

Effect of Treatment with Selective Caries Removal Associated to Antimicrobial Photodynamic Therapy on Children's Oral Health-Related Quality of Life: A Non-Randomized Clinical Study

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*How patients perceive impact of diseases is an essential component when characterising different disease impacts, and effects of dental treatments should be perceived by the patients. This study aimed to assess the impact of conservative treatment of deep caries lesions using the selective caries removal (SCR) associated to a low laser therapy (antimicrobial photodynamic therapy–aPDT) on oral health-related quality of life (OHRQoL). **Study Design:** A non-randomized clinical before-and-after study was conducted on children aged 4 to 8 years. The data was obtained applying the Brazilian version of the Early Childhood Oral Health Impact Scale (ECOHIS) to the caretakers in an interview before and after treatment. The paired T-student test considering $p < 0.05$ and the treatment responsiveness detecting the effect size by means of standardized response mean (SRM) was evaluated. **Results:** The mean impact on OHRQoL on the total scale was 5.46 ± 4.54 for before and 2.42 ± 3.54 for after treatment ($p < 0.01$). The ECOHIS demonstrated satisfactory longitudinal responsiveness except for psychological, self-image/ social interaction and Family function domain ($SRM < 0.5$). **Conclusion:** This study demonstrated that the association of a low laser therapy (aPDT) with SCR did not influence negatively on OHRQoL. In the practice of pediatric dentistry, this conservative dental treatment improved the OHRQoL after 3 months of follow up.*

Keywords: Child, caries, photodynamic therapy, treatment, quality of life, oral health

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INTRODUCTION

Minimal invasive dentistry prioritizes conservative intervention when a surgical approach is necessary, reducing the loss of dental tissue. In more advanced caries lesions, several techniques have been developed to stop the progression of the lesion and its possible pulp involvement. The selective caries removal (SCR), recommends conservative caries removal and it has been showing positive results with the reduction of the risk of pulp exposure and preservation of healthy dental structure.¹

Associated with this technique, the use of antimicrobial photodynamic therapy (aPDT) has been used as an adjunct in the cavity preparation.^{2,3} According to the literature, aPDT seems to be efficient to reduce microorganisms in carious dentin in deep caries.^{2,3} Moreover, *in vitro* studies it is suggested that aPDT may be used in cavities with enamel margins to decrease the microbial load and prevent secondary caries.⁴ In addition, studies recently published have been observed that the performance of primary molar resin restorations was not affected by SCR associated to aPDT after 6 and 12 months of follow-up.⁵⁻⁷

Dental patient-reported outcomes (dPROs) and their Patient-Reported Outcome Measures (dPROMs) are fundamental for evidence-based dentistry. How patients perceive impact of diseases is an essential component when characterising different disease impacts, and effects of dental treatments should be perceived by the patients. The widely used concept oral health-related quality of life (OHRQoL) is the most important dPRO.⁸ In the literature, it is observed that the treatment of caries improves OHRQoL.⁹ However, there are no studies that assess the impact on OHRQoL of caries treatment using aPDT as an adjunct to SCR for the treatment of deep caries. Thus, this study aimed to assess the impact on conservative treatment of deep caries lesions using the selective caries removal (SCR) associated to a low laser therapy (antimicrobial photodynamic therapy-aPDT) on OHRQoL

MATERIALS AND METHOD

This before-and-after *não* randomized clinical study was conducted in accordance with CONSORT standards¹⁰ and registered in the ClinicalTrials.gov (NCT # 02908789 and in the Brazilian clinical trial platform-ReBEC (UTN# U1111-1183-0523). The clinical interventions were conducted in a public health institution, following the approval of the local Ethics Committee in Research (CAAE: 46451115.1.0000.5626 / protocol number: 1177743). All procedures were performed with the permission of patients and their caregivers, by reading and signing the terms of free and enlightened assent and consent, respectively.

Sample selection

The sample size was calculated using the impact on OHRQoL difference observed before (mean 6.62, standard deviation 2.72) and after treatment SCR + aPDT (mean 4.00 standard deviation 4.10) in a pilot study with 8 patients (not included in this study). The OpenEpi (Open Source Epidemiological Statistics for Public Health) version 3.01 (http://www.openepi.com/Menu/OE_Menu.htm) was used for the calculation. A convenience sample of participants was recruited from August to December 2017. Patients from 4-8 years old needing for treatment for dental caries were recruited from Pediatric dentistry clinics at a public university. A significance level of 5% was adopted

for a two-column test with a power of 80% for obtaining a sample of 20. To compensate for any drop-outs, 10% more participants were added, resulting in a final sample of 30 participants.

Inclusion criteria were: healthy children aged 4 to 8 years with active deep dental caries on primary teeth involving no more than two thirds of the dentin, determined by primary radiographic analysis; parents able to understand spoken Brazilian Portuguese. Participants were excluded if they presented pulp involvement or advanced root resorption (2/3), early loss of primary teeth or prosthetic and orthodontic appliance (once can be a confounding factor to detect the OHRQoL); were not treated with SCR + aPDT; or were included in the pilot study. It was considered lost if they did not answer the OHRQoL questionnaire until 3 months after the treatment due to lost of contact.

Clinical and OHRQoL evaluation

A single trained, calibrated and blinded examiner for the procedures conducted the interview collecting data such as sex, age, ethnicity, social status, as well as the OHRQoL measured before and 3-months after treatment. The data was collected from a period of two years (2018-2019). Parents or guardians responded to the ECOHIS validated for children aged 2 to 5 years.¹¹ However, in this study, the age range of application was extended since its psychometric properties in older age groups were considered satisfactory in studies previous studies.¹² This questionnaire consists of 13 questions divided into two sections: impact on the child and impact on the family. The child impact section has four subscales: symptoms (one question), function (four questions), psychology (two questions) and self-image / social interaction (two questions). The family impact section has two subscales: parental distress (two questions) and family function (two questions). The ECOHIS response categories were coded on a five-point scale: 0 = never; 1 = almost never; 2 = occasionally; 3 = frequently; and 4 = very often. The score for each domain is calculated by simply adding the scores for each item. The total score ranges from 0 to 52, with higher scores showing greater impact on oral health and lower OHRQoL.¹¹

The clinical and observational stages of the research were carried out at the Pediatric Dentistry Clinics of Nova Friburgo Health Institute at Universidade Federal Fluminense / (Nova Friburgo, Rio de Janeiro, Brazil). The initial periapical and interproximal radiographs were performed with a radiographic positioner. The children were examined using the DMFT / dmft¹³ simplified oral hygiene¹⁴ malocclusions (open bite, overjet, cross-bite)¹³ as well as dental trauma following the guidelines of the recommended index by Andreassen (1994).¹⁵

Interventions and Treatments

The treatments were carried out under local anesthesia and absolute isolation. The carious dentin lesion, when necessary, was accessed with a diamond tip (Microdont, São Paulo, Brazil) in high rotation (KG Sorensen, São Paulo, Brazil) and with refrigeration to remove unsightly enamel. The cavity preparation was limited to the total removal of decayed dentin from the sidewalls with a low-speed spherical carbide drill (KG Sorensen, São Paulo, Brazil). The SCR on the pulp wall was performed with manual excavators (Fava, Piratuba, Brazil) and limited the removal of small fragments of superficial dentin (in the form of scales) and interrupted when the dentin

showed greater resistance to cutting, following clinical criteria of consistency and texture.¹⁶ After the selective removal of decayed tissue (RSTC), a 0.01% methylene blue (MB) solution (Chimiolux, DMC, São Carlos, SP, Brazil) was added, filling the entire cavity for five minutes. Then, the excess was removed with sterile cotton. The laser irradiation was carried out in contact and in continuous wave mode for 90 sec. The insert was placed in direct contact with the cusp close to the center of the caries lesion. A red laser Laser Duo® source of aluminum gallium phosphide (InGaAlP) with a wavelength of 660 ± 10 nm, and with the power of 100mW output, 9 J output energy, 300 J / cm² fluency, 3.33 W / cm² irradiance and 3mm² output point (MM Optics, São Carlos, SP, Brazil). The power of the red laser device was checked at the beginning of each clinical day using a laser check (MM Optics™, São Carlos, SP, Brazil) to confirm the power of 100 ± 20 mW. The cavity was restored with composite resin (Filtek Z 250, 3M ESPE) after applying the Adper Single Bond 2™ adhesive system (3M ESPE, São Paulo, Brazil) according to the manufacturer's specification.

Statistical Analysis

The data obtained was inserted into a statistical program (SPSS version 20.0). Based on the Kolmogorov-Smirnov test, the sample normality was confirmed. Parametric test (student t test) was used to assess potential confounding factor (dental trauma and malocclusion) and to compare the means of impact before and after treatment (paired t test) considering a value of $p \leq 0.05$.

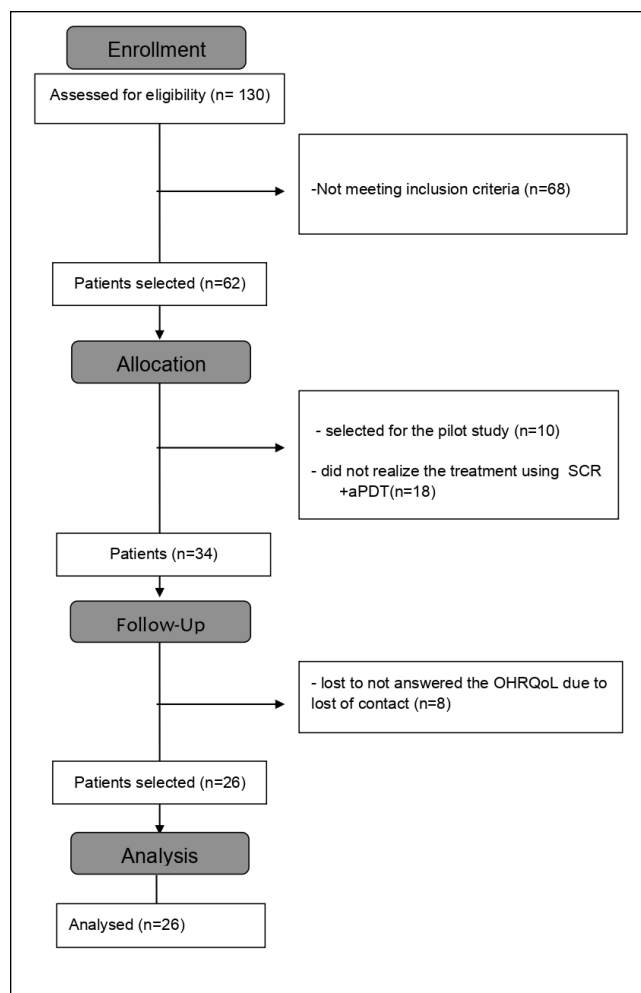
Change scores were calculated by subtracting follow-up scores from baseline scores. A positive value indicated improvement in OHRQoL. Effect sizes were calculated for change scores to assess the magnitude of change was assessed by standardized response mean (SRM). The SRM is one of several available effect size indices used to gauge the responsiveness of scales to clinical change. The SRM is computed by dividing the mean score change (i.e., follow-up minus baseline) by the standard deviation of the change. The with effect sizes of <0.5 and >0.5 representing small responsiveness and satisfactory responsiveness.¹⁷

RESULTS

One hundred and thirty participants were accessed for eligibility, from those, 34 were eligible for the study and 26 participants were included the final analysis. Ten participants were lost and the reason was not return until 3 months after treatment to answer the OHRQoL questionnaire (Figure 1). The sample mean age was $6.15 (\pm 1.48)$, 09 (34.6%) was male and 17 (65.4%) was female. Regarding socioeconomic classification 16 (61.5%) were from class C1 and C2 and 10 (38.5%) from class D and E. The dmft and DMFT indexes mean was $5.42 (\pm 3.05)$ and $0.19 (\pm 0.63)$ respectively. The oral hygiene index was 76.9%, which is good. In the sample, there were only 2 (7.7%) cases of children with malocclusion and 4 (15.3%) with dental trauma (Table 1) that did not influence the impact on OHRQoL ($p > 0.05$) (Table 2).

The mean impact on OHRQoL total scale was $5.46 (\pm 4.55)$ before and $2.42 (\pm 3.55)$ after treatment ($p < 0.01$). In the child subscale it was $4.42 (\pm 3.36)$ before and $2.12 (\pm 3.19)$ after treatment ($p < 0.01$). In the family subscale, the impact on OHRQoL was $1.04 (\pm 2.16)$ before and $0.31 (\pm 0.74)$ after treatment ($p = 0.04$). In child subscale, the symptoms domain had a mean of $1.27 (\pm 1.15)$ before

Figure 1: Fluxogram describing participant flow



and $0.54 (\pm 0.95)$ after treatment ($p < 0.01$). The function domain had a mean of $2.12 (\pm 1.90)$ before and $0.92 (\pm 1.29)$ after treatment ($p < 0.01$). The psychological domain had a mean of $0.81 (\pm 1.52)$ before and $0.65 (\pm 1.47)$ after treatment ($p = 0.35$). The self-image / social interaction domain averaged $0.23 (\pm 0.59)$ before and zero after treatment ($p = 0.05$). Thus, it was possible to observe that only the psychological domain did not have a statistical difference ($p > 0.05$).

In the family subscale, the domain of parental suffering had a mean of $0.73 (\pm 1.54)$ before and $0.15 (\pm 0.54)$ after treatment ($p = 0.04$) and the domain of family function had a mean of $0.31 (\pm 1.05)$ before and $0.15 (\pm 0.54)$ after treatment ($p = 0.21$), the latter showing no statistical difference (Table 3).

Table 4 shows the results of longitudinal validity and responsiveness testing by SRM. The impact on OHRQoL after treatment evaluated by ECOHIS demonstrated satisfactory longitudinal responsiveness except for psychological, self-image/ social interaction and Family function domain (SRM <0.5 denoting small responsiveness).

Table 1: Sample characterization (n=26)

Variables	
Age	mean (SD)
	6.15 (1.48)
Sex	n (%)
Male	09 (34.6)
Female	17 (65.4)
Ethnicity	n(%)
Caucasian	20 (76.9)
Afro-descendent	6 (23.1)
Economic classification	n (%)
C1/C2	16 (61.5)
D/E	10 (38.5)
dmft	mean (SD)
	5.42 (3.05)
DMFT	mean (SD)
	0.19 (0.63)
IHOS-Oral Health	n (%)
Good	20 (76.9)
Regular	6 (23.1)
Poor	-
Malocclusion	n(%)
Presence	2 (7.7)
Absence	24 (92.3)
Dental trauma	n (%)
Presence	4 (15.3)
Absence	22 (84.7)

DISCUSSION

Children’s OHRQoL are negatively influenced by untreated cavitated dentine lesions and their consequences.¹⁸ Therefore, studying techniques that can restore function and aesthetics promoting quality of life is extremely important. The conservative treatment of deep caries (SCR + aPDT), did not influence negatively on OHRQoL demonstrating, after 3 months of follow up improvement the OHRQoL to these children and the family, with the reduction of the negative impact generated by the disease, thus confirming the importance of access to dental treatment and how it has influence on the well-being of individuals and the use of new technologies.

The literature has demonstrated that dental caries has a negative impact on children’s lives, affecting their physical and emotional well-being and that the treatment of oral disorders has restored the OHRQoL.^{19,20} Its treatment has been related to improvement in OHRQoL.⁹ Thus, the present study is in agreement with what was pointed out in the literature, demonstrating that after dental treatment, pediatric patients had improvements both with regard to functionality and also in psychosocial aspects. These measures can help weigh risks and benefits, as well as assess the cost effectiveness of treatments, thus influencing treatment recommendations and health policies. The incorporation of these measures into a professional’s daily life not only represents an improvement in professional performance, but also addresses a humanitarian concern.²¹

Table 2: Evaluation of confounding factors presented in the sample (dental trauma and malocclusion)

Dental trauma (no=22; yes=4)		Mean	SD	P value
Total Scale	no	5.54	4.79	0.83
	yes	5.00	3.37	
Child Subscale	no	4.36	3.46	0.83
	yes	4.75	3.20	
Symptoms domain	no	1.27	1.20	0.97
	yes	1.25	0.96	
Function domain	no	1.95	1.86	0.32
	yes	3.00	2.16	
Psychological domain	no	0.86	1.61	0.67
	yes	0.50	1.00	
Self-image/social interaction domain	no	0.27	0.63	0.40
	yes	0.00	0.00	
Family Subscale	no	1.18	2.32	0.43
	yes	0.25	0.50	
Parental distress domain	no	0.81	1.65	0.50
	yes	0.25	0.50	
Parental distress domain	no	0.36	1.13	0.53
	yes	0.00	0.00	
Malocclusion (no=24; yes=2)		Mean	SD	P value
Total Scale	no	5.58	4.63	0.64
	yes	4.00	4.24	
Child Subscale	no	4.50	3.34	0.69
	yes	3.50	4.95	
Symptoms domain	no	1.29	1.16	0.73
	yes	1.00	1.41	
Function domain	no	2.08	1.84	0.77
	yes	2.50	3.53	
Psychological domain	no	0.87	1.57	0.44
	yes	0.00	0.00	
Self-image/social interaction domain	no	0.25	0.61	0.57
	yes	0.00	0.00	
Family Subscale	no	1.08	2.24	0.72
	yes	0.50	0.70	
Parental distress domain	no	0.75	1.59	0.83
	yes	0.50	0.70	
Parental distress domain	no	0.33	1.09	0.65
	yes	0.00	0.00	

Student t test, p<0.05

Table 3: OHRQoL evaluation before and after treatment.

ECOHis instrument	Questionnaire application				P value
	Before treatment		After treatment		
Scale/Subscale/Domain	Mean	SD	Mean	SD	
Total Scale	5.46	4.55	2.42	3.55	<0.01
Child Subscale	4.42	3.36	2.12	3.19	<0.01
Symptoms domain	1.27	1.15	0.54	0.95	<0.01
Function domain	2.12	1.90	0.92	1.29	<0.01
Psychological domain	0.81	1.52	0.65	1.47	0.35
Self-image/social interaction domain	0.23	0.59	0.00	0.00	0.05
Family Subscale	1.04	2.16	0.31	0.74	0.04
Parental distress domain	0.73	1.54	0.15	0.54	0.04
Family function domain	0.31	1.05	0.15	0.54	0.21

Paired t test, $p < 0.05$, bold indicate statistical significance

Table 4. Scores obtained in the ECOHis questionnaire of patients before and after the conservative treatment of the deep caries lesion using the SCR + aPDT technique

ECOHis instrument	Mean score change	Standard deviation of changed scores	SRM'
Total Score	3.04	3.55	0.86
Child Subscale	2.30	3.19	0.72
Symptoms domain	0.73	0.95	0.77
Function domain	1.20	1.29	0.93
Psychological domain	0.16	1.47	0.10
Self-image/social interaction domain	0.23	0.00	0.00
Family Subscale	0.73	0.74	0.98
Parental distress domain	0.58	0.54	1.07
Family function domain	0.16	0.54	0.30

Effectall responsiveness; >0.5 to 1.0 = satisfactory responsiveness

The present work sought to control biases by performing sample calculations and controlling factors that could potentially be confusing. However, as a limitation, as this is the first study to assess the impact on quality of life using a laser associated with a SCR technique, which makes greater comparisons with the literature was difficult. Hence, it is suggested more studies on this topic considering other groups of children to confirm or to refute the present findings.

In this study, only psychological domain (in child subscale) and family function domain (in family subscale) showed no statistical difference. It also was observed in the responsiveness evaluated by ECOHis in relation to impact on OHRQoL after treatment. It is believed that the young age of the participants influenced the result of the psychological domain. Children with lower age are expected to be less impact on OHRQoL compared to those of a larger age due to a more advanced in the psychological development phase.²² Regarding the family function domain, which includes the expenses of that family, there was possibly no statistical difference because it was a free service provided by a public institution.

The search for more scientific evidence, the adoption of a minimally invasive dentistry is increasing. Studies observed the non-necessity of total removal of carious dentin in deep cavities, since there is the possibility of recovery of the innermost layer and paralysis of the lesion of caries.²³⁻²⁶ Based on this philosophy, SCR showed an increase in radiopacity, a decrease in the depth of the lesion and deposition of tertiary dentin with high rate of success rate.²⁷

The advancement of aPDT's knowledge is changing the current scenario in the area of health. aPDT used as an adjunct to SCR is a reality, reducing the removal of the dental structure during the management of the carious lesion with the guarantee of maximum reduction of microorganisms in the cavity before the restoration.³ In addition, clinical studies have provided further support to indicate the association of aPDT with SCR, since it does not affect the longevity of composite resin restorations in primary molars.^{8,28,29}

The findings described in this study demonstrated that the association of a low laser therapy (aPDT) with SCR did not influence negatively on OHRQoL. In the practice of pediatric dentistry, this conservative dental treatment improved the OHRQoL after 3 months of follow up. These findings should be interpreted with caution. Other types of treatment and the consideration of more time follow up should also be evaluated suggesting new studies. However, this study is a first step to give more information about the application of aPDT on pediatric dental clinic considering a OHRQoL outcome. It can be one more advantage of the association of these techniques which, in addition to safely returning biological conditions, can also help in the return of health and psychosocial aspects, taking a holistic view of the patient. Knowledge about the impact of these procedures on OHRQoL is of pivotal importance in deciding whether to advocate the adoption of such treatments.²¹

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