Mendes Fausto Medeiros (Orcid ID: 0000-0003-1711-4103)
Lara Juan Sebastian (Orcid ID: 0000-0001-9434-4127)

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

Renata Pereira Samuel Marques[1]; Natalia Matsuda Oliveira[1]; Vanessa Ribeiro Pires Barbosa[1]; Carmela Rampazzo Bresolin[2]; Anna Carolina Volpi Mello-Moura[3]; Juan Sebastian Lara[4]; Tatiane Fernandes Novaes[5]; Fausto Medeiros Mendes[1, *]

[1] Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, São Paulo, Brazil

[2] School of Dentistry, Faculdades Metropolitanas Unidas São Paulo, Brazil

[3] Universidade Catolica Portuguesa, Faculty Dental Medicine, Center for Interdisciplinary Research in Health - SalivaTec Lab, Viseu, Portugal

[4] Department of Cariology, Operative Dentistry and Dental Public Health, Indiana University School of Dentistry, Indiana, USA.

[5] Cruzeiro do Sul University, São Paulo, Brazil

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*** Corresponding author**

Fausto Medeiros Mendes

ORCID ID: 0000-0003-1711-4103

Faculdade de Odontologia da Universidade de São Paulo

Av. Lineu Prestes, 2227

São Paulo – SP – Brazil, Zip Code: 05508-000

Tel: 55 11 3091-7835 Fax: 55 11 3091-7854

E-mail: fmmendes@usp.br

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**Conflict of interest disclosure**

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

**Ethics approval statement and document**

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**Patient consent statement**

Parents and/or caregivers were asked to sign an informed consent form, and children were asked to assent to participate in the research study.

**Permission to reproduce material from other sources**

Not applicable

**Clinical trial registration**

The study was also registered in the platform clinicaltrials.gov on march 5, 2018 (NCT03453658).

**Your co-author details, including affiliation and email address.**

- Renata Pereira Samuel Marques

E-mail: resamuel@gmail.com

ORCID ID: 0000-0002-3686-982X

Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, São Paulo, Brazil

- Natalia Matsuda Oliveira

E-mail: natalia.matsuda.oliveira@usp.br

ORCID ID: 0000-0002-1534-1815

Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, São Paulo, Brazil

- Vanessa Ribeiro Pires Barbosa

E-mail: vanessaribeiropires@hotmail.com

ORCID ID: 0000-0001-8619-1044

Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, São Paulo, Brazil

- Carmela Rampazzo Bresolin

E-mail: carmela_rb@hotmail.com

ORCID ID: 0000-0003-3996-917X

School of Dentistry, Faculdades Metropolitanas Unidas São Paulo, Brazil

- Anna Carolina Volpi Mello-Moura

E-mail: acvmello@gmail.com

ORCID ID: 0000-0002-9420-1721

Universidade Católica Portuguesa, Faculty Dental Medicine, Center for Interdisciplinary Research in Health - SalivaTec Lab, Viseu, Portugal

- Juan Sebastian Lara

E-mail: laraseb@iu.edu

ORCID ID: 0000-0001-9434-4127

Department of Cariology, Operative Dentistry and Dental Public Health, Indiana University School of Dentistry, Indiana, USA.

- Tatiane Fernandes Novaes

E-mail: tatiane.novaes@cruzeirodosul.edu.br

ORCID ID: 0000-0003-1288-6470

Cruzeiro do Sul University, São Paulo, Brazil

- Fausto Medeiros Mendes

E-mail: fmmendes@usp.br

ORCID ID: 0000-0003-1711-4103

Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, São Paulo, Brazil

## Author contributions

ACVM-M, TFN and FMM conceived the study. FMM designed, supervised and was the Principal Investigator of the study. RPSM performed the endodontic treatments. NMO and VRPB were outcome assessors from the immediate outcomes. CRB was the primary outcome assessor. FMM conducted the statistical analysis. RPSM, JSL and FMM drafted the manuscript. All authors contributed to discussions and manuscript review, gave the final approval of the version to be published and agreed to be accountable for all aspects of the work.

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


## Abstract

**Background:** Although reciprocating instrumentation has been extensively studied for permanent teeth, stronger evidence for its use in primary teeth lacks. **Aim:** The aim 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. **Design**: Primary molars with indication of endodontic treatment were randomly into two groups: MAN or RECIP. Treatments were performed and root canals were filled with Calcium Hydroxide and iodoform paste. Teeth were later restored with bulk-fill composite resin and 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 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 were also evaluated as secondary endpoints. **Results:** A total of 151 primary molars in 107 children were included, and 137 were followed-up at 24 months. Success rate of teeth allocated to MAN group was 57.3% and 55.3% for RECIP (p=0.792); MAN instrumentation, however, was more time consuming (p=0.005). **Conclusion:** The efficacy of endodontic treatment in primary molars using reciprocating and manual instrumentation is similar after 24 months.

Trial registered on march 5, 2018 (NCT03453658), in the clinicaltrials.gov platform.

**Keywords**: Pulpectomy, Reciprocating, Root canal instrumentation, Primary Teeth

## Introduction

Dental caries is the most common childhood disease worldwide[1] affecting both permanent and primary dentitions. Untreated advanced caries lesions may lead to infection, swelling, pain, pulp necrosis and other symptoms, indicating the need of endodontic treatment. However, unlike endodontic treatment in permanent dentition, the evidence surrounding root canal treatment in primary teeth is not as strong.[2,3]

The use of mechanized instrumentation is already part of the modern endodontics routine for permanent teeth. Nevertheless, there are several barriers to update, adapt and apply the already established technologies into paediatric dentistry. Some evidence on mechanized instrumentation is already available for primary teeth, however, the vast majority is related to rotary systems. Reciprocating systems are viable alternatives to rotary methods,[3] and have been subject of previous studies in primary teeth.[2,4,5] Still, most studies with both rotary and reciprocating techniques only evaluated short-term outcomes such as instrumentation time, quality of root canal filling and post-operative pain teeth.[2,4,5] Treatment success has also been previously evaluated,[6-8] but through studies with small sample and high risk of bias.[2,5]

Despite the several studies presenting the mechanized instrumentation as a feasible option in primary teeth, [2,5] there is still a lack of studies evaluating the long-term success of endodontic treatment. Hence, the main objective of this randomized clinical trial was to compare the success rate of endodontic treatment in primary molars using reciprocating and conventional manual instrumentation after 24 months.

## Material and methods

### *Study design and ethical considerations*

This randomised clinical trial has been written according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 guideline. The CONSORT checklist was presented as supplemental file, and the CONSORT flowchart sets out the design of the study is presented in the Figure 1.

This single blind, two-arm parallel 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 using two different instrumentation techniques in primary molars: Manual and Reciprocating instrumentation. In the present study, a two-tailed hypothesis was tested considering the primary and secondary outcomes.

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). Initially, we had planned in the protocol a follow-up of 24 months. However, some participants returned for the last recall after this time due to the COVID 19 pandemics. These differences were adjusted in the statistical analysis.

### *Participants*

Children from 3 to 9 years of age, seeking dental care, and with at least one primary molar with indication for endodontic treatment, were eligible for the study. If a child presented more than one molar indicated for root canal, they were assessed for eligibility and inclusion. Parents and/or caregivers were asked to

sign an informed consent form, and children were asked to assent to participate in a research study.

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

Data were collected at a 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 endodontics specialist (RPSM). After local anaesthesia and rubber dam isolation, endodontic access was performed with the use of high-speed round and cylindrical burs. For both groups the working length was stablished at the

radiographic root length minus 2 mm. Initial exploration with #08 or #10 hand files was performed in both groups.

Right after pulp chamber access and initial root canal preparation, another researcher (NMO) revealed the allocation group and procedures were applied accordingly. For manual instrumentation (MAN), a #1 Gates Glidden bur (Dentsply, Maillefer, Ballaigues, Switzerland) was used to allow root canal entrance. 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. On the other hand, reciprocating instrumentation (RECIP) 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 palatal canals of upper molars by introducing them into the canal, aiming the working length with minimal apical pressure applying in-and-out (pecking) movements.

Canals in both groups were irrigated during the instrumentation with 1% Sodium Hypochlorite (Asfer, São Caetano do Sul, SP), aided by ENDO PTC gel (Officinalis, São Paulo, SP) and EDTA-T (Officinalis, São Paulo, SP) in the final irrigation.

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 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.

A week after treatments, participants and their caregivers were asked to return for clinical follow up. Additional clinical assessments were planned after 3 and 18 months, and both clinical and radiographic after 6, 12 and 24 months. Children's caregivers were also instructed to contact the research team if any symptoms occurred.

*Outcomes*

Endodontic treatment success after 24 months, clinically and radiographically assessed, was considered as primary outcome. Follow-up clinical and radiographic evaluations were performed by another researcher (CRB), unaware of the previous recruiting, allocated group and treating phases.

Clinical treatment success was determined in absence of fistula, edema, pain, or pathological mobility. The presence of periodontal health or physiological primary molar exfoliation was also considered as success. Radiographic signs of success were the absence of bone rarefaction in the furcation region, or if in presence of previous endodontic lesion at baseline, its reduction or non-evolution. Also, success was registered if there was maintenance of peri-radicular space, absence of pathological root resorption and presence of restorative material isolating the filling paste from the oral cavity. Consequently, an

unsuccessful treatment was registered when in presence of any sign of failure. The time when the failure was detected (in months) was also recorded.

Other secondary outcomes were also considered: i) Instrumentation time, measured with digital chronometer from immediately after rubber dam isolation until root canal filling completion; ii) Quality of obturations, evaluated by a blind assessor (CRB), by registering them as underfilled, optimal and overfilled, according to a previously described criterion.[9] iii) Discomfort after treatment, using a Wong-Baker face scale (WBS), that was showed to the child right after treatment with the question "which of these faces reflect how you feel after treating your tooth?".[10] iv) Late postoperative pain, assessed by phone after 48 hours of treatment completion, made by an independent and blind assessor (VRPB), who asked questions on the presence of pain (yes/no), edema or fistula (yes/no), and/or analgesic needs (yes/no).

Primary and secondary outcomes were fully described in the registered protocol prior to participants' inclusion. A comparison of the cost efficacy, which was part of the study protocol, will be reported in a future manuscript.

*Sample calculation*

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, considering a comparison between two proportions (chi-square test). We anticipated a success rate of 80% for manual instrumentation, considering a previous clinical trial,[11] and a minimally significant difference of 25% between groups. Fifty-two teeth per group was reached. However, since each child could contribute with more than one tooth (cluster effect), 20% was added to this

number. Also, contemplating possible dropouts an extra 20% was included. Consequently, a minimum of 75 teeth per group was calculated. No interim analysis was planned due to the long time for the outcomes to occur.

*Randomization and allocation concealment*

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

The generated sequence was enclosed in individual opaque envelopes sequentially numbered considering the different stratum. If a child had more than one included tooth, the order of treatment was decided by chance. The allocated group was disclosed by an external researcher (NMO) right after rubber dam isolation and pulp chamber access, and prior to canal instrumentation.

*Blinding*

Procedure blinding in participants, caregivers and operators was not achieved given the differences of both interventions. Nevertheless, the clinical and radiographic follow-up assessor (CRB) was blinded.

*Statistical analysis*

Each endodontically treated molar was defined as the unit of analysis, and the intention-to-treat approach was used. Dropouts were handled by multiple conditional imputation using logistic regression, considering the variables 'group' and 'presence of lesion'.[12]

Treatment success comparison in groups (primary outcome) was performed through survival analysis, using Cox regression analysis, adjusted by the cluster. As some follow-ups were delayed due to the COVID-19 pandemic, the last time of follow-up for each sample was considered. Hazard ratio (HR) values and respective 95% confidence intervals (95%CI) were obtained. An imbalance in baseline characteristics between groups led to the performance of sensitivity analyses adjusted by sex, age group, type of tooth, dental arch and the presence of endodontic lesion at baseline.

Success was also analysed with the 24-month follow-up results, using multilevel logistic regression. Unadjusted and adjusted analyses were also carried out. Sensitivity analysis using per protocol approach was also conducted for the primary endpoint.

Secondary outcomes were analysed using multilevel linear regression analysis (instrumentation time), multilevel multinomial regression analysis (quality of obturation), and multilevel logistic regression analysis (discomfort after 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 periapical lesions in the included teeth was conducted using Cox regression adjusted by the cluster and multilevel logistic regression comparing treatment success between groups. All analyses were performed using 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 as planned from February 2018 to March 2020. However, from March to July 2020 no follow-up examinations were conducted 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 participants who were followed-up until the end of the study, 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 groups considering the participants who were followed-up after 24 months ($p = 0.624$, by chi-square test).

Figure 1 shows the PRIRATE 2020 flowchart including the participants and dropouts. One hundred and fifty-one primary molars from 107 children were included. Fifty-three (49.5%) were girls. Almost half of the sample, (n=51, 47.7%) were 3–5-year-old children whereas 56 (52.3%) were 6 to 9. The participants' mean age (standard deviation) was 5.6 (1.3) years old. The baseline characteristics of the included teeth are presented in Table 1.

Analyses of the secondary outcomes are presented in the Table 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 analyses (Table 2). No differences were observed in relation to discomfort, late post-operative pain, and quality of root canal filling between groups (Table 2).

A similar success rate was observed for both groups in the primary outcome main analysis with the ITT population, in both unadjusted and adjusted

Cox regression analyses (Table 3). Same trends were observed for the success rate after 24 months in the multilevel analyses, that did not consider the time of failure occurrence (Table 3). The sensitivity analyses with the per protocol population corroborated this similarity in both Cox and multilevel regression analyses (Table 3).

No significant differences were also found in the stratified analysis by considering the presence or absence of endodontic lesions (Table 1S). However, failures were more frequent in RECIP teeth without previous endodontic lesions. On the other hand, failure rate was higher in MAN teeth with signs of previous endodontic lesions (Table 1S – Supplemental file).

Reasons for treatment failure are described in Table 4. Rupture of alveolar bone crypt, followed by restoration failure were the most frequent reasons of unsuccess, with the former around twice more frequent in RECIP molars (Table 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 in both groups, possibly due to the effect of clamps on the gingiva during rubber dam isolation.

## Discussion

This study was conducted as an attempt of strengthening the scientific evidence around the use of mechanized instrumentation for endodontic treatment in primary teeth. The success of endodontically treated primary molars using manual and reciprocating techniques was compared after 2 years through a randomized clinical trial. The overall observed success obtained with both methods was around 55%, with no differences between instrumentation

techniques. In this sense, reciprocating instrumentation could be an alternative for root canal treatment of primary teeth.

Efficacy similarities between instrumentation techniques were also observed in previous studies that assessed other mechanized methods – mainly with rotary files - for root canal instrumentation.[6-8] Likewise, one clinical trial investigated the treatment success of reciprocating instrumented teeth after 12 months finding a similar efficacy among groups.[13] Unfortunately, most of the available clinical trials included small samples,[6,8,13] short follow-up periods,[6,8,13] and presented high or unclear risk of bias,[2,5] which are considered the main advantages, and therefore, strengths in the present research.

In the present study, restoration failure was a usual reason associated to endodontic treatment unsuccess (about 37%), matching findings of some earlier studies.[11,14,15,16] 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.[17]

The slightly higher failure rate obtained in the reciprocating instrumented teeth with no endodontic lesions at baseline was an interesting trend observed in the subgroup analysis. Reciprocating treated primary molars with endodontic lesions, on the other hand, presented 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 canal shaping, although there is no evidence of these effects in previous studies.[2,5] In any event, findings obtained from subgroup analysis should be interpreted with caution, and further clinical trials including only primary molars with endodontic lesions should be designed to better understand such trends.

Similarities were also observed between instrumentation groups in terms of children's discomfort and variables related to postoperative pain, contrastingly to previous studies that observed least postoperative pain after the application of rotary techniques.[18,19] Other discrepancy was the obturation quality, that was superior for mechanized methods in previous findings,[2] but was similar in the present study.

Reciprocating instrumentation time was significantly shorter (around 4 min) in comparison to manual instrumentation.[2,5] This difference is consistent with previous studies that compared rotary and manual instrumentation and found an overall difference varying from 3.5 min [5] to 5 min [2] between methods. Furthermore, a clinical trial comparing reciprocating and manual methods found a difference of 4 min, favouring the mechanized technique.[13]

In this study, all endodontic procedures were performed by an experienced endodontist which could explain most outcome similarities between techniques and seen as a limitation. Differences between instrumentation techniques could be more evident in a more pragmatic context when root canal treatments are performed by general dentists or less experienced paediatric dentists.

As mentioned before, the COVID-19 pandemic delayed some follow-up appointments, with the last recall reaching 29 months for some participants. This may have aroused the treatment failure rate, since failure occurrence was slightly more frequent than observed in previous studies.[2,5,11,20] However, this protocol deviation probably did not influence the comparability between techniques since delays were balanced and the primary endpoint statistical analysis took this delay into account.

Other possible limitation is related to the sample size. Although our study is the clinical trials with the largest sample size on this issue,[2,3] the minimal important difference that we used for the sample size calculation was relatively large. On the other hand, the difference in the failure rate between the groups was small, increasing the certainty on the absence of differences considering the instrumentation techniques.

Therefore, given the found similarities in terms of treatment success and the shorter instrumentation time provided by the reciprocating instrumentation, clinicians could use it as an intervention option in their daily practice. However, costs and training are important variables to take into consideration when deciding to use reciprocating systems. Since no information is available for this matter, the economic analysis of the application of both techniques will be published in a future manuscript.

Another relevant point concerns the preferences of the operator. Perhaps a considerable number of paediatric dentists are not trained in the use of reciprocating techniques, and therefore, they would choose manual instrumentation. However, and with the establishment of mechanized instrumentation in Endodontics, Dental schools are implementing mechanized instrumentation in their undergraduate programs which can change the preference choice in a future nearby. In this sense, both manual and reciprocating techniques are acceptable and feasible alternatives for root canal instrumentation in primary teeth.

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.

## Bullet points

*Why this paper is important to paediatric dentists*

- Manual and reciprocating instrumentation in the pulpectomy of primary teeth can be used with similar success rates and safety.
- Instrumentation conducted with reciprocating method can lead to shorter clinical time.
- Since both instrumentation methods are similar, clinicians can opt for their preference choice.

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Table 1. Baseline characteristics of included teeth

| Baseline characteristics | Manual | Reciprocating | With follow-up | 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 participants with follow-up (p = 0.118, calculated by logistic regression adjusted by cluster)

Table 2. Secondary outcomes evaluated at baseline after endodontic treatment of primary molars using manual instrumentation (n=75) and reciprocating instrumentation (n=76)

| | Manual | Reciprocating | 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.

Table 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)* | | |
| Difference | 2.7 (-14.5 to 18.6) | | | |
| **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)* | | |
| Difference | 0.0 (-17.0 to 17.0) | | | |

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

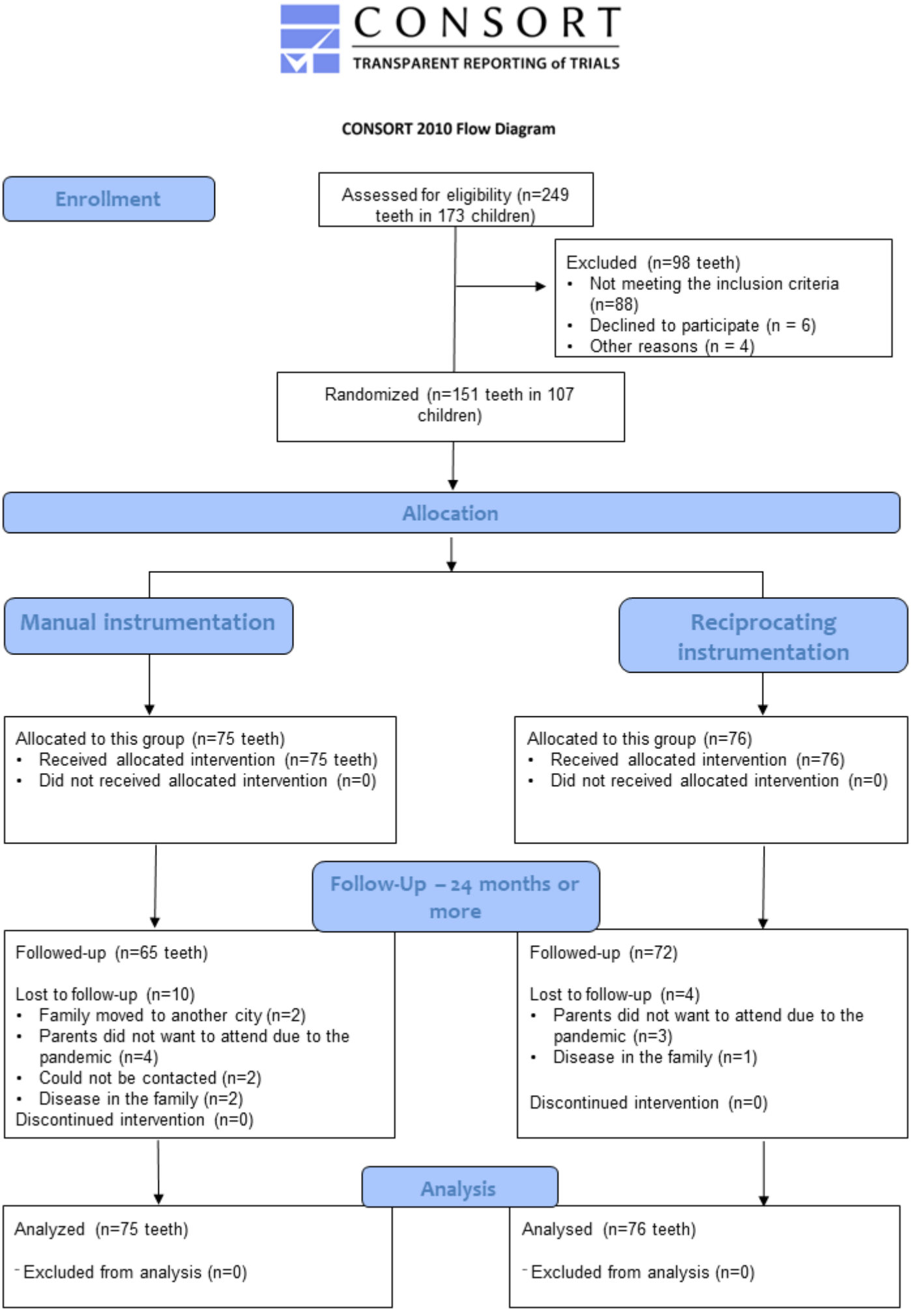
** p value calculated by multilevel logistic regression, adjusted by sex, age, tooth type, dental arch and presence of lesion

Table 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) |

## Figure legends

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) 2010 flowchart

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