

**COMPARISON OF CLINICAL EFFICIENCY OF
CENTION - N (WITH AND WITHOUT ADHESIVE) AND
COMPOSITE RESIN (TETRIC N CERAM BULK FILL)
AS CLASS 1 RESTORATIONS –
A RANDOMIZED CONTROLLED CLINICAL TRIAL**

**A Dissertation submitted in partial fulfillment of the
requirements for the degree of**

**MASTER OF DENTAL SURGERY
BRANCH – IV**

CONSERVATIVE DENTISTRY AND ENDODONTICS



**THE TAMILNADU DR. MGR MEDICAL UNIVERSITY
CHENNAI – 600 032.**

2017– 2020

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I hereby declare that this dissertation titled **“COMPARISON OF CLINICAL EFFICIENCY OF CENTION – N (WITH AND WITHOUT ADHESIVE) AND COMPOSITE RESIN (TETRIC N CERAM BULK FILL) AS CLASS 1 RESTORATIONS – A RANDOMIZED CONTROLLED CLINICAL TRIAL”** is a bonafide and genuine research work carried out by me under the guidance of **Dr.M.Kavitha, MDS., Professor & HOD**, Department Of Conservative Dentistry and Endodontics, Tamil Nadu Government Dental College and Hospital, Chennai-600003.

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I am taking pride to acknowledge my deep sense of gratitude and respect to my Guide, **Dr. M. Kavitha, M.D.S.**, Professor and H.O.D., Department of Conservative Dentistry and Endodontics, Tamilnadu Government Dental College and Hospital, Chennai, to whom I am greatly indebted for her constant encouragement, valuable guidance and relentless support throughout the course of this study. Words are few to express my gratitude to her for sparing her precious time, valuable energy and knowledge throughout my post graduate course.

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Above all, I am always grateful to **God Allah,** who is always beside me.

TRIPARTITE AGREEMENT

This agreement herein after the “Agreement” is entered into on this day Jan 2020 between the Tamil Nadu Government Dental College and Hospital represented by its **Principal** having address at Tamil Nadu Government Dental College and Hospital, Chennai - 600 003, (hereafter referred to as, 'the college')

And

Mrs.Dr.M.Kavitha, aged 49 years working as **Professor & HOD** in Department of Conservative Dentistry & Endodontics at the college, having residence address at 69/4, Mettu street, Ayanavaram, Chennai - 23(herein after referred to as the 'Principal Investigator')

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Mr.Dr.M.H.MOHAMED ABUBACKER, aged 35 years currently studying as **Post Graduate student** in Department of Conservative Dentistry & Endodontics, Tamil Nadu Government Dental College and Hospital, Chennai - 3 (herein after referred to as the 'PG student and co-investigator').

Whereas the PG student as part of his curriculum undertakes to research

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1.

2.

ABSTRACT

AIM:

The aim of this study is to compare and evaluate the clinical efficiency of Cention N (with and without adhesive) and composite resin (Tetric N Ceram Bulk Fill) as class 1 restorations using Modified USPHS criteria.

MATERIALS AND METHODS:

This study is a single center prospective randomized controlled clinical trial. This study is about comparison of clinical performance of three different restorative system (Cention-N with adhesive, Cention-N without adhesive and Composite Resin) during 2 years of clinical service, using the Modified US public health service criteria. The restorations are evaluated at baseline, 6, 12, and 24 months. The study evaluates the following criteria--marginal discoloration (MD), marginal integrity (MI), surface texture (ST), wear(W), postoperative sensitivity (PS), recurrent caries (RC).

RESULTS:

At the end of 6,12 and 24 months, Cention N (with and without adhesive) exhibited acceptable clinical performance as comparable to that of resin composite (Tetric N Ceram Bull Fill) in terms of all parameters. Overall, Cention N with adhesive and Tetric N Ceram Bulk Fill was found to be marginally better than Cention N without adhesive but there was no statistically significant difference between them.

CONCLUSION:

Cention N with and without adhesive is found to be promising posterior restorative material with their clinical efficiency comparable to that of resin composite (Tetric N Ceram Bull Fill).

KEY WORDS:

Cention N, Tetric N Ceram bulk fill, modified USPHS Criteria

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ABBREVIATIONS

C	CENTION N WITHOUT ADHESIVE
CA	CENTION WITH ADHESIVE
TC	TETRIC N CERAM
MD	MARGINAL DISCOLORATION
MI	MARGINAL INTEGRITY
ST	SURFACE TEXTURE
W	WEAR
PS	POST OPERATIVE SENSITIVITY
RC	RECURRENT CARIES
A	ALPHA
B	BRAVO
Ch	CHARLIE

INTRODUCTION

Numerous direct filling materials are available to the modern dental practice from amalgam through to modern resin composite. Amalgam materials were first introduced to western dentistry in the 19th century ⁷⁰, Glass ionomer cements (GICs) were introduced around the 1970s, Composite resins became standard during the 1980s, Resin modified glass ionomers⁷⁴ and compomers⁵⁷ were introduced in the 1990s and the current decade saw the launch of several bulk-fill composites.

Amalgams and glass ionomer cements can be viewed as basic filling materials. Basic in the sense that they are long established, economical and simple to use. They are usually applied in bulk without an adhesive, are self-curing and do not require complicated dental equipment.

Great strides forward in direct filling materials have been made with dental composites and their accompanying adhesives in recent decades; however simple, basic restoratives such as amalgam and glass ionomer cements remain popular still as class 1 restorations.

Evolutionary development of filling materials leads to an increasing need for better tooth colored restorative materials to replace missing tooth structure and to modify tooth color and contour, thus enhance facial esthetics. Polymeric restoratives have continued to evolve into the direct restorative materials of choice mainly because of their superior aesthetic characteristics.

Even though the amalgam, GIC and Composite have been widely used as a restorative material, but none of these materials fulfils the esthetic, functional as well as biological properties together. Each restorative material has certain drawbacks.

In case of amalgam, its possible toxicity due to mercury release and poor esthetics are its major drawbacks⁶⁷. Glass Ionomer Cement (GIC) has wide range of applications in dentistry. But, its relatively high solubility, low abrasion resistance and questionable compressive strength are the major concerns.

Currently resin-based composites have been widely used to restore posterior teeth. Concerns about aesthetics, the content of mercury in amalgam restorations and the possibility of more conservative restorations, using the minimally invasive technique, has been essential in the selection of these materials in stress-bearing areas⁶³. However, some intrinsic characteristics from resin composite, for example, polymerization shrinkage and elastic modulus different of dental structure can produce several problems³¹ including postoperative sensitivity, secondary caries, pulp inflammation, restoration fractures, and defects in the margin of the composite with the adjacent tooth structure⁶⁴.

Frequently, a range of experimental resins is launched on the market aiming to better physical and chemical properties, and consequently, an increase in the longevity of restorations. Thus, variations in the form and amount of inorganic particles in the polymeric matrix^{80,81,46}, in the photoinitiator system^{43,8,58}, handling, indications, among other factors, are increasingly frequent. However, the characteristics and effects of these composites are not yet fully elucidated, especially in the short term (early failure) making it difficult to choose the ideal restorative material.

Nanohybrid bulk fill composite resin is widely used as a direct filling restorative material for posterior teeth. In this study, Tetric® N-Ceram Bulk Fill (Ivoclar Vivadent) was used and it was recently introduced with the claim that it would substitute both conventional non flowable composite and bulk-fill flowable composite that needed an

increment of 2 mm when using the incremental layering technique. As per the manufacturer's commercials, this new composite will achieve full-depth bulk fill up to 4 mm without a superficial capping layer. The manufacturer states that Tetric® N-Ceram Bulk Fill contains a shrinkage stress reliever (Isofiller) to minimize polymerization shrinkage⁷³.

Recently, a new restorative material, Cention N is introduced into the dental market. Cention N is an "alkasite" restorative⁷². Alkasite refers to a new category of filling material, which like compomer or ormocer materials is essentially a subgroup of the composite material class.

Cention N is a tooth-coloured, restorative material for direct restorations. It is self-curing with optional additional light-curing. It is radiopaque, and releases fluoride, calcium and hydroxide ions. As a dual-cured material it can be used as a full volume (bulk) replacement material⁷².

In this study, clinical effectiveness of Cention N with Nanohybrid bulk fill composite resin (Tetric N Ceram) was compared as class 1 restoration for marginal discoloration, marginal integrity, surface texture, wear, postoperative sensitivity and recurrent caries using modified USPHS (United States Public Health Service) criteria

USPHS criteria for clinical evaluation of the restoration was developed by Cvar and Ryge in 1971 and has been used extensively for clinical evaluation of restorations¹².

There are numerous invitro studies evaluated the several characteristics of Cention N like flexural strength, compressive strength, bond strength, microleakage, hardness, wear behaviour, fluoride ion release etc. The measure of success of a restorative treatment appears to be strongly associated to its longevity¹⁷. Although invitro studies

can provide relevant information on the restoration longevity, the long-term performance of these systems still depends on clinical evaluations

Moreover, very few in vivo studies have been done to clinically evaluate the marginal integrity, gross fracture of Cention N. But there are no in vivo studies available to evaluate the clinical performance of Cention N in long term period.

Hence the purpose of this study is to compare the clinical performance of Cention N in long term basis and to compare it with nanohybrid bulk fill composite resin (Tetric N Ceram)

AIM AND OBJECTIVE

AIM:

The aim of this randomized controlled clinical trial is to compare the clinical efficiency of Cention N (with or without adhesive) with composite resin (Tetric N Ceram bulk fill) in class 1 restorations using **modified USPHS** (United States Public Health Service) Criteria.

OBJECTIVE:

1. To evaluate clinically marginal discoloration, marginal integrity, surface texture, wear, postoperative sensitivity and recurrent caries at baseline, after 6,12 and 24 months **in Cention N with adhesive class 1 restorations.**
2. To evaluate clinically marginal discoloration, marginal integrity, surface texture, wear, postoperative sensitivity and recurrent caries at baseline, after 6,12 and 24 months **in Cention N without adhesive class 1 restorations.**
3. To evaluate clinically marginal discoloration, marginal integrity, surface texture, wear, postoperative sensitivity and recurrent caries at baseline, after 6,12 and 24 months **in composite resin (Tetric N Ceram bulk fill) class 1 restorations.**

The restoration is classified and demonstrated by score. Alpha, bravo and Charlie.

REVIEW OF LITERATURE

CENTION N & TETRIC N CERAM

Agarwal RS et al (2015)³ evaluated the cervical marginal and internal adaptation of posterior bulk fill resin composites of different viscosities (Sonic Fill, Gr.SDR, Tetric N Ceram Bulk Fill or a conventional composite designed for 2-mm increments (Tetric N Flow along with Tetric N Ceram)., before and after thermo-cycling (TMC) in restored class II cavities. They concluded that: Both bulk fill restorative materials and incrementally layered composite resulted in a similar proportion of gap-free, marginal interface in enamel. All the experimental groups except for Tetric N Ceram Bulk Fill demonstrated similar dentin adaptability when compared with the control group. Thus, the viscosity of the bulk fill restorative material influenced the proportion of gap-free marginal interface and the internal adaptation in dentine.

Abuelenain DA et al (2015)² investigated the compressive and flexure properties as well as surface hardness, hardness ratio (as an indication of bottom to top conversion ratio) and roughness of six different commercially available dental composites {Filtek Z250, Filtek Z350 XT, Filtek P90, Tetric N-Ceram Bulk Fill, Tetric N-Ceram, IPS Empress Direct} having different organic matrix, filler loading and filler types, under the same curing and testing conditions. They concluded that for high stress bearing applications, the materials of choice would be Filtek Z250 and Z350 XT. With low stress-bearing applications when a high resiliency and flexibility are required, e.g., cervical and abfraction lesions, IPS Empress and Tetric N-Ceram could be the material of choice.

Alkurdi RM and Abboud SA. (2016)⁵ Compared the efficiency of two different bulk-fill techniques (Tetric N Ceram Bulk Fill, Sonic Fill) used to restore class II cavities, and comparing them intraindividually with conventionally layered technique (Tetric Evo Ceram). The null hypothesis tested was that there would be no difference between the different techniques under investigation. Both the bulk-fill techniques are clinically functional over the 12-month observation period.

Suhasini K et al (2016)⁷⁶ evaluated the clinical performance of nanohybrid composite restorations using resin-modified glass-ionomer and flowable composite liners using US Public Health Service modified criteria. it was concluded that the secondary outcomes such as retention, secondary caries, postoperative sensitivity, marginal adaptation, marginal discoloration, color match, anatomic form, and surface roughness were clinically acceptable for Tetric N-Ceram restorations with flowable composite liner and RMGIC liner.

Nabeel A and Manjunath MK. (2016)⁵⁵ compared the fracture resistance of everX posterior (Fibre Reinforced Composite, GC), SDR(Bulk Fill Flowable composite, DENTSPLY), Tetric®N Ceram (Ivoclar Vivadent) and Filtek™ Z350 XT (3M ESPE) on maxillary first premolars with class II Mesio- Occluso-Distal(MOD)cavities using an Instron machine and to evaluate the mode of failure/fracture using stereomicroscope at 10x after staining. They conclude that everX posterior along with occlusal lining using a universal composite can be a material of choice for restoration of large class II cavities and exhibited more cohesive failure. Tetric® N-Ceram Bulk Fill and SDR also showed good results of fracture resistance however showed more of Mixed type of failure. Filtek™ Z350 XT showed least fracture resistance and more Mixed failure.

Al-Abdullah AS et al (2017)⁴ evaluated the color stability of Tetric® N-Ceram Bulk Fill composite restorative material after immersion in three different (energy drink, protein supplement solution, and combination of energy drink and protein supplement solution) drinks. He concluded that Tetric® N-Ceram Bulk Fill composite restorative material was found to be more color stable in deionized water than the energy drink (Red Bull), protein supplement (ISOPURE), and combined immersion in energy drink and protein supplements and also suggested that the energy drink (Red Bull), protein supplement (ISOPURE), and combined immersion in energy drink and protein supplements caused perceptible and clinically unacceptable color change in the Tetric® N-Ceram Bulk Fill composite material. This color change was remarkably high with a combined immersion in energy drink and protein supplement solution.

Nair SR et al (2017)⁵⁶ compared the color stability and microhardness of three composites G aenial Universal Flo (GC India), Filtek Z350XT (3MESPE) and Tetric N Ceram (Ivoclar Vivadent) and they concluded that Greatest Color stability and Vickers hardness was seen in Filtek Z350XT followed by Tetric N Ceram and least values were seen in G aenial Universal Flo.

Vandana S et al (2017)⁷⁸ evaluated the flexural strength and compressive strength of three bulk-fill composite restorative materials(Bulk-fill posterior restorative material (Filtek™ Bulk-Fill Posterior Restorative material, 3MTM ESPETM, St. Paul, USA), Posterior bulk-fill flowable resin material (Smart Dentin Replacement, SDRTM, Dentsply, Konstanz, Germany), Nano-hybrid bulk-fill material (Tetric N-Ceram Bulk-Fill, Ivoclar Vivadent, AG, Liechtenstein). It was concluded that higher the weight percentage of the fillers higher were the flexural and compressive strength values. This

study findings shows that Filtek bulk-fill composite showed significantly higher flexural and compressive strength values compared to Tetric N-Ceram bulk-fill and SDR.

Abuelenain DA et al (2017)¹ evaluated surface and mechanical properties of bulk fill composites (Filtek Bulk Fill, Sonic Fill, SDR Smart Dentin Replacement and Tetric-N-Ceram Bulk Fill) compared to conventional incremental composites (Filtek Z350 × T and Herculite XRV Ultra). Result showed that there was no statistically significant difference in wettability and surface roughness between bulk fill and incremental composites, except the SDR that showed statistically significance higher roughness than incremental composites. All composites showed significantly lower hardness than Filtek Z350; the lowest hardness was recorded for SDR. There was no significant difference between bulk fill and incremental composites in flexure strength and modulus. SDR showed the lowest flexure strength and modulus but the highest strain% ($P < 0.05$) compared to all tested materials. Sonic fill system showed significantly higher flexure strength and modulus when compared to other bulk fill materials ($P < 0.05$)

Savadamoorthi KS et al (2017)⁷¹ evaluated the depth of cure in newer bulk fill composite resin (Smart Dentin Replacement, Dentsply) and traditionally used hybrid composite resin (Tetric N – Ceram, Ivoclar), and microfill (Te-Econom Plus, Ivoclar) which used two different light sources quartz-tungsten-halogen (QTH) and light emitting diode (LED) unit with three varying intensities in conventional standard curing mode for 20 s. They concluded that bulk fill composite resin was found to be more successful than hybrid and microfill composite resin with respect to the depth of cure.

Herda E et al (2017)³⁶ conducted a study aimed to identify the shear bond strength of two different restorative particulate resin composites G-aenial Posterior and Tetric N-Ceram with a short fiber-reinforced resin composite (SFRC) substructure (everX

posterior™). They concluded that the shear bond strength value is higher in the Tetric N-Ceram™ restorative particulate resin composite with SFRC as a substructure than the G-aenial Posterior™ restorative particulate resin composite.

Mishra A et al (2018)⁵³ compared the compressive strength and flexural strength of Cention N with other conventionally used restorative materials {Composite (Tetric N-Ceram Ivoclar Vivadent), GIC (Fuji Type IX, GC America) and silver amalgam (DPI alloy, Mumbai, India). They concluded that composite had the highest compressive strength and flexural strength of the four materials tested. However, Cention N can be used as alternative restorative material since it has good comparable mechanical properties and unlike composite, it's economical to patients.

Mazumdar P et al (2018)⁵⁰, evaluated the bond strength of nanohybrid composite resin (Tetric N Ceram) and Cention N to enamel and dentin with and without etching. They concluded that Cention N showed higher bond strength value than composite resin. Among etching groups, etched specimen showed more bond strength than unetched specimens, enamel surfaces showed greater bond strength with the materials than dentin surfaces.

Dayananad Chole et al (2018)²² compared the flexural strength of Cention-N, bulk-fill composites (Tetric N Ceram), light cure nanocomposites and resin-modified glass ionomer cement. They concluded that Cention-N showed highest flexural strength followed by bulk-fill composites, light cure nanocomposites and least flexural strength is shown by resin-modified glass ionomer cement.

Hirani RT et al (2018)³⁷ conducted a study on Comparative evaluation of postoperative sensitivity (POS) among three bulk fill restorative materials (Cention N, Equia Forte, Activa™ Bioactive restorative) in Class I posterior restorations and assessed with a

standardized cold test and air stimulus by air blow from the air syringe. They concluded that POS was seen more in Cention N contrast to Equia forte and Activa™ bioactive restorative material.

Mazumdar P et al (2018)⁴⁸ evaluated the hardness of four restorative materials, nanohybrid composite resin, Cention N, silver amalgam and type II GIC. They concluded that Cention N showed better microhardness properties becoming a more clinically suitable option for minimal invasive treatments.

Mishra A et al (2018)⁵³ compared the compressive strength and flexural strength of Cention N with other conventionally used restorative materials (Amalgam, Glass Ionomer Cement and Hybrid composite resin). They concluded that composite had the highest compressive strength and flexural strength of the four materials tested. However, Cention N can be used in various restorative procedures in daily dental practice as a basic filling material along with tooth matching ability.

Mazumdar P & Chowdhury D (2018)⁴⁷ evaluated the effect of tooth brushing on the surface roughness of composite resin, Cention N, glass ionomer cement, silver amalgam by using a dentifrice and a customized automated brushing machine under a profilometer. They concluded that there was significant change in surface roughness was observed in type II glass ionomer cement followed by nanohybrid composite resin and Cention N and there was insignificant change in surface roughness was observed in silver amalgam.

Meetkumar S et al (2018)⁵² compared and evaluated the clinical performance of Silver Amalgam and Cention class I carious restoration in permanent molars using modified USPHS Criteria. They concluded that there was no statistically significant difference seen in the clinical performance of Silver Amalgam and Cention-N and both materials

show equal and acceptable clinical performance at the end of one year. Cention N can be used as an alternative to amalgam in class I lesions.

George P and Bhandary S (2018)³² Compared and evaluated the microleakage of a newly introduced restorative material, Cention N(with and without adhesive), with the commonly used posterior restorative materials(amalgam, GIC and packable composite) under stereomicroscope .The study showed that Cention N to have lesser microleakage compared to GIC and composite restorations, thereby having better sealing ability. Moreover, groups restored using Cention N without adhesive showed lesser microleakage compared to that with adhesive.

Sahadev C K et al (2018)⁶⁹ compared marginal microleakage of CENTION-N with bulk FILL SDR and ZIRCONOMER using confocal microscopy. Based on the results of this study, it can be concluded that bulkfill SDR showed least microleakage scores followed by Cention-N and Zirconomer.

Talukder MFH et al (2018)⁷⁷ compared the clinical performance of bulk-fill composite resin (Ivoclar Vivadent's Tetric N Cream Bulk-fill) with that of layered composite resin restorations (3M ESPE's Filtek P60) in occlusal class I cavity of permanent molar teeth at baseline, 3, 6- and 12-months interval by using the modified USPHS criteria. They concluded that Bulk-fill composite resin is superior to layered composite resin in respect to retention and marginal adaptation in class I restorations of permanent molar teeth.

Patel MC et al (2018)⁵⁹ compared the marginal sealing of three different bulk-fill composite restorations {Filtek Bulk Fill (Group I), Tetric N-Ceram Bulk Fill (Group II) and X-tra Fil Bulk Fill (Group III)} of Class II cavities under *in vitro* conditions. Based on the limitations of this *in vitro* study, it can be concluded that in Class II restorations, microleakage is observed regardless of the bulk-fill composite used, and Tetric N-

Ceram and X-tra Fil Bulk Fill composites shows more microleakage when compared to Filtek Bulk Fill composite.

Almozainy M (2018)⁶ evaluated the curing efficiency of various flowable bulk fill resin materials using Vickers hardness measurements and compare them to conventional resin-based composite. Four composite materials were used: Tetric N-Ceram, Tetric N-flow Bulk fill, Filtek bulk fill flowable composite and Surefil SDR bulk fill flowable. The finding suggests that manufacturers' recommendations in regards to curing protocol of resin-based composite could result in lower hardness value ratio. Accordingly, the curing time protocol should be longer than that indicated by the manufacturer to achieve 70%- 80% bottom-surface hardness in relation to the top.

Gunwala MK et al (2018)³⁴ evaluated the fracture resistance and mode of failure of maxillary premolar restorations restored with nanohybrid Composite (Tetric N Ceram), ORMOCER and Ceramic Inlays. MOD cavity restored with ceramic inlays showed highest fracture resistance followed by Ormocer group. Tetric N Ceram showed the least fracture resistance.

Dodiya et al (2019)²⁵ compared clinical effectiveness of Cention–N and Nanohybrid composite (Tetric N Ceram) resin as a restoration of non-carious cervical lesion for gross fracture, marginal integrity & surface texture using USPHS, Ryge criteria for direct clinical evaluation. They concluded that Cention – N is as effective as Tetric N Ceram for gross fracture and marginal integrity but Cention – N has an inferior surface characteristic than Tetric N Ceram.

Aman Abrol et al (2019)⁹ evaluated and compared the microleakage in class II cavity (mesio-occlusal) restored in premolars with ZIRCONOMER (SHOFU Inc., Kyoto, Japan), TETRIC-N CERAM (Ivoclar Vivadent), CENTION-N (Ivoclar Vivadent),

GLASS IONOMER CEMENT (GC Universal Restorative), using Stereomicroscope. They concluded that all the restored groups showed microleakage. Tetric N Ceram and Cention N showed the least microleakage showing statistically significant differences with Glass Ionomer Cement and Zirconomer showing highest microleakage.

Mazumdar P et al (2019)⁴⁹ compared the microleakage of three different direct restorative materials (amalgam [AA], glass ionomer cements [GICs], and Cention N [CN]) in Class II restorations using stereomicroscope. They concluded that out of all the restorative materials, Cention N, a newer restorative material displayed minimum microleakage compared to AA and GICs.

Roulet JF et al (2019)⁶⁸ measured the in vitro wear of two bioactive smart composite restorative materials {Activa (Pulpdent) and Cention N (Ivoclar Vivadent)} and one glass ionomer cement Fuji IX (GC). They concluded that the tested bioactive smart composites are suitable for posterior fillings (as an amalgam replacement) while the great wear to the glass ionomer cement confirms this indication (non load-bearing class I and II fillings).

Gupta N et al (2019)³⁵ conducted a study to evaluate fluoride ion release by Cention-N (self-cure and light-cure) and conventional glass-ionomer cement (GIC) at different pH and time intervals. They concluded that Cention-N (self-cure) has the highest fluoride ion release and alkalizing potential in acidic pH as compared to Cention-N (light-cure) and GIC.

TETRIC N BOND

Kumari RV et al (2015)⁴¹ compared the shear bond strength of nanocomposite resin to superficial dentin and deep dentin using two different dentin bonding systems (Tetric N

Bond and Single Bond Universal. The result showed that bond strength values of fifth generation bonding system (Tetric N Bond) showed higher mean shear bond strength compared to seventh generation bonding system (Single Bond Universal).

Duddu MK et al (2015)²⁶ compared the shear bond strength (SBS) and microleakage of Tetric N-Bond, G-bond, and Xeno V (seventh generation dentin adhesives) in primary anterior teeth. The result suggested that the three bonding agents, there were no statistically significant differences in SBS. G bond showed higher microleakage when compared to the others.

Jayasheel A et al (2017)³⁸ evaluated the degree of bond strength produced by these new commercially available bonding agents [Tetric N Bond Universal Vivapen (Ivoclar Vivadent) and Single Bond Universal (3M ESPE)], and compare their bond strength produced by a total etch bonding system (Tetric N Bond) and Self Etch (Clearfil SE). They concluded that the bond strength values of the TBU regardless of application mode were comparable to SBU making them reliable for working under different clinical conditions.

MODIFIED USPHS CRITERIA

Chadwick RG et al (1991)²¹ This paper describes monitoring the wear of restorations borne by partial dentures over a 12-month period using a novel photogrammetric technique and modified United States Public Health Service (USPHS) criteria. It is concluded that the photogrammetric technique is more valuable in the *in vivo* assessment of the performance of restorative materials.

Celik C et al (2010)¹⁹ evaluated and compared the 12month clinical performances of two different posterior composites (nanohybrid composite (Grandio) and low-shrinkage

composite (Quixfil), in Class I and Class II restorations using modified USPHS criteria. They assessed clinically that nanohybrid (Grandio) and low-shrinkage posterior composite (Quixfil) exhibited good clinical results with predominating alpha scores after 12 months.

Konde S et al (2012)⁴⁰ clinically evaluated and compared the nano ionomer (Ketac Nano 100 3M ESPE) and high-viscosity glass ionomer (Fuji IX GC) using United States Public Health Services (USPHS) Modified Cvar/Ryge Criteria with ART approach. The results indicate that nanoionomer can be a successful alternative restorative material for use with ART technique.

Efes B G et al (2013)²⁸ compared the 2-year clinical performance of a Silorane-based resin composite (Filtek Silorane) with that of an established nanoceramic resin composite (Ceram.X Duo) for class 1 posterior restorations and evaluated using the modified USPHS criteria at baseline and 6, 12, and 24 months. They concluded that Filtek Silorane, a low-shrinkage Silorane -based resin composite, showed comparable clinical performance to Ceram.X Duo, an established nanoceramic resin composite, for class 1 posterior restorations.

Celik C et al (2014)²⁰ evaluated the clinical performance of a nanohybrid resin composite Grandio and its self-etch adhesive Futurabond NR (Voco) or with the microhybrid resin composite Quixfil and its self-etch adhesive Xeno III (Dentsply, Germany) in class I and II restorations after 3 years using modified United States Public Health Service (USPHS) criteria. The study showed that both the nanohybrid and the microhybrid composites were clinically functional after 3 years.

Moncada G et al (2014)⁵⁴ compared the efficacy of a direct clinical evaluation method (modified Ryge Criteria) with an indirect digital photographic method in assessing the

quality of dental restorations. Seven parameters (color, occlusal marginal adaptation, anatomy form, roughness, occlusal marginal stain, luster, and secondary caries) were assessed in Class I and Class II restorations. The digital photographic method providing information that goes unnoticed with the visual-tactile clinical examination method. Additionally, the digital photographic method revealed a significant increase of defects compared to those clinically observed with the naked eye.

Gianordoli-Neto R et al (2016)³³ assessed the clinical performance of restorative systems (Filtek Z250 and P60), during 2 years of clinical service, using the US Public Health Service system. They concluded that after 24 months of evaluation, both restorative systems exhibited acceptable clinical performance.

Alomairy A et al (2018)⁷ compared the clinical performance of class II restored with Tetric Evo Ceram bulk-fill, Filtek bulk-fill resin composite, and layered Filtek Z250 resin composite restorations using Modified USPHS Criteria for the following characteristics: anatomical form, marginal adaptation, color match, marginal discoloration, surface roughness, and secondary caries. The restorations were evaluated at a baseline, and then blindly at 6 months by two independent examiners. The result showed that all restorations showed no statistically significant differences detected between their performance regarding the retention, marginal discoloration, recurrent caries, marginal adaptation and interproximal contact at base line and after 6-months recall. Hence concluded that Bulk fill restorative materials (Tetric Evo ceram bulk fill & Filtek bulk-fill) showed clinical outcomes like that of conventional resin-based composite.

MATERIALS AND METHODS

This study is a single center prospective randomized controlled clinical trial. This study is about comparison of clinical performance of three different restorative materials Cention N with adhesive, Cention N without adhesive and composite resin (Tetric N Ceram bulk fill)

ARMAMENTARIUM (Fig 2 A-C)

1. Mouth mirror.
2. Probe.
3. Tweezer.
4. Sterile cotton, sterile gauze.
5. Disposable Gloves, Face Mask, Head Cap, Patient Apron, Suction Tip.
6. High speed airotor handpiece (NSK, Tokyo, Japan)
7. Dental Magnifying loupes 3.5X (NMD, KOREA)
8. Pear shaped bur (no: 245, MANI carbide Burs FG)
9. Inverted cone bur (no:33 ½, MANI Carbide Burs FG)
10. TF-12EF (MANI Dia burs inc).
11. Rubber dam kit (GDC, Germany)
12. Plastic spatula and mixing pad.
13. Plastic filling instrument
14. Light cure unit Blue phase N MC (IVOCLAR VIVADENT)
15. Applicator tip for applying bonding agent and etchant
16. Composite finishing & polishing kit (Super-Snap Mini-Kit, SHOFU, Kyoto, Japan)

Table-1

Fig-3

EXPERIMENTAL MATERIAL	COMPOSITION	MANUFACTURER
1. CENTION N	Available as powder and liquid. The liquid comprises dimethacrylates (UDMA, DCP, an aromatic aliphatic-UDMA and PEG-400 DMA) and initiators, whilst the powder contains various glass fillers (barium aluminium silicate glass filler, ytterbium trifluoride, an Isofiller, a calcium barium aluminium fluorosilicate glass filler and a calcium fluorosilicate (alkaline) glass filler, initiator (Ivocerin) and pigments.	(IVOCLAR, VIVADENT)
2. TETRIC N CERAM BULK FILL COMPOSITE	Dimethacrylates (Bis-GMA, Bis-EMA and UDMA), Polymer Filler (barium aluminium silicate glass), an Isofiller, ytterbium fluoride and spherical mixed oxide. Additive, Initiators- Ivocerin - a dibenzoyl germanium derivative, Stabilizers, Pigments	(IVOCLAR, VIVADENT)
3. TETRIC N BOND	Bis-GMA, HEMA, Urethane dimethacrylate, Phosphoric acid acrylate, Nano-fillers (SiO ₂), Ethanol, Initiators and stabilizers	(IVOCLAR, VIVADENT)
4. NETCH	Phosphoric acid (37 wt.% in water), thickeners and pigments.	(IVOCLAR, VIVADENT)

CRITERIA FOR SELECTION**INCLUSION CRITERIA:**

1. Apparently healthy with good hygiene.
2. Permanent molars requiring class 1 for treating primary carious lesions.
3. Patient with at least 8 posterior teeth in occlusion.
4. Patient older than 15 years and less than 50 years.
5. Patient not receiving orthodontic treatment.

EXCLUSION CRITERIA:

1. Poor oral hygiene.
2. Patient needing endodontic treatment or those with non-vital teeth and periodontal problems.
3. Patient with known allergy to any material in the study.
4. Patient who cannot come for follow up based on medical history.
5. Fractured or cracked teeth.
6. Atypical extrinsic staining of teeth.
7. Defective restoration adjacent to the tooth.
8. Long term history of taking psychotropic drugs.
9. Patient with habitual history of tobacco, pan betel nut chewing.
10. Teeth not conducive for rubber dam isolation.

PATIENT RECRUITMENT

Patients were recruited in the order they appear for the screening session in the Government Dental College and Hospital, Chennai, thus forming a convenience sample of patients.

STUDY PROTOCOL

1. Institutional review board approval
2. Pre-operative clinical evaluation of patient.
3. Restoration done with Cention N without adhesive, Cention N with adhesive (Tetric N Bond) and resin composite (Tetric N Ceram bulk fill).
4. Post-operative clinical evaluation done at one week, 6, 12 and 24 months using modified USPHS Criteria.

STUDY DESIGN METHODOLOGY

In this study Ethical clearance was obtained from the Institution's Ethical Committee. The randomized clinical trial was carried out in the Department of Conservative Dentistry and Endodontics, Tamil Nadu Government Dental College and Hospital, Chennai, India. Patients were selected in the age group 15-50 years, with primary carious (class 1) in maxillary and mandibular molars with no radiographic evidence of deep caries approximating the pulp chamber and no evidence of thickening/ widening of periodontal ligament. Patients who fulfilled the above-mentioned criteria were selected for the study with no discrimination based on sex, caste, religion or socioeconomic status. The complete treatment procedure was explained to the patients and a written informed consent was obtained from all the patients selected for the study. The subjects were randomly divided into 3 groups.

Group I : Cention N without adhesive as restorative material (n=50)

Group II : Cention N with adhesive as restorative material (n=50)

Group III : Composite Resin (Tetric N Ceram Bulk Fill) as restorative material (n=50)

METHODOLOGY**PREOPERATIVE EVALUATION OF THE PATIENTS:**

Medical and dental history were recorded for all the patients selected for the study. Preoperative clinical and intraoral assessment was done in terms of pain, tenderness on percussion, periodontal status and restorability of the tooth.

CLINICAL PROCEDURE**Group I: CENTION-N WITHOUT ADHESIVE (Fig 4 A- H):**

Under isolation, the cavity preparation was done using no.245 pear shaped bur (MANI Carbide burs FG). The geometry of the cavity was predetermined by the dimension of the carious lesion. The depth of the cavity was 1.25 to 1.5mm or approximately 0.2mm inside the DEJ. The cavosurface margin of the cavity was 90° (i.e. enamel margins were not beveled). Cavity walls were occlusally converged & pulpal floor was made flat.

Cention N was hand mixed in the liquid powder ratio of 4.6:1 (1 scoop of powder & 1 drop of liquid) as per the manufacturer's instructions. Mix the powder & liquid on the mixing pad using a plastic spatula until a homogeneous consistency was achieved (45-60 s). Cention N (shade A2) was applied in bulk without an adhesive resin and the setting time is 4 minutes. After setting time, excess material was removed with fine grit diamond (TF-12EF, MANI Dia Burs Inc). Polishing of the restoration was done using SHOFU kit on the same day of restoration.

Group II: CENTION-N WITH ADHESIVE (TETRIC N BOND) (Fig 5A-O):

Under isolation, the cavity preparation was done using inverted cone diamond (no:33½ MANI Carbide-burs FG,). The geometry of the cavity was predetermined by the dimension of the carious lesion. The depth of the cavity was 1.25 to 1.5mm or

approximately 0.2mm inside the DEJ. Slightly bevel or round out the enamel margins (cavosurface margins is greater than 90°) to increase the surface area for bonding using finishing diamonds (grit size 25-40µm).

Subsequently, cavity was rinsed with water to remove all residue. Then N-etch (Ivoclar Vivadent) was applied onto the prepared cavity for 15 seconds. Etchant was thoroughly rinsed with water spray and gently dried with air jet.

A thick layer of Tetric N Bond (Ivoclar Vivadent) was applied on the enamel & dentin surface using a disposable applicator. Brush the material gently into the dentin for at least 10 sec. Then Tetric N bond was light cured using a polymerisation unit with a light intensity of $> 1000 \text{ mWcm}^2$ for 10 sec according to manufacturer's instruction.

Cention N was manipulated and bulk filled inside the cavity and excess material was removed using fine grit diamond (TF-12EF, MANI Dia Burs Inc) & polishing was done using Shofu kit on the same day of restoration.

GROUP III: COMPOSITE RESIN (TETRIC N CERAM BULK FILL) (Fig 6A-O):

Shade selection done using Tetric N Ceram bulk fill shade guide. Under isolation, cavity preparation was done using small inverted cone diamond (No:33 ½ MANI Carbide burs FG). The initial pulpal depth is 1.25- 1.5mm or approximately 0.2mm inside the DEJ. Slightly bevel or round out the enamel margins (cavosurface margins is greater than 90°) to increase the surface area for bonding using finishing diamonds (grit size 25-40µm). Cavity preparation do not require any typical resistance and retention features.

Subsequently, cavity was rinsed with water to remove all residue. Then N-etch (Ivoclar Vivadent) was applied onto the prepared cavity for 15 seconds. Etchant was thoroughly rinsed with water spray and gently dried with air jet.

A thick layer of Tetric N Bond (Ivoclar Vivadent) was applied on the enamel & dentin surface using a disposable applicator. Brush the material gently into the dentin for at least 10 sec. Then Tetric N bond was light cured using a polymerisation unit with a light intensity of $>1000\text{Mw}/\text{cm}^2$ for 10 sec according to manufacturer's instruction.

Tetric n Ceram bulk fill (Ivoclar Vivadent) was bulk filled inside the cavity and light cured using a polymerisation unit with a light intensity of $> 1000\text{ mWcm}^2$ for 15 sec according to manufacturer's instruction.

The restoration was finished by removing excess material and polishing done using composite polishing kit (Shofu Inc. Kyoto japan)

CLINICAL FOLLOW UP

The clinical evaluation of the restoration is done at 1 week, after 6, 12 and 24 months using modified US Public health service criteria (USPHS).

Post-Operative radiograph was taken for all the subjects at all time intervals.

The restoration is classified and demonstrated by score. Alpha – ideal clinical situation, bravo- clinically acceptable and Charlie- clinically unacceptable situations.

MODIFIED USPHS CRITERIA ⁽¹⁶⁾

Table-2:

CATEGORY	RATING	CRITERION
Marginal discoloration (MD)	Alfa(A)	No discoloration.
	Bravo(B)	Superficial staining (without axial penetration).
	Charlie(C)	Deep staining with axial penetration
Marginal integrity (MI)	Alfa(A)	Closely adapted, no visible crevice.
	Bravo(B)	Visible crevice, explorer will penetrate.
	Charlie(C)	Crevice in which dentin is exposed.
Surface texture (ST)	Alfa(A)	As smooth as the surrounding enamel.
	Bravo(B)	Rougher than surrounding enamel.
	Charlie(C)	Very rough.
Wear (W)	Alfa(A)	Continuous
	Bravo(B)	Discontinuous, no dentin exposed.
	Charlie(C)	Discontinuous, dentin exposed.
Post-operative sensitivity	Alfa(A)	None.
	Charlie(C)	Present.
Recurrent caries (RC)	Alfa(A)	No caries presents.
	Charlie(C)	Caries present.

STATISTICAL ANALYSIS

At the end of the review period, the following data was obtained:

- Assessment of clinical parameters
- Evaluation using modified USPHS

The data obtained was analyzed using statistical software SPSS version 25.

FIG-1: PROCEDURAL FLOW CHART

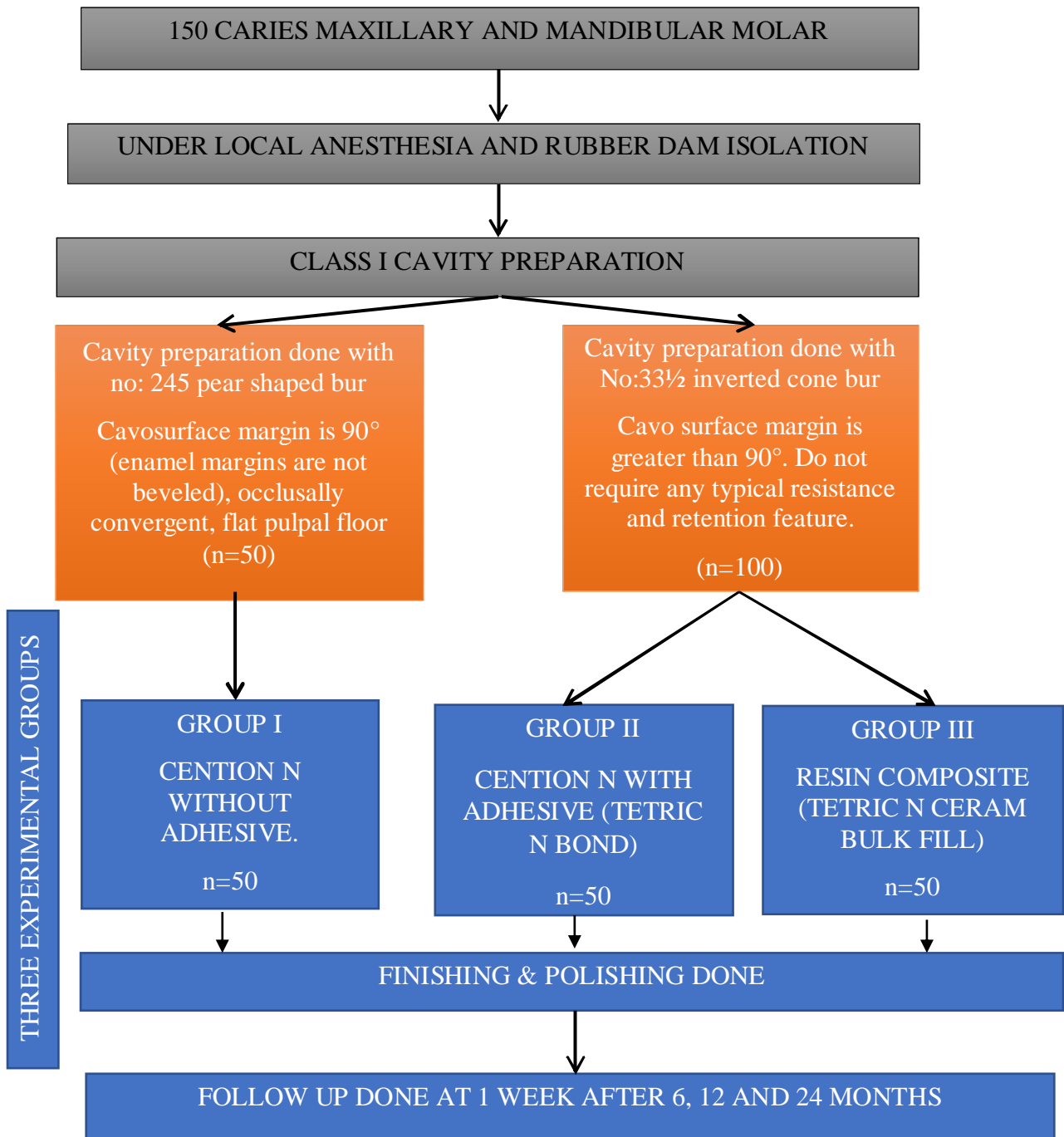


Fig-2A: ARMAMENTARIUM



FIG -2B: DENTAL MAGNIFYING LOUPES 3.5X (NMD, KOREA)



FIG -2C: LIGHT CURING UNIT BLUE PHASE N (IVOCLAR VIVADENT)



FIG-3: EXPERIMENTAL MATERIAL

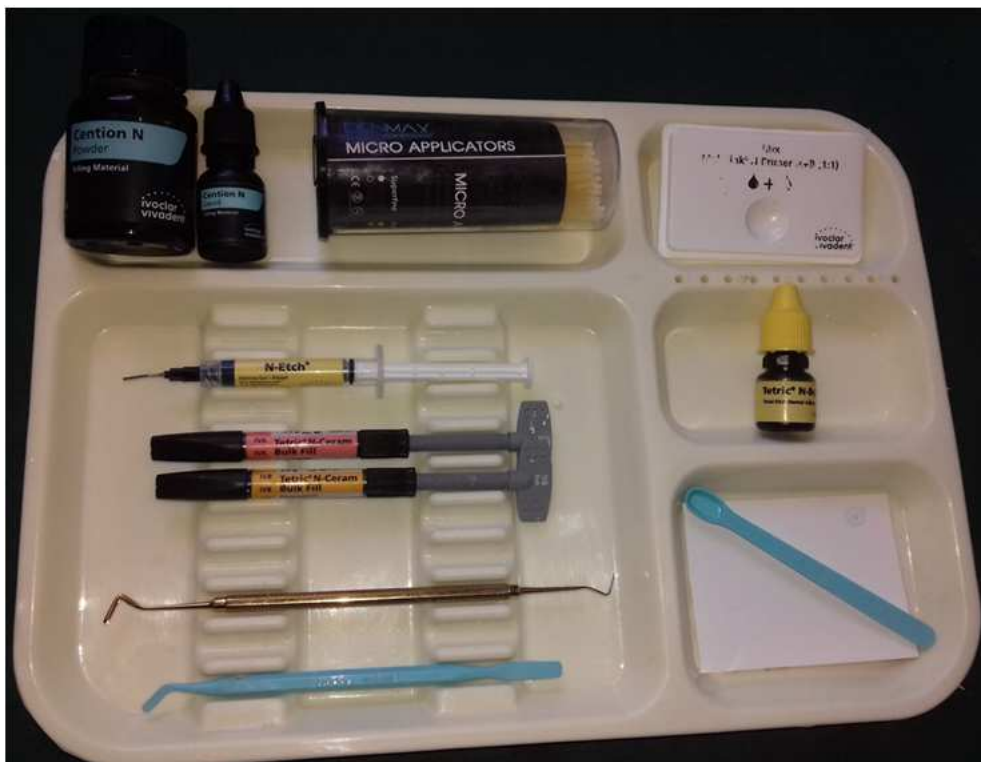


FIG-4: GROUP-1: CENTION N WITHOUT ADHESIVE



A. PRE OPERATIVE PHOTOGRAPH



B. PREOPERATIVE RADIOGRAPH



C. CLASS 1 CAVITY PREPARATION



D. CENTION N RESTORED WITHOUT ADHESIVE



E. RADIOGRAPH (BASE LINE)



F. RADIOGRAPH (6 MONTH)



G.RADIOGRAPH (12 MONTHS)



H.RADIOGRAPH (24 MONTHS)

FIG-5: GROUP 2 (CENTION N WITH ADHESIVE)



A.PRE-OPERATIVE PHOTOGRAPH



B.PRE-OPERATIVE RADIOGRAPH



C.CLASS 1 CAVITY PREPARATION



D.ETCHING DONE USING N-ETCH
(IVOCLAR VIVADENT)



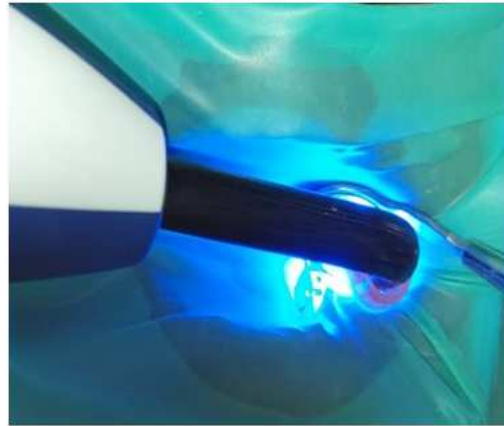
E.ETCHING DONE FOR 15 SECONDS



F.RINSED AND AIR DRIED



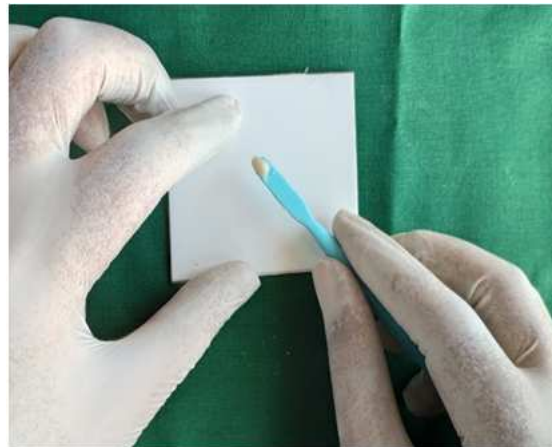
G.TETRIC N BOND (IVOCLAR VIVADENT) APPLIED FOR 10 SEC



H.LIGHT CURED FOR 10 SEC USING BLUEPHASE N



I.CENTION N LIQUID POWDER RATIO OF 4.6:1



J. MIXING TIME 45-60 SECONDS



K.CENTION N RESTORED WITH ADHESIVE



L.POST OPERATIVE RADIOGRAPH BASELINE



M.6 MONTHS



N.12 MONTHS



O.24 MONTHS

FIG-6: GROUP 3 (TETRIC N CERAM BULK FILL)



A. PREOPERATIVE PHOTOGRAPH



B. PREOPERATIVE RADIOGRAPH



C. CLASS 1 CAVITY PREPARATION



D. ETCHING DONE USING N-ETCH (IVOCLAR VIVADENT)



E. ETCHING DONE FOR 15 SEC



F. RINSED AND AIR DRIED



G. TETRIC N BOND APPLIED FOR 10 SEC



H. TETRIC N BOND CURED FOR 10 SEC USING BLUE PHASE N



I. TETRIC N CERAM RESTORED



J. TETRIC N CERAM BULK FILL KIT



K. FINISHING AND POLISHING DONE USING SHOFU



L. POST OPERATIVE RADIOGRAPH



M.6 MONTHS



N.12 MONTHS



O.24 MONTHS

RESULTS

RESULTS

Table 3 denotes total number of distributions of Alpha, Bravo, Charlie among three groups for all parameters.

Table 4 shows percentage distribution of grading among 3 groups for all parameters.

Table 5 (A, B, C, D, E, F) denotes descriptive statistics of the gradings.

STATISTICAL ANALYSIS

The data were tabulated in an excel sheet and analyzed statistically using SPSS Software version 25

Among the total number of patients (50) recruited in group 1, follow up done for all the patients till 6 months. 3 patients did not come for the follow up for 12 and 24 months. Drop out -3. So totally 47 patients were reviewed and the readings were tabulated.

Among the total number of patients (50) recruited in group 2, all patients were reviewed without any drop outs and the readings were tabulated.

Among the total number of patients (50) recruited in group 3, one patients did not attend the 6 months review (one drop out), in 12 months review, another two patients failed to attend, in 24 months review, one more patients did not come for follow up. So totally 4 drop outs in group 3, and 46 patient's readings were tabulated.

The readings were graded as 1,2,3 for alpha, bravo, Charlie respectively. Kruskal Wallis test and chi square test were employed in detecting the statistically significant difference among the 3 groups for all 6 parameters at different time intervals. The p value was set at 0.05.

TABLE-3: DISTRIBUTIONS OF ALPHA, BRAVO, CHARLIE AMONG THREE GROUPS

		Marginal Discoloration (MD)			Marginal Integrity (MI)			Surface Texture (SI)			Wear (W)			Post-operative Sensitivity (PO)		Recurrent Caries (RC)	
		A	B	Ch	A	B	Ch	A	B	Ch	A	B	Ch	A	Ch	A	Ch
Base line (1 Week)	C	47	0	0	47	0	0	47	0	0	47	0	0	47	0	47	0
	CA	50	0	0	50	0	0	50	0	0	50	0	0	50	0	50	0
	TC	46	0	0	46	0	0	46	0	0	46	0	0	46	0	46	0
6 Months	C	45	2	0	47	0	0	45	2	0	47	0	0	45	2	47	0
	CA	49	1	0	50	0	0	50	0	0	50	0	0	49	1	50	0
	TC	46	0	0	46	0	0	46	0	0	46	0	0	45	1	46	0
12 months	C	44	3	0	47	0	0	47	0	0	46	1	0	45	2	47	0
	CA	49	1	0	50	0	0	49	1	0	50	0	0	47	3	50	0
	TC	46	0	0	45	1	0	46	0	0	46	0	0	42	4	46	0
24 Months	C	43	4	0	47	0	0	45	2	0	46	1	0	43	4	47	0
	CA	47	3	0	50	0	0	48	2	0	50	0	0	47	3	50	0
	TC	45	1	0	44	2	0	45	1	0	46	0	0	41	5	46	0

A-alpha; B-bravo; Ch- Charlie.

C-Cention N Without adhesive; CA- Cention N with adhesive; TC- Tetric N Ceram

TABLE-4: PERCENTAGE DISTRIBUTION OF GRADING AMONG 3 GROUPS

		Marginal Discoloration (MD)			Marginal Integrity (MI)			Surface Texture (ST)			Wear (W)			Post-Operative Sensitivity (PS)		Recurrent Caries (RC)		p-Value
		A	B	Ch	A	B	Ch	A	B	Ch	A	B	Ch	A	Ch	A	Ch	<i>Chi Square Test</i>
BASE LINE	<i>C</i>	100	0	0	100	0	0	100	0	0	100	0	0	100	0	100	0	<i>p>0.05</i>
	<i>CA</i>	100	0	0	100	0	0	100	0	0	100	0	0	100	0	100	0	
	<i>TC</i>	100	0	0	100	0	0	100	0	0	100	0	0	100	0	100	0	
6 MONTHS	<i>C</i>	95.75	4.25	0	100	0	0	95.75	4.25	0	100	0	0	95.75	4.25	100	0	<i>p>0.05</i>
	<i>CA</i>	98	2	0	100	0	0	100	0	0	100	0	0	98	2	100	0	
	<i>TC</i>	100	0	0	100	0	0	100	0	0	100	0	0	97.82	2.17	100	0	
12 MONTHS	<i>C</i>	93.61	6.38	0	100	0	0	100	0	0	97.87	2.12	0	95.75	4.25	100	0	<i>p>0.05</i>
	<i>CA</i>	98	2	0	100	0	0	98	2	0	100	0	0	94	6	100	0	
	<i>TC</i>	100	0	0	97.82	2.17	0	100	0	0	100	0	0	91.30	8.70	100	0	
24 MONTHS	<i>C</i>	91.48	8.52	0	100	0	0	95.75	4.25	0	97.87	2.12	0	91.48	8.52	100	0	<i>p>0.05</i>
	<i>CA</i>	94	6	0	100	0	0	96	4	0	100	0	0	94	6	100	0	
	<i>TC</i>	97.82	2.17	0	95.65	4.35	0	97.82	2.17	0	100	0	0	89.13	10.87	100	0	

C-Cention N Without adhesive; CA- Cention N with adhesive; TC- Tetric N Ceram

BASE LINE – 1 WEEK.

Chi-square test reveals that no statistically significant difference among all the 3 groups for all the parameters. P value greater than 0.05(table 4).

TABLE 5A Descriptive statistics for Marginal Discoloration

GROUPS		Report			
		MD 1W	MD 6M	MD 12M	MD 24M
Cention	Mean	1.00	1.04	1.06	1.09
	Std. Deviation	.000	.204	.247	.282
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	2	2	2
	N	47	47	47	47
Cention+Adhesive	Mean	1.00	1.02	1.02	1.04
	Std. Deviation	.000	.141	.141	.198
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	2	2	2
	N	50	50	50	50
Tetric N Ceram	Mean	1.00	1.00	1.00	1.02
	Std. Deviation	.000	.000	.000	.147
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	2
	N	46	46	46	46
Total	Mean	1.00	1.02	1.03	1.05
	Std. Deviation	.000	.144	.165	.217
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	2	2	2
	N	143	143	143	143

TABLE 5B Descriptive statistics for Marginal Integrity

GROUPS		MI 1W	MI 6M	MI 12M	MI 24M
Cention	Mean	1.00	1.00	1.00	1.00
	Std. Deviation	.000	.000	.000	.000
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	1
	N	47	47	47	47
Cention+Adhesive	Mean	1.00	1.00	1.00	1.00
	Std. Deviation	.000	.000	.000	.000
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	1
	N	50	50	50	50
Tetric N Ceram	Mean	1.00	1.00	1.02	1.04
	Std. Deviation	.000	.000	.147	.206
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	2	2
	N	46	46	46	46
Total	Mean	1.00	1.00	1.01	1.01
	Std. Deviation	.000	.000	.084	.118
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	2	2
	N	143	143	143	143

TABLE 5C Descriptive statistics for Surface Texture

GROUPS		ST 1W	ST 6M	ST 12M	ST 24M
Cention	Mean	1.00	1.04	1.00	1.04
	Std. Deviation	.000	.204	.000	.204
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	2	1	2
	N	47	47	47	47
Cention+Adhesive	Mean	1.00	1.00	1.02	1.04
	Std. Deviation	.000	.000	.141	.198
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	2	2
	N	50	50	50	50
Tetric N Ceram	Mean	1.00	1.00	1.00	1.02
	Std. Deviation	.000	.000	.000	.147
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	2
	N	46	46	46	46
Total	Mean	1.00	1.01	1.01	1.03
	Std. Deviation	.000	.118	.084	.184
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	2	2	2
	N	143	143	143	143

TABLE 5D Descriptive statistics for Wear

GROUPS		Wear 1W	Wear 6M	Wear 12M	Wear 24M
Cention	Mean	1.00	1.00	1.02	1.02
	Std. Deviation	.000	.000	.146	.146
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	2	2
	N	47	47	47	47
Cention+Adhesive	Mean	1.00	1.00	1.00	1.00
	Std. Deviation	.000	.000	.000	.000
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	1
	N	50	50	50	50
Tetric N Ceram	Mean	1.00	1.00	1.00	1.00
	Std. Deviation	.000	.000	.000	.000
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	1
	N	46	46	46	46
Total	Mean	1.00	1.00	1.01	1.01
	Std. Deviation	.000	.000	.084	.084
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	2	2
	N	143	143	143	143

TABLE 5E Descriptive statistics for Postoperative Sensitivity

GROUPS		PS 1W	PS 6M	PS 12M	PS 24M
Cention	Mean	1.00	1.09	1.09	1.17
	Std. Deviation	.000	.408	.408	.564
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	3	3	3
	N	47	47	47	47
Cention+Adhesive	Mean	1.00	1.04	1.12	1.12
	Std. Deviation	.000	.283	.480	.480
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	3	3	3
	N	50	50	50	50
Tetric N Ceram	Mean	1.00	1.04	1.22	1.26
	Std. Deviation	.000	.295	.629	.681
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	3	3	3
	N	46	46	46	46
Total	Mean	1.00	1.06	1.14	1.18
	Std. Deviation	.000	.331	.512	.577
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	3	3	3
	N	143	143	143	143

TABLE 5F Descriptive statistics for recurrent caries

GROUPS		RC 1W	RC 6M	RC 12M	RC 24M
Cention	Mean	1.00	1.00	1.00	1.00
	Std. Deviation	.000	.000	.000	.000
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	1
	N	47	47	47	47
Cention+Adhesive	Mean	1.00	1.00	1.00	1.00
	Std. Deviation	.000	.000	.000	.000
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	1
	N	50	50	50	50
Tetric N Ceram	Mean	1.00	1.00	1.00	1.00
	Std. Deviation	.000	.000	.000	.000
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	1
	N	46	46	46	46
Total	Mean	1.00	1.00	1.00	1.00
	Std. Deviation	.000	.000	.000	.000
	Median	1.00	1.00	1.00	1.00
	Minimum	1	1	1	1
	Maximum	1	1	1	1
	N	143	143	143	143

TABLE 6A-INFERENTIAL STATISTICS FOR MARGINAL DISCOLORATION

Null Hypothesis	Test	Sig.	Decision
The distribution of MD 1W is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of MD 6M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.361	Retain the null hypothesis.
The distribution of MD 12M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.162	Retain the null hypothesis.
The distribution of MD 24M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.346	Retain the null hypothesis.

TABLE 6B- INFERENTIAL STATISTICS FOR MARGINAL INTEGRITY

Null Hypothesis	Test	Sig.	Decision
The distribution of MI 1W is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of MI 6M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of MI 12M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.348	Retain the null hypothesis.
The distribution of MI 24M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.120	Retain the null hypothesis.

TABLE-6C INFERENCE STATISTICS FOR SURFACE TEXTURE

Null Hypothesis	Test	Sig.	Decision
The distribution of ST 1W is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of ST 6M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.128	Retain the null hypothesis.
The distribution of ST 12M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.395	Retain the null hypothesis.
The distribution of ST 24M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.838	Retain the null hypothesis.

TABLE-6D INFERENCE STATISTICS FOR WEAR

Null Hypothesis	Test	Sig.	Decision
The distribution of Wear 1W is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of Wear 6M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of Wear 12M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.360	Retain the null hypothesis.
The distribution of Wear 24M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.360	Retain the null hypothesis.

TABLE-6E INFERENCE STATISTICS FOR POSTOPERATIVE SENSITIVITY

Null Hypothesis	Test	Sig.	Decision
The distribution of PS 1W is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of PS 6M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.761	Retain the null hypothesis.
The distribution of PS 12M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.434	Retain the null hypothesis.
The distribution of PS 24M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	.483	Retain the null hypothesis.

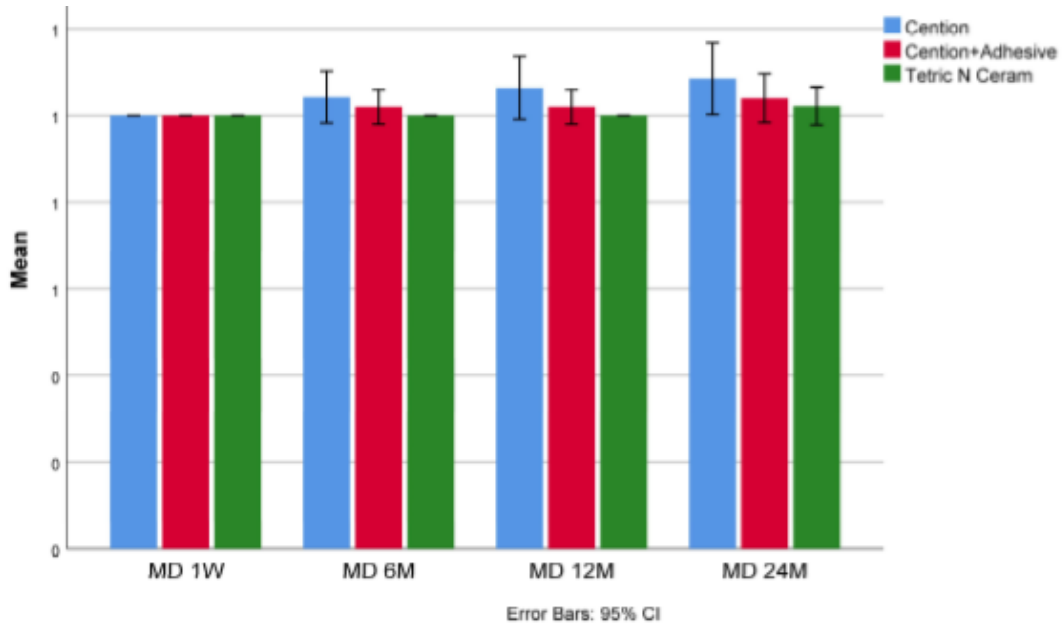
TABLE-6F INFERENCE STATISTICS FOR RECURRENT CARIES

Null Hypothesis	Test	Sig.	Decision
The distribution of RC 1M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of RC 6M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of RC 12M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.
The distribution of RC 24M is the same across categories of GROUPS.	Independent-Samples Kruskal-Wallis Test	1.000	Retain the null hypothesis.

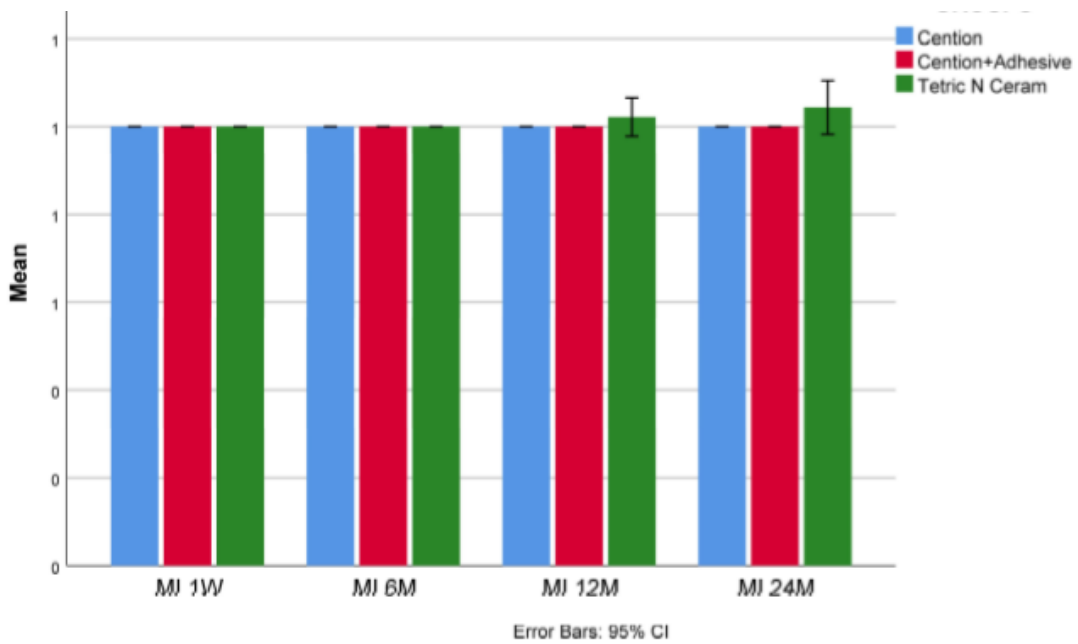
Kruskal Wallis test reveals that no statistically significant difference among all the 3 groups for all parameters (Table 5A-5F).

GRAPHICAL REPRESENTATION

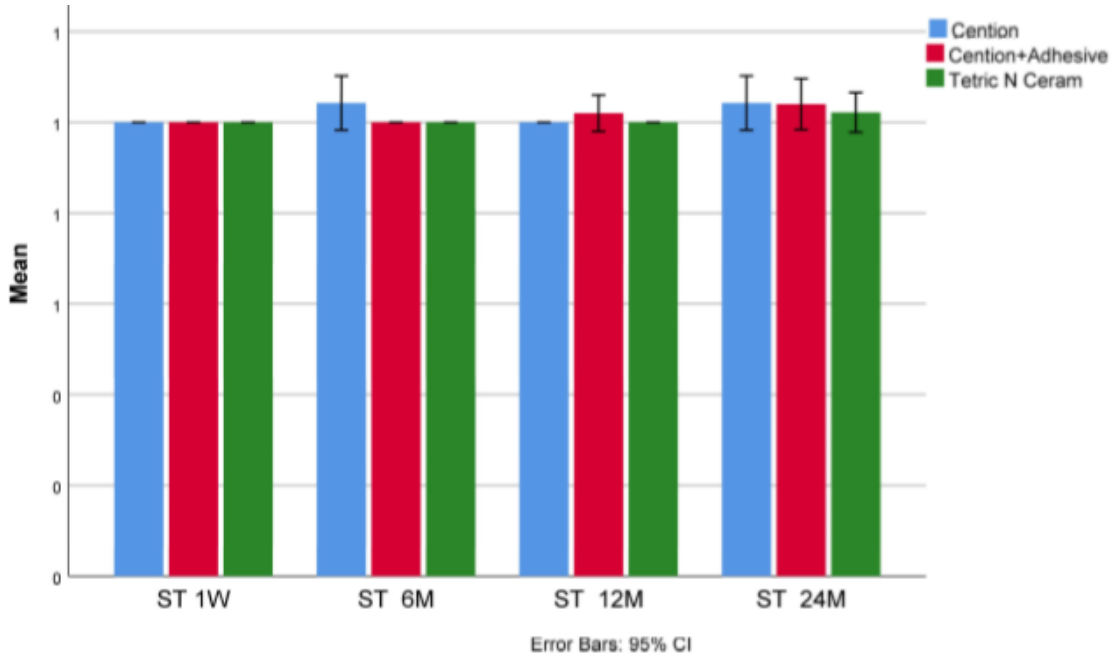
Bar diagram (1) depicting marginal discoloration (MD)



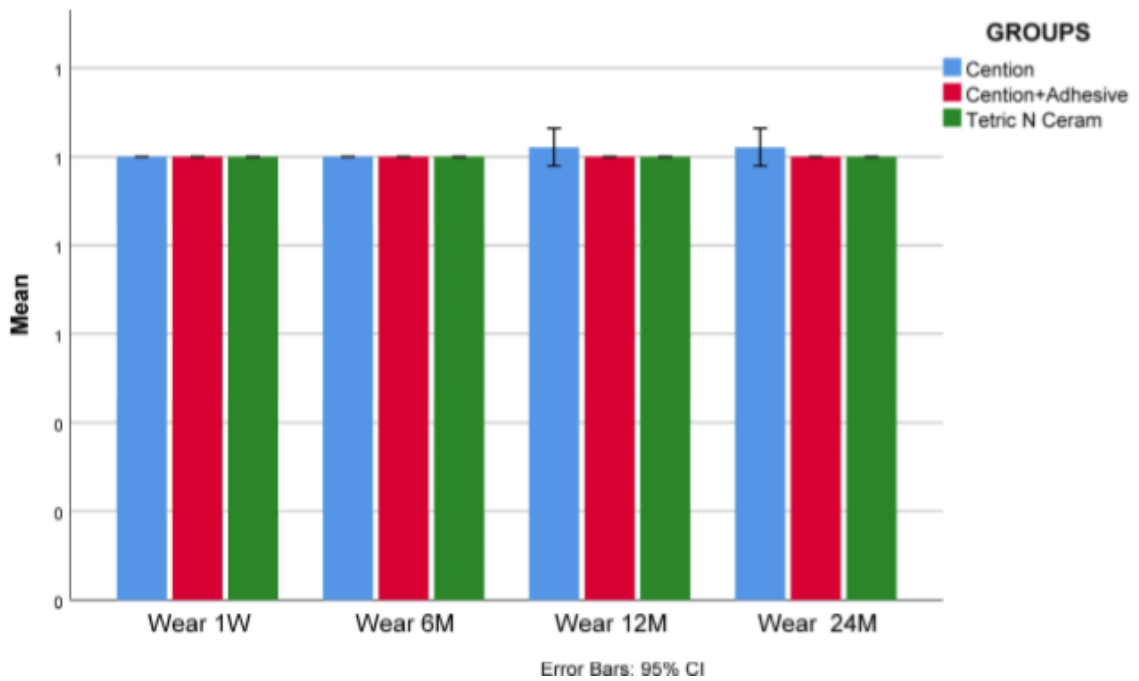
Bar diagram (2) depicting marginal integrity (MI) for three materials (Cention, Cention+Adhesive, Tetric N Ceram) at four time points (MI 1W, MI 6M, MI 12M, MI 24M). The Y-axis represents Mean (0 to 1). Error Bars: 95% CI.



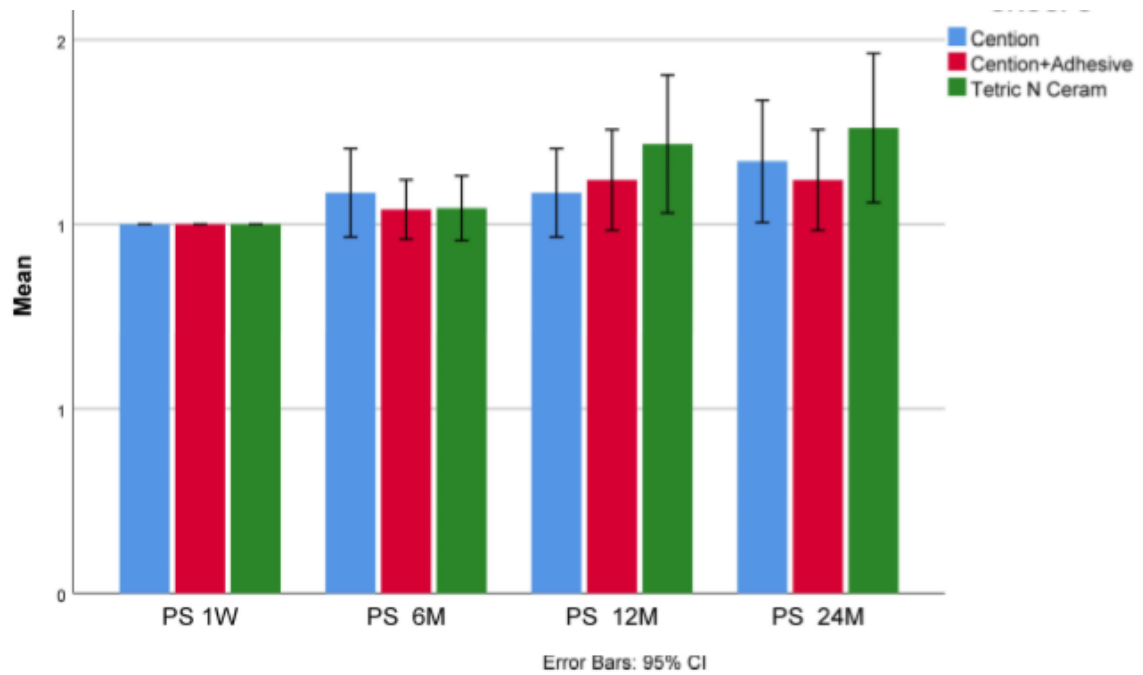
Bar diagram (3) depicting Surface Texture (ST)



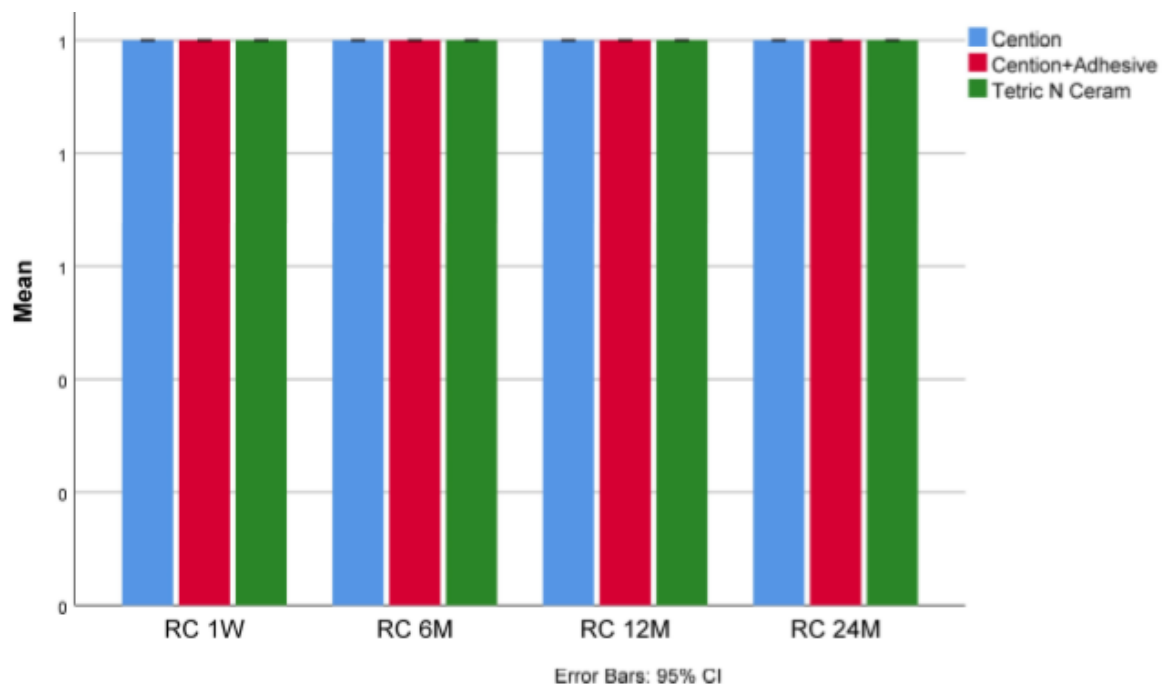
Bar diagram (4) depicting Wear(W)



Bar diagram (5) depicting Postoperative Sensitivity (PS)



Bar diagram (6) depicting Recurrent Caries (RC)



INFERENCE

CLINICAL PARAMETERS

MARGINAL DISCOLORATION

- After 6 months, in group 1, only two restoration shows bravo score, in group 2, only one restoration shows bravo score and group 3 all restoration shows alpha score.
- After 12 months, in group 1, only three restoration shows bravo score, in group 2 only one restoration shows bravo score and group 3 all restoration shows alpha score.
- After 24 months, in group 1, four restoration shows bravo score, in group 2, three restoration shows bravo score and group 3 only one restoration shows bravo score.

However, there was no statistically significant difference among three groups in all the time interval(6,12,24months) in terms of marginal discoloration

MARGINAL INTEGRITY

- After 6 months, all the restoration shows alpha score in all the three experimental groups.
- After 12 and 24 months, all the restoration shows alpha score in group 1 and group 2
- In group 3, After 12 months, only one restoration shows bravo score and after 24 months only two restoration shows bravo score.

None of the restoration shows Charlie score in all the time interval in all the experimental groups

However, there was no statistically significant difference among three groups in all the time interval(6,12,24months) in terms of marginal integrity

SURFACE TEXTURE

- After 6 months, in group 1, only two restoration shows bravo score, in group 2 and group 3 all restoration shows alpha score.
- After 12 months, in group 1 and group 3, all restoration shows alpha score, in group 2 only one restoration shows bravo score
- After 24 months, in group 1 and group 2, two restoration shows bravo score, in group 3, only one restoration shows bravo score.

None of the restoration shows Charlie score in all the time interval in all the experimental groups

However, there was no statistically significant difference among three groups in all the time interval(6,12,24months) in terms of surface texture.

WEAR

- After 6 months, all the restoration shows alpha score in all the three groups
- After 12 months, in group 1, only one restoration shows bravo score. In group 2 and 3, all the restoration shows alpha score.
- After 24 months, in group 1, only one restoration shows bravo score. In group 2 and 3, all the restoration shows alpha score

None of the restoration shows Charlie score in all the time interval in all the experimental groups

However, there was no statistically significant difference among three groups in all the time interval(6,12,24months) in terms of wear.

POST OPERATIVE SENSITIVITY

- After 6 months, in group 1 two restoration shows Charlie score. In group 2 and 3, one restoration shows Charlie score respectively.
- After 12 months, in group 1, two restoration shows Charlie score. In group 2 , 3 restoration shows Charlie score , and group 3, four restoration shows Charlie score.
- After 24 months, in group 1, four restoration shows Charlie score. In group 2 , 3 restoration shows Charlie score , and group 3, five restoration shows Charlie score.

However, there was no statistically significant difference among three groups in all the time interval(6,12,24months) in terms of post-operative sensitivity.

RECURRENT CARIES

All the restoration shows alpha score (no evidence of secondary caries) in all the time interval in all the experimental groups.

DICUSSION

Amalgam has long been the most widely used posterior restorative material since it has many advantages like less technique-sensitive, less sensitive to the presence of moisture and easier to place, less chair side time, bactericidal^{14,79} and cost effective and also offers good longevity.

But amalgam has certain disadvantages like bulk fractures and marginal degradation⁶², require more tooth preparation than bonded restorations, delayed expansion, mercury disposal etc. More importantly, poor esthetics is the main reason why patients increasingly prefer the use of direct tooth coloured posterior restorations

Acrylic was the first introduced tooth coloured restoration. Subsequently, silicates and (di)methacrylate materials were came into use. Initially, silicates and composite materials were used only for anterior restorations due to its less strength. Another major drawback with Silicate cements is its high failure rate⁶¹.

Early resin-based composite restorations were an improvement over silicate cements; however, they were self-curing and required mixing of a base and a catalyst for curing, resulting in operator error during mixing and difficulties in timely and accurate placement. In addition, strength, bonding and retention were poor.

Later in 1970s light cured dimethacrylate composite were introduced⁷⁴. Posterior tooth-colored restoration introduced in the decade of 1980s and these restorations continued to evolve to improve their physical properties, user-friendliness and esthetics. Bonding systems and techniques have also evolved.

First, composites were mainly used in the anterior region, where the color of amalgam was deemed unaesthetic, however since effective bonding agents became available at

the beginning of the 1990s, composites becomes the most commonly used restorative material. But the composite resin also has certain drawbacks.

Composite restorations are subjected to polymerization shrinkage. Polymerization shrinkage results in stresses that can lead to enamel cracks, marginal degradation and microleakage, and postoperative sensitivity. Another drawback includes debonding of the tooth-composite interface^{78,60,15,16,66}

Recent developments and investigations of composite materials are aimed at reducing polymerization shrinkage of composites to increase the longevity of these restorations and reduce the potential for failure. Many modifications in terms of filler size (micro, macro, hybrid), percentage of filler, incorporating nanoparticles, in terms of viscosity etc have been introduced²³.

The ideal requirements of posterior restorative material - dimensionally stable, no expansion/shrinkage, wear resistance, sufficient compressive and flexural strength, able to withstand occlusal and masticatory load, biocompatibility, antibacterial preferably should be bactericidal, user-friendly, less operating time and ease of placement. Finally, it should also be esthetically pleasing to the patient and be color-stable and stain-resistant.

Even though ideal restorative material does not exist, Composite resin is by far the most commonly used restorative material for direct tooth coloured posterior restoration.

There is different type of posterior composite material available nowadays (low shrink posterior composite, nano fill composite, flowable composite, bulk fill composites, sonicated bulk fill composites)¹⁸.

Tetric N-Ceram Bulk Fill was introduced recently and it belongs to a category of nanohybrid⁷³ composite for direct restorations in posterior teeth, and may also be used

for Class V restorations, extended fissure sealing in molars and premolars and for reconstructive build-up. It can be bulk filled up to 4 mm without affecting the material's polymerisation behaviour or mechanical properties. It can be cured with conventional LED curing lights and also in just 10 seconds using a light source with $> 1000 \text{ mWcm}^2$, such as Bluephase N®.

For many years it has been advised to apply thin layers (up to 2 mm increment) of composite on top of one another, which are successively cured. This was deemed necessary to avoid unnecessary polymerisation shrinkage. The curing of 4 mm increments represents a paradigm shift in dentistry. This is achieved in Tetric N Ceram bulk fill through the addition of pre-polymer shrinkage stress reliever, the photo initiator Ivocerin® (polymerisation booster), and a light sensitivity filter⁷³.

Bulk fill composite material was mainly developed to reduce the polymerization shrinkage, to save the clinician's time, and simplify the application technique. However, the current scientific evidence about this new category is too weak, and sometimes confusing. Nevertheless, many laboratory studies^{45,30,65} and a few clinical case reports⁵¹ showed the efficiency of bulk filling restorative techniques.

Majority of nonbiased evidence-based studies recommended to conduct future randomized clinical trials. Furthermore, long term clinical follow up for bulk fill restorations is highly recommended.

The advent of new composite restorative materials, together with new adhesives has brought enormous benefits - notably in terms of esthetics and strides towards minimally invasive dentistry. They may however be perceived as expensive, time-consuming and technique sensitive. Their existence has not eliminated the need for or appropriateness of traditional "basic" dental materials (GIC and amalgam).

Dentists have long sought after a real alternative to currently available restorative material – a cost-effective, fluoride releasing product that is quick and easy to use without complicated equipment and that offers both strength and good esthetics.

New product has been introduced in the market, Cention N (Ivoclar Vivadent), a new basic filling material offering many advantages like cost-effective, dual curing, fluoride releasing product that is quick and easy to use without complicated equipment and also provides strength and esthetics. It can be used with and without adhesive⁷².

Cention N is an “alkasite” restorative. Alkasite belongs to a subgroup of the composite material class. This new category utilizes an alkaline filler, capable of releasing acid-neutralizing ions⁷².

Cention N is a tooth-coloured, restorative material for direct restorations. It is self-curing with optional additional light-curing. It is radiopaque, and releases fluoride, calcium and hydroxide ions.

As a dual-cured material it can be used as a full volume (bulk) replacement material. Optional light curing is carried out with blue light in the wavelength range of approximately 400 – 500 nm thus all standard polymerization lights can be used to cure the material. Cention N consists of a powder and liquid that are mixed by hand directly before use.

However, these developments have been so rapid that long-term clinical data on specific products are rarely available, because of the regular introduction of “improved” versions.

Mishra A et al (2018)⁵³ compared the flexural strength and compressive strength of nano hybrid composite, Tetric N ceram and Cention N and he concluded that

nanohybrid composite, has highest compressive strength and flexural strength than Cention N.

Mazumdar P et al (2018)⁵⁰ compared the bond strength between nano hybrid composite, Tetric N ceram and Cention N & they concluded that Cention N showed higher bond strength value than composite resin.

Both Cention N and Tetric N ceram bulk fill contains same filler composition like Isofiller (shrinkage stress reliever), barium aluminium silicate glass, Ytterbium trifluoride, photo initiator Ivocerin. Both releases fluoride ions. Both have comparable mechanical properties that was proven by many invitro studies.

These in vitro studies might provide useful data regarding the potential performance of a material; however, such tests cannot adequately evaluate the clinical performance of a material or the handling characteristics. In addition, in vitro studies cannot answer questions about the in vivo longevity of these tooth-colored restorations²⁷. However, long-term results with some of these newly developed materials are lacking and remain controversial as studies report inconsistent clinical results^{44,29}.

Hence in the current longitudinal randomized-controlled clinical study, we compared the performance of the newly introduced alkasite Cention N (with and without adhesive) to the resin composite (Tetric N Ceram Bulk fill) for two years.

All restorations in all the three groups were clinically evaluated after 1 week (baseline), 6 months, 12 months and 24 months by single operator who placed the restorations. All evaluations were carried out under a dental magnifying loupe 3.5x(NMD, Korea) using flat-surfaced mouth mirrors and dental explorers.

Even-though new methods and materials have been introduced to improve their characteristics, it is difficult for the restorative material to withstand the oral

environment against failures. Failure of the Restoration occur due to a variety of reasons. The reason for the failures includes secondary caries, surface wear, microleakage, marginal fracture, bulk fracture, discoloration, corrosion, lack of biocompatibility, and pain.

There are no well-defined criteria for quantifying the clinical failure of the restoration, and diagnostic techniques used to determine the quality of restorations are inadequate. Such criteria are necessary for determining factors like clinical significance of leakage, recurrent caries, and marginal fracture.

Several methods for the assessment of the quality of clinical dental procedures have been developed. In recent years, research activities relating to assessment of the quality of restorations have yielded several systems like USPHS Criteria, modified USPHS criteria, FDI criteria, Photogrammetric technique²¹. Even though FDI criteria covers a wide range of assessment parameters, Modified USPHS criteria is a simpler and more feasible method of assessment. Also, it is more relevant to the clinical parameters assessed in this study.

Hence, in this clinical study modified USPHS (United States Public Health Service) Criteria was used to evaluate the clinical performance of Cention-N with Tetric N ceram bulk fill as class 1 restoration. USPHS criteria for clinical evaluation of the restoration was developed by Cvar and Ryge in 1971 and has been used extensively for clinical evaluation of restorations which is the widely employed criteria used for long-term evaluation of restorations, and is considered valid for comparison purpose among studies at different observation periods²⁴.

The modified USPHS criteria for marginal discoloration, marginal integrity, recurrent caries, surface texture, wear, and postoperative sensitivity were used. Restorations were

scored as follows: Alfa - the ideal clinical situation; Bravo - a clinically acceptable situation, and Charlie - a clinically unacceptable situation in which case the restoration had to be replaced. For recurrent caries detection, radiographs were also taken at every follow-up.

For marginal discoloration, after 6 months, Group 1 showed 95% alpha scores and 4.25% bravo scores, group 2 showed 98% alpha score and 2% bravo score. In group 3 all restoration showed alpha score (100%). In 12 months, group 1 showed 93.6% alpha score and 6.3% bravo score, group 2 showed 98% alpha score and 2% bravo score and group 3 showed 100% alpha score. In 24 months, group 1 showed 91.5% alpha score and 8.5% bravo score, group 2 showed 94% alpha score and 6% bravo score and group 3 showed 98% alpha score and 2% bravo score. All the three experimental groups show slight marginal discoloration which was clinically acceptable, there was no statistically significant difference among them.

Problems in tooth restoration interface such as marginal integrity, marginal discoloration, and secondary caries are associated to physical and mechanical properties of material like elastic modulus, thermal expansion coefficient, polymerization shrinkage. A low elastic modulus determines a greater material deformation when force is applied, damaging adhesive bonding due to fatigue in tooth restoration interface. Tooth and restorative materials show different thermal expansion coefficient; therefore, temperature change that takes place in oral cavity leads to stress in adhesive interface breaking hybridization bonding. That situation plus curing shrinkage ends up with leakage and marginal discoloration^{13,10}.

Tetric N-Ceram Bulk Fill can be applied in bulk up to 4 mm, thereby reducing polymerisation shrinkage is one of the most important advantage. Problems associated

with polymerisation shrinkage include marginal discoloration, marginal gaps, secondary caries, cracking and hypersensitivity. Polymerization shrinkage in Tetric N Ceram bulk fill is minimized because of the incorporation of special filler which is partially functionalized by silanes, acts as a unique shrinkage stress reliever.

When the composite is cured, the monomer chains present on the fillers together with the silanes commence a cross-linking process and forces between the individual fillers occur and place stress on the cavity walls. This stress is mainly dependent by both volumetric shrinkage and the modulus of elasticity of the composite. A high modulus of elasticity denotes inelasticity and a low modulus of elasticity denotes higher elasticity. Because of its low elastic modulus (10 GPa) the shrinkage stress reliever present in the Tetric N-Ceram Bulk Fill acts like a spring (expanding slightly as the forces between the fillers grow during polymerisation) amongst the glass fillers which have a higher elastic modulus of 71 GPa.

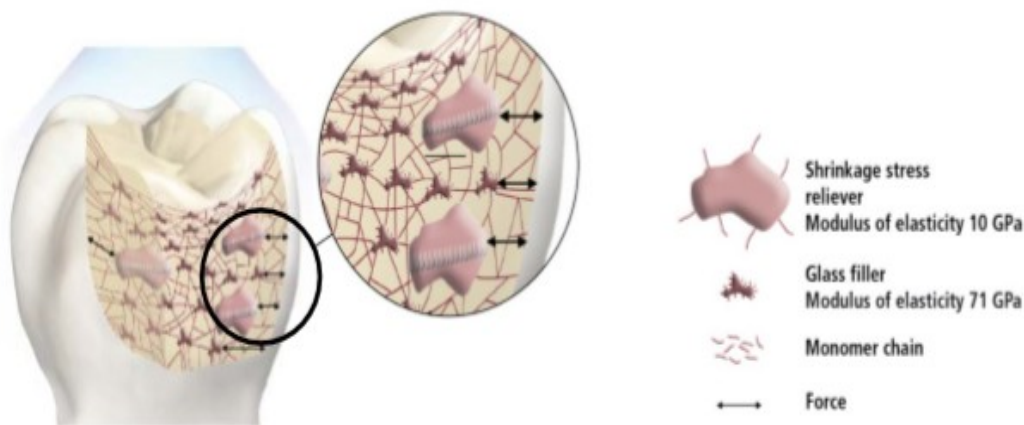


Fig :7 Schematic representation of the shrinkage stress reliever in a Tetric N-Ceram Bulk Fill restoration acting like a spring and reducing stress within the restoration

The shrinkage stress reliever essentially “holds on” to the cavity walls along with the matrix and the adhesive. The silanes improve the bond between the inorganic filler (glass and quartz particles) and the monomer matrix as they are able to establish a chemical bond between the fillers and the matrix. Eventually both the volumetric

shrinkage and shrinkage stress in Tetric N-Ceram Bulk Fill are reduced during polymerisation – allowing increments of up to 4 mm to be placed whilst ensuring a tight marginal seal.

Cention N also contains the Isofiller component in its composition. Thus, both Cention N and Tetric N Ceram bulk fill contain specially patented filler, Isofiller (shrinkage stress reliever) which helps in ensuring tight marginal seal, thereby preventing marginal discoloration.

Moreover, Cention N monomer contains Aromatic aliphatic-UDMA, a partially aromatic urethane dimethacrylate is a hydrophobic, high-viscosity cross-linker which combines the favourable properties of aliphatic (low tendency to discolor) and aromatic (stiffness) diisocyanates.

Cention N monomer contains PEG-400 DMA. 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, and reducing the gap between tooth and the restoration which provides good marginal seal.

Marginal integrity criteria showed distinct values; nevertheless, there was no statistically significant difference. In Group I and group 2, all the restoration showed 100% alpha score in all the interval (6,12 and 24 months). In group 3 after 12 months, showed 97.8% alpha score and 2.17% Bravo score and after 24 months showed 95.65% alpha score and 4.35% bravo score. Marginal integrity is important to increase the longevity of any restoration. polymerization shrinkage leads to microleakage, thereby compromising this integrity. Both the Cention N and Tetric N ceram contains shrinkage stress reliver, Isofiller, this reduces polymerization shrinkage by the same mechanism already discussed above.

This reduced polymerisation shrinkage should translate as lower volumetric shrinkage, improved marginal integrity and reduced shrinkage stress force over the restoration surface/on the adhesive bond.

In analyzing the result of wear, all the restoration in group 2&3 received 100% alpha score at the end of two years. In group 1, only one restoration received bravo score after 12 and 24 months. Important issue concerning the longevity of posterior restorations is the wear of the material. The wear rates of early composites were very high. Resistance to wear of resin composites has greatly improved as advances in the materials have been made. Newer composites have better physical properties, because of changes in filler content and changes in their matrices and polymerization capability.

Cention N consists of four different dimethacrylates (UDMA, DCP, an aromatic aliphatic-UDMA and PEG-400 DMA) which represent 21.6% wt. of the final mixed material. A combination of dimethacrylates interconnects (cross-links) during polymerization resulting in strong mechanical properties and good long-term stability⁷²

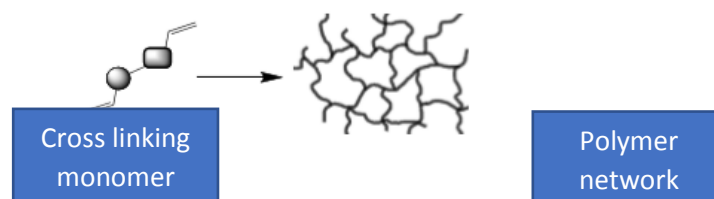


Fig:8 Schematic representation of cross-linking monomers resulting in a polymer network after curing

Basically, Tetric N ceram bulk fill composite is a nanohybrid composite⁷³. The term 'hybrid' means, a different type of fillers is employed to optimally combine the properties of all types of fillers, further improving the mechanical properties of the final

material. This gives a very high filler load, resulting in high physical strength and reduced polymerisation shrinkage.

Tetric N-Ceram Bulk Fill and Cention N incorporates several different types of filler (Barium aluminium silicate glass, Ytterbium trifluoride, Isofiller, Calcium barium aluminium fluorosilicate glass). Glass fillers result in less wear and more favorable polishing properties i.e. low surface roughness and high gloss. Tetric N Ceram bulk contains spherical mixed oxide, which reduces wear and provides favorable consistency. The spherical particles reduce the thickening effects of fillers, since it provides the largest volume with the smallest surface area possible.

In the current study, both of the restorative materials demonstrated acceptable surface texture in all the time interval. In group 1, after 6 months, showed 95.75% alpha score and 4.25% bravo score and after 24 months, showed 95.75% alpha score and 4.25% bravo score. In group 2, after 6 months all restoration showed 100% alpha score and after 12 months showed 98% alpha score and 2% bravo score and after 24 months showed 96% alpha score and 4% bravo score. In group 3, after 6 and 12 months all the restoration showed 100% alpha score and after 24 months, showed 97.82% alpha score and 2.17% bravo score. This implies that Tetric N Ceram showed slightly improved surface smoothness over Cention N. however there was no statistically significant difference between them.

According to Anusavise^{10,11} and Leinfelder⁴², decreasing size, changing composition and increasing quantity of filler particles made composites 10–15 times superior than the previous ones in wear resistance and surface texture maintenance.

The filler particle size in Tetric N-Ceram Bulk Fill is between 0.4 μm and 0.7 μm which is smaller when compared to other bulk fill composites like Filtek Bulk Fill/3M Espe, QuiXfil/Dentsply which contain relatively large fillers.

In Cention N, the particle size is between 0.1 μm and 35 μm . Glass fillers result in low wear and favorable polishing properties i.e. low surface roughness and high gloss. The filler particle size and mix³⁷ are responsible for the excellent polishability and high gloss of Tetric N-Ceram Bulk Fill. It is composed of fillers of comparatively small size as large fillers are unable to produce the same smooth, glossy surface as small fillers.

Concerning secondary caries, Cention N and Tetric N Ceram materials showed identical clinical behavior after 24 months which was 100% alpha score. Cention N contains Calcium barium aluminium fluorosilicate glass, Calcium fluoro silicate glass, Ytterbium trifluoride in the filler component. It releases a significantly larger number of ions (F⁻, OH⁻, Ca²⁺) when the pH-value is acidic thereby prevent demineralization of the tooth substrate

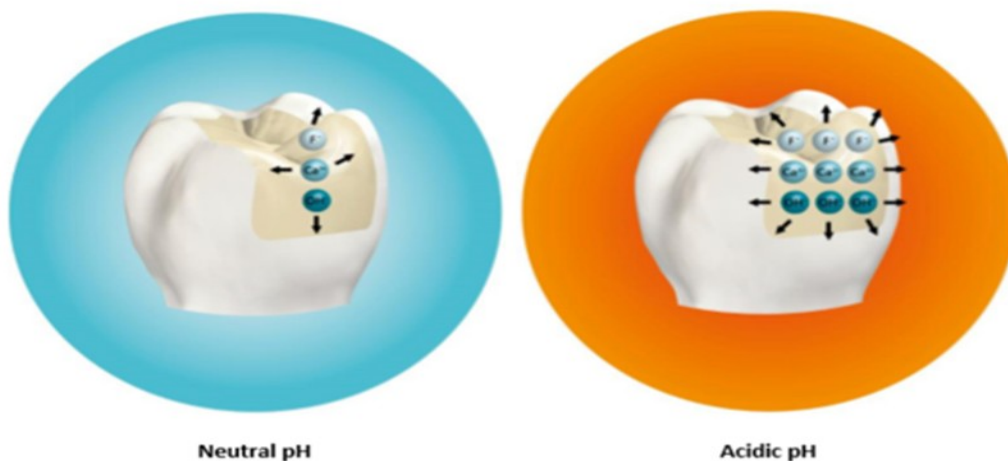


Fig:9 Schematic representation of low (left) and high (right) levels of calcium, fluoride and hydroxide ion release, depending on the pH in the oral cavity

Both Tetric N Ceram and Cention N contains Ytterbium fluoride. It confers high radiopacity to dental materials and is capable of releasing fluoride and also facilitates the diagnosis of secondary caries.

In analyzing the results of postoperative hypersensitivity, in group 1, after 6 and 12 months showed 95.75% alpha score and 4.25% bravo score, after 24 months showed 91.48% alpha score and 8.52% bravo score. In group 2, after 6 months, showed 98% alpha score and 2% bravo score, after 12 and 24 months showed 94% alpha score and 6% bravo score. In group 3, after 6 months showed 97.82% alpha score and 2.17% bravo score, after 12 months 91.30% alpha score and 8.70% bravo, after 24 months showed 89.13% alpha score and 10.87% bravo score. There was no significant difference between the groups. However, Cention N with adhesive (Tetric N Bond) shows less postoperative sensitivity when compared without adhesive and Tetric N Ceram bulk fill.

Polymerization shrinkage results in microleakage and debonding of the restoration. The clinical effects are increased risk of secondary caries and post-operative sensitivity. Tetric N Ceram bulk fill has been developed to reduce the shrinkage stress during polymerization and offer much greater depth of cure. This is achieved by the addition of fillers such as barium aluminum silicate filler, ytterbium trifluoride and mixed oxides and incorporation of a prepolymer filler (a shrinkage stress reliever) and polymerisation booster, Ivocerin.

Cention N contains almost the same filler component. Both the Cention N and Tetric N Ceram bulk fill is suitable to reduce polymerization shrinkage as well as post-operative sensitivity.

All restorations using both experimental materials after 24 months appeared to be clinically acceptable but are important to follow-up these restorations for a longer period to analyze the clinical performance.

Performing the study for longer follow up periods and using recent evaluation criteria with better sensitivity will open newer avenues for the use of CENTION-N as a good alternative for the existing posterior restorative materials.

Since Cention N exhibits comparable clinical performance as Tetric N Ceram bulk fill and also Cention N is user friendly, it can be considered as a viable option for tooth coloured restoration.

SUMMARY

The aim of this randomized controlled clinical trial was to compare the clinical efficiency of Cention N (with or without adhesive) with composite resin (Tetric N Ceram bulk fill) in class 1 restorations using **modified USPHS** (United States Public Health Service) Criteria.

150 subjects were selected in the age group 15-50 years, with primary caries (class 1) in maxillary and mandibular molars with no radiographic evidence of deep caries approximating the pulp chamber and no evidence of thickening/ widening of periodontal ligament.

The 150 subjects were randomly divided into 3 groups as follows:

Group I : Cention N without adhesive as restorative material (n=50)

Group II : Cention N with adhesive as restorative material (n=50)

Group III : Composite Resin (Tetric N Ceram Bulk Fill) as restorative material (n=50)

Under rubber dam isolation, Class 1 cavity preparation done for Cention N (with and without adhesive) and Tetric N Ceram group according to the manufacturer's instruction.

Cention N and Tetric N Ceram were manipulated according to the manufacturer's instruction and were placed in the class 1 cavity preparation. Tetric N bond was used as an adhesive.

POSTOPERATIVE FOLLOW UP:

Among the total number of patients (50) recruited in group 1, follow up done for all the patients till 6 months. 3 patients did not come for the follow up for 12 and 24 months. Drop out -3. So totally 47 patients were recalled at the end of 24 months

Among the total number of patients (50) recruited in group 2, all patients were recalled in all the time interval without any drop outs.

Among the total number of patients (50) recruited in group 3, one patient did not attend the 6 months review (one drop out), in 12 months review, another two patients failed to attend, in 24 months review, one more patient did not come for follow up. 4 drop outs in group 3. So totally 46 patients were recalled at the end of 24 months.

CLINICAL EVALUATION

The clinical evaluation of the restorations was done at baseline (1 week), 6,12 and 24 months using modified US Public health service criteria (USPHS).

Clinical parameter assessed were marginal discoloration, marginal integrity, surface texture, wear, postoperative sensitivity and recurrent caries.

Post-operative radiograph taken at 6,12 and 24 months for diagnosis of recurrent caries

The restoration is classified and demonstrated by score. Alpha – ideal clinical situation, bravo- clinically acceptable and Charlie- clinically unacceptable situations.

All the restorations exhibited acceptable clinical performance in all the clinical parameter at the end of two years. Overall Cention N with adhesive and Tetric N ceram group is marginally better than Cention N without adhesive, but there was no statistically significant difference.

CONCLUSION

Within the limitations of this study, the following conclusions can be drawn:

1. Cention N with adhesive and Tetric N Ceram restoration demonstrated marginally better than Cention N without adhesive. However, there was no statistically significant difference between them.
2. Cention N (with and without adhesive) can be used as a viable alternative to Tetric N Ceram Bulk fill restorative material since it has comparable clinical outcomes at the end of two years.
3. The benefits (strong mechanical properties, dual curing, user friendliness, esthetics, cost effectiveness, can be used with and without adhesive) provided by Cention N shows that it will be a promising posterior restorative material in future and hence, it can be used as a substitute for amalgam & Fuji IX GIC in stress bearing areas like ideal class 1 and class 2 cavities.

Long-term clinical trials are certainly needed because they remain the ultimate way to collect scientific evidence on the clinical effectiveness of restorative treatments.

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ANNEXURE-I
DEPARTMENT OF CONSERVATIVE DENTISTRY AND
ENDODONTICS
TAMIL NADU GOVERNMENT DENTAL COLLEGE AND
HOSPITAL
CHENNAI-60003

“COMPARISON OF CLINICAL EFFICIENCY OF CENTION-N (WITH AND WITHOUT ADHESIVE) AND COMPOSITE RESIN (TETRIC N CERAM BULK FILL) AS CLASS 1 RESTORATIONS- A RANDOMISED CONTROLLED CLINICAL TRIAL”.

PROFORMA

Date:	O.P No:	Group No:
Name:	Age/Sex:	Case No:
Address:	Tel No :	Mobile No :
Occupation:		
Patient's Complaint :		

Pre operative Evaluation:

Clinical:

Systemic Condition:

Treatment done:

ANNEXURE-III

INFORMATION SHEET

Name of the Investigator

Dr.M.H.Mohamed Abubacker

Name of the Guide

Dr.Kavitha.M, MDS

Name of the Institution:

Tamilnadu Government Dental
College & Hospital, Chennai-3

We are conducting a study on titled **“COMPARISON OF CLINICAL EFFICIENCY OF CENTION- N (WITH AND WITHOUT ADHESIVES) AND RESIN COMPOSITE AS CLASS 1 RESTORATIONS – A RANDOMISED CONTROLLED CLINICAL TRIAL”** among patients attending TNGDCH.

PROCEDURE

- An intraoral and extraoral examination will be carried out before the treatment procedure
- Under Isolation, decayed tooth is cleaned and the filling material is placed inside and filled.
- Patient is advised to report for postoperative review after 1 week, 6,12 and 24 months.

RISKS OF PARTICIPATING IN THE STUDY

Pain or allergy as a result of any of the materials used for the treatment, may occur.

The treatment for such complications, if any, will be given appropriately.

BENEFITS OF PARTICIPATING IN THE STUDY

Your disease will be treated, by the removal of the tooth decay. The treatment will result in the formation of new tooth structure.

CONFIDENTIALITY

The identity of the patients participating in the research will be kept confidential throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

PARTICIPATING RIGHTS

Taking part in the study is voluntary. You are free to decide whether to participate in the study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

Name of the patient

Signature /Thumb impression

Any queries regarding the study,
Contact

Dr.M.H.Mohamed Abubacker
PG Student,
Tamilnadu Government Dental
College and Hospital,
Chennai-3
Phone No:7373877222

Contact Details regarding rights of
the participants

Dr.Saravanan.B, MDS., PhD.,
Principal,
Tamilnadu Government Dental
College and Hospital,
Chennai-3

ANNEXURE-IV

**TAMILNADU GOVERNMENT DENTAL COLLEGE AND HOSPITAL,CHENNAI-3
DEPT OF CONSERVATIVE DENTISTRY AND ENDODONTICS**

**NAME OF THE INVESTIGATOR:
Dr. M.H.Mohamed Abubacker**

**NAME OF THE GUIDE:
Dr. M.Kavitha MDS**

INFORMED CONSENT FORM

STUDY TITLE:

“COMPARISON OF CLINICAL EFFICIENCY OF CENTION-N (WITH AND WITHOUT ADHESIVE) AND COMPOSITE RESIN (TETRIC N CERAM BULK FILL) AS CLASS 1 RESTORATIONS- A RANDOMISED CONTROLLED CLINICAL TRIAL”

Name:

Address:

O.P. No:

S.No:

Age/ Sex:

Tel.no:

I, _____ age _____ years

exercising my free power of choice, hereby give my consent to be included as my son or daughter participant in the study

I agree to the following:

- I have been informed to my satisfaction about the purpose of the study and study procedures including investigations to monitor and safeguard my body function
- I agree to undergo the procedure involved in the study process
- I have informed the doctor about all medications I have taken in the recent past and those I am currently taking.
- I agree to cooperate fully throughout the study period.
- I hereby give permission to use my medical records for research purpose. I am told that the investigating doctor and institution will keep my identity confidential
- I understand that i have rights to withdraw from the study and also that the investigator has the right to exclude me from the research at any point of time

Name of the patient:

signature/Thumb impression of the guardian

Name of the investigator:

Date

ஆராய்ச்சி பற்றிய தகவல் படிவம்

ஆராய்ச்சி மேற்கொள்பவர்
மரு. M.H. முகம்மது அபுபக்கர்

வழி நடத்துபவர்
மரு. கவிதா மகேந்திரன் எம்.டி.எஸ்

ஆராய்ச்சி நிறுவனத்தின் பெயர்

தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி
மற்றும் மருத்துவமனை, சென்னை

ஆராய்ச்சியின் தலைப்பு

சென்டியான்-N (பசையுடன்/பசையற்ற) மற்றும் காம்போசைட் பயன்படுத்தி வகுப்பு-1 மீட்டமைத்தலில் மருத்துவ திறன் ஒப்பிடுதல்-மருத்துவ சோதனை முறை

ஆராய்ச்சியின் நோக்கம்

சென்டியான்-N (பசையுடன்/பசையற்ற) மற்றும் காம்போசைட் பயன்படுத்தி வகுப்பு-1 மீட்டமைத்தலில் மருத்துவ திறன் ஒப்பீடு செய்து திருத்தம் செய்த USPHS அடிப்படை கொண்டு மருத்துவ திறனை மதிப்பீடு செய்தல்

செய்முறை

கீழ்க்கண்ட ஆய்வுகள் பரிசோதனைகள் உங்களுக்கு செய்யப்படும்.

வாய் பரிசோதனை

- உட்புறம்
- வெளிப்புறம்
- ❖ பற்சொத்தை சுத்தம் செய்த பின் சென்டியான்-N (பசையுடன்/பசையற்ற) அல்லது காம்போசைட் பயன்படுத்தப்படும்.
- ❖ மருத்துவ திறன் மதிப்பீடு தொடக்க நிலையில் 6 மாதங்களுக்கு, 12 மற்றும் 24 மாதங்களுக்குப் பின் செய்யப்படும்.

பங்கேற்புதீனால் வரக்கூடிய பக்க விளைவுகள்

பற்கூச்சம் அல்லது வலி மற்றும் பயன்படுத்தும் பொருட்களினால் சில நேரங்களில் ஒவ்வாமை ஏற்பட வாய்ப்புண்டு. அதற்காக தேவைப்படும் மருந்துகளும் மருத்துவமும் வழங்கப்படும்.

இரகசிய காப்பு

உங்களைப் பற்றிய குறிப்புகள் பிறர் அறியாவண்ணம் ஆராய்ச்சி முடியும் வரை இரகசியமாக பாதுகாக்கப்படும். அதை வெளிப்படுத்தும் நேரங்களில் எந்த தனி அடையாளங்களும் வெளிப்பட வாய்ப்பு கிடையாது.

தன்னார்வ பங்கேற்பு

இந்த ஆராய்ச்சியில் பங்குபெறுவது தங்களின் தனிப்பட்ட முடிவு மற்றும் இந்த ஆராய்ச்சியில் இருந்து நீங்கள் எப்போது வேண்டுமானாலும் விலகிக் கொள்ளலாம். தங்களின் இந்த தீர் முடிவு உங்களுக்கோ அல்லது ஆராய்ச்சியாளருக்கோ எந்தவித பாதிப்பும் ஏற்படுத்தாது என்பதை தெரியப்படுத்துகிறோம்.

நோயாளியின் பெயர்

கையொப்பம்/கைரேகை

ஆராய்ச்சி தொடர்புடைய
தகவல்களுக்கு
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மற்றும் மருத்துவமனை, சென்னை

