

Evaluation of Efficacy of a New Custom-Made Pulse Oximeter Dental Probe in Comparison With the Electrical and Thermal Tests for Assessing Pulp Vitality

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Abstract

Pulse oximetry is a noninvasive method of measuring vascular health by evaluating oxygen saturation. This study evaluated the efficacy of a new custom-made pulse oximeter dental probe in comparison with the electrical and thermal tests for assessing pulp vitality. Sensitivity, specificity, negative predictive value, and positive predictive value for each test were calculated by comparing the test results with the actual pulpal status, as evaluated by direct visual inspection. The sensitivity of the pulse oximeter was found to be 1.00, as compared to 0.81 with the cold test and 0.71 with the electrical test. The specificity of the pulse oximeter was 0.95, as compared to 0.92 with the cold and electrical pulp tests. Thus, the custom-made pulse oximeter dental probe is an effective, accurate, and objective method of evaluating pulp vitality. (*J Endod* 2007;xx:xxx)

Key Words

Pulse oximeter, pulp vitality, pulse oximeter dental sensor holder

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The assessment of pulp vitality is a crucial diagnostic procedure in the practice of endodontics. Conventionally, the dentist has relied on tests that depend on the patient's perceived response to a stimulus as well as the dentist's interpretation of that response. These methods include thermal stimulation (as in the case of heat or cold application), electric stimulation, or direct dentin stimulation (test cavity).

A major shortcoming with the present pulp testing methods is that they indirectly monitor pulp vitality by measuring neural response, not vascular circulation. Stimulation of nerve fibers is not the ideal method to determine vitality status. Thus, vascular supply, not innervation, is the most accurate determinant for assessing pulp vitality (1, 2, 3, 4). As a result, teeth that have temporarily or permanently lost their sensory function (e.g., teeth damaged by trauma) will be nonresponsive to these tests. However, they may have intact vasculature (5, 6). Moreover, the nervous tissue, being highly resistant to inflammation, may remain reactive long after the surrounding tissues have degenerated. Therefore, thermal and electrical tests may give false-positive responses if only the pulp vasculature is damaged (2). Further, all these tests have the potential to produce an unpleasant and occasionally painful sensation, and inaccurate results may be obtained (3).

Recent attempts to develop a method for determination of pulpal circulation have involved the use of laser Doppler flowmetry, dual-wavelength spectrophotometry, and pulse oximetry. Although laser Doppler flowmetry has met with some success in medical applications, its use in dentistry has been hampered by the sizeable expense, lack of reproducibility, and sensitivity of the device to motion (7). Dual-wavelength spectrophotometry has been examined in the laboratory setting; it detects the presence of hemoglobin, not the circulation of blood (8).

The pulse oximeter is a noninvasive monitoring device widely used in medical practice to record blood oxygen saturation levels during the administration of intravenous anesthesia, using finger, foot, or ear probes. It was invented by Takuo Aoyagi, a biomedical engineer working for the Shimadzu Corporation in Kyoto, Japan, in the early 1970s (9). Pulse oximetry is a completely objective test that directly measures blood oxygen saturation levels, requiring no subjective response from the patient. It is based on principles of spectrophotometry (10) and optical plethysmography.

The sensor consists of two light-emitting diodes (LEDs); one transmits red light (640 nm) (Fig. 1, *a*), and the other transmits infrared light (940 nm) (Fig. 1, *b*). The LEDs transmit red and infrared light through a vascular bed, such as a finger or an ear, to a receiving photodetector (Fig. 1, *c*). Oxygenated hemoglobin and deoxygenated hemoglobin absorb different amounts of red and infrared light. The pulsatile change in the blood volume causes periodic changes in the amount of red and infrared light absorbed by the vascular bed before reaching the photodetector. The relationship between the pulsatile change in the absorption of red light and the pulsatile change in the absorption of infrared light is analyzed by the pulse oximeter to determine the saturation of arterial blood (11, 12).

Earlier studies by Schnettler and Wallace (13) reported a correlation between pulp and systemic oxygen saturation readings using a modified pulse oximeter ear probe on a tooth. They recommended its use as a definitive pulp vitality tester. Kahan et al. (14) designed, built, and tested a reflectance tooth probe using a Biox 3740 oximeter. Pulse wave readings from the teeth were found to be synchronous with readings from the finger probe, but not consistently. They concluded that the accuracy

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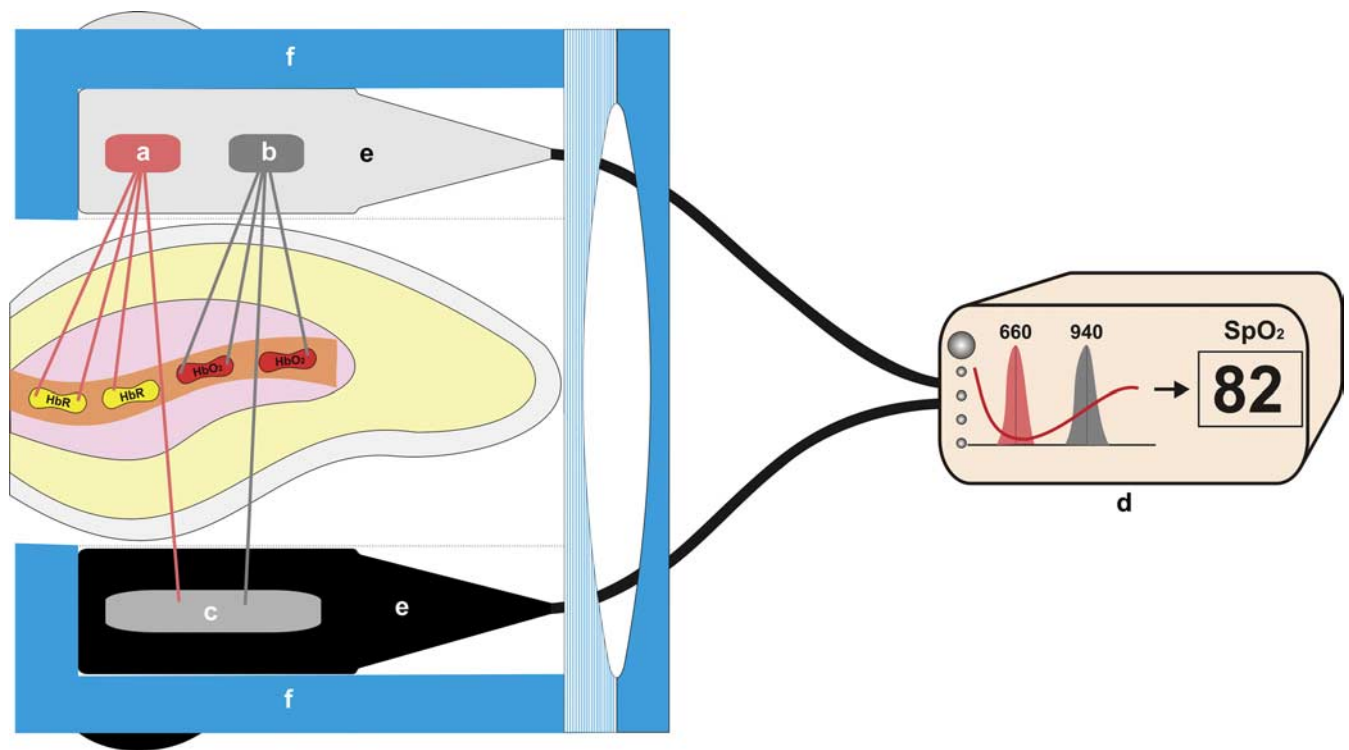


Figure 1. Mechanism of the dental pulse oximeter. (a) Light-emitting diode emitting red light at 660 nm. (b) Light-emitting diode emitting infrared light at 940 nm. (c) Photodetector. (d) Pulse oximeter monitor. (e) Pulse oximeter sensor. (f) Custom-made pulse oximeter sensor holder. HbO₂, oxygenated hemoglobin; HbR, deoxygenated hemoglobin; SpO₂, oxygen saturation of arterial blood.

of the commercial instrument was disappointing, and in its present form, it was not considered to have predictable diagnostic value (14).

The pulse oximetry equipment consists of a *pulse oximeter monitor* (POM) (Fig. 1, d), which gives the digital display of oxygen saturation values, connected to a *pulse oximeter sensor* (POS) (Fig. 1, e), which is designed to anatomically conform to the area where oxygen saturation values are to be assessed, e.g., ear, finger, or toe sensor. The POS is held in place with a *sensor holder* (Fig. 1, f) to ensure accurate adaptation of the sensor in the area being assessed.

The critical requirement of using pulse oximetry in dentistry is that the sensor should conform to the size, shape, and anatomical contours of teeth. The sensor holder should also keep the LED and the photoreceptor as parallel as possible to each other so that the photoreceptor sensor receives the light transmitted through the tooth. Moreover, the sensor holder should ensure firm placement of the sensor on the tooth to obtain accurate measurements.

Taking into consideration the preceding requirements, the objectives of our study were, first, to design and build a custom-made dental POS holder that would facilitate the use of a commercially available multisite POS in determining the vitality of permanent teeth; and second, to compare the accuracy of the customized dental probe with thermal and electrical pulp tests by calculating the sensitivity, specificity, and negative and positive predictive values for these tests.

Materials and Methods

Eighty single-rooted incisors, canines, and premolars requiring endodontic therapy were selected for the study. Eighty patients were involved, as the sample was restricted to one tooth per patient. Before the tests were performed, the patients were apprised of the procedures and aim of the experiment. A signed informed consent form was obtained from each patient.

The accuracy of a pulp vitality testing device is based not only on its ability to identify teeth that are diseased, but also on accurately identifying teeth free of disease. Hence, the test group in this study was comprised of both vital and nonvital teeth requiring endodontic therapy. The inclusion criteria for these teeth were as follows:

1. Single-rooted teeth requiring endodontic therapy, in order to eliminate false-positive responses in multirrooted teeth.
2. Teeth otherwise normal but requiring intentional endodontic therapy due to prosthodontic considerations such as overdenture abutments or supraerupted teeth.
3. Teeth with deep carious lesions with history, clinical, and radiographic changes indicative of irreversible pulpal changes.

All the vitality tests were done prior to the start of the endodontic therapy. Three blinded operators assessed the vitality status of the test teeth, each using one of the pulp vitality testing devices. The order of testing was first the electrical pulp test, followed by pulse oximetry, and then the cold test, with a time lag of 30 minutes between each test.

For the electrical test, the Parkell pulp vitality tester (Parkell Electronics Division, Farmingdale, NY) was used. The contralateral tooth was used as control. If the current required to gain a response from the test tooth was the same as needed to excite the control, the pulp of the test group was considered normal, and was recorded as a positive response. The pulp of the test group was considered to be degenerating when much more current was required to gain a response compared to the control, and was recorded as a negative response. Lack of response was also recorded as a negative response. Two readings were taken for each tooth, with an interval of 5 minutes, and the average was recorded.



Figure 2. Pulse oximeter dental probe placed on patient's tooth.

For pulse oximetry testing, the following equipment was used:

1. A Nellcor 5th generation OxiMax 550 pulse oximeter (Tyco Healthcare Group LP, Pleasanton, CA) was selected, as it can detect motion and wrong placement of sensors. The "Sensor Message" feature of the OxiMax system examines the information available from the sensor, and uses a proprietary algorithm to evaluate parameters programmed into the memory chip of the particular sensor being used and current signal characteristics coming from the patient (15).
2. A Nellcor OxiMax™ Dura-Y D-YS multisite oxygen sensor (Tyco Healthcare Group LP) was selected, as the dimensions of this sensor were smaller than the mesiodistal dimensions of human permanent dentition.
3. A POS holder (patent pending) for the abovementioned sensor was designed and custom made to ensure accurate placement and adaptation of the sensor on human permanent teeth. This assembly of the existing POS adapted to the custom-made sensor holder is termed the pulse oximeter dental probe (PODP).

The PODP was placed on the teeth to be tested (Fig. 2). The probe was placed in such a way that the light would travel from the facial to the lingual surfaces through the middle of the crown. The values were recorded after 30 seconds of monitoring each tooth. The pulse oximetry value for a particular tooth was taken as a positive response if it was within the range of 75 to 85% oxygen saturation. Any value below 75% was taken as a negative response. The normal range for oxygen saturation values was determined by another study completed by our group, which compared results using this customized PODP with finger saturation values (16). That study demonstrated two things:

1. The oxygen saturation values for human permanent teeth using the customized PODP were in the range of 75 to 85%.
2. The oxygen saturation values for teeth (75–85%) were lower than for fingers (98%), possibly due to diffraction of the infrared light by the enamel prisms and dentin.

The thermal test studied was the cold application test. The test consisted of soaking a cotton pellet with 1,1,1,2-tetrafluoroethane (Endo ice® refrigerant spray, Coltène/Whaledent Inc., Mahwah, NJ) and placing it on the middle third of the facial surface of the tooth to be tested. A tooth was rated as having no response to cold if the patient felt no sensation after two 15-second applications at 2-minute intervals.

After the completion of pulp vitality testing, the pulp chamber was opened in all the test teeth, and the pulp status was registered as either

vital or necrotic by direct visual inspection (17). On opening the pulp chambers in the 80 tested teeth that were in need of endodontic treatment, it was observed that 42 pulps were necrotic (no bleeding, pulp tissue destruction) and 38 pulps were vital (bleeding from pulp tissue). This gave a disease prevalence of 52%.

The number of true positive, false positive, true negative, and false negative test results was calculated for each method, as compared to the assessment made on clinical visual examination. Based on this, the sensitivity, specificity, and positive and negative predictive values were calculated for each method.

Results

The cold test identified 34 of the 42 necrotic pulps as necrotic, whereas 8 teeth with necrotic pulps gave a sensitive reaction. Of the 38 teeth with vital pulp in need of endodontic treatment, the cold test identified 35, whereas 3 of the vital pulps did not react to cold.

The electrical test identified 30 of the 42 necrotic pulps as necrotic, whereas 12 teeth with necrotic pulps gave a sensitive reaction. Of the 38 teeth with vital pulp in need of endodontic treatment, the electrical test identified 35 teeth as sensitive, whereas 3 were identified as nonsensitive.

The pulse oximetry test identified all of the 42 necrotic pulps as necrotic. Of the 38 teeth with vital pulp in need of endodontic treatment, the pulse oximetry test identified 36, whereas 2 of the vital pulps did not react to pulse oximetry.

On the basis of these findings, the sensitivity, specificity, and positive and negative predictive values were calculated for each test method (Table 1).

The accuracy rate was 86% for the cold test, 81% for the electrical test, and 97.5% for the pulse oximetry test.

Discussion

A perfect diagnostic test would always be positive in the presence of disease and negative in the absence of disease. The extent to which a test correctly classifies patients defines its accuracy. The concepts of sensitivity, specificity, and positive and negative predictive value have been developed to characterize test accuracy and to compute the benefits of test usage.

Because the calculations are based on a comparison of the test results and "true" disease status, identification of this true disease status becomes an important part of the evaluations. This assessment of the definitive disease or health status usually refers to a definitive diagnosis attained by biopsy, surgery, long-term follow-up, or any other standard (17). Petersson et al. (17) assessed the definitive disease status of the pulp in teeth requiring endodontic therapy by direct visual inspection of the pulp and evaluated the sensitivity, specificity, and positive and negative predictive values of heat and cold application and electrical pulp tests. Many studies on pulp vitality (sensitivity) testing have dealt with the precision of the thermal and electrical pulp tests (17, 18). However, no study to date has evaluated the accuracy of pulse oximetry testing. Hence, the present study was designed to test the accuracy of pulse oximetry in comparison with thermal and electrical pulp tests by calculating their sensitivity, specificity, and predictive values.

TABLE 1. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for the cold test, electrical test, and pulse oximeter test

Test	Sensitivity	Specificity	PPV	NPV
Cold	0.81	0.92	0.92	0.81
Electrical	0.71	0.92	0.91	0.74
Pulse oximeter	1.00	0.95	0.95	1.00

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For pulse oximetry testing, a Nellcor OxiMax Dura–Y D-YS multi-site oxygen sensor was selected, as the dimensions of this sensor (4 × 5 mm) were suitable to be employed on human teeth. A customized holder was designed and fabricated to provide a stable relationship between the sensor elements and the tooth. This allowed the maintenance of a constant path length for the light emitted from the LED and received by photoreceptor sensor, thus enabling accurate readings.

Sensitivity denotes the ability of a test to detect disease in patients who actually have the disease (18). Thus, sensitivity of a pulp vitality test indicates the test's ability to identify nonvital teeth. It is defined as a ratio, the number of persons with a positive test result who have the disease divided by the number of tested persons with the disease (18). A test with a sensitivity of 0.80 has an 80% chance of returning positive results when persons with the disease are tested. In the current study, the sensitivity of the pulse oximeter was 1.00, as compared to the cold test (0.81) and the electrical pulp test (0.71). Thus, there is a 100% chance of returning positive results when persons with the disease are tested with the pulse oximeter, as compared to 81% with the cold test and 71% with the electrical pulp test. This finding is of great diagnostic importance, as this implies that the pulse oximeter is a definitive and accurate tool for identifying nonvital teeth.

Specificity, conversely, describes the ability of a test to detect the absence of disease (18). Thus, specificity of a pulp vitality test indicates the test's ability to identify vital teeth. It is defined as a ratio, the number of patients with negative test results without the disease divided by the number of tested patients without the disease (18). A test with a specificity of 0.90 has a 90% chance of returning negative results when performed on persons without the disease. The specificity of the pulse oximeter was 0.95, as compared to the cold test (0.92) and the electric pulp test (0.92). Thus, there is a 95% chance of returning negative results when persons without the disease are tested with the pulse oximeter, as compared to 92% with the cold test and 92% with the electrical pulp test. The lower specificity of the pulse oximeter (95%) could be attributed to the physical limitations of pulse oximetry. For pulse oximetry to be accurate, normal arterial blood flow is required. When arterial pulsatile blood flow is low, pulse oximetry measurements are unobtainable. This occurs during hypovolemia, hypothermia, and intense peripheral vasoconstriction (high-dose phenylephrine HCl) (11). Apart from these medical conditions, the authors hypothesize that the pulse oximeter might have a lower specificity in cases where the coronal pulp is undergoing calcific changes. This could be in cases with history of trauma, deep restorations, or physiological conditions such as aging. In such cases, radicular vital pulp with coronal calcification can potentially cause a false-negative response.

Positive predictive value is the probability that the positive test result actually represents a disease-positive person. Negative predictive value is the probability that a person with a negative test result is actually free of disease (18). In the evaluation of the predictive values of the different vitality test agents, it is important to consider the prevalence of the disease that the test is supposed to disclose, because the predictive values change with the prevalence of the disease (17). The predictive values found in our study were based on a disease prevalence of 52%. The study by Petersson et al. (17), which also reports on predictive values of cold and electrical pulp tests, uses a disease prevalence of 39% only for the calculations. Thus, the predictive values between these two studies cannot be directly compared.

The negative predictive value for the pulse oximeter was 1.00, as compared to 0.81 for the cold test and 0.74 for the electrical pulp test. Thus, when tested with the pulse oximeter, it is very likely that the patients who have a negative test result are indeed disease negative. Positive predictive value for the pulse oximeter was 0.95, as compared to 0.92 for the cold test and 0.91 for the electrical pulp test. Thus, there is a 95% chance that patients who are test positive with the pulse oximeter may, in fact, be free of disease.

Conclusion

This in vivo study showed that the custom-built PODP is an effective, accurate, and objective method of determining the vitality of permanent teeth. On comparing the accuracy of the PODP with thermal and electrical pulp tests, it was found that the probability of a negative test result representing a vital pulp was 81% with the cold test, 74% with the electrical test, and 100% with the pulse oximeter. The probability of a positive test result representing a necrotic pulp was 92% with the cold test, 91% with the electrical test, and 95% with the pulse oximeter.

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References

1. Fratkin RD, Kenny DJ, Johnston DH. Evaluation of a laser Doppler Flowmeter to assess blood flow in human primary incisor teeth. *Pediatr Dent* 1999;21:53–6.
2. Munshi AK, Hedge AM, Radhakrishnan S. Pulse oximetry: a diagnostic instrument in pulp vitality testing. *J Clin Pediatr Dent* 2002;26:141–5.
3. Noblett WC, Wilcox LR, Scamman F, Johnson WT, Arnold AD. Detection of pulpal circulation in vitro by pulse oximetry. *J Endod* 1996;22:1–5.
4. Sasano T, Onodera D, Hashimoto K, Iikubo M, Satoh-Kuriwada S, Shoji N, Miyahara T. Possible application of transmitted laser light for the assessment of human pulp vitality. Part 2. Increased laser power for enhanced detection of pulpal blood flow. *Dent Traumatol* 2005;21:37–41.
5. Ikeda H, Suda H. Subjective sensation and objective neural discharges recorded from clinically nonvital and intact teeth. *J Endod* 1998;24:552–6.
6. Yanpiset K, Vongsavan N, Sigurdsson A, Trope M. Efficacy of laser Doppler flowmetry for the diagnosis of revascularization of reimplanted immature dog teeth. *Dent Traumatol* 2001;17:63–70.
7. Ramsay DS, Artun J, Martinen SS. Reliability of pulpal blood flow measurements using laser Doppler flowmetry. *J Dent Res* 1991;70:1427–30.
8. Nisson R, Trope M, Zhang CD, Chance B. Dual wavelength spectrophotometry as a diagnostic test of the pulp chamber contents. *Oral Surg Oral Med Oral Pathol* 1992;74:508–14.
9. Salyer JW. Neonatal and pediatric pulse oximetry. *Respir Care* 2003;48:386–96.
10. Healy TE, Cohen PJ, Adams CA. Essential monitoring. In: Healy TE, Cohen PJ, eds. *Wylie and Churchill—Davidson's a practice of anaesthesia*, 6th ed. London: Edward Arnold; 1995:454–7.
11. Wilson WC, Shapiro B. Preoperative hypoxia: The clinical spectrum and current oxygen monitoring methodology. In: Wilson WC, ed. *Anesthesiol Clin North America: Monitoring through clinical events*. Philadelphia: WB Saunders, 2001;19:799–804.
12. Goho C. Pulse oximetry evaluation of vitality in primary and immature permanent teeth. *Pediatr Dent* 1999;21:125–7.
13. Schnettler JM, Wallace JA. Pulse oximeter as a diagnostic tool of pulp vitality. *J Endod* 1991;17:488–90.
14. Kahan RS, Gulabivala K, Snook M, Setchell DJ. Evaluation of a pulse oximeter and customized probe for pulp vitality testing. *J Endod* 1996;22:105–9.
15. A technology overview of the Nellcor OxiMax pulse oximeter system: 1–8. Available from www.nellcor.com.
16. Gopikrishna V, Kandaswamy D, Tinagupta K. Assessment of the efficacy of an indigenously developed pulse oximeter dental sensor holder for pulp vitality testing—an in vivo study. *Ind J Dent Res*. 2006. In press.
17. Petersson K, Soderstrom C, Kiani-Anaraki M, Levy G. Evaluation of the ability of thermal and electrical tests to register pulp vitality. *Endod Dent Traumatol* 1999;15:127–31.
18. Hyman JJ, Cohen ME, Lakes G. The predictive value of endodontic diagnostic tests. *Oral Surg* 1984;58:343–6.

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