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Pulp Diagnostic. Flow Oximetry – Comparative analysis between healthy and restored teeth

Clinical Study

Ana Rita Gonçalves Dias

Dissertação conducente ao Grau de Mestre em Medicina Dentária (Ciclo Integrado)

Gandra, 27 de setembro de 2021

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Trabalho realizado sob a Orientação de Professor Doutor Paulo Miller

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Agradecimentos

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RESUMO

Introdução: O diagnóstico da vitalidade pulpar é indispensável para a escolha correta do tratamento dentário. A oximetria é um teste de vitalidade avalia a saturação dos vasos. Neste estudo iremos avaliar possíveis discrepâncias entre valores obtidos no dedo e no dente e entre dentes hígidos e restaurados, também a possibilidade de interferência das restaurações na leitura.

Materiais e Métodos: No estudo participaram 71 pessoas com um total de 354 dentes (297 hígidos e 57 com pelo menos uma superfície restaurada), sendo todos foram testados com teste elétrico, teste térmico e oximetria. Os valores de saturação foram tanto recolhido no dedo indicador como nos dentes. A análise estatística foi realizada com ANOVA e SPSS.

Resultados: A saturação média no dente e no dedo foram 84,01% e 97,04%, respetivamente. A saturação média nos dentes hígidos e nos dentes restaurados foram 85,08% e 78,40%, respetivamente. A saturação média nos dentes hígidos e nos dentes restaurados por tipo de dente foram 86,20% e 78,06% nos centrais; 87,07% e 80,84% nos laterais; 82,10% e 72,50% nos caninos.

Conclusão: A saturação é inferior nos dentes restaurados em relação aos hígidos e inferior no dente em relação ao dedo. Como a difração da luz é diferente nos constituintes do dedo, do dente e no material da restauração a intensidade da luz que alcança o sensor também difere, causando as diferenças de valores.

PALAVRAS-CHAVE

"Oximetry"; "Pulp Vitality"; "Permanent teeth"; "Pulse Oximeter"; "Dental Pulp Test".

Abstract

Introduction: A correct diagnosis of pulp vitality is essential to the choice of treatment. PO is a vitality test that relies on the % SpO2 and has an accurate reading. This study aims to evaluate possible discrepancies between the read in the finger and the teeth, between healthy teeth and restored teeth, and the possibility of restoration's interference on %SpO2 reading.

Materials and Methods: 71 patients were included in this study with a total of 354 teeth (297 healthy and 57 with at least one surface restored) and they were all tested with ET, TPT, and PO. Oxygen saturation levels were measured on the index finger as well as on the teeth. Results were analyzed by using ANOVA and SPSS.

Results: The average of saturation on the teeth and the finger were 84.01% and 97,04%, respectively. The average of saturation of healthy teeth and restored teeth were 85.08% and 78.40%, respectively. By each type of group of teeth, the average of saturation of healthy teeth and restored teeth were 86,20% and 78,06% on CI; 87,07% and 80,84% on LI and 82,10% and 72,50% on canines, respectively.

Conclusion: The saturation is lower in restored teeth than healthy teeth and on the teeth compared to the finger. As the diffraction of light is different on the constituents of the finger, teeth and the material of restoration, the intensity of light which reaches the sensor also differs causing different values.

KEYWORDS

"Oximetry"; "Pulp Vitality"; "Permanent teeth"; "Pulse Oximeter"; "Dental Pulp Test"

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Acronyms and Abbreviations

% → Percentages

%SpO2 → Oxygen saturation

η^2 → eta^2

Bpm → Beats per minute

CI→ Central Incisors

ET → Electric Test

Fig.→ Figure

Hb → Haemoglobin

LI→ Lateral Incisors

M → Means

Mdn → Medians

N → Frequencies

P → Percentiles

PO → Pulse Oximetry/Pulse Oximeter

SD → Standard Deviations

Tab → Table

TPT → Thermal Pulp Test

1. Introduction

Dental pulp can offer beneficial information to achieve a better diagnostic and treatment [1]. The pulp vitality represents the vascular supply to the teeth, and an accurate diagnosis is essential to reach a good treatment[2]. Despite being a crucial factor, the hard tissues covering makes the examination difficult [1].

The pulp vitality is verified by different methods like, sensibility tests (electrical pulp tests and thermal pulp test (TPT)) and vitality tests, like pulse oximetry (PO).

Although the pulp sensibility tests (electrical pulp tests and TPT) indirectly evaluate the state of the pulp, they are the most common methods which are used to classify the pulp status. They collect neural response rather than the pulp vitality[3–5] being less trustworthy. In the thermal test cold or heat is applied to the tooth in order to stimulate the nerve fibres and produce pain[6].

The pulp vitality test can recognize blood flow without relying on patients' answers and give a more realistic pulp status[7]. Non-invasive tools monitor have been developed to help to diagnose actual pulp vitality[8] being one of them the pulse oximeter (PO) and it is considered one of the most reliable diagnostic devices[9]. Despite being a reliable indicator and able to overcome most of the problems, PO can also fail to translate the actual state of the pulp because, sometimes, the pulp is committed but still has a viable blood supply. Like this it isn´t a fail proof[4].

The function of PO is to determine the oxygen saturation and pulse rate of any vascularized tissues[10], also commonly placed on the patient's finger. In dentistry, to match the tooth it is needed a specific equipment [11]. Oxygen saturation has been used to estimate pulp vitality. However, it is not a substitute measure of blood circulation since it indicates the portion of oxygenated haemoglobin (Hb) regarding the total haemoglobin[1].

The PO is composed of a pulse oximeter monitor, sensor holder, and sensor holding probe[12]. It consists of 2 light-emitting diodes of distinct wavelengths: red light energy (600nm) and infrared light energy (940nm) operated in cycles of 500 times per second[3,5]. Both types of light are required because oxygenated and deoxygenated have distinct colours and absorb the frequencies differently[5,6,13]. At 660nm, oxygenated haemoglobin absorbs less light than deoxygenated haemoglobin, while at 940nm it's the opposite[5,6]. The lights

are collected by a photodetector diode attached to a signal-processing unit. The pulsatile variates the amount of light absorbed by the vascular bed and it is used by the oximeter to measure and determine the saturation levels of arterial blood[5,9,13].

By controlling the blood flow and the oxygen saturation of the pulp, it is likely to verify the variations that occur and thus detect pulp inflammation or even necrosis on teeth that still react to other tests[5].

The average oxygen saturation levels to healthy pulps differ from 75% to 94%, reversible pulpitis 87,4%, irreversible pulpitis 83,1%, and pulp necrosis 74,6%. However, some researches register lower values like 70% to a healthy pulp. These discrepancies can be associated with different experimental designs[3].

This study has several aims: the main one is to analyse % SpO2 between the total of healthy and restored teeth and observe the difference; the second is to compare the same variable of the main one but by the type of teeth; the third is to compare % SpO2 between finger and teeth.

2. Materials and Methods

This study derives from the project "Effectiveness of pulse oximetry in measuring pulp condition. Comparison with commonly used tests", ("Eficácia da oximetria de pulso na aferição da condição pulpar. Comparação com os testes habitualmente utilizados"), which was approved by IUCS Ethics Committee - CESPU (ref. CE/IUCS/CESPU-15/21).

All human people who participated in the experimental investigation and are described in this article, signed informed consent forms after the nature of the procedure and the possible discomforts and risks were explained.

The study has taken place in CESPU university clinic (Gandra, Paredes, Porto) with the approval of the clinic director and was taken by 5 undergraduate dental students coordinated by two professors.

Inclusion criteria: patient with healthy anterosuperior teeth or at least one restored in that teeth section.

2.1. Bibliographic Research

The research was made in EBSCO and Pubmed's database and the last search in February 2021 with five keywords (Oximetry, Pulp Vitality, Permanent teeth, Pulse Oximeter, Dental Pulp Test) and two combinations ("Oximetry AND Pulp Vitality AND Permanent teeth"; "Pulse Oximeter AND Dental Pulp Test"). The articles selected were between 2011 and February 2021.

Inclusion criteria: Papers published, in 2011 or later, are in English and with the keyword selected.

Exclusion Criteria: Papers published, before 2011, are in another different language not English. Studies that not involved humans.

Once removed duplicate ones there was a total of 26 papers that remained. In order to have a better research, it was done a deeper analysis by reading the title and abstract (11 articles excluded) and others after reading the full-text (2 articles excluded), outlasting 13 articles.

2.2. Population

The population included in the study are 71 patients (354 teeth) between the age of 22 and 73 years old from both genres.

2.3. Thermal Pulp Test

The TPT classifies teeth with a response as vital pulp teeth and with no response as non-vital pulp teeth. The cold spray was applied with a cotton ball in the vestibular face of the tooth crown until the person felt pain or had passed at least 15s.

2.4. Pulse Oximeter

The oximeter (Fig.1) model and sensor used in this study were ARSTN 2.8 TFT LCD handheld pulse oximeter H381V (Certificate: CE/ISO13485) and S906V Veterinary sensor SpO2 sensor DB9 Probe cable, respectively.

Oxygen saturation (%SpO2) levels were firstly collected from the index finger (Fig.1) and after from teeth pulp with a custom-made sensor holder (Fig. 2) purposefully manufactured for this study. This sensor holder was created to guarantee better positioning, adaptation to the permanent teeth, and vestibular-palatal adjustment. A standard probe (Fig. 4) was used when the anatomy of the tooth was incompatible with the custom-made holder.

For a better reading, cotton rolls isolated the teeth, and we put saliva on the surface to maintain them hydrated.

Figure 1- Oximeters

Figure 2- Custom-made Sensor Holder

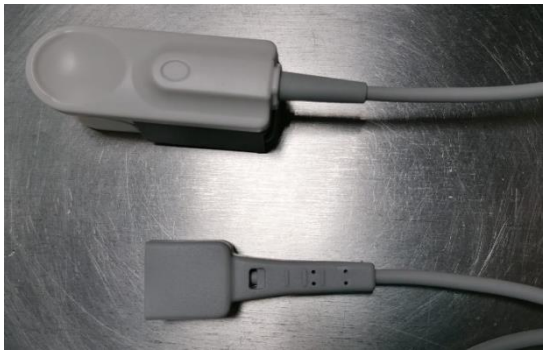

Figure 4-Index Finger Sensor Holder

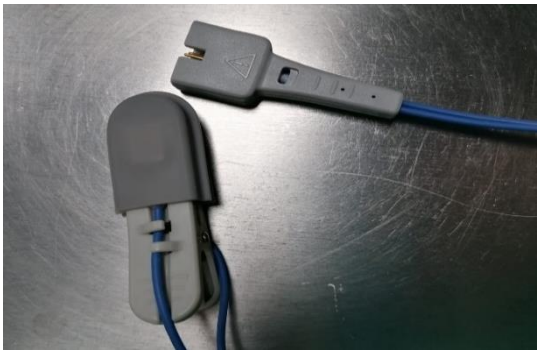

Figure 3- Veterinary Standard Holder

2.5. Statistical analysis

Statistical analysis was executed with SPSS, version 24. For descriptive statistics of categorical variables, we calculated frequencies (n) and percentages (%). For continuous variables with symmetric distribution, we calculated means (M) and standard deviations (SD); medians (Mdn) and percentiles P25 and P75 were calculated for asymmetrical continuous variables. Symmetry was assessed with symmetry coefficient [-2, 2] and by checking histograms.

Oxygen saturation and teeth bpm had 15 missing values that we imputed by using a simple strategy of mean replacement considering teeth groups stratification. The same was done for two values of teeth bpm (bpm=206 e bpm=170) considered as faulty results. Hence, we replaced missing values for oxygen saturation and teeth bpm, respectively with 84, 76 (centrals), 86, 77 (laterals), and 82, 77 (canines). Missing imputation assumed missings completely at random (MCAR), which does not alter oxygen saturation and teeth bpm global and stratified estimations.

Bifactorial ANOVAs were performed to assess the association of restored vs non-restored teeth and teeth groups with the measures of oxygen saturation and teeth bpm. Assumptions were assessed and confirmed, namely, residuals normality, evaluated with Kolmogorov-Smirnov test (n>50) and checking histogram and variances homoscedasticity, evaluated with Levene test. Effect size was assessed with eta^2 (η^2), following Cohen's (1988) suggestion: 0.01 (low), 0.06 (moderate) and 0.14 (high).

ROC curves were built to assess the sensitivity and specificity of oxygen saturation and teeth bpm considering the cold test as gold-standard to identify the vitality of the teeth.

The decision of significance was maintained at 5%. We also checked the tendency for significance considering p<.10.

3. Results

EBSCO and Pubmed were the databases used, being the last search in February 2021 with five keywords (Oximetry, Pulp Vitality, Permanent teeth, Pulse Oximeter, Dental Pulp Test) and two combinations ("Oximetry AND Pulp Vitality AND Permanent teeth"; "Pulse Oximeter AND Dental Pulp Test"). A total of 26 articles were found after removing the duplicates from these eleven were excluded after reading the title and abstract and the other two after reading the full-text, remaining thirteen articles.

A total of 354 teeth were enrolled in this study, 297 (83.9%) healthy and 57 (16.1%) with at least one surface restored from 71 patients, 47 (66.2%) females and 24 (33.8%) males, aged from 22 to 73 years old, average 30.62 years (SD=13.33). (Tab. 1).

Type of tooth	*N*	*%*
Centrals	**139**	**39.3%**
11	70	19.8%
21	69	19.5%
Laterals	**109**	**30.8%**
12	53	15.0%
22	56	15.8%
Canines	**106**	**29.9%**
13	54	15.2%
23	52	14.7%
Number of surfaces restored	*N*	*%*
0	297	83.9%
1	14	4.0%
2	16	4.5%
3	16	4.5%
4	11	3.1%

Table 1- Teeth Features

Table 2 presents teeth assessments. The cold test showed positive results for 331 (93.5%) teeth. For the positive tests, the median of the elapsed time was 1 second, (P25=1.0, P75=2.0), varying from 1 to 20 seconds.

Electric test results showed 302 (85.3%) normal teeth, 29 (8.2%) teeth with some pathology, and 23 (6.5%) necrotic teeth. The electric test had an average of 6.0 (P25=2.0, P75=17.3), with a minimum of 1 and a maximum of 80. Oxygen saturation thresholds divided the sample into pulp vitality (53.4%), reversible pulpitis (19.2%), irreversible pulpitis (18.6%), and pulp necrosis (8.8%). The average oxygen saturation (% SpO_2) was 84.01

(SD=13.36), varying from 2% to 99%. Average teeth bpm was 75.97 (SD=8.95), varying from 60 to 93. Average of finger oxygen saturation (% SpO_2) was 97,04 (0,97), varying from 97 to 96 (Tab 2).

Cold test	
Negative	23 (6.5%)
Positive	331 (93.5%)
Time (a)	1.0 (1.0 – 2.0) [1-20]
Electric test	6.0 (2.0 – 17.3) [1-80]
Normal (<40)	302 (85.3%)
Some pathology (40-79)	29 (8.2%)
Necrotic (≥ 80)	23 (6.5%)
Oxygen saturation (% SpO_2)	84.01 (13.36) [2-99]
Pulp vital (95-86)	189 (53.4%)
Reversible pulpitis (85-82)	68 (19.2%)
Irreversible pulpitis (81-71)	66 (18.6%)
Pulp necrosis (<71)	31 (8.8%)
Teeth bpm	75.97 (8.95) [60-117]
Finger Oxygen Saturation	97,90 (0,97) [96-99]

(a) Calculated for positive cold tests; results presented as n (%) for categorical variables, M(SD) [min-max] for symmetrical continuous variables and Mdn (P25-P75) [min-max] for asymmetrical continuous variables

Table 2- Teeth assessments

Table 3 presents the results of the bifactorial ANOVAs for oxygen saturation and teeth bpm. A significant association was found for the restored surface variable, $F_{(348,1)}$=12.02 (p=.001), η^2=0.33, with high effect size, suggesting higher oxygen saturation for teeth without any surface restored (M=85.08, SD=12.17), compared to teeth with at least one surface restored (M=78.40, DP=17.42). No effect was found for the teeth group (p=.116) and the restored surface x teeth group (p=.840). A marginal significant result was found for the association of the restored surface variable and teeth bpm, $F_{(348,1)}$=2.79 (p=.096), η^2=0.01 with low effect size. Teeth with at least one surface restored had a lower mean result (M=74.81, SD=8.91) when compared with teeth without any surface restored (M=76.19, SD=8.96). Teeth bpm was not associated with teeth group, $F_{(348,1)}$=0.64 (p=.526), $\eta^2\approx$0.00 or with the interaction between restored surface and teeth group, $F_{(348,1)}$=1.58 (p=.207), η^2=0.01. Residuals normality and variances homoscedasticity were verified and confirmed,

as referred in the statistical analysis. Figures 5 and 6 show the average distribution of oxygen saturation and teeth bpm.

	Teeth group	*Oxygen saturation*	*Teeth bpm*
Restored surface			
No	Centrals (n=107)	86.20 (9.11)	74.80 (8.44)
	Laterals (n=90)	87.07 (7.61)	75.97 (8.11)
	Canines (n=100)	82.10 (16.97)	77.89 (9.97)
	Total (n=297)	85.08 (12.17)	76.19 (8.96)
Yes	Centrals (n=32)	78.06 (16.23)	74.97 (9.37)
	Laterals (n=19)	80.84 (20.41)	76.16 (8.19)
	Canines (n=6)	72.50 (14.21)	69.67 (8.04)
	Total (n=57)	78.40 (17.42)	74.81 (8.91)
Total	Centrals (n=139)	84.32 (11.61)	74.84 (8.63)
	Laterals (n=109)	85.98 (11.08)	76.00 (8.09)
	Canines (n=106)	81.56 (16.91)	77.42 (10.03)
F tests			
Restored surface		**$F_{(348,1)}$=12.02 (p=.001)** **η^2=0.33**	$F_{(348,1)}$=2.79 (p=.096) η^2=0.01
Teeth group		$F_{(348,1)}$=2.17 (p=.116) η^2=0.01	$F_{(348,1)}$=0.64 (p=.526) $\eta^2\approx$0.00
Restored surface x teeth group		$F_{(348,1)}$=0.17 (p=.840) $\eta^2\approx$0.00	$F_{(348,1)}$=1.58 (p=.207) η^2=0.01

Table 3- Bifactorial ANOVAs for oxygen saturation and teeth bpm

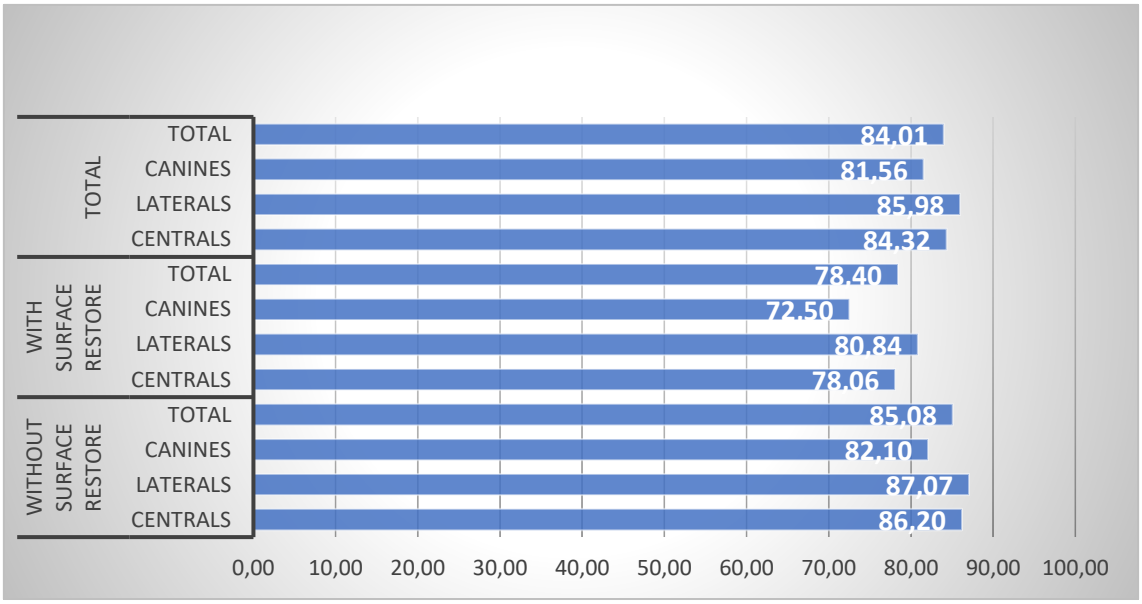

Figure 5- Oxygen saturation distribution according to restore and teeth group

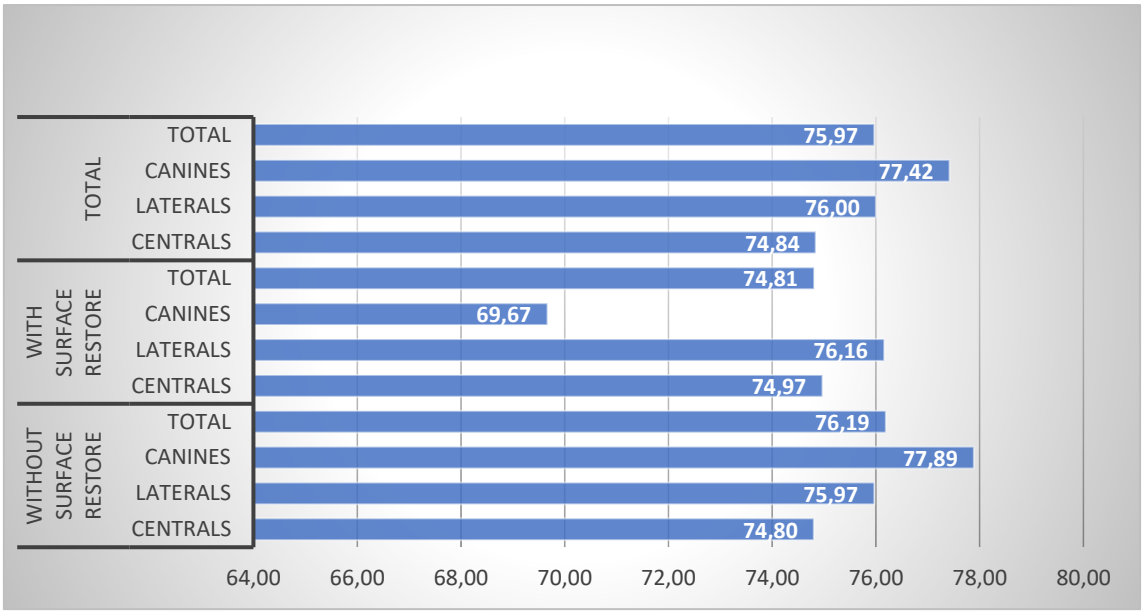

Figure 6- Teeth bpm distribution according to restore and teeth group

Finally, we assessed the sensitivity and specificity of oxygen saturation and teeth bpm considering the cold test as gold-standard for detecting teeth vitality. Oxygen saturation and teeth bpm did not prove to be good measures to detect the pulp vitality. Precision, measured as the area under the ROC curve, resulted in 65.9% and 63.4% for oxygen saturation and teeth bpm, respectively, both poor results. Hence, no cut-off was proposed for assessing sensitivity and specificity.

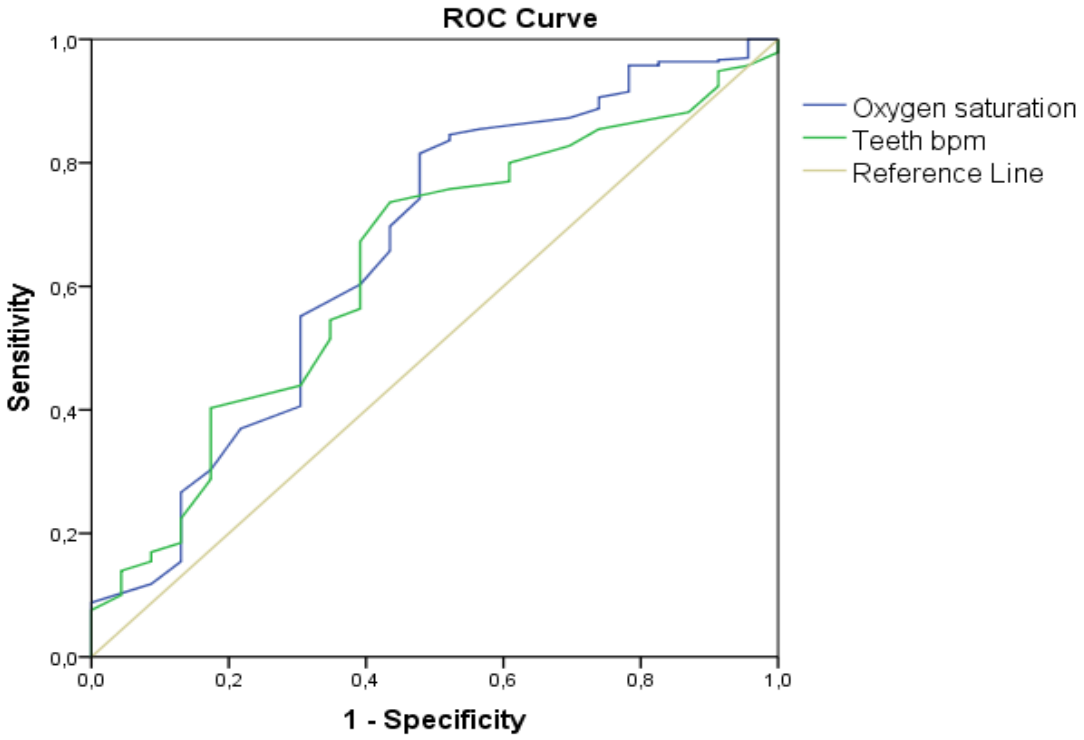

Figure 7- ROC curves for oxygen saturation and teeth bpm with the cold test as reference for detecting teeth vitality

4. Discussion

To preserve pulp vitality is a necessary efficient blood supply that allows support to the teeth metabolic demands[1,5]. When this supply is committed, correct evaluation of pulp status is especially relevant to achieve a good treatment outcome[2,12].

Unlike conventional tests that convey a stimulation associated with an unpleasant sensation, which indirectly assess the state of the pulp by nervous response. Pulp oximetry is non-invasive and evaluates the blood supply of the pulp. It is a better diagnostic method because the vitality of pulp tissues depends on blood supply instead of nerve function which means that the nerve can be damaged, yet the pulp can still be vital[2,3,8,10]. Pulse oximetry results have mathematic values associated, which we can quantify this way it doesn´t depend on patients' qualitative response make it more credible because it cannot be adulterated by the patient[11].

Oxygen saturation is connected to the haemoglobins' capacity to carry oxygen. In total, a haemoglobin transport four oxygen molecules, and max occupation correspond to 100% saturation. A healthy person's arterial oxygen saturation is between 95% and 100%[3,11]. It is quantified by transmitting light through the finger or teeth and then collected by a sensor. The amount transferred influences the reading because insufficient light can create values lower than the actual ones[1].

Theoretically, oxygen saturation obtained in the finger is equal in teeth pulp when healthy[1]. In this study, however, the average in the finger was higher (97.90%) than in the teeth (84,01%). The difference detected is probably associated to the fact that the finger has a Standard Probe with a perfect fitting that allows a more accurate reading without light leaks. However, the teeth have a custom-made probe that does not prevent light leaks also the diffraction that happens in the enamel and dentin, causing loss of light intensity lowering the saturation values regarding the finger[6]. (Tab. 2)

The teeth are composed of hard tissues (enamel and dentin) that can provide diffraction through the enamel prism and dentinal tubules and reduce the amount of infrared light that reaches the pulp inside the teeth[1,3,5].

In the study, there were only anterosuperior teeth, being in total 354. Their division was made into different groups being some based on the teeth type: 139 (39,3%) central

incisors, 109 (30,8%) lateral incisors, and 106 (29,9%) canines; and others the presence or absence of restoration: 297 (83,9%) with zero surfaces and 57 (16,1%) one or more surfaces (Tab. 1). The standard pulse oximetry values used to classify the pulp's vitality were: 95%-86% to Healthy Pulp, 85%-82% to Reversible Pulpitis, 81%-71% to Irreversible Pulpitis and <71% to Pulp Necrosis (Tab. 2). The oxygen saturation is inversely proportional to the severity of the pulp state[9].

In table 2 we can observe that the percentage of normal pulp in the PO test is inferior (53,3%) in comparison to the cold test (93,5%) and electric test (85,3%). These differences can be associated to some variables as false-positive caused by vicious answers that patients give, diffraction, and tissues mineralization.

The light transmitted can easily suffer from reflection, refraction, dispersion due to different variables. These light losses may reduce the intensity that reaches the sensor, thus giving values lower than the real ones[1,5]. We still need into consideration a lot of other variables that can cause interference as extrinsic (type of probes, room's light and head movement, light absorbed by gingiva, background absorption) and intrinsic (haemoglobin disorders, cardiovascular diseases, hypotension, vasoconstriction, higher venous pressure, low peripheral perfusion, mineralization of tissues)[3,5,9,12,13]. The mineralization of tissues causes an increase in dentin thickness and a pulp chamber atrophy increasing this way light diffraction lowering the oxygen saturation values[11]. Also, the sensor holder not being a perfect fit for the dental crown structured causes light scattering due to light leakage and the parallelism between sensors, rising the lower saturation values registered[1,3,5,11]. However, it´s necessary more scientific evidence to determine the oxygen levels regarding a normal pulp since several data have been documented[3].

The oxygen saturation values were compared between teeth without surfaces restored and with at least one surfaces restored. The total mean % SpO2 was 85,08% to teeth without surfaces restored and 78,40% with surfaces restored. By individual group types 86,20% and 78,06% to central incisors; 87,07% and 80,84% to lateral incisors and 82,10% and 72,50% to canines, referring to teeth without surfaces restored and teeth with at least one surface restored respectively. (Tab. 3 and Fig. 5)

We can observe that the teeth with restored surfaces have lower oxygen saturation than teeth without surfaces restored. The difference is probably associated to the material

used in the restoration because it absorbs and diffracts a lot more light, reducing the quantity and intensity that reaches the sensor, registering lower oxygen saturation values comparative to enamel and dentin.

The ROC curve evaluates the sensitivity and specificity of oxygen saturation. The values in the area under the ROC curve were 65,95% which are considered statistically poor results. Consequently, no cut-off was purposed to assess sensitivity and specificity. Statistically, the result obtained did not prove the oxygen saturation to be a good measure. (Fig. 7)

Nonetheless, a few studies were done with a pulse oximeter to corroborate its accuracy in the pulp vitality diagnosis. It is relevant to highlight that some of the lower values collected in this study don´t reflect the authentic oxygen saturation of the teeth due to diverse limitations with the need to be overtaken.

The standard oxygen saturation values need widening to include lower values of normal pulp to include teeth that suffer mineralization of tissues and still have vital pulp.

5. Conclusion

This study shows that restored teeth present oxygen saturation values lower than healthy teeth, because the material used to restore teeth is more diffractor than the enamel and dentin, causing a larger light leakage and less reach the sensor. The teeth oxygen saturation is lower than the finger oxygen saturation since enamel and dentin are more diffractor than the bone and soft tissues in the index finger, inducing light leakage. Loss of light intensity associated to the leaks and diffraction interferes with the oxygen saturation reading.

For a more sustained conclusion, a larger sample is required. That's why that more studies in this area are inevitable in order to support the results which were obtained.

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7. Attachment- Ethics Committee's Approval

CESPU
INSTITUTO UNIVERSITÁRIO
DE CIÊNCIAS DA SAÚDE

Comissão de Ética

Exmo. Senhor Investigador
Paulo Manuel Cruz Miller

N/Ref.ª: CE/IUCS/CESPU-15/21 **Data:** 2021/junho/21

Assunto: - **Parecer relativo ao Projeto de Investigação:** 15/CE-IUCS/2021
- **Título do Projeto:** *"Eficácia da Oximetria de pulso na aferição da condição pulpar. Comparação com os testes habitualmente utilizados."*
- **Investigador responsável:** Paulo Manuel Cruz Miller

Exmo. Senhor,

Informo V. Exa. que o projeto supracitado foi analisado na reunião da Comissão de Ética do IUCS, da CESPU, CrI, no dia 17/06/2021.

A Comissão de Ética emitiu um parecer **favorável** à realização do projeto tal como apresentado.

Com os melhores cumprimentos.

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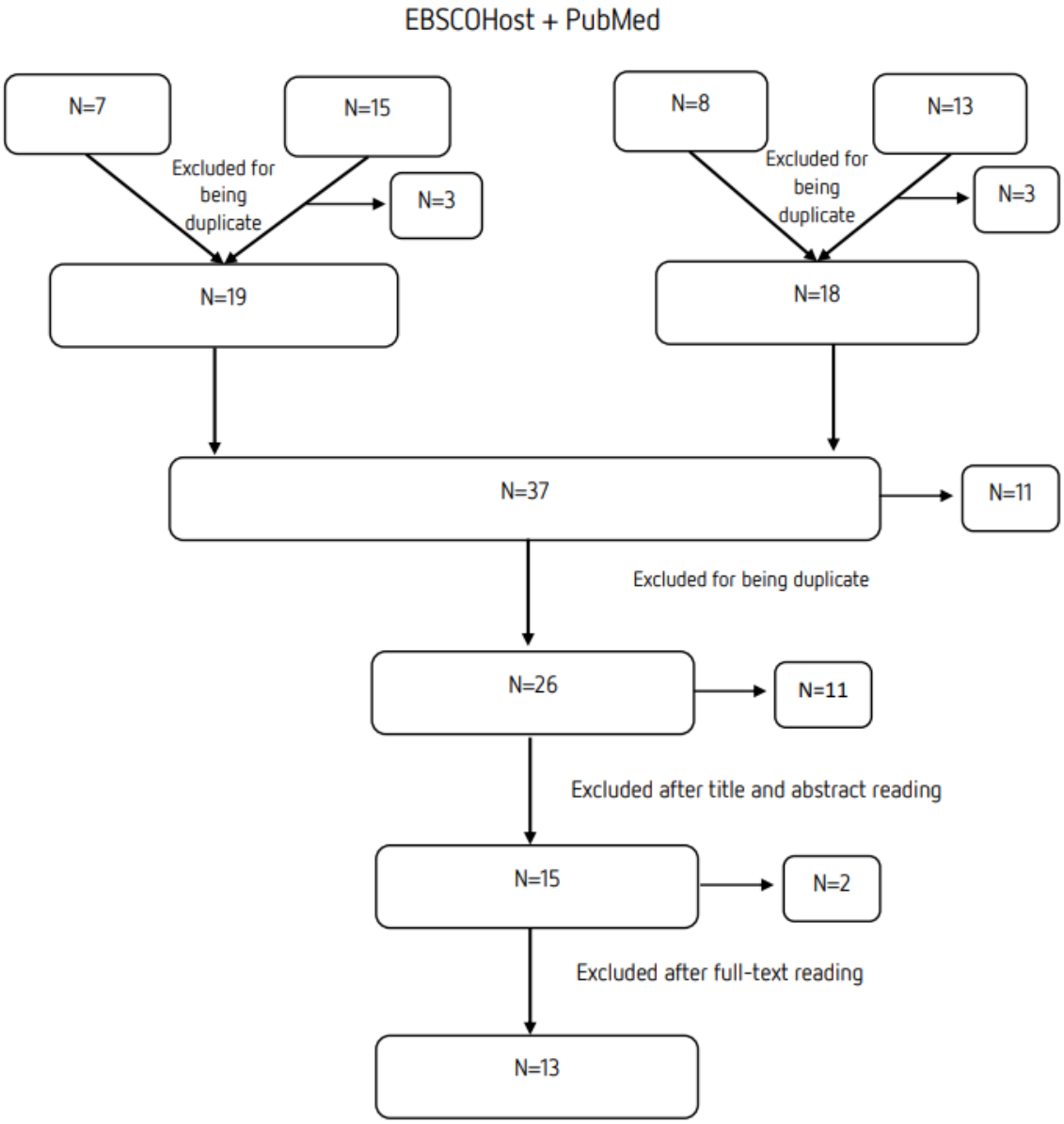
Prof. Doutor José Carlos Márcia Andrade
Presidente da Comissão de Ética do IUCS

8. Attachment- Flowchart



9. Attachment- Patient Informed Consent

"Eficácia de diferentes testes na aferição da condição pulpar"

CARTA EXPLICATIVA DO ESTUDO AOS PARTICIPANTES

O meu nome é _____, sou estudante do Mestrado integrado em Medicina Dentária no Instituto Universitário de Ciências da Saúde na CESPU. Gostaria de convidá-lo(a) a participar num estudo que estamos a desenvolver, para o trabalho de dissertação de Mestrado, integrado num Grupo de Investigação sobre diagnóstico pulpar, que tem como principal objetivo determinar a eficácia e comparar testes de diagnóstico da condição da saúde da polpa dentária.

Recoberta pela dentina, a polpa é um tecido mole que se estende da coroa até a raiz do dente e é composta por nervos, vasos sanguíneos, células de tecido conjuntivo e fibras. A polpa dentária é a responsável pela vitalidade dos dentes.

Os testes pulpares (testes de vitalidade e de sensibilidade) são utilizados como recurso complementar do exame clínico, para auxiliar no diagnóstico da normalidade ou da patologia pulpar.

Os testes de sensibilidade térmicos e elétricos são executados rotineiramente na prática clínica.

O teste de vitalidade por oximetria de pulso é uma técnica não invasiva e completamente indolor, não causando qualquer incómodo ou risco.

A informação recolhida neste estudo poderá, no futuro, possibilitar a obtenção dum diagnóstico mais fundamentado e menos subjetivo da condição pulpar dentária, fator que influencia diretamente a decisão clínica no que respeita à pertinência de se realizar, ou não, determinados tratamentos face ao conhecimento do mesmo.

A escolha de participar, ou não, no estudo é voluntária.

O presente estudo não acarreta qualquer risco, não trazendo também qualquer vantagem direta para os que nele participam e não irá interferir no plano de tratamento. Serão aproveitadas todas as consultas normalmente programadas para a recolha de dados, evitando deslocação extra aos serviços. Se decidir participar no estudo, poderá abandonar o mesmo em qualquer momento sem ter que fornecer qualquer tipo de explicação. Todo o material recolhido será codificado e tratado de forma anónima e confidencial, sendo conservado à responsabilidade do Prof. Doutor Paulo Manuel Cruz Miller, Professor Auxiliar nesta instituição e responsável pelo estudo.

A decisão de participar implica a autorização para utilização de recolha de dados sócio- demográficos e clínicos registados e recolhidos do seu processo clínico. Os dados recolhidos irão avaliar a resposta aos testes de sensibilidade e vitalidade pulpar. O responsável pelo seu tratamento irá recolher esta informação durante o seu período normal de tratamento.

Os resultados do estudo serão apresentados no âmbito da apresentação do Trabalho de Dissertação do Mestrado Integrado em Medicina Dentária, nunca sendo os participantes identificados de forma individual. Uma vez apresentados os resultados, os dados originais serão coligidos e aproveitados para investigações futuras.

Caso surja alguma dúvida, ou necessite de informação adicional, por favor contacte através do email paulo.miller@iucs.cespu.pt.

"Eficácia de diferentes testes na aferição da condição pulpar"

DECLARAÇÃO DE CONSENTIMENTO INFORMADO

Reconheço que os procedimentos de investigação descritos na carta anexa me foram explicados e que todas as minhas questões foram esclarecidas de forma satisfatória. Compreendo igualmente que a participação no estudo não acarreta qualquer tipo de vantagens e/ou desvantagens potenciais.

Fui informado(a) que tenho o direito a recusar participar e que a minha recusa em fazê-lo não terá consequências para mim.

Compreendo que tenho o direito de colocar agora e durante o desenvolvimento do estudo, qualquer questão relacionada com o mesmo.

Compreendo que sou livre de, a qualquer momento, abandonar o estudo sem ter de fornecer qualquer explicação.

Assim, declaro que aceito participar nesta investigação, com a salvaguarda da confidencialidade e anonimato e sem prejuízo pessoal de cariz ético ou moral.

O Responsável pelo estudo:

_____

(Paulo Manuel Cruz Miller)

Responsável pela recolha dos dados

_____

O Participante ou Representante:

_____

Gandra, ____ de _____ de 2021