Clinical and Radiographic Assessment of an Innovative Pulpotomy Technique Compared to Conventional in Primary Molars (Randomized Clinical Trial)

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ABSTRACT

Purpose: The purpose of this study was to access post-operative clinical as well as radiographic success of Diode Laser / Mineral Trioxide Aggregate (MTA) and Diode Laser / Biodentine (BD) pulpotomy procedures in comparison to conventional technique using Formocresol / Zinc Oxide Eugenol (FC/ZOE) pulpotomy for human primary molars. Materials and Methods: A total of 90 lower primary molars that had deep carious lesion and need pulpotomy treatment from 66 healthy and cooperative patients, aged 4-6 years old were chosen for this study. After removal of the coronal tissue and depending on the type of radicular pulp medicament, the teeth were divided randomly and equally into three groups; Group A (FC/ZOE), Group B (Diode Laser/MTA) and Group C (Diode laser/BD). Treatments in all groups were completed with Glass Ionommer restoration then stainless steel crowns. Results: The cumulative clinical and radiographic success rates after 12 months follow up were 90.3%, 96.3% and 100% for the FC/ZOE, Diode Laser/MTA and Diode Laser/BD pulpotomy groups respectively. Conclusion: Laser assessed pulpotomy in combination with MTA or Biodentine had a more advanced clinical and radiographic success rate correlated to FC/ZOE pulpotomy technique in primary molar. Statistically, no significance difference was found between the three study groups in the overall clinical and radiographic success rate.

INTRODUCTION

In pediatric dentistry, one of the most important goals is to maintain the primary dentition till eruption of permanent one (1). Pulpotomy
technique is performed when accidental or carious exposure of dental pulp happens in painless tooth with a deep carious lesion and without periradicular pathology, this is achieved by cutting of the pulpal tissues in the pulp chamber and then covering the radicular pulp stump by a medicated dressing to keep radicular pulp tissue vital (2). Classically, formocresol (FC) was expressed as the gold standard pulp dressing material for pulpotomized primary molars (3), but concerns against the use of FC in humans as it has a deleterious effects, possible carcinogenic action, mutagenicity and cytotoxicity have been raised (4).

Moreover, many studies demonstrated that the clinical success of FC pulpotomies decline as time pass (5). In order to decrease the mischievous effects of the FC, laser irradiation in vital pulp therapy has been offered as a promising substitute. Laser has the ability to control hemorrhage. It has bactericidal effect as well as a stimulation effects on the dental pulp cells. It is faster in action, user-friendly and welcomed by the patient (6,7).

New innovations and researches in dentistry endorsed new materials that are bioinductive and regenerative like MTA and BD which had biocompatibility, alkalinity and sealing ability for pulp tissue. However BD showed shorter setting time, easily handling properties and higher mechanical properties with no discoloration potential (8,9). Profit of combing Diode Laser and regenerative materials as a pulpotomy technique in primary teeth are promising and open an era for further researches (10-12).

MATERIALS AND METHODS

This research was authored as stated in the Consolidated Standards of Reporting Trials (CONSORT) statement (13). It is a double–blinded randomized clinical trial.

Patient selection:

Total of 90 lower right and left primary molars with deep carious lesions from 66 healthy and cooperative patients, aged 4-6 years old and need pulpotomy treatment were selected for this study. The children were diagnosed, selected, treated and followed up in the clinics of Pedodontic department, Faculty of Dental Medicine for Girls, Al-Azhar University and the National Institute of Laser Enhanced Science (NILES) – Cairo University. The children were 31 male and 35 female.

Ethical consideration:

Written informed consent was gained. Research Ethics Committee approval was taken from Faculty of Dental Medicine for Girls, Al-Azhar University.

Randomization:

• Regulated by the type of radicular pulp medicament, the lower molars were branched randomly and equally into three groups using envelopes simple randomization as following: Group A (FC/ZOE pulpotomy group), Group B (Diode Laser/MTA pulpotomy group) and Group C (Diode Laser/BD pulpotomy group).

Inclusion Criteria (12):

Clinically the primary molar must be symptomless with a deep carious lesion. There must beno swelling, tenderness on percussion, sinus trace opening, pathological mobility or spontaneous pain. Molars must be restorable after finishing of the procedure.

Radiograph criteria constituted no internal resorption, no intraradicular bone destruction, no periapical bone destruction and no loss of the lamina dura /widening of periodontal ligament space. Presence of permanent successor must be evident.

Exclusion Criteria (12):

Including excessive bleeding during pulp amputation, non vital/necrotic teeth, any sort of medical history contraindicating the pulp treatment, teeth approximate exfoliation, patient gradient not intending to be part of the study and retreatment of previously pulpotomy treated molar.
Diagnosis of cases:

Before treatment, a thorough medical and dental history was earned then a clinical checking and radiographic examination with a standardized paralleling technique employing size 2 films D speed (Kodak Insight, Eastman Kodak, Rochester, NY, USA), an XCP posterior film holder and an X-ray machine (70KVP, 8mA).

Treatment protocol:

Molars were anesthetized by local anesthesia (Septocaine® and epinephrine 1:100,000,Septodont, USA). The rubber dam was used for isolation. Caries removal and deroofing of the pulp chamber was achieved then pulpual tissue amputation with sharp excavator and irrigation was done from the pulp chamber. Subsequent irrigation, initial hemorrhage control was carried out in 3-5 minutes by wet cotton pellets under slight pressure. According to radicular pulp medicament type, the treatment was preceded as following:

- **In Group (A):** Complete hemostasis was obtained by applying small cotton pellet soaked in Formocresol; dried by squeezing over the orifices of the canals for 5 minutes. The FC pellet was then eliminated and pulp stump was dressed with a layer of ZOE paste (Prevest Dent Pro, India) then restored with Glass-Ionemer restoration (EQUIA fort ® system (Fil & coat) GC corporation, Tokyo, Japan.ALSIP,IL 60803).

- **In Group B:** After initial hemostasis was gained, the 30 molars were managed by exhibiting root canal orifices to diode laser exactly as in group B then Biodentine mixture allocated in the pulp chamber and allowed to finish setting completely then restored with Glass-Ionemer restoration . Treatment in the three groups was completed with stainless steel crown and immediate post operative radiograph was done.

Follow up and outcome evaluation:

Clinical and radiographic monitoring of the treated molars at 1, 3, 6, 9, and 12 months was done. The clinical evaluation and periapical radiographs were done in every follow up visit using same parameters as preoperative radiograph; data were documented in the patient evaluation and follow up form.

Outcome assessment criteria

**a- Clinical evaluation criteria:**

Teeth showing the following characters were considered as success: free of pain symptoms on percussion as well as during mastication, pathological mobility absence, no swelling of pulpal origin and no sinus tract

**b- Radiographic evaluation criteria:**

Teeth demarcating the following criteria were accepted as success: no internal root resorption, no external root resorption, no periapical or furcation radiolucency and no widening of periodontal ligament space.

RESULTS

Chi-squared test declare that no statistical difference between the three groups in the cumulative clinical and radiographic success rate as well as at each follow up period was found. The clinical and radiographic success after 12 months follow up for FC/ZOE, Diode Laser/MTA and Diode Laser/BD pulpotomy groups were 90.3%, 96.3% and 100% respectively.
Clinically, the three study groups showed 100% success rate at 1, 3, 6, and 9 months check up period. At the last follow up period, the clinical success rate decreased in FC/ZOE group to 90.3% with three cases showed swelling, two of them had pain, abscess and pathological mobility. Diode Laser/MTA group showed 96.3% clinical success as one case showed pathological mobility and swelling with pain. Diode Laser/BD group showed 100% clinical success rate (Fig. 1).

Radiographically, the present study showed 100% success in the three study groups till 6 months follow up. At 9 months follow up, the radiographic success rate in FC/ZOE group was 93.3% as two cases showed internal/external root resorption while the success rate was 100% for Diode Laser/MTA and Diode Laser/BD groups. At 12 months follow up period, the FC/ZOE group had 90.3%, success rate. There were three cases showed failure in form of periodontal ligament space widening and internal/external root resorption. Additionally, one case of them showed periapical radiolucency. In Diode Laser/MTA group, the success rate was 96.3%. One case showed periodontal ligament space widening and bone radiolucency. In Diode Laser/BD group, the success rate was 100% (Fig. 2).

Figure (1) Bar chart showing percentage of clinical success at 1, 3, 6, 9, and 12 months follow up in FC/ZOE group (Group A), Diode Laser/MTA group (Group B), and Diode Laser/BD group (Group C).

Figure (1) Bar chart showing percentage of radiographic success at 1, 3, 6, 9, and 12 months follow up in FC/ZOE group (Group A), Diode Laser/MTA group (Group B), and Diode Laser/BD group (Group C).
DISCUSSION

This research was implemented to determine the effectiveness of primary molars pulpotomy using Diode Laser combined with MTA or Biodentine in an attempt to reach for the best successful pulpotomy technique to replace FC pulpotomy. It was a double blinded study, as both participants and statistician were blinded. RCT is the gold standard for a clinical trial and the highest level of evidence (16).

The success rate of this research after 12 months follow up was 90.3%, 96.3% and 100% for FC/ZOE group, Diode Laser/MTA group and Diode laser/BD group respectively. According to Chi-squared test, differences between the three groups in this study were not statistically significant. This go in agreement with the findings of another study in which it used laser /MTA pulpotomy, no significant difference was seen between the tested materials (17). Systematic reviews as well as meta analysis found no significant difference as well between the different pulpotomy techniques including FC, MTA , BD ,Diode laser ,Diode laser /MTA (2,18,19). On the contrary, another systematic review exhibited that MTA and FC had a significant higher results than Laser therapies in pulpotomy of the primary molar (20).

Outcomes of the contemporary research agreed with the high clinical and radiographic success rates which were reported for FC/ZOE (17, 21). However, the present study disagrees with another study that reported a 78.9% success rate for the FC group (22). The clinically failed cases in FC/ZOE pulpotomy group may be clarified as FC fix upper parts of the radicular pulp tissue than to promote healing (23,24). The pulp tissues at the apical region displayed signs of inflammation, which sequentially increase the probability of pain and periapical changes (22). Formocresol has smaller molecular size that can reach into the apical region through the pulp canals (25). Radiographically, the present study results demonstrated internal root resorption in 9.3% (3/30) of the treated molars after 12 months follow up. It was speculating that the risk of internal root resorption increased in the primary teeth that have been manged with FC as it do not have the capability to induce new dentin deposition (23). A study showed that internal resorption is correlated with Eugenol (from the ZOE past) that cause moderate to severe inflammatory response (26). Widening of the periodontal membrane and periapical radiolucency was found to be typical with FC treated teeth due to the FC filtrates into the circumferential tissues leading to inflammatory reaction radiolucency (26).

Regarding Diode Laser /MTA pulpotomy group, the outcomes of the this study conceded with preceding studies that emphasized the high success rate of Diode Laser /MTA pulpotomy techniques in primary teeth (13). High success rate after using Diode Laser in primary teeth pulpotomy could be credit to its non-invasive and non-pharmaceutical nature, powerful ability to control hemorrhage, decontamination and sterilization effect together with its ability to preserve the radicular pulp and to boost pulp wound healing (3,6,12). Mineral Trioxide Aggregate high success rate might be due to its superlative sealing ability, biocompatibility, antimicrobial effect and its regenerative ability (12,25,27,30).

The high success rates in Diode Laser/ BD group mirrors the beneficial effect of combining Diode laser with its unique actions as it mentioned before and BD which approve its importance as a highly successful pulpotomy material in primary teeth owing to its ability to stimulate cell differentiation and boost mineralization in the dental pulp cells of the humans as well as its high physico-mechanical properties. It also possess easier handling and less setting time than MTA that allow finishing vital pulpotomy treatment in one visit (7-9).

The current study showed high success rate clinically and radiographically as it gathered between Diode Laser advantages and two regenerative materials which were MTA and Biodentine respectively as new pulpotomy techniques in primary teeth. These results agreed with previous studies that...
favored as well laser effect before regenerative materials as calcium-enriched mixture cement, MTA and Calcium Hydroxide\(^{(10-12)}\). On the other hand, a previous study used 980-nm diode laser with 3W until hemostasis was carried out before applying MTA and expressed less radiographic success in correlation to FC pulpotomy which suggest thermal damage to pulp cells \(^{(17)}\). The parameters used in this study regarding Diode laser output power and time of application in addition to remove the coronal pulpal tissue applying a hand instrument rather than laser and using proper water irrigation as well reflected the improvement in understanding laser method of application and prevented excessive heat generation which corporate previous studies \(^{(14,15)}\).

**CONCLUSION**

The following could be concluded:

Combination of Diode laser and MTA or BD is uprising pulpotomy technique in primary molars.

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**REFERENCES**


