Title
Effectiveness of Calvital®, a Calcium Hydroxide
Formulation, on Persistent Apical Periodontitis
Caused by Over-enlargement of Apical Foramen

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Journal
Bulletin of Tokyo Dental College, 52(4): 209-213

URL
http://hdl.handle.net/10130/2607
Abstract

This study aimed to evaluate the effectiveness of Calvital®, which is a calcium hydroxide formulation, on persistent apical periodontitis caused by over-enlargement of the apical foramen. The study included patients referred to the Department of General Dentistry at Tokyo Dental College Suidobashi Hospital on a diagnosis of persistent apical periodontitis at an external dental clinic. Of them, 20 showing considerable enlargement of the apical foramina were included in the study. Complete disappearance of symptoms was observed in all patients after intracanal application of Calvital®. We believe that this was due to effective wound-healing brought about the strong alkaline nature of this formulation. We regard Calvital® as a highly effective agent for root canal treatment of teeth with persistent apical periodontitis.

Key words: Persistent apical periodontitis—Over-enlargement—Calcium hydroxide formulation—Root canal treatment—Clinical symptoms

Introduction

In daily practice, conventional root canal treatment of teeth with chronic suppurative apical periodontitis is likely to result in cure in the vast majority of cases. However, in many cases, symptoms such as occlusal pain and pain on percussion can be persistent following treatment, leading to a diagnosis of persistent apical periodontitis. Persistent apical periodontitis is often considered to be iatrogenic, that is, occurring as a result of over-instrumentation, with enlargement of the apical foramen to a greater size than necessary, or perforation of the pulp floor or root canal wall. In such cases, the cause of the symptoms is clear. Although symptoms can be monitored, root canal treatment with conventional intracanal medicaments tends to be ineffective. Consequently, practitioners are frequently at a loss in prescribing appropriate treatment methods, and sometimes resort to extraction. The adverse effects of formaldehyde-based treatment agents has been identified in recent years, and it would be no exaggeration to say that calcium
hydroxide formulations are now considered the most effective root canal treatment agents. The Calvital® formula was developed 50 years ago, and has undergone a number of improvements since then. To date, many studies on Calvital® have been performed at our college2,9–11,13, and as a result of its excellent ability to induce the formation of hard tissue, it is currently used in various endodontic procedures, including vital pulpotomy, direct pulp capping, and root canal treatment. A vital feature of this formulation is that it contains a large proportion of calcium hydroxide and maintains its strongly alkaline pH over a prolonged period in triturated form10.

Calcium hydroxide formulations have been used for various dental procedures, including those mentioned above, for almost a century. Its use as an intracanal medicament during root canal treatment has been associated with periradicular healing1,4,12,14–17. This has been promoted by a series of articles documenting the antibacterial efficacy of calcium hydroxide in infected root canals5,12. Although Calvital® was first developed approximately 50 years ago, it is still widely used as a modified formulation in various endodontic procedures. However, many aspects of its clinical effectiveness remain unclear. In this study, we investigated the effectiveness of Calvital® as an intracanal medicament during the root canal treatment of 20 patients with persistent apical periodontitis and excessively enlarged apical foramina.

Methods

The study included 20 patients referred to the Department of General Dentistry at Tokyo Dental College Suidobashi Hospital on a diagnosis of persistent apical periodontitis at an external dental clinic. They had been initially treated with conventional root canal treatment agents and irrigants, as well as with compounds like such as formalin guaiacol, and guaiacol-parachlorophenol (Methocol™). In all patients, the apical foramen showed enlargement to greater than #45. Persistent apical periodontitis was diagnosed at our hospital and Calvital® applied as an intracanal medicament at intervals ranging from 2 weeks to 1 month. Postsurgical course was observed. Triturated Calvital® was either transferred to the root canal and applied with a spiral filler fitted to a contra-angle hand piece, or was condensed in increments in the canal using a plugger under microscopy. The number of times that the infected root canal had been treated with conventional agents and irrigants at private clinics following pulp extirpation varied widely. Such treatment appears to have been applied by the referring dentist over a period varying from around 1 month to 7 years, although we can not say for certain as this data was unavailable in many cases. However, in many cases, this information was unknown due to insufficient data from the referring dentist. In each case, therefore, the diagnosis of persistent apical periodontitis was based

![Fig. 1 A: Preoperative diagnostic radiograph of tooth #80 with an open apex and small periapical lesion. B: Recall radiograph at 3 months after root canal filling.](image1)

![Fig. 2 A: Preoperative diagnostic radiograph of tooth #45 with an open apex and small periapical lesion. B: Recall radiograph at 6 months after retreatment.](image2)
solely on the opinion of a general dentist. In a previous study, we described that an apical foramen with a major axis over 350\( \mu m \) (due to pathologic absorption or manipulation of the apical foramen with an instrument larger than #35) may cause lesions requiring intervention with surgical endodontics. The standard used in this study was based on the results of that research. This study was approved by the Ethics Committee of Tokyo Dental College (approval no. 288).

### Results

#### 1. Clinical observations

Symptoms of persistent apical periodontitis disappeared in all 20 patients (Table 1). The average number of root canal treatments using Calvital\textsuperscript{®} was 4.85. After alleviation of symptoms using Calvital\textsuperscript{®}, root canals were filled by the lateral condensation method in all patients using Finapec\textsuperscript{®} APC, a hydroxyapatite root canal sealer. There was no reinfection in any patient, and all of them currently have a good prognosis.

#### 2. Radiographic observations

Complete healing was observed in all 20 teeth prior to insertion of the root canal filling.

### Discussion

In general, symptoms persist in cases of persistent apical periodontitis, even after conventional treatment of the infected root canal, and these symptoms are not alleviated by treatment. Regrettably, numerous cases of persistent apical periodontitis are iatrogenic, either as a result of unintended perforation during root canal treatment or over-enlargement of the apical foramen owing to clinician errors.

With respect to over-enlargement of the apical foramen, we have previously reported that persistent apical periodontitis occurs more frequently if the apical foramen is

![Image](image-url)

Table 1 Persistent cases caused by over-enlargement of the apical foramen

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Patient age (y)</th>
<th>Patient sex</th>
<th>Teeth No.</th>
<th>Apical foramen size</th>
<th>The Number of RCT</th>
<th>Remarks</th>
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<tbody>
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<td>F</td>
<td>46</td>
<td>#100 (P)</td>
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<td>26</td>
<td>#80 (P)</td>
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<td>F</td>
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<td>47</td>
<td>#60 (P)</td>
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</table>

P: Palatal canal, M: Mesial canal, D: Distal canal.
enlarged to greater than #35. The apical foramen was enlarged to greater than #40 in all of the patients in the present study, and this excessive enlargement was regarded as the cause of the seemingly intractable nature of the disorder. In such patients, granulation tissue intrudes into the canal from the over-enlarged apical foramen, causing hemorrhage and rendering the root canal treatment ineffective. Under these circumstances, the use of conventional intracanal medicaments does not bring about healing of the wound area and the number of patient visits is extended in vain, leading to the mistaken belief that this disorder is intractable. In all of the patients in this study, Calvital® came into direct contact with the soft tissues in the apical region. In the vast majority of patients, no hemorrhage was observed under microscopy after the second application of this agent; moreover, the apical foramen of straight root canals could be clearly seen. This means that the wound was healing swiftly, and that Calvital® was exerting an effective action on the wound in the initial stages of treatment.

When Calvital® is used on soft tissues such as the wound surfaces of dental pulp, it forms a necrotic layer, presumably due to the agent’s strong alkalinity. Although opinions concerning the significance of this necrotic layer vary, the use of Calvital® on dental pulp tissue reportedly contributes to hard tissue formation directly beneath this layer, and some believe that this layer also forms a defensive wall against treatment agents. It has been reported that this necrotic layer is observed in dental pulp tissue three days after Calvital® application, and that its expansion halts when a hard tissue substrate has been formed after around 5 days. The agent also causes surface necrosis when used in areas of perforation, initiating wound healing and subsequent progress toward recovery. A study in which Calvital® was used at the site of perforation of the pulp floor in dogs also revealed initiation of healing after a short period, with this tendency increasing over a longer period, although hard tissue formation was not induced.

In addition to calcium hydroxide, Calvital® also includes iodoform, which promotes the proliferation of granulation tissue and exerts an antiseptic effect, sulfathiazole, which is an antibiotic, and T-cain, which is an analgesic. These ingredients have a synergistic effect, adding to the antibacterial effect of calcium hydroxide in alleviating clinical symptoms.

From these findings, we conclude that Calvital® has the specific wound-healing effect of removing inflammatory granulation tissue and alleviating clinical symptoms.

**Conclusion**

In this study, we recruited 20 patients with an over-enlarged apical foramen from among patients in whom a diagnosis of persistent apical periodontitis had been made by general dentists in private practices and who had been referred to the Department of General Dentistry at Tokyo Dental College Suidobashi Hospital for further treatment. In these patients, we applied Calvital®, a calcium hydroxide formulation, as an intracanal medicament and observed changes in symptoms. Symptoms disappeared in all patients. This was attributed to the effectiveness of Calvital® and its wound-healing action derived from its strongly alkaline nature.

We therefore regard Calvital® as a highly useful agent in the endodontic treatment of teeth with persistent apical periodontitis caused by over-enlargement of the apical foramen.

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