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Clinical evaluation of an alkasite restorative material A Three years Randomized Controlled trial

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Abstract:

Aim: to evaluate the clinical performance of an alkasite restorative material (Cention N) compared to amalgam fillings.

Materials and Methods: Thirty Patients having two similar moderate class I carious cavities of posterior teeth on different sides of the same arch and with the same order were selected. A split-mouth design was adopted. Restorations were handled, finished, and polished according to manufacturer instructions. The restorations were evaluated following the revised FDI (International Dental Federation) criteria. The restorations were evaluated regarding retention/fracture of the restoration, marginal integrity, postoperative sensitivity, and patient view. The patients were recalled for evaluation at baseline (one week from the last restoration), after six months, after one year, after two years, and after three years. Statistical analysis was performed. **Results:** For marginal integrity and retention/fracture resistance of the restoration, there was no statistically significant difference between the two groups in all recalls or even in the same group over time (P-value = 1, Effect size = 0). Post-operative sensitivity and patient view results revealed a statistically significant difference between the two groups (P-value <0.001). In all recalls both restorations were clinically acceptable. **Conclusion:** Cention N is an acceptable alternative to amalgam in class I cavities of posterior teeth.

Key words: Alkasite, Cention N, FDI Criteria, Split-Mouth.

Introduction:

Dental amalgam has been used as a posterior restoration for more than 150 years and is still used due to its durability, technique simplicity, and low cost¹⁻³. Although its safety in patients has been proven in many studies⁴⁻⁹, fear of mercury toxicity and the increased demand for an aesthetic restoration led to the decreased use of amalgam¹⁰⁻¹². The global phase-down of amalgam decision taken by the Minamata Convention on Mercury will restrict the use of amalgam in the future.

The need for a restorative material that provides durability, technique simplicity, and low cost to replace dental amalgam restorations was challenging to the restorative materials manufacturers. Manufacturers have introduced many alternatives in recent years like Giomer, Alkasites, Amalomer, and Zirconomer. One of these alternatives is Cention N, a new alkasite, tooth-coloured filling material intended for restoring deciduous and permanent teeth in class I, II, and V cavities. It releases fluoride, calcium, and hydroxyl ions. It can be used with or without adhesive. It is self-curing with optional additional light curing and is available in shade A₂. From the previous review^{13, 14} it was postulated that it would be of interest to carry out longitudinal studies to evaluate the clinical performance of this material compared to Amalgam fillings.

Null hypothesis: there will be no differences between Amalgam and Cention N fillings regarding retention/fracture of the restoration, marginal integrity of restoration, postoperative sensitivity, and patient view.

Materials and Methods:

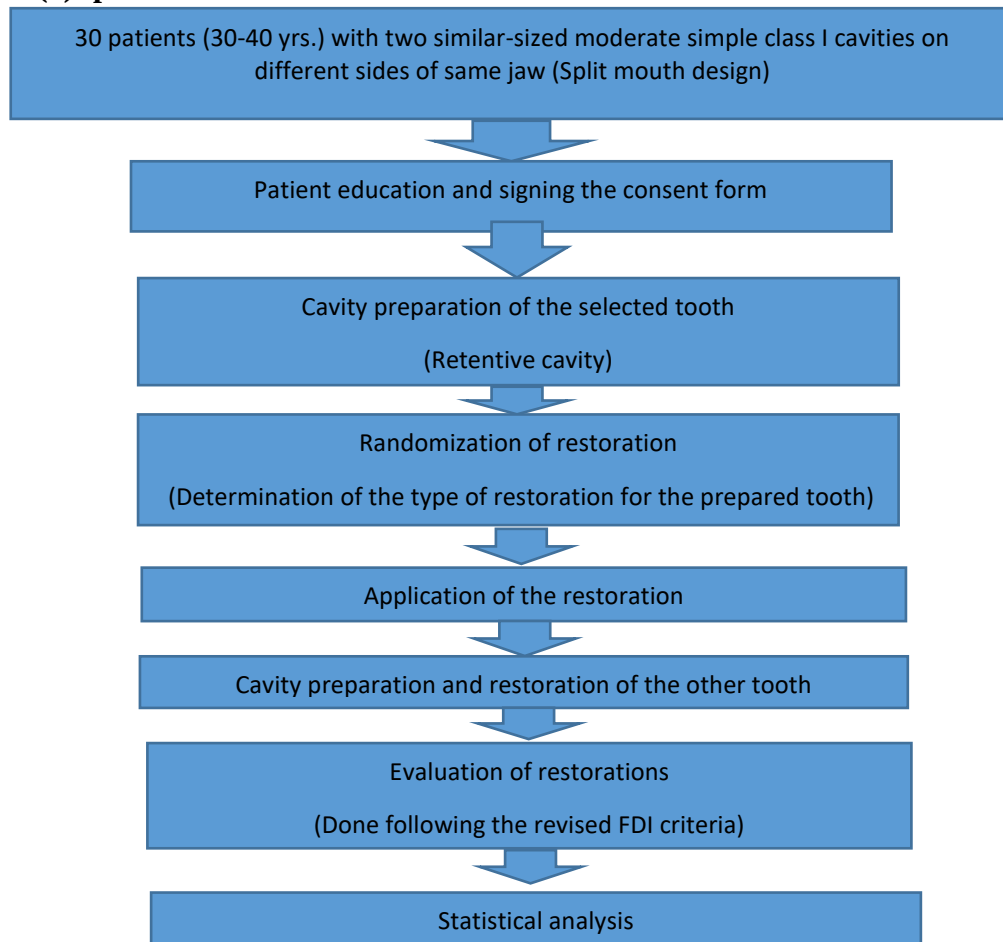
Study design: A randomized controlled clinical trial which is the gold standard in comparing new materials¹⁵⁻¹⁷, was carried out to evaluate certain criteria of Cention N (Ivoclar Vivadent, Schaan, Liechtenstein) and Amalgam (SDI, Southern Dental Industries Ltd, Australia). A split-mouth design was adopted. The study followed good clinical practice principles of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)¹⁸. *Study population:* This project has been reviewed and approved by the Ethical Committee of Al Azhar University, Faculty of Dental Medicine, Cairo, Boys (code 950/6167). *Patient education and consent form:* The selected patients have been educated about the nature of the study and signed a consent form denoting his/her approval to be enrolled in the study. *Inclusion criteria:* Patients selected having two moderate classes I carious cavities of similar size of posterior teeth;

having functional occlusion and free from symptoms of pulpitis and/or apical periodontitis. Patients were selected from the age group of 30 to 40 years old¹⁹. *Exclusion criteria:* parafunctional habits, serious illness, disability, poor oral hygiene, non-vital, fractured, mobile, or visibly cracked teeth²⁰⁻²². *Sample size determination:* $N = (Z\alpha/2)^2 s^2 / d^2$ (where N sample size, $Z\alpha/2$ normal deviate for two-tailed alternative hypothesis and it is 1.96 for 1% level of significance, s is standard deviation while d is the difference between means and they were considered 5 and 2 respectively depending on a previous study²³. $N = (1.96)^2 (5)^2 / 2^2 = 24$. And we assumed a 20% dropout, so the corrected sample size = $24 / (1 - 0.2) = 30$. *Randomization of teeth:* Randomization has been done using the sealed envelope method to determine which side to prepare first. *Cavity preparation of the selected tooth:* A retentive cavity was prepared in the tooth of the selected side using No. 245 carbide bur (SS White, USA).

Randomization of restoration: Randomization has been done again in the same way to determine which material to use in the restoration of the prepared cavity. Thus both the operator and patient were blind in the selection of the first tooth to be restored and the type of restoration used. *Application of the restoration:* The restorations were prepared and applied according to the manufacturer's instructions. Both types of restorations were placed under cotton roll isolation. For Centon N; the recommended liquid/powder ratio advised by the manufacturer (1:4.6) was mixed using a plastic spatula till we gained a homogenous mix that was packed into the prepared cavity within 2-3 minutes, then light-cured using LED blue light (X-Cure; woodpecker) in the wavelength range of approximately 400-500 nm for 20 seconds. The restoration was then finished and polished using tungsten carbide finishing burs and flexible finishing discs (Polishing Disc 10mm 900,100 / 100, Meisinger, Ivoclar). For amalgam restorations; a spill 2 regular set capsule was triturated for 8 seconds using amalgamator (Hangzhou Zhongrun Medical Instrument). Finishing and polishing of amalgam restorations were done after 24 hours from restoration placement. The other tooth was prepared and restored with the other restorative material in another appointment in the same week. *Evaluation of restorations:* Evaluation of the restorations was done following the revised FDI (International Dental Federation) criteria²⁴ for evaluation of direct restorations. The restorations were evaluated regarding retention/fracture of the restoration, marginal integrity of restoration, postoperative sensitivity, and patient view. The patients were recalled for evaluation of the restorations at baseline (one week from the last restoration), after six months, after one year, after two years, and after three years. Restoration Fracture/retention evaluated using visual examination

and short air drying. Marginal integrity evaluated using visual examination, short air drying, and regular sharp dental examination explorers with hand and finger endodontic spreaders to overcome the unavailability of the 250 μ probes suggested by FDI evaluation criteria authors. Postoperative hypersensitivity evaluated using the cold test. Patient's view evaluated by directly asking the patient about his opinion on the restoration. *Statistical analysis:* Categorical data were presented as frequencies and percentages. Wilcoxon signed-rank test was used to compare clinical evaluation scores in the two groups. Friedman's test was used to study the changes by time within each group. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

Flowchart (1): procedures



Results:

I. Marginal adaptation

There was no statistically significant difference between the two groups (P-value = 1, Effect size = 0) after one week (baseline), six months, and one year. After two years, there was no statistically significant difference between the two groups (P-value = 1, Effect size = 0) and one case dropped out. After three years, although one case of the amalgam group failed (score 5), there was no statistically significant difference between the two groups (P-value = 0.317, Effect size = 0.371).

II. Retention/Fracture of the restoration

In all evaluation periods, there was no statistically significant difference between the two groups (P-value = 1, Effect size = 0). All cases in the two groups showed (Score 1) except one case dropped out after two years, and one amalgam restoration of one case failed (score not applicable) after three years.

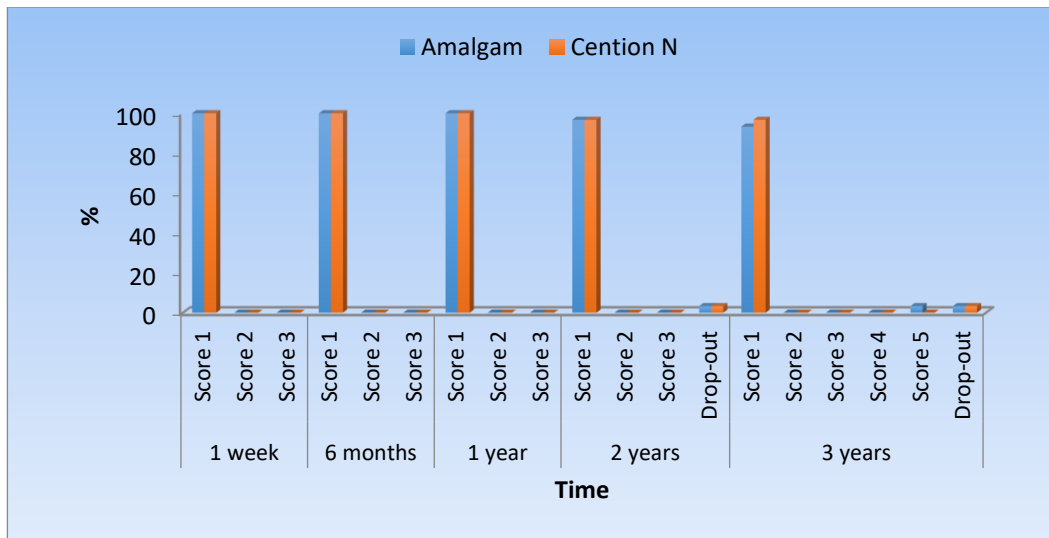
III. Postoperative sensitivity

In all evaluation periods, there was a statistically significant difference between the two groups (P-value <0.001). Amalgam showed a lower prevalence of (Score 1) and a higher prevalence of (Score 2) and (Score 3) than Cention N. One case dropped out and one amalgam restoration failed (score not applicable)

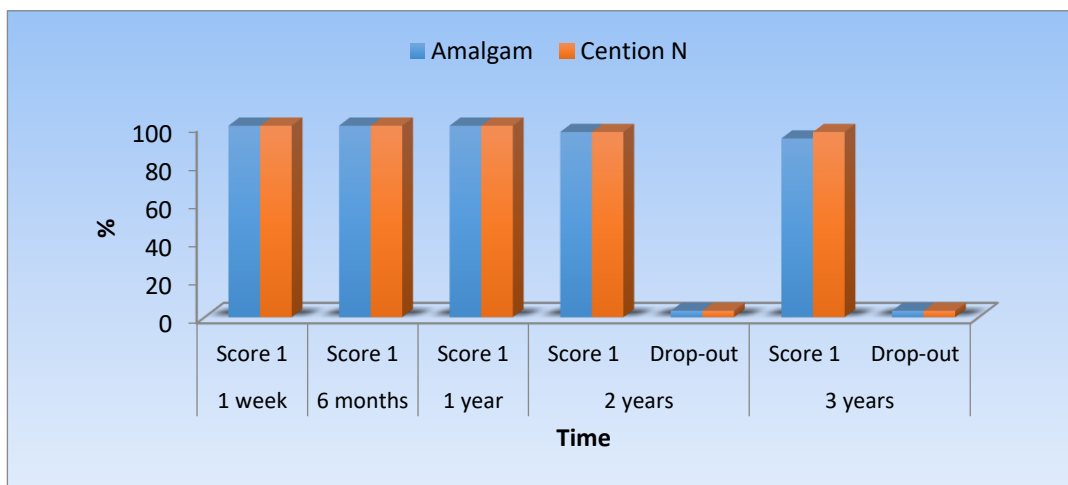
IV. Patient View

In all evaluation periods, there was a statistically significant difference between the two groups (P-value <0.001). Amalgam showed a lower prevalence of (Score 1) and a higher prevalence of (Score 2) and (Score 3) than Cention N. One case dropped out.

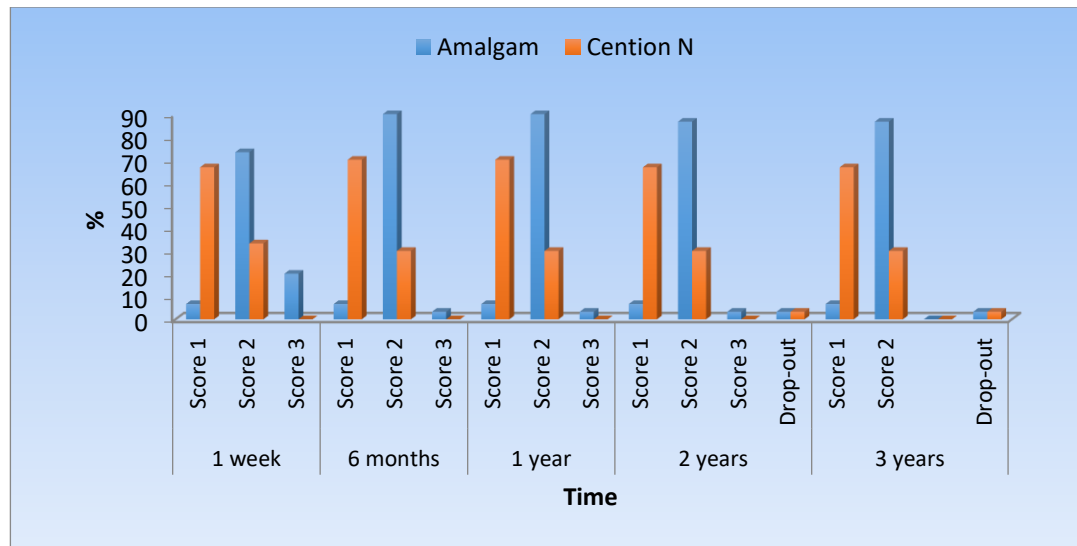
Bar chart 1: representing marginal adaptation scores in the two groups



Bar chart 2: representing restoration fracture and retention scores in the two groups



Bar chart 3: representing postoperative sensitivity scores in the two groups



Bar chart 4: representing patient view scores in the two groups

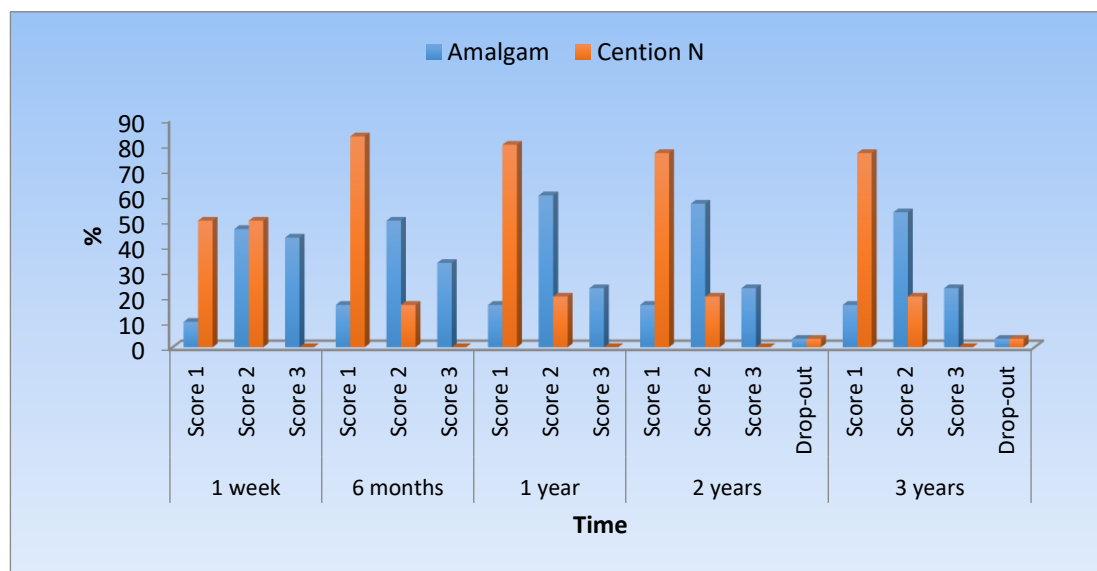
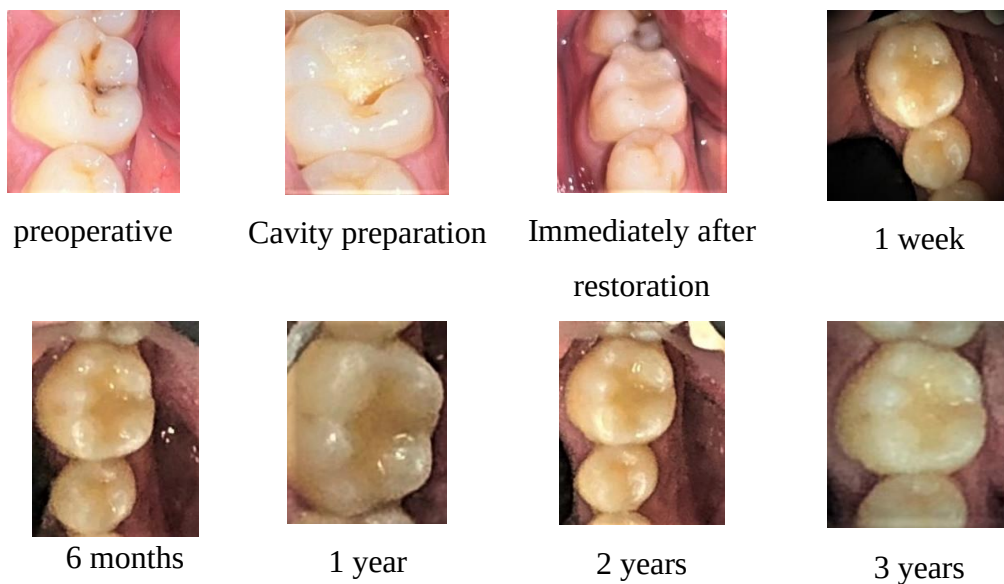


Figure 1: Photographs for an amalgam restoration case



Figure 2: Photographs of a Cention N restoration case:



Discussion:

Being introduced as an amalgam alternative, it is logical to compare Cention N to amalgam as it is considered the gold standard restoration regarding durability in stress-bearing areas of posterior teeth²⁵⁻²⁷. Also, Cention N was used without adhesive which is more convenient for comparison

with amalgam. A split-mouth design was used in the current study as it eliminates much of variability among patients involved in the study for better standardization²⁸. Patients were selected having two moderate classes I carious cavities of similar size of posterior teeth (depth not more than 3mm from cavosurface margin, width not more than 2/3 intercuspal distance) to avoid deep cavities that may necessitate the application of base material that may modify the response of restoration. A significant increase in the use of FDI criteria, compared to the modified USPHS criteria, has been observed since 2010, thereafter reaching 50% of the published studies in 2016²⁹. The results showed clinically accepted marginal integrity, retention, and resistance to fracture of both types of restorations at all recalls in almost all patients. At the two years recall one patient did not attend for evaluation. At the three years recall one amalgam restoration failed (case represented with recurrent caries around the amalgam restoration). The restoration was replaced and reported.

The improved *marginal integrity* of Cention N could be attributed to the Isofiller component in its composition. Isofiller (shrinkage stress reliever) reduces polymerization shrinkage. This leads to lower volumetric shrinkage, improved marginal integrity, and reduced shrinkage stress force over the restoration surface ensuring a tight marginal seal, whereas the organic/inorganic ratio is responsible for the low volumetric shrinkage. Also, Cention N monomer contains PEG-400 DMA (Polyethylene glycol 400 dimethacrylate). It is a liquid monomer that enhances the flowability of Cention N. Its hydrophilic character also promotes Cention N's ability to wet tooth substrate (enamel and dentin) and adapt to the smear layer, reducing the gap between the tooth and the restoration which provides a good marginal seal. The results of the current study agreed with Minocha et al. (2021)³⁰, and Firouzmandi M et al. (2021)³¹.

Improved *Retention and resistance to fracture* of Cention N may be attributed to that it consists of four different dimethacrylate (UDMA Urethane dimethacrylate, DCP Tricyclodecan-dimethanol dimethacrylate, an aromatic aliphatic-UDMA Tetramethyl-xylylen-diurethane dimethacrylate, and PEG-400 DMA Polyethylene glycol 400 dimethacrylate) which represent 21.6% wt. of the final mixed material. A combination of dimethacrylate interconnects (cross-links) during polymerization results in high compressive and flexural strengths and good long-term stability³². These results agreed with Kaur M et al. (2018)³³ who concluded that Cention N restorations have good mechanical properties. Some cases showed a degree of *postoperative sensitivity* in both restorations but all were within the clinically acceptable range. The decreased postoperative

sensitivity of Cention N restorations may be attributed to the presence of isofiller which acts as a stress shrinkage reliever with a low modulus of elasticity, decreased conductivity of the Non-metallic Cention N restoration, and long-term release of acid-neutralizing ions (fluoride, and calcium). This was in agreement with Dedania M *et al.* (2018)³⁴.

Generally speaking, *patient satisfaction* improved in successive recalls. However, patients' views about Cention N were generally better than amalgam. For Cention N, the main cause of incomplete satisfaction for most of the patients was its bad taste but it was tolerable by most of them. For amalgam, the main causes of incomplete satisfaction for most of the patients were its anaesthetic colour and the high thermal conductivity. These results agreed with Abdel Fattah R *et al.* (2022)³⁵.

Since our results revealed that there was no statistically significant difference between the two groups regarding marginal adaptation and restoration retention/fracture, and there is a statistically significant difference between the two groups regarding postoperative sensitivity and patient view, so the null hypothesis is partially accepted.

Conclusions:

Under the conditions of the present study, the following conclusions could be derived:

1. Cention N and amalgam restorations showed clinically acceptable marginal integrity, retention, and resistance to fracture.
2. Regarding postoperative sensitivity and patient view, there were statistically significant differences between Cention N and amalgam restorations with preference to Cention N.

Conflict of interests: The authors had no conflict of interest to declare

Financial disclosure: The authors declared that they have received no financial support

Data availability: Datasets related to this article will be available upon request

References:

1. Letzel H, Van't Hof M, Marshall G and Marshall S. (1979). The influence of the amalgam alloy on the survival of amalgam restorations: a secondary analysis of multiple controlled clinical trials. *J Dent Res*; 76(11):1787-98.
2. Hickel R and Manhart J. (2001). Longevity of restorations in posterior teeth and reasons for failure. *J Adhes Dent*; 3(1):45-64.
3. Antony K, Genser D, Hiebinger C and Windisch F. (2008). Longevity of dental amalgam in comparison to composite materials. *GMS Health Technol Assess*;13; 4: Doc12.
4. SCENIHR (Scientific Committee on Emerging and Newly-Identified Health Risks), (2015). scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users (update). doi: 10.2772/42641, ISSN: 1831-4783.
5. ADA Federal Council Policy Statement 6.18 –Dental Amalgam; Adopted November 18/19, 2010. Amended 2012, 2015, 2017, and 2020. Redrafted March 24, 2023
6. Ajiboye A and Mossey P ;(2020). IADR Science Information Committee, Fox C. International Association for Dental Research Policy and Position Statements on the Safety of Dental Amalgam. *J Dent Res*; 99(7):763-768.
7. Amalgam (Part 2) (2022): Safe Use and Phase Down of Dental Amalgam: Adopted by the FDI General Assembly: Sydney, Australia. *Int Dent J*; 72(1):12-13.
8. FDI World Dental Federation. FDI policy statement on dental amalgam and the Minamata Convention on Mercury (2014): adopted by the FDI General Assembly: New Delhi, India. *Int Dent J*; 64(6):295-6
9. Gallusi G, Libonati A, Piro M, Di Taranto V, Montemurro E and Campanella V. (2021). Is Dental Amalgam a Higher Risk Factor rather than Resin-Based Restorations for Systemic Conditions? A Systematic Review. *Materials (Basel)*; 14(8):1980.
10. Burke F (2004). Amalgam to tooth-coloured materials--implications for clinical practice and dental education: governmental restrictions and amalgam-usage survey results. *J Dent*; 32(5):343-50.

11. Rekow E, Fox C, Petersen P and Watson T (2013). Innovations in materials for direct restorations: why do we need innovations? Why is it so hard to capitalize on them? *J Dent Res*; 92(11):945-7.
12. Yang L, Liu F, Su N, Wang Y, Yang P and Chang Y (2023). Decreased trends of using dental amalgam filling for decayed teeth in Taiwan from 1997 to 2013. *J Dent Sci*; 18(1):400-406.
13. George P and Bhandary S (2018). A Comparative Microleakage Analysis of a Newer Restorative Material – An Exvivo Study. *IOSR Journal of Dental and Medical Sciences*; e-ISSN: 2279-0853, p-ISSN: 2279-0861. Volume 17, Issue 12 Ver. 4, PP 56-60.
14. Punathil S, Almalki S, AlJameel A, Gowdar I, Mc V and Chinnari K (2019). Assessment of Microleakage Using Dye Penetration Method in Primary Teeth Restored with Tooth-colored Materials: An In Vitro Study. *J Contemp Dent Pract*; 20(7):778-782.
15. Schwendicke F and Opdam N (2018). Clinical studies in restorative dentistry: Design, conduct, analysis. *Dent Mater*; 34(1):29-39.
16. Opdam N, Collares K, Hickel R, Bayne S, Loomans B, Cenci M, Lynch C, Correa M, Demarco F, Schwendicke F and Wilson N (2018). Clinical studies in restorative dentistry: New directions and new demands. *Dent Mater*; 34(1):1-12.
17. Murray D, Varnell S and Blitstein J (2004). Design and analysis of group-randomized trials: a review of recent methodological developments. *Am J Public Health*; 94(3):423-32.
18. Guideline IH. Integrated addendum to ICH E6 (R1) (2023): guideline for good clinical practice E6 (R3). Step 2b; 1–73
19. Hadler E and Jönsson B (2021). Oral health and use of dental services in different stages of adulthood in Norway: a cross-sectional study. *BMC Oral Health*; 21(1):257.
20. Tomisaki E, Costa M, Silva D, Hoepfner M and Cardoso S (2021). Parafunctional habits and their relationship with fractures of composite resin restorations. *Research, Society, and Development*. [S. l.], v. 10, n. 9, p. e48410918087.

21. McCracken M, Gordan V, Litaker M, Funkhouser E, Fellows J, Shamp D, Qvist V, Meral J and Gilbert G (2013); A 24-month evaluation of amalgam and resin-based composite restorations. *Journal of the American Dental Association*; 144(6):583-93.
22. Fernandes N, Vally Z and Sykes L (2015). The longevity of restorations -A literature review. *South African Dental Journal*; 70(9): 410-413.
23. Burgess J (2017). clinical evaluation of an amalgam replacement restoration. *IADR: oral presentation*; March 22-25.
24. Hickel R, Mesinger S, Opdam N, Loomans B, Frankenberger R, Cadenaro M, Burgess J, Peschke A, Heintze S and Kühnisch J (2023). Revised FDI criteria for evaluating direct and indirect dental restorations-recommendations for its clinical use, interpretation, and reporting. *Clin Oral Investig*; 27(6):2573-2592.
25. Moraschini V, Fai C, Alto R and Dos Santos G (2015). Amalgam and resin composite longevity of posterior restorations: A systematic review and meta-analysis. *J Dent*; 43(9):1043-1050.
26. Rasines G, Veitz A, Sahrman P, Schmidlin P, Davis D and Iheozor Z (2021). Direct composite resin fillings versus amalgam fillings for permanent or adult posterior teeth. *Cochrane Database Syst Rev*; 8: CD005620. PMID: 24683067.
27. Hurst D (2014). Amalgam or composite fillings--which material lasts longer? *Evid Based Dent*; 15(2):50-1.
28. Smaïl V, Fron H, Courson F and Durieux P (2015). Comparison of intervention effects in split-mouth and parallel-arm randomized controlled trials: a meta-epidemiological study [published correction appears in *BMC Med Res Methodol*; 15:72].
29. Marquillier T, Doméjean S, Le Clerc J, Chemla F, Gritsch K, Maurin J, Millet P, Pérard M, Grosogeat B and Dursun E (2018). The use of FDI criteria in clinical trials on direct dental restorations: A scoping review. *J Dent*; 68:1-9.
30. Minocha A, Sharma V, Gupta A and Sharma N (2021). Comparative evaluation of Cention N and Amalgam in Class II posterior restorations. *University J Dent Science*, 7(1): 58 – 61,

31. Firouzmandi M, Alavi A, Jafarpour D and Sadatsharifee S (2021). Fracture Strength and Marginal Adaptation of Conservative and Extended MOD Cavities Restored with Cention N. Int J Dent; 5599042.
32. Scientific documentation (2016): Cention N. Schaan, Liechtenstein: Ivoclar Vivadent press, pp 1-58.
33. Kaur M, Singh N, Jhamb A and Batra D (2019). A comparative evaluation of compressive strength of Cention N with glass Ionomer cement: An in-vitro study. Int J Appl Dent Sci; 5(1):05-09.
34. Dedania M, Shah N, Bhadra D, Bajpai N and Sapariya K (2018). One Year Comparative Evaluation of Clinical Performance of Silver Amalgam and Cention N in Simple Class I Carious Lesions in Permanent Molars – A Split Mouth Randomized Clinical Study. International Journal of Current Research, 10 (8): 72993-72996. ISSN: 0975-833X.
35. Fattah R, Jamil W and Elezz A (2022). Comparative Evaluation of Clinical Performance of Three Different Glass Hybrid Restorations in High Caries Risk Patients: A Randomized Control Trial. Open Access Maced J Med Sci [Internet].10(D):398-405. Available from: doi: <https://doi.org/10.3889/oamjms.2022.10354>.