In Vivo Evaluation of Customized Pulse Oximeter and Sensitivity Pulp Tests for Assessment Of Pulp Vitality

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Objective: *The purpose of this study was to test a customized pulse oximeter (CPO) for evaluation of pulp vitality in primary and permanent teeth against clinical diagnosis (vital and untreated non-vital) in order to expand its clinical use for pulp preservation.* ***Study design:*** *CPO was evaluated on intact primary and permanent central or lateral incisor (CI, LI) teeth- vital (group 1, 20n each); untreated non-vital (group 2, 10n each) and; root filled non-vital (group 3, 10n each) of children 4-12 years according to inclusion/ exclusion criteria. For each patient CPO was first applied on finger followed by vitality tests in following sequence- electrical, pulse oximetry and thermal tests.* ***Results:*** *Mean oxygen saturation (%SpO2) in permanent and primary–vital teeth was 88.78% & 87.77% respectively; non-vital teeth was 74.67% & 75.00% respectively; and in all root filled teeth was 0%. Tooth and finger oxygen saturation values showed strong positive relationship in vital primary or permanent teeth and; no correlation in untreated non-vital primary or permanent teeth. The accuracy rate of thermal pulp test and pulse oximetry was 100% and for electrical pulp test it was 90% for permanent and 86.67% for primary teeth.* ***Conclusion:*** *The CPO tested in this study proved to be a valuable adjunct for diagnosing pulp vitality by objective means.*

Key words: Pulp vitality, Pulp test, Pulse oximeter

INTRODUCTION

In pediatric endodontics, subjective responses by a child are not reliable because of the age and the presence of multiple carious teeth. Thermal and electrical pulp testing have been the most popular means of diagnosis of pulp status. Nonetheless both tests not only are subjective but also rely on sensory nerve response in pulp. Nervous tissues may remain active even after full necrosis of pulp, and thus may give false positive result.[1]On the other hand traumatized tooth where nerves get injured, may give false negative results with electrical or thermal tests.[1]The clinical diagnostic terms such as 'reversible/ irreversible pulpitis', and 'necrosis' were made on the basis of sensitivity tests.[1] It is well proven now that diagnosis of pulp status based on sensitivity tests may not correlate with histologic diagnosis.[2] Many vital teeth having signs and symptoms of irreversible pulpitis have been saved with vital pulpotomy recently[3,4]and therefore shows importance of pulp vitality to be evaluated in terms of blood supply for a child's tooth to assure its continued dentinal and root development. Therefore an apparatus with definite readings and assessing vascular health of teeth will be more meaningful in pedodontics.

As pulp vitality is the function of vascular health, recently developed non-invasive tools to monitor may be more helpful in diagnosing actual pulp vitality. Commonly known are Laser doppler flowmetry, dual wavelength spectrophotomerty and pulse oximetry. Emshoff *et al.*[5] successfully tested Laser doppler flowmetry as a valuable diagnostic adjunct for luxated teeth showing signs of adverse outcome.

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Nonetheless pulse oximeter (PO) has been tested by many more authors for its efficacy not only for vital/ non-vital root filled teeth and traumatized teeth but also to differentiate inflammatory conditions of pulp ranging from normal, necrosed and root filled teeth.[6-10]

Modern pulse oximetry was developed on two physical principles; firstly that pulsatile changes in light transmission through living tissue are due to alteration of arterial blood volume in the tissue and secondly that oxy-hemoglobin and reduced hemoglobin have different absorption spectra. PO has sensors consist of two light emitting diodes (LEDs)- one transmits red light (640nm) and the other infra-red light (940nm) through vasculature (finger, toe, ear lobe, crown of tooth) to receiving photodetector.[11]Because of commercial non-availability, many a custom made PO have been tried successfully in dentistry.[6-10,12-14] However these designs should have good sensitivity and specificity before using it for diagnostic purpose.

Studies evaluating efficacy of PO in known vital and root filled non-vital teeth are very well documented but to the best of our knowledge no study is there to know vitality status of clinically diagnosed non-vital untreated teeth. The purpose of this study therefore was to test a customized pulse oximeter (CPO) for evaluation of pulp vitality in primary and permanent teeth against clinical diagnosis of clinically diagnosed non-vital but untreated teeth so that its efficacy against inflammatory/ ischemic condition of pulp can be evaluated in order to expand its clinical use for planning of preservation of pulp.

MATERIALS AND METHOD

Prior permission from Institutional Ethical Committee was obtained for the study. For evaluation of CPO on primary and permanent teeth, intact vital and non-vital central and lateral incisors (CI, LI) of children 4-12 years of age were selected. Inclusion criteria for both primary and permanent vital teeth were to be free of caries, restoration, developmental defects, and mobility. In radiograph primary teeth should have full root without any internal, external or physiologic resorption.

Inclusion criteria for both primary and permanent teeth non-vital were presence of intact/ partially broken crown with-past history of severe, dull, lingering or spontaneous pain with or without periapical radiolucency[5,10] but without crown discoloration. Teeth with these conditions should not have pain on percussion, pain on palpation and thermal response as described by Setzer *et al*.[10]

Patients having, teeth with pain or history of trauma affecting face, mouth or teeth were excluded.

Following sample selection, these were divided into 3 groups:

1. Group 1(20n each)–Vital maxillary single rooted permanent and primary teeth (CI, LI) (positive control)
2. Group 2(10n each) -Non-vital untreated maxillary single rooted permanent and primary teeth (CI, LI)
3. Group 3(10n each)–Known root filled maxillary single rooted permanent and primary teeth (CI, LI) (negative control).

The author SM was trained by DSS for taking all the pulp tests on 5 patients. All pulp vitality tests then after were done by one author only i.e. by SM. Patient was seated on dental chair and tooth was examined without chair side illumination. First electrical test was performed followed by pulse oximetry and thermal test with 10 minutes time gap between each.

For electrical pulp testing, pulp tester (Digitest, Parkell Pulp Vitality Tester, Parkell, INC., Edgewood, New York, USA) was used. Tooth surface was air dried followed by isolation with cotton rolls. The electrode was placed on middle third of the crown on labial surface. Pain with increasing current was entered in preformed format. Early and delayed response was considered as response only while no response on maximum current was as no response.

A commercial PO (Dr. Morepen PO 04, Morepen Laboratories Limited, Delhi, India) was modified for dental application by an electrical engineer with the suggestions by author NRB. First sensor of PO was placed on index finger of hand and reading noted. Same tooth as in electrical and thermal tests, was checked for vitality (%%SpO2in systemic blood) with CPO. Same sensor was applied on frontal tooth (primary or permanent) permitting parallel positioning of the emitting diode with the photo receiver. The values were recorded after 30 seconds of monitoring each tooth (figure-1). Three digital readings displayed on LED screen of CPO after a gap of 5 seconds for each tooth were noted in format. Average of three readings was taken for final reading of each tooth.

For thermal test, gutta-percha stick was heated on bunsen burner and applied on middle third of labial surface of tooth (not more than 7 seconds) to be examined. Results were noted as positive (vital) or negative (non-vital) for tooth being responsive/ non-responsive respectively.

P value <.05 was considered statistically significant. Data analysis was performed using Statistical package for social science (SPSS VERSION 21.0, IBM Corporation, Armonk, New York, USA).

RESULTS

CPO

The minimum to maximum range and mean of %SpO2 values for vital (permanent and primary), non-vital (permanent and primary) and root filled (permanent and primary) teeth are summarized in table-1. Tooth and finger oxygen saturation values showed strong positive relationship in permanent as well as primary vital teeth ($P < 0.01$, $P < 0.05$). There was no correlation between tooth and finger oxygen saturation values in permanent as well as primary non-vital teeth ($p > 0.05$) (table-2, figure-2). All root filled primary and permanent teeth did not give any readings on CPO i.e. 0%.

The pulse oximetry test identified all non-vital pulp as non-vital and all vital teeth as vital for identified range of %SpO2. So the accuracy rate of pulse oximetry was 100% (table-3).

Thermal Pulp Test

The thermal pulp test identified all non-vital pulp and root filled teeth as non-vital (no response) and all vital pulp as vital (response). So the accuracy rate was 100% (table-3).

Electrical Pulp Test:

The electrical pulp test showed variable early, delayed and no response in vital as well as non-vital teeth (permanent and primary). The accuracy rate for electrical pulp test was 90% for permanent and 86.67% for primary teeth (table-3).

Table-4 represents sensitivity, specificity, positive and negative predictable values (PPV, NPV) for different tests to assess pulp vitality with our CPO and other tests.

Figure 1- Application of customized pulse oximeter on vital tooth

Figure 2- Correlation of oxygen saturation in finger and teeth with customized pulse oximeter

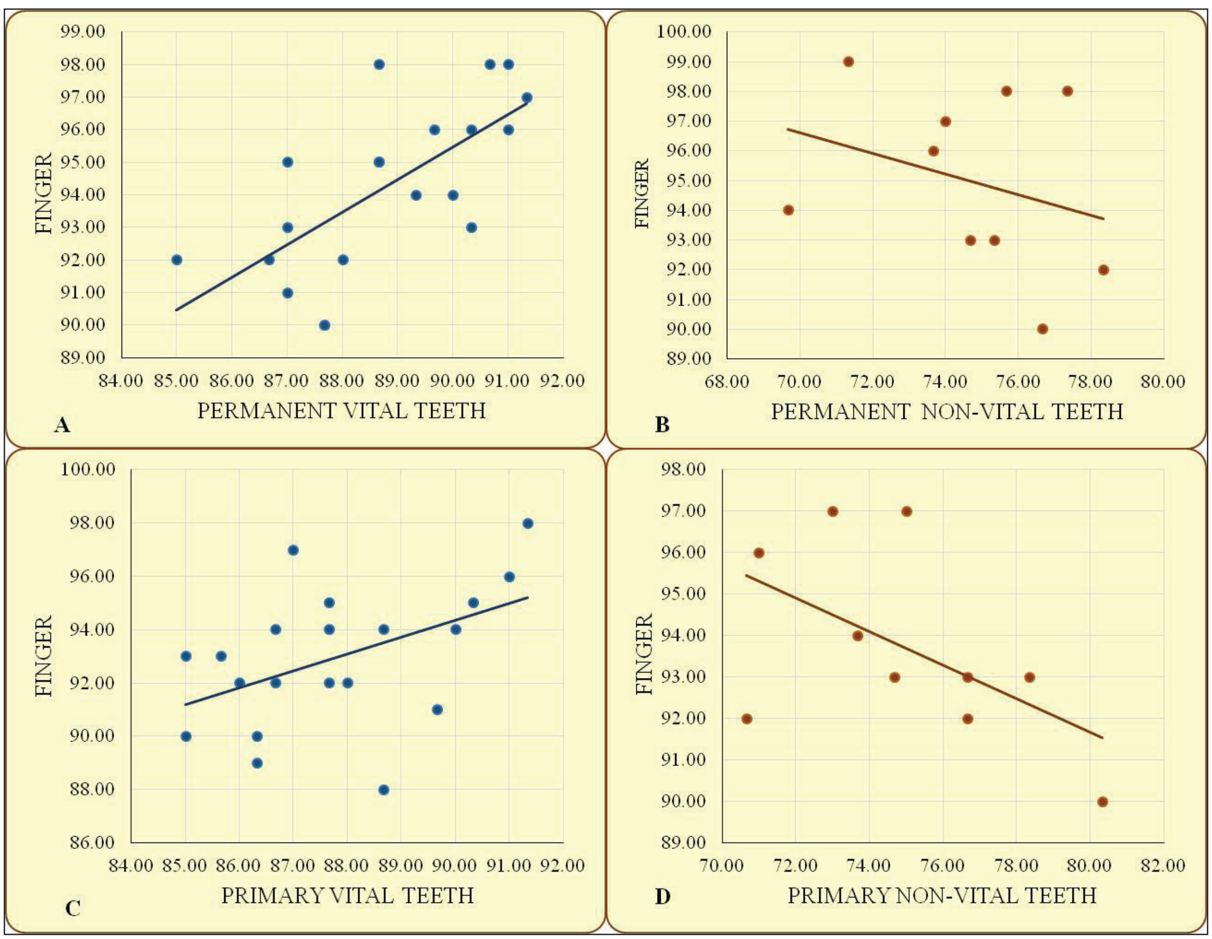

Table 1: Oxygen saturation values in teeth and finger in permanent and primary teeth

Groups		Oxygen saturation value (%SpO2)			
		Permanent		Primary	
		Mean ± SD	Min- Max	Mean ± SD	Min- Max
Vital teeth	Teeth	88.78 ± 1.76	85.00-91.33	87.77 ± 1.92	85.00-91.33
	Finger	94.25 ± 2.57	90.00-98.00	92.95 ± 2.61	88.00-98.00
Non-vital teeth	Teeth	74.67 ± 2.66	69.67-78.33	75.00 ± 3.09	70.67-80.33
	Finger	95.00 ± 3.02	90.00-99.00	93.70 ± 2.31	90.00-97.00
Overall (vital + non-vital)	Teeth	84.08 ± 7.07	69.67-91.33	83.51 ± 6.55	70.67-91.33
	Finger	94.50 ± 2.70	90.00-99.00	93.20 ± 2.50	88.00-98.00

Table 2: Correlation between tooth and finger oxygen saturation values in permanent and primary teeth

Correlation between tooth and finger values		Pearson's correlation coefficient	P value
Vital teeth	permanent	0.684^{Φ}	0.001 (< 0.01)*
	primary	0.464^{Φ}	0.039 (< 0.05)*
Non-vital teeth	permanent	-0.305€	0.392 (> 0.05)
	primary	-0.540€	0.107 (> 0.05)
Overall (vital + non-vital)	permanent	-0.061^{δ}	0.748 (> 0.05)
	primary	-0.115^{δ}	0.546 (> 0.05)

Φ-strong positive relationship; *- significant; €- Moderate negative relationship; δ- no relationship

Table 3: Accuracy rate of thermal pulp test, electric pulp test and pulse oximetry in primary and permanent teeth.

Test	Accuracy rate (%)	
	Permanent teeth	Primary teeth
Thermal pulp test (heat test)	100.00%	100.00%
Electric pulp test	90.00%	86.67%
Pulse oximetry (SpO_2)	100.00%	100.00%

Table 4: Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) for thermal pulp test, electric pulp test and pulse oximetry in primary and permanent teeth (vital & non-vital).

Test	Sensitivity (95% CI) Permanent	Primary	Specificity (95% CI) Permanent	Primary	PPV (95% CI) Permanent	Primary	NPV (95% CI) Permanent	Primary
Thermal pulp test (heat test)	1	1	1	1	1	1	1	1
Electric pulp test	.7	.6	1	1	1	1	.8	.8
Pulse oximetry (SpO_2)	1	1	1	1	1	1	1	1

DISCUSSION

Pulse oximetry is a non-invasive and safe method to find objective values of vitality by measuring %SpO2 in pulpal blood. The algophobia (fear and pain) in pediatric patients often leads to false positive or negative results making endodontic diagnosis unreliable.[15] Therefore we verified our CPO for its efficacy for dental purpose as there were variations found in readings of %SpO2 by various authors.

Our results confirmed that CPO could differentiate between vital, non-vital and root filled teeth not only in permanent but in primary teeth as well. All vital teeth had %SpO2 above 85% (table-2). Gopikrishna *et al*.[6] and Pozzobon *et al.*[16] found their mean %SpO2 for vital teeth as 79.30% (78-80) and 85.27% (63-98). Important to notice, that minimum value found by them, was found for non-vital teeth with our CPO (table-2). For customization of PO, small sensors were secured on tip of arm of rubber-dam forcep which allowed easy and firm placement on both teeth as suggested by Vaghela *et al.*[12] Probably the difference in designs of CPO made difference in values of %SpO2 in vital teeth. This also shows the importance of sensors to be closely adapted to tooth surface. Other than that differences may be due to the age of subjects. Our results were very close to Bargrizan *et al.*[17] probably because of almost similar design of PO and age of sample patients. Calil *et al*.[18] inspite of adult age sample found mean %SpO2 91.29% (85- 95). Their design of PO was not shown but. Goho[19]found %SpO2 more than ours i.e. 94% for permanent and 93% for primary teeth with modified ear probe, made by removing outer coverings to facilitate close adaptation of sensors on tooth, the measures very similar to ours. Jurban A[20] emphasized that different probes used with a PO also affect the accuracy of %SpO2 values. Ear probes generally are more sensitive to oxygen saturation changes in blood, likewise display more accurate average on screen.[20] Higher %SpO2 values by Calil *et al.*[18] and Goho[19] may be because they used ear probe.

Dastmalchi *et al.*[14]considered 86%-100% oxygen saturation as normal for testing vitality with CPO and counter confirmed it with gold standard i.e. entering the pulp space, and found its sensitivity 0.93. Schnettler and Wallace[21] also found oxygen saturation more than 86% for vital permanent teeth. Bruno *et al.*[1] in a review concluded normal oxygen saturation values by PO to be above 87% for single rooted teeth. Our %Spo2 values for vital teeth with CPO support their findings and conclusion.

All clinically diagnosed non-vital but untreated teeth showed %SpO2 upto 78.33 in permanent and 80.33 in primary with our CPO (table-2). Our results for untreated non-vital teeth were similar to that of the necrosed teeth by Setzer *et al*.[10]Our findings for non-vital teeth seem correct. Jurban A[20] mentioned in his article that accuracy of PO deteriorates when %SpO2 falls to 80% or less; that bias precision was 1.7± 1.2% for %SpO2 values more than 90%, which deteriorates to 5.1± 2.7% when %SpO2 was less than 90%. Standard organizations such as Food and Drug Administration (FDA) certified PO efficacy between 70-100%.[15] Manufactures instruct that %SpO2 values below 70% to be considered non-specific in commercial PO, used in operation theatres and intensive care units.[16]Accordingly, all %SpO2 values below 78% in permanent and 80% in primary by our CPO proved to be for non-vital teeth (as diagnosed clinically), therefore should be considered non-specific. Furthermore to verify the efficacy of CPO, we applied it on root filled non-vital teeth in mouth and other non-vital articles outside of mouth, which did not show any readings on monitor. This proved some phenomenon occurring in mouth only. Wong JK[22] had explained reasons for false readings with pulse oximetry. Accordingly as signal noise and interference with light transmission were kept under control, dyshaemoglobins present in non-vital pulp may be the reason of false readings. Furthermore, as he also stated that venous blood has %SpO2 of 75%, our readings probably represented arterial ischemia and venous congestion (necrosis) in pulp chamber. Nonetheless there was 100% accuracy for tested range of %SpO2 for clinically diagnosed non-vital but untreated teeth (table-3). For the above explained reasons of non-specificity below 70%SpO2, our %SpO2 values for vital teeth and finger showed strong positive correlation as %SpO2 values were ≥85%, while that of for non-vital teeth had no relation as %SpO2 values were ≤80% (table-2, figure-2 B & D). Again, this may be the very reason that other authors[6,16,17] found no or weak relation between %SpO2 of vital teeth and that of finger.

We had tested extreme conditions of pulp vitality i.e. vital, non-vital and root filled teeth. Introspection of %SpO2 ranges, found in each category revealed that the range of 78%-85% in permanent and 80%-85% in primary teeth was not recorded by our CPO. Setzer *et al.*[10] tested PO for inflammatory condition of pulp and this range (79%-86%) was found for irreversible pulpitis, the condition we did not test.

Thermal and CPO tests were very accurate while electrical pulp test was not, probably for the reason that EPT excites C fibres and thermal excites A fibres, the oxygen dependent fibres (table-3).[10] PPV and NPV proved our CPO to be used for clinical diagnosis of pulp status (table-4). As %SpO2 values below 70% are non-specific owing to increased bias of apparatus, further studies to test this range of %SpO2 and other inflammatory conditions against gold standard and treatment options are currently in plan to broaden the scope of PO in endodontics.

According to Batchelder and Raley[23], as there is no standard reference to calibrate POs, and there is no accepted method to verify their correct calibration, other than testing in humans, each custom-made PO should be tested and verified for their calibration for measuring vitality status of dental pulp.

CONCLUSION

The CPO tested in this study proved to be a valuable adjunct for diagnosing pulp vitality by objective means. In order to make PO popular in dental clinics, there is a need of uniformly designed PO with verified ranges of %SpO2 to diagnose inflammatory conditions of dental pulp, which probably may save many teeth with debatable subjective clinical diagnosis especially in pediatric dentistry.

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