

## CLINICAL RESEARCH

# An evaluation of quantitative percussion diagnostics for determining the probability of a microgap defect in restored and unrestored teeth: A prospective clinical study

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Structural integrity is an engineering field that helps ensure that a structure or structural component is fit for purpose under normal operational conditions and safe, even if conditions exceed those of the original design.<sup>1</sup> Structural integrity includes supporting its own weight and aiming to prevent deformation, fracture, or catastrophic failure and needs to be maintained for the life of a structure, necessitating periodic inspection and maintenance.<sup>2</sup>

Identification of common dental conditions related to structural integrity, particularly microscopic or hidden defects, has been challenging. Improved evidence-based guidelines are needed to prevent, diagnose, and treat cracks in teeth.<sup>3-5</sup> Conventional dental diagnostic aids based upon imagery and patient symptoms have only been partially effective for the

### ABSTRACT

**Statement of problem.** Current dental diagnostics are image based and cannot detect a structural microgap defect such as a crack in a tooth. Whether percussion diagnostics can effectively diagnose a microgap defect is unclear.

**Purpose.** The purpose of the present study was to determine from a large multicenter prospective clinical study whether quantitative percussion diagnostics (QPD) could detect structural damage in teeth and whether a probability of its presence could be provided.

**Material and methods.** A nonrandomized prospective and multicenter clinical validation study with 224 participants was performed in 5 centers with 6 independent investigators. The study used QPD and the normal fit error to determine whether a microgap defect was present in a natural tooth. Teams 1 and 2 were blinded. Team 1 tested teeth scheduled for restoration with QPD, and Team 2 disassembled the teeth aided by a clinical microscope, transillumination, and a penetrant dye. Microgap defects were documented in written and video formats. Controls were participants without damaged teeth. The percussion response from each tooth was stored on a computer and analyzed. A total of 243 teeth were tested to provide approximately 95% power to test the performance goal of 70%, based on an assumed population overall agreement of 80%.

**Results.** Regardless of the collection method, tooth geometry, restoration material used, or restoration type, the data on detecting a microgap defect in a tooth were accurate. The data also reflected good sensitivity and specificity consistent with previously published clinical studies. The combined study data showed an overall agreement of 87.5% with a 95% confidence interval (84.2 to 90.3), beyond the 70% predetermined performance goal. The combined study data determined whether it was possible to predict the probability of a microgap defect.

**Conclusions.** The results showed that the data on detecting microgap defects in a tooth site were consistently accurate and confirmed that QPD provided information to aid the clinician in treatment planning and early preventative treatment. QPD can also alert the clinician of probable diagnosed and undiagnosed structural problems via the use of a probability curve. (J Prosthet Dent 2023;■:■-■)

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## Clinical Implications

A noninvasive aid to diagnostics can help predict the probability of microgap defects in a tooth or implant structure to aid in treatment planning. Examples of microgap defects include cracks in teeth or implants, failing crowns or restorations, and weakened bone support. Early identification of a microgap defect can allow preventive treatments to slow fatigue damage processes and identify areas of concern needing immediate evaluation or treatment.

detection of microgap defects such as cracks in teeth or restorations, cracks or gaps between the tooth and its restoration, and microgaps between a tooth root or implant and bone.<sup>6</sup> Radiographic identification is typically impossible unless the X-ray beam is aligned with the defect, while relying on symptoms may lead to identification that has been delayed until advanced structural breakdown has occurred.<sup>7-15</sup> Often, gaps associated with these defects are smaller than the resolution of the imaging system.<sup>8</sup>

Identifying microgaps is further complicated as established dental nomenclature does not have terms that clearly identify fatigue failure conditions in teeth and dental implants. Fatigue failure processes have been well-documented in engineering literature and for dental materials<sup>16</sup> but seldom mentioned for teeth or implants. However, the term microgap has been accepted into the peer-reviewed dental literature.<sup>17</sup> Therefore, it follows that microgap defects can be evaluated as a group of differing manifestations of this physical finding.

Patients who exhibit long-term parafunction generally experience more frequent tooth and implant fracture.<sup>4,18,19</sup> Dental literature refers to the “cracked tooth syndrome” and classifies cracks by their location in the tooth.<sup>20</sup> However, tooth fracture is only one manifestation of fatigue failure in a tooth that will oscillate upon percussion. Other microgap defects within dental structures can also result in oscillation. For example, a damaged periodontal ligament (PDL) because of periodontal disease or occlusal overload constitutes a microgap defect because of the narrowness of the PDL (approximately 200  $\mu\text{m}$ ).<sup>21</sup> Fatigue loading can also produce a microgap defect between a restoration and tooth structure, for example, subsequent to cement breakdown between a restoration and a tooth.<sup>22</sup> Additionally, biological overloading of the bone surrounding an implant will create a microgap defect during early stage failure because of bone loss.<sup>23,24</sup>

Microgap defects can continue to grow under occlusal and parafunctional loading if there is no intervention. Sufficient repeated loading opens a microgap defect over

time (unprotected parafunction, bruxism, gum chewing, or ice crunching) and extends the depth. If a microgap defect could be monitored, a clinician could intervene when appropriate. Detection of microgap defects is important as crack growth resistance decreases as cracks extend deeper into tissue.<sup>25</sup>

Quantitative percussion diagnostics (QPD) is a mechanics-based test and data analysis system designed to noninvasively determine the structural stability of objects.<sup>26</sup> QPD can be used to assess the structural stability of teeth and dental implants by lightly percussing their buccal surface. The energy returned to the percussion probe as a function of time is plotted as an energy return graph (ERG). From these data, the normal fit error (NFE) is calculated based on a nonlinear regression fit. Previous studies have described how NFE increases with the amount of disruption in the ERG and therefore is indicative of the presence of a microgap defect.<sup>26-31</sup>

QPD can therefore provide knowledge of the presence of a microgap defect in intraoral sites during comprehensive examinations before and after restorations and as a long-term monitoring device, as determined in previous *in vitro*, *ex vivo*, and clinical studies.<sup>26-31</sup>

Since an increase in the oscillation in a site indicates extension of the corresponding microgap defect, a new paradigm for assessing structural deterioration of teeth or implants through detection and monitoring of microgap defects would aid the clinician in establishing appropriate treatment plans and help assess the effectiveness of those treatments over time.

An adjunct methodology to current clinical standards would allow a clinician to avoid an invasive procedure on nonstructurally compromised teeth or implants when a patient presents with vague pain that cannot be localized. Reliable detection of the microgap defect causing this pain could lead to more preventive and less invasive treatments. Also, an accurate, fast, noninvasive, nonradiation-based diagnostic aid could provide further verification of structural strength before needed invasive treatments.

The primary objective of the present study was to perform a prospective clinical validation of QPD as an aid in detecting the probability of damage in natural teeth as represented by an increase in NFE. The null hypothesis was that predicting the probability of the presence of microgap defects in a tooth would not be possible based upon the ERG and NFE.

## MATERIAL AND METHODS

A nonrandomized prospective and multicentered clinical validation study was performed in 5 study centers with 6 independent investigators. Three of the centers were in California (01CS, 01W in Newport Beach, 03S in San Luis

**Table 1.** Summary of participant demographics

Demographic	Estimated Statistics
Age (years)	55.7 ±19.91 (220) [18.0 - 94.0]
<b>Sex</b>	—
Female	134/220 (60.9%)
Male	86/220 (39.1%)
<b>Ethnicity</b>	—
White	181/220 (82.3%)
Asian	15/220 (6.8%)
Hispanic/Latino	14/220 (6.4%)
African American	8/220 (3.6%)
Pacific Islander	2/220 (0.9%)

Continuous variables summarized as mean ±standard deviation (n)[minimum–maximum]. Categorical variables summarized as number of participants in each category/cohort size (percentage).

Obispo, and 04J in Torrance), 02H in Florida (Venice), and 05S in Indiana (Noblesville). Both prospective and retrospective data were generated by 01CS. Only retrospective results were provided by 05S. The other investigators generated prospective data only. The goal was to determine whether a novel QPD medical device (Periometer; Perimetrics Inc) could aid the clinician in identifying microgap defects in natural teeth using NFE. The device handpiece contained a probe that tapped the facial or buccal surface of the tooth. The percussion response was analyzed to compute an NFE value displayed in the user interface. NFE has been further described previously.<sup>26</sup>

The recruited 224 participants between the ages of 18 to 94 were patients of the principal investigators (PIs) scheduled for restorative procedures. Their demographics are summarized in Table 1 and were consistent with the demographics of the intended participant population.

Each clinical study center had in-person training from experienced investigators in the administration of the testing device, the protocol for disassembly, and the needed documentation. The testing software program was developed using a graphical programming environment (LabVIEW; National Instruments Corp) running on an operating system (Windows 10; Microsoft Corp). Data from the software and participant charts were recorded onto patient report forms secured at the study center and transferred electronically in secure files to the chief research assistant. All clinical centers were trained in current Good Clinical Practices and issued a Good Clinical Research Practice Manual.

The principal investigator (J.C.W.) ensured voluntary participation, signed informed consents, and single visit testing. Each clinical study center had 2 teams, the testing team, composed of a research data administrator to administer the percussion testing and the disassembly team, composed of the dentist PI and a dental assistant, both blinded to QPD results.

**Figure 1.** Participant being tested with Periometer.

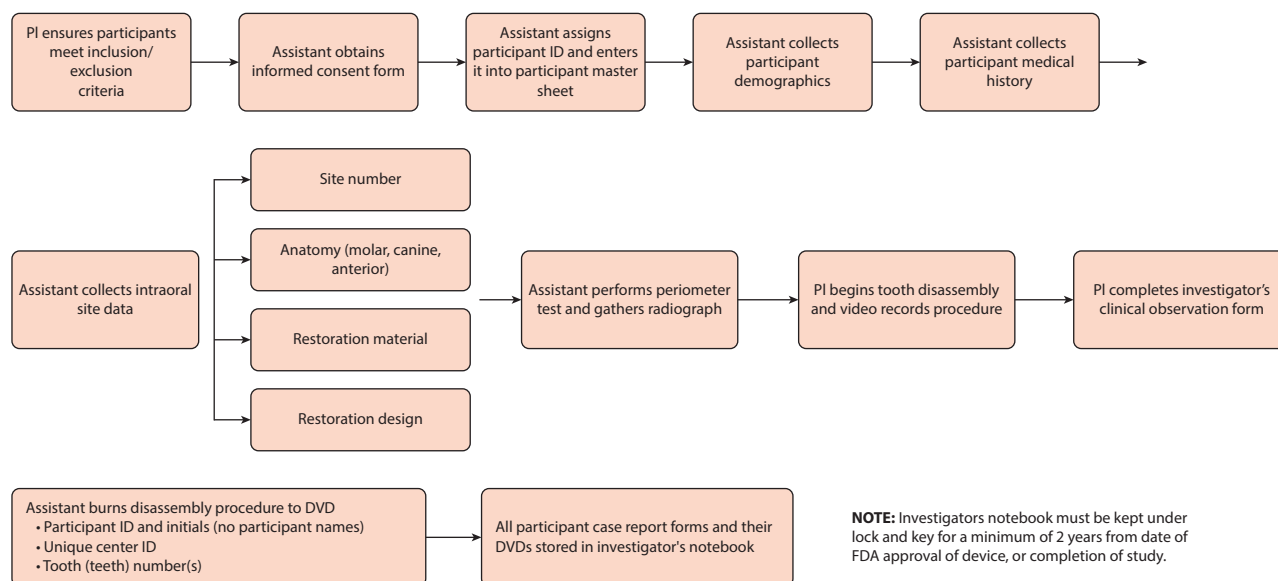
Each participant was seated upright for the QPD test. The handpiece was placed with the tip tab on the buccal cusp or incisal edge of the tooth, the tip face flush to the buccal surface and the handpiece horizontal as indicated by a level on the handpiece (Fig. 1). The participant could tilt their head for proper handpiece orientation. The NFE was recorded in the patient report form.

During the disassembly, the PI was aided by the clinical microscope (Global Surgical) at ×10, transillumination, penetrant dye (Toluidine Blue; Taylor), and video documentation for evaluating sites for microgap defects as described previously.<sup>27,28</sup> In the final video documentation, the tip of the explorer was used to highlight the presence of microgap defects.

Patient report forms were entered into a Health Insurance Portability and Accountability Act (HIPAA)-compliant cloud database validated to meet Food and Drug Administration (FDA) regulation 21 Code of Federal Regulations (CFR) Part 11 according to a standard operation procedure. An independent quality assurance review ensured data integrity (Fig. 2).

Inclusion criteria specified the participant needed to be between the ages of 18 and 100, in general good health, and provided written informed consent and to agree not to participate in any other oral or dental product clinical study and to follow the study procedures. Participants had current radiographs and a planned restoration that would expose dentin, except for the control patients who did not need restorations. Participants were excluded if they had any medical condition that might interfere with the study procedures or had received orthodontic treatment within the previous 18 months. Sites that were excluded from the study were those overlapping with an adjacent site, teeth restored with precious metal crowns, and fixed partial denture abutments or splinted restorations.

The study goal was to evaluate a total of 243 disassembled teeth for a microgap defect. However, all study participants were scheduled for restorative treatment, so most had one or more microgap defects present, and few participants presented with teeth without



**Figure 2.** Study flowchart. DVD, digital video disc; FDA, Federal Drug Administration.

defects. Of concern was how to create a mix of damaged and potentially undamaged teeth for the blinded investigator to evaluate. A plan was approved to help identify control participants without causing damage to identified control teeth. A protocol addendum retained the blinded clinician component of the original study by mixing teeth with no or minimal microgap defects with unrestored teeth with microgap defects. The protocol used a dental hygienist to screen appointed hygiene recall patients to identify teeth that appeared to have no visual or radiographic defects. Qualifying patients with informed consent were given a QPD test by the testing team.

In previous studies, an NFE of approximately 0.020 was identified as a transitional zone (that is, not a distinct cutoff) from no damage to beginning damage. Therefore, any natural tooth site that fit the inclusion criteria and had an NFE of 0.020 or below was deemed to have less probability of a microgap defect and, if chosen by the blinded PI as a control tooth, was included in the study.

After QPD testing of the potential control participant, the dental assistant identified tooth sites that had an NFE of 0.020 or below. Candidate teeth had no restorations, had not received orthodontic treatment within the previous 18 months, and were free of outward signs of trauma or damage. The dental assistant then randomly chose an equal number of teeth above the NFE threshold of 0.020 and randomized the order of the teeth below and above the 0.020 threshold under the guidance of the clinical study director. When possible, anterior and posterior teeth were included. Everyone except the dental assistant was blinded to the screening criteria.

The disassembly team examined the combined and randomly intermixed tooth groups containing potential

microgap defects. The PIs were not informed that the teeth they tested were from a predetermined pool and had no knowledge of why any teeth were chosen. The PIs were instructed to examine each tooth for the presence of a microgap defect with the identical protocol of the validation study using the clinical microscope at  $\times 10$  magnification, transillumination, and penetrant dye, without tooth disassembly. The examination was video documented with and without transillumination, and findings recorded on the patient report form.

The primary effectiveness endpoint of the study was to show that the Periometer detected the presence or absence of microgap defects (cracks). Since there are no commercially available percussion devices cleared by the FDA that aid the clinician in crack diagnosis, the performance goal was set for 70% and considered a clinically acceptable performance. This value was prespecified and was the basis for the sample size calculations for the study. The null hypothesis was the proportion of sites with overall agreement between the Periometer and clinician assessment of the presence of cracks would be 70% or less. The alternative hypothesis was that this agreement would be greater than 70%. The test was to be based on an exact test of a binomial proportion at the one-sided 0.025 alpha level. Successful rejection of the null hypothesis would indicate that the classification performance statistically exceeds the performance goal of 70%. In the protocol, a total of 243 teeth were planned, as this would provide approximately 95% power to test the performance goal based on an assumed population overall agreement of 80%.

Unfortunately, because of the COVID-19 pandemic, all PIs had been required to close their centers, which

**Table 2.** Summary of tooth characteristics

Tooth Characteristic	Estimated Statistics
<b>Tooth geometry</b>	—
Molar	224/481 (46.6%)
Premolar or canine	132/481 (27.4%)
Anterior	125/481 (26%)
<b>Restoration material</b>	—
Unrestored	218/481 (45.3%)
Amalgam	108/481 (22.5%)
Composite resin	68/481 (14.1%)
Ceramic	45/481 (9.4%)
Noble metal-ceramic	15/481 (3.1%)
Base metal-ceramic	15/481 (3.1%)
Veneered zirconia	6/481 (1.2%)
Gold	3/481 (0.6%)
Other	2/481 (0.4%)
Amalgam/Composite resin	1/481 (0.2%)
<b>Restoration type</b>	—
Unrestored	219/481 (45.5%)
Filling	169/481 (35.1%)
Complete crown	38/481 (7.9%)
Onlay	21/481 (4.4%)
Crown	18/481 (3.7%)
Veneer	14/481 (2.9%)
Inlay	1/481 (0.2%)
Other: sealant (occlusal)	1/481 (0.2%)
<b>No crack</b>	—
False	238/481 (49.5%)
True	226/481 (47%)
<b>Crack in tooth</b>	—
Absent	309/481 (64.2%)
Present	155/481 (32.2%)
<b>Crack in restoration</b>	—
Absent	415/481 (86.3%)
Present	49/481 (10.2%)
<b>Crack between restoration and tooth</b>	—
Absent	333/481 (69.2%)
Present	131/481 (27.2%)

Continuous variables summarized as mean  $\pm$  standard deviation (n)/(minimum–maximum). Categorical variables summarized as number of participants in each category/cohort size (percentage).

resulted in the collection of only 173 teeth of the proposed 243. A second addendum was filed to collect additional data from investigators' retrospective data to meet the goal of 243 teeth: data were collected retrospectively on 76 teeth that had been disassembled and documented with the identical protocol for the present study from the offices of 2 PIs to meet the goal of 243 teeth.

The present study also investigated tooth characteristics that could influence results other than microgap defects in restorations, for example, between restorations and tooth structure and within the tooth. The effects of different tooth geometries, restoration materials, and restoration types were evaluated and are summarized in [Table 2](#).

**Table 3.** Agreement from prospective study data

MGD Classification	Blinded Clinical Assessment			
	MGD	No MGD	Total	
Periometer classification	MGD	173 (42.1%)	43 (10.5%)	216 (52.6%)
	No MGD	16 (3.9%)	179 (43.6%)	195 (47.4%)
	<b>Total</b>	189 (46.0%)	222 (54.0%)	411 (100.0%)

MGD, microgap defect. Overall agreement: 352/411 = 85.6%. 95% confidence interval: (81.9 - 88.9). *P* value from testing proportion  $\geq$  70%: <.010.

**Table 4.** Agreement from retrospective data

QPD Finding	Blinded Clinical Assessment			
	MGD	No MGD	Total	
Periometer classification	MGD	66 (94.3%)	1 (1.4%)	67 (95.7%)
	No MGD	0 (0.0%)	3 (4.3%)	3 (4.3%)
	<b>Total</b>	66 (94.3%)	4 (5.7%)	70 (100.0%)

MGD, microgap defect. Overall agreement: 69/70 = 98.6%. 95% confidence interval: (92.3 - 100.0). *P* value from testing proportion  $\geq$  70%: <.010.

## RESULTS

Using an exact binomial proportion test, overall agreement between QPD and clinician assessed microgap defects is summarized in [Table 3](#). The observed overall agreement was 85.6% with an associated lower confidence bound of 81.9%. This exceeded the prespecified performance goal of 70% ( $P < .01$ ). Compared with the clinician assessment, there were a total of 173 true positives, 179 true negatives, 16 false negatives, and 43 false positives. Based on both the blinded clinical assessment and the QPD classification, a relatively large number of participants had both a microgap defect present and no microgap defect.

Retrospective data were also collected as summarized in [Table 4](#). Like the prospective study data, overall agreement was 98.6%, more than the performance goal of 70%. Most of these data involved teeth with microgap defects. The prospective and retrospective data are aggregated and summarized in [Table 5](#), with an overall agreement of 87.5% with a 95% confidence interval and  $P < .01$  from testing proportion  $\geq$  70%. To exclude any concern about combining data sets, a test was conducted for heterogeneity with  $Q = 33.4$ ,  $P < .001$ .

Since multiple tooth sites were collected for participants, there was potential for within-participant correlation (that is, clustering). Additionally, there was some evidence of variation in agreement between corresponding tooth sites. To provide estimates of overall agreement that account for within-participant or within-center clustering, as a sensitivity analysis, 2 separate random effects logistic regression models were fit via generalized estimating equations ([Table 6](#)). Note that while the protocol used an estimator based on the Rao-Scott chi-square test, a modification was made to use a generalized estimation equation approach. The generalized estimation equation approach is a more modern and

**Table 5.** Agreement from combined study data

QPD Finding	Blinded Clinical Assessment			
	MGD	No MGD	Total	
Perimeter classification	MGD	239 (49.7%)	44 (9.1%)	283 (58.8%)
	No MGD	16 (3.3%)	182 (37.8%)	198 (41.2%)
	<b>Total</b>	<b>255 (53.0%)</b>	<b>226 (47.0%)</b>	<b>481 (100.0%)</b>

MGD, microgap defect. Overall agreement: 421/481 = 87.5%. 95% confidence interval: (84.2 - 90.3). *P* value from testing proportion  $\geq$  70%: <.010.

**Table 7.** Agreement by clinical study center for combined prospective and retrospective data

Study Center	Agreement % (N/Study Center Total)
01CS	100.0% (23/23)
01W	91.8% (145/158)
02H	83.2% (79/95)
03S	82.2% (37/45)
04J	84.1% (116/138)
05S	95.5% (21/22)
All study centers combined	87.5% (421/481)

*P* value for study center heterogeneity: <.012.

standard approach for handling clustering and is more generalizable and suited to additional sensitivity analyses, if required. The results are summarized alongside results from a logistic regression model without clustering in Table 6. All results were consistent and demonstrated better performance relative to the 70% performance goal.

Overall agreement by study center is presented in Table 7. Note that the study sample size was not determined based on power requirements for individual centers and so results should be interpreted with caution. There was some evidence of variation between centers based on a logistic regression model ( $P=.012$ ). However, overall agreement exceeded 70% for all centers, and sensitivity analysis showed results that accounted for center clustering and were consistent with prospective results (Table 3).

Agreement by baseline demographic and clinical characteristics is summarized in Table 8. Note that the study was not powered for analyses within levels of subgroups and so results of an individual subgroup should be interpreted with caution as samples in some subgroups were limited. However, there was an overall high degree of consistency between subgroups, with a high overall agreement across various parameters. A probabilistic curve was developed to see the relationship between measured NFE and the probability that a microgap defect was present.

## DISCUSSION

The clinical endpoint for the present investigation was the probabilistic overall agreement of QPD and

**Table 6.** Sensitivity analysis

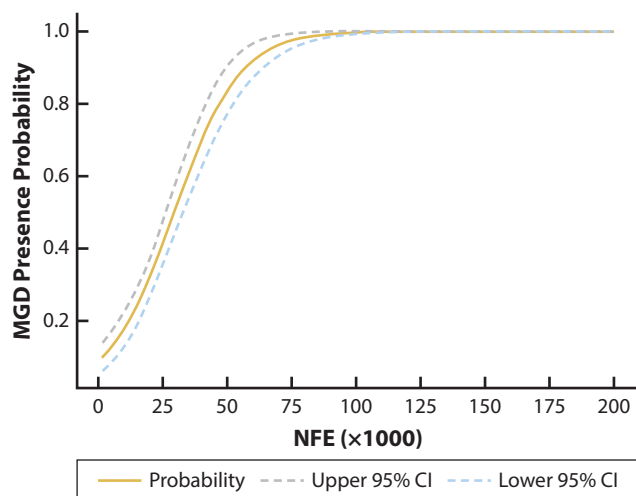
Cluster	Model-estimated Agreement	95% Confidence Interval	<i>P</i>
None	87.5	84.3 - 90.2	<.01
Within tooth sites	87.7	82.9 - 91.3	<.01
Within participants	86.9	83.3 - 89.8	<.01

Estimates from generalized estimating equations models accounting for clustering at level in cluster column.

**Table 8.** Agreement by subgroups

Subgroup	Agreement % (N/Subgroup Total)	95% Confidence Interval
<b>Age</b>	—	—
65 years or over	87.0% (114/131)	80.0 - 92.3
Under 65 years	87.7% (307/350)	83.8 - 91.0
<b>Sex</b>	—	—
Female	88.5% (262/296)	84.3 - 91.9
Male	85.9% (159/185)	80.1 - 90.6
<b>Tooth</b>	—	—
Anterior	88.0% (110/125)	81.0 - 93.1
Premolar or canine	85.6% (113/132)	78.4 - 91.1
Molar	88.4% (198/224)	83.5 - 92.3
<b>Restoration material</b>	—	—
Amalgam	86.1% (93/108)	78.1 - 92.0
Amalgam/Composite resin	100.0% (1/1)	2.5 - 100.0
Ceramic	93.3% (42/45)	81.7 - 98.6
Composite resin	91.2% (62/68)	81.8 - 96.7
Gold	100.0% (3/3)	29.2 - 100.0
Other	0.0% (0/2)	0.0 - 84.2
Noble metal-ceramic	100.0% (15/15)	78.2 - 100.0
Base metal-ceramic	86.7% (13/15)	59.5 - 98.3
Veneered zirconia	100.0% (6/6)	54.1 - 100.0
Unrestored	85.3% (186/218)	79.9 - 89.7
<b>Restoration type</b>	—	—
Crown	83.3% (15/18)	58.6 - 96.4
Filling	88.8% (150/169)	83.0 - 93.1
Full crown	86.8% (33/38)	71.9 - 95.6
Inlay	100.0% (1/1)	2.5 - 100.0
Onlay	100.0% (21/21)	83.9 - 100.0
Other: sealant (occlusal)	100.0% (1/1)	2.5 - 100.0
Unrestored	84.9% (186/219)	79.5 - 89.4
Veneer	100.0% (14/14)	76.8 - 100.0
<b>No MGD</b>	—	—
False	93.7% (223/238)	89.8 - 96.4
True	80.5% (182/226)	74.8 - 85.5
<b>MGD in tooth</b>	—	—
Absent (specificity)	85.1% (263/309)	80.6 - 88.9
Present (sensitivity)	91.6% (142/155)	86.1 - 95.5
<b>MGD in restoration</b>	—	—
Absent (specificity)	86.3% (358/415)	82.6 - 89.4
Present (sensitivity)	95.9% (47/49)	86.0 - 99.5
<b>MGD between restoration and tooth</b>	—	—
Absent (specificity)	84.4% (281/333)	80.0 - 88.1
Present (sensitivity)	94.7% (124/131)	89.3 - 97.8

MGD, microgap defect.



**Figure 3.** MGD presence probability distribution for NFE value. MGD, microgap defect; NFE, normal fit error.

microscopic examination for detecting microgap defects. The prespecified performance goal of 70% was met with an observed agreement of 85.6% (lower 95% confidence bound 81.9%). This provides clinically acceptable performance, since no other device exists for the noninvasive detection of cracks. Thus, the null hypothesis was rejected as the data showed that predicting the probability of the presence of microgap defects in a tooth or implant is possible based upon the ERG and NFE. The endpoint statistics also support previous clinical study findings that damage severity increased as oscillatory micromobility of the site increased.

Conventional diagnostic methodologies involve the combination of visual diagnostics and patient history or symptoms. The only method of validating QPD results indicating that a microgap defect is present reliably is to disassemble the tooth and any pre-existing restorations to examine for signs of cracks. The assessment of the quality of cement adherence to a crown is not possible by any current nondestructive diagnostic aid.

One use of the present statistical data was to construct a probability curve for the presence of a microgap defect based on the NFE value for a given site. A logistic regression curve was fit to the binary outcome for each site as a function of the single covariate of NFE. Modeling was based on a generalized linear model fit via iteratively reweighted least squares. Analysis was performed with a statistical software program (R 3.6.3; R Foundation for Statistical Computing). The resulting probability curve is shown in Figure 3, plotted using Python 3.10.8 and Statsmodel 0.13.5, with the plotted 95% confidence interval bands calculated using the delta method. If presented with a high microgap defect probability in a test site, the clinician should follow-up with other diagnostic tools to discover the source of the oscillations.

Limitations of the present study included the time required to carefully document the disassembly of natural teeth and the addition and justification of the addendums. Future research could include finite element models and physiological accuracy in in vitro models to facilitate the identification of different types of microgap defects while determining their severity.

## CONCLUSIONS

Based on the findings of this prospective clinical study, the following conclusions were drawn:

1. QPD was consistently accurate in detecting microgap defects in a tooth site regardless of geometry, restoration material, or restoration type.
2. QPD detected micromovement that occurred when a tooth containing a microgap defect was lightly percussed with an 87.5% overall agreement with disassembly findings.
3. QPD indicated that a microgap defect was present between the restoration and the tooth with 94.7% accuracy, within a tooth with 91.6% accuracy, and within a restoration with 95.9% accuracy.
4. QPD provided a noninvasive solution for detecting microgap defects as an aid to diagnosis. Finding a microgap defect early allows preventive techniques to be more effective.

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**CRediT authorship contribution statement**

**Cherilyn G. Sheets:** Writing – original draft, Conceptualization, Investigation, Visualization, Validation, Data curation, Methodology, Writing – review & editing. **Dennis A. Quan:** Writing – original draft, Conceptualization, Investigation, Visualization, Validation, Data curation, Methodology, Writing – review & editing. **Jean C. Wu:** Investigation, Writing – review & editing. **James C. Earthman:** Supervision, Conceptualization, Methodology, Data curation, Writing – review & editing.

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