2. S.A. DEDEYAN, I.P. DONKAYA. USE OF "PULPOTEC" FOR TREATMENT OF ODONTITIS IN PEDIATRICS.  
HEAD OF PEDIATRICS THERAPEUTIC DENTISTRY  
CENTRAL RESEARCH INSTITUTE OF STOMATOLOGY / MOSCOW  
(TRANSLATION OF THE ORIGINAL RUSSIAN TEXT)

Medical testing of the preparation for treatment of the caries aftereffects ‘Pulpotec’ was provided in the in-patient unit of the children’s therapeutic stomatology of the Central research Institute of Stomatology from April till October, 2003. Clinical trials were run due to agreement with the company ‘Valleks M’ that provided ‘Pulpotec’ in standard packing containing 30 g of powder and 15 mg of liquid of the following solution:

Powder: polyoxymethylene, iodoform, zinc;  
Liquid: dexamethasone, formaldehyde, phenol, guaiacol and subsidiary substances.

Documents provided by the company (toxicological and clinical trials logs from the foreign clinics, scientific articles) contain summary for 13 years lasting experience of successful use of the preparation for treatment of the caries aftereffects.

The main indication for use of ‘Pulpotec’ is treatment of odontitis in temporary and permanent teeth of children with keeping of viable root pulp. The problem is not solved till now due to uncertain results of use of preparations based on calcium hydrate, eugenol paste, glutaronic aldehyde, etc. in vital amputation method. Viable pulp in root canals serves as safe barrier for germ intrusion into periapical tissues preventing from development of dental infection. Infection of tissues surrounding roots of the temporary tooth makes a big danger for rudiments of permanent teeth as may tend to violation in the normal development even to loss.

Keeping of children’s pulp viable in temporary teeth with incomplete development of roots is the most actual thing because only at the condition of the normal functioning of the root pulp the final development of a root, closing of the apical opening and development of the valuable peridental membrane are possible.

Dentists deal with the need of the vital amputation in the adult practice at treatment of molars quite often, especially it refers to treatment of wisdom teeth having canals of the complex shape and inaccessible for valuable root canal treatment with difficult access.

They do not possess materials meeting all demands in full for vital amputation of pulp till now. The preparation used shall provide haemostatic, anesthetic, antiphlogistic and long-term antiseptic state of pulp’s stump and its hermetic closing.
The clinic trials of ‘Pulpotec’ provided were aimed at estimation of its effectiveness and tolerance by patients, detection of possible complications during the process of treatment, in the nearest time afterwards and dynamic observation up to 6 months with X-ray control at stages of the treatment.

42 patients, male and female, ages from 4 to 56 years have taken part in clinical trials. Treatment of odontitis in molars by method of vital amputation was provided. Children in the age 4-6 years have made the biggest group of 30 persons with ‘Pulpotec’ used for treatment of odontitis in temporary molars. 7 kids in the age of 8-10 years have made the second group with preparation used for treatment of permanent molars with incomplete development of roots. 5 persons with dystopic third molars and difficult access to root canals.

Evidence of individual sensitivity to ‘Pulpotec’ ingredients uncovered by data of anamnesis collected was considered to be the contra-indication to participation in trials.

All patients were recruited for trials only with the evidence of their autographic written consent or consent of their plenipotentiary (Amendment #1). To provide such a consent they were supplied by irrefragable explanation from the medical doctor on aims and duration of the research work, method of use of the preparation, possible discomfort and adverse effects. Patients were given the possibility to ask questions on any aspects of the research work and refuse to participate at any time without any explanations and consequences.

After receiving of deliberate consent for treatment the patient was sent for X-ray trial in order to verify the state of periapical tissues nearby the tooth to be treated.

Treatment of odontitis by method of vital amputation was provided in two visits. During the first visit the carious cavity was prepared after anesthetization, the tooth cavity was lanced and opened by the sterile bur and amputation and thorough hemostasis (with the help of ‘Catalugel’ preparation) were provided by the sterile sharp spherical dental drill. Wad of cotton wool moistened in the solution of the preparation was put onto the mouth of canals for 2-3 minutes to provide hemostasis. The procedure was repeated upon necessity. After the stanching a portion of ‘Pulpotec’ mixed to crème-like consistence was deposited over the stump of the pulp. Tooth cavity was closed by the temporary cement ‘PD’ in paste. In order to provide good adjacency of the paste to canal sides and mouth the wad of cotton wool was placed between the upper and lower molars. The patient was asked to bite it slightly at first and then stronger. The temporary inlay and preparation were removed during the second visit after 8-10 days, the fresh portion of ‘Pulpotec’ of denser consistence was deposited into the tooth cavity and the final sealing was provided. X-ray trials were run before and 6 months after the treatment to observe dynamics of the process of treatment.

Thorough stanching before depositing of the preparation to avoid blood clot that may prevent from access of the preparation to the stump of the pulp and tend to complications upon evidence of infection was the matter of the special attention.

Easiness and simplicity of use of ‘Pulpotec’ were ascertained during the medical trials. The paste hardens quickly after mixing of ingredients that preventing isolation of volatile fractions, providing optimal conditions for depositing of cavity liner and seal and decreasing the time for treatment radically. Preparation does not adhere to tools and does not strive after them, has good adhesion ability relatively tooth cavity sides. It is important to mention that uniform paste is produced after mixing of ingredients of the preparation having no pungent, foul smell and causing no negative reaction of the patient.

Clinical trials provided have shown absence of pains at all patients without exception after use of ‘Pulpotec’. Even if the pain syndrome was found evident at diagnostics of odontitis it was completely arrested after depositing of the first portion of the preparation. No complaints
were lodged by patients either in the intervals between visits to clinic or during the dynamic observation (from 4 to 6 months). No swelling of gum in the area of the treated tooth was detected during the given period, no evidence of a fistula and no mobility of a tooth. No signs of destruction of osseous tissue in periapical tissues were found at control X-ray observation of 14 teeth 6 months after the treatment.

Let us use as example the case of treatment of odontitis (child aged 5) when the evidence of anti-inflammatory and analgesic action of ‘Pulpotec’ was complete. The patient Botchkareva T. (born 1998, file #88070) applied to the clinic with complaints for sharp pains in the area of the lower jaw, left side, evidence of swell and pains at swallowing. Upon examination acute form of hyperemia and edema at diminishing fold in the area of the 74th tooth were found, acute morbidity of edema at diminishing fold, submaxillary lymphadenopathy and pains upon palpation. Acute odontitis of the 74th tooth with signs of periodontitis was diagnosed. Tooth cavity was opened under anesthesia, coronal pulp ablated, hemostasis with use of ‘Catalugel’ provided and liquid portion of ‘Pulpotec’ was deposited over the stump of pulp and the tooth was temporary sealed. Sufficient decrease of edema and pains upon palpation of lymph nodes were observed during the examination next day, no pains were reported. After removal of the temporary seal a new portion of ‘Pulpotec’ was deposited into the tooth cavity and the tooth was permanently sealed. In this case we have deviated from the traditional scheme of treatment when the evidence of inflammation in peridental membrane serves contra-indication for temporary sealing of teeth. According to the actual standard we should have made pulp amputation, leave a tampon with anti-inflammatory preparation in the tooth cavity and proceed with treatment by de-vitalization of pulp method after stopping of inflammation. Traditional treatment shall take 3-4 visits with pain symptoms kept during several days.

CONCLUSION.

According to the clinical trials provided the high efficiency of ‘Pulpotec’ for treatment of odontitis in molars of temporary and permanent teeth by vital amputation method and absence of negative dynamics during 6 months of the observation were ascertained. The preparation surpasses in efficiency similar drugs being in possession of pediatric dentists. Simplicity in use, absence of pain symptoms during the treatment, decreasing of terms of treatment to two visits, keeping of pulp vital shall be considered to be advantages of the preparation. Positive results of medical trials of ‘Pulpotec’ preparation enable to recommend it for use in extensive clinical practice.

The following publications were prepared upon research studies provided:


Head of Pediatric Therapeutic Dentistry
Department, Candidate M.S.