RANDOMIZED CONTROL TRIAL

A Randomized Controlled Clinical Trial Comparing Tricalcium Silicate and Formocresol Pulpotomies Followed for Two to Four Years

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Abstract: ***Purpose:*** *Tricalcium silicate (Biodentine), a new synthetic inorganic restorative cement, has shown a high rate of success in pulpotomy treatments, with few side effects. The purpose of the present randomized clinical control trial was to evaluate the long-term success of pulpotomies in human primary molars using tricalcium silicate versus formocresol.* ***Methods:*** *Healthy two- to 10-year-olds were treated with pulpotomies on primary molars as part of their scheduled regular dental treatment. Pulp dressing alternated randomly between tricalcium silicate and formocresol. Data were analyzed at follow-up periods up to 48 months.* ***Results:*** *Thirty-seven (51.4 percent) teeth with tricalcium silicate and 35 (48.6 percent) teeth with formocresol in 58 healthy children (31 boys and 27 girls) were studied. The overall success rate of the pulpotomies in this study was 94.4 percent. Tricalcium silicate was successful in 97.3 percent (36 out of 37) of the cases, and formocresol in 91.4 percent (32 out of 35). No association was found between success and type of tooth or time range from treatment to last follow-up.* ***Conclusion:*** *Tricalcium silicate shows a higher (though not statistically significant) success rate than formocresol in human primary molars pulpotomies followed for two to four years.* *(Pediatr Dent 2019;41(6):446-50) Received April 15, 2019 | Last Revision August 13, 2019 | Accepted August 16, 2019*

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Pulpotomy is considered by many to be the treatment of choice for vital pulp exposure due to deep carious lesions in symptom-free primary molars[1-3] and has an overall success rate of 82.6 percent within a follow-up period of 24 months.[4,5] The technique involves coronal pulp amputation to the orifices of the root canals while preserving the vitality of the radicular pulp and applying a medicament to those amputated orifices.[5] Buckley's formocresol, ferric sulfate, electrosurgery and mineral trioxide aggregate (**MTA**) have demonstrated long-term success in pulpotomies.[2,5] Reports on formocresol's cytotoxicity and potential mutagenicity (especially in children)[6-8] motivate clinicians to search for alternative materials that will satisfy the biologic approach to pulp therapy in the primary dentition.[9]

Biodentine™ (Septodont, Saint Maure des Fosse´s, France) is a new synthetic tricalcium silicate-based (Ca_3SiO_5) inorganic restorative commercial cement that does not contain heavy metals. It has a powder and liquid system, where the powder is composed of tricalcium silicate (main component), calcium carbonate (filler material), zirconium oxide (radiopacifier), dicalcium silicate (traces), calcium oxide (traces), and iron oxide (traces), and the liquid is an aqueous solution of a hydrosoluble polymer (water-reducing agent) with calcium chloride (which decreases the setting time).[10] It increases dentinogenesis in deep cavities and osteoblasts' activity in cytocompatibility assays.[11-14] Its biocompatibility and bioactivity make it a promising pulp dressing material that has demonstrated high success with pulpotomy treatments, with few side effects[15]; cytocompatibility assays reported overproduction of IL-1α.[14] In a recent study, tricalcium silicate showed significant cytotoxicity against dental pulp stem cells but also upregulated alkaline phosphatase and vascular endothelial growth factor expression.[16] Nowicka et al. reported that Biodentine™ had better material handling properties when compared to MTA, which was more time consuming and difficult to manipulate.[15]

Studies comparing the effectiveness of formocresol with that of tricalcium silicate in primary molar pulpotomies reported a 100 percent success rate for both materials, with no significant clinical or radiographic differences three, six, and 12 months after treatment, with only one radiographic failure of furcal radiolucency in the formocresol group at the 12-month evaluation.[17,18]

Rajasekharan et al. compared the clinical and radiographic efficacy of Biodentine™, ProRoot White Mineral Trioxide Aggregate (**WMTA**), and Tempophore and found no differences between these materials after 18 months of follow-up.[19] This study was limited to carious primary teeth with vital pulps without spontaneous pain or history of swelling. A similar study investigating the outcomes of pulpotomies using tricalcium silicate and MTA in comparison to formocresol showed favorable results for tricalcium silicate and MTA over formocresol during a period of 18 months[18]; other studies comparing tricalcium silicate to MTA showed similar results with both agents.[20,21] As tricalcium silicate is a promising alternative to the pulpotomy agents used currently, it is essential to evaluate its effectiveness over a longer follow-up period than previously reported.[2]

The purpose of this randomized clinical controlled trial was to compare the long-term success of pulpotomies in human primary molars using tricalcium silicate versus those performed

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with formocresol. In this trial, treated teeth were considered successful if no evidence of internal or external root resorption existed or further treatment (i.e., extraction due to pathology or pulpectomy) was necessary.

Methods

Study design. Healthy two- to 10-year-old children were treated with pulpotomies on primary molars as part of their scheduled regular dental treatment at the Pediatric Dentistry Clinic of the Hebrew University – Hadassah School of Dental Medicine, Jerusalem, Israel, between 2012 and 2016.

Sample size and power calculation. The success percentages of the two treatment groups—tricalcium silicate (96.8 percent) and formocresol (87.4 percent)—were derived from the literature with similar methodology.[22,23] The sample size was calculated for binary primary outcome measures for a non-inferiority trial (non-inferiority limit of 12 percent) with the aforementioned parameters using Sealed Envelope (Sealed Envelope Ltd., London, UK)[24]; 27 teeth per group were required to detect a significant difference for a two-sided type I error at five percent and 90 percent power. The sample size was increased by 30 percent to compensate for loss during follow-up or due to other causes of attrition. Therefore, a sample size of 35 in each intervention group was planned.

Ethical considerations. The study protocol was approved by the Institutional Human Subjects Ethics Committee of Hadassah Medical Organization IRB, Jerusalem. All procedures performed were in accordance with the ethical standards of the institutional and national research committee. The study protocol was also enrolled, and the full trial protocol can be accessed at *clinicaltrials.gov* (NCT 01655342). A detailed information sheet in simple non-technical language was provided in advance, and parents/guardians were requested to sign an informed consent. No compensation was provided for the participating patients. The patients and parents were blinded by not being provided any information about the treatment group to which they were selected.

Randomization. Teeth were assigned by a single trained disinterested investigator to one of the groups (tricalcium silicate or formocresol) by simple randomization[25] (flipping of a coin) per tooth and not per patient. Randomization was performed after the pulp was reached.

Experienced residents (in their second or third year of residency) in pediatric dentistry who were being supervised by senior pediatric dentists performed all treatments. After attainment of hemostasis using a moist cotton pellet, the pulp dressing alternated randomly between tricalcium silicate and formocresol. Each material was applied according to the manufacturer's instructions. For each child, if more than one tooth needed pulp therapy and it was not part of the split-mouth design, only one tooth was randomly chosen (coin flip). In a case where a child needed two pulpotomy treatments for analogous teeth, random allocation was performed for the first tooth treated and the second tooth was treated with the second material, thus using the split-mouth design. Of the 72 teeth, 28 were found to be 'split-mouth teeth'. One of them was included in the study, despite a five-month follow-up period (instead of six months), to compare the two teeth in the same mouth. In patients where split-mouth was applied, random allocation was performed only for the first tooth.

Data were collected by reviewing the treatment files filled out between 2012 and 2016. Missing data (i.e., failure to show up for follow-up appointments) was handled as termination of the follow-up period for that individual.

Study population and inclusion criteria. Primary molars treated with pulpotomy were included in the study if they fulfilled the following requirements: primary molars with a deep carious lesion and no spontaneous pain; exposure of a vital pulp by caries; no clinical or radiographic evidence of pulp degeneration, such as excessive bleeding from the root canal, internal or external root resorption, inter-radicular and/or periapical bone destruction, swelling or sinus tract; a prospect of proper restoration of the teeth; and follow-up of the tooth condition within a minimum of six months.

The follow-up period was defined as the time elapsed from the pulpotomy treatment and one of the following: detection of pulpotomy failure; naturally exfoliated tooth; and patient's last visit for recall checkup. Treated teeth were reviewed during follow-up appointments by one of two experienced pediatric dentists who were investigators in the study. Blinding of reviewers was not optional, as pulps treated with tricalcium silicate have specific radiographic characteristics. Treatment failure was declared if: internal or pathological external root resorption was detected; furcation radiolucency or widened periodontal ligament (PDL) (including asymptomatic); the tooth has been extracted due to pathology (including unresolved

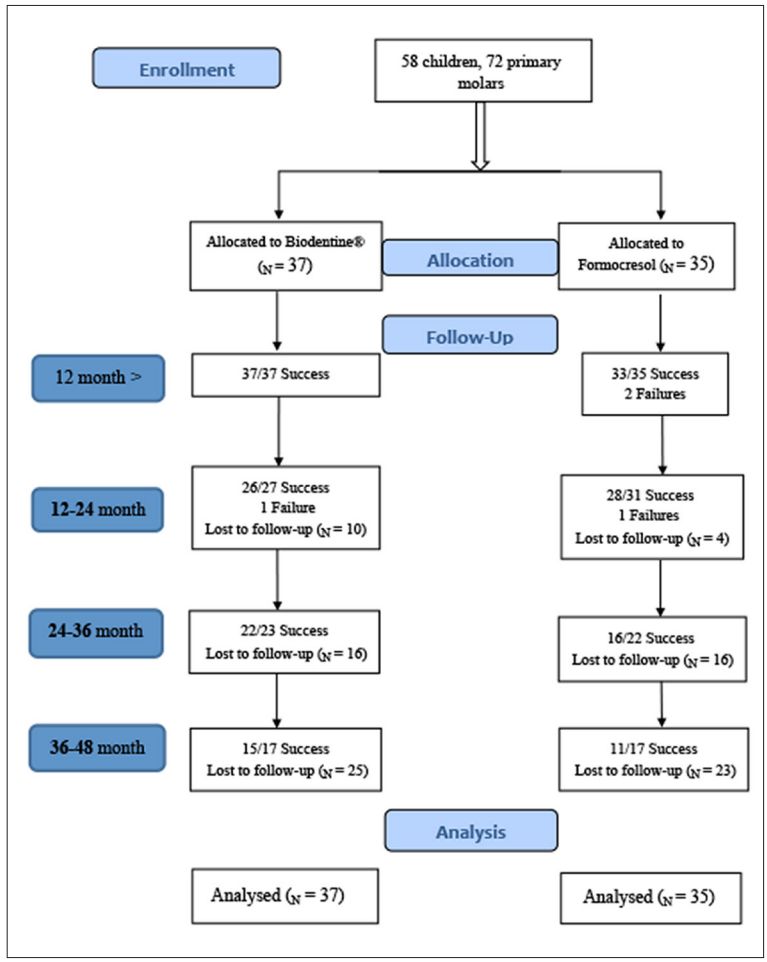

Figure 1. Allocation flow diagram.

pain); or a pulpectomy has been performed. If none of these apply, treatment was considered successful. Internal resorption was considered a failure in this study, even with no clinical symptoms, because it indicates that treatment failed in achieving a non-pathological state of the pulpal tissue.[26]

If a treated tooth exfoliated after more than six months (with no pathological external resorption), it was thereafter counted as a success in future calculations. If a tooth failed at any time period, it was counted as a failure in all future time periods. If a tooth was not available because the patient had dropped out or moved, it was removed from determination of the success rate and not in the numerator or denominator, in accordance with Coll et al.[5]

Treatment procedure. After a local anesthetic with 2% Xylocaine Dental with epinephrine 1:100,000 (lidocaine HCl and epinephrine Injection, USP, Dentsply Pharmaceutical, York, Pa., USA) was administered, a rubber dam was placed. Access was gained with a high-speed 330 SSW diamond bur (SS White Burs, Inc., Lakewood, N.J., USA) under an air-water coolant. Dental caries was removed using low-speed, round steel burs (Emil Lange, Engelskirchen, Germany).

Following removal of the coronal pulp with a round bur and attaining hemostasis, the pulp stumps in the experimental group were covered with tricalcium silicate paste prepared according to the manufacturer's instructions. Biodentine™ was introduced carefully into the prepared cavity, avoiding trapped air bubbles and condensed to ensure good adaptation to the cavity walls and margins. After condensation, the tricalcium silicate paste was covered with a reinforced zinc oxide-eugenol (IRM, Bayer, Leverkussen, Germany). In the control group, a cotton pellet lightly moistened with full-strength formocresol was placed for five minutes on the amputated pulp. The pulp stumps were then covered with IRM (Bayer, Leverkussen, Germany). The crowns of all teeth were restored with a stainless-steel crown. Each pulp treatment was completed during a single visit. Stainless steel crowns on teeth treated with a pulpotomy were placed on the same appointment.

Statistics. The data were analyzed at various follow-up periods. Intergroup differences stratified by age, gender, and type of tooth were statistically analyzed using Fisher's exact test. The software used for statistical analysis was SPSS 20.0 software for Windows (IBM Corp., Armonk, N.Y., USA). All tests applied were two-tailed, and a *P*-value of 0.05 or less was considered a statistically significant inter-group difference.

Results

A total of 72 teeth treated with pulpotomy were studied: 37 teeth (51.4 percent) treated with tricalcium silicate and 35 (48.6 percent) with formocresol. The study group included 58 healthy children (31 boys and 27 girls). Their ages ranged between 2.58 years and 9.58 years at the time of treatment, with a mean age of 5.9±1.66 (standard deviation [SD]) years (median equals 5.25 years) in the formocresol group and 6.2±1.54 (SD) years (median equals 5.83 years) in the tricalcium silicate group, with no differences observed (*P*=0.910). Of the 72 teeth treated with pulpotomy, 38 (52.8 percent) of the teeth were from boys and 34 (47.2 percent) were from girls, with no differences noted between the groups (Mann-Whitney test; *P*=0.910). Figure 1 is the flow diagram. The most common tooth treated with pulpotomy was the first primary mandibular left first molar; the least common was the primary maxillary right second molar. The mandibular molars comprised more than half of the teeth treated with pulpotomy (46 out of 72; 63.9 percent), with an equal distribution between the left and right sides of the mouth, whereas in the whole mouth, more than half of the teeth treated with pulpotomy were on the left side (41 out of 72; 56.9 percent).

Success rate. Tricalcium silicate was successful in 97.3 percent (36 out of 37) of the cases, and formocresol was successful in 91.4 percent (32 out of 35). Fisher's exact test disclosed no statistically significant differences between the two treatment (*P*=0.350). The success rates of the pulpotomies by type of treatment at one to four years follow-up is presented in the Table.

There was a statistically significant association between success or failure and gender; all failures (N equals four; 5.6 percent) were found in teeth belonging to girls, while no failures were recorded for boys (*P*=0.045). Of the four failures, three were with formocresol and one with tricalcium silicate. Of the three formocresol-failed pulpotomies, two were in 'split-mouth' girls, each of which had a successful tricalcium silicate pulpotomy in their other tooth.

No association between success or failure and type of tooth (*P*=0.920) was found (Fisher's exact test), and no significant difference (*P*=0.098) was found-between success and failure when age and time range from treatment to last follow-up were considered (Mann-Whitney test). Figure 2 illustrates a primary mandibular right second molar before treatment and 44 months after a

Table. CLINICAL AND RADIOGRAPHIC SUCCESS RATE (%) FOLLOWING PULPOTOMY AT 12- TO 48-MONTH FOLLOW-UPS

		Follow-up of treated teeth (months)				
		6=<, >=12	12-24	24-36	36-48	**Total N (%)**
Biodentine	Success N/total evaluated	37/37	26/27 Excluded: 7 dropped Included: 2 shed	22/23 Excluded: 4 dropped Included: 2 shed	15/17 Excluded: 6 dropped	**36/37 (97.3)**
	Failure N		1: Internal resorption			**1 (2.7)**
Formocresol	Success N/total evaluated	33/35	28/31 Excluded: 4 dropped	16/22 Excluded: 9 dropped	11/17 Excluded: 5 dropped Included: 1 shed	**32/35 (91.4)**
	Failure N	1: Internal resorption 1: Sinus tract	1: Inter-radicular radiolucency			**3 (8.6)**
***P*-value (Fisher's exact test)**		0.2328	0.6153	0.3129	0.3155	**0.3505**
Total		**72**	**60**	**45**	**34**	**72 (100)**

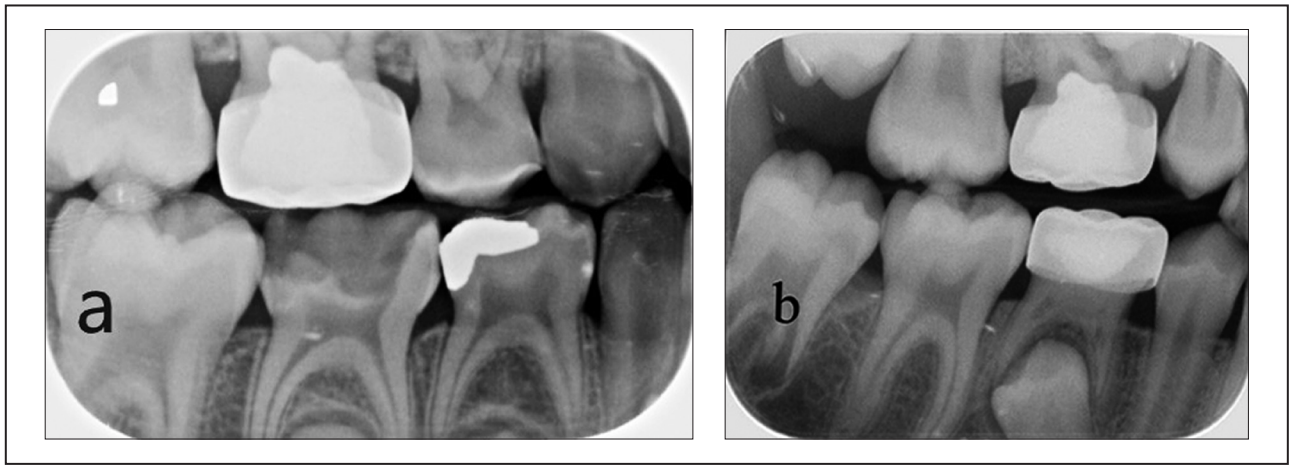

Figure 2. (a) Primary mandibular right second molar before treatment and (b) 44 months after a successful pulpotomy using tricalcium silicate where pulp canal obliteration can be noted.

successful pulpotomy using tricalcium silicate, where pulp canal obliteration can be noted.

Discussion

Pulpotomy is an effective option for vital pulp therapy in carious pulp exposure,[4] as it provides minimal intervention through vitality preservation, decreasing the need for pulpectomies and unnecessary extractions, improving children's quality of life. The results of the present study show that both tricalcium silicate and formocresol have high long-term success rates of up to four years, like those found in short-term studies of tricalcium silicate.[20,27,28] The results of the present study resemble those in a study comparing tricalcium silicate with other agents in primary teeth of female pigs at different time ranges, both with pulpotomy and with direct pulp capping.[23]

The high success rate may be attributed to the favorable traits of tricalcium silicate, like those discussed by Nowicka et al., including comparable sealing ability but after shorter setting time when compared to MTA,[15] high alkalinity, high biocompatibility, and encouraging repair of the original pulp tissues when placed in contact with the dental pulp.[15,21,30-32] It is also nontoxic, noncarcinogenic, insoluble in tissue fluids, and dimensionally stable.[32]

Another possible reason for the high long-term success of tricalcium silicate is its histologic characteristics; in the primary teeth of pigs, tricalcium silicate has promoted beneficial calcification in contact with vital pulp after pulpotomy and direct pulp capping.[29] It has also been demonstrated that, when tricalcium silicate is applied to pulp fibroblasts, they release TGF-β1, the growth factor that recruits pulp stem cells, regenerating the missing dentin in the form of reparative dentin bridge,[9] similar to MTA.[21]

Tricalcium silicate can be placed in direct contact with pulp tissue and used in bulk, since it does not require photo activation; it's also easy to handle and has good marginal integrity.[33] Due to these characteristics, tricalcium silicate has been found to be a suitable dentin substitute sharing the same indications and mode of action as calcium hydroxide and MTA, without their drawbacks.[31,32] A previous study raised concerns regarding the introduction of a confounding factor by using tricalcium silicate on a range of ages, due to varied regenerative ability of dental pulp over age.[21] The present study found no correlation between age and success rate.

A limitation of this study is the sample size. The noninferiority trial was chosen, because at the time the authors designed this study formocresol had similar rate of success as Biodentine,[27] and we were looking for a more biocompatible material with similar success rates. Although we studied 72 documented teeth, there was a high dropout rate. Another limitation is that only 28 teeth were found to be of 'split-mouth' design; therefore, this study cannot be considered a split-mouth design. Future studies should try to have larger sample sizes using a superiority trial design (i.e., that can demonstrate that that one treatment is superior to another) for the power and sample size calculation, preferably with a 'split-mouth' design.

Conclusions

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

1. All Failures were observed during the first 24 months post restorations.
2. It can be concluded that tricalcium silicate shows comparable (i.e., higher, though not statistically significant) success rate than formocresol in human primary molars pulpotomies followed for up to four years.
3. Based on this study's results the more biocompatable tricalcium silicate is preferred over formocresol for human primary molar pulpotomies.

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