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Review Article

Clinical and radiographic success of TheraCal versus Formocresol in primary teeth pulpotomy: A systematic review and meta-analysis

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ABSTRACT

Background: Various dressing materials have been evaluated for pulpotomy of primary teeth. However, an ideal pulp dressing material has not been identified yet. This systematic review investigated the effectiveness of TheraCal compared to Formocresol in pulpotomy of primary teeth.**Materials and methods:** This research was conducted in the form of a secondary study, with a systematic search of texts until 2023 in Scopus, Web of Science, PubMed and Google Scholar databases. The articles were selected based on the inclusion and exclusion criteria and, finally the search results were reported in the PRISMA chart. The quality of the studies was evaluated based on the NIH checklist. The extracted information was entered into Stata17 software. Heterogeneity was evaluated using Cochran's chi-square test and I^2 statistics. Egger's tests were used to detect publication bias.**Results:** After removing duplicate articles and articles that did not meet the inclusion criteria, 4 studies were selected for qualitative analysis. The odds' ratio of success rate between Formocresol and TheraCal pulpotomy for absence of the pain, abscess, Mobility, internal root resorption and bone radiolucency was obtained 1.12 (95 % CI: 0.32, 3.85, $P = 0.86$), 0.47 (95 % CI: 0.1, 2.14, $P = 0.33$), 0.82 (95 % CI: 0.21, 3.21, $P = 0.78$), 0.89 (95 % CI: 0.3, 2.67, $P = 0.84$), and 1.96 (95 % CI: 0.68, 5.62, $P = 0.21$) respectively.**Conclusion:** The study results revealed that there was no significant difference in clinical and radiographic success between pulpotomy with TheraCal and Formocresol.

1. Introduction

Dental caries is an infectious, multifactorial and the most common chronic disease among children (Bossù et al., 2020; Smail-Faugeron et al., 2018). Despite the preventive strategies considered in developed countries, many children are exposed to severe dental caries (Vos et al., 2017). Preserving primary teeth till the eruption of permanent teeth is necessary because of their role in determining the dental arch, esthetic considerations, speech problems and chewing function in children (Guo et al., 2023).

Due to the structural differences of primary teeth compared to permanent teeth, such as the larger pulp chamber, longer and more pointed pulp horns and less dentin and enamel thickness, caries in these teeth progress faster and endanger the pulp. As a result, effective and early treatment is mandatory (Casamassimo et al., 2019). One of the common treatments for maintaining primary teeth until their normal exfoliation

is pulpotomy (El Sadek et al., 2016).

Pulpotomy is a procedure in which the inflamed coronal pulp is completely removed, and vital radicular pulp tissue preserved (Jha et al., 2021), and should be covered with an ideal dressing material for the pulp. An ideal dressing material should be bactericidal, harmless to the pulp and the surrounding structure, promotes pulp healing and does not prevent the physiological root resorption of primary teeth. (Ahmadi et al., 2020). An ideal pulp dressing material has not been identified yet.

Due to its easy use and antibacterial properties, Formocresol has become the most popular pulp dressing material for pulpotomy, with a success rate of 76–97 % (El Meligy et al., 2019; Lin and Lin, 2020; Sushynski et al., 2012). However, there is concern about toxicity, mutagenicity and potential carcinogenicity for this material in high doses in humans (Casas et al., 2005). As a result, various dressing materials have been evaluated for pulpotomy of primary teeth (Vargas et al., 2006). One of the materials proposed to cover the pulp of primary

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teeth is TheraCal. TheraCal was developed in 2011 to overcome the poor adhesion of calcium silicate materials to resins in the final restoration (Arandi and Rabi, 2018).

TheraCal is a hydrophobic monomer that contains trichium silicate particles that help to form dentin bridges by releasing calcium (Dawood et al., 2017). Compared to other silicate-based materials, TheraCal has several advantages, such as easy application, setting time, good mechanical properties, acceptable bonding ability, low solubility and prevention of microleakage. TheraCal is commercially available in a syringe, making it easy to use. All these advantages make TheraCal a good choice for children who cannot tolerate prolonged visits and may lose cooperation over time (Nielsen et al., 2014; Peskersoy et al., 2021; Sameia et al., 2020).

Although clinical research in primary and permanent teeth reported an acceptable success rate for TheraCal (Moselhy et al., 2022; Abdullah et al., 2020; ElHasaneen et al., 2019; Sahin et al., 2021), a systematic review study has not investigated its effectiveness compared to other conventional materials in pulpotomy of primary teeth. Therefore, this systematic review study was conducted to evaluate the effectiveness of TheraCal compared to Formocresol in pulpotomy of primary teeth.

2. Materials and methods

This systematic review was in accordance with guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA statement) (Liberati et al., 2009) and its protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) with the approval code CRD42022339237. Ethics Committee of Isfahan University of Medical Sciences, Isfahan, Iran, confirm this research project (ID number of IR.MUI.RESEARCH.REC.1402.122.).

2.1. Search strategy

Studies were searched after determining PICO question based on the subject. The inclusion and exclusion criteria were defined. In the present study, clinical trial studies conducted in this field were considered. In the articles on children who need pulpotomy treatment (P, population) the efficacy of TheraCal (I, intervention) versus Formocresol (C, comparison) in success rate of pulpotomy treatment was evaluated (O, outcome).

The search line was created based on keywords selected from Medical Subject Headings (MeSH) and non-MeSH terms. The main keywords research were “TheraCal”, “primary teeth”, “Formocresol” and, “pulpotomy”. In this review, the Scopus, PubMed, and Web of Science databases were searched to find relevant articles. Only English language articles and the articles with participants under 18-year-olds were selected.

The search strategy used to retrieve the articles involved (TheraCal” or Resin-Modified Calcium Silicate Pulp protectant or resin-modified Portland cement-based material or tricalcium silicate or tricalcium silicon pentoxide or biodentine or tricalcium silicate-based material) and (Formocresol or Formaldehyde or Formalin) and (Primary teeth OR deciduous teeth OR pediatric dentistry OR child dentistry OR pediatric OR pedodontics OR dentistry for children) and (pulpotomy or pulpotomies or pulp therapy or vital pulp therapy). For hand searching, two authors independently searched the key journals, checked the references of the studies enrolled in the study and consulted with experts in this field. Also, an additional search was applied through searching in Google scholar motosearch. In this review, in order to retrieve all relevant information, no restrictions were applied on the search period and geographical area. The last updated search was conducted in August 2023.

2.2. Selection of studies

To upload all relevant studies and to limit the duplicate articles, the

reference management system (EndNote) was employed. The search process was done by two trained reviewers independently and according to a developed search strategy. Two reviewers were trained by a third person who was an expert in the process of systematic reviews. The articles should be chosen based on the inclusion and exclusion criteria.

To resolve discrepancies between two reviewers, specific consensus and third reviewer methods were used. First, the titles of the studies were reviewed, and relevant studies were selected in terms of titles. Then the abstracts of the enrolled studies were considered. The articles that matched inclusion criteria were selected. Finally, reviewers screened the full texts of the selected articles. The correlation coefficients between the results of reviewers’ search were 0.95 and 1 in the abstract and full-text levels, respectively. Any disagreements between the two researchers were resolved by the third researcher’s final decision.

2.3. Assessment of risk of bias

The risk of bias of the studies included, was evaluated based on the NIH (National Institute of Health) quality assessment tool of clinical trial studies. The scale domains were assessed by 14 questions.

Enrolled articles were assessed as having poor, fair, and good quality based on the NIH scores < 50 %, 50 %-75 %, and > 75 %, respectively.

Study characteristics such as author name, publication year, study design, study groups, sample characteristics (sample size/participant age and sex), clinical and radiographic success were collected for each study.

Using the Comprehensive Meta-Analysis Software Stata 17 (Stata Crop, College Station, TX, USA), a meta-analysis was performed to evaluate the effect of materials used for pulpotomy in primary teeth on clinical and radiographic success of pulpotomy treatment. For statistical analysis, the percentage of clinical (absence of pain, abscess and mobility) and radiographic success (absence of periapical or inter-radicular radiolucency and internal root resorption) in two groups treated with TheraCal and Formocresol were extracted. In addition, the odds’ ratio between two groups (pulpotomy using TheraCal and formocresol) was calculated with a 95 % confidence interval (CI) and restricted maximum likelihood (REML) method.

To analyze heterogeneity in studies, the p-value and I^2 statistics were used. As a p-value < 0.05 or an I^2 > 50 % reveals heterogeneity.

A forest plot was used to depict the results of the meta-analysis. To determine publication bias, Egger’s test was applied. In all tests, the significance level was determined to be $P < 0.05$.

3. Results

3.1. Study selection;

According to the search flow chart, a total of 163 studies (82 on Google scholar, 28 on Web of Science, 30 on Scopus, and 23 on PubMed) were found. The duplicate and irrelevant studies were excluded and in 82 studies the abstracts were assessed. Ultimately, the full texts of 6 articles were analyzed, from which 2 were excluded. (Fig. 1)(Table 1).

3.2. Risk of bias

The NIH quality assessment tool for clinical trial studies is rating system with fourteen items, All the articles enrolled in the review scored higher than 10 and therefore were of high quality.

3.3. Study characteristics

All the included studies were randomized clinical trials that evaluated the clinical and radiographic success of TheraCal or Formocresol in primary tooth pulpotomy.

In 4 studies reviewed in the systematic review, several factors were

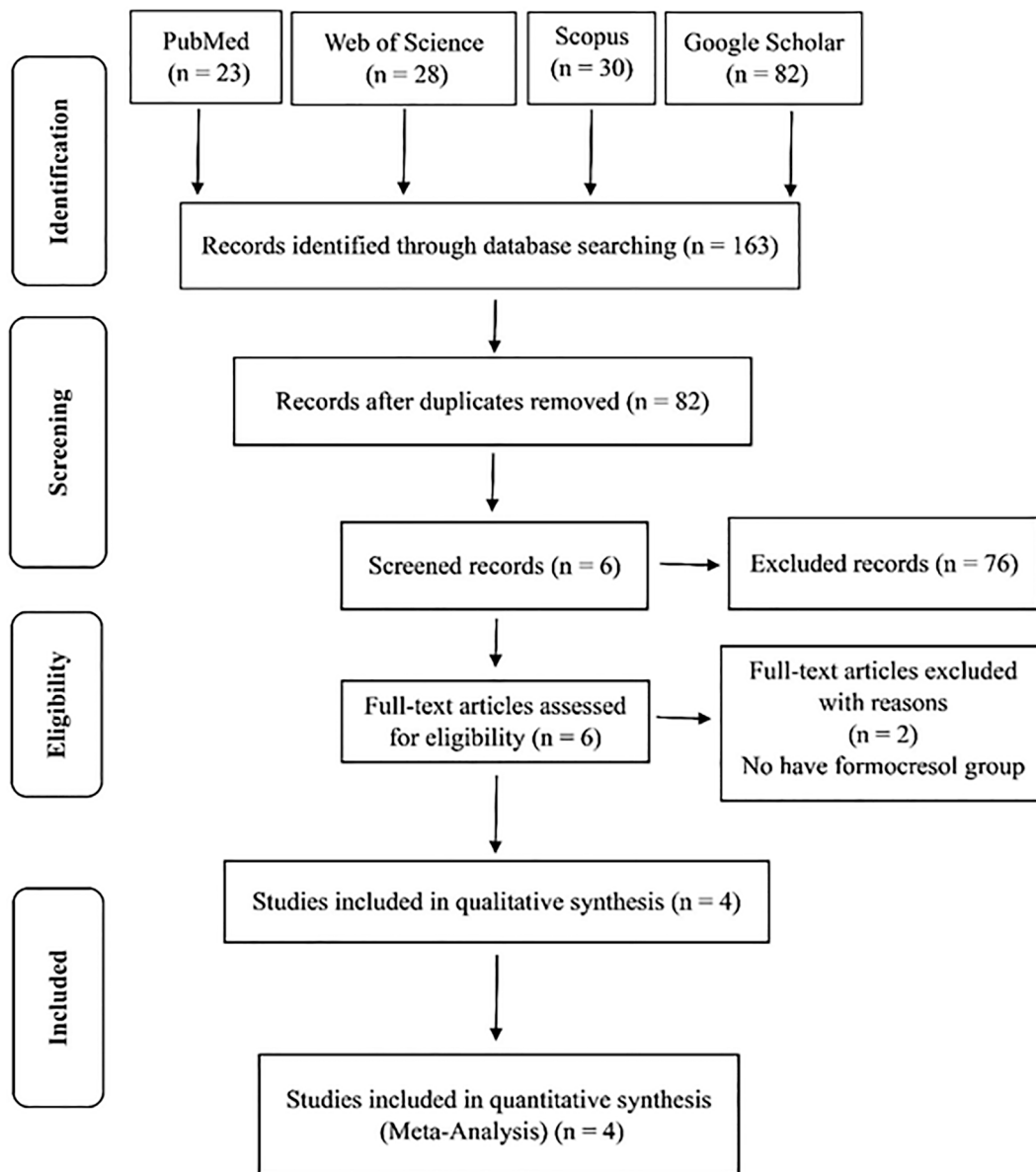


Fig. 1. Flow diagram of the search strategy.

Table 1
Evidence table of main characteristics of studies included in the systematic review.

Author	Contry	Study Design	Participants	Age	Tooth Evaluated	Groups	Follow up	Final conclusion
ElHasaneen et al., 2019	Egypt	Parallel	60 Patients	4 – 7 Years	60 mandibular second primary molars	3 group (n = 20), formocresol, TheraCal and calcium sulphate	in 3, 6, 9 and 12 months	TheraCal and calcium sulphate are successful substitutes to formocresol as pulp medicaments for primary molars pulpotomy
Wassel et al., 2017	Egypt	Parallel	50 Patients	4 – 7 Years	60 mandibular primary molars	2 group (n = 30), TheraCal and formocresol	3and 6 month	TheraCal LC was found to be as successful as FC over a 6 months period
Abdullah et al., 2020	Egypt	Parallel	60 Patients	4 – 7 Years	60 mandibular second primary molars	2 group (n = 30), TheraCal and formocresol	3, 6, 9 and 12	TheraCal LC can be an effective medicament for vital pulpotomy in primary molars
Abdelhafez et al.2022	Egypt	Parallel	30 Patients	3 – 6 Years	60 s primary molars	3 groups (n = 10), TheraCal, MTA, and formocresol	6, 9, 12 and 15 months	TheraCal LC can be an effective medicament for vital pulpotomy in primary molars

considered for clinical and radiographic success. In clinical success, the factors were categorized into absence of pain, absence of abscess (chronic or acute) and absence of mobility. Similarly, in the

radiographic success, the factors were classified as absence of bone radiolucency (*peri*-apical or inter-radiolar) and absence of root resorption (external or internal). In different studies, the success of pulpotomy

treatment was compared with different substances, but Formocresol and TheraCal should be among them to consider in this review. Also, in different studies, different periods of time were considered for follow up. In Abdelhafez et al. study the clinical and radiographic success of three different materials (Formocresol, TheraCal and MTA) was assessed in 6, 9, 12 and 15 months. (Abdelhafez, 2022) Wassel et al. in their study evaluated the clinical, radiographical and histological success of vital pulpotomy with TheraCal and Formocresol in 3 and 6 months follow up. (Wassel et al., 2017) Elhasaneen et al. investigated the efficacy of TheraCal, Formocresol and calciumsulphate in success rate of pulpotomy in 3, 6, 9 and 12 months. (Elhasaneen et al., 2019) While in the Abdullah et al. study, the efficacy of TheraCal and Formocresol in 3, 6, 9 and 12 months, follow-up was compared.(Abdullah et al., 2020) However, in all studies, the longest follow-up time was considered to assess the clinical and radiographic success. In two studies, only mandibular second primary molars were considered for pulpotomy treatment. (Elhasaneen et al., 2019; Abdullah et al., 2020). While in wassel et al. and Abdelhafez et al. studies, mandibular primary molars (maybe first or second primary molar) and second primary molars (maybe maxillary or mandibular) were considered respectively. (Wassel et al., 2017; Abdelhafez, 2022) The design of all the studies were parallel.

3.4. Quantitative analysis

3.4.1. Absence of pain

Four studies with similar methodology evaluated the clinical success rate of two materials (TheraCal and Formocresol) used for vital pulpotomy in terms of the absence of pain. No heterogeneity was found among the 4 studies ($I^2 = 0.0\%$; p -value = 0.54) and a fixed-effects model was used for meta-analysis. In the current meta-analysis study, the odds' ratio for success rate in the absence of pain was obtained OR = 1.12 (95 % CI: 0.32 to 3.85) (p -value = 0.86). (Table 2) Thus, the success rate of pulpotomy (absence of pain) had no significant difference between usage of two different materials (TheraCal and Formocresol). Publication bias for the variables of absence of the pain was not significant. ($P = 0.791$).

3.4.2. Absence of abscess (chronic or acute)

Four studies with similar methodology evaluated the clinical success rate of two materials (TheraCal and Formocresol) used for vital pulpotomy in terms of the Absence of abscess. No heterogeneity was found among the 4 studies ($I^2 = 0.0\%$; p -value = 0.89) and a fixed-effects model was used for meta-analysis. In the current meta-analysis study, the odds' ratio for success rate in the absence of abscess was obtained OR = 0.47 (95 % CI: 0.10 to 2.16) (p -value = 0.33). (Table 3) Thus, the success rate of pulpotomy (absence of abscess) had no significant

difference between usage of two different materials (TheraCal and Formocresol). Publication bias for the variables of absence of abscess was not significant. ($P = 0.221$).

3.4.3. Absence of tooth mobility

Four studies with similar methodology evaluated the clinical success rate of two materials (TheraCal and Formocresol) used for vital pulpotomy in terms of the absence of tooth mobility. No heterogeneity was found among the 4 studies ($I^2 = 0.0\%$; p -value = 0.67) and a fixed-effects model was used for meta-analysis. In the current meta-analysis study, the odds' ratio for success rate in the absence of tooth mobility was obtained OR = 0.82 (95 % CI: 0.21 to 3.21) (p -value = 0.78). (Table 4) Thus, the success rate of pulpotomy (absence of tooth mobility) had no significant difference between usage of two different materials (TheraCal and Formocresol). Publication bias for the variables of absence of tooth mobility was not significant. ($P = 0.647$).

3.4.4. Absence of root resorption

Four studies with similar methodology evaluated the radiographic success rate of two materials (TheraCal and Formocresol) used for vital pulpotomy in terms of the absence of root resorption. No heterogeneity was found among the 4 studies ($I^2 = 0.0\%$; p -value = 0.6) and a fixed-effects model was used for meta-analysis. In the current meta-analysis study, the odds' ratio for success rate in the absence of root resorption was obtained OR = 0.89 (95 % CI: 0.30 to 2.67) (p -value = 0.84). (Table 5) Thus, the success rate of pulpotomy (root resorption) had no significant difference between usage of two different materials (TheraCal and Formocresol). Publication bias for absence of root resorption was not significant. ($P = 0.374$).

3.4.5. Absence of bone radiolucency

Four studies with similar methodology evaluated the radiographic success rate of two materials (TheraCal and Formocresol) used for vital pulpotomy in terms of the absence of bone radiolucency. No heterogeneity was found among the 4 studies ($I^2 = 0.0\%$; $P = 0.91$) and a fixed-effects model was used for meta-analysis. In the current meta-analysis study, the odds' ratio for success rate in the absence of bone radiolucency was obtained OR = 1.96 (95 % CI: 0.68 to 5.62) ($P = 0.21$). (Table 6) Thus, the success rate of pulpotomy (absence of bone radiolucency) had no significant difference between usage of two different materials (TheraCal and Formocresol). Publication bias for the variables of absence of bone radiolucency was not significant. ($P = 0.139$).

4. Discussion

In pulpotomy, the remaining radicular pulp in the orifices is covered

Table 2
Forest plot of success rate in term of absence of pain.

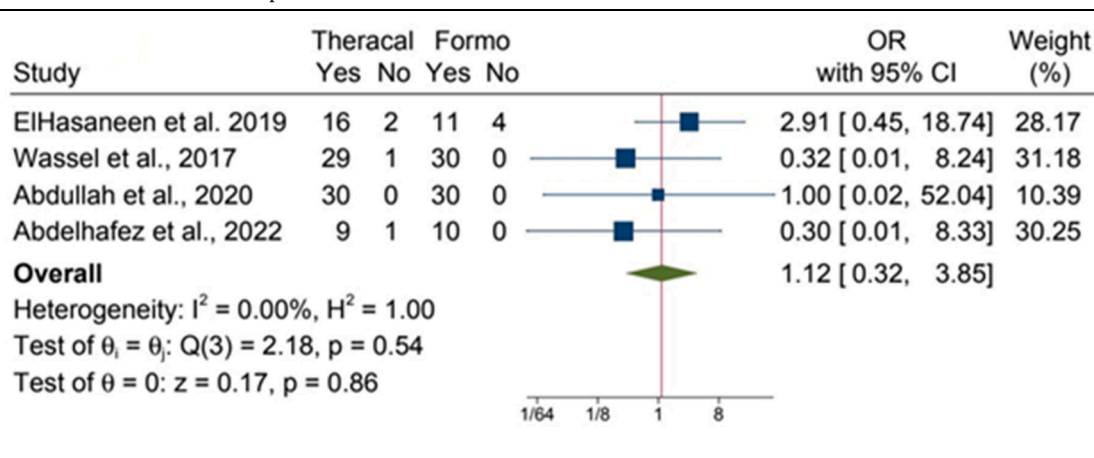


Table 3
Forest plot of success rate in term of absence of abscess.

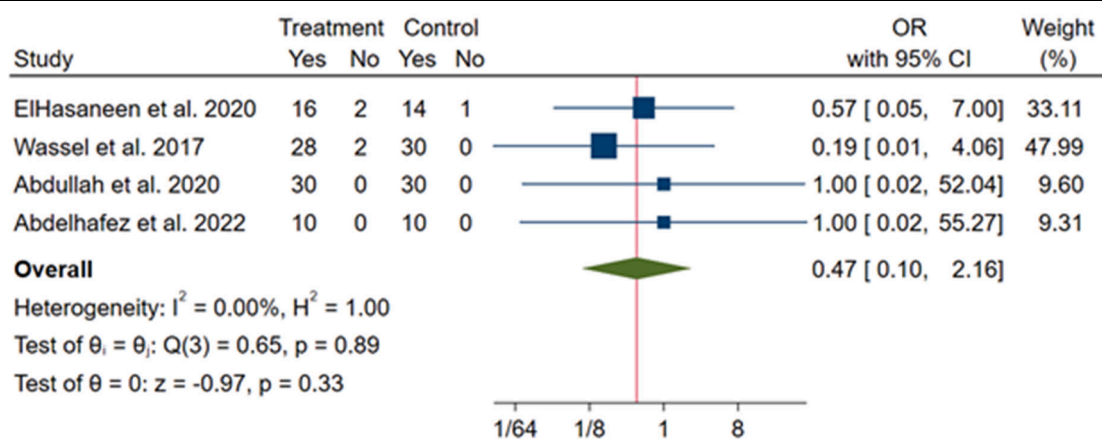


Table 4
Forest plot of success rate in term of absence of mobility.

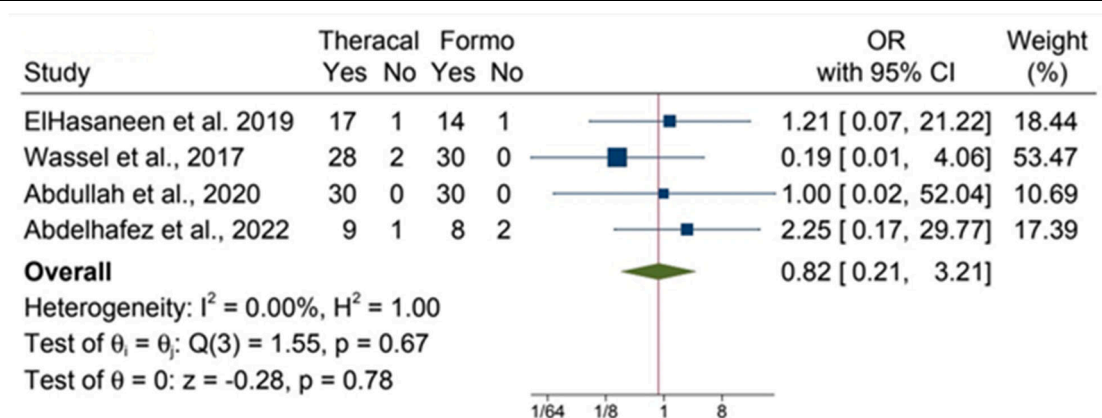
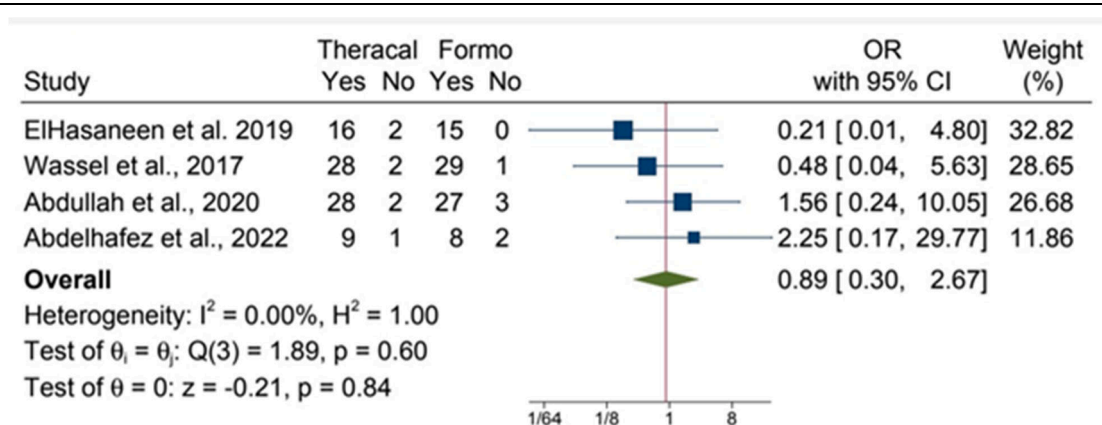


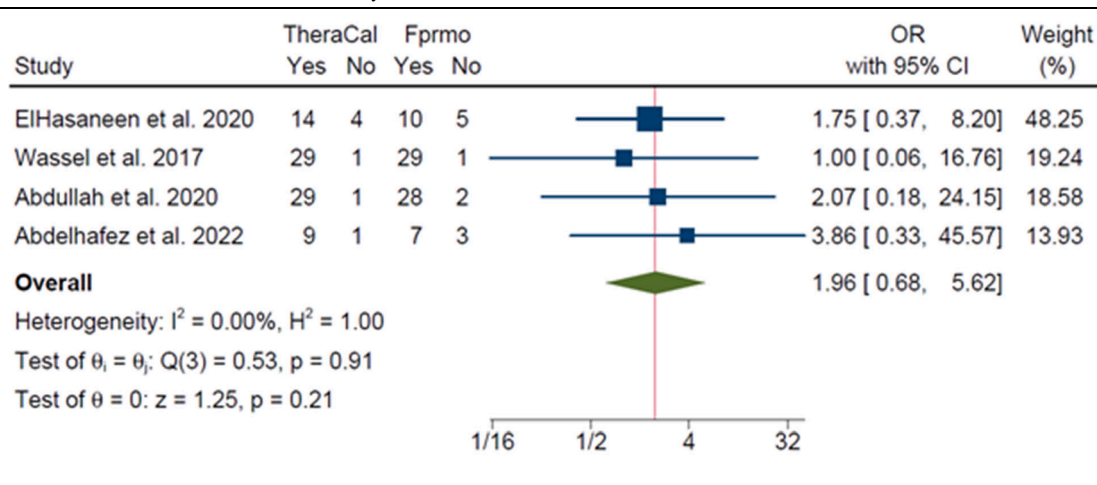
Table 5
Forest plot of success rate in term of absence of Root Resorption.



with dental materials in order to speed up healing or fix it. Various materials such as Formocresol, ferric sulfate and mineral trioxide aggregate and sodium hypochlorite are used in dental pulpotomy

(Casamassimo et al.,2019). The most common material used for pulp dressing is Formocrosol (El Meligy et al., 2019; Lin and Lin, 2020; Sushynski et al., 2012). However, there is concern about toxicity,

Table 6
Forest plot of success rate in term of absence of radiolucency.



mutagenicity and potential carcinogenicity for this substance in high doses in humans (Casas et al., 2005; Havale et al., 2013; Agamy et al., 2004). In addition, in children who have many teeth treated with Formocresol under general anesthesia, the serum level of Formocresol is likely to increase and may cause more concerns. As a result, various covering materials have been considered and tested for pulpotomy of primary teeth.

One of the materials proposed today to cover the pulp of primary teeth is TheraCal. TheraCal is a radiopaque, light-cured, resin-modified calcium silicate. The primary chemical composition in TheraCal is similar to mineral trioxide aggregated (MTA). While, TheraCal has a hydrophilic resin in its composition that facilitates calcium release. TheraCal has an appetite stimulating capability, making it a good choice for vital pulp therapy treatments (Saltzman et al., 2005).

This systematic review summarized the available studies on the clinical and radiographic success of TheraCal compared to Formocresol in pulpotomy of primary teeth. The results of this systematic review and meta-analysis showed that pulpotomy using TheraCal showed the same results as Formocresol and there was no statistically significant difference in the clinical success (no pain, abscess or tooth mobility) and radiographic success (no internal root resorption or bone radiolucency) between the TheraCal and Formocresol groups. This conclusion suggests that TheraCal can have the same clinical and radiographical success as Formocresol without the toxicity and mutagenicity concerns of Formocresol.

All 4 studies reviewed in the systematic review were clinical trials and had a parallel design, and all of them had at least two treatment groups, including TheraCal and Formocresol. Also, in all the included articles, the clinical and radiographic success rates were analyzed and presented separately. Only in two articles the overall clinical and radiographic success were mentioned (Abdelhafez, 2022; Wassel et al., 2017). Therefore, the overall percentage of clinical and radiographic success was not included in the analysis.

In the study of ElHasaneen et al., in addition to TheraCal and formocresol, the clinical and radiological success of calcium sulfate was also investigated. The results revealed that TheraCal and calcium sulfate are successful alternatives for Formocresol as a pulp dressing material in primary teeth pulpotomy. (ElHasaneen et al., 2019) In the study of Abdelhafez et al., the comparison of partial pulpotomy with complete pulpotomy in primary molar teeth using three different materials was examined clinically and radiographically. (Abdelhafez, 2022) The results demonstrated that the success of complete pulpotomy is superior to partial pulpotomy. Also, the results showed that MTA was more successful compared to TheraCal and Formocresol. It was also stated that TheraCal can be considered as a good substitute for formocresol. On the

other hand, TheraCal is cheaper and easier to use than MTA.

Sahin et al. showed that the clinical and radiographic success rates of Dycal, Biodentine and TheraCal materials were almost equal and no significant difference was observed between them. (Sahin et al., 2021) However, the histological investigations in the mentioned study showed that the condition of the pulp is affected by the selected dressing material, especially when choosing a resin-containing material such as TheraCal. Moselhy et al. also reported that TheraCal as a dressing material in pulpotomy of primary molars shows acceptable results. (Moselhy et al., 2022) In the study of Erfanparast et al. radiographic and clinical findings showed that TheraCal showed comparable results with MTA in direct pulp capping of primary molars after 12 months. (Erfanparast et al., 2018).

Gandolfi et al. in a study revealed that TheraCal, compared to other pulp dressing materials such as ProRoot MTA and Dycal, has higher calcium release ability and lower solubility, which features make it suitable for direct pulp cap treatment. (Gandolfi et al., 2012) It has also been shown that direct pulp cap and indirect pulp cap using TheraCal can be a reliable treatment option for the treatment of primary molars (Moselhy et al., 2022). Mahapatra et al. also demonstrated that TheraCal can be used in indirect pulp cap treatment as an alternative to calcium hydroxide with a similar success rate in children with deep caries. (Mahapatra et al., 2022) Also, TheraCal is a clinically and radiographically desirable material for direct pulp capping (DPC) that creates an adequate dentin bridge and minimal expansion of the periodontal ligament space (Sameia et al., 2020).

Recently, a meta-analysis study demonstrated that direct pulp cap (DPC) using calcium silicate light cure materials had a significant superiority compared to calcium hydroxide. This may indicate the weak performance of calcium hydroxide, including lack of adhesion to dentin, porosity in calcified bridge and high solubility. Also, the results of this study revealed no significant difference between TheraCal Light Cure, MTA and Biodentine in short follow-ups. When the success of TheraCal was examined in the 12-month follow-up, it had the highest failure compared to other groups, which probably indicates the damage to the pulp cells from the heat created by the Light Cure device. (García-Mota et al., 2022).

There is controversy among researchers regarding the properties of TheraCal. Its disadvantages include creating a pulpal inflammatory reaction due to the presence of resin monomers in the composition of the non-polymerized resin components after contact with the pulp and less biocompatibility. (Lee et al., 2015; Poggio et al., 2015).

According to Hebling et al. all resin-based liners have toxic effects on odontoblast-like cells in the laboratory environment. (Hebling et al., 2009) However, it should be noted that according to the US safety

information, Tracal LC does not contain BisGMA monomer in its composition. (Nilsen et al., 2017). Therefore, TheraCal is approved by FAD and is used as a liner and base under the final restoration in direct and indirect pulp cap is acceptable (Arandi and Rabi, 2018).

One of the most important limitations of the current study is that the studies conducted in this field are not enough. It is recommended that more studies be conducted on the success of TheraCal in the pulpotomy of primary teeth compared with other conventional materials.

5. Conclusion

This systematic review and meta-analysis revealed that pulpotomy using TheraCal had similar results compared to formocresol, and there was no statistically significant difference in clinical and radiographic success between the TheraCal and Formocresol groups.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript].

Acknowledgments

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