"A COMPARATIVE EVALUATION OF CLINICAL PERFORMANCE OF TOOTH COLOURED RESTORATIVE MATERIALS IN PERMANENT MOLARS"

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In

PEDIATRIC AND PREVENTIVE DENTISTRY

By

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S.NO	ABBREVIATED FORM	FULL FORM
1.	%	Percentage
2.	USPHS	United States Public Health Service

ABSTRACT

BACKGROUND

Smart materials have revolutionised several aspects of dentistry. They are biomimetic and mimic the dentin and enamel seen in natural teeth. Smart dentistry is a brand-new age, and materials like Cention N and ACTIVA BioACTIVE RESTORATIVE provide a promising future in terms of greater efficacy and reliability.

AIM

To determine the clinical performance of tooth-coloured restorative materials in permanent molars.

MATERIALS AND METHOD

This *in-vivo* split-mouth experiment was conducted following approval by the BBDCODS, Lucknow ethical committee. Children who fulfilled the inclusion criteria were chosen for the study. The study received written informed consent from the parents. The short case histories of the research participants were received. Both the regular Class I cavity preparation and the restoration were completed by the same operator. Ryge's USPHS Criteria were amended for clinical inspection of Surface texture, Marginal integrity, Cavosurface marginal discoloration Anatomic contour, Secondary caries, Colour match and Gross fracture at 1 week, 1 month, and 3 months intervals.

RESULT

The study assesses the currently available "smart materials" employed in dentistry in order to bring in a new age of bio-smart dentistry.

INTRODUCTION

Dentistry has been through an era which has seen widespread use of passive and inert materials. The science of materials is now not what it was once. The future of dental restorative material will be determined by dental advancements in the future and the need for the best oral healthcare. Based on their interactions with the environment, dental materials are currently broadly categorized as bioinert, bioactive, and bioresponsive or smart materials. The interaction along the tooth-restoration interface is a crucial factor in the effectiveness of an optimum restorative material. The preservation of caries, periodontal disease, and their consequences, as well as the rehabilitation of absent, damaged, or destroyed hard and soft tissues, will continue to be the main goals of dentistry.

The advances in material science are functional, perform tasks and go through intentional modifications. The use of the terms 'smart' and 'intelligent' describe materials and systems that came from the United States in the 1980's.[1] They were developed by the government agencies working on military and aerospace projects. In recent years, their use has been transferred into the civil sector for applications in various areas.

Traditionally, dental materials have been submissive and static. They interact with human fluids and tissues sparingly or not at all. Materials utilised in the mouth were frequently evaluated their survival depends on their capacity to avoid oral contact. Materials that may dramatically alter their properties in reaction to their environment are referred to as "Smart Materials." They are frequently referred to as "responsive materials."[2] Recent developments in smart material design have opened up new possibilities for its use in bio-medical domains. Dental restoratives are one of the applications. The ability of smart materials to transform into original state after stimulus removal makes them distinct.

According to Akhras Georges (2000)[3], Smart or intelligent materials are those that have intrinsic and extrinsic capabilities. They should react to stimuli and changes in their environment, and must activate their functions in response to these changes which could originate internally or externally. "Smart materials" are substances with one or more properties that can be considerably altered in a controlled way by

outside factors such pressure, temperature, moisture, pH, and electric or magnetic fields.[4]

Initially carious teeth were restored with dark gray restorative materials, however this has changed and phased into an era of restorative dentistry where patients' preference for tooth-coloured restorations has increased the usage of resin-bonded materials in recent years. Signs of the dental caries process cover a continuum from the first molecular changes in the apatite crystals of the tooth, to a visible white spot lesion, dentin involvement and eventual cavitation. Progression through these stages requires a continual imbalance between pathological and protective factors that results in the dissolution of apatite crystals and the net loss of calcium, phosphate and other ions from the tooth leading to demineralization.

The quintessential quality of an optimum restorative material should be aesthetically pleasing, maintain crown strength, and retain the anatomy of the occlusal surface. Good compressive strength is one of the major properties which a direct posterior restorative material must possess in order to ensure the longevity of the restoration.

For years, glass ionomers and amalgam have been successfully used as filling materials. The main reason includes the low flexural strength of glass ionomer cement and the intrinsic grey colour of amalgam. Cention N is an innovative filling material for the complete and permanent replacement of tooth structure in posterior teeth. This alkasite restorative utilizes an alkaline filler, capable of releasing acid-neutralizing ions.[5]

Over the previous two decades, resin composite technology has advanced significantly, and gave way to a smart bio-mimetic material naming it ‘Activa’. Activa is a Resin Bonded Composite with Resin Modified Glass Ionomer properties. ACTIVA products are the first bioactive dental materials with an ionic resin matrix, a shock-absorbing resin component, and bioactive fillers that mirror the physical and chemical features of natural teeth.[6,7,8,9,10,11,13,14]

In the twenty-first century, science and technology rely largely on the development of novel materials that are expected to respond to environmental changes and exhibit their own functions in ideal conditions. Smart materials are a response to the need for environmentally friendly, responsive materials. Smart materials are a new generation of materials in the field of "bio-smart dentistry" that show great potential

for the future.[12] Paediatric dentists should be aware of these materials in order to make the best use of their properties in daily practise and deliver high-quality, holistic treatment. Thus, due to the increasing attention and interest in the use of bioactive materials and materials that are tooth coloured, resistant to wear, nontoxic, biocompatible to the tissue in dentistry, particularly in an attempt to remineralize dentin, the present study is thus carried out to compare the in vivo clinical performance of ACTIVA Bioactive restorative and Cention N.

AIM

The aim of the study was to determine the clinical performance of tooth colored restorative materials in permanent first molars.

OBJECTIVES

- To evaluate and compare the surface texture, marginal integrity, cavosurface marginal discoloration and anatomic contour for Cention N and ACTIVA BioACTIVE-RESTORATIVE in first permanent molars in children.

- To evaluate and compare secondary caries, colour match and gross fracture for Cention N and ACTIVA BioACTIVE-RESTORATIVE in first permanent molars in children.

REVIEW OF LITERATURE

The clinical performance of Cention N and ACTIVA BioACTIVE-RESTORATIVE in permanent molars that fulfil modified Ryge's USPHS criteria is less well documented. Therefore, the findings of this study were compared to other studies that employed different tooth restorative materials. Due to the increasing attention and interest in the use of bioactive materials that are tooth coloured, resistant to wear, non-toxic, biocompatible to the tissues in dentistry, the present study is thus carried out to compare the *in-vivo* clinical performance of Cention N and ACTIVA BioACTIVE RESTORATIVE.

N. M. Kilpatrick et al. (1993)[15] conducted a study related to the concern of Amalgam, Composite and Glass ionomer cerment as well as extracoronal restorations. Stainless steel/nickel chrome crowns provide the most durable restoration. Over the shorter-term resin-based composites appear to be at least as durable as amalgam particularly with respect to the maintenance of a good anatomical form. In contrast, when assessed at 6 years the failure rate of composite restorations is high, 62% whereas the failure rate of amalgam restorations at 5 years is as low as 20%. The resin composite restorations failed due to secondary caries and bulk fractures, whereas the glass ionomer cerment and amalgam restorations failed due to bulk fractures.

P. Anastasios, Martin F.J, Curzon, Fairpo C (1994)[16] calculated the survival rates of restorations in primary molars from a study population of 1,065 children. The order of the survival rate of restorations from higher to lower success was Preformed Crowns, Amalgam, Composite Resin, and Glass Ionomer restorations. For preformed crowns and amalgam restorations, the median survival time was more than 5 years. The 5-year survival estimate for preformed crowns was 68% and for Amalgam restorations was 60%. Composite resin restorations had a median survival time of 32 months and a 4-year survival estimate of 40%, while glass ionomer restorations had a median survival time of 12 months and a 4-year survival estimate of 5%.

Matis, Bruce A, Cochran, Carlson T (1996)[17] evaluated three restorative materials used for cervical erosion/abrasion lesions clinically after 10 years. Thirty adult patients with at least four cervical lesions received one restoration of each of Ketac-Fil, finished immediately, Ketac-Fil, finished after a delay, Chelon-Fil (all glass-ionomer cements), and Cervident (a resin composite). All three Glass-ionomer restorative materials exhibited statistically significantly greater retention than did Cervident. When a non-invasive procedure is performed, Glass-ionomer materials are the restorative material of choice for abrasion/erosion lesions because of their long-term retention values.

Welbury R, Shaw A, Murray J, Gordon P, McCabe J (2000)[18] undertook a clinical trial comparing the efficiency of a Compomer restoration with a Glass Ionomer restoration in the management of caries in primary molar teeth. The durability of the restorations was assessed during a 42-month follow-up period using modified United States Public Health Service criteria. The Compomer restorations had a higher mean survival time (42 months, SE 1.40) compared with 37 months (SE 1.90) for the Glass Ionomer restorations and this was significant at the 5% level. The Compomer also performed significantly better in terms of anatomical form, marginal integrity, cavo-surface discoloration and maintenance of interproximal contact.

Gaengler P, Hoyer I, Montag R. (2001)[19] compiled the clinically significant information from a 10-year study of posterior restorations made from glass-ionomer cement and composite material.The participants were clinically evaluated at the beginning of the study, and then every six months for up to ten years. The USPHS-compatible CPM Index was used to assess various criteria such as anatomic form, color match, surface quality, wear, marginal integrity, marginal ledge, marginal discoloration, secondary caries, and clinical acceptability. The initial risk of failure in posterior composite restorations is due to bulk fractures and partial loss of filling material. The maximum longevity of these restorations over 10 years is 74.2%. However, their low rate of secondary caries and high percentage of anatomical correctness confirm their clinical safety.

Loa Y, Luoa M.W, Wei F (2001)[20] compared the clinical performance of two Glass-ionomer cements, ChemFlex (Dentsply DeTrey) and Fuji IX GP (GC), when used with the atraumatic restorative treatment (ART) approach in China. Eighty-nine school children aged between 6 and 14 years who had bilateral matched pairs of carious posterior teeth were included. A split-mouth design was used in which the two materials were randomly placed on contralateral sides. The performance of the restorations was assessed directly and also indirectly from diestone replicas at baseline and after 6, 12, and 24 months. The 24-month cumulative survival rates of ART restorations in the primary teeth were 93 and 90% for the ChemFlex and Fuji IX GP class I restorations, respectively, while 40 and 46% of class II restorations placed with the respective materials were satisfactory. In the permanent dentition, only class I restorations were involved and the cumulative survival rates were 95 and 96% for ChemFlex and Fuji IX GP. For the primary teeth after 24 months, net mean occlusal wear was 87 μm for ChemFlex and 85 μm for Fuji IX GP.

Türkün LŞ, Aktener BO, Ateş M. (2003)[21] evaluated the clinical performance of three different types of resin composite materials, namely Z100, Clearfil Ray-Posterior, and Prisma TPH, were evaluated in posterior restorations over a period of seven years. Ryge's criteria, which assess color match, marginal discoloration, marginal adaptation, secondary caries, surface texture, and anatomic form, were used to evaluate the restorations at baseline, 1, 2, 5, and 7 years. After a period of 7 years, the clinical performance of the three tested posterior composite materials was found to be satisfactory.

Xiaoming Xu, Burgess J (2003)[22] evaluated the compressive strength, fluoride release and recharge profiles of 15 commercial fluoride-releasing restorative materials. The materials include Glass Ionomers (Fuji IX, Ketac Molar, Ketac Silver, and Miracle Mix), Resin-modified Glass Ionomers (Fuji II LC Improved, Photac-Fil, and Vitremer), Compomers (Compoglass, Dyract AP, F2000, and Hytac) and Composite Resins (Ariston pHc, Solitaire, Surefil and Tetric Ceram). They concluded that current restorative materials with a high fluoride release generally have lower mechanical properties. Composite resin and some Compomers (e.g.,

Hytac), though mechanically stronger, usually release only a small amount of fluoride. Fluoride release from even the highest fluoride-releasing materials declines rapidly.

Sachdeo A, Gray GB, Sulieman MA, Jagger DC (2004)[23] conducted a study to evaluate the wear and clinical performance of a control group of Amalgam restorations compared with that of a group of posterior Composite resin restorations fillings and another group of compomer/composite restoration where open sandwich restorations were placed by a single general dental practitioner. The duration of the study was 2 years. One hundred and thirty-three (71.4%) patients were successfully recalled and the wear and clinical performance of each restoration after 6, 12 and 24 months was measured, indirectly. With regards to clinical performance of the restorations, occlusal and proximal contacts in each group of restoration remained satisfactory throughout the study.

Hickel R et al. (2005)[24] conducted a study to know the longevity and reasons for failure of Stainless-Steel Crowns, Amalgam, Glass-ionomer, Composite and Compomer restorations in stress-bearing cavities of primary molars. Annual failure rates of Stainless-steel crowns, Amalgam, Glass ionomer, Composite and Compomer restorations were determined and failure reasons were discussed. Annual failure rates in stress-bearing cavities of primary molars were determined to be: 0-14% for stainless steel crowns, 0-35.3% for amalgam restorations, 0-25.8% for glass-ionomer restorations, 2-29.1% for atraumatic restorative treatments, 0-15% for composite restorations, and 0-11 for compomer restorations. Main reasons for failure were secondary caries, marginal deficiencies, fracture, and wear.

Ersin N, Candan U, Aykut A, Önçag Ö, Eronat C, Kose T (2006)[25] evaluated the 24-month performance of a packable resin-based composite/dentin bonding system and a high-viscosity Glass Ionomer Cement (GIC) in restorations placed in primary molars with the atraumatic restorative treatment (ART) approach. The authors evaluated the restorations according to U.S. Public Health Service Ryge criteria.

After 24 months, 96.7 percent of the Class I GIC restorations and 91 percent of the Resin-based Composite restorations survived, while the success rates for the Class II restorations were 76.1 percent and 82 percent for the GIC and Resin-based Composite restorations, respectively. The survival rate of the Class II Resin-based Composite restorations was 5.9 percent higher than that of the GIC restorations at the 24-month evaluation, but this difference was not statistically significant.

Tyas M J et al. (2006)[26] mentioned the general structure, properties and clinical performance of Conventional and Resin-modified Glass Ionomer Cements, focusing on adhesion, caries inhibition effect and recommendations of their use. Glass-ionomer cement is often known as a biomimetic material, because of its similar mechanical properties to dentine. This, together with the important benefits of adhesion and release of fluoride, render it an ideal material in many restorative situations. However, it's relatively poor mechanical properties must be appreciated, and therefore it should only be used as a final restorative material in low stress areas, and it must be protected by resin composite or amalgam in areas of high stress.

Burrow MF, Tyas MJ et al. (2007)[27] conducted a study on the use of adhesive materials to restore non-carious cervical lesions. This study compared the retention of a self-etching adhesive, Clearfil SE Bond, with Clearfil ST Resin Composite (SE), with the phosphoric acid-etch single bottle adhesive Single Bond with A110 Resin Composite (SB) and a Resin Modified Glass Ionomer Cement, Fuji II LC, (FJ). Ninety-two restorations in 20 patients (mean age 61 years) were placed. The teeth were restored randomly and manufacturers' instructions were followed. Patients were recalled at 6 months, 1, 2 and 3 years and the restorations were evaluated for marginal staining. At one year, 80 restorations were available for evaluation; at 2 years, 65 restorations were evaluated and at 3 years, 55 restorations were evaluated. RM-GIC performed the best, followed by Clearfil SE Bond/Clearfil ST.

Celik C, Arhun N, Yamanel K (2010)[28] purposed a study to evaluate and compare the 12 months clinical performances of two different posterior Composites in Class I and Class II restorations. Thirty-one patients (10 male, 21 female) were recruited into the study. A total of 82 Class I and Class II cavities were restored with either a nanohybrid Composite (Grandio) or a low-shrinkage Composite (Quixfil), using their self-etch adhesives (Futura Bond and Xeno III) according to manufacturers' instructions. The restorations were clinically evaluated 1 week after placement as baseline, and after 6 and 12 months post-operatively using modified USPHS criteria by two previously calibrated operators. Clinical assessment of nanohybrid (Grandio) and low-shrinkage posterior Composite (Quixfil) exhibited good clinical results with predominating alpha scores after 12 months.

Gurunathan D, Tandon S (2010)[29] compared the clinical performance of two Glass ionomer cements, Amalgomer CR and Fuji IX in small and medium cavities prepared using Atraumatic restorative treatment approach in India. One hundred school children in the age group of 4–9 years who had bilateral matched pair of carious lesions in primary posterior teeth were included. The performance of the restorations was assessed after 1 year using Frenken's criteria (1996). The clinical performances of both materials were satisfactory at the end of 1 year and ART is suitable procedure to be done in a dental clinic for children.

Santiago S L et al. (2010)[30] evaluated the 2-year clinical performance of a one-bottle etch-and rinse Adhesive and Resin Composite system compared to a Resin-modified Glass Ionomer Cement (RMGIC) (Vitremer/3M) in non-carious cervical lesions. All restorations were evaluated blindly by 2 independent examiners using the modified USPHS criteria at baseline, and after 6, 12 and 24 months. The one-bottle etch-and-rinse bonding system/resin composite showed an inferior clinical performance compared to the RMGIC.

R C. Vishnu, Varma B, Jayanthi (2012)[31] evaluated the tensile bond strength and microleakage of Fuji IX GP (Glass Ionomer Restorative), Fuji II LC (Resin Modified Glass Ionomer), and Compoglass and compared the bond strength with degree of microleakage exhibited by the same materials. Compoglass showed highest tensile strength and Fuji II LC showed least microleakage. Fuji II LC and Compoglass can be advocated in primary teeth because of their superior physical properties when compared with Fuji IX GP.

Poggio C, Beltrami R, Scribante A, Colombo M, Lombardini M (2014)[32] examined the impact of various surface treatments on the shear bond strength of a standard Glass-Ionomer Cement and a Glass-Ionomer Cement modified with Resin to dentin. There were 80 bovine permanent incisors used. GIC and RMGIC (Fuji II LC) cylindrical specimens in the numbers of 40 each were affixed to the dentin. Groups 1 and 2 each contain GC Cavity Conditioner, 37% phosphoric acid gel, Clearfil SE Bond, while Group 4 does not have any dentin conditioning (control). RMGIC had a stronger shear binding to dentin than GIC. The shear bond strength values of RMGIC were greatly increased by the use of a Self-etch adhesive system, while those of GIC were significantly decreased.

Diwanji A, Dhar V, Arora R, Madhusudan A, Rathore A (2014)[33] compared the microleakage of recently developed nano ionomers to those of conventional and Resin-modified glass ionomers. On 120 juvenile permanent teeth, standardised class I and class V cavities were created. Subgroups were created by further dividing the samples into group I (class I restorations) and group II (class V restorations). With the help of Fuji IX, Fuji II LC, and the recently released KetacTM N 100, the subgroups were recreated. The most leakage was seen in Fuji IX, followed by LC II, while the least was seen in KN 100.

Gurgan SE, Kutuk ZB, Ergin ES, Oztas SS, Cakir FY (2015)[34] in a four-year randomised clinical investigation compared the clinical efficacy of a Glass Ionomer restorative system to a micro filled hybrid posterior Composite. According to the updated US Public Health Service criteria, two independent examiners examined the restorations at baseline and one, two, three, and four years after the restoration. For both restorative materials used in Class 1 and Class 2 restorations, significant variations in marginal adaption and discolouration were discovered at four years compared to baseline.

Donmez S B, Uysal S, Dolgun A, Turgut M D (2016)[35] examined the aesthetic restorative materials' clinical efficacy in young children's teeth using FDI standards. Composite resin, Compomer, and Resin-modified Glass Ionomer Cement restorations (n=93) were created for 31 patients. The restorations were clinically assessed using the FDI criteria at baseline, six, twelve, and eighteen months. In primary teeth, compomer restorations outperform resin-modified glass ionomer and composite resin restorations in terms of clinical performance.

Mishra A, Singh G, Singh S, Agarwal M, Qureshi R, Khurana N (2018)[37] compared the mechanical characteristics of Cention N, Amalgam, Glass Ionomer Cement and Hybrid composite resin.80 samples in all were evaluated. Using aluminium split moulds, 40 samples (n = 10 each) were made for compressive strength, and another 40 samples (n = 10 each) were prepared for flexural strength. It was discovered that composites had much greater compressive and flexural strengths than Centon N, GIC, and Amalgam. The compressive strength of Cention N was noticeably greater than GIC. Cention N was shown to have a substantially greater flexural strength than GIC and Amalgam.

Parth V Dodiya, Parekh V, Gupta M,Patel N, Shah M (2019)[38] performed a clinical assessment of Cention-N and nano hybrid Composite Resin for the repair of non-carious cervical lesions. A total of 24 individuals were chosen, both of whom had two class V non-carious cervical lesions in the same arch that were almost the

same size and form. One operator used Cention-N and Tetric N Ceram (Ivoclar - Vivadent) to repair, complete, and polish both teeth. On the same day as the repair, a second operator evaluated the surface texture and marginal integrity. (USPHS, direct clinical examination Ryge criterion). The USPHS Ryge Criteria were followed in the collection of all the data. The study found that for large fracture and marginal integrity up to six months, Cention-N is as effective as Tetric-N-Ceram.

Kaur M, Mann N, Jhamb A, Batra D (2019)[39] evaluated and compared the compressive strength of Cention N with Glass Ionomer cement as a restorative material. For the fabrication of ten samples of Cention N (Ivoclar Vivadent) and Glass Ionomer Cement, custom cylindrical moulds with dimensions of 6 mm in height by 4 mm in diameter were done (GC IX High strength Posterior restoration). The compressive strength of Cention N was discovered to be much higher than Type IX GIC, and thus it was assumed that it is a preferable material for restoration of posterior teeth.

García S L et al. (2019)[40] examined the biological effects of three novel bioactive materials on *in-vitro* cell migration, adhesion, survival, and morphology. The following products were handled and conditioned using a serum-free culture medium: ACTIVA Kids BioACTIVE Restorative (Pulpdent, Watertown, MA, USA), Ionolux (Voco, Cuxhaven, Germany), and Riva LightCure UV (SDI, Bayswater, Australia). According to the findings, Activa outperformed Riva and Ionolux in terms of inducing cell migration, adhesion, and survival.

Amaireh I, Al‐ Jundi S, Alshraideh H.A (2019)[41] in a study used ACTIVA™, Composite Resin, and Resin Modified Glass Ionomer as the three adhesive materials in an in vitro examination of microleakage in primary teeth. 154 extracted primary molars were divided into three groups at random. Class II cavities were prepared and repaired in each group using either ACTIVA, Filtek Z250, or Vitremer, one of the three restorative materials. Leakage analyses per tooth revealed no statistically

significant differences between ACTIVA, Filtek Z250, and Vitremer in terms of microleakage percentages.

Naz F et al. (2020) [42] examined the mechanical and physical characteristics of a fresh alkasite in bulk using traditional restorative supplies. Premolars that had been removed from humans were utilised to examine the shear bond strength. The dentine surface was covered with restorative materials, which were aged in deionized water for 14 days. Before and after chewing simulation cycles, the 3-D surface roughness was assessed (50,000). Alkasite (Cention N) had much higher shear bond strengths than GIC. However there was no statistically significant difference between Alkasite and Nano-hybrid Composite.

Sujith R, Yadav T, Pitalia D, Babaji P, Kommula A, Sharma A (2020)[43] examined the mechanical and microleakage characteristics of the restorative cement materials made of Glass ionomer, Composite, and Cention-N. With 15 samples of each type of restorative material—Cention-N, GIC, and hybrid Composite—45 specimen blocks overall were created. On the buccal surface of orthodontically removed premolars, Class V cavities were made, and each test material was then restored. With the exception of 1 mm around the edges of the restorations, the whole surface of the tooth was covered in clear nail polish. For Centon-N, the mean microleakage was lowest. A more recent restorative material called Cention-N has better mechanical characteristics and less microleakage.

Mosallam S, Gawad R, Shehaby F, Elchaghaby M (2021)[44] compared the ability of ACTIVA Bioactive Restorative Material and Resin Modified Glass Ionomer to remineralize teeth while restoring premolars in an *in-vitro* investigation. 42 sound human premolars that had been removed underwent standardised Class V cavity preparation. Before and after demineralization, the mineral content of the teeth was measured, and the demineralized teeth were either left as a negative control (Group I) or restored with either ACTIVA Bioactive restorative material (Group II) or light-cured resin-reinforced glass ionomer restorative (Group III).The mineral content was examined using energy dispersive x-ray and scanning electron microscope

(EDX/SEM) in each group after 24h, 1 month later and after three months. Greater fluoride release is seen in resin-modified glass ionomer materials compared to resin-based ones.

Alrahlah A. (2021)[36] investigated and compared the microleakage in class V lesions repaired with nanohybrid Composite Resin and Activa Bioactive restorative utilising two distinct bonding agents. In this investigation, 50 newly removed teeth with class V cavities were produced. Activa Bioactive (Pulpdent, USA) + No bonding; Activa Bioactive + Tetric N Bond (IvoclarVivadent, Colombia); Activa Bioactive + G Bond (GC Corp., Tokyo, Japan); Nanohybrid Composite (IvoclarVivadent, Colombia) + Tetric N Bond; Nanohybrid Composite+ G Bond. This analysis came to the conclusion that all of the materials had some degree of microleakage. When Tetric N Bond was combined with Activa Bioactive restorative, the least amount of microleakage was seen across all the groups.

Durão MA, Andrade AKM, Santos MDCMDS, Montes MAJR, Monteiro GQM (2021)[45] compared the 12-month clinical performance of two full-body bulk-fill resin composites Filtek bulk fill/3M ESPE (FBF) and Tetric EvoCeram bulk fill/Ivoclar Vivadent (TBF) and a conventional microhybrid resin composite Filtek Z250/3M ESPE (Z250), using modified United States Public Health Service (USPHS) and Federation Dentaire Internationale (FDI) criteria. Following the manufacturer's instructions, 138 class I and II restorations were put in the posterior teeth (split-mouth design) of 46 volunteers and bonded with a self-etching bonding agent (Clear fill SE Bond/Kuraray). After 12 months, the bulk-fill resin composites surpassed standard resin composites in terms of clinical performance. Due to differences in the score descriptions for each criterion, the percentage of acceptable scores for the USPHS criteria was much higher.

Firouzmandi M, Alavi A, Jafarpour D, Sadatsharifee S (2021)[46] investigated the marginal adaption and fracture strength of Cention N-restored conservative and extended MOD cavities. 120 human maxillary premolars were used in this investigation, and they were placed into six groups at random based on the kind of

restoration and cavity volume (n = 20). The following conservative MOD restorations are listed in order: (I) conservative MOD restored with Cention N; (II) conservative MOD restored with bonded Cention N; (III) conservative MOD restored with Z250 resin composite; (IV) extended MOD restored with Cention N; (V) extended MOD restored with bonded Cention N; and (VI) extended MOD restored with Z250 resin composite. Regarding fracture strength and little adaptation in either standard or extended MOD cavities, Cention N demonstrated encouraging findings.

MATERIALS & METHODS

The present *in-vivo* split mouth study was conducted in the Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences (BBDCODS) after obtaining clearance from Institutional Ethical Committee of BBDCODS,Lucknow.

PARTICIPANTS

25 patients with 80 samples, who fulfilled the inclusion and exclusion criteria, were enrolled in the study. A written informed consent was obtained from the parent before the examination. The study was done with an aim to determine the clinical performance of tooth-coloured restorative materials in permanent first molars.

SAMPLE SIZE CALCULATION

The minimum sample size was calculated to be 80 by using the following criteria.

The difference between two proportions represents a new parameter, $P_{1} - P_{2}$. In the epidemiologic literature, this difference is called risk difference and it gives the absolute difference in risk between the two groups.

Were,

P_{1}: Proportion in first group

$P_{2:}$ Proportion in second group

$d^{2:}$ Population risk difference

1-Desired risk difference

ELIGIBILITY CRITERIA:

Inclusion Criteria:

1. Carious pit/fissure (moderate and enlarged) maxillary and mandibular unrestored permanent first molar. (Mount and Hume,1998)
2. Healthy children between age group of 7-11 years.

Exclusion Criteria:

1. Endodontically and periodontally involved teeth.
2. Heavy bruxism habit.
3. Fractured and visibly cracked teeth.

MATERIALS USED:

- Cention N (Ivoclar,Vivadent,Liechtenstein)
- ACTIVA BioACTIVE- RESTORATIVE (Pulpdent,USA)
- Sterilised gloves (Nulife latex surgical gloves)
- Mouth mask (Klinic disposable facemask)
- Kidney tray (API., GERMANY)
- Diagnostic instruments (API., GERMANY)
  - Mouth mirror
  -Straight probe
  -Tweezer
  -Explorer
- Restorative instruments (API., GERMANY)
  - Spoon excavator
  -Cement carrier
  -Chisel
  -Condenser
- Airotor (NSK INC., JAPAN)
- Diamond points (Small round bur- ISO 001/010, Finishing bur- EX-21EF)
- Etchant gel (DPI, INDIA)
- Visible light curing (Waldent,INDIA)
- Rubber dam kit (Coltene,Henan,CHINA)

STUDY DESIGN

- The present *in-vivo* split mouth study was carried out in children with the age group between 7-11 years including both the genders with a sample size of 80.
- The subjects were randomly divided into two groups on the basis of split mouth technique which allowed each tooth to receive one of the treatments to enable comparison among the two restorative materials.
- The patients received treatment on each side of the mouth, divided as quadrant or as sextant.
- Group A consist of 40 patients whose teeth were restored with ACTIVA BioACTIVE Restorative and Group B consist of 40 patients whose teeth were restored with Cention N both in the maxillary and mandibular arch respectively.
- Patients recalled at an interval of 1 week, 1 month and 3 months.

METHODOLOGY:

The present study was conducted in the Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Lucknow, after obtaining clearance by the Institutional Ethical Committee of BBDCODS, Lucknow.The research participants' short case histories were received. 25 Children with 80 samples meeting the inclusion requirements were chosen after assessing the tooth clinically. After confirmation of the diagnosis, a written informed consent informing the parents about the study was taken.

Children were divided into two groups:

Group A – 40 Children

Group B – 40 Children

Isolation was done using a rubber dam. Cavity preparation was limited to removal of carious lesion. Standardized Class I cavities were prepared initially using a high-speed bur and refined using slow speed diamond points. The cavity walls were then planed using chisel.

The cavity was washed and cleaned properly with saline. Restoration was done using the two restorative materials according to the manufacturers' instructions. A post occlusal adjustment was made using articulating paper.

GROUP A-

The Cention N liquid container was hold in vertical position. The bottle was squeezed lightly and evenly to dispense 1 drop, making sure that the drop separates from the bottle itself without touching the mixing pad. After use the bottle was closed tightly. The bottle containing powder was shaken before use and then the required quantity was taken using the measuring spoon.

The mixing ratio of the powder and liquid was 1:1. The powder and liquid were then mixed using a plastic spatula until a homogeneous mixture was formed. After that it was placed in the condenser and was placed into the cavity prepared followed by its condensation and the excess was removed.

The working time was 2 minutes and 30 seconds, once the setting time of 4 minutes was reached the occlusion was checked and adjusted necessarily. The excess material was then removed using finishing diamond point.

GROUP B-

Etchant was applied for 20 seconds in the cavity prepared and washed with water. Excess moisture was removed from the cavity. Auto mix syringe was applied to the ACTIVA BioACTIVE - Restorative tube and the cement was placed into the cavity prepared. Excess material was removed and condensed. After a delay of 20 seconds to allow for the acid component to react with the tooth surface, the visible light beam was applied for 20 seconds.

In both the group, occlusion was checked with the articulating paper. Patients were advised to brush their teeth twice daily (using toothbrush and toothpaste) and practicing no other oral hygiene measures both professional and home based.Patient was recalled at the interval of 1 week, 1 month and 3 months.

Clinical evaluation of the restorations was done by an examiner who was unaware of the materials used in this double-blind study and was scored using modified Ryge's

USPHS criteria at the interval of 1 week, 1 month and 3 months for wear resistance, retention of restoration, marginal integrity, Cavo surface marginal discoloration, recurrent caries, surface texture, and post-operative sensitivity

MODIFIED UNITED STATES PUBLIC HEALTH SERVICE (USPHS) RYGE CRITERIA FOR DIRECT CLINICAL EVALUATION OF RESTORATION

1. SURFACE TEXTURE

- Alpha (A) Explorer

Surface texture similar to polished enamel as determined by means of a sharp explorer.

- Bravo (B) Explorer

Surface texture gritty or similar to a surface subject to a white stone or similar to a composite containing supramicron-sized particles.

- Charlie (C) Explorer

Explorer Surface pitting is sufficiently coarse to inhibit the continuous movement of an explorer across the surface.

2. MARGINAL INTEGRITY

- Alpha (A) Visual inspection and explorer

The explorer does not catch when drawn across the surface of the restoration toward the tooth, or, if the explorer does not catch, there is no visible crevice along the periphery of the restoration.

- Bravo (B) Visual inspection and explorer

The explorer catches and there is visible evidence of a crevice, which the explorer penetrates, indicating that the edge of the restoration does not adapt closely to the tooth structure. The dentin and/or the base is not exposed, and the restoration is not mobile.

- Charlie (C) Explorer

The explorer penetrates crevice defect extended to the dento-enamel junction.

3. CAVOSURFACE MARGINAL DISCOLORATION

- Alpha (A) Visual inspection

There is no visual evidence of marginal discoloration different from the colour of the restorative material and from the colour of the adjacent tooth structure.

- Bravo (B) Visual inspection

There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, but the discoloration has not penetrated along the restoration in a pulpal direction.

- Charlie (C) Visual inspection

There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has penetrated along the restoration in a pulpal direction.

4. WEAR RESISTANCE (ANATOMIC CONTOUR)

- Alpha (A) Visual inspection and explorer

The restoration is a continuation of existing anatomic form or is slightly flattened. It may be over contoured. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing Cavo surface line angles at the same time.

- Bravo (B) Visual inspection and explorer

A surface concavity is evident. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing Cavo surface line angles at the same time, but the dentin or base is not exposed.

- Charlie (C) Visual inspection and explorer

There is a loss of restorative substance such that a surface concavity is evident and the base and/or dentin is exposed.

5. **SECONDARY CARIES**

- Alpha (A) Visual inspection

The restoration is a continuation of existing anatomic form adjacent to the restoration.

- Bravo (B) Visual inspection

There is visual evidence of dark keep discoloration adjacent to the restoration (but not directly associated with Cavo surface margins).

6. **COLOR MATCH**

- Alpha (A) Visual inspection

The restoration appears to match the shade and translucency of adjacent tooth tissues.

- Bravo (B) Visual inspection

The restoration does not match the shade and the translucency of adjacent tooth tissues, but the mismatch is within the normal range of tooth shades. (Within normal range: Similar to silicate cement restorations for which the dentist did not quite succeed in matching tooth color by his choice among available silicate cement shades)

- Charlie (C) Visual inspection

The restoration does not match the shade and translucency of adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency.

7. **GROSS FRACTURE**

- ALPHA (A)

Restoration is intact and fully retained.

- Bravo (B)

Restoration is partially retained with some portion of the restoration still intact.

- Charlie (C)

Restoration is completely missing

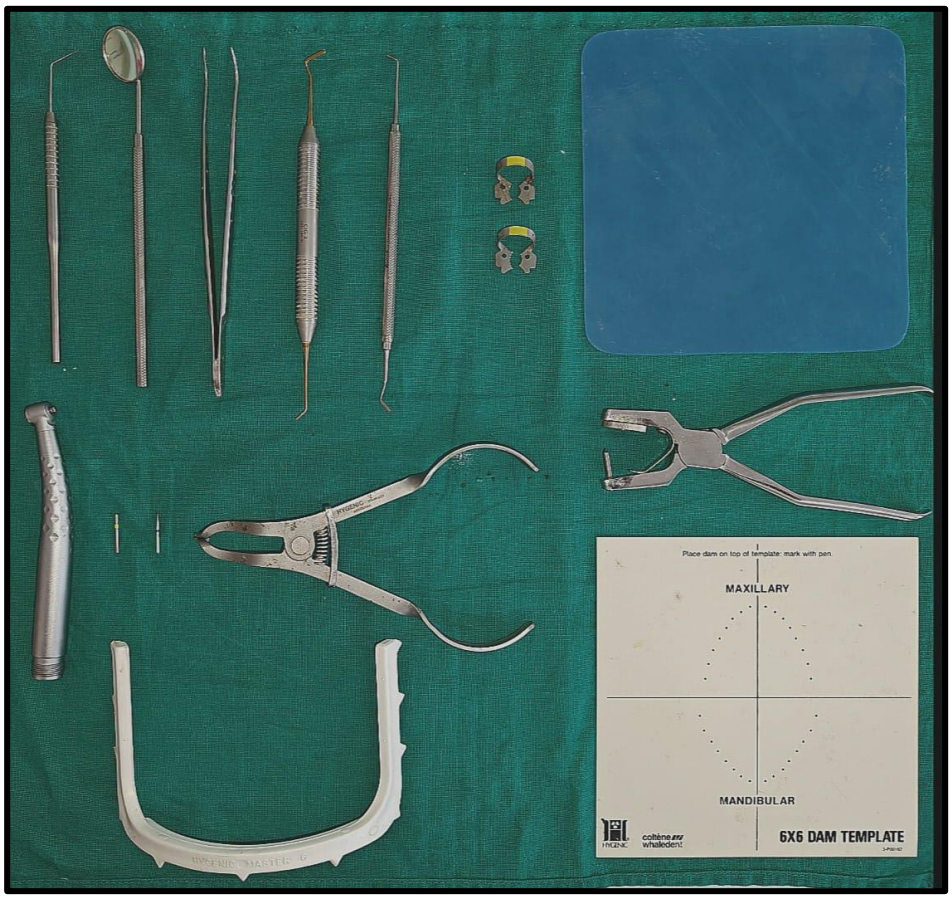


Figure 1: Diagnostic and Restorative Intruments

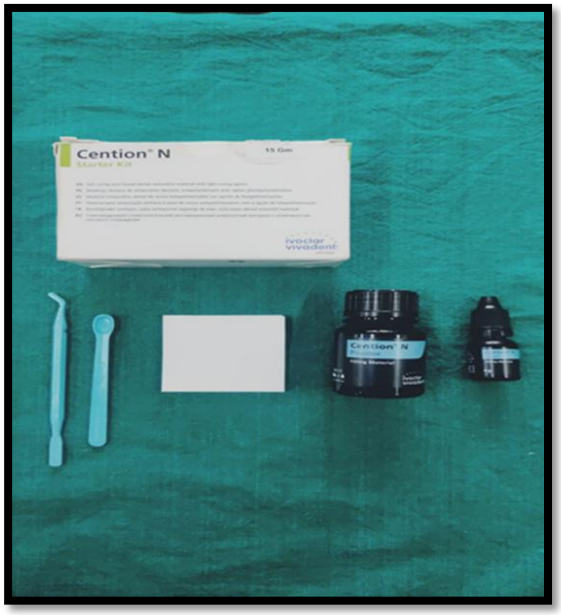


Figure 2: Cention-N

Figure 3: ACTIVA BioACTIVE RESTORATIVE

CLINICAL STEPS FOR CENTION-N

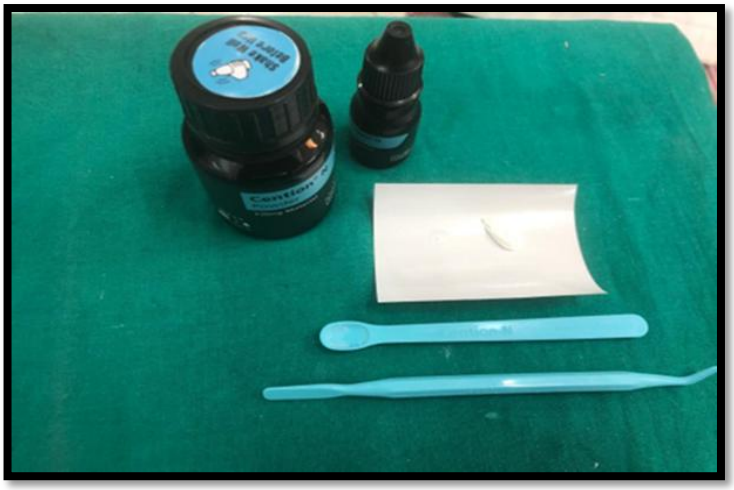


Figure 4A: Powder:Liquid=1:1

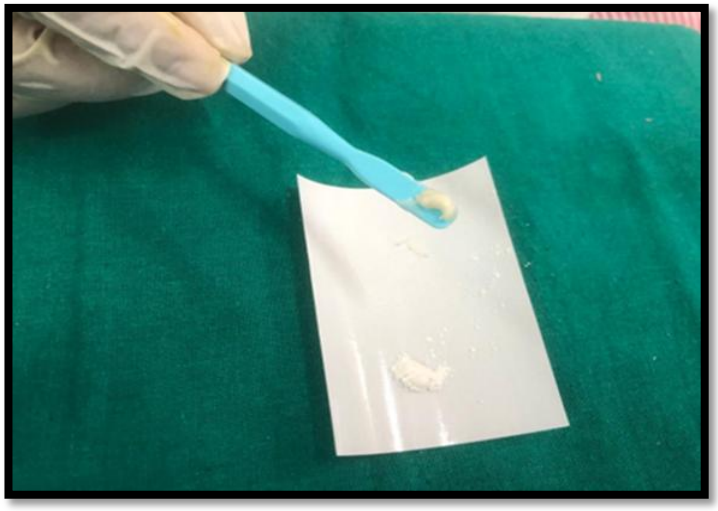


Figure 4B: Homogeneous mixture

Figure 4C: Immediate Post- operative photograph (Cention N)

CLINICAL STEPS FOR ACTIVA BIOACTIVE RESTORATIVE

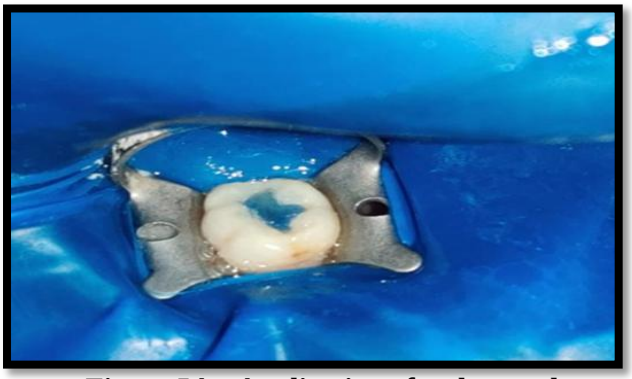


Figure 5A: Application of etchant gel

Figure 5B: Restoration with ACTIVA BioACTIVE- Restorative

Figure 5C: Curing of tooth

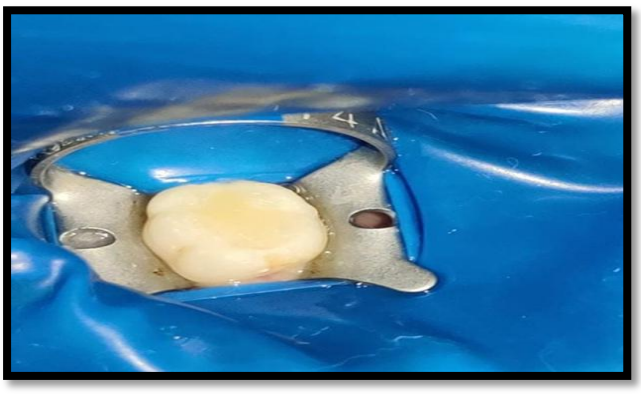


Figure 5D: Immediate Post-operative image (ACTIVA BioACTIVE-RESTORATIVE)

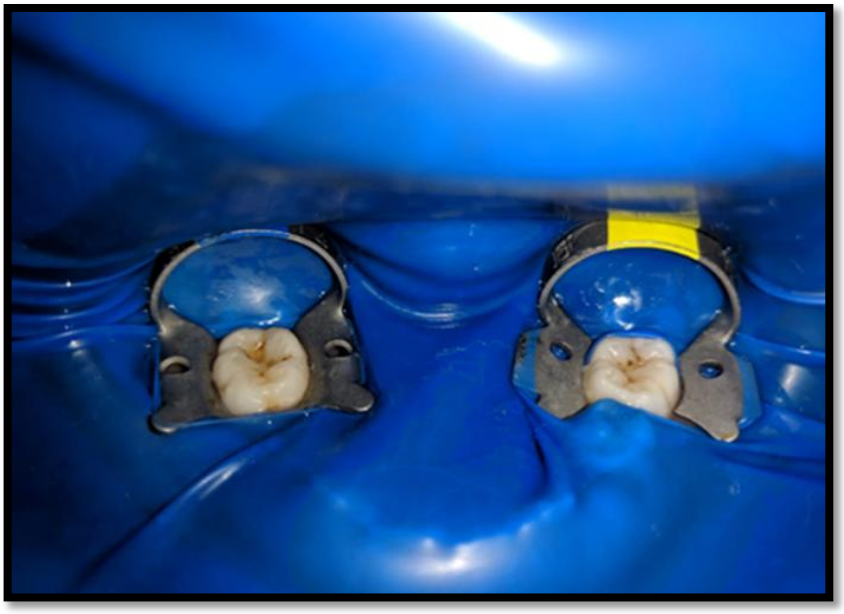


Figure 6: Preoperative carious teeth wrt 36 and 46

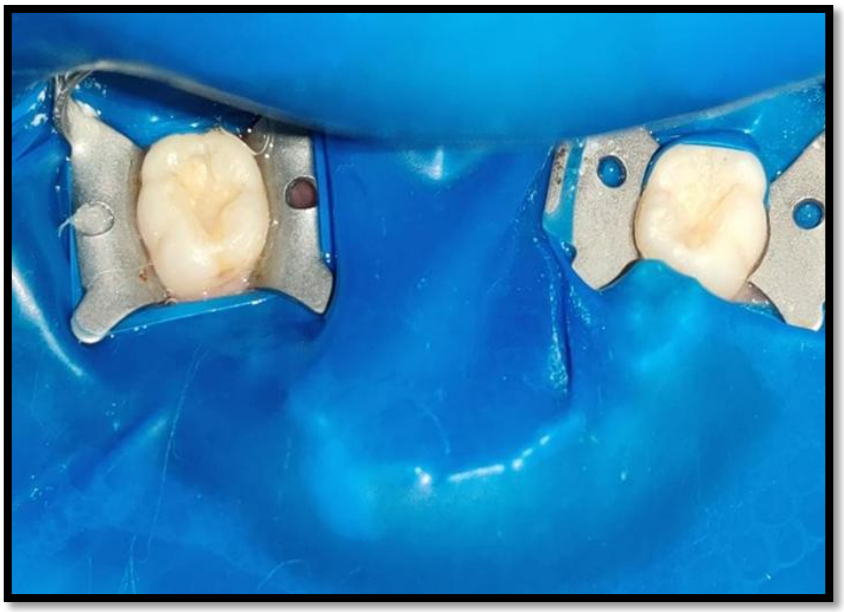


Figure 7: Postoperative carious teeth wrt 36 and 46

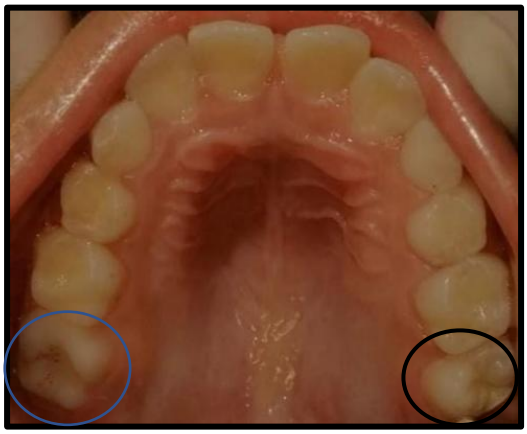


Figure 8A: Post-operative image at 1 week

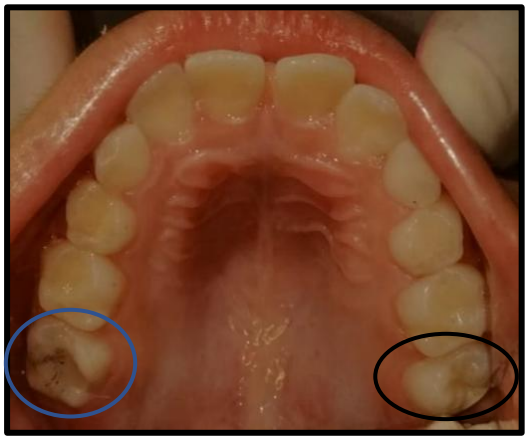


Figure 8B: Post-operative image at 1 month

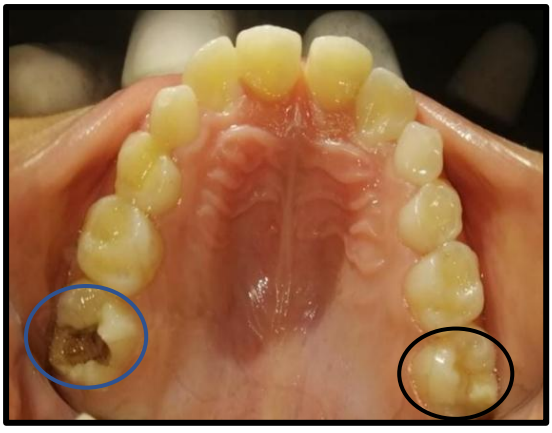


Figure 8C: Post-operative image at 3 months

CENTION N

ACTIVA

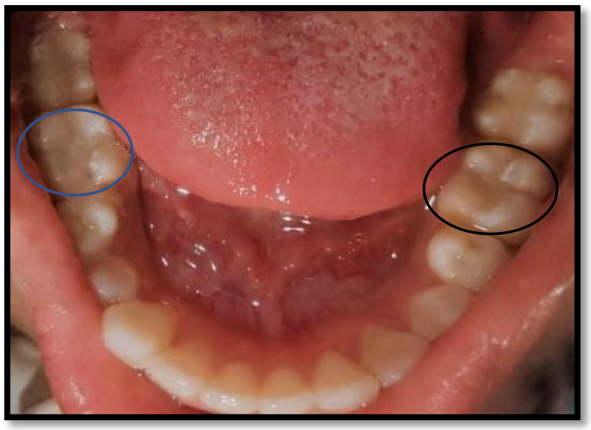


Figure 9A: Postoperative image at 1 week

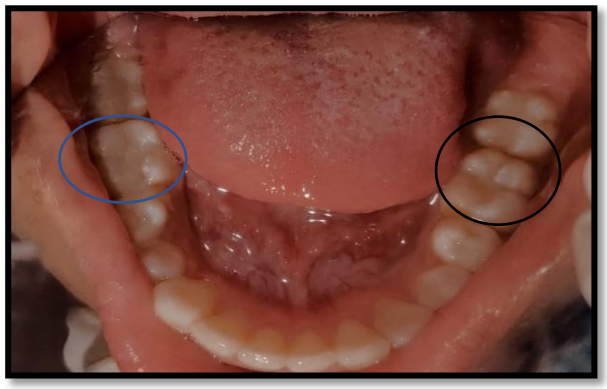


Fig 9B: Postoperative image at 1 month

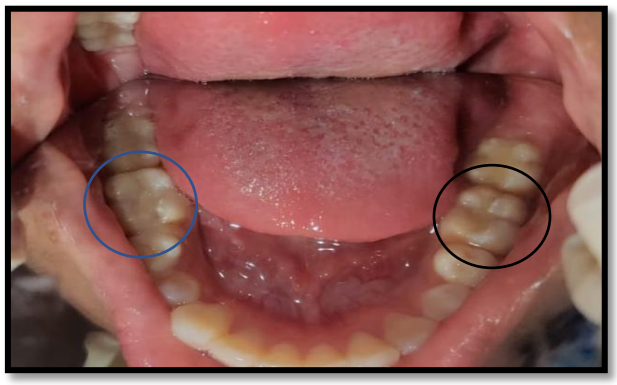


Fig 9C: Postoperative image at 3 months months

CENTION N

ACTIVA

RESULTS & OBSERVATIONS

Data analysis

Data was entered into Microsoft Excel spreadsheet and was checked for any discrepancies. Summarized data was presented using Tables and Graphs. The data was analysed by SPSS (21.0 version). Chi square test was used for inferential statistics of categorical variables. Level of statistical significance was set at p-value less than 0.05

I. CHI-SQUARED TEST

- It is to determine if there is any association between categorical data from two or more groups.
- Categorical data are data that can be separated into distinct groups that do not have a numerical relationship or order between them.

Methodology.

(a) Make a contingency table. Data are organized into a contingency table comprising row, and columns. The categories for one variable define the rows, and the categories for the other variable defines column.

(b) Test the difference between observed and expected values.

1. Test compares the size of the discrepancy between the numbers observed in the rows and columns against the number that would be expected if the null hypothesis (that there are no differences between the groups) was true.

2. If the observed and expected values are close then it would be reasonable to anticipate that the null hypothesis is true.

3. Chi square distribution is a family of probability density curves that are defined by the number of degrees of freedom.

4. The test statistic CHI square is a squared value it will, always be positive and greater than zero irrespective of the direction of the difference between samples (i.e., greater than or less than).

5. Right hand tail of the CHI square distribution therefore represents the two-tailed probability that the samples were derived from the same population. 2 CHI square tests are therefore always regarded as two sided.

Assumptions

1. Sample is randomly selected from the population.

2. Actual frequencies (not percentages or proportions) are entered into the contingency table.

3. Observations should be independent (not paired) if data are paired, McNemar's test should be used.

4. All values must be greater than 1. 5. 80% of the expected values must be >5.

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

O: OBSERVED FREQUENCY

E: EXPECTED FREQUENCY

25 children were enrolled in the study, with a total of 80 restorations that was allocated into two different groups (n=40). There was a dropout of 4 children leading to deduction of 12 restorations each from group A and B. Finally, 68 restorations were evaluated at the end of 3 months. The restorations were clinically and radiographically evaluated post operatively and 1 week, 1 month and 3 months of time period.

ASSESSMENT OF DISTRIBUTION OF TEETH IN STUDY PARTICIPANTS AT FOLLOW UP VISITS

Table 1: Comparison of distribution of teeth in study participants

Total N=80	1 week	1month	3 months
N	76	70	68
%	95%	87.5%	85%

Graph 1: Assessment of distribution of teeth in study participants at follow up visits

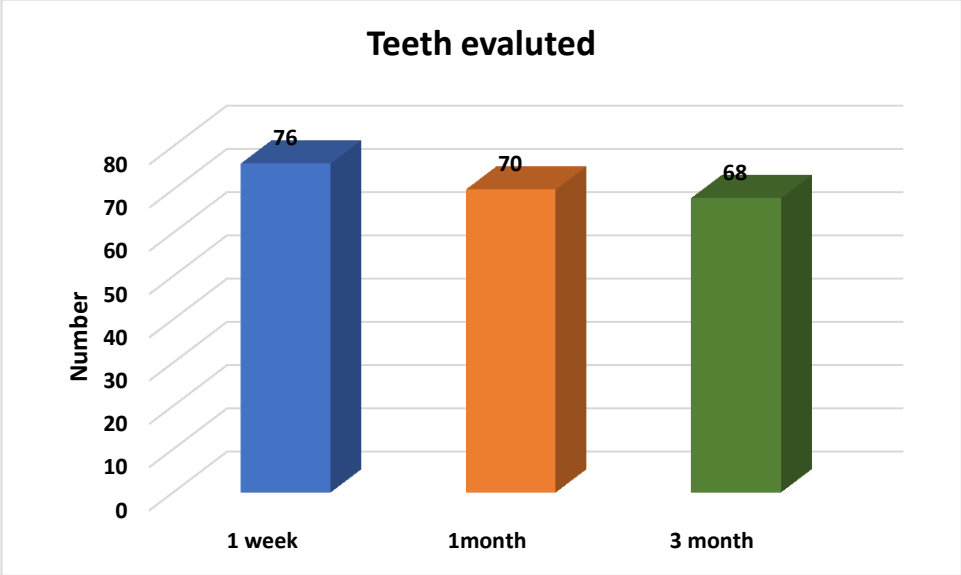


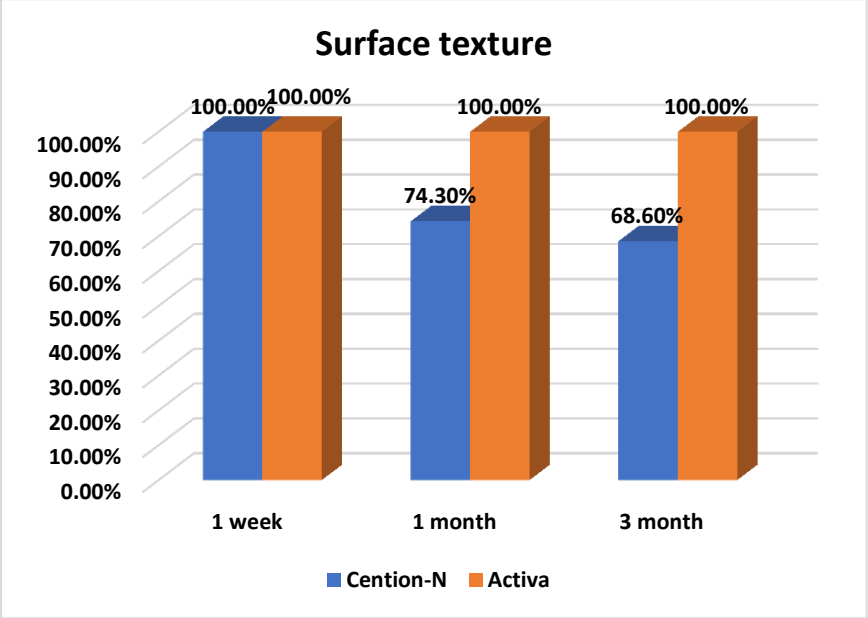
Table 1 and Graph 1 depicts four patients dropped out, resulting in the exclusion of 12 restorations at varied intervals. At the one-week interval, one patient (95%), with four restored teeth dropped out. At the one-month interval, there was a dropout of two participants (87.5%), one of whom had two restored teeth and the other had four teeth restored. At the third month, there was a dropout of one patient (85%) who got two teeth restored. As a result, 21 patients (N=68 teeth) were eventually assessed at the end of the third month.

ASSESSMENT OF SURFACE TEXTURE USING CENTION N AND ACTIVA BIOACTIVE-RESTORATIVE

Table 2: Comparison of surface texture with two restorative materials

			Surface texture		
			1 week (N=76)	1 month (N=70)	3 months (N=68)
Material	Cention -N	N	38	26	24
		%	100.0%	74.3%	68.6%
	Activa	N	38	35	35
		%	100.0%	100.0%	100.0%
Total		N	76	61	59
		%	100%	87.1%	84.3%
P value			-	0.001*	0.001*

Graph 2: Comparison of surface texture with two restorative materials



CENTION N-

All 38 teeth (100%) showed an intact surface texture after one week, followed by 26 teeth (74.3%) after one month, and 24 teeth (68.6%) at the end of the third month.

ACTIVA BioACTIVE-RESTORATIVE-

At one week, all 38 teeth (100%) had an intact surface texture, followed by 35 teeth (100%) at the end of the second month and at the end of the third.

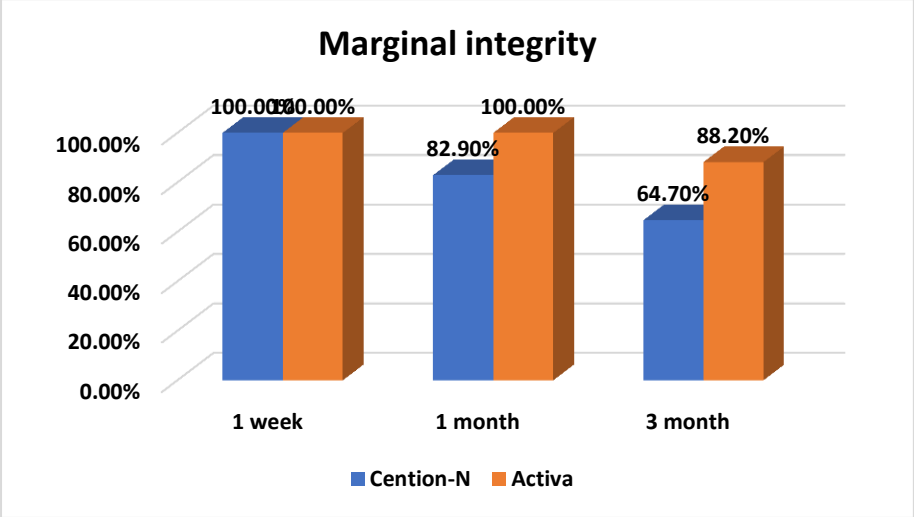
At 1 month and 3-month surface texture was found to be more intact with ACTIVA as compared with CENTION-N.($P<0.05$)

ASSESSMENT OF MARGINAL INTEGRITY USING CENTION N AND ACTIVA BIOACTIVE-RESTORATIVE

Table 3: Comparison of marginal integrity with two restorative materials

			Marginal integrity		
			1 week (N=76)	1 month (N=70)	3 months (N=68)
Material	Cention - N	N	38	29	22
		%	100.0%	82.9%	64.7%
	Activa	N	38	35	30
		%	100.0%	100.0%	88.2%
Total		N	76	64	52
		%	100%	91.4%	76.5%
P value			-	0.012*	0.022%

Graph 3: Comparison of marginal integrity with two restorative materials



CENTION N-

At 1 week, all the 38 teeth (100.0%) had intact marginal integrity, at 1 month, 29 teeth (82.9%) had intact marginal integrity and in 3rd month, marginal integrity was found to be intact in 22 teeth (64.7%).

ACTIVA BioACTIVE-RESTORATIVE-

At 1 week, all the 38 teeth (100.0%) had intact marginal integrity with no change in the first month. At the 3rd month, 30 teeth (88.2%) had intact marginal integrity.

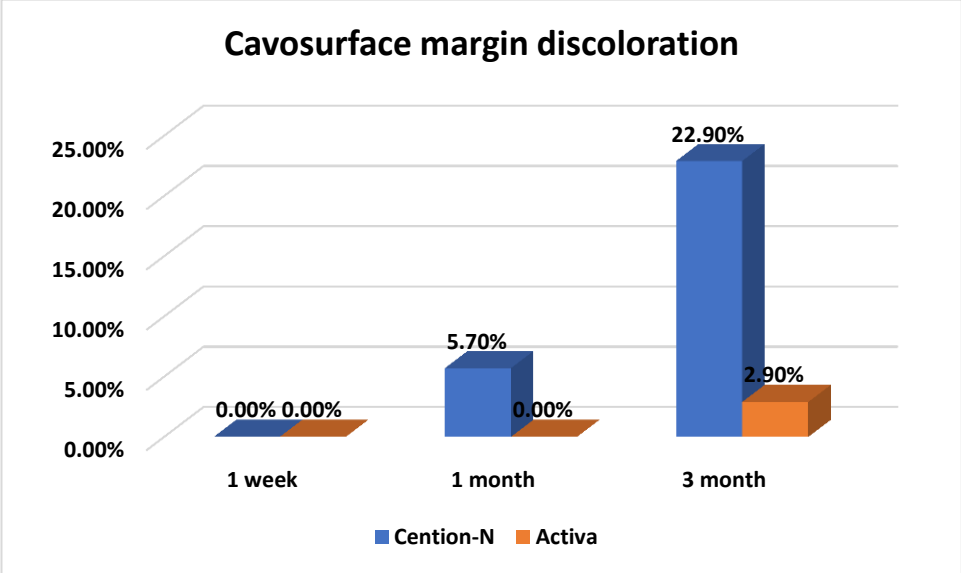
At 1 week, no statistically significant difference was seen in the marginal integrity of the either group (P>0.05), at 1 month and 3-month marginal integrity was found to be statistically significant with ACTIVA as compared to Cention N (P<0.05).

ASSESSMENT OF CAVOSURFACE MARGIN DISCOLOURATION USING CENTION N AND ACTIVA BIOACTIVE-RESTORATIVE

Table 4: Comparison of Cavosurface margin discoloration with two restorative materials

			Cavosurface margin discoloration		
			1 week (N=76)	1 month (N=70)	3 months (N=68)
Material	Cention - N	N	0	2	8
		%	0.00%	5.7%	22.9%
	Activa	N	0	0	1
		%	0.00%	0.00%	2.9%
Total		N	0	2	9
		%	0.00%	2.9%	12.9%
P value			-	0.246	0.014*

Graph 4: Comparison of Cavosurface margin discoloration with two restorative materials



CENTION N-

At 1 week, there was no cavosurface marginal discoloration in any of the teeth (0.00%),

at 1 month, 2 teeth (5.7 %%) had cavosurface marginal discoloration and at the end of 3rd month, 8 teeth (22.9%) had cavosurface marginal discoloration.

ACTIVA BioACTIVE-RESTORATIVE-

At 1 week and 1 month, no teeth (0.00%) had cavosurface marginal discoloration. At the end of the 3rd month, 1 tooth (2.9%) had a cavosurface marginal discoloration.

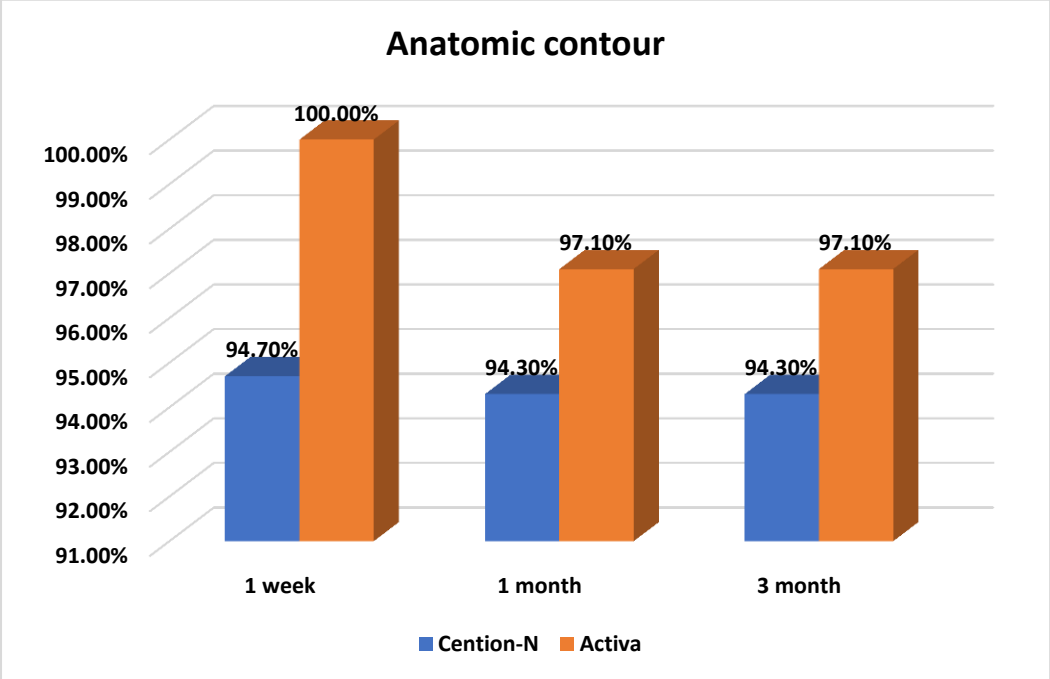
At 1 week and 1 month, there was no statistically significant difference in the cavosurface marginal discoloration of the either group ($P>0.05$), though there was a statistically significant difference between CENTION-N and ACTIVA BioACTIVE-RESTORATIVE at the end of 3rd month ($P<0.05$). At 3 months cavosurface marginal discoloration was found to be significantly more with Cention-N.

ASSESSMENT OF ANATOMIC CONTOUR USING CENTION N AND ACTIVA BIOACTIVE-RESTORATIVE

Table 5: Comparison of Anatomic Contour with two restorative materials

			Anatomic contour		
			1 week (N=76)	1 month (N=70)	3 months (N=68)
Material	Cention -N	N	36	33	33
		%	94.7%	94.3%	94.3%
	Activa	N	38	34	34
		%	100.0%	97.1%	97.1%
Total		N	74	67	67
		%	97.4%	95.7%	95.7%
P value			0.247	0.500	0.500

Graph 5: Comparison of Anatomic Contour with two restorative materials



CENTION N-

At 1 week, 36 teeth (94.7 %) were evaluated with a change in anatomic contour in two teeth.
At 1 month, 33 teeth (94.3 %) were evaluated out of which anatomic contour changes occurred in 2 teeth. At the end of 3rd month, no changes were seen in anatomic contour of the 33 teeth (94.3%).

ACTIVA BioACTIVE-RESTORATIVE-

At 1 week, 38 teeth (100.0 %) were evaluated with no changes in the anatomic contour. At 1 month, 34 teeth (97.1%) were evaluated out of which 4 teeth showed changes in the anatomic contour, with no changes in the anatomic contour at the end of 3rd month. (97.1 %)

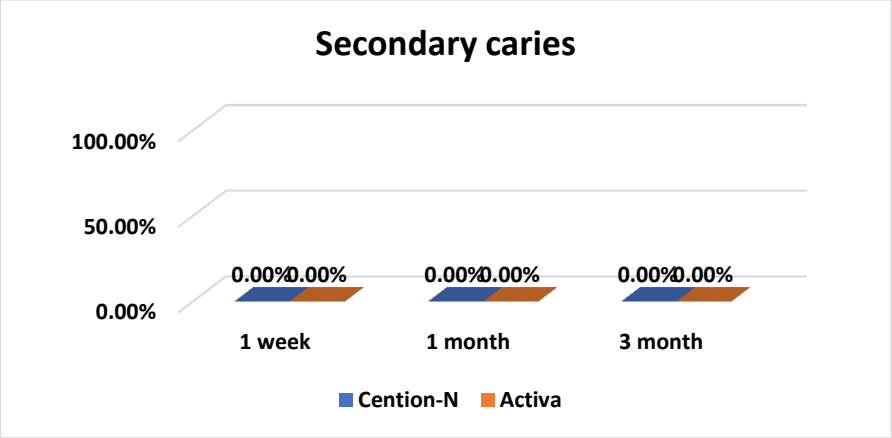
At one week, one month, and three months, there was no statistically significant difference in the anatomic contour of the either groups, CENTION-N or ACTIVA BioACTIVE-RESTORATIVE ($P>0.05$).

ASSESSMENT OF SECONDARY CARIES USING CENTION N AND ACTIVA BIOACTIVE-RESTORATIVE

Table 6: Comparison of secondary caries with two restorative materials

			Secondary caries		
			1 week (N=76)	1 month (N=70)	3 months (N=68)
Material	Cention - N	N	0	0	0
		%	0.00%	0.00%	0.00%
	Activa	N	0	0	0
		%	0.00%	0.00%	0.00%
Total		N	0	0	0
		%	0.00%	0.00%	0.00%
P value			-	-	-

Graph 6: Comparison of secondary caries with two restorative materials



CENTION N-

In any of the three follow-up intervals, none of the teeth (0.00%) showed any secondary caries.

ACTIVA BioACTIVE-RESTORATIVE-

In any of the three follow-up intervals, not a single tooth (0.00%) had secondary caries.

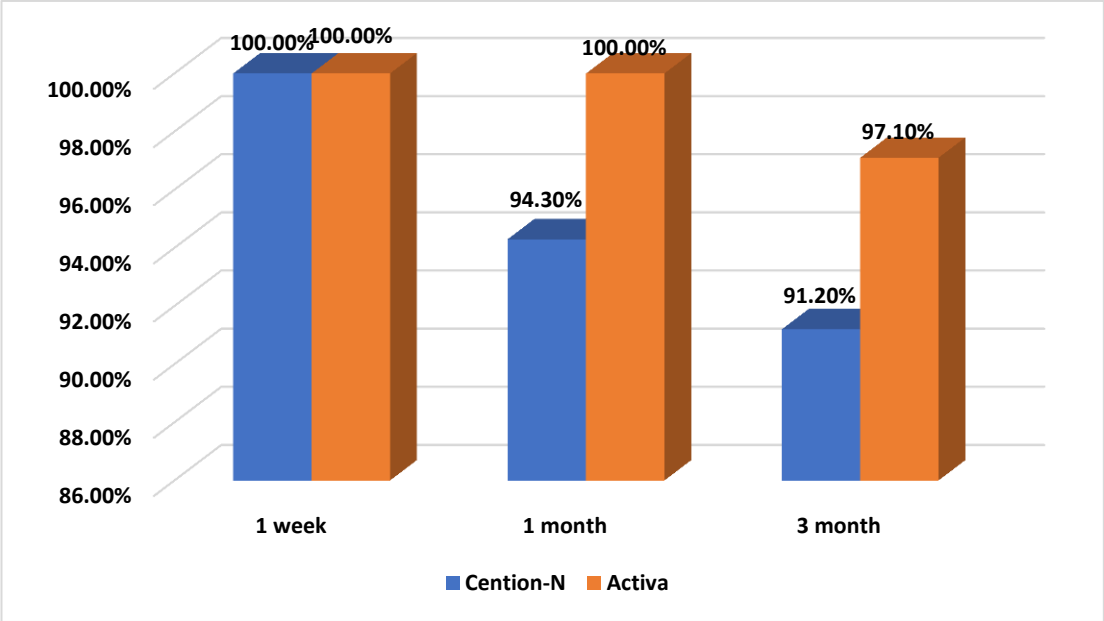
None of the research patients who received either of the two restorations were found to have secondary caries at 1 week, 1 month, or 3 months.

ASSESSMENT OF COLOUR MATCH USING CENTION N AND ACTIVA BIOACTIVE-RESTORATIVE

Table 7: Comparison of colour matching with two restorative materials

			Colour match		
			1 week (N=76)	1 month (N=70)	3 months (N=68)
Material	Centio n -N	N	38	33	31
		%	100.0%	94.3%	91.2%
	Activa	N	38	35	33
		%	100.0%	100.0%	97.1%
Total		N	76	68	64
		%	100%	97.1%	94.1%
P value			-	0.246	0.307

Graph 7: Comparison of colour matching with two restorative materials



CENTION N-

At 1 week, 38 teeth (100.0 %) were evaluated with no colour changes in any of the teeth.

At 1 month, 33 teeth (94.3 %) were evaluated out of which colour changes occurred in 2 teeth, while 2 teeth (91.2%) had a change in colour at the end of 3rd month.

ACTIVA BioACTIVE-RESTORATIVE-

At 1 week, 38 teeth (100.0 %) were evaluated with no colour changes in any of the teeth. At 1 month, 35teeth (100%) were evaluated out of which no colour changes occurred in any of the teeth while 2 teeth (97.1%) had a change in colour at the end of 3rd month.

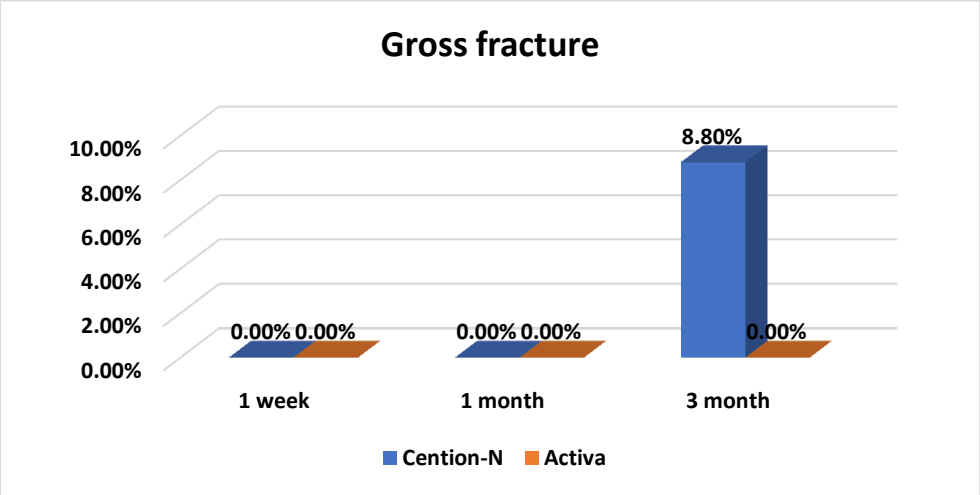
At one week, one month, and three months, there was no statistically significant difference in the colour matching of the either groups, CENTION-N or ACTIVA BioACTIVE-RESTORATIVE ($P>0.05$).

ASSESSMENT OF GROSS FRACTURE USING CENTION N AND ACTIVA BIOACTIVE-RESTORATIVE

Table 8: Comparison of Gross fracture with two restorative materials

			Gross fracture		
			1 week (N=76)	1 month (N=70)	3 months (N=68)
Material	Centio n -N	N	0	0	3
		%	0.00%	0.00%	8.8%
	Activa	N	0	0	0
		%	0.00%	0.00%	0.0%
Total		N	0	0	3
		%	0.00%	0.00%	4.4%
P value			-	-	0.199

Graph 8: Comparison of Gross fracture with two restorative materials



CENTION N-

At 1 week and 1 month, there was no evidence of gross fracture in any of the teeth (0.00%). But three teeth (8.8%) developed gross fracture in the third month.

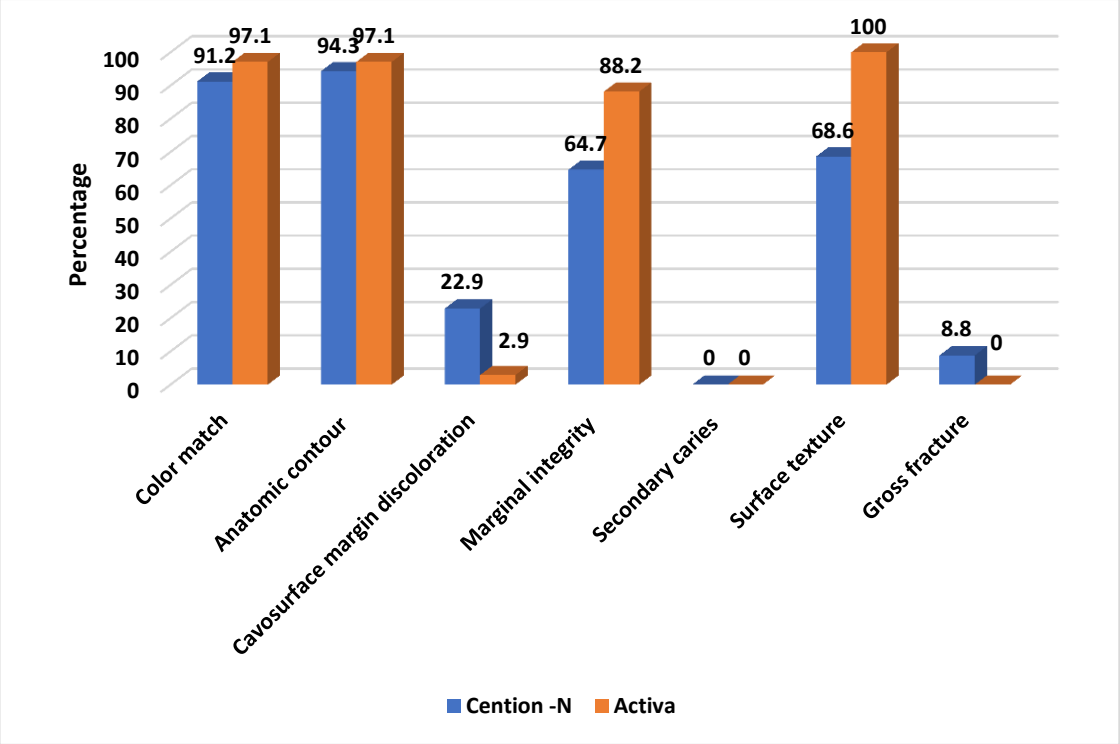
ACTIVA BioACTIVE-RESTORATIVE-

None of the teeth showed signs of gross fracture after one week, one month, or three months (0.00%).

At 1 week, 1 month and 3rd month no statistically significant difference was observed in the gross fracture in the groups given Cention-N and ACTIVA(P>0.05)

ASSESSMENT OF INTERGROUP COMPARISON OF THE CLINICAL PERFORMANCE OF CENTION-N AND ACTIVA AT ALL THE INTERVALS

Graph 9: Overall comparison of Cention N and Activa



Graph 9: At all follow-up intervals, it was determined that Activa was superior to Cention N in terms of colour match, anatomic contour, cavosurface margin discolouration, marginal integrity, surface texture, gross fracture, and secondary caries.

DISCUSSION

A proactive approach to patient treatment and oral health care is now possible because of advancements in dental materials. Patients' preference for tooth-colored restorations has increased the usage of resin-bonded materials in recent years. Over the previous two decades, resin composite technology has advanced significantly. Nature, where water is the wellspring of life, has inspired the development of bioactive materials. Smart materials are extremely receptive and have an inherent capacity for sensing and reacting to changes in the environment. They respond to changes in the oral environment by altering the characteristics of saliva and the materials themselves for the better. Saliva is rich in water, proteins and ionic components, and is the life source in the oral cavity. The oral environment is subjected to constant hydrogen ion concentration, and saliva and tooth structure are involved in a never-ending mineral exchange cycle. The demineralization process releases calcium and phosphate ions from the tooth surface when the pH is low.

The advent of these smart restorative materials, together with newer adhesives has brought enormous changes- notably in terms of esthetics. They have taken a stride towards minimally invasive dentistry. However, due to the frequent introduction of "better" versions, long-term clinical data on particular products are rarely accessible. Laboratory tests, however, may be able to shed light on a material's potential performance or clinical handling qualities. Furthermor, *in-vitro* research cannot provide information on the durability of these tooth-colored restorations. Since studies reveal varying therapeutic outcomes, long-term findings with several of these recently produced materials are absent and remain debateable.

Cvar and Ryge created the United States Public Health Service (USPHS) criteria for clinical evaluation of the restoration in 1971, and it has been widely used for clinical evaluation of restorations ever since.[47] It is the only criteria readily available that is widely used for long-term evaluation of restorations, and it is considered valid for comparison purposes among studies at different observation periods. The following system was used to grade restorations: Alpha indicated the optimum clinical circumstance, Bravo clinical acceptability, and Charlie clinical unsatisfactory conditions necessitating replacement of the restoration. Several writers have somewhat adjusted these criteria during the previous 40 years, adjusting them to

their own requirements, and the list of criteria has been expanded to includeadditional objects of interest. Surface texture, postoperative sensitivity, proximal contact, occlusal contacts, fracture, and other characteristics are included in the extended list. These changes are outlined and easily available in contemporary dentistry scientific literature as modified Ryges USPHS criteria. Hence, in our study we included modified USPHS criteria to serve as the foundation for current discussions on the further development of clinical assessment procedures for dental restorative treatments.[48]

Cention N is a basic, resin-based, self-curing powder/liquid "alkasite" restorative material. Alkasite is a novel class of filler material that, like composite or organic rubber, is essentially a division of the composite material class. Cention N is a tooth-coloured, basic filling material for direct restorations. It releases fluoride, calcium, and hydroxide ions and is radiopaque.[5] ACTIVA BioACTIVE-RESTORATIVE is a highly aesthetic, bioactive composite that incorporates all of the benefits of glass ionomers into a strong, resilient resin matrix that will not chip or crumble. It chemically adheres to teeth, seals against microleakage, releases more calcium, phosphate, and fluoride than glass ionomers, is more bioactive than composites, and is more resilient and fracture resistant than composites.[6,7,8,9]

The present *in-vivo* study investigated surface texture, marginal integrity, cavosurface marginal discoloration , anatomic contour, secondary caries, colour match and gross fracture for Cention N and ACTIVA BioACTIVE-RESTORATIVE in first permanent molars in children.This study was conducted in the Departrment Of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow. Clearance was taken from Institutional Ethical Committee and written informed consents were obtained from parents prior to enrollment of the children in the study.The requisites for the use of the split mouth design was to investigate uniformly the clinical procedure with the objective to compare clinical performance was to evaluate the clinical efficacy of tooth-colored restorations in first permanent molars.

Participants' teeth were restored contralaterally using two different materials. Two skilled, calibrated examiners examined the results post operatively and at intervals of one week, one month, and three months.

There is less literature about the clinical performance of these two restorative materials in permanent molars that meet modified Ryge's USPHS criteria. Therefore, the results of this study were contrasted with those of studies that used alternative dental restorative materials.

The present study included 25 children and a total of 80 restorations that were divided into two groups (n=40). During the study period a attrition rate of 4 subjects was seen. One patient (95%), with four restored teeth, dropped out after one week. At the one-month interval, two individuals (87.5%) dropped out, one with two restored teeth and the other with four restored teeth. One patient (85%), who had two teeth restored, dropped out after the third month. At the end of the third month, 21 patients (N=68 teeth) were evaluated **(Table 1 and Graph 1).**

The surface texture of a natural tooth is made up of horizontal and vertical concavities and convexities that differ in intricacy and intensity from tooth to tooth. When these components are not properly replicated, it is difficult to achieve the necessary level of aesthetics in restorations, (Kahng S.Luke 2005**)**[49].The surfaces of adjacent teeth always condition the surfaces of a tooth. A smooth tooth compared to a tooth with a more noticeable texture will produce a dominant contrast in which the rougher tooth appears to be of lower value than the smoother tooth, (Romeo G et al.2022).[50]

In the present study, the surface texture was measured with an explorer according to modified Ryge's USPHS criteria.Cention N showed greater increase in surface roughness at an interval of 1 month and 3 months with surface texture being gritty or similar to a surface subject to a white stone or similar to a composite containing supramicron-sized particles. No statistical significant difference was observed in between the two restorative materials at an interval of 1 week. The surface roughness for Cention N was found to be 25.7% in 26 teeth at an interval of 1 month and by 3rd month it was 31.4% for 24 teeth, whereas ACTIVA showed 0% surface roughness or any changes in the surface texture at all the three intervals **(Table 2 and Figure2)**. The initial adherence and retention of dental plaques are significantly influenced by the surface roughness of dental materials. Rough surfaces are anticipated to increase the incidence of tooth cavities and periodontal disorders. The colour, gloss, and stain susceptibility of dental restorative materials are also impacted by surface roughness.

According to (John Burgess et al 2016)[51], surface texture with Cention N was significantly lower than amalgam due to the gloss that can be achieved with amalgam; however this is less of an esthetic drawback when comparing a tooth coloured material with a grey amalgam. Fariha Naz (2020)[52] in a study revealed SEM images which show the surface texture of Filtek Z250 XT,Cention N, and Fuji IX after chewing simulation The images show more surface roughness with Fuji IX compared to other groups, and Cention N show the least pits and valleys and better reisistance. Dodiya P et al. (2019)[53] claim that Centon N, which is available in both liquid and powder form, has poorer surface qualities to Tetric N Cream after one week due to a variety of factors, including the kind of mixing and material particle size. Lardani L et al(2022)[54] unveiled in SDR Bulk-fill and Activa BioActive Composite have comparable aesthetic behaviour in class I cavities.

The marginal integrity of restorations is an important parameter as marginal gap formation is associated with recurrent caries and pulpal diseases. Altering the amount and the quality of filler particles can change the esthetics and mechanical properties of restorative materials. In our present study, in the Cention-N group at the end of 1 week, total 38 teeth (100.0%) had intact marginal integrity. Whereas, at the end of 1 month, out of 35 teeth, 6 teeth (17.1%) lost their marginal integrity and at the end of 3rd month total 12 teeth (35.3 %) showed a decline in the marginal integrity out of 34 teeth. The marginal interigity of ACTIVA was intact at the end of 1 week and 1 month in all the restored teeth. But the end of 3rd month,4 teeth (11.8 %) showed a decline in the marginal integrity **(Table 3 and Figure 3).**

Cention N contains alkaline ions such as fluoride and calcium in the powder that neutralizes the acidic ions in the restoration, while the liquid contains monomer to improve the flowability and adaptation to the smear layer.[5] Although it has a high 78.4% inorganic filler content for better compressive strength and reduced stress on cavity walls, the study showed the lowest marginal integrity for Cention N when compared with ACTIVA BioACTIVE RESTORATIVE. Peutzfeldt and Asmussen (1998) found in their study that ACTIVA BioACTIVE RESTORATIVE, which contains bisphenol A glycol dimethacrylate (Bis GMA), triethylene glycol dimethacrylate (TEGDMA), and substituted urethane dimethacrylate (UDMA) monomers,[55] had increased flexural strength, which is in line with our study.

Marginal discoloration is often associated with imperfections at the margin of the restoratons such as gaps, fractures,etc. In our analysis, we found at 1 week and 1 month, there was no statistically significant difference in the cavosurface marginal discoloration in the either groups,(P>0.05) but at 3 months, Cention N was shown to have a considerably higher level of cavosurface marginal discoloration as compared to Activa. Cavo-surface marginal discoloration was 0.00% for both Cention N and ACTIVA at the end of 1 week, whereas, in the Cention N group at 1 month, 2 teeth (5.7%) showed marginal discoloration and at 3 months 8 teeth (22.9%) out of 34 teeth showed discoloration in the cavosurface margin. In ACTIVA restored teeth, only at the end of 3rd month 1 tooth (2.9%) had a cavosurface marginal discoloration. **(Table 4 and Figure 4)** This could be attributed to the fact that ACTIVA-RESTORATIVE is the first bioactive dental materials with an ionic resin matrix, a shock-absorbing resin component, and bioactive fillers that mimic the physical and chemical properties of natural teeth. This combination provides aesthetics, strength, and durability while reducing shrinkage stress, by chemically bonding to teeth.

Manhart et al. (2018)[56] conducted a study over 18 months to investigate the effectiveness of bulk-fill composite (Quixfil) and found a significant increase in marginal discoloration over time.The cause of many of these marginal flaws was believed to be due to the fracture of small bits of resin composite material that extended on the enamel surfaces near the cavity borders. The use of phosphoric acid etching and aggressive self-etch adhesives may reduce the frequency of these flaws, especially in high-stress areas, due to enhanced enamel etching. Abdalla and Garcia-Godoy found that the application of adhesive resin after enamel etching improved the clinical performance of FuturaBond NR in class V lesions, but there was still some room for improvement in terms of marginal adaptation and discoloration. Arhun N et al. (2010)[57] discovered faults at the margins in non-hybrid and low-shrinkage posterior resin composites, but no restorations showed marginal discoloration.

In our study, we also evaluated the anatomic contour as a criteria. Contour is a term used to describe a degree of convexity and concavity on the facial/buccal and lingual/palatal surfaces of all teeth that protect the supporting tissue during mastication." .The antomic coutour with both the materials was in continuation of

existing anatomic form. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing cavo surface line angles at the same time. At 1 week and 1 month, 2 teeth (5.3%) each were evaluated with a change in the anatomic contour with Cention N restored teeth. At the 3rd month, no changes were seen in anatomic contour of all the 33 teeth (94.3%). At one week, 38 teeth (100%), with no changes in anatomic shape, were assessed. In ACTIVA group at one month, 34 teeth (97.1%) were assessed, with 4 teeth showing changes in anatomic contour and no changes in anatomic contour at the end of the third month. (97.1 %). At the third month interval, no statistically significant variation in anatomic contour was seen in either group. **(Table 5 and Figure 5)**

According to, Askar H et al.(2020)[58] "Secondary (or recurrent) caries is defined as a lesion associated with restorations or sealants."While the type of restorative material used can play a role in the development of secondary caries, other factors such as the size of gaps around the restoration, the patient's risk for developing cavities, and the skill level of the dentist performing the procedure are considered more important. In the present study, none of the research subjects who received either of the two restorations were found to have secondary caries at 1 week,1 month and 3 months **(Table 6 and Figure 6)**. The study by Özcan M et al. (2016)[59] reported that Cention N fillings were successful during a six-month observation period and received positive feedback from patients. Additionally, no problems such as debonding, fractures, endodontic complications, or secondary caries were reported.

The absent of secondary caries in the study is in accordance with the findings of Hugar SM et al. (2017)[60] who reported only 1% recurrent caries incidence after one year. The non-appearance of secondary caries at the occlusal margins may be related to the lack of marginal gaps. However, Papagiannoulis L et al. (2017)[60], reported a 6% of secondary caries rate in Dyract restorations. Peters et al. (1996)[61], reported a 1% incidence of recurrent caries after 1 year with Dyract material, and Kavvadia et al. (2006), who reported 1.7% caries with F2000 restorations.[62] However, Papagiannoulis et al. (2004), revealed secondary caries rate of 6% at cervical margins 24 months after Dyract restorations.[63] According to Mjor et al. (2007), deterioration of marginal integrity and development of secondary caries is not only due to the material itself.[64] Clinical environment, caries experience of patients, criteria for replacements , different handling properties appeared to affect clinical

results.Additionally, Bernardo et al.(2007) reported that the overall frisk of failure due to secondary caries was 3.5 times higher in composite restorations than in amalgam restorations.[65] It has been reported that young patients who are allowed to choose the colour of their restorations are more likely to accept the idea of treatment. The accomplishment of the treatment is aided even further by the dentist's justification to the child that the fillings will continue to look good as long as the patient maintains them well.

In the current study, the evaluation of color match showed that all the Cention N restored teeth had no color changes (100%) at 1 week. After 1 month, 94.3% of the teeth still had no change in color, and 91.2% of the teeth had no color change at the end of the third month. The color compatibility of both restorative materials was 100% at 1 week and 1 month, but at the end of the third month, only 2.9% of the teeth had a color change. **(Table 7 and Figure 7).** Cention N is a self-curing material with the option of light curing and contains a copper salt, peroxide, and thiocarbamide initiator system, while ACTIVA BioACTIVE-RESTORATIVE is a composite material with bioactive and fluoride-releasing characteristics. The current study followed the manufacturer's instructions and did not use any varnish, which is known to reduce fluoride release. According to a study by C. Cigdem et al. (2010), both resin composite and universal light-curing nanohybrid resin composite showed good color stability.[66]

According to a study by Arhun N et al. (2010), nanohybrid resin composite had a larger selection of accessible color shades, while QuiXfil resin composite was only available in one universal shade.[67] At the start of the study, none of the restorations had Bravo scores. The chameleon effect of QuiXfil, which blends in with the surrounding tooth structure, could explain the favorable color match results. However, a study by Donmez S et al. (2016)[68] found that resin-modified glass ionomer restorations declined in color match and translucency. The use of a protective varnish after polishing the material can reduce color changes.

The flexural strength, which indicates ability of the material to withstand breaking, was analyzed in the current study. The results showed that there was no significant difference between the two restorative materials in terms of fracture resistance at 1

week, 1 month, and 3 months. Only three teeth (8.8%) in the Cention N group had a gross fracture at the end of the third month. **(Table 8 and Figure 8)**.

The correlation between flexural strength and clinical performance was shown by Heintze et al. (2017).[69] According to them, composite fillings with a flexural strength lower than the ISO norm of 80 MPa for polymer-based restorative materials are more likely to fracture. In the current study, no significant difference in the gross fracture rate was observed between the two restorative materials at 1 week, 1 month, and 3 months. However, at the end of the third month, only 3 teeth (8.8%) in the Cention N group showed gross fracture. The flexural strength of Cention N was tested using the ISO 4049:2009 standard, and it was found to be greater than that of the glass ionomer materials tested. In addition, the compressive strength of Cention N was also determined to be superior to resin modified glass ionomer cements and composite materials, as per the ISO 9917-1 and ISO 4049 standards.[5] According to Sujith R et al. (2020)[43], the highest mean compressive and flexural strength was found in hybrid composite, followed by Cention N and least in GIC, which was statistically significant The lowest average microleakage was discovered in Cention N, which is different from the results of the current study.

The rubberized resin component in ACTIVA provides exceptional strength and resilience. The term toughness refers to a material's ability to withstand stress and resist fracture when subjected to a load, which was measured using a 3-point bend test. ACTIVA was found to have 2 to 3 times higher break deflection than composites and 5 to 10 times greater break deflection than GICs and RMGICs, meeting the ISO 4049 standards for occlusal restorations. Additionally, ACTIVA showed comparable flexural fatigue to flowable composites and higher than standard RMGICs and GICs. It's worth noting that ACTIVA does not contain bisphenol A (BPA), bisphenol A glycidyl methacrylate (bis-GMA), or any BPA derivatives.[7] The mineral deposits in ACTIVA also protect the margins from microleakage and secondary caries, helping to prevent breakage.

ACTIVA outperformed Cention N in terms of surface texture, marginal integrity, cavosurface marginal discoloration , anatomic contour, secondary caries, colour match and gross fracture at all follow-up intervals **(Figure 9)**.

ACTIVA BioACTIVE RESTORATIVE proved to be superior restorative material because of its longer duration of fluoride releasing property and good overall clinical performance than Cention N. The bioactive smart material offers advantages in terms of ease of use and improved aesthetics. This is due to the fact that it comes in an automix syringe, eliminating the need for additional mixing tools, and its ability to chemically bond with the tooth structure for a more natural appearance.

The uniqueness of this study lies in the fact that it is the first of its kind in- vivo study performed to evaluate the clinical performance between these two materials with uniform age group patients distributed in both the study groups.

There is a scarcity of information in the literature about the use of Cention N and ACTIVA BioACTIVE for tooth-colored restorations, with limited clinical evidence for a pediatric dentist to assess the reliability of these restorations in various clinical situations. Most of the existing studies are either laboratory-based or retrospective, leading to a significant demand for a prospective clinical trial to compare these smart restorative materials. With growing attention towards bioactive materials in dentistry, particularly for the purpose of remineralizing dentin, this study provides important information in the field.

The characteristics of restorative materials play a crucial role in the field of pediatric dentistry, particularly in terms of preserving the longevity of teeth, specially permanent first molars. This is because this teeth is vital to proper occlusion. Therefore, it is important to carefully consider the properties of restorative materials to ensure the long-term health and function of teeth.Additional research is necessary to determine the other features of bioactive materials so that they can gain acceptance.

CONCLUSION

The present *in-vivo* study made an attempt to determine the clinical performance of tooth colored restorative materials in permanent first molars. On the basis of observation made during the course of the study and their analysis, the following conclusions have been drawn:

1. ACTIVA BioACTIVE Restorative outperforms Cention N in terms of clinical performance.

2. When comparing the surface texture and marginal integrity of the restoration with ACTIVA BioACTIVE and Cention N at the 1 month and 3 month intervals, updated Ryge's USPHS criteria revealed statistically significant differences.

3. At the end of the third month, there was a statistically significant difference between the two materials in the cavosurface marginal discoloration.

4.The assessment of anatomic contour, colour match, cavo-surface marginal discolouration, secondary caries, and gross fracture did not reveal any statistically significant differences.

5. The development of these bio-responsive dental restorative materials will allow for a proactive method of treating patients' oral health needs.

6. The study assesses the already accessible "smart material" employed in dentistry as we move toward a new era of bio-smart dentistry.

SUMMARY

This split-mouth *in-vivo* study was carried out at the Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, in the department of Paediatric and Preventive dentistry. The aim of the study was to compare the surface texture, marginal integrity, cavosurface margin discoloration, anatomic contour, secondary caries, colour matching and fracture strength of Cention N and ACTIVA BioACTIVE-RESTORATIVE in the first permanent molars of children between 7 and 11 years of age. The study involved 25 children with a total of 80 samples that met the criteria for inclusion and exclusion. The guardians of the children gave informed consent before the examination. The clinical evaluation of the restorations was carried out using modified Ryge's USPHS criteria, at intervals of 1 week, 1 month and 3 months. The children were divided into two groups (n=40), but there was a dropout of 4 children, resulting in 6 restorations being removed from each group. In the end, 68 restorations were evaluated after 3 months. The results of the study showed that there was a statistically significant difference between Cention N and ACTIVA BioACTIVE in terms of surface texture and margin quality after 1 month and 3 months, respectively. There was also a statistically significant difference in cavosurface marginal discoloration at the end of the third month. The study found that ACTIVA BioACTIVE RESTORATIVE demonstrated better clinical results than Cention N in treating Class I cavities in children's permanent molars and showed excellent performance as a long-lasting restorative material. However, more randomized controlled trials with larger sample sizes and longer follow-up periods are needed to confirm its long-term effectiveness. In recent years, there has been a lot of innovation in Pediatric restorative dentistry, and it is important for dentists to have a good understanding of the different materials available and their unique properties, strengths, limitations, and requirements. As new materials are developed and introduced, they will likely improve in user-friendliness and quality, and may add to the selection of options. To reduce stress and increase confidence in dental treatment for children, it is important for pediatric dentists to stay up-to-date on the latest materials and advancements in the field, which will ultimately improve the benefits for the patient and the quality of dental therapy

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ANNEXURE-I

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"A Comparative Evaluation of Clinical Performance of Tooth Coloured Restorative Materials in Permanent Molars"** submitted by **Dr Saheli Basu** Post graduate student from the **Department of Pediatric and Preventive Dentistry** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **12th October 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

ANNEXURE-II

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 19 **BBDCODS/04/2022**

Title of the Project: A Comparative Evaluation of Clinical Performance of Tooth Coloured Restorative Materials in Permanent Molars.

Principal Investigator: Dr Saheli Basu **Department:** Pediatric and Preventive Dentistry

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Saheli Basu,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. Puneet Ahuja)
Principal
BBDCODS
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

ANNEXURE-III

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study- "A COMPARATIVE EVALUATION OF CLINICAL PERFORMANCE OF TOOTH COLOURED RESTORATIVE MATERIALS IN PERMANENT MOLARS"

Study Number…….
Subject's Full Name…….
Date of Birth/Age ……
Address of the Subject…….
Phone no. and e-mail address……
Qualification ……
Occupation: Student / Self Employed / Service /
Housewife/Other (Please tick as appropriate)
Annual income of the Subject……
Name and of the nominees(s) and his relation to the subject.....(For the purpose of
compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated ……..for the above study and have had the opportunity to ask questions. **OR** I have beenexplained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor 's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided sucha use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes [✓] No [ ]**

Not Applicable [ ]

I agree to participate in the above study. I have been explained about the complications andside effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally AcceptableRepresentative: …….
Signatory 's Name…….
Date …….
Signature of the Investigator……
Date…….
Study Investigator 's Name.....
Date…….
Signature of the witness……
Date…….
Name of the witness……
Received a signed copy of the PID and duly filled consent form Signature/thumb impression of the subject or legally acceptable representative Date…….

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय)

बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

सहमति प्रपत्र (अंग्रेज़ी)

अध्ययन का शीर्षक- ″स्थायी दाढ़ों में टूथ कलर्ड रिस्टोरेटिव सामग्री के नैदानिक प्रदर्शन का तुलनात्मक मूल्यांकन"

स्टडी नंबर·····..

विषय का पूरा नाम .....

जन्म तिथि/आयु .....

विषय का पता·····.

फोन नंबर। और ई-मेल पता .....

योग्यता .....

व्यवसाय: छात्र / स्वरोजगार / सेवा / गृहिणी / अन्य (कृपया उपयुक्त के रूप में टिक करें)

विषय की वार्षिक आय·····

नाम और नामांकित व्यक्ति (ओं) और विषय के साथ उसका संबंध (के प्रयोजन के लिए)

मुकदमे से संबंधित मौत के मामले में मुआवजा)।

1. मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक . को पढ़ और समझ लिया है

·····..उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।

2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।

3. मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी। इसके संबंध में आयोजित किया जा सकता है, भले ही मैं

परीक्षण से हट जाऊं। हालांकि, मैं समझता हूं कि तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में मेरी पहचान प्रकट नहीं की जाएगी।

4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।

5. मैं भविष्य के शोध के लिए संग्रहीत नमूने (दांत/ऊतक/रक्त) के उपयोग की अनुमति देता हूं। हाँ [] नहीं [ ]

लागू नहीं [ ]

मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। मुझे जटिलताओं और दुष्प्रभावों के बारे में समझाया गया है, यदि कोई हो, और उन्हें पूरी तरह से समझ लिया है। मैंने प्रतिभागी/स्वयंसेवक के मुझे दिए गए सूचना दस्तावेज को भी पढ़ और समझ लिया है।

विषय/कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान):.....

हस्ताक्षरकर्ता का नाम……. तारीख .....।

अन्वेषक के हस्ताक्षर ..... तारीख……..

अध्ययन अन्वेषक का नाम ..... तारीख…….

गवाह के हस्ताक्षर…… तारीख…….

गवाह का नाम .....

पीआईडी की एक हस्ताक्षरित प्रति और विधिवत भरे हुए सहमति फॉर्म विषय के हस्ताक्षर/अंगूठे का निशान या कानूनी रूप से स्वीकार्य प्रतिनिधि
दिनांक…….

ANNEXURE-IV

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

PARTICIPANT INFORMATION DOCUMENT

1. Study Title

A comparative evaluation of clinical performance of tooth-coloured restorative materials in permanent molars

2. Invitation Paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. What is the purpose of the study?

This study aims to to determine the clinical performance of tooth-colored restorative materials in permanent first molars.

4**. Why have I been chosen?**

You have been chosen for this study as you are fulfilling the required criteria for this study.

5. **Do I have to take part?**

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you are still free to withdraw at any time and without giving a reason.

6. **What will happen to me if I take part?**

The participant will be benefited as the required dental treatment will be carried out with the newest available restorative smart material. This will also help the patients to get the treatment done with tooth coloured, hydrophilic, user-friendly restorative material.

7**. What do I have to do?**

This study requires treatment to be carried out only after the parent has given consent, and assent from the patient for the undergoing restorations. Children of both the gender (male and female) with an age group of 7-11years, requiring dental treatment will be included in the study.

8. What is the procedure that is being tested?

The study will be carried out to evaluate and compare the surface texture, marginal integrity, cavosurface marginal discoloration, anatomic contour, secondary caries, colour match and gross fracture for Cention N and ACTIVA BioACTIVE-RESTORATIVE in first permanent molars in children.

9. What are the interventions for the study?

Dental procedures requiring restoration of Class I cavities in permanent first molars.

10. What are the side effects of taking part?

Although there are no reports of serious side effects of the procedure, but the participant may have minimum side effects. If anything happens during the procedure, we have skilled personnel and specialized equipments to manage any emergency.

If the participant suffers any other symptom post operatively, the guardian should immediately talk to the doctor.

11. What are the possible disadvantages and risks of taking part?

There are no disadvantages of taking part in this study, there can be minimum side effects of the restorations.

12. What are the possible benefits of taking part?

The participant will be benefited as the required dental treatment will be carried out with the newly available restorative smart material.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

Nothing will happen to the participants.

15. What if something goes wrong?

The problems/complaint will be handled by the HOD or the IRC.If something serious happens the institute will take care of the problems.

16. Will my taking part in this study be kept confidential?

Yes, it will be kept confidential.

17. What will happen to the results of the research study?

The results of the study will be used to compare determine the clinical performance of tooth-colored restorative materials in permanent first molars in pediatric dental patients. Your identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

The research is been done in the DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY, BBDCODS. The research is self -funded. The participants will have to pay for procedural charges as given by the institution.

19. Will the results of the study be made available after study is over?

Yes

20. Who has reviewed the study?

The HOD and the members of IRC/ IEC of the institution has reviewed and approved the study.

21. Contact for further information

Dr. Saheli Basu

Department of Pediatric and Preventive Dentistry

Babu Banarasi College of Dental Sciences.

Lucknow-227105

Mob- 8777327477

Dr. LaxmiBala

Member Secretary of Ethics Committee of the institution,

Babu Banarasi College of Dental Sciences.

Lucknow

bbdcods.iec@gmail.com

THANK YOU FOR TAKING OUT YOUR PRECIOUS TIME FOR READING THE DOCUMENTS AND PARTICIPATING IN THE STUDY.

Signature of PI……
Name…….
Date…….

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय)

बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

प्रतिभागी के लिए सूचना पत्र

1. अध्ययन शीर्षक

अध्ययन का शीर्षक- ″स्थायी दाढ़ों में टूथ कलर्ड रिस्टोरेटिव सामग्री के नैदानिक प्रदर्शन का तुलनात्मक मूल्यांकन"

2. निमंत्रण अनुच्छेद

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो दोस्तों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक/पारिवारिक चिकित्सक के साथ इस पर चर्चा करें। किसी भी स्पष्टीकरण या अधिक जानकारी के लिए हमसे पूछें। आप भाग लेना चाहते हैं या नहीं, यह आपका निर्णय है।

3. **अध्ययन का उद्देश्य क्या है**?

इस अध्ययन का उद्देश्य दाढ़ों में दांतों के रंग की पुनर्स्थापनात्मक सामग्री के नैदानिक प्रदर्शन को निर्धारित करना है।

4. मुझे क्यों चुना गया है?

आपको इस अध्ययन के लिए चुना गया है क्योंकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं।

5. क्या मुझे भाग लेना है?

शोध में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप ऐसा करते हैं, तो आपको यह सूचना पत्रक रखने के लिए दिया जाएगा और सहमति प्रपत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप किसी भी समय और बिना कोई कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6. अगर मैं भाग लूंगा तो मेरा क्या होगा?

प्रतिभागी लाभान्वित होंगे क्योंकि नवीनतम उपलब्ध रिस्टोरेटिव स्मार्ट सामग्री के साथ आवश्यक दंत चिकित्सा की जाएगी। इससे मरीजों को टूथ कलर, हाइड्रोफिलिक, उपयोगकर्ता के अनुकूल रिस्टोरेटिव सामग्री से उपचार करने में भी मदद मिलेगी।

7. मुझे क्या करना है?

इस अध्ययन में माता-पिता की सहमति के बाद ही उपचार किए जाने की आवश्यकता है, और रोगी से पुनर्स्थापन के लिए सहमति दें। 7-11 वर्ष की आयु के साथ दोनों लिंग (पुरुष और महिला) के बच्चों को दंत चिकित्सा की आवश्यकता होगी अध्ययन में शामिल।

8. **वह प्रक्रिया क्या है जिसका परीक्षण किया जा रहा है**?

बच्चों में पहले स्थायी दाढ़ में सेन्शन एन और एक्टिवा बायोएक्टिव-रिस्टोरेटिव के लिए सतह की बनावट, सीमांत अखंडता, कैवोसफेस सीमांत मलिनकिरण, शारीरिक समोच्च, द्वितीयक क्षय, रंग मिलान और सकल फ्रैक्चर का मूल्यांकन और तुलना करने के लिए अध्ययन किया जाएगा।

9. अध्ययन के लिए हस्तक्षेप क्या हैं?

स्थायी प्रथम दाढ़ में कक्षा I गुहाओं की बहाली की आवश्यकता वाली दंत प्रक्रियाएं।

10. **भाग लेने के दुष्प्रभाव क्या हैं**?

हालांकि प्रक्रिया के गंभीर साइड इफेक्ट की कोई रिपोर्ट नहीं है, लेकिन प्रतिभागी को कम से कम साइड इफेक्ट हो सकते हैं। अगर प्रक्रिया के दौरान कुछ भी होता है, तो हमारे पास किसी भी आपात स्थिति से निपटने के लिए कुशल कर्मचारी और विशेष उपकरण हैं।

यदि प्रतिभागी को ऑपरेशन के बाद कोई अन्य लक्षण दिखाई देता है, तो अभिभावक को तुरंत डॉक्टर से बात करनी चाहिए।

11. **भाग लेने के संभावित नुकसान और जोखिम क्या हैं**?

इस अध्ययन में भाग लेने के कोई नुकसान नहीं हैं, दवा के न्यूनतम दुष्प्रभाव हो सकते हैं।

12. **भाग लेने के संभावित लाभ क्या हैं**?

प्रतिभागी लाभान्वित होंगे क्योंकि आवश्यक दंत उपचार नए उपलब्ध रिस्टोरेटिव स्मार्ट मटेरियल के साथ किया जाएगा।

13. **यदि नई जानकारी उपलब्ध हो जाए तो क्या होगा**?

यदि अनुसंधान के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है, तो आपको इन के बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ इस पर चर्चा करने के लिए स्वतंत्र हैं, आपका शोधकर्ता आपको बताएगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता आपकी वापसी की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति पत्र पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. **जब शोध अध्ययन रुक जाता है तो क्या होता है?**

प्रतिभागियों को कुछ नहीं होगा।

15. **अगर कुछ गलत हो जाए तो क्या होगा?**

समस्याओं / शिकायत को HOD या IRC द्वारा नियंत्रित किया जाएगा। अगर कुछ गंभीर होता है तो संस्थान समस्याओं का ध्यान रखेगा।

16. **क्या इस अध्ययन में भाग लेने को गोपनीय रखा जाएगा?**

हां इसे गोपनीय रखा जाएगा।

17. **शोध अध्ययन के परिणामों का क्या होगा?**

अध्ययन के परिणामों का उपयोग बाल चिकित्सा दंत रोगियों में स्थायी प्रथम दाढ़ में टूथ कलर्ड रिस्टोरेटिव सामग्री के नैदानिक प्रदर्शन को निर्धारित करने के लिए किया जाएगा। किसी भी रिपोर्ट/प्रकाशन के मामले में आपकी पहचान गोपनीय रखी जाएगी।

18. **अनुसंधान का आयोजन कौन कर रहा है?**

अनुसंधान को समर्पित और पूर्व दंत चिकित्सा, बीबीडीसीओडीएस के विभाग में किया गया है। अनुसंधान स्व-आधारित है। प्रतिभागियों को संस्था द्वारा दिए गए प्रक्रियात्मक शुल्क के लिए भुगतान करना होगा।

19. **क्या अध्ययन के परिणाम अध्ययन के बाद उपलब्ध कराए जाएंगे?**

हाँ

20. **अध्ययन की समीक्षा किसने की?**

संस्था के एचओडी और आईआरसी / आईईसी के सदस्यों ने अध्ययन की समीक्षा और अनुमोदन किया है।

21. **अधिक जानकारी के लिए संपर्क करें**

डा0 सहेली बासू

बाल रोग और निवारक दंत चिकित्सा विभाग

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-227105

मोब- 8777327477

डॉ लक्ष्मी बाला

संस्था की आचार समिति के सदस्य सचिव,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ

bbdcods.iec@gmail.com

अध्ययन के दौरान दस्तावेजों और साझेदारी के लिए आपका समय निकालने के लिए धन्यवाद।

प्रमुख अन्वेषक के हस्ताक्षर.....

नाम .....

दिनांक.....

ANNEXURE-V

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

CHILD INFORMATION DOCUMENT

Study title: ― A comparative evaluation of clinical performance of tooth-coloured restorative materials in permanent molars

Introduction

To evaluate and compare the surface texture, marginal integrity, cavosurface marginal discoloration, anatomic contour, secondary caries, colour match and gross fracture for Cention N and ACTIVA BioACTIVE-RESTORATIVE in first permanent molars in children.

We invite you to participate in this study.

What will you have to do?

To participate in this research study, you will be examined by pediatric dentist and if found to fulfill pre-specified criteria, you will be eligible to be enrolled in this research study.

Since you are in the age group between 7 and 11 years old, we ask your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

Risks and discomforts

There is no foreseen significant risk / hazard to your health, if you wish to participate in the study.

Benefits

Dental caries is a highly prevalent disease, which remains a major public health problem.

Thus, preservation of permanent teeth is important for the development of occlusion, maintenance of arch length, optimum function of chewing and speech and preservation of healthy oral environment.Dental caries is a highly prevalent disease, which remains a major public health problem. Thus, preservation of permanent teeth is important for the development of occlusion, maintenance of arch length, optimum function of chewing and speech and preservation of healthy oral environment.

Confidentiality

Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study. Information about you will be collected and stored in files with an assigned number, and not directly with your name. All documents related to the study will only be accessed by the study investigator, sponsor, the Ethics Committee and the Regulatory authority.

Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent / guardian can take away your authorization to collect process and disclose data about you at any time.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. You may stop participating in the research at any time you wish. The study investigator may decide to withdraw you from the study if he/she considers it is in your best interest.

You will be informed of important new findings developed during the course of the study so you will be able to consider your participation in the study in light of new information.

Parents responsibilities

It is the responsibility of your parent / guardian to provide all the necessary information as asked by the researcher. We expect your co-operation throughout the study.

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय)

बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

बच्चों के लिए सूचना पत्र

अध्ययन का शीर्षकः -

स्थायी दाढ़ों में टूथ-कलर्ड रिस्टोरेटिव सामग्रियों के नैदानिक प्रदर्शन का तुलनात्मक मूल्यांकन

परिचय

सतह की बनावट, सीमांत अखंडता, कैवोसफेस सीमांत मलिनकिरण, शारीरिक समोच्च, द्वितीयक क्षरण, रंग मिलान और बच्चों में पहले स्थायी दाढ़ में सेंशन एन और एक्टिवा बायोएक्टिव-रिस्टोरेटिव के लिए सकल फ्रैक्चर का मूल्यांकन और तुलना करना।
हम आपको इस अध्ययन में भाग लेने के लिए आमंत्रित करते हैं।

आपको क्या करना होगा?

इस शोध अध्ययन में भाग लेने के लिए, बाल रोग विशेषज्ञ द्वारा आपकी जांच की जाएगी और यदि आप पूर्व-निर्धारित मानदंडों को पूरा करते पाए जाते हैं, तो आप इस शोध अध्ययन में नामांकित होने के पात्र होंगे।

चूँकि आपकी आयु 7 से 11 वर्ष के बीच है, हम आपके साथ जाने वाले माता-पिता/अभिभावक से भी इसी तरह के फॉर्म पर हस्ताक्षर करने के लिए कहते हैं, जिसे पेरेंट इनफॉर्म्ड कंसेंट फॉर्म कहा जाता है।

लाभ

दंत क्षय एक अत्यधिक प्रचलित बीमारी है, जो एक प्रमुख सार्वजनिक स्वास्थ्य समस्या बनी हुई है। इस प्रकार, रोड़ा के विकास, मेहराब की लंबाई के रखरखाव, चबाने और भाषण के इष्टतम कार्य और स्वस्थ मौखिक वातावरण के संरक्षण के लिए स्थायी दांतों का संरक्षण महत्वपूर्ण है। दंत क्षय एक अत्यधिक प्रचलित बीमारी है, जो एक प्रमुख सार्वजनिक स्वास्थ्य समस्या बनी हुई है। इस प्रकार, रोड़ा के विकास, मेहराब की लंबाई के रखरखाव, चबाने और भाषण के इष्टतम कार्य और स्वस्थ मौखिक वातावरण के संरक्षण के लिए स्थायी दांतों का संरक्षण महत्वपूर्ण है।

गोपनीयता

आपके मौजूदा मेडिकल रिकॉर्ड तक पहुंचा जा सकता है; अध्ययन करने के उद्देश्य से अध्ययन जांचकर्ताओं द्वारा आपके बारे में व्यक्तिगत स्वास्थ्य जानकारी एकत्र और संसाधित की जा सकती है। आपके बारे में जानकारी एकत्र की जाएगी और निर्दिष्ट संख्या के साथ फाइलों में संग्रहीत की जाएगी, न कि सीधे आपके नाम के साथ। अध्ययन से संबंधित सभी दस्तावेजों तक केवल अध्ययन अन्वेषक, प्रायोजक, आचार समिति और नियामक प्राधिकरण की पहुंच होगी।

आपके माता-पिता / अभिभावक के पास किसी भी समय अध्ययन चिकित्सक के पास आपकी व्यक्तिगत जानकारी तक पहुँचने का अधिकार होगा और इस व्यक्तिगत जानकारी को सही करने का अधिकार होगा। आपके माता-पिता / अभिभावक किसी भी समय प्रक्रिया एकत्र करने और आपके बारे में डेटा प्रकट करने के लिए आपका प्राधिकरण वापस ले सकते हैं।

माता-पिता की जिम्मेदारियां

यह आपके माता-पिता/अभिभावक की जिम्मेदारी है कि वे शोधकर्ता द्वारा मांगी गई सभी आवश्यक जानकारी प्रदान करें। हम पूरे अध्ययन में आपके सहयोग की अपेक्षा करते हैं।

ANNEXURE-VI

Modified United States Public Health Service (USPHS) Ryge Criteria for Direct Clinical Evaluation of Restoration

COLOR MATCH

Alpha (A) *Visual inspection*
The restoration appears to match the shade and translucency of adjacent tooth tissues.

Bravo (B) *Visual inspection*
The restoration does not match the shade and translucency of adjacent tooth tissues, but the mismatch is within the normal range of tooth shades. (Within normal range: Similar to silicate cement restorations for which the dentist did not quite succeed in matching tooth color by his choice among available silicate cement shades.)

Charlie (C) *Visual inspection*
The restoration does not match the shade and translucency of the adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency.

CAVOSURFACE MARGINAL DISCOLORATION

Alpha (A) *Visual inspection*
There is no visual evidence of marginal discoloration different from the color of the restorative material and from the color of the adjacent tooth structure.

Bravo (B) *Visual inspection*
There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, but the discoloration has not penetrated along the restoration in a pulpal direction.

Charlie (C) *Visual inspection*
There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has penetrated along the restoration in a pulpal direction.

SECONDARY CARIES

Alpha (A) *Visual inspection*
The restoration is a continuation of existing anatomic form adjacent to the restoration.

Bravo (B) *Visual inspection*
There is visual evidence of dark keep discoloration adjacent to the restoration (but not directly associated with cavosurface margins).

ANATOMIC CONTOUR

Alpha (A) *Visual inspection and explorer*
The restoration is a continuation of existing anatomic form or is slightly flattened. It may be overcontoured. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing cavosurface line angles at the same time.

Bravo (B) *Visual inspection and explorer*
A surface concavity is evident. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing cavosurface line angles at the same time, but the dentin or base is not exposed.

Charlie (C) *Visual inspection and explorer*
There is a loss of restorative substance such that a surface concavity is evident and the base and/or dentin is exposed.

MARGINAL INTEGRITY

Alpha (A) *Visual inspection and explorer*
The explorer does not catch when drawn across the surface of the restoration toward the tooth, or, if the explorer does not catch, there is no visible crevice along the periphery of the restoration.

Bravo (B) *Visual inspection and explorer*
The explorer catches and there is visible evidence of a crevice, which the explorer penetrates, indicating that the edge of the restoration does not adapt closely to the tooth structure. The dentin and/or the base is not exposed, and the restoration is not mobile.

Charlie (C) *Explorer*
The explorer penetrates crevice defect extended to the dento-enamel junction.

SURFACE TEXTURE

Alpha (A) *Explorer*
Surface texture similar to polished enamel as determined by means of a sharp explorer.

Bravo (B) *Explorer*
Surface texture gritty or similar to a surface subjects to a white stone or similar to a composite containing supramicron-sized particles.

Charlie (C) *Explorer*
Surface pitting is sufficiently coarse to inhibit the continuous movement of an explorer across the surface.

GROSS FRACTURE

Alpha (A)
Restoration is intact and fully retained.

Bravo (B)
Restoration is partially retained with some portion of the restoration still intact.

Charlie (C)
Restoration is completely missing.

PLAGIARISM REPORT

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