Success of formocresol versus other medicaments used in vital pulpotomy In children with primary teeth

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ABSTRACT

This evidence-based study of the literature assessed the relative efficacy of non-aldehyde medicaments as opposed to formocresol in vital pulpotomy to treat primary teeth with extensive carious lesions involving the pulp. The review was based on literatures from PUBMED. A total of 134 articles were retrieved. Of these, 22 were deemed relevant and were critically appraised according to the "efficacy checklist". The 11 studies met the criteria of scoring 14/17 on the checklist. Included trials investigated Ferric sulfate pulpotomy, Mineral trioxide aggregate pulpotomy, laser pulpotomy and calcium hydroxide pulpotomy and formocresol pulptomy. Based on the available studies, Calcium hydroxide has a low success rate while the other alternatives like Ferric Sulphate, MTA and Lasers had demonstrated equivalency to formocresol in vital pulpotomy procedure. However, there is insufficient long term, clinical evidence to make a strong recommendation regarding an alternative to formocresol as a medicament for pulpotomy in primary teeth.

Key Words: Primary teeth, Pulpotomy, Formocresol, Calcium hydroxide, Mineral Trioxide Aggregate, Lasers, Ferric sulphate, Electrosurgery, Primary molar, Pediatric dentistry, Vital pulp therapy.

INTRODUCTION

Pulpotomy is the procedure by which the vitality of the uninfected radicular pulp is maintained by removal of infected coronal pulp tissue. The goal of vital pulpotomy in primary teeth is to maintain the space and to retain the functions of esthetics, speech and mastication until exfoliation.

Formocresol was introduced approximately a century ago and is the most widely used pulpotomy material in North America[30] The ideal pulpal dressing material is still not available but Formocresol is considered the gold standard of primary teeth pulpotomies. It is available as Buckley's formocresol (19% formaldehyde, 35% cresol, 17.5% glycerin), but commonly used in a 1:5 dilution in pulpotomy. It is frequently used due to its bacteriostatic and fixative properties, with success rates varying from 55 % to 98%[4,16.]

During recent times, concern has arisen over formocresol having dire implications as a pulpotomy medicament. The constituent that has been implicated as being harmful or toxic is the 'aldehyde' in the formocresol formulation[1]. Several investigations have resulted in the conclusion that the formaldehyde portion is toxic to connective tissue and since it does not stay localised to the dental pulp, it is absorbed systemically and produces an array of effects in other areas of the body[3].

Casas et al[1] states that the three areas of concern regarding formaldehyde are its mutagenicity, carcinogenicity and immune sensitization. A number of animal studies have demonstrated that chromosomal as well as carcinogenic alterations in epithelium occur due to the exposure to formocresol[1.]

Zarzar et al through an in vivo study reported that 10 % of children treated with a single formocresol pulpotomy demonstrated a statistically significant increase in chromosomal abberations[2]. The International Agency for Research on Cancer (IARC) of the World Health Organization recently reclassified formaldehyde as a known human carcinogen[1].

However, In a great study by Jeff Kahl and his colleagues[29], he showed that:

1. Formaldehyde is *undetectable* above baseline *physiologic* concentrations in plasma
2. It is *unlikely* that formocresol when used in doses typically employed for vital pulpotomies pose *any* risk to children[29].
   Although some studies nullify any systemic effects of formocresol, still because of its devitalizing effects on pulp, a search for alternative approaches, which are reparative and biological, is not only welcome but absolutely necessary[42].

We have endeavored to compare various common alternatives to Formocresol in an attempt to research the efficacy of other such agents and to determine if a suitable alternative can be used to replace Formocresol, sans its side effects.

ALTERNATIVE MEDICAMENTS

Among the most exciting materials to be introduced is MTA composed of tri calcium silicate, dicalcium silicate, tricalcium aluminate, tetra calcium aluminoferrite, calcium sulfate and bismuthoxide[17]. Eidelman et al[14] states that several in vitro and in vivo studies have shown that MTA prevents microleakage, is biocompatible, and promotes regeneration of original tissues when it is placed in contact with the dental pulp or periradicular tissues[14]. Not only has MTA yielded high success rates, it has not been found to induce internal resorption, which has been observed in teeth treated with some other medicaments [18]. MTA has a promising potential to become a replacement for formocresol in primary teeth[14].

Ferric sulphate has also been reported to show promising results as a dressing material for primary teeth pulpotomies[5]. When ferric sulphate comes in contact with blood it forms a ferric ion protein complex which occludes vessels and promotes hemostasis. Since the plugs occlude the capillary orifices, the chances of inflammation and internal resorption decrease[19-21]. Ferric sulphate as a pulpotomy agent was able to produce the same effect as formocresol in primary teeth[15].

Calcium hydroxide was proposed as an alternative to FC for pulpotomies in primary teeth in 1962 [22]and was the first agent to show the ability to induce dentine regeneration[23]. Failure with calcium hydroxide is most frequently attributed to internal resorption[24]. Calcium hydroxide appears to be clinically less appropriate than FC, FS, MTA[12]

Some studies investigating the application of lasers to dental tissues have shown their potential to increase healing, stimulate dentinogenesis and preserve vitality of the dental pulp[25].

Due to the concerns that prevail regarding the choice of formocresol as a pulp medicament with regard to its toxicity and devitalizing approach, other medicaments should be studied, on their efficacy as a viable alternative to formocresol, which is the rationale for this systematic review.

In our study, our primary purpose is to evaluate clinical and radiographic effects of various alternative medicaments and compare the results to formocresol pulpotomies.

MATERIALS & METHODS

Data Sources

To identify all the published articles assessing and comparing the alternative medicaments used in pulpotomy to formocresol, via PUBMED.

The key words used in the search strategy were Primary teeth, Pulpotomy, Formocresol, Calcium hydroxide, Mineral Trioxide Aggregate, Lasers, Ferric sulphate, Electrosurgical, Primary molar, Pediatric dentistry, Vital pulp therapy. The search strategy is presented in **Table No. 2.**

We also searched the related articles in Pub Med besides the regular search strategy.

Types of studies

Inclusion criteria:

1. Randomised and Quasi randomized clinical trials were used to compare pulpotomies using Formocresol and other medicaments like MTA, Calcium hydroxide, Lasers, Ferric sulphate, etc.

2. Human studies were only considered

3. Pulpally exposed primary teeth only

4. Only articles in English were taken into account

Exclusion criteria:

1. Animal studies

2. Pulpotomies involving permanent teeth

3. Other pulp therapies like Indirect/Direct Pulp capping, Pulpectomy

Evaluation of Success:

1. Evaluation was based on Clinical and Radiographic success.

2. Histopathologic evaluation was not taken into account.

3. Different bases were not a consideration.

Study Selection

Study selection was done using the PICO-C form (Presented in **Table No. 1**).

The Evidence Based Dentistry questions we are trying to answer in this Systematic review is:

How effective the other medicaments like Ferric sulphate, MTA, Lasers and Calcium hydroxide are as pulpotomy medicaments compared to Formocresol as the gold standard?

Study evidence assessment

Each study was analysed by three members, using a check list to assess evidence of efficacy of therapy. Each question in the check list marked one point with a maximum possible score of 17. Studies with a score less than 14 were excluded. The evidence table was constructed using CTFPHC(Canadian Task Force On Preventive Health Care)and the quality of evidence (I-III) and the classification of the final recommendation (A-E, I) was used to stratify the studies .

STEP 1:

A total of 134 articles were retrieved. Titles and abstracts were reviewed by 3 groups of 2 reviewers each, of which 22 articles were selected and divided into two groups and were analysed by three members. 11 articles were rejected at the full copy stage, due to inappropriate design, weak evidence and also using checklist criteria **(Appendix2)** 11 articles met the criteria.

STEP 2:

We sought the opinion of an expert in the field.

STEP 3:

We also searched the related articles in Pub Med besides the regular search strategy.

Table of search history is presented in **Table No. 3**.

Rejection table for these articles is presented in **Table No. 4**.

The search results yielded 11 articles in total and have been presented in four tables of Formocresol Vs Ferric sulphate, Formocresol Vs MTA, Formocresol Vs Lasers and Formocresol Vs Calcium hydroxide in **Appendix 1.** For evaluating the strength of the findings we followed CTFPHC (Canadian Task Force on Preventive Health Care).

RESULTS

After a detailed database search to assess the success of formocresol versus other medicaments used in vital pulptomy for primary teeth, we selected eleven articles[4,5,6,8,10,11,12,13,14,15,16]

The eleven articles included in our evidence-based study met all the inclusion criteria and are listed in **Appendix 1**. Out of the eleven articles, 10 are Randomized Controlled Trial articles[4,5,6,8,10,11,12,13,14,15,16] and one study[6] being Quasi RCT. The age range considered in these studies is 2 to 11 years, and comprised of boys and girls in relatively equal ratios. The sample size ranges from 15 to 50 primary carious molars. Formocresol (control group) is used in a strength of 1:5 dilution as the pulpotomy agent in all studies.

Two Studies[4,15] were performed in Pediatric Dental Hospitals, while all other studies[5,6,8,10,11,12,13,14,,16] were performed in University Clinics.

In most studies, clinical and radiographic results have been combined to give an overall or total success rate except in studies[6,8,13,16] where clinical and radiographic outcomes have been mentioned separately.

Formocresol versus Ferric Sulphate

4 RCT studies[5,10,12,15] were selected in this category to evaluate the success of formocresol and ferric sulphate as pulpotomy medicaments. In all these studies[10,5,15,12] Ferric Sulfate is used with strength of 15.5%.

K.C Huth[10] has the highest level of evidence(Level 1, GradeA) stating that there is no significant difference at the end of 24 months.

Ay-Luen Fei et al[5] with Level 1 Grade B recommendation and second in the hierarchy of evidence reports that at 3 and 6 months, there was no significant difference between the two treatments, but, at 1 year recall, the overall success rate for Ferric sulphate group was significantly greater.

Ibricevic et al [15] (Level 1 Grade B recommendation) study recommends the use of Ferric Sulphate as a pulpotomy agent on the basis of their results that revealed 100% clinical success rate and 97.2% radiographic success rates in both groups. The probable 2.8% radiographic failure in both treated groups was the result of inaccurate evaluation of the degree and extent of pulpal inflammation that would have benefited from pulpectomy procedure instead.

Sonmez et al[12] with Level 1 Grade B recommendation reports high success rates for both groups and no statistical difference between them.

Formocresol versus Mineral Trioxide Aggregate

5 RCT studies[8,11,12,13,14] were selected in this category. In these studies, Mineral Trioxide Aggregate paste was obtained by mixing MTA powder with sterile saline at 3:1 powder/ saline ratio except A.B.S. Moretti[11] that used 1:1 powder/saline ratio. All studies[,8,11,12,13,14] state that there was no significant finding between the two groups.

But in Farsi N et al[8] though there was no significant difference between the two groups, but there was a 38% loss of follow up.

2 studies[11,14] had a sample size of 15 teeth allotted to each group. Since the sample sizes are too small, further studies with larger sample sizes are recommended.

Formocresol versus Lasers

2 studies[6,10] used to evaluate the success of lasers as a non- medicament pulpotomy agent.

K.C Huth et al[10] with Level 1 Grade A uses Er: YAG laser to perform pulpotomy and shows no significant difference between the two groups. This was a double-blinded study.

The other study[6] uses Nd-YAG Lasers and reports insignificant difference between the two groups. The author recommends the laser as an alternative to formocresol because it doesn't cause any adverse reactions. However, the study is not randomized and since the study was 12 months in duration, the need for longer follow up is required.

Formocresol versus Calcium hydroxide

Five studies[4,10,11,12,16] were selected in this category. Aqueous calcium hydroxide was used in all studies except the fourth study[16] that used light cured calcium hydroxide. Two studies[10,11] showed that calcium hydroxide performed worse than Formocresol, and three studies[4,16,12] stated that there was no significant difference between the two groups.

K. C Huth et al[10] (with Level 1 Grade A recommendation), the strongest study in this category, reported that Calcium hydroxide performed significantly worst than formocresol in the success rates on a 24 month follow-up period. Only one study[4] stated that calcium hydroxide had a greater success rate that may be attributed to strict case selection criteria and use of calcium hydroxide in pure powder form.

DISCUSSION

The analysis of this systematic review reveals that there are possible alternative medicaments to formocresol, which may be considered equally efficacious.

The results of various studies need to be interpreted with caution due to certain shortcomings inherent in each study. After the appraisal of all the studies, we found that some of the studies did not evaluate histological success and effects on permanent teeth were not taken into consideration. In a few of the studies, the restorative materials employed were different in the treatment and control groups. Some of these studies lacked an ethical approval, while some were not blinded, which could amount to a certain degree of bias. Also there is need for further studies with a greater number of teeth treated with various medicaments to determine the long-term effects on permanent teeth.

Relative to lasers, the need for specialization to carry out treatment and the equipment cost also comes into consideration, while determining its efficacy.

Calcium hydroxide performed significantly worse than formocresol in a few studies, while its greater success in some other studies may be due to strict selection criteria.

In most of the studies comparing ferric sulphate with formocresol, there was no conflicting evidence regarding their clinical and radiographic results, but one study[5] showed a significantly greater success rate which could be attributed to small sample size or due to operator error despite pulpotomies performed in both groups by the same operator under rigorous conditions.

MTA also showed comparable success rates with formocresol and all the studies showed no conflicting evidence regarding the clinical and radiographic success in both the groups.

CONCLUSION

After a thorough evaluation of articles regarding ferric sulphate, it can be concluded that ferric sulphate can become the medicament of choice in future because of its equal or higher success rate clinically and radiographically. In addition it requires less manipulation time, has haemostatic effect and has same cost **(Appendix 3)**. But more studies are required to evaluate its systemic effects as well as its effects on permanent teeth.

Newly developed materials like MTA have shown some promise as a pulpotomy medicament but more clinical research is required before MTA can be used as an alternative dressing material to Formocresol. Manipulation consideration and cost **(Appendix 3)** may limit widespread use of MTA.

Lasers can be considered as an alternative to Formocresol in pulpotomies of primary teeth but longer follow-ups are required for these results to be confirmed. When considering lasers as an alternative, cost **(Appendix 3)** and a need for specialization to carry out treatment, also comes into play.

Calcium hydroxide is a less viable alternative for pulpotomy in primary teeth **(Appendix 3)** as compared to

Formocresol. It has less favorable outcome over a period of time which leads to failure of treatment.

The studies that were considered in this systematic review were carried out in ideal conditions, in University clinics. Hence most of the studies taken into consideration evaluated the efficacy of the material. Determining the effectiveness of the material would be imperative, as that would guide the clinician in deciding the best medicament available.

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Table No.1

PICO-C

Population	Primary teeth, Deciduous teeth, Children.
Intervention	Mineral Trioxide Aggregate pulpotomy, Ferric sulphate pulpotomy, Calcium hydroxide pulpotomy, Lasers pulpotomy, Electrosurgical pulpotomy, Glutaraldehyde pulpotomy,
Comparison	Formocresol Pulpotomy
Outcome	Success
Critical appraisal	Randomized Clinical trails, Non-Randomized Clinical Trials, Prospective and Retrospective Cohort study designs.

Table No. 2

Search strategy

Steps	Search terms	No. of article returned
1	"Tooth, Deciduous"[Mesh] OR "pediatric dentistry" OR "pediatric dentistry" OR "primary molar"	17244
2	"Pulpotomy"[Mesh] OR "Pulpectomy"[Mesh] OR "dental pulp therapy" OR "dental pulp treatment" OR "vital pulp therapy"	8553
3	"ferric compound" OR "ferric sulphate pulpotomy" OR "MTA pulpotomy" OR "mineral trioxide aggregate pulpotomy" OR "electrosurgical pulpotomy" OR "laser pulpotomy" OR "zinc chloride pulpotomy" OR "zinc oxide eugenol pulpotomy" OR "composite pulpotomy	256
4	Formocresol therapy" OR "formaldehyde therapy" OR "Formocresol pulpotomy	1202
5	1 and 2 and 3 and 4	134

Table No. 3

Search history	**No. of articles**
Total no. of articles found with key words in Pub Med	134
Articles rejected at Title stage	95
Articles at abstract stage	39
Articles rejected at Abstract stage	22
Articles at Full copy stage	17
Articles found by related searches	5
Total no. of articles at Full copy stage	22
Articles rejected at Full copy stage	11
Total no. of articles selected	11

Table No. 4

REJECTION TABLE

Authors' name	**Reason of rejection**
Mack RB et al 1993	Control group not in the study
Prakash C et al 1989	Not met checklist criteria of 14/17 (10/17)
Alacam A 1989	No clinical and radiographic success evaluated.
Aeinechi M et al 2007	Observation period is less.
Jeng- fen Liu 2006	Checklist criteria not met - (12/17)
Kaaren et al 2005	Evaluating failure and combination FC and FS used in one sample
Bahrololoomi Z 2009	Only one electrosurgical pulpotomy study present that met the criteria.
Saltzman B et al 2005	Combined two things, like laser and MTA, Formocresol and ZOE.
Alacam A 1989	Using two different bases.
Robert D Elliot et at-1999	Observation period not enough.

Formocresol vs. Ferric Sulphate **Appendix 1**

Author, date	Population (Age, sex, location)	Intervention, or Test treatment (Number studied))		Control treatment (Number studied)		Outcome			Critical appraisal comments	Conclusion, Strength of evidence and classification
		N	Material	N	Material	Material	Clinical success	Radiographic success		
K.C Huth et al 2005	•Age : 2-8 years •107 children •200 carious primary molars •University Clinic	50 50 50	Er:Yag Laser Aqueous Calcium Hydroxide FerricSulphate (15.5%)	50	Dilute Formocresol (1:5)	Laser Ca(OH)2 FS FC At 24 Months	78% 53% 86% 85% Combined results		RCT, double blinded -Check list Score= 15/17	No significant difference between the 2 groups. Level 1 Grade A
Ay-Luen Fei et al 2000	•Age: 3.2-10.1 yrs •37 M, 27F •84 carious primary molars •Pediatric Dental clinic Southern California.	29	Ferric sulphate (15.5%)	27	FC (1:5 Dilution)	FS FC At 12 months	96.6% 77.8% Combined results		-RCT with strong study design. - Check list score 14/17	No significant difference between 2 groups. FS greater success than FC, need further observation Level 1,Grade-B
Ibricevic et al 2000	•Age: 3-6 yrs •24 boys 46 girls •70 carious primary molars •Al Amiri Dental Centre , Kuwait	35	Ferric sulfate (15.5%)	35	FC Buckley's formula	FS FC At 20 months	100% 97.2% Combined results		-RCT -Checklist score: 15/17	-ferric sulfate can be recommended as a pulpotomy agent in primary teeth in substitution for FC -Level I grade B
Sonmez et al 2008	•Ages: 4 -9 years •6 females and 10 males •60 primary carious molars •University Clinic-Ankara	**20** **20** **20**	FerricSulphate (15.5%)Aqueous Calcium Hydroxide solution MTA sterile saline at 1:1 powder/saline	20	diluted FC(1:5 Buckley s	FS Ca(OH)2 MTA FC At 24 months	73.3% 46.1% 66.6% 76.9% Combined results		-RCT, Study design average -single blinded study. - different restoration -no rubber dam isolation - Check list 14/17	No significant difference, FS was suggested an appropriate material Level 1 Grade –B

Formocresol vs. MTA

Author, date	Population (Age, sex, location	Intervention, or Test treatment (Number studied))		Control treatment (Number studied)		Outcome			Critical appraisal comments	Conclusion, Strength of evidence and classification
		N	Material	N	material	material	Clinical success	Radiographic success		
Noorollahian. 2007	Age: 5 to 7yrs. 29 M, 17 F 60 carious primary molars University Clinic-Zahedan Iran	30	MTA powder (3:1 ratio with sterile saline,)	30	diluted FC (1 :5)	MTA FC At 24 months.	100% 100%	94.4% 100%	RCT Double blind Checklist score 15/17	MTA had the same success rate as with FC. MTA could be used as a safe substitute for FC. Level 1 Grade A
A.B.S Moretti et al 2008	Ages: 5 -9 yrs 9 F and 14 M. 45 primary carious molars University Clinic-Sap Paulo.	15 15	MTA powder with sterile saline at 1:1 powder/saline Calcium Hydroxide Powder	15	diluted FC(1:5 Buckleys solution	MTA Ca(OH)2 FC At 24 months	60.0% 33.3% 66.6% Combined results		Double blinded RCT Modified GI restoration Checklist score 16/17	FC and MTA had similar efficacy and both had better outcomes than CH Level 1 ,Grade - A
Sonmez et al 2008	Ages:4 -9 years 6 females and 10 males 60 primary carious molars University Clinic-Ankara	**20** **20** **20**	FerricSulphate (15.5%) Aqueous Calcium Hydroxide solution MTA sterile saline at 3:1 powder/saline	20	diluted FC(1:5 Buckleys	FS Ca(OH)2 MTA FC At 24 months	73.3% 46.1% 66.6% 76.9% Combined results		-RCT, Study design average --no blinding - different restoration -no rubber dam isolation - Check list 14/17	No significant difference, Level 1 Grade –B
Eidelman, et al 2001	Age: 5-12 yrs 11 M, 7F 32 Carious pulp exposures Pediatric Dentistry at Clinic Hebrew University-Hadassah	17	MTA powder (3:1 ratio with sterile saline,)	15	FC	MTA FC At 30 months	100% 93.3% Combined results		-RCT, Single blinded Checklist score 14/17	MTA can be considered as an alternative to FC. Level I, Grade B
Farsi N, et al 2005	Age: 3-8 years 100 children, 74 carious primary teeth	38	MTA powder (3:1 ratio with sterile saline,)	36	FC	MTA FC At 24 months	100% 98.6%	100% 86.8%	RCT, no blinding mentioned 38% loss of follow-up Checklist score 15/17	Significant difference between 2 groups in 24 months Level I, grade I

Formocresol vs. Lasers

Author, date	Population (Age, sex, location	Intervention, or Test treatment (Number studied))		Control treatment (Number studied)		Outcome			Critical appraisal comments	Conclusion, Strength of evidence and classification
		N	Material	N	material	material	Clinical success	Radiographic success		
K.C Huth et al 2005	Age : 2-8 years 107 children 200 carious primary molars University Clinic	50 50 50	Er:Yag Laser Aqueous Calcium Hydroxide Ferric Sulphate (15.5%)	50	Dilute Formo cresol (1:5)	Laser Ca(OH)2 FS FC At 24 Months	78% 53% 86% 85% Combined results		RCT, double blinded study. Checklist Score= 15/17	Er:Yag lasers and FS had insignificant failure rates compared to FC Level 1 Grade A
Mesut et. al 2007	Age 6-9 years 14 M 16 F, 42 carious primary molars University Clinic-Pediatric Dentistry, Turkey	21	Nd-YAG Laser 2w, 20Hz, 100mJ	21	FC	Laser FC 12 months.	85.71% 90.47%	71.42% 90.47%	- single blinded quasi randomized clinical Checklist score 14/17	-May be considered as an alternative to FC , need longer follow ups. Level II-1 , GRADE A

Formocresol vs. Calcium Hydroxide

Author, date	Population (Age, sex, location	Intervention, or Test treatment (Number studied))		Control treatment (Number studied)		Outcome			Critical appraisal comments	Conclusion, Strength of evidence and classification
		N	Material	N	material	material	Clinical success	Radiographic success		
K.C Huth et al 2005	Age: 2-8 years 107 children 200 carious primary molars University Clinic	50 50 50	Er:Yag Laser Aqueous Ca(OH)2 Ferric Sulphate (15.5%)	50	Dilute Formocresol (1:5)	Laser Ca(OH)2 FS FC At 24 Months	78% 53% 86% 85% Combined results		RCT, triple blinded Checklist Score= 15/17	Ca(OH) performed significantly worse than FC Level 1 Grade A
A.B.S Moretti et al 2008	Ages: 5 -9 yrs 9 F and 14 M. 45 primary carious molars University Clinic-Sap Paulo	15 15	MTA w/sterile saline at 1:1 Calcium Hydroxide Powder	15	diluted FC 1:5 Buckleys solution	MTA Ca(OH)2 FC At 24 months	60.0% 33.3% 66.6% Combined results		Double blinded RCT Modified GI restoration Checklist score 16/17	Internal resorption most common adiographic finding. Level 1 ,Grade - A
P.J. Waterhouse Et al 1991	Age: 3.3-12.5yr 26 males and 26 females. 84 carious primary molars. Pediatric dental hospital New castle U.K	38	Ca(OH)2 (pure powder)	46	FC (1:5 dilution)	Ca(OH)2 FC At 12 months	77% 84% Combined results		RCT with strong study design. Checklist score 15/17	Ca(OH)2 can be used under strict selection criteria and pure powder form used as an alternative to formocresol. Level1, Grade-B
Derek Zurn et al 2006	Age: 2.3-8.5 yrs 7 females and 13 males 76 carious primary molars Pediatric Dentistry, Dallas	38	light cured calcium hydroxide	38	FC	Ca(OH)2 FC At 24 months	84% 97%	72% 97%	RCT Clinical and radiographic sample size did not match due to lack of cooperation Checklist score 15/17	Calcium hydroxide does not appear to be a viable alternative to formocresol LEVEL 1 , GRADE B
Sonmez et al 2008	Ages:4 -9 years 6 females and 10 males 60 primary carious molars University Clinic-Ankara	20 20 20	Ferric Sulphate (15.5%) Aqueous Ca(OH)2 MTA w/sterile saline at 1:1	20	diluted FC(1:5 Buckleys	FS Ca(OH)2 MTA FC At 24 months	73.3% 46.1% 66.6% 76.9% Combined results		RCT, Study design average. -different restoration. . no rubber dam isolation Checklist score 14/17	No significant difference, Ca(OH)2 less appropriate than the others Level of evidence 1 Grade –B

Appendix 2

Checklist to Assess Evidence of Efficacy of Therapy or Prevention

Citation: _____

_____

1. Was the study ethical? ___
2. Was a strong design used to assess efficacy? ___
3. Were outcomes (benefits and harms) validly and reliably measured? ___
4. Were interventions validly and reliably measured? ___
5. What were the results?
   Was the treatment effect large enough to be clinically important? ___

   Was the estimate of the treatment effect beyond chance and relatively precise? ___

   If the findings were "no difference" was the power of the study 80% or better ___
6. Are the results of the study valid?

   - Was the assignment of patients to treatments randomised? ___
   - Were all patients who entered the trial properly accounted for and attributed at its conclusion?

   i) Was loss to follow-up less than 20% and balanced between test and controls ___

   ii) Were patients analysed in the groups to which they were randomised? ___

   - Was the study of sufficient duration? ___
   - Were patients, health workers, and study personnel "blind" to treatment? ___
   - Were the groups similar at the start of the trial? ___
   - Aside from the experimental intervention, were the groups treated equally? ___
   - Was care received outside the study identified and controlled for ___
7. Will the results help in caring for your patients?

   Were all clinically important outcomes considered? ___

   Are the likely benefits of treatment worth the potential harms and costs? ___

Adapted from: Fletcher, Fletcher and Wagner. Clinical epidemiology – the essentials. 3rd ed. 1996, and Sackett et al. Evidence-based medicine: how to practice and teach EBM. 1997

Appendix 3

Technology assessment table for Formocresol Vs Ferric Sulphate

Compared to the control the test intervention costs	Compared to the control or standard intervention the test intervention works		
	Better	The same	Worse
Less			
The same		√	
More			

Technology assessment table for Formocresol Vs MTA

Compared to the control the test intervention costs	Compared to the control or standard intervention the test intervention works		
	Better	The same	Worse
Less			
The same			
More		√	

Technology assessment table for Formocresol Vs Lasers

Compared to the control the test intervention costs	Compared to the control or standard intervention the test intervention works		
	Better	The same	Worse
Less			
The same			
More		√	

Technology assessment table for Formocresol Vs Calcium Hydroxide

Compared to the control the test intervention costs	Compared to the control or standard intervention the test intervention works		
	Better	The same	Worse
Less			
The same			√
More			