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ORIGINAL ARTICLE

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Efficacy of fluoride varnish, low-level laser therapy, and the association of therapies in dentin hypersensitivity: a randomized split-mouth clinical trial

Eficácia do verniz de fluoreto, terapia com laser de baixa intensidade e terapia associada na hipersensibilidade dentinária: um ensaio clínico randomizado de boca dividida

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ABSTRACT

Objective: The present study aimed to compare the efficacy of 5% sodium fluoride varnish, LLLT, and the association of fluoride varnish with LLLT in dentin hypersensitivity (DH). **Material and Methods:** Fifteen patients meet the inclusion criteria. Sixty selected teeth were distributed among the groups through a randomized allocation sequence and received a single application of therapies in the split-mouth scheme: 5% fluoride varnish (F Gr), 780 nm GaAlAs laser (LLLT Gr) - dose of 52.5 J / cm^2 (70 mW and 30 seconds) or 2.1 J per point, for 6 seconds in 5 points of application per tooth, the association of both (F + LLLT Gr) and control group (C Gr). The visual analog scale (VAS: 0-10) was used to record dentin hypersensitivity. The results were evaluated at baseline, 24 hours, 30-, 90-, and 180-days periods. The data were analyzed with Friedman and Kruskal-Wallis tests (α=0.05). **Results:** The therapeutic modalities, fluor varnish, low-level laser therapy, and association of both demonstrated significant reduction of DH from baseline to 30-, 90-, and 180-days. **Conclusion:** The therapeutic modality that was most effective in reducing DH and sustaining the reduction was the association of 5% fluoride varnish with LLLT.

KEYWORDS

Controlled clinical trial; Dentin sensitivity; Evaluation of efficacy of interventions; Low power laser therapy; Sodium fluoride.

RESUMO

Objetivo: O presente estudo teve como objetivo comparar a eficácia do verniz de fluoreto de sódio a 5%, da LLLT isolada e da associação do verniz de fluoreto com a LLLT no tratamento da DH. **Material e Métodos:** Quinze pacientes preencheram os critérios de inclusão. Sessenta dentes selecionados foram distribuídos entre os grupos através de uma sequência de alocação aleatória e receberam uma única aplicação das terapias no desenho de boca dividida: verniz fluoretado a 5% (Gr F), laser GaAlAs 780 nm (Gr LLLT) - dose de 52,5 J / cm^2 (70 mW e 30 segundos) ou 2,1 J por ponto, durante 6 segundos em 5 pontos de aplicação por elemento, a associação de

ambos (Gr F + LLLT) e grupo controle (Gr C). A escala visual analógica (EVA: 0-10) foi utilizada para registar a hipersensibilidade dentinária. Os resultados foram avaliados no período basal, 24 horas, 30, 90 e 180 dias após a terapia instituída. Os dados foram analisados pelos testes de Friedman e de Kruskal-Wallis (α=0,05). **Resultados:** As modalidades terapêuticas, verniz fluoretado, laserterapia de baixa intensidade e a associação de ambas, demonstraram redução significativa da DH do período basal para os períodos de 30, 90 e 180 dias. **Conclusão:** A modalidade terapêutica que foi capaz de reduzir a DH mais rapidamente e manter a estabilidade dessa redução foi a associação do verniz fluoretado a 5% associado ao LLLT.

PALAVRAS-CHAVE

Ensaio clínico controlado; Sensibilidade da dentina; Avaliação de eficácia de intervenções; Terapia com luz de baixa intensidade; Fluoreto de sódio.

INTRODUCTION

Dentin hypersensitivity (DH) is characterized by an acute and momentary painful sensation, its etiology is multifactorial, and several theories seek to explain the mechanism of pain, which can be triggered by chemical, thermal, evaporative, tactile, or osmotic stimuli when applied to exposed dentin [1-5].

Currently, the most accepted, the hydrodynamic theory of Braennstroem [6], states that the protoplasmic fluids move quickly inside the dentinal tubules when they suffer external stimuli the movement followed by capillarity, deforms the nerve endings of myelinated type A fibers that are found in the pulp, invade the initial portion of the dentinal tubule, generating a nervous impulse of rapid and intense response. Therefore, the ability to block the dentinal tubules, reduce fluid movement in the dentinal tubules, and/or block the pulpal nerve are considered among the needs of optimal treatment of dentinal hypersensitivity [7].

To reduce painful symptoms, investments were made in means to treat this injury, such as changes in diet, avoiding the consumption of acidic foods, re-education of oral hygiene with the removal of aggressive brushing, use of desensitizing chemicals, and treatment with low-level laser therapy [1,8-12].

Fluorides are the leading chemical materials used for the treatment of HD the difference is in the fluorine salt and in the presentation in different forms and concentrations, in which varnishes, due to their higher concentration, are elected as the most used material for the treatment. This product causes the formation of calcium fluoride in the opening of the dentinal tubules. This product causes the formation of calcium fluoride in the opening of the dentinal tubules, sealing of its opening exposed to the oral cavity [8,13,14]. The literature points to good long-term results in reducing painful symptoms with chemical desensitizers, such as fluoride, in the sealing of dentinal canaliculi. Although some products have a high solubility in oral fluids as a disadvantage, it is possible to reverse it by continuous use [8,13].

Another therapeutic possibility for the treatment of DH can be low-level laser therapy (LLLT). Lasers are an innovative treatment technology, low-intensity lasers, also called therapeutic lasers, have anti-inflammatory effects and analgesic action. Its low wavelengths keep the pulp temperature constant, stimulate blood circulation and cell activity, and increase the excitability threshold, resulting in immediate analgesia by maintaining the resting potential of the pulp's nociceptive receptor membrane; and a late analgesia, stimulating the increase in the metabolic activity of odontoblasts that produce tertiary dentin and promote the sealing of canaliculi [2,15-19]. Studies have shown satisfactory results in HD reduction when applying different types of LLLT, alone or in association with desensitizing agents [4,5,16-19].

Even with several dental treatments, the literature is still scarce on the use of associated techniques of dentinal desensitization, there is no defined protocol for the treatment of DH, and there is little information on the use of LLLT for this type of treatment. Thus, this study aimed to compare the efficacy of 5% sodium fluoride varnish, LLLT alone, and the association of fluoride varnish with LLLT in the treatment of DH.

MATERIAL AND METHODS

Ethical aspects

The methodology of the present study followed the norms and regulations of the CONSORT STATEMENT 2010 [20] for randomized clinical studies. The Committee for Ethics in Research on Human Beings (CEPh) of ICT-UNESP (2.127.016) approved this study is registered in The Brazilian Registry of Clinical Trials (ReBEC) under the number RBR-8yq5b8h.

Study design

This study was a randomized, triple-blind, split-mouth, controlled clinical trial.

Study population

The population was composed of ICT-UNESP ambulatory patients. Patients who fit the inclusion criteria were invited to participate in the study. Each patient received a Free and Informed Consent Form after an ample explanation of the nature, risks, and benefits of the clinical investigation. The inclusion criteria were: men or women between 20 and 65 years of age presenting good general and oral health; with a healthy periodontium, without periodontitis or gingivitis; teeth without caries, cracks, fractures, or extensive restorations; teeth without premature contact; patients who had understood the study design; patients who had at least four sensitive teeth, presenting a sensitive tooth in each oral quadrant; and who had signed and agreed to the Free and Informed Consent Form.

The exclusion criteria were: pregnant or breastfeeding patients; participants in other clinical trials; individuals treated for hypersensitivity or using desensitizing products within three months prior to the study; those with a history of maxillofacial cancer in the past five years; patients requiring systemic infection treatment; chronic users of anti-inflammatory, analgesic, or psychotropic drugs; individuals allergic or reactive to research product components; those with parafunctional habits, eating disorders, gastric or emotional conditions linked to dentin sensitivity; patients with severe medical or psychological conditions; those with alcohol or drug intoxication; patients with bleeding disorders or systemic conditions predisposing to dentin sensitivity; individuals with high consumption of acidic foods; those who underwent periodontal surgery or orthodontic treatment in the past three months; patients with dental or periodontal pathologies, defects causing pain (e.g., caries, brackets, extensive restorations), abutment teeth, crowns, restorations in the test area, or irreversible pulp inflammation.

Sample size calculation

The optimal sample size was calculated and estimated for a test power of 80% (alpha, type I error = 5%) and an effect size of 35%. The sample size obtained was fifteen (15) individuals in each of four (4) therapeutic modalities. The program used was G*Power (version 3.1.9.2). The calculation was performed according to Prajapati et al. [21].

Selection of the elements for therapeutic modalities.

Relative isolation was conducted for the saliva to not interfere with the results. A brief burst of air from a triple syringe, 3 mm away from the sensitive tooth, was applied to the selected tooth for one second, and a protective wax covered the adjacent teeth. The pain response was analyzed with the visual analog scale (VAS 0-10). The subjects were instructed to use the VAS scale from 0 to 10, scoring themselves the perceived pain after tooth stimulation. The most sensitive tooth of each quadrant was selected as the study tooth.

After the initial therapy and the selection of the most sensitive tooth of each quadrant, the selected tooth of each quadrant received one of the following therapeutic modalities: Control Group (n=15): (C Gr); 5% Sodium fluoride Group (n=15): (F Gr); Irradiated with Low-level Laser Therapy Group (n=15): (LLLT Gr); 5% Sodium fluoride associated with Low-level Laser Therapy Group (n=15): (F+LLLT Gr).

Randomization and allocation concealment

The randomization occurred as described: first, each dental element selected received a code. A sequence randomly generated by a computer designates the therapeutic modalities: Control Group (C Gr), 5% Sodium fluoride (F Gr), Irradiated with Low-level Laser Therapy Group (LLLT Gr), and 5% Sodium fluoride associated to Low-level Laser Therapy Group (F+LLLT Gr), to the selected tooth. This sequence was then put in opaque sealed envelopes. In each envelope,

there were the dental elements of the individual as well as the respective therapeutic modalities. This step was performed so that the individual responsible for recruiting the patients was blind to the random sequence of type of treatment each dental element received, the treatment, and the collection of the VAS scale data. Besides the allocation concealment, no patient was allowed to know which elements were selected for 'control' and 'test.' The blinding and randomization parameters were performed according to the norms of the CONSORT statement 2010 [20].

Treatment protocol

An examinator performed a clinical examination, which initially registered the primary hypersensitivity using a visual analog scale (VAS: 0-10) to quantify the subjective pain felt by the patient after the stimuli with the ice spray (Endo Ice® - Maquira) on the tooth, at baseline.

Each patient received all four therapeutic modalities according to randomization and described in the envelope. The researcher who performed treatments was informed of randomized therapeutic modalities at the time of treatment. Another researcher, blinded to the therapeutic modalities registered hypersensitivity using the VAS to quantify the subjective pain felt by the patient after the stimuli with the ice spray at baseline, and in intervals of 24 hours, 30 days, 90 days, and 180 days. The masking of the patients was performed with a sleeping mask under the laser goggles, thus making it possible to simulate the application of another treatment. In the Control Group (C Gr), distilled water was applied with a micro brush to simulate a treatment. The interventions and recording of the VAS scale were always done by researchers who did not participate in the evaluations.

The treatments were always conducted in relative isolation and prior to prophylaxis, only once, after the registration of the grades on *baseline.* For the 5% Sodium fluoride Group (F Gr), Colgate Duraphat® fluoride varnish was used, and the chosen tooth was applied with a micro brush type brush (KG Brush®).

The device used for the application of LLLT was the GaAlAs (Gallium Aluminum Arsenide) diode laser with a wavelength of 780 nanometers (Twin Flex II Multifunctional System - MM Optics® LTDA, São Carlos, Brazil), which was used according to the manufacturer's instructions.

For each tooth, five points received LLLT, four points in the cervical region, and one point corresponding to the root apex if the element was single rooted if the tooth was multi-rooted, the application points were also five, three in the cervical region, and two in the root apex region. The dose was 52.5 J / cm2 (70 mW and 30 seconds) or 2.1 J per point, 6 seconds per point. The device was only turned on during application.

The 5% Sodium fluoride associated with the Low-level Laser Therapy Group received the application of LLLT as previously described, followed by an application of 5% Sodium fluoride aided by a micro brush (Brush KG Brush®).

Statistical analysis

The data obtained from the 'VAS' scale was analyzed using the Friedman and the Kruskal-Wallis' tests, both adopting a significance level of 5% using the SigmaPlot® 12.0 software (SYSTAT SOFTWARE, 2011). The variable was patient-dependent, and the assessment was paired.

RESULTS

Fifteen participants fulfilled the inclusion criteria in this study. Sixty teeth were randomized and allocated to the respective groups. One participant did not attend the 90-day and 180-day follow-ups, and another participant did not attend the 180-day follow-up. Thus, an intention-to-treat analysis was performed. A consort flowchart of the study can be observed in Figure 1.

The fifteen patients included (13 women, and 2 men) aged 21 to 65 years (mean 45.27± 14.81). According to gender and age, the Chi-Square Pearson test did not reveal a significant difference between these parameters ($p = 0.471$). To evaluate the effects of the treatments on the experimental groups Kruskal-Wallis' test was used for the inter-group comparison (Table I, Figure 2), and Friedman's test was used for the intra-group comparisons in the periods evaluated (Table II).

While comparing intergroups it was possible to observe that there were no differences among the groups during the evaluation period ($p > 0.05$).

In the intra-group comparison of the values obtained in the VAS scale, it was observed that only in the C group there were no differences among the experimental periods.

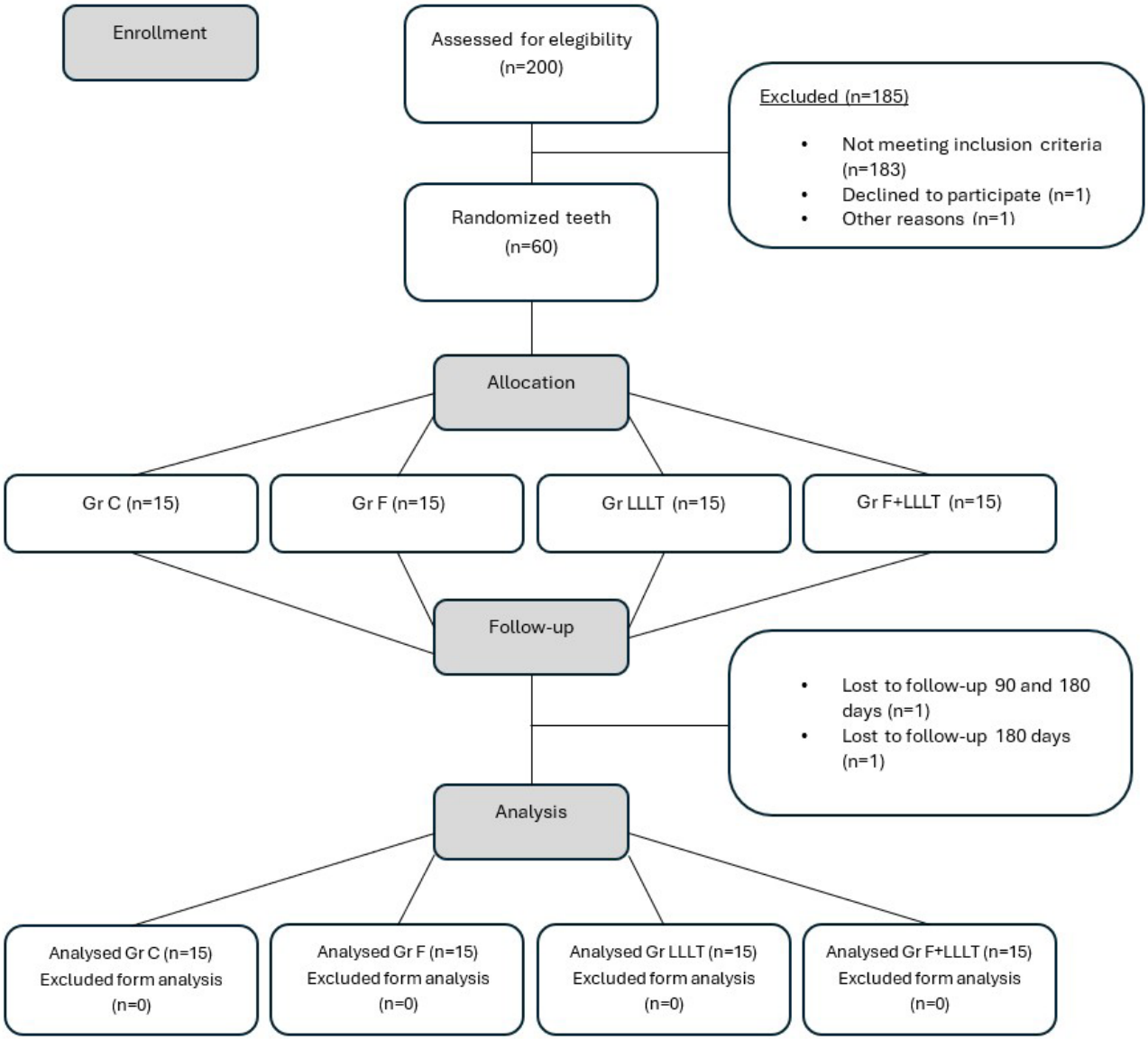

Figure 1 - Consort Flow Diagram.

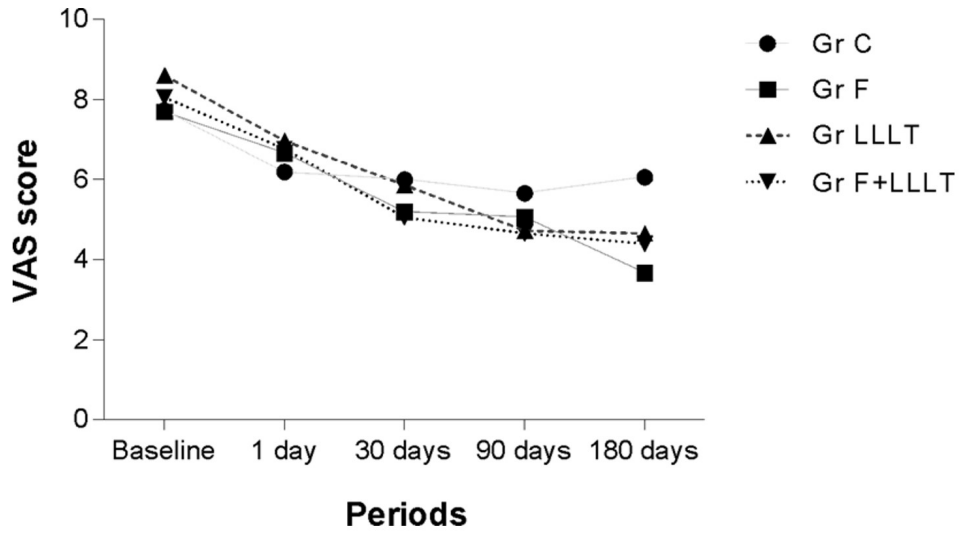

Figure 2 - Visual Analogic Scale (VAS) Scores. Legend: Median VAS scores for different treatment time points.

Table I - VAS Scale. Median values of experimental groups - intergroup evaluation

Group	Median	25%	75%	p value
C Gr Baseline	9	5	10	0.735
FGr Baseline	8	6	10	
LLLT Gr Baseline	9	7	10	
F+LLLT Gr Baseline	8	7	10	
C Gr 1 day	8	5	8	0.979
F Gr 1 day	8	5	8	
LLLT 1 day	8	5	9	
F+LLLT 1 day	8	4	9	
C 30 days	8	3	8	0.671
F 30 days	6	2	7	
LLLT 30 days	6	5	8	
F+LLLT 30 days	5	3	7	
C 90 days	6	4	8	0.732
F 90 days	5	2	8	
LLLT 90 days	5	2	8	
F+LLLT 90 days	4	2	7	
C 180 days	7	4	8	0.173
F 180 days	3	0	6	
LLLT 180 days	5	3	6	
F+LLLT 180 days	4	1	6	

Legend: Intergroup evaluation of the effects of treatments in experimental periods. Kruskal-Wallis, p <0.05.

Table II - VAS scale. Median values of experimental groups - intragroup evaluation

Group	Differences	Median	25%	75%	p-value
C Gr Baseline		9	5	10	
C Gr 1 day		8	5	8	
C Gr 30 days		8	3	8	0.267
C Gr 90 days		6	4	8	
C Gr 180 days		7	4	8	
F Gr Baseline	A	8	6	10	
F Gr 1 day	AB	8	5	8	
F Gr 30 days	AB	6	2	7	0.002
F Gr 90 days	AB	5	2	8	
F Gr 180 days	B	3	0	6	
LLLT Gr Baseline	A	9	7	10	
LLLT Gr 1 day	AB	8	5	9	
LLLT Gr 30 days	AB	6	5	8	<0.001
LLLT Gr 90 days	B	5	2	8	
LLLT Gr 180 days	B	5	3	6	
F+LLLT Gr Baseline	A	8	7	10	
F+LLLT Gr 1 day	AB	8	4	9	
F+LLLT Gr 30 days	B	5	3	7	<0.001
F+LLLT Gr 90 days	B	4	2	7	
F+LLLT Gr 180 days	B	4	1	6	

Legend: Uppercase letters in the vertical indicate significant statistical differences. Intragroup differences, Friedman's test, p<0.05.

The differences were observed in the other experimental groups. In the F Group, there was a difference while comparing the baseline and 180 days. In the LLLT Group, there was a difference of baseline when compared to the period of 90- and 180-days. In the F+LLLT Group, there was a difference while comparing the baseline and the periods of 30-, 90-, and 180-days.

DISCUSSION

This work aimed to compare the efficacy of fluoride varnish to treatment with low-level laser therapy, and the association of both.

During the intra-group analysis, the three treatment modalities, F Gr, LLLT Gr, and F+LLLT Gr, presented a significant reduction of DH at the end of the study follow-up period (180 days), despite that, the treatment modality that first demonstrated a reduction of the DH score was the association of F+LLLT Gr in 30 days, which agrees with Gojkov-Vukelic et al. [16], this reduction remained significant over the period of 90 days and 180 days, followed by the LLLT Gr that showed significant DH reduction in 90 days and 180 days, the F Gr presented significant DH reduction in 180 days, meaning, in the last of the study follow- up period, corroborating with Jain et al. [17].

Given this information, one could presume that in a clinical situation, when one expects short and medium-term results regarding DH reduction and stability, the most appropriate treatment modality is the association of F+LLLT Gr.

In the intergroup analysis, there were no significant differences regarding the effects of treatments according to experimental periods.

According to Figure 2, the F Gr showed a more significant DH reduction in 180 days, despite that, during the intergroup analysis (Table II), the three treatment modalities, F Gr, LLLT Gr, and F+LLLT Gr present a reduction in the VAS scale score in 180 days about the baseline. Taking these aspects into consideration, one can also suppose in a clinical situation that the impossibility of using LLLT isolated or associated with fluoride varnish, the option for treatment with 5% fluoride varnish could lead to a reduction of DH in 180 days.

The possibility of associating treatments with reducing painful sensations made many researchers look for new treatment techniques. Orhan et al. [15] conducted a clinical study comparing the effectiveness of a dentin desensitizer with low-level laser therapy and showed that both treatments act effectively on the sensitivity of the teeth. Yilmaz et al. [14] conducted a similar study, comparing sodium fluoride varnish to low-level laser therapy, and obtained statistically significant differences after three (3) months of follow-up. Suri et al. [18] found that the combined use of laser and sodium fluoride was more effective in reducing hypersensitivity compared to sodium fluoride or laser alone. This is because sodium fluoride has more time to interact with the tooth surface before the laser treatment, and the laser can effectively seal the dentinal tubules.

According to the literature, the 24-hour period is a short period for the beginning of therapeutic action, where the light emitted by the device reaches the deeper tissues and stimulates the production of restorative dentin, sealing it from the dentinal canaliculi. Under this aspect, the present study had a follow-up period of 180 days, which could be considered a plausible medium-term follow-up, which can translate the stability and lasting effects of the therapeutic modalities. Comparably, Jain et al. [17] and Naghsh et al. [19] monitored the efficiency of the therapeutic modalities for periods of 60 and 180 days respectively, whereas, in the studies of Alencar et al. [22], Gojkov-Vukelic et al. [16], Moeintaghavi et al. [23], and Pantuzzo et al. [24] the follow-up periods ranged between initial periods (hours), a week, and up until 30 days.

The action of the fluoride is established by the action of the sodium fluoride varnish, which takes more than 24 hours to start its mechanism of action, where it deposits calcium fluoride in the opening of the dentinal tubules to seal the stimulus entrance, but provides temporary protection in low concentrations, according to Cardoso et al. [25]. This explanation is corroborated by the studies of Pandit et al. [13] that obtained satisfactory results with 6% fluoride varnish.

Among the strengths of the present study, the rigor of the methodological criteria can be highlighted by the split-mouth design employed and the triple-blind (evaluator, operator, and patient) in the case. The divided drawing of the mouth used in the present study allowed the elimination of possible inherent variables of the participants, that is, the possible variables among the individuals. However, among the limitations of this study, the inclusion criteria hindered the increase of the sample size and made it impossible to evaluate patient-centric aspects, such as the evaluation of the quality of life.

Considering future perspectives, more clinical trials can be designed with methodological rigor to establish appropriate protocols for DH treatment.

CONCLUSION

The therapeutic modalities, fluoride varnish, low-level laser therapy, and association of both demonstrated significant reduction of DH from baseline to 30-, 90-, and 180-day periods. The therapeutic modality that was able to reduce DH more quickly and maintain the stability of this reduction was the association of 5% fluoride varnish with LLLT.

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Author's Contributions

ACBNS: Conceptualization, Data Curation, Investigation, Writing – Original Draft Preparation. AKP: Conceptualization, Data curation, Investigation. CMMN: Formal Analysis, Writing – Original Draft Preparation, Writing–Review & Editing. TRM: Data Curation, Investigation. LCT: Formal Analysis, Writing – Original Draft Preparation. TMFC: Methodology. IB: Formal Analysis, Methodology. DRL: Methodology. ACM: Conceptualization, Investigation, Methodology, Project Administration, Resources, Supervision, Writing – Original Draft Preparation, Writing–Review & Editing.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and policies. This study protocol was reviewed and approved by The Committee for Ethics in Research on Human Beings (CEPh) of ICT-UNESP approved this study approval number (nº 2.127.016) and The Brazilian Registry of Clinical Trials (ReBEC) under number RBR-8yq5b8h.

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