The efficacy of a computerized caries detector in intraoral digital radiography

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Visually diagnosing radiographs for proximal caries is difficult because of variations in radiographs due to exposure level, tooth structure and tooth shape, and because the eye tends to smooth out shades of gray. A 1984 study by researchers at the University of California Los Angeles, or UCLA, School of Dentistry showed that dentists using film radiographs misdiagnosed the depth of caries up to 40 percent of the time and that healthy teeth were misdiagnosed as having caries up to 20 percent of the time.[1] Other studies have similarly demonstrated the difficulties of visually diagnosing proximal surfaces using film radiographs.[2-8]

Caries detector software enabled dentists to find 20 percent more cases of caries penetrating into dentin than they were able to find without it.

A more recent study with a digital radiography system showed no improvement in caries detection over film radiographs by visual evaluation alone.[9] Wenzel[10] did a thorough job of reviewing the long history of caries diagnosis with film and digital radiography systems through 1997 with similar conclusions. In March 2001, the National Institutes of Health, or NIH, published a consensus statement on diagnosis and management of dental caries, expressing a need for advances in radiographic methods of diagnosing noncavitated lesions and a need for both clinical trials and laboratory studies to evaluate the efficacy of new methods. The work reported in this article contributes to both of these needs as identified by the NIH panel of nonadvocate, nonfederal experts after hearing a number of presentations from prominent investigators in the field.[11]

ABSTRACT

Background. A unique software tool has been developed to assist dentists in the difficult task of diagnosing radiographs for proximal caries. The software, called Logicon Caries Detector (Northrop Grumman Information Technology, Herndon, Va.), extracts image features and correlates them with a database of known caries problems. The Logicon software was combined with the digital radiography system Trophy RadioVisioGraphy (Trophy Radiologie, Croissy-Beaubourg, France) and its effectiveness was measured in a clinical study, the results of which are reported here.

Methods. The manufacturer trained 18 dentists in private practices and one university clinic across the United States to use the Logicon Caries Detector software. The dentists diagnosed 175 surfaces with potential caries and adjacent teeth expected to be clean but included as control surfaces. The dentists first did a visual diagnosis only and then repeated the diagnosis using the software. If their final diagnosis called for it, a restoration was performed and the depth of caries was recorded.

Results. Effectiveness was gauged by calculating three measures of performance—sensitivity, specificity and accuracy—for dentin caries diagnosis by each dentist both before and after using Logicon Caries Detector. Sensitivity among all dentists before using the Logicon software was 70.3 percent and afterward was 90.5 percent, an improvement of 20.2 percent. Dentists' specificity was 88.6 percent before using the software and 88.3 percent afterward, with a difference of -0.3 percent. Dentists' accuracy was 75.6 percent before using the software and 88.3 percent afterward, with an improvement of 12.7 percent.

Conclusions. Logicon Caries Detector enabled dentists to find 20 percent more cases of caries penetrating into dentin than they were able to find without it, while not causing them to mistreat any additional healthy teeth.

Clinical Implications. Digital radiography and smart software like Logicon Caries Detector will improve dentists' diagnostic abilities and lead to better patient care.

The advent of digital radiography has brought new opportunities for smart software to aid the dentist. Logicon Inc. (now Northrop Grumman Information Technology, Herndon, Va.) developed a unique software tool to assist the dentist in the task of diagnosing proximal caries. (The Logicon Caries Detector is distributed worldwide by Trophy Radiologie, Croissy-Beaubourg, France, and in the United States by Trophy Dental Inc., Danbury, Conn.) The tool analyzes changes in radiographic density (directly related to the tooth density) to identify demineralized regions of the tooth and determines the probability that a carious lesion is present in the enamel and dentin. A graphic interface displays an enlarged radiographic image outlining the potential lesion site on the tooth in question with separate plots of tooth density variations and lesion probability.

Other researchers have developed software tools for caries detection that emphasize finding incipient caries in the enamel.[12-23] Logicon developed the first software tool to trace the caries from the surface through the enamel and into the dentin, to correlate the lesion features in the enamel and the dentin, and to produce probabilities that enamel and dentin lesions are present based on a comparison with a database of known caries cases developed at UCLA. Logicon received a U.S. patent for its process[24] and demonstrated its effectiveness first in a laboratory study on extracted teeth and then in a clinical study during normal patient care. Because there was no predicate device, Logicon applied for and received premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, for this software device.[25] The results of the clinical study are presented in this article, while the results of the laboratory study can be found in an FDA report available in print and online.[25]

MATERIALS AND METHODS

Hardware and software. Logicon Caries Detector runs on a Pentium (Intel Corporation, Santa Clara, Calif.) personal computer. It is a stand-alone software program that has been interfaced with the Trophy RadioVisioGraphy, or RVG, digital radiography system (Trophy Radiologie). The study reported here used Trophy's RVG-4 sensor. The dentist uses the Logicon software to inspect a potential lesion on a proximal surface to determine whether it penetrates deep enough to deserve treatment. After the dentist designates the region of interest with a custom computer mouse tool called the V-tool, the program runs automatically and produces three diagnostic aids, as shown in Figures 1 through 3. The program first finds the outer edge of the tooth and the dentinoenamel junction, or DEJ. (The software offers a manual mode in case the dentist prefers to trace these boundaries.) The radiographic density variation (that is, variations in shades of gray) and, hence, the density variation of the tooth then are analyzed along contours paralleling the tooth surface and the DEJ (Figure 1). Changes in the radiographic density are determined along each contour and displayed for the dentist in a separate plot labeled "Tooth Density" (Figure 2). Ten equally spaced contours are analyzed through the enamel and five in the dentin. (Figure 1 shows examples of the contours.) The program then looks for a correlation in the density dips that could be related to caries disease. If it finds such a pattern, it highlights the pattern on the density plot with red dots (Figure 2), and outlines the edges of the density dips in red on the tooth image (Figure 1).

To calculate the probability of a lesion's being present, the program extracts density and spatial information about the most obvious local radiolucencies—features such as magnitude (darkness), area, depth of penetration and alignment in the enamel and dentin. These features are used to classify lesions, which are then correlated with features in a database of 608 images of teeth (including molars, premolars, canines and incisors) with lesions at a range of depths seen in normal practice (including caries-free, lesion confined to outer one-half of enamel, lesion penetrating more than halfway through the enamel but not into the dentin, and lesion penetrating through the enamel but less than halfway through the dentin). The database was developed at the UCLA School of Dentistry using extracted teeth that were radiographed, then histologically sectioned and examined under a microscope to determine the true lesion status.[25] Using mathematical methods developed for image analysis in the defense industry (neural network techniques), the correlation produces the probabilities of a lesion in the enamel and dentin, as shown in Figure 3. This entire process is described more fully in the patent documentation.[24]

Course of treatment. Using Logicon Caries Detector's three diagnostic aids—the image with the radiolucency outlined, the tooth density plot and the lesion probabilities—the dentist can

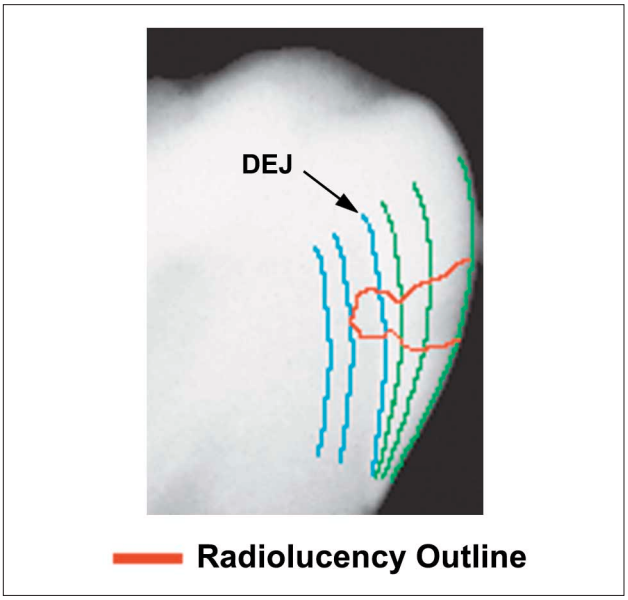

Figure 1. Diagnostic output 1 from Logicon Caries Detector (Northrop Grumman Information Technology, Herndon, Va.): tooth image showing selected analysis contours and radiolucency site. DEJ: Dentinoenamel junction. Reproduced with permission of Northrop Grumman Information Technology.

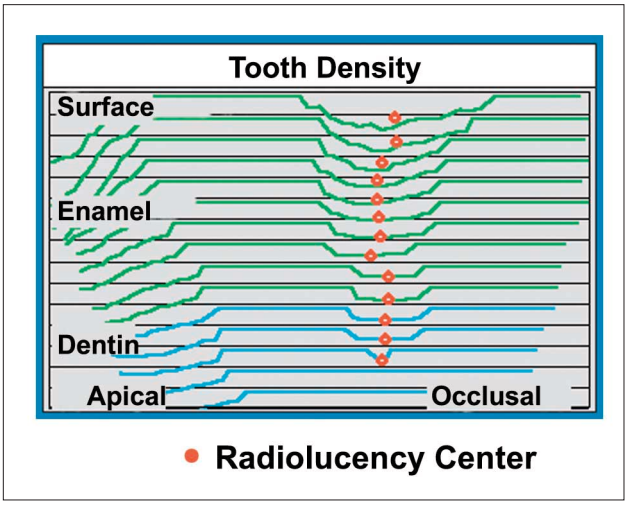

Figure 2. Diagnostic output 2 from Logicon Caries Detector (Northrop Grumman Information Technology, Herndon, Va.): tooth density change through enamel and into dentin, with radiolucency center highlighted. Reproduced with permission of Northrop Grumman Information Technology.

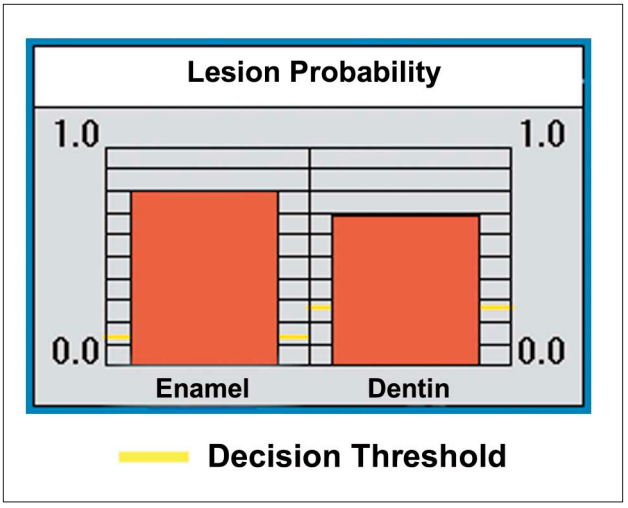

Figure 3. Diagnostic output 3 from Logicon Caries Detector (Northrop Grumman Information Technology, Herndon, Va.): lesion probability with decision threshold for 15 percent false-positive results. Reproduced with permission of Northrop Grumman Information Technology.

decide on a course of treatment. The bar graph of lesion probabilities uses a yellow horizontal line to indicate the decision threshold (Figure 3). The decision threshold is based on a 15 percent false-positive detection rate. If the probability bar for a dentinal lesion is well above this decision threshold, the dentist is advised to consider restorative treatment of the tooth. On the other hand, if the probability bar is near or below the decision threshold, the dentist is advised to wait and re-evaluate the case at a later date. The current analysis can be stored and compared with a later analysis. The dentist can change the decision threshold.

When the probability bar is above the decision threshold for an enamel lesion alone, the decision to treat is based more on the dentist's judgment than on the software's output. An enamel lesion, for example, may not progress or, alternatively, may recalcify. The dentist will decide on a case-by-case basis whether to perform a restoration or treat the tooth with fluoride and re-evaluate with another radiograph at a later date.

Dentist selection and training for clinical study. Eighteen dentists from throughout the eastern and western United States, including dentists in private practice and dentists in the faculty group practice at UCLA, volunteered to participate in the study. All were general practitioners. All had some experience with computers, and all the dentists in private practice had experience with the digital radiography system used in the study (Trophy RVG).

I headed the team of Logicon researchers who trained dentists in person in the use of Logicon Caries Detector, including how to start the software with the V-tool, interpret the highlighted features displayed on the radiographic image and interpret density variation plots and probability

bar graphs. We asked dentists to analyze a set of images of teeth for which the lesion status was known, and dentists were accepted into the study only after they demonstrated proficiency with the software. (We advised them that the analyses were sensitive to exactly what tooth anatomy was included in the region being analyzed, and to repeat the analyses so that they could understand this sensitivity.) We reviewed accepted radiographic criteria for the presence of caries with each dentist.[26] We advised dentists that we expected the software would be most helpful in determining whether lesions penetrated the dentin. All the dentists agreed that caries penetrating into dentin should be treated.

Patient inclusion criteria. We asked the dentists to impose no restrictions or bias on patient selection based on race or sex. In selecting teeth for analysis, we asked dentists to place no restriction on tooth type (that is, molar, premolar, canine or incisor). But in accordance with the product's indications for use and contraindications, we asked the dentists to include only proximal surfaces on permanent teeth, and to work around previous restorations and overlapping contacts if possible (or avoid them if necessary).

We instructed the dentists to select proximal surfaces potentially requiring restorative treatment on a first-come, first-served basis, to avoid biasing toward any subclass of patients or tooth surfaces. Specifically, we told the dentists to include all cases ranging from incipient caries (caries penetrating less than halfway into the enamel) to moderate and advanced caries (penetrating up to halfway through the dentin). The dentists were to exclude only the obvious (severe) cases of caries where the lesion was readily seen radiographically to penetrate more than halfway through the dentin. Qualifying surfaces with lesions were identified by each participating dentist (according to the agreed-on criteria) as test surfaces. In addition, we asked the dentists to include, whenever possible, a control surface with each test surface. These were surfaces that initially were interpreted (before being analyzed with Logicon Caries Detector) to be caries-free and that would be exposed to direct visual and physical examination if the test surfaces were prepared for restoration. Generally, the control surfaces were the surfaces adjacent to the test surfaces.

Test and evaluation conditions and data collection. The study was performed in a normal clinical setting with dentists following their normal procedures (with the addition that they obtained written patient consent). Each dentist performed an initial evaluation of test and control surfaces without Logicon Caries Detector. 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 Logicon Caries Detector to the radiographic images of both test and control surfaces and performed a second evaluation of these surfaces. 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. We asked each dentist to record the lesion's percentage of penetration into the enamel and its depth, in millimeters, of penetration into the dentin. The dentist assessed the control surface exposed during the preparation of the test surface to be caries-free if it exhibited no signs of cavitation or surface demineralization as indicated by a catch with a dental explorer. (However, in the absence of surface preparation, the possibility of subsurface demineralization cannot be excluded.) If a control surface showed signs of cavitation and the dentist chose to restore the surface, then we asked the dentist to record the same lesion data as for the test surface. For validation purposes, the dentists took intraoral camera images of all prepared and exposed surfaces.

Endpoint of clinical study. The endpoint of the study for each tooth surface was either the completion of the final restoration (such as amalgam restoration, crown or composite) or the dentist's decision not to restore the tooth because of lack of caries in the dentin. The determination of caries status for each surface was made once, and it was not the intention of this study to follow a given tooth surface over time.

The endpoint of the study as a whole was the point when a sufficient sample size was reached to obtain a statistically significant measure of the efficacy of Logicon Caries Detector in diagnosing dentinal lesions. To estimate the number of dentists and surfaces required, the Logicon researchers looked at the preliminary results from seven dentists. Each of these dentists looked at roughly 10 surfaces with an average improvement in diagnostic accuracy of about 20 percent and

standard deviation of approximately 35 percent. Assuming similar results from additional dentists, each analyzing 10 surfaces, and assuming a *t* distribution for the difference between means,[27] we estimated that a sample size of 10 dentists, each analyzing at least 10 surfaces, would be required to establish significance at the 5 percent level ($P = .05$). Ultimately, we obtained valid data on 175 surfaces from 18 dentists, each of whom analyzed an average of 9.7 surfaces, and this population proved to be adequate to obtain a statistically significant measure of efficacy.

Demographic data. The demographic data for the clinical study are summarized in Tables 1 and 2. The subjects represented a range of geographic locations, ages and races, while the sex distribution was nearly equal to that in the general population. Although the incidence of dental caries can depend on many factors, including diet (which generally changes with the patient's age) and local water mineral content, as well as treatment methods, the dentist's ability to detect caries generally is not dependent on these factors. As a result, we saw no reason to control for any of these demographic parameters except that, as mentioned above, all patients were to be of an age that they had permanent teeth (because our caries database includes only permanent teeth). Otherwise, we specifically wanted patients treated on a first-come, first-served basis to avoid any accidental bias due to patient selection. Our resulting data on caries detection, in fact, showed no dependence on the demographic parameters in Tables 1 and 2.

TABLE 1

DISTRIBUTION OF DENTISTS AND PATIENTS BY GEOGRAPHICAL REGION.

U.S. REGION AND STATE	NO. OF DENTISTS	NO. OF PATIENTS	NO. OF SURFACES
West			
California	7	32	61
Utah	1	8	19
Idaho	1	3	5
Washington	3	24	42
Southeast			
North Carolina	4	18	39
Georgia	1	2	3
Northeast			
New York	1	3	6
TOTAL	**18**	**90**	**175**

TABLE 2

DISTRIBUTION OF DENTISTS AND PATIENTS BY AGE, RACE AND SEX.

VARIABLE	NO. OF PATIENTS	NO. OF SURFACES
Age Group (Years)		
10-19	13	29
20-29	20	47
30-39	23	40
40-49	18	32
50-59	6	11
60-69	5	9
70-79	3	5
> 80	0	0
Unreported	2	2
Race/Ethnic Group		
Caucasian (non-Hispanic)	68	130
African-American (non-Hispanic)	2	4
Hispanic	3	5
Asian	2	5
Other or unreported	15	31
Sex		
Male	42	85
Female	48	90

RESULTS

We obtained valid data from 18 general-practitioner dentists with 90 patients in 16 private practice offices (including three dentists in the UCLA Faculty Group Practice). These dentists assessed a total of 175 valid proximal tooth surfaces for the presence of lesions penetrating into the dentin. Initially, a total of 218 tooth surfaces were enrolled in the study, but for 27 of these surfaces, the treatment was not completed because the patient did not return for treatment or the dentist was unable to schedule the patient

TABLE 3

RESULTS OF LOGICON CARIES DETECTOR* CLINICAL STUDY.†

MEASURE	SCORE AT MEASUREMENT POINT (%)		DIFFERENCE (%)	SIGNIFICANCE P VALUE
	Before Using LCD	After Using LCD		
Sensitivity (True Positive)	70.3‡ (± SD§ 33.6) (± SEM¶ 8.1)	90.5 (± SD 14.4) (± SEM 3.5)	+20.2 (± SD 36.4) (± SEM 8.8)	Mean .0357# Median .0371**
Specificity (True Negative)	88.6 (± SD 23.2) (± SEM 5.6)	88.3 (± SD 25.6) (± SEM 6.2)	-0.3 (± SD 3.7) (± SEM 0.9)	Mean .754 Median .99
Accuracy	75.6 (± SD 23.8) (± SEM 5.6)	88.3 (± SD 17.0) (± SEM 4.0)	+12.7 (± SD 24.7) (± SEM 5.8)	Mean .0428 Median .0537

* Logicon Caries Detector, or LCD, is manufactured by Northrop Grumman Information Technology, Herndon, Va.
† The study involved 18 dentists treating a total of 175 surfaces. The treatment criterion was caries penetration into dentin.
‡ Mean values based on performance of each dentist.
§ SD: Standard deviation.
¶ SEM: Standard error of the mean.
\# Based on unweighted paired *t* test.
** Based on Wilcoxon signed rank test.

for the study. An additional 16 surfaces were eliminated from the study because of deviation from the study protocol, resulting in the absence of usable valid data.

We gauged effectiveness by calculating three measures of performance—sensitivity, specificity and accuracy—for dentin caries diagnosis by each dentist both before and after using Logicon Caries Detector. As shown in Table 3, the average (mean) sensitivity among all the dentists before they used Logicon Caries Detector was 70.3 percent; after they used the software, their sensitivity was 90.5 percent, with a difference of 20.2 percent. Considerable variation exists in the performance between dentists (as reflected in the large value of standard deviation), but we observed a strong trend toward improvement for most dentists (as reflected in the much smaller value of standard error of the mean).

To control for dentist variability, we performed an unweighted paired *t* test[28] and the Wilcoxon signed rank test[29] to determine whether the observed mean and median differences in sensitivity were significant. The resulting *P* values were .0357 and .0371, respectively, for the two tests. Since the *P* values are small, we are able to reject the null hypothesis and conclude that there is a significant improvement in sensitivity associated with the use of Logicon Caries Detector.

One cannot make the same conclusion for specificity. As shown in Table 3, the average (mean) specificity for all dentists before using Logicon Caries Detector was 88.6 percent and after using it was 88.3 percent, with a difference of -0.3 percent. The observed mean difference has a *P* value of 0.754 (based on the paired *t* test), and the observed median difference has a *P* value of .99 (based on the Wilcoxon test). That is, the observed result is consistent with the true mean (and median) difference being zero, and we can conclude that there is no change in specificity.

Finally, as shown in Table 3, the average (mean) accuracy for all dentists before using Logicon Caries Detector was 75.6 percent and after using it was 88.3 percent, with a difference of 12.7 percent. The observed mean difference has a *P* value of .0428 (based on the paired *t* test), and the observed median difference has a *P* value of .0537 (based on the Wilcoxon test).

Thus our observed mean and median differences are significantly different from zero, and we can conclude there is a significant improvement in diagnostic accuracy associated with the use of Logicon Caries Detector. In view of the findings of this study, it is reasonable to conclude that the improvement in accuracy is due entirely to the improvement in sensitivity.

DISCUSSION

Evaluating radiographs for caries can be a challenging problem. The advent of digital radiography makes it possible to use advanced pattern recognition methods to aid the dentist in the diagnosis of caries problems that are difficult to see. Logicon Caries Detector was designed to accomplish several things:

- to extract the maximum information from the shades of gray in digital radiographic images, which provide more information than the human eye can normally see (the Trophy RVG System

displays 256 shades of gray, as is typical for digital radiographic systems, while the human eye generally can discern about 40 shades of gray);
- to correlate the extracted image features with a database of known caries disease features;
- to display the information in a format that helps the dentist make a treatment decision and helps in explaining the decision to the patient.

The performance of the dentists participating in the clinical study described in this article demonstrates that Logicon Caries Detector can help dentists find 20 percent more cases of caries penetrating into the dentin without causing them to misdiagnose additional healthy teeth. This improvement was found by 18 dentists who treated 175 surfaces with difficult-to-see caries problems (the obvious cases of dentin penetration were not included in the study). We found the results to be statistically significant using standard statistical tests. It would be of interest to collect additional clinical data with other sensors. Since the software analyzes shades of gray, there is no reason to believe that its performance would be different, but we would like to verify that. We also would like to apply the techniques used in this study to other caries problems, such as recurrent caries under existing restorations.

It is important to note that this improvement in caries detection was found in a clinical environment where dentists made decisions to treat or not treat and actually performed the treatment when appropriate. A recently published laboratory study involving use of Logicon Caries Detector concluded that the product did not improve the observers' ability to detect caries.[30] However, that study did not involve practicing dentists treating patients in a clinical setting. Thus, those testers received no feedback on how to use the tool. Another recent laboratory study found significant improvement using Logicon Caries Detector over visual diagnoses alone (by a factor of three), although the sensitivity of Logicon Caries Detector was below what is reported here (A.G. Farman, Ph.D., D.Sc., and B.C. Kang, D.D.S., Ph.D., University of Louisville, School of Dentistry, personal communication, March 2001).

CONCLUSION

The advent of digital radiography for the dentist's office has provided the opportunity for the development of smart image analysis tools to assist the dentist in evaluating radiographs. We have demonstrated that Logicon Caries Detector can enable dentists to find 20 percent more cases of caries penetrating the dentin than they were able to find without it, while not causing them to mistreat any additional healthy teeth. This same tool provides the dentist a graphic way of explaining to the patient why treatment is needed when it is called for. Logicon Caries Detector is the first diagnostic tool of its type to be demonstrated as efficacious in a clinical study under normal dental operating conditions and to be approved by the FDA at its highest level (normally reserved for lifesaving drugs and devices). There are many more opportunities to develop smart software to assist dentists in evaluating radiographs. ■

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