

## Epidemiological Inquiry about the Use the Pulpotec® in the Private Sector of Casablanca, Morocco

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### Abstract

**Introduction:** As part of a thesis of 2nd cycle of the Department of Conservative Dentistry-Endodontics, we have conducted a survey of dentists around the private sector in Casablanca. Descriptive cross-sectional study was carried out to:

- Know how these dentists have got informed about this product;
- Determine the number of dentists who use Pulpotec®;
- Determine if the practitioners understand the principles of this therapy with its advantages and drawbacks.

**Material and Method:** A questionnaire of 15 questions was sent to 300 practitioners randomly selected from a list provided by the National Order Council of the Dentists (NOCD).

**Results:** The results show that 45,3% of these dentists use Pulpotec® in their dental practices, which prompted us to ask about their reasons and arguments on its use in daily practice.

The analysis of the results show with that the majority of those dentists were informed of Pulpotec® through their colleagues and the product is provided by most of suppliers of dental equipment.

According to some practitioners, the results showed that Pulpotec® presents some drawbacks and generates complications.

The results of this study have showed that the perception of the majority of private practitioners in Casablanca on the use of Pulpotec® in their daily treatments is not generally consistent with any current scientific evidence.

**Discussion:** No similar study has been conducted on the use of Pulpotec® in the private sector. Our study is the first of its kind, making it impossible to compare our results with other cities or countries. The results of this study showed that almost half of dentists 45, 3% use pulpotec® without ensuring proper follow-up for the patient. This product is used on temporal, permanent, mature and immature teeth. 67.6% of practitioners consider it as a definitive treatment. In addition, the perception of the majority of private practitioners in Casablanca about the use of Pulpotec® in their daily treatments is generally not consistent with current science data.

**Conclusions:** The use of pulpotec® must be limited to the temporary treatment of an irreversible pulpitis on a permanent tooth, because of the various complications caused by this product and the insufficiency of the scientific proofs on its efficiency.

**Keywords:** Pulpotomy; Formaldehyde, Pulpotec

### Introduction

The development of more sophisticated dental materials and the appearance of new drugs have allowed dentistry to guarantee the success of several treatments.

Otherwise, some of these drugs could not convince dentistry professionals of the necessity of their use because of the lack of scientific evidence of their benefits such as The Pulpotec® (Swiss medicine).

The active ingredient of this drug is the formaldehyde, which acts mainly by the mummification of the root's pulp [1,2].

In 1998 after the evaluation of their product, the manufactures take it to the market. Switzerland was the first country that marked it, and then it was sold in more than 60 countries [1].

The wide diffusion of this product is explained by its clinical success and its technical simplicity. However, after having had its moments of glory, the mummification also had those of the defeat to the point of being abandoned in teaching and be considered as the privilege of the bad practitioners.

Indeed, it has been showed that this therapy has a formidable enemy, which is the infection: Germs find in mummified necrotic pulp a culture medium that allows them to grow slowly apart from oral cavity.

The mummification is also considered as the origin of too many gangrene, granulomas, cysts, afferent complications [3].

## Material and Methods

We opted for cross-sectional epidemiological survey by random sampling. This survey took place in private dental clinics of Casablanca. Our target population is the practitioners who work in private sector in the WILAYA of CASABLANCA.

They are about 1391 dentists according to the national order council of the dentists (NOCD).

Nevertheless, we have excluded from our survey:

- Locked or abandoned dental offices
- Specialists in orthodontics
- Specialists in periodontics
- Specialists in oral surgery.

The survey was conducted with a sample of 300 dentists of private sector out of 1391 dentists whose elements were chosen by random sampling from a list provided by the National Council of the order of dentists (NCOD).

To collect the data, we have elaborated a questionnaire of three pages written in French.

It contains 15 questions divided to 4 sections:

- Identification of the practitioner.
- Knowledge circumstances of pulpotec.
- Basic knowledge of pulpotec.
- Advantages and disadvantages of pulpotec.

Two Casablanca dental faculty's students conducted the survey.

However, a pre-survey was essential in order to test and validate the questionnaire with 10 dentists who present the same characteristics of the population chosen by the survey.

After obtaining the list from the national council order of dentists and once the sample was assembled, we visit dental offices to fill the questionnaires.

Our survey has started the 29 October 2013 and finished the 06 December 2013 (a period of 1 month 9 days).

Some practitioners have asked to leave the questionnaire and come back to retrieve it some preferred to fill it immediately and others refused to fill.

The epidemiological component of this work was carried out in the epidemiological laboratory (CCTD CASABLANCA).

The data processing was carried out using epi Info 6 software. We used the chi squared test  $\chi^2$  to compare the percentages obtained. The difference was judged statistically significant when  $p \leq 0,05$ .

## Results

The first question was about the origin of the 300 practitioners' degree, in fact 214 practitioners (71,3%) have graduated from Casablanca dental faculty. 25 practitioners (8,3%) from Rabat dental faculty and 61 practitioners did their studies abroad (France, Tunisia, Russia, Belgium, Senegal, Romania and Spain).

Some of those 300 practitioners of our sample 59.3% had graduated before 2000: 24% graduated from 2001 to 2006 and 16.7% graduated from 2007 to 2013.

Regarding the use of pulpotec in daily practice, we have identify 139 users (45.3%) against 164 non-users (54.7%). We have also noticed that the majority of the users (46.3%) have obtained their diploma before 2000.

We asked the dentists to tell us about the circumstances of knowing of this product, so 52.3% learned about it from their colleagues, 9.3% from medical delegates, 13.7% from the both, 3.7% from their colleagues and the internet. 2.7% from internet and 1% from their colleagues, medical delegates and their colleagues, 4% responds otherwise (at medical conferences or by patients already treated with this product) 13.3% do not know it at all.

Graduation's year of Pulpotec® users	Headcount	Percentage
≤ 2000	63	46,3
[2001 - 2006]	43	31,6
[2007 - 2013]	30	22,1
Total	136	100

**Table 1:** Cross Comparison between the graduation's year and the use of Pulpotec®.

Circumstances of knowing Pulpotec®	Headcount	Percentage
Colleagues	157	52,3
Medical delegates	28	9,3
Medical delegates + Colleagues	41	13,7
Colleagues + Internet	11	3,7
Internet	8	2,7
Medical delegates + Colleagues + Internet	3	1
Other answers	12	4
Ignorance of the product	40	13,3
Total	300	100

**Table 2:** Circumstances of knowing of Pulpotec®.

As regards the tooth's type on which they use this product, the results are shown in tables 3 and 4.

Tooth type	Headcount	Percentage
Temporary teeth	24	17,6
Permanent teeth	65	47,8
The both	47	34,6
Total	136	100

**Table 3:** Teething type on which practitioners use pulpotec.

Teeth type	Headcount	Percentage
Monorooted teeth	4	2,9
Bi-rooted teeth	15	11
Multi-rooted teeth	121	89
All teeth's type	14	10,3

**Table 4:** Teeth's type on which practitioners use pulpotec.

The response of 136 users interviewed on the indication of the use of this product revealed that 89.7% use it in irreversible pulpitis treatment, 4% in necrotic pulp and 5.9% in both cases.

The main reasons for using this product in the private sector are shown in table 5.

Advantages of Pulpotec®	Headcount	Percentage
Technical simplicity	102	75
Time saving	100	73,5
Lifespan	90	66,2
Healing of the pulp	29	21,3
Low cost	18	13,2
No need for reoperating	15	11
Other responses	15	11

**Table 5:** Motivating Criteria of using Pulpotec®.

From 136 users questioned if they experienced any complications during their treatment with pulpotec:

- 58.1% have never had a complication.
- 41.9% admit that they had complications such as the persistence of acute pain after the treatment; Irritation or necrosis of the gingival septum in cases of overflow, cellulitis, periodontitis and periapical reactions (Table 6).

Complications	Headcount	Percentage
Not	79	58,1
Yes	57	41,9
Total	136	100

**Table 6:** Presence or not complications during treatments with Pulpotec®.

Among the 55 practitioners who ensure the follow up, 35 specified the duration of the control of their patients treated with this product.

74.3% ensure the medical follow up of their patients in a period of 1 year; 2.9% in 2 years; 5.7% in 3 years; 2.9% in 4 years; 5.7% in 5 years; 2.9% in 6 years; 2.9% in 7 years and 2.9% in 10 years.

### Discussion

Our sample's size is 300 dentists representing 21.57% of the total number of dentists in Casablanca for the year 2013 is considered statistically significant, to be able to extend the results to the whole target population.

The main objective of our study is to know if pulpotec is widely used by casablanca's private dentists. The survey revealed that 136 from 300 dentists use pulpotec, which represents 45.3%.

For our study we have noticed that there is non-significant relationship between the graduation's year and the use of pulpotec (p = 0.08).

Therefore, we conclude that the use of pulpotec by dentists is not influenced by their graduation's year.

We have also noticed that the majority of the dentists (85,3%) agreed that pulpotec is present in all dental equipment suppliers while the rest only gets the product from a few suppliers or after a pre-order.

This shows the easy access to this product, it is imported from abroad, and it is sold in a normal way like any drug or dental material.

From 136 users of pulpotec only 10.3% know its exact composition: 75.7% gave a wrong answer and 14% did not give any response.

According to the website, (www.pulpotec.com) [1] pulpotec is composed by:

- A powder of polyoxymethylene, iodoform
- A liquid containing formaldehyde, dexamethasone acetate, phenol, guaiacol.

It is noted that the parent company has only mentioned the components and did not specify the dosage of each one. Practitioner's ignorance of pulpotec's components and its mode of action could lead to failure [1].

In our sample, among 136 users, 47.8% use it in permanent teeth, 17, 6% use it in temporal teeth, while 34.6% use it in the both types of teeth.

These results are similar to those found on the website www.Pulpotec.com which the indication of Pulpotec® is not limited to temporary teeth only but it is also indicated for permanent teeth whether they are immature or mature [1].

However, the majority of articles claim that the use is limited to temporary or immature permanent teeth.

As a matter of fact, according to the article published in 2010 by N. M. Khattab and Coll and the article published in 2013 by P. Kakarla and Coll, the authors conducted a study on the evaluation of the pulpal response in contact with Pulpotec®. This study only concerns temporary teeth.

In the same context, in 2012, K. AL-Salman and Coll evaluated the efficiency of Pulpotec® in the treatment of temporary teeth and immature permanent teeth by pulpotomy.

In conclusion, these three studies recommend the use of Pulpotec® on temporary teeth as well as on immature permanent teeth.

Even if the use of Pulpotec® has been recommended in the treatment of temporary teeth, the technique of non-vital pulpotomy with this product has never been used in the Department of Pedodontics of our Faculty of Dental Medicine in Casablanca. Furthermore, the technique of pulpotomy by Formocresol was adopted in the first years within this service, but it was later rejected because the French literature does not recommend it anymore.

The parent company was based on a single article published in 2008 by VV Tairov, *et al.* to support the use of pulpotec in permanent teeth. The study was conducted during a period between 2003 and 2008 and evaluated the evaluation of pulpotomy treatment of permanent teeth with pulpitis. The authors proved the effectiveness of Pulpotec® in this kind of treatment [7].

According to the website www.Pulpotec.com, Pulpotec® is indicated for the pulpotomy treatment of all types of teeth: temporary or permanent. However, the lack of scientific evidence concerning its use on permanent teeth must draw dentist's attention and should be thought through before use [1].

From the 136 dentists, 89% use it on multi-rooted teeth; 11% use it on bi-rooted teeth; 2.9% use Pulpotec® on the mono-rooted teeth while 10.3% use it on the 3 types of teeth. But, all the researches were carried out only on molars: temporary, permanent immature or mature.

Indeed, VV Tairov and Coll from 2003 to 2008, have made observations on the effect of Pulpotec® as well as the gel Collapan - a bio-active material and a broad spectrum antibiotic that exerts a bactericidal action on 31-molar's microorganisms of 31 patients of both sexes, in age ranging from 11 to 54 years.

The results of this study demonstrated a high efficacy of these two products in the treatment of molars with pulpitis [7].

Among the 136 dentists who use Pulpotec®, 89.7% use it in the treatment of irreversible pulpitis; four, 4% in the treatment of teeth with necrotic pulp while five, 9% use it in both cases. According to the website, www.Pulpotec.com Pulpotec® is indicated for adults, in the treatment of pulpitis on vital teeth, in gerontology, in the treatment of molars with calcified root canals, which provides clinical silence of the tooth by pulpotomy so it does in pedodontics, in the treatment of pulpitis on temporary or permanent vital teeth. It is noted that the type of pulpitis was not mentioned in the site [1].

Indeed, according to the literature, the indications for the amputation-mummification method or referred to as pulpotomy after scarification are described as follows:

1. **Pathological indications:** Amputation-mummification is indicated where the radicular pulp is infected with non-reversible infectious or inflammatory lesions if the root pulp on the desire to preserve is not infected or inflamed.
2. **Anatomical indications:** Amputation-mummification is indicated in the case where the practitioner assumes that anatomic conditions will oppose an action of complete excision of the radicular portion of the pulp such as: very thin or flattened molars and premolar's root canals
3. **Biological indications:** Amputation-mummification may be indicated in the treatment of teeth with open apices with reached pulp, which must not be completely removed.

4. **Mechanical indications:** Amputation-mummification finds its indication when the situation of the cavity with exposed pulp requires a treatment that would dangerously weaken the tooth, if it were treated by other methods [2].

Studies on Pulpotec® were performed on teeth with pulpitis, but it remains difficult to specify the histopathological stage of the pulp. In the same context, Mr. Abdul-Kareem and Coll conducted a study on comparison of the effect of Pulpotec®, formocresol and ferric sulfate in the treatment of pulpitis in temporary molars. The results showed that Pulpotec® is the best of these three drugs [8].

However, Talaat DM., *et al.* evaluated in 2014 the inflammatory response of the pulp in contact with pulpotec® and formocresol. The study was conducted on temporary puppy's teeth and revealed histologically unfavorable pulpal responses for both products [9].

Finding dentists who use Pulpotec® on necrotic teeth should sound the alarm. Some practitioners don't know the exact indication of Pulpotec®.

As well as the use of Pulpotec® outside of its indication specified by the parent company, can only lead to serious complications such as the development of the infection, gangrenes, granulomas, cysts.

When exploring our results, we noticed that among the 136 dentists who use Pulpotec®; 67.6% found that it is a definitive treatment while the rest of the sample considers it a provisional treatment. Practitioners, who find the Pulpotec® treatment is temporary, have reported that they use it as an intersession's temporary treatment before performing conventional endodontic treatment. This will help to avoid the pain.

According to the article published in 2013, MF Bestoon of Conservative Odontology department of Sulaiman University in Iraq, has shown that Pulpotec® used as a drug temporarily or permanently deposited in the canal has a rapid action on the reduction of pain in the case of acute pulpitis [9].

Conforming to the website [www.Pulpotec.com](http://www.Pulpotec.com) treatment with Pulpotec® is a definitive treatment if its protocol is well respected:

- A diagnosis must be precise, although it is difficult determine clinically the pulp pathological condition.  
Only a histological study allows it;
- A pulpotomy must be performed scrupulously;
- A permanent filling covering the Pulpotec® must be perfectly sealed [1].

In our study we have found that the main reasons for using Pulpotec are:

Its technical simplicity, the time saving, the lifespan and its timeliness of processing compared to conventional endodontic treatment. We noticed that our results are similar to those reported on the website [www.Pulpotec.com](http://www.Pulpotec.com) which indicate that pulpotomy with Pulpotec® on temporary and permanent's teeth with pulpitis remains a simple fast and durable treatment [1].

Other practitioners claim that the main reason for using Pulpotec® may be its healing ability and/or its low cost, no need for reoperation and/or the absence of post-operative complications and its indication in special cases (elderly people, non-cooperating patients, and wisdom teeth).

Furthermore, the literature data revealed that the main reasons for using Pulpotec® are:

- His rapid action on the reduction of pain according to Mr. F Bestoon in 2013 [10,11];
- Its efficacy in temporary molar's pulpitis treatment according to P. Kakarla and Coll in 2013 [4], K. AL-Salman and Coll in 2012 [6] and N.M. Khattab and Coll in 2010 [5];
- Its effectiveness in the treatment of mature permanent molar's pulpitis according to the study conducted by V.V. Tairov and Coll between 2003 and 2008 [7].

Regarding the complications caused by this product, from the 136 dentists who use Pulpotec®, 41.9% mentioned that they had complications during their Pulpotec® treatments while 59.1% said that their Pulpotec® treatments have been in good condition. These practitioners consider that the absence of complications is because of three factors:

- The establishment of a good diagnosis,
- The perfect handling of the product
- The elimination of all the cameral pulp.

In addition, the various complications encountered by dentists are essentially related to the persistence of acute pain after Pulpotec® treatment. This complication is the most mentioned by dentists, which necessarily requires a clinical intervention. However, according to the site [www.Pulpotec.com](http://www.Pulpotec.com), the majority of cases treated with Pulpotec® cause little pain type arthritis or high intensity or no pain [1].

For all these reasons, there is no question of using Pulpotec® in a systematic way instead of conventional endodontic treatment, so it is necessary to exhort the colleagues to not use it clumsily in their treatments and regularly update their knowledge and to be aware of current scientific data.

In addition, several disadvantages were mentioned in our study, such as the toxicity of Pulpotec® as it contains formaldehyde, the carcinogenic character of Pulpotec® in case of inhalation, the absence of disinfection and sealing of root canals. The disadvantage which is most mentioned by practitioners is its canal's calcification induction and therefore the impossibility to do a root canal treatment in case of the failure of Pulpotec® treatment.

This way, studies have been conducted to prove the toxicity of formaldehyde. According to the article published in 2004 by the International Center for Research on Cancer, P Boyle Director of International Agency for Research on Cancer announces that formaldehyde is carcinogenic. After much research and based on new information, a group of experts determined that there is now sufficient evidence that formaldehyde causes nasopharyngeal cancer in humans [12].

Similarly, according to the article published in 2011, K Arai and Coll showed that the daily inhalation of formaldehyde by the practitioner, the patient and the dental assistant can be harmful but this risk decreases considerably in the case of using an extra and intra-oral air evacuator [13].

Also, according to the article published in 2003 by JJ Braun and Coll concerning the evaluation of a root canal filling paste whose active ingredient is formaldehyde, the observations and the results showed that 7 cases developed an allergy to formaldehyde, 3 cases had generalized Urticaria (rash and hives) while 4 cases developed anaphylactic shock [14].

In the same context, Kunisada and Coll found the same reactions of urticaria and anaphylactic shock in patients treated with a canal disinfectant containing formaldehyde. The question is the dose of formaldehyde in Pulpotec® toxic and cause serious complications for the patient and the practitioner? [15].

Of the 136 dentists who use Pulpotec®, only 40.4% provide clinical and/or radiographic monitoring of their patients. The lack of control was justified by the lack of patient's motivation. Concerning the duration of control, the majority of the practitioners (74,3%) provide the control during 1 year, while this duration differs between 2 and 10 years for the rest of the sample. As for the interval time between testing sessions, almost half of the practitioners (46.3%) monitor their patients every 6 months, while the rest of the sample follow up their patients every 2 weeks, monthly or when the patient has pain on the tooth in question.

According to the website [www.Pulpotec.com](http://www.Pulpotec.com), the control of patients treated with Pulpotec® only concerns permanent teeth. In

this way, a radiographic examination is done each time the patient comes to the dental office. More than 400 cases could be followed by radiographic examinations between 3 and 18 years.

They present a healthy radiographic image during the second radiographic picture, no sign of apical area's infection; moreover, these teeth are not painful and occur a normal chewing [1].

It is noted that no other studies have been conducted to report the complications that Pulpotec® can cause.

## Conclusion

Pulpotec® has been marketed for 16 years. Since then, it has sold in more than 60 countries. Morocco experienced the commercialization of this product in 2004.

The problem of our study was to know better the practitioners habits and their feelings about the use of Pulpotec® in their practice, also know the advantages that have encouraged them to use this product, determine the disadvantages as well as the complications they encountered in their Pulpotec® treatments

In fact, the results of our survey show that 45.3% of dentists use Pulpotec® in their daily treatments. However, the use of it is not taught in Moroccan dental schools. This work also revealed that many practitioners are changing their habits after they leave the faculty and that for many practitioners the use of Pulpotec® has become a daily habit that has allowed them to escape conventional endodontic treatment.

The lack of the scientific evidence proving the efficiency of Pulpotec® especially for the permanent teeth must require a lot of thinking by the practitioners who use it.

On our part, it might be necessary to carry out similar surveys in other Moroccan cities to better understand the subject and to be able to compare the various results identified.

## Conflict of Interest

The authors deny any conflicts of interest.

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