

Effectiveness and Safety of Tisuacryl in Treating Dentin Hypersensitivity (DH)

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ABSTRACT

Introduction Dentin hypersensitivity (DH) is a painful tooth condition affecting a large proportion of the world population. While DH is not a direct cause of tooth loss, it does cause discomfort and stress. DH treatment methods include desensitizers, such as fluoride compounds; polycyanoacrylate coating; low intensity laser therapy; and surgery as a last resort. In Cuba, a fluoride varnish, Profilac, is widely used with acceptable results. Tisuacryl, an *N*-butyl-2-cyanoacrylate-based tissue adhesive is licensed in Cuba as a medical device used for closing wounds and as a protective covering or dressing for oral tissues. Experimental use of Tisuacryl in DH treatment has begun recently with good results.

Objective Evaluate the effectiveness and safety of Tisuacryl in treating dentin hypersensitivity.

Methods An experimental, prospective, longitudinal, multicenter, non-controlled clinical investigation was conducted using the licensed medical device Tisuacryl. The study universe consisted of patients with DH symptoms who sought treatment at three dental clinics in Havana

Province between May 2007 and February 2009. The sample consisted of 152 patients who met inclusion and diagnostic criteria for the study. DH was classified as severe, moderate, or mild. Remission of dentinal pain was the principal variable for evaluating effectiveness. Safety variables were mucosal irritation and burning sensation at the treatment site. Treatment was considered successful if DH was cured, defined as remission of pain and relief of discomfort (irritation or burning sensation) with no other adverse events by the final evaluation on day 6 after treatment initiation.

Results Tisuacryl treatment was successful in 96.7% of patients (81.5% with severe DH and 100% with mild to moderate DH). Mucosal irritation was observed in only 1 patient at first evaluation on day 2 but disappeared by the second evaluation. No other adverse events were reported.

Conclusions Tisuacryl was shown to be an effective, safe treatment of dentin hypersensitivity, especially moderate and mild cases.

Keywords: Dentin hypersensitivity, tooth, hyperesthesia, tissue adhesives, cyanoacrylates, biomaterials

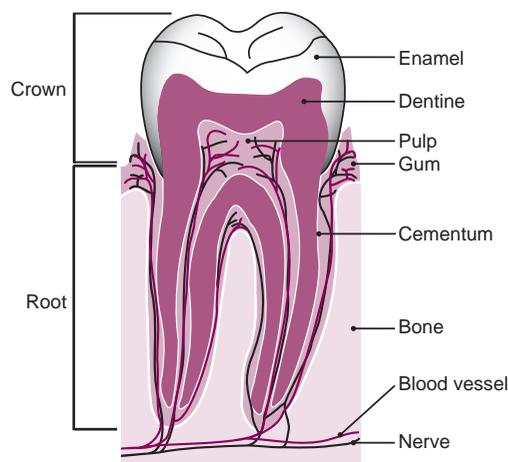
INTRODUCTION

Primary care dentists confront some kind of pain almost every day, primarily in teeth or surrounding tissue.[1] Dentin hypersensitivity (DH) is defined as short, sharp pain arising from exposed dentin in response to thermal, tactile, osmotic, or other stimuli and not attributable to any other tooth defect.[2-4]

Dentin is the calcified tissue arranged in parallel tubes (dental tubules) surrounding the dental pulp (Figure 1). Its primary function is isolating blood vessels and nerves in the pulp from external elements.[2,3] Dentin is covered by enamel on the visible portion of the tooth and by cementum on the root. It can become exposed due to loss of enamel and cementum in the area where these join (cemento-enamel junction or cervical margin of the tooth), as a result of erosion by acidic substances, abrasion or abfraction. Dentin exposure coupled with shrinkage of the gums or gingiva is known as gingival recession and is the site where DH occurs. Grinding of the teeth, tooth malformations, unilateral chewing, root scraping and planing, and missing teeth are among the causes of gingival recession.[2-8] Several theories exist to explain DH, but the most accepted is the hydrodynamic theory, according to which stimuli, such as a blast of cold air or contact with hypertonic sugars, cause fluid in the dental tubules to move, exciting nerve endings and causing pain.[2-6]

Estimates of DH prevalence vary. According to Kielbassa, 15% to 18% of patients seek dental care because of DH, and 9% to 30% of the adult population suffer from DH,[9] while Dowell, et al. estimate that 50% of the population is affected and 100% of patients with periodontal conditions have experienced DH at some time.[10]

Figure 1: Tooth Structure



Dentin hypersensitivity is generally diagnosed through patient interview and clinical exam, detecting an exaggerated pain response to minimal stimuli, even while brushing teeth.[4,10] DH is classified as mild, moderate, or severe, based on intensity of pain.[4,5,10]

A variety of treatments have been tried to stop or minimize pain caused by DH. The most complex and effective is mucogingival surgery by which the site of gum recession is covered using epithelial or subepithelial gingival grafts, totally eliminating sensitivity.[11]

The most widespread treatments involve application of desensitizing agents and other materials on the affected area.[4,5] Toothpaste containing strontium salts (chloride or acetate) or potassium salts (chloride or nitrate), as well as high-concentration fluoride varnishes and phosphate salts, act by combining with the calcium in the hydroxyapatite, forming strontium phosphate crystals, which block the dentinal tubules and reduce fluid movement inside them.

Dentin adhesives and restorative materials have also been used to seal dentinal tubules.[4,12] Specifically, cyanoacrylate adhesives have been reported to relieve DH by forming a film over exposed dentin, acting as a protective covering with a desensitizing effect, thereby reducing sensitivity to cold and air.[13–15] Despite the large number of published studies, however, there is still no consensus on which product constitutes the “gold standard” for DH treatment.[4]

Low intensity laser therapy, alone or in combination with fluoride and/or propolis, has also been used for over a decade.[16] Severe DH generally does not respond to chemical treatments, however. In these cases, surface reconstruction of the root may be necessary, but proximity of restorations to gingival tissue can produce sites of bacterial plaque retention, which are harmful to the tooth.[17]

In Cuba, DH has been treated for more than two decades with a fluoride varnish, Profilac (Quimefa, Cuba), with 90% effectiveness. However, this product has the disadvantage of causing a burning sensation at the application site in some cases.[18]

Tisuacryl, a tissue adhesive based on *N*-butyl-2-cyanoacrylate (Biomaterials Center-BIOMAT, University of Havana) was developed and licensed in Cuba as a medical device for use in general surgery, dentistry and maxillofacial surgery.[19] This strong adhesive is used primarily to close cutaneous wounds and wounds of the oral mucosa, and as a protective covering or dressing on oral tissues.[20–22]

Limited experimental use of Tisuacryl as a DH treatment has recently begun with good results. A 2006 controlled study with 60 patients compared the effectiveness of Tisuacryl (experimental) and Profilac (control) in DH treatment and found Tisuacryl to be 7% more effective than Profilac.[18] Barroso, et al. also reported good results with Tisuacryl in 30 patients with DH.[23] These results justified conducting a study with Tisuacryl on a larger sample of patients to evaluate the tissue adhesive's effectiveness in treating DH under normal conditions of use in dental practice.

The objective of this investigation was to evaluate the effectiveness and safety of Tisuacryl tissue adhesive in DH treatment under normal conditions of use in Cuban dental practice. The working hypothesis was that the product would be ≥95% effective in curing DH.

METHODS

General characteristics of the product Tisuacryl is a tissue adhesive formulated from the monofunctional monomer *N*-butyl-2-cyanoacrylate, its primary component, constituting >97% of the final product; other components of the formula are gentian violet, as a biocompatible colorant, and polymerization inhibitors (hydroquinone and *p*-Toluenesulfonic acid). Tisuacryl comes in 0.15 ml polypropylene ampules, packaged in boxes of 5 or 20 ampules. It can be used for up to two years from the date of manufacture. The

product must be kept cold, <5°C, protected from light and ultraviolet radiation. Proper functioning is ensured if the product remains fluid inside the ampule. When applied in the presence of bodily fluids, the material polymerizes, forming a resin. Its therapeutic function is neither pharmacological, immunological nor metabolic; Tisuacryl is therefore classified as a medical device, a term that covers materials and products for medical use according to the Regulations for Government Evaluation and Control of Medical Equipment,[24] and was licensed in Cuba in October 1998 by the Center for Government Control of Medical Equipment for Dentistry and Oral Surgery.[19]

Type of study and patients An experimental, prospective, longitudinal, multicenter, non-controlled clinical investigation was conducted in accordance with ISO standards 14155–1:2003 and 14155–2:2003 for clinical investigation of medical devices for human subjects. This study extends the application of Tisuacryl in dentistry.

The study universe consisted of patients with DH symptoms who sought treatment at dental teaching clinics in Bauta, Caimito, and San Antonio de los Baños in Havana Province between May 2007 and February 2009. The sample consisted of all patients in the study universe who met the diagnostic and inclusion criteria established for the investigation.

Sample design A one-tailed binomial hypothesis test was used for a population sample with a reference value or established proportion of success. The formula for sample sizes corresponding to this design is:[25]

$$n = \left(\frac{\sqrt{\pi_0(1-\pi_0)}z_{1-\alpha} + \sqrt{\pi_1(1-\pi_1)}z_{1-\beta}}{\delta} \right)^2$$

where π is the proportion of effectiveness corresponding to Tisuacryl tissue adhesive.

α = level of significance or type I error
 β = type II error (or $1-\beta$ = power of test)
 π_0 = established proportion of success
 π_1 = expected proportion of success
 δ = $\pi_1 - \pi_0$ = minimum difference to detect

Assuming a 5% level of significance, a power of 80%, and a minimum difference to detect of 0.05, the values for these parameters were:

$\alpha = 0.05$, $\beta = 0.2$, $\pi_0 = 0.90$, $\pi_1 = 0.95$, $\delta = 0.05$.

Based on this data, a sample size of 150 patients was calculated, which was expanded to 152, considering the possibility of 1% withdrawal.

Diagnostic criteria DH was detected in patient interviews based on self-reported response to cold, heat, sour and sweet; response to air and touch was confirmed by exploration of the affected site with a fine metal instrument and application of air from the dental unit. Other causes of tooth pain, including pulp conditions, periodontal pockets and tooth damage, were thoroughly differentiated and excluded from the DH diagnosis.

DH Classification DH is classified in three categories according to severity: severe, when the patient reports pain in response to

all known stimuli (air, touch, cold, heat, sweet, sour); moderate, when the patient reports pain in response to more than two of these stimuli; and mild, when the patient reports mild pain in response to one or two of the stimuli.

Inclusion criteria Ambulatory patients of both sexes, aged 18–75 years, who met the diagnostic criteria for DH established in this study, were able to keep follow-up appointments, and gave written consent to participate in the study.

Exclusion criteria Malignant neoplasms in areas close to the treatment site; mental disability and/or severe psychological disorder; pregnancy or lactation; allergy to gentian violet or acrylics; uncontrolled diabetes; alcoholism or other drug addictions; or failure to consent to participate in the study.

Withdrawal criteria Failure to complete follow-up after giving consent and undergoing initial treatment.

Ethical aspects The investigation was conducted according to Helsinki Declaration and Cuban good clinical practices standards.[26,27] Patients were given detailed information about the nature and objectives of the investigation, treatment and medical procedures, and written informed consent was obtained. The study was approved by the Review and Ethics Committee of the Bauta Dental Teaching Clinic, Havana, Cuba (coordinating center for the investigation).

Description of treatment A registry of patients who met the inclusion criteria was created and a Clinical Report Form (CRF) prepared for each participant. Each patient underwent a 1-minute antiseptic mouth rinse with 0.2% chlorhexidine mouthwash. (At this dose, the drug has no therapeutic effect but ensures necessary hygiene for dental procedures.) The operative field was isolated, the tooth surface dried with air from the dental unit for 15 seconds, and 90% alcohol was applied with a wood and cotton applicator. After a 15-second wait, Tisuacryl was applied directly on the DH site using a truncated needle and let dry for 60 seconds. Care was taken to ensure none of the product touched other zones of the oral mucosa. If symptoms persisted, treatment was repeated at follow-up on days 2 and 4 using the same technique. Results were recorded in the CRF.

Effectiveness evaluation Dentinal pain was used as the primary response variable for evaluating effectiveness of Tisuacryl treatment. Two levels were used: Level 1 = absence of pain; Level 2 = persistence of pain. Each patient was interviewed and examined by the clinical investigator at follow-up on days 2, 4, 5, and 6 (final evaluation) after initial treatment.

Safety evaluation Two safety variables were evaluated: irritation and burning sensation in the mucosa next to the treatment site. Each variable was evaluated on two levels. For irritation of the mucosa, change in color and texture of treated mucosa was evaluated using gum tissue around the treatment site as reference; responses were evaluated as Level 1 = no change in color or texture, and Level 2 = change in color or texture. For burning sensation, the patient was questioned and responses were classified as Level 1 = no burning sensation at treatment site, and Level 2 = burning sensation at treatment site. Evaluations were conducted during follow-up visits on days 2, 4, 5, and 6 after initial treatment.

Provisions were also made to record adverse events (AE), understood as any unfavorable medical event that occurred during the study, not necessarily attributable to the experimental treatment. Such events might include erythema or redness on any part of the skin, stinging, fever, or headache following Tisuacryl application in the mouth. Patients were instructed to go to the clinic immediately if these or any other AE appeared. A dichotomous AE variable (yes/no) was established, and the following information was to be recorded: type of AE; intensity (mild, moderate, moderately severe, severe); causal relationship to the product under study (due to product/not due to product); duration of AE; treatment applied and outcome (recovered, improved, persists, sequelae).

Criteria for evaluating treatment success/failure Final response to treatment was classified as rapid cure, slow cure, or no cure, as follows: rapid cure = absence of pain and other symptoms (irritation, burning) by day 2 or 4 with no adverse events attributable to the product; slow cure = absence of pain and other symptoms (irritation, burning) by day 5 or 6 with no adverse events attributable to the product; no cure = symptoms persisted at final evaluation on day 6 or adverse event attributable to the product. These outcomes were reclassified using the dichotomous variable for treatment success/failure, as follows: success = rapid or slow cure; failure = no cure.

Data collection and processing Data was entered into the study's database. For all variables, frequency tables were created for each treatment outcome. Statistical analysis (one-tailed binomial test of the hypothesis, $\alpha=0.5$) was performed using SPSS 11.5 for Windows statistical software.

RESULTS

The study sample was predominantly female with a mean age of 42 years. Regarding severity, 59.2% of all DH was moderate, followed by mild (23.0%) and severe DH (17.8%) (Table 1).

Table 1: Characteristics of Sample Treated with Tisuacryl for Dentin Hypersensitivity (DH)

Characteristics	Number	(%)
Sex		
Female	90	59.2
Male	62	40.8
Age		
18–30 years	27	17.8
31–50 years	89	58.5
51–75 years	36	23.7
Type of DH		
Severe	27	17.8
Moderate	90	59.2
Mild	35	23.0
Total	152	100.0

Remission of pain was achieved in 61.8% of patients by day 4 and in 96.7% of patients by day 6 (Table 2). Mucosal irritation was observed in only 1 patient at first evaluation on day 2 but disappeared by the second evaluation on day 4, when the patient also reported absence of pain. By final evaluation on day 6, remission of pain was achieved in 100% of patients with moderate or mild DH (Table 3). In patients with severe DH, treatment was 81.5%

Table 2: Remission of Pain Following Tisuacryl Treatment of Dentin Hypersensitivity (DH)

Evaluation	Level 1: Absence of Pain		Level 2: Persistence of Pain	
	n	%	n	%
Day 2	47	30.9	105	69.1
Day 4	94	61.8	58	38.2
Day 5	133	87.5	19	12.5
Day 6	147	96.7	5	3.3

Table 3: Effectiveness and Success of Tisuacryl Treatment for Dentin Hypersensitivity (DH), by Severity

DH	Rapid Cure		Slow Cure		No Cure		Success	
	n	%	n	%	n	%	n	%
Severe	6	22.2	16	59.3	5	18.5	22	81.5
Moderate	56	62.2	34	37.8	0	0	90	100
Mild	32	89.0	3	11.0	0	0	35	100

successful, since pain symptoms persisted in 5 patients at final evaluation. Rapid cure was achieved in 89.0% of mild DH, 62.2% of moderate DH and 22.2% of severe DH.

Hypothesis testing of the 152-patient sample and 147 successes showed that HD treatment with Tisuacryl was more effective (96.7%) than the established conventional treatment (90%). The hypothesis that the success rate found with Tisuacryl would differ from the expected success rate ($\geq 95\%$) was therefore rejected (Table 4).

Table 4: Hypothesis Testing, Success of Tisuacryl Treatment for Dentin Hypersensitivity (DH)

Category	N	Proportion Observed	Test Proportion (established)	Asymptotic Significance (one-tailed)	Test Proportion (expected)	Asymptotic Significance (one-tailed)
Success	147	0.97	0.90	0.002(a)	0.95	0.224*
Failure	5	0.03				
Total	152	1.00				

* Based on Z approximation

DISCUSSION

Distribution of DH according to severity observed in this study is consistent with Kielbassa's observation that moderate DH is more prevalent than severe or mild varieties.[9] A mean age of 42 years in the study sample coincides with data reported by Cum-

mins indicating that DH affects primarily adults aged 20–50, with a prevalence of 15–20%.[28]

Mechanisms contributing to tooth sensitivity seem to diminish with age or after chronic irritation, since reparative or secondary dentin increases as a result of these processes, thereby decreasing the flow of fluid in the dentinal tubules. Current therapeutic methods for blocking dentinal pain described in the literature are aimed at physically obstructing the flow of fluid in the dentinal tubules;[1,4] applying a resin on exposed dentin is therefore consistent with these types of DH treatment. Furthermore, Addy's suggestion that coating dentinal tubules is effective in over 95% of cases,[2] coincides with the results of this study and with Tisuacryl's method of action.[24] The lower success rate with severe DH (81.5%), compared to moderate and mild DH (100%), in this study may be explained by the greater transmission of painful stimulus with severe DH.

Although in the 1980s and 1990s, some authors reported the use of cyanoacrylates in DH treatment,[13–15] there are no recent reports in the international literature on the use of these products for this application. Cyanoacrylate tissue adhesives equivalent to Tisuacryl, such as Dermabond (Johnson & Johnson, USA) and Histoacryl (B. Braun Corporation, Germany), are only marketed for cutaneous use. Studies using Tisuacryl for DH treatment and other dental applications show the safety and effectiveness of this product when used on the oral mucosa.[18,21–23,29,30]

The proportion of DH patients cured with Tisuacryl in this study (96.7%) is similar to that obtained using other techniques in Cuba, such as laser therapy combined with fluoride varnish[31] or laser therapy combined with propolis,[32] with the advantage that Tisuacryl treatment is quicker and simpler. In studies using potassium oxalate, Pereira et al. also observed a reduction in DH similar to that found with Tisuacryl in this study.[33]

Although sample size was calculated to meet the objectives of the present investigation, future studies involving a larger number of patients to evaluate long-term effects of DH treatment with Tisuacryl are recommended. Expanding the use of Tisuacryl for DH treatment in all Cuban dental clinics will help corroborate its effectiveness and safety and may result in this product becoming the treatment of choice for moderate and mild dentin hypersensitivity. 

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