## ORIGINAL RESEARCH



# The Efficacy of Calcium Hydroxide Powder mixed with 0.2% Chlorhexidine Digluconate or mixed with Normal Saline as Intracanal Medicament in the Treatment of Apical Periodontitis

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## **ABSTRACT**

**Aim:** To compare the efficacy of calcium hydroxide powder mixed with 0.2% chlorhexidine digluconate or mixed with normal saline as intracanal medicament in the treatment of apical periodontitis.

Materials and methods: Subjects were 55 in number aged 17 to 60 years. Two-visit conventional root canal treatment was performed on 70 teeth. The teeth were divided by randomization (balloting) into two groups: control group and experimental group, each with 35 teeth treated with calcium hydroxide mixed with normal saline or with 0.2% chlorhexidine digluconate as intracanal medicament respectively. All treated teeth were evaluated clinically and radiographically for signs and symptom of periapical infection at specified periods postoperatively. Overall efficacy of medicament was rated based on quality guidelines for endodontic treatment by the European Society of Endodontology 2006.

**Results:** A postoperative favorable outcome of 97.1% in the control group and 94.3% in the experimental group was observed at 6-month review. This difference was not statistically significant (p > 0.05).

**Conclusion:** The use of normal saline or 0.2% chlorhexidine digluconate to mix calcium hydroxide used as intracanal medicament during endodontic treatment resulted in high postoperative favorable outcomes.

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**Clinical significance:** Efficacy of 0.2% chlorhexidine digluconate as a vehicle for mixing calcium hydroxide as an intracanal medicament in the treatment of apical periodontitis is comparable to the efficacy of calcium hydroxide mixed with normal saline.

**Keywords:** Calcium hydroxide, Chlorhexidine digluconate, Intracanal medicament, Randomized clinical study, Root canal treatment.

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# INTRODUCTION

Microorganisms of root canal infections have been implicated in the pathogenesis of the periradicular lesions and healing of these lesions depends on their reduction or elimination. Mechanical preparation of the root canal alone is insufficient for total canal cleansing. Efficient reduction or elimination must also involve the use of chemicals because of the complex anatomy of the root canal which makes it impossible to access all areas during mechanical preparation. Antimicrobials used as irrigating solutions and intracanal medicaments are, therefore, useful adjuncts in root canal treatment. The use of intracanal medications maximizes the chances of eliminating microorganisms from the root canal system. They exert their antimicrobial activity either by direct contact with the microorganism (calcium hydroxide) or by the release of its vapor (formocresol).<sup>1,2</sup>

Valera et al assessed residual intracanal infection following one visit endodontic treatment.<sup>3</sup> Even after

irrigation of the canal with 5.25% sodium hypochlorite and then rinsing with 17% ethylenediaminetetraacetic acid (EDTA), they concluded that instrumentation and irrigation alone in a one visit treatment could not remove the flora in inaccessible areas of the canal system, even though a significant reduction in the microflora was observed.

Calcium hydroxide is one of the most widely used intracanal medication in patients undergoing multiplevisit endodontics. 4 Its interappointment use is to eliminate bacteria, act as a barrier against their ingress and also cut-off their nutrient supply.<sup>5,6</sup> Studies on calcium hydroxide based pastes used in endodontics observed that the vehicle used in mixing the calcium hydroxide determines its working characteristics.<sup>7,8</sup> It was also noted that calcium hydroxide is not effective against all bacteria species, e.g. Enterococcus faecalis found in the root canal, and suggested that it should be used in combination with other medicaments so as to enhance its efficacy. Calcium hydroxide powder can be mixed with different vehicles. Some of these vehicles include: distilled water, dental anesthetic solution, normal saline solution, ringers' solution, metacresylacetate (cresatin) and recently, chlorhexidine.<sup>2,9</sup>

In a study by Zerella et al, it was observed that the effectiveness of aqueous chlorhexidine as a mixing vehicle on enhancing the antimicrobial efficacy of calcium hydroxide slurry had not been fully examined *in vivo*. <sup>10</sup> In a recent systematic review of the efficacy of calcium hydroxide dressing in endodontic infection treatment, only one study compared the efficacy of chlorhexidine to that of normal saline as vehicle for mixing calcium hydroxide. <sup>10</sup> They advocated that further clinical investigation is necessary to clarify whether addition of chlorhexidine or other substance to calcium hydroxide dressing will significantly impact its clinical efficacy.

This study thus sought to determine the efficacy of calcium hydroxide powder mixed with 0.2% chlorhexidine digluconate, and that mixed with normal saline, as intracanal medicament in the treatment of apical periodontitis and compare the clinical outcome of both using the quality guidelines for endodontic treatment.<sup>5</sup> The hypotheses tested were that the vehicle used has no effect on the clinical outcome ( $H_0$ ), or that the vehicle used does have an impact on the clinical outcome ( $H_1$ ).

## **MATERIALS AND METHODS**

This study was a randomized, double-blind, controlled, parallel-group clinical trial carried out at the restorative dental clinic of a Nigerian teaching hospital. The study was carried out on patients that were 16 years and above

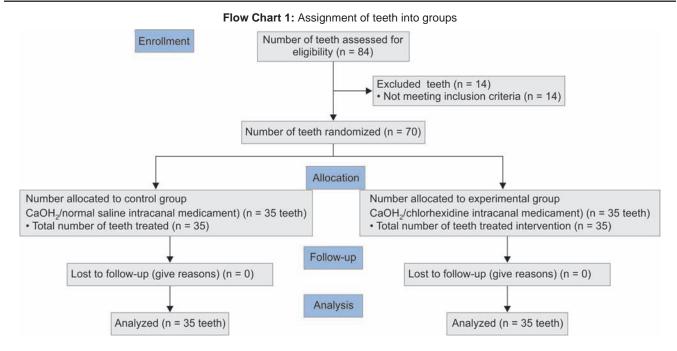
with teeth diagnosed of having apical periodontitis and required endodontic treatment. The patients included in the study gave written informed consent. Treated teeth included those with apical periodontitis with none or minimal ( $2.0 \times 2.0$  mm) periapical radiolucency that are restorable, had closed apex and favorable root morph ology. Exclusion criteria included teeth with dentoalveolar abscess or swelling, retreatment cases, periodontally compromised teeth, teeth that require surgical endodontics and those that required more than two endodontic treatment visits. Also, excluded were medically immunecompromised patients.

The teeth were divided into two groups by randomization (balloting). Group A was the control group and comprised teeth treated with calcium hydroxide mixed with normal saline intracanal medicament. Group B was the experimental group and comprised teeth treated with calcium hydroxide mixed with 0.2% chlorhexidine digluconate intracanal medicament (Flow Chart 1). Where a subject had more than one tooth for treatment, each tooth was assigned by balloting. Incisor, canine, premolar and molar teeth were treated. The subjects in each group were reviewed at 1 day, 1 week, 1, 3 and 6 months. The sample size was calculated to be approximately 25 teeth per group based on the outcome results of previous studies representing the control and experimental groups. 10-12 To ensure validity and correctness for possible attrition, the number of teeth treated in each group was increased to 35, giving a total of 70 treated.

## **Treatment Protocol**

A detailed history, clinical examination, investigations, diagnosis and treatment planning was done for each patient. Conventional root canal treatment was performed by one investigator (MIN). The operative procedure was undertaken under local anesthesia and rubber dam isolation. Irrigation of the canals was done using 2% sodium hypochlorite solution (Milton, Suffolk, UK). The orifices of the root canals were located with the aid of loupes (Stardent, France). The working length was determined by the use of paralleling radiographic method with the use of XCP kit (Dentsply, De Trey, Germany) and was estimated 0.5 mm short of the radiographic apex, using K-files with stoppers. The step-back biomechanical preparation technique was performed on each canal using manually operated files. The last irrigating solution used in each tooth was normal saline. The canals were then dried with paper point before placing canal dressings in the canals. Mixture of calcium hydroxide/normal saline was placed into the canals of teeth in group A using lentulo spiral fillers (Henry Schein, New York, USA)





and calcium hydroxide/0.2% chlorhexidine digluconate (Corsodyl, Middlesex, UK) mixture was placed in teeth of group B.

A sterile cotton wool pellet was placed on the pulp chamber floor to cover the pulp canal orifices and the access cavity packed with zinc phosphate cement. The dressing was left *in situ* for 7 days. <sup>13</sup> At the 2nd visit, teeth were examined to note if the zinc phosphate dressing was intact, and the tooth symptom-free, i.e. no pain, tenderness or associated swelling. The dressing was then removed and the following assessments made: the cotton pellet for wetness, the canal for foul smell or exudate discharge from the canal.

All the treated teeth were symptom free at the 2nd visit and were obturated.

The master cone was selected based on the size of the last file that was used to work the apex. A master cone radiograph was then taken to confirm this. Sealing of the canal was done with appropriate sizes of gutta-percha, AH26 as the sealant, and adequate number of assessory cones using the cold lateral compaction technique. The access cavities were filled appropriately using composite (20/20 composite, Henry Schein, New York, USA) for the anterior teeth and amalgam (Ivoclar vivadent) for the posterior teeth.

#### **Evaluation of Teeth at Recall Visits**

Patients were given review appointments as follows: 1 day, 1 week, 1, 3 and 6 months postobturation. They were reminded of their appointment by telephone calls. At each follow-up visit, clinical assessment of the treated teeth was carried out by two experienced dentists (AIC, OOH) who were blinded to the treatment received by the teeth.

Assessments were done using the quality guidelines for endodontic treatment: consensus report of the European Society of Endodontology 2006.<sup>5</sup>

- Pain assessment was done using the universal pain assessment tool.<sup>14</sup> The use or not of analgesic was also considered.<sup>5</sup>
- Swelling was assessed as being absent or present.<sup>12</sup>
  If present, a tape measure and recording of the relationship of the swelling to the facial structures was done and recorded as being same size, decreasing or increasing in size.
- Tooth mobility was assessed using Miller's index. 15
- Sinus tract was assessed as being present or absent.
  The presence of a sinus track would be confirmed
  by gently threading a gutta-percha cone through the
  opening of the sinus tract to the tooth from which it
  originated.
- Radiographic assessment: All the radiographs were assessed while mounted on a brightly lit radiograph viewer and a meter ruler was used to measure the dimensions of the radiolucency.<sup>5</sup> This was observed at each review visit to determine if the radiolucency was absent or present, same size, decreasing or increasing in size. The series of preoperative and postoperative radiographs for each treated tooth were independently evaluated by the two experienced dentists. In cases where there was no consensus, the radiographs were re-evaluated until one was reached. Before the study, the two assessors were calibrated by evaluating a series of randomly selected pre- and postoperative radiographs from 15 adults. The intra- and interexaminer reproducibility were calculated by Cohen's unweighted Kappa statistics and 85 was recorded.

These parameters (i.e. clinical and radiographic assessment) were used to classify the outcome of treatment as follows:

- Favorable outcome: (a) absence of pain, (b) absence of swelling, (c) no sinus tract, (d) no loss of function, and (e) radiological evidence of a normal periodontal ligament space around the tooth.
- Uncertain outcome: If radiographs reveal that a lesion has remained the same size or has only diminished in size.
- Unfavorable outcome: (a) tooth associated with signs and symptoms of infection, (b) radiologically visible lesion has appeared subsequent to treatment or a pre-existing lesion has increased in size and (c) signs of continuing root resorption.

## **DATA ANALYSIS**

The data were analyzed using Epi info 2000 (window version) and presented using tables, bar and pie charts. Association between age, sex, pain score and other symptoms using Chi-squared test or Fisher exact test was determined (significance level set at, p < 0.05). Comparison of pain score between the two groups was done using Mann-Whitney rank-sum.

## **RESULTS**

# Sample Demography

Seventy teeth in 55 patients were treated and reviewed over a 6-month period. In 43 of the patients, a single tooth each was treated and reviewed, while in 11 others, two teeth each were treated and reviewed. In one patient five teeth were treated and reviewed. The study population comprised of 27 males and 28 females with an age range of 17 to 60 years and a mean of  $34.8 \pm 9.91$ . The two treatment groups were similar with respect to age, gender and teeth treated. (p > 0.05) (Table 1 and Graph 1).

Table 1: Tooth distribution by age and gender

	Group A (n = 35)		Group B (n = 35)			p-
Variable	Frequency	%	Frequency	%	$\chi^2$	value
Age (years)						
11–20	1	2.9	1	2.9		$0.75^{t}$
21–30	19	54.3	20	57.3	0.06	0.80
31–40	8	17.1	7	19.8	0.08	0.77
41–50	2	5.7	4	11.4		$0.33^{t}$
51–60	5	8.6	3	2.9		$0.35^{t}$
Gender						
Total	35	100	35	100		
Male	16	45.7	15	42.9	0.06	0.80
Female	19	54.3	20	57.1	0.06	0.80
Total	35	100	35	100		

<sup>‡</sup>Fisher exact p-value

# **Preoperative Signs and Symptoms**

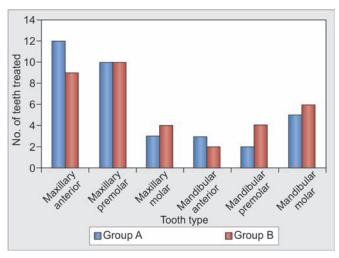
The differences in the distribution of preoperative signs and symptoms in the two treatment groups were not statistically significant (Table 2).

# **Review of Postoperative Signs and Symptoms**

*Pain*: A postoperative review of the incidence of pain showed a marked decrease from the preoperative pain incidence in the two treatment groups. The incidence of pain in the two treatment groups occurred at only the 1-day and 1-week postoperative review periods. There were no significant statistical differences in incidence between the two treatment groups (p > 0.05) (Table 3). On the intensity of pain, the incidence of worst possible pain was the same (5.7%) in both groups reported at 1-day and 1-week postoperative reviews (Graph 2).

Periapical radiolucency: In both treatment groups, the radiographic feature remained the same as seen preoperatively at both 1-day and 1-week postoperative review periods. Thereafter, the normal saline treatment group recorded lower incidence of periapical radiolucency than the chlorhexidine treatment group, except at the 3-month postoperative review when a higher incidence was recorded. However, these differences were not statistically significant (p > 0.05). At 6-month postoperative review, one patient (2.9%) in the normal saline treatment group and two patients (5.7%) in the chlorhexidine treatment group still showed evidence of periapical radiolucency. While the patient in the normal saline treatment group showed a further decrease in the size of the periapical radiolucency, the two patients in the chlorhexidine treatment group showed an increase in the size of the periapical radiolucency (Graph 3).

*Tenderness to percussion (TTP)*: The TTP in the two treatment groups occurred at only 1 day and 1 week postoperative



**Graph 1:** Distribution of treated teeth according to tooth type and treatment group



**Table 2:** Preoperative clinical and radiographic features in the treatment groups

	Group A (n = 35)		Group B (n = 35)			p-
	Frequency	%	Frequency	%	$\chi^2$	value
Clinical finding	gs					
No signs/ symptoms	10	28.6	10	28.6	0.00	1.00
Symptoms of pain	25	71.4	25	71.4	0.00	1.00
Tenderness to percussion	24	68.6	18	51.4	2.14	0.14
Radiographic	findings					
Normal features	14	40.0	11	34.1	0.56	0.45
Periapical radiolucency	21	60.0	24	68.6	0.56	0.45

**Table 3:** Comparison of clinical signs between the treatment groups

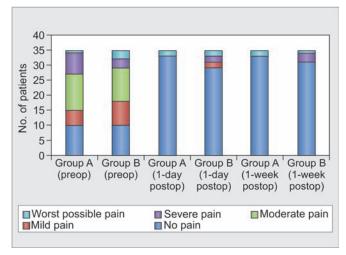
Review periods	Group A (n = 35)		Group B (n = 35)			p-	
	Frequency	%	Frequency	%	$\chi^2$	value	
Incidence of pain							
1 day	2	5.7	6	17.2		$0.12^{t}$	
1 week	2	5.7	4	11.4		$0.33^{t}$	
Incidence of TTP							
1 day	19	54.3	24	68.6	1.51	0.21	
1 week	1	2.9	5	14.3		0.09 <sup>t</sup>	

<sup>‡</sup>Fisher exact p-value

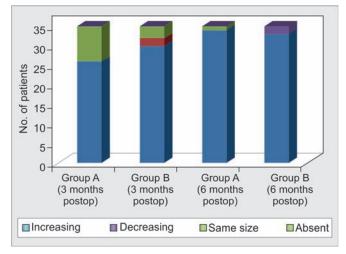
reviews. The differences in incidence between the two treatment groups were, however, not statistically significant (p > 0.05) (Table 3).

Swelling, tooth mobility and sinus tract: During the 6-month review period, there was no incidence of swelling, mobility or sinus tract in both groups.

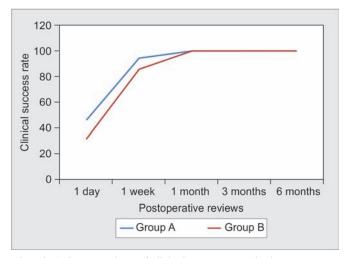
Clinical outcome: An overview of the clinical assessment showed that both treatment groups had favorable and similar clinical outcome of 100% at review times 1, 3 and 6 months. There was a difference in the favorable clinical outcome rate at 1-day and 1-week postoperative reviews, but the difference was not statistically significant (p > 0.05) (Graph 4). The radiographic assessment showed a favorable outcome of 40.0% in the normal saline treatment group and 34.1% in the chlorhexidine treatment group at both 1-day and 1-week postoperative reviews. Thereafter, there was improvement in the rate of favorable radiographic outcome in both treatment groups. At the 6-month review, the favorable radiographic outcome was 97.1% in the normal saline treatment group and 94.3% in the chlorhexidine treatment group, with the difference in incidence rates between the two groups not being statistically significant (p > 0.05) (Graph 5). Combining both the clinical and the radiographic assessments yielded a summary of the treatment outcome. At the end of this study, the group treated with calcium hydroxide mixed



**Graph 2:** A comparison of preoperative and postoperative incidence of intensity of pain in the treatment groups

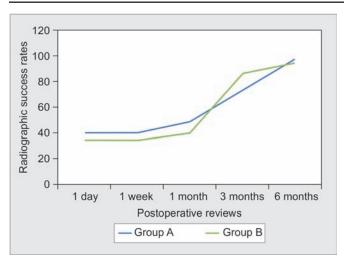


**Graph 3:** Incidence of changes in the radiographic features at 3 and 6 months postoperative review



**Graph 4:** A comparison of clinical success rate in the treatment groups over the 6-month review periods

with normal saline as intracanal medicament recorded a favorable outcome rate of 97.1%, an uncertain outcome rate of 2.9% and 0 unfavorable outcome. The result in the chlorhexidine treatment group was slightly different; in that there was a favorable outcome rate of 94.3%,



**Graph 5:** A comparison of radiographic success rate in the treatment groups over the 6-month review periods

0 uncertain outcome and 5.7% unfavorable outcome. The differences were, however, not statistically significant (p > 0.5).

## **DISCUSSION**

There is paucity of literature on protocols using clinical outcome to measure success with calcium hydroxide mixed with 0.2% chlorhexidine as intracanal medicament. Traditionally, normal saline has been the vehicle in use at our center.

In this study, pain was rated with the universal pain assessment tool. 14 Findings revealed that the incidence of pain was 5.7% at both 1-day and 1-week postoperative reviews in the normal saline treatment group, and although the incidence was higher in the chlorhexidine treatment group (17.2 and 11.4% at 1-day and 1-week postoperative reviews respectively), the difference was not statistically significant. Al-Negrish and Habahbeh reported a 24.1% incidence at 2-day and 5.3% incidence at 7-day postoperative review. 16 Their finding at 7-day postoperative review is similar to that of this study. Ghoddusi et al measured the severity of pain 6-hourly for up to 72 hours and reported a 15% incidence of postoperative pain. 17 This differs from the figures for this study possibly due to differences in the timing of postoperative review and the vehicle for mixing calcium hydroxide (aqua). Using similar rating criteria for pain as with this study, Udoye and Aguwa reported a 10% incidence of postoperative pain. 18 This figure is also significantly higher than the incidence rate for the normal saline treatment group but comparable to that of chlorhexidine treatment group in

our study. Yoldas et al reported using calcium hydroxide mixed with 0.2% chlorhexedine as intracanal medicament; they observed a 19% incidence of pain in the pretreatment asymptomatic group and 51.5% incidence in the pretreatment symptomatic group. 19 The observed combined incidence of postoperative pain at 1 week period was 28.6%. This was significantly higher than the incidence of postoperative pain in the chlorhexidine treatment group in this study. The reason for this difference might be because the study was re-treatment based. Postoperative periapical radiolucency: Molander et al using the same technique for measurement of periapical radiolucency as in the present study, and reported healing rate of 75% as against the higher rates (97.1 and 94.3%) recorded in our study.<sup>20</sup> In another study, Gesi et al observed a similar healing rate as with this study (93%) with calcium hydroxide dressing. 21 The high healing rates attest to the efficient antibacterial effects of these intracanal medicaments used in all of these studies.

*Tenderness to percussion (TTP)*: Gesi et al reported that 19% of the patients treated with calcium hydroxide dressing recorded TTP at the 1-week recall.<sup>21</sup> This was higher than the 1-week review value of 2.9% reported in this study for the normal saline treated group. This difference could be attributed to the fact that pain perception is highly subjective.

Clinical outcome: The overall outcome of success in this study was defined by the criteria for success by the European society of endodontology, 2006.5 The favorable outcome was 97.1% in the normal saline treatment group and 94.3% in the chlorhexidine treatment group at the 6-month review. Results from other studies are 60% with the use of normal saline as a vehicle for mixing calcium hydroxide and 91.7% with the use of chlorhexidine as the mixing vehicle. 10,12 Travassos et al, using similar criteria for assessing success rate as with this present study, reported an overall success rate of 82.9%.<sup>22</sup> This outcome is significantly lower than those of the present study. The treatment was performed by dental students and the authors noted the report by other workers that endodontic treatment performed at dental schools and by practitioners engaged in endodontics tends to have higher success rates than treatments performed in outside institutions for the general population. The present study was performed in a dental school by a practitioner engaged in endodontic practice. Various other reports have noted endodontic treatment success rates ranging from 30 to 98% for conventional root canal treatment. 23-25

Over the years, there have been varying conclusions from studies done on calcium hydroxide as intracanal medicament; while some believe that it does not significantly reduce bacterial load, it has a contrary view that



calcium hydroxide has the strongest influence against all microorganisms. <sup>9,26-28</sup> Another report noted that the mixture of calcium hydroxide and chlorhexidine showed synergistic action and greater efficacy than calcium hydroxide alone. <sup>2,3,8,29</sup> A 4th conclusion is that canal dressing with a mixture of chlorhexidine and calcium hydroxide is as efficacious as aqueous calcium hydroxide as an intracanal medicament. <sup>9,10</sup>

## CONCLUSION

Findings in this study demonstrate that the mixture of chlorhexidine and calcium hydroxide is as efficacious as the mixture of calcium hydroxide and normal saline as intracanal medicaments. This is in agreement with the null hypothesis for this study.

## **CLINICAL SIGNIFICANCE**

Efficacy of 0.2% chlorhexidine digluconate as a vehicle for mixing calcium hydroxide as an intracanal medicament in the treatment of apical periodontitis is comparable to the efficacy of calcium hydroxide mixed with normal saline.

## **ACKNOWLEDGMENT**

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