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Débora Santos Sityá

AVALIAÇÃO DE PULPECTOMIAS EM MOLARES DECÍDUOS UTILIZANDO DIFERENTES MATERIAIS OBTURADORES: ENSAIO CLÍNICO RANDOMIZADO DE 2 ANOS DE ACOMPANHAMENTO

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Projeto de Dissertação apresentado ao Curso de Mestrado do Programa de Pós-Graduação em Ciências Odontológicas, ênfase em Odontopediatria, da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para obtenção do título de **Mestre em Ciências Odontológicas.**

Orientadora: Profª. Drª Marta Dutra Machado Oliveira

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RESUMO

AVALIAÇÃO DE PULPECTOMIAS EM MOLARES DECÍDUOS UTILIZANDO DIFERENTES MATERIAIS OBTURADORES: ENSAIO CLÍNICO RANDOMIZADO DE 2 ANOS DE ACOMPANHAMENTO

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ORIENTADORA: Dra. Marta Dutra Machado Oliveira

Manter os dentes decíduos na cavidade bucal é muito importante para prevenir danos às dentições decídua e permanente, resultando em distúrbios no desenvolvimento do indivíduo. Em vista disso, em casos de traumatismos ou lesões de cárie extensas com envolvimento pulpar, a pulpectomia tem sido indicada. Ao realizar tratamento endodôntico em dentes decíduos, diferentes materiais vêm sendo empregados, com propriedades e resultados clínicos e radiográficos variáveis. Desse modo, esse trabalho teve como objetivo avaliar clínica e radiograficamente as pulpectomias em molares decíduos inferiores realizadas na clínica de Odontopediatria da Universidade Federal de Santa Maria, comparando diferentes pastas obturadoras. Foram selecionados os pacientes com necessidade de tratamento endodôntico que radiograficamente apresentavam lesão periapical ou em furca, obedecendo a critérios de inclusão e exclusão. Os procedimentos foram realizados de acordo com um protocolo clínico padrão previamente estabelecido e utilizando-se pastas obturadoras diferentes. A amostra foi aleatoriamente dividida em 3 grupos: pasta Guedes-Pinto (Rifocort®, PMCC e iodofórmio); pasta Guedes-Pinto Modificada (Nebacetin, PMCC e Iodofórmio); e pasta de Hidróxido de cálcio espessada com óxido de zinco (hidróxido de cálcio pró-análise, propilenoglicol e óxido de zinco). Os resultados clínicos e radiográficos foram avaliados 30, 60 e 90 dias, 6 meses, 1 ano e 2 anos após realizadas as pulpectomias e não demonstrou-se diferença estatisticamente significante entre os grupos analisados. Dessa forma, podemos considerar as 3 pastas viáveis para utilização na prática clínica gerando uma taxa de sobrevida elevada após 24 meses de acompanhamento dos casos.

Palavras-chave: Dente Decíduo. Obturação do Canal Radicular. Pulpectomia.

ABSTRACT

EVALUATION OF PULPECTOMIES IN MANDIBULAR PRIMARY MOLARS USING DIFFERENT ROOT CANAL FILLINGS: RANDOMIZED CLINICAL TRIAL OF 2 YEARS OF EVALUATION

AUTHOR: Débora Santos Sityá
ADVISOR: Prof. Dra. Marta Machado Dutra Oliveira

To maintain primary teeth in the oral cavity is very important to prevent damage in primary and permanent dentition, resulting in disturbance to development of the individual. In view of this, in trauma cases or extensive caries with pulp involvement, pulpectomy has been indicated. Different materials have been used in endodontic treatment to primary teeth, with different properties and variable clinical and radiographic results. Thus, this study aims to evaluate clinically and radiographically the pulpectomy in mandibular primary molars performed in the clinic of Pediatric Dentistry, Federal University of Santa Maria, comparing different pastes. Children with teeth presenting periapical or furcation injury was select to receive endodontic treatment, in line with inclusion and exclusion criteria. Procedures were performed according to a pre-established standard clinical protocol and using different root filling materials. The sample was randomly divided into three groups: Guedes-Pinto paste (Rifocort®, camphorated paramonochlorophenol (PMCC) and iodoform); Modified Guedes-Pinto paste (Nebacetin, PMCC and Iodoform); and Calcium hydroxide paste thickened with zinc oxide – (Calcium hydroxide P.A., propylene glycol and zinc oxide). Clinical and radiographic results were evaluated at 30, 60 and 90 days, 6 months, 1 year and 2 years after treatment, and no statistically significant difference was found between groups. The clinical assessment was performed regarding pain, swelling, fistula and/or mobility. The radiographic assessment was performed by a single, calibrated and blinded operator regarding the root filling material, according to pre-defined criteria to evaluation. Thus, the three pastes were considered viable for use in clinical practice generating a high survival rate after 24 months of follow-up.

Keywords: Tooth, Deciduous. Root Canal Obturation. Pulpectomy

LISTA DE ANEXOS

SUMÁRIO

1. INTRODUÇÃO

A dentição primária apresenta papel fundamental na alimentação, fonética, relações sociais do indivíduo, desenvolvimento da musculatura e ossos da face e estabelecimento da oclusão funcional (ALENCAR, CAVALCANTI, BEZERRA, 2007). Em vista disso, é indicada a realização do tratamento endodôntico em dentes decíduos diagnosticados com inflamação pulpar irreversível ou necrose pulpar, decorrentes da doença cárie ou traumatismos, para mantê-los em posição no arco dentário de modo a evitar danos às dentições decídua e permanente por perda precoce de um elemento dentário (CUNHA, BARCELOS, PRIMO, 2005; CAMP, 2008; BARJA-FIDALGO et al., 2011).

Ao realizar tratamento endodôntico em dentes decíduos é necessário que se tenha conhecimento das propriedades desejadas do material obturador para dentes decíduos que deve ser reabsorvível, em uma velocidade semelhante à reabsorção fisiológica da raiz do dente, não provocar danos aos tecidos periapicais e ao germe do permanente, ter propriedade antimicrobiana capaz de atingir a grande variedade de microorganismos presentes no complexo radicular de dentes decíduos (PAULA et al., 2014), promover adequado preenchimento e aderência às paredes dos canais radiculares, ser removido facilmente, se necessário, ter radiopacidade, não provocar alteração de cor no dente e ser reabsorvido em caso de extravasamento para os tecidos periapicais. (MANI et al., 2000; CUNHA, BARCELOS, PRIMO, 2005; MELLO-MOURA, CERQUEIRA, SANTOS, 2007; PINTO et al., 2011; ANTONIAZZI et al., 2015)

Estes materiais de preenchimento dos canais radiculares podem ser classificados em três grupos: materiais a base de óxido de zinco e eugenol, pastas iodoformadas e pastas a base de hidróxido de cálcio (CUNHA, BARCELOS, PRIMO, 2005). A seleção do material a ser utilizado deve basear-se nas propriedades de cada substância que o compõe e das evidências científicas que suportam o uso desses materiais.

Pires et al. (2015) avaliaram *in vitro* quatro pastas iodoformadas e três pastas a base de hidróxido de cálcio. Através desse estudo foi possível verificar que as pastas iodoformadas são biocompatíveis, justificando seu uso clínico.

Pinto et al. (2011), comparou os resultados clínicos e radiográficos apresentados por dentes decíduos obturados com pasta de óxido de zinco e eugenol com os obturados com pasta Calen® espessada com óxido de zinco, visando aumentar o tempo de reabsorção do material e melhorar sua consistência. Os resultados de 18 meses de acompanhamento mostraram que os dois materiais obturadores utilizados apresentaram taxas de sucesso estatisticamente similares.

Em uma revisão de literatura de 26 anos, Mello-Moura, Cerqueira e Santos (2007) afirmaram que a pasta Guedes-Pinto, material obturador mais utilizado nas universidades brasileiras (BERGOLI et al., 2010) apresenta resultados clínicos, histológicos, microbiológicos e de citotoxicidade melhores quando comparados com outras pastas obturadoras.

Entretanto, o material base para manipulação desta pasta, Rifocort®, foi removido do mercado, deste modo tem-se realizado pesquisas laboratoriais e clínicas para avaliar os materiais substitutos deste fármaco em pastas iodoformadas. Antoniazzi et al. (2015) analisou a atividade antimicrobiana de pastas iodoformadas compostas por Nebacetin, gel de digluconato de clorexidina 2% ou Maxitrol. A partir de seus resultados pode-se concluir que todos materiais obtiveram propriedades antimicrobianas similares quando comparadas com a pasta Guedes-Pinto.

Contudo, segundo Barcelos et al. (2011), em uma revisão sistemática, poucos estudos com metodologia adequada foram realizados para avaliar as diferenças entre as pastas obturadoras. Barja-Fidalgo et al. (2011) também afirmaram que há um pequeno número de estudos clínicos randomizados, comparando as pastas de óxido de zinco com outros materiais obturadores.

Em adição, Smaïl-Faugeron et al. (2014), realizaram uma revisão sistemática de ensaios clínicos randomizados comparando as diferentes pastas obturadoras utilizadas em pulpectomias de dentes decíduos entre si, dentre elas: Vitapex (hidróxido de cálcio + iodofórmio), pasta de óxido de zinco e eugenol, pasta de hidróxido de cálcio, Metapex (hidróxido de cálcio + iodofórmio), Endoflas (hidróxido de cálcio + óxido de zinco e engenol + iodofórmio), RC Fill (óxido de zinco e eugenol + iodofórmio), 3Mix (ciprofloxacin + metronidazole + minocycline). A partir dos resultados obtidos pode-se concluir que, devido ao limitado número de ensaios clínicos randomizados sobre o assunto, não há evidência científica suficiente para determinar a superioridade clínica e radiográfica de um material obturador para ser utilizado em pulpectomias de dentes decíduos.

Dessa forma, tendo em vista que ainda não existe consenso quanto ao melhor material obturador para pulpectomias de dentes decíduos, é necessária a realização de estudos clínicos controlados, bem delineados, de longo prazo de acompanhamento, para a obtenção de evidência a respeito do desempenho clínico e radiográfico desses materiais, justificando, assim, a realização desta pesquisa.

2. ARTIGO - EVALUATION OF PULPECTOMIES IN MANDIBULAR PRIMARY MOLARS USING DIFFERENT ROOT CANAL FILLINGS: RANDOMIZED CLINICAL TRIAL OF 2 YEARS OF EVALUATION

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EVALUATION OF PULPECTOMIES IN MANDIBULAR PRIMARY MOLARS USING DIFFERENT ROOT CANAL FILLINGS: RANDOMIZED CLINICAL TRIAL OF 2 YEARS OF EVALUATION

Sityá, DS, Pires, CW, Rocha, RO, Ardenghi, TM, Oliveira, MDM

Summary

Background. There is no consensus for the best root filling paste for primary teeth. This subject has not been elucidated because is one of the major doubts in the clinical practice of pediatric dentistry because of the lack of qualified clinical studies that produce useful information for clinical discussions based on evidence. **Aim**. To compare clinical and radiographic success rates of three root filling pastes, two iodoform pastes and one calcium hydroxide paste, in pulpectomized primary molars. **Methods**. This is a double-blind, randomized, and controlled clinical trial. 111 mandibular primary molars, from 95 children (average 5,66 years old), were randomly allocated into three groups according to the root filling paste: Guedes-Pinto paste (Rifocort®, camphorated paramonochlorophenol (PMCC) and iodoform); Modified Guedes-Pinto paste (Nebacetin, PMCC and Iodoform); and Calcium hydroxide paste thickened with zinc oxide (Calcium hydroxide P.A., propylene glycol and zinc oxide). The clinical (pain, edema, fistula and mobility) and radiographic follow-up were performed 30, 60 and 90 days, 6 months, 1 year and 2 years after endodontic treatment. **Results**. The survival rate of endodontically treated teeth was, on average, 22 months, with no statistically significant diference between groups. For all groups there was clinical improvement of all symptoms 30 days after pulpectomy. **Conclusion**. The three root filling pastes used can be considered suitable for use in clinical practice in pediatric dentistry presenting high success rate after 24 months.

Keywords: Pulpectomy; Root Canal Obturation; Tooth, deciduous.

Introduction

Endodontic treatment in primary teeth is indicated in cases diagnosed with irreversible pulpal inflammation or pulp necrosis due to dental caries or trauma, to keep

them in position in the dental arch in order to avoid damage to primary and permanent dentitions due to early loss of a dental element[1,2,3] . In this way, it is possible to preserve the primary teeth in conditions to reestablish its fundamental role in feeding, phonetics, social relations of the individual, development of musculature and bones of the face and establishment of functional occlusion[4].

However, there are no consensus on the teaching of pulp therapy in primary teeth due to the inconsistency and lack of high-level scientific evidence studies to determine the best technique and materials to be used[5]. This fact is one of the main obstacles for the adoption of a protocol or of consensual attitudes for the teaching of the clinical approach of pulp therapy of primary teeth in institutions.

Several clinical[8-12] and laboratory[6,10,11,13] studies were developed with different root filling pastes in order to determine the superiority of one material relative to the other, considering the following desirable properties of these: being resorbable at a rate similar to the physiological reabsorption of the root, not to damage the periapical tissues and the permanent germ, to have an antimicrobial property capable of reaching the large variety of microorganisms present in the root complex of primary teeth[11], to promote adequate filling and adherence to the walls of root canals, be easily removed if necessary, to present to be radiopaque, do not cause color change in the tooth and be reabsorbed in case of extravasation to the periapical tissues. [1,6,9,10,12]

The most widely used for root canal filling in the pulp treatment of primary teeth are calcium hydroxide-based pastes, iodoformed pastes and zinc oxide and eugenol paste. In Brasil, a recente survey showed that the iodoform-based paste, called Guedes-Pinto paste[14], was the filling more used in the universities, followed by calcium hydroxide paste.[15]

However, due to the difficulty in finding one of the components of the Guedes-Pinto paste and the scarcity of controlled clinical studies, Antoniazzi *et al*.(2015)[6] proposed three new pharmacological mixtures as iodoform filling materials: Nebacetin ointment, (ii) 2% chlorhexidine gluconate gel and (iii) Maxitrol ointment. The antimicrobial activity of these materials was tested *in vitro* and compared with the Guedes-Pinto paste, obtaining satisfactory results[13].

In view of the absence of a controlled clinical study of this new formulation of iodoform paste and a shortage of controlled studies of other root filling materials such as the Guedes-Pinto paste, this study was carried out to assist the choosing of the material to be used in pulp therapy of deciduous teeth with a clinical and radiographic

analysis for 2 years, analyzing the following differents root canal filling: Guedes Pinto paste, Guedes-Pinto paste modified by Nebacetin and Paste based on calcium hydroxide.

Material and Methods

Experimental design

This is a double-blind Randomized Clinical Trial, elaborated based on the CONSORT[16] guidelines, submitted and approved by the research ethics committee of the Federal University of Santa Maria (UFSM) (CAAE: 784.862) and the Brazilian Registry of Clinical Trials (REBEC - UTN: U1111-1175-2899).

Children aged 2 to 10 years of both genders, undergoing treatment at the Pediatric Dentistry Clinic of UFSM during the years 2014-2017 and who had the need for endodontic treatment were selected according to the following inclusion criteria: (i) mandibular primary molars with expectation of permanence in the mouth of at least 2 years, evaluated by age and degree of root resorption; (ii) deciduous teeth with clinical and / or radiographic characteristics indicative of irreversible pulpal alteration; (iii) with a cavity allowing restorative recovery; (iv) who have not received any previous pulp treatment. Patients should have good systemic health (ASA I) and these data were verified in the previous anamnesis.

Patients with any of the following exclusion criteria were not included in the sample: (i) teeth with root resorption equivalent to 2/3 or more; (ii) with radiographic rupture of the pericoronary sac of the permanent successor, (iii) with internal radicular resorption; (iv) obliteration of root canals; (v) clinical signs and symptoms of an active spreading infection with systemic involvement that require antibiotic therapy such as tachycardia, facial swelling, cellulitis, limited mouth opening, high temperature, difficulty in swallowing, and regional lymphadenitis.[17]

Prior randomization was performed through the Random Allocation Software Program, which determined the technique to be employed in the sequence. The choice was made by randomization using intervals of 9 to 9, in order to avoid influences of the method and/or operator. Sequential numbered, brown, opaque and sealed sequential envelopes were used to ensure randomization concealment.*Preoperative Steps*

The clinical and radiographic evaluation of the teeth to be included in the sample of this research was carried out exclusively by 2 professionals trained and calibrated to evaluate the listed inclusion criteria.

In all cases, a standard diagnostic protocol was followed: anamnesis (including reports of pain by the patient or sponsor), clarification and signing of the Free and Informed Consent Term.

The clinical criteria evaluated by the examiners included evaluation of the dental crown, checking cavity type and staining, the presence of fistula and/or edema, the presence of previous restoration and its conditions, and presence of mobility.

The radiographic evaluation prior to the procedure was performed after the periapical radiographic acquisition of the involved tooth, using a child radiographic positioner (Kodak Insight Film, size 0, F-speed), following the pre-established criteria for this research. (Figure 1)

Pulpectomy procedures

The clinical procedures of the pulpectomies were performed by a post graduate student (D.S.S.) and a teacher (M.D.M.O) trained and calibrated for the procedures. All teeth selected for the study were approached following the same sequence, with the exception of the root canal obturation stage, using the randomization technique.

Initially, local anesthesia, rubber dam, removal of the carious tissue with dentin spoons and low rotation drills with compatible cavity sizes, opening of the pulp chamber and initial access to the root canals, instrumentation of the canals (K-files, of the first series, up to size 35) obeying the root length defined in previously performed odontometry, as suggested by Guedes-Pinto (2003), were performed. In addition, irrigation of the conducts with 1% Sodium Hypochlorite (20ml) and aspiration with a cannula were performed, and as a final touch, an irrigation with physiological solution followed by final aspiration were done. The canals were dried with absorbent paper cones, observing the penultimate measure used in the instrumentation. Then, randomization was performed to select the fill material to be used. The obturator pastes were manipulated and the teeth were filled by a trained and experienced operator (M.D.M.O.) according to the technique defined by randomization and the groups were determined (Figure 2):

Guedes-Pinto paste (GP) - teeth filled with a paste composed of equal parts of Iodoform, PMCC and Rifocort ® (Prednisolone acet. 5mg / g + rifamycin sodium sv 1.5mg / g + vehicle QSP 10g - by the Fórmula & Ação pharmaceutics, SP) – Guedes-Pinto paste[14], introduced with a 25 gauge file with additional cotton balls at the entrance of the canals and finishing with Lentulo (spiral drill) positioned in the initial third of each conduit;

Modified Guedes-Pinto paste (mGP) - teeth filled with a paste composed of Iodoform, PMCC, and Nebacetin® (Neomycin sulfate 5mg/g + Bacitracin Zinc 250 UI + Cetyl alcohol, mineral oil and white petrolatum.) –Guedes-Pinto modified paste[6,13], obeying the same technique indicated to Group 1;

Calcium Hydroxide paste thickened with zinc oxide (CH) - The teeth were filled with calcium hydroxide pro-analysis, Propylene Glycol, and Zinc Oxide powder[18], the technique being performed in two sessions with a 30-day interval between them. In the first, the paste was inserted as described for groups 1 and 2. In the second, the material was removed with substantial irrigation with 1% Sodium Hypochlorite, instrumentation with the finalizer file of preparation (caliber 35) and final irrigation with Physiological Solution, the canals were dried with absorbent paper cones and again the conduits were filled following the same procedure executed in GP and mGP.

After this step, a preheated and condensed gutta-percha blade was inserted to seal the entrance of root canals in the pulp chamber, and then the final restoration was performed with composite resin with suitable finishing/polishing.

Immediately after the end of the clinical stage, the teeth were radiographed following the technique previously performed in order to verify if the filling was satisfactory, that is, the root canal was filled in the pre-defined working length and/or extravasation of the material to the periapical region. In the same way, radiographs corresponding to 30, 60, 90 days, 6 months, 1 year and 2 years were performed.

Clinical and radiographic evaluation

All examiners (R.O.R., C.W.P.) were blinded to the type of material and trained and calibrated for clinical and radiographic evaluation (Kappa=0.84). Follow-up intervals occurred at 30, 60 and 90 days, 6 months, 1 year and 2 years after pulpectomy.

The clinical evaluation of the endodontically treated teeth was performed observing the following criteria: presence/absence of pain, fistula, edema or mobility and evaluation of restoration integrity or dental fracture.

The radiographic criteria analyzed obeyed the pre-established characteristics for use in this research (Fig. 1). In which were considered as a radiographic success the cases that presented regression of the scores in the evaluated criteria or stability of the lesion. The cases that presented an increase of the lesion, progressing to the more severe scores of each radiographic criterion, were considered as radiographic failure.

Statistical analysis

The sample calculation was performed through the Version 3 of the OpenEpi software, using as reference the study by Barcelos et al. (2011). A ratio of exposed to non-exposed of 1 was used, resulting in a sample of 36 units (teeth) per group, totalizing 108 teeth at the end of the study. It was considered 80% power and significance level of 95.

Results were recorded and analyzed using the statistical software Stata 14.0 (Stata 14.0 for Windows; Stata Corporation, College Station, TX, USA). In all analyses, data were grouped according to the treatment groups to which teeth were randomly assigned. Kaplan-Mayer curve of the cases and for each group was performed according to the root canal filling used separately. The significance level was 5% ($p< 0.05$). Radiographic success was considered in cases in which radiolucent lesion regressed or the lesion remained stable, however, the clinical criteria predominated over the radiographic to determine the success of pulpectomy.

RESULTS

The final sample of this clinical trial consisted of 111 teeth in 95 eligible participants recruited from June 2014 to December 2016 (boys, 52.63%; girls, 47.37%), whose average age is 5.66 years (sd = 1.49). Demographical, clinical, and radiographical baseline characteristics were not statistically different between the groups and have no correlation with success/failure rate of root canal fillings. (Table 1).

These teeth were randomly divided into 3 groups according to the root filling material to be used and were included for statistical analysis after clinical and radiographic follow-up. 36 teeth were filled with Guedes-Pinto paste (33.03%), 37 with Pastes Guedes-Pinto modified by Nebacetin (33.94%) and 36 with paste based on Calcium Hydroxide (33.03%).

When evaluating the clinical characteristics of the patients, such as pain, fistula, edema, and mobility, before the endodontic procedure, 40.54% (15) of the patients reported pain, 13.51% (5) had a fistula, 16.22% (6) edema and 5.41% (2) mobility. However, 30 days after treatment, total remission of clinical signs and symptoms was observed in all cases analyzed. There was no recurrence of symptoms in subsequent times in any case. (Table 1)

However, restorative failures (15.31%), such as fractures and caries recurrence, were observed in some cases. In these cases the restorations were repaired (4.5%), maintaining the gutta-percha blade, which remained sealing the entrance of the root canals. In cases in which the restorative failure or fracture of the dental remnant compromised the pulp therapy of the evaluated teeth, it was chosen to perform retreatment of the canal (0.90%) in cases where there was restorative possibility, and exodontia (4.5%) of cases in that endodontic treatment and adequate restorative recovery was no longer a viable option.

Patients who did not return to the clinic, who moved to another city and patients who required a reintervention that compromised pulp therapy – such as endodontic retreatment and restorative repair after a recurrence of caries and extensive coronary destruction reaching the root canals – were considered to be a loss of follow-up.

Considering the dependence of the outcomes of this study, radiographic scores, type of root canal filling and time, a Cox regression analysis was chosen. From this analysis, it was observed that there was no statistically significant difference in the risk of progression of clinical and radiographic scores according to the root canal filling used ($p = 0.73$).

Survival analysis showed through the Kaplan-Meier curve that the survival rate of endodontic treatments performed in mandibular primary molars was 22 months, and at 24 months, a 62% (95% CI: 46 % -74%) percentage of success (survival) of the treatment were obtained (Fig 3). These values were not statistically different according to the filling materials among those tested in this study, Pasta Guedes-Pinto, Pasta Guedes-Pinto modified by Nebacetin or Paste based on Calcium Hydroxide. (Fig. 3)

DISCUSSION

Currently, because there is no consensus on the best material to be used for obturation of primary teeth[3], this study was performed as an attempt to provide greater safety to the clinician for the use of filling materials for deciduous teeth already on the market, and to propose a new formulation to a paste that is widely used but difficult to handle, such as the Guedes-Pinto paste[6,14]. Thus, although no statistically significant differences were found between the materials tested, this randomized clinical trial may, together with other appropriate methodology and long-term follow-up of the cases, help to resolve a frequent doubt among clinicians and researchers: which is the best root canals filling for deciduous teeth and thus allow each professional, based on scientific evidence, to establish the best alternative capable of keeping the root canal complex free of infections and microorganisms.[5]

When evaluating the survival rate of endodontically treated teeth, it was found that, after treatment, regardless of the root canal filling used, it is possible to keep these teeth in the mouth in good condition, on average, for 22 months. Thus, we were able to restore function and maintain a good development of the child over a long period of time, achieving the main objective of endodontic treatment and pediatric dentistry.[1,2,3]

The clinical evaluation of the cases showed that there was complete remission of all clinical criteria evaluated (pain, fistula, edema, and mobility) 30 days after treatment. This data is consistent with what has been studied, in which it can be analyzed that in all cases the patients presented a positive response regarding the decrease of pain, fistula, and edema after pulpectomy, only finding changes in dental mobility in some cases.

In addition, the number of visits to perform endodontic treatment, either in one session, when using iodoformed pastes (GP and mGP), or in 2 sessions, when filled with calcium hydroxide paste did not interfere with the remission of the initial clinical symptoms, and clinical improvement was observed within 30 days after the first treatment, independently of the group to which each patient belonged[7,19,20].

The radiographic results demonstrate, as in the study by Barja-Fidalgo (2011), that in most of the cases evaluated in this study there was regression or stability of the lesion size in periapical tissues or furcation region after performing pulpectomy. In a few cases there was progression of radiographic scores, with an increase in the size of the lesion, which was not considered failure of the treatment due to the integrity of

the hard blade of the pericoronary sac and did not result in clinical worsening of the symptoms, being chosen to maintain the teeth in the dental arch and perform a longer follow-up period[7]. Thus, the need for long-term follow-up of cases is justified in order to compare the difference in the rate of radiographic scores between the materials in order to achieve more conclusive results.

Considering that there are no statistically significant differences in the clinical and radiographic success rate for the filling material used, even in the cases of pulp necrosis with periapical lesions, it is suggested, aiming at a shorter time of care in children, to perform the treatment in only one session with iodoformed pastes.[7,19,20]

The composite resin restorations in large cavities can be perceived a limitation of this study, and may compromise the success rate of endodontic treatments[21,22] due to adhesive failures or fractures found in some cases, regardless of the sealed material used, considering that it does not interfere with the adhesive capacity of the restorative material[23]. In addition, the use of this restorative material is based on the question that composite resin restorations result in less negative influence to the success of pulpectomies in deciduous teeth when compared to those of glass ionomer and present a good cost-benefit to the patient[24].

Moreover, although significant failures were found in some cases, compromising the maintenance of the tooth in the arch, a low restorative failure rate was achieved, unlike that found in numerous recent studies that reported an increase in the number of restorative failures in deciduous teeth submitted to pulp therapy[21,25,26,27]. This can be justified by the fact that the restorations in teeth with great coronary destruction do not present an ideal reconstruction of the anatomical form, and it was chosen only by the sealing of the cavities with composite resin in cases of extensive coronary destruction and little remnant in enamel. These restorations possibly suffered less mechanical stress, considering that they were not in occlusal contact, however they fulfilled the role of sealing, preventing the entry of new microorganisms and recurrence of the pathology in these teeth. This decision was made based on previous studies that demonstrated that in teeth with little dental remnant, that is, multiple face restorations, there is less longevity of this restoration[26,27,28].

It is understood that in controlled randomized clinical trials, a long-term evaluation, such as 24 months, and follow-up of the cases to obtain conclusive and definitive results on the best root canal filling for primary teeth is of paramount

importance[5] and it is suggested development of further studies with rigorous methodology for more conclusive results aiming at rectifying the question of which filling material meets the ideal characteristics established[1,9,10,12] and allows an excellent maintenance of the deciduous teeth and a correct development of the child[1,3].

However, although the results of this research do not demonstrate the superiority of a filling material in relation to the other, they could collaborate with the development of new researches with these materials and generated a prediction of the success rate of each material after 24 months of follow-up, which supports the need for a correct endodontic treatment, with adequate sanitization of the root canals and obturation with materials that present antimicrobial activity capable of reducing the inflammatory process and allow bone recovery and physiological resorption of the root in its adequate period.[1,3]

CONCLUSIONS

In conclusion, this study suggested that endodontic treatment, when performed correctly, promoting the sanitization of the root canals and adequate sealing, results in clinical improvement of the cases in 30 days after the procedure, independently of the filling material used and a number of sessions, and presents an excellent survival rate of treated teeth after 24 months. Thus, we can consider the three root canal fillings used in this research (Guedes-Pinto paste, Modified Guedes-Pinto paste using Nebacetin and Calicum Hydroxide paste thickened with zinc oxide) as viable options in the pediatric clinical practice, generating excellent clinical and radiographic results over the long term.

Bullet Points:

- This is a double-blind, randomized, and controlled design with appropriate randomization of the sample in important factors and a long-term follow-up helped to validate this research and provided strong evidence for the presented results;
- The results present strong evidence for the use of the iodoform-based pastes in comparation with calcium hydroxide in pulpectomy of the primary teeth.

- As there was no statistically significant difference between the materials when evaluated radiographically and there was clinical improvement in 30 days;

Conflic of interest

There is no conflict of interest associated with the present study.

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Table 1. Radiographic Status of endodontic treatment of mandibular primary molars according to the initial clinical and sociodemographic characteristics.

Clinical and Sociodemographyc caracteristics	Radiographic status of endodontic treatmente	
	Success n(%)	Failure n(%)
Sex		
Male	36 (72.00)	14 (28.00)
Female	39 (86.67)	6 (13.33)
Root filling materials		
Rifocort	24 (82.76)	5 (17.24)
Nebacetin	26 (76.47)	8 (23.53)
Hcal	25 (78.13)	7 (21.88)
Pain		
Absent	45 (78.95)	12 (21.05)
Present	30 (78,95)	8 (21.05)
Edema		
Absent	65 (77.38)	19 (22.62)
Present	30 (78.95)	1 (9.09)
Fístula		
Absent	69 (79.31)	18 (20.69)
Present	10 (90.91)	2 (25.00)
Mobilidade		
Absent	73 (78.49)	20 (21.52)
Present	2 (100.00)	0 (0.00)

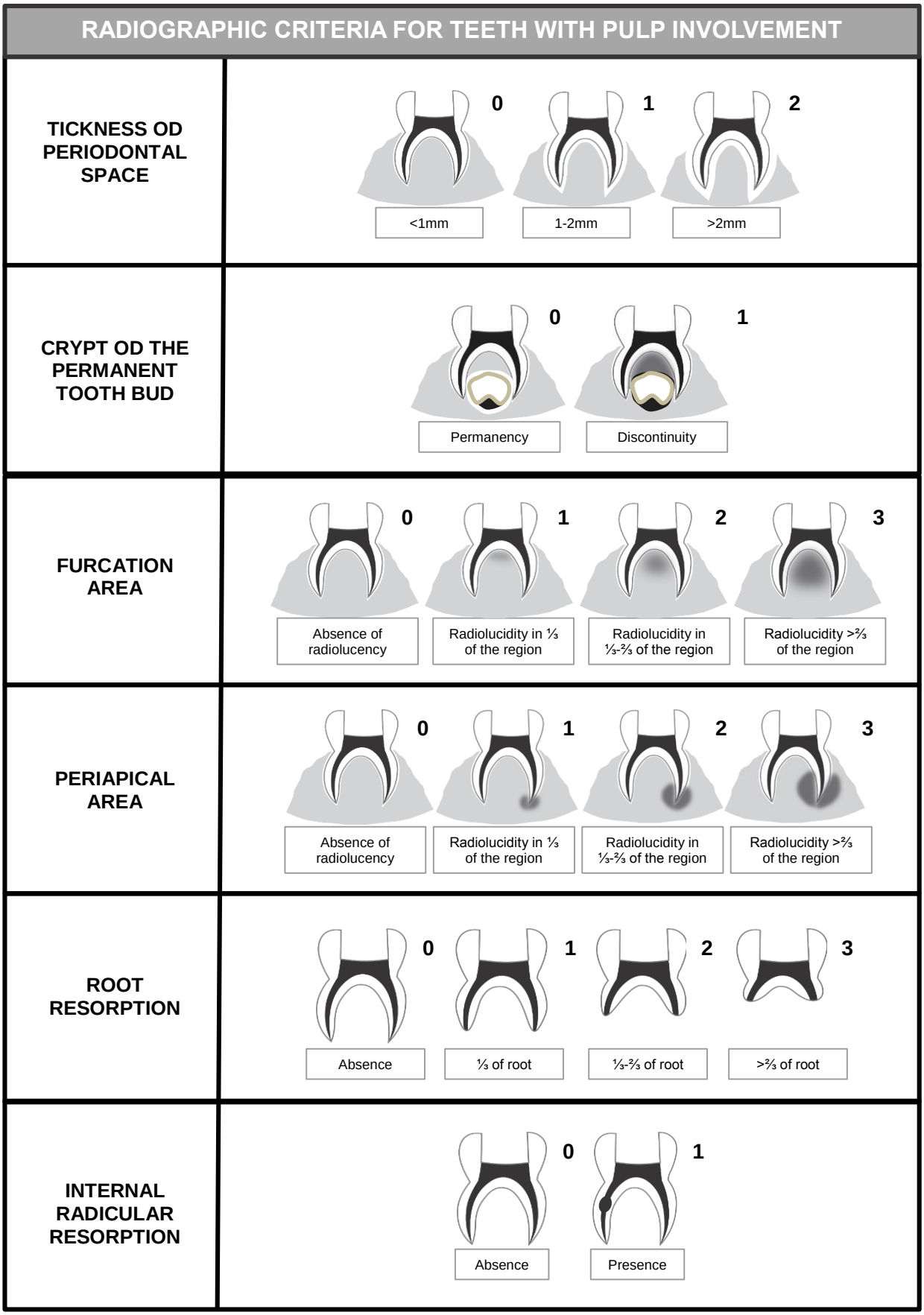

Fig. 1 Radiographic criteria for teeth with pulp involvement.

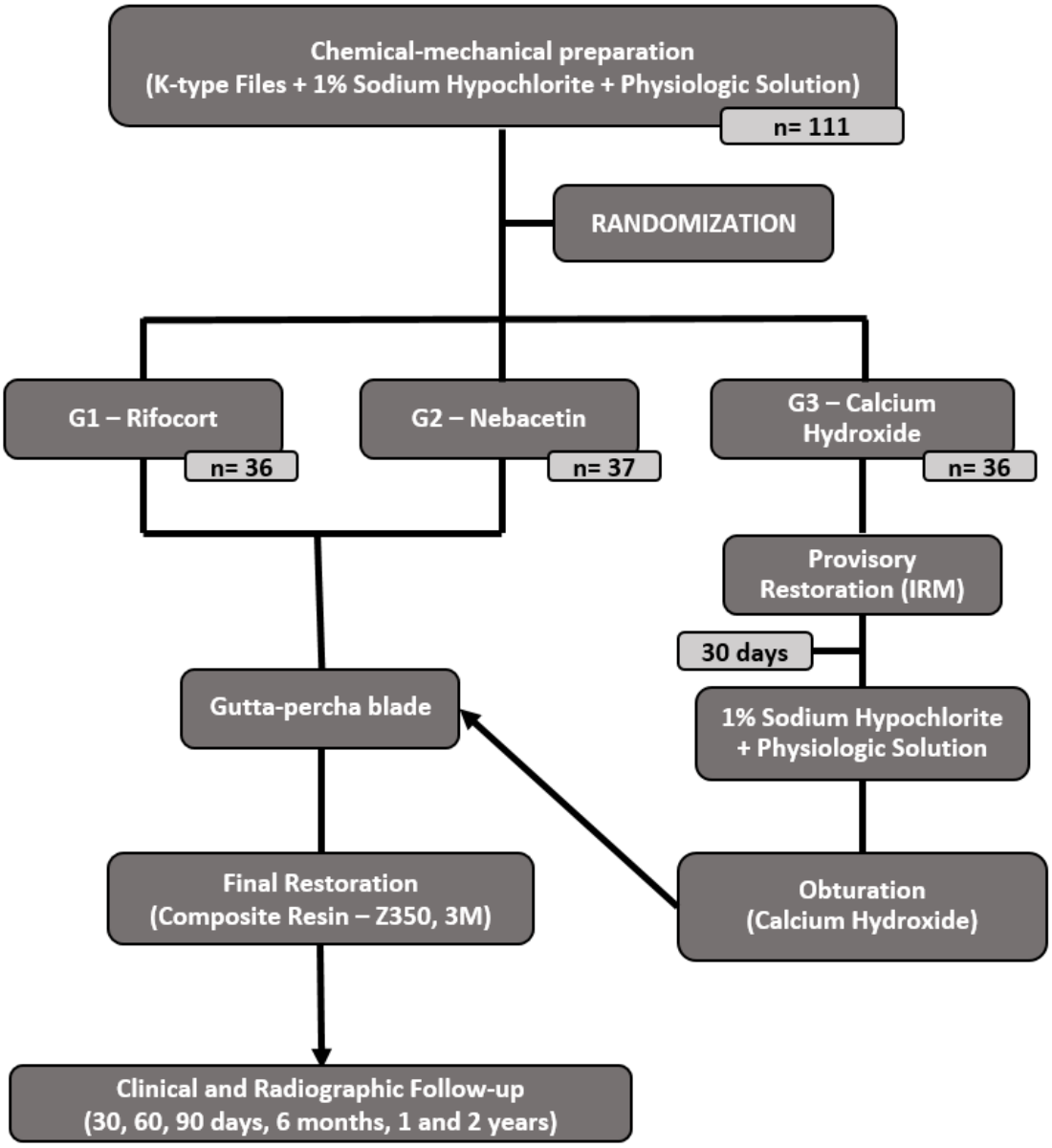

Fig. 2 Flow Chart of clinical procedures

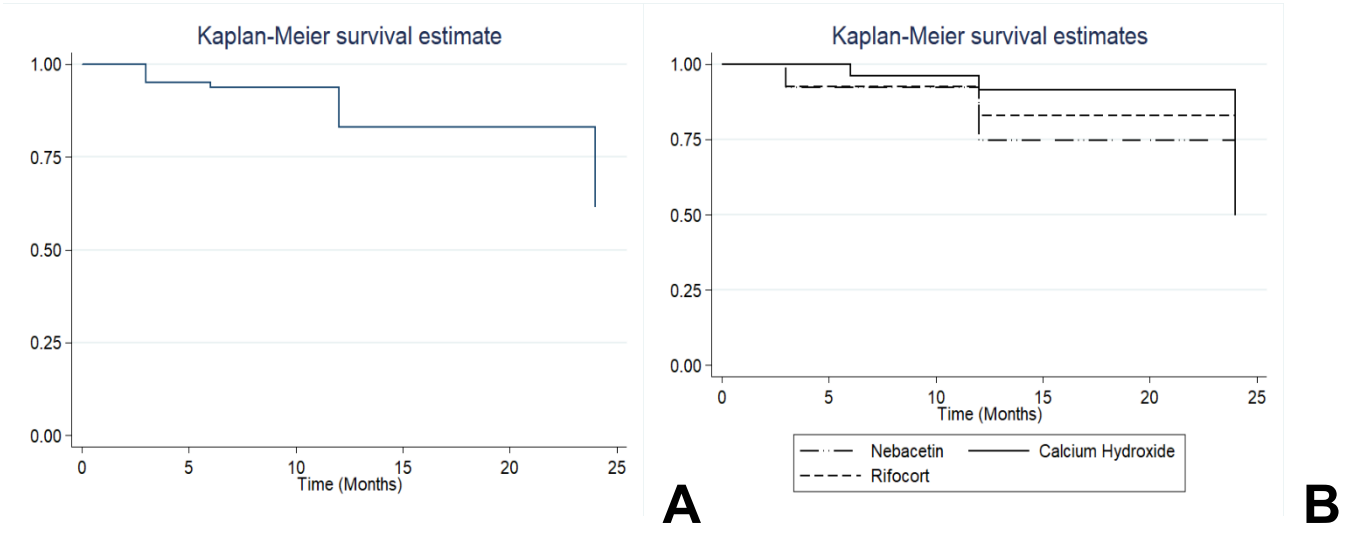

Fig. 3 (A) Survival curve of endodontically treated teeth.(B) Survival curve of the teeth belonging to each experimental group according to the root canal filling.

3. CONSIDERAÇÕES FINAIS

O presente estudo, a partir do número amostral obtido e tempo de acompanhamento dos casos, apesar de perdas de seguimento demonstra que o tratamento endodôntico, quando executado de maneira correta, promovendo a sanificação dos canais radiculares e adequado selamento, resulta em melhora clínica dos casos, 30 dias após realizado o procedimento, independentemente do material obturador utilizado e não apresenta diferença radiográfica em 2 anos de acompanhamento.

Somando-se a isso, sugere-se a elaboração de mais estudos clínicos randomizados, com metodologia adequada e longo tempo de acompanhamento, para agregar aos resultados obtidos neste ensaio clínico e, então, obter-se um embasamento científico mais consistente que permita maior segurança na utilização destes materiais no tratamento endodôntico de dentes decíduos.

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ANEXO A - TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Este termo tem como objetivo **informar, esclarecer e solicita**r autorização para a participação de seu/sua filho (a) na pesquisa intitulada "**Avaliação clínica e radiográfica de pulpectomias em molares inferiores decíduos: Ensaio Clínico Randomizado**" a ser desenvolvida pelas pós-graduandas Débora Santos Sityá e Carine Weber Pires, sob orientação das professoras Dra. Marta Dutra Machado Oliveira e Dra. Rachel de Oliveira Rocha.

A realização do tratamento endodôntico em dentes decíduos é indicada, sempre que possível, para que haja preservação do dente no arco dentário evitando prejuízos ao seu sucessor permanente e/ou ao desenvolvimento da criança. Assim, o objetivo deste estudo é avaliar clínica e radiograficamente as pulpectomias realizadas em dentes decíduos dos pacientes atendidos na clínica de Odontopediatria da Universidade Federal de Santa Maria.

O tratamento endodôntico, após correto diagnóstico clínico e radiográfico, será sempre realizado ou supervisionado por um dos pesquisadores. Após o tratamento será realizado acompanhamento do caso em 30, 60, 90 dias, 6 meses, 1 ano e 2 anos, necessitando do retorno de seu filho(a) à clínica de Odontopediatria.

Essa pesquisa trata-se da avaliação clínica e radiográfica do tratamento endodôntico proposto para seu filho.

Entretanto, é necessário ressaltar que poderão ocorrer alguns desconfortos relacionados às técnicas e que são listados a seguir:

- sensibilidade no momento da anestesia;
- desconforto devido a sensação anestésica;
- reação adversa causando choro em função do paciente desconhecer os procedimentos utilizados;
- sensação de pressão do grampo do isolamento absoluto;
- cansaço relativo em função do procedimento ser complexo e de maior duração;
- sensibilidade pós operatória;
- possibilidade de insucesso das técnicas realizadas pela persistência da infecção;

- possibilidade de não compreensão das orientações fornecidas.

Para a solução dos prováveis riscos serão efetuados os seguintes procedimentos:

- serão empregados todos os recursos para a diminuição do desconforto no ato anestésico, tais como: aplicação de anestésico tópico, aquecimento do tubete, injeção lenta, tracionamento da mucosa;
- a duração do efeito poderá ser de algumas horas após o atendimento, cuide para seu filho(a) não morder lábios, bochechas ou língua, se tiver mais dúvidas procure orientação;
- se seu filho(a) chorar isso deve ser encarado de maneira normal, pois nesta fase da vida existe insegurança e medo;
- poderá ser receitado analgésico (remédio para alívio da dor) em caso de sensibilidade devido ao grampo do isolamento absoluto já na saída do atendimento, solucionando também, a questão de sensibilidade de uma forma geral;
- há vantagem em realizar o procedimento em sessão única e o cansaço devido a isso é normal;
- existe possibilidade de o tratamento não dar certo, como em qualquer tratamento clínico, embora os procedimentos sejam realizados dentro de rigor técnico, por profissional treinado;
- em caso de não ter entendido qualquer informação citada neste termo, peça ao profissional que este explicará a você de outra forma, utilizando desenhos e imagens.

Os pacientes participantes da pesquisa terão assistência gratuita na clínica de Odontopediatria. Além disso, serão realizadas orientações periódicas sobre saúde bucal, o que contribuirá para a qualidade de vida de toda sua família.

A participação no estudo é voluntária e não possui nenhuma obrigação ou premiação para os participantes. Todos os dados de seu/sua filho (a) serão mantidos em sigilo. Seu/sua filho (a) poderá retirar-se do estudo a qualquer momento sem que ocorra penalização ou prejuízo de qualquer natureza. Para esclarecer qualquer dúvida,

o (a) senhor (a) poderá falar com o pesquisador pelo telefone escrito no final deste documento.

Eu,_____, RG_____, abaixo assinado, autorizo a participação do meu/minha filho/filha, _____, no estudo "**Avaliação clínica e radiográfica de pulpectomias em molares inferiores decíduos: Ensaio Clínico Randomizado** como sujeito. Declaro que fui suficientemente informado a respeito das informações que li ou que foram lidas para mim, descrevendo o estudo. Eu discuti com as Profas. Marta Dutra Machado Oliveira e Rachel de Oliveira Rocha sobre a minha decisão em concordar com a participação do meu/minha filho/filha no estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos, as garantias de confidencialidade e de esclarecimentos permanentes. Ficou claro também que a participação é isenta de despesas. Concordo voluntariamente com a participação do meu/minha filho/filha neste estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades, prejuízo ou perda de qualquer benefício que meu/minha filho/filha possa ter adquirido, ou no seu acompanhamento/assistência/tratamento neste serviço.

Local e data:

_____

Nome e Assinatura do sujeito ou responsável:

_____

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste sujeito de pesquisa ou representante legal para a participação neste estudo.

Santa Maria, ____ de _____ de 201_

_____

Pesquisador responsável

Telefone para contato: (55) 991884333

ANEXO B - TERMO DE CONFIDENCIALIDADE

TERMO DE CONFIDENCIALIDADE

Título do projeto: **Avaliação clínica e radiográfica de pulpectomias em molares inferiores decíduos: Ensaio Clínico Randomizado**

Pesquisador responsável: Prof. Dra. Marta Dutra Machado Oliveira

Instituição/Departamento: Departamento de Estomatologia

Telefones para contato: (55) 32229428, (55) 99781757, (55) 91884333

Os pesquisadores do presente projeto se comprometem a preservar a privacidade dos participantes desta pesquisa, cujos dados serão coletados por meio de exames clínicos e radiográficos realizados antes e após realizadas pulpectomias em dentes decíduos na clínica de Odontopediatria da Universidade Federal de Santa Maria. Informam, ainda, que estas informações serão utilizadas, única e exclusivamente, para execução do presente projeto.

As informações somente poderão ser divulgadas de forma anônima e serão mantidas na UFSM - Rua Marechal Floriano Peixoto, 1184, CEP - 97015372- Santa Maria - RS, por um período de cinco anos, sob a responsabilidade da Prof. Dra. Marta Dutra Machado Oliveira. Após este período os dados serão destruídos.

Este projeto de pesquisa foi revisado e aprovado pelo Comitê de Ética em Pesquisa da UFSM em __/__/_____, e recebeu o número Caae_____.

Santa Maria, ____ de _____ de 2014

_____

Pesquisador responsável

Telefone para contato: (55) 991884333

ANEXO C - FICHA CLÍNICA

UNIVERSIDADE FEDERAL DE SANTA MARIA
CENTRO DE CIÊNCIAS DA SAÚDE
CURSO DE ODONTOLOGIA
DEPARTAMENTO DE ESTOMATOLOGIA

Avaliação clínica e radiográfica de pulpectomias em molares inferiores decíduos: Ensaio Clínico Randomizado

Pesquisadoras: Débora Santos Sityá e Carine Weber Pires

Orientadoras: Dra. Marta Oliveira e Dra. Rachel Rocha

Dados teóricos:

1. Nome do paciente:_____

2. Data de Nascimento: __/__/____

3. Raça: _____**4. Sexo:**( ) Masculino ( ) Feminino

5. Endereço:_____

6.Telefone(s):_____

7. Queixa referida (sintoma): _____**8. Dente:**____

9. Data do exame inicial: __/__/____

10.( ) **Biopulpectomia** ( ) **Necropulpectomia**

Exame clínico:

Sinal/Sintoma	Inicial	30 dias	60 dias	90 dias	6 meses	1 ano	2 anos
Dor							
Fístula							
Edema							
Mobilidade							

ANEXO D - PARECER CONSUBSTANCIADO DO CEP

UNIVERSIDADE FEDERAL DE SANTA MARIA/ PRÓ-REITORIA DE PÓS-GRADUAÇÃO E

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação clínica e radiográfica das pulpectomias realizadas em dentes decíduos na clínica de Odontopediatria - UFSM

Pesquisador: Marta Dutra Machado Oliveira

Área Temática:

Versão: 1

CAAE: 35173614.6.0000.5346

Instituição Proponente: Departamento de Estomatologia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 784.862

Data da Relatoria: 09/09/2014

Apresentação do Projeto:

Trata-se de um estudo clínico randomizado que avaliará os resultados clínicos e radiográficos das pulpectomias realizadas em dentes decíduos dos pacientes com idade entre 1 e 10 anos, de ambos os sexos, que estejam em tratamento na clínica de Odontopediatria da Universidade Federal de Santa Maria.

Os pacientes atendidos serão divididos de forma aleatória, com auxílio do Programa Randon Alocation Software, em 3 grupos, de acordo com o material obturador a ser utilizado, sendo o grupo 1 obturado com uma pasta Guedes-Pinto (composta por Rifocort, PMCC e Iodofórmio), grupo 2 pasta Guedes-Pinto Modificada (composta por Nebacetin, PMCC e Iodofórmio) e grupo 3 pasta de hidróxido de cálcio pró-análise, propilenoglicol e óxido de zinco. Os resultados clínicos e radiográficos serão analisados 30, 60, 90 dias, 6 meses, 1 ano e 2 anos após
realizadas as pulpectomias.

Objetivo da Pesquisa:

Hipótese: todos os tratamentos terão sucesso clínico e radiográfico demonstrando resultados equiparados ao final de 30, 60, 90 dias, 6 meses, 1 ano e 2 anos.

Endereço: Av. Roraima, 1000 - prédio da Reitoria - 2º andar
Bairro: Camobi **CEP:** 97.105-970
UF: RS **Município:** SANTA MARIA
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Objetivo Primário: avaliar clínica e radiograficamente as pulpectomias realizadas em dentes decíduos na clínica de Odontopediatria - UFSM.

Objetivo Secundário:

- Avaliar clínica e radiograficamente as pulpectomias realizadas em dentes decíduos, utilizando-se pasta iodoformada composta por Rifocort, PMCC e Iodofórmio (Pasta Guedes-Pinto), considerando os períodos de 30, 60 e 90 dias, 6 meses, 1 ano e 2 anos;

- Avaliar clínica e radiograficamente as pulpectomias realizadas em dentes decíduos, utilizando-se pasta iodoformada composta por Nebacetin, PMCC e Iodofórmio (Pasta Guedes-Pinto Modificada), considerando os períodos de 30, 60 e 90 dias, 6 meses, 1 ano e 2 anos;

- Avaliar clínica e radiograficamente as pulpectomias realizadas em dentes decíduos, utilizando-se pasta de hidróxido de cálcio composta por hidróxido de cálcio pró-análise, propilenoglicol, óxido de zinco, considerando os períodos de 30, 60 e 90 dias, 6 meses, 1 ano e 2 anos;
- Comparar os resultados das avaliações clínicas e radiográficas obtidas considerando os grupos entre si.

Avaliação dos Riscos e Benefícios:

Riscos:

- sensibilidade no momento da anestesia;
- desconforto devido a sensação anestésica;
- reação adversa causando choro em função do paciente desconhecer os procedimentos utilizados;
- sensação de pressão do grampo do isolamento absoluto;
- cansaço relativo em função do procedimento ser complexo e de maior duração;
- sensibilidade pós operatória;
- possibilidade de insucesso das técnicas realizadas pela persistência da infecção;
- possibilidade de não compreensão das orientações fornecidas.

Para minimizar ou solucionar os prováveis riscos serão efetuados os seguintes procedimentos: • serão empregados todos os recursos para a diminuição do desconforto no ato anestésico, tais

como: aplicação de anestésico tópico, aquecimento do tubete, injeção lenta, tracionamento da mucosa; • a duração do efeito poderá ser de algumas horas após o atendimento, serão repassadas informações ao responsável para que o paciente cuide para não morder lábios, bochechas ou lingua; • os responsáveis serão orientados para encarar o choro de maneira normal, pois nesta fase da vida existe insegurança e medo; • poderá ser prescrito analgésico em caso de sensibilidade devido ao grampo do isolamento absoluto já na saída do atendimento, solucionando também, a questão de sensibilidade de uma forma geral; • o responsável será informado sobre a vantagem em realizar o procedimento em sessão única e que o cansaço devido a isso é normal; • será que ressaltado que existe possibilidade de o tratamento não dar certo, como em qualquer tratamento clínico, embora os procedimentos sejam realizados dentro de rigor técnico, por profissional calibrado; • em caso de não ter entendido qualquer informação citada neste termo, o responsável
poderá solicitar ao profissional maiores explicações de outra forma, utilizando desenhos e imagens. Os resultados da pesquisa serão publicados, sejam esses favoráveis ou não. Será garantido ao participante dessa pesquisa, o sigilo e a continuidade do acompanhamento e do tratamento, independente da sua participação na pesquisa. A qualquer momento o participante pode desistir de participar da pesquisa, não interferindo no seu tratamento.

Benefícios:
Os pacientes terão assistência gratuita na clínica de Odontopediatria, serão realizadas orientações periódicas sobre saúde bucal o que contribuirá para a qualidade de vida de toda sua família. Ainda na necessidade de atendimento fora de horário de funcionamento da clínica esse será executado.

Comentários e Considerações sobre a Pesquisa:

.

Considerações sobre os Termos de apresentação obrigatória:
Presentes e adequados, mas no TCLE pede-se que seja previsto espaço para o assentimento da criança que possui compreensão, seja pela assinatura ou outra forma, junto à assinatura do responsável.

Recomendações:
No TCLE pede-se que seja previsto espaço para o assentimento da criança que possui

compreensão, seja pela assinatura ou outra forma, junto à assinatura do responsável.

Conclusões ou Pendências e Lista de Inadequações:

.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

SANTA MARIA, 09 de Setembro de 2014

Assinado por:
CLAUDEMIR DE QUADROS
(Coordenador)

ANEXO E – NORMAS PARA PUBLICAÇÃO NO PERIÓDICO INTERNATIONAL JOURNAL OF PAEDIATRIC DENTISTRY

Author Guidelines

Content of Author Guidelines: 1. General, 2. Ethical Guidelines, 3. Manuscript Submission Procedure, 4. Manuscript Types Accepted, 5. Manuscript Format and Structure, 6. After Acceptance.

Relevant Documents: Sample Manuscript

Useful Websites: Submission Site, Articles published in *International Journal of Paediatric Dentistry*, Author Services, Wiley-Blackwell's Ethical Guidelines, Guidelines for Figures.

CrossCheck

The journal to which you are submitting your manuscript employs a plagiarism detection system. By submitting your manuscript to this journal you accept that your manuscript may be screened for plagiarism against previously published works.

1. GENERAL

International Journal of Paediatric Dentistry publishes papers on all aspects of paediatric dentistry including: growth and development, behaviour management, prevention, restorative treatment and issue relating to medically compromised children or those with disabilities. This peer-reviewed journal features scientific articles, reviews, clinical techniques, brief clinical reports, short communications and abstracts of current paediatric dental research. Analytical studies with a scientific novelty value are preferred to descriptive studies.

Please read the instructions below carefully for details on the submission of manuscripts, the journal's requirements and standards as well as information concerning the procedure after acceptance of a manuscript for publication in *International Journal of Paediatric Dentistry*. Authors are encouraged to visit Wiley-Blackwell Author Services for further information on the preparation and submission of articles and figures.

In June 2007, the Editors gave a presentation on How to write a successful paper for the *International Journal of Paediatric Dentistry.*

2. ETHICAL GUIDELINES

Submission is considered on the conditions that papers are previously unpublished, and are not offered simultaneously elsewhere; that authors have read and approved the content, and all authors have also declared all competing interests; and that the work complies with the Ethical Policies of the Journal and has been conducted under internationally accepted ethical standards after relevant ethical review.

3. CONFLICT OF INTEREST AND SOURCE FUNDING

Journal of Oral Rehabilitation requires that all authors (both the corresponding author and co-authors) disclose any potential sources of conflict of interest. Any interest or relationship, financial or otherwise that might be perceived as influencing an author's objectivity is considered a potential source of conflict of interest. These must be disclosed when directly relevant or indirectly related to the work that the authors describe in their manuscript. Potential sources of conflict of interest include but are not limited to patent or stock ownership, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company. If authors are unsure whether a past or present affiliation or relationship should be disclosed in the manuscript, please contact the editorial office at IJPDedoffice@wiley.com. The existence of a conflict of interest does not preclude publication in this journal.

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Conflict of Interest Disclosure Form

4. MANUSCRIPT SUBMISSION PROCEDURE

Articles for the *International Journal of Paediatric Dentistry* should be submitted electronically via an online submission site. Full instructions and support are available on the site and a user ID and password can be obtained on the first visit. Support is available by phone (+1 434 817 2040 ext. 167) orhere. If you cannot submit online, please contact Daricel Borja in the Editorial Office by e-mail IJPDedoffice@wiley.com.

4.1. Getting Started

Launch your web browser (supported browsers include Internet Explorer 5.5 or higher, Safari 1.2.4, or Firefox 1.0.4 or higher) and go to the journal's online submission site: http://mc.manuscriptcentral.com/ijpd

*Log-in or, if you are a new user, click on 'register here'.
*If you are registering as a new user.
- After clicking on 'Create Account', enter your name and e-mail information and click 'Next'. Your e-mail information is very important.
- Enter your institution and address information as appropriate, and then click 'Next.'
- Enter a user ID and password of your choice (we recommend using your e-mail address as your user ID), and then select your area of expertise. Click 'Finish'.
*If you are already registered, but have forgotten your log in details, enter your e-mail address under 'Password Help'. The system will send you an automatic user ID and a new temporary password.
*Log-in and select 'Author Center'.

4.2. Submitting Your Manuscript

After you have logged into your 'Author Center', submit your manuscript by clicking on the submission link under 'Author Resources'.
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• Word count (excluding tables)
• Authors’ names, professional and academic qualifications, positions and places of work. They must all have actively contributed to the overall design and execution of the study/paper and should be listed in order of importance of their contribution

• Corresponding author address, and telephone and fax numbers and email address

*Click the 'Next' button on each screen to save your work and advance to the next screen.

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- Click on the 'Browse' button and locate the file on your computer.
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* Review your submission (in HTML and PDF format) before completing your submission by sending it to the Journal. Click the 'Submit' button when you are finished reviewing.

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Manuscripts should be uploaded as Word (.doc) or Rich Text Format (.rtf) files (not write-protected) plus separate figure files. GIF, JPEG, PICT or Bitmap files are acceptable for submission, but only high-resolution TIF or EPS files are suitable for printing. The files will be automatically converted to HTML and a PDF document on upload and will be used for the review process. The text file must contain the entire manuscript including title page, abstract, text, references, tables, and figure legends, but no embedded figures. In the text, please reference figures as for instance 'Figure 1', 'Figure 2' to match the tag name you choose for the individual figure files uploaded. Manuscripts should be formatted as described in the Author Guidelines below. Please note that any manuscripts uploaded as Word 2007 (.docx) is now accepted by IPD. As such manuscripts can be submitted in both .doc and .docx file types.

4.4. Review Process

The review process is entirely electronic-based and therefore facilitates faster reviewing of manuscripts. Manuscripts will be reviewed by experts in the field (generally two reviewers), and the Editor-in-Chief makes a final decision. *The International Journal of Paediatric Dentistry* aims to forward reviewers´ comments and to inform the corresponding author of the result of the review process. Manuscripts will be considered for 'fast-track publication' under special circumstances after consultation with the Editor-in-Chief.

4.5. Suggest a Reviewer

International Journal of Paediatric Dentistry attempts to keep the review process as short as possible to enable rapid publication of new scientific data. In order to facilitate this process, please suggest the names and current email addresses of a potential international reviewer whom you consider capable of reviewing your manuscript and their area of expertise. In addition to your choice the journal editor will choose one or two reviewers as well.

4.6. Suspension of Submission Mid-way in the Submission Process

You may suspend a submission at any phase before clicking the 'Submit' button and save it to submit later. The manuscript can then be located under 'Unsubmitted Manuscripts' and you can click on 'Continue Submission' to continue your submission when you choose to.

4.7. E-mail Confirmation of Submission

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4.9. Submission of Revised Manuscripts

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referee's comments, and b) a revised manuscript highlighting exactly what has been changed in the manuscript after revision.

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Original Articles: Divided into: Summary, Introduction, Material and methods, Results, Discussion, Bullet points, Acknowledgements, References, Figure legends, Tables and Figures arranged in this order. The summary should be structured using the following subheadings: Background, Hypothesis or Aim, Design, Results, and Conclusions and should be less than 200 words. A brief description, in bullet form, should be included at the end of the paper and should describe Why this paper is important to paediatric dentists.

Review Articles: may be invited by the Editor.

Short Communications: should contain important, new, definitive information of sufficient significance to warrant publication. They should not be divided into different parts and summaries are not required.

Clinical Techniques: This type of publication is best suited to describe significant improvements in clinical practice such as introduction of new technology or practical approaches to recognised clinical challenges.

Brief Clinical Reports/Case Reports: Short papers not exceeding 800 words, including a maximum of three illustrations and five references may be accepted for publication if they serve to promote communication between clinicians and researchers. If the paper describes a genetic disorder, the OMIM unique six-digit number should be provided for online cross reference (Online Mendelian Inheritance in Man).

A paper submitted as a Brief Clinical/Case Report should include the following:

- a short **Introduction** (avoid lengthy reviews of literature);
- the **Case report** itself (a brief description of the patient/s, presenting condition, any special investigations and outcomes);
- a **Discussion** which should highlight specific aspects of the case(s), explain/interpret the main findings and provide a scientific appraisal of any previously reported work in the field.
- Please provide up to 3 bullet points for your manuscript under the heading: 1. Why this clinical report is important to paediatric dentists. Bullet points should be added to the end of your manuscript, before the references.

Letters to the Editor: Should be sent directly to the editor for consideration in the journal.

6. MANUSCRIPT FORMAT AND STRUCTURE

6.1. Format

Language: The language of publication is English. UK and US spelling are both acceptable but the spelling must be consistent within the manuscript. The journal's preferred choice is UK spelling. Authors for whom English is a second language must have their manuscript professionally edited by an English speaking person before submission to make sure the English is of high quality. It is preferred that manuscript is professionally edited. A list of independent suppliers of editing services can be found

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6.2. Structure

The whole manuscript should be double-spaced, paginated, and submitted in correct English. The beginning of each paragraph should be properly marked with an indent.

Original Articles (Research Articles): should normally be divided into: Summary, Introduction, Material and methods, Results, Discussion, Bullet points, Acknowledgements, References, Figure legends, Tables and Figures arranged in this order.

Please include a statement of author contributions, e.g. Author contributions: A.S. and K.J. conceived the ideas; K.J. and R.L.M. collected the data; R.L.M. and P.A.K. analysed the data; and A.S. and K.J. led the writing.

Summary should be structured using the following subheadings: Background, Hypothesis or Aim, Design, Results, and Conclusions.

Introduction should be brief and end with a statement of the aim of the study or hypotheses tested. Describe and cite only the most relevant earlier studies. Avoid presentation of an extensive review of the field.

Material and methods should be clearly described and provide enough detail so that the observations can be critically evaluated and, if necessary repeated. Use section subheadings in a logical order to title each category or method. Use this order also in the results section. Authors should have considered the ethical aspects of their research and should ensure that the project was approved by an appropriate ethical committee, which should be stated. Type of statistical analysis must be described clearly and carefully.

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***(iii)DNA Sequences and Crystallographic Structure Determinations*:** Papers reporting protein or DNA sequences and crystallographic structure determinations will not be accepted without a Genbank or Brookhaven accession number, respectively. Other supporting data sets must be made available on the publication date from the authors directly.

Results should clearly and concisely report the findings, and division using subheadings is encouraged. Double documentation of data in text, tables or figures is not acceptable. Tables and figures should not include data that can be given in the text in one or two sentences.

Discussion section presents the interpretation of the findings. This is the only proper section for subjective comments and reference to previous literature. Avoid repetition of results, do not use subheadings or reference to tables in the results section.

Bullet Points should include one heading: *Why this paper is important to paediatric dentists. Please provide maximum 3 bullets per heading.

Review Articles: may be invited by the Editor. Review articles for the *International Journal of Paediatric Dentistry* should include: a) description of search strategy of relevant literature (search terms and databases), b) inclusion criteria (language, type of studies i.e. randomized controlled trial or other, duration of studies and chosen endpoints, c) evaluation of papers and level of evidence. For examples see: Twetman S, Axelsson S, Dahlgren H et al. Caries-preventive effect of fluoride toothpaste: a systematic review. Acta Odontologica Scandivaica 2003; 61: 347-355. Paulsson L, Bondemark L, Söderfeldt B. A systematic review of the consequences of premature birth on palatal morphology, dental occlusion, tooth-crown dimensions, and tooth maturity and eruption. Angle Orthodontist 2004; 74: 269-279.

Clinical Techniques: This type of publication is best suited to describe significant improvements in clinical practice such as introduction of new technology or practical approaches to recognised clinical challenges. They should conform to highest scientific and clinical practice standards.

Short Communications: Brief scientific articles or short case reports may be submitted, which should be no longer than three pages of double spaced text, and include a maximum of three ilustrations. They should contain important, new, definitive information of sufficient significance to warrant publication. They should not be divided into different parts and summaries are not required.

Acknowledgements: Under acknowledgements please specify contributors to the article other than the authors accredited. Please also include specifications of the source of funding for the study and any potential conflict of interests if appropriate. Suppliers of materials should be named and their location (town, state/county, country) included.

Supplementary data

Supporting material that is too lengthy for inclusion in the full text of the manuscript,

but would nevertheless benefit the reader, can be made available by the publisher as online-only content, linked to the online manuscript. The material should not be essential to understanding the conclusions of the paper, but should contain data that is additional or complementary and directly relevant to the article content. Such information might include the study protocols, more detailed methods, extended data sets/data analysis, or additional figures (including). All material to be considered as supplementary data must be uploaded as such with the manuscript for peer review. It cannot be altered or replaced after the paper has been accepted for publication. Please indicate clearly the material intended as Supplementary Data upon submission. Also ensure that the Supplementary Data is referred to in the main manuscript. Please label these supplementary figures/tables as S1, S2, S3, etc.

Full details on how to submit supporting information, can be found at http://authorservices.wiley.com/bauthor/suppinfo.asp

6.3. References

A maximum of 30 references should be numbered consecutively in the order in which they appear in the text (Vancouver System). They should be identified in the text by superscripted Arabic numbers and listed at the end of the paper in numerical order. Identify references in text, tables and legends. Check and ensure that all listed references are cited in the text. Non-refereed material and, if possible, non-English publications should be avoided. Congress abstracts, unaccepted papers, unpublished observations, and personal communications may not be placed in the reference list. References to unpublished findings and to personal communication (provided that explicit consent has been given by the sources) may be inserted in parenthesis in the text. Journal and book references should be set out as in the following examples:

1. Kronfol NM. Perspectives on the health care system of the United Arab Emirates. East Mediter Health J. 1999; 5: 149-167.
2. Ministry of Health, Department of Planning. Annual Statistical Report. Abu Dhabi: Ministry of Health, 2001.
3. Al-Mughery AS, Attwood D, Blinkhorn A. Dental health of 5-year-old children in Abu Dhabi, United Arab Emirates. Community Dent Oral Epidemiol 1991; 19: 308-309.
4. Al-Hosani E, Rugg-Gunn A. Combination of low parental educational attainment and

high parental income related to high caries experience in preschool children in Abu Dhabi. Community Dent Oral Epidemiol 1998; 26: 31-36.

If more than 6 authors please, cite the three first and then et al. When citing a web site, list the authors and title if known, then the URL and the date it was accessed (in parenthesis). Include among the references papers accepted but not yet published; designate the journal and add (in press). Please ensure that all journal titles are given in abbreviated form.

We recommend the use of a tool such as Reference Manager for reference management and formatting. Reference Manager reference styles can be searched for here: www.refman.com/support/rmstyles.asp.

6.4. Illustrations and Tables

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Figures and illustrations: All figures should be submitted electronically with the manuscript via ScholarOne Manuscripts (formerly known as Manuscript Central). Each figure should have a legend and all legends should be typed together on a separate sheet and numbered accordingly with Arabic numerals. Avoid 3-D bar charts.

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