RENATA PEREIRA DE SAMUEL MARQUES

Evaluation of reciprocating instrumentation in endodontic treatment of primary molars

São Paulo
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Corrected Version

Thesis presented to the Faculty of Dentistry, University of São Paulo, by the Graduate Program in Dentistry (Orthodontics and Pediatric Dentistry) to obtain the title of Doctor of Science.

Advisor: Prof. Dr. Fausto Medeiros Mendes

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Vasco, Rodrigo, Ricardo e Hercules,
sempre a melhor parte do meu dia.

"Como sou pouco e sei pouco, faço o pouco que me cabe me dando por inteiro."
Ariano Suassuna

RESUMO

Marques, RPDS. Avaliação da instrumentação reciprocante no tratamento endodôntico de molares decíduos [tese]. São Paulo: Universidade de São Paulo, Faculdade de Odontologia; 2021. Versão corrigida.

Esta pesquisa teve como objetivo investigar o uso de duas técnicas de instrumentação do canal radicular no tratamento endodôntico de molares decíduos. As técnicas aplicadas foram instrumentação manual convencional, com o uso de limas K manuais de aço inoxidável, e instrumentação reciprocante, um tipo de instrumentação mecanizada que aplica instrumentos acionados a motor introduzidos no canal enquanto realizam movimentos de rotação alternada. Assim, foi realizado um ensaio clínico randomizado com acompanhamento de 24 meses, comparando os resultados obtidos com as duas técnicas. Esta tese é composta por dois estudos relacionados ao tema principal: (I) um ensaio clínico randomizado (ECR) com 24 meses de acompanhamento avaliando o sucesso do tratamento endodôntico, (II) um estudo aninhado no ECR avaliando fatores associados ao tempo de instrumentação, desconforto e dor pós-operatória no tratamento endodôntico de molares decíduos. O principal objetivo do ECR (I) foi comparar a taxa de sucesso da instrumentação reciprocante à instrumentação manual convencional no tratamento endodôntico de molares decíduos após 24 meses. Como desfecho primário, o sucesso do tratamento após 24 meses foi avaliado por exame clínico e radiográfico. Outros desfechos secundários também foram analisados, tais como: tempo de instrumentação, qualidade da obturação, desconforto após o tratamento e dor pós-operatória. O estudo aninhado ao ECR (II) teve como objetivo analisar os dados disponíveis do ECR observando uma possível associação entre a técnica de instrumentação e outras variáveis (relacionadas às crianças e aos dentes), no tempo de instrumentação e na ocorrência de dor pós-operatória no tratamento endodôntico de molares decíduos. Como resultados principais, observou-se que ambas as técnicas forneceram resultados semelhantes quanto à taxa de sucesso do tratamento endodôntico após 24 meses de acompanhamento. Não foi observada diferença estatisticamente significante entre as técnicas. Também foi observado que, na dentição decídua, o tipo de técnica de instrumentação aplicada influencia no tempo de instrumentação; por outro lado, não parece estar relacionado à ocorrência de dor pós-operatória. Em conclusão, não há diferenças em termos de sucesso no

tratamento endodôntico de molares decíduos instrumentados pela técnica manual ou reciprocante.

Palavras-chave: Endodontia. Tratamento endodôntico. Dentes decíduos.

ABSTRACT

Marques, RPDS. Evaluation of reciprocating instrumentation in endodontic treatment of primary molars [thesis]. São Paulo: University of São Paulo, Faculty of Dentistry; 2021. Corrected Version.

This research aimed to investigate the use of two different root canal instrumentation techniques in endodontic treatment of primary molars. The techniques applied were manual conventional instrumentation, with the use of stainless-steel hand K files, and reciprocating instrumentation, a mechanized instrumentation that applies engine motor-driven files introduced into the root canal while performing reciprocating movements. Thus, a randomized clinical trial with 24 months of follow-up, comparing the results obtained with both techniques was conducted. This thesis comprises two studies related to the main topic: (I) a randomized clinical trial (RCT) with 24 months of follow-up evaluating the success of endodontic treatment, (II) a study nested in an RCT assessing the variables associated with instrumentation time, children's discomfort and postoperative pain in endodontic treatment of primary molars. The main objective of the RCT (I) was to compare the success rate of reciprocating instrumentation and conventional manual instrumentation in endodontic treatment of primary molars after 24 months. As primary outcome, success after 24 months was evaluated by clinical and radiographic assessment. Other secondary outcomes were analyzed, such as: instrumentation time, quality of obturation, discomfort after treatment, postoperative pain. The nested study (II) aimed to analyze the available data from the RCT observing a possible association among the instrumentation technique and other variables (related to the child or to the tooth), on instrumentation time duration and the occurrence of postoperative pain in endodontic treatment of primary molars. The main results were that both techniques provided similar results concerning the success rate of endodontic treatment after 24 months of follow-up. There was no statistically significant difference between the techniques. It was also observed that, in primary teeth, instrumentation technique exerted influence on instrumentation time; on the other hand, it was not related to the occurrence of postoperative pain. In conclusion, there is no difference between the tested techniques concerning the success of endodontic treatment of primary molars.

Keywords: Pulpectomy. Endodontics. Root canal preparation. Primary Teeth.

LIST OF ABBREVIATIONS AND ACRONYMS

95%CI	95% confidence interval
CAPES	Coordination for the Improvement of Higher Education Personnel
CEP	Comitê de Ética em Pesquisa
CNPq	National Council for Scientific and Technological Development
CNS	Conselho Nacional de Saúde
CONSORT	Consolidated Standards of Reporting Trials
CRB	Carmela Rampazo Bresolin
ECR	Ensaio clínico randomizado
FMM	Fausto Medeiros Mendes
FOUSP	University of São Paulo School of Dentistry
HR	Hazard Ratio
ITT	Intention-to-treat
MAN	Manual instrumentation
NiTi	Nickel-Titanium
NMO	Natália Matsuda de Oliveira
OR	Odds Ratio
RCT	Randomized clinical trial
RECIP	Reciprocating Instrumentation
RPSM	Renata Pereira de Samuel Marques
SD	Standard Deviation
WBS	Wong Baker Scale
WOG	Wave One Gold

PREFACE

The present thesis comprises two chapters, presented in the order of development. All of them are based on the findings of the Clinical Trial. The study was submitted and approved by the Research Ethics Committee of the University of São Paulo Dental College (approval #2.291.644) and registered in the database for clinical trials, clinicaltrials.gov on May, 2018 (NCT03453658). CAPES supported the study through CAPES scholarship. Both author and supervisor declare none conflict of interests related to the materials used in the study, or any other materials or manufacturers.

Chapter I and II are being reviewed by the co-authors and will be soon submitted for publication in international journals.

I- Reciprocating Instrumentation for Endodontic Treatment of Primary Molars: 24-Month Randomized Clinical Trial

II- Factors associated with instrumentation time and postoperative pain in Endodontic Treatment of Primary Molars

CONTENTS

1 INTRODUCTION

The main objective of Pediatric Dentistry is to maintain the primary teeth healthy in mouth, performing its functions until the time of its physiological exfoliation and substitution by permanent successors (1). Despite the great advances towards caries diagnosis and preventive dentistry, not rarely, due to different reasons such as dental caries or dental trauma, pediatric dentists face the need of performing endodontic treatment of primary teeth (2).

Among the fields of Dentistry, Endodontics is one of the most linked to technological advances in terms of instruments and equipment. In the last few decades, plenty of new technological developments have helped endodontic treatment to become a much easier procedure for both dentists and patients. Digital radiographs, apex locators, ultrasound, were some of the important advances in Endodontics (3,4,5,6). The use of Nickel-Titanium (NiTi) in endodontic files resulted in instruments with greater flexibility and resistance, able to work closer to the root canal walls. Moreover, NiTi instruments are able to work inside the root canal with rotating movements activated by engine motors, offering greater cutting precision, enabling better cleaning and shaping of the root canal. This concept of mechanized instrumentation is already well-stablished in Endodontics. Several different instrumentation systems have been released on the market, offering different protocols of use. Among those, rotary systems and reciprocating systems stand out (7).

Rotary instrumentation applies the use of a sequence of files that with larger tapers and rotary continuous clockwise movements step by step cleans and shapes the canal (7). Reciprocating systems work in an oscillatory motion with clock-wise and counter-clockwise movements that, allied to its variable taper and tridimensional shape, allows the whole cleaning and shaping of the root canal to be performed with one single file (8).

The appliance of these new technologies in primary teeth suffers a delay caused by the lack of long-term studies to support its use. The best available evidence in Pediatric dentistry concerning mechanized instrumentation regards Rotary systems (9,10,11). However, reciprocating systems brought innovation to endodontic treatment since they stand out for being “single file systems”. The results

of endodontic treatment with the use of Reciprocating systems are outstanding in terms of success, ease of use, comfort for both patient and professional, shortness of clinical time, presenting similar characteristics of transportation, centering ability and debris extrusion (12). Nevertheless, its use in primary dentition still remains under-investigated. There is still not only a lack of long-term randomized clinical trials but also of studies with large samples to endorse its use.

Some aspects of endodontic treatment in primary dentition are still unclear. The occurrence of postoperative pain and the duration of clinical procedure of endodontic treatment in primary teeth are believed to be directly influenced by the instrumentation technique applied. In the endodontic treatment of permanent teeth, the association between postoperative pain and instrumentation technique is a very controversial issue (13,14,15,16). In primary teeth, evidence regarding rotary systems has been related to less occurrence of postoperative pain, but the evidence on this issue with reciprocating systems still lacks.

With regard to clinical time, there is already enough evidence to support that mechanized instrumentation provides faster clinical time than conventional manual instrumentation (11). This is an interesting topic in pediatric dentistry, since many authors already studied the possible relationship between the extension of clinical procedures and pediatric patient behavior (17). As reciprocating is a newly used technique in Pediatric dentistry, we still do not have robust evidence to show its advantage in terms of shortening the treatment.

In this sense, a comparison between the results obtained with the use of reciprocating instrumentation and manual conventional instrumentation in primary teeth would be of great relevance to stablish strong scientific evidences of its use in pediatric dentistry.

2 PROPOSITION

The present research aims to evaluate the use of reciprocating instrumentation in endodontic treatment of primary molars. For this, a randomized clinical trial was designed. The specific objectives were:

I. To evaluate the success of endodontic treatment of primary molars, instrumented by reciprocating system, comparing to manual conventional instrumentation. Other secondary outcomes were evaluated.
II. To evaluate if other variables, in addition to the instrumentation technique, are associated to instrumentation time, children's discomfort and postoperative pain.

The next two chapters were related to each of these specific aims abovementioned.

3 CHAPTER I: MAIN RANDOMIZED CLINICAL TRIAL

Reciprocating Instrumentation for Endodontic Treatment of Primary Molars: 24-Month Randomized Clinical Trial

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Abstract

Introduction: Although reciprocating instrumentation has been extensively studied for permanent teeth, a stronger evidence testing this technique in primary teeth lacks. Therefore, the purpose of this randomized clinical trial was to compare the efficacy of endodontic treatment in primary molars using reciprocating (RECIP) and manual (MAN) instrumentation techniques after 24 months of follow-up.

Methods: In this randomized clinical trial, primary molars with necessity of endodontic treatment were randomly allocated into two groups: MAN or RECIP. Treatments were performed by one experienced dentist, and teeth were filled with a paste composed by Calcium Hydroxide and iodoform and restored with bulk-fill composite resin. Teeth were re-evaluated after 6, 12, 18 and 24 months. The primary outcome was the success of the endodontic treatment evaluated by Cox regression analysis adjusted by the cluster and success rate after 24 months in the intention-to-treat (ITT) population. Instrumentation time, discomfort, post-operative pain and quality of root canal filling (secondary endpoints) were also evaluated.

Results: A total of 151 primary molars in 107 children were included, and 137 were followed-up until 24 months or more. We did not observe statistically significant differences between the groups using Cox regression. Success rate of teeth allocated to MAN group was 57.3% and of RECIP method was 55.3% ($p = 0.792$). However, MAN instrumentation took a longer instrumentation time than RECIP group ($p = 0.005$).

Conclusion: Endodontic treatment of primary molars with the use of RECIP instrumentation is similar in terms of success after 24 months when compared to conventional manual instrumentation.

Keywords: Reciprocating, Root canal instrumentation, Primary Teeth

Introduction

Dental caries is the most common childhood disease worldwide (1) affecting both permanent and primary teeth, and the most severe stages of the disease may provoke dental pulp necrosis, leading to the necessity of endodontic treatment. However, differently from endodontic treatment of permanent teeth, this procedure for primary teeth is not yet based on a strong scientific evidence (2).

The use of mechanized instrumentation is already part of the modern Endodontics routine for permanent teeth. Nevertheless, there is a time gap for updating and applying the technologies already established in Endodontics into the field of Pediatric Dentistry. With regard to primary teeth, some evidence concerning mechanized instrumentation is already available, but the vast majority is related to rotary systems (3,4,5,6). Reciprocating systems are viable alternatives to rotary methods (7), and have also been subject of previous studies in primary teeth (8). Nevertheless, most studies with both rotary and reciprocating techniques evaluated short-term outcomes such as instrumentation time, quality of root canal filling and post-operative pain (3,4,5). Treatment success has also been previously evaluated (6,8,9), but through studies with small sample and high risk of bias (2, 3).

Despite the several studies already available presenting mechanized instrumentation as a feasible option in primary teeth (3,4), there is still a lack of studies evaluating the long-term success of the endodontic treatment. Therefore, the main objective of this randomized clinical trial was to compare the success rate of reciprocating instrumentation and conventional manual instrumentation in endodontic treatment of primary molars after 24 months.

Material and methods

Study design and ethical considerations

This single blind, two arm paralleled group randomized clinical trial with an allocation rate of 1:1 and 24 months of follow-up was carried out to evaluate the success of endodontic treatment performed with the use of two different instrumentation techniques in primary molars: Manual and Reciprocating instrumentation.

This study was approved by the Research Ethics Committee of the University of São Paulo School of Dentistry and registered in the platform clinicaltrials.gov on march 5, 2018 (NCT03453658). The manuscript report followed the Consolidated Standards of Reporting Trials (CONSORT).

Participants

Children aged 3 to 9 years old, who sought dental treatment and with at least one primary molar requiring endodontic treatment were eligible for the study. If the child presented more than one tooth in this condition, all teeth were assessed to be included in the study. Children's parents or legal guardians were asked to sign an informed consent form (Appendix A), and children were asked to assent with their participation in the study (Appendix B).

Tooth presenting clinical and/or radiographic signs of irreversible pulp involvement were included in the study. Pain report, history of abscess or fistula were also considered. Moreover, the presence of pulp exposure due to caries, presence of fistula or swelling were assessed by clinical examination. Teeth with suspected pulp involvement were submitted to periapical radiographs. One examiner assessed radiographic signs of pulp exposure due to caries lesion, previous endodontic lesions in the furcation region or pathological resorption. In the presence of one of these signs, regardless tooth's vitality, the tooth was included in the study.

The exclusion criteria were teeth with: more than 1/3 of root resorption, internal resorption, pulp floor perforation, rupture of the permanent follicle crypt or endodontic lesions involving more than 2/3 of the root. Non-collaborating children in the initial appointment and patients with systemic or neurological disorders were also excluded.

The data were collected at dental office setting. Treatments and assessments were carried out at the School of Dentistry, University of São Paulo, São Paulo, Brazil.

Interventions

All endodontic treatments were performed in a single visit by one operator (RPSM), specialized in Endodontics. After local anesthesia and rubber dam isolation, endodontic access was performed with the use of high-speed round and cylindrical burs. In both groups working length was stablished as radiographic root length minus

2 mm. Initial exploration with #08, #10 and #15 hand files was performed in both groups.

After the access and the initial preparation, another researcher (NMO) would then reveal the group to which the tooth would be allocated, related to the method of instrumentation of the root canals:

- Manual instrumentation (MAN)

Initially in this group, we used a #1 Gates Glidden bur (Dentsply, Maillefer, Ballaigues, Switzerland) to prepare the root canal entrance and the cervical part of the canal. The instrumentation was performed with 21mm stainless steel endodontic hand K-files (Dentsply Maillefer, Ballaigues, Switzerland). A sequence of at least 3 files with increasing diameters was used for each canal, with ISO tip varying from #08 to #35.

- Test group - Reciprocating instrumentation (RECIP)

The RECIP instrumentation was performed with Nickel-titanium Wave One Gold® (WOG, Dentsply Maillefer, Ballaigues, Switzerland) 21mm endodontic files, driven in VDW Silver Reciproc engine Sirona Endo (VDW GmbH, Munich, Germany). WOG Primary files (ISO tip 25, taper.07) were used to shape mesial canals of lower molars and buccal canals of upper molars. WOG medium files (ISO tip 35, taper .06) were used to shape distal canals of lower molars and palatine canals of upper molars. The instrument was introduced into the canal, aiming the working length with minimal apical pressure applying in-and-out (pecking) movements.

For both groups, during the instrumentation, after each file change, the canals were irrigated with 10 ml of 1% Sodium Hypochlorite (Asfer, São Caetano do Sul, SP), aided by ENDO PTC light (Officinalis, São Paulo, SP), a combination of Urea Peroxide,Tween 80 detergent on a Carbowax basis. The final irrigation was performed with 5ml of 1% Sodium Hypochlorite alternated with 10ml of EDTA-T (Officinalis, São Paulo, SP).

Root canals were then dried with paper points (Dentsply Maillefer, Ballaigues, Switzerland) and filled using a commercially available paste composed by calcium Hydroxide and iodoform (Vitapex®, NEO Dental Chemical Products Co., Tokyo, Japan). After that, a layer of Gutta Percha (Dentsply, Petrópolis, Brazil) was placed over the root canal entrances, and the tooth was then definitively restored using a coating with Riva Self Cure® Glass Ionomer Cement (SDI, Bayswater, Australia) and

Filtek Bulk Fill® composite resin (3M ESPE, St.Paul, United States). All operative procedures were detailed and described as Standard Operating Procedures – SOP (Appendix C).

The participants and their guardians were asked to return in one week after the treatment for a clinical follow up. The following assessments would take place in 3 and 18 for a clinical assessment, and after 6, 12 and 24 months for a clinical and radiographic evaluation. Children's parents were also instructed to contact the researcher to schedule an appointment if their children presented any symptoms or complaints.

Outcomes

The primary outcome was the treatment success after 24 months evaluated by clinical and radiographic assessment. Another researcher (CRB), who did not participate in the previous phases of the study and unaware of the allocated groups, conducted the clinical and radiographic evaluations at the follow-ups.

Clinical criteria for determining success were the absence of fistula, edema, pain or pathological mobility, and presence of periodontal health or physiological primary molar exfoliation. Radiographic signs of success were: absence of bone rarefaction in the furcation region, or in the presence of previous endodontic lesion at baseline, reduction or non-evolution of this endodontic lesion, maintenance of the peri-radicular space, absence of pathological root resorption and presence of restorative material isolating the filling paste from the oral cavity. Thus, in the presence of any signs of failure, the treatment was considered unsuccessful, and the time of occurrence of the event (in months) was recorded. In the absence of these signs after the last follow-up, or in cases of physiological primary molar exfoliation, treatment was considered successful.

Other secondary outcomes were also considered.

- Instrumentation time: The operating time from immediately after rubber dam isolation until the completion of root canal filling was recorded with a digital chronometer.

- Quality of obturation: This outcome was evaluated by a blind assessor (CRB), who classified the obturations as underfill, optimal fill and overfill, according to a criteria previously described (10).
- Discomfort after treatment: Wong-Baker face scale (WBS) was used to assess the discomfort immediately after the treatment (11). Immediately after the treatment was finished, the assistant showed the scale to the child and asked: “Which of these faces reflects how you feel after treating your tooth?”.
- Late postoperative pain: 48 hours after the endodontic treatment, the operator made a phone call to the children’s parents, asking questions regarding the presence of pain (yes or no), edema or fistula (yes or no), and necessity of analgesic medication intake (yes or no).

Both primary and secondary outcomes were described in the protocol register prior to the beginning of the participants’ inclusion. The cost efficacy, also described in the protocol, will be analyzed further due to its particular nature.

Sample calculation

The sample size calculation was based on the primary outcome. A type 1 error of 5%, a power of 80% and a two-tailed hypothesis were considered for the estimation. We anticipated a success rate of 78% for manual instrumentation, considering a previous clinical trial still with unpublished results (NCT02216942), and a minimally significant difference of 25% between the groups. With these parameters, we reached a number of 42 teeth per group. Adding 20% to this number due to the fact that each child could contribute with more than one tooth (cluster effect), and adding another 20% to contemplate possible drop-outs, a minimum number of 75 teeth per group was obtained. No interim analysis was planned due to the long time for the outcomes to occur.

Randomization and allocation

The unit of randomization was the tooth, with an allocation rate of 1:1. The randomization strategy was stratified by presence of endodontic lesions and in permuted blocks (4, 6 or 8 samples), and the sequence was generated on the website www.sealedenvelope.com .

The sequence generated were enclosed in individual opaque envelopes numbered sequentially considering the different stratum. If the child had more than

one tooth included in the study, the order of the treatments was defined by chance. The allocated group was disclosed by an external researcher (NMO) when the included tooth was isolated, with the pulp chamber accessed, previously to the instrumentation procedure.

Blinding

Due to the different characteristics of the two treatments, the participants, their parents and the operator were not blinded. Nevertheless, the outcome assessor (CRB) who conducted the clinical and radiographic evaluations in the different follow-up periods was blinded.

Statistical analysis

The unit of analysis was the tooth, and intention-to-treat approach was used. Drop-outs were handled by conditional imputation, considering the variables ‘group’ and ‘presence of lesion’.

The comparison of success of the endodontic treatment (primary outcome) between groups was performed through survival analysis, using Cox regression analysis adjusted by the cluster. As some follow-ups were delayed due to the pandemic, we considered the last time of follow-up for each sample. Hazard ratio (HR) values and respective 95% confidence intervals (95%CI) were obtained. Due to an imbalance in baseline characteristics (sex, age group, type of tooth and dental arch), sensitivity analyses adjusted by these variables, as well as presence of endodontic lesion in the included tooth were also performed.

Treatment success was also analyzed considering the results obtained at the 24 months follow-up, using multilevel logistic regression for this comparison. Unadjusted and adjusted analyses were also carried out. Sensitivity analysis using per protocol approach was also conducted for the primary endpoint.

Secondary outcomes were analyzed using multilevel linear regression analysis (instrumentation time), multilevel multinomial regression analysis (quality of obturation), and multilevel logistic regression analysis (discomfort after the treatment, pain reported after 48 h, post-operative swelling and analgesic medication intake after treatment). Adjusted analysis by sex, age group, type of tooth and dental arch were also performed.

Subgroup analysis considering the presence or absence of endodontic lesions in the included teeth was conducted using Cox regression adjusted by the cluster and multilevel logistic regression comparing treatment success between the groups. All analyses were performed using a statistical package (Stata 15.0, Stata Corp, College Station, USA), and the level of significance was set at 5%.

Results

Recruitment period went from November 2017 to August 2018. The follow-ups occurred normally from February 2018 to March 2020, but from March to July, 2020 the study was suspended due to the COVID-19 pandemic. The last follow up appointments were concluded from August to October, 2020. In summary, 14 participants were not followed-up until at least 24 months (attrition rate of 9.3%). From the 137 stay-ins, 92 children were re-evaluated after 24 months, 22 participants returned after 25 or 26 months, 18 after 27 or 28 months, and 5 after 29 months. No differences were observed between the groups considering the participants who were followed-up after 24 months ($p = 0.624$, by chi-square test).

The overall flow chart with the participants included in the study with the reasons for the drop-outs is presented in Figure 1. We included 151 teeth from 107 children. From these children, 53 (49.5%) were girls, 51 (47.7%) were 3 to 5 years old and 56 (52.3%) were 6 to 9 years old. The mean age (standard deviation) of the participants was 5.6 (1.3) years old. The baseline characteristics of the teeth included are presented in Table 3.1.

The analyses of the secondary outcomes are presented in the Table 3.2. Instrumentation time spent with RECIP instrumentation was about 4 min shorter than with MAN instrumentation, and this difference was statistically significant in both unadjusted and adjusted analysis (Table 3.2). No differences between the groups were observed related to discomfort, late post-operative pain and quality of root canal filling (Table3.2).

In the main analysis of the primary outcome with the ITT population, we observed a similar success rate between groups in both unadjusted and adjusted Cox regression analysis (Table 3.3). The same trends were observed considering the success rate after 24 months in the multilevel analyses, that did not consider the time of failure occurrence (Table 3.3). Sensitivity analysis with the per protocol population

corroborated this similar success rate between the groups in both Cox and multilevel regression analyses (Table 3.3).

The stratified analysis considering the presence or absence of endodontic lesions also showed absence of significant differences considering the tested groups (Table 3.5). However, we observed that failure was more frequent in RECIP group in teeth without previous endodontic lesions. On the other hand, in teeth presenting signs of previous endodontic lesions, failure rate was higher in MAN group (Table 3.5).

Treatment failure reasons were described in table 3.4. Rupture of alveolar bone crypt was the most frequent reason of failure, and was around twice more frequent in the RECIP group. The second more frequent occurrence was restoration failure (Table 3.4). No severe nor moderate adverse events (such as allergic reactions, post-operative edema, or intense pain, etc.) were observed or reported. Mild discomfort was referred by some children, possibly due to the effect of clamps on the gingiva during rubber dam isolation. The latter occurred similarly in both groups.

Discussion

To strengthen the evidence regarding the use of mechanized instrumentation for endodontic treatment of primary teeth, we compared the success of endodontic treatment after 2 years using manual or reciprocating techniques through a randomized clinical trial. We observed similar success rates obtained with both methods with no significant differences between instrumentation techniques. Therefore, reciprocating instrumentation could be an alternative to be used in the endodontic treatment of primary teeth.

This similarity in the efficacy was also observed in previous studies using other mechanized techniques for root canal instrumentation, mainly with rotary files (6, 9). As regards the reciprocating method, one clinical trial investigated the treatment success after 12 months, also presenting similar efficacy with the methods (8). However, most previous clinical trials were conducted with a small sample (8, 9) and a short follow-up (6, 8, 9). Moreover, these studies presented high or unclear risk of bias (3, 4). Therefore, the strength of our study is the low risk of bias and adequate sample size and time of follow-up.

Restoration failure was an usual reason associated to endodontic treatment failure (about 37%). This is similar to the findings of some earlier studies (12-14). A possibility to minimize this kind of failure would have been the use of stainless-steel crowns, although no differences were observed comparing its use with bulk fill composite resin restorations in a recent clinical trial (15).

An interesting trend observed in our subgroup analysis was that the failure rate obtained in teeth with no endodontic lesion at the baseline was slightly higher reciprocating instrumentation. On the other hand, in primary molars with endodontic lesions, treatment performed with reciprocating instrumentation had higher success rate, although not statistically significant. We could speculate that the mechanized instrumentation could be more efficacious in reducing the microbial contamination or improving the canal shaping, although there is no evidence of these effects in previous studies (3,4). However, findings obtained from subgroup analysis should be interpreted with caution, and further clinical trials using only primary molars with endodontic lesions should be designed to clarify this issue.

Considering children's discomfort and the variables related to the postoperative pain, we also observed a similarity between the techniques, differently from previous studies that observed least postoperative pain for rotary techniques (16, 17). Other discrepancy is related to the quality of the obturation, that was superior for mechanized methods (3). In our study, both techniques provided similar scores regarding this outcome.

Nevertheless, corroborating previous findings (3, 4), the instrumentation time was significantly shorter (around 4 min) with the reciprocating compared to manual technique. This difference is consistent with previous studies that compared rotary and manual instrumentation, that found an overall difference varying from about 3.5 min (4) and 5 min (3) between the techniques. Furthermore, a clinical trial comparing reciprocating and manual methods found a difference of 4 min, favoring the mechanized technique (8).

A limitation of our study, which could explain the similarity between the techniques for most outcomes, is that the treatments were conducted by an experienced clinician, specialized in Endodontics. Differences between the instrumentation techniques could be more evident in a more pragmatic context, when the endodontic treatments are performed by general dentists or less experienced pediatric dentists.

Another problem was that the time of follow-up was delayed in some children because the COVID-19 pandemic, with the last recall reaching 29 months for some participants. This problem may have aroused the treatment failure rate, since failure occurrence was slightly more frequent than observed in previous studies (3, 4). However, this protocol deviation probably did not influence the comparability between techniques since the delays were balanced, and the statistical analysis of the primary endpoint took this delay into account.

Therefore, considering the similarity between success rates and shorter instrumentation time provided by the reciprocating instrumentation, the clinicians could opt to use this instrumentation technique in their daily practice. However, the costs involved in the endodontic treatment of primary teeth using reciprocating system may be high, even considering the reduced instrumentation time. The economic analysis of this study will be considered in a further manuscript. Another relevant point concerns the preferences of the operator. Perhaps a great number of pediatric dentists do not have appropriate skills to use reciprocating techniques, and therefore, they could prefer to conduct the endodontic treatment with conventional manual files. On the other hand, with the establishment of mechanized instrumentation in Endodontics, there is the possibility of dentistry schools adopting mechanized instrumentation since graduate courses in a future nearby. In this sense, reciprocating technique is proved to be an acceptable alternative to the root canal instrumentation in primary teeth.

Conclusions

In conclusion, the success of endodontic treatment of primary molars using reciprocating instrumentation is similar to the one obtained with the use of manual instrumentation after 24 months of follow-up.

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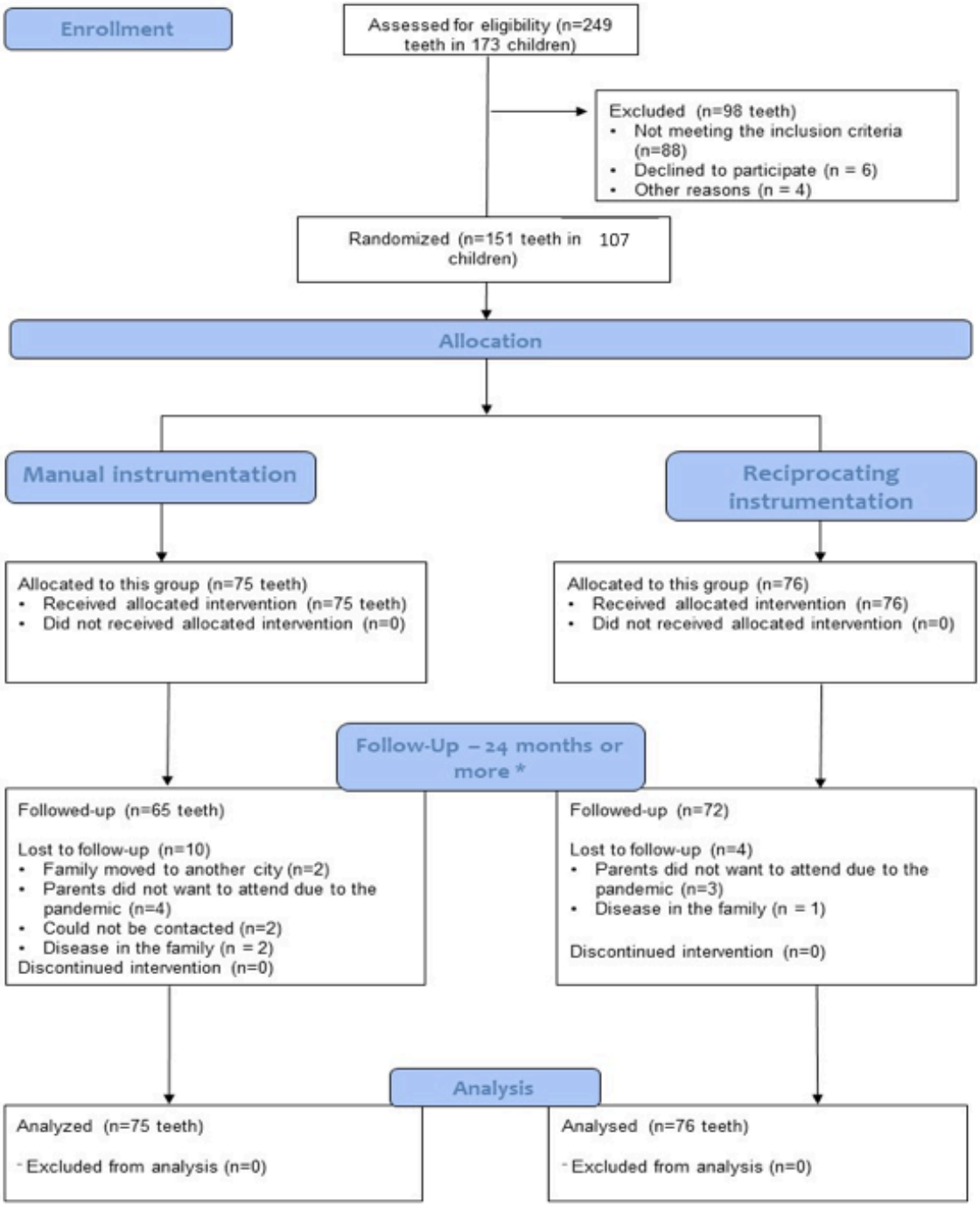
Figure 3.1- Consolidated Standards of Reporting Trials study flowchart of participants enrolled, followed, and analyzed.



Source: The author.

Table 3.1 - Baseline characteristics of the teeth included in the study

Baseline characteristics	Randomized teeth		Included sample	
	Manual N(%)	Reciprocating	Stay-ins	Drop-outs
	N (%)	N (%)	N	N
N total	75	76	137	14
Trial group				
Manual			65	10
Reciprocating			72	4
Sex	N (%)	N (%)		
Male	33 (42.9)	44 (57.1)	73	4
Female	42 (56.8)	32 (43.2)	64	10
Age				
3 to 5 years old	32 (43.2)	42 (56.8)	65	9
6 years old or more	43 (55.8)	34 (44.2)	72	5
Tooth type				
1st Molar	35 (56.5)	27 (43.5)	59	3
2nd Molar	40 (44.9)	49 (55.1)	78	11
Dental arch				
Lower	44 (45.8)	52 (54.2)	84	12
Upper	31 (56.4)	24 (43.6)	53	2
Presence of endodontic lesion				
No	38 (50.7)	37 (49.3)	69	6
Yes	37 (48.7)	39 (51.3)	68	8

* No differences were observed between groups considering drop-outs and stay-ins (p = 0.118, calculated by logistic regression adjusted by cluster)

Source: The author.

Table 3.2 - Secondary outcomes evaluated at the baseline after endodontic treatment of primary molars using manual instrumentation (n=75) and reciprocating instrumentation (n=76)

	Manual	Reciprocanting	p	p [§]
Clinical time (min)			0.005 *	0.013
Mean (SD)	40.0 (7.6)	36.3 (8.8)		
Discomfort after treatment – N (%)			0.271 [†]	0.161
No	48 (64.0)	55 (72.4)		
Yes	27 (36.0)	21 (27.6)		
Pain reported after 48 hours – N (%)			0.695 [†]	0.625
N (%)				
No	58 (77.3)	58 (76.3)		
Yes	17 (22.7)	18 (23.7)		
Post-operative swelling – N (%)			0.891 [†]	0.323
No	73 (97.3)	72 (94.7)		
Yes	2 (2.7)	4 (5.3)		
Analgesic medication intake after treatment – N (%)			0.190 [†]	0.217
No	64 (85.3)	58 (76.3)		
Yes	11 (14.7)	18 (23.7)		
Obturation quality – N (%)			0.625 [‡]	0.246
Optimal filling	35 (46.7)	36 (47.4)		
Underfilling	22 (29.3)	18 (23.7)		
Overfilling	18 (24.0)	22 (28.9)		

SD = Standard deviation; IR = Interquartile range
* p value calculated by linear regression with standard error adjusted by the cluster
[†] p value calculated by logistic regression with standard error adjusted by the cluster
[‡] p value calculated by multinomial logistic regression with standard error adjusted by the cluster
[§] p value adjusted by tooth type, arch, sex and age of the child.

Source: The author.

Table 3.3- Intention-to treat analysis (n = 151) of success in endodontic treatment (primary outcome) of primary molars instrumented by manual or reciprocating techniques

Treatment groups	Survival analysis			
	Unadjusted HR (95%CI)	**Unadjusted p value**	**Adjusted HR (95%CI)**	**Adjusted p value ***
Intention-to-treat analysis				
Manual	1.00		1.00	
Reciprocating	0.93 (0.55 to 1.57)	0.789	0.89 (0.51 to 1.57)	0.697
Per protocol analysis				
Manual	1.00		1.00	
Reciprocating	0.92 (0.55 to 1.55)	0.765	0.88 (0.50 to 1.55)	0.656

	Failures at 24 months of follow-up			
Treatment groups	**Success N (%) *(95%CI)***	**Failure N (%) *(95%CI)***	**Unadjusted p value**	**Adjusted p value ****
Intention-to-treat analysis				
Manual	43 (57.3) *(45.1 to 68.7)*	32 (42.7) *(31.3 to 54.8)*	0.792	0.971
Reciprocating	42 (55.3) *(43.5 to 66.5)*	34 (44.7) *(33.5 to 66.5)*		
Per protocol analysis				
Manual	37 (56.9) *(43.5 to 69.3)*	28 (43.1) *(30.6 to 56.4)*	0.982	0.693
Reciprocating	41 (56.9) *(44.9 to 68.2)*	31 (43.1) *(31.8 to 55.1)*		

HR = Hazard ratio; 95% CI = 95% confidence interval

* p value calculated by Cox regression adjusted by the cluster, adjusted by sex, age, tooth type, dental arch and presence of lesion

** p value calculated by multilevel logistic regression, adjusted by sex, age, tooth type, dental arch and presence of lesion

Source: The author.

Table 3.4 - Reasons of failure of endodontic treatments according to groups

Failure reasons	Manual	Reciprocating
	N (%)	N (%)
Restoration failure	3 (10.7)	5 (16.1)
Fistula or abscess	7 (25.0)	2 (6.4)
Rupture of follicle bone crypt	5 (17.9)	14 (45.2)
Fistula + Rupture of follicle bone crypt	3 (10.7)	4 (12.9)
Restoration failure + fistula	5 (17.9)	2 (6.4)
Restoration failure + Rupture of follicle bone crypt	4 (14.3)	3 (9.8)
Reason not assessed	1 (3.5)	1 (3.2)
Total number of failures	28 (100.0)	31 (100.0)

Source: The author.

Table 3. 5 - Intention-to-treat subgroup analysis considering the presence of endodontic lesion and the success of endodontic treatment of primary molars using manual or reciprocating techniques

Survival analysis	Hazard Ratio (95% Confidence interval)	p
Teeth with no endodontic lesion		
Manual	1.00	0.533
Reciprocating	1.32	
	(0.55 to 3.14)	
Teeth with endodontic lesion		
Manual	1.00	0.202
Reciprocating	0.66	
	(0.34 to 1.25)	

Failure after 24 months of follow-up	Success N (%)	Failures N (%)	Odds Ratio (95% Confidence interval)	p
Teeth with no endodontic lesion				
Manual	29 (79.3)	9 (23.7)	1.00	0.187
Reciprocating	23 (62.2)	14 (37.8)	1.96	
			(0.72 to 5.33)	
Teeth with endodontic lesion				
Manual	14 (37.8)	23 (62.2)	1.00	0.275
Reciprocating	19 (48.7)	20 (51.3)	0.31	
			(0.04 to 2.51)	

Source: The author.

4 CHAPTER II – STUDY NESTED IN THE RANDOMIZED CLINICAL TRIAL

Factors associated with instrumentation time, children's discomfort and postoperative pain in Endodontic Treatment of Primary Molars

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Abstract

Background: In addition to the technical steps, other tooth- and child-related variables that could influence instrumentation time and the occurrence of postoperative pain in endodontic treatment of primary teeth have not been studied. **Aim:** To evaluate the influence of instrumentation technique and other factors on instrumentation time, discomfort and postoperative pain in endodontic treatment of primary molars. **Design:** Children aged 3 to 9 years with primary molar with pulp involvement were included. These teeth were treated using manual (MAN) or reciprocating instrumentation (RECIP). Other explanatory variables related to the teeth and children were also evaluated. The outcomes were instrumentation time, discomfort and postoperative pain. Instrumentation time was compared by multilevel linear regression. Discomfort reported by children after the treatment procedure and postoperative pain was assessed through a phone call to children's parents, 48h later. Association was evaluated through multilevel logistic regression. **Results:** RECIP offered a statistically significant shorter instrumentation time (p=0.005). Treatment made in upper molars took longer time than in lower teeth. No statistically significant associations were observed between discomfort and postoperative pain and the instrumentation technique applied. **Conclusion:** Instrumentation conducted with reciprocating system and treatment in lower primary molars are faster than MAN instrumentation and treatment in upper molars, respectively. Moreover, the type of instrumentation technique applied does not exert influence on discomfort and postoperative pain.

Introduction

Endodontic treatment in primary teeth is a common procedure for pediatric dentists, but there is a lack of strong scientific evidence concerning some steps of this procedure (1). Children discomfort, the occurrence of postoperative pain and the extension of instrumentation time are among the unanswered questions around endodontic treatment of primary teeth.

Previous studies have demonstrated that mechanized methods require shorter instrumentation time than manual instrumentation not only in permanent (2) but also in primary teeth (2-7). However, other variables not related to the technique and that could be able to influence the instrumentation have not yet been investigated, such as presence of endodontic lesion, anatomical characteristics of certain dental groups, dental position on the arch, or characteristics related to the child, such as sex and age.

For example, in the endodontic treatment of permanent teeth, the anatomical characteristics of some dental groups are considered to hinder root canal instrumentation, contributing to a longer instrumentation time. It can be observed in permanent teeth that endodontic treatment of anterior and premolar teeth is easier to perform and often presents more successful results than molar teeth treatments (8). Nevertheless, to our knowledge, no similar studies with primary teeth were published.

The same gap of knowledge can be observed considering children's discomfort during endodontic treatment procedure or considering the postoperative pain after treatment. The relationship between the use of mechanized instrumentation and the occurrence of postoperative pain has been studied in permanent teeth, leading to controversial results (9,10). In primary teeth there is still a lack of strong evidence concerning this topic, but some authors have stated that mechanized instrumentation provoked less postoperative pain when compared to manual instrumentation (6,7,11,12).

With regard to the other variables related to postoperative pain, however, the literature is scarce. Some authors related that the sex of patient is associated to the occurrence and duration of postoperative pain (9), but in a study with endodontic treatment of permanent teeth. A previous study showed that endodontic treatment in children did not provoke higher levels of dental anxiety or worse behavior than other types of treatment. These authors observed that children's age was associated with

dental anxiety; however, they did not investigate discomfort or postoperative pain provoked by the procedures (13).

Instrumentation techniques apart, there is a paucity of studies investigating factors associated to instrumentation time, discomfort and postoperative pain in the endodontic treatment of primary teeth. Therefore, the aim of this study was to evaluate the association of tooth- and child-related variables, including the instrumentation method, with outcomes such as instrumentation time, discomfort reported by the children immediately after the treatment and postoperative pain, in children submitted to endodontic treatment of primary molars.

Methods

Study design

This longitudinal study is nested in a randomized clinical trial designed to compare the success rate of two methods of endodontic instrumentation in primary molars. A single blind, randomized clinical trial, with two parallel arms was approved by the Research Ethics Committee of University of São Paulo School of Dentistry under protocol number 2.291.644.151 and registered in the platform ClinicalTrials.gov (NCT03453658), on May, 2018. More details of the randomized clinical trial and the analysis of primary and other secondary outcomes will be published elsewhere.

The present study is focused on the association of independent variables with instrumentation time and the discomfort related to endodontic treatment of primary teeth. These were secondary outcomes in the main clinical trial.

Participants and setting

Patients aged between, 3 and 9 years, who looked for dental treatment in our dental school and with at least one tooth with necessity of endodontic treatment were eligible for the study. All treatments were conducted at our dental school, and the inclusion of the participants went from November, 2017 till August, 2018.

Children's primary molars with suspect of pulp involvement were initially evaluated through clinical and radiographic examination. To be included in the study, teeth should present signs of irreversible pulp damage, considering information obtained in the anamnesis (report of pain, abscess or fistula), clinical signs (presence of pulp exposure by caries, fistula or abscess) and radiographic signs of pulp damage

(pulp exposure and/or presence of endodontic lesion, pathological root resorption). Previous endodontically treated teeth, teeth presenting more than 2/3 of root resorption, internal resorption, perforation or rupture of permanent germ crypt, not cooperative patients and patients with special needs were not included in the study.

If the child presented more than one tooth fulfilling the inclusion criteria, they would all be included in the study. Therefore, the analysis was conducted considering the teeth, and the cluster nature of the sample was considered in the analysis. The sample size was estimated in 150 molars, and this estimation was based on the primary outcome of the clinical trial (success of the endodontic treatment) and an allocation rate of 1:1 considering the instrumentation methods (trial groups).

All endodontic treatments were performed in a single visit by one operator, a PhD student also specialist in Endodontics (RPSM), previously trained for all steps of the study.

After topic and local anesthesia, rubber dam isolation was applied. At this moment, the assistant (NMO) set the chronometer (Oregon Scientific, Portland, USA) on and instrumentation time started to be recorded. The root canals were then accessed with high-speed diamond-coated burs (#1014, #1016, #1014L, Endo Z) (Dentsply, Maillefer, Ballaigues, Switzerland), then initially explored with a manual K-file #10 until working length, defined as 2mm less than radiographic root canal extension. Then, the allocated group was disclosed by the assistant.

For manual group (MAN), the root canal instrumentation was performed using manual K-files (Dentsply, Maillefer, Ballaigues, Switzerland). The canals were initially explored with the use of #08 to #15K files. The instrumentation followed up to 2 more files, achieving approximately K file # 30 in the buccal canals of maxillary molars and mesial canals of mandibular molars and # 35 in the palatine canals of maxillary molars and distal canals of mandibular molars.

For the reciprocating instrumentation group (RECIP), the instrumentation was conducted using Nickel-titanium Wave One Gold® (WOG) 21mm reciprocating files (Dentsply Sirona, York, Pennsylvania, United States) activated by a VDW Silver Reciproc engine motor, Sirona Endo (VDW GmbH, Munich, Germany). After an initial exploration of the root canal with #10 and #15 hand K-files (Dentsply Maillefer, Ballaigues, Switzerland), in the presence of a canal irrigant, WOG files were introduced into the canal, with short 3 mm amplitude strokes in a gentle inward motion to passively advance the file. Copious irrigation, recapitulation with a #10K-

File and new irrigation was performed, repeating this penetration movement until working length was reached.

All teeth were irrigated with 5 ml of 1.0% sodium hypochlorite (Asfer, São Caetano do Sul, SP) delivered in a syringe with a 27-gauge needle (Ultradent Products Inc, South Jordan, UT). Appropriate tips (Navi-Tips®, Ultradent Products Inc, South Jordan, UT) were used to aspirate and dry the canals. As a final irrigation, 3ml of EDTA 17% was alternated with 3 ml of 1,0% sodium hypochlorite (Asfer, São Caetano do Sul, SP). Paper points (Dentsply, Maillefer, Ballaigues, Switzerland) were used to dry the canals. All teeth were then filled with Vitapex® paste (NEO Dental Chemical Products Co., Tokyo, Japan), and a layer of Guta-Percha was placed sealing the root canal entrance orifices in the pulp chamber. At this point the chronometer was stopped, recording the considered final instrumentation time. Teeth restauration was performed using a layer of GIC Riva Self Cure® (SDI, Bayswater, Australia), adhesive system Single Bond Universal® (3M ESPE, St.Paul, USA) and Filtek Bulk Fill®(3M ESPE, St.Paul, USA) composite resin. After rubber dam removal, a final periapical radiograph of the tooth was obtained obeying the same standards of the initial radiograph.

Outcome and explanatory variables

Three different outcome variables were considered in this study: instrumentation time, children's discomfort provoked by the treatment, and postoperative pain.

Instrumentation time was assessed by the dental assistant, who would start the digital chronometer (Oregon Scientific, Portland, USA) immediately after rubber dam isolation was in place and would stop it right after the complete filling of the canal. This is a quantitative variable measured in minutes.

Discomfort provoked by treatment was assessed immediately after the endodontic procedure, through Wong-Baker visual faces scale (14). This instrument is graduated in 6 faces, ranging from a very happy and smiley face that represents "no hurt", to a very sad and crying face, representing the answer "hurts worst" (14). The faces scale was shown to the children by the dental assistant (NMO), with the question: "Which one of these faces represents how you feel after treating your

tooth?". The variable was dichotomized considering no hurt (first face) versus any other face that represents a range varying from "hurts little bit" to "hurts worst".

To assess late postoperative pain after 48 hours, through a phone call, the first researcher (RPSM) asked the child's parents or legal guardians whether the child had related any kind of pain or complaint and if analgesic medication intake was needed. These answers were combined in a dichotomous variable, considering no pain for two negative answers or pain occurrence when the parents answered yes for at least one of those questions.

The explanatory variables were related to the children or treated teeth. Variables related to the children were sex (male or female) and age (3 to 5 years old and 6 years old or more). The considered variables related to the tooth were the applied instrumentation technique (manual or reciprocating), tooth type (first or second primary molar), dental arch (mandibular or maxillary molars), and presence of endodontic lesion (yes or no).

Statistical methods

To deal with the cluster nature of the sample, multilevel analyses were conducted considering two levels: children (2^{nd} level) and teeth (1^{st} level). For instrumentation time, data was firstly submitted to Shapiro-Francia and Levene test to evaluate normality and homogeneity of variances, respectively. As a normal and homocedastic distribution was verified, multilevel linear regression was conducted to evaluate the association of the explanatory variables and instrumentation time. With this procedure, linear regression coefficients and standard errors were calculated.

For discomfort provoked by the procedure, answers were dichotomized and the association with the explanatory variables was analyzed by multilevel logistic regression analysis. This procedure permitted the derivation of odds ratio (OR) and respective 95% confidence intervals (95%CIs). Association with postoperative pain was also evaluated by multilevel regression analysis.

For all outcomes, association with explanatory variables was firstly evaluated by univariate regression. Variables with a p value lower than 0.20 were tested through multiple analysis, but only variables with p value lower than 0.05 were kept in the final model. Data was analyzed with the use of Stata 15.0 (Stata Corp., College Station, USA), considering a level of significance of 0.05.

Results

We included 107 children, with at least one eligible tooth. From these children, 54 were boys (50.5%) and 53 (49.5%) were girls; 51 (47.7%) were 3 to 5 years old and 56 (52.3%) were 6 to 9 years old. The mean age (standard deviation - SD) of the participants was 5.6 (1.3) years old.

As children could have more than one tooth included, a total of 151 teeth were endodontically treated. The instrumentation technique was performed according to the allocated group, being 75 teeth instrumented with manual technique, and 76 with reciprocating method. The distribution of these teeth according to other explanatory variables can be derived from the Table 4.1.

In table 4.1, the mean (SD) of instrumentation time according to different variables was shown. The frequency of explanatory variables according to the discomfort reported by the children and occurrence of postoperative pain are also presented in the Table 4.1.

In the univariate analysis, we found that reciprocating instrumentation spent significantly less time than the manual instrumentation. Moreover, treatments performed in teeth located in upper dental arch and in older children required longer instrumentation time than treatments in lower arch and in younger children, respectively (Table 4.2).

In the multiple analysis, association between children's age and instrumentation time was not significant, probably due to a collinearity with children's age. Actually, we observed that children aged from 3 to 5 years had 42.7% of maxillary primary molars treated, while children aged 6 or more years old presented 65.5% of maxillary teeth ($p = 0.014$ by chi-square test adjusted by the cluster). Therefore, in the multiple analysis, we found that treatments performed with reciprocating instrumentation and in lower dental arch spent less time compared to manual instrumentation and treatments performed in maxillary primary molars (Table 4.2).

With regard to discomfort provoked by the treatment procedure, the instrumentation technique did not influence children's response, since no significant difference was observed in the univariate analysis. At the same way, other explanatory variables were not significantly associated with this outcome. In the multiple analysis with variables presenting a p value lower than 0.20, no variable was significantly associated (Table 4.3). Likewise, no explanatory variables were

associated with the occurrence of postoperative pain in both univariate and multiple analysis (Table 4.3).

Discussion

Although endodontic treatment in primary teeth is an extensively investigated issue, most studies are focused on factors related to the technical steps of the treatment (1,6,7,15) evaluating different outcomes, such as instrumentation time and postoperative pain. However, few studies have investigated the influence of other variables on these outcomes. Therefore, this longitudinal study nested in a randomized clinical trial was proposed to evaluate if variables related to the treated teeth, including instrumentation technique, or related to the children could influence the instrumentation time, discomfort reported by the children and postoperative pain. We observed that, in addition to the use of reciprocating instrumentation, treatments conducted in mandibular primary molars were faster than treatments of maxillary primary molars.

Previous in vitro and in vivo studies have observed that endodontic treatment of primary teeth performed with rotary instruments are usually faster than treatments with manual instrumentation (2,6,7). With regard to reciprocating systems, although less studies have been published, this tendency is similar, with reciprocating instrumentation spending less clinical time than instrumentation with manual endodontic files (3,5).

The analysis made in the main clinical trial and in the present study corroborated those previous findings. In our study, reciprocating instrumentation was nearly 4 minutes faster than manual instrumentation, a similar result to a recent trial in primary teeth evaluating reciprocating instrumentation (3), and slightly better when compared to rotary systems (1), that were 2 minutes faster than manual instrumentation. This difference is probably because the majority of rotary systems are multi-file systems. Reciprocating instrumentation, on the other hand, are single-file systems, enabling the clinicians to prepare the whole canal using only one instrument, providing a faster procedure.

In addition to the technique, we also observed in the univariate analysis that the instrumentation was faster in younger children and in teeth positioned in the mandibular molars. With regard to the dental arch, this finding is understandable, considering that mandibular molars require not only direct and easier access, but

also an easier instrumentation itself, due to anatomical reasons. The faster instrumentation in younger children, however, was an unexpected result. Nevertheless, when we added these two variables in the multiple models, we observed a collinearity. Analyzing the relationship between involved teeth and children's age, we found a higher proportion of maxillary teeth in older children. Therefore, in the final regression model, we opted to keep the variable dental arch, because its association with the instrumentation time is more plausible. Actually, a higher proportion of caries occurrence in lower primary molars for younger children was observed (16,17).

Considering the discomfort reported by the children, immediately after the procedure, no differences were observed neither among instrumentation techniques, nor for other explanatory variables. We found a trend that older children were less likely to report some discomfort, although this association was not statistically significant. Regards other dental procedures, previous studies have observed that younger children are more likely to report higher degrees of discomfort (13,18,19). However, to investigate if younger children present more complaints related to endodontic treatment than older children, a higher sample would be necessary. This is a limitation of our study, since it was designed as a clinical trial, and sample size calculation was done related to the primary endpoint of the trial (success rate of the endodontic treatment after 24 months).

Furthermore, no differences were observed in terms of postoperative pain in the period of 48 hours after the procedure in relation to the instrumentation technique. Previous studies using rotary instrumentation for endodontic treatment of primary teeth showed that this method provoked less postoperative pain than manual instrumentation (10,12). With regard to the reciprocating technique, the method used in the present research, no previous studies in primary teeth have assessed this variable. In permanent dentition, there is no consensus about the occurrence of postoperative pain with the use of manual or mechanized instrumentation. Some authors stated that reciprocating instrumentation may cause more postoperative pain than manual or other types of mechanized techniques (20) while others claim that one of the advantages of using reciprocating technique would be the lower occurrence of postoperative pain (21,22). A recently published systematic review has demonstrated no differences related to postoperative pain comparing rotary and reciprocating instruments (23). However, in pediatric dentistry, there is still a lack of

strong evidence on the influence of instrumentation methods and other variables on the occurrence of postoperative pain (1).

Therefore, it was observed that the instrumentation method and the position of the teeth in the upper or lower arch influenced the instrumentation time, but no variables were significantly associated with discomfort or postoperative pain. However, this study was nested in a randomized clinical trial. Hence, the research was not designed to evaluate directly the association of the explanatory variables on the considered outcomes of the present study. On the other hand, the study strength is the fact that this is the first study to investigate the association of variables related to the teeth and patients in addition to the instrumentation technique. More robust studies should be conducted to investigate these factors, as well as other possible variables that could influence these outcomes.

Conclusions

In conclusion, the use of reciprocating instrumentation provides shorter clinical time than manual instrumentation. Likewise, endodontic treatment performed in lower molars demands shorter clinical time than in upper molars. Nevertheless, the type of instrumentation technique applied and characteristics related to the teeth or the children do not exert influence neither on discomfort reported by children nor on postoperative pain occurrence.

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Table 4.1 - Instrumentation time and discomfort according to explanatory variables

Explanatory variables	Time of instrumentation (min)	Discomfort provoked by the treatment N (%)		Postoperative pain N (%)	
	Mean (SD)	No	Yes	No	Yes
Tooth-related variables (n = 151 teeth)					
Type of instrumentation					
Manual	40.0 (7.6)	48 (64.0)	27 (36.0)	58 (77.3)	17 (22.7)
Reciprocating	36.3 (8.8)	55 (72.4)	21 (27.6)	52 (68.4)	24 (31.6)
Tooth type					
1st molar	37.5 (7.7)	44 (71.0)	18 (29.0)	43 (69.4)	19 (30.6)
2nd molar	38.6 (8.9)	59 (66.3)	30 (33.7)	67 (75.3)	22 (24.7)
Dental arch					
Lower arch	36.9 (8.6)	61 (63.5)	35 (36.5)	66 (68.8)	30 (31.3)
Upper arch	40.4 (7.7)	42 (76.4)	13 (23.6)	44 (80.0)	11 (20.0)
Presence of endodontic lesion					
No	38.1 (8.0)	49 (65.3)	26 (34.6)	55 (73.3)	20 (26.7)
Yes	38.2 (8.9)	54 (71.1)	22 (28.9)	55 (72.4)	21 (27.6)
Child-related variables (n = 151 teeth in 107 children)					
Sex					
Girls	38.1 (8.5)	57 (74.0)	20 (26.0)	58 (75.3)	19 (24.7)
Boys	38.2 (8.4)	46 (62.2)	28 (37.8)	52 (70.3)	22 (29.7)
Age group					
3 to 5 years old	35.6 (8.3)	44 (59.5)	30 (40.5)	53 (71.6)	21 (28.4)
6 to 9 years old	40.6 (7.8)	59 (76.6)	18 (23.4)	57 (74.0)	20 (26.0)

SD = Standard deviation; IQ = Interquartile range

Source: The author.

Table 4.2 - Association of explanatory variables and instrumentation time

Explanatory variables	Unadjusted multilevel linear regression coefficient (SE)	p	Adjusted multilevel linear regression coefficient (SE)	p
Type of instrumentation (ref. Manual)				
Reciprocating	-3.67 (1.29)	0.005	-3.34 (1.28)	0.009
Tooth type (ref.: 1st molar)				
2nd molar	0.96 (1.37)	0.483		
Dental arch (ref.: Lower arch)				
Upper arch	3.52 (1.40)	0.012	3.10 (1.38)	0.025
Presence of endodontic lesion (ref.: no)				
Yes	0.25 (1.35)	0.853		
Sex (ref.: girls)				
Boys	0.20 (1.45)	0.891		
Age group (ref.: 3 to 5 years old)				
6 to 9 years old	5.16 (1.36)	<0.001		

SE = standard error

* p value calculated by multilevel linear logistic regression

Source: The author.

Table 4.3 - Association of explanatory variables and discomfort reported by the children after the treatment

Explanatory variables	Discomfort provoked by the treatment		Post-operative pain	
	Unadjusted odds ratio (95%CI)	p *	Unadjusted odds ratio (95%CI)	p *
Group (ref. Manual)				
Reciprocating	0.30 (0.07 to 1.34)	0.114	1.96 (0.64 to 6.00)	0.237
Tooth type (ref.: 1st molar)				
2nd molar	1.70 (0.44 to 6.56)	0.439	0.62 (0.21 to 1.89)	0.402
Dental arch (ref.: Lower arch)				
Upper arch	0.24 (0.04 to 1.36)	0.106	0.45 (0.14 to 1.49)	0.192
Presence of endodontic lesion (ref.: no)				
Yes	0.35 (0.07 to 1.76)	0.204	0.82 (0.27 to 2.46)	0.724
Sex (ref.: girls)				
Boys	2.25 (0.45 to 11.14)	0.321	1.75 (0.51 to 6.07)	0.376
Age group (ref.: 3 to 5 years old)				
6 to 9 years old	0.15 (0.02 to 1.08)	0.060	0.89 (0.26 to 3.04)	0.853

95%CI = 95% confidence intervals

* p value calculated by multilevel logistic regression

Source: The author.

5 FINAL CONSIDERATIONS

Considering all the data available in this thesis, we may conclude that reciprocating instrumentation represents an alternative to manual instrumentation in endodontic treatment of primary molars. The similar results regarding treatment success, discomfort after treatment and the occurrence of postoperative pain presented by reciprocating technique when compared to manual conventional instrumentation, allow us to consider both techniques as good options for endodontic treatment of primary molars. Furthermore, reciprocating instrumentation provides a shorter clinical time than manual instrumentation, which, in Pediatric Dentistry might be of great relevance.

With regard to the occurrence of discomfort after treatment and occurrence of postoperative pain, according to our findings, no relationship neither between the child's sex or age, nor the presence of endodontic lesion was observed. Likewise, both types of instrumentation technique applied provided similar results of discomfort and postoperative pain. On the other hand, the results showed that instrumentation time was influenced not only by the type of instrumentation technique, but also by the position of the teeth on the arch: upper molars required more clinical time to be treated than lower molars.

It must be considered that the use of reciprocating systems implies greater expenses on equipment and instruments than manual instrumentation, even considering the reduced instrumentation time. In this sense, the economic analysis of this research, as well as the preferences of the operator are of great relevance for the decision making. Data for economic evaluation was also collected in the present research, and are being analyzed. Some pediatric dentists, or clinicians might need a learning period to have the appropriate skills to use reciprocating techniques, and for this reason, prefer to conduct the endodontic treatment with conventional manual files. On the other hand, with the establishment of mechanized instrumentation in Endodontics, there is the possibility of dentistry schools adopting mechanized instrumentation since graduate courses in a future nearby.

Since it is a long-term and a study with a large sample, it provides scientific evidence strong enough to support that reciprocating technique is an acceptable alternative technique to root canal instrumentation in primary teeth. In this sense, the decision whether or not to incorporate the use of reciprocating technique in the endodontic treatment of primary teeth may be up to clinicians. Economic evaluations will provide an important additional information on this topic.

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[1]According to Vancouver style

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APPENDIX A - Consent form

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

- **Título:** "Avaliação da instrumentação mecanizada no tratamento endodôntico de dentes decíduos - Ensaio Clínico Randomizado"
- **Pesquisador Responsável:** Prof. Dr. Fausto Medeiros Mendes
- **Instituição/Departamento**: FOUSP – Odontopediatria
- **Telefone**: (11) 9 9153-9355 ou (11) 3091-7835
- **Local da Pesquisa:** São Paulo/SP.

Por esse documento, o Sr(a) está sendo convidado para que seu (sua) filho (a) participe voluntariamente da nossa pesquisa. A qualquer etapa desse estudo você terá acesso aos profissionais responsáveis, abaixo citados, para o esclarecimento de qualquer dúvida. Todas as etapas desta pesquisa foram elaboradas de acordo com as normas que regulamentam pesquisas envolvendo seres humanos, atendendo à resolução n° 466, do Conselho Nacional de Saúde/Ministério da Saúde- Brasília -DF.

Pesquisadores envolvidos na pesquisa: FAUSTO MEDEIROS MENDES (Pesquisador Responsável), RENATA PEREIRA DE SAMUEL MARQUES, BRUNA LORENA PEREIRA MORO, LAURA REGINA ANTUNES PONTES, CARMELA RAMPAZO BRESOLIN, CACIO MOURA-NETTO, ANA CAROLINA VOLPI MELLO-MOURA.

O objetivo do nosso trabalho é fazer o tratamento de canal dos dentes que necessitem deste tipo de tratamento para comparar duas técnicas diferentes ao longo do tempo. Para avaliar isso nós precisamos fazer o tratamento do canal e acompanhar esse dente durante um tempo, em retornos que serão agendados com o senhor.

Primeiramente será realizado um exame, na clínica da FOUSP do qual participarão: o pesquisador, a criança e seu responsável. O pesquisador realizará uma radiografia para avaliar a real necessidade do tratamento. Caso o dente se encaixe na pesquisa e o paciente e o responsável concordem em participar do trabalho, daremos início ao tratamento.

Para fazer o tratamento de canal é obrigatório que se faça anestesia local para que a criança não sinta nenhum desconforto ao se colocar o isolamento absoluto (borracha que impede que qualquer material caia na boca do paciente). O tratamento será realizado de forma padronizada: as crianças serão distribuídas em dois grupos de tratamento: grupo de tratamento manual e grupo de tratamento mecanizado. No grupo de tratamento manual, o canal será tratado pela técnica convencional (com uso de limas), no grupo de tratamento mecanizado, o canal será tratado pela técnica que utiliza limas acionadas por um motor para instrumentar os canais. Ao terminar, faremos mais uma radiografia para controle. A criança participante da pesquisa precisará retornar periodicamente quando chamada (3 meses, 6 meses, 1 ano e 2 anos após a conclusão do tratamento).

As crianças participantes da pesquisa que não ficarem paradas para o tratamento ou se debaterem durante o mesmo poderão ser seguradas pelos responsáveis, para se fazer os procedimentos com segurança e para que ela não se machuque. Participantes da pesquisa que possuirem outros problemas dentários detectados no exame serão orientados e encaminhados a atendimentos odontológicos específicos da FOUSP. Os tratamentos não terão custo algum.

Como risco inerente a esta pesquisa, as crianças participantes poderão se sentir cansadas e por serem crianças pequenas, poderão chorar. Entretanto, é preciso fazer o tratamento por se tratarem de dentes que podem vir a infeccionar. O tratamento de canal é o tratamento indicado, e tem grande chance de sucesso, entretanto nos casos de falha do tratamento endodôntico, os participantes da pesquisa serão encaminhados para as clínicas da FOUSP para receber o tratamento necessário.

O participante da pesquisa terá direito a indenização em caso de danos decorrentes do estudo além de ressarcimento de gastos decorrentes da pesquisa.

Todas as dúvidas dos participantes da pesquisa ou suas perguntas relacionadas à pesquisa serão esclarecidas, sendo que o responsável tem a liberdade de retirar o consentimento a qualquer momento e deixar de participar do estudo caso se sinta cansado ou incomodado por qualquer motivo. O tratamento integral da criança será garantido, mesmo com a interrupção de sua participação na pesquisa por sua própria vontade ou caso o estudo seja interrompido.

Como principal benefício ao participante da pesquisa pode-se citar a possibilidade de ter acesso a informações e tratamentos que se baseiam em pesquisas científicas. Além disso, os participantes da pesquisa receberão orientações sobre higiene oral e tratamento odontológico GRATUITO por, no mínimo, 2 anos.

Não será revelada, sob nenhuma hipótese a identidade do participante bem como de seu responsável, mesmo na divulgação dos resultados. Os pesquisadores garantem o caráter confidencial das informações e o participante da pesquisa recebe o compromisso do pesquisador responsável de utilizar os dados coletados somente para esta pesquisa. Ao final da pesquisa, os participantes receberão os resultados encontrados. Os resultados obtidos serão publicados independentemente de serem favoráveis a uma ou a outra técnica.

Havendo qualquer problema ou dúvida durante a realização da pesquisa, os pesquisadores responsáveis podem ser encontrados pelos telefones (11) 9 9153-9355 ou (11) 3091-7835, ramal 208, para falar com Fausto Medeiros Mendes.

Se houver dúvidas em relação aos aspectos éticos da pesquisa, contatar o CEP-FOUSP - Comitê de Ética em Pesquisa da Faculdade de Odontologia da Universidade de São Paulo – Avenida Professor Lineu Prestes nº 2227 – 05508-000 – São Paulo – SP – Telefone (11) 3091.7960 – e-mail cepfo@usp.br. O horário de atendimento ao público e pesquisadores é: de segunda a sexta-feira das 9 as 12h e de 14 as 16h (exceto em feriados e recesso universitário). O Comitê é um colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade para contribuir no desenvolvimento da pesquisa dentro de padrões éticos. (Resolução CNS nº 466 de 2012).

Este documento foi elaborado em duas vias, sendo uma do participante da pesquisa e a outra do pesquisador responsável.

Declaro ter sido suficientemente informado a respeito das informações que li ou que foram lidas para mim, descrevendo a pesquisa "**AVALIAÇÃO DA INSTRUMENTAÇÃO MECANIZADA NO TRATAMENTO ENDODÔNTICO DE DENTES DECÍDUOS – ENSAIO CLÍNICO RANDOMIZADO**".
Concordo voluntariamente com os termos da pesquisa e autorizo a participação na pesquisa do menor _____. Estou consciente de que poderei retirar o meu consentimento a qualquer momento, sem penalidades ou prejuízo ou perda de qualquer benefício que eu possa ter adquirido neste serviço.

NOME DO PARTICIPANTE DA PESQUISA: _____

NOME DO RESPONSÁVEL_____**RG:**_____

ASSINATURA DO RESPONSÁVEL: _____

Data _____/_____/_____

Declaro que obtive de forma apropriada e voluntária o consentimento Livre e esclarecido deste participante da pesquisa ou representante legal para a participação neste estudo.

PESQUISADOR RESPONSÁVEL: FAUSTO MEDEIROS MENDES

ASSINATURA: _____

Data _____/_____/_____

APPENDIX B - Assent form

TERMO DE ASSENTIMENTO

Nesta pesquisa, a dentista vai cuidar de um dentinho seu que está cheio de bichinho da cárie.

O bichinho da cárie entra no dente quando a criança come muito doce e não escova muito o dente. Quando o bicho está lá dentro, ele come o dentinho e faz doer. Então, a dentista tem que tirar o bichinho do dente.

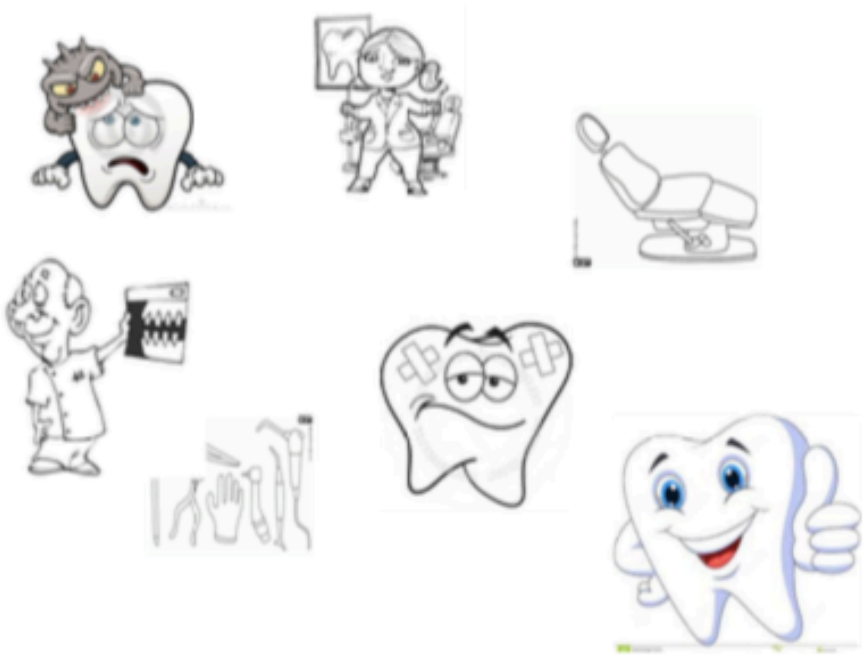
Prá isso, ela vai precisar da ajuda de alguns materiais muito legais: a máquina de retrato de dente, o espelho, a pinça, a cama elástica, o avião, o anelzinho, o algodão, a massinha...

Primeiro a dentista vai tirar um retrato do dente, depois faz o dentinho dormir prá não acordar o bicho, daí vai colocar uma cama elástica prá segurar o bicho quando ele sair, vai passar o aviãozinho prá limpar bem limpinho o dente e depois vai tirar o bicho usando uma varinha de pescar.

Prá tampar o buraquinho que o bichinho fez, a tia vai usar uma massinha da cor do dente e com uma luz azul especial vai fazer essa massinha ficar pronta. Daí vamos tirar outro retrato e acabou.

Depois, a dentista vai te chamar aqui de novo só prá tirar retrato!

Vamos tratar o seu dentinho?



_____

Escreva seu nome na linha acima se concordar em receber o tratamento.

APPENDIX C – Standard Operation Procedures (SOP)

PROCEDIMENTO OPERATÓRIO PADRÃO

1. Organização criteriosa da mesa clínica;
2. Condicionamento do paciente;
3. Radiografia para diagnóstico.
4. Determinação do comprimento de trabalho. Com a radiografia de diagnóstico em mãos, determinar-se-á o comprimento aparente do dente na radiografia (CAD). Em seguida, respeitando-se o bizel da rizólise, serão subtraídos 2mm como margem de segurança. Com isso, será encontrado o Comprimento de Trabalho, que corresponderá ao CAD – 2mm.
5. Anestesias tópica e local.
6. Antissepsia intrabucal com solução de clorexidina 0,12% (crianças acima de 6 anos)
7. Isolamento absoluto com grampo metálico e dique de borracha. DISPARAR O CRONÔMETRO
8. Remoção de tecido cariado.
9. A cirurgia de acesso será realizada com brocas esféricas diamantadas de tamanho compatível com o dente #1014, #1016, #1014L(KG Sorensen, Cotia, SP) e para a determinação da forma de contorno e conveniência e remoção do restante do teto da câmara, utiliza-se a broca tronco-cônica sem corte na ponta, ENDO-Z (Dentsply, Maillefer, Ballaigues, Switzerland).
10. Remoção da polpa coronária (se presente) com curetas de dentina e irrigação com solução de hipoclorito de sódio a 0,5% (Officinalis, São Paulo, SP) através das pontas Navi Tips® (Ultradent, South Jordan, USA). A aspiração será realizada com as cânulas Cappilary Tips e White Mac – Ultradent® (Ultradent, South Jordan, USA).
11. Localização e preparo da entrada dos canais radiculares com sonda exploradora reta.
12. Exploração dos canais radiculares com lima tipo Kerr #08 #10 (Dentsply, Maillefer, Ballaigues, Switzerland).
13. Quando o preparo químico cirúrgico for realizado com instrumentação manual: será realizado o preparo das entradas dos canais radiculares com brocas Gates Glidden #1 ou #2. A partir da primeira lima de diâmetro compatível com o conduto, serão utilizadas mais duas outras limas de diâmetro subsequente. Em seguida um "recuo escalonado anatômico" será realizado até a lima #K40, com o objetivo de dar conicidade ao preparo facilitando a penetração do material obturador. Quando o preparo químico cirúrgico for realizado com instrumentação reciprocante, será utilizada a lima reciprocante Wave One Gold Primary 25/.07 (Dentsply Sirona, York, Pennsylvania, United States) nos canais mesiais dos molares inferiores e nos canais vestibulares dos molares superiores. Nos canais Distais dos molares inferiores e Palatinos dos molares superiores, será utilizada a lima reciprocante Wave One Gold Medium 35/.06 (Dentsply Sirona, York, Pennsylvania, United States). As limas reciprocantes serão acionadas pelo motor VDW Silver Reciproc, Sirona Endo (VDW GmbH, Munique, Alemanha).

14. A cada troca de lima a irrigação com Hipoclorito de sódio será alternada com Endo PTC gel (Officinalis, São Paulo, SP), levado em seringas até a entrada dos condutos.
15. Ao final da instrumentação será efetuada a irrigação alternada com Hipoclorito de Sódio 0,5% - EDTA 17%- Hipoclorito de Sódio 0,5%.
16. Finalizado o preparo químico-cirúrgico, os condutos serão secos com o auxílio de pontas finas de sucção (Capillary tips- Ultradent®) e em seguida com cones de papel absorvente.
17. A obturação dos condutos será realizada utilizando-se a pasta Vitapex® (NEO Dental Chemical Products Co., Tóquio, Japão), padrão ouro em termos de material obturador de canais radiculares de dentes decíduos. O método de introdução da pasta será a utilização da seringa e agulhas disponíveis no próprio kit da pasta VITAPEX®, sem o auxílio de brocas lentulo ou similares.
18. O selamento coronário será realizado em camadas: em contato com a pasta obturadora, é colocado uma porção de Guta Percha em bastão (Dentsply, Petrópolis, Brasil). Sobre a Guta Percha, após a limpeza da câmara pulpar com bolinha de algodão embebida em álcool, será aplicada uma camada de cimento ionômero de vidro Riva Self Cure® (SDI, Bayswater, Austrália) e sobre este será realizado o condicionamento com ácido com ácido fosfórico gel a 37% (Biodinâmica, Ibiporã, Brasil) do remanescente coronário (esmalte / dentina), lavagem, secagem rápida, aplicação do adesivo Single Bond Universal® (3M ESPE, St.Paul, Estados Unidos), polimerização e restauração com e resina composta Filtek Bulk Fill®(3M ESPE, St.Paul, Estados Unidos).
19. Radiografia final
20. Orientações ao paciente.

APPENDIX D – Assessment file:

Universidade de São Paulo
Faculdade de Odontologia

FICHA DE TRATAMENTO ENDODÔNTICO

DE DENTES DECÍDUOS

DRA. RENATA PEREIRA DE SAMUEL MARQUES

PRONT:_____

DENTE :_____

GRUPO: ( )A ( )B

PACIENTE:_____

RESPONSÁVEL: _____**PARENTESCO:**_____

ENDEREÇO _____

CEP:_____ **CIDADE:**_____

TELEFONES:( )_____( )_____( )_____

EXAME CLÍNICO

- **Diagnóstico:** ( )Polpa Viva ( )Necrose SEM rarefação ( ) Necrose COM rarefação furca/ápice
- **Dor** ( )ausente ( )provocada ( )espontânea
- **Edema** ( )ausente ( )intraoral ( )extraoral
- **Condição do dente:** ( )Hígido ( )restaurado ( )cariado
- **Fístula** ( )ausente ( ) presente
- **Pólipo Pulpar** ( )ausente ( )presente
- **Mobilidade patológica:** ( ) ausente ( ) presente
- **Abcesso**: ( )ausente ( ) presente
- **Alteração do contorno gengival** ( )presente ( )ausente
- **Cavidade de Classe** _____

EXAME RADIOGRÁFICO

- **Reabsorção radicular:** ( ) integras ( ) reabsorção 1/3 da raiz ( ) reabsorção > 1/3 da raiz
- **Espaço LP**: ( ) íntegro ( ) aumentado
- **Rarefação óssea posterior**: ( ) ausente ( )< 1/3 área da furca ( ) entre 1/3 e 2/3 da furca
- **Rizólize**: ( )ausente ( )presente < 1/3 da raiz ( ) presente >1/3 da raiz

1

PRONT:_____

DENTE :_____

GRUPO: ( )A ( )B

DIAGNÓSTICO: ( ) POLPA VIVA ( ) NECROSE PULPAR

( )ABSCESSO ( )FÍSTULA ( )LESÃO ( ) PÓLIPO

GRAMPO:_____

ODONTOMETRIA:

CR ( )____ REFERÊNCIA _____

CR ( )____ REFERÊNCIA _____

CR ( )____ REFERÊNCIA _____

CR ( )____ REFERÊNCIA _____

MANUAL	RECIPROCANTE
GRUPO A	GRUPO B
CR ( ) _____	CR ( ) _____
CR ( ) _____	CR ( ) _____
CR ( ) _____	CR ( ) _____
CR ( ) _____	CR ( ) _____

SOL. IRRIGADORA: ( )HIPOCLORITO 1% + EDTA ( )_____

MATERIAL OBTURADOR: ( )VITAPEX

NÚMERO DE SESSÕES: _____

MIC:_____

PROCEDIMENTO RESTAURADOR REALIZADO:

RESTAURAÇÃO: ( ) IONÔMERO DE VIDRO /MARCA:_____

( ) RESINA COMPOSTA/MARCA:_____

TEMPO DE CONSULTA: _____

OBS: _____

_____

2

APPENDIX E – Follow-up assessment file:

DRA. RENATA PEREIRA DE SAMUEL MARQUES

ENDODONTIA EM DECÍDUOS

PRONT. _____

REAV. _____

FICHA DE REAVALIAÇÃO PÓS OPERATÓRIA

DATA: ___/_____/_____

DENTE _____ PRONT._____

GRUPO: ( )A ( )B

SUCESSO ( )

INSUCESSO ( )

OBS:_____

PACIENTE:_____

RESPONSÁVEL: _____PARENTESCO: _____

ENDEREÇO _____

CEP:_____ CIDADE:_____

TELEFONES:( ) _____( )_____( )_____

Exame clínico - SUCESSO ( ) INSUCESSO ( )

Fístula: ( )ausente ( )presente igual ( )presente menor ( )presente maior

Raio x: ( ) sem alteração ( )pasta reabsorvida ( )dente ausente POR EXO ( ) dente esfoliado

Restauração: ( ) presente em bom estado ( ) necessita reparo ( ) necessita substituição-FALHA

Cárie: ( )ausente ( )presente

Dor: ( )ausente ( ) presente provocada ( )presente espontânea

Mobilidade: ( ) ausente ( )presente fisiológica ( )presente patológica

Alteração do contorno gengival: ( )ausente ( ) presente

Edema (fundo de saco): ( )ausente ( )presente

Alteração da coloração coronária: ( ) ausente ( ) presente

Exame radiográfico: SUCESSO ( ) INSUCESSO ( )

Reabsorção radicular: ( ) integras ( ) reabsorção 1/3 da raiz ( ) reabsorção > 1/3 da raiz

Espaço LP: ( ) íntegro ( ) aumentado

Rarefação óssea POSTERIORES: ( ) ausente ( )< 1/3 área da furca ( ) entre 1/3 e 2/3 ( ) > que 2/3 ____mm.

Condição radiográfica geral: ( ) se manteve igual ( )redução da lesão ou formação óssea

( )aumento da lesão sem rompimento de cripta ( )rompimento de cripta

APPENDIX F- Wong Baker Scale

Universidade de São Paulo
Faculdade de Odontologia

TRATAMENTO ENDODÔNTICO DE DENTES DECÍDUOS

DRA. RENATA PEREIRA DE SAMUEL MARQUES

NOME DO PACIENTE:_____ **PRONTUÁRIO** _____

DENTE _____ **DATA:** _____ **GRUPO: ( )A ( )B**

Escala de Faces Wong-Baker

0 1 2 3 4 5

Classificação de dor:

0 - sem dor
1 - 2 - dor leve
3 - dor moderada
4 - dor forte
5 - dor insuportável

ANNEX A – Ethics Committee Approval

FACULDADE DE ODONTOLOGIA USP - SÃO PAULO

Continuação do Parecer: 2.291.644

Conclusões ou Pendências e Lista de Inadequações:

Não constam pendências ou inadequações.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_982808.pdf	15/09/2017 11:53:03		Aceito
Projeto Detalhado / Brochura Investigador	Projeto.pdf	15/09/2017 11:45:21	Fausto Medeiros Mendes	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	tcle.pdf	15/09/2017 11:44:51	Fausto Medeiros Mendes	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	termoassentimento.pdf	27/08/2017 18:28:57	Fausto Medeiros Mendes	Aceito
Declaração de Instituição e Infraestrutura	autorizacao_clinica.pdf	27/08/2017 18:26:07	Fausto Medeiros Mendes	Aceito
Folha de Rosto	folha_de_rosto.pdf	27/08/2017 17:13:27	Fausto Medeiros Mendes	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

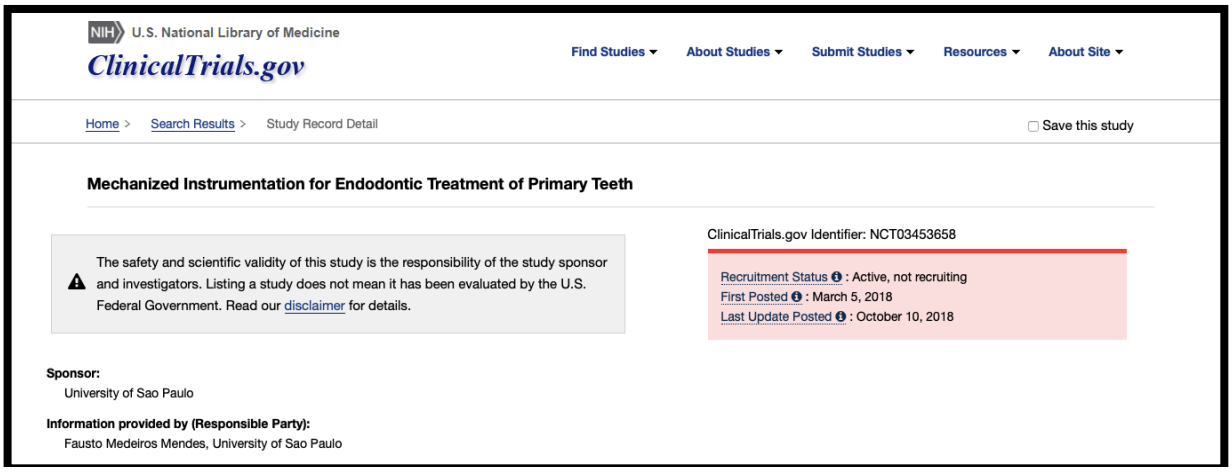
Não

SAO PAULO, 22 de Setembro de 2017

Assinado por:
Maria Gabriela Haye Biazevic
(Coordenador)

Endereço: Av Prof Lineu Prestes 2227
Bairro: Cidade Universitária **CEP:** 05508-900
UF: SP **Município:** SAO PAULO
Telefone: (11)3091-7960 **Fax:** (11)3091-7814 **E-mail:** cepfo@usp.br

ANNEX B – Clinical Trials.gov registration



NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies | About Studies | Submit Studies | Resources | About Site

Home > Search Results > Study Record Detail

Save this study

Mechanized Instrumentation for Endodontic Treatment of Primary Teeth

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03453658

Recruitment Status : Active, not recruiting
First Posted : March 5, 2018
Last Update Posted : October 10, 2018

Sponsor:
University of Sao Paulo

Information provided by (Responsible Party):
Fausto Medeiros Mendes, University of Sao Paulo