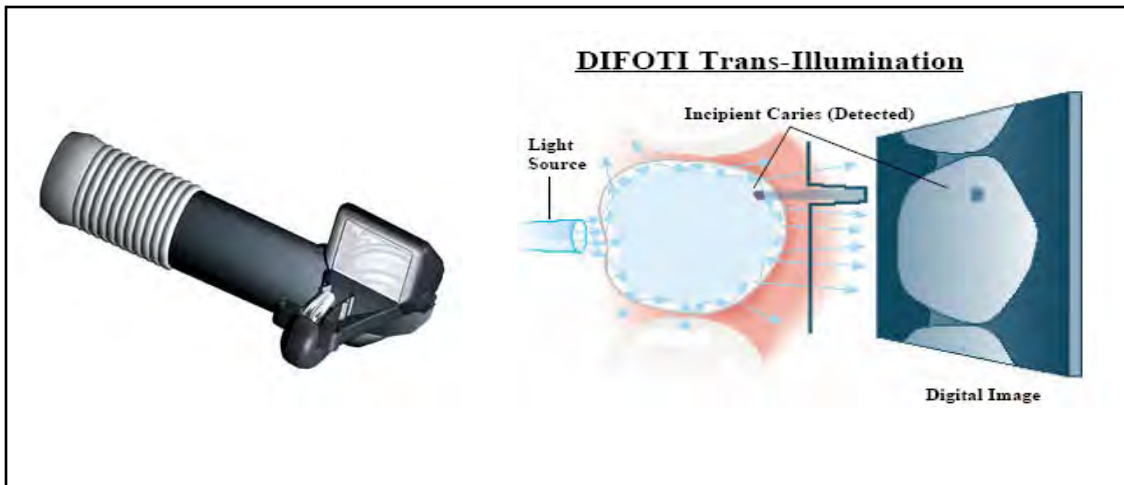
Fig 2. DIFOTI, working mechanism, (Courtesy: www.difoti.com).

2.3.4 Radiographs:

On the day of treatment two quality pre-operative bitewing radiographs for the carious lesion were exposed. Before exposing the tooth with the proximal decay to the radiographs, a measurement device (3-mm segment sectioned from the tip of a periodontal probe) was bonded to the occlusal surface of the decayed tooth or the adjacent tooth to act as a reference instrument (Fig 3). The conventional radiograph was then taken using size 2 Kodak Ultraspeed (D-speed), double pack film (Kodak Company, Rochester, NY, USA) exposed with Gendex GX-770 x-ray unit (Gendex Coperation, Des Plaines, IL, USA) following the posted guidelines (70 kVp, 7Ma, 25 pulses). One film was used for the study while the duplicate was placed in the patient record. The unit utilizes an 8-inch, round cone that was placed in contact with the ring of the RINN XCP film holding system (Dentsply Company, York, PA, USA) which was placed in contact with the patient's cheek during exposure. The digital image was made by exposing the Kodak RVG-6000 size 2 digital sensor (super CMOS sensor with optical fiber technology, 20 Line Pairs/mm, 2.76 megapixels, 45 x 32 x 8 mm outside dimensions; Kodak

Company, Rochester, NY, USA) with the same x-ray unit following the posted guidelines (70 kVp, 7Ma, 10 pulses) using RINN XCP-DS positioner (Dentsply Company, York, PA, USA). All radiographic images and films were exposed by the primary investigator using the same x-ray unit at the Graduate General Dentistry Clinic, School of Dentistry University of Michigan. The film was considered unacceptable for the study if there was an overlapping of the proximal contacts or if there was any artifact such that accurate interpretation would not be possible. In such cases another film was exposed. For patients with multiple qualified lesions, additional radiographs were exposed only if the first one did not adequately depict all of the lesions. Each conventional film was developed in an automatic roller-type processor (Gendex GXP Model 110-0096 G1, Gendex Corporation, Des Plaines, IL, USA) with self-replenishing solutions (Supermax GX solutions, Gendex Corporation, Des Plaines, IL, USA) while the digital radiographic images were saved directly to the electronic patient record.

(a)   (b)
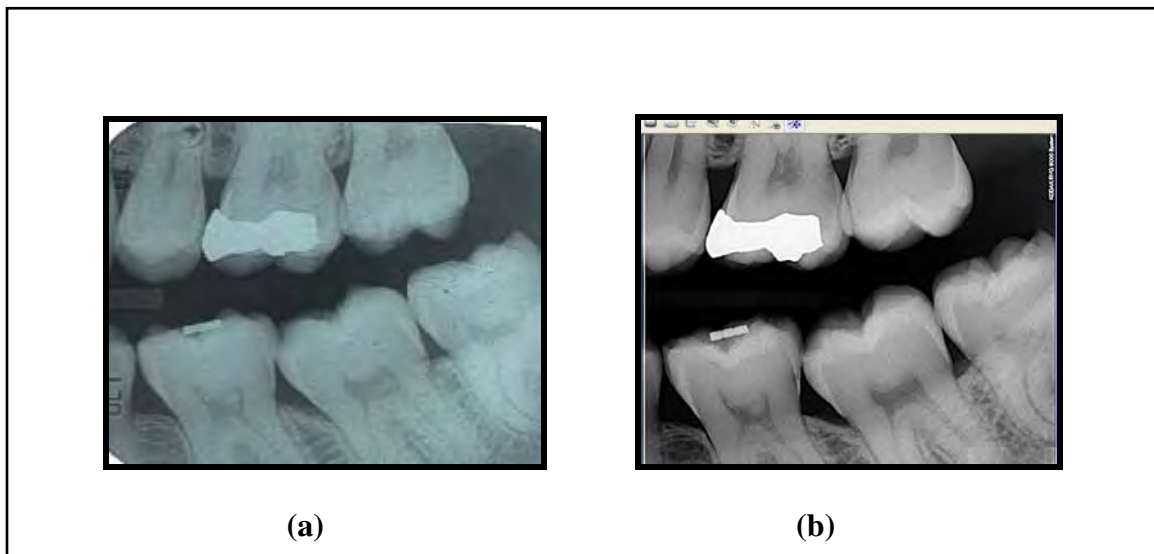
Fig 3. Interproximal lesion on the distal surface of the mandibular left first molar tooth radiographed with (a) D-speed film, and (b) RVG-6000 CMOS sensor (Note the reference device fixed to the occlusal surface of the tooth).

2.3.5 Patient's Questionnaire:

After exposing the carious tooth to the x-rays by using both radiographs, the patient was asked to fill a one page questionnaire to report any discomfort that either one or both of the sensors had caused during the radiographic examination (Fig 4). The first question evaluated the difference between the two radiographs in terms of the patient's discomfort while the second and the third questions investigated the sources of the possible patient's discomfort with each radiographic sensor.

Please check (√) on the appropriate box (es) in the following:

1. While taking X-rays A* and B:**
□ X-ray **(A)** was more comfortable than **(B)**
□ X-ray **(B)** was more comfortable than **(A)**
□ They were the same

2. What did bother you while taking x-ray (A)? You could check more than one box
□ Size of the film (too big to bite on)
□ Sharp edges of the film (it hurts when you bite)
□ Biting on this film makes me gag
□ Others, please specify _____
□ Nothing bothered me with this X-ray

3. What did bother you while taking x-ray (B)? You could check more than one box
□ Size of the film (too big to bite on)
□ Sharp edges of the film (it hurts when you bite)
□ Biting on this film makes me gag
□ Biting on the film cord is uncomfortable
□ Others, please specify _____
□ Nothing bothered me with this X-ray

*__X-ray (A):__ Conventional D-speed radiograph
**__X-ray (B):__ Digital Kodak RVG-6000 sensor

Fig 4. Patient's discomfort questionnaire.

2.3.6 Operative Procedure:

Validation of the radiographic, visual and DIFOTI examinations was attained by direct visualization of the carious lesions *in-situ* during the operative procedure. The true clinical extension of the proximal carious lesion was established by making measurements from photographs that were taken serially during the operative procedure.

2.3.6a Operative Technique:

All of the restorative treatments were performed by the primary investigator. Dental local anesthetic agent was used for all procedures. A preoperative photograph was taken with a digital camera [Nikon D70 SLR 6.1 megapixels digital camera body (Nikon Corp., Japan) with Sigma 105 mm F2.8 EX DG macro lens, and Sigma EM-140 DG Ring Flash for Nikon D70 camera (Sigma Corp., Japan)]. The teeth were isolated with rubber dam; the lesion was then accessed by a suitable carbide bur and carefully dissected in a step-wise manner down through the carious tissue. A series of occlusal intra-oral photographs was taken in an attempt to capture the cross-sectional views of the lesions at their deepest point. Before taking each photograph, the same measurement device used when exposing the tooth to the radiographs (3-mm segment sectioned from the tip of a periodontal probe) was placed in the operative field as a reference instrument. The photographic sequence was repeated at approximately 1 mm intervals until the maximum depth of the caries was exposed. The tooth was then prepared and restored with the suitable restorative material using standard acceptable procedures. No recall visits were needed in this study (Fig 5).

Fig 5. Illustration for the operative technique to expose the axial extension of the lesion.

2.3.6b Cavitation Status:

During the operative procedure, the cavitation status of the external proximal surface of the affected tooth was recorded on the patient's data form as: no cavitation, cavitation limited to enamel, or cavitation extending to dentin.

2.3.7 Data Collection and Analysis:

2.3.7a Radiographic Scoring:

Each radiographic image was scored by two experienced clinicians, each with over 25 years of clinical teaching and private practice experience.

A standard fluorescent dental viewing box (8 in. x 10 in.) was used for examining the D-speed films, with all areas peripheral to the radiographic mounts blocked out to minimize the glare. The RVG-6000 images were measured directly from a 19-inch computer monitor (Dell UltraSharp 1905FP 19-inch Flat Panel LCD TFT monitor with 1280 x 1024 pixels maximum resolution and 24-bit color depth; Dell Inc., Round Rock, TX, USA) with the RVG-6000 image being automatically enhanced and magnified (7x magnification compared to the size 2 D-speed film). The reference device in each radiographic image (D-speed and RVG-6000) was measured using a clear plastic millimeter ruler. As the distance between each black notch was known to be equal to 1.0 mm, the distance between the centers of the notches of the reference device was measured and the value was recorded. Next, the carious lesion itself was measured with relation to the DEJ. Once the second value was obtained and recorded, the radiographic value of the lesion depth was obtained by dividing the measured value of the lesion by the measured value of the reference device. A calibration exercise utilized a subset of 5 radiographic sets out of the 52 lesions was carried out to standardize the radiographic

scoring procedure with the two evaluators prior to beginning the actual data collection. Seven days following the calibration exercise, both examiners scored the radiographic sets together and utilized a forced consensus to determine the final radiographic score. The examiners were blinded in regard to the corresponding clinical data for each lesion.

2.3.7b DIFOTI Scoring:

The DIFOTI images were viewed and scored at the same computer screen by the experienced clinicians and the primary investigator after discussing each case to utilize a forced consensus. The lesion extension was determined by the size of the black shadow and was scored as: shadow not present, small shadow, medium shadow or large shadow present (Fig 6).

(a)   **(b)**   **(c)**
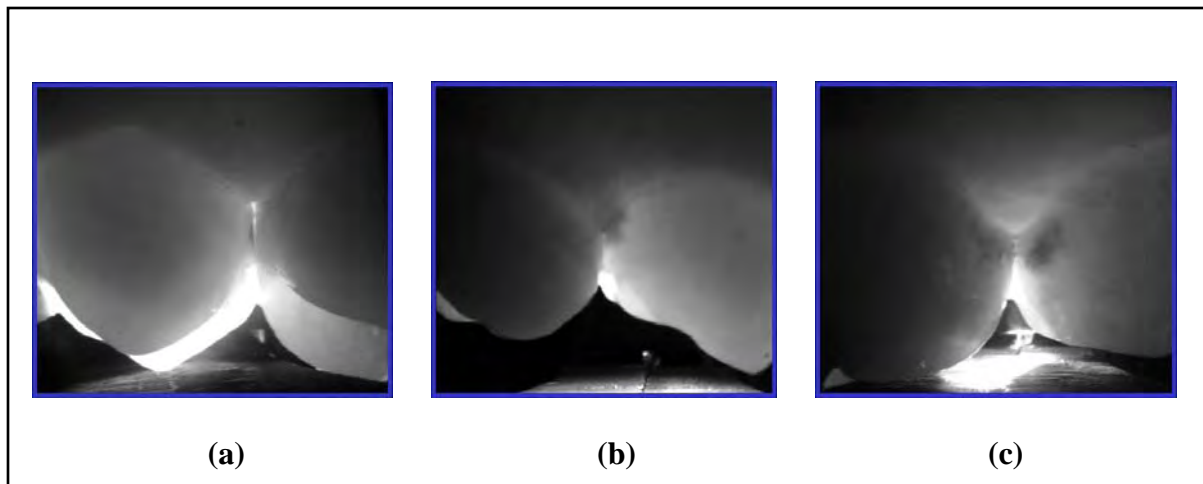
Fig 6. Three DIFOTI images represent the lesion scoring system: (a) small lesion, (b) medium lesion, (c) large lesion.

2.3.7c Clinical Scoring:

The true clinical depth of the carious lesion was measured from the photographic images by the primary investigator. For each case, several photographs were taken, resulting in a series of photographs depicting the carious process at different depths. The images were examined carefully to identify the one that depicted the lesion at its deepest point in the axial direction. The selection of the photographic images was performed

twice, five days apart. In all of the cases, the same image was selected both times. Therefore, this procedure was considered reliable. Measurements of the lesions were made directly from the same computer monitor (Dell UltraSharp 1905FP 19-inch Flat Panel LCD TFT monitor with 1280 x 1024 pixels maximum resolution and 24-bit color depth; Dell Inc., Round Rock, TX, USA) using the same clear plastic millimeter ruler that was used in measuring the radiographic images. In each case, the distance between the centers of the black marking bands of the reference device was measured first, as this distance was known to be equal to 1.0 mm. Next, the deepest axial boundary of the carious lesion was measured from the DEJ, as evidenced by visual changes in dentin (Fig 7). The actual clinical value of the lesion depth was obtained by dividing the measured value of the lesion by the measured value of the reference device. The measurements were made twice, five days apart to avoid recall bias. The final measured value for each lesion was obtained by taking the average of the two measurements. Once the radiographic and clinical scores were obtained for each lesion, analysis of the collected data was accomplished.
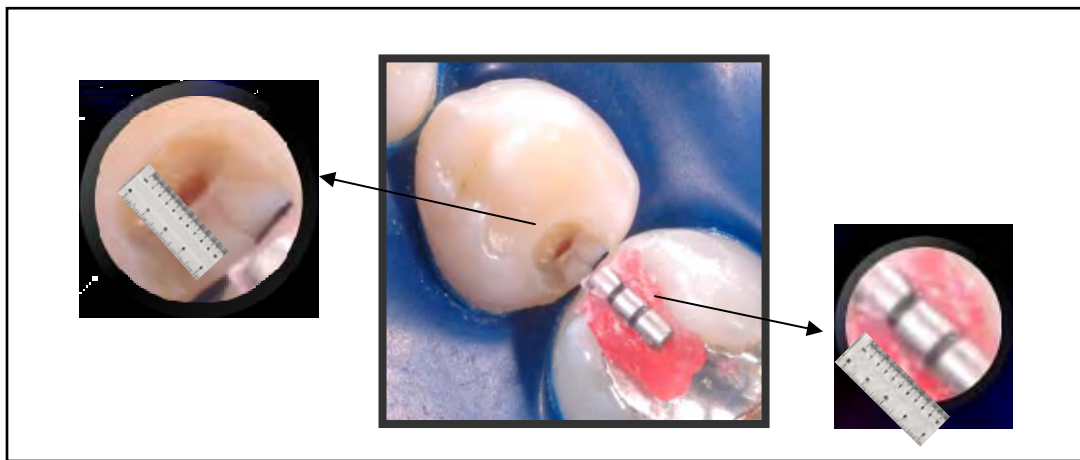
Fig 7. Photographic image shows the clinical measurement of an interproximal carious lesion (The actual clinical depth in mm = carious lesion depth from DEJ/ reference device length).

2.4 RESULTS:

Fifty three lesions in 21 patients (15 females and 6 males) with ages ranging from 20 to 54 years old were originally included in the study. Two lesions in two patients were excluded from the study. For the first patient, both radiographs did not show carious lesions extending to the dentinoenamel junction (DEJ) and therefore no treatment was performed. For the second patient, the examiners could not measure the carious lesion due to presence of an abnormality in the structure of the tooth and a decision was made to exclude this case from the study. However, in both cases the data for patient's discomfort questionnaire was included. Therefore, a total of 51 lesions (33 premolars and 18 molars) comprised the subjects for this study.

2.4.1 Examiners Calibration and Reliability:

The examiners completed the calibration exercise, which was similar to the calibration exercise for a similar previous study (2005) [5]. In both radiographic sets, the two examiners reviewed the radiographs together and utilized a forced consensus to determine the final radiographic score.

2.4.2 Radiographic Data Sets:

Table 1 shows the distribution of the lesions for the radiographic caries depth from the DEJ. Out of the 51 lesions, 33% (17/51) of the D-speed and 14% (7/51) of the RVG-6000 radiographic scorings were at the DEJ (0 mm). Seventy three percent (37/51) of the lesions in the RVG-6000 radiographic set were scored between 0.1 and 1.0 mm while 75% (38/51) of the lesions in the D-speed radiographic set were scored between 0 and 0.5 mm. Lesions in dentin accounted for 67% (34/51) and 86% (44/51) of scores in the D-speed and RVG-6000 radiograph scoring sets, respectively.

Table 1: D-speed and RVG-6000 radiographic sets, distribution of scores.

Category	D-speed	RVG-6000
0 mm	17 (33)	7 (14)
0.1-0.5 mm	21 (41)	21 (41)
0.6-1.0 mm	6 (12)	16 (31)
1.1-1.5 mm	7 (14)	2 (4)
1.6-2.0 mm	0 (0)	5 (10)
> 2.0 mm	0 (0)	0 (0)
Total	51 (100)	51 (100)

The average radiographic depths of the 51 lesions were 0.40 mm and 0.53 mm for the D-speed and the RVG-6000 respectively. A difference of 0.13 mm was found between the overall mean depth values of both radiographic sets.

The depth ranged from 0 to 1.5 mm for D-speed radiographic set and from 0 to 2 mm for the RVG-6000 radiographs set.

2.4.2a RVG-6000 vs. D-Speed Radiographs:

Both radiographic sets were plotted against each other (Table 2) to compare between the scores in each set. The results showed that 31% (16/51) of the lesions were given the same categorical score for both radiographic sets. However, 57% (29/51) were given higher scores (deeper caries extension) for RVG-6000 radiographic set compared to the D-speed set. The remaining 12% (6/51) were scored deeper in the D-speed radiographic set.

The difference in scores between the RVG-6000 and D-speed radiographic sets, Delta value (Δ_1), was calculated (Δ_1 = RVG-6000 Radiographic score – D-speed Radiographic score). A negative Δ_1 value indicated a higher D-speed radiographic score than RVG-6000 score, while a positive score indicated the opposite (Table 3).

Comparing the D-speed radiographic set to the RVG-6000 radiographs, 76% (39/51) of the cases showed a difference of 0.1-0.5 mm (plus or minus) of the axial caries extension measurement between the two radiographic sets.

Table 2. RVG-6000 radiographic scores plotted against D-speed scores.

	RVG-6000 Radiographic Scores						Total
Category (in mm)	**0**	**0.1-0.5**	**0.6-1.0**	**1.1-1.5**	**1.6-2.0**	**> 2.0**	
0	**4**	11	2				17
0.1-0.5	3	**8**	10				21
0.6-1.0		2	**3**	1			6
1.1-1.5			1	**1**	5		7
1.6-2.0							0
> 2.0							0
Total	7	21	16	2	5	0	51

D-speed Radiographic Scores (row label, left side)

Table 3. Δ_1 Values comparing D-speed to RVG-6000 radiographic scores.

	Δ_1 **Values**														
	-0.7	-0.6	-0.5	-0.4	-0.3	- 0.2	-0.1	0	+0.1	+0.2	+0.3	+0.4	+0.5	+0.6	+0.7
Total	1	0	1	2	2	1	4	8	10	2	7	6	4	3	0

Sensitivity of each radiographic modality was calculated at the level of clinical penetration of carious lesions into dentin (Table 4a & b). The specificity could not be calculated as all of the carious lesions were extended beyond the DEJ. The sensitivity table showed that 86% of the RVG-6000 images and 67% of the D-speed radiographs were able to detect the dentinal lesions.

Table 4. Sensitivity values for lesions into dentin for the RVG-6000 and D-speed radiographs.

	Dentin Lesion				Dentin Lesion		
	+	-	T		+	-	T
RVG-6000 +	44	0	44	D-speed +	34	0	34
RVG-6000 -	7	0	7	D-speed -	17	0	17
RVG-6000 T	51	0	51	D-speed T	51	0	51

*Sensitivity = 0.86   Sensitivity = 0.67

(a)   (b)

[*Sens. = True positives / (True positives + False negatives)]

2.4.3 Clinical Scoring:

All of the 51 lesions showed caries extended beyond the DEJ clinically (Table 5). No lesion was scored at the DEJ (0 mm). Seventy two percent (37/51) of the lesions were scored between 0.1 and 1.0 mm. Only one lesion was scored above 1.6 mm from the DEJ.

Table 5. Clinical set, distribution of scores.

Category	Total (%)
0 mm	0 (0)
0.1-0.5 mm	14 (27)
0.6-1.0 mm	23 (45)
1.1-1.5 mm	13 (26)
1.6-2.0 mm	1 (2)
> 2.0 mm	0 (0)
Total	51 (100)

The overall mean clinical depth from the DEJ for the 51 lesions was 0.83 mm and the clinical depth ranged from 0.1 to 2 mm.

2.4.4 Radiographic Vs. Clinical Scores:

By comparing the D-speed radiographic scores to the clinical scores (Table 6.), it was found that 29% (15/51) of the lesions were given the same categorical score for both D-speed radiographs and clinical scores. Seventy one percent of the lesions (36/51) were scored deeper into dentin clinically than their scores in the D-speed radiographic set. No lesion was scored deeper in the D-speed radiographic set than what it was clinically. For the RVG-6000 radiographic set (Table 7), 43% of the lesions (22/51) were given the same categorical score for both RVG-6000 radiographs and clinical scores. Forty nine percent of the lesions (25/51) were scored deeper into dentin clinically than their scores radiographically using the RVG-6000 sensor. Four cases out of 51 (8%) were scored deeper in the RVG-6000 radiograph images than what it was clinically The mean differences of the carious depth between the radiographic and the clinical images for each radiographic set were 0.29 mm and 0.42 mm for the RVG-6000 and D-speed images respectively. Fig 8 presents the overall mean depth values for the D-speed, RVG-6000 radiographic sets and clinical scores.
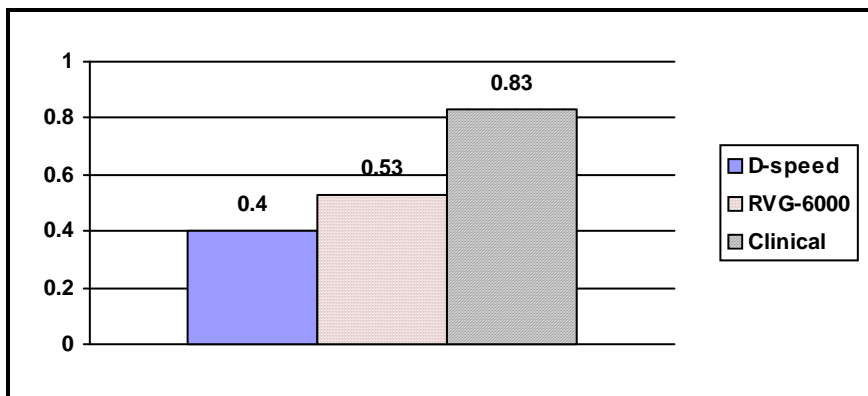
Fig 8. Bar graph shows the mean depth scores in mm for D-speed, RVG-6000 and clinical images.

Differences between clinical and radiographic scores were calculated (Tables 8 & 9).

Δ_2: Is the difference between the clinical scores and radiographic scores (Δ_2 = Clinical score – Radiographic score), a negative Δ value indicated a higher radiographic than clinical score, while a positive score indicated the opposite. For the D-speed radiographs, 57% of the cases (29/51) showed difference of 0.1-0.5 mm (plus or minus) in radiographic caries extension from the clinical penetration. For the RVG-6000 radiographs, 69% (35/51) of the cases showed the same range of difference (0.1-0.5 mm).

Table 6. D-speed radiographic scores plotted against clinical scores.

		D-speed Radiographic Scores						Total
	Category (in mm)	**0**	**0.1-0.5**	**0.6-1.0**	**1.1-1.5**	**1.6-2.0**	**> 2.0**	
Clinical Scores	**0**							0
	0.1-0.5	9	**5**					14
	0.6-1.0	7	12	**4**				23
	1.1-1.5	1	4	2	**6**			13
	1.6-2.0				1			1
	> 2.0							0
Total		17	21	6	7	0	0	51

Table 7. RVG-6000 radiographic scores plotted against clinical scores.

	RVG-6000 Radiographic Scores						Total
Category (in mm)	0	0.1-0.5	0.6-1.0	1.1-1.5	1.6-2.0	> 2.0	
0							0
0.1-0.5	6	8					14
0.6-1.0	1	11	11				23
1.1-1.5		2	5	2	4		13
1.6-2.0					1		1
> 2.0							0
Total	7	21	16	2	5	0	51

(Clinical Scores on the vertical axis)

Table 8. Δ_{2a} Values comparing clinical scores to the D-speed radiographic scores.

	Δ_{2a} Values													
	-0.3	-0.2	-0.1	0	+0.1	+0.2	+0.3	+0.4	+0.5	+0.6	+0.7	+0.8	+0.9	+≥1.0
Total	0	0	0	5	8	5	4	6	6	7	2	3	2	3

Table 9. Δ_{2b} Values comparing clinical scores to the RVG-6000 radiographic scores.

	Δ_{2b} Values															
	-0.5	-0.4	-0.3	-0.2	-0.1	0	+0.1	+0.2	+0.3	+0.4	+0.5	+0.6	+0.7	+0.8	+0.9	+≥1.0
Total	1	0	0	2	1	7	3	7	10	7	4	5	2	0	1	1

2.4.5 Intraoral Examination:

In this study two intraoral examination modalities were performed to detect the interproximal carious lesions, the visual examination (presence of black shadow under the marginal ridge) and DIFOTI examination. Sensitivity and specificity values for both modalities were calculated at two different clinical levels. The first level included lesions into dentin which was determined from the clinical measurements. At this clinical level,

all of the lesions had extended into dentin. There were no true negative or false positive values. Therefore, specificity could not be calculated at that level (Table 10).

The second level at which sensitivity and specificity values of the visual and DIFOTI examinations were calculated was cavitation of the proximal surface (Table 11). The status of the proximal surface was validated clinically during the operative procedure.

Table 10. Sensitivity values for lesions into dentin for visual and DIFOTI examinations.

Dentin Lesion				Dentin Lesion			
	+	**-**	**T**		**+**	**-**	**T**
Visual **+**	42	0	42	DIFOTI **+**	43	0	43
Visual **-**	9	0	9	DIFOTI **-**	8	0	8
T	51	0	51	**T**	51	0	51

$$*Sensitivity = 0.82$$
(a)

$$Sensitivity = 0.84$$
(b)

[*Sens. = True positives / (True positives + False negatives)]

Table 11. Sensitivity and specificity values for cavitated lesions for visual and DIFOTI examinations.

Cavitation				Cavitation			
	+	**-**	**T**		**+**	**-**	**T**
Visual **+**	18	24	42	DIFOTI **+**	15	28	43
Visual **-**	0	9	9	DIFOTI **-**	3	5	8
T	18	33	51	**T**	18	33	51

$$*Sensitivity = 1.0$$
$$**Specificity = 0.27$$
(a)

$$Sensitivity = 0.83$$
$$Specificity = 0.15$$
(b)

[*Sens. = True positives / (True positives + False negatives), **Spec. = True negatives / (True negatives + False positives)]

2.4.5a Visual Examination:

The presence of a black shadow under the marginal ridge of the affected tooth was scored in the patient's data form. Eighty two percent of the lesions (42/51) showed the presence of a black shadow under the marginal ridge. The distribution of the clinical depth scores to the presence of black shadow is shown in Table 12. Sixty one percent (31/51) of the lesions with visual black shadow showed clinical caries extension ranging from 0.6-1.5 mm into dentin.

Table 12. Distribution of black shadow scores under the marginal ridge in relation to the clinical depth.

Black shadow score	Clinical score (in mm from DEJ)					
	0	0.1-0.5	0.6-1.0	1.1-1.5	1.6-2.0	> 2.0
Absent	0	4	5	0	0	0
Present	0	7	17	14	3	0
Total	0	11	22	14	3	0

2.4.5b DIFOTI Examination:

Forty three lesions showed the presence of small, medium, or large shadows on the digital images captured by the DIFOTI imaging modality. Eighty one percent of the lesions detected with the DIFOTI (35/43) showed a visual black shadow under the marginal ridge. Lesions that were scored to have a small shadow (18 lesions) had clinical depth measurements that ranged from 0.1-1.5 mm, while 94% of the lesions with medium shadow (17/18) had clinical depth measurements that ranged from 0.6-2.0 mm (Table 13).

Table 13. Distribution of DIFOTI scores in relation to the clinical depth scores.

DIFOTI score	Clinical scores (in mm from DEJ)					
	0	0.1-0.5	0.6-1.0	1.1-1.5	1.6-2.0	> 2.0
No shadow	0	4	2	2	0	0
Small shadow	0	8	8	2	0	0
Medium shadow	0	1	10	7	0	0
Large shadow	0	1	3	2	1	0

2.4.6 Cavitation:

During the operative procedure 18 of the 51 lesions were cavitated. In 13 cases the cavitation was confined to enamel, whereas in 5 lesions the cavitation extended into dentin. The distribution of cavitated lesions to the clinical, D-speed, and RVG-6000 depths is shown in Table 14. For all three sets the percentage of the cavitated lesions increased with lesion depth.

Table 14. Cavitated lesions per scoring category for radiographic and clinical sets.

Depth category	*D-speed set*		Cavitated lesions %	*RVG-6000 set*		Cavitated lesions %	*Clinical set*		Cavitated lesions %
	N*	*T***		*N*	*T*		*N*	*T*	
0	3	17	18	0	7	0	0	0	-
0.1-0.5 mm	6	21	29	5	21	24	0	14	0
0.6-1.0 mm	2	6	33	6	16	38	6	23	26
1.1-1.5 mm	7	7	100	2	2	100	11	13	85
1.6-2.0 mm	0	0	-	5	5	100	1	1	100
> 2.0 mm	0	0	-	0	0	-	0	0	-
Total	18	51	35	18	51	35	18	51	35

N* = Number of cavitated lesions, T**= Total number of cases in depth category.

The results of the different clinical examination modalities were compared in Table 15. The average and the range of the clinical lesion depth along with the percentage of the cavitated lesions were also shown. Only one lesion was not detected by any of the two examination modalities while 35 lesions were detected by two of them.

Table 15. Findings from different combination of examinations.

Detection by examination modality	No.	Average measured clinical depth (mm)	Range of clinical depth (mm)	Cavitated lesions (%)
None	1	0.1	0.1	0
Visual only	7	0.79	0.3- 1.2	43
DIFOTI only	8	0.53	0.3- 0.8	0
Visual and DIFOTI	35	0.95	0.2- 2	43
Total	51	0.85	0.1- 2	35

2.4.7 Radiographic Sensors and Patient's discomfort:

The evaluation of the patient's discomfort while taking both radiographs was performed using a one page questionnaire. Three questions were asked to evaluate any discomfort that either one of the sensors could cause while taking the radiograph before initiating the operative procedure (Fig 4). Thirty three responses were collected for the 51 cases. The discrepancy between the number of the lesions and the total number of the questionnaire responses is due to the fact that some radiographs were used for more than one lesion in each patient. Table 16 shows the distribution of the patient's responses to the first question. Twenty five responses out of 33 (76%) thought that the D-speed radiograph was less unpleasant than the RVG-6000 sensor. Only 5/33 (15%) felt both sensors to be the same. By asking the patients about sources of discomfort with each radiograph (Tables 17 & 18, Fig 9), 21/33 (64%) and 26/33 (79%) found discomfort to be from either sharp edges of the sensor, size of the sensor or both for the D-speed film and RVG-6000 sensor respectively. However, 11/33 (33%) and only 4/33 (12%) did not have any discomfort with the D-speed and RVG-6000 sensors respectively. One response stated that what bothered the most with the RVG-6000 sensor was the difficulty in placing the sensor in the mouth, another patient said that the RVG-6000 sensor pushed her tongue down and was difficult to bite down all the way.

Table 16. Radiographs and patient's discomfort.

Subject's response	No. (%)
D-speed film was more comfortable	25 (76)
RVG-6000 sensor was more comfortable	3 (9)
Both sensors were the same	5 (15)
Total	33 (100)

Table 17. D-speed film and sources of patient's discomfort.

Subject's response	No. (%)
(a) Size of the film (too big)	5 (15.2)
(b) Sharp edges of the film	11 (33.3)
(c) Makes me gag	1 (3)
(d) Nothing bothered me	11 (33.3)
(a), (b) and (c)	1 (3)
(a) and (b)	4 (12.2)
Total	33 (100)

Table 18. RVG-6000 and sources of patient's discomfort.

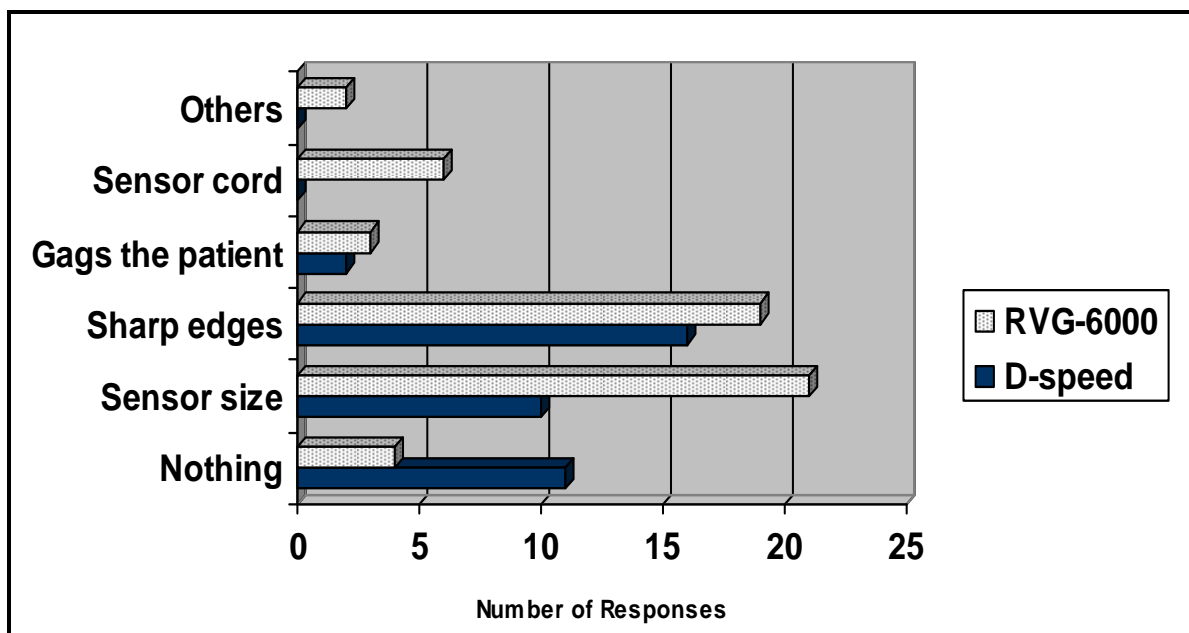| Subject's response	No. (%)
(a) Size of the film (too big)	6 (18.2)
(b) Sharp edges of the film	5 (15.2)
(c) Makes me gag	0 (0)
(d) Biting on the cord is uncomfortable	1 (3)
(e) Nothing bothers me	4 (12.2)
(a), (b), (c) and (d)	3 (9.1)
(a), (b) and (d)	1 (3)
(a) and (b)	10 (30.3)
(a) and (d)	1 (3)
Others	2 (6)
Total	33 (100)

Fig 9. Bar graph shows the distribution of the type of radiograph
to the sources of patient's discomfort.

2.4.8 Statistical Analysis:

Multiple statistical tests were conducted to analyze the results using SAS 9.1.2 software.

ANOVA:

ANOVA analysis showed a highly significant difference ($p<0.0001$) between mean lesion depths of the three images (D-speed films, RVG-6000 images, and clinical depth). It is important to mention that ANOVA analysis did not take DIFOTI readings into account. Therefore, $H0_1$ was rejected and it was concluded that at least one of the three means was significantly different from the others.

Tukey Student Range Test:

Tukey analysis showed a significant difference between D-speed films and RVG-6000 images ($p=0.0031$) in estimating the clinical caries depth. Highly significant differences were found between D-speed film and clinical images and between RVG-6000 and clinical images ($p<0.0001$). A highly significant difference was also found between any radiographic image (RVG-6000 image or D-speed film) and clinical images ($p<0.0001$). Therefore, $H0_2$ was rejected and it was concluded that there is a significant difference between the D-speed bitewing radiographs and the RVG-6000 images in estimating the axial extension of the class II carious lesions.

Scatter Plots:

Two scatter plots were drawn. The first one compared the D-speed film readings with the clinical depth (Fig 10). The second plot compared RVG-6000 radiograph readings with the clinical depth (Fig 11). For both comparisons, a greater scatter was associated with shallower lesions. It was observed that the larger the lesion the better the linearity, especially for comparing D-speed films with clinical depth. When RVG-6000 readings

were plotted against clinical depth of the lesions (Fig 11), a slight curvature of the data was observed for larger lesions; therefore, RVG-6000 images tend to slightly overestimate the size of larger lesions. For small lesions RVG-6000 performed better than D-speed in estimating the caries depth
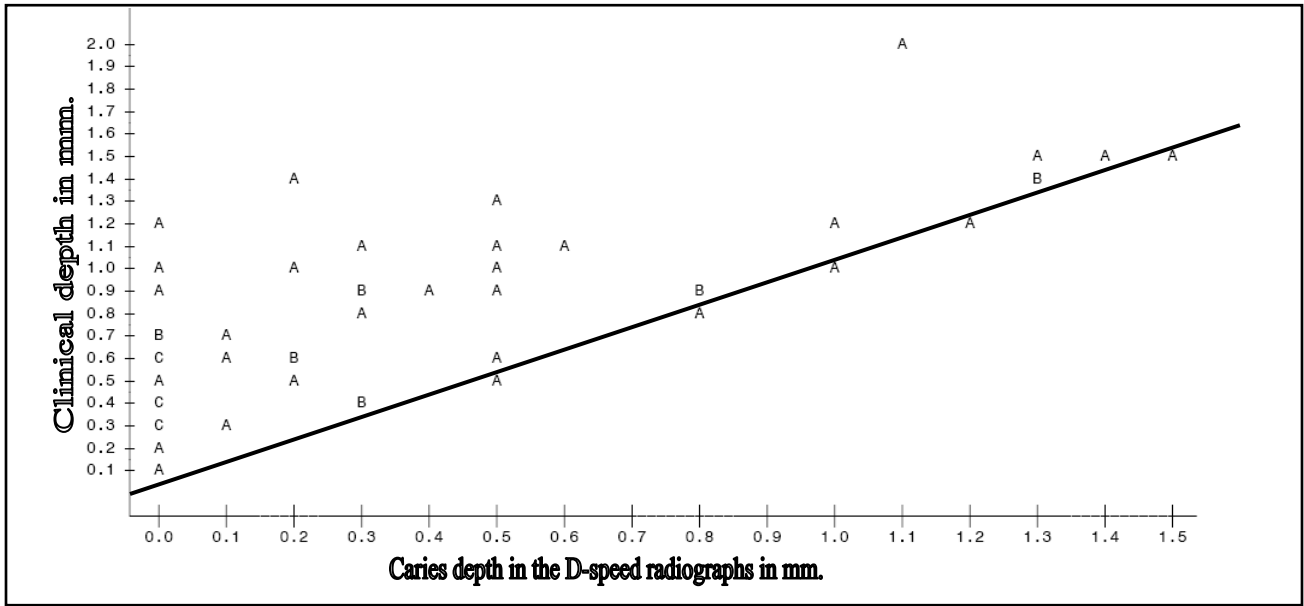

Fig 10. Scatter plot for the clinical depth of caries against caries depth captured by D-speed radiographs. Letters represent number of cases for each score (A= 1case, B= 2 cases, C= 3 cases).
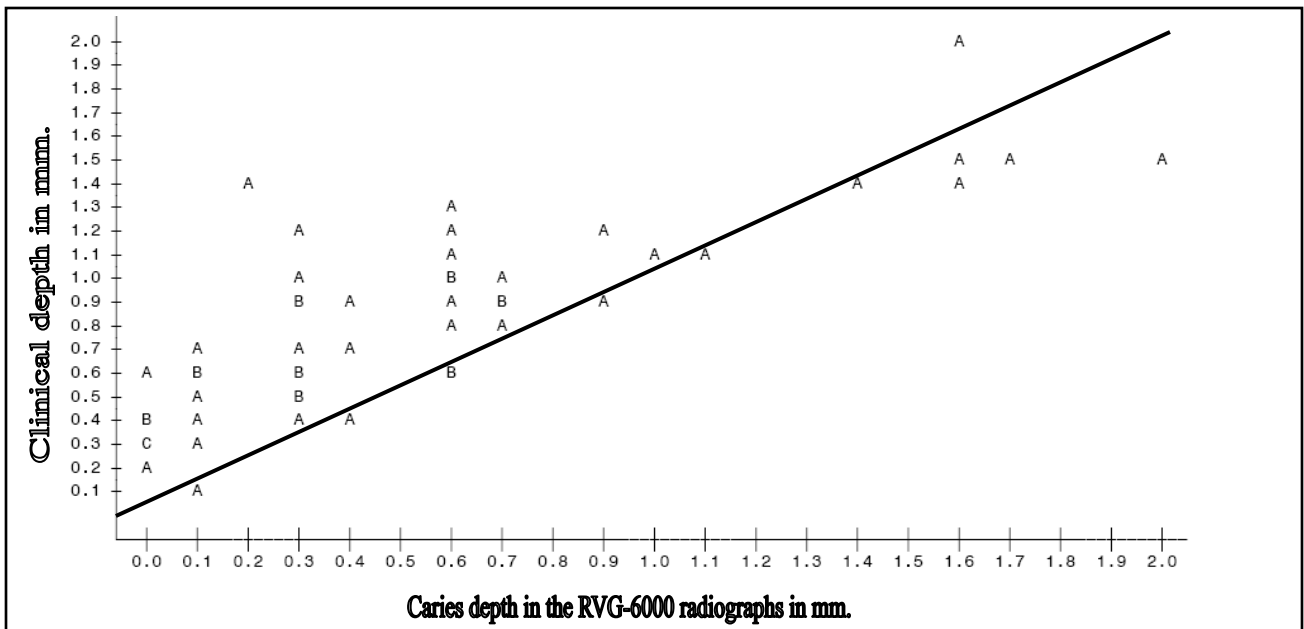

Fig 11. Scatter plot for the clinical depth of caries against caries depth captured by RVG-6000 radiographs. Letters represent number of cases for each score (A= 1case, B= 2 cases, C= 3 cases).

On both plots most data points are above the equality line (reference line where clinical = radiograph), which means that when either D-speed film or RVG-6000 image detect decay, the lesion is likely to be larger clinically. Two new plots (Figs 12 & 13) were generated by overlaying DIFOTI readings for each depth score on the previous two plots (Figs 10 & 11). The purpose was to evaluate if DIFOTI, when used in conjunction with either imaging methods, could explain some of the variation observed with smaller lesions. By looking at the DIFOTI scores in both plots, it was noticed that smaller scores (smaller lesions) tend to be concentrated where the scatter is the greatest. Therefore, we can say that DIFOTI may help diagnose smaller lesions when used in conjunction with one of the two tested radiographic methods.
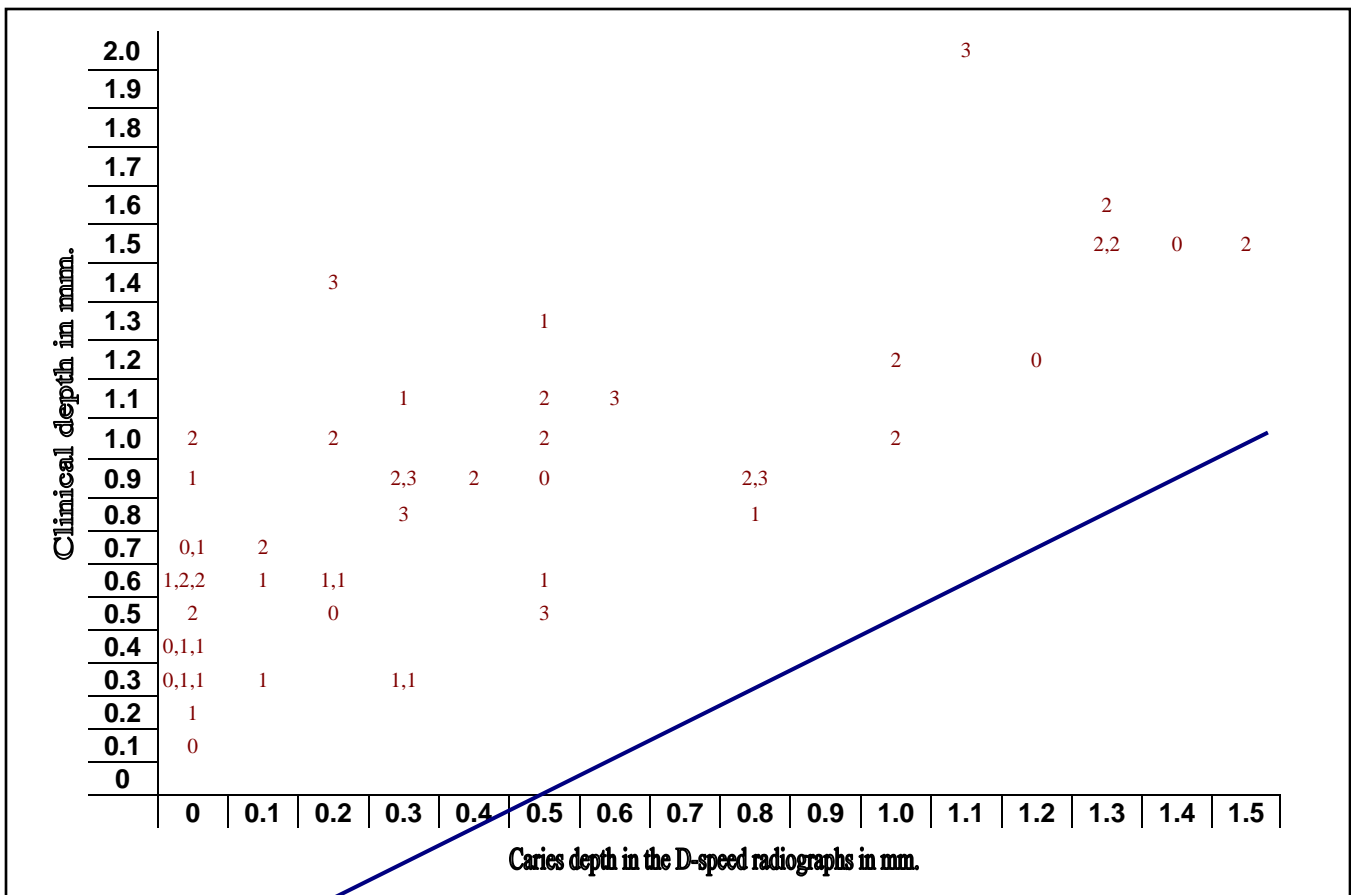

Fig 12. Scatter plot for the clinical depth of caries against caries depth captured by D- speed radiographs. Numbers represent DIFOTI scores (0= no lesion, 1= small lesion, 2= medium lesion, 3= large lesion).
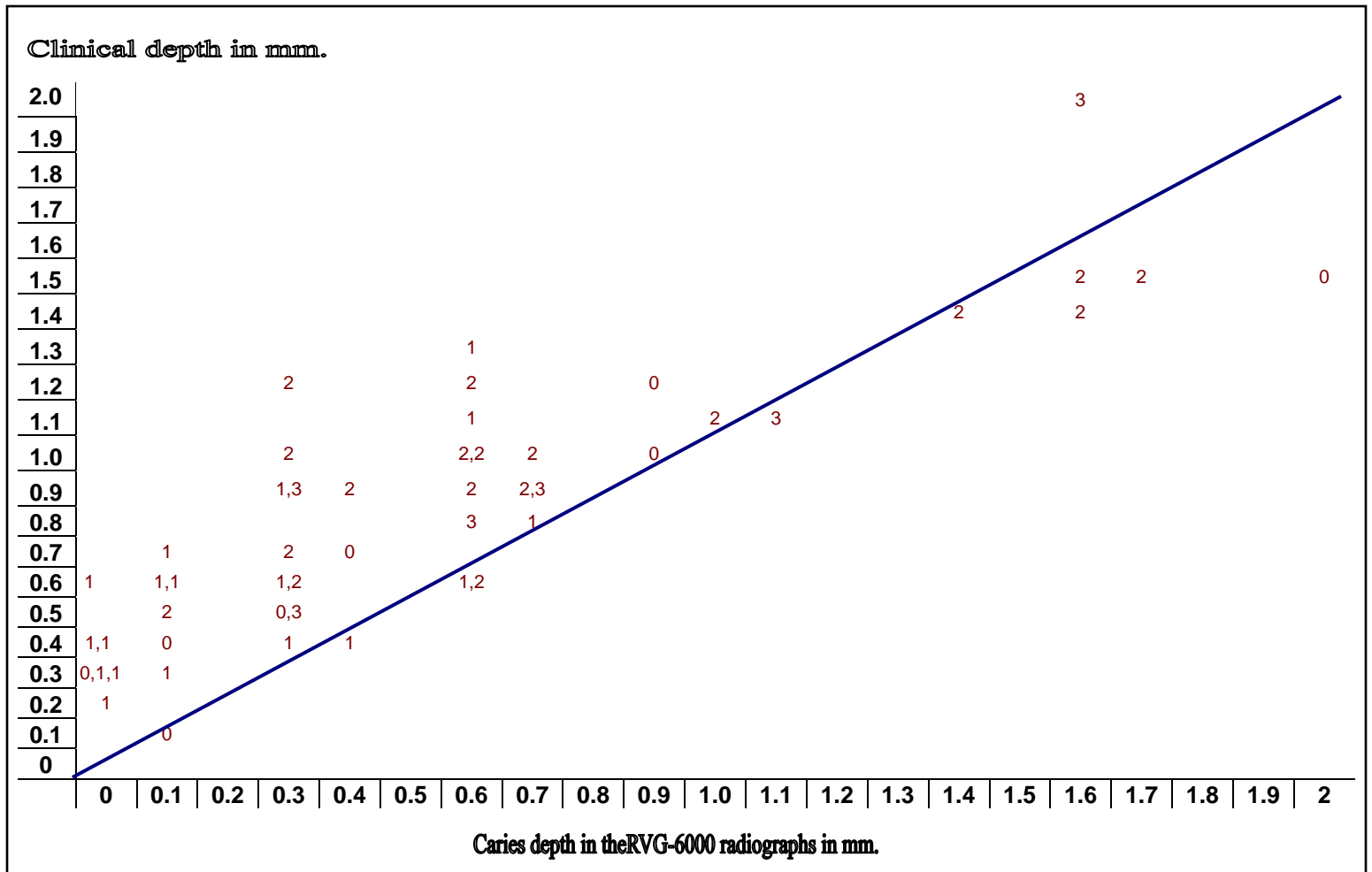
Fig 13. Scatter plot for the clinical depth of caries against caries depth captured by RVG-6000 radiographs. Numbers represent DIFOTI scores (0= no lesion, 1= small lesion, 2= medium lesion, 3= large lesion).

Simple Linear Regression Analysis:

Simple linear regression analysis confirmed the results from scatter plots. Based on the R^2 values, the association between RVG-6000 and DIFOTI (R^2= 0.7210) provided readings closer to true clinical measures than D-speed film and DIFOTI (R^2= 0.6215). The depth of the lesion captured by both RVG-6000 *and* DIFOTI and D-speed film *and* DIFOTI did increase with the true clinical depth (p<0.0001), but the relationship was stronger with RVG-6000 *and* DIFOTI. DIFOTI significantly improved the estimation of

106

the size of the lesion when used in conjunction with D-speed films (p= 0.0039) and RVG-6000 images (p= 0.0024). Therefore, $H0_3$ was rejected and it was concluded that DIFOTI in conjunction with either the RVG-6000 digital radiographic images or the D-speed images improves the diagnostic ability of these methods.

Pearson Correlation Coefficients Analysis:

Pearson correlation coefficients (PC) confirmed the results of the regression analysis. Clinical depth of decay was more highly correlated (PC= 0.81303, p<0.0001) with RVG-6000 images than with D-speed film (PC= 0.74090, p<0.0001).

DIFOTI correlated with the true clinical depth of decay but to a lesser extent than the radiographs, however, this correlation was still significant (PC= 0.43189, p= 0.0016).

Even though DIFOTI readings were poorly correlated with RVG-6000 images (PC= 0.23866, p= 0.0917) and D-peed (PC= 0.22893. p= 0.1001) readings, the scatter plots (Figs 12 & 13) had shown that it may be useful to diagnose smaller size lesions when used in conjunction with either radiographic method.

2.5 DISCUSSION:

2.5.1 Radiographic vs. Clinical Findings:

The primary objective of this study was to compare the radiographic axial extension of class II carious lesions using RVG-6000 digital images and D-speed films to the actual clinical extension. The average clinical depth of the 51 lesions studied was 0.83 mm compared to 0.40 and 0.53 mm for the D-speed and RVG-6000 radiographs respectively. Looking at the radiographic scores plotted against the clinical scores (Tables 6 & 7) shows that both radiographic sets underestimated the actual extension of the carious lesions in general (71% and 49% for the D-speed and RVG-6000 images respectively).

The differences between the clinical and both radiographic sets were highly significant (p<0.0001). Therefore, the primary null hypothesis was rejected.

Similar results were reported by Kooistra et al and Jesse et al [5, 16]. The level of agreement between the D-speed sets and the clinical set in this study was 29% (15/51). Jesse et al found that 23.3% of the D-speed films agreed with the gold standard (histological sections) [16]. Kooistra et al reported similar findings using F-speed films (13% for the conservative set and 29% for the aggressive set) [5]. Thylsturp et al found that 82% of the radiographic cases in his study were scored the same as the clinical cases [17]. That study however, included the participation of 263 dentists who were not standardized. Espelid and Tveit found a level of agreement of approximately 60% in their study of extracted teeth. However, they utilized much broader scoring categories and histological validation of lesion depth [18].

Using a small category size to describe carious extension makes correlation between radiographic and clinical scoring more difficult. However, as remineralization

of shallow and non-cavitated lesions has become a more highly accepted treatment option, the accurate monitoring of lesion size over time becomes more critical [5].

Gungor et al found that the corrected depth diagnosis for D-speed films was 55.8% and 26.8% of the films underestimated the lesions depths [19]. In that study the examiners did not quantify the lesion depth and the true depth was validated histologically.

Jacobsen et al found that direct digital radiographic systems (Sidexis and Dixi) significantly underestimated the interproximal carious lesion extension [20]. In that study each of the four observers underestimated the carious lesions except one. However, the observers used a computer program to do the measurements which were validated histologically. Syriopoulos et al found that both CCD and PSP based digital radiography underestimated the carious lesion depth [12].

2.5.2 RVG-6000 vs. D-speed radiographs:

One of the objectives of this study was to compare the diagnostic findings of the D-speed films with that of the RVG-6000 images. Results showed that 31% (16/51) of the lesions were given the same categorical score for both radiographic sets, while 57% (29/51) were given higher scores (deeper caries extension) for RVG-6000 radiographic set compared to the D-speed set (Table 2). The mean differences of the carious depth between the radiographic and the clinical images for each radiographic set were 0.42 mm and 0.29 mm for the D-speed and RVG-6000 respectively. Although the difference between the two sets was not very high, it was found to be statistically significant (p= 0.0031). However, for the RVG-6000 images there is a slight curvature of the data for larger lesions (Fig 11), which means RVG-6000 images tend to slightly overestimate the size of larger lesions. That overestimation is not clinically significant since large lesions would have been treated based on their clinical appearance. It can be concluded from

109

these results that RVG-6000 images are more accurate in estimating the small to medium size carious lesions than the D-speed films. Part of this difference in the diagnostic accuracy of the RVG-6000 to estimate the carious depth could be explained by the auto-enhancement and the 7x magnification (which was provided automatically by the manufacturer) compared to the D-speed films.

The sensitivity table (Table 4) showed that 86% of the RVG-6000 images and 67% of the D-speed radiographs were able to detect the dentinal lesions. Although a great effort was made to make the x-rays at the right angle with the digital sensor, in some of the cases it was difficult for the patient to bite down completely with the digital sensor in place. This was especially true when the lesion was located closer to the front of the mouth (first premolars) due to the size and rigidity of the RVG-6000 sensor. This difference in angulation may have affected the presentation of carious lesion extension in some cases.

Hintze et al found no statistical difference in their *in-vitro* study between the D-speed, E-speed (0.61) and RVG (0.59). However, the RVG system that was used here was the old system (1990), and the validation method was based on histological examination of the lesions [10].

Uprichard et al in their study found that examiners were significantly more accurate in diagnosing proximal surfaces of extracted teeth using either D-speed or E-speed Plus films (0.7595, 0.7557) than they were using a CCD based direct digital system (0.5928) [21]. In that study, the examiners (five pediatric dentists) were not allowed to use the enhanced image to read the digital image.

Erten et al in their *in-vitro* study found the sensitivity of the new RVG (0.49) system to be higher than the Ultraspeed, Ektaspeed plus and Insight (0.39, 0.48, and 0.45

110

respectively) [22]. However, the lesions were validated histologically to be present or absent using a five point scale with some lesions being confined in enamel. In this study all of the test lesions were into dentin and that was validated clinically.

2.5.3 Cavitation:

Many dental professionals believe in remineralization therapy of incipient carious lesions and the decision to restore a carious lesion is influenced by the presence of a cavitation on the proximal lesion.

In this study, the cavitated lesions had clinical caries extension ranging from 0.7 to 2 mm. Thirty five percent (18/51) of the lesions were cavitated, in 5 cases the cavity extended into dentin (clinical depth ranged from 1.1 to 2 mm).

The results showed that cavitation percentage increases as the lesion depth increased both radiographically and clinically (Table 14).

Eighteen percent (3/17) and 0% (0/7) of the lesions scored to have caries at the DEJ on the D-speed and RVG-6000 images respectively were cavitated. Lesions with radiographic depth ranging from 0.1 to 1 mm into dentin were 30% cavitated (8/27 for D-speed and 11/37 for RVG-6000). Only 16% (6/37) of the cases with lesion depth ranging from 0.1 to 1.0 mm clinically were cavitated. The cases scored to have lesion depth of 1.1 to 2.0 mm radiographically were all cavitated. However, only 86% (12/14) of the cases scored to have lesion depths of 1.1 to 2.0 mm clinically were cavitated. These results were similar to the study conducted by Kooistra et al who reported that 26% of the 62 cases were cavitated and all lesions diagnosed as being greater than 1.0 mm into dentin were cavitated. The authors mentioned that cavitation of the proximal surface increases with the clinical depth of the class II lesions [5].

Pitts and Rimmer found the percentages of the surfaces cavitated for radiolucencies to the outer half of dentin and inner half of dentin from D-speed radiographs were 40.9% and 100% respectively [23]. Bille and Thylstrup found that 34% of the 158 tested lesions were cavitated and 52% of the lesions extending halfway through dentin radiographically were cavitated [24]. The literature shows that as radiographic lesions reach dentin, the percentage of cavitated surfaces increases dramatically [5].

2.5.4 DIFOTI:

New diagnostic devices such as digital imaging fiber-optic transillumination (DIFOTI™) have been introduced to improve early detection of carious surfaces [15].

Very few studies have been conducted to correlate the DIFOTI to different diagnostic tools. One of the objectives of this study was to compare the findings of the two radiographic images to the results of the DIFOTI examination and to correlate that with the true clinical findings. It was shown in the results that 84% of the lesions (43/51) were detected by the DIFOTI yielding a sensitivity of 0.84 for detecting dentinal lesions (Table 4). Schneiderman et al found sensitivity of DIFOTI to detect the presence of proximal caries in 50 mounted extracted teeth to be 0.69 and the specificity was 0.73 [16].

In this study, all 51 lesions were penetrating into dentin, therefore, the specificity could not be calculated. Due to the difficulty in measuring the caries extension from the DIFOTI images, a categorical scale was used to describe the size of the lesion (Fig 6). Comparing a continuous rating scale such as the one used to rate the caries extension in the radiographic and clinical images with the categorical scale used to describe the size of the lesion in the DIFOTI image may not give much information. Interestingly, this study showed that 72% (13/18) of the lesions scored to have a small shadow had clinical depth ranging from 0.1 to 0.6 mm and 72% (13/18) of the lesions which scored to have a

112

medium shadow had clinical depth ranging from 0.6 to 1.2 mm but only 29% (2/7) of the lesions with a large shadow were found to have clinical depth ranging from 1.4 to 2 mm. It can be concluded from these results that DIFOTI may be more accurate in predicting the small size lesions. The correlation between the DIFOTI images and the radiographs becomes stronger with small lesions. Statistical analysis showed that DIFOTI significantly improves the estimation of the size of the lesion clinically when used in conjunction with D-speed (p= 0.0039) or RVG-6000 (p= 0.0024) and the depth of the lesion captured by the DIFOTI with either one of the radiographs (D-speed film or RVG-6000 sensor) significantly increases with the increase in the true depth (p<0.0001).

One of the limitations of this study was the possible errors in capturing or reading the images because of the inexperience of the investigators in using or interpreting the DIFOTI. It is important to understand the limitations of the DIFOTI device when comparing a DIFOTI image to a radiograph to diagnose a proximal carious lesion. The DIFOTI captures only the light emerging from the tooth surface that is close to the digital camera, while the radiographic beam penetrates through the entire tooth and adjacent structures to show any changes in the density or structure. The manufacturer of the DIFOTI specified its use to be for detection of carious lesions not determining the caries extension. Therefore, DIFOTI does not replace bitewing radiographs, but serves as an adjunctive diagnostic tool.

2.5.5 Visual examination:

The results of this study showed that the percentage of the visually detected shadow under the marginal ridge increases with clinical depth. All lesions penetrating 1.1 to 2 mm into dentin were visually detected (Table 12). This information implies that visual examination has a very high sensitivity to detect lesions penetrating deep into dentin.

Eighty two percent of the lesions (42/51) showed the presence of a black shadow under the marginal ridge with clinical caries extension ranging from 0.6-1.5 mm into dentin. Visual examination showed very high sensitivity to detect cavitated lesions (1.0). However, the specificity of the visual examination for cavitation was low (0.27) but still higher than DIFOTI (0.15). It is worth noting that only one lesion with a clinical depth of 0.1 mm was not detected by either of the two intraoral examination modalities. Sixty nine percent (35/51) of the lesions were detected by both visual and DIFOTI examinations. The results of this study proved the effectiveness of combining more than one intra oral examination modality to detect the interproximal carious lesions. Therefore, using the diagnostic results of the DIFOTI and visual examinations in conjunction with the radiographic images would aid the clinician in diagnosis of a lesion for restorative treatment.

2.5.6 Radiographic sensors and patient's discomfort:

Patient's discomfort while taking the radiographs may lead to some errors in the image or may lead to an increase in the number of retakes which subsequently increases the radiation exposure to the patient. This study documented patient experience after having two different radiographs taken at the same time in the same location.

It was obvious from the results of the first question (Table 16) that the D-speed film was less unpleasant in the patient's mouth than the RVG-6000 size 2 sensor (76%). However, 15% (5/33) thought that both sensors were the same in terms of discomfort.

Wenzel et al found that 58% of the patients preferred the Digora plate (PSP based digital radiographic system), 30% preferred the RVG sensor, and 12% had no preference [25].

114

Bahrami et al found no statistically significant difference between the DenOptix (PSP based digital radiographic system) and conventional film, which were scored as the most comfortable receptors compared with Planmeca, Digora and Trophy [26].

In this study the sharp edge and/or the size of the film caused most of the discomfort when taking either one of the radiographs, 21/33 (64%) and 26/33 (79%) for the D-speed film and RVG-6000 sensor respectively. However, 11/33 (33%) and only 4/33 (12%) reported no discomfort with the D-speed and RVG-6000 sensors respectively. In one response, the difficulty in placing the sensor in the mouth was the most uncomfortable experience with the RVG-6000 sensor. Another patient was bothered by the RVG-6000 sensor pushing her tongue down and therefore, making it difficult to bite down completely. Only three responses reported a gagging problem when taking the RVG-6000 image and two responses reported that problem with the D-speed films (Fig 9).

It is worth mentioning that one of the difficulties of using RVG-6000 size 2 sensor in this study was to place the sensor anteriorly and ask the patients to bite down with the sensor in place. This problem was more prevalent with patients who have a small mouth or bony exostoses. This was documented in Bahrami et al study, who concluded that CCD sensors were the most difficult to position anteriorly enough to display the canine and 1st premolar in a bitewing examination, compared to the PSP based digital radiograph systems and conventional film [26]. However, only size 2 sensor was used in this study which was too big for some patients. Therefore, more than one sensor size would need to be used to comfortably accommodate size variations among patients.

2.6 CONCLUSIONS:

Within the limitations of this study, the following conclusions can be drawn:

1. Both radiographs Ultraspeed (D-speed) film and RVG-6000 size 2 super CMOS based digital radiographic sensor significantly underestimated the actual clinical extension of the class II carious lesions. The mean radiographic differences in estimating the carious depth compared to the true depth were 0.29 mm and 0.42 mm for the RVG-6000 and D-speed film respectively.

2. RVG-6000 images were significantly more accurate than D-speed films in estimating the axial extension of the carious lesions especially in smaller size lesions.

3. DIFOTI correlated significantly with the clinical depth but to a lesser extent than the radiographs (D-speed and RVG-6000) and that correlation tended to be better with smaller lesions. DIFOTI significantly improved the estimation of the size of the lesion when used in conjunction with RVG-6000 and D-speed images. The sensitivity of the DIFOTI to detect the cavitated lesions was 0.83. Therefore, DIFOTI could be considered a useful adjunct to the clinical and radiographic examination in detecting interproximal carious lesions.

4. The cavitation percentage increased as the lesion depth increased radiographically and clinically. The cavitated lesions had clinical caries extension ranging from 0.7 to 2 mm and the lesions penetrating 1.1 to 2.0 mm into dentin clinically were 86% cavitated.

5. Visual examination has very high sensitivity to detect the lesions penetrating deep into dentin. All lesions penetrating 1.1 to 2 mm into dentin were visually detected.

6. Using the diagnostic results of the DIFOTI and visual examinations in conjunction with the radiographic images would definitely help the clinician when planning restorative treatment.

7. D-speed film was less unpleasant in the patient's mouth than the RVG-6000 size 2 sensor.

2.7 REFERENCES:

1. Kidd EAM, Pitts NB. A reappraisal of the value of the bitewing radiograph in the diagnosis of posterior approximal caries. Br Dent J 1990; 169:195-200.

2. Mann J, Pettigrew JC, Revach A, Arwas JR, Kochavi D. Assessment of the DMF-S index with the use of bitewing radiographs. Oral Surg Oral Med Oral Pathol 1989; 68(5):661-5.

3. De Vries HC, Ruiken HM, Konig KG, Van 't Hof MA. Radiographic versus clinical diagnosis of approximal carious lesions. Caries Res 1990; 24(5):364-70.

4. Hintze H. Screening with conventional and digital bite-wing radiography compared to clinical examination alone for caries detection in low-risk children. Caries Res 1993; 27(6):499-504.

5. Kooistra S, Dennison JB, Yaman P, Burt BA, Taylor GW. Radiographic versus clinical extension of class II carious lesions using an F-speed film. Oper Dent. 2005; 30(6):719-26.

6. Chong MJ, Seow WK, Purdie DM. Visual-tactile examination compared with conventional radiography, digital radiography, and diagnodent in diagnosis of occlusal occult caries in extracted premolars. Pediatric dentistry 2003; 25(4):341-9.

7. Parks ET, Williamson GF. Digital radiography: An overview. J Contemp Dent Pract 2002; 3(4):23-39

8. Tyndall DA, Ludlow JB, Platin E, Nair M. A comparison of Kodak Ektaspeed Plus film and the Siemens Sidexis digital imaging system for caries detection using receiver operating characteristic analysis. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1998; 85(1):113-8.

9. Wenzel A. Digital imaging for dental caries. Dent Clin North Am 2000; 44(2):319-38, vi.

10. Hintze H, Wenzel A, Jones C. *In-vitro* comparison of D- and E-speed film radiography, RVG, and Visualix digital radiography for the detection of enamel approximal and dentinal occlusal caries lesions. Caries Res. 1994; 28(5):363-7.

11. Nair MK, Nair UP. An in-vitro evaluation of Kodak Insight and Ektaspeed Plus film with a CMOS detector for natural proximal caries: ROC analysis. Caries Res 2001; 35(5):354-9.

12. Syriopoulos K, Sanderink GC, Velders XL, van der Stelt PF. Radiographic detection of approximal caries: a comparison of dental films and digital imaging systems. Dentomaxillofacial Radiol 2000; 29(5):312-8.

13. Pretty IA, Maupome G. A closer look at diagnosis in clinical dental practice: Part 5. Emerging technologies for caries detection and diagnosis. J Can Dent Assoc 2004; 70(8): 540, 540a-540i.

14. Schneiderman A, Elbaum M, Shultz T, Keem S, Greenebaum M, Driller J. Assessment of dental caries with digital imaging fiber-optic transillumination (DIFOTI): *In-vitro* study. Caries Res 1997; 31:103-10.

15. Young DA, Featherstone JDB. Digital fiber-optic trans-illumination, F-speed radiographic film and depth of approximal lesions. J Amer Dent Assoc 2005; 136:1682-7.

16. Jessee SA, Makins SR, Bretz WA. Accuracy of proximal caries depth determination using two intraoral film speeds. Gen Dent 1999; 47(1):88-93.

17. Thylstrup A, Bille J, Qvist V. Radiographic and observed tissue changes in approximal carious lesions at the time of operative treatment. Caries Res 1986; 20(1):75-84.

18. Espelid I, Tveit AB. Clinical and radiographic assessment of approximal carious lesions. Acta Odontol Scand 1986; 44:31-7.

19. Gungor K, Erten H, Akarslan ZZ, Celik I, Semiz M. Approximal carious lesion depth assessment with insight and ultraspeed films. Oper Dent 2005; 30(1):58-62.

20. Jacobsen JH, Hansen B, Wenzel A, Hintze H. Relationship between histological and radiographic caries lesion depth measured in images from four digital radiography systems. Caries Res 2004; 38:34–8.

21. Uprichard KK, Potter BJ, Russell CM, Schafer TE, Adair S, Weller RN. Comparison of direct digital and conventional radiography for the detection of proximal surface caries in the mixed dentition. Pediatric Dent 2000; 22(1):9-15.

22. Erten H, Akarslan ZZ, Topuz O. The efficiency of three different films and radiovisiography in detecting approximal carious lesions. Quintessence Int 2005; 36(1):65-70.

23. Pitts NB, Rimmer PA. An *in-vivo* comparison of radiographic and directly assessed clinical caries status of posterior approximal surfaces in primary and permanent teeth. Caries Res 1992; 26:146-52.

24. Bille J, Thylstrup A. Radiographic diagnosis and clinical tissue changes in relation to treatment of approximal carious lesions. Caries Res 1982; 16: l-6.

25. Wenzel A, Frandsen E, Hintze H. Patient's discomfort and cross-infection control in bitewing examination with a storage phosphor plate and a CCD-based sensor. J Dent 1999; 27(3):243-6.

26. Bahrami G, Hagstrom C, Wenzel A. Bitewing examination with four digital receptors. Dentomaxillofacial Radiol 2003; 32:317-21.

<u>APPENDICES</u>

APPENDIX A:

Consent Form:

<center>PATIENT'S CONSENT FORM</center>

<u>Research Project:</u> Clinical Evaluation of Dental Caries Extension using Different Diagnostic Tools.

<u>Investigators:</u> 1. Dr. Joseph Dennison, D.D.S., M.S
                      2. Dr. Peter Yaman, D.D.S., M.S.
                      3. Dr. Mohammed Bin-Shuwaish, B.D.S.

<u>Purpose of the Project:</u>
To compare the extent of tooth decay involving posterior teeth (back teeth) using different imaging procedures including digital x-ray, conventional x-ray, and Digital Image Fibro-Optic Trans-Illumination (DIFOTI), a Food and Drug Administration (FDA) approved diagnostic instrument that uses safe white light and instantly creates digital pictures to be used for tooth decay detection.

<u>Description of Human Subject Involvement:</u>
You have been selected as a possible participant in this study because you have tooth decay located in a posterior tooth (back tooth) surface that is contacting the next tooth and it needs to be filled.

The research: The dental medical records will be accessed to review the dental and medical history. One digital x-ray and one digital image with the DIFOTI tool will be taken for each decayed tooth. Several camera photographs of each lesion will be taken at various steps during the treatment procedure (intra-oral photographs that will not lead to personal identification of the participant subject).

The treatment: Filling(s) of your tooth (teeth) will be done, after finishing the research part, according to the normal, currently accepted methods, utilizing a conventional filling material. A conventional x-ray of each decayed tooth is part of the regular treatment.

The x-rays, photographs and dental treatment will be performed by Dr. Bin-Shuwaish (Graduate dental student) and be supervised by Dr. Dennison and Dr. Yaman (Directors of the graduate restorative program at the University of Michigan School of Dentistry).

<u>Length of Human Subject Participation:</u>
Each session will last for about 1 to 3 hour(s) of which about 40 minutes will be related to the research. If the subject has more than one decayed lesion then additional sessions may be scheduled. There are no follow-up or recall appointments.

Risk and Discomforts of the Participation:
The only anticipated risk related to the research is related to the extra radiation exposure for the digital radiograph. The extra radiation exposure by taking a digital radiograph will be about 70% less than a conventional radiograph. One dental conventional radiograph is 1/10,000 of the yearly maximum recommended dose. There is no anticipated risk related to the DIFOTI device

Benefits
Although you may not receive direct benefit from your participation, others may ultimately benefit from the knowledge obtained in this study. Results from this study should provide useful information to dentists in estimating the extension of dental decay into the tooth and making clinical decisions to place fillings.

Costs to Subject Resulting from Participation in the Study:
There will be **no cost** to subjects resulting from participation in the study

Payments to Subject for Participation in the Study:
There will be no financial reimbursement or incentive payment for participation in the study.
In order to show our appreciation for your participation in the study **the normal fee for placing the restoration will be waived,** and **free parking** will be provided during the time you come to the school to participate in the study.

Confidentiality of Records/Data:
You will not be identified in any reports on this study. The dental records, photographs, x-rays and electronic data will be kept confidential in a secured area to the extent provided by federal, state, and local law. However, the Institutional Review Board, the sponsor of the study (i.e. NIH, FDA, etc.), or university and government officials responsible for monitoring this study may inspect these records.

Management of Physical Injury:
In the unlikely event of physical injury resulting from research procedures, the University will provide first-aid medical treatment. Additional medical treatment will be provided in accordance with the determination by the University of its responsibility to provide such treatment. However, the University does not provide compensation to a person who is injured while participating as a subject in research.

Availability of Further Information:
If significant new knowledge is obtained during the course of this research which may relate to your participation, you will be informed of this knowledge.

Contacts Information:
If you have any questions regarding this project or any injury you may feel is related to this study, you may contact Mrs. Carol Stam (Clinical Research Coordinator) in Restorative Research, School of Dentistry, (734) 936-3276 or Dr. Mohammed Bin-Shuwaish (Investigator), School of Dentistry,
(734) 764-1532.

One copy of this document will be kept together with our research records on this study. A second copy will be placed in your dental record and a third copy will be given to you if requested.

Should you have any questions about your rights as a research participant, please contact the Institutional Review Board, Kate Keever, 540 E. Liberty Street, Suite 202, Ann Arbor, MI 48104-2210, (734) 936-0933, email: irbhsbs@umich.edu

<u>Voluntary Nature of Participation:</u>
Your participation in this project is voluntary. Even after you sign the informed consent document, you may decide to leave the study at any time without jeopardizing your eligibility for treatment within the School of Dentistry.

I have read the information given above and understand the meaning of this information. <u>Dr. Bin-Shuwaish</u> has offered to answer any question that I may have concerning the study. I hereby consent to participate in the study.

_____   _____

Adult subject (printed)   Consenting signature

_____   _____

Witness   Date

APPENDIX B:

Patient's questionnaire:

University of Michigan School of Dentistry
Graduate Operative Dentistry

Project Title: A Comparison of the Clinical Axial Extension of Class II Carious Lesions with Different Diagnostic Images.

Investigator: Mohammed Bin-Shuwaish, B.D.S

Patient's Name: _____   Tooth No.: _____

Date of Birth: _____   Code No.: _____

Please check (√) on the appropriate box (es) in the following:

1. While taking X-rays A* and B**:

☐ X-ray (A) was more comfortable than (B)
☐ X-ray (B) was more comfortable than (A)
☐ They were the same

2. What did bother you while taking x-ray (**A**)? You could check more than one box

☐ Size of the film (too big to bite on)
☐ Sharp edges of the film (it hurts when you bite)
☐ Biting on this film makes me gag
☐ Others, please specify _____
☐ Nothing bothered me with this X-ray

3. What did bother you while taking x-ray (**B**)? You could check more than one box

☐ Size of the film (too big to bite on)
☐ Sharp edges of the film (it hurts when you bite)
☐ Biting on this film makes me gag
☐ Biting on the film cord is uncomfortable
☐ Others, please specify _____
☐ Nothing bothered me with this X-ray

 * X-ray (A): Conventional D-speed radiograph
** X-ray (B): Digital Kodak RVG-6000 sensor

APPENDIX C:

Oral Findings Form:

A comparison of the Clinical Axial Extension of Class II Carious
Lesions with Three Diagnostic Images

A clinical study By: Mohammed Bin-Shuwaish, B.D.S.

Patient's Name: ---

Code No.: ------------------

Tooth No.: ---------------

<u>Oral Findings Form</u>

Tooth surface	"Black shadow" visible under marginal ridge		Presence of cavitation		
	Yes	No	Enamel	Dentin	No cavitation