Cyanoacrylate Versus Laser in the Treatment of Dentin Hypersensitivity: A Controlled, Randomized, Double-Masked and Non-Inferiority Clinical Trial

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Background: Dentin hypersensitivity (DH) is a painful, exaggerated response to normal stimuli, such as cold, sweetness, and brushing. The aim of the present controlled, randomized, double-masked, non-inferiority clinical trial is to evaluate the effectiveness of cyanoacrylate in the treatment of DH when compared to the application of low-intensity laser.

Methods: The study includes 434 sensitive teeth from 62 patients. A total of 216 teeth were treated with laser and 218 with cyanoacrylate. A numeric rating scale was used to record the parameters of pain related to the stimuli at baseline and after the treatment at intervals of 24 hours and 30, 90, and 180 days.

Results: Both groups had significant reductions in DH. However, there was no significant difference between the two groups ≤6 months. Intragroup analysis showed that the effect of cyanoacrylate obtained at 24 hours remained for 90 days in response to air-jet test and 30 days for cold-spray test. There was a statistically significant difference between all other intragroup comparisons at the time intervals ($P<0.001$).

Conclusions: It was concluded that cyanoacrylate is as effective as low-intensity laser in reducing DH. In addition, it is a more accessible and low-cost procedure and can be safely used in the treatment of DH. *J Periodontol 2013;84:287-294.*

KEY WORDS

Cyanoacrylates; dentin hypersensitivity; dentin sensitivity; laser therapy, low-level; randomized controlled trial.

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Dentin hypersensitivity (DH) is characterized by short, sharp pain arising from exposed dentin in response to stimuli, typically thermal, evaporative, tactile, osmotic, or chemical, which cannot be ascribed to any other form of dental defect or pathology,[1] and ceases after removal of the stimuli.[2] Up to now, the most widely accepted theory to explain DH is the hydrodynamic theory proposed previously.[3-5] For the DH to occur, dentin must be exposed to the oral environment, which occurs as a result of removal of the enamel layer and/or dental cementum by attrition, abrasion, erosion, or gingival recession. Moreover, in ≈10% of individuals, as a result of a developmental anomaly, the enamel and the cementum do not meet, leaving an area of exposed dentin.[6-8]

Low-level lasers have been used to reduce DH[9] by increasing the cellular metabolic activity of odontoblasts and obliterating dentinal tubules, leading to intensification in tertiary dentin production.[10] Because laser devices are still relatively costly, there is limited access to them.[11] Cyanoacrylate has an immediate desensitizing effect on hypersensitive dentin, has been shown to be biocompatible, and may be used to treat hypersensitive teeth. It blocks the dentinal tubules, prevents displacement of

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fluids within the tubules, and results in little or no response to stimuli.[12] A commercial presentation of cyanoacrylate in the form of glue[‡] has proven to be biocompatible.[13] It has the advantages of being a low-cost product, readily available, easily applicable, effective, and safe.[14] Although some authors have reported the use of cyanoacrylate in DH treatment,[12,15] to the best of our knowledge, there are no recent reports in the literature on the use of this type of product for this application.[16]

The aim of the present study is to evaluate the effectiveness of cyanoacrylate glue in the treatment of DH compared to the application of low-intensity laser by means of a controlled, randomized, double-masked, non-inferiority clinical trial. The secondary objectives are to determine: 1) whether significant changes occurred in the participants' quality of life after the treatment of DH; 2) report the main etiologic factors of DH; 3) which teeth in the selected sample showed more prevalence of DH; and 4) whether any adverse effects of treatment were observed.

MATERIALS AND METHODS

The study was conducted from May 2008 through May 2009 at the periodontology clinic of the Department of Dentistry of the Federal University of Jequitinhonha and Mucuri Valleys (UFVJM), Diamantina, Minas Gerais, Brazil. The study protocol was approved by both the Research Ethics Committee of the UFVJM (no. 061/06) and Research Ethics Committee of the Federal University of São Paulo (no. 0530/08). The study was also conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000.

The sample consisted of patients of both sexes with DH who met the research requirements. Participants were informed about the research and signed the statement of free and informed consent. Participants had good general and oral health, complained of pain in teeth located in different hemiarches of the mouth, manifested pain or discomfort in response to stimulus caused by the jet of air from a triple syringe, and initially responded to this stimulus with a score ≥5 in the numeric rating scale. The criteria for exclusion from the study included the following: 1) patients who had undergone previous professional desensitizing treatment or had used over-the-counter desensitizing products; 2) those with chronic use of anti-inflammatory, analgesic, or psychotropic drugs; 3) pregnant and breastfeeding females; 4) patients presenting allergies and idiosyncratic responses to product ingredients; 5) eating disorders; 6) systemic conditions that are etiologic factors or predisposing for DH, excessive dietary or environmental exposure to acids; and 7) patients who underwent periodontal surgery or orthodontic treatment in the preceding 3 months. In addition, the following teeth were excluded: 1) teeth or periodontium with pathology or defects likely to cause pain; 2) those that were restored in the preceding 3 months; 3) those that served as abutment for fixed or removable prostheses; 4) those that were crowned or had extensive restorations; and 5) those with restorations extending into the test area (cervical). Participants were instructed not to use desensitizing products during the study period.

In a study of good methodologic quality,[9] a 67% reduction in the mean value of thermal sensitivity (air jet) was found when a low-intensity laser was compared to a placebo. Based on both statistical reasoning and clinical judgment, as recommended by Le Henanff et al.,[17] 15% was considered an adequate non-inferiority margin (Δ),[18] and thus, to calculate the sample size, the following data were entered into a program of epidemiology and statistics[§] for the comparison of two proportions: 1) proportion in the first group = 67% (laser); 2) proportion in the second group = 52% (cyanoacrylate) (67 – 15 = 52); 3) level of significance = 5%; 4) power of the test = 90%; 5) tailed test. Result: sample size of 181 teeth + 20% (safety margin because of losses) = 218 teeth in each group.

A paired (split-mouth) study design was used, and selection of quadrant was randomized. The teeth of the different quadrants received different desensitizers, and adjacent teeth received the same treatment. The laser device used was a gallium–aluminum–arsenide (GaAlAs) infrared diode laser.[‖] Laser application was performed in accordance with the manufacturer's standard advice in three sessions, at intervals of 48 hours. The irradiation parameters were: nominal wavelength of 795 nm, infrared, nominal power of 120mW, spot size of 0.031cm2. The deposited energy density was 2.88 J/cm² applied for 8 seconds at three points around the neck of the tooth. The teeth assigned to the cyanoacrylate group were treated with three applications of cyanoacrylate glue using a microdisposable applicator, at intervals of 48 hours, following the laser protocol.

An independent researcher (PG), who was masked to the patients and interventions, conducted randomization using opaque envelopes that had been prepared previously and sealed. Each patient received both of the allocated interventions, which were removed from the envelope at the time of the treatment. The researchers who applied the treatments were only informed of the treatment to be performed when it was time to do so. Masking was done by replacing the laser

‡ Loctite Super Bonder, Henkel, Itapeví, São Paulo, Brazil.
§ LEE, Epidemiology and Statistics Laboratory, São Paulo, SP, Brazil.
‖ Easy Laser, Clean Line, Taubaté, São Paulo, Brazil.

goggles with sleeping masks for each patient and simulating the application of the other treatment. Interventions were always performed by the same researcher who did not participate in treatment evaluations.

The teeth were tested before and after interventions by means of thermal testing with an air jet from the triple syringe and tetrafluoromethane spray. The air jet was applied to each tooth involved at a distance of 3 to 4 mm from its surface for 4 seconds. The sensitive tooth was isolated from the adjacent teeth with utility wax. The cold spray was applied to each sensitive tooth with a cotton swab for 4 seconds. The stimuli were immediately removed when the patient did not tolerate the pain. The pain scores were recorded using a numeric rating scale. Data from the initial evaluation were considered baseline. Assessments at all subsequent time intervals (24 hours and 30, 90, and 180 days) were made by the same investigator (OF) who was masked to the treatments until the end of the interventions.

Statistical analysis¶ was performed at a 5% level of significance. The Kolmogorov-Smirnov test showed a non-normal distribution of data. Mann-Whitney *U* and Wilcoxon tests were used for intergroup and intragroup comparisons, respectively. In this study it is decided to analyze "per protocol;" in other words, the data of participants who adhered to the designated intervention and completed the predefined procedures through the end without any deviation from the main protocol were included in the analysis.

RESULTS

Sixty-two patients were enrolled in the study, 15 (24.2%) males and 47 (75.8%) females, 12 to 60 years old (mean ± SD age, 31.4 ± 10.7 years). The study included 434 sensitive teeth: 216 (49.8%) teeth were allocated to the laser group and 218 (50.2%) to the cyanoacrylate glue group (Fig. 1).

A single tooth (treated with laser) presented acute sensitivity, spontaneous pain, had to be covered with glass ionomer cement, and was excluded from statistical analysis. All other teeth remained vital after treatment and presented no adverse reactions or complications at the exams during 6 months of follow-up.

At baseline, there was equality between the groups in terms of tooth sensitivity. There was no statistically significant difference between the two groups when submitted to tests with air jet and cold spray (Table 1). In the intergroup comparison (Table 1), there was a statistically significant difference only in 24 hours for the air jet ($P=0.002$) and cold spray ($P<0.001$). There were statistically significant differences in the intragroup analysis (Table 1) when the scores obtained at baseline were compared to those obtained after 180 days with both stimuli in both groups.

Figures 2 and 3 show the time course of the mean scores with the follow-up in response to air-jet and cold-spray stimuli.

Primary Outcome

The effectiveness of cyanoacrylate glue in the treatment of DH was proved, when compared to low-intensity laser within the established limits of non-inferiority, in the short, medium and long term.

Secondary Outcomes

Statistically significant differences in the quality of life were found after the application of cyanoacrylate glue and laser in patients with DH. Gingival recession was found to be the most prevalent etiologic factor, and the maxillary left premolars were the teeth most frequently affected by DH in the selected sample. No adverse effects were observed.

DISCUSSION

The aim of a non-inferiority trial is to demonstrate that the response to the investigational product is not clinically inferior to a comparative agent by more than a prespecified, small amount. This amount is known as the non-inferiority margin, or (Δ), and must be based on both statistical reasoning and clinical judgment.[17-20] Thus, 15% was considered an adequate non-inferiority margin; in other words, the group treated with cyanoacrylate in the present study could have a performance ≤15% worse in reducing the mean DH value when compared to the group treated with laser. The results demonstrated non-inferiority of cyanoacrylate glue compared to laser and showed that there was no statistically significant difference between groups at the study endpoint.

In the clinical trial of Gerschman et al.,[9] teeth treated with laser and subjected to the air-jet test showed a 67% reduction in sensitivity when comparing the scores obtained at baseline to those obtained at the final follow-up. In the present study, the results are similar, with a 68% reduction in sensitivity to the air jet between baseline and final follow-up. Confirming the non-inferiority of cyanoacrylate glue compared to laser, the reduction in sensitivity observed in the cyanoacrylate group was 67% when the same parameters were compared. In tests with cold spray, the reduction in sensitivity was 39% and 40% in groups treated with laser and cyanoacrylate, respectively.

Recent clinical trials[21,22] have produced divergent results regarding the effectiveness of laser therapy for DH. Wide variations have been seen in the

¶ SPSS v.17.0 for Windows, IBM, Chicago, IL.

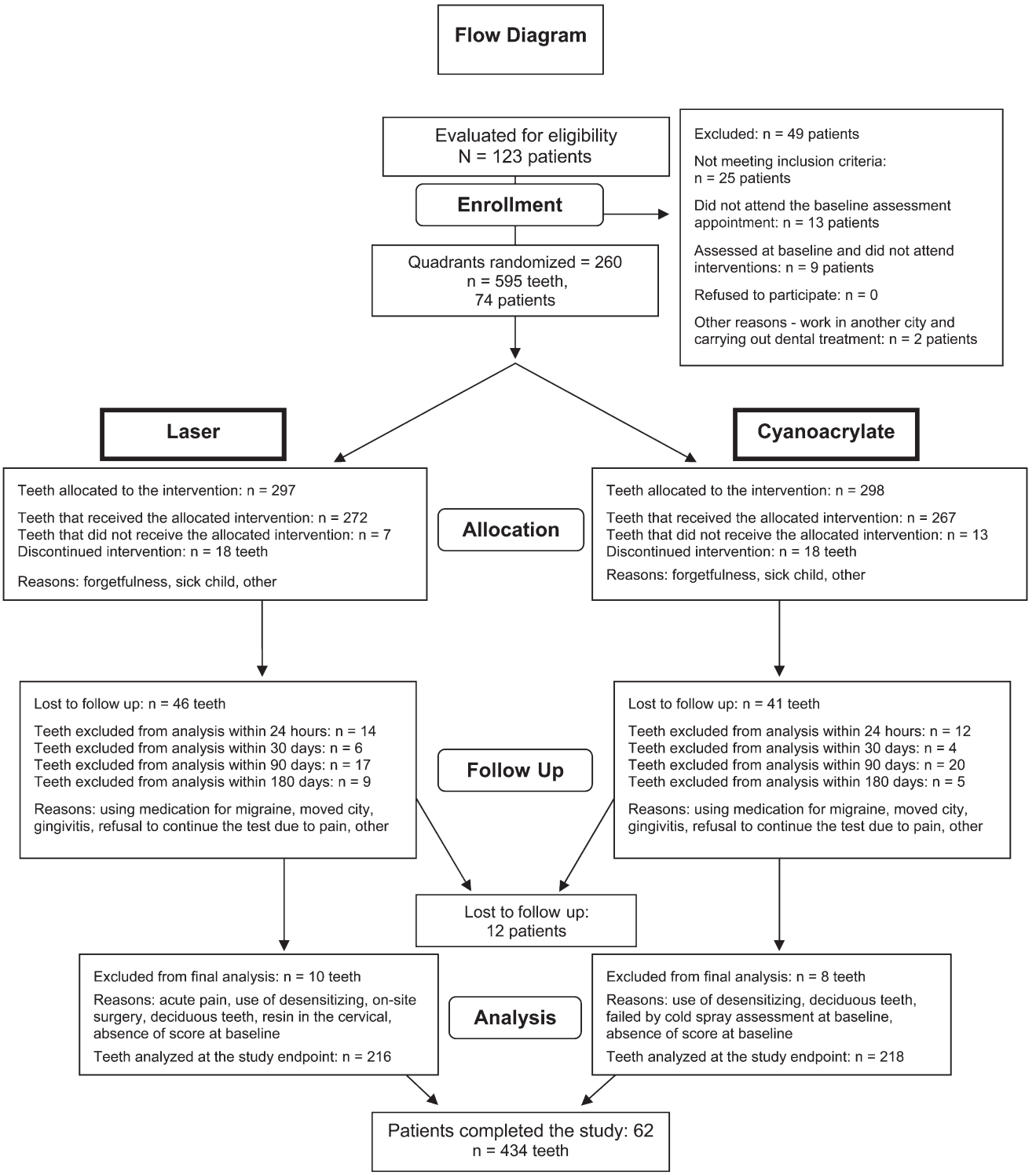

Figure 1.
Flow diagram.

Table 1.

Time Course of Mean, Median, and Percentiles of the Pain Scores Obtained by Thermal Stimuli Tests During 180 Days After Baseline

Stimuli by Group and Time	Mean (SD)	Median (25%, 75%)	*P**	*P*†
Air jet				
Laser			Baseline x 24 hours <0.001	
Baseline	7.49 (1.7)	7.0 (6.0, 9.0)	Baseline x 30 days <0.001	**Stimuli: Air Jet**
			Baseline x 90 days <0.001	
24 hours	4.67 (2.9)	5.0 (2.0, 7.0)	Baseline x 180 days <0.001	*Laser*
			24 hours x 30 days <0.001	*x*
30 days	3.58 (2.7)	3.0 (1.0, 6.0)	24 hours x 90 days <0.001	*Cyanoacrylate*
			24 hours x 180 days <0.001	
90 days	2.97 (2.8)	2.0 (0.0, 5.0)	30 days x 90 days <0.001	Baseline 0.090
			30 days x 180 days <0.001	
180 days	2.36 (2.7)	1.0 (0.0, 4.0)	90 days x 180 days <0.001	24 hours 0.002
Cyanoacrylate				30 days 0.476
			Baseline x 24 hours <0.001	
Baseline	7.77 (1.7)	8.0 (7.0, 9.0)	Baseline x 30 days <0.001	90 days 0.472
			Baseline x 90 days <0.001	
24 hours	3.77 (3.0)	3.0 (1.0, 6.0)	Baseline x 180 days <0.001	180 days 0.508
			24 hours x 30 days 0.816	
30 days	3.84 (3.0)	3.0 (1.0, 6.0)	24 hours x 90 days 0.013	
			24 hours x 180 days <0.001	
90 days	3.23 (3.0)	3.0 (0.0, 6.0)	30 days x 90 days <0.001	
			30 days x 180 days <0.001	
180 days	2.57 (2.9)	2.0 (0.0, 4.0)	90 days x 180 days <0.001	
Cold spray				
Laser			Baseline x 24 hours <0.001	
Baseline	9.20 (1.3)	10.0 (9.0, 10.0)	Baseline x 30 days <0.001	**Stimuli: Cold Spray**
			Baseline x 90 days <0.001	
24 hours	7.98 (2.0)	8.0 (7.0, 10.0)	Baseline x 180 days <0.001	*Laser*
			24 hours x 30 days <0.001	*x*
30 days	6.74 (2.7)	7.0 (5.0, 9.0)	24 hours x 90 days <0.001	*Cyanoacrylate*
			24 hours x 180 days <0.001	
90 days	6.27 (2.7)	6.0 (4.0, 8.0)	30 days x 90 days 0.001	Baseline 0.664
			30 days x 180 days <0.001	
180 days	5.62 (3.0)	6.0 (3.0, 8.0)	90 days x 180 days <0.001	24 hours <0.001
Cyanoacrylate				30 days 0.731
			Baseline x 24 hours <0.001	
Baseline	9.14 (1.3)	10.0 (9.0, 10.0)	Baseline x 30 days <0.001	90 days 0.909
			Baseline x 90 days <0.001	
24 hours	6.93 (2.6)	8.0 (5.0, 9.0)	Baseline x 180 days <0.001	180 days 0.526
			24 hours x 30 days <0.001	
30 days	6.83 (2.6)	7.0 (5.0, 9.0)	24 hours x 90 days <0.001	
			24 hours x 180 days <0.001	
90 days	6.25 (2.8)	7.0 (4.0, 8.0)	30 days x 90 days <0.001	
			30 days x 180 days <0.001	
180 days	5.45 (3.0)	5.0 (3.0, 8.0)	90 days x 180 days <0.001	

* Wilcoxon test.
† Mann-Whitney *U* test.

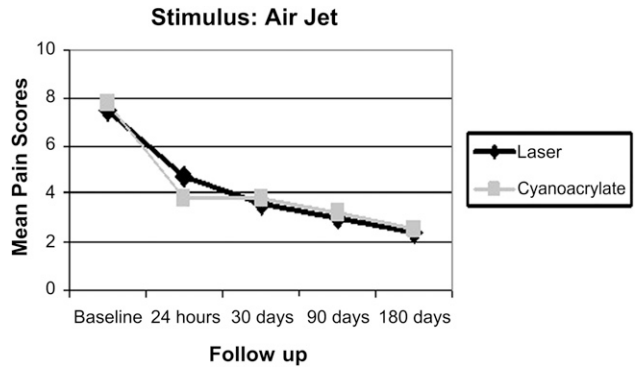

Figure 2.
Time course of mean scores with follow-up in response to air jet.

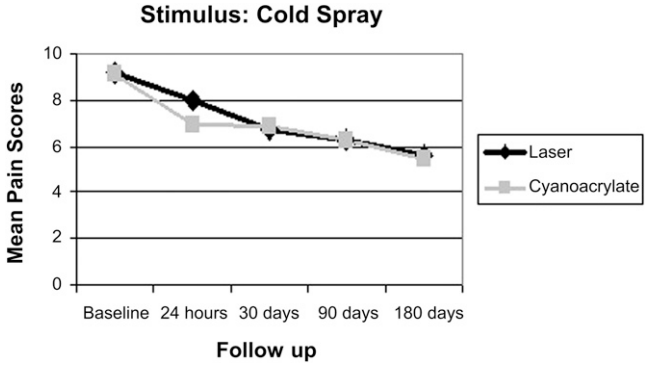

Figure 3.
Time course of mean scores with follow-up in response to cold-spray stimuli.

effectiveness rate, which reflects the percentage of 30% to 53.3% teeth showing a zero score in DH-related pain at 1-month follow-up after GaAlAs laser application.[21,22] At the end of the study presented here, 274 teeth (63.3%) had mild pain with air-jet stimulus and 77 teeth (17.74%) to the stimulus with cold spray. Of the 274 teeth that had mild pain response to the air jet, 77 (35.5%) had a score of zero (no pain) in the laser group and 71 (32.6%) in the cyanoacrylate group, in agreement with previous results found[21,22] regarding the teeth treated with GaAlAs laser.

Several studies[10,21-26] have evaluated the effects of low-intensity laser for treating DH. The exact action mechanism of low-intensity lasers in DH is not thoroughly understood, and its use has not been well investigated as a treatment choice. There are only a few studies in the literature about this treatment modality.[27] A recent systematic review[28] was performed with the aim of comparing the effectiveness of laser therapy to that of topical desensitizing agents in treating DH. A total of eight trials that met all inclusion criteria involving 234 participants was reviewed, and only one study was classified as the best level of evidence.[25] Half of the studies included in the review compared GaAlAs laser with topical desensitizing agents, but the findings were conflicting. In view of this controversial situation, the authors recommended that it would be helpful to perform adequately high-quality randomized clinical trials to compare the GaAlAs laser with other topical desensitizing agents.

In the study by Javid et al.,[12] 33% sodium fluoride (NaF) paste was compared to cyanoacrylate in patients with DH. The NaF paste was applied at weekly intervals for a total of six applications. The other group received a single application of cyanoacrylate. Sensitivity was tested 1 day after treatment and then weekly for 6 weeks. It was concluded that cyanoacrylate had an immediate desensitizing effect on hypersensitive dentin and was statistically more effective than NaF in reducing sensitivity to cold-air stimulation; if used on a continuing basis during a longer period, the effectiveness of NaF could eventually surpass that of the single cyanoacrylate treatment, which should be repeated after 6 weeks. The study presented here also showed immediate results of cyanoacrylate to be better than those obtained with a laser. This is justified by the different modes of action of the two products. Cyanoacrylate obliterates the entry of dentinal tubules, whereas the NaF causes a granular precipitation in peritubular dentin[12] and has a gradual, progressive therapeutic action in time.[29] In contrast to the author's suggestion,[12] the cyanoacrylate results in the present clinical trial are maintained for 90 days in response to the test with air jet and progressively improved ≤180 days at the end of the study. Perhaps because three applications were made instead of one application of cyanoacrylate, the results were more enduring.

An experimental, prospective, longitudinal, multicenter, non-controlled clinical investigation[16] was conducted using the licensed medical device, a tissue adhesive based on *N*-butyl-2-cyanoacrylate.# The sample consisted of 152 patients with symptoms of DH. The treatment was considered successful in 96.7% of patients (81.5% with severe DH and 100% with mild-to-moderate DH). It was concluded that tissue adhesive based on *N*-butyl-2-cyanoacrylate was shown to be an effective, safe treatment of DH, especially for moderate and mild cases. However, this study had no control group, so it was impossible to establishing a parameter.

Tisuacryl, BIOMAT, Center of Biomaterials of University of Havana, Havana, Cuba.

Considering the mentioned deficiency of randomized controlled clinical trials with good methodologic quality in the treatment of DH with low-intensity lasers,[27,28] the study presented here is conducted in accordance with the CONSORT recommendations,[19] with the intention of producing a good level of evidence in the area. Although in the 1980s and 1990s some authors[12,15] reported the use of cyanoacrylates in DH treatment, to the best of our knowledge, there are no recent reports in the international literature on the use of these products for this application.[16] Thus, the present clinical trial is an unhackneyed study, produced with all methodologic rigor to ensure that the level of bias is as low as possible and that the study has high internal validity.

It is important to remember that non-inferiority trials intend to show whether a new treatment is effective, often with the premise that it has some other advantage, such as greater availability, reduced cost, less invasiveness, fewer side effects, or ease of administration. The new treatment may also present an alternative or second-line therapy.[17,18] Because laser devices are still relatively costly, there is limited access to them.[11] The ethyl cyanoacrylate–based adhesive has the advantages of being inexpensive, is easily accessible, has good availability,[14] and has proven to be biocompatible.[13] Public health services may be able to use the technique effectively and safely and at minimal cost. This also gives the study extensive external validity.

CONCLUSIONS

Cyanoacrylate glue is as effective as low-intensity laser in the reduction of DH in the short, medium, and long term, in addition to being a low cost and more accessible procedure. It may be safely used in the treatment of DH.

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