 DOI: 10.21608/adjalexu.2024.279575.1492

CLINICAL PERFORMANCE OF AN ALKASITE BASED RESTORATIVE MATERIAL (A SPLIT MOUTH RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: Cention N, is a newly introduced alkasite restorative which incorporates unique reactive fillers. Its potential significance in restorative dentistry lies in its capability to decrease polymerization shrinkage and facilitate the remineralization of carious lesions.

AIM OF THE STUDY: Assessing the clinical effectiveness of Cention N, a novel alkasite bioactive restorative material, in comparison to a traditional bulk fill composite resin.

MATERIALS AND METHODS: A sample of 12 participants with two or more class I cavities, were assigned randomly to two research groups. One tooth underwent restoration with Cention N, while the counterpart tooth received treatment with Filtek Bulk Fill. The restorations were observed and evaluated utilizing the World Dental Federation (FDI) criteria at baseline (one week), three, and six-month intervals. In this trial, postoperative sensitivity, recurrent caries, and marginal staining were evaluated. To compare between the groups, the chi-square test and the Monte Carlo correction were applied. Friedman's test was utilized to assess variations within each study group at each time interval as well as the differences between time intervals. A significance level of ($P \leq 0.05$) was adopted for each test.

RESULTS: Clinically acceptable FDI scores were recorded for every restoration, at each time interval, and for every criterion. No discernible difference ($p \geq 0.05$) in the clinical performance between the two research groups was observed at baseline or during the three- and six-month follow-up periods.

CONCLUSION: In terms of clinical performance over the span of six months, both tested materials showed comparable results.

KEYWORDS: Cention N, class I cavity, bulk fill, FDI criteria, clinical performance.

RUNNING TITLE: Clinical performance of Cention N

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INTRODUCTION

The most widely used direct restorative material at the present time is composite resin. Since their introduction, they have undergone major modifications and advancements leading to substantial improvements in their clinical performance (1,2). Incidentally, bulk fill composites have surfaced to serve as successors to the traditional incrementally filled composites, which assert that composite restorations can be applied in layers up to 4-5 mm thick (3). Bulk fill composites surpass their predecessors in terms of wear resistance, reduced polymerization shrinkage, and enhanced curing depth. Bulk cavity fillings also have advantages like reduced treatment time, less air void entrapment, and higher-quality final restorations (4,5).

Nevertheless, it is noteworthy to acknowledge the likelihood of marginal gap occurrence in any material that sets through polymerization, and to recognize the potential consequences, which include microleakage, post-operative hypersensitivity, staining, and secondary caries. To address these issues, the optimal solution involves developing materials with reactive fillers designed to provide a protective barrier against secondary caries (6). These substances are classified as "bioactive restoratives," according to Vallitu et al (7,8).

Bioactive materials release different remineralizing ions into the oral cavity, enhancing the longevity of restorations and lowering the incidence of recurrent caries (9,10).

Furthermore, they respond to pH variations, neutralizing the oral environment, eliminating bacteria, and encouraging remineralization in the process. To tackle challenges related to the polymerization shrinkage of resin-based restoratives and the mechanical limitations associated with Glass Ionomer Cements (GICs), new dental materials have been recently created (11).

One of the notable materials in this category is the innovative dual-cured, bioactive resin known as Cention N. This newly developed tooth-

colored filling material is designed for bulk application and falls within the composite resin subgroup (12,13). It is marketed as an amalgam substitute with great flexural strength and is indicated for permanent restorations in Class I, II, or V cavities, in addition to deciduous teeth (14). This alkasite contains alkaline fillers which release "acid-neutralizing" ions in addition to iso fillers which decrease polymerization shrinkage (15,16). Since the introduction of Cention N, various in vitro research (17-20) has been carried out to evaluate several characteristics; nevertheless, clinical investigations have not yet fully validated its clinical behaviour. Consequently, the goal of this trial was to assess the clinical performance of an alkasite material in Class I cavities over a six-month period by comparing it with a conventional bulk fill composite. The null hypothesis was that there would be no difference in clinical performance of the alkasite resin composite and bulk fill resin composite in restoring class I cavities.

MATERIALS AND METHODS

Ethical Considerations

The Alexandria University Faculty of Dentistry's Ethical Committee granted ethical approval; with the reference number (0453-6/2022). All patients signed informed consent prior to beginning any treatment after being educated about the purpose, methods, risks, and benefits of the trial.

Patients

Twelve participants with a minimum of two class I cavities were selected for this trial. Subjects were chosen from the Conservative Dentistry Department Clinics, Faculty of Dentistry, Alexandria University. Volunteers were assigned randomly into two study groups; Group (I) Cention N and Group (II) Filtek Bulk Fill posterior composite. Patients received one CN and one FBF restoration each, resulting in a total of twenty-four restorations. (Figure 1)

Inclusion criteria

For this clinical investigation, twelve participants with occlusal pit and fissure caries, and good oral hygiene with ages ranging from 18 to 45 were chosen. Additionally, occlusal contact with opposing teeth should be present.

Exclusion criteria

Teeth that showed signs of any pathologic pulpal disease, wear-related surface loss, or were deemed inappropriate for rubber dam isolation were excluded from this trial. Furthermore, teeth with prior restorations and any flawed restorations opposing to or adjacent to the affected tooth were further rejected (21).

Materials

The materials utilized in this trial were:

Cention N.

N-etch.

Tetric N Bond universal.

Filtek Bulk Fill posterior composite.

Methods

Preoperative assessment

The medical and dental histories of all research participants were documented Preoperative sensitivity was assessed using, air stimulus by applying air from a dental syringe with a standardized distance of 5 mm . To shield the neighbouring teeth from the air effect, cotton rolls were placed over them (21,22). All groups went through the following process preceding the restorative application:

One week prior to the intervention, all subjects received instructions on maintaining good oral hygiene (23). Oral prophylaxis was carried out using a low-speed handpiece and pumice slurry applied with a rubber cup, followed by rinsing and drying to remove any remaining biofilm (24). Preoperative intraoral digital photographs and radiographs were also obtained.

Clinical procedure

Both teeth received class I cavity preparation using a 245-carbide bur with a high-speed handpiece under ample amount of water. The bur was replaced after 5 cavities. The carious lesion's dimensions dictated the cavity's geometry. The cavity's depth of 1.25 to 1.5 mm was further determined using a periodontal probe to ensure uniformity in cavity size (16,22,25). Pulpal walls were made flat with rounded line and point angles.

To ensure complete moisture control, rubber dam was utilized for tooth isolation following preparation. Cavities were then cleaned, dried, and inspected for debris. The teeth were allocated at random into two groups: Group (I) Cention N, Group (II) Filtek Bulk Fill posterior composite.

Group I: Selective enamel etching of the prepared cavity was carried out for 15 seconds with N-etch (Ivoclar Vivadent AG Bendererstr. 2 9494 Schaan Liechtenstein). Thorough rinsing of the etchant with a water jet followed by gentle drying with an air jet (16,21). Using a disposable applicator, the dentin and enamel surfaces were covered with a substantial coating of Tetric N Bond universal (Ivoclar Vivadent AG Bendererstr. 2 9494 Schaan Liechtenstein). The adhesive was carefully brushed into the dentin for at least 10 seconds. To ensure that the enamel and dentin are completely covered by the adhesive without pooling, a gentle air stream was utilized to remove the surplus material followed by a 10 second light cure (16). Cention N (Ivoclar Vivadent AG Bendererstr. 2 9494 Schaan Liechtenstein) was manually mixed using the standard 4.6:1 powder to liquid ratio (one scoop of powder for every drop of liquid) following the manufacturer's instructions. The powder and liquid were dispensed onto the mixing pad and combined until a uniform consistency was reached, using a plastic spatula (45- 60 s). From the onset of the mixing, the working period lasted three minutes. The

application of Cention N (shade A2) was done in bulk, with careful adaptation and condensing (16,21) followed by removal of any occlusal excess, preliminary surface contouring then a 20-second light cure. (Figure 2)

Group II: Selective enamel etching of the prepared cavity was carried out for 15 seconds with N-etch (Ivoclar Vivadent AG Bendererstr. 2 9494 Schaan Liechtenstein). Thorough rinsing of the etchant with a water jet followed by gentle drying with an air jet (16,21) Using a disposable applicator, the dentin and enamel surfaces were covered with a substantial coating of Tetric N Bond universal (Ivoclar Vivadent AG Bendererstr. 2 9494 Schaan Liechtenstein). The adhesive was carefully brushed into the dentin for at least 10 seconds.

To ensure that the enamel and dentin are completely covered by the adhesive without pooling, a gentle air stream was utilized to remove the surplus material followed by a 10 second light cure (16). Filtek Bulk Fill Posterior Restorative, (3M Center, St. Paul, MN 55144-1000, USA) was bulk filled inside the cavity and then anatomically carved followed by a 20 second light cure (25). (Figure 3)

Following removal of the rubber dam, analysis of occlusion was conducted using articulating paper, and any high points were eliminated by fine-grit diamond burs. Sequentially, rubber cups, diamond discs, and finishing and polishing burs were utilized for the final finishing of the restoration. To maintain consistency, all the operative procedures were performed by a single qualified practitioner within the conservative dentistry department.

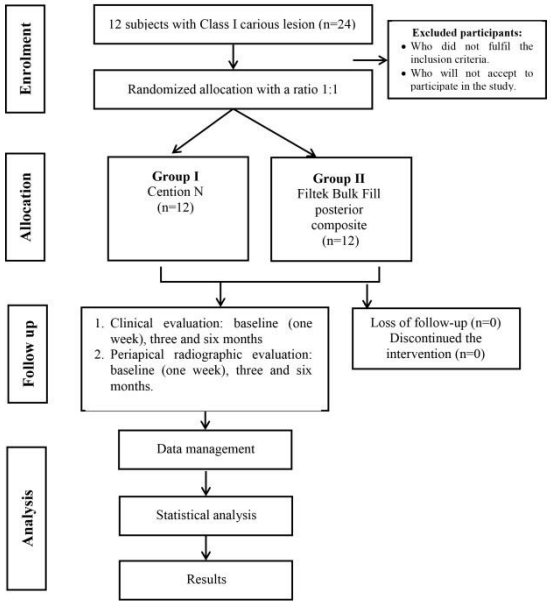
Calibration

Prior to the study, these evaluators underwent calibration through assessing twenty direct composite restorations from individuals not partaking in the study (26). Furthermore, a reproducible and standardized periapical digital radiograph was obtained by employing a paralleling cone technique using an EndoRay aiming device. All patients underwent uniform exposure parameters using a Genoray portable x-ray system, with a tube current of 2 mA, tube voltage of 60 kVp, and processed through a DIGIRAY FireCR Dental Reader. The OnDemand3D, App 1.0.9.3223 software was used to view and examine the x-rays. Prior to the evaluation, a minimum of 85% intra- and inter-examiner agreement was required.

Follow up phase

The clinical evaluation involved two qualified and experienced evaluators who did not participate in the operative process and therefore were blinded to the treatment allocation. Restoration assessments were conducted at baseline (one week), followed by evaluations at three and six months, employing the FDI criteria (Table 1). The parameters chosen for assessment were recurrent caries, marginal staining, and postoperative sensitivity. Visual and tactile examinations aided with postoperative intraoral photos, and radiographs obtained at each recall appointment were used for conducting the evaluation process. (Figures 4, 5)

Figure (1): Study design. (CONSORT) guidelines.



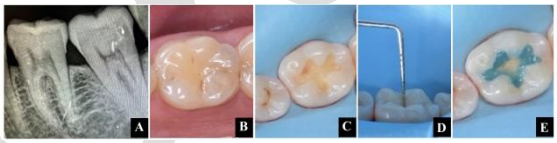


Figure 2: Complete treatment sequence of **Group I** (Cention N) (A) perioperative radiograph (B) Preoperative intraoral photograph showing pit and fissure caries, (C) class I cavity preparation, (D) measuring cavity depth (E) selective etching

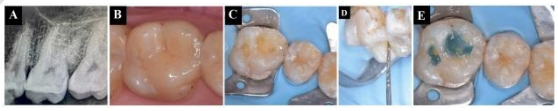


Figure 3: Complete treatment sequence of **Group II** (Filtek Bulk Fill composite) (A) perioperative radiograph (B) Preoperative intraoral photograph showing pit and fissure caries, (C) class I cavity preparation, (D) measuring cavity depth (E) selective etching,

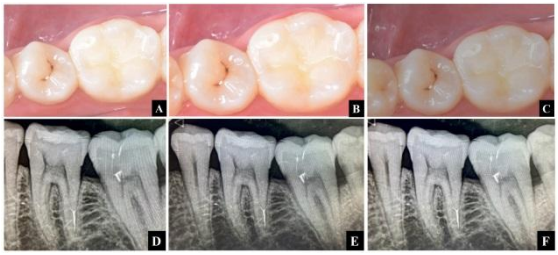


Figure 4: Complete follow up sequence of **Group I** (A-C) 1week, 3-and 6-month follow-up images,

(D-F) 1week, 3 and 6- month follow-up radiographs.

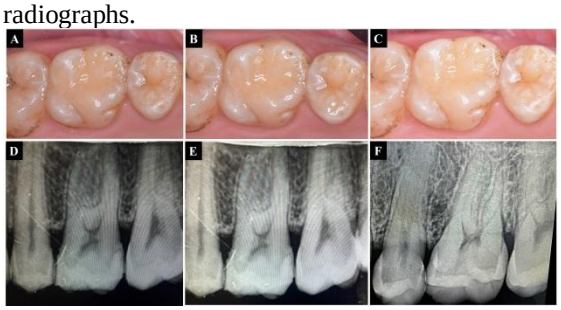


Figure 5: Complete follow up sequence of **Group II.** (A-C) 1week, 3- and 6- month follow-up images, (D-F) 1week, 3- and 6- month follow-up radiographs.

World Dental Federation's assessment criteria for dental restorations are based on a scale of 1 to 5 with the following scores: (1) clinically excellent/very good; (2) clinically good; (3) clinically satisfactory; (small flaws, no unacceptable effects, but not adjustable with/or damage to the tooth); (4) clinically unsatisfactory but repairable; and (5) clinically poor/irreparable that requires necessary replacement. Consequently, scores 1, 2, and 3 are regarded as clinically successful, while scores 4 and 5 are deemed as clinically unsuccessful.

Statistical analysis

Analysis of data was implemented employing the IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Numbers and percentages were used to display the qualitative data. To compare different groups, the chi-square test and Monte Carlo correction were used. Friedman's test was applied to assess the differences within and between each study group at each time interval. A statistical threshold of 0.05 was employed for each test.

Table (1): FDI criteria used for clinical evaluation

	Esthetic properties	**Biological properties**	
	1.Marginal staining	2.Postoperative sensitivity	3.Recurrence of caries
1. Clinically excellent/very good	1.1 No marginal staining.	2.1 No hypersensitivity, normal vitality.	3.1 No secondary or primary caries
2.Clinically good (after polishing very good)	1.2 Minor marginal staining, easily removable by polishing.	2 .2 Minor hypersensitivity for a limited period of time, normal vitality	3.2 Small and localized demineralization. No operative treatment required.
3. Clinically sufficient/ satisfactory (minor shortcomings, no unacceptable effects but not adjustable without damage to the tooth)	1.3 Moderate marginal staining, not esthetically unacceptable.	2.3.1 Moderate hypersensitivity 2.3.2 Delayed/mild sensitivity; no subjective complaints, no treatment needed	3.3 larger areas of demineralization, but only preventative measures necessary (dentin not exposed)
4.Clinically unsatisfactory (but reparable)	1.4 Pronounced marginal staining; major intervention necessary for improvement.	2.4.1 Intense hypersensitivity. 2.4.2 Delayed with minor subjective symptoms. 2.4.3 No clinical detectable sensitivity. Intervention necessary but not replacement	3.4 Caries with cavitation and suspected undermined caries localized and accessible can be repaired
5. Clinically poor (replacement necessary)	1.5 Very rough, unacceptable plaque retentive surface.	2.5 Intense, acute pulpitis or non-vital tooth. Endodontic treatment is necessary, and restoration has to be replaced.	3.5 Deep secondary caries or exposed dentin that is not accessible for repair

RESULTS

The sample comprised of 12 patients, representing a total of 24 restorations; having a 100% recall rate. The restorations were assessed at baseline (one week), three, and six-month follow-ups. Clinical results for the evaluated groups were presented in Table 2.

Regarding postoperative sensitivity, both groups, Group I (CentionN) and Group II (Filtek bulk fill) had similar initial sensitivity levels, which were temporary and decreased during the subsequent follow-up intervals. Over the course of the 6-month evaluation period, both showed declining trends in score 2, from 25% to 8.3%, yielding an ideal(score1) at 91.7% at the end of the period for Group I, while Group II had a decreasing score 2 from 25% to 16.7% recording an ideal (score 1) at 83.3%. No discernible statistical difference was detected among the two groups (p= 0.384). Concerning the two study groups, only

clinically acceptable scores were recorded (scoring 1-2) at each assessment interval, and no treatment was required. A statistically significant ($p<0.05$) difference did not exist among the groups.

In terms of marginal staining Group I (Cention N) didn't represent any marginal staining till the end of the assessment duration (score 1,100%). In Group II (Filtek bulk fill) none of the volunteers developed any staining up to the 3-month evaluation period, however at the 6-month period one case recorded minor (score 2) marginal staining yielding an ideal (score 1) at 91.7% at the end of the study. Despite the staining, the results are considered clinically acceptable with slightly inferior results in Group II. However, the two groups did not differ in a way that was statistically significant ($p<0.05$) ($p=0.384$), and only polishing is required.

Regarding recurrent caries none of the restored teeth in any study group displayed any signs of secondary caries over the evaluation period of 6 months.

Table (2): Comparison between the different studied periods according to Postoperative sensitivity and Marginal staining

		Baseline		3months		6months		Fr	p
		No.	%	No.	%	No.	%		
Postoperative sensitivity	Group I								
	1	9	75.0	11	91.7	11	91.7	1.00	0.384
	2	3	25.0	1	8.3	1	8.3		
	Group II								
	1	9	75.0	11	91.7	10	83.3	1.00	0.384
	2	3	25.0	1	8.3	2	16.7		
Marginal staining	Group I								
	1	12	100.0	12	100.0	12	100.0	–	–
	2	0	0.0	0	0.0	0	0.0		
	Group II								
	1	12	100.0	12	100.0	11	91.7	1.00	0.384
	2	0	0.0	0	0.0	1	8.3		

Fr: **Friedman test**
p: p value for comparison between the studied categories
Group I: Cention N
Group II: Composite resin (Filtek Bulk Fill)

DISCUSSION

Resin composites have undergone major advances in its formulations to address a range of clinical issues (27,28). Bulk placement techniques, simplified adhesion protocols, and innovative filler compositions have facilitated its usage.

Nevertheless, the clinical issues of technique sensitivity, polymerization shrinkage and absence of antibacterial properties still persist (29). To tackle these challenges, hybrid materials that incorporate the advantages of both composites and glass-ionomers were developed. These materials include resin-modified glass ionomer cements, compomers, giomers, and most recently bioactive composites (30).

This current investigation aimed to assess the clinical performance of a novel bioactive resin (Cention N) in comparison to a traditional bulk fill composite (Filtek bulk fill) in Class I cavities, owing to the fact that Class I cavities have the highest C- factor which is useful for the detection of microleakage. In short-term clinical trials, the FDI criteria is thought to be more sensitive and discriminatory than the USPHS criteria for identifying early minor changes, ensuring more accurate scoring. This allowed the assessment of the clinical performance of the investigated materials with respect to marginal staining, postoperative sensitivity, and secondary caries. Only relevant criteria assessing the clinical performance of bioactive restoratives derived from prior research was employed (31).

Considering that the two research groups' clinical performance does not differ in a way that is statistically significant, the null hypothesis of this investigation was accepted.

Conducting studies in laboratory settings is valuable for enhancing and assessing restorative materials initially. However, replicating the dynamic conditions of the mouth remains challenging, hindering the precise representation of the materials' clinical performance. Therefore, to compare diverse restorative materials and evaluate the effectiveness of recently developed ones, well-designed randomized controlled clinical trials are

essential, which has been implemented in this study (32).

In this trial, the bioactive material employed was Cention N, markerted as an "alkasite" material and essentially a composite subgroup. This innovative category incorporates alkaline fillers known for their high reactivity in acidic conditions, facilitating the release of acid-neutralizing ions. It also includes unique iso fillers that minimize polymerization shrinkage, behaving like a gradually expanding spring during the polymerization process. Cention N has dual curing properties allowing it to be utilized as a full volume bulk replacement. Consequently, it presents a competitive option to bulk-fill resin composites which offer easier application in fewer increments and shorter periods of time (13).

Within the present study, postoperative sensitivity has been reported more in Filtek bulk fill than Cention N. One possible explanation for this could be the presence of a highly effective self-cure initiator in Cention N, coupled with cross-linking methacrylate monomers resulting in a substantial level of polymerization throughout the restorations' depth. Additionally, the inclusion of iso-fillers in Cention N acts as a stress reliever, mitigating shrinkage forces and leading to minimal microleakage and low volumetric shrinkage.

In vivo trials assessing postoperative sensitivity in relation to Cention N are limited however, several in vitro studies examined its microleakage, which could lead to post operative sensitivity, marginal staining, and secondary caries (1). Sujith et al (15) noticed lowest microleakage with Cention-N in comparison to hybrid composites and GIC, while Sahu et al (33) observed that Cention N with adhesive exhibited lower microleakage compared to bulk fill composite. These results align with our own research outcome. However, in contrast to our findings, Hirani et al (21) reported a higher incidence of postoperative sensitivity in Cention N compared to ActivaTM and Equia forte.

The postoperative sensitivities noticed at baseline but subsiding before the subsequent evaluation may be as a result of the operative technique (e.g., caries excavation, rubber dam application, and drying) rather than the tested restoratives themselves. Prior clinical studies have similarly documented hypersensitivities in the initial days or weeks post-operative, which shortly resolved (24).

Group II (FBF) displayed minimal discoloration at clinically acceptable levels, while Group I (CN) exhibited no staining at the end of the evaluation period. This is likely due to both materials' low polymerization shrinkage characteristics. The material's ability to adapt at the margins is dependent on the forces created by polymerization shrinkage, which leads to debonding of the material at the tooth restoration junction and frequently results in margin discoloration (34). This may be accredited to Cention Ns' UDMA based formulation and iso-fillers with a low modulus of elasticity which reduce stress, resulting in low polymerization shrinkage. Moreover, Filtek Bulk Fill includes stress-modulating components like Aromatic Urethane Dimethacrylate (AUDMA) and Addition Fragmentation Monomer (AFM), which effectively lower shrinkage (35). Furthermore, the bulk fill placement technique of both materials contributes to further shrinkage. These results align with the research conducted by Sharma et al (36).
Both study groups exhibited no signs of recurrent caries, possibly influenced by the study's university setting, under standardized conditions with patients maintaining good oral hygiene or due to a short evaluation period. The findings align with a study by Oz et al (37) assessing Cention N's clinical performance using modified USPHS criteria. Nevertheless, several in vitro studies (6,9,18,19) have extensively investigated the ion release potential of Cention N in controlled laboratory environments.

Di Lauro et al (10) showcased Cention N's ability to efficiently release Ca^{2+} and F^{-} ions in response to variations in pH and temperature. Moreover, Vidal et al (38) demonstrated that Cention N exhibited the highest fluoride release over time. Additionally, Francois et al. (30) observed that Cention N exhibits similar chemistry to IRCs and given the fact it's the only material that has shown true bioactivity when placed without adhesive, it ought to be categorized as a new family of materials.

The study utilized a split-mouth design, enhancing the clinical examination of restorative materials by ensuring similarities in patient-related factors across groups. It is noteworthy to mention that neither a loss of follow-up nor an intervention discontinuation occurred among the recruited subjects during the trial. This degree of participant retention increases the validity of the results. Nonetheless, it's critical to acknowledge the trial's limitations in that some clinical professionals may view the manual mixing of Cention N restoration as a drawback. Moreover, future research should concentrate on patients with moderate to high caries levels, where the use of ion-releasing materials becomes crucial for aiding in remineralization amidst recurrent declines in pH. To deepen our understanding of innovative alkasite restorative materials, extending the evaluation period and increasing the sample size would be beneficial.

CONCLUSION

Both the resin composite and the alkasite-based restorative material showed clinically acceptable and comparable results, as evidenced by each

restoration receiving a "clinically acceptable" score. Thus, the innovative alkasite restorative Cention N may be indicated for clinical usage.

Conflict of interest

The authors declare that they have no conflicts of interest.

Funding

The authors did not receive specific funding for this study.

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