Use of Papain Gel in Disabled Patients

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ABSTRACT

Purpose: This study's purpose was to evaluate complete caries removal time (CCR) and patient acceptance of the chemomechanical caries removal agent and papain gel Papacárie in disabled patients.

Methods: Fifty-one consecutive patients entered a prospective, controlled, randomized, open study. Patients were divided into 2 groups: (1) group 1=28 children 3 to 10 years old with or without visual or hearing impairments, motor disability on upper limbs, and inability to respond to simple orders; and (2) group 2=23 children, without visual or hearing impairments, with motor disability on the upper limbs and the ability to respond to simple orders. CCR time was measured in both groups. Patients' acceptance was assessed only in group 2 by using the visual analogy of face scale. The visual scale was presented in phase A – after the radiography with the child sitting on the dental chair before the beginning of the treatment, phase B – during the treatment, after total removal of the carious tissue and phase C – after the restoration was complete (treatment was finished).

Results: The total CCR average time was 8 minutes for each tooth when groups 1 and 2 were considered. Group 2 patients' acceptance in the first treatment was not statistically significant in all stages.

Conclusions: Papacárie gel had a completed caries removal time of 8 minutes per tooth and is well accepted by the patients in all phases and in the first and subsequent visits. (**J Dent Child 2008;75:222-8**)

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Decayed tooth tissue removal is routinely made with drilling or hand instruments. Despite its proven efficacy in removing carious tissue, the conventional drilling technique presents negative experiences to the patient, such as tooth vibration, "noise," temperature increase on the surface of the tooth provoked by the spinning drill, and dentin sensibility.[1] These factors trigger reactions such as pain and discomfort, and this method usually requires local anesthesia.[2]

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Fear and anxiety are known barriers to the receptivity of dental treatment and in detriment to oral health, since the conventional drilling techniques are associated with discomfort, especially among children.[3-5] Normally, the triggering factors are local anesthesia, low and high spinning rates, and previous dental treatment.[6-8] For children, is difficult to differentiate between fear and anxiety-originated behavior problems. The most anxiety-provoking procedure for children, however, is the local anesthetic injection.[9] Thus, changes in dentistry routines—such as the chemomechanical caries removal, sedation with nitrous oxide, and general anesthesia—are necessary.[10]

The chemomechanical caries removal method was deve-loped specifically to overcome these barriers and to preserve the healthy dentine tissue.[11,12] This method is characterized by the use of a material that acts on the predegraded collagen of the lesion, promotes its softening, doesn't

affect the adjacent healthy tissues, and avoids pain stimuli (chemical action). This method is further characterized by removing the softened carious tissue via gentle excavation (mechanical action), which makes this technique an efficacious alternative method to treat carious lesions since it allies nontraumatic characteristics with bactericide and bacteriostatic action.[13,14]

In 1985, a formula composed of N-monochloroglycine and aminobutyric acid was developed and received the trade name Caridex.[15] This compound had many drawbacks, such as cost, need to be heated, and a proper place to be stored.[13,14,16-18] Thus, a new material to remove caries was introduced in the market–Carisolv. Its main difference from the remaining products was the use of 3 amino acids: glutamic acid, leucine, and lysine instead of aminobutyric acid.[12-14]

Despite the effectiveness of Carisolv in removing carious dentine tissue, it presented some disadvantages, such as the need to certify dental surgeons and acquire specific equipment and the high cost, which made its popularization impossible—turning the chemomechanical removal of caries a privilege of a few.[12]

In 2003, a Brazilian gel was developed based on papain, chloramines, and toluidine blue called Papacárie.[18,19] The union of these 3 components confers antibiotic, bacteriostatic, and anti-inflammatory properties to this agent. Papain is an endoprotein from the proteolytic cysteine family that acts only upon damaged tissue, since plasma antiprotease is not present in the infected tissue, preventing papain's proteolytic action in tissues considered normal.[20] Chloramine is a compound containing chlorine and ammonia with antibiotic and disinfecting properties, used for the irrigation of root canals.[21] Toluidine blue is a photosensitive pigment that fixates to the bacterial membrane.[18]

Papacárie gel (Fórmula & Ação, São Paulo, Brazil) can be successfully used in special health care needs (**SHCN**) patients and phobic adults in pediatric dentistry and public health sectors.[18]

Currently, research in dentistry has concentrated its efforts on the quality of treatment given to SHCN patients, those who present some deviation from the normal standards (identifiable or not), and those who, for this reason, require special attention and approaches for a given length of time or indefinitely.[22] Therefore, the chemomechanical technique for removing caries is an efficient option when approaching and supplying oral care for these patients.

This study's objective was to assess the duration of treatment and the acceptance of the chemomechanical technique using the Papacárie gel in patients with special health care needs.

METHODS

Fifty-one SHCN patients who were being treated in the dentistry sector of the Disabled Children Assistance Association (AACD) of São Paulo, São Paulo, Brazil in 2005 were prospectively assessed. The data were collected after the institution's research ethics committee approved the study (approval no. CEP–AACD 38/2005) and the guardians of each child signed a free and informed consent form.

The sample was composed of patients from the cerebral palsy (N=44), myelomeningocele (N=5), congenital malformation (N=1), and medullary lesion (N=1) clinics.

Data that referred to general information of the patients (name, age, pathology, general health status, and previous dental treatment experience) were obtained through a questionnaire filled out by the guardian of the child during the first visit (Figure 1).

The cases were selected through a simple clinical examination (clinical mirror and exploratory probe) complemented by periapical radiography. The inclusion criteria were: absence of spontaneous pain symptomatology; collaboration of the patient to undergo periapical radiography; and carious lesion without pulpal involvement (shallow and medium cavities).

The patients were divided into 2 groups. The groups differed mainly in sensorial impairments (visual and auditory), motor disability of the upper limbs, and response to simple verbal commands (when the child receives only one linguistic information and/or request).

Group 1 consisted of 28 3- to 10-year-old boys and girls with motor disability of the 2 upper limbs and visual and/or auditory impairments and who did not respond to simple verbal commands. Group 2 consisted of 23 boys and girls without motor disabilities of the upper limbs and who responded to simple verbal commands, divided into 2 age subgroups: (1) 0- to 7-year-olds; and (2) 8-year-olds and older. The only response requested was that the child be able to indicate the face corresponding to their discomfort or pain level in the face scale.

Papacárie gel (Figure 2) was used in the selected children from both groups by 2 dental surgeons according to the use protocol[23]:

1. evaluation of carious lesions in the dental elements;
2. periapical radiography of the dental elements involved;
3. drying of the dental elements involved;
4. Papacárie gel application (40 seconds). You must do a new application if still have contaminated dental tissue (more 40 seconds) OBS: This is part of the product's protocol. If you see that still have contaminated dental tissue you must do a new application. Each application must take 40 seconds.
5. removal of softened carious tissue;
6. rinsing of the cavities with a cotton pellets immersed in 10% chlorhexidine;
7. drying of the cavities with cotton pellets; and
8. restoration of the dental elements with conventional glass ion-omer cement, resin composite, or adhesive amalgam.

In cases where discomfort or pain was expressed by the patient and/or by their guardian during the procedure, local anesthesia was used.

Questionnaire

Name: _____
Responsible's name: _____
Age: _____ Gender: F ☐ M ☐
Adress: _____
City: _____ State: _____

Pathology: _____

Group: I ☐ II ☐

General Health Status:

_____
_____
_____
_____
_____

Previous dental treatment experience:

_____
_____
_____
_____
_____

Papacárie data:

Application (n)	Phase A (score)	Phase B (score)	Phase C (score)

Figure 1. Questionnaire

The number of applications for each tooth necessary for the procedure and the dental elements involved were documented.

All dental elements were restored with conventional glass ionomer cements.

The duration of the procedure was measured by a digital chronometer in groups 1 and 2 and began after the radiography, with the child sitting on the dental chair, and ended when the restoration was finished. Duration of treatment was measured for each dental element, each group, and the total.

For group 1, only the treatment duration was assessed since the limitations of these patients did not allow the acceptance assessment to be made.

The visual analogy of faces (VAF) scale by Whaley and Wong[24] was applied only for group 2. It was applied to measure the degree of pain and/or discomfort of the patients regarding the chemomechanical removal technique and, therefore, assess its acceptance during the first and subsequent visits of each patient. The scale is composed of 6 facial expression scores: 1 and 2=without pain/discomfort; 3=slight pain/discomfort; 4=moderate pain/discomfort; 5=considerable pain/discomfort; and 6=unbearable pain/discomfort.[24] The scores were determined to make a quantitative assessment of the data. The happiest face is blue, the saddest is dark red, and the intermediate faces show varying degrees of happiness and sadness (Figure 3).

The scale was presented to patients with the following question: "If you were this face right now, which one would you be?" The child would then point to the corresponding face that best represented their degree of pain or discomfort. The scale was presented in 3 distinct phases:

1. phase A—after the radiography with the child sitting on the dental chair before the beginning of the treatment;
2. phase B—during the treatment, after total removal of the carious tissue; and

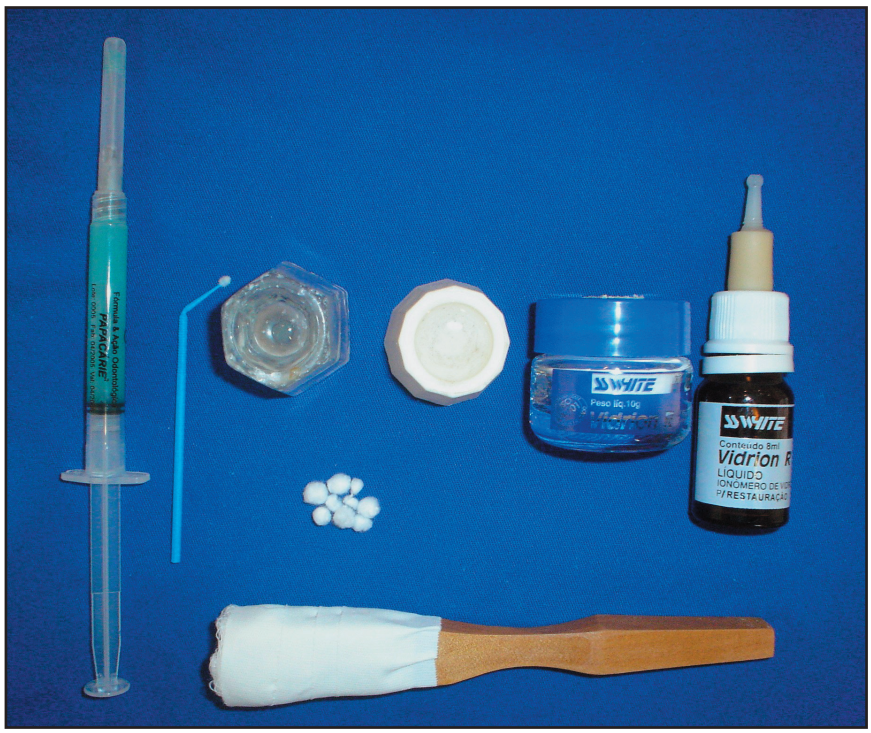

Figure 2. Papacárie gel, 10% chlorhexidine, cotton balls, glass ionomer cement, and mouth gag.

3. phase C—after the restoration and treatment were finished.

Each child of each age subgroup was allowed to choose faces in every visit.

The following tests were used to analyze the results (group 2):

1. Friedman's 2-way analysis of variance by ranks to study the scores obtained with the visual analog scale of the faces in the stages before, during, and after treatment; this test was made at the first and subsequent visits of each patient and for the age subgroups separately.[25]
2. The Mann-Whitney test (1988) to compare the 2 age subgroups in each treatment phase and at each patient's first and subsequent visits.[25]

The null hypothesis was rejected at the 5% (0.05) significance level.

RESULTS

Papacárie was applied on 38 teeth among 51 patients. Local anesthesia was not necessary during any of the procedures. Of the 138 treated teeth, 96% (133) were from the primary dentition and 4% (5) were from the permanent dentition.

The treatment durations were 7 and 10 minutes per tooth for groups 1 and 2, respectively. The total average duration of the treatment was 8 minutes per tooth. Data regarding the acceptance of the technique determined by the VAF scale (group 2) are shown in Tables 1 and 2.

When only the first visit of each patient was taken into account in the age subgroups, there was no significant difference for phases A, B, and C. Regarding the comparison between ages, the difference was also not significant for the same phases (Table 1). The same result was obtained with the assessed parameters when all visits of each patient were taken into account (Table 2).

DISCUSSION

Papacárie gel was developed in 2003. The product aimed to globalize the chemomechanical caries removal, overcome the drawbacks of Carisolv, and promote the use of this technique, especially in the public health sector.[11]

The use of Carisolv as a chemical agent to chemomechanically remove caries is broadly discussed in the dental literature.[14,16,21,26-31] Although it is effective in removing carious tissue, it presents some disadvantages—such as the need to certify dental-surgeons, acquire specific equipment and its high cost—making it available for just a privileged few.[11,12]

Since Papacárie was developed recently, there are not many references in the dental literature on it. Therefore, this study's results were compared with the results of studies using Carisolv, since the technique is the same (chemomechanical caries removal), where the only difference resides in the composition of the formula. Besides, there are no references using this technique in SHCN patients.

On the other hand, there are many published works on Carisolv regarding the duration of treatment, which averages 6 to 13 minutes.[21,26,28-30] A similar value was found

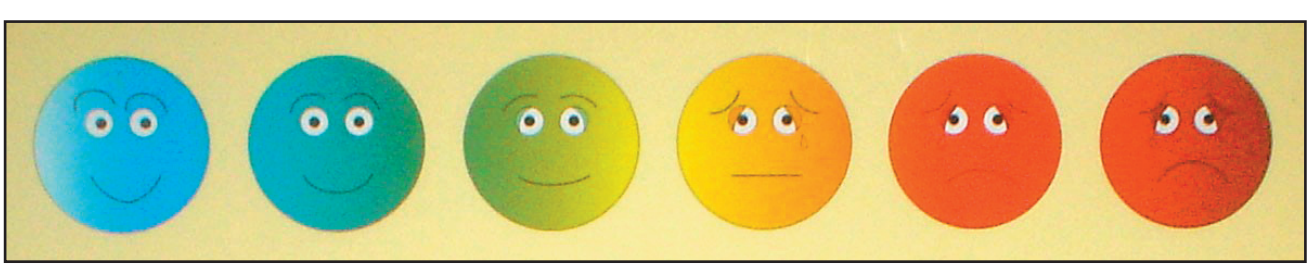

Figure 3. Visual analogy of faces scale.

Table 1. Values of the Visual Face Scale in Special Health Care Need Patients From 0 to 7 Years Old and From 8 Years and Older in the Phases Before (A), During (B), and After (C) Dental Treatment—Taking Into Account Only the First Visit (*),(**)

Age group (ys)	0-7			≥8		
Phase	A	B	C	A	B	C
	1	1	1	2	2	2
	2	2	4	2	1	1
	2	3	1	2	5	4
	6	4	3	2	1	2
	1	4	3	6	3	2
	2	3	2	2	2	2
	1	3	3	1	1	1
	2	4	5	2	1	2
	2	1	3	2	1	1
	4	3	1	2	5	3
	1	4	4			
	1	1	1			
	1	5	3			
Mean	**2.00**	**2.92**	**2.61**	**2.30**	**2.20**	**2.00**
Median	**2.00**	**3.00**	**3.00**	**2.00**	**1.50**	**2.00**

** Friedman analysis of variance A x B x C (p≤0.05): chis quare=2.85 and 1; p=0.24 (0 to 7 years) and p=0.61 (8 or more years).*

*** Mann–Whitney Test (0 to 7) x (8 or more), (z calc=1.96): z calc=1.29 (A), z calc=1.25 (B) and z calc=1.16 (C).*

in this study where the average treatment duration varied from 7 to 10 minutes (averaging 8 minutes) in the assessed groups. This demonstrates that, even though the patient has special needs, this fact did not influence the duration of treatment.

Comparing Carisolv with the conventional drilling technique revealed that the average time to mechanically remove caries was 4 minutes.[21,28,29] Most of the patients treated with Carisolv, however, considered it faster than the conventional hand excavation techniques.[16] Although the duration of treatment is lower for the conventional drilling technique, this technique has disadvantages, such as discomfort, tooth vibration, stress for the patient and for the dentist, "noise," and need for local anesthesia.[13]

This study observed that the degree of discomfort reported by group 2 patients remained within the 3 first facial expressions (scores 1, 2, and 3) of the VAF scale during the phases A, B, and C regardless of the patient's age ($P>.05$) in all visits of each patient. This shows that this technique does not cause pain and can be used successfully in patients of any age undergoing dental treatment. This is an extremely important fact when approaching SHCN patients, since any stimulus, be it auditory, sensorial, or emotional, can lead to negative responses.

As described previously, the face scale was used to measure pain and/or discomfort of the patient regarding the chemomechanical caries removal and, therefore, assess the acceptance of this technique by SHCN patients. The VAF scales are considered true tools to measure pain or discomfort and have been used for more than 20 years to quantify their intensity.[32]

VAF scales are efficient to detect signs of pain or discomfort in children. Additionally, they are simple, easy to use, and inexpensive.[33] In the same way, these scales can be used in Pediatrics as long as the psychomotor and cognitive abilities of the child are respected.[34,35] Thus, this study used this scale only for group 2 children. Furthermore, the VAF scale is used more frequently for younger children, specifically those age 3 until the preverbalization phase, even though this scale can be used for older children with excellent results.[33]

Other factors also influence the child and their response to dental treatment. Fear and anxiety are mentioned as barriers to oral care, especially among children.[36] Children who were submitted to prolonged treatment or hospitalized are usually more fearful and afraid of hospitalization regarding dental treatment.[10] Therefore, the chemomechanical caries removal technique is an efficient therapeutic alternative to prevent fear and anxiety among these patients.

Another positive factor regarding this technique is that it does not require local anesthesia during the procedure since the carious tissue is softened by the gel and its removal by gentle hand instruments does not promote any stimulus or pressure that would lead to discomfort and/or pain.[37-39] The fact that local anesthesia was not required during any of the procedures in this study proves it.

Children who were submitted to local anesthesia during dental treatment demonstrated more fear in 66,8% than those who were not submitted to anesthesia (50, 8%).[40] In all studies involving Carisolv, the removal of carious dentine was successful and did not cause any pain (60%); yet, in some cases, there was a small degree of pain involved (39%), which required the use of anesthesia.[16,26,30]

Despite the Papacárie gel advantages, it is important to point out the need for a minute assessment of the cases based on indications and inclusion criteria for its application. Furthermore, treatment success is only reached with the restoration of the element involved by an adhesive material which promotes a good sealing and retention of the dental tissue.[11,12,38] The material of choice for this study was the conventional glass ionomer, since it presents advantages such as gradual flour release in the oral cavity, good adhesiveness, possibility of repair, and ease of use.[41,42]

Given its low resistance to wear, however, this material presents low durability (infiltrations).[43] Thus, periodical control is necessary to assess and follow-up the restorations performed.[44] These periodic visits are advantageous, however, when dealing with SHCN patients, since they present a high incidence of oral disease—especially caries and periodontal disease.[45]

The use of Papacárie gel proved to be an alternative for treating SHCN patients, although more studies are necessary to claim it as a new and useful alternative in treating caries.

CONCLUSIONS

Based on this study's results, the following conclusions can be made:

1. The chemomechanical removal of carious tissue using the Papacárie gel presented a treatment duration of 8 minutes per tooth.
2. Papacárie gel presented good acceptance, regardless of age, in phases A- after the radiography with the child sitting on the dental chair before the beginning of the treatment, phase B – during the treatment, after total removal of the carious tissue and phase C – after the restoration was complete (treatment was finished) and in each patient's first and subsequent visits.

Table 2. Values of the Visual Face Scale in Special Health Care Need Patients From 0 to 7 Years Old and From 8 Years and Older in the Phases Before (A), During (B), and After (C) Dental Treatment, Taking Into Account All Visits From Each Patient (*), (**)

Age group (ys)	0-7			≥8		
Phase	A	B	C	A	B	C
	1	1	1	2	2	2
	5	4	3	2	1	1
	2	4	2	2	5	4
	2	2	2	2	1	2
	2	3	1	6	3	2
	6	4	3	2	2	2
	1	6	3	1	1	1
	1	4	3	2	1	2
	2	2	1	2	1	1
	2	3	1	2	5	3
	2	3	2	2	1	1
	1	3	3			
	2	4	5			
	1	2	4			
	2	1	3			
	4	3	1			
	1	4	4			
	1	1	1			
	1	5	3			
Mean	2.05	3.11	2.53	2.27	2.10	1.91
Median	2.00	3.00	2.00	2.00	1.00	2.00

** Friedman analysis of variance A x B x C (p≤0.05): chis quare=2.0 and 5.03; p=0.368 (0 to 7 years) and p=0.081 (8 or more years).*

*** Mann–Whitney Test (0 to 7) x (8 or more), (z calc=1.96): z calc=1.26 (A), z calc=1.90 (B) and z calc=1.32 (C).*

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