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Bioceramic versus calcium hydroxide intracanal medicaments: A comparative clinical study

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Abstract:

Complete elimination of microorganisms from infected root canals remains a major challenge despite chemomechanical preparation. Therefore, it is of interest to compare the Bio-C Temp and calcium hydroxide in 60 single-rooted teeth with periapical pathology using aerobic and anaerobic CFU counts before and after 7 days. Both groups showed comparable baseline bacterial counts and highly significant intragroup microbial reductions after medicament placement ($p < 0.001$). Bio-C Temp produced significantly lower post-treatment bacterial counts than calcium hydroxide ($p = 0.001$), achieving 99.98% versus 99.00% aerobic and 99.99% versus 99.15% anaerobic reduction. Thus, Bio-C Temp showed superior antimicrobial efficacy, supporting its use as an effective intracanal medicament for persistent endodontic infections with periapical pathology.

Keywords: Bioceramic intracanal medicament, Bio-C Temp, calcium hydroxide, calcium silicate, root canal disinfection, periapical pathology, colony-forming units, *Enterococcus faecalis*, endodontics

Background:

Successful root canal therapy depends on eliminating bacteria, necrotic tissue and infected dentin, as residual microorganisms are a major cause of persistent infection and post-treatment disease [1]. However, complete disinfection of the root canal system remains difficult because mechanical instrumentation and irrigation cannot effectively reach bacteria within isthmuses, lateral canals and other inaccessible anatomical areas, allowing microbial persistence and continued periapical inflammation [2]. Among the microorganisms associated with endodontic failure, *Enterococcus faecalis* is particularly resistant because it penetrates dentinal tubules, forms biofilms, adheres to collagen and survives highly alkaline conditions through an efficient proton-pump mechanism [3]. *Candida albicans* also contributes to persistent apical periodontitis owing to its ability to invade dentinal tubules, rapidly form biofilms, switch between yeast and hyphal forms and tolerate extreme pH conditions [4]. These characteristics limit the effectiveness of conventional chemomechanical preparation and necessitate intracanal medicaments with prolonged antimicrobial activity. Calcium hydroxide has remained the gold-standard intracanal medicament since the 1980s because of its antimicrobial action through hydroxyl-ion release, high alkalinity and ability to promote periapical healing [5]. Nevertheless, its antimicrobial efficacy is reduced in deeper dentinal tubules and inaccessible canal regions, prompting modifications such as chlorhexidine, chitosan, nanoparticle formulations and thermosensitive delivery systems to improve its performance [6]. Despite these advances, complete microbial elimination is rarely achieved, contributing to persistent endodontic infections. Calcium silicate-based bioceramic medicaments have emerged as promising alternatives to conventional calcium hydroxide. Bio-C Temp (Angelus, Londrina, Brazil) is a ready-to-use calcium silicate-based paste with a highly alkaline pH, excellent biocompatibility and bioactive properties that promote calcium-ion release and hydroxyapatite formation [7]. Experimental studies have demonstrated that bioceramic medicaments possess enhanced antimicrobial and anti-biofilm activity while

supporting periapical tissue repair [8]. Their antimicrobial effectiveness is commonly assessed by measuring reductions in colony-forming units per millilitre (CFU/mL) before and after intracanal medication, providing a direct estimate of viable bacterial reduction [9]. Although several laboratory investigations have compared bioceramic medicaments with calcium hydroxide, clinical evidence evaluating their antimicrobial efficacy against cultivable bacteria from infected root canals with periapical pathology remains limited [10]. Therefore, it is of interest to evaluate and compare the antimicrobial efficacy of a bioceramic intracanal medicament and conventional calcium hydroxide against cultivable bacteria from infected root canals with periapical pathology using CFU/mL analysis.

Materials and Methods:

This clinical study was conducted in the Department of Conservative Dentistry and Endodontics, Santosh Dental College and Hospital, Ghaziabad, after approval by the Institutional Ethics Committee of Santosh Deemed to be University and written informed consent from all participants. The sample size was estimated using OpenEpi (comparison of two means; 80% power, 95% confidence interval), yielding 60 teeth. Single-rooted teeth with radiographic evidence of periradicular pathology, symptomatic teeth with periapical changes and teeth with sufficient coronal structure for rubber-dam isolation were included. Medically compromised patients and teeth with periodontal pockets deeper than 4 mm, sinus tract or fistula, intraradicular posts, vertical root fractures, or inadequate coronal structure were excluded. The materials used were calcium hydroxide powder (Prevest DenPro, India) and the bioceramic intracanal medicament Bio-C Temp (Angelus, Londrina, Brazil). After rubber-dam isolation, the tooth and surrounding field were cleaned with 30% hydrogen peroxide and decontaminated with 3% sodium hypochlorite. The access cavity was refined and the cavity was swabbed with 5% sodium thiosulphate to inactivate residual sodium hypochlorite before bacterial sampling. Working length was determined with an

apex locator and biomechanical preparation was completed with K-files using 3% sodium hypochlorite irrigation through 30-gauge needles, followed by 17% EDTA (5 mL) for one minute, a final rinse with 3% sodium hypochlorite (10 mL) and normal saline. The canal was dried with paper points and a first sample (S1) was obtained by retaining a paper point in the canal for one minute before transfer to a vial containing reduced transport fluid (RTF). Patients were then randomly allocated (online sequence generator) to the calcium hydroxide group or the bioceramic group and the assigned medicament was placed in gel form to the working length using lentulo spirals. The access cavity was sealed with a temporary restorative material. After seven days, the tooth was re-isolated and disinfected as before, the medicament was flushed out with normal saline, the canal was dried and a second sample (S2) was obtained in the same manner and transferred to RTF. Samples were cultured on brain-heart infusion (BHI) media and incubated for aerobic and anaerobic colony counting.

Outcome measures:

The primary outcome was the cultivable bacterial load in the root canal, expressed as colony-forming units per millilitre (CFU/mL), assessed separately for aerobic and anaerobic organisms at baseline (S1) and after seven days of medication (S2). The percentage reduction in aerobic and anaerobic counts from baseline to post-treatment was calculated for each group. All counts were recorded by a single trained operator using a colony counter under standardized microbiological conditions.

Statistical analysis:

Data were analysed using IBM SPSS Statistics version 23.0. Descriptive statistics (mean and standard deviation) were Computed for each group.

The Shapiro-Wilk test was used to assess data distribution and Levene’s test to assess homogeneity of variance. Intergroup comparisons were performed using the independent t-test (or Mann-Whitney U test where appropriate) and intragroup (baseline versus post-treatment) comparisons using the paired t-test. The level of statistical significance was set at $p < 0.05$.

Results:

The intergroup comparison of aerobic and anaerobic microbial counts at baseline and after treatment is presented in (Table 1) and the percentage reductions are summarized in (Table 2). At baseline, the two groups were statistically comparable for both aerobic (calcium hydroxide $5.84 \times 10^6 \pm 1.83 \times 10^6$ CFU/mL versus bioceramic $5.41 \times 10^6 \pm 2.00 \times 10^6$ CFU/mL; $p = 0.393$) and anaerobic counts (4.98×10^6 versus 4.96×10^6 CFU/mL; $p = 0.968$), confirming baseline homogeneity. After seven days of medication, both medicaments produced a highly significant intragroup reduction in aerobic and anaerobic counts ($p < 0.001$). Intergroup comparison of the post-treatment counts showed that the bioceramic group achieved significantly lower residual loads than the calcium hydroxide group for both aerobic (8.37×10^2 versus 5.82×10^4 CFU/mL; $p = 0.001$) and anaerobic bacteria (4.18×10^2 versus 4.24×10^4 CFU/mL; $p = 0.001$). Correspondingly, the percentage reduction was greater in the bioceramic group for both aerobic (99.98% versus 99.00%) and anaerobic organisms (99.99% versus 99.15%), with the intergroup differences being highly significant ($p < 0.001$). No adverse clinical events were recorded during the study period.

Table 1: Intergroup comparison of aerobic and anaerobic microbial counts (CFU/mL) at baseline and post-treatment

Parameter	Time point	Calcium hydroxide (mean ± SD)	Bioceramic (mean ± SD)	P
Aerobic	Baseline	$5.84 \times 10^6 \pm 1.83 \times 10^6$	$5.41 \times 10^6 \pm 2.00 \times 10^6$	0.393 (NS)
Aerobic	Post-treatment	$5.82 \times 10^4 \pm 1.80 \times 10^4$	$8.37 \times 10^2 \pm 1.02 \times 10^3$	0.001*
Anaerobic	Baseline	$4.98 \times 10^6 \pm 2.35 \times 10^6$	$4.96 \times 10^6 \pm 2.54 \times 10^6$	0.968 (NS)
Anaerobic	Post-treatment	$4.24 \times 10^4 \pm 2.53 \times 10^4$	$4.18 \times 10^2 \pm 1.11 \times 10^2$	0.001*

Independent t-test; * = statistically significant ($p < 0.05$); NS = not significant. n = 30 per group.

Table 2: Percentage reduction in microbial counts after treatment

Parameter	Calcium hydroxide (% reduction)	Bioceramic (% reduction)	P
Aerobic	99.00	99.98	<0.001
Anaerobic	99.15	99.99	<0.001

Percentage reduction from baseline (S1) to post-treatment (S2)

Discussion:

Achieving complete three-dimensional disinfection of the root canal system is difficult because bacteria colonize complex anatomical spaces that mechanical instrumentation cannot fully reach and intracanal medicaments are therefore essential adjuncts to chemomechanical preparation [11, 12]. In the present study, both calcium hydroxide and the bioceramic medicament produced significant reductions in aerobic and anaerobic cultivable bacteria, but the bioceramic medicament achieved significantly lower residual counts and greater percentage

reductions, indicating superior antimicrobial efficacy under the conditions tested. The antimicrobial action of calcium hydroxide is attributed to its dissociation into calcium and hydroxyl ions, producing a highly alkaline environment that disrupts bacterial membranes and enzymatic activity; however, its effect is buffered by dentin and is limited against biofilms and organisms deep within tubules [13, 14]. The bioceramic medicament, based on calcium silicate, likewise generates an alkaline environment and releases calcium ions, but its smaller particle size and sustained release may allow deeper penetration and a broader

bactericidal effect, which is consistent with the greater reduction observed in this study [3, 11]. These findings are in line with comparative laboratory and clinical evidence. A micro computed tomography-guided model using S1-S2 sampling reported that Bio-C Temp and calcium hydroxide pastes both significantly reduced bacterial load, with all medications outperforming an untreated control [15]. Reviews of bioceramic and calcium silicate-based materials have documented their antimicrobial and antibiofilm activity and their capacity to release calcium ions and form hydroxyapatite [16]. Comparative studies of bioceramic and calcium hydroxide-based root canal sealers against pathogenic endodontic biofilms similarly support the antimicrobial potential of hydraulic calcium silicate materials [6]. It should be noted, however, that some laboratory studies have reported comparable or even lower direct antibacterial activity for Bio-C Temp relative to certain calcium hydroxide formulations, underscoring that outcomes vary with methodology, exposure time and the organisms tested [17]. The improved microbial reduction achieved with the bioceramic medicament has clinical relevance, because persistent infection is a major cause of endodontic failure and periapical disease. In addition to antimicrobial activity, calcium silicate-based medicaments have shown favourable biocompatibility, calcium-ion release and the ability to modulate growth-factor release from dentin, which may support periapical healing [18]. Advances in delivery, such as calcium hydroxide loaded into biodegradable nanoparticles or dispersed in thermosensitive gels, further illustrate ongoing efforts to enhance penetration and sustained antimicrobial action of intracanal medicaments. Nonetheless, laboratory-derived and short-term clinical findings should be extrapolated to routine practice with caution, since the oral environment introduces variables that cannot be fully reproduced experimentally.

Conclusion:

Both medicaments significantly reduced cultivable aerobic and anaerobic bacteria from infected root canals. The bioceramic intracanal medicament showed significantly greater antimicrobial efficacy than calcium hydroxide. These findings support bioceramic medicaments as a promising alternative for intracanal disinfection, although long-term clinical studies are warranted.

Limitations:

This study assessed cultivable bacteria using colony counts over a single seven-day medication interval; culture-based methods may underestimate viable-but-non-culturable organisms and do not identify individual species. Only one medication period and two commercial medicaments were evaluated, long-term periapical healing was not assessed and the study was conducted at a single centre. Molecular microbiological methods, longer follow-up with radiographic assessment of healing and larger multicentre randomized trials are needed to confirm these findings and to establish the broader clinical applicability of bioceramic intracanal medicaments.

Conflict of interest: The authors declare no conflict of interest.

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