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**AVALIAÇÃO DO IMPACTO DA EXPANSÃO RÁPIDA DA MAXILA E
LASERTERAPIA NA QUALIDADE DE VIDA RELACIONADA À
SAÚDE BUCAL EM CRIANÇAS**

Santa Maria, RS
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Dissertação apresentada ao Programa de Pós-Graduação em Ciências Odontológicas da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para obtenção do título de **Mestre em Ciências Odontológicas com Ênfase em Ortodontia**.

Orientadora: Prof^a. Dr^a. Mariana Marquezan

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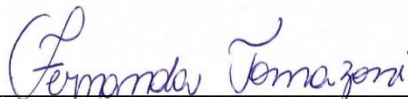
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RESUMO

AVALIAÇÃO DO IMPACTO DA EXPANSÃO RÁPIDA DA MAXILA E LASERTERAPIA NA QUALIDADE DE VIDA RELACIONADA À SAÚDE BUCAL EM CRIANÇAS

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O objetivo desta pesquisa foi avaliar o impacto do tratamento ortodôntico interceptativo com expansão rápida da maxila (ERM) e laserterapia na qualidade de vida relacionada à saúde bucal (QVRSB) de crianças. Foi realizado um ensaio clínico controlado randomizado, com 27 crianças com idade entre 8 e 12 anos, na fase de dentição mista, apresentando atresia maxilar e mordida cruzada posterior aparente ou relativa, divididas em dois grupos: grupo experimental (GE, n=13) – que realizou ERM e laserterapia em 10 pontos do palato, sendo 4 na sutura palatina mediana e 6 lateralmente; e grupo controle (GC, n=14) – que realizou apenas ERM. Os tempos de avaliação foram: T0 – fase pré-tratamento (antes da instalação do disjuntor), T1 – dia da estabilização do parafuso, T2 – 3 meses após a estabilização do parafuso, T3 – imediatamente após a remoção do disjuntor (após 6 meses de contenção), e T4 – 3 meses após a remoção do disjuntor. A avaliação da QVRSB foi realizada por meio da aplicação da versão brasileira do questionário *Child Perceptions Questionnaire* (CPQ8-10), respondido pelas crianças em todos os tempos experimentais. A análise multinível de regressão de Poisson foi utilizada para comparar os escores gerais e por domínios do questionário de acordo com o grupo e tempo de tratamento. Resultados: Quando considerada a avaliação da QVRSB de todas as crianças, a pontuação dos escores do CPQ8-10 diminuiu 22% em 3 meses (T2, Taxa de incidência, IRR 0,78; Intervalo de Confiança, IC 95% 0,68-0,90), 41% em 6 meses (T3, IRR 0,59 IC 95% 0,50-0,69) e 50% após 9 meses de acompanhamento (T4, IRR 0,50; IC 95% 0,42-0,59) em relação ao T0. Os escores dos domínios específicos limitação funcional, bem-estar emocional e bem-estar social apresentaram redução significativa ao longo do tempo, sendo observado um maior efeito após os 9 meses de acompanhamento nos domínios de limitação funcional 66% (IRR 0.34; IC 95% 0.25-0.48), bem estar emocional 45% (IRR 0.55; 95% CI 0.34-0.89) e bem-estar social 65% (IRR 0.35; IC 95% 0.23-0.54). Quando avaliada a diferença intergrupos, não houve diferença estatisticamente significativa nos escores gerais do CPQ8-10 (IRR 1.01; IC 95% 0,62 -1,63). Conclusões: Houve diminuição dos escores gerais e dos domínios específicos do CPQ8-10 ao longo do período de avaliação, indicando melhora gradual da QVRSB em crianças tratadas com ERM. Na população estudada, a utilização da laserterapia não teve influência significativa nos escores do CPQ8-10.

Palavras-chave: Expansão maxilar. Terapia a Laser. Qualidade de vida. Criança.

ABSTRACT

ASSESSMENT OF THE IMPACT OF RAPID MAXILLARY EXPANSION AND LASERTHERAPY ON THE ORAL HEALTH RELATED QUALITY OF LIFE IN CHILDREN

AUTHOR: Caroline Kolling Fensterseifer

ADVISOR: Mariana Marquezan

The aim of this research was to evaluate the impact of the interceptive orthodontic treatment with rapid maxillary expansion (RME) and lasertherapy in oral health related quality of life (OHRQoL) in children. A randomized clinical trial (RCT) was performed with 27 children, aged 8 to 12 years, in mixed dentition stage, who had maxillary atresia and apparent or relative posterior crossbite, divided into two groups: experimental group (EG, n= 13) – who underwent RME and laser therapy in 10 points of the palate, four on the midpalatal suture and six laterally; and control group (CG, n= 14) – who underwent RME only. Evaluation time intervals were: T0 – pre-treatment phase (before expander installation); T1 - screw stabilization day; T2 – 3 months after screw stabilization; T3 – immediately after expander removal (after 6 months of retention) and T4 – 3 months after expander removal. The OHRQoL was assessed using the Brazilian version of the Child Perceptions Questionnaire (CPQ8-10) that the children answered at all experimental times. Multilevel Poisson regression analysis was used to compare general and domains questionnaire scores between groups of the RCT according to the evaluation time interval. Results: When considering the assessment of OHRQoL of all children, CPQ8-10 scores decreased 22% in 3 months (T2, Incidence Rate Ratio IRR 0.78; 95%, Confidence Interval, CI 0.68-0.90), 41% in 6 months (T3, IRR 0.59 95% CI 0.50-0.69) and 50% after 9 months of follow-up (T4, IRR 0.50; 95% CI 0.42-0.59) when compared to T0. The scores for the specific domains of functional limitation, emotional well-being and social well-being decreased significantly over time, with a greater effect being observed after 9 months of follow-up in the domains of functional limitation 66% (IRR 0.34; 95% CI 0.25-0.48), emotional well-being 45% (IRR 0.55; 95% CI 0.34-0.89) and social well-being 65% (IRR 0.35; 95% CI 0.23-0.54). When the intergroup difference was assessed, there was no statistically significant difference in the general scores of CPQ8-10 (IRR 1.01; 95% CI 0.62 -1.63). Conclusions: There was a decrease in the general scores and specific domains of CPQ8-10 over the evaluation period, indicating a gradual improvement in OHRQoL in children treated with ERM. For the studied population, the use of laser therapy had no significant influence on the scores of CPQ8-10.

Keywords: Maxillary expansion. Laser therapy. Quality of life. Child.

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1. INTRODUÇÃO E REVISÃO DE LITERATURA

A saúde bucal vem historicamente sendo avaliada por meio de critérios exclusivamente clínicos, restritos à avaliação do profissional em relação aos sintomas dos indivíduos, tais como dor, desconforto e alterações estéticas (GOURSAND et al., 2008; MARQUES et al., 2006). Porém, esses critérios não permitem a determinação do real impacto dos problemas bucais na vida dos indivíduos (MARQUES et al., 2006). Diante da necessidade de determinar a repercussão integral de alterações presentes na cavidade bucal, foram desenvolvidos instrumentos de avaliação da qualidade de vida relacionada à saúde bucal (QVRSB), que são utilizados com uma frequência cada vez maior em pesquisas odontológicas (JOKOVIC et al., 2002).

A qualidade de vida relacionada a saúde é constituída de um conjunto complexo e multidimensional de aspectos psíquicos, cognitivos, emocionais e sociais (DIJKERS, 2007). Os primeiros artigos referentes a esse termo, foram publicados em meados de 1980 e, desde, então, foram realizadas diversas mudanças e adaptações no conceito e na forma de mensuração da qualidade de vida (POST, 2014). Sabe-se que a qualidade de vida pode ser modulada direta ou indiretamente pelos desequilíbrios da saúde, sejam eles distúrbios, lesões, problemas de saúde geral e bucais, além dos sinais, sintomas e efeitos de tratamentos também estão ligados à essa questão. Sua mensuração pode servir como uma relevante medida após intervenções de saúde bucal e auxiliar os profissionais na identificação das preocupações do paciente (CHAFFEE et al., 2017). Assim, a qualidade de vida pode ser avaliada tanto por abordagens gerais, quanto por específicas, como a saúde bucal (ZUCOLOTO; MAROCO; CAMPOS, 2016).

O *Child Perceptions Questionnaire* (CPQ8-10) faz parte de um conjunto de instrumentos chamado COHQoL (*Child Oral Health-Related Quality of Life*) que são questionários sobre a qualidade de vida relacionada à saúde bucal em crianças. Esse conjunto de instrumentos, foi previamente adaptado e transcrito culturalmente para ser utilizado em crianças brasileiras (GOURSAND et al., 2008; MARTINS et al., 2009; TORRES et al., 2009). Esses questionários mensuram a extensão do impacto dos problemas bucais na qualidade de vida relatada em saúde através de quatro subescalas: sintomas bucais, limitação funcional, bem-estar social e bem-estar emocional (JOKOVIC et al., 2002).

Diferentes pesquisas na área da odontologia têm utilizado esses questionários de qualidade de vida, para avaliar o impacto dos tratamentos de maloclusões na vida dos pacientes, inclusive na correção da deficiência maxilar transversal em crianças portadoras de distúrbios do sono e respiração bucal (KATYAL et al., 2013). A deficiência maxilar transversal é uma

deformidade dentofacial comum na clínica ortodôntica, na qual se observa constrição da arcada superior e sua base óssea em sentido transversal, frequentemente acompanhada de mordida cruzada posterior aparente (SUZUKI et al., 2018). De acordo com a Pesquisa Nacional de Saúde Bucal (SB BRASIL 2010) estima-se que, a prevalência de mordidas cruzadas posteriores em crianças brasileiras de 5 anos seja de 21,9%, sendo a menor prevalência encontrada na Região Norte (10,1%) e a maior na Região Sudeste (25,3%). Dentre os fatores etiológicos envolvidos na atresia maxilar, destacam-se, a respiração bucal, os hábitos bucais deletérios, como sucção não nutritiva, postura inadequada de língua, disfunção da fala e deglutição atípica (BELLUZZO et al., 2012; CAPPELLETTE et al., 2017; PROFFIT; FIELDS JR., 2007).

A correção da atresia maxilar em pacientes em crescimento, promove o aumento transversal da maxila, por meio de respostas às forças ortopédicas e dentoalveolares aplicadas por aparelhos disjuntores que promovem a separação da sutura palatina mediana (HAAS, 1961). Com a utilização desses aparelhos ortopédicos, faz-se a expansão rápida da maxila (ERM). Devido à imaturidade da sutura palatina mediana durante a infância, que se apresenta alargada e sem interdigitações, pode-se observar sua abertura com aparelhos tanto de expansão rápida, como Haas e Hyrax que são fixos, quanto de expansão lenta, como os aparelhos removíveis com parafusos expansores (PROFFIT; FIELDS JR., 2007). Sabe-se que no decorrer da disjunção maxilar, é possível observar um diastema entre os incisivos superiores, que se fecha pela ação das fibras transeptais (ARAÚJO, 1999). Ainda, é possível confirmar a expansão por meio da radiografia oclusal da maxila (MOYERS, 2014).

A palavra laser é um acrônimo que significa Amplificação de Luz por Emissão Estimulada de Radiação. Na Odontologia, os lasers possuem duas principais aplicações: bioestimulação e cirurgia. Para bioestimulação, que é a ativação do processo de cicatrização e reparo, são utilizados os lasers de baixa potência (LBP), que operam abaixo de 500mW. Entre os LBP encontra-se os lasers de He-Ne (Hélio-Neônio) e diodo (Arseniato de gálio - AsGa e Arseniato de gálio e alumínio - AsGaAl). O LBP promove efeitos terapêuticos, tais como: anti-inflamatório, analgésico e cicatrizante (DE OLIVEIRA et al., 2018; NEVES et al., 2005; SANT'ANNA et al., 2017). A radiação emitida pelo LBP afeta os processos metabólicos das células alvo, que produz efeitos bioestimulantes, resultando na ocorrência de eventos vasculares e celulares que possuem um papel importante na aceleração do processo de reparo dos tecidos irradiados (LINS et al., 2010).

Na Ortodontia, os LBPs têm sido utilizados para o alívio da dor associada à movimentação dentária durante o tratamento ortodôntico, acelerar o processo de reparação

óssea após ERM, e potencializar a movimentação dentária induzida ortodonticamente (SANT'ANNA et al., 2017). A utilização do LBP após a ERM visa a aceleração do processo de reparo da sutura palatina mediana (NEVES et al., 2005). O estudo de Saito e Shimizu 1997 mostrou que o osso neoformado quando irradiado por LBP apresentou uma qualidade superior ao osso formado não irradiado. Porém, pouca ênfase tem-se dado à possibilidade de os efeitos do uso do laser influenciarem na qualidade de vida durante o procedimento.

A correção da atresia maxilar, além de trazer os benefícios mastigatórios, respiratórios e estéticos, pode alterar a auto percepção da qualidade de vida relacionada à saúde bucal das crianças, uma vez que a saúde bucal influencia na alimentação, sorriso, fala e socialização (YUSUF et al, 2006). Apesar de haver evidência científica na melhora da estrutura nasal e redução de problemas relacionados à atresia maxilar com a utilização da ERM (BARATIERI et al., 2011; HAAS 1961; WEISSHEIMER et al., 2011; CANAN et al., 2017; MACHADO-JÚNIOR et al., 2016; CAPPELLETTE et al., 2017), poucos trabalhos investigaram o quanto essas alterações são capazes de causar melhoras significativas na QVRSB dos pacientes com atresia maxilar (KATYAL et al., 2013; IZUKA et al., 2015; GONÇALVES et al., 2013).

As hipóteses conceituais do presente estudo são de que a ERM promoverá melhora na QVRSB das crianças tratadas e o grupo tratado com ERM associado ao LBP apresentará uma melhora mais expressiva da QVRSB.

1.1. OBJETIVOS

1.1.1. Objetivo geral:

Avaliar o impacto do tratamento ortodôntico interceptativo de expansão rápida da maxila (ERM) com e sem o uso de laserterapia na qualidade de vida relacionada à saúde bucal das crianças tratadas.

1.1.2. Objetivos específicos:

Avaliar o impacto da ERM na qualidade de vida relacionada à saúde bucal dos pacientes;
Avaliar o efeito do tratamento em cada uma das subescalas: sintomas bucais, limitação funcional, bem-estar social e bem-estar emocional;

Avaliar se houve diferença na qualidade de vida relacionada à saúde bucal entre o grupo que recebeu LBP e o grupo controle.

2. ARTIGO

Será submetido ao periódico *American Journal of Orthodontics and Dentofacial Orthopedics*.

Oral Health-related Quality of Life after Rapid Maxillary Expansion and Laser Therapy in Children: a randomized clinical trial

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Abstract

Introduction: The aim of this study was to assess the impact of interceptive orthodontic treatment with rapid maxillary expansion (RME) and laser therapy on oral health-related quality of life (OHRQoL) in children with maxillary atresia. **Methods:** Twenty-seven children, mean age 9.1 years, were randomized into two groups: Experimental Group (EG, n = 13) – who underwent RME and laser therapy in 10 points of the palate; and Control Group (CG, n= 14) – who underwent RME only. Evaluation time intervals were: T0, initial; T1, stabilization day; T2, 3 months after T1; T3, immediately after expander removal (6 months of retention) and T4, 3 months after T3. The OHRQoL was assessed using the Child Perceptions Questionnaire (CPQ8-10). Multilevel Poisson regression analysis was used to compare general and domains questionnaire scores between groups according to the evaluation time interval. **Results:** CPQ8-10 scores decreased by 22% in 3 months, 41% in 6 months and 50% after 9 months of follow-up ($p<0.05$). There were no statistically significant differences in the general CPQ8-10 scores between groups ($p<0.05$). The scores for the specific domains decreased significantly over time, with a greater effect being observed after 9 months of follow-up in the domains of functional limitation 66%, emotional well-being 55%, and social well-being 65%. **Conclusions:** There was a decrease in the CPQ8-10 general and specific domains scores over the evaluation period, indicating a gradual improvement in OHRQoL in children treated with RME. For the studied population, the use of laser therapy had no significant influence on CPQ8-10 scores.

Keywords: Maxillary expansion. Laser therapy. Quality of Life. Children.

Introduction

The oral health-related quality of life (OHRQoL) is considered a multidimensional construct composed of psychological, cognitive, emotional and social aspects. OHRQoL reflects the extent to which oral disorders interfere in the self-perception of daily life and well-being of individuals^{1,2}. In this context, OHRQoL can be modulated directly or indirectly by oral health imbalances, in addition to the signs, symptoms and effects of treatments from the perception of the individuals^{2,3}. The subjective measurement of OHRQoL can serve as a relevant measure after oral health interventions and assist professionals in identifying patient concerns^{2,3}.

Previous researches in the field of dentistry have evaluated OHRQoL to measure the impact of malocclusion treatments on patients' lives⁴⁻⁶, including in the correction of transverse maxillary deficiency in children with sleep disorders and mouth breathing^{5,6}. Transverse

maxillary deficiency is a prevalent dentofacial deformity observed in the orthodontic clinic, due to constriction of the maxillary arch and its bone base in a transversal direction, often accompanied by an apparent posterior crossbite⁷. Among the most important etiological factors involved in maxillary atresia are mouth breathing, deleterious oral habits, such as non-nutritive sucking and inadequate tongue posture, speech dysfunction and atypical swallowing⁸⁻¹⁰.

In growing patients, maxillary atresia is corrected by performing rapid maxillary expansion (RME) that promotes transversal increase in the maxilla, in response to orthopedic forces applied by expanders and result in separation of the midpalatal suture¹¹. Previous studies have found that RME promoted benefits to patients, such as: increased nasal width⁹, improved breathing^{9,12} and gains in the maxillary arch perimeter^{11,13,14}.

The use of lower-level laser therapy (LLLT) during and after RME aims to accelerate the midpalatal suture repair, since LLLT is biostimulant and promote cellular and vascular effects that accelerate the metabolism¹⁵. The effect of LLLT on the repair process of the midpalatal suture after RME has been verified in studies with guinea pigs¹⁶ and humans¹⁷. Laser can also be used for pain relief in orthodontics¹⁸. However, there has been little emphasis on the possibility of RME treatments using laser therapy to influence subjective outcomes, such as OHRQoL. Studying these factors in a child population during the RME procedure is extremely important since the goal of all dental treatments is to promote patients' health and well-being. Moreover, adverse experiences by children undergoing treatment can have a negative impact that could last over a long period throughout their lives.

Although some studies have indicated improvement in OHRQoL after RME^{5,6,19}, there is no data in literature in relation to assessing the effect of RME associated with laser therapy on OHRQoL. Thus, the aim of the study was to evaluate the impact of interceptive orthodontic treatment with RME and laser therapy on the OHRQoL of children, in a period of 9 months of follow-up, after the expansion has stabilized. The conceptual hypothesis was that all patients undergoing RME would have improvement in OHRQoL, after 9 months follow-up; and that the laser therapy would promote a more significant improvement in OHRQoL.

Material and methods

Study design and sample

The present randomized controlled clinical trial was part of an umbrella clinical trial, registered on the REBEC platform (Brazilian Registry of Clinical Trials) with UTN code: U1111-12060888 (<https://ensaiosclinicos.gov.br/rg/RBR-6y979g>). The study was conducted between April 2019 and October 2020, with 27 volunteer children from the city of Santa Maria

(RS, Brazil), who participated in the research. The patients were divided into two groups: Experimental Group (EG, n = 13) - who underwent RME and laser therapy; and Control Group (CG, n = 14) - who underwent only RME. Randomization was performed using the online tool Randomizer (<http://www.randomizer.at>).

The sample size calculation was performed using data published by Katyal et al ⁵, who have found a difference of means in the OHRQoL scores of 39.9 (SD: 15.6) and 28.4 (SD: 13.3) before and after RME in individuals at high risk for pediatric respiratory sleep disorders. For the sample size calculation, a significance level of 5%, power of 80% and a 1:1 ratio of unexposed and exposed subjects was used. Thus, the minimum total sample required to assess the effect of RME on OHRQoL was 26 participants.

The inclusion criteria were children and adolescents from 8 to 12 years old, in the mixed dentition stage, who had maxillary atresia and apparent or relative posterior crossbite. The exclusion criteria were patients with a history of previous orthodontic treatment, who needed other types of interceptive orthodontic treatment within the experimental period (10 months), such as the use of headgear and face mask; patients who had systemic diseases that interfered with bone metabolism, or who used medications that alter bone metabolism; patients with craniofacial malformations; patients with suspected or diagnosis of oral cancer. Patients with gingivitis or active caries disease underwent treatment for promoting an adequate oral environment prior to their inclusion in the study.

Socioeconomic questionnaire

To assess the comparability between the groups of the RCT, demographic and socioeconomic variables were collected by applying a structured questionnaire, answered by the parents and/or guardians of the children, only once in the beginning of the study. Demographic variables included gender (female and male), age, skin color and family income. Age was collected in years and dichotomized into <9 and > 9 years of age. Skin color was determined by using the Brazilian Institute of Geography and Statistics criteria²⁰ and dichotomized into white and non-white individuals. Income was measured in Brazilian Reais (R\$) and subsequently categorized according to the Brazilian Minimum Wage (BMW) as: \geq 1BMW and < 1BMW.

Intervention

The patients included in the study underwent an initial assessment, in which anamnesis, intra and extra-oral clinical examination, and request for orthodontic documentation (intra and

extra-oral photographs, plaster casts, panoramic radiography, lateral telerradiograph) were performed. Additionally, a radiography was taken using the occlusal technique in the anterior region of the midpalatal suture with a CMOS digital sensor #2 (RVG 5100, Carestream Health, Rochester, USA) and an x-ray unit (Timex 70E; Gnatus, São Paulo, Brazil; 70kVp, 7.0mA and 0.1s exposure time).

For the rapid maxillary expansion, the modified Hyrax expander was used, as it exposed a larger area of the palate and facilitated the application of the LLLT. The Hyrax screw posterior segments were welded to the first permanent molar bands', and the anterior segments of the screw were welded to a segment of 0.9 mm CrNi elastic hard steel wire (Morelli, Sorocaba, SP, Brazil) that was adapted along the palatal contour of the teeth up to the canines (Figure 1). The appliance was fixed by cementing the bands with glass ionomer cement (Meron C, VOCO do Brazil Ltda, Porto Alegre, RS, Brazil) and bonding the contoured segments using the acid conditioning protocol with 37% phosphoric acid (FGM, Joinville, SC, Brazil) for 30 seconds, application of the Transbond XT adhesive primer (3M ESPE, 3M Brasil, Sumaré, SP, Brazil), application of Transbond XT resin (3M ESPE, 3M Brasil, Sumaré, SP, Brazil) and light curing on each tooth for 40 seconds.

After cementing the expander, activation of the appliance began. At the time of installation, $\frac{1}{2}$ turn was activated and those responsible for the patient were instructed to activate $\frac{1}{4}$ turn 2 times a day on subsequent days¹¹. The device was activated until the maxillary expansion was overcorrected, observing the position of the permanent maxillary first molars: the palatal cusps of these should occlude with the buccal cusps of the permanent mandibular first molars. When overcorrection was observed, the device was stabilized with the use of light polymerized composite resin applied to the screw. The size of the expander screw varied between 9 and 11 mm, according to the size of each patient's palate, and amount of transverse gain required.

The low-level laser was applied only by one operator, using the Photon Lase III device (DMC Equipment's LTDA, São Carlos, SP, Brazil), which has two application tips: a red laser (InGaAlP, $\lambda=608$ nm) and an infrared (AsGaAl, $\lambda=808$ nm). The proposed protocol was based on the recommendations of the appliance manufacturer and study of Cepera et al¹⁷. The infrared laser tip (AsGaAl, $\lambda = 808$ nm), with power of 100mW, was used continuously, applying a fluency of 90 J/cm² per point for 25 seconds. The points of application of LLLT on the palate were the same as those described by Cepera et al. (2012), four on the midpalatal suture and six on the side (3 on each side) (Figure 1). Two sessions of LLLT application were performed weekly, for five weeks after beginning the screw opening, totaling 10 laser therapy sessions.

For laser application in the control group (placebo), the red laser tip (inactive) was positioned over the application points, while the infrared laser tip was kept close to the device (active, but with the tip obstructed by black rubber). When the pedal of the appliance was activated, the laser sound was emitted by the infrared tip, but the tip used was inactive.

Oral Health-related Quality of Life Assessment

The OHRQoL was assessed by application of the Brazilian version of the Child Perceptions Questionnaire (CPQ8-10) that enabled the research participants to express their self-perception about the impact of the interceptive treatment performed on their quality of life^{21,22}. CPQ8-10 consists of 25 questions, subdivided into four domains: oral symptoms, functional limitation, emotional well-being, and social well-being. The response options vary on a Likert scale from 0 to 4. The final score is the sum of all items. The total result of the questionnaire can vary from 0 to 100 points. The higher the score obtained, the greater the impact of oral health conditions on the child's OHRQoL. The first question of oral symptoms domain is: "Did you feel tooth pain or pain in the mouth?". This question was also considered for pain evaluation during the study.

The questionnaire was applied in 5 stages: T0 - pre-treatment phase (before expander installation), T1 - on the day of the screw stabilization, T2 - 3 months after the screw stabilization, T3 - immediately after the expander was removed (6 months after stabilization of the screw) and T4 - 3 months after removing the expander (and after 9 months of monitoring subsequent to the date of screw stabilization). The patients answered the questionnaire in the form of a structured interview conducted by the examiners.

Statistical analysis

The data were analyzed using the Stata 14.1 software (StataCorp. 2014. Stata Statistical Software: Release 14.1. College Station, TX: StataCorp LP). Descriptive analysis of the sample was carried out according to the demographic and socioeconomic characteristics of the groups. Comparison between the characteristics of the groups (Experimental and Control) at the beginning of the study (T0) was analyzed using Fisher's exact test (categorical variables) or the t-test (numerical variable). Paired T-test was performed for comparing the CPQ8-10 scores over the experimental time intervals. Unadjusted multilevel Poisson regression analysis for repeated measures was performed to compare the total scores, and according to each domain of CPQ8-10 between the groups of the RCT according to the evaluation time interval. Unadjusted multilevel Poisson regression analysis for mixed-effects was performed to compare CPQ8-10

pain question between RCT groups according to the evaluation time interval. In the structure of the analysis, repeated measures of OHRQoL (level 1) were nested in children (level 2). The data are presented as Incidence Rate Ratio (IRR) and 95% confidence interval (95% CI); $p < 0.05$ was considered significant.

Ethical precepts

Ethical permission was granted by the UFSM Research Ethics Committee under the protocol number (CAAE: 66295617.7.0000.5346). An Informed Consent Form was obtained from all parents or guardians and the children signed the consent form written in language compatible with the age group of the individuals before data collection for the study.

Results

Approximately 63% of the total sample were of the female sex, and 83% of white skin color. The mean age in the sample was 9.1 (SD 1.46) years (Table 1). When comparing the individuals allocated in the Control and Experimental (laser therapy) groups, there was no difference in the majority of characteristics ($p > 0.05$). There was a difference between the sexes regarding the RCT allocation group. However, the bootstrap sensitivity test was performed and showed that this difference did not influence the results.

The amount of activation of the expander screw varied according to the need for transverse gain for each patient. The average activation time was 18 days, with a minimum of 15 and a maximum of 22 days.

Table 2 presents the total scores according to each domain of CPQ8-10 and group to which the participants belonged and the time of assessment. The overall scores for each CPQ8-10 domain decreased gradually in both groups during all follow-up periods.

The association between the predictive variables (group and time of evaluation) with CPQ8-10 overall and subscales scores over time is shown in Table 3. As regards the total CPQ8-10 scores of the total sample (both EG and CG), there was a significant reduction after the RME indicating an improvement in OHRQoL. The overall score decreased by 22% in 3 months after screw stabilization (IRR 0.78; 95% CI 0.68-0.90) and 41% in 6 months (IRR 0.59 95% CI 0.50-0.69). Positive impacts in OHRQoL were also observed in the long term, with a 50% reduction of CPQ8-10 total scores after 9 months of follow-up (IRR 0.50; 95% CI 0.42-0.59).

With regard to the specific domains, functional limitation, emotional well-being, and social well-being showed a significant reduction in scores over time, with a more significant long-term effect (T4) being observed in the functional limitation (IRR 0.34; 95% CI 0.25-0.48),

emotional well-being (IRR 0.55; 95% CI 0.34-0.89), and social well-being (IRR 0.35; 95% CI 0.23-0.54) domains. The intergroup comparison showed no significant differences in the total CPQ8-10 scores between CG and EG (IRR 1.01; 95% CI 0.62 -1, 63). The same was observed relative to specific domains.

Table 4 shows unadjusted multi-level analysis of repeated measures from the CPQ8-10 pain question according to RCT time and group. There was no difference in the pain question between the laser and control groups ($p=0.39$). There was a statistically significant difference between T0 and T1 in the general sample (both groups), increasing pain scores (IRR 2.40; 95% CI 1.18-4.87).

Discussion

The results obtained in this research partially confirmed the conceptual hypotheses. There was a decrease in the CPQ8-10 scores, meaning an improvement in OHRQoL in patients after RME. This indicates that correction of the maxillary atresia, in addition to masticatory²³, respiratory^{9,24}, and esthetic benefits²⁵, also changed children's self-perception of OHRQoL, since oral health influences nutrition, the smile, speech, and socialization³. However, there was no difference between the Control and Experimental Groups, indicating that there was no further improvement in the OHRQoL with the application of laser therapy using the proposed protocol in the studied sample. Although previous studies have evaluated the use of LLLT in the midpalatal suture during RME using different treatment protocols^{17,22}, the assessment of OHRQoL had not yet been explored.

Previous studies have also observed an improvement in OHRQoL after RME. Izuka et al⁶ evaluated mouth breathing children before and immediately after the RME overcorrection and demonstrated that the total OHRQoL scores were significantly lower after the maxillary expansion. Considering a longer period of evaluation, Gonçalves et al¹⁹ assessed the OHRQoL of children with sleep-disordered breathing (SDB) before and 6 months after RME using the Obstructive Sleep Apnea-18 questionnaire (OSA-18). The authors concluded that the total scores reduced significantly (from 90.95 to 46.68), with a decrease in snoring and apnea in all cases. Whereas Katyal et al⁵ assessed the OHRQoL after RME, in an evaluation period lasting between 7 and 9 months. The authors compared the change in OHRQoL after RME in children with low and high risk of developing sleep-disordered breathing and found that children at high risk had an improvement of over 14% in OHRQoL scores when compared with the low risk group.

In the literature, few studies that analyzed transversally the impact of malocclusions in OHRQoL using CPQ8-10 were found. In these studies, patients had lower OHRQoL scores, 9.0 (SD: 6.2) for Piassi et al ²⁶, and 5.1 (SD: 5.1) for Kallunki et al ²⁷, than those in the present study in T0 (15.7 SD: 12.5). This could be attributed to methodological differences, such as study design, sample size, geographic region, malocclusion severity. Worth mentioning is that no research to date has evaluated the OHRQoL longitudinally during and after RME by using the CPQ8-10 questionnaire.

As a general rule, overall mean scores gradually decreased in both groups during the follow-up period. The Experimental Group showed a slight increase in scores from T0 to T1 (with no statistically significant difference) and a decrease from T1 to T4. This slight initial increase in scores could have been related to the fact that the patients had never used an intraoral device on the palate, which led to the expansion and pain caused during the period of expander activation, changes in speech, chewing, and impaired esthetics resulting from opening of the diastema between the maxillary incisors ^{25,28,29}. Increase in the OHRQoL score during the activation period was also reported by Altieri and Cassetta ⁴, who used the OHIP-14 questionnaire (Oral Health Impact Profile) to evaluate the OHRQoL after RME with the use of two different devices, on the 3rd (T1) and 7th (T2) days of activation. In the present study, as the expansion stabilized and the diastema closed (T1 to T4), the scores decreased, demonstrating an improvement in OHRQoL.

Relative to the questionnaire domains: functional limitation, social well-being and emotional well-being showed significant improvements over time. The oral symptoms domain, which is related to pain, bad breath, mouth sores, and oral hygiene, showed no statistically significant changes from the beginning to the end of the pre-treatment phase. A possible explanation for this result may be the ease of cleaning the modified Hyrax appliance, as it does not come into direct contact with the palate, making it more difficult for prolonged food retention and bad breath to occur. Even though there was an increase in pain for both groups, the oral symptoms domain was not affected. In the studies by Gecgelen et al ³⁰ and Feldmann and Bazargani ³¹ patients also reported pain during the expander activation period.

There were changes in both the functional and emotional well-being domains in T2, T3, and T4 when compared to T0, with significant improvements in OHRQoL. The first domain showed the extent to which the treatment influenced the patients' difficulty/ease of eating, chewing hard food, talking, and taking longer than others to finish a meal. The second domain referred to the extent to which the treatment interfered with the patient's feelings, sensations, and self-esteem ^{21,22}. The positive changes in OHRQoL observed 3 months after expander

stabilization (T2), 6 months after expander stabilization (T3) and 3 months after its removal (T4) could be explained as being due to closure of the diastema that occurred approximately four months after expansion²⁵ and had direct influence on the smile esthetics. Moreover, the impact of functional benefits previously known to result from RME, such as: improvement in breathing⁹, chewing and speech³², were possibly more significantly expressed in the children's OHRQoL during this period.

The social well-being domain showed significant improvements in time intervals T3 and T4 in comparison to baseline. In this domain, the children answered questions related to interpersonal relationships, such as whether they stopped talking or playing, suffered any type of bullying, or were asked questions about why they used the appliance^{21,22}. In the last 6 and 9 months of patient's follow-up, the domain of social well-being improved by 65%. The expander removal, realized in T3, must have impacted in this result. This might have turned the patient more confident to interact with other children, without them asking about their orthodontic device. Moreover, the RME procedure promotes changes the dental positions and esthetics of the smile, possibly influencing on patients' self-esteem, making them feel more confident in long term³¹. Furthermore, favorable dental esthetics have positive impacts on these children's social interactions, avoiding episodes of exclusion and dental bullying^{32,33}, which directly impacts well-being social and OHRQoL.

This study is part of an umbrella clinical trial that evaluated the use of LLLT during RME as an aid to the repair of the midpalatal suture. In orthodontics, laser therapy is known to have been used to relieve pain associated with tooth movement during orthodontic treatment, accelerate the bone repair process after RME, potentiate orthodontically induced tooth movement, among other applications¹⁸. The LLLT protocol used in the present study was specific for bone repair¹⁷ which, in turn, had no influence on the OHRQoL scores, or in the domain of oral symptoms, where pain was assessed.

As for the strengths of this research, the period of approximately 10 months of monitoring the patients stands out (active period of the RME, plus 9 months of monitoring). To date, only one study⁵ had evaluated the OHRQoL in a similar period but using the OHIP-14 questionnaire and without specifically evaluating the domains. In the present study, not only the total scores were evaluated, but also the results of the domains in five experimental time intervals, during which improvements were observed in different aspects of the OHRQoL.

A limitation of the present study was the small sample size in both the Experimental and Control Groups, and the consequently low statistical power for intergroup comparison. The original project was registered with REBEC with 20 patients per group. However, with the

occurrence of the COVID-19 pandemic throughout the study³³, patient enrollment was interrupted in March 2020 and from then on only patients who were already being followed up continued to be treated. The sample size requirements were assessed according to the calculation of power for the sample in this study. The calculation considered an alpha error probability of 0.05 and the CPQ8-10 mean scores in the general sample and between groups. Considering the comparison of means between the Experimental and Control Groups, the power lower than 40%. As regards the total sample used to assess the change in OHRQoL over time, the power to detect differences between T0 and T4 was 80%, which is in line with the sample calculation expressed in the methodology of this manuscript. Future studies are suggested to assess the difference between groups with larger sample sizes, different protocols for laser therapy, such as those for modulating pain, and evaluating patients of other ages.

Conclusions

RME had a beneficial effect on the OHRQoL of patients treated. There was a trend towards gradual improvement in the total scores and for each domain of CPQ8-10 during the course of the follow-up periods. However, in the sample evaluated, the use of LLLT did not have a significant effect on further improving the OHRQoL.

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Figure 1. Occlusal picture of the maxillary dental arch showing the modified Hyrax expander and the low-level laser application points.

Table 1. Demographic and socioeconomic characteristics at baseline of the individuals included in the clinical trial (n = 27).

Variables	Total	Control	Laser	p-value
Sex [n (%)]				0.015*
Female	17 (63.0)	12 (85.7)	5 (38.4)	
Male	10 (37.0)	2 (14.3)	8 (61.4)	
Age [n (%)]				0.445*
≤ 9 years	18 (66.6)	10 (71.4)	8 (61.5)	
> 9 years	9 (33.4)	4 (28.5)	5 (38.5)	
Skin color [n (%)]				0.067*
White	20 (83.3)	9 (69.2)	11 (100.0)	
Non-white	4 (16.7)	4 (30.8)	0 (0.0)	
Household income [n (%)]				0.398*
≥ 1 BMW	3 (13.6)	1 (7.7)	2 (20.0)	
< 1 BMW	19 (84.4)	12 (92.3)	8 (80.0)	
CPQ8-10 [mean (SD)]	15.7 (12.5)	14.6 (7.4)	16.8 (16.6)	0.405 [†]

Values less than 27 are due to missing data; BMW, Brazilian minimum wages (approximately U\$200); SD, standard deviation; *Fisher's exact test; [†]T-test.

Table 2. Mean and standard deviation of CPQ8-10 overall and subscales scores according to experimental group and time of assessment.

CPQ₈₋₁₀ scores	Overall [mean (SD)]	Control group [mean (SD)]	Laser group [mean (SD)]
Overall			
T0	15.7 (12.5)	14.6 (7.4)	16.8 (16.6)
T1	14.8 (15.4)	13.0 (8.5)	18.6 (20.2)
T2	12.3 (8.8)	12.2 (5.7)	12.4 (11.5)
T3	9.3 (6.4)*	9.0 (6.0)*	9.6 (7.0)
T4	7.8 (8.1)*	7.2 (7.3)*	8.6 (9.2)
Oral symptoms			
T0	4.0 (2.3)	4.9 (2.2)	3.0 (2.2)
T1	4.7 (3.1)	5.1 (3.8)	4.2 (3.9)
T2	3.8 (2.9)*	4.5 (2.9)*	3.2 (2.9)
T3	4.5 (2.5)*	4.2 (2.5)*	4.6 (2.9)
T4	3.5 (3.1)*	4.2 (3.7)*	2.7 (2.0)*
Functional limitation			
T0	5.4 (4.4)	5.5 (4.4)	5.3 (4.6)
T1	5.6 (4.3)	4.9 (4.3)	6.4 (4.5)
T2	4.2 (3.7)*	4.2 (3.3)	4.2 (4.2)
T3	2.5 (3.1)	2.3 (3.0)	2.7 (3.2)
T4	1.8 (2.4)	1.7 (2.6)	1.8 (2.2)
Emotional well-being			
T0	1.8 (3.2)	1.0 (1.2)	2.7 (4.3)
T1	1.5 (4.3)	0.4 (1.0)	2.5 (6.0)
T2	1.0 (3.0)	0.4 (0.8)	1.6 (4.2)
T3	0.6 (1.8)	0.5 (1.0)	0.6 (1.3)
T4	1.0 (2.1)	0.3 (0.9)	1.6 (2.8)
Social well-being			
T0	3.0 (7.3)	0.6 (1.4)	5.6 (9.9)
T1	2.1 (5.5)	0.7 (1.6)	3.6 (7.5)
T2	2.2 (2.9)	1.7 (1.9)	2.8 (3.7)
T3	1.0 (1.9)	0.8 (2.2)	1.1 (1.7)
T4	1.1 (3.2)	0.1 (0.5)	2.0 (4.4)

CPQ, Child Perception Questionnaire; SD, standard deviation; *p-value <0.05 from paired t-test.

Table 3. Unadjusted association among predictors variables in CPQ 8-10 overall and subscales scores over time, using multilevel Poisson regression analysis for repeated measures.

Variables	CPQ ₈₋₁₀ scores				
	Overall	Oral symptoms	Functional limitation	Emotional well-being	Social well-being
	IRR (95% CI)	IRR (95% CI)	IRR (95% CI)	IRR (95% CI)	IRR (95% CI)
ECR group					
Control	1.00 (reference)	1.00 (reference)	1.00 (reference)	1.00 (reference)	1.00 (reference)
Laser	1.01 (0.62-1.63)	0.80 (0.59-1.07)	0.99 (0.63-1.55)	0.5 (0.15-2.82)	1.59 (0.44-5.72)
Time					
T0	1.00 (reference)	1.00 (reference)	1.00 (reference)	1.00 (reference)	1.00 (reference)
T1	0.97 (0.84-1.12)	1.17 (0.89-1.54)	1.03 (0.81-1.31)	0.82 (0.52-1.29)	0.74 (0.51-1.06)
T2	0.78 (0.68-0.90)*	0.96 (0.73-1.25)	0.78 (0.61-0.99)*	0.56 (0.35-0.88)*	0.73 (0.52-1.02)
T3	0.59 (0.50-0.69)*	1.12 (0.87-1.46)	0.46 (0.35-0.62)*	0.32 (0.18-0.56)*	0.32 (0.21-0.50)*
T4	0.50 (0.42-0.59)*	0.86 (0.65-1.14)	0.34 (0.25-0.48)*	0.55 (0.34-0.89)*	0.35 (0.23-0.54)*

IRR, incidence rate ratio; CI, confidence interval; *p<0.05.

Table 4. Unadjusted association of the ECR group in the oral pain, using multilevel Poisson regression analysis for repeated measures

Variables	Oral pain	
	IRR (95% CI)	p-value
ECR group		
Control	1.00 (reference)	
Laser	0.67 (0.27-1.67)	0.399
Time		
T0	1.00 (reference)	
T1	2.40 (1.18-4.87)	<0.01
T2	0.99 (0.44-2.22)	1.000
T3	1.33 (0.63-2.81)	0.451
T4	0.83 (0.36-1.92)	0.670

IRR, incidence rate ratio; CI, confidence interval.

3. CONCLUSÃO

A ERM promoveu efeito benéfico na QVRSB dos pacientes tratados. Houve melhora gradual dos escores gerais e para cada domínio do CPQ8-10 nos grupos controle e experimental durante todos os períodos de acompanhamento. Porém, com base na amostra utilizada, não foram encontradas diferenças estatisticamente significativas quando comparados os dois grupos, indicando que a utilização do LBP não promoveu melhora adicional na QVRSB.

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APÊNDICE A – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Título do projeto de extensão: “Utilização do laser de baixa potência na expansão rápida da maxila” Pesquisador responsável: Mariana Markezan Departamento/ Instituição: Departamento de Estomatologia, Universidade Federal de Santa Maria. Telefone e endereço: (55) 3220-9301. Rua Mal. Floriano Peixoto, 1184, sala 409, 97015-372 - Santa Maria - RS.

Através desse termo, convidamos você e seu filho(a) a participar do Projeto de Pesquisa “Utilização do laser de baixa potência na expansão rápida da maxila”. As informações importantes para você tomar sua decisão quanto a participação estão aqui descritas.

1. Objetivos: Os objetivos dessa pesquisa são avaliar e comparar algumas medidas do palato (céu da boca) e das vias aéreas antes e após o tratamento; avaliar se aplicações de laser são capazes de melhorar a estabilidade do tratamento com expansão rápida da maxila (ERM, alargamento do céu da boca); e a avaliar a possível modificação da qualidade de vida após o tratamento.

2. Justificativa: É importante estudar formas de melhorar a estabilidade do tratamento de ERM, para que seu resultado seja mais efetivo, e também estudar o quanto esse tratamento pode melhorar a qualidade de vida desses pacientes e a forma das estruturas associadas.

3. Procedimentos: A participação de seu filho(a) consistirá na realização de exames para o diagnóstico, tratamento ortodôntico interceptativo através ERM, exames para a avaliação dos resultados do tratamento, e preenchimento de dois questionários para avaliação da qualidade de vida. Dependendo do sorteio realizado para a divisão dos grupos, seu filho (a) poderá ou não receber aplicação de laser durante 10 sessões.

4. Imagens: As imagens obtidas (fotografias, radiografias, tomografias e modelos) serão arquivados para serem utilizados como material didático (durante aulas), instrumento de pesquisa e material bibliográfico (para publicação em jornais e revistas especializados, livros, cadernos didáticos, páginas odontológicas especializadas na rede mundial de computadores). Será preservado o anonimato dos indivíduos. Fotografias extra-bucais terão tarjas ou alterações junto aos olhos para impedir o reconhecimento.

5. Desconfortos e riscos: O desconforto esperado para realização da pesquisa é mínimo. Todavia, os pacientes poderão sentir dor, ansiedade e/ou medo com os procedimentos. Ressalta-se, porém, que o tratamento de ERM visa restabelecer a largura ideal da arcada superior, não apresenta caráter experimental, e será realizado em caso de necessidade diagnosticada. A aplicação do laser visará acelerar o reparo ósseo na sutura. Os riscos específicos da utilização do laser envolvem problemas oculares (cegueira), APENAS quando não se utiliza óculos de proteção e se irradia laser sobre a retina, e manchamento na pele na região de aplicação APENAS se o paciente estiver tomando alguma medicação que seja fotossensível, como ácido retinóico, tetraciclina, gluseofulvina, sulfaminas e furocumarinas. É contraindicado aplicar laser sobre massas neoplásicas (câncer), uma vez que poderá favorecer o seu desenvolvimento, sobre focos de infecção bacteriana, pois o laser causará sua proliferação e disseminação, e sobre áreas de hemorragia, pois aumentará o fluxo. As doses e os riscos das radiografias intrabucais são mínimos, comparáveis com a exposição à radiação natural de fundo. O protocolo de aquisição tomográfico adotado oferece uma dose de aproximadamente 30mGy, comparável, ou inferior, à dose das radiografias extrabucais combinadas que seriam necessárias para o diagnóstico ortodôntico do paciente. Ademais, durante as radiografias intrabucais serão utilizados coletes protetores, barrando qualquer radiação que possa atingir órgãos sensíveis da linha do queixo até a área pélvica.

6. Benefícios: A realização da pesquisa poderá beneficiar o paciente diretamente, pois está previsto tratamento ortodôntico interceptativo durante a vigência do projeto. Haverá ainda benefício indireto, pois acredita-se que a percepção da modificação na qualidade de vida possa

estimular o paciente a aderir a novos tratamentos de saúde quando forem necessários. Além disso, esse estudo possivelmente colaborará para o estabelecimento de um protocolo de contenção mais efetivo para a ERM em futuros tratamentos.

7. Retirada do consentimento: Seu filho (a) poderá abandonar a pesquisa, sem justificativa ou necessidade de aviso prévio, não havendo comprometimento na continuidade do tratamento.

Eu _____(responsável), RG _____ certifico que, após a leitura desse documento e de outras explicações dadas pelos alunos abaixo nominados, estou de acordo com a participação de meu/minha filho(a), o(a) menor _____, no Projeto de Pesquisa “Utilização do laser de baixa potência na expansão rápida da maxila”.

Santa Maria, ____ de _____ de 201__.

Nome do responsável: _____ Assinatura: _____

Pesquisador responsável: Mariana Marquezan Assinatura: _____

(55)99674 4678 mariana.marquezan@ufsm.br

Comitê de Ética em Pesquisa da UFSM: Av. Roraima, 1000 - 97105-900 - Santa Maria - RS -
2º andar do prédio da Reitoria. Telefone: (55) 3220-9362 - E-mail: cep.ufsm@gmail.com.

APÊNDICE B – TERMO DE ASSENTIMENTO DO MENOR

TERMO DE ASSENTIMENTO DO MENOR

Você está convidado para participar da pesquisa “Utilização do laser de baixa potência na expansão rápida da maxila”. Queremos saber se aplicações de laser no céu da boca são capazes de melhorar o resultado do tratamento para seu alargamento; e se esse tratamento é capaz de melhorar sua qualidade de vida e forma do céu da boca e vias respiratórias. Seus pais permitiram que você participe.

A pesquisa será feita na Universidade Federal de Santa Maria, onde as crianças farão exames, tratamento ortodôntico, e preencherão questionários com perguntas sobre vários aspectos da sua vida. Durante as consultas, o desconforto esperado é mínimo. Os pacientes poderão sentir ansiedade, medo, e até dor com alguns procedimentos. Porém, o tratamento irá melhorar a largura do céu da boca e será realizado quando for realmente necessário. A aplicação do laser tem por objetivo melhorar o resultado final. Deve-se ter cuidado com o laser, usando SEMPRE óculos de proteção escuros porque se sua luz for colocada no olho pode levar à cegueira. Alguns remédios podem causar manchas na pele quando se aplica o laser. Para fazer os exames raio-X, você receberá colete para proteger das radiações. Caso você se sinta cansado, constrangido ou nervoso e não queria continuar participando, poderá desistir. Caso aconteça algo errado, você pode nos procurar pelos telefones (55) 3220-9276/ 99674-4678, que são da pesquisadora Mariana Marquezan.

Existem coisas boas que podem acontecer com a sua participação na pesquisa, como receber gratuitamente o tratamento para alargar o céu da boca; estimular você a fazer novos tratamentos de saúde quando forem necessários; e ajudar os profissionais da Odontologia a entenderem melhor sobre as características do problema e também sobre o tratamento.

Ninguém saberá que você está participando da pesquisa, não falaremos a outras pessoas, nem daremos suas informações para estranhos. Os resultados da pesquisa serão publicados, mas sem identificar as crianças que participaram da pesquisa. Se você tiver alguma dúvida, você pode me perguntar ou à pesquisadora Mariana Marquezan. Seus telefones estão na parte de cima desse texto.

Eu _____ aceito participar da pesquisa “Utilização do laser de baixa potência na expansão rápida da maxila”. Entendi as coisas ruins e as coisas boas que podem acontecer. Entendi que posso dizer “sim” e participar, mas que, a qualquer momento, posso dizer “não” e desistir que ninguém vai ficar furioso. Os pesquisadores tiraram minhas dúvidas e também conversaram com os meus responsáveis.

Santa Maria, ____ de _____ de _____.

Assinatura do menor

Assinatura da pesquisadora

ANEXO 1 – QUESTIONÁRIO SOBRE A QUALIDADE DE VIDA RELACIONADA À SAÚDE BUCAL DE CRIANÇAS NA IDADE 8 A 10 ANOS.

Data: ___/___/___ Nome: _____

Idade: _____ Data de Nascimento: ___/___/___ Tempo Experimental: _____

Você acha que os seus dentes e sua boca são:

() Muito bons () Bons () Mais ou menos () Ruins

Quanto os seus dentes ou a sua boca te incomodam?

() Não incomodam () Quase nada () Um pouco () Muito

PERGUNTAS SOBRE PROBLEMAS BUCAIS

No último 1 mês, quantas vezes...

	Nenhuma vez	1 ou 2 vezes	às vezes	Muitas vezes	todos os dias ou quase todos
1. Você sentiu dor de dentes ou dor na boca?					
2. Você teve feridas na sua boca?					
3. Você sentiu dor nos seus dentes quando comeu alguma coisa ou bebeu alguma coisa gelada?					
4. A comida ficou agarrada em seus dentes?					
5. Você ficou com cheiro ruim na sua boca?					

No último 1 mês, por causa dos seus dentes ou de sua boca, quantas vezes...

	Nenhuma vez	1 ou 2 vezes	Às vezes	Muitas vezes	todos os dias ou quase todos
6. Você gastou mais tempo do que os outros para comer sua comida?					
7. Você teve dificuldade para morder ou mastigar comidas mais duras como: maçãs, pão, milho ou carne?					
8. Foi difícil para você comer o que você queria?					

9. Você teve problemas para falar?					
10. Você teve problemas para dormir à noite?					

PERGUNTAS SOBRE SENTIMENTOS E/OU SENSações

Você já experimentou esse sentimento por causa de seus dentes ou de sua boca? Se você se sentiu desta maneira por outro motivo, responda “nunca”.

No último mês, quantas vezes...

	Nenhuma vez	1 ou 2 vezes	Às vezes	Muitas vezes	todos os dias ou quase todos
11. Você ficou chateado (a)?					
12. Você se sentiu triste?					
13. Você ficou com vergonha?					
14. Você ficou preocupado com o que as pessoas pensam sobre seus dentes ou sua boca?					
15. Você achou que você não era tão bonito quanto outras pessoas por causa dos seus dentes ou de sua boca?					

PERGUNTAS SOBRE SUAS ATIVIDADES EM SEU TEMPO LIVRE E NA COMPANHIA DE OUTRAS PESSOAS

Você já teve estas experiências por causa dos seus dentes ou de sua boca? Se for por outro motivo, responda “nunca”.

No último 1 mês, quantas vezes você:

	Nenhuma vez	1 ou 2 vezes	Às vezes	Muitas vezes	todos os dias ou quase todos
16. Faltou à aula?					
17. Teve problemas para fazer seu dever de casa?					
18. Teve dificuldade para prestar atenção na aula?					
19. Não quis falar ou ler em voz alta na sala de aula?					

20. Deixou de sorrir ou dar risada quando estava junto de outras crianças?					
--	--	--	--	--	--

Isso aconteceu por causa de seus dentes, lábios, maxilares e boca?

No último mês, quantas vezes:

	Nenhuma vez	1 ou 2 vezes	Às vezes	Muitas vezes	todos os dias ou quase todos
21. Você não quis falar com outras crianças?					
22. Não quis ficar perto de outras crianças					
23. Você ficou de fora de jogos e brincadeiras?					
24. Outras crianças fizeram gozação ou colocaram apelidos em você?					
25. Outras crianças fizeram perguntas para você sobre seus dentes ou sua boca?					

ANEXO 2 – QUESTIONÁRIO SÓCIO-ECONÔMICO (PAIS RESPONDEM no início 1 vez)

Data: ____/____/____ Nome: _____

Idade: _____ Data de Nascimento: ____/____/____ Sexo: F () M ()

1. **Você considera seu filho(a) da raça:** ()branca ()negra ()mulato ()outro(oriental, índio)

2) **No mês passado, quanto receberam em Reais, juntas, todas as pessoas que moram na sua casa? (incluindo valores de salários, bolsa família, pensão, aposentadoria e outros rendimentos)** _____

3) **Quantos cômodos tem a casa (exceto banheiro)?** _____

4) **Quantas pessoas, incluindo o Sr(a), moram na casa?** _____

5) **O pai trabalha?** ()sim ()não

6) **A mãe trabalha?** ()sim ()não

7) **A mãe estudou até:** () não estudou; ()1º grau incompleto; ()1º grau completo; ()2º grau incompleto; ()2º grau completo; ()3º grau incompleto; ()3º grau completo

8) **O pai estudou até:** () não estudou; ()1º grau incompleto; ()1º grau completo; ()2º grau incompleto; ()2º grau completo; ()3º grau incompleto; ()3º grau completo

9) **Quantas vezes ao dia seu filho(a) escova os dentes:**

() não escova () menos de uma vez ao dia (escova somente alguns dias)
() 1 vez por dia () 2 vezes por dia () Três vezes ou mais que três vezes por dia.

10) **Seu filho(a) procurou o dentista nos últimos 6 meses?** ()sim () não

11) **Quando foi a última visita ao dentista?** () até 3 meses () 3 a 6 meses
() 6 meses a 1 ano () mais que 1 ano () nunca visitou;

12) **Motivo da última consulta:**

() dor de dente () dor na boca () batidas e quedas () exame e rotina
() outros: _____

13) **Tipo de serviço que você levou seu filho(a) na última consulta:**

() dentista particular () dentista público (posto de saúde, faculdade, escola)

ANEXO 3 - GUIA PARA AUTORES AMERICAN JOURNAL OF ORTHODONTICS AND DENTOFACIAL ORTHOPEDICS.

AMERICAN JOURNAL OF ORTHODONTICS AND DENTOFACIAL ORTHOPEDICS

Official Journal of the American Association of Orthodontists, its constituent societies, the American Board of Orthodontics, and the College of Diplomates of the American Board of Orthodontics

Article structure

Introduction

Provide an adequate background so readers can understand the nature of the problem and its significance. State the objectives of the work. Cite literature selectively, avoiding a detailed literature survey or a summary of the results.

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Provide sufficient detail to allow the work to be reproduced. If methods have already been published, indicate by a reference citation and describe only the relevant modifications. Include manufacturer information (company name and location) for any commercial product mentioned. Report your power analysis and ethics approval, as appropriate.

Results

Results should be clear and concise.

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Explain your findings and explore their significance. Compare and contrast your results with other relevant studies. Mention the limitations of your study, and discuss the implications of the findings for future research and for clinical practice. Do not repeat information given in other parts of the manuscript.

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Write a short Conclusions section that can stand alone. If possible, refer back to the goals or objectives of the research.

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individuals who provided help during the research (eg, providing help with language or writing assistance, or proofreading the article).

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List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

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2. Strunk Jr W, White EB. *The elements of style*. 4th ed. New York: Longman; 2000.

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