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PRODUCT OVERVIEW

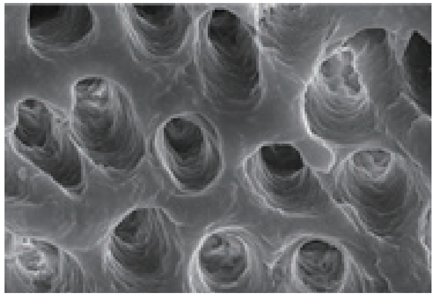
with a Scientific Foundation

MARUCHI

Product Description

CleaniCal® is a calcium hydroxide-based intracanal paste developed by MARUCHI, utilizing N-2-methylpyrrolidone (NMP) as its carrier. Designed for syringe delivery, this paste is sealed in an airtight syringe for direct application into the root canal. CleaniCal® offers both ease of use and effectiveness, demonstrating strong antibacterial activity against various bacteria commonly found in root canal infections.

Notably, CleaniCal® exhibits excellent efficacy in removing Enterococcus faecalis biofilms, thanks to the superior dissolving properties of NMP on organic substances. Compared to other products that use saline (e.g., Calasept Plus™) or propylene glycol (e.g., Calcipex II®) as carriers, CleaniCal® has been proven to be more effective in biofilm removal. This highlights CleaniCal® as an innovative solution for root canal infection control.



Representative FE-SEM images after removal of pastes from E. faecalis biofilms formed on the specimens

Formulation with $Ca(OH)_2$ and NMP

Traditional calcium hydroxide pastes have often utilized carriers such as glycerol, polyethylene glycol, polypropylene glycol, or propylene glycol. While these carriers offer high viscosity and excellent moisturizing properties, preventing hardening within syringes and enhancing user convenience, they also present limitations. Specifically, glycol-based carriers reduce the solubility of calcium hydroxide, thereby lowering its antibacterial efficacy and making it difficult to completely remove the paste from the root canal after use.

CleaniCal® was designed to overcome these limitations. By using NMP as its carrier, it addresses the shortcomings of traditional products and offers the following key features:

1. Superior Antibacterial Activity:

CleaniCal® demonstrates strong antibacterial effects against various bacterial species, particularly excelling in E. faecalis biofilm removal.

2. Ease of Removal:

The NMP-based carrier allows for easy removal from the root canal, ensuring minimal residue after treatment.

3. Safety:

CleaniCal® does not induce toxic reactions in the human body, making it a safe intracanal medicament.

The high antibacterial activity and biofilm removal capabilities of CleaniCal® are not solely dependent on the calcium hydroxide content or hydroxide ion release. Instead, the carrier's unique properties play a significant role. NMP, compared to other carriers (e.g., saline, PEG, PG), demonstrates exceptional performance in dissolving organic substances and exhibiting antibacterial properties.

CleaniCal®'s development is protected by the following patents:
US 108865-9 / JP 7138633 / CN5253419 / KR 10-2233620

CleaniCal®
Hydrosoluble Calcium Hydroxide Paste

Product Description

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Cleanical® Contains;

- **Core material** : 30% Calcium Hydoxide (and Vehicle, NMP)
- **Radiopacifier** : Zirconium Dioxide
- **Vehicle** : N-2-methyl-pyrrolidone(NMP) is included as removal for biofilm and a non-reactive diluent to ensure the paste has appropriate flow properties.
- **Thickening agents** : Included to enhance viscosity and consistency.

[Table 1] provides an overview of the core material properties of CleaniCal® compared to other medicaments, such as Calcipex and Calasept, based on findings from various studies.

Content	CleaniCal® (Maruchi)	Calasept Plus™ (Nordiska)	Calcipex II® (Nishika)	ApexCal (Ivoclar)	UltraCal™ XS (Ultradent)	Source
$Ca(OH)_2$	30%	41-46%	24%	20-25%	35%	Studies & MSDS
Vehicle	NMP	Saline	PG	PEG	PG	
Antibacterial Effect	Cleanical > Calcipex II > Calasept Plus					J Appl Oral Sci. 2020;28:e20190516
Cytotoxicity	CleaniCal > Apexcal > Calcipex II					Restor Dent Endod. 2017;42(4):290-300
Radiopacity	Apexcal ≥ CleaniCal > Calcipex					
Removal efficacy	CleaniCal > Calcipex ≒ Apexcal					
The effect of NMP on dissolving biofilms		-	-	-	-	Dent Mater J. 2022-012
Removal efficacy of NMP		-	-	-	-	EUR Endod J 2021;6:309-13
PH	CleaniCal vs Calcipex vs Ultracal Refer to page ??					J Oral Sci. 2025;67(1):35-40.
Folwability						

* Table 1 : Summary and evaluation of study outcomes presented in the product overview.

1. Biofilm Removal Efficacy

1-1

Taegun KIM, Mi-Ah KIM, Yun-Chan HWANG, Vinicius ROSA, Massimo DEL FABBRO, Kyung-San MIN, Effect of a calcium hydroxide-based intracanal medicament containing N-2-methyl pyrrolidone as a vehicle against Enterococcus faecalis biofilm, J Appl Oral Sci.2020;28:e20190516

Enterococcus faecalis (E. faecalis) is a grampositive facultative anaerobe mainly related to failed root canal treatment. [1] It can resist very harsh environmental conditions by invading dentinal tubules, and forming intraradicular biofilms that are more resistant to antimicrobial agents. [2-4]

CH has a long history of use as an endodontic intracanal medicament due to its antibacterial effect.[5] Thus, liquid vehicles are required for CH to facilitate the delivery of dry powder and the release of hydroxyl ions.[6] The vehicles are also used to improve antibacterial effect and biocompatibility. [7,8]

If the vehicle per se has antibacterial effects on biofilms, it would be more beneficial for the prognosis. However, most vehicles currently used do not have a remarkable antibacterial effect.

NMP is a colorless organic solvent with high boiling point, low viscosity, low toxicity, and good biocompatibility. [9] CleaniCal® is the first commercially available CH-based intracanal medicament containing NMP.

This study aimed to investigate the effect of a CH-based paste containing NMP as a vehicle on E. faecalis biofilms formed in bovine root canals in comparison with other products containing water-soluble (SL: saline) or viscous (PG: propylene glycol) vehicle

The outcomes are the following

• **Antibacterial Effect**

- All the materials tested had antibacterial effects of 96% (CleaniCal®), 82% (Calcipex II®), and 70% (Calasept Plus™)
- NMP had the highest antibacterial activity, followed by PG ($p<0.05$)

Antibacterial Effect	Vehicle	NMP(Cleanical) >	PG(Calcipex) >	SL (CalAsept)
	Product	CleaniCal®	Calcipex II®	Calasept Plus™
		96%	82%	70%

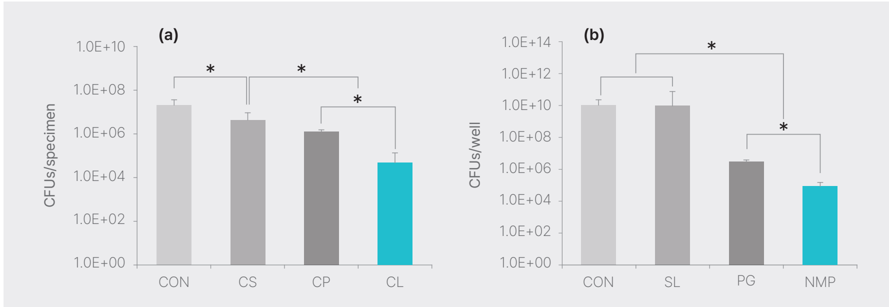
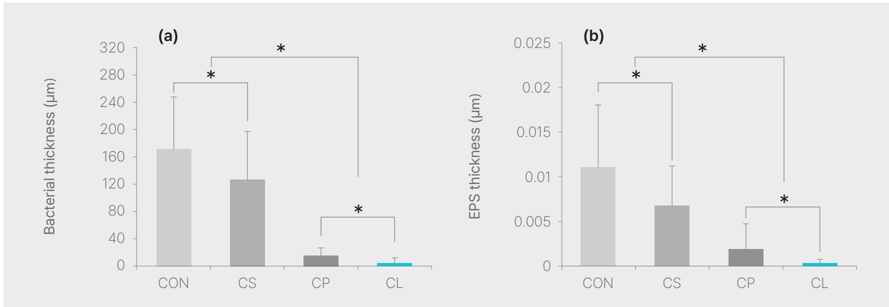


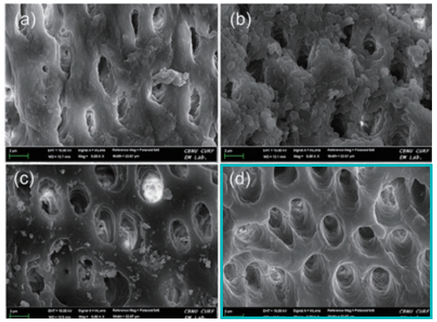
Figure 1-(a and b) CFU counting values of the medicaments tested and the vehicles, respectively. one-way ANOVA and Tukey test were performed. *Statistical significance was determined at $p<0.05$. CON: control, CS: Calasept Plus™, CP: Calcipex II®, CL: CleaniCal®, SL: Saline, PG: propylene glycol, NMP: *N*-2-methyl-pyrrolidone

• **Bacterial microcolonies and EPS thickness.**

- Calcipex II® and CleaniCal® groups were significantly lower than those of the control and Calasept Plus™ groups ($p<0.05$).

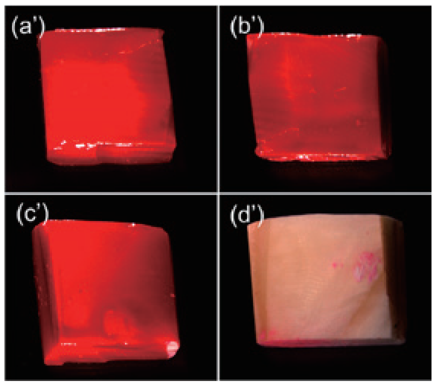


- **Representative FE-SEM images after removal of pastes from E. faecalis biofilms formed on the specimens (5,000X)**



Control (a), Calasept Plus™ (b), Calcipex II® ©, CleaniCal® (d)

the nail polish on the enamel surface of the bovine tooth block immersed in NMP was completely dispelled after 24 h, whereas the nail polish was not dispelled at all in the other groups.



The content of CH in the medicament and hydroxyl ion releasing efficacy are the main key attributes to remove biofilms. According to the manufacturer's information, the CH content of the products tested are different (Calasept Plus™ ≈ 41%, Calcipex II®”” ≈ 24%, CleaniCal® ≈ 30%). Although Calasept Plus™ contains more CH, the antibacterial effect on E. faecalis was lower than that of other products that contain less CH.

Therefore, it was assumed that the vehicle per se might be the factor and the antibacterial effect of each vehicle including saline, PG, and NMP was assessed.

It was demonstrated that the NMP based medicament, CleaniCal®, exerted the best dispelling effect on E. faecalis biofilms compared with other medicaments containing water or PG. These results also indicate that the structure of biofilms was dispersed and dispelled easily by irrigation.

In fact, NMP is used for paint stripping, graffiti removal, and industrial cleanup, has been approved by Food and Drug Administration (FDA) as a biodegradable solvent and is listed as generally recognized as safe (GRAS).[10] In this respect, it was assumed that nail polish could model a biofilm and NMP could serve as the "stripper" intracanal medicament.

1-2

Mi-Ah KIM, Prasanna NEELAKANTAN2, Kyung-San MIN, Effect of N-2-methyl-pyrrolidone on Enterococcus faecalis Biofilms, Dent Mater J. 2022 Oct 2;41(5):774-779.

The presence of persistent bacteria inside the root canal or/and poor cleaning of the canals can induce failure of root canal treatment. Enterococcus faecalis (E. faecalis) is one of the most frequently isolated bacteria from cases of failed endodontic treatment [11,12]

Calcium hydroxide [$Ca(OH)_2$] has been widely used as a intracanal medicament. Liquid vehicles are required to improve the delivery of $Ca(OH)_2$ into the root canal and to facilitate the release of hydroxyl ions [13,14].

Currently, various types of liquid vehicles are available, including water-soluble, viscous, and oil-based substrates. Furthermore, it is considered more benefi cial if the vehicles themselves possess antibacterial effects;

NMP is a colorless solvent that is miscible with water and many organic compounds. NMP is applicable in different fi elds of industry with high boiling point and low toxicity and viscosity [15,16].

Furthermore, it has also good biocompatibility and enhances penetration of some drugs [17]

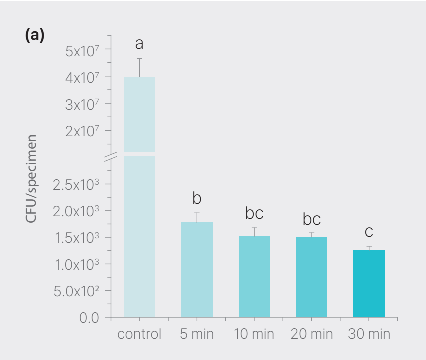
NMP has high solubility in water and is considered to be a safe solvent in pharmaceuticals with low toxicity and non-carcinogenicity[18]. It is also used for the successful dispersion of nanomaterials and elimination of bacteria in the root canal system[19-21]

This study investigated the role of NMP in the removal of E. faecalis biofilm and the expression of the various virulence-associated factors listed above.

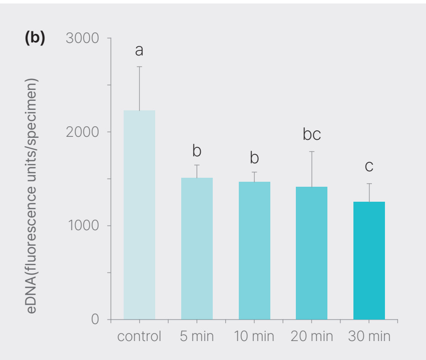
For the study, a 3-week-old E. faecalis biofilm was treated with NMP for 5, 10, 20, and 30 min. The 5-min treatment signifi cantly decreased CFUs, eDNA levels, and the biofi lm biomass ($p<0.05$)

The outcomes are the following

Figure 1



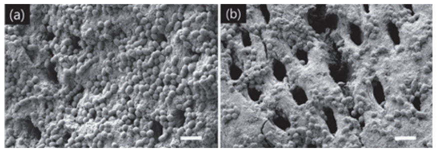
The effects of NMP on E. faecalis biofilms. E. faecalis was grown on bovine root canal for 3 weeks and analyzed by (a) CFU counting,



Speculating that NMP might exert antibacterial/biofilm effects by eliminating eDNA, which plays an important role in the stabilization and maintenance of the biofilm structure [22].

The results of Fig. 1b, which showed the dramatic decrease of eDNA levels ($p<0.00001$), suggest that NMP might induce instability of the biofilm.

The SEM observations showed that considerable amount of the NMP-treated biofi lm was removed from the root canal wall and numerous dentinal tubules were exposed. Furthermore, the biofilm had more pores and less bacteria than the control biofilm, which showed compact and clear shapes of E. faecalis.



SEM observations of E. faecalis biofilms. The biofilms were formed on a bovine root canal for 3 weeks, and then treated with (a) PBS or (b) NMP for 5 min. The magnification of the images was ×5,000. Bar=2 μm.

2. Paste Removability

2-1

Myung-Jin Lim, Hyun-Jin Jang, Mi-Kyung Yu, Kwang-Won Lee, Kyung-San Min. Removal efficacy and cytotoxicity of a calcium hydroxide paste using N-2-methyl-pyrrolidone as a vehicle. Restor Dent Endod. 2017 Nov;42(4):290-300

Calcium hydroxide (Ca[OH]2) is highly recommended and widely accepted as an interappointment intracanal endodontic dressing [23].

However, if Ca(OH)2 remains in the root canal system, it can play negative roles in the prognosis of endodontic treatment. Ca(OH)2 that remains on dentinal walls prevents the penetration of sealer into dentinal tubules and causes considerable changes to the sealing ability of the material [24,25]. Furthermore, Ca(OH)2 dressing has an adverse effect on the bond strength of a resin-based sealer [26].

Vehicles are used in an attempt to maintain pH [27] and improve antimicrobial activity [28], biocompatibility [29], ionic release [30], and diffusion [9]. Several authors and clinicians have considered associations of Ca(OH)2 with different vehicles including polyethylene glycol (PEG) [31], propylene glycol (PG) [32], and glycerin [33]. However, most Ca(OH)2 products cannot be removed completely from complex root canal systems even with various technical methods [34,36].

CleaniCal is the first commercially available NMP-based Ca(OH)2 paste. NMP is a very strong solubilizing agent that has important applications in different fields of industry [37].

Tthe purpose of this study was to investigate the removal efficacy and cytotoxicity of the newly developed NMP-based Ca(OH)2 paste in comparison with ApexCal (Ivoclar Vivadent, Schaan, Liechtenstein) and Calcipex II (Nishika, Shimonoseki, Japan) which contain commonly used vehicles such as PEG and PG, respectively.

The outcomes are the following

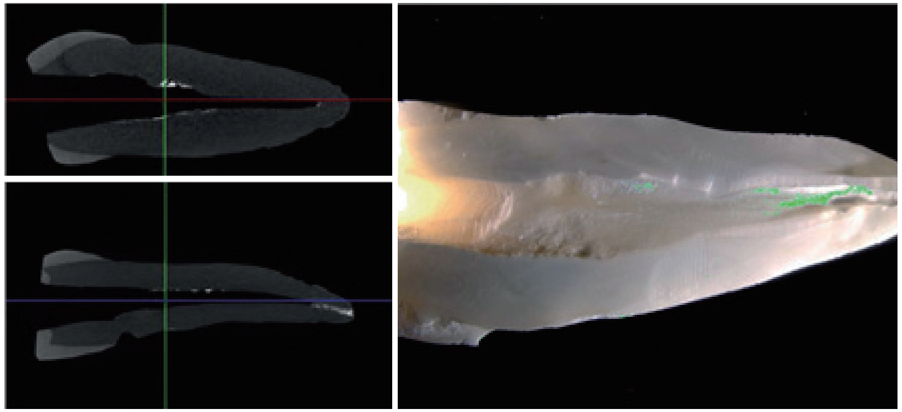


Figure 1. (A) Representative micro-computed tomographic (μ-CT) images show the radiopaque remnants of each material. (B) A stereomicroscopic image shows the coated surface (indicated as the green area) with the remaining material in a split root canal system.

Removal efficacy

In μ-CT analysis, as shown in Figure 2A, the CleaniCal group exhibited less residual volume percentage than the ApexCal and Calcipex II groups ($p < 0.05$) Similarly, in the stereomicroscopic analysis, the cleaniCal group showed less area percentage of residual paste than the other groups ($p < 0.05$, Figure 2B)

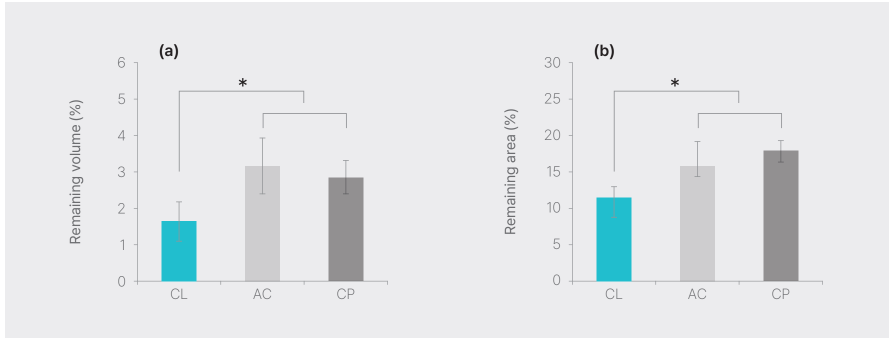
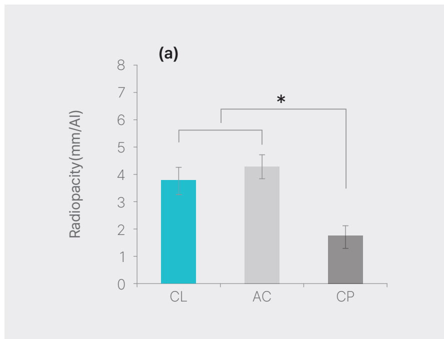


Figure 2. Removal efficacy and radiopacity of the tested materials. Mean percentage and standard deviation of the remaining volume (A) and remaining area (B) of the remnants in micro-computed tomographic (μ-CT) and stereomicroscopic assessments,
CL, cleaniCal; AC, ApexCal; CP, Calcipex II.



CleaniCal exhibited significantly higher radiopacity compared to Calcipex II ($p < 0.05$) and a similar value to ApexCal

Cytotoxicity

CleaniCal, which uses NMP as a vehicle, showed a higher cytotoxicity compared to the other groups (4B). The MTT assay showed that the cell viability of NMP is significantly lower than that of PEG and PG (Figure 4C).

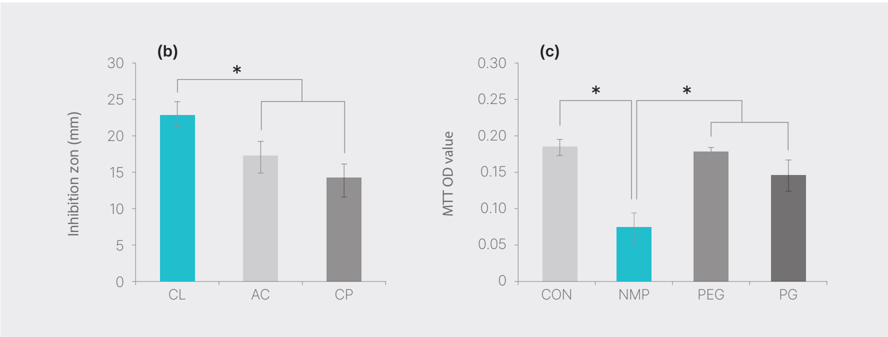


Figure 4. (B) Mean and standard deviation of the inhibition zone of each material. (C) Cell viability of the vehicle for each product.

* CON, control; CL, cleaniCal; AC, ApexCal; CP, Calcipex II

Intracanal medicaments such as Ca(OH)2 used in clinical practice should be removed from the root canal system because the remnants may have adverse effects on the outcomes of endodontic treatment.

Recently, a new Ca(OH)2 product, CleaniCal, which contains NMP as a vehicle, was introduced with the anticipation of promoting removal efficacy because of its potent solubility. The removal efficacy of CleaniCal, the NMP-based Ca(OH)2 paste, was higher than the other pastes that ApexCal and Calcipex II which use PEG and PG as vehicles.

2-2

Afzal ALI, Banu ARICIOĞLU, Hakan ARSLAN, Removal of Calcium Hydroxide Pastes Containing N-Methyl-2-Pyrrolidone, Local Anaesthesia, Glycerine, and Methylcellulose from Artificial Radicular Grooves: An In-vitro Study. EUR Endod J 2021; 6: 309-13

Calcium hydroxide (CaOH) paste is mainly composed of powder, a vehicle, and a radioopacifier. The vehicles combined with CaOH can change CaOH paste's physical and chemical properties by affecting antibacterial action, radiopacity, flow, ionic release, and diffusion [38].

They are commonly classified as aqueous, viscous, or oily [39]. Aqueous vehicles (such as water, saline, anaesthetic solution, and methylcellulose) rapidly dissociate the CaOH to ions and provide a high concentration when in contact with fluids [40]. Viscous vehicles, such as glycerine, polyethene glycol, and propylene glycol, dissolve more slowly due to their molecular weight and minimise the distribution of CaOH to the tissues. Thus, the medicament can stay longer in the root canal [41]. Oily vehicles (such as olive oil, silicone oil, camphor, and parachlorophenol oil) are non-water-soluble substances and provide lower solubility and diffusion than other vehicles [42]

The present study aimed to compare CaOH pastes containing NMP, lidocaine, glycerine, methylcellulose, or water in terms of removal from artificially created grooves.

The outcomes are the following

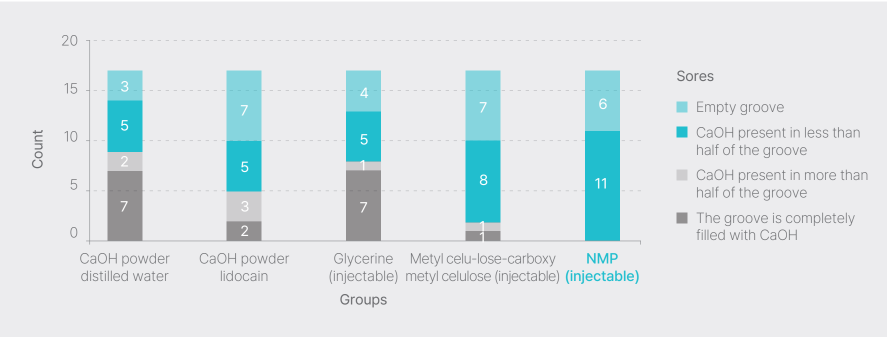


Figure 1. Distribution of the sample size according to the scores

According to the present study results, the NMP-based group exhibited better removal efficacy than the CaOH in distilled water.

The medicament combined with an aqueous vehicle can quickly permeate with the direct contact of the tissuev fluids and dissolve away from the root canal [38]. However, due to their molecular weight, viscous vehicles dissolve more slowly than aqueous vehicles [39]. In addition, the residue of CaOH prevents the penetration of sealers into the dentinal tubules and negatively affects hermetic sealing [43]

The percentage of CaOH powder in the manufactured products can differ to achieve optimum consistency, conductivity, and pH, depending on the type of vehicle used.

Although the amount of CaOH powder in the medicament can affect the antimicrobial activity or ionic dispersion [44], it was reported that ıt did not affect the removal activity, but the vehicle did [45]. Thus, different CaOH powder ratios in the products were not thought to affect removal efficiency for this study.

The NMP-based CaOH medicament exhibited better removal efficacy than the control group. However, the methylcellulose-, lidocaine-, and glycerine-based groups showed a similar removal efficacy as the distilled water group.

3. Physicochemical properties

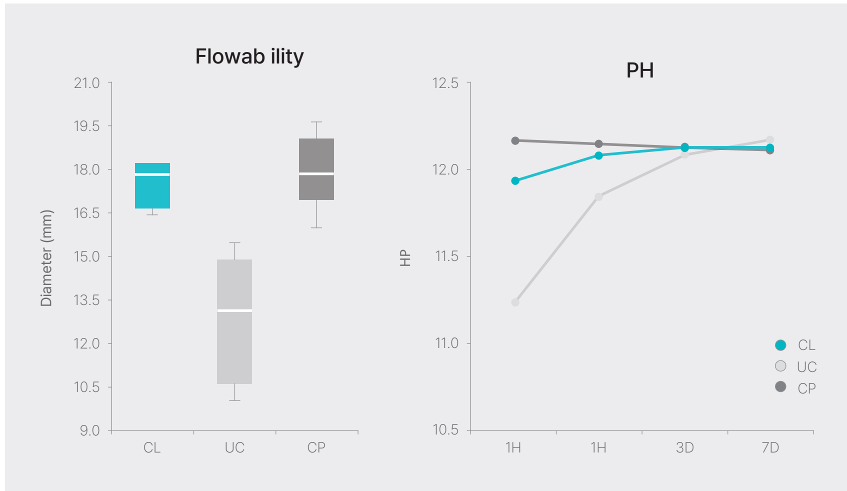
3-1

Mi-Ah Kim, Min-Kyeong Kim, Eun-Sook Kang, Kyung-San Min. Synergistic effects of reduced graphene oxide on the antibacterial activity of calcium hydroxide-based intracanal medicaments containing different vehicles. Journal of Oral Science, Vol. 67, No. 1, 35-40, 2025

This study investigated the synergistic effects of reduced graphene oxide (RGO) on the antibacterial activity of three calcium hydroxide-based intracanal medicaments. The document was designed to evaluate the essential properties of the products, analyzing only the experimental results of flowability and pH measurements.

Intracanal medicaments should have appropriate flowability, so that they can be easily placed into root canals, and alkalinity should be high, to improve antibacterial activity. Thus, flowability and pH were evaluated in this study.

The outcomes are the following



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