Clinical Performance of Nanohybrid Resin Composites in Non-Carious Cervical Lesions : One-year Results of a Randomized Controlled Clinical Trial

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Clinical Performance of Nanohybrid Resin Composites in Non-Carious Cervical Lesions : One-year Results of a Randomized Controlled Clinical Trial

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감사의 글

먼저 제 삶의 이정표가 되어 주시고 어떠한 일이 있더라도 항상 저를 믿고 지지해주신 사랑하는 아버지, 어머니께 감사드립니다. 그리고 언제나 제 편이 되어주었던 사랑하는 동생, 가장 가까운 곳에서 든든한 버팀목이 되어 무너지지 않도록 힘이 되어준 조성욱에게 고마움을 전합니다.

석사 과정 5 학기 동안 한없이 부족한 저를 세심한 지도와 격려로 이끌어 주신 박성호 교수님께 깊은 존경과 감사를 드립니다. 더불어, 바쁘신 중에도 사랑을 보여주시고 많은 관심으로 더 좋은 논문이 될 수 있도록 조언해주신 신유석 교수님, 김도현 교수님께도 진심으로 감사드립니다. 보존과 수련 과정 동안 아낌없는 가르침을 주신 노병덕 교수님, 김의성 교수님, 정일영 교수님, 박정원 교수님, 신수정 교수님, 김선일 교수님, 전미정 교수님, 최명락 선생님께도 감사의 마음을 전합니다. 또한 3 년의 수련 동안 즐거움과 괴로움을 함께했던 동기 권승경, 김성욱, 임보현, 황정환, 그리고 의국 선후배님들에게도 고마움을 전합니다.

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Abstract

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The aim of this study was to evaluate the clinical efficacy of Denfil NX resin composite (Vericom, Chuncheon, South Korea) in the direct restoration of non-carious cervical lesions compared to the existing nanohybrid resin composite, Ceram X SphereTEC One (Dentsply Sirona, Charlotte, USA), in a randomized controlled clinical trial.

A prospective, blinded, randomized controlled split-mouth study was conducted on

thirty-seven patients (25 females, 12 males; mean age 58.24y; range 33-78y) from the Department of Conservative Dentistry at Yonsei University Dental Hospital. The restorative procedures were performed by eighteen specially instructed and experienced dentists. After exclusion of one pair of restorations with unclear records and inappropriate shade selection, a total of seventy-two class V restorations (DN group: n=36, Denfil NX; CX group: n=36, Ceram X SphereTEC One) were included in the assessment, and each patient had one restoration from each of the two groups. Clinical evaluation was performed by two blinded examiners according to FDI clinical criteria and scoring system at baseline, one month, six months, and one year. The Wilcoxon signed-rank test was used for the analysis of evaluation scores of the two groups for each of the eleven selected criteria.

One patient dropped out at the six-month evaluation and another patient was lost to follow-up at the one-year evaluation. As a primary efficacy variable, the retention rate was presented based on the scores of 'fracture of material and retention (B5)'. All restorations in both groups showed 100% retention rate at the one-month recall. However, in the DN group, one restoration had a partial fracture at the beveled area at the six-month recall, and one additional restoration exhibited a partial fracture in the mesial portion at the one-year evaluation. In the CX group, one restoration had a partial fracture at the cervical margin leading to dentin exposure at the six-month recall. Those were considered clinically unacceptable, resulting in a retention rate of 94.12% and 97.06% in DN group and CX group, respectively. However, none of the restorations were completely lost, and there was no significant difference between the two materials.

There were no significant differences between the two groups for the other evaluation criteria, except for ‘adjacent mucosa (C15)’. In this category, the DN group showed an inferior result compared to the CX group (p=0.025), but all restorations were within clinically acceptable limits. This appears to be a secondary outcome associated with inadequate marginal adaptation of the restoration, rather than the restorative material itself.

In conclusion, both Denfil NX and Ceram X SphereTEC One exhibited satisfactory retention and similar functional and esthetic clinical performance in the direct restoration of non-carious cervical lesions over the one-year follow-up period. Denfil NX exhibited slightly inferior but clinically fully acceptable biological properties as compared to Ceram X SphereTEC One.

Keywords : Non-carious cervical lesions; Nanohybrid resin composites; Dental material; FDI clinical criteria; Randomized controlled trial

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I. Introduction

Resin composite is a material with esthetics and functionality that can be effectively used on both anterior and posterior teeth while requiring the least amount of tooth preparation among all dental restorative materials. (Lynch et al. 2014) Resin composite has several advantages over other restorative materials. The most representative of these is the esthetics,

which is similar to the color of natural teeth. (Bayne et al. 2019) When treated properly, it is difficult to distinguish treated teeth from natural teeth.

Furthermore, a robust chemical connection is established between the resin and dentin, as the adhesive deeply infiltrates dentinal tubules, ensuring a strong attachment between the tooth and resin. Therefore, unnecessary removal of tooth structure can be avoided and the strength of the remaining tooth structure can be preserved. (Bayne et al. 2019) Additionally, because the resin composite is a high polymer, it exhibits excellent flexibility and infrequent fractures. (Szczesio-Wlodarczyk et al. 2022) Unlike metal restorative materials, it has low thermal conductivity, so it causes less sensitivity after restoration. In addition, the use of the adhesive method reduces the need for retreatment in the event of secondary dental caries, as it can be partially removed and treated without removing the entire restoration.

However, it has been reported that the resin composite has volume shrinkage during the polymerization process, and the degree reaches 2~5%. (Al Sunbul, Silikas, and Watts 2016; Khoramian Tusi et al. 2022) This may lead to staining of the restoration margin, and the restoration may fall out due to the formation of microleakage or gaps between the tooth and the restorative material. Postoperative hypersensitivity, secondary dental caries, or pulp irritation may also occur. (Mjör 1997; Balhaddad et al. 2019; Moussa, Fok, and Aparicio 2019) In addition, since it is susceptible to moisture, it is difficult to apply to areas such as the subgingival area, which is difficult to seal from moisture. (Magne and Spreafico 2012) Meanwhile, every patient has a different tooth color, so it is a disadvantage to have products

with a variety of shades to treat teeth.

To overcome these disadvantages, nanohybrid resin composites have gained significant popularity due to their capacity to enhance the dispersion of fillers within the matrix through the combination of nanoparticles with submicron particles, resulting in superior mechanical, chemical, and optical characteristics. (Saen et al. 2016; Wang, Habib, and Zhu 2018; Lin et al. 2020) One such nanohybrid resin composite currently used in clinical settings is Ceram X SphereTEC One, manufactured by Dentsply Sirona in the United States. The manufacturer's introduction of "SphereTEC", a proprietary spherical filler, resulted in reduced shrinkage and improved physical properties. This monodispersed spherical filler is also noteworthy for its ease of polishing, capacity to enhance esthetics, and shade simplification through the chameleon effect. Following this trend, Denfil NX resin composite (Vericom, Chuncheon, South Korea) was introduced with the goal of launching an upgraded product with monodispersed filler and its shape. Efforts were made to minimize shrinkage through structural control of the polymer and monitoring the shape and size of the filler. Furthermore, a chameleon effect was achieved by incorporating an optimal filler system in an attempt to decrease dentists' stress and increase patient satisfaction by simplifying the selection from sixteen to five different shades.

The aim of this study was to evaluate the clinical efficacy of Denfil NX in the direct restoration of non-carious cervical lesions compared to the existing nanohybrid resin composite, Ceram X SphereTEC One, in a randomized controlled clinical trial. The null hypothesis was that there would be no difference in the retention rate and clinical

performance, as evaluated by the FDI clinical criteria and scoring system, between the two materials.

II. Material and methods

1. Test materials

Denfil NX (DN) and Ceram X SphereTEC One (CX) were used in this study, both applied in combination with a two-step self-etching adhesive (Clearfil SE Bond; Kuraray Noritake, Okayama, Japan).

DN is a nano-hybrid, tooth-colored, light-cured, radiopaque, universal composite based on polymers. It is a paste mixture of unpolymerized dimethacrylate monomer, inorganic filler, and photoinitiator. It is in compliance with all the requirements outlined in ISO 4049 (Dentistry—polymer-based restorative materials) for a type 1 (polymer-based restorative materials claimed by the manufacturer as suitable for restorations involving occlusal surfaces), class 2 material (materials whose setting is effected by the application of energy from an external source, such as blue light or heat ("external-energy-activated" materials)), group 1 (materials whose use requires the energy to be applied intra-orally) and group 2 (materials whose use requires the energy to be applied extra-orally. When fabricated, these materials will be luted into place).

CX is a nano-hybrid, light-cured, radiopaque, universal composite based on the SphereTEC filler technology. It also meets all the requirements outlined in ISO 4049 for a type 1, class 2 material. It is designed as a single translucency system and includes five

shades covering the full VITA® color range. In this study, five shades were used for each of the two resin composites; A1, A2, A3, A3.5, and A4.

2. Study design

The present study is a one-year follow-up examination of a prospective, blinded, randomized controlled trial with split-mouth design evaluating the clinical performance of two restorative materials, DN and CX, for the restoration of non-carious cervical lesions in canines, premolars and molars. Sample size calculation was based on a previous systemic review and meta-analysis of the longevity of posterior composite restorations. (Opdam et al. 2014) As a result of the sample size calculation for the non-inferiority test with a significance level of 0.05, a power of 80%, and an equivalence limit of 10%, the minimum sample size was calculated to be 31 patients. (Julious 2009) To compensate for a possible drop-out rate of 20%, it was decided to recruit a minimum of 36 patients. The experimental design followed the requirements outlined in the CONSORT statements (Consolidated Standards of Reporting Trials). (Schulz, Altman, and Moher 2011) The study was approved by the Institutional Review Board of Yonsei University Dental Hospital (IRB number: 2-2021-0124).

3. Patient selection

Patients were recruited from the patient pool of the Department of Conservative Dentistry at Yonsei University Dental Hospital. All participants were informed about the study and gave written informed consent prior to the first treatment. Patients were included if they were 19 years of age or older, in good general health, and in need of class V restorative treatment with resin composite in two or more posterior teeth for non-carious cervical lesions invading the dentin. Teeth to be restored required antagonist teeth and had to have an overall favorable survival prognosis during the follow-up period.

Patients were excluded if they had difficulty understanding this test even after receiving sufficient explanation. Exclusion criteria at the restoration level involved teeth with moderate or severe chronic periodontitis, horizontal mobility greater than 1 mm, or vertical mobility. Teeth diagnosed as cracked teeth, dental caries invading the pulp chamber, irreversible pulpitis or pulp necrosis, or teeth requiring indirect restoration due to excessive tooth structure damage were also excluded.

4. Clinical procedures

The restorative procedures were performed by eighteen specially instructed and experienced dentists, consisting of two professors and sixteen residents, in the Department of Conservative Dentistry at Yonsei University Dental Hospital. The standardized treatment

protocol was followed, and the only variation was in the restorative materials used. Prior to patient recruitment, all eighteen dentists underwent detailed training on this standardized treatment protocol. Based on a pre-assigned randomization table, two teeth from each patient were assigned to the DN group and the CX group respectively. The patient was not informed which material would be used to restore each tooth.

The selection of the appropriate shade was made using the VITAPAN® classical shade guide (Vita Zahnfabrik, Bad Säckingen, Germany). Every procedure was performed under local anesthesia with a 2% lidocaine hydrochloride solution containing 1:100,000 epinephrine (Huons, Seongnam, South Korea). A gingival retraction cord (SURE-Cord® Plus; Sure Dent Corporation, Seongnam, South Korea) was packed in the gingival sulcus if necessary. The sclerotic dentin or the carious lesion was removed mechanically and a class V cavity was prepared by using a high-speed handpiece and a tapered diamond bur under sufficient water cooling. Soft carious dentin detected was removed with low-speed round carbide burs and a spoon excavator until firm dentin was reached. Selective enamel etching was performed with 35% phosphoric acid (V-Etch; Vericom, Chuncheon, South Korea). After water rinsing and air drying, moisture control and a dry operating field were achieved using cotton rolls and a saliva ejector. Clearfil SE Bond, a two-step self-etching adhesive, was applied according to the manufacturer's instructions. Flowable resin lining was performed with Denfil Flow (Vericom, Chuncheon, South Korea). DN or CX was then applied according to the manufacturer's instructions. Incremental fillings within 2mm and light curing for 20 seconds with Bluephase® N G4 (Ivoclar Vivadent, Schaan,

Liechtenstein) were performed for each step. After the completion of polymerization, excess resin was removed, and final polishing was performed with silicone-based abrasive polisher points (Astropol®; Ivoclar Vivadent, Schaan, Liechtenstein).

Table 1. Composition of the materials used

Material	Type	Matrix composition	Filler composition	Filler degree	Manufactur-er
Denfil NX	Nano-hybrid	Bis-GMA, UDMA, TEGDMA	Barium aluminosilicate (<1 μm), Fumed silica (0.04 μm)	76–78 vol%, 81 wt%	Vericom, Chuncheon, South Korea
Ceram X SphereTEC One	Nano-hybrid	Bis-EMA, TEGDMA	The Sphere TEC fillers (15 μm), Non-agglomerated barium glass fillers (0.6 μm), Ytterbium fluoride (0.6 μm), Methacrylic polysiloxane, nanoparticles	59–61 vol%, 77–79 wt%	Dentsply Sirona, Charlotte, USA
Denfil Flow	Nano-hybrid	Bis-GMA, TEGDMA	Barium glass (0.01–2.5 μm), Silica	60 wt%	Vericom, Chuncheon, South Korea

Material	Type	Primer composition	Adhesive composition	Manufactur-er
Clearfil SE Bond	Self-etching Adhesive	Silanated silica, BisGMA, 2-hydroxyethyl methacrylate, hydrophilic dimethacrylate, 10-MDP, toluidine, camphorquinone	2-Hydroxyethyl methacrylate, hydrophilic dimethacrylate, 10-MDP, N,N-Diethanol p-toluidine, camphorquinone (2,3-bornane-dione), water	Kuraray Noritake, Okayama, Japan

Bis-EMA : Ethoxylated bisphenol a glycol dimethacrylate; Bis-GMA: bisphenol A-glycidyl methacrylate; TEGDMA : Triethylene glycol dimethacrylate; UDMA : Urethane dimethacrylate; 10-MDP : 10-methacryloyloxy methacrylate

5. Clinical examination

Clinical examinations were performed by two blinded examiners who were unaware of the restorative material used in each tooth. The restorations were evaluated at baseline (right after restorative procedures) as well as after one month, six months, and one year. The FDI clinical criteria and scoring system was used to evaluate the restorations. (Hickel et al. 2007; Hickel et al. 2010) Table 2 shows the categories selected to evaluate the clinical performance of the restorations in this study.

Clinical evaluation of each criterion was performed using a five-score scale (Table 3). Tooth vitality was assessed using the ice test or electric pulp test and postoperative hypersensitivity was determined by interview of the patients. Each restoration was examined independently by both examiners. In case of any disagreement between the examiners, a consensus was reached by discussion to derive a single result.

Table 2. Selected FDI clinical criteria

Esthetic properties	Functional properties	Biological properties
■ Surface lustre (A1) ■ Surface staining (A2a) ■ Marginal staining (A2b) ■ Color match and translucency (A3)	■ Fracture of material and retention (B5) ■ Marginal adaptation (B6) ■ Radiographic examination (B9) ■ Patient's view (B10)	■ Postoperative sensitivity and tooth vitality (C11) ■ Recurrence of caries, erosion, abfraction (C12) ■ Adjacent mucosa (C15)

Table 3. Gradings of selected FDI criteria (Hickel et al. 2010)

A. Esthetic properties	**1. Surface lustre**	**2a. Surface staining**	**2b. Marginal staining**	**3. Color match and translucency**
1. Clinically excellent / very good	1.1 Lustre comparable to enamel.	2a.1 No surface staining.	2b.1 No marginal staining.	3.1 Good color match, no difference in shade and/or translucency
2. Clinically good (after polishing probably very good)	1.2.1 Slightly dull, not noticeable from speaking distance. 1.2.2 Some isolated pores.	2a.2 Minor surface staining, easily removable by polishing.	2b.2 Minor marginal staining, easily removable by polishing.	3.2 Minor deviations in shade and/or translucency.
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth)	1.3.1 Dull surface but acceptable if covered with film of saliva. 1.3.2 Multiple pores on more than one third of the surface.	2a.3 Moderate surface staining that may also present on other teeth, not esthetically unacceptable.	2b.3 Moderate marginal staining, not esthetically unacceptable.	3.3 Distinct deviation but acceptable. Does not affect esthetics: 3.3.1 more opaque 3.3.2 more translucent 3.3.3 darker 3.3.4 brighter
4. Clinically unsatisfactory (but reparable)	1.4.1 Rough surface, cannot be masked by saliva film, simple polishing is not sufficient. Further intervention necessary. 1.4.2 Voids	2a.4 Unacceptable surface staining on the restoration and major intervention necessary for improvement.	2b.4 Pronounced marginal staining; major intervention necessary for improvement	3.4 Localized clinically deviation that can be corrected by repair: 3.4.1 too opaque. 3.4.2 too translucent. 3.4.3 too dark. 3.4.4 too bright.
5. Clinically poor (replacement necessary)	1.5 Very rough, unacceptable plaque retentive surface	2a.5 Severe surface staining and/or subsurface staining, generalized or localized, not	2b.5 Deep marginal staining, not accessible for intervention.	3.5 Unacceptable. Replacement necessary.

		accessible for intervention.		
B. Functional properties	**5. Fracture of material and retention**	**6. Marginal adaptation**	**9. Radiographic examination (when applicable)**	**10. Patient's view**
1. Clinically excellent / very good	5.1 No fractures / cracks.	6.1 Harmonious outline, no gaps, no white or discolored lines.	9.1 No pathology, harmonious transition between restoration and tooth.	10.1 Entirely satisfied with esthetics and function.
2. Clinically good	5.2 Small hairline crack.	6.2.1 Marginal gap (<150 µm) white lines. 6.2.2 Small marginal fracture removable by polishing 6.2.3 Slight ditching, slight step/flashes, minor irregularities.	9.2.1 Acceptable material excess present. 9.2.2 Positive/negative step present at margin <150 µm.	10.2 Satisfied. 10.2.1 Esthetics. 10.2.2 Function, e.g., minor roughness
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth)	5.3 Two or more or larger hairline cracks and/or material chip fracture not affecting the marginal integrity or approximal contact.	6.3.1 Gap < 250µm not removable. 6.3.2. Several small marginal fractures. 6.3.3 Major irregularities, ditching or flash, steps	9.3.1 Marginal gap < 250 µm. 9. 3. 2 Negative steps visible < 250 µm. No adverse effects noticed. 9.3.3 Poor radiopacity of filling material.	10.3 Minor criticism but no adverse clinical effects. 10.3.1 Esthetic shortcomings. 10.3.2 Some lack of chewing comfort. 10.3.3 Unpleasant treatment procedure.
4. Clinically unsatisfactory (but reparable)	5.4.1 Material chip fractures which damage marginal quality or approximal contacts. 5.4.2 Bulk	6.4.1 Gap > 250 µm or dentine/base exposed. 6.4.2. Severe ditching or marginal	9.4.1 Marginal gap >250 µm. 9.4.2 Material excess accessible but not removable. 9.4.3 Negative	10.4 Desire for improvement 10.4.1 Esthetics. 10.4.2 Function, e.g., tongue irritation Reshaping of

	fractures with partial loss (less than half of the restoration).	fractures. 6.4.3 Larger irregularities or steps (repair necessary)	steps >250µm and reparable.	anatomic form or refurbishing is possible.
5. Clinically poor (replacement necessary)	5.5 (Partial or complete) loss of restoration or multiple fractures.	6.5.1 Restoration (complete or partial) is loose but in situ. 6.5.2 Generalized major gaps or irregularities.	9.5.1 Secondary caries, large gaps, large overhangs 9.5.2 Apical pathology 9.5.3 Fracture/loss of restoration or tooth.	10.5 Completely dissatisfied and / or adverse effects, incl. pain.

C. Biological properties	**11. Postoperative (hyper-)sensitivity and tooth vitality**	**12. Recurrence of caries (CAR), erosion, abfraction**	**15. Adjacent mucosa**
1. Clinically very good	11.1 No hypersensitivity, normal vitality.	12.1 No secondary or primary caries.	15.1 Healthy mucosa adjacent to restoration.
2. Clinically good (after correction maybe very good) No treatment required.	11.2 Minor hypersensitivity for a limited period of time, normal vitality.	12.2 Small and localized 1. Demineralization 2. Erosion or 3. Abfraction.	15.2 Healthy after minor removal of mechanical irritations (plaque, calculus, sharp edges etc.)
3.Clinically sufficient / satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	11.3.1 Moderate hypersensitivity 11.3.2 Delayed/mild sensitivity; no subjective complaints, no treatment needed.	12.3 Larger areas of 1. Demineralization 2. Erosion or 3. Abrasion/abfraction, dentine not exposed Only preventive measures necessary.	15.3 Alteration of mucosa but no suspicion of causal relationship with restorative material.
4. Clinically unsatisfactory (repair for prophylactic reasons)	11.4.1 Intense hypersensitivity. 11.4.2 Delayed with minor subjective symptoms. 11.4.3 No clinical detectable sensitivity.	12. 4.1 Caries with cavitation and suspected undermining caries 12.4.2 Erosion in dentine 12.4.3 Abrasion/	15.4 Suspected mild allergic, lichenoid or toxic reaction.

	Intervention necessary but not replacement.	abfraction in dentine. Localized and accessible can be repaired.	
5. Clinically poor (replacement necessary)	11.5 Intense, acute pulpitis or non-vital tooth. Endodontic treatment is necessary and restoration has to be replaced.	12.5 Deep caries or exposed dentine that is not accessible for repair of restoration.	15.5 Suspected severe allergic, lichenoid or toxic reaction.

6. Data analysis

The retention rate (%) for the primary efficacy variable, *fracture of material and retention* (B5), was presented. For the secondary efficacy variable at each follow-up point, the Wilcoxon signed-rank test was used to analyze the evaluation scores for eleven selected clinical criteria of the two types of resin restorations. The overall percent agreement was calculated to indicate the degree of accordance between the two examiners. Cohen's kappa statistics were presented together when available. All statistical analyses were performed using IBM SPSS for Windows, version 25 (IBM, Armonk, NY, USA). A significance level of 0.05 was used to determine statistical significance.

III. Results

1. Study population

Table 4. Characteristics of the patients and restorations

Variable	**Overall characteristics (n=37)**		
		n(%)	
Age (years)	Mean (SD)	58.24	
	Median	60	
	Min-Max	33-78	
Sex	Male	12 (32.4)	
	Female	25 (67.6)	
		DN	**CX**
Localization of the restoration	Maxilla	24	24
	Mandible	13	13
Type of tooth restored	Canine	3	2
	Premolar	32	28
	Molar	2	7

Thirty-seven patients with thirty-seven pairs of teeth (seventy-four teeth in total) were enrolled in this study. Baseline characteristics are presented in Table 4. At the one-month evaluation, the recall rate was 100%. However, at the six-month evaluation, one pair of restorations dropped out because of the death of a patient, leading to a recall rate of 97.3%.

At the one-year evaluation, another patient was lost to follow-up, resulting in a recall rate of 94.6%. Meanwhile, in another case, the record was unclear and an inappropriate shade of resin composite was used from the beginning of the procedure. Consequently, this pair was excluded from the assessment even though follow-up was completed.

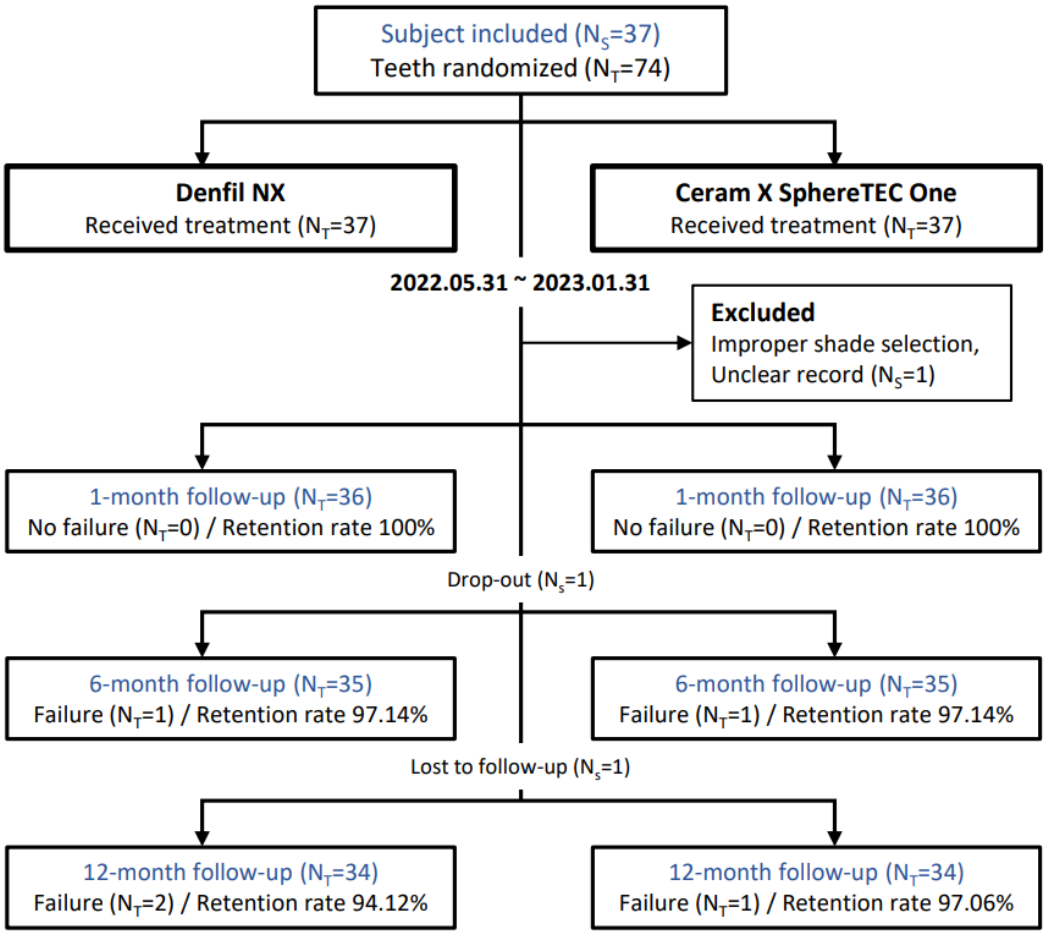

Fig 1. Flow diagram

2. Retention rate

A total of seventy-two restorations (DN 36, CX 36) from thirty-six patients were evaluated at the one-month recall. Regarding ‘fracture of material and retention (B5)’, as the primary efficacy variable, there were only clinically acceptable scores for both materials. Therefore, both DN and CX groups maintained a 100% retention rate at this time point.

At the six-month follow-up, seventy restorations (DN 35, CX 35) from thirty-five patients were evaluated. None of the restorations were completely lost; however, one restoration in the DN group had a partial fracture at the beveled area and one restoration in the CX group had a partial fracture at the cervical margin leading to dentin exposure. Both were considered clinically unacceptable, resulting in a retention rate of 97.14% for both DN and CX groups.

At the one-year recall, sixty-eight restorations (DN 34, CX 34) from thirty-four patients underwent evaluation. One additional case in the DN group exhibited a partial fracture in the mesial portion, which was considered clinically unacceptable. No additional fractures were found in the CX group. Retention rates for the DN and CX groups were 94.12% and 97.06%, respectively. However, there was no significant difference between the two materials.

3. Clinical performance according to the FDI criteria

3.1. Agreement rate between examiners

Among all evaluated FDI criteria in all patients using a five-score scale, dissents between the two examiners at baseline, one-month, six-month, and one-year assessments amounted to 13.01%, 15.40%, 16.75%, and 19.52%, respectively. The overall percent agreement was 83.88%.

When these assessments were dichotomized into the clinical evaluation score (clinically acceptable or unacceptable), there were dissenting scores of 0.76%, 1.14%, 1.43%, and 2.01% noted between the two examiners at the baseline, one-month, six-month, and one-year evaluation points, respectively. The overall percent agreement was 98.68%. The Cohen's kappa coefficient yielded non-significant values in this study.

3.2. Esthetic properties

Table 5 shows the clinical data for all pairs of restorations at each examination time point (baseline, 1-mo, 6-mo, 12-mo) for selected criteria from the esthetic properties panel.

For ‘surface lustre (A1)’ and ‘surface and marginal staining (A2)’, there were only clinically acceptable scores (scores 1-3) for both materials at all examination time points. With respect to ‘surface staining (A2a)’, both DN (score 1; baseline: 100%; 1-mo: 91.7%; 6-mo: 94.3%; 12-mo: 88.2%) and CX (score 1; baseline: 97.2%; 1-mo: 91.7%; 6-mo:

94.3%; 12-mo: 82.4%) showed clinically excellent aspect, with the DN group having a slightly higher percentage. But there were no significant differences.

In terms of 'color match and translucency (A3)', one of the DN group received a score of 4, indicating clinical unacceptability, at the one-month and one-year evaluations. However, the CX group only presented clinically acceptable scores (scores 1-3). Nevertheless, there were no significant differences observed at any of the four examination time points. Clinical examples of both materials are depicted in Figure 2.

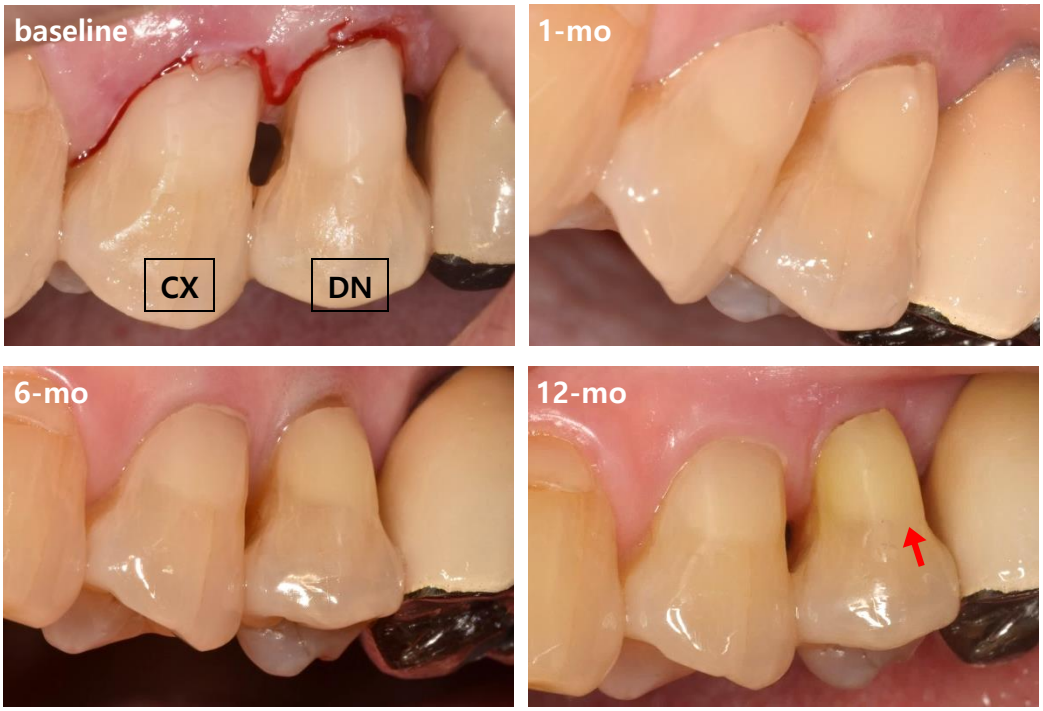

Fig 2. Exemplary depiction of differences in 'color match and translucency' between the two materials. CX restoration on tooth 24, DN restoration on tooth 25. Top row; baseline and 1-mo, Bottom row; 6-mo and 12-mo. Note the alteration in color of the DN restoration at 12-mo (indicated by red arrow), which was evaluated as clinically unacceptable.

Table 5. Clinical data for the esthetic properties. Frequencies of FDI scores 1–5 (number of restorations (n) and percentages (%)) are depicted for DN and CX. Clinically acceptable scores (1–3) are highlighted in blue, non-acceptable scores are highlighted in red. *p*-values show significant differences between materials at a respective examination time.

FDI criteria	Examination time point		DN					CX					Significant difference
			FDI score					FDI score					
			1	2	3	4	5	1	2	3	4	5	
A1 Surface luster	baseline	n	**25**	**10**	**1**	-	-	**25**	**10**	**1**	-	-	-
		%	69.4	27.8	2.8			69.4	27.8	2.8			
	1-mo	n	**26**	**9**	**1**	-	-	**22**	**12**	**2**	-	-	-
		%	72.2	25.0	2.8			61.1	33.3	5.6			
	6-mo	n	**25**	**9**	**1**	-	-	**22**	**13**	-	-	-	-
		%	71.4	25.7	2.9			62.9	37.1				
	12-mo	n	**23**	**9**	**2**	-	-	**20**	**14**	-	-	-	-
		%	67.6	26.5	5.9			58.8	41.2				
A2a Surface staining	baseline	n	**36**	-	-	-	-	**35**	**1**	-	-	-	-
		%	100.0					97.2	2.8				
	1-mo	n	**33**	**3**	-	-	-	**33**	**3**	-	-	-	-
		%	91.7	8.3				91.7	8.3				
	6-mo	n	**33**	**2**	-	-	-	**33**	**2**	-	-	-	-
		%	94.3	5.7				94.3	5.7				
	12-mo	n	**30**	**4**	-	-	-	**28**	**6**	-	-	-	-
		%	88.2	11.8				82.4	17.6				
A2b Marginal staining	baseline	n	**36**	-	-	-	-	**36**	-	-	-	-	-
		%	100.0					100.0					
	1-mo	n	**33**	**3**	-	-	-	**33**	**3**	-	-	-	-
		%	91.7	8.3				91.7	8.3				
	6-mo	n	**29**	**5**	**1**	-	-	**29**	**6**	-	-	-	-
		%	82.9	14.3	2.9			82.9	17.1				
	12-mo	n	**24**	**9**	**1**	-	-	**24**	**10**	-	-	-	-
		%	70.6	26.5	2.9			70.6	29.4				
A3 Color match and translucency	baseline	n	**4**	**25**	**7**	-	-	**6**	**28**	**2**	-	-	-
		%	11.1	69.4	19.4			16.7	77.8	5.6			
	1-mo	n	**18**	**16**	**1**	**1**	-	**9**	**24**	**3**	-	-	-
		%	50.0	44.4	2.8	2.8		25.0	66.7	8.3			
	6-mo	n	**21**	**13**	**1**	-	-	**14**	**20**	**1**	-	-	-
		%	60.0	37.1	2.9			40.0	57.1	2.9			
	12-mo	n	**17**	**16**	-	**1**	-	**10**	**23**	**1**	-	-	-
		%	50.0	47.1		2.9		29.4	67.6	2.9			

3.3. Functional properties

Table 6 shows the clinical data for all pairs of restorations at each examination time point (baseline, 1-mo, 6-mo, 12-mo) for selected criteria from the functional properties panel.

For ‘fracture of material and retention (B5)’, all restorations were clinically acceptable (score 1-3) until the one-month follow-up. However, at the six-month evaluation, one restoration in each of the two groups received a clinically unacceptable score (score 4). One case in the DN group exhibited a partial fracture of the restoration at the beveled area, while another case in the CX group showed a partial fracture at the cervical margin. In addition, at the one-year evaluation, another case in the DN group had a partial fracture in the mesial portion, which was also rated as score 4. But there were no significant differences observed between the groups. Examples of the fractured restorations are shown in Figure 3.

Similarly, for ‘marginal adaptation (B6)’, all restorations had clinically acceptable scores (score 1-3), except for two cases in the DN group (score 4). Also, both DN (score 1; baseline: 69.4%; 1-mo: 66.7%; 6-mo: 62.9%; 12-mo: 58.8%) and CX (score 1; baseline: 83.3%; 1-mo: 66.7%; 6-mo: 57.1%; 12-mo: 55.9%) showed a gradual decrease in the proportion of clinically excellent aspect. However, there were no significant differences between the two materials for this criterion.

Regarding ‘radiographic examination (B9)’, a fracture line was detected on one CX restoration from the one-month recall, resulting in a score of 5. (Fig 4) Although a fracture line was observed on the radiograph, no actual loss of restoration occurred, and the

restoration was maintained over the one-year follow-up. Other restorations received clinically acceptable scores, and there were no significant differences.

Both materials showed similar results in 'patient's view (B10)', with no significant differences observed. Some patients reported minor discomfort with both materials, such as slight lack of chewing comfort at the one-month examination point, but after six months all these minor issues appeared to have resolved.

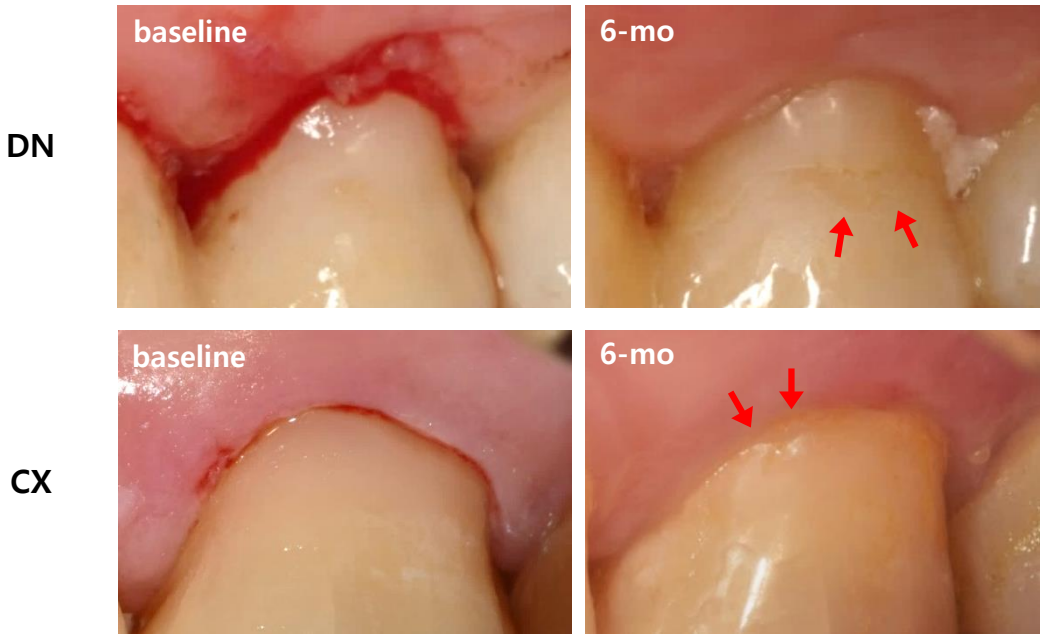

Fig 3. Exemplary depiction of clinically unacceptable cases in 'fracture of material and retention' of both materials. Top row; DN restoration on tooth 25 at baseline and 6-mo, Bottom row; CX restoration on tooth 26 at baseline and 6-mo. Material chip fractures occurred (indicated by red arrows), damaging the marginal quality.

Table 6. Clinical data for the functional properties. Frequencies of FDI scores 1–5 (number of restorations (n) and percentages (%)) are depicted for DN and CX. Clinically acceptable scores (1–3) are highlighted in blue, non-acceptable scores are highlighted in red. *p*-values show significant differences between materials at a respective examination time.

FDI criteria	Examination time point		DN					CX					Significant difference
			FDI score					FDI score					
			1	2	3	4	5	1	2	3	4	5	
B5 Fracture of material and retention	baseline	n	**36**	-	-	-	-	**36**	-	-	-	-	-
		%	100.0					100.0					
	1-mo	n	**34**	**1**	**1**	-	-	**35**	-	**1**	-	-	-
		%	94.4	2.8	2.8			97.2		2.8			
	6-mo	n	**31**	**1**	**2**	**1**	-	**33**	-	**1**	**1**	-	-
		%	88.6	2.9	5.7	2.9		94.3		2.9	2.9		
	12-mo	n	**28**	**3**	**1**	**2**	-	**31**	-	**2**	**1**	-	-
		%	82.4	8.8	2.9	5.9		91.2		5.9	2.9		
B6 Marginal adaptation	baseline	n	**25**	**8**	**3**	-	-	**30**	**3**	**3**	-	-	-
		%	69.4	22.2	8.3			83.3	8.3	8.3			
	1-mo	n	**24**	**8**	**4**	-	-	**24**	**8**	**4**	-	-	-
		%	66.7	22.2	11.1			66.7	22.2	11.1			
	6-mo	n	**22**	**7**	**4**	**2**	-	**20**	**10**	**5**	-	-	-
		%	62.9	20.0	11.4	5.7		57.1	28.6	14.3			
	12-mo	n	**20**	**7**	**5**	**2**	-	**19**	**10**	**5**	-	-	-
		%	58.8	20.6	14.7	5.9		55.9	29.4	14.7			
B9 Radiographic examination	baseline	n	**25**	**10**	**1**	-	-	**27**	**9**	-	-	-	-
		%	69.4	27.8	2.8			75.0	25.0				
	1-mo	n	**26**	**9**	**1**	-	-	**27**	**8**	-	-	**1**	-
		%	72.2	25.0	2.8			75.0	22.2			2.8	
	6-mo	n	**24**	**10**	**1**	-	-	**25**	**9**	-	-	**1**	-
		%	68.6	28.6	2.9			71.4	25.7			2.9	
	12-mo	n	**23**	**8**	**3**	-	-	**26**	**7**	-	-	**1**	-
		%	67.6	23.5	8.8			76.5	20.6			2.9	
B10 Patient's view	baseline	n	**36**	-	-	-	-	**36**	-	-	-	-	-
		%	100.0					100.0					
	1-mo	n	**33**	**1**	**2**	-	-	**32**	**1**	**3**	-	-	-
		%	91.7	2.8	5.6			88.9	2.8	8.3			
	6-mo	n	**35**	-	-	-	-	**35**	-	-	-	-	-
		%	100.0					100.0					
	12-mo	n	**34**	-	-	-	-	**34**	-	-	-	-	-
		%	100.0					100.0					

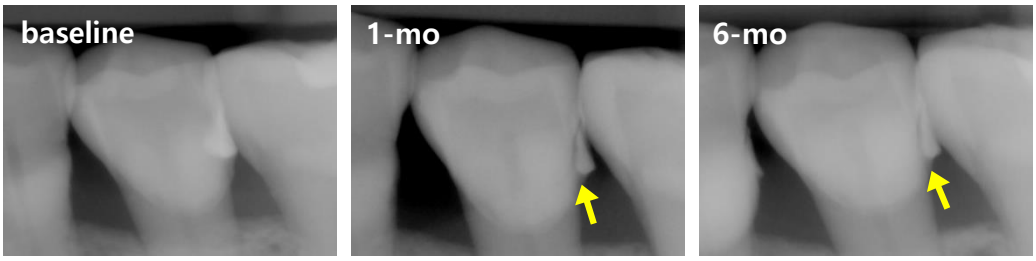

Fig 4. Radiographic image of a clinically unacceptable case in 'radiographic examination'. CX restoration on tooth 35 of a 67-year-old female patient. A fracture line was detected (indicated by yellow arrows) from the one-month recall, resulting in score 5.

3.4. Biological properties

Table 7 shows the clinical data for all pairs of restorations at each examination time point (baseline, 1-mo, 6-mo, 12-mo) for selected criteria from the biological properties panel. There were only clinically acceptable scores (scores 1–3) for both materials at all study time points.

There were no statistically significant differences in 'postoperative sensitivity and tooth vitality (C11)'. Mild hypersensitivity was observed in some DN and CX restorations at the one-month examination time point, but no sensitivity was observed in either group after one year. Additionally, neither group experienced any recurrence of caries, erosion, or abfraction during the one-year follow-up period (C12).

For 'adjacent mucosa (C15)', both DN (score 1; baseline: 100%; 1-mo: 91.7%; 6-mo: 82.9%; 12-mo: 76.5%) and CX (score 1; baseline: 100%; 1-mo: 88.9%; 6-mo: 88.6%; 12-mo: 85.3%) exhibited a decrease in score 1 values over time, and the DN group showed a greater decline. At the one-year evaluation, the DN group resulted in a significantly worse

adjacent mucosal condition than the CX group (p=0.025), but all restorations were in clinically acceptable limits. Figure 5 shows clinical examples.

Table 7. Clinical data for the biological properties. Frequencies of FDI scores 1–5 (number of restorations (n) and percentages (%)) are depicted for DN and CX. Clinically acceptable scores (1–3) are highlighted in blue, non-acceptable scores are highlighted in red. p-values show significant differences between materials at a respective examination time.

FDI criteria	Examination time point		DN					CX					Significant difference
			FDI score					FDI score					
			1	2	3	4	5	1	2	3	4	5	
C11 Posteoperative sensitivity and tooth vitality	baseline	n	**36**	-	-	-	-	**36**	-	-	-	-	-
		%	100.0					100.0					
	1-mo	n	**34**	**2**	-	-	-	**33**	**3**	-	-	-	-
		%	94.4	5.6				91.7	8.3				
	6-mo	n	**33**	**2**	-	-	-	**35**	-	-	-	-	-
		%	94.3	5.7				100.0					
	12-mo	n	**34**	-	-	-	-	**34**	-	-	-	-	-
		%	100.0					100.0					
C12 Recurrence of caries, erosion, abfraction	baseline	n	**36**	-	-	-	-	**36**	-	-	-	-	-
		%	100.0					100.0					
	1-mo	n	**36**	-	-	-	-	**36**	-	-	-	-	-
		%	100.0					100.0					
	6-mo	n	**35**	-	-	-	-	**35**	-	-	-	-	-
		%	100.0					100.0					
	12-mo	n	**34**	-	-	-	-	**34**	-	-	-	-	-
		%	100.0					100.0					
C15 Adjacent mucosa	baseline	n	**36**	-	-	-	-	**36**	-	-	-	-	-
		%	100.0					100.0					
	1-mo	n	**33**	**3**	-	-	-	**32**	**3**	**1**	-	-	-
		%	91.7	8.3				88.9	8.3	2.8			
	6-mo	n	**29**	**6**	-	-	-	**31**	**4**	-	-	-	-
		%	82.9	17.1				88.6	11.4				
	12-mo	n	**26**	**6**	**2**	-	-	**29**	**5**	-	-	-	0.025
		%	76.5	17.6	5.9			85.3	14.7				

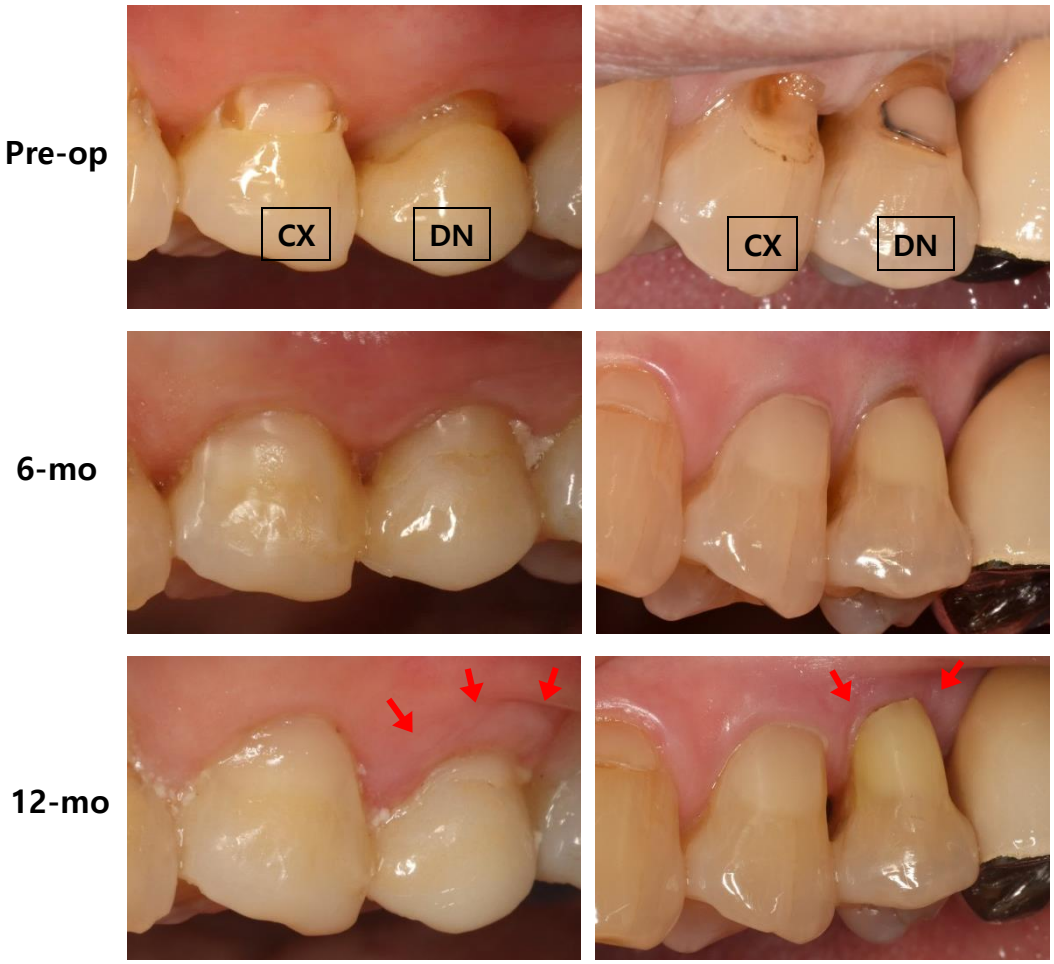

Fig 5. Exemplary depiction of differences in 'adjacent mucosa' between the two materials. Two 69-year-old female patients with CX restoration on tooth 24 and DN restoration on tooth 25. At 12-mo, gingival swelling around DN restorations was observed (indicated by red arrows), and these findings were not observed around CX restorations of adjacent teeth.

IV. Discussion

Resin composites are presently the favored substances for direct dental restorations (Moraschini et al. 2015), and fillers are responsible for most of the mechanical properties of the restorations. (Habib et al. 2016) Accordingly, ongoing research is typically dedicated to the advancement and fine-tuning of fillers, including considerations such as the type of filler used (e.g., silica, zirconia, hydroxyapatite), its dimensions, and geometric configuration. (Habib et al. 2016; Rodríguez, Kriven, and Casanova 2019; Wille et al. 2016) The introduction of nanotechnology also represents a recent advancement within the domain of resin composites. (Angerame and De Biasi 2018) Resin composites infused with nanoparticles have recently been introduced and have found widespread use in operative dentistry. According to the manufacturers, these resin composites exhibit enhanced esthetic qualities and improved mechanical and physical resistance in the oral conditions. (Mitra 2012; Senawongse and Pongprueksa 2007) In addition, these materials exhibit improved surface smoothness, wear resistance, and a low marginal microleakage level owing to the reduced size of particles and increased filler content. (Terry 2004; Sadeghi, Davari, and Lynch 2013)

The present prospective split-mouth randomized controlled trial demonstrated that class V restorations made with two nanohybrid resin composites, DN and CX, performed similarly in terms of retention and clinical performance over a one-year observation period,

except for the FDI criteria's 'adjacent mucosa' category where DN exhibited inferior biological properties compared to CX. Therefore, the null hypothesis of no difference between the two materials can be partially rejected.

A pair of restorations were excluded from the evaluation even though the follow-up was complete. The exclusion resulted from unclear documentation and incorrect shade selection from the beginning of the procedure. Shade selection has been considered a subjective process that depends on several influences, including the light source, the object, and the observer. (Takatsui et al. 2012) Even if a unified method was used, it remains difficult to select and reproduce the exact color and translucency of natural teeth. This error resulted in clinically unacceptable scores from the baseline evaluation, and both examiners agreed to exclude the pair from the assessment. The use of digital photography and spectrophotometric measurements in the shade selection procedure would have resulted in reduced color discrepancies and fewer incorrect shade matches. (Hardan et al. 2022)

In this study, the retention rates for the DN and CX groups were 94.12% and 97.06%, respectively. Within the DN group, two restorations had to be repaired. One case was restored in an upper left second molar of a 78-year-old female patient and another case was restored in an upper right second premolar of a 69-year-old female patient. Meanwhile, there was one restoration requiring repair in the CX group, which was restored in an upper left first molar of a 44-year-old female patient. But there was no significant difference between the two groups. In addition, while the fractures in these cases were located at the restoration margin and deemed clinically unacceptable based on FDI criteria, it should be

noted that they were small in size and there was no loss of more than half of the restoration. Thus, it can be concluded that both materials demonstrated comparably acceptable retention performance.

Although the failure rate is low, a limitation of this study is that the patient characteristics and specific conditions in the oral cavity were not considered in the evaluation. Proper operative technique is not the only factor in the longevity of resin composite restorations on non-carious cervical lesions. The higher failure rates of restorations on these lesions can be attributed to the role of mechanical stresses due to occlusal loading at the cervical margin leading to cuspal flexure and lack of mechanical retention. (Vasudeva et al. 2011) Lower retention rate, more marginal discoloration and defects can be observed in restorations in non-carious cervical lesions with occlusal wear facets. (Oginni and Adeleke 2014) Therefore, individuals who have parafunctional habits or suffer from temporomandibular disorders like bruxism appear to have a notably increased likelihood of experiencing restoration failures in their posterior teeth. Those with a high susceptibility to dental caries are also at a higher risk of restoration failure due to secondary dental caries. (Nedeljkovic et al. 2015) Given this perspective, it would have been more advantageous if this study had excluded individuals with poor oral hygiene or parafunctional habits and bruxism from its participant criteria. Although the split-mouth design used in this study is considered preferable to a parallel design for the clinical evaluation of restorative materials because these factors affect both groups equally (Tobi et al. 1998), more material-specific results could have been obtained by controlling patient-related aspects.

The two nanohybrid resin composites used in this study are similar in that they both have adjusted filler systems to minimize polymerization shrinkage and pursue esthetics through the chameleon effect. Results of the year-long observation indicated no detectable occurrences of secondary dental caries or hypersensitivity caused by polymerization shrinkage. Moreover, marginal discoloration remained within clinically acceptable thresholds. In addition, both materials showed an improvement in shade and translucency up to six months after placement compared to immediately following placement, indicating a satisfactory blending effect. All patients expressed complete satisfaction with their restorations at the one-year evaluation. Therefore, it can be concluded that both DN and CX as nanohybrid resin composites have outstanding clinical performance, both functionally and esthetically.

The evaluation category that showed a significant difference in this study was ‘adjacent mucosa’ in the biological property. At the one-year evaluation, gingival swelling was observed around two DN restorations, which differed from adjacent teeth restored with CX. However, according to an *in vitro* study by Jiang et al. investigating the cytotoxicity and reactive oxygen species production of nanohybrid resin composites, DN had lower cytotoxicity and higher cell viability than CX, which may be due to the lower content of matrix monomer and the absence of any fluoride compounds in DN. (Jiang et al. 2023) In addition, both cases received clinically unacceptable scores for ‘fracture of material and retention’ and ‘marginal adaptation’, suggesting that the alteration of adjacent periodontal tissue was likely caused by facilitated plaque deposition around the restoration. Therefore,

the gingival change was not considered to be causally related to the restoration itself, and a score of 3 was assigned by agreement between the two examiners. Meanwhile, since both types of restorations showed an increase in higher scores regarding the ‘adjacent mucosa’ and ‘marginal adaptation’, the two parameters appear to be related, highlighting the critical role of marginal adaptation quality in maintaining periodontal health. (Lang, Kiel, and Anderhalden 1983)

V. Conclusion

In conclusion, the null hypothesis that there is no difference between the two nanohybrid resin composites can be partially rejected. Over the one-year observation period, both materials showed satisfactory retention and similar functional and esthetic clinical performance in the direct restoration of non-carious cervical lesions. For the biological properties, DN exhibited slightly inferior but clinically acceptable outcomes when in comparison to CX. Further evaluations are necessary regarding the long-term clinical performance of these nanohybrid resin composites.

VI. Acknowledgements

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Abstract (In Korean)

비우식성 치경부 병소에서 나노 하이브리드 복합 레진의 임상적 수행 능력에 관한 무작위 배정 임상 시험의 1년 결과

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본 연구의 목적은 비우식성 치경부 병소의 직접 수복에 있어서 Denfil NX 복합 레진(DN; Vericom, Chuncheon, South Korea)의 임상적 수행 능력을 무작위 배정 임상 시험을 통해 기존의 나노 하이브리드 복합 레진인 Ceram X SphereTEC One(CX; Dentsply Sirona, Charlotte, USA)과 비교하여 평가하기 위함이다.

연세대학교 치과대학병원 치과보존과에 내원한 37 명의 환자를 대상으로 한 전향적 무작위 대조 구강 분할 연구가 진행되었으며, 2 명의 교수 및 16 명의 전공의를 포함한 총 18 명의 술자가 술식을 시행하였다. 기록이 불명확하고 색조 선정 과정의 오류가 있었던 한 쌍의 수복물을 제외하고 총 72 개의 5 급 와동 수복물이 평가에 포함되었으며, 환자마다 두 그룹에서 각각 하나의 재료로 수복치료를 시행하였다. (DN 그룹: n=36, Denfil NX; CX 그룹: n=36, Ceram X SphereTEC One). 수복물에 대한 임상 평가는 수복 직후(baseline) 및 술 후 1 개월, 6 개월, 1 년 내원 시 선정된 11 가지의 FDI 임상기준 및 점수체계에 따라 두 명의 검사자가 시행하였으며, 이를 Wilcoxon signed−rank test 를 사용하여 분석하였다.

6 개월 평가에서 한 명의 환자가 사망하였고, 1 년 평가에서 다른 한 명의 추적관찰이 중단되었다. 1 차 유효성 변수로서 ‘fracture of material and retention (B5)’ 점수를 기준으로 유지율을 제시하였다. 6 개월 평가 시점에서 두 그룹에서 각각 1 개의 수복물과, 12 개월 평가 시점에서 DN 그룹에서 추가적인 1 개의 수복물의 부분적인 파절이 관찰되어, 이는 임상적으로 부적절한 것으로 평가되었다. 이에 DN 그룹과 CX 그룹의 유지율은 각각 94.12%와 97.06%였다. 그러나 수복물이 완전히 탈락한 경우는 없었으며, 두 그룹 간의 유의미한 차이는 없었다.

‘Adjacent mucosa (C15)’ 항목을 제외한 다른 평가 기준에서는 두 그룹 간에 유의한 차이가 없었으며, 해당 항목에서는 DN 그룹이 CX 그룹보다 더 열등한 결과를 보였다. (p=0.025). 그러나 모든 수복물이 임상적으로 허용 가능한 범위 내에 있었으며, 인접 조직의 변화는 수복물 자체보다는 수복물의 부적절한 변연과 관련된 이차적인 결과로 추정된다.

결론적으로, 비우식성 치경부 병소의 직접 복합 레진 수복을 대상으로 한 1 년의 추적 관찰에서 Denfil NX 와 Ceram X SphereTEC one 은 모두 충분한 유지력 및 유사한 기능적, 심미적 임상 수행 능력을 나타내었다. Denfil NX 는 Ceram X SphereTEC One 에 비해 생물학적 특성이 다소 떨어지나 임상적으로는 완전히 허용 가능한 결과를 보인다.

핵심 되는 말 : 비우식성 치경부 병소; 나노 하이브리드 복합레진; 치과용 재료; FDI 임상 평가 기준; 무작위대조시험