What's new for the clinician?

Summaries of and excerpts from recently published papers

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1. Mineral trioxide aggregate (MTA) versus Biodentine for pulpotomies in primary molars: a randomized clinical trial

C Cuadros-Fernández, AI Lorente Rodríguez, S Sáez-Martínez. *et al*. Clin Oral Invest; 2016: 20: 1639.

Pulpotomy is a common procedure where the coronal pulp is amputated and the remaining vital radicular pulp tissue surface is treated with a pulp-dressing agent such as Formocresol which has long been considered the gold standard. However, its continued use has been controversial due to its potential mutagenic and toxic effects. With the development of materials that are both biocompatible and bioinductive, the emphasis has shifted from preservation to regeneration of residual pulp tissue. MTA has gained popularity among pediatric dentists for use in pulpotomy because of its excellent sealing ability, biocompatibility, and ability to stimulate hard tissue formation. More recently though, Biodentine, a calcium silicate-based cement, packaged as powder and liquid, has been introduced to combine the high biocompatibility and bioactivity of calcium silicates with enhanced properties such as rapid setting time (conferred by the calcium chloride) and high strength (conferred by the low water-to-cement ratio). These properties make Biodentine a viable choice for use as a pulp-dressing agent for pulpotomies in primary molars.

Cuadros-Fernández *et al* (2016)[1] reported on a trial that sought to clinically and radiographically evaluate and compare the performance of MTA and Biodentine as pulp-dressing materials following pulpotomy in human primary molars in a 12-month follow-up study.

MATERIALS AND METHODS

This is a randomized open label clinical trial reported in the CONSORT (Consolidated Standards of Reporting Trials) format. An open-label trial or open trial is a type of clinical trial in which both the researchers and participants know which treatment is being administered.

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Patients eligible to participate were healthy individuals aged 4–9 years requiring pulpotomy in one or two primary molars. The criteria for the selection of teeth to be included in the study comprised the following:

- Carious pulp exposure in symptom-free vital primary molars found during the removal of caries
- No clinical or radiographic evidence of pulp degeneration (excessive bleeding from the root canal, internal root resorption, or inter-radicular and/or furcal bone destruction)
- The potential for proper restoration of the tooth with a minimum of three walls present
- Physiologic resorption of less than one third of the root

The exclusion criteria included the presence of systemic pathology and any history of allergic reaction to local anesthetics or to the constituents of the test pulp-dressing agents.

A single postgraduate student in paediatric dentistry performed the procedures, and one investigator checked to ensure that the pulp was exposed during preparation and that the teeth were suitable for pulpotomy. The molars were randomly assigned to either the Control (MTA) or Experimental (Biodentine) Groups using a random number table.

A standardised treatment protocol was used in both groups prior to the application of the control and experimental materials. Rubber dam isolation was used in all cases. After gaining access to the pulp orifice, the coronal pulp tissue was removed using a sterile slow-speed round bur. The remaining radicular pulp tissue was treated with either MTA paste (obtained by mixing MTA powder with sterile saline in a ratio of 3:1) or Biodentine (obtained by mixing Biodentine powder with a single dose of liquid) according to group allocation.

The pulp chambers of the molars in both groups were filled with a polymer-reinforced zinc-oxide–eugenol restorative material and all molars were restored with stainless steel crowns cemented with glass ionomer cement (Ketac-Cem).

At the 6-month and 1-year recall visits, clinical and radiographic examinations were performed. Teeth were evaluated clinically by a single investigator and scored as a clinical success if the patient had no symptoms of pain, and there was no swelling or gingival inflammation, fistulation, or pathologic mobility. Teeth were scored as a radiographic success if they showed no evidence of internal or external resorption or periradicular radiolucency.

RESULTS

The final study population comprised 68 children (35 boys, 33 girls) with a mean age (± standard deviation) at the time of treatment of 6.6 (± 1.3) years.

A total of 90 primary molars were initially included in the study, but six were excluded because of uncontrollable bleeding during treatment. In total, 84 pulpotomies were performed on teeth randomly assigned to either the MTA or Biodentine Groups. Twenty-five patients had one pulpotomy with Biodentine, 27 patients had one pulpotomy with MTA, and 16 patients had two pulpotomies (one with MTA and one with Biodentine). This made a total of 41 pulpotomies with Biodentine and 43 pulpotomies with MTA. The types of teeth were as follows: 24 mandibular first primary molars, 18 mandibular second primary molars, 24 maxillary first primary molars, and 18 maxillary second primary molars. After 6 months of follow-up, all molars were clinically and radiographically evaluated without any drop-out; whereas, at the 12-month follow-up evaluation, which had a recall rate of 93 % (78/84), six molars could not be checked as a result of four drop-outs from the MTA Group and two drop-outs from the Biodentine Group.

After 6 months of follow-up, three clinical failures had occurred. All involved gingival inflammation (two molars from the MTA Group and one from the Biodentine Group). One molar from the MTA Group showed gingival inflammation at the 12-month follow-up visit. These molars were re-evaluated after educating the patient on oral hygiene, and the gingival inflammation was resolved. No clinical failures were observed in the Biodentine Group at the 12-month follow-up evaluation. Therefore, the clinical success rate in the MTA Group after 12 months was 92% (36/39), whereas the clinical success rate in the Biodentine Group after 12 months was 97 % (38/39) (p=0.346). No patients showed signs of pain, tooth mobility, fistula, or swelling.

No evidence of internal or external resorption or periradicular radiolucency was observed in any molar in either group at the 6-month recall. All radiographic failures were observed at the 12-month follow-up evaluation. One molar from the MTA Group showed internal resorption; therefore, use of MTA yielded a radiographic success of 97 % (38/39). Use of Biodentine yielded a radiographic success of 95% (37/39). One molar showed internal resorption and a second exhibited periradicular radiolucency (p = 0.635).

CONCLUSIONS

The researchers concluded that Biodentine showed similar clinical results as MTA with comparable success rates when used for pulpotomies of primary molars over a 12 month follow-up.

IMPLICATIONS FOR PRACTICE

Compared with MTA, Biodentine offers many advantages (shorter setting time, enhanced compressive strength, micro-hardness, and lower cost) and should be considered as a viable alternative.

Reference

1. Cuadros-Fernández, C., Lorente Rodríguez, A.I., Sáez-Martínez, S. *et al*. Short-term treatment outcome of pulpotomies in primary molars using mineral trioxide aggregate and Biodentine: a randomized clinical trial. Clin Oral Invest; 2016: 20: 1639.

2. Dentoalveolar effects of slow versus rapid maxillary expansion in complete bilateral cleft lip and palate patients: a randomized clinical trial

A C de Medeiros Alves, D G Garib, G Janson. *et al*. Clin Oral Invest (2016) 20: 1837

Cleft lip and palate (CLP) are considered the most common craniofacial anomalies and usually involve the upper lip, alveolar ridge or/and the palate which often results in aesthetic, functional, and/or psychosocial impairments.[1] Complete bilateral cleft lip and palate (BCLP) is the most severe type of cleft and these patients usually show severe deficiencies of maxillary growth, demonstrating maxillary dental arch constrictions and posterior crossbites.[1]

Orthodontic treatment of patients with BCLP commonly requires maxillary expansion either with slow maxillary expansion (SME) using the quad-helix appliance and its variations or rapid maxillary expansion (RME) with Haas-type or Hyrax expanders.[1]

de Medeiros Alves and colleagues (2016)[1] reported on a randomized clinical trial that sought to compare the dentoalveolar effects of slow and rapid maxillary expansions in patients with bilateral complete cleft lip and palate using three-dimensional analyses on digital dental models. The null hypothesis was that SME and RME are not different regarding the maxillary dental arch changes in patients with BCLP.

MATERIALS AND METHODS

This study was a randomized clinical trial involving two parallel groups randomized with a 1:1 allocation ratio.

Eligibility criteria for the participants were patients with complete bilateral cleft lip and palate, ages ranging from 7 to 11 years, lip and palate repair performed from 3 to

24 months of age, and presence of maxillary dental arch constriction and need of maxillary expansion prior to secondary alveolar bone grafting. Exclusion criteria were the presence of associated syndromes, carious lesions, and history of previous orthodontic treatment.

At the initial orthodontic exam, the participants and their legal guardians were informed about the need of a maxillary dental arch expansion prior to secondary alveolar bone grafting and they received invitation to participate in the study. Once informed consents were signed by parents, the patients were randomly allocated into two study groups: slow maxillary expansion group (SME group) or rapid maxillary expansion group (RME group). After at least a month after the initial orthodontic exam, the patients returned for appliance installation.

The SME group was treated with the quad-helix appliance. The expander was constructed using 0.036-in. stainless steel round wires. Molar bands were adapted preferentially on maxillary first permanent molars. When these teeth were partially erupted, second deciduous molars were banded. The quad-helix appliance was activated 6mm (3mm per side), and subsequent reactivations were performed extraorally at a 2-month interval. The expansion active phase ranged from 4 to 21 months. Expansions were considered adequate when the palatal cusp tip of the maxillary posterior teeth contacted the buccal cusp tip of the mandibular posterior teeth. After the active expansion phase, the appliance was maintained in the oral cavity as a retainer for six months. Dental models were obtained immediately pre-expansion (T1) and six months after the end of the active expansion when the appliance was removed (T2).

The RME group was treated with the Hyrax expander. Considering that the participants were in the mixed dentition, appliance anchorage was provided by bands adapted on either the maxillary first permanent molars or the second deciduous molars, and circumferential clamps were bonded to the deciduous canines. When the second deciduous molars were banded, a lingual extension wire was placed in the partially erupted maxillary first permanent molars. The 11-mm screw (Dentaurum) was activated two-quarter turns in the morning and two-quarter turns in the evening. The expansion active phase ranged from 7 to 14 days. Expansions were considered adequate when the palatal cusp tip of the maxillary posterior teeth contacted the buccal cusp tip of the mandibular posterior teeth. After this phase, the appliance was kept as a retainer for six months. Similarly to the SME group, dental models were obtained immediately pre-expansion (T1) and six months after expansion at the occasion of expander removal (T2).

Standardized dental models were scanned using the 3Shape R700 3D© scanner. Measurements were performed on the pre- and post-expansion maxillary digital dental models using OrthoAnalyzer 3D©.

The primary outcomes were the changes in the maxillary dental arch widths (3-3, 4-4, 5-5, 6-6), arch perimeter, arch length, palatal depth, and buccolingual inclination of posterior teeth (I3, I5, I6). The secondary outcome was the differential amount of expansion accomplished at the canine and molar regions. There were no outcome changes after trial commencement.

Computer-generated randomization based in random permuted blocks of 20 patients was accomplished with Stata© software to ensure equal distribution of participants in the groups. Allocation concealment was achieved with sequentially, numbered, sealed, opaque envelopes containing the expansion modality allocation cards, which were prepared before the trial. One operator was responsible for opening the next envelope in sequence and implementing the randomization process.

Blinding of patients and operator regarding the modality of expansion was not possible; however, the outcome assessment was blinded because digital dental models were unidentified during analysis.

One operator performed all the measurements on the digital dental models and repeated the measures in 30 % of the sample at least one month later.

Inter-phase changes analysis for both groups was performed using paired t tests. Intergroup comparisons of primary outcomes and intragroup and intergroup comparisons of secondary outcome were performed using t tests. Differential expansion assessment was performed comparing the difference between 3-3 change and 6-6 change between SME and RME groups using t tests.

A statistical significance level of 5% was accepted for all tests, and associated 95% confidence intervals (CI) were calculated. All analyses were conducted with Statistica©, version 11.

RESULTS

Eighty-three participants were considered for this trial but 21 patients (25.30%) were excluded because they did not meet the eligibility criteria. Sixty-two patients were then randomized in a 1:1 ratio to study groups (SME group, 31; RME group, 31). The trial ended when the sample size allowed a dropout rate of 20%.

Baseline characteristics showed that the patients' initial mean ages were similar in both groups. Treatment time was significantly greater for the SME group compared to RME group. Most of the patients of both groups were male, and no intergroup differences were found for sex distribution.

Five out of 31 (16.12%) and six out of 31 (19.35%) patients from the SME and RME groups, respectively, were lost during enrolment because canines or maxillary deciduous molars had exfoliated and there was not enough dental anchorage to install the appliances. Expanders were installed in 26 patients of the SME group and 25 participants of the RME group. One patient from the SME group was excluded from the sample because the quad-helix appliance was misadjusted. Twenty-five patients for each group were properly analyzed in their original assigned groups. The primary analysis was carried out on an intention-to-treat basis involving all patients randomized after consideration of missing data.

No significant differences were found between the maxillary dental arch dimensions of both groups at T1.

SME and RME caused significant increases of arch widths and arch perimeters. Arch length and palatal depth decreased nonsignificantly with SME but significantly with RME. Buccal tooth tipping was significant only for the maxillary deciduous canines in both groups. No significant differences were observed between SME and RME changes.

The quad-helix appliance produced a differential expansion with a statistically significant greater increase of the intercanine width compared with the intermolar width. No significant differences were found between the differential expansions of SME and RME.

No serious harm was observed other than variable pressure sensations around the teeth, under the eyes, and at the nasal area reported during treatment by participants of the RME group. However, these symptoms rapidly disappeared with no major discomfort.

CONCLUSIONS

The researchers concluded that Slow and Rapid maxillary expansions caused similar maxillary dental arch changes in patients with complete bilateral cleft lip and palate. However, slow maxillary expansion required greater treatment time compared with rapid maxillary expansion.

IMPLICATIONS FOR CLINICAL PRACTICE

Although both interventions (SME & RME) showed equivalence in treatment effect, the significantly shorter time required for RME must be a serious consideration in determining the choice of treatment in these patients.

References

1. de Medeiros Alves, A.C., Garib, D.G., Janson, G. et al. Analysis of the dentoalveolar effects of slow and rapid maxillary expansion in complete bilateral cleft lip and palate patients: a randomized clinical trial. Clin Oral Invest (2016) 20: 1837