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مخطط بحث

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مدرسة في قسم طب أسنان الأطفال

Comparison of clinical and radiographic success rates of Pulpotomy in primary molars using Formocresol, Ferric Sulfate and Five Mineral Oxides (5MO)

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Introduction:

Pulpotomy technique consists of removing the coronal pulp and treating the radicular pulp with a medicament. It is the most widely accepted clinical procedure for treating primary teeth with coronal pulp inflammation caused by caries with no involvement of the radicular pulp [(1)] .

According to Ranly, Pulpotomy therapy for primary teeth has developed along three Lines [(2):]

- Devitalization: by using drugs or other methods, the pulp in the orifice becomes nonvital and nonfunctional, for example the Formocresol technique is classified in this category.
- Preservation: the function of the remaining pulp demonstrates minimal changes which are reversible. Preservation is exemplified by the ferric sulfate technique.
- Regeneration: The remaining pulp is not only vital and functional, but is also stimulated to form a dentin bridge. In addition regeneration causes Odontoblast to surround the pulp. Regeneration is exemplified by the MTA technique.

Formocresol (FC) applied to radicular pulp stumps has been shown to distribute systemically. Moreover, Formocresol and one of its constituents, formaldehyde, have demonstrated mutagenic and carcinogenic potential in animal studies [(3)].
Therefore, additional biocompatible treatment alternatives have been sought to replace Formocresol Pulpotomy [(4)].

Ferric Sulfate (FS) (15.5%) has been investigated widely and reported in animal and human studies as a hemostatic agent in Pulpotomy procedures. On contact with blood, a ferric ion-protein complex is formed, and the membrane of this complex seals the cut vessels mechanically, producing hemostasis, and the agglutinated Protein complex forms plugs that occlude the capillary orifices, preventing blood clot formation [5] [6] [7] . Based on the available evidence so far, FS and Formocresol (FC) produce similar treatment outcomes [8] ; however, FS requires much technical sensitivity [9] [10].
It is worth mentioning that FS has been proposed as a substitute for FC, which some would consider as a new gold standard [11] [12].

Five mineral oxides (5MO) is a new material, developed by Dr. Maisour Alarachi in Syria at Damascus University. In 2010 The Minister of Economy and Trade approved 5MO as a therapeutic dental material for human use (Syrian Patent number: 5770). This material is a hydrophilic micro particles, consisting of Calcium Silicate witch is the essential component, Calcium oxide, Silicate oxide, Titanium oxide, Aluminum oxide, Magnesium oxide.
5MO has the same indications, mechanism of action, and benefits of MTA, better sealing ability and mechanical properties than MTA, better antibacterial property, better handling and application than MTA, and it is less expensive than MTA. [16]

Histological and Laboratory studies approved that the material (5MO) shows: No mutagenic or cytotoxic properties, Biocompatibility, Excellent sealing ability, Its PH was found to be 13, 3 - 13, 5 which is higher than MTA (PH= 11-12 even after 72 hours), and low solubility, antibacterial effects against some facultative bacteria.
A high compressive strength (1, 5 mm of the material is sufficient to tolerate the strength), and good opacity. [16]

5MO has been used as a root filling (retro-filling) material, as seal root canal and for furcation perforation, for internal resorption treatment, for direct pulp capping material [13], and in Apexogenesis and in Apexification. [16]
There is only one study regarding 5MO clinical efficacy as a Pulpotomy agent in human primary molars, with successful clinical and radiographical outcomes; and this formed the basis of our study.

Aim of study

The present study aimed to compare these three methods of Pulpotomy in primary molars (Formocresol (FC), ferric sulfate(FS) and five mineral oxides (5MO)) both clinically and radiographically after 1, 3, and 6 months of observation.

Materials and methods:

The study will be carried out at SPU, Faculty of Dentistry.

The clinical procedure and associated risks and benefits will be fully explained to the parents, and written informed consent will be obtained from parents prior to treatment.

Selection criteria:

Each child has to meet the following criteria for inclusion in the study: Aged from 4 to 9 years, with Good health, and has cooperative behaviour, has one lower right or left first primary molar with large carious lesion witch are restorable, with no spontaneous or night pain, and at least 2/3rd of the root length is still present, no sign of internal or pathological external root resorption or radiolucency in the furcation area, hemorrhage from amputated sites easy to control, no presence of fistula or tooth mobility , and no percussion sensitivity [(14)].

Clinical procedure:

90 primary carious (first lower) molars will be randomly divided into three groups with 30 each depending on the type of Pulpotomy medicament used.

After administering local anesthesia, the tooth will be isolated with a rubber dam. All caries will be removed and coronal access will be achieved using a sterile No. 330 high speed bur with water spray to expose the pulp chamber. A spoon excavator will be used for coronal pulp amputation. Sterile cotton pellets moistened with distilled water will be placed over the pulp stumps, and light pressure will be applied for 5 minutes for obtaining hemostasis. Depending on the type of pulp medicament, the teeth will be treated as follows:

Group I (control group/Formocresol): A cotton pellet moistened and squeezed in diluted Formocresol ($1/5^{th}$ dilution of Buckley Formocresol) will be placed in contact with the pulp orifices for 5 minutes. After fixation, zinc oxide eugenol paste will be applied on the pulp tissue.

Group II (Ferric sulfate): A sterile cotton pellet moistened with 15.5% ferric sulfate (Astringedent ; Ultradent products, USA) will be placed in contact with the radicular pulp for 15s. After irrigation with normal saline and observation of hemostasis, zinc oxide eugenol paste will be applied on the pulp tissue [(15)] .

Group III (5MO): After obtaining hemostasis with sterile cotton, pulp stumps will be covered with a thin layer of 5MO paste (5MO, Sham Dental.co. SAR) , which will be

prepared by mixing 5MO powder with distilled water at a 3:1 powder/ distilled water ratio (as per the manufacturers' instructions) to obtain a thick, creamy consistency. The 5MO base will be placed on the floor of the pulp chamber and condensed against the pulp orifices with a moist cotton pellet, after that a wet cotton pellet with distilled water will be placed for at least (3) hours For optimal hardening of 5MO (as per the manufacturers' instructions), and the cavity will be coved with IRM; after 24 h. Children will be recalled, the cotton pellet will be removed.

Following Pulpotomy, all the teeth will be restored with glass ionomer cement (GC Fuji II, GC America, Alsip, IL, USA) , and stainless steel crown (3M) as a final restoration .

Children will be recalled for clinical and radiographical evaluation after 1 month, 3 months and 6 months after treatment .

Clinical criteria for successful pulp therapy [14]
No pain.
No percussion sensitivity
No swelling / fistula
No pathologic tooth mobility

Radiographic criteria for successful pulp therapy [14]:
No Furcation and/or periapical radiolucency
No internal root resorption
No external root resorption

Statistical analysis:

The differences will be statistically analyzed using the Fisher's exact and McNamara tests. The level of significance will be set at $P < 0.05$.

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Keywords: Pulpotomy; Primary molars; Formocresol; Ferric Sulfate; Five Mineral Oxides (5MO) ; Mineral Trioxides Aggregate (MTA) .