

## FORMOCRESOL AND FERRIC SULPHATE PULPOTOMY OUTCOMES IN PRIMARY MOLARS: A SYSTEMATIC REVIEW

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### ABSTRACT:

**Background:** Formocresol and ferric sulfate were used as pulpotomy medicaments since long time in pediatric dentistry. Formocresol is regarded a gold standard in devitalization group while ferric sulfate is regarded gold standard in preservation group. Various literature shows Formocresol has been challenged due to its carcinogenicity and mutagenicity.

**Objective:** The objective of this systematic review is to assess the literature regarding the efficacy of Formocresol & Ferric Sulphate pulpotomy on primary molars and to assess its clinical and radiographic success rate.

**Data sources:** Databases used for the search were PubMed and GoogleScholar from 1<sup>st</sup> January 1994 to 31<sup>st</sup> December 2015. In addition hand-search of dissertations and journals on pediatric dentistry related to the topic of interest was performed in the institutional library.

**Study eligibility criteria:** Articles published between 1<sup>st</sup> January 1994 and 31<sup>st</sup> December 2015 in English with Randomized controlled trials and Original prospective clinical trials comparing Formocresol and Ferric sulfate Pulpotomy agents reporting follow up period of 6 months or more, clinical and radiographic success rates in primary molars were selected for the review.

**Results:** 9 Articles were selected for the systematic review. No significant difference was seen in the outcome of pulpotomy medicaments using formocresol & Ferric sulfate.

**Conclusion:** In human carious primary molars, a pulpotomy performed with either ferric sulphate or formocresol is likely to have a similar clinical and radiographic success. But a nontoxic and easy to manipulate, ferric sulfate can be recommended as a pulpotomy agent for replacement of formocresol.

**Key-Words:** Formocresol, Ferric Sulphate, Primary Teeth, Vital Pulp Therapy.



### INTRODUCTION:

Dental caries, the most common chronic childhood disease, creates unique problems in the primary dentition.<sup>[1]</sup> Children and young adults who have not received early and adequate dental care and optimal systemic fluoride and do not have adequate oral hygiene often develop deep carious lesions in the primary and permanent teeth. Many of the lesions appear

radiographically to be dangerously close to the pulp or to actually involve the dental pulp. Approximately 75% of the teeth with deep caries have been found from clinical observations to have pulpal exposures.

As early as 1756, Pfaff reported placing a small piece of gold over a vital exposure in an attempt to promote healing. Although it has been established that the pulp is capable of healing, there is still much to

learn regarding the control of infection and inflammation in the vital pulp.<sup>[2]</sup> The goal of pulp therapy in primary teeth is to maintain the primary tooth until it exfoliates in order to maintain the integrity of the dental arch.

Pulpotomy therapy evolved slowly over the first 40 years, the pace of change since the 1960s has continued to accelerate. Pulpotomy in a primary tooth is a procedure performed when the coronal pulp tissue is exposed by caries, during caries removal or trauma.<sup>[3]</sup> The infected and inflamed coronal pulp is amputated, leaving vital and uninfected radicular pulp tissue. The pulp stump could be treated by electro surgery, Er:YAG laser or with a dressing such as formocresol, calcium hydroxide, glutaraldehyde, enriched collagen solution, ferric sulphate or mineral trioxide aggregate to protect it and promote healing. The ideal pulp dressing material/method should be able to provide hermetic seal, be antibacterial and non-toxic, promote healing of the radicular pulp, and not interfere with the physiological process of exfoliation.<sup>[4]</sup>

Formocresol is regarded as the 'gold standard' and was first used for pulpotomy by Sweet with a 97% success rate.<sup>[5]</sup> Formocresol produces an area of necrosis in the adjacent pulp tissue with the fixative effect diminishing as it progresses apically. The apical third of the pulp is unaffected, and retains its vitality for an extended time.<sup>[6]</sup> Formocresol has been the most popular pulp-dressing material for pulpotomized primary molars for the past 60 years. However, the use of formocresol has been challenged because of its

deleterious effects, potential carcinogen in action, immune sensitization, mutagenicity and cytotoxicity. The major concern has been with the formaldehyde component of formocresol. Formaldehyde has been shown to be distributed systemically after pulpotomy. Cresol is also locally destructive to vital tissue.<sup>[7]</sup> It is also stated that FC can lead to premature exfoliation of primary teeth.<sup>[8]</sup>

Ferric sulphate ( $\text{Fe}_2[\text{SO}_4]_3$ ) has been used as a coagulative and a haemostatic agent for crown and bridge impressions.<sup>[9]</sup> The agglutination of blood proteins results from the reaction of blood with ferric and sulphate ions and with the acidic pH of the solution. The agglutinated proteins form plugs that occlude the capillary orifices,<sup>[10]</sup> and thereby minimizes the chance for inflammation and internal resorption.<sup>[4]</sup>

Fei et al. (1991) reported the application of ferric sulphate in pulpotomized human primary molars with clinical and radiographic success rates of 100% and 97%, respectively. Ferric sulphate prevented problems arising from clot formation after the removal of the coronal pulp and produced a local, but reversible, inflammatory response in oral soft tissues.<sup>[11]</sup> No concerns about toxic or harmful effects of ferric sulphate have been recorded in the dental or medical literature.

Systematic reviews have gained an important position in the dental literature, aiding in clinical decision making. Therefore purpose of this Systematic Review of the literature was to evaluate the effects of

formocresol versus ferric sulphate primary molar pulpotomy in terms of clinical and radiographical outcomes.

### **FOCUSED QUESTION**

How effective are Formocresol and Ferric sulfate as pulpotomy medicament in primary molar with respect to clinical and radiographic success rate?

### **OBJECTIVE**

The objective of this systematic review,

1. To assess the literature regarding the efficacy of Formocresol & Ferric Sulphate pulpotomy on primary molars.
2. To assess its clinical and radiographic success rate.

### **ELIGIBILITY CRITERIA**

#### **Inclusion criteria:**

- 1) Articles in English or those having detailed summary in English.
- 2) Studies published between 1<sup>st</sup> January 1994 and 31<sup>st</sup> December 2015.
- 3) Studies that provided information for age groups of 3 to 14yrs old.
- 4) Randomized controlled trials and Original prospective clinical trials comparing Formocresol and Ferric sulfate Pulpotomy agents.
- 5) Pulpotomy performed on human vital primary molars with carious pulp exposure.
- 6) Follow-up periods of at least 6 months or more.

- 7) Reporting clinical or radiographic success and failure rates.

#### **Exclusion criteria:**

- 1) Review, case reports, abstracts, letters to editors, editorials and in vitro studies are excluded.
- 2) Articles published in languages other than English.
- 3) Studies having follow-up shorter than 6 months.

### **PICOS**

P - Participants: People of age group 3-14yrs

I - Intervention: Use of Formocresol Pulpotomy

C - Comparison: with Ferric sulfate Pulpotomy

O - Outcome measure: Clinical and Radiographic Success rate

S - Study design: Clinical trials and original research

### **INFORMATION SOURCES**

A comprehensive computerized search (since 1<sup>st</sup> January 1994 and 31<sup>st</sup> December 2015) was conducted in PubMed and Google Scholar and manual search using DPU college library resources. In PubMed the Clinical Queries filter, facilitated finding the controlled clinical trials (RCTs) for comparing FC and FS as primary pulpotomy agents. All cross reference lists of the selected studies were screened for additional papers that could meet the eligibility criteria of the study. The databases were searched up using the search strategy.

**SEARCH STRATEGY USED FOR PUBMED DATABASE**

Combinations of the following keywords were used to develop search strategies applied for the PubMed database search up to 31<sup>th</sup> December 2015:-

Formocresol	Buckley's Formocresol
Ferric Sulphate	Ferric Sulfate
Pulpotomy	Pulp Therapy OR Vital Pulp Therapy OR Pulp Treatment
Primary Molar	Deciduous Molars OR Primary Teeth
Evaluation	Clinical success OR Radiographic success rate

The following Search Strategies were used with different combinations for trial searching in PubMed.

Sr. No.	Search Strategies	No. of Results	Selected
1	Formocresol AND Ferric Sulfate AND Pulpotomy AND Primary Molar OR Deciduous Molar AND Outcomes	27	11
2	Formocresol AND Ferric Sulfate AND Pulpotomy AND Primary Molar OR Deciduous Molar AND Evaluation	107	12
3	Buckley's Formocresol AND Ferric Sulfate AND Pulpotomy OR Vital Pulp Therapy AND Primary Molar AND Outcomes	12	5
4	Buckley's Formocresol AND Pulpotomy AND Primary Molar AND Clinical OR Radiographic Success Rate	223	17
5	Formocresol AND Ferric Sulfate AND Vital Pulp Therapy AND Primary Molar OR Deciduous Molar AND Clinical OR Radiographic Success Rate	422	33
6	Formocresol AND Ferric Sulfate AND Pulp Therapy OR Pulp Treatment AND Primary Molars AND Evaluation	35	8
7	Formocresol AND Ferric Sulfate AND Pulpotomy AND Primary Molar OR Deciduous Molar AND Clinical OR Radiographic Success Rate	618	39
8	Formocresol AND Pulpotomy AND Primary Molar AND Clinical OR Radiographic Success Rate	219	15
9	Formocresol AND Pulpotomy AND Primary Molar OR Deciduous Molar AND Clinical Success Rate OR Radiographic Success Rate	242	15
10	Formocresol AND Vital Pulp Therapy AND Primary Molar OR Deciduous Molar AND Evaluation	114	13
11	Ferric Sulfate AND Vital Pulp Therapy AND Primary Molar OR Deciduous Molar AND Evaluation	114	12
	<b>TOTAL</b>	<b>2133</b>	<b>180</b>

## **STUDY SELECTION**

Selection of studies was done initially by reading the title and abstract of the articles obtained from each database. Only those articles that were relevant to the review were collected and put for further evaluation. Articles reporting information based on Pulpectomy, endodontic treatment for permanent teeth and animal studies were excluded. Also Case reports, case series, review articles, abstracts, editorials, and in vitro studies were not included. Clinical trials and fulfilling the inclusion criteria were assessed further for the review.

Full text articles of the selected abstracts were then evaluated independently. The selection process involved two independent investigators and a consensus decision was made with a third evaluator to shortlist the articles that met all the inclusion criteria for the systematic review. Reference lists of the selected articles were also searched for additional data that may have been missed. There were no restrictions placed on the maximum follow up period or sample size for the studies selected.

The titles and abstracts of the identified studies were reviewed for relevance. Also hand searching was performed which

added one more article data to the digital search results.

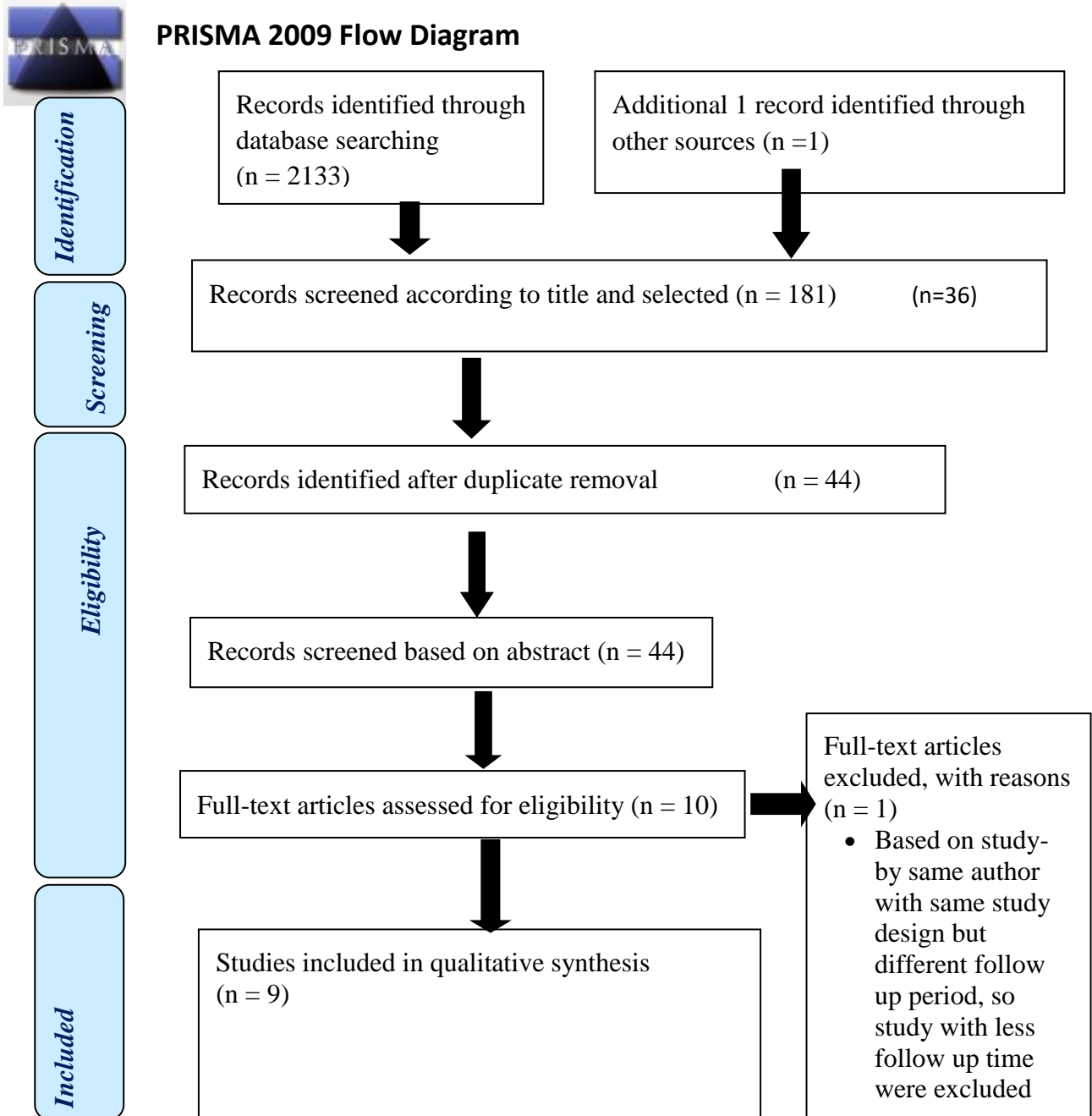
Out of 181 articles, after removal of duplication 44 articles are remained. Out of 44 articles only 10 articles had both Formocresol and Ferric Sulphate. Remained 34 articles had either formocresol or Ferric sulphate, so for this systematic review only 10 articles were taken into consideration. After getting full text of 10 articles we found that the two articles with same author had published two studies with same study design with different follow-up period, so we excluded the study which having lower follow-up period, so after studying all full text articles 9 articles are included in this systematic review.

## **DATA COLLECTION PROCESS**

A standard pilot form in excel sheet was initially used and then all those headings not applicable for review were removed. Data extraction was done for one article and this form was reviewed by an expert and finalized. This was followed by data extraction for all the articles.

**RESULTS:**

**STUDY SELECTION**



Pulpotomy is currently the accepted standard of care for carious exposures of asymptomatic vital primary teeth.<sup>[12]</sup> The procedure involves coronal pulp amputation and the remaining vital radicular tissue surface is treated with long-term clinically evaluated medicaments to

preserve the vitality and function of radicular pulp.<sup>[13]</sup>

The original aim of pulpotomy for primary teeth was devitalisation. In 1904, Buckley introduced formocresol to treat non-vital permanent teeth.<sup>[14]</sup> In 1930, Sweet introduced the formocresol pulpotomy technique. Formocresol

has subsequently become a popular pulpotomy medicament for primary teeth. Initially, the technique involved five visits. By 1960, a single visit procedure was advocated.<sup>[15]</sup> There are concerns over the use of formocresol regarding cytotoxicity, allergenicity, mutagenicity, carcinogenicity, and teratogenic effects on animals, chromosomal damage to the dental pulp cells in tissue culture, chromosomal breaks and aberrations in peripheral lymphocytes and mutagenesis of stem cells.<sup>[16]</sup> In the presence of formaldehyde, an increased risk of myeloid leukaemia has been found.<sup>[17]</sup> These problems have caused concern among dental professionals over the use of formocresol. In June 2011, the United States Department of Health and Human Health Services issued a report that classified formaldehyde as a carcinogen for humans.<sup>[18]</sup> The dental profession has therefore looked for alternative pulpotomy medicaments that are both clinically and biologically more acceptable.<sup>[19]</sup>

Monsef's solution, which is a 20% ferric sulphate, is widely used as a strong styptic agent in skin and mucosal biopsies [20]. It causes reactive and degenerative changes when used as a styptic agent. However, another form of this chemical, ferric sulphate,<sup>[21]</sup> produces local and reversible inflammatory response to oral soft tissues, but no toxic or harmful effects have been published in dental or medical literature.<sup>[22,23]</sup> In contact with the blood, ferric ions form a ferric complex and the membrane of this complex seals the cut blood vessels mechanically and provides haemostasis and an agglutinated protein complex, which produces a blood clot that occludes the capillary orifices.<sup>[24]</sup> This non-aldehyde chemical (ferric sulphate) has therefore been proposed as a pulpotomy agent as its mechanism of controlling

haemorrhage might minimise the chances of inflammation and internal resorption and it is believed to be associated with physiologic clot formation.<sup>[25]</sup> Fie *et al.* (1991) demonstrated good clinical results using ferric sulphate in human primary teeth.<sup>[21]</sup> Since then, it has been used as an alternative pulpal medicament.

Although ferric sulphate and Formocresol is not a new pulp medicament for pulpotomized primary molars, the number of clinical studies, especially high quality RCTs, is limited. With the limited number of studies and different or even controversial results, aggregating the results of different studies by systematic review is an optional way to provide reliable results and suggestions for clinical practice.

For this systematic review we taken clinical trials published between January 1994 to December 2015 which having both formocresol and ferric sulphate as a pulpotomy agent. We selected total 9 studies out of which 7 are RCTs and 2 are CCTs.

Havale *et al.* <sup>[16]</sup> performed a RCT comparing three pulpotomy medicament formocresol, ferric sulphate & glutaraldehyde. The procedure was performed under rubber dam and after completion of treatment teeth were restored by stainless steel crown. In this study there was no loss of follow-up at the end of 12 months, but in this study author had not described a method of randomization and also overall success rate. The conclusion of article states that in comparison with FC and FS, FS had a good clinical Success rate, so

according to clinician and parent's Point of view Ferric sulphate is better than formocresol.

Fernandez et al.<sup>[26]</sup> performed a RCT comparing four pulpotomy medicament formocresol (FC), mineral trioxide aggregate (MTA), ferric sulphate, and sodium hypochlorite (NaOCl). The procedure was performed under rubber dam and after completion of treatment teeth were restored by stainless steel crown. The high dropout rate was the huge limitation was the study. Also the author doesn't described about radiographic feature such as pulp anal obliteration and didn't came to a proper conclusion regarding the study. According to this study results FC & FS have a similar success rate.

Karin Huth et al.<sup>[27]</sup> performed a RCT comparing four pulpotomy medicament Er:YAG laser, calcium hydroxide and ferric sulphate with dilute formocresol. The procedure was performed under rubber dam and after completion of treatment teeth were restored by stainless steel crown or composite resin restoration. As a study duration is long the loss of sample size is still acceptable. Authors concluded that ferric sulphate is the most effective in comparison with formocresol but doesn't have any significant relation.

Erdem et al.<sup>[28]</sup> performed a RCT comparing four pulpotomy medicament formocresol, ferric sulphate, Zinc Oxide Eugenol & MTA. The procedure was performed under rubber dam and after completion of treatment teeth were restored by Dental amalgam. In this study Author doesn't

explained about clinical and radiographic failure criteria. The final results of the study are somehow promising as the author during calculation of results the dropouts were excluded from the study.

Sonmez et al.<sup>[29]</sup> performed a RCT comparing four pulpotomy medicament formocresol, ferric sulphate, Calcium Hydroxide & MTA. The procedure was performed under cotton roll isolation and after completion of treatment teeth were restored by Dental amalgam. The limitation of studies were less sample size, no rubber dam isolation, no SS Crown after completion of procedure. As the raising controversies against FC author advices the use of FS as a pulpotomy medicament.

Markovic et al.<sup>[30]</sup> performed a RCT comparing three pulpotomy medicament formocresol, ferric sulphate & Calcium Hydroxide. The procedure was performed under cotton roll isolation or rubber dam based on child's cooperation and after completion of treatment teeth were restored by Dental amalgam.. The results clinical and radiographic features were given properly but overall success rate was not mentioned. Author's conclusion was in favour of ferric sulphate.

Ibricevic et al.<sup>[31]</sup> performed a CCT comparing two pulpotomy medicament formocresol & ferric sulphate. The procedure was performed under rubber dam and after completion of treatment teeth were restored by stainless steel crown. The author didn't described about radiographic features such as pulp canal



obliteration, dentin bridge formation & overall success rate.

Anna Fuks et al.<sup>[32]</sup> performed a CCT comparing two pulpotomy medicament formocresol & ferric sulphate. The procedure was performed under rubber dam and after completion of treatment teeth were restored by stainless steel crown. The author neither described about any clinical feature nor clinical success rate. In this study there is no specific follow up period and no overall success rate mentioned. The conclusion of study states equal result for both the groups.

Esmā Yildiz et al.<sup>[33]</sup> performed a RCT comparing four pulpotomy medicament formocresol, ferric sulphate, Calcium Hydroxide & MTA. There is no information about the isolation protocol during the procedure. The teeth were restored by composite resin as a final restoration. The author didn't mentioned about overall success rate and conclusion of article states except calcium hydroxide remaining all three material had equal success rate.

Most of the included RCTs failed to follow the guidelines. First, the randomization method (i.e. computer, envelope, random sequence, etc.) will exclude subjective interference in case selection and distribution. Cristina Fernandez et al.<sup>[26]</sup> used the table of random numbers. Other studies failed to describe their ways of randomization clearly. Secondly, allocation concealing, which means the estimator, the patient himself and outcome reporter were blinded to the treatments allocation, will guarantee an objective and accurate

assessment. This was reported only in the studies of Havale et al,<sup>[16]</sup> Cristina Fernandez et al,<sup>[26]</sup> Huth et al,<sup>[27]</sup> Erdem et al,<sup>[28]</sup> Markovic et al,<sup>[30]</sup> Yildiz et al,<sup>[33]</sup> Thirdly, a small sample size will lead to a lower power of test and lack of adequate evidence, whereas a large one will cause the difficulties of trial control and obtaining long-term data, waste of labour, money and time. In addition, withdrawal rates that are caused by emigration, death, etc. during a long-term follow-up should be <10% of the total number of the included cases. For children, the reason for dropout from studies is mainly caused by naturally exfoliated teeth.

Stainless steel crowns (SSCs) were highly recommended for treating pulpotomized teeth, based on the assumption that there is less leakage in crowned teeth than those restored with amalgam.<sup>[34]</sup> Out of 9 studies only 5 studies used a Stainless steel crown as a restoration after completion of treatment. Many of the studied failed to perform a pulpotomy procedure under rubber dam isolation which is the best way to prevent contamination from saliva.

Not every pathological finding in a primary tooth requires intervention, as the primary tooth survival or the permanent successor may not necessarily be affected. Pulp canal obliteration was the most common radiographical finding in both groups. Pulp canal obliteration is the result of extensive activity of odontoblast-like cells, demonstrating that the tooth has retained some degree of vitality. Therefore, it was not regarded as failure.<sup>[35]</sup>

Compared with permanent teeth, deciduous teeth have a shorter life span. As a result, studies with longer follow-up time will be at the risk of losing case information. In addition, the increasing rate of loss to follow up and some uncertainty factors, such as emigration or death, will affect the accurate estimation of success/failure rates. Therefore, longer observation periods may lead to observed lower success rates than at shorter time periods.

#### LIMITATIONS

This systematic review based on two databases namely PubMed & Google Scholar, Inclusion of other databases would have given more authentication.

The pulpal diagnosis is dependent on the combination of a good history, clinical and radiological examination and various tests (Percussion, Pulp vitality tests), but most of the tests are subjective which may lead to inaccurate diagnosis which may lead to an inappropriate treatment plan.

Though formocresol and Ferric sulphate were widely used pulpotomy medicament there are very less numbers of literature regarding clinical trials comparing these two medicament which can be a limitation to this systematic review.

#### CONCLUSION:

Based on 9 studies results following conclusions were drawn from the present Systematic review:

1. No significant difference was shown between formocresol and ferric sulphate as medicaments for use following pulpotomy

as both are having an equal amount of clinical and radiographic success rate.

In human carious primary molars, a pulpotomy performed with either ferric sulphate or formocresol is likely to have a similar clinical and radiographic success. But a nontoxic and easy to manipulate, ferric sulfate can be recommended as a pulpotomy agent for replacement of formocresol.

2. Internal resorption and furcal radiolucency were common radiographic finding in both pulpotomy medicament groups.

3. At recall, pulpotomised teeth should be assessed radiographically to monitor any pathological changes.

4. In the present systematic review, most of the studies showed that the clinical success rate was higher than the radiological success. From this observation, it can be assumed that from the point of view of a clinician as well a parent, clinical success may count more than radiologic changes.

#### FUTURE IMPLICATION

1. Large number of studies are required to be carried out considering the factors like age, diagnosis, standard post-operative restoration, radiographic consideration, the assessment of symptoms to be considered for the prognosis of treatment to be considered as success and failure.

2. More precise studied needs to be carried out considering proper study protocol and

unique assessment scale to score the success and failure.

3. As this systematic review based on two databases namely PubMed & Google Scholar, for new systematic review inclusion of other databases would have given more authentication.

4. There is also a need to develop new pulpotomy medicaments which will have a better clinical and radiographic success rate as these both materials considered are used since long time in pediatric dentistry.

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### **TABLES:**

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