Comparative Evaluation of the Effect of Two Different Types of Calcium Hydroxide On Periapical Granulomas: A Randomized Controlled Trial

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ABSTRACT

Objective

The mere surgical removal of periapical granulomas through root-end surgery, without proper biomechanical preparation of the canal, placement of calcium hydroxide intracanal medicament, and obturation, does not result in the desired healing of periradicular tissues. The objective of this study was to determine the difference between injectable calcium hydroxide and powder/liquid calcium hydroxide in the resolution of pain (using the Numerical Pain Rating Scale) and periapical granulomas through periodic assessment and measurement of periapical radiolucency, radiographically and using periapical index (PAI) scores.

Methods

This six-month randomized controlled trial was conducted at the Restorative Unit of the National Hospital, Abuja, from 9 August 2018 to 10 February 2020. A total of 128 participants with 128 maxillary anterior teeth presenting with periapical granulomas and a PAI score of ≥4 with horizontal diameter ≥5 mm were recruited. They were randomly assigned to two groups: Group A (n=64) received proprietary injectable calcium hydroxide (Calasept), while Group B (n=64) received the powder/liquid mixture. Participants were recalled at 1 week post-treatment and then monthly for 6 months. Healing was assessed using periapical radiographs and PAI scores. Canals were redressed at 3 months. The primary outcome was lesion size reduction in millimeters and PAI score changes; the secondary outcome was pain resolution. Statistical analysis was performed using Student's t-test, regression analysis, and Friedman test with IBM SPSS version 20.0. A p-value < 0.05 was considered significant.

Results

At 6 months, 100% of participants in both groups had resolution of pain symptoms. Both groups showed significant reduction in periapical lesion size from month 2 to month 6, with faster resolution in Group A. PAI scores significantly reduced in both groups at 6 months, with comparable scores throughout ($P < 0.05$).

Conclusion

The findings suggest that both preparations of calcium hydroxide are effective, but the injectable form (Calasept) promotes faster resolution of lesions and symptoms.

INTRODUCTION

Periapical granulomas, also referred to as chronic periapical periodontitis, are chronic inflammatory lesions consisting of proliferating granulation tissue and bacteria in response to necrotic pulp tissue in root canals.[1] They are the most common sequelae of pulpitis or acute periapical periodontitis and appear radiographically as radiolucent areas around the apical foramen of non-vital teeth.[2] Periapical lesions can be classified as dental granulomas, radicular cysts, and abscesses.[3] The prevalence of periapical cysts ranges from 6% to 55%, periapical granulomas from 9.3% to 87.1%, and periapical abscesses from 28.7% to 70.07%.[3] This wide range may be attributed to the limitations of two-dimensional imaging techniques for assessing three-dimensional lesions, and variations in search methods within databases like PubMed regarding non-surgical management of periapical lesions.

Historically, periapical granulomas were managed by extraction or surgical means such as apicectomy.[2] However, advancements in endodontics now support conventional root canal therapy for these lesions.[2] Surgical curettage alone fails to address the etiological factors, and removal of canal irritants alone is insufficient, as bacteria in the root canal system play a central role in the development and persistence of periradicular granulomas. Successful treatment requires effective removal of necrotic tissue and a hermetic three-dimensional seal of the root canal to facilitate healing.[2] The aim of root canal therapy is to eliminate bacteria and prevent reinfection using conservative, nonsurgical procedures.[3] One of the most widely used intracanal medicaments for this purpose is calcium hydroxide.[4]

Calcium hydroxide is favored due to its high solubility, strong alkaline pH, and ability to promote periapical healing and osseous repair.[5,6] Clinical and radiographic evidence supports its efficacy in the non-surgical management of periapical granulomas.[7] Its high pH leads to leaching of calcium and hydroxyl ions into periapical tissues, encouraging repair and mineralization.[5] Traditionally, calcium hydroxide was mixed chairside, but prolonged mixing could incorporate air, forming calcium carbonate and reducing its effectiveness.[8] Proprietary injectable preparations like Calasept (Scania Dental AB, Knvista, Sweden), introduced in the 1980s, offer premixed formulations with higher antibacterial efficacy and better osseous healing.[9,10,11] Calasept has been used in apexification , pulp capping, retreatment, and management of non-vital luxated teeth.[12] Success rates of 94.4% for complete or partial healing of periapical lesions have been reported.[3]

Despite existing comparative studies on different calcium hydroxide preparations against microorganisms,[5,8,18] few have evaluated their clinical effects on periapical lesion healing. Hence, this study addresses this gap to support evidence-based protocols for non-surgical management.

METHODS

Ethics: Ethical approval was obtained from the Health Research Ethics Committee of the National Hospital Abuja (NHA/EC/077/2016). The study was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines and in adherence to the Declaration of Helsinki. It was retrospectively registered with the Pan African Clinical Trials Registry (PACTR202504838489580).

Trial Design: A single-blind, randomized, comparative study with a 6-month follow-up was conducted at the Restorative Unit, Dental and Maxillofacial Department, National Hospital Abuja, from 9 August 2018 to 10 February 2020. Informed consent was obtained from all participants.

Participants

Inclusion Criteria

- Adults aged 18–50 years with anterior teeth diagnosed with periapical granuloma
- No prior root canal treatment
- Well-circumscribed unilateral periapical radiolucencies without sclerotic margins
- Periapical radiolucency with PAI score (Orstavik) ≥ 4
- Horizontal lesion diameter ≤ 5 mm

Exclusion Criteria

- Age outside 18–50 years
- Calcified or obliterated canals
- Prior root canal treatment
- Systemic conditions affecting bone healing (e.g., poorly controlled diabetes)
- Immunosuppressant therapy
- Chronic periodontitis in target teeth

Recruitment Procedure

Participants were recruited from the Oral Diagnosis Clinic of the National Hospital Abuja, applying the inclusion and exclusion as summarized in the CONSORT flowchart below.

Interventions (detailed $Ca(OH)_2$ preparation methods for both groups)

Group A (Intervention): Calasept (Nordiska Dental Ab, Framtidsgatan ib SE-26273 Sweden), a premixed calcium hydroxide paste, was injected into the canals of participants in Group A using the accompanying dispensing needle tip.

Group (B):Control The dental assistant manually prepared the calcium hydroxide paste. A measuring scoop provided by the manufacturer of the calcium hydroxide powder (Henry Schein) was used to dispense two level scoops of calcium hydroxide powder and one scoop of normal saline on a sterile glass slab (ratio 2:1) to form a paste with a creamy consistency.

Outcomes: The primary outcome assessed was lesion size reduction in millimeters (mm) using periapical radiographs and changes in the periapical index (PAI) scores over time. The secondary outcome assessed was resolution of pain.

Randomization

Participants were randomly assigned to two groups using a web-generated table of random numbers.

Sample size determination

The sample size of 128 participants (with 128 teeth) was calculated using an alpha value of 0.05 at a 95% confidence interval, with a power of 80% and a 10% attrition rate. All 128 participants who met the inclusion criteria were randomly assigned to either intervention Group A (treated with proprietary injectable calcium hydroxide—Calasept, Nordiska Dental Ab, Framtidsgatan ib SE-26273 Sweden) or control Group B (treated with calcium hydroxide powder from Henry Schein and 0.9% normal saline from Juhel). Sixty-four (64) teeth and participants were assigned to each group. Two participants (one from each group) were lost to follow-up due to relocation. Hence, the total number of studied teeth was 126 (63 per group).

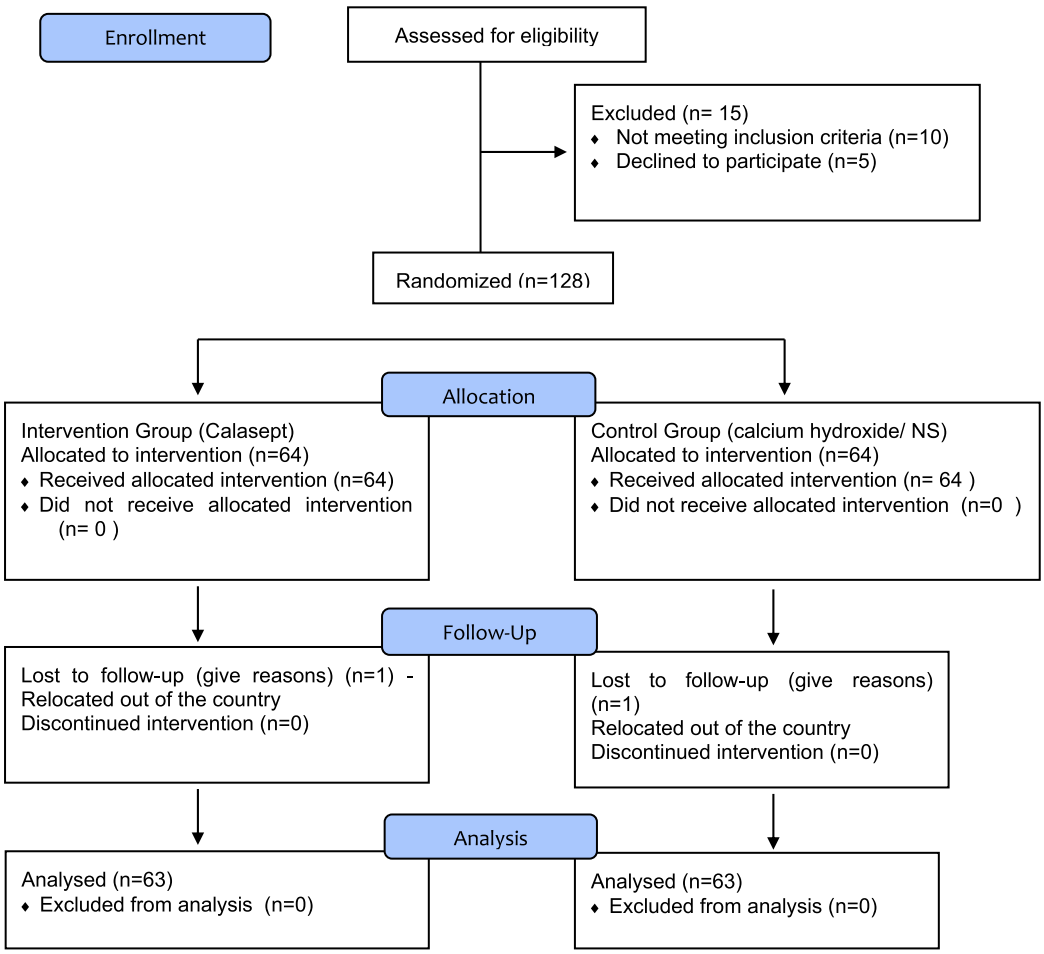
Blinding

Single blinding was adopted; only the participants were blinded to the type of calcium hydroxide placed in their root canals.

Clinical evaluation and patient selection

All involved teeth were examined and assessed clinically and radiographically using periapical radiographs.

Clinical evaluation included assessment of pain, tenderness to percussion, intraoral swelling (with or without a discharging sinus), and discolored non-vital teeth. Pain was assessed using the Numeric Pain Rating Scale (NPRS).[21] The periapical status was assessed using the PAI of Ørstavik.[20] Lesion size was measured using Sopro imaging software to determine the reduction in the horizontal diameter of the granuloma.



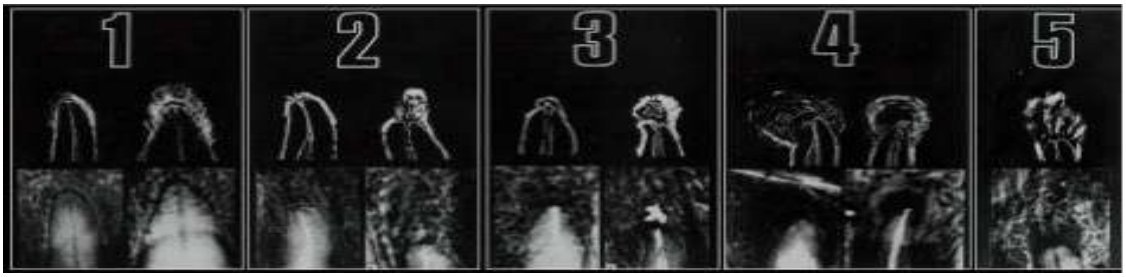
*NS= Normal Saline

Clinical Procedures

All treatments were performed under aseptic conditions using a rubber dam (Coltene Whaledent, USA) and sterile instruments. The same examiner placed the calcium hydroxide in all canals to control for operator variability. Local anesthesia (2% lidocaine with 1:80,000 adrenaline, Human Biologics Products and Services Private Limited, India) was administered using a dental syringe. Short disposable dental needles (Shinhung Shineject 27G, 21mm) were used for infiltration around anterior teeth. Access cavities were created using a turbine handpiece (NSK, Japan) with round burs (Ask HI-DI, Dental Sky Ltd., Ashford, Kent) under copious irrigation.

Canals were located and checked for patency using smooth broaches (Tire-nerfs stainless steel, Produits Dentaires SA, CH-1800 Vevey, Switzerland). Pulp tissue was extirpated with barbed broaches or K-files (Limes, Micro Mega, Gurugram, Haryana, India) in necrotic cases. Working lengths were determined radiographically. Cleaning and shaping were done with K-files using the step-back technique, with irrigation using 3% sodium hypochlorite (Produits Dentaires SA, Switzerland) and normal saline (Juhel 0.9%). Canals were dried with sterile paper points (Perfect Plus Ltd., Hampshire S040, United Kingdom).

Figure 1: PAI scoring criteria



The examiner was unaware of the medicament to be used until after cleaning and shaping. The factory-mixed Calasept paste was injected into canals in Group A using the needle tip placed 3 mm short of working length to avoid extrusion. The chairside mix for Group B was handed over by the dental assistant and introduced into canals using an anticlockwise motion of a file. Intraoperative periapical radiographs confirmed medicament placement. Access cavities were sealed with restorative glass ionomer cement (Nova Glass F, Imicryl, Turkey).

Antibiotics were not prescribed. Patients received 1000 mg of paracetamol three times daily for 3 days and were recalled at 1 week, 1 month, 2 months, 3 months, 4 months, 5 months, and 6 months for clinical and radiographic reviews. Calcium hydroxide was reapplied at the 3-month visit. At 6 months, the paste was removed using files and irrigation with sodium hypochlorite and normal saline. Canals were dried and obturated with gutta-percha (Gapadent ISO 9001) using cold lateral compaction. Access cavities were restored with light-cured composite (I XCITE LCN, Lithuania).

Radiographic Examination

Radiographic evaluations were done by two calibrated examiners using the PAI scoring criteria to classify each case from 1 to 5. During calibration, the study methodology was explained, and the examiners reviewed 41 archived radiographs showing varying lesion sizes (10% of the study's expected total). These calibration radiographs were not part of the study.

Training included using the Sopro imaging software to measure the largest horizontal dimension of each granuloma (average of two readings). Examiners independently reviewed the 41 radiographs, and reproducibility was assessed by repeating the scoring after two weeks. Cohen's kappa coefficient was 0.80, indicating substantial agreement. Final radiographic assessments were made jointly.

Radiographs were taken using digital radiography (Gendex, 65 kV, 7 mA) with standardized angulations to prevent distortion.

The PAI scoring criteria were as follows (Figure 1):

1. Normal periapical structures or normal apical periodontium.
2. Small changes in periapical bone structure, not pathognomonic for apical periodontitis.
3. Bone structural changes with some mineral loss, characteristic of apical periodontitis.
4. Demineralization of periapical bone with a well-defined radiolucent area.
5. Demineralization with exacerbating features or radiating expansions of bone changes.

Figure 1 described above shows the visual references for root evaluation based on the Periapical Index (PAI) scoring system as proposed by Ørstavik et al.[20]

Radiographs in which the periapical area most closely resembled a Periapical Index (PAI) score of 4 or higher (≥4) were selected for inclusion in the study. Periodic measurements of the reduction in the size of periapical granulomas were performed using PAI scores and Sopro imaging measurement software at 1 week, 1 month, 2 months, 3 months, 4 months, 5 months, and 6 months. The horizontal diameter of each granuloma was used as the measurement parameter.

Criteria for success included the absence of pain (assessed using the Numeric Pain Rating Scale [NPRS]), no tenderness to percussion, resolution of symptoms, absence of tooth mobility, preservation of tooth function, and radiographic reduction or absence of the periapical lesion. Each tooth had its baseline radiograph stored, and subsequent assessments were made at the specified follow-up intervals.

Statistical Methods and Analyses

Data were analyzed using IBM SPSS Statistics for Windows, Version 20.0. Frequency distributions were generated for categorical variables, and measures of central tendency (mean and standard deviation) were computed for numerical variables. The Kolmogorov–Smirnov test was used to assess data normality.

Changes in the periapical radiolucencies over time were analyzed using the Student's t-test. Regression analysis

and the Friedman test were applied for repeated measures of lesion size reduction.

Inter-examiner measurement consistency was assessed using kappa statistics for PAI scores and intra-class correlation coefficients (ICC) for lesion size measurements. A two-way mixed-effects model with absolute agreement was used to compute the ICC, which showed excellent reliability: ICC = 0.976; 95% CI, 0.966–0.983; F = 83.479; p < .0001. Cohen's kappa was used to assess inter-examiner agreement for baseline radiographic measurements, with results indicating substantial agreement: κ = 0.720; SE = 0.043; t = 21.186; p < .001.

RESULTS

Demographics

A total of 128 participants were enrolled in the study, comprising 33 males and 30 females in Group A (intervention) and 26 males and 37 females in Group B (control), with no significant difference in sex distribution (p = 0.213). Two participants (one from each group) were lost to follow-up, resulting in 126 teeth (63 per group) being included in the final analysis.

Sociodemographic characteristics (age and sex) were comparable across the two groups. The mean age in Group A was 29.4 ± 11.1 years, while Group B had a mean age of 32.2 ± 11.2 years. Age distribution by sex was statistically comparable in Group A (χ^2 for linear trend = 0.369; p = 0.543) and Group B (χ^2 for linear trend = 2.885; p = 0.089). The majority of participants in both groups were within the 20–29-year age range (Table 1).

Table 1: *Socio-demographic profile of participants by their group*

Social-demographic characteristics	Group A (n=63)	Group B (n=63)	Total (n=126)	Test of statistic; d. f	p
Age (years); Mean (SD)	29.4 (11.1)	32.2 (11.2)	30.8 (11.2)	t=1.413; 124	0.160*
Age group (years)					
<20 years N (%)	14 (22.2)	11 (17.5)	25 (19.8)		
20-29years N (%)	24 (38.1)	19 (30.1)	43 (34.1)		
30-39years N (%)	10 (15.9)	16 (25.4)	26 (20.6)	X^2=2.451; 4	0.484*
40-50years N (%)	15 (23.8)	17 (27.0)	32 (25.4)		
Sex					
Male N (%)	33 (52.4)	26 (41.3)	59 (46.8)		
Female N (%)	30 (47.8)	37 (58.7)	67 (53.2)	F. E= 1.549; 1	0.213*

Note: N – Frequency; numbers in parentheses represent percentages.
t – Independent t-test; χ^2 – Chi-square test for linear trend; F.E – Fisher's Exact Test; Differences in means or distributions not statistically significant (p > 0.05); d.f. – Degrees of freedom.

Aetiology of Periapical Granuloma

Trauma to the anterior teeth accounted for the highest proportion of cases in both groups—46% in Group A and 52.4% in Group B—followed by dental caries.

Table 2: *Aetiology of Periapical granuloma*

Indicator	Group A (n=63)	Group B (n=63)	X^2; df. P
Carious lesion with Pulpal involvement	25 (39.7)	26 (41.3)	0.020;1; 0.889
Trauma	29 (46.0)	33 (52.4)	0.258;1; 0.612
Unknown aetiology	9 (14.3)	4 (6.3)	1.923;1; 0.166

The aetiology of periapical granuloma was comparable between both groups (P > 0.05).

Periapical Radiolucency Measurements

Radiographic measurements from baseline to six months were compared between Group A (Calasept) and Group B (Chairside mix) using the Mann-Whitney U test. The

results revealed significant differences between the groups at the 2nd month (p = 0.017), 3rd month (p = 0.003), 4th month (p = 0.005), 5th month (p = 0.001), and 6th month (p = 0.001), with consistently lower values observed in Group A across all time points (months 1 to 6) [Table 3]. Additionally, a Friedman test was conducted to assess lesion size reduction over time. The result indicated a statistically significant reduction across the repeated measures (p < 0.0001).

For radiographic measurements and periapical index scoring, the Mann-Whitney U statistics were 1792.5 (p = 0.325) and 1804.5 (p = 0.338), indicating that the values for the two groups were comparable (p > 0.05). Additionally, a significant reduction in the sizes of the lesions was observed in the third month (p = 0.018) [Tables 3 and 4].

Table 3: *Comparison of radiographic measurements (mm) between Group A (Calasept) and Group B (Chairside mix) over time*

Radiographic measurements	Group A (Calasept) (mm)	Group B (Chairside)(mm)	Mann Whitney U	P
Baseline	4.9 [3.7-5.0]	4.6 [3.7-5.0]	1792.5	0.325
week1	4.7 [3.5-4.9]	4.5 [3.8-4.9]	1821.0	0.421
month1	3.7 [3.0-4.5]	4.0 [3.2-4.5]	1837.5	0.472
month2	2.8 [2.5-3.5]	3.5 [2.7-3.5]	1495.5	0.017
month3	2.5 [1.8-3.0]	3.0 [2.4-3.5]	1385.0	0.003
month4	2.0 [1.5-2.5]	2.5 [1.9-3.0]	1411.5	0.005
month5	1.7 [1.1 -2.0]	2.2 [1.5-2.5]	1316.5	0.001
month6	1.5 [0.8 -1.8]	2.0 [1.3-2.2]	1292.5	0.001

Values are presented as median [Interquartile Range]

Table 4: *Comparison of periapical index (PAI) scores between Group A (Calasept) and Group B over time*

PAI scoring at	Group A (Calasept) (mm)	Group B (Chairside) (mm)	Mann Whitney U	P
Baseline	5.0 [3.0-5.0]	4.0 [3.0-5.0]	1804.5	0.338
Week1	4.0 [3.0-5.0]	4.0 [3.0-5.0]	1941.5	0.824
Month1	3.0 [3.0-4.0]	4.0 [3.0-4.0]	1811.5	0.363
Month2	3.0 [2.0-3.0]	3.0 [2.0-4.0]	1667.0	0.101
Month3	2.0 [2.0-3.0]	3.0 [2.0-3.0]	1541.0	0.018
Month4	2.0 [2.0-2.0]	2.0 [2.0-3.0]	1732.5	0.161
Month5	2.0 [2.0-2.0]	2.0 [2.0-2.0]	1860.5	0.465
Month6	2.0 [1.0-2.0]	2.0 [1.0-2.0]	1752.5	0.208

Values are presented as median [Interquartile Range]

Regression analysis was conducted to determine the predictors of radiographic measurements based on various time points. The baseline was a significant negative predictor of radiographic measurements, B = -0.516, p = 0.004. Other predictors included Week 1, B = 0.447, p = 0.030. Month 3 was a significant positive predictor, B = 0.462, t(126) = 2.790, p = 0.006 (Table 5).

Table 5: *Multiple Linear Regression Analysis (Model 1): Effect of Study Groups on Radiographic Measurements Over Time*

Model 1	Unstandardized Coefficients		P	95.0% Confidence Interval for B	
Radiographic measurements	B	Std. Error		Lower Bound	Upper Bound
(Constant)	1.748	0.197	0.000	1.359	2.137
Baseline	-0.516	0.173	0.004	-0.858	-0.173
week1	0.447	0.203	0.030	0.045	0.850
month1	-.0194	0.137	0.162	-0.466	0.079
month2	0.008	0.081	0.924	-0.153	0.168
month3	0.462	0.166	0.006	0.134	0.790
month4	-0.273	0.224	0.225	-0.716	0.170
month5	0.010	0.257	0.968	-0.498	0.519
month6	0.093	0.178	0.605	-0.261	0.446

Furthermore, regression analysis of periapical index scores revealed that Month 3 was a significant positive predictor (Table 6).

Table 6: *Multiple Linear Regression Analysis (Model 1): Effect of Study Groups on periapical index scoring Over Time*

Model 1 PAI scoring	Unstandardized Coefficients		Standardized Coefficients	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta		Lower Bound	Upper Bound
(Constant)	0.786	0.276		0.006	0.233	1.340
Baseline	-0.078	0.118	-0.161	0.512	-0.315	0.159
week1	-0.128	0.178	-0.254	0.476	-0.485	0.229
month1	0.144	0.159	0.219	0.370	-0.175	0.462
month2	0.218	0.144	0.320	0.135	-0.070	0.505
month3	0.350	0.167	0.444	0.041	0.015	0.685
month4	-0.238	0.163	-0.286	0.149	-0.565	0.088
month5	-0.036	0.165	-0.042	0.826	-0.368	0.295
month6	0.140	0.127	0.170	0.275	-0.114	0.395

Among patients treated with *Calasept*, a significant reduction in periapical lesion size was observed as early as the 1st-month follow-up. In contrast, Group B exhibited statistically significant reductions only from the 2nd month onward, with this trend persisting until the 6-month follow-up ($P < 0.0001$) (Table 7).”

Table 7: *Periapical Index Scoring according to treatment group*

Period of measurement	Periapical index scoring Group A (n=63) Mean ± SD	[% reduction]	Periapical index scoring Group B (n=63) Mean ± SD	[% reduction]	t	P
Baseline	4.25±1.0	-	4.10± 1.0	-	0.886	0.377
Week 1	4.05 ±1.0	4.7%	4.06 ±1.0	1.0%	0.090	0.928
1st month	3.43±0.8	19.3%	3.51 ± 0.8	14.4%	0.551	0.583
2nd month	2.84± 0.9	33.2%	3.05 ± 0.9	25.6%	1.335	0.184
3rd month	2.44 ± 0.8	42.6%	2.71 ± 0.7	33.9%	1.982	0.050
4th month	2.21 ± 0.7	48.0%	2.33 ± 0.7	43.2%	0.975	0.332
5th month	1.98± 0.8	53.4%	2.03 ± 0.7	50.5%	0.375	0.708
6th month	1.63 ± 0.8	61.7%	1.78± 0.8	56.6%	1.028	0.306

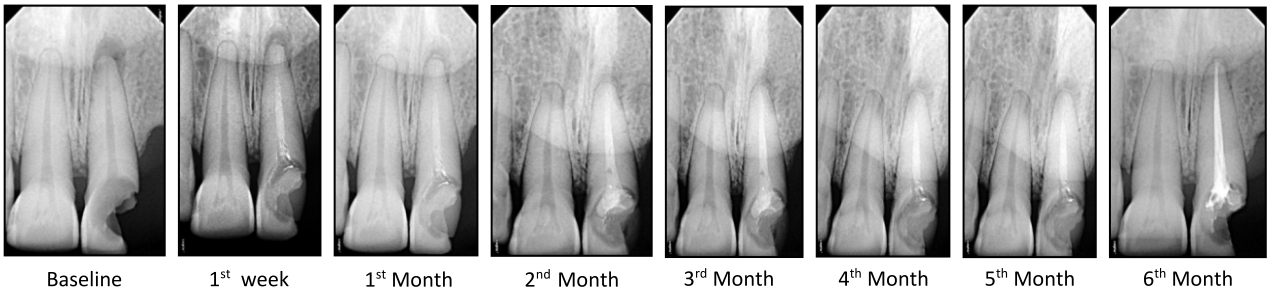


Figure 2: Serial periapical radiographs of a maxillary left central incisor with periapical granuloma, monitored monthly from baseline to 6 months following intracanal placement of Calasept.

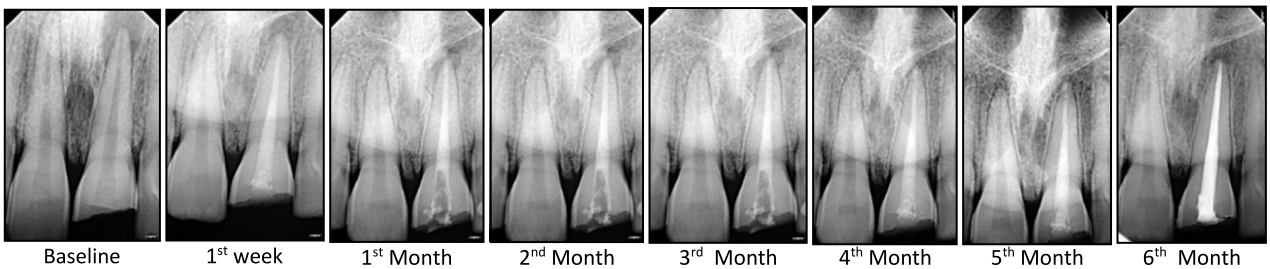


Figure 3: Serial periapical radiographs of a maxillary left incisor with periapical granuloma, monitored monthly from baseline to 6 months following intracanal placement of a calcium hydroxide powder/normal saline liquid mixture.

Pain Intensity

At baseline, most patients reported severe or the worst pain ever experienced. By the first-week follow-up, pain had decreased to mild or moderate levels in both groups. Group A exhibited a higher proportion of pain-free teeth than Group B from the 1st to the 3rd month. By the 4th month, neither group reported any pain (Table 8).

Table 8: *Pain intensity at different periods of measurement by study group*

	Baseline N (%)	1 week N (%)	1 month N (%)	2 months N (%)	3months N (%)	4-6months N (%)
Group A						
No Pain (score 0)	1 (1.6)	0 (0.0)	36 (57.1)	54 (85.7)	62 (98.4)	63 (100.0)
Mild pain (score 1-3)	2 (3.2)	43(68.3)	27 (42.9)	9 (14.3)	1 (1.6)	0 (0.0)
Mod pain (score 4-6)	16 (25.4)	20 (31.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Severe pain (7-9)	39 (61.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Worst pain ever (score 10)	5 (7.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Group B						
No Pain (score 0)	0 (0.0)	1 (1.6)	18 (28.6)	38 (60.3)	51 (81.0)	63 (100.0)
Mild pain (score 1-3)	0 (0.0)	35 (55.6)	45 (71.4)	25 (39.7)	12 (19.0)	0 (0.0)
Mod pain (score 4-6)	15 (23.8)	27 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Severe pain (7-9)	43 (68.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Worst pain ever (score 10)	5 (7.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
X^2 for linear trend	1.226	1.114	10.417	10.230	10.296	-
P (Group A vs. B)	0.268	0.285	0.001**	0.001**	0.001**	-

P <0.05 was considered statistically significant**

DISCUSSION

Findings: Pulpal pathosis often progresses to periapical lesions if left untreated. Cleaning and shaping of the root canal are essential to remove causative microorganisms, thereby preventing further periapical damage. However, interim intracanal medicaments with both bactericidal and osteogenic properties are often necessary. Among these, calcium hydroxide is widely used due to its proven antibacterial efficacy and ability to stimulate periapical tissue healing. It remains a preferred non-surgical treatment for periapical lesions of various etiologies.

The etiology of periapical granuloma is well-established. In this study, trauma was the predominant cause in both groups, likely due to the absence of restorative intervention following injury, which could have protected the pulp from degeneration. Additionally, patients frequently delay seeking treatment until symptoms arise, by which point pulpal necrosis has often progressed to periapical involvement.

Pain was the primary reason for clinical presentation, consistent with prior studies demonstrating that toothache drives emergency dental visits.[22] The pain, caused by microbial-induced intra-pulpal pressure, can be alleviated through pulp extirpation, biomechanical canal preparation, and intracanal medicaments like calcium hydroxide. At baseline, 61.9% (Group A) and 68.3% (Group B) of participants reported severe pain, while 7.9% in each group described the worst pain ever experienced. By the 1st week, pain decreased significantly in both groups, transitioning to mild or moderate levels by the 1st–2nd months and resolving completely by the 4th month. These findings align with Menakaya et al.[23] but contrast with Saatchi,[7] who reported pain reduction within 24 hours of treatment initiation.

Our results corroborate those of Cvek,[18] Fernandes and Ataide,[3] who highlighted calcium hydroxide's efficacy in non-surgical periapical resolution. Success was defined as either complete radiolucency resolution or increased periradicular rarefaction, criteria met in this study.[2,3]

Microbial elimination is a critical treatment goal. Studies suggest root canal disinfection typically occurs within one week, coinciding with the onset of periapical healing.[24] While some authors report healing timelines of 3–12

months,[4,17,18] others observed complete resolution at 6 months, [7,25] consistent with our findings. Notably, periapical repair without calcium hydroxide may take up to two years,[3] underscoring its therapeutic advantage.

Radiographic analysis revealed accelerated lesion reduction in Group A (Calasept), beginning in the first week and progressing through the 6th month. This likely reflects Calasept's optimized delivery system, ensuring direct application and efficient ion release. Mohammadi and Dummer,[26] noted similar mineralized tissue formation within one week of proprietary calcium hydroxide use. In contrast, Group B (powder/saline mix) exhibited delayed reduction (1st month), aligning with Soares et al.,[10] who reported bone repair stimulation by the 1st month with chairside mixtures. The osteogenic properties of calcium hydroxide likely explain these outcomes in both groups.[4]

The faster reduction in periapical radiolucency size and PAI scores in Group A aligns with prior studies [18,27,28] and may stem from Calasept's pre-mixed, air-free formulation, which minimizes variability inherent in manual mixing. Treatment with calcium hydroxide in both groups significantly reduced lesion size and PAI scores.

Implications: Calasept is a viable intracanal medicament for periapical lesions, including granulomas, due to its reduced chairside time and faster action.

Trade-offs (Limitations): This study was limited by its reliance on periapical radiographs, a two-dimensional imaging tool (based on Orstavik's periapical index), rather than CBCT, which offers superior three-dimensional visualization and accuracy.

Take-home (Conclusion): Both Calasept and traditional calcium hydroxide effectively treat periapical granulomas, but Calasept offers faster resolution and reduced chairside time.

Expectations for Future Research: Replicating this study using CBCT would yield valuable insights.

Recommendations: Future studies should employ larger sample sizes and three-dimensional imaging (e.g., CBCT).

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