Clinical Evaluations

1. **FINAL REPORT OF CLINICAL TRIALS OF PULPOTEC**
   (TRANSLATION OF THE ORIGINAL FRENCH TEXT)

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)

3. TREATMENT OF THE MULTIROOTED TEETH PULPITIS BY THE AMPUTATION METHOD USING "PULPOTEC" (PD, SWITZERLAND)
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   (TRANSLATION OF THE ORIGINAL TEXT)

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1. FINAL REPORT OF CLINICAL TRIALS OF PULPOTEC
(TRANSLATION OF THE ORIGINAL FRENCH TEXT)

1. <u>Synopsis</u> :

Following 17 years of utilization of the Pulpotec Filling Paste on approximately 3'000 permanent and temporary molars with a clinical success rate of 80%, it would appear that the advantages offered by its utilization are clearly superior to any inconveniences, which are only minor, under normal conditions of use.

2. <u>Introduction</u> :

It was following an apical leak during a technique of total pulpectomy carried out about 15 years ago on an inferior molar, which was developing in a worrying fashion, that the idea was born of updating pulpotomy. This had already been proposed by A. Marmasse, Professor at the Paris Dental School a few years previously.

The usual treatment applied to pulpitis on a living tooth involves removing the totality of the pulp in the treated tooth and filling the cavity with an obturating material like an antiseptic paste, based on Zinc Oxide and Eugenol, or a paste based on Bakelite or condensed Gutta. This type of operation, when practiced on a molar, proves to be long and complicated due to the complexity of the shape of the roots, the narrowness of the buccal cavity and the difficulty of inducing total anesthesia in mandibular molars in

particular.

In this sense, recent studies (1) have shown that the failure rates of endodontic treatments by pulpectomy are over 50% throughout the world, including Switzerland, Sweden and the U.S.A. These failures are characterized by an infection which starts at the extremity of the root. One must then imperatively have access to the roots of the tooth in order to repeat the treatment. This is not always easy due to the fact that any paste for canals, in particular Bakelite, is particularly difficult to remove. If the tooth cannot be treated again, it will have to be extracted. In addition, studies concerning the anatomy of the radicular canals (2) have shown that these contain numerous branches which cannot be reached during a total pulpectomy.

In addition, the practice of pulpectomy is accompanied by numerous risks like the inhaling by the patient of canal instruments used to extract the nerve from its cavity or the penetration of obturating material beneath the roots. In this latter case, the complications can be extremely serious, since they range from fungal sinusitis of the upper maxillary (3) to the onset of permanent pain in the lower maxillary for which no therapy currently exists (4-5).

At one time, the practice of pulpotomy was considered to be an alternative to pulpectomy. Rather than remove the totality of the pulp in a tooth, the dental surgeon performed a selective amputation in the coronal part of the tooth pulp contained in the pulpal chamber, and then sealed the cavity with a classical sealing material.

Pulpotomy presents numerous advantages when compared with pulpectomy (8). Amongst these, one can mention significant time saving, easy access to the part of the pulp which is to be treated and simplified technical procedures for the practitioner. The combination of these factors means that the principal risks which accompany pulpectomy are eliminated, in particular those linked with the use of canal instruments and to the leakage of filling material beneath the roots.

Nevertheless, the obturating materials used to date for pulpotomy have not been satisfactory, as they have caused cases of degeneration and infection in the residual pulp. Consequently, due to the numerous difficulties based on the inadequacy of the obturating material used, the practice of pulpotomy has been abandoned, despite its indisputable advantages. It should also be noted that pulpotomy is the only technique which authorizes complete radicular edification of immature permanent molars.

Recent studies (6), taking into account the observations of Professor A. Marmasse on pulpotomy (7), have revealed that the pulp has a great capacity for healing. This has led us to investigate the possibilities of perfecting a filling material capable of compensating for the inconveniences mentioned above and also generating the cicatrisation of the radicular pulp and its perenniality with the help of substances which would initially ensure antisepsis and hemostasis and then the maintenance of long term antisepsis and impermeability by means of a good volumetric stability.

3. <u>Treatment</u> :

In 1989 it was decided (after having treated a few cases in 1987) to treat all the permanent and temporary molars of the patients exhibiting pulpitis on a vital tooth by

pulpotomy, being convinced that the risks incurred were much less important than those linked to a pulpectomy, a failure implying, in the majority of the cases, a simple return to treatment by so -called total pulpectomy.

Pulpotomy consists in amputating the cameral pulp and then capping the pulpal stumps with an obturating paste. To do this, the ceiling of the pulpal chamber should be removed by means of a Zekrya surgical bur, then the cameral pulp should be removed with a Zekrya Endo type bur. The pulpal chamber should be re-shaped with a pear-shaped diamond bur. It is important to use high speed rotary instruments in order to avoid tearing the radicular fibres, which must imperatively remain in the canals.

The pulpotomy as such is completed by placing Pulpotec in the cavity chamber by means of a rotary Paste Filler of large diameter. The Pulpotec is then covered with a temporary dressing. A cotton roll should then be inserted between the two arches and the patient requested to bite firmly so that the Pulpotec adheres closely to the walls of the pulpal chamber and the openings of the radicular canals, thereby ensuring perfect impermeability.

During a second session, approximately 8 days later, a permanent filling should be placed and followed, where necessary, by the placement of a crown prosthesis.

4. Clinical investigation :

To date approximately 3'000 teeth have been treated, half of which were permanent and the other half temporary.
An initial X-ray was taken on the day of treatment by pulpotomy and then, after the first 3 years, each time the patient returned to the practice. (The X-ray follow-up was carried out for permanent teeth only).

To this day, 310 radiological cases have been followed for periods between 3 and 13 years (3 years : 48 teeth; 4 years : 54 teeth; 5 years : 50 teeth; 6 years : 26 teeth; 7 years : 20 teeth; 8 years : 26 teeth; 9 years : 36 teeth; 10 years : 21 teeth; 11 years : 17 teeth; 12 years : 8 teeth; 13 years : 6 teeth; 15 years : 1 tooth). When analyzing the results, the absence of pain for a long period was also taken into consideration as well as the efficiency of mastication.

In the majority of cases concerning permanent teeth, a crown prosthesis was placed in order to ensure the best possible tightness of the filling. In addition, it should be noted that this prosthesis also acts as an "early-warning device" because, given its cost, the patient will not hesitate to come for a consultation in case of pain and pain could indicate an infection of the radicular system.

5. Results :

5.1) Deciduous teeth :

Immediate pain relief after treatment in 80% of cases; mild pain which lasts only 2 to 3 days in 20% of cases. These teeth are clinically mute and function until they disappear from the dental arch to give way to the permanent teeth which follow them. This is the

case for deciduous teeth which have remained in place until their "natural" elimination.

It should be noted that some 30% of generally uncrowned temporary teeth, fracture during mastication and have to be extracted by the practioner. In this case, treatment by Pulpotec is, obviously, not at fault.

5.2) <u>Permanent teeth</u> :

a) The 310 cases X-rayed present a healthy physiological image with no trace of periapical infection in the second X-ray, added to which, these teeth were not painful and mastication was perfectly normal.
During the same period of 13 years, 61 permanent teeth had to undergo further treatment by total pulpectomy. It seems logical to be able to compare these two figures. Effectively, in both cases, it is impossible to follow all the patients treated. This suggests a success rate of 80%, a figure which also corresponds to that quoted by Professor A. Marmasse in his work (7).

b) Undesirable side-effects :

Following utilization of Pulpotec, 3 types of undesirable side-effects have been noticed :

> In 15% of the cases of teeth treated, a more or less intense pain of an arthritic type was felt during the days which followed the treatment. It lessened progressively on its own or with the help of anti-inflammatory medication taken orally to speed up the process.

> In 3% of the cases of teeth treated, pain of medium intensity (also quoted by Professor Marmasse) was felt until the second session 8 days later. This was treated by the immediate removal of the Pulpotec from the pulpal chamber, followed by the placement of a new dose of Pulpotec. Pain ceased immediately in each case.

> Exceptionally (2 cases in this study) pain of high intensity can occur. This was due to the fracture of a tooth which had not been detected during the initial examination or to the perforation of the floor of the pulpal chamber which had also been overlooked. In such cases the tooth most often has to be extracted which is precisely the same consequence which would have prevailed following treatment by pulpectomy.

6. <u>Discussion and conclusions</u> :

Obviously, it is difficult to expect that X-rays and a clinical follow-up alone will prove the perenniality of pulpal vitality after treatment with Pulpotec.

Proof of this type, stated by Dr Marmasse to be very difficult to establish after vital pulpotomy (7), has not been included in these clinical trials for both ethical and practical reasons.

On the other hand, post-operative functional tests, as well as the X-rays, appear to confirm the perenniality of pulpal vitality after treatment with Pulpotec.

This is further confirmed by the fact that the follow-up of immature permanent molars treated with Pulpotec, has indicated normal, progressive radicular edification until complete maturity.

Finally, if one considers that, on the one hand, in addition to the important risks linked to periapex, the further risks linked to pulpectomy are (with the exception of point N° 2) identical to those linked to pulpotomy, that is to say essentially pain of an arthritic type and, on the other hand, the percentage of clinical failure is significantly higher for pulpectomy than for pulpotomy (50% versus 20%), it would seem sensible to prefer this technique. All the more so as it grants an additional span of life for the tooth and simplifies the work of the dental surgeon. As a result, it can be considered more reliable and likely to optimize the chances of survival for the teeth treated by pulpotomy with Pulpotec.

The investigator :
Dr J. B.
Dental-surgeon

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January 15th 2002

APPROVED

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October 10, 2003

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: polyoxymethene, 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 jam, 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:

1. I.P. Donskaya, S.A. Dedeyan. Treatment of odontitis in pediatrics by method of vital amputation with use of 'Pulpotec'. Transactions of the VIII Congress of the Dentists Association of Russia. Moscow, 2003, pp. 287-288 (Amendment #2).

2. S.A. Dedeyan, I.P. Donskaya. Use of 'Pulpotec' for treatment of odontitis in pediatrics. (Delivered for publishing).

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3. TREATMENT OF THE MULTIROOTED TEETH PULPITIS BY THE AMPUTATION METHOD USING "PULPOTEC" (PD, SWITZERLAND)

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(TRANSLATION OF THE ORIGINAL TEXT)

Number of ailments related to the pulpitis is nowadays about 40% as illustrated by the stomatological practice (E. Borovsky and others, 2002). Currently the most commonly treatment method as to all forms of the pulpitis is a vital and devital extirpation. These methods offer some advantages but also having substantial shortcomings such as: need for a wide range of the expensive endodontic tools, possible tooling damage within a root channel, complications related to some under- or oversealing of the channel, labour intensiveness, duration and expensiveness of the treatment process. The extirpation alternative for the multirooted teeth pulpitis treatment may be coronal pulp amputation. This given method is old-known (A. Rybakov, V. Ivanov, 1980) although its usage is of

limited occurrence due to difficulties of creating aseptic conditions and encapsulated pulp stump within both treatment procedure and after permanent sealing, especially in the II class cavities by Black (J.C. Hess., 2002).

The goal of this given work is to evaluate efficiency of the using the «Pulpotec» material (PD, Switzerland) for a multi-rooted teeth pulpitis treatment by amputation method.

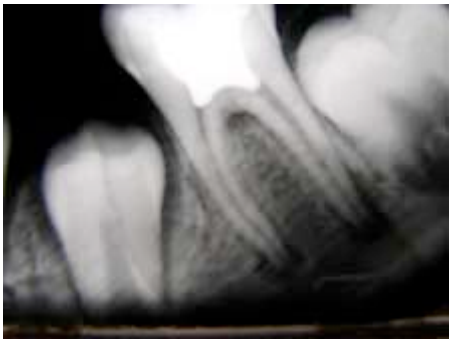
Investigation materials and methods. The amputation method of the pulpitis treatment has been used for 16 patients. Eighteen teeth (all molar ones) were cured. Twelve teeth (66,7%) have been characterised by carious cavity as per II class by Black, six teeth (33,3%) – as per I class respectively. The abovesaid teeth were cured by classical pulp amputation method. Upon pulpotomy and stoppage the bleeding a pulp stump has been covered with special paste made ex tempore of the Pulpotec powder and liquid material included in Pulpotec set.

Above paste a layer of the non-eugenol temporary cement in paste («PD») was laid. This cement layer has been carefully condensed with cotton pellet in order to create encapsulated pulp stump. Such condensed area may be also established if patient bites a wad of cotton wool located between relevant cured tooth and its antagonist (as recommended by the manufacturer). In two-three days the permanent sealing was made while a temporary cement layer has not been removed completely and that cement layer facing a pulp stump served as some insulation seal. Special composites for chemical and photosensitive hardening were used as permanent sealing material. Prior to and after treatment procedure a pulp viability was determined by EOD. Immediately upon the treatment procedure a tooth radiography was made.

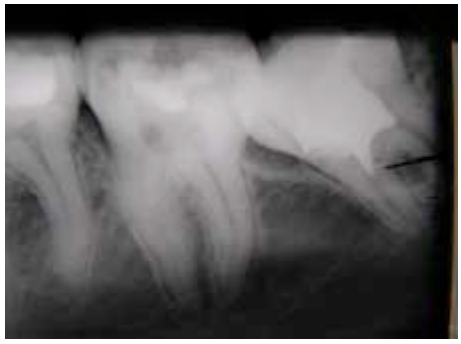
Results. At the time of investigation the EOD parameters were within 25-45 mA featuring with 37±8 mA at average suggesting a pulp viability. The 15 patients' (83.3%) sensation of pain (syndrome) disap-peared immediately after treatment procedure and three patients (17.7%) referred to it the next day. As long-term effects (after 6 months) the pulp electroexcitability was reduced reliably (_<0.05) up to 52±8 mA although relevant clinical and roentgenologic conditions have been kept constant.

A vital amputation should be considered well proved especially under pulpitis treatment of the con-stant teeth (molars) with non-shaped roots, teeth irregularly located (vestibular crown incline), semiretinal 8th teeth, teeth with strongly curved channels.

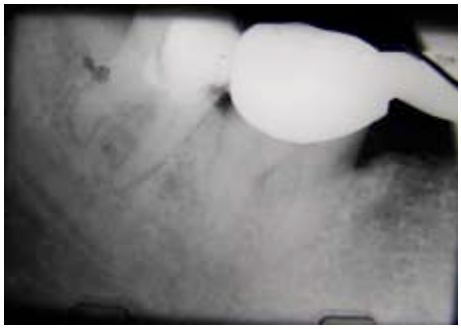
Below are shown X-rays of some teeth subjected to a vital amputation procedure.



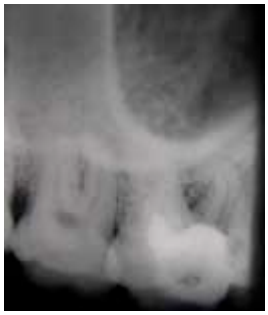
A. Injoyan, 8 y.o. The 46th tooth root was not formed completely.



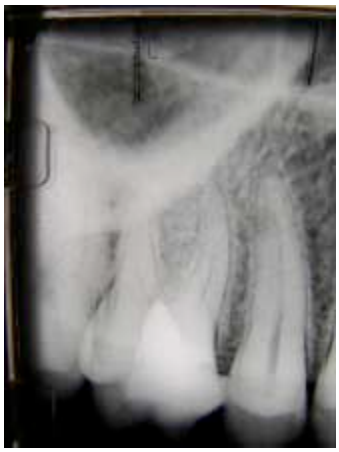
O. Konyukhova, 19 y.o. The 48th tooth com-plicated eruption.



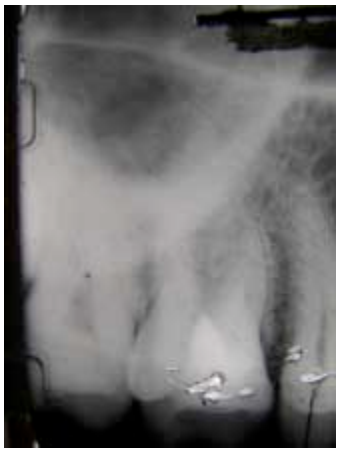
S. Minosyan, 50 y.o. The 48th tooth was inaccessible by endodontic tools.



A. Grishin, 30 y.o. The 16th tooth's medial-cheek root top was curved.



Y. Ioannis, 23 y.o. The 26th tooth immediately upon treatment procedure.



Y. Ioannis, 23 y.o. The 26th tooth after six months' period upon treatment procedure

Discussion upon results obtained

It has been found that despite removal of the pulp crown portion a root pulp may be partly viable. At first glance this occurrence may be considered doubtful because of the mummification properties of the components, but we suggest a mummification process refers to the pulp mouth part which closely adjoins the Pulpotec layer while the apical portion remains viable enabling, in particular, the apical edification of the immature tooth.

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