Objectives: This study aimed to assess the reaction of dental pulp of pulpotomized teeth with/without applying a capping agent. This study was performed as a randomized clinical trial.

Materials and Methods: This split-mouth clinical trial was conducted on eight pairs of primary canine teeth scheduled for extraction as part of orthodontic treatment. The teeth were randomly assigned to the intervention and control groups. In the intervention group, canine teeth were restored with amalgam after pulpotomy with formocresol. In the control group, zinc oxide eugenol paste was applied as the capping agent after pulpotomy with formocresol, and the teeth were then restored with amalgam. After 1 month, the teeth were extracted in both groups and stained with hematoxylin and eosin for histological analysis. Pulp reaction was assessed in terms of pathological parameters. Data were analyzed using the Mann–Whitney U-test and Fisher’s exact test. The statistical analysis software was SPSS 16.

Results: No significant difference was found between the two groups in terms of inflammation, vitality, internal resorption, bleeding, presence of osteoclasts and dentinoclasts, and internal regeneration. Dentinal bridge did not form in any group.

Conclusion: According to the results of this study, formocresol pulpotomy of primary teeth can be completed without the application of a capping agent.

Keywords: Histological analysis, primary teeth, pulp capping agent, pulpotomy.
A previous study evaluated the biocompatibility of high-copper amalgam, intermediate restorative material (IRM), mineral trioxide aggregate (MTA), and MTA combined with chlorhexidine. The results showed that all these materials were well tolerated by the connective tissue. An animal study evaluated and compared the biocompatibility of amalgam and gray and white MTA and revealed no significant difference among the three groups after 3 weeks. Another animal study assessed the reaction of connective tissue to high-copper amalgam and ProRoot MTA and indicated that the connective tissue of rats well tolerated these materials.

Thus, according to the results of the aforementioned animal studies (no human studies have been investigated reaction of pulp following pulpotomy with formocresol with and without zinc oxide coverage) showing no significant difference in pulp tissue response to high-copper amalgam, IRM, and white and gray MTA, it may be presumed that amalgam may be applied directly after removing the coronal pulp without the application of ZOE. Based on literature and the efficacy of this method has not been tested in human studies.

This study aimed to histopathologically assess the pulp of primary teeth following pulpotomy with formocresol with/without the use of pulp capping agents.

**Materials and Methods**

Design of this study was parallel. This split-mouth clinical trial was conducted between March and June 2017 on eight pairs of primary canine teeth scheduled for extraction as part of orthodontic treatment (the reason for choosing a canine as sample size was that the canine that goes out of the orthodontic treatment process can be completely healthy). This sample size was selected based on pilot study (this pilot study was conducted for sample determination and has not been published), and considering this study was done as split mouth one, statistical consultant defined this sample size. This study was approved in Ethics Committee of Shahed University and its approval number is Shahed.REC.1394.25.

These teeth were sound and the children were systemically healthy and had no contraindication for anesthesia. The children were 7–8 years old and three of them were male and five were female. After obtaining written informed consent from the parents, dental treatments were performed. In this triple randomized clinical trial (participants, care providers, and those assessing outcomes), the samples were randomly (using a coin) sorted into two groups. Randomization was done using a coin by a person who was blinded to the study design and each side of the coin identified a group. In each patient, canine teeth were randomly assigned to the intervention and control groups. In the intervention group, anesthesia was induced and pulpotomy was performed using diamond fissure bur. A cotton pellet dipped in formocresol was then placed in the pulp chamber and removed after 5 min. The cavity was then restored with amalgam (SDI, USA). In the control group, anesthesia was induced and pulpotomy was performed using a diamond fissure bur. A cotton pellet dipped in formocresol was then placed in the pulp chamber and removed after 5 min. Next, ZOE paste was applied in the cavity followed by amalgam restoration. All the procedures were done by a pedodontist. After 1 month, the teeth in the two groups were extracted, stained with hematoxylin and eosin, and prepared for histological analysis. Inflammation grading was evaluated as follows: inflammation<10%: no infl ammation; 10%–30%: mild infl ammation; 30%–50%: moderate infl ammation; >50%: severe infl ammation, vitality, internal resorption, bleeding, presence of osteoclasts and dentinoclasts, and internal regeneration were assessed. Data were analyzed using the Mann–Whitney U-test and Fisher’s exact test. The statistical analysis software was IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 16 (IBM Corp, Armonk, NY).

**Results**

This split-mouth clinical trial was performed on eight pairs of primary canine teeth scheduled for extraction for orthodontic reasons.

The children who participated in this study were 7–8 years old.

As this study was done as split-mouth design, eight teeth in eight participants were received intended treatment.

Figures 1 and 2 show the pulp reaction in the two groups of with and without the capping agent (>100 magnification).

The two groups were not significantly different in terms of the grade of inflammation [Wilcoxon signed-rank test, P = 0.785, Table 1].

McNemar test showed no significant difference between the two groups in terms of pulp vitality (P = 0.625).

McNemar test found no significant difference between the two groups in terms of internal resorption [P = 0.250, Table 2].

McNemar test showed no significant difference between the two groups regarding the presence of osteoclasts and dentinoclasts [P = 0.625, Table 3].

McNemar test found no significant difference regarding internal regeneration in the two groups (P = 0.625).
Table 1: Mild and moderate and severe inflammation of teeth after formocresol pulpotomy with and without capping (×100 magnification)

| Type of treatment | Without inflammation (%) | Mild inflammation (%) | Moderate inflammation (%) | Severe inflammation (%) | Wilcoxon signed-rank test (P) |
|-------------------|--------------------------|-----------------------|---------------------------|-------------------------|------------------------------|
| With capping      | 5 (62.5)                 | 1 (12.5)              | 1 (12.5)                  | 1 (12.5)                |                              |
| Without capping   | 5 (62.5)                 | 2 (25)                | 1 (12.5)                  | 0                       | 0.785                        |

Table 2: Internal resorption of teeth after formocresol pulpotomy with and without capping (×100 magnification)

| Type of treatment | Without resorption (%) | With resorption (%) | McNemar test (P) |
|-------------------|------------------------|---------------------|-------------------|
| With capping      | 3 (37.5)               | 5 (62.5)            | 0.250             |
| Without capping   | 2 (25)                 | 6 (75)              |                   |

Table 3: Presence of osteoclasts and dentinoclasts of teeth after formocresol pulpotomy with and without capping (×100 magnification)

| Type of treatment | Presence of osteoclasts and odontoclasts (%) | Absence of odontoclast and osteoclast (%) | McNemar test (P) |
|-------------------|---------------------------------------------|------------------------------------------|-------------------|
| With capping      | 4 (50)                                      | 4 (50)                                   | 0.625             |
| Without capping   | 2 (25)                                      | 6 (75)                                   |                   |

DISCUSSION

Pulpotomy is the treatment of choice for primary teeth with pulp involvement due to extensive carious lesions.[1,2] Formocresol is commonly used for pulpotomy of primary teeth through devitalization of dental pulp. After devitalization of dental pulp with formocresol, several materials can be used for capping of the remaining pulp tissue. ZOE is the most commonly used capping agent.[1] Considering the significance of the reduction of treatment steps for children, it seems that if the pulp capping step after application of formocresol is eliminated, the duration of treatment would decrease. This is particularly important in pediatric dentistry.

This study histopathologically assessed the dental pulp of primary teeth following pulpotomy with formocresol with/without the application of capping agent. Based on the results of this study, there was no significant difference in terms of inflammation, vitality, internal resorption, and bleeding between the two groups. Furthermore, the presence of osteoclasts and dentinoclasts and internal regeneration did not have any significant difference in two groups. Dentinal bridge did not form in any group.

Search of the literatures showed that no human studies were performed in this field to compare that results with this study. Sumer et al., in an animal study, evaluated the connective tissue response to amalgam, IRM, MTA, and MTA combined with chlorhexidine. They reported weak inflammatory response to these materials after 15, 30, and 60 days. The materials had been surrounded by fibrous connective tissue, which indicates that they were well tolerated by the tissue.[7] Their findings confirm our results, showing no severe inflammatory reaction of the connective tissue to amalgam, although our study was conducted on human teeth. Shahi et al., in an animal study, evaluated the biocompatibility of white and gray MTA and amalgam when applied on the connective tissue of rats. They found no significant difference in this respect among the groups after 3 weeks. Their findings were in agreement with ours.[8] Yaltırık et al. assessed the effect of ProRoot MTA and amalgam on the connective tissue in a 3-month period and demonstrated that the connective tissue well tolerated them in the 3-month period.[9] This study was conducted during a 4-week period and the results showed no significant difference in pulp reaction between the two groups. Shahi et al. evaluated the effect of white and gray MTA and amalgam on the connective tissue of rats after 3 days and 1 and 3 weeks and found no significant difference among the three materials at the end of the 3rd week. However, white and gray MTA was superior in terms of biocompatibility at 3 days and 1 week, respectively.[8]

The present study evaluated changes in dental pulp following pulpotomy without the application of capping agent, and based on the positive results of this study, one of the stages of treatment can be reduced, which is very
important for pediatric dentistry, and this is the strength of this study. Furthermore, ZOE, which has undesirable taste, especially for children, is eliminated.

This study was conducted on eight pairs of primary canine teeth scheduled for extraction in the process of orthodontic treatment. One of the limitations of this study was finding the teeth scheduled for extraction and be healthy.

According to animal studies, amalgam is well tolerated by the connective tissue.\(^7\)\(^9\) Thus, no adverse reaction such as inflammation or internal resorption should be expected after pulpotomy without the application of ZOE on the remaining pulpal connective tissue.

Hence, according to the above, the results of this study seem to be reasonable.

The current study evaluated changes in dental pulp following pulpal devitalization with formocresol with/without the application of capping agent histopathologically. Future studies are recommended to do similar assessments using other materials (such as polycarboxylate) and techniques (such as electrosurgery).

Furthermore, it is recommended to comparison of clinical and radiographic success rates of devitalization pulpotomy with and without application of capping agents.

**CONCLUSION**

According to the results of this study, primary teeth can be restored without the application of ZOE following pulpotomy with formocresol.

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Nil.

**CONFLICTS OF INTEREST**

There are no conflicts of interest.

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**Figure 2:** Control group with capping