ejpmr, 2017,4(5), 569-575

SJIF Impact Factor 4.161

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

"A COMPARATIVE EVALUATION BETWEEN FORMOCRESOL AND DIODE LASER ASSISTED PULPOTOMY IN PRIMARY MOLARS– AN IN VIVO STUDY"

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Article Received on 20/03/2017 **Article Revised on 10/04/2017** **Article Accepted on 01/05/2017**

ABSTRACT

Objective: To evaluate the effect of formocresol and diode laser on the clinical and radiographic success of pulpotomies in primary molars at 3,6 & 12 months. **Study design:** A double-blind clinical study was carried out on 20 children aged between 4-9 years. A total of 40 carious teeth were selected from 20 children based on clinical and radiographic criteria. All teeth were randomly assigned to either the diode laser or the formocresol pulpotomy group and were followed up clinically and radiographically at 3, 6 and 12 months. **Results:** Statistical analysis was done using Chi-square Test. All the clinical parameters i.e pain, sinus/fistula and pathological mobility showed 100% success in both groups at 3, 6 and 12 months. Radiographically, after 3 months, overall success rate in formocresol group (94.4%) was found to be lower as compared to laser group (100%). Similarly at 6 and 12 months, success rate was higher in laser group (6 months - 94.4% and 12 months – 78.8%) as ompared to formocresol (6 months - 78.8% and 12 months –57.8 %). **Conclusion:** laser pulpotomy showed better clinical as well as radiographical results than formocresol pulpotomy. Laser pulpotomy being a non pharmacological technique can be considered more favorable.

KEYWORDS: Pulpotomy, Formocresol, Diode Laser.

INTRODUCTION

Dental caries continues to be a major problem in pediatric dentistry and it has received significantly less attention in everyday practice, not only from the standpoint of restorative procedures but also in terms of preventive practices designed to reduce the problem.[1] Despite modern advances in the prevention of dental caries and an increased understanding of the importance of maintaining the natural dentition, many teeth are still lost prematurely due to caries. The premature loss of the deciduous teeth can lead to malocclusion, esthetics, phonetics and functional problems which may be transient or permanent in nature.[2] Primary dentition is usually affected by dental caries due to a myriad of reasons ranging from anatomical vulnerability to the lack of manual dexterity. Therefore, modern pediatric dentistry seeks to preserve primary teeth maintaining its developmental, esthetic and functional capabilities.

The retention of the pulpally involved deciduous teeth until the time of normal exfoliation is acknowledged to be of great importance to the child. Pulp therapy is one such measure performed to prevent extraction of carious or traumatized primary teeth. Depending on the extent of pulpal involvement, pulp therapy may include pulp capping or pulpotomy procedures. One of the frequently used treatments for preserving decayed primary molars from extraction is pulpotomy.[3,4] Pulpotomy is commonly defined as removal of the coronal portion of the pulp and then covering the remaining pulp stump with a medicated dressing in order to maintain the vitality of radicular pulp tissue.[5] Various materials have been recommended for these purposes like formocresol, glutaraldehyde, ferric sulfate, calcium hydroxide, mineral trioxide aggregate, bone morphogenic proteins (BMP), dentin bonding agents, enamel matrix derivatives,

portland cement, freeze dried bone, growth factors and various techniques like electrosurgery and lasers have been tried with variable clinical, radiological and histological success.[6,7,8,9]

Traditionally, formocresol has been the material of choice for pulpotomy procedure because of its ease in usage and proven clinical excellence**.** It is regarded as the 'gold standard' and it has been the most popular pulp-dressing material for pulpotomized primary molars for the past 80 years. However, the use of formocresol has been challenged because of its deleterious effects, potential carcinogenic action, immune sensitization, mutagenecity and cytotoxicity.[10,11,12] In order to reduce the deleterious effects of the formocresol, laser irradiation in vital pulp therapy has been proposed as one such alternative to conventional pharmacotherapeutic techniques. Lasers, including the CO_2 laser, Nd:YAG, Er:YAG and diode laser have found wide application in general and oral surgery procedures involving soft tissues. Recently, the use of diode laser has also been implicated in dentistry especially as one of the treatment modality in vital pulp therapy.[13,14] Based on the characteristics of the diode laser, it appears to be a promising alternative to conventional pulpotomy therapy. Hence, the present study was carried out to evaluate the effect of formocresol and diode laser on the clinical and radiographic success of pulpotomies in primary molars at 3, 6 & 12 months.

MATERIALS AND METHOD

Study was carried out on 40 carious teeth selected from 20 children aged between 4-9 years. The participating children and their parents were informed about the protocol of the study and prior parental consent was obtained. Ethical clearance to conduct the study was obtained from the institution. Patients were divided randomly into two groups of 20 teeth each. Group A was treated with formocresol as a pulpotomy medicament and Group B was treated with diode laser as a pulpotomy technique. Inclusion and exclusion criteria were based on the following parameters.

Inclusion criteria	**Exclusion criteria**
Clinical-	**Clinical-**
Healthy patient.	History of unprovoked tooth ache
Cariously exposed primary molars	Pathologic Mobility
History of spontaneous pain	Presence of draining tract
Radiographical-	**Radiographical-**
2/3rd of remaining root length	Dystrophic calcification
	Inter-radicular bone loss
	Exfoliating tooth

The procedure was carried out step by step in a single visit in all the selected teeth. Local anaesthesia was administered followed by rubber dam application to isolate the teeth. Complete caries removal was done and access cavity was prepared. Coronal pulp was amputated with a clean round bur mounted on a low speed handpiece and rinsed with sterile saline. In Group A, hemostasis was promoted by placing a cotton pellet at the pulp chamber. A cotton pellet moistened with the one-fifth diluted formocresol was then applied over the pulp stumps for five minutes, removed and temporized using zinc oxide mixed with equal amounts of eugenol. In Group B, complete hemostasis was achieved by exposing root canal orifices to diode laser of 980 nm with continuous mode of application for 2 seconds delivered by 200 microns optical fiber tip in contact mode and 1.5 watt power. All patients and clinical staff wore appropriate eye protection during application of the laser. A zinc oxide eugenol cement layer was placed to seal the coronal pulp chamber and later restored with glass ionomer cement in both the groups. A pre-formed stainless steel crown was placed; occlusal contacts were checked and adjusted where necessary in both the groups. Clinical and radiographic follow-up was carried out at 3, 6 and 12 months.

RESULTS

All the clinical parameters i.e. pain, mobility, sinus/fistula and pathological mobility showed 100% success in both the groups at the end of 3 months [Table 1]. 100% success was observed in both the groups, for all the radiographic parameters i.e furcal radiolucency, root resorption and damage to underlying tooth except periapical radiolucency which was observed in 5.26% of formocresol group whereas 0% periapical radiolucency was observed in laser group [Table 2]. All the clinical parameters i.e. pain, mobility, sinus/fistula and pathological mobility showed 100% success in both the groups at the end of 6 months [Table 3]. At 6 months follow up, periapical radiolucency was observed in 21% of formocresol group and 5.26% in laser group, furcal radiolucency was observed in 10.5% of the formocresol cases and 5.26% of the laser cases. Root resorption was seen in 21% of formocresol and 5.26% of laser cases. These differences were statistically insignificant ($p>0.05$). However, 100% success was observed in both the group in terms of damage to underlying tooth [Table 4]. All the clinical parameters i.e. pain, mobility, sinus/fistula and pathological mobility showed 100% success in both the groups at 12 months follow up [Table 5]. Regarding radiographic parameters, periapical radiolucency was observed in 36.8% of formocresol group whereas 10.5% was observed for the laser group. Furcal radiolucency was seen in 42.1% of the formocresol group and 21% of the laser group. Root resorption was seen in 42.1% of formocresol and 5.26% of laser cases at 12 months follow up. All these differences were found to be statistically not significant ($p>0.05$) and no damage was seen to underlying tooth in both the groups [Table 6].

Table 1: Comparison of clinical parameters between formocresol and laser pulpotomy at 3 months

Parameter		Formocresol	Laser	Chi-square value	P value
Pain	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
Sinus/Fistula	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
Pathological Mobility	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
	Total	**19 (100%)**	**19 (100%)**		

Table 2: Comparison of radiographic parameters between formocresol and laser pulpotomy at 3 months

Parameter		Formocresol	Laser	Chi-square value	P value
Periapical Radiolucency	Absent	18 (94.74%)	19 (100%)	-----	-----
	Present	1 (5.26%)	0 (0%)		
Furcal Radiolucency	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
Root resorption	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
	Present	0 (0%)	0 (0%)		
Damage to succedaneous tooth follicle	Absent	19 (100%)	19(100%)	-----	-----
	Present	0 (0%)	0 (0%)		
	Total	**19(100%)**	**19(100%)**		

Table 3: Comparison of clinical parameters between formocresol and laser pulpotomy at 6 months

Parameter		Formocresol	Laser	Chi-square value	P value
Pain	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
Sinus/Fistula	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
Pathological Mobility	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
	Total	**19 (100%)**	**19 (100%)**		

Table 4: Comparison of radiographic parameters between formocresol and laser pulpotomy at 6 months

Parameter		Formocresol	Laser	Chi-square value	P value
Periapical Radiolucency	Absent	15 (78.8%)	18 (94.74%)	0.289	0.596
	Present	4 (21%)	1 (5.26%)		
Furcal Radiolucency	Absent	17 (89.5%)	18 (94.74%)	0.124	0.725
	Present	2 (10.5%)	1 (5.26%)		
Root resorption	Absent	15 (78.8%)	18 (94.74%)	0.289	0.596
	Present	4 (21%)	1 (5.26%)		
	Present	2 (10.5%)	1 (5.26%)		
Damage to succedaneous tooth follicle	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
	Total	**19 (100%)**	**19 (100%)**		

Table 5: Comparison of clinical parameters between formocresol and laser pulpotomy at 12 months

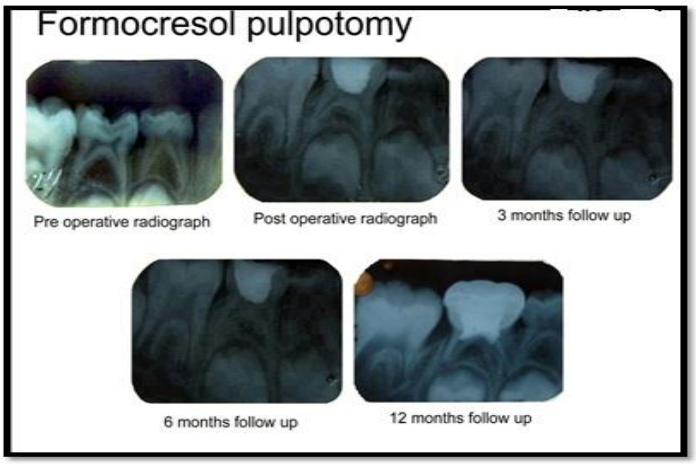
Parameter		Formocresol	Laser	Chi-square value	P value
Pain	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
Sinus/Fistula	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
Pathological Mobility	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
	Total	**19 (100%)**	**19 (100%)**		

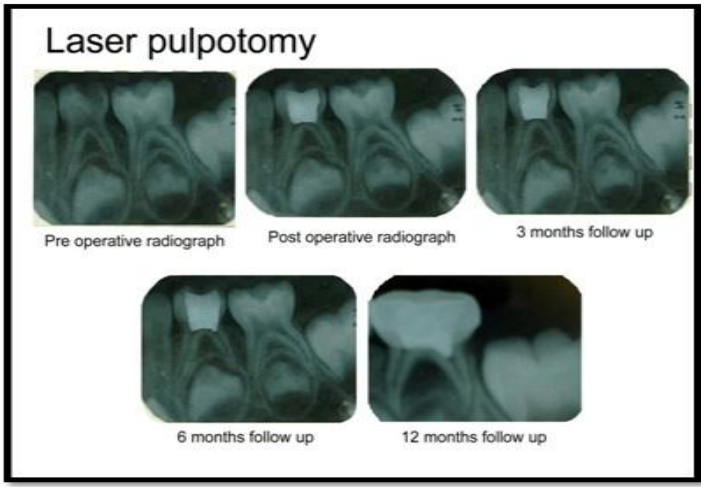
Table 6: Comparison of radiographic parameters between formocresol and laser pulpotomy at 12 months

Parameter		Formocresol	Laser	Chi-square value	P value
Periapical Radiolucency	Absent	12 (63.1%)	17 (89.5%)	0.94	0.703
	Present	7 (36.8%)	2 (10.5%)		
Furcal Radiolucency	Absent	11 (57.8%)	15 (78.8%)	2.11	0.14
	Present	8 (42.1%)	4 (21%)		
Root resorption	Absent	11 (57.8%)	18 (94.74%)	0.083	0.737
	Present	8 (42.1%)	1 (5.26%)		
	Present	7 (36.8%)	2 (10.5%)		
Damage to succedaneous tooth follicle	Absent	19 (100%)	19 (100%)	-----	-----
	Present	0 (0%)	0 (0%)		
	Total	**19 (100%)**	**19 (100%)**		

Table 7: Success rate of radiographic parameters between formocresol and laser pulpotomy in primary molars at 3, 6 & 12 months

		Formocresol	Laser	Chi-square value	P value
3 Months	Success	18 (94.4%)	19 (100%)	-----	-----
	Failure	1 (5.6%)	0 (0%)		
6 Months	Success	15 (78.8%)	18 (94.4%)	0.289	0.596
	Failure	4 (21%)	1 (5.6%)		
12 Months	Success	11 (57.8%)	15 (78.8%)	2.11	0.14
	Failure	8 (42.1%)	4 (21%)		





DISCUSSION

Pulpotomy is one of the frequently used treatment in primary dentition and has been the treatment of choice for cariously exposed pulps in vital primary teeth. This treatment helps to maintain the integrity of primary teeth having inflammation limited to the coronal pulp. Due to the complicated anatomy of the root canals in primary teeth, the proximity of the permanent tooth germ and the difficulties in finding a root-canal filling material compatible with physiological root resorption, pulpotomy has become a dominating pulp therapy procedure. It is based on the rationale that the radicular pulp tissue may be healthy or capable of healing after surgical amputation of the affected or infected coronal pulp. It is a conservative therapy performed to remove the inflamed coronal pulp tissue followed by application of an effective and compatible bactericidal medicament which encourages the tissue in the root canals to remain vital.[13] An ideal pulpotomy material to be placed on the radicular pulp should be bactericidal, harmless to pulp and surrounding structures, promote healing of remaining radicular pulp without interfering with the physiologic root resorption and not possess any toxicity.[14] In search of an ideal pulpotomy medicament, various materials and techniques have been explored. According to Ranly, pulpotomy for primary teeth has been developed on three lines: devitalization (mummification, cauterization), preservation (minimal devitalization, noninductive), regeneration (inductive, reparative). The reparative and biologic approach to pediatric pulp therapy is the devitalization approach of formocresol pulpotomy. Formocresol has been used for deciduous teeth pulpotomy since 80 years.[6,7,8] In 1904, Buckley was the first to introduce formocresol to treat non-vital permanent teeth. Later in 1930, Sweet introduced formocresol pulpotomy in primary teeth technique which became very popular. Initially, he used a multiple sitting technique, which has been subsequently modified to either a single or two stage technique due to economic and behavior management considerations.[15] In 1982, Garcia– Gordoy et al had first suggested 1 minute application time of formocresol.[16] Primosh (1997) concluded that a 1:5 dilution of formocresol applied for five minutes is the preferred technique in a pulpotomy procedure.[17] The mechanism of formocresol as a pulpotomy medicament revealed a zone of fixation usually which is evident where the pulp is in direct contact with the medicament. The apical third of the pulp is unaffected and it retains its vitality for an extended period of time.[18] In spite of its good clinical response, it has also shown a toxic effect on living tissues because of the formaldehyde component. Formocresol applied to vital pulp tissue is absorbed readily into the systemic circulation and distributed throughout the body. A portion of the absorbed formocresol is metabolized and excreted by the kidney and lungs. The remaining formocresol is tissue bound with the liver, kidney and lungs which are the predominant sites of tissue binding. Also, it increases the prevalence of hypoplastic, hypomineralization defects, necrosis and sloughing of the tissue when it touches the gingiva. The International Agency for Research on Cancer (IARC) classified formaldehyde, a constituent of Buckley's formocresol, as carcinogenic to humans. There was sufficient evidence that it causes nasopharyngeal cancers in humans. However, recently, the organization for economic co-operation and development stated that "formaldehyde is not likely to be a potent carcinogen to humans if used under low exposure conditions." Inspite of difference of opinion regarding its use, it has been a gold standard as a pulpotomy medicament. Hence, formocresol was considered as a control in the present study. However, concerns regarding the formocresol have led investigators to search for safe and effective alternatives, laser being one of them. Lasers have been used in pediatric dentistry because of its advantages like reduced chair side time, elimination of high speed drill and controlled energy. It is quick, efficient, self-limiting, has good visibility of the operating field and shows no systemic effects at the site of application. The use of laser also eliminates the pain of injections, which is considered to be a barrier to effective dental treatment for children.[13,19,20]

Along with the advantages of lasers, the effect of the power and time of application of laser on pulp tissue needs to be considered. Saltzman used diode laser with 3W until hemostasis was achieved and reported less radiographic success compared to formocresol pulpotomy.[21] Mareddy A et al reported regressive changes with 5-s laser application and stated that 1-s and 3-s applications to be ideal for diode laser pulpotomy.[22] Coster PD stated that thermal strain on the pulp or thermal damage of the proximal pulp tissue exerted by laser application may also affect the treatment outcome in pulpotomy procedures. Pulpal ablation through successive laser application results in pulp stumps free of haemorrhage, might raise hyperaemia of the residual pulp tissue which in turn potentially influences the treatment outcome.[23] In this context, potential thermal damage may be prevented by reducing either or both the power emitted pulse frequency, or total application time. Neto NL found lasers used at low power may be considered as an effective alternative for primary molars pulpotomies as they have shown their potential to increase healing, stimulate dentinogenesis and preserve the dental pulp vitality.[24] Considering the proven beneficial effect of diode laser, the efficacy of diode laser was evaluated in the present study using 1.5 W power lasing energy with 2 seconds of application time. Laser sterilization reinforces the overall sterilizing procedure, and laser coagulation produces a thin necrotic layer over the remaining vital pulp. A thin laser-induced necrotic layer is formed which prevents the pulp to have a direct contact with the covering materials which avoids or reduces the possible chemical or toxic effects of the materials.[25] It was observed that laser irradiation induces enhancement of calcification in wound surface and stimulates the formation of calcified tissue.[26] These

observations indicate that laser irradiation is a useful method for vital pulpotomy.

Usually longer terms of follow up have seen to cause lower rates of success due to elimination of data of some samples. However, follow up periods of 9 and 12 months have also shown successful results. Furze HA observed that there is development of the dentin bridge at 1-year follow-up.[26] Hence, a maximum period of 12 months follow up was considered in the present study.

In the present study, all the clinical parameters i.e pain, mobility, sinus/fistula and pathological mobility showed 100% success in both formocresol and laser group at 3, 6 and 12 months respectively. The clinical results obtained in the present study were in accordance with a study carried out by Gupta G. et al in 2015 who also observed 100% clinical success at the end of 12 months followup.[27] Radiographically, after 3 months, overall success rate in formocresol group (94.4%) was found to be lower as compared to laser group (100%). Similarly at 6 and 12 months, success rate was higher in laser group (6 months - 94.4% and 12 months – 78.8%) as compared to formocresol (6 months - 78.8% and 12 months – 21%). But, there was no significant difference in overall success between the two groups at 3, 6 and 12 months. Periapical radiolucency was seen in 36.8% of cases in the formocresol group and 10.5% of cases in the laser group. Furcal radiolucency was seen in 42.1% of the formocresol group and 21% of the laser group. Root resorption was seen in 42.1% of formocresol and 5.26% of laser cases. No damage to succedaneous tooth follicle was observed in all the cases of both the groups. The failure of pulpotomy treatment in primary molars could be attributed to the number of factors, one of which may be clinical errors in diagnosis and selection of the case; for example, chronically inflamed radicular pulp was believed to be non-inflamed. Laser irradiation caused carbonization, necrosis and infiltration of inflammation cells, edema in the pulp tissue that could be a reason for pathology seen in laser group. Another possible reason could be the use of ZOE as sub-base which is in direct contact with the highly perfused environment of pulp and it may undergo hydrolysis of the zinc eugenolate to yield free eugenol. In formocresol, only the clot is the entity separating the eugenol from the vital tissue; therefore, zinc oxide eugenol may not be an ideal base for formocresol pulpotomies due to the inflammatory tissue response.[28] The results obtained in this study were in accordance with Neto LN et al and Huth CK et al.[24,29] However the study carried out by Sonmez D et al showed the success rate of 73.3%, with the possible explanation of the differences in the applied techniques.[30] The clinical and radiographical success of laser pulpotomy in the present study could be attributed to its non-invasive and non-pharmaceutical nature of technique, efficient control of hemorrhage, decontamination and sterilization effect simultaneously with preservation of the radicular pulp and faster pulpal wound healing that did not affect either the inflammatory function of monocytes and endothelial cells or the adhesion of endothelial cells.[27] A relatively newer non pharmacotherapeutic method that has emerged is the use of laser in which the laser energy is able to overcome the histologic deficits there by accelerating the wound healing of the pulp and the expression of the lectins and collagens.[25,27] Also, pulpotomised teeth in both the groups were followed by placement of stainless steel crowns as suggested by Randall RC as it prevents leakage of the final restoration thereby leading to a better treatment outcome.[31]

The present study was carried out in search of ideal pulpotomy material to replace formocresol, due to its disputed controversy regarding biocompatibility. Although, in the present study, an attempt was made to compare the two techniques available for pulpotomy, the use of formocresol proved to be less acceptable as a pulpotomy agent. One of the most intriguing aspects of the present study was the use of laser, which showed an acceptable success.

CONCLUSION

Although there was no statistically significant difference between formocresol and diode laser, clinically the overall success rate of laser group was greater than formocresol at 3, 6 and 12 months. Hence, diode laser can be considered as a better substitute as compared to other pulpotomy techniques.

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