**Title:** Comparison of Lesion Sterilization and Tissue Repair Technique With Conventional Pulpectomy in the Treatment of Pulpal Lesions in Primary Molars in Children

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# Study Protocol and Statistical Analysis Plan

This study will be carried out in the Department of Pediatric Dentistry of Atatürk University and pediatric patients between the ages of 4-10 who need endodontic treatment in primary molars I and II will be included in the study.

**Inclusion Criteria**

***A. The criteria for inclusion in the study group are as follows:***

1. Clinically and radiographically diagnosed with a pulpal lesion,
2. Inability to perform traditional pulpectomy treatment due to pathological or physiological root resorption exceeding 2/3 rate,
3. Not having a systemic disease,
4. No history of allergies (against antibiotics),
5. The patient and their parents agree to come to routine dentist check-ups and participate in the study, and
6. It is the refusal of the child and/or family to accept tooth extraction.

***B. The criteria for inclusion in the study in the control group are as follows:***

1. Clinically and radiographically diagnosed with a pulpal lesion,
2. Teeth that do not have pathological resorption and have physiological root resorption not exceeding 2/3 or have a traditional pulpectomy indication without physiological resorption,
3. Not having a systemic disease and
4. It is the agreement of the patient and their parents to come to routine dentist check-ups and participate in the study.

**Exclusion Criteria**

***A. The study exclusion criteria in the study group are:***

1. Those with systemic diseases,
2. Those who do not give the necessary consent for participation in the study, and
3. They are those who are allergic to antibiotics or other drugs.

***B. In the control group, the study exclusion criteria were:***

1. Those with systemic diseases,
2. Those who do not give the necessary consent for participation in the study, and

They are those who are allergic to antibiotics or other drugs.

**Ethics Committee Approval**

For our study, ethics committee approval was obtained with the letter "Atatürk University Faculty of Medicine Clinical Research Ethics Committee 12.07.2024 / Meeting number B.30.2.ATA.0.01.00 / Decision No: 477".

**Sample Size:**

It is planned to investigate the relationships between measurements in the main hypotheses of the research. Similar studies that can be used in the calculation of sample size were examined and the sample size calculation, which gives the highest number according to the statistical methods to be applied in line with the main hypotheses, was taken into account. In this study, using the program "G. Power-3.1.9.2" (Faul, F., Erdfelder et al. (2009)), at the 95% confidence level ($\alpha$=0.05), the standardized effect size was 0.4423 (Doneria, D., et al. (2017), Table 3; 6th month) (s.d.: 6) and the minimum sample size was obtained as 70 with a theoretical power of 0.80.

30% of the sample size (21 observations) was added to the study, which was calculated by taking into account the probability of observation loss over time. The minimum sample size for each time was calculated as 91. (Doneria et al., 2017; Faul et al., 2009)

The result of the analysis is as follows.

**$\chi^2$ tests -** Goodness-of-fit tests: Contingency tables

**Analysis:** A priori: Compute required sample size

| | | | |
|---|---|---|---|
| **Input:** | Effect size w | = | 0.4423761 |
| | α err prob | = | 0.05 |
| | Power (1-β err prob) | = | 0.80 |
| | Df | = | 6 |
| **Output:** | Noncentrality parameter λ | = | 13.6987630 |
| | Critical $\chi^2$ | = | 12.5915872 |
| | Total sample size | = | 70 |
| | Actual power | = | 0.8025413 |

**Treatment Protocol**

This controlled clinical trial included a comparison of the LSTR method with conventional pulpectomy in pulp lesions in primary molar teeth. The study involved 110 primary molar teeth and was divided into two groups: 55 with LSTR and 55 with conventional pulpectomy. In the LSTR group, 28 teeth will be covered with stainless steel crowns and 27 teeth will be restored with Compomer fillings. Likewise, in the traditional pulpectomy group, 28 teeth will be covered with a stainless steel crown and 27 teeth will be restored with a Compomer filling. Stainless steel crown and Compomer restoration teeth was determined according to the patient's compatibility status and the wishes of the parents/children.

**Table**

| | Working Group (LSTR) | | Control Group (Pulpectomy) | |
|---|---|---|---|---|
| **Restoration** | Compomer | SSC | Compomer | SSC |
| **Number of Teeth** | 27 | 28 | 27 | 28 |
| **Total** | 55 | | 55 | |

**LSTR Group (Study Group):** After local anesthesia is provided, rubber dam insulation will be made. The entrance cavity will be prepared using the #4 round bur and the necrotic tissue will be removed. Then, irrigation with saline and sodium hypochlorite will be performed. A cavity will be prepared for antibiotic paste with a depth of 2mm and a width of 1mm with a #4 tungsten carbide rond bur at the channel mouths. If there is bleeding, a cotton pellet moistened with 5% sodium hypochlorite, which is an effective hemostatic agent, will be kept in the pulp chamber to stop the bleeding. 35% phosphoric acid was applied for 15 seconds to remove the smear layer, then the cavity will be washed and dried with saline. Since ciprofloxacin 500 mg antibiotic tablets are enteric-coated, their enteric coating will be completely scraped off with a scalpel and then pulverized in a clean mortar and stored in a moisture-free environment in glass bottles that do not receive light. The powder form of metranidazole is available on the market. In order to gain radioopacity of the powder (metronidazole and ciprofloxacin) prepared from a mixture of two antibiotics, it will be mixed with primary tooth canal filling material (Calcium Hydroxide Paste with Iodofome) (Viopex-Spident-Korea) to give a paste consistency. Antibiotic powders will be available in individual containers and the powders will be mixed with Viopex in the determined proportions (1:1) just before the application and the paste will be prepared freshly. Then, after the cavity is dried, the prepared pulp is placed in its cavity and covered with a light-curing, ready-to-use glass ionomer composite base cement (Ionoseal-VOCO-Germany) and the thread will be

restored with a stainless steel crown (Icrown-Seil Global-Korea) or composite filling (Twinky star-VOCO-Germany) (Picture 1). The upper restoration will be determined according to the child's adaptation status. (Stainless steel crown will be performed in children treated under general anesthesia, and composite restoration will be performed in children treated in routine dental clinics.) In case of swelling and lymphadenopathy in the tooth, additional systemic antibiotics will also be prescribed.

**Pulpectomy Group (Control Group):** Traditional pulpectomy treatment will be applied. Local anesthesia will be applied to the lesion area and the cavity will be opened. The pulp tissue will be removed and after the canals are cleaned and irrigated, the primary tooth will be filled with canal paste (Calcium Hydroxide Paste with Iodofome) (Viopex-Spident-Korea). After the pulp chamber is sealed with a light-curing, ready-to-use glass ionomer composite base cement (Ionoseal-VOCO-Germany), the upper restoration will be done with a stainless steel crown (Icrown-Seil Global-Korea) or compound filling (Twinky star-VOCO-Germany) (Figure 2).

Clinical evaluations of the teeth in both the study and control groups will be performed at 3 months, 6 months and 1 year, and radiographic evaluations will be made at 6 and 12 months. These evaluations are necessary to monitor the effectiveness and course of treatment.

**Evaluation Criteria in Follow ups**

**The effectiveness of the treatment will be evaluated on the following criteria:**

- √ Relief of clinical symptoms (pain, swelling, etc.).
- √ Radiographically the state of healing of the lesion.
- √ In post-treatment follow-ups (3rd month, 6th month). Month and 12 Months) the status of lesion sterilization and tissue repair.

- √ Cessation of existing pathological root resorption (internal or external)
- √ Continuation of physiological root resorption in accordance with the age of the child.

**Statistical & Analytical Methods:**

The data obtained from our study will be entered into the Microsoft Excel program. Afterwards, necessary analyzes will be made with the IBM SPSS 20 statistical analysis program. Survival analyzes of the teeth participating in the study will be made according to months.