

Original Article

Enhancing the Physicochemical Properties of Sodium Iodide-based Root Canal Filling Material with Lanolin Incorporation

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Abstract

This study aimed to enhance the physicochemical properties of sodium iodide-based root filling materials, particularly solubility. In earlier developmental stages, the iodoform-containing paste exhibited high antibacterial efficacy but failed to meet only the solubility requirement among the ISO 6876 criteria. Therefore, this study focused on enhancing the physicochemical properties of the paste under development, particularly centering on reducing its solubility. Four experimental groups were established, including three control group. The previously developed D30 paste was named the Oil 33 group, and the control group was named the Vitapex[®] group. The Oil 50 group, in which the oil content was increased, and the Oil 45L group, in which lanolin was incorporated. The physical properties (solubility, pH, flowability, and film thickness) of the four pastes were evaluated according to the ISO 6876 standards. No significant differences were observed between the Oil 45L and Vitapex[®] groups in any of the physical property evaluations. While the Oil 33 and Oil 50 groups met the ISO 6876 standards for flowability and film thickness, the Oil 45L group met all the physical properties. However, reducing the overall oil content may be necessary to enhance the antimicrobial properties. The result of the physicochemical experiments showed that the Oil 45L group with the newly formulated composition and incorporated lanolin exhibited low solubility meeting the ISO 6876 standard of $\leq 3\%$. We were able to develop a paste with more stable solubility than previous iodide-based root-filling materials. Therefore, the oil content must be further adjusted to improve its antimicrobial properties. If other physical properties also meet the ISO 6876 standards and demonstrate excellent results in cytotoxicity tests, this root filling material could potentially replace existing options. [J Korean Acad Pediatr Dent 2024;51(2):140-148]

Keywords

Sodium iodide, Primary tooth, Root filling material, Solubility, Flowability, Film thickness, pH, Vitapex, Lanolin

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Introduction

Successful root canal treatment of deciduous teeth is crucial for preventing premature tooth loss[1,2]. Proper pulpectomy of the deciduous teeth can help to maintain teeth that have developed asymptomatic irreversible pulpitis[3]. Early loss of deciduous teeth due to deep caries and missing congenital teeth can lead to malocclusion[4]. Although accurate diagnosis, treatment planning, and procedural techniques are essential for successful treatment, the choice of an appropriate root canal filling material is equally important.

Vitapex® has been used as a root canal filling material for pulpectomy of deciduous teeth since 2003[5-7]; however, numerous case reports have indicated that root canal treatment of deciduous teeth is associated with apical lesions and external root resorption[8-12]. Iodoform has been reported to induce cystic changes, potentially leading to radicular cyst development and root resorption[13]. However, the combination of calcium hydroxide and iodoform in deciduous root filling materials demonstrated the highest antibacterial activity among all calcium hydroxide-based root filling materials[14]. Therefore, studies have been conducted investigating the replacement of iodoforms with other materials[15,16].

A previous study introduced an innovative root-filling material for deciduous teeth. In this material, iodoform, one of the three primary components of Vitapex® (calcium hydroxide, iodoform, and silicone oil), was replaced with sodium iodide. During the experiments evaluating their influence on osteoclast differentiation, it was observed that a root-filling material based on sodium iodide effectively suppressed osteoclast differentiation, thus preventing root resorption[15]. Subsequent experiments were conducted to increase injectability for practical clinical applications by applying various silicone oils. Subsequent analysis showed that the paste containing low-density silicone oil exhibited the lowest compressive load[17].

According to the ISO 6876 standards, the solubility of root-filling materials should not exceed 3%. However, in a previous study, the solubility of this paste was 20.01%.

This indicates that further improvements in the solubility of the paste are required to meet the ISO standard requirements for clinical use as a root-filling material. In previous experiments, the material composition of the paste was $\text{Ca}(\text{OH})_2$: NaI : Silicone oil in a 1 : 1 : 1 ratio (Table 1). In 2013, Kuga et al. revealed that the addition of iodoform to an endodontic sealer increased the setting time, and the addition of calcium hydroxide increased solubility[7]. Furthermore, Marques et al. (2020) reported that the addition of silicone oil provided aggregating properties and reduced the solubility[18]. In this study, lanolin was used as an additive to decrease solubility. Lanolin is a component of Maisto's paste, which is an iodoform-based root filling material[1]. Maisto's paste was introduced in 1967 as a combination of iodoform and zinc oxide eugenol (ZOE), and has demonstrated higher success rates than ZOE alone[19]. This iodoform-based root-filling material is considered a biocompatible paste and it has better properties than the ZOE-only sealers[20,21]. Based on these findings, our goal was to modify the composition ratios of the materials and introduce additional components to enhance their solubility.

This study aimed to enhance the properties of sodium iodide-containing pastes currently in development, with a particular focus on improving their solubility. In earlier developmental stages, the iodoform-containing paste exhibited high antibacterial efficacy but failed to meet only the solubility requirement among the ISO 6876 criteria. Therefore, this study focused on improving the physicochemical properties of the paste under development, particularly enhancing its solubility.

Materials and Methods

1. Material preparation

Calcium hydroxide ($\text{Ca}(\text{OH})_2$, Sigma-Aldrich, Burlington, MA, USA), sodium iodide (NaI, Sigma-Aldrich, Burlington, MA, USA), low-density silicone oil (Shin-Etsu Silicone KF-96 350 cst; Shin-Etsu Chemical Co., Tokyo, Japan), and lanolin (Daejung, Siheung, Korea) were used to prepare the materials. The scale is measured by EX-

PLORES™ EX224G (Ohaus, Seoul, Republic of Korea). In the experimental group, a mixture of Ca(OH)₂, NaI, and silicone oil in a 1 : 1 : 1 ratio was prepared on a glass slide using a sterilized spatula; this group was designated as the Oil 33 group. To observe the changes in solubility with variations in oil ratio, pastes were prepared by mixing Ca(OH)₂, NaI, and silicone oil in a 1 : 1 : 2 ratio, and this group was named Oil 50. To evaluate the effect of lanolin addition on solubility, lanolin was added at a concentration of 5% and an equal amount of silicone oil was excluded. A mixture of Ca(OH)₂, NaI, silicone oil, and lanolin in was prepared in a 25 : 25 : 45 : 5 ratio and named the Oil 45 L group (Table 1). These groups were compared with Vitapex® (Neo Dental, Tokyo, Japan), a deciduous tooth root filling material commonly used in clinical practice.

2. Physicochemical experiments

1) Solubility

Ring-shaped molds made of Teflon (polytetrafluoroethylene polymer from DuPont, HABIA, Knivsta, Sweden) were used, with dimensions of 20 mm for the internal diameter and 1.5 mm for the height. The two molds were filled with sealer and positioned inside the Petri dish, after which 50 ± 1 mL of distilled water was added. The initial weights of the specimens, which were measured at approximately 0.001 g, were recorded. They were placed under conditions of 37 ± 1°C and 95% relative humidity for 24 h. After 24 h, 50 mL of the solution was filtered into a beaker using a funnel and dried at a temperature of 80 ± 2°C. The initial weight of the beaker and the weight of the beaker after drying the solution were

measured.

$$\text{Solubility} = \frac{\text{Final weight of beaker (I2)} - \text{initial weight of beaker (I1)}}{\text{initial weight of sample (I0)}} \times 100 (\%)$$

2) Flow

An aliquot of 0.05 ± 0.005 mL sealer was applied to the center of a glass plate measuring 40 mm × 40 mm, with a thickness of 5 mm and a weight of 20 g. After 3 minutes ± 5 seconds, another glass plate of the same dimensions and a weight of 100 g was placed on top of the sealer. After 7 min, the weight was removed, and the minimum and maximum diameters were measured. If the difference was less than 1 mm, the average value was calculated.

3) Film thickness

Two glass plates with a minimum thickness of 5 mm and a contact area of 200 ± 25 mm² were prepared. The combined thickness of the two glass plates was measured with an accuracy of 1 µm. Subsequently, 0.01 mL of sealer was applied to one side of one of the glass plates, and the other glass plate was placed on top. After 3 minutes ± 10 seconds, samples were placed in a loading device, and a vertical load of 150 ± 3 N was applied. After 7 min, the thicknesses of the two glass plates with the sealer fully spread between them were measured. The thicknesses of the two glass plates without the sealer were subtracted to measure the film thickness.

4) pH

A total of 1 ± 0.1 g of sealer was placed and combined with 5500 µL of distilled water. Subsequently, the mix-

Table 1. Composition of each of the experimental groups

	Ca(OH) ₂ (%)	NaI (%)	Iodoform (%)	Silicone oil (%)	Lanolin (%)	Others (%)	Sum (%)
Oil 33	33.3	33.3		33.3			100
Oil 50	25.0	25.0		50.0			100
Oil 45 L	25.0	25.0		45.0	5		100
Vitapex®	30.0		40.4	22.4		6.9	100

ture was incubated in a shaking incubator at $37 \pm 1^\circ\text{C}$ for 24 h. Following this incubation period, the solution was filtered through a $0.22\text{-}\mu\text{m}$ filter (Corning Inc., Corning, NY, USA), and a pH test was conducted utilizing the Orion VESTA Star Pro (Thermo Fisher Scientific, Waltham, MA, USA). The instrument was calibrated using buffer solutions of pH 4.01, 7.00, and 10.01.

5) Microscopic analysis

For microscopic analysis, 0.01 mL of each sample (Oil 33, Oil 50, and Oil 45 L) was applied to a glass slide, and a $25\times$ microscope (S39A, Microscopes Instrument, Suwon, Republic of Korea) was used to examine the surface characteristics.

6) Statistical methods

The experimental data were analyzed using SPSS software (version 21.0; SPSS Inc., Chicago, IL, USA). Statistical analyses were conducted using Kruskal-Wallis test, with the significance level set at 0.05 to assess the results (Table 2). After confirming a normal distribution within each group, five samples were selected from each for statistical analysis.

Results

1. Solubility

The ISO 6876 standard for solubility, which requires a solubility of $\leq 3\%$, was met only in the Oil 45 L and Vitapex® groups. When the solubility was ranked from highest to lowest, the order was Oil 33, Oil 50, Oil 45 L,

and Vitapex® (Fig. 1A). Oil 33 exhibited a significant difference compared to the Oil 45 L and Vitapex® groups, whereas Oil 50 demonstrated a significant difference compared to the Vitapex® group. Importantly, no significant difference in solubility was observed between the Oil 45L and Vitapex® groups.

2. Flow

Each group satisfied the ISO 6876 standard for flow of 17 mm. The order of flow from highest to lowest was observed to be Oil 50, Vitapex®, Oil 45 L, and Oil 33 (Fig. 1B). The only significant difference observed was between the Oil 33 and Oil 50 groups. In terms of flow, no significant differences were noted between the Oil 45 L and Vitapex® groups.

3. Film thickness

The ISO 6876 standard for film thickness, which defines a limit of $\leq 50\ \mu\text{m}$, was fulfilled by all groups. The order of film thickness, from thinnest to thickest, was Oil 50, Vitapex®, Oil 45 L, and Oil 33 (Fig. 1C). In addition, significant differences were identified between oils 33 and 50.

4. pH

According to the experimental results, Oil 33 had the highest pH level, followed by Vitapex®, Oil 45 L, and Oil 50 (Fig. 1D).

Table 2. Solubility, flow, film thickness, and pH of the samples (mean \pm standard deviation)

Variable	Solubility (%)	Flow (mm)	Film thickness (μm)	pH
Oil 33	$22.5 \pm (4.95)^a$	$17.6 \pm (0.38)^b$	$13.3 \pm (0.34)^a$	$12.5 \pm (0.04)^a$
Oil 50	$8.49 \pm (0.86)^b$	$19.3 \pm (1.42)^a$	$3.0 \pm (0.42)^b$	$11.1 \pm (0.67)^b$
Oil 45L	$1.15 \pm (0.11)^a$	$17.6 \pm (0.51)^b$	$12.9 \pm (0.43)^a$	$11.7 \pm (0.48)^b$
Vitapex®	$0.34 \pm (0.03)^{a,b}$	$17.9 \pm (0.44)^b$	$3.3 \pm (0.51)^b$	$12.0 \pm (0.06)^a$

Statistical analyses were conducted using Kruskal-Wallis test. Data with different superscript letters are significantly different ($p < 0.05$).

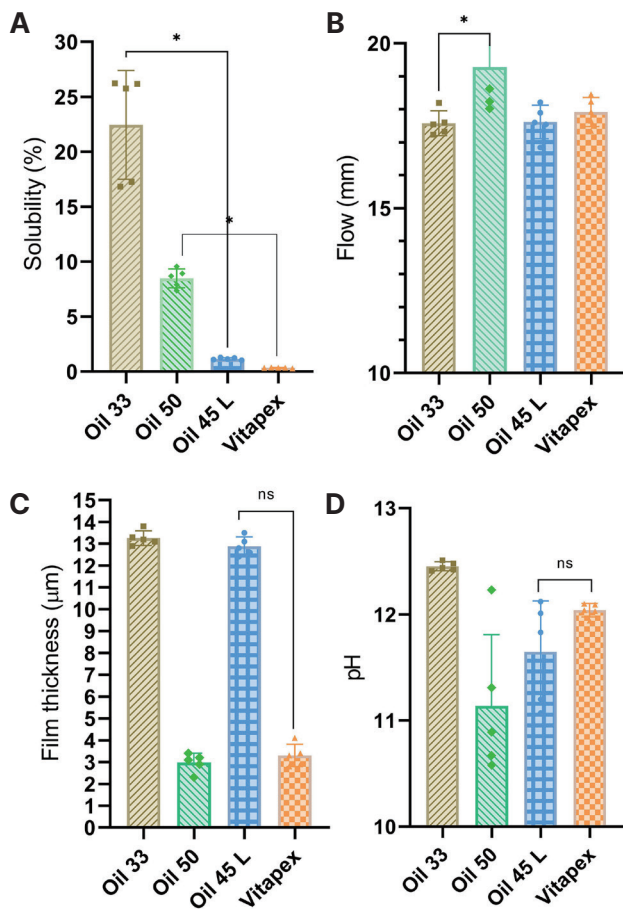


Fig. 1. (A) Solubility. Oil 45 L and Vitapex® were < 3% (ISO standard), (B) Flowability. All values were > 17 mm (ISO standard), (C) Film thickness. All values were < 50 µm (ISO standard), (D) pH.

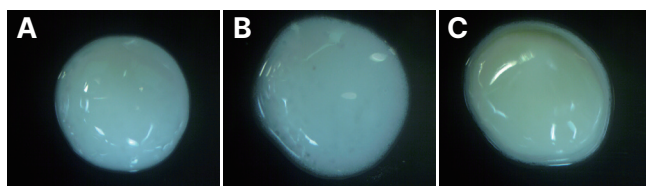


Fig. 2. (A) Oil 33, (B) Oil 50, and (C) Oil 45 L pastes observed under an optical microscope.

5. Optical images

When the optical microscopy images of the Oil 33, Oil 50, and Oil 45 L groups were compared, Oil 50 exhibited a lower dense and increasing flowing texture (Fig. 2).

Discussion

Zinc oxide eugenol (ZOE) has been used as a root canal filling material for pulpectomy of deciduous teeth since the 1930s[22]; however, ZOE has been associated with certain drawbacks, including a slow absorption rate when extruded outside the root canal[23], a potential to induce inflammation at the apex[24], necrosis of the bone and cementum[25], and the possibility of affecting the eruption of permanent teeth[26]. A silicone oil-based paste containing calcium hydroxide (Ca(OH)₂) was introduced by Hermann in 1920, and iodoform was subsequently added by Estrela et al.[27]. The combination of calcium hydroxide and iodoform paste has been reported to have a success rate of 84 - 100%[20]. Consequently, Vitapex® has been used as a root canal filling material for pulpectomy of deciduous teeth since 2003[5-7].

Iodoform-based paste has long been used as root-filling material in the primary teeth[5-7]. The ideal properties of a root canal filling material include its ease of application and removal within the root canal; an absorption rate compatible with the physiological resorption of deciduous teeth; and a lack of substances that can interfere with the eruption of permanent teeth, appropriate radiopacity, no discoloration of deciduous teeth, good adhesion to the root canal walls, antimicrobial properties, no harm to periapical tissues, and the development of permanent teeth[28]. Although ZOE-based paste has been reported to be more biocompatible than iodoform-based paste[29], it has a higher solubility when the sealer overfills beyond the apex[30]. However, in the short term, the clinical and radiographic success rates of Vitapex® were higher, whereas in the long term, it demonstrated a similar performance[31]. Therefore, research continues to identify new primary tooth root filling materials that can replace iodoform-based materials[32-34].

However, numerous case reports have indicated that root canal treatment of deciduous teeth is associated with apical lesions and external root resorption[8-12]. Furthermore, an experimental study conducted by Nakornchai et al. in 2010 compared the use of 3Mix paste, a combination of triple antibiotics and calcium hydroxide,

with Vitapex® for root canal filling of deciduous teeth; radiographic images taken 6 and 12 months after treatment revealed a higher incidence of external resorption in teeth treated with Vitapex®[35]. Additionally, when comparing the extent of root resorption between deciduous teeth that underwent pulpectomy and those that did not, the former exhibited more significant root resorption[36]. An experiment revealed that iodoform-containing root canal filling material has a higher cytotoxicity and induces cell stress and proliferation in RAW 264.7, macrophages, and RKO epithelial cells than other calcium hydroxide-based root canal filling materials, potentially leading to cystic changes[13]. To solve this problem, studies have been conducted to replace iodoform with another material that can effuse iodine ions for higher antibiotic effects when used with calcium hydroxide[15,16].

Calcium hydroxide is widely recognized for its strong antibacterial properties, making it a key component of dental root canal treatment materials[37-39]. The combination of calcium hydroxide and iodoform in root-filling materials demonstrated the highest antibacterial activity among calcium hydroxide-based root filling materials[14]. This enhanced antibacterial action is attributed to the release of iodine ions from the iodoform, which precipitates proteins and oxidize essential enzymes, thereby activating enzymes[20].

Therefore, sodium iodide was used instead of iodoform as the root canal filling material. This substitution aimed to retain the synergistic antibacterial effect of calcium hydroxide and iodine ions while preventing root resorption that can potentially be induced by iodoform. However, it is highly soluble and does not satisfy clinical conditions [40,41]. In this study, lanolin was used as an additive to decrease solubility. Lanolin, an iodoform-based root filling material, is a component of Maisto paste[1]. Maisto paste has previously shown a clinical success rate of 91.5% and a radiographic success rate of 88.3% in root canal filling, indicating a high success rate[42]. Excess material overfilling beyond the apex was absorbed within 3 months, with 93% demonstrating bone regeneration[43]. Additionally, successful apical

closure was observed six months after treatment initiation, further demonstrating its clinical success[20,44]. Lanolin is widely used in various applications, including cosmetics and pharmaceuticals[45]. One notable use is as a key ingredient in ointments applied to the breast tissues of patients with nipple trauma resulting from breastfeeding[46]. Recently, researchers have explored the use of lanolin to create membranes for capsules[47] and as a carrier for direct blood flow injection therapy using glyceryl trinitrate[48].

In this experiment, the lanolin-enhanced NaI paste satisfied the flowability, film thickness, and solubility conditions specified by the ISO 6876. Unlike previously developed pastes, the solubility now meets specifications for root canal filling use, enabling application in open apices. Additionally, reduced injection force facilitates easier clinical handling. However, because lanolin was added to assess its impact on solubility for clinical use, the overall percentage of calcium hydroxide, which can enhance antimicrobial properties[37-39], and sodium iodide, which can increase radiopacity, may decrease. Additional experiments are needed to verify whether this root-filling paste satisfies all of the physical property criteria laid by the ISO 6876 standard, and cytotoxicity experiments are required. If the sodium iodide-based root-filling paste meets all the criteria of ISO 6876 and can be used in clinical situations, the paste can provide high antibiotic effects similar to Vitapex® and reduce concerns about early root resorption and exfoliation.

Experiments confirmed that increasing the silicone oil content and adding lanolin could improve the solubility of iodide-based root-filling materials. However, to meet the criteria for high antimicrobial properties, which are essential for an ideal root-filling material, in vitro antimicrobial testing and efforts to reduce silicone oil content are needed in subsequent research.

Conclusion

The results of the physicochemical experiments showed that the Oil 45 L group with the newly formulated composition and incorporated lanolin exhibited

low solubility meeting the ISO 6876 standard of $\leq 3\%$. The flow and film thickness values also fulfilled the ISO 6876 specifications. Compared to the conventional Oil 33 paste, the Oil 45 L paste displayed lower solubility and consequently lower pH. As evident in the optical microscopy images, the newly developed lanolin-containing paste, with a higher oil content than Oil 33, appeared smoother but had lower flow than Oil 50.

As a result, the lanolin-enhanced sodium iodide-based root-filling material developed herein satisfied the flowability, film thickness, and solubility criteria of the ISO 6876 standards. Further experiments are required to determine whether this material can surpass other physical property standards outlined in ISO 6876, and to demonstrate its high biocompatibility. If these additional tests are successful, these materials could potentially be used clinically as new materials to replace iodoform-based root-filling materials.

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Conflict of Interest

The authors have no potential conflicts of interest to disclose.

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