

**“TO ASSESS AND COMPARE THE CLINICAL
PERFORMANCE OF TOOH JEWEL LUTED WITH THREE
COMMERCIALY AVAILABLE FLOWABLE COMPOSITES IN
YOUNG ADULTS-A RANDOMISED CONTROLLED TRIAL.”**

*Dissertation submitted to
Maharashtra University of Health Sciences, Nashik
in the Partial Fulfillment of Regulations
for the award of the Degree of*

**MDS
IN
CONSERVATIVE DENTISTRY AND ENDODONTICS**

BRANCH IV

2020

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LIST OF ABBREVIATIONS



| SR. NO | ABBREVIATIONS | FULL FORM |
|--------|---------------|---|
| 01. | WHO | World Health Organisation |
| 02. | BC | Before Christ |
| 03. | MPa | Mega Pascal |
| 04. | USPHS | United States Public Health Service |
| 05. | IEC | Institutional Ethics Committee |
| 06. | CTRI | Clinical Trials Registry India |
| 07. | OPD | Out Patient Department |
| 08. | LED | Light Emitting Diode |
| 09. | SPSS | Statistical Package for the Social Sciences |
| 10. | min | Minutes |
| 11. | RCT | Randomised Controlled Trial |
| 12. | SD | Standard Deviation |
| 13. | S | Significant |
| 14. | NS | Not Significant |
| 15. | HS | Highly Significant |
| 16. | n | Number of specimens |
| 17. | p-value | Probability of obtaining a test statistic at least as extreme as the one that was actually observed |
| 18. | Max. | Maximum |
| 19. | Min. | Minimum |
| 20. | No. | Number |
| 21. | CI | Confidence Interval |
| 22. | UDMA | Urethane Dimethacrylate |
| 23. | Bis-GMA | Bisphenol A-Glycidyl Methacrylate |

INTRODUCTION

“Somewhere, something incredible is waiting to be discovered.”

The need for beauty has existed since time immemorial. The idea of perfect appearance has a strong impact on the behaviour and thinking of the beauty conscious society. This has led to an increased awareness of esthetic treatments and restorations.

Esthetic comes from the Greek word “*aistheticos*” meaning pertaining to sense perception. **PK Vallittu et al. (1996)** revealed that esthetic perception is different for different group of people. It entails application of advanced technology, superior skills and clinical expertise.¹

According to WHO, oral health is not only the absence of oral disease and dysfunction but it includes its influence on the subject’s social life and dentofacial self confidence.²

The dental appearance is an integral component of facial beauty. Esthetic dentistry combines beauty and dental function with the values and individual needs of every patient.

One of the major aims of esthetic dentistry is to enhance the smile of the patient by esthetic rehabilitation or addition of accessories. The latest esthetic trends include jewelled crowns, oral piercings, tooth rings, dental grills, grill jewellery, dazzlers, twinkles, veneer jewellery, tongue studs, lip studs, lip rings and cheek studs.³

One such important esthetic procedure is the *tooth jewel*. Tooth jewel was introduced a decade back by the skillful and artistic craftsmans of the Maya.⁴ In the 9th century, they embellished the teeth with jade and turquoise.⁵ Also, according to **McGeary et al.**, native Americans added jewel to their teeth as far back as 2500 years ago.⁶ Earlier tooth jewellery was known as a part of the religious rituals and traditions, but today it is concerned with the cosmetic function.³

Tooth jewel is an esthetic dental procedure involving the luting of a crystal glass on the surface of the tooth.⁷ The crystal is surface treated for dental application and is mounted on a thin foil of aluminium to ensure mechanical bonding.⁸

Bachani et al. (2014) mentioned that tooth jewellery is a non invasive procedure as it does not involve tooth preparation, so there is no loss of tooth structure.⁹ **Patil et al. (2010)** stated that there is no pain, infection, and damage to tooth.¹⁰ **Kim Hee-Jin et al. (2012)** described the management of white spot lesions by using tooth jewellery and highlighted patients' preference for tooth jewellery as an esthetic concern.¹¹

The procedure involves luting the jewel on the tooth surface with the help of a luting agent. ‘Luting’ is derived from a Latin word *Lutum*-meaning mud. The function of a luting agent is to attach the restoration to the tooth surface through mechanical, micro-mechanical or chemical bonding.¹²

The selection of an appropriate luting agent influences the long-term clinical success and longevity of restorations. Hence, proper selection is based on knowledge of physical and biological properties of both restorative materials and luting agents.¹³

Luting of a tooth jewel is similar to the bonding of an orthodontic bracket. **Pus et al. (1980)** mentioned that during bonding of an orthodontic bracket, the bond strength should be sufficient to withstand the forces of mastication and stresses. Thus, the composite technique was widely adopted in contemporary orthodontic practice.¹⁴

Recently, flowable composites have been applied for orthodontic use by many clinicians. **Ryou et al. (2007)** concluded in their study that flowable composites can be effectively used in orthodontic bracket bonding. Unlike orthodontic bonding systems, flowable composites can be applied to acid-etched enamel without the use of intermediate bonding resins because of their low filler loading and improved flowability. By reducing the number of steps during bonding, clinicians save time and reduce potential errors related to contamination during the bonding procedure.^{15, 37}

Loguercio et al. (2007) evaluated and compared the clinical performance of a microfilled composite resin, hybrid composite resin and a nanofilled composite resin and concluded that the nanofilled composites showed the best surface appearance after 12 months.¹⁶

These were developed using nanotechnology keeping in mind the elasticity, adaptation, favorable handling characteristics, minimized polymerization shrinkage. This enhanced the mechanical and physical properties of flowable composites and enabled their usage in minimally invasive esthetic restorations.

Meerbeek et al. (1998) stated that incomplete marginal sealing clinically results in post-placement sensitivity, marginal staining and, eventually, recurrent caries, which are still the most common symptoms associated with clinical failure of adhesive restorations.²⁹ Hence, these properties need to be researched extensively for a better clinical performance of flowable composites. It is clinically relevant to study these materials when used for esthetic procedures like cementation of tooth jewel.

There is scarcity of data regarding clinical performance of tooth jewel when luted with these flowable composites. Hence the aim of this study is to assess the clinical performance of the tooth jewel when luted with flowable composites.

The null hypothesis was that there is no difference in the clinical performance of tooth jewel luted with three commercially available flowable composites - G-aenial Universal Flo, Filtek Supreme Flow Plus, Tetric EvoFlow.

AIM & OBJECTIVES

AIM

To evaluate three flowable composites based on the marginal discoloration and marginal integrity and to observe the clinical performance of tooth jewel after it's cementation.

OBJECTIVES

- 1) To evaluate and compare the marginal discoloration of G-aenial Universal Flo, Filtek Supreme Flow Plus, Tetric EvoFlow.
- 2) To evaluate and compare the marginal integrity of G-aenial Universal Flo, Filtek Supreme Flow Plus, Tetric EvoFlow.
- 3) To observe the longevity of the tooth jewel cemented with G-aenial Universal Flo, Filtek Supreme Flow Plus, Tetric EvoFlow.

REVIEW OF LITERATURE

“Studying the past is a pre – requisite to define the future, because, in history, lies the secret of innovation.”

Dentistry was portrayed beautifully in the epic of Mahabharata where Lord Krishna, in order to test the benevolence of dying Karna in the battle field of Kurukshetra, asked for gold in donation & Karan proved his worth by donating his gold filled tooth. This part of the epic indicates the existence of dentistry even around 2500 BC, wherein defective teeth were restored with *gold*.¹⁷

Reynolds et al. (1975) explained the contrast between orthodontic and restorative bonding. He stated that the problem of adhesion for the orthodontist is considerably less than that faced in conservative dentistry. Bonding to enamel, rather than to dentin, is easier to achieve because of the lower water and organic content of

the enamel. Acid pretreatment of the enamel surface does not produce pulpal irritation. Accurate colour match, although desirable, is not essential; and the bulk volume of adhesive is relatively small. There is little problem with abrasion resistance, although the possibility of shear forces is increased.

The marked improvement in bond strengths, found after acid pretreatment of the enamel surface without long term deleterious effects, has been well documented.

But mechanical retention is necessary and is normally provided by perforated backings or by the use of **stainless steel mesh gauze**, both of which reduce the surface area of attachment and weaken the bond.

The pretreatment of enamel with phosphoric acid greatly improves adhesion without long term deleterious effects on the enamel surface. This will probably be an essential part of any direct bonding system based on the adhesives at present available.¹⁸

Asmussen et al. (1986) concluded that poor oral hygiene increases the susceptibility to staining of restorative resins, and that this increase may be explained by the plasticizing effect of plaque-produced organic acids.¹⁹

Pearson et al. (1989) evaluated the water sorption and solubility of three hybrid and one microfine composite and concluded that these properties are dependent on the resin system used and the generic type of composite. These have long term clinical significance as it directly affects the durability of the restoration.²⁰

Kemp-Scholte et al. (1990) stated that the use of composite restoratives with low viscosity provides for better marginal adaptation. This can be partly attributed to better wetting capacity of the restorative to the cavity walls. However, apart from better marginal adaptation, increased wetting should also result in higher bond strength.²¹

Nakabayashi et al. (1992) explained the fourth generation bonding agents. An acidic conditioner (typically 32-40 percent phosphoric acid) is applied to both enamel and dentin. In addition to removing the smear layer, the etchant demineralizes the superficial surface of inter- tubular dentin, exposing a porous network of collagen fibrils. Etching also dissolves peritubular dentin at the orifice of the dentinal tubules, leaving the tubule orifices somewhat funnel- shaped. Next, a primer to promote wetting between the hydrophilic demineralized dentin surface and the hydrophobic adhesive resin to be applied in the next step. The primer contains amphiphilic monomers, which contain hydrophilic and hydrophobic groups at opposite ends of their molecules. The monomers usually are dissolved in an organic solvent such as acetone or ethanol, which serves to displace moisture from the conditioned dentin surface. This action allows intermingling of the monomers with the collagen network and formation of resin tags in the demineralized dentin surface. In some systems, the primer component is light-activated, which results in a layer of resin-reinforced dentin called “the hybrid layer.” However, in most systems, the hybrid layer develops only after the third step (etching and priming), during which the dentist applies and light-activates the bonding agent.²²

Duke et al. (1994) reported the early one-year results and **Trevino et al. (1996)** the three-year data of a study involving Scotchbond Multi- Purpose (3M). No significant difference between the three-year retention rates of 98 and 100%, respectively, were found for Class-V restorations placed with or without rubber dam isolation. It was concluded that this specific adhesive appeared less sensitive to moisture contamination than earlier systems. A 4% restoration loss at one year was recorded for Scotchbond Multi-Purpose (3M) by **Platt et al. (1996)** deviating from these results are the substantially worse results reported by **Tyas et al. (1995)** for

Scotchbond Multi- Purpose (3M), who recorded a loss rate of 27% at two years.²³⁻²⁶

Swift et al. (1995) mentioned that the acid etch technique for bonding composite resins to enamel has revolutionized the practice of restorative dentistry. The ability of clinicians to bond restorative materials to enamel has fundamentally changed such diverse areas as cavity preparation, caries prevention and esthetic treatment options. He explained that shear bond strengths of composite resin to phosphoric acid etched enamel are typically in range of 20 MPa which routinely provide successful retention of resins for orthodontic brackets.²⁷

Pashley et al. (1997) stated that successful bonding of resin to enamel has been routine and predictable because enamel is essentially inorganic and dry, and it presents a relatively homogeneous substrate to bond. Dentin is different. It is inherently wet because of outward flow of fluid through the dentinal tubules. It contains far more organic material and fluid than does enamel, and, by volume, is less than one-half inorganic hydroxylapatite. The heterogeneity of dentin can affect the quality and durability of the resin-dentin bond.²⁸

Meerbeek et al. (1998) explained that retention is no longer the main cause of clinical failure, although today's adhesive systems still can not guarantee restoration margins free of marginal discoloration and thus micro-leakage. Rather than retention, the clinical micro-leakage index may better aid in differentiating modern and future adhesive systems on their clinical effectiveness. Unfortunately, retention is a very objective criterion, whereas assessing clinical micro-leakage is much more subjective and requires training and calibration among examiners. Although current adhesive systems should be able to provide sealed margins, the progressive loss of marginal

integrity and successive marginal discoloration by micro-leakage is probably still mainly caused by residual stresses from polymerization shrinkage of the composite restorative material and stresses resulting from thermal dimensional changes.²⁹

Chimello et al. (2002) concluded that the restorations with flowable composite and those with hybrid composite from the same group showed similar results of microleakage for both occlusal and cervical margins.³⁰

McGeary et al. (2002) said that earlier the preparations were made on teeth to accommodate the jewellery. To bond the semiprecious stone to teeth, a paste of natural resin such as plant sap was mixed with other natural chemicals and crushed bones. This was certainly long lasting as the semiprecious stones are still in place after hundreds of years.⁶

Mjor et al. (2002) explained that a poor marginal seal, manifested clinically as poor marginal adaptation and interfacial staining, is the most common reason for failure of adhesive resin-based restorations, and it predisposes the restorations to retention failure and recurrent caries.³¹

Kim et al. (2002) stated that little information exists regarding the filler morphology and loading of composites with respect to their effects on selected mechanical properties and fracture toughness. The objectives of this study were to: (1) classify commercial composites according to filler morphology, (2) evaluate the influence of filler morphology on filler loading, and (3) evaluate the effect of filler morphology and loading on the hardness, flexural strength, flexural modulus, and fracture toughness of contemporary composites. Filler loading was influenced by filler

morphology. Composites containing prepolymerized filler particles had the lowest filler content whereas composites containing round particles had the highest filler content. The mechanical properties of the composites were related to their filler content. Composites with the highest filler by volume exhibited the highest flexural strength, flexural modulus, and hardness. Fracture toughness was also affected by filler volume, but maximum toughness was found at a threshold level of approximately 55% filler volume. The commercial composites tested could be classified by their filler morphology. This property influenced filler loading. Both filler morphology and filler loading influenced flexural strength, flexural modulus, hardness, and fracture toughness.³²

De Munck et al. (2005) stated that hybridization is the primary mechanism of retention for adhesive restorations in the absence of mechanical features such as retention grooves. Among current adhesives, three-step etch-and-rinse adhesives (also referred to as “total-etch adhesives”) are considered the gold standard for durability.³³

Cvar et al. (2005) stated that relevant criteria can be applied consistently during clinical trials to assess the performance of restorations, and the United States Public Health Service (USPHS) evaluation system is the most commonly used direct method for quality control of restorations. This scoring system was designed to provide comprehensive evidence for clinical acceptance rather than in degrees of clinical success.³⁴

Bayne et al. (2005) stated that the USPHS guidelines exist as a “system of clinical evaluation steps” that (a) defines key intraoral events to be measured for any clinical trial, (b) describes or ranks the key clinical stages of change, and (c) provides a

calibration system for evaluators who might be involved in clinical trials using the system.³⁵

Gallo et al. (2006) concluded that although flowable resin composites are advocated for occlusal restorations, it is recommended that they be limited to small and moderate-sized restorations.³⁶

Ryou et al. (2008) tested the bonding characteristics of four flowable composites for orthodontic bracket bonding. Brackets were bonded to acid-etched human enamel using four flowable composites, an orthodontic bonding system, and a restorative composite. The orthodontic bonding system showed a significantly higher value of shear bond strength. The flowable composites also demonstrated a significantly superior flowability, yet inferior flexural strength than orthodontic bonding system and restorative composite. They concluded that flowable composites with no intermediate bonding resin could be conveniently applied for orthodontic bracket bonding.³⁷

Xie et al. (2008) assessed the dentine bond strength and microleakage of three Class V restorations viz. flowable composite, compomer and glass ionomer cement. None of the systems tested in this study completely eliminated microleakage. However, both the flowable composite and compomer provided stronger dentine bond strengths and better margin sealing than the conventional glass ionomer cement. Occlusal forces exerted the same effects on microleakage of the occlusal margin and gingival margin in cervical cavities.³⁸

Vincente et al. (2009) evaluated the effects of thermocycling on microleakage beneath brackets bonded with an orthodontic composite and different flowable materials. The giomer, Beautiful-Flow, demonstrated the best performance after thermocycling, while composite resins and, in particular, the flowables showed a poorer performance.³⁹

Patil et al. (2010) concluded that tooth jewel could be attached to anterior healthy tooth with composite resin cement. They shine brightly and enhance the natural whiteness of enamel. They are bonded to tooth without pain, infection, and damage to tooth.¹⁰

Bebber et al. (2011) determined how filler content and an acidic environment affect the retention of sealants placed on smooth enamel surfaces. Three experimental sealants with identical formulas, with the exception of the amount of filler content (18%, 30%, 50%), were applied according to manufacturers' recommendations. Filler content of resin sealant material affects the retention of sealants on smooth enamel surfaces; exposure to an acid environment has no effect on sealant retention. Within the limits of this study, highly filled resin sealants once saturated have the ability to endure the oral environment and remain on a smooth enamel surface, regardless of the amount of filler content.⁴⁰

Weiner et al. (2012) reported that in the 9th century Mayan culture, teeth were embellished with jade and turquoise, but current trends in dentistry include the addition of gold, jewels or crowns that appear similar to stainless steel crowns, previously considered nonaesthetic.⁵

Kim Hee-Jin et al. (2012) described the management of white spot lesions by using tooth jewellery and highlighted the patients' preference for tooth jewellery as an esthetic concern.¹¹

Poggio et al. (2012) evaluated surface discoloration of three microhybrid and five nanohybrid composite resins and concluded that microhybrid and nanohybrid composite resins had similar *in vitro* surface discoloration when stained with tea.⁴¹

Malekipour et al. (2012) investigated the effects of common drinks consumed by patients on Filtek Z100 in an in-vitro study and concluded that it was susceptible to color change. The colour change was visually perceptible and clinically unacceptable.⁴²

Vazhiyodan et al. (2013) described that tooth jewellery is not a new concept as native Americans also added bling to their teeth as far back as 2500 years ago.⁷

Peter et al. (2013) mentioned that tooth jewellery is believed to enhance appearance and, by doing so, improve the patient's self esteem and self confidence. Tooth jewellery should be advised only in patients with good oral hygiene maintenance. This is because the attachment area of the jewellery to teeth is highly prone for plaque accumulation. The area has to be kept extremely clean as possible. It should not be advised in a patient with high caries index. Tooth jewellery is advised only in patients with good oral hygiene maintenance. This is because the attachment area of the jewellery to teeth is highly prone for plaque accumulation. The area has to be kept extremely clean as possible. It should not be advised in a patient with high caries index.³

Bachani et al. (2014) mentioned that tooth preparation is not involved in tooth jewellery so there is no loss of tooth structure. It is temporary, so it can be removed any time patient desires. The stones are bonded to the labial surfaces of natural teeth without invasive preparation.⁹

Lokhande et al. (2014) conducted a study to evaluate the microleakage when flowable composite is used as a restorative material and a liner and concluded that the microleakage of flowable resin composite as a restorative material is similar to hybrid composite and when used as a liner under hybrid and packable composites have shown a trend towards lesser leakage.⁴³

Bhatia et al. (2015) explained that their flat back is surfaced with a special coating to create a sparkle and shine like a diamond. The crystals have a special coating on the back and their facet cut reflects the light and makes it sparkle like a diamond. Unlike earlier methods which involved drilling and setting the jewel into the tooth, a little bit of dental composite material can attach the crystal onto the teeth and lasts upto year or longer.⁴⁴

Baroudi et al. (2015) mentioned advantages of the flowable resin composites namely (1) high flowability, useful for applying to tooth by means of a small-gage dispenser, especially for those cavities that are not easy to access; (2) ability to form layered structure of minimum thickness to improve or eliminate air inclusion or entrapment; (3) high flexibility, less likely to be displaced in stress concentration areas.⁴⁵

Orlowski et al. (2015) concluded that bulk-fill flowable or sonic-activated flowable composite restorations have better marginal sealing in comparison with bulk-fill paste-like composites.⁴⁶

Keerthi et al. (2015) evaluated the 2-year clinical performance of a flowable nanohybrid resin composite, and packable nanohybrid resin composite in Class I occlusal cavities. They showed a statistically similar clinical performance at 2 years.⁴⁷

Arregui et al. (2016) concluded that the bulk-fill composite showed the highest discoloration and the nanohybrid flowable composite showed the lowest discoloration. They also suggested that water sorption is one factor associated with the ability of composites to discolour.⁴⁸

Bhatia et al. (2016) assessed the knowledge and practice of tooth jewellery among practicing dentists of Tricity, India. The study concluded that dental practitioners had sufficient knowledge about tooth jewellery. Practice of tooth jewellery in the dental clinics was found to be adequate but it was also associated with some complications. To overcome this, it was advised that professional and government bodies should create strategies for enhancing and improving people's knowledge as well as make them aware of the pros and cons while using tooth jewellery which shall further enhance their smile.⁴⁹

Szesz et al. (2017) concluded that similar marginal discoloration and better marginal adaptation was observed for flowable composites when compared with regular resin composites.⁵⁰

Ceci et al. (2017) reported that nanohybrid composites reported the lowest color variations when compared with different esthetic restorative materials.⁵¹

Farrukh et al. (2019) stated that oral jewellery and piercings are highly acceptable by the dental students but the uniqueness of oral jewellery was more recognized by the dentists. Modified oral jewellery has been fairly accepted among all but the preferable type of design varied. A recording of those by the dentist could potentially aid in forensic dental identifications. General dentists should be trained at undergraduate level to be familiar with different types of piercings and modifications. Therefore, an elaborated oral charting system to document oral jewellery and tooth modifications and respective abbreviations were also suggested to grant a useful reason to this fashion.⁵²

MATERIALS & METHOD

“If one cannot describe the process, they don’t know what they’re doing.”

The present study was conducted in the Department of Conservative Dentistry And Endodontics with the objective to assess and compare the clinical performance of tooth jewel when luted with three different flowable composites.

IEC Approval: Approval from the Institutional Ethics Committee was obtained.

Clinical Trials Registry India Number: CTRI/2018/12/016573

Study Participants: Subjects included in the study were selected from the regular pool of patients visiting the OPD of Department of Conservative Dentistry And Endodontics. Seventy five patients willing to participate were selected for the study.

SELECTION CRITERIA:

INCLUSION CRITERIA:

1. Patients belonging to age group of 18-35 years.
2. Self motivated patients who were interested in getting a tooth jewel to enhance their smile.
3. Patients with Low caries index
4. Sound canine.
5. Patient not having a traumatic bite.
6. Patients not having any prosthesis associated with the canine.

EXCLUSION CRITERIA:

1. Patients with high caries index.
2. Patients with poor oral hygiene.
3. Carious canine.
4. Prosthesis with canine.
5. Traumatic bite.
6. Hypoplastic canine.
7. Fluorosis.

SUBJECT WITHDRAWAL CRITERIA:

1. Patients who did not turn up for the recalls.
2. Patients who encountered an accidental fracture of the tooth.
3. Patient who encountered any trauma.

Patient Consent: Patients identified as suitable for the study were asked to give their consent to be involved. A detailed explanation of the purpose of the study was given. It was also explained that the treatment would not generate additional risks or adverse sequelae. Patients were also informed about confidentiality of the data to be collected. Participation was entirely on voluntary basis.

Randomisation:

Sampling Technique: Computer generated numbers. Block Randomisation.

Blinding: Procedure was done by single operator who was blinded for the type of flowable composite used in each participant.

Allocation Concealment: The flowable composite syringes were covered with a white opaque tape.

Armamentarium:

Instruments and Equipments:

- Mouth Mirror(GDC) [PLATE I]
- Straight Probe(GDC) [PLATE I]
- Explorer(GDC) [PLATE I]
- Pair of Tweezers(GDC) [PLATE I]
- Scaler (Satelec P5 Newton Worktop Scaler, Satelec Aceton)
- Cotton Holder(GDC) [PLATE I]
- Waste Receiver(GDC) [PLATE I]
- Zeiss Eyemag Smart Loupes (Carl Zeiss) [PLATE I]
- Rubber Dam Kit (Hygiene Dental dam kit, Coltene) [PLATE I]

- Clamp
- Forcep
- Sheet
- Frame
- Microbrush [PLATE III]
- Three Way Syringe
- LED Light Curing Gun(Bluephase N, Ivoclar Vivadent)[PLATE III]
- Jewel Picker (Kryste) [PLATE III]

Materials:

- 3M ESPE Scotchbond Etchant (3M) [PLATE II]
- 3M ESPE Scotchbond Multi-purpose Primer (3M) [PLATE II]
- 3M ESPE Adper Scotchbond Multipurpose plus Bonding Agent (3M) [PLATE II]
- Nanohybrid Flowable Composites :
 - Group I: Gaenial Unviversal Flo (GC) [PLATE II]
 - Group II: Filtek Supreme Flo (3M) [PLATE II]
 - Group III: Tetric Evoflow (Ivoclar Vivadent) [PLATE II]
- Tooth Jewel Kit (Kryste) [PLATE III]

Procedure:

- Pre procedural photographs were taken. [PLATE IV]
- Site selection: The maxillary Left/Right canine were selected individually based on the esthetic demands.
- The location of the tooth jewel was decided depending upon the position of the lip line and was placed on the mesial incline of the canine.
- The tooth was cleaned with a polishing paste following which it was completely

dried and isolated.

- The tooth was isolated using rubber dam.[PLATE V]
- The site was etched with 3M ESPE Scotchbond Etchant (3M ESPE) for 15 seconds. [PLATE V]
- The surface was rinsed thoroughly with water and dried for 10 seconds. Adper Scotchbond Multipurpose plus Primer (3M ESPE) was applied and dried for 5 seconds. [PLATE V]
- A light-cure bonding agent, Adper Scotchbond Multipurpose plus (3M ESPE) was applied, left for 20 seconds. [PLATE V]
 - It was light-cured for 20 seconds using LED Light Curing Gun (Bluephase N,Ivoclar Vivadent). [PLATE V]
 - The patients were then divided into 3 groups of 25 each depending upon the flowable composite used for bonding the tooth jewel in place.

Distribution of study groups:

All the samples were divided into three groups as under:

| Group no. | Name of group | Name of sub - groups | No. of subjects per group |
|------------------|--------------------------|---------------------------------------|----------------------------------|
| GROUP I | G-aenial Universal Flo | GROUP I A Marginal Discoloration | 25 |
| | | GROUP I B Marginal Integrity | |
| | | Group I C Longevity | |
| GROUP II | Filtek Supreme Flow Plus | GROUP II A Marginal Discoloration | 25 |
| | | GROUP II B Marginal Integrity | |
| | | Group II C Longevity | |
| GROUP III | Tetric EvoFlow | GROUP III A Marginal Discoloration | 25 |
| | | GROUP III B Marginal Integrity | |
| | | Group III C Longevity | |

A small amount of respective nanohybrid flowable composite [Gaenial Unviversal Flo (GC) / Filtek Supreme Flo (3M) / Tetric Evoflow (Ivoclar Vivadent)] was applied to the site. [PLATE VI]

- The Jewel was picked up by a jewel picker (Kryste) and pressed into the centre of composite.
- Slight adjustment of the jewel positioning was done. [PLATE VI]
- Curing of composite was done gingivally, incisally and proximally to ensure complete curing. [PLATE VI]
- Total curing time was approximately 80 seconds.
- Post procedural photographs were taken. [PLATE VII]
- The complete treatment was carried out in a single visit by a single operator.
- Post-operative instructions were given. [PLATE VIII]
- The patients were recalled after 1st month, 3rd month and 6 months for clinical evaluation regarding marginal integrity, discoloration of flowable composites and longevity of tooth jewel.
- For the post – operative evaluation, the margins were assessed based on the Modified United States Public Health Service (USPHS) Ryge Criteria.

MODIFIED UNITED STATES PUBLIC HEALTH SERVICE (USPHS) RYGE CRITERIA.⁵³

MARGINAL DISCOLORATION: It is the ability of the composite to sustain it's original colour.

| | | |
|-------------|-------------------|--|
| 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, but the discoloration has not penetrated along the tooth jewel. |
| Charlie (C) | Visual inspection | There is visual evidence of marginal discoloration that has penetrated along the tooth jewel. |

MARGINAL INTEGRITY: It refers to the marginal fit and marginal adaptation thereby increasing the longevity of the restorative material.

| | | |
|-------------|--------------------------------|--|
| Alpha (A) | Visual inspection and explorer | The explorer does not catch when drawn across the surface, there is no visible crevice along the periphery of the tooth jewel. |
| Bravo (B) | Visual inspection and explorer | The explorer catches and there is visible evidence of a crevice, which the explorer penetrates. |
| Charlie (C) | Explorer | The explorer penetrates crevice defect extended to the tooth jewel. |

LONGEVITY OF TOOTH JEWEL:

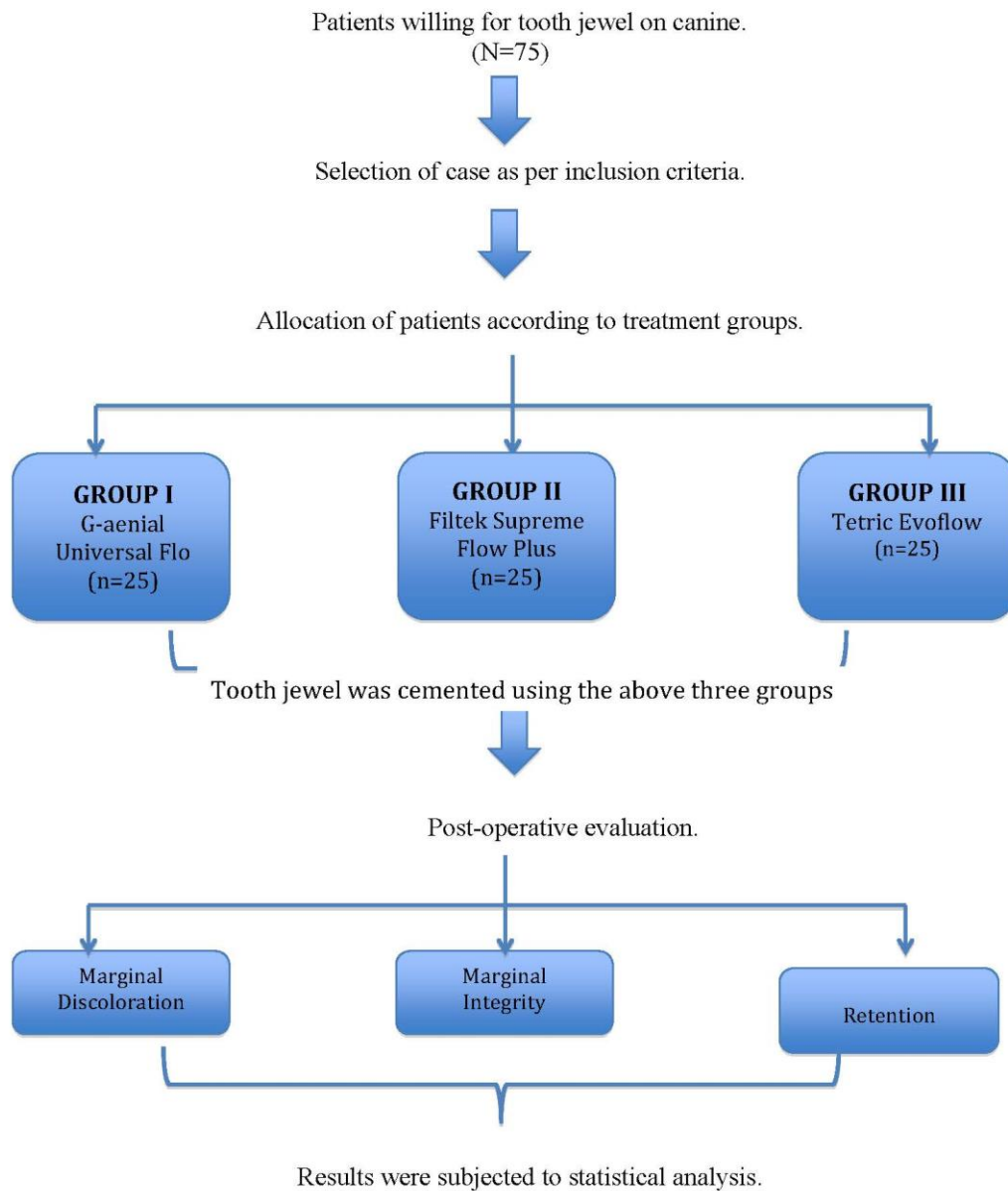
The ability of the composite material to sustain the tooth jewel for a long period of time.

| | |
|---|-----------------------|
| 1 | Intact after 1 month |
| 2 | Intact after 3 months |
| 3 | Intact after 6 months |

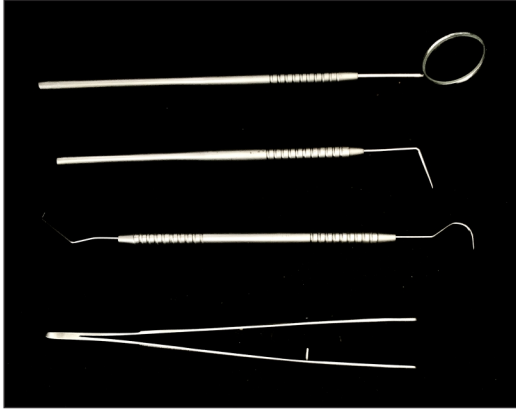
Appropriate data management and analysis procedure:

The data was collected and tabulated using an Excel sheet (Microsoft Office). The data collected was analyzed using the Statistical Package for the Social Sciences statistical software (SPSS version 20.0).

ALGORITHM FOR METHODOLOGY



ARMAMENTARIUM



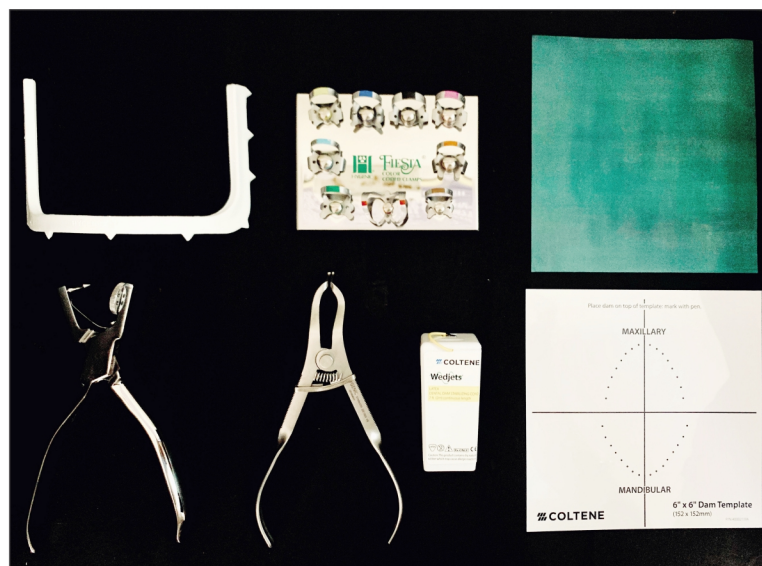
Hand Instruments



Cotton Holder And Waste Receiver



Magnifying Loupes (EyeMag Smart loupes, Carl Zeiss, Germany)



Rubber Dam Kit (Hygiene Dental Dam Kit, Coltene)

MATERIALS



Etchant (3M ESPE, Germany)



Primer (3M ESPE, Germany)



Adhesive (3M ESPE, Germany)



G-aenial Universal Flo (GC, Japan)



Filtek Supreme Flow Plus (3M ESPE, Germany)

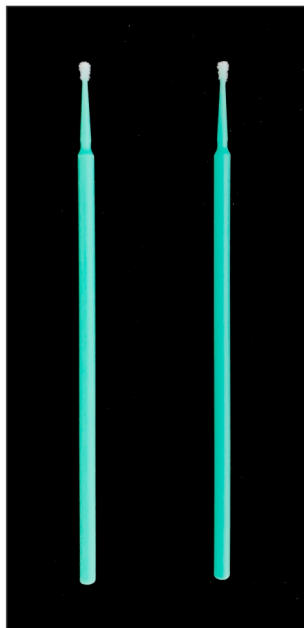


Tetric Evoflow (Ivoclar Vivadent, Liechtenstein)

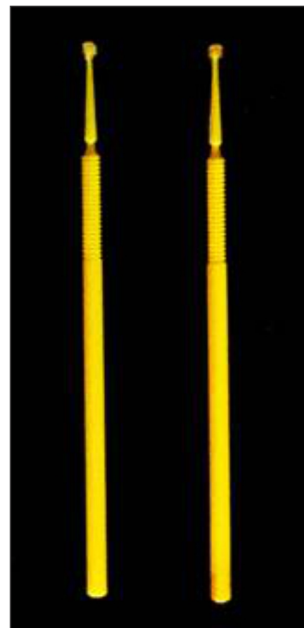
MATERIALS



Tooth Jewel Kit (Kryste,India)



Applicator Tip



Jewel Picker



Light Curing Gun
(Bluephase N,Ivoclar Vivadent,Liechenstein)

METHODOLOGY



Pre operative smile - frontal view



Pre operative smile - lateral view



Pre operative anterior esthetics - frontal view



Pre operative anterior esthetics-
lateral view

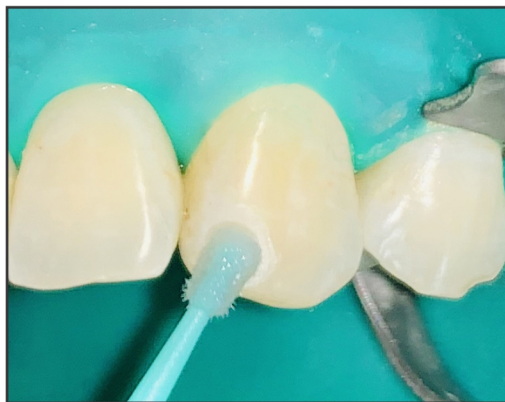


Pre operative anterior esthetics-
lateral view
with contrast

METHODOLOGY



Isolation with Rubber Dam



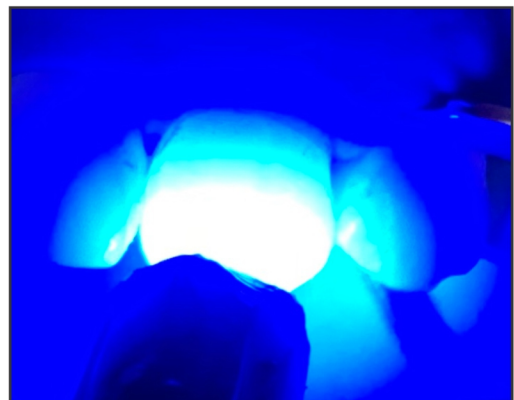
Application of etchant



Application of primer

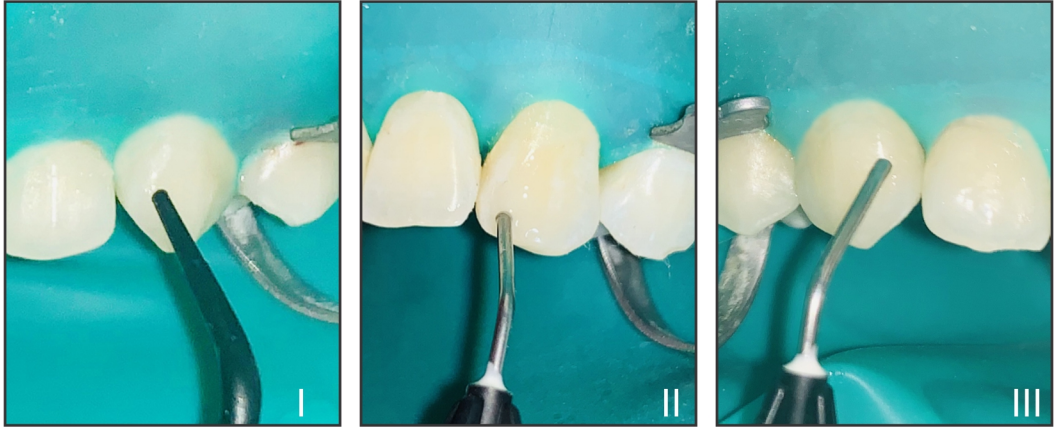


Application of Bonding Agent



Light Curing with LED gun

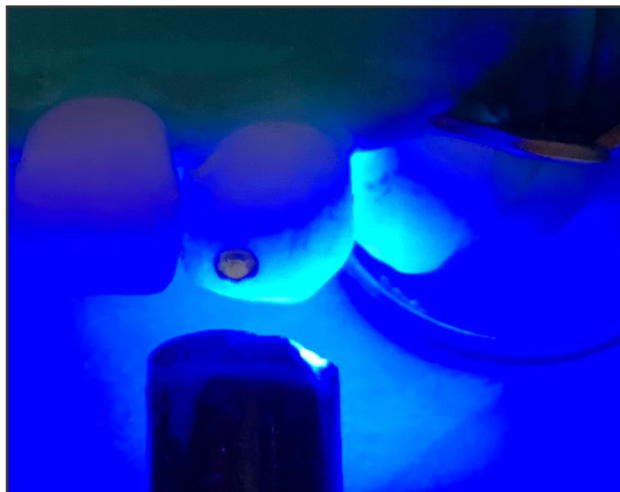
METHODOLOGY



Dispensing the flowable composite (Group I,II,III)



Positioning the tooth jewel



Light Curing with LED gun

METHODOLOGY



Post operative smile - frontal view



Post operative smile - lateral view



Post operative anterior esthetics - frontal view



Post operative anterior esthetics-lateral view

METHODOLOGY



Immediate post operative photograph



Follow up after 6 months

RESULTS

The present in vivo study was carried out to assess and compare the clinical performance of tooth jewel luted with three different commercially available flowable composites. (G-aenial Universal Flo, Filtek Supreme Flow and Tetric Evoflow) through a prospective randomized controlled trial.

Patients identified as suitable for the study were asked to give their consent to be involved.

Three groups were formed in accordance with the three flowable composites:

Group I: G-aenial Universal Flo (n=25)

Group IA: Marginal Discoloration

Group IB: Marginal Integrity

Group IC: Longevity

Group II: Filtek Supreme Flow (n=25)

Group IIA: Marginal Discoloration

Group IIB: Marginal Integrity

Group IIC: Longevity

Group III: Tetric Evoflow (n=25)

Group IIIA: Marginal Discoloration

Group IIIB: Marginal Integrity

Group IIIC: Longevity

STATISTICAL METHODS:

The demographic characteristic like gender was expressed in terms of numbers and percentage. The retention time for the three composites used in the jewel was summarized as mean, standard deviation, median and range. The comparison of median retention time was carried out using *Kruskal-Wallis test* and pair wise comparison was performed using *Mann-Whitney U test* with BH multiple testing correction. The comparison of marginal discoloration and marginal integrity was carried out using *Pearson's Chi-square test* across groups at 1st, 3rd and 6th months independently. The change in the level of marginal discoloration between two consecutive time points was determined using *McNemar's test* for each composite material. On similar lines, the change in the level of marginal integrity was also evaluated between two consecutive

times using *McNemar's test* for each material. The comparison of retention time for each material between gender types was carried out using *Mann-Whitney U test*. The retention time across three composites in each gender category was performed using *Kruskal-Wallis test*. Further the change in the levels of marginal discoloration and integrity were also studied between two consecutive times independently for each gender using *McNemar test*.

All the analyses were performed using SPSS ver 20.0 (IBM Corp, ARMONK USA) and the statistical significance was tested at 5% level.

The formulations and test procedures used in the study are as below:

If x_1, x_2, \dots, x_n are the observations on random variable X, then

A) **Sample mean** for a set of observations is given by

$$\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i$$

B) **Standard deviation** for a set of observations is given by

$$s = \sqrt{\frac{1}{(n-1)} \sum_{i=1}^n (x_i - \bar{x})^2}$$

where x_i = observation on each object

n = number of objects

C) **Median**: It is the middle value of a set of values when arranged in the increasing order of magnitude.

D) **Range** is the difference between maximum and minimum value of the variable.

E) Wilcoxon rank sum test

The test is a non-parametric equivalent of Student's t-test for independent samples, when the assumption of normality is violated. It evaluates the null hypothesis that the two populations are the same against alternative that particular population has larger values than the other. It involves computation of a test statistics based on ranked series. The observations are ranked according to magnitude irrespective of the two groups. The steps involved are as under:

- i) Add the ranks for observations from group 1.
- ii) Since sum of all ranks equal $N(N+1)/2$, the sum of ranks in group 2 is total sum minus the sum of group 1.
- iii) A statistic U is defined as:

$$U_1 = R_1 - \frac{n_1(n_1 + 1)}{2}$$

where n_1 is the size of sample 1 and R_1 is the sum of ranks of sample 1. Equally valid formula for U is

$$U_2 = R_2 - \frac{n_2(n_2 + 1)}{2}$$

The smaller of U_1 and U_2 is for significance testing.

For large sample sizes ($N > 30$), U is approximately normally distributed, and the standardized value is given by

$$z = \frac{U - m_U}{\sigma_U}$$

where

m_U and σ_U are the mean and standard deviation of U . The significance of z can

be obtained from normal probability tables. Here m_U and σ_U are given by:

$$m_U = \frac{n_1 n_2}{2}; \quad \sigma_U = \sqrt{\frac{n_1 n_2 (n_1 + n_2 + 1)}{12}}$$

F) Kruskal-Wallis test

The test is a non-parametric equivalent of one-way analysis of variance for comparing three or more groups. It is used for testing if the samples originate from same or different populations. The procedure for determining significance of difference across groups using the test is as below:

- i) The n_1, n_2, \dots, n_k observations from k samples are combined into a single series of size n and arranged in order of magnitude from smallest to largest. The observations are then replaced by ranks from 1 assigned to smallest observation to n assigned to largest observation. When two or more observations have same value, each observation is given a mean of the ranks for which it is tied.
- ii) The ranks assigned to observations in each of the k groups are added separately to give k rank sums.
- iii) The test statistic is defined as:

$$H = \frac{12}{n(n+1)} \sum_{j=1}^k \frac{R_j^2}{n_j} - 3(n+1)$$

where k is the number of groups; n_j is the number of observation in j^{th} group; n is the total number of samples from all the groups and R_j is the sum of ranks from j^{th} group.

- iv) When there are more than 5 observations in one or more groups, H is

compared with the tabulated value of χ^2 with $k-1$ degrees of freedom.

G) Pearson's Chi-square test

Let X and Y be two variables under study with r and s levels respectively; and the data on $r \times s$ levels be in the form of counts. Let the null hypothesis be that the two variables are independent. That is, knowing the levels of X does not help in predicting the levels of Y ; against the alternative hypothesis that the two factors are not independent. That is, knowing the level of X can help in predicting levels of Y . To decide about the acceptance of hypothesis, the Chi-square test statistic is used which is defined as:

$$\chi^2 = \sum_{i=1}^r \sum_{j=1}^s \frac{(O_{ij} - E_{ij})^2}{E_{ij}}$$

where O_{ij} is the observed frequency count for i^{th} level of variable X and j^{th} level of variable Y . E_{ij} is the expected frequency count for same cell. The expected count is given by

$$E_{ij} = \frac{n_i \times n_j}{n}$$

where n_i and n_j are the total counts for i^{th} level of variable X and j^{th} level of variable Y ; and n is the total count. The calculated Chi-square value is compared with the tabulated one for $(r-1) \times (s-1)$ degrees of freedom. If the corresponding p -value is smaller than the pre-decided significance level, say 0.05, then we reject the null hypothesis and accept the alternative one. If the p -value is more than 0.05, then we accept null hypothesis.

H) McNemar test

The test is a non-parametric test for paired data on nominal scale, and typically used for finding the changes in the proportions in the paired data with time on the same set of observations. The main assumptions for applying the test are:

- a) One nominal variable with two categories and one independent variable connecting two groups.
- b) The two groups in the dependent variables must be mutually exclusive.

The data is arranged in the 2×2 contingency table with cell frequencies equal to number of pairs. If the structure of the table is

| | Condition B | |
|-------------|-------------|---|
| Condition A | a | b |
| | c | d |

Then the discordant cells b and c are used for calculating the test statistic.

$$\chi^2 = \frac{(b-c)^2}{b+c}$$

The probability value is determined for observed chi-square value for 1 degree of freedom and compared with theoretical value to determine the statistical significance of change.

OVERALL RESULTS:

Table 1 provides the mean age of subjects in three composite groups. The mean age of patient in G-aenial Universal Flo group was 21.68 ± 2.75 years, while the mean age in group Filtek Supreme Flow Plus groups was 21.52 ± 2.96 years and the mean age was 22.68 ± 3.65 years in the group Tetric EvoFlow. The difference in mean age across three composites was statistically insignificant with p-value of 0.3728. A bar chart representation of the distribution of patients is given in **Figure 1**.

Table 2 provides the gender wise distribution of subjects in three composite groups. In G-aenial Universal Flo group, there were 18 (72%) females while 7 (28%) males. In the Filtek Supreme Flow Plus group, there were 17 (68%) females and 8 (32%) males, while in Tetric EvoFlow group, there were 19 (76%) females and 6 (24%) females. The gender distribution was insignificantly different across groups as indicated by a p-value of 0.82 using Chi-square test. A bar chart representation of the distribution of patients as per gender is given in **Figure 2**.

Table 3 provides the agreement between the investigators for marginal discoloration using Cohen's Kappa coefficient. The kappa coefficient was obtained for the grading provided on marginal discoloration by two observers at different time points. The coefficient ranged between 0.965 to 0.993 indicating excellent agreement between the two observers.

Table 4 provides the agreement between the investigators for marginal integrity using Cohen's Kappa coefficient. The kappa coefficient was obtained for the grading provided on marginal integrity by two observers at different time points. The coefficient ranged between 0.960 to 1.000 indicating excellent agreement between the two observers.

Table 5 provides the comparison of retention of tooth jewel using three different composites. The mean retention time for G-aenial Universal Flo was maximum i.e. 6 months (SD: 0), followed by Filtek Supreme Flow Plus with a mean time of 4.12 months (SD: 2.26 months), and then Tetric EvoFlow with a mean of 3.92 months (SD: 2.31 months). The difference in the means was statistically significant with p-value < 0.0001 using Kruskal-Wallis test. Further, the paired analysis revealed that the difference of mean retention between composite G-aenial Universal Flo and each of the other two composites were statistically significant ($p < 0.05$), while the difference between Filtek Supreme Flow Plus and Tetric EvoFlow was statistically insignificant. A bar chart representation with error bar showing mean retention time in each study group is given in **Figure 3**.

Table 6 provides the comparison of marginal discoloration of samples across three different composite groups referring to USPHS RYGE criteria at one month. It is evident from the table that for marginal discoloration, nearly for all samples, the level was Alpha irrespective of the composite, and thereby the attribute i.e. marginal discoloration was insignificantly different across three groups ($p=0.3629$). A bar chart representing the number of samples according to grades of marginal discoloration in each study group at 1st month is given in **Figure 4**.

Table 7 provides the comparison of marginal integrity of samples across three different composite groups referring to USPHS RYGE criteria at one month. The marginal integrity was at Alpha level for almost all the samples in each group, resulting into statistically insignificant difference across composite groups ($p=0.3629$). A bar chart representing the number of samples according to grades of marginal discoloration in each study group at 1st month is given in **Figure 5**.

Table 8 provides the comparison of marginal discoloration of samples across three different composite groups referring to USPHS RYGE criteria at three months. It is evident from the table that marginal discoloration in G-aenial Universal flo composite group for all samples was at level Alpha, while in Filtek Supreme Flow Plus group, 15 (60%) had level Alpha, while 3 (12%) had Bravo. There were 7 (28%) cases with loss of retention in this composite group. In the third group, 18 (72%) samples had level Alpha, and there were 7 (28%) cases of loss of retention. The proportion of samples with Alpha level across three composite groups was statistically significant with p-value of 0.0231. A bar chart representing the number of samples according to grades of marginal discoloration in each study group at 3rd month is given in **Figure 6**.

Table 9 provides the comparison of marginal integrity of samples across three different composite groups referring to USPHS RYGE criteria at three months. It is evident from the tables that in G-aenial Universal flo composite group, all 25 (100%) samples had level Alpha, while in Filtek Supreme Flow Plus group, 17 (68%) samples had level Alpha, 1 (4%) and 7 (28%) had loss of retention. In Tetric EvoFlow group, 18 (72%) had level Alpha, while 7 (28%) had loss of retention. The difference in the proportion of samples with Alpha level of marginal integrity across three groups was statistically insignificant ($p=0.2969$). A bar chart representing the number of samples according to grades of marginal integrity in each study group at 3rd month is given in **Figure 7**.

Table 10 provides the comparison of marginal discoloration of samples across three different composite groups referring to USPHS RYGE criteria at six months. It is evident from the table that marginal discoloration in G-aenial Universal flo composite group for 23 (92%) samples was at level Alpha and 2 (8%) were at Bravo, while in Filtek Supreme Flow Plus group, 12 (48%) had level Alpha, while 2 (8%) had Bravo.

There were 11 (44%) cases with loss of retention in this composite group. In the third group, 12 (48%) samples had level Alpha and 2 (8%) had Bravo. There were 11 (44%) cases of loss of retention. The proportion of samples with Alpha level across three composite groups was statistically insignificant ($p=0.7711$). A bar chart representing the number of samples according to grades of marginal discoloration in each study group at 6th month is given in **Figure 8**.

Table 11 provides the comparison of marginal integrity of samples across three different composite groups referring to USPHS RYGE criteria at six months. It is evident from the table that for marginal integrity, in G-aenial Universal flo composite group, 23 (92%) samples had level Alpha and 2 (8%) had Bravo, while in Filtek Supreme Flow Plus group, 12 (48%) samples had level Alpha, 2 (8%) had Bravo, and 11 (44%) had loss of retention. In Tetric EvoFlow group, 13 (52%) had level Alpha and 1(4%) had Bravo, while 11 (44%) had loss of retention. The difference in the proportion of samples with Alpha level of marginal integrity across three groups was statistically insignificant ($p=0.7665$). A bar chart representing the number of samples according to grades of marginal integrity in each study group at 6th month is given in

DISCUSSION

“When it is all finished, you will discover it was never random...”

The dental appearance of a person plays a critical role in their self-image, self-esteem; oral and psychological health. Owing to the current demands, dentistry has witnessed a paradigm shift from restorations and pain relief to beautification and esthetic enhancements. Dentists are witnessing demanding patients who desire perfectly aligned teeth and sometimes auxiliary treatments like tooth jewellery.³

Earlier tooth jewellery was used as a part of the religious rituals and traditions, but today it is more of an esthetic demand. There have been case reports mentioning use of tooth jewellery for treatment of white spot lesions.¹¹ **Farrukh et al. (2019)** have also mentioned its importance in forensic dentistry.⁵²

Tooth jewellery is a cosmetic dental procedure which involves attaching a diamond, *Swarovski* crystal or a stone to the tooth surface in order to enhance esthetics. Unlike earlier methods, which involved drilling and setting the jewel into the tooth, dental composites can attach the crystal onto the teeth for a durable result.⁸

Over the past 140 years, dentistry has matured from the original tenets of G.V. Black by moving from "extension for prevention" to evidence based minimal intervention dentistry.⁵⁴

Composite resins are one of the most suitable dental materials for minimally invasive treatments due to their aesthetics, easy handling, biocompatibility and primarily adhesive properties.

Among the available composites, the clinical use of flowable composites has been increasing because of easy operability and good cavity wall adaptation leading to porosity free restorations.⁵⁵ Previously used flowable composites contained less filler, and were mainly used in non-stress bearing areas.^{56,57}

Recently, nanotechnology, as well as filler surface preparation technology, have greatly improved the properties of flowable composites, which has led to development of a material with good strength, abrasion resistance, and excellent sculptability, and expanded clinical application to better receive occlusal and flexural stresses.⁵⁸⁻⁶⁰

However, easy discoloration during their long-term clinical performance in the oral cavity and poor marginal sealing are the main disadvantages of their use and directly related to their composition and mechanical properties.

Khokar et al. (1991) also stated that the type of resin matrix used in the materials probably plays an important role in stain susceptibility.⁶¹

Despite their large use, the data available in literature regarding the use of flowable composites does not provide a conclusive evidence and none of these modern systems appear to be able to guarantee hermetically sealed restorations with margins free of discoloration for a long time.

There is lack of literature related to the clinical performance of a tooth jewel with regards to its longevity. The circumferential margins of the luting material i.e. flowable composites have yet another clinical relevance as they form the blueprint giving us a direct insight into the durability of the jewel in the oral cavity.

Hence, the aim of this study was to assess and evaluate the marginal integrity, marginal discoloration and longevity of tooth jewel when luted with different flowable composites.

Approval from the Institutional Ethics Committee was obtained. The study was enrolled under Clinical Trials Registry- India (CTRI) and the registration number assigned was: **CTRI/2018/12/016573**.

The strength of the randomized trial is based on aspects of design which eliminates various types of bias.

Efird (2011) stated that block randomization is a preferred method to ensure equal size of treatment groups and uniform distribution.⁶² Hence, block randomization was carried out to ensure randomization of samples. **Karanicolas et al. (2010)**

mentioned that although randomization reduces the potential for selection bias, it does not prevent subsequent biased assessment of outcomes.⁶³ Blinding reduces performance and ascertainment bias. Hence, it was a double blinded trial where the operator and investigator were blinded for the type of flowable composite used. **Altman et al. (2001)** stated that the allocation concealment eliminates selection bias during the process of recruitment and randomization.⁶⁴ Hence, the flowable composite syringes used in the present study were concealed with sequentially labelled white opaque tapes.

A double-blinded randomized clinical trial was designed in which seventy five subjects were recruited from the regular pool of patients visiting the Department of Conservative Dentistry and Endodontics. For sample size estimation, a study by **Vichi et al.**⁶⁵ was referred, where after six months, out of 40 restorations, 37 (92.5%) scored ‘alfa’ for marginal discoloration and marginal integrity. However, in order to have 85% success i.e. alfa score on this parameter, and 15% margin of error, the estimated number of samples was decided to be 21 that would provide the true estimate with 95% confidence and 80% power of test, for a two sided test.

Thus, a minimum of 21 samples per group was considered for the study. The formulation used in the study was:

$$n = \left[\frac{z_{1-\alpha/2} \sqrt{p_0(1-p_0)} + z_{1-\beta} \sqrt{p_1(1-p_1)}}{\delta} \right]^2$$

where $z_{1-\alpha/2}$ and z_{β} are the critical values of 95% confidence interval and 80% power. P_0 is the probability under null hypothesis; δ is the margin of error and $p_1=p_0+\delta$.

But, with the possibility of attrition in this prospective clinical trial, the sample size was increased to **25** per group.

In this study, three substantially homogenous groups were selected with the selection criteria. **Cunha-Cruz J et al. (2010)** concluded that moderate to severe tooth wear is a prevalent condition in the adult population. These extreme age variations could affect the standard protocol of the study.⁶⁶ Hence, patients belonging to age group of 18-35 years were involved, also taking into consideration the adolescent population and their inclination towards esthetic enhancements. Self motivated patients who were interested in getting a tooth jewel were considered and consent form was filled by them to ensure the same.

Patients with a carious canine were excluded as it hampers the conditioning pattern and infiltration of resin monomers. Patients with poor oral hygiene were excluded as the attachment area of tooth jewel is prone for plaque accumulation which might further affect the final result.³ Teeth with prosthesis, hypoplasia and fluorosis were excluded as the bonding protocol is different for these clinical situations. Patients who did not turn up for the recalls or encountered an accidental fracture of the tooth were withdrawn from the study.

Jafari et al. (2017) stated that the anterior maxillary teeth form are considered as one of the most substantial aspects of smile esthetics; it is in line with the study conducted by **Ong et al.**, which indicated that the anterior teeth form has the highest impact on the smile attractiveness.^{67,68}

Bhuvaneshwaran (2010) explained that maxillary canine plays a critical point in creating a pleasing smile as they are

- 1) The junction between the anterior and posterior dental segments; hence, only

the mesial half of the canine is visible from the frontal view when the patient smiles;

- 2) It depicts the personality characterization.⁶⁹
- 3) Upper canines are not only important for dynamic occlusion as required in gnathological concepts, but they, together with the central and lateral incisors, define the character of a smile.⁷⁰ Hence mesial aspect of the maxillary canines was chosen for the present study.

Generations of bonding agents play vital role in the success of the final restoration. **Buonocore (1955)** stated that the fourth generation materials were the first to achieve complete removal of smear layer and revolutionised the concept of bonding.⁷¹ **Kugel (2000)** concluded that bond strengths for these adhesives are comparatively high and they show significantly reduced margin leakage compared to earlier systems.⁷² **Sofan et al. (2017)** mentioned that these systems are very effective when used correctly, have good long-term clinical track record, and are still considered as the **gold standard** in bonding.⁷³ **These systems are still the standards by which the newer systems are judged.** Hence, fourth generation adhesives were used in the present study.

Helvatjoglu-Antoniades (2006) explained that flowable resin composites are low-viscosity resin based restorative materials that differ from conventional resin composites. These materials are less rigid and have modulus of elasticity lower than that of conventional hybrid composites.⁷⁴ **Bayne et al. (1998)** suggested that this characteristic could contribute to the dissipation of contraction stresses during polymerization. Since it has less filler content, the coefficient of thermal expansion of

flowable composite is close to that of the tooth structure, which might further increase the marginal adaptation.⁷⁵

Xavier et al. (2010) explained that the low modulus of elasticity of these composites allows them to flow during polymerization and compete with the stress development, helping maintain a marginal seal and avoiding debonding during cervical flexure. Composites with low shrinkage, although associated with a low modulus, will tend to generate low stresses at the bonded interface.⁷⁶

With the advent of new technology in material sciences in recent years, the quality of composite resin restorations have been improved. *However, discoloration and wear of composite resin materials remains to be a major problem in long-term clinical studies.*⁷⁷ **Torii et al. 1999** stated that filler particle-related features such as the concentration, size of the filler reinforcement and resin formulation are known factors affecting the wear and discoloration of composites.⁷⁸

Baroudi et al. (2015) said that flowable composites have low filler loading and high monomer content, which permit these materials to flow, but often at the expense of inferior physical properties. These methacrylate based nano hybrid composites have better strength, gloss and lower shrinkage, making them an ideal choice for luting the tooth jewel. In a nutshell, the introduction of nanohybrid composites provide good flexural strength with minimal polymerization shrinkage producing margins with high polishability and smoothness.⁴⁵

Esthetics, flow and acceptable adaptation were the prime concerns for the luting agent making nanohybrid flowable composites the material of choice for the present

study. However, lack of literature regarding the characteristics and effects of these composites makes this a study of clinical relevance.

The shade selected was A2 as it is a universal colour for all materials according to **Uchida et al. (1998)** as a function of shade. It is a light composite shade and therefore susceptible to greater colour changes making it easy to evaluate and make it visually discernible.^{79, 80} Hence, all the flowable composites used in the present study belonged to the shade A2.

Tooth jewel manufactured by Kryste were used in the present study. They are Swarovski crystals supplied with a hologram certificate highlighting the authenticity of the jewels. They are supplied in various colours to cater to the patients' esthetic preferences.

The evaluation of the marginal integrity and marginal discoloration around the tooth jewel was done with reference to the **modified United States Public Health Service (Ryge) criteria**. **Cvar et al. (2005)** stated that United States Public Health Service (USPHS) evaluation system is the most commonly used direct method for ensuring quality control of restorations. This scoring system was designed to provide comprehensive evidence for clinical acceptance rather than in degrees of clinical success.⁸¹ Hence, these USPHS criteria were used to evaluate the clinical performance of flowable composites. According to **McHugh (2012)**, Cohen's kappa is a robust statistic which is known to be useful for inter evaluator reliability testing.⁸² Therefore, the kappa coefficient was obtained for the grading of marginal discoloration and integrity by two observers at three appointments. The coefficient ranged between 0.965 to 0.993 and 0.96 to 1 indicating excellent agreement between two observers.

The retention of the tooth jewel was recorded with reference to a scoring criteria devised for the study. After the statistical analysis, the following results were obtained.

1] Marginal Discoloration:

It refers to the visual evidence of change in colour at the margins different from the restorative material and adjacent tooth structure. It is primarily related to the composition of the composites, quality of bonding to the tooth structure and the stresses generated at the tooth -restorative material interface.⁸³ (**Rodrigues et al. 2010**)

It is an important yet underestimated attribute as it has been stated as an early clinical sign of microleakage (**Kidd et al. 1976**)⁸⁴ and is an indication for future possibility of failure of restoration.⁸⁵ (**Larsson et al. 2012**)

At the one month evaluation, the difference between the three groups was statistically insignificant (p-value = 0.3629). These findings could be attributed to the fact that initial periods of evaluation depict minor deviations from the baseline colour.^{86,87} (**Abdalla et al. 1996 and Leinfelder et al. 1995**)

At the third month evaluation, statistically significant difference was observed among the three groups with p-value = 0.0231. Group 1 showed least marginal discoloration.

Marginal discoloration is dependent on the composition of the composite resin. Therefore these findings could be attributed to the formulations of the three flowable composites. Group 1 i.e. G-aenial Universal Flo primarily contains UDMA which is more stain resistant than Bis-GMA, which is the primary component of Group 2 and Group 3 i.e. Filtek Supreme Flow Plus and Tetric Evoflow respectively.⁶¹ (**Khokar et al.)**

At the final sixth month evaluation, again statistically insignificant difference was observed among the three groups ($p=0.7711$). These findings could be attributed to the fact that few samples got debonded and were removed from the group.

2] **Marginal Integrity:**

It refers to the marginal fit and adaptation thereby increasing the longevity of the restorative material.⁸⁸

It is one of the most crucial aspects for the predictable, long term clinical results of adhesive restorations (**Kramer 2000**)⁸⁹. Loss of marginal integrity can initiate interfacial gaps at the composite- tooth interface, (**Botha et 1994, Griffith 1999**)^{90,91} thereby leading to marginal discoloration and eventually loss of the restoration. (**Dhingra et al. 2014, Shafiei et al. 2014**).^{92,93}

In the present study, visual evidence of a crevice and a catch on the explorer was used to evaluate the loss of marginal integrity.

At the first, third and sixth month evaluation, the difference among the three groups was statistically insignificant (p values = 0.3629, 0.2969 and 0.7665 respectively). This could probably be attributed to the similar bonding agents used in all the three groups. Marginal disintegration may be reduced or eliminated by the use of excellent bonding complex. The adhesives are therefore critical for the success of the restorative margins (**Sofan et al. 2017**)⁷³.

The fourth generation adhesives used in the present study are proved to provide acceptable bond strength and durability (**De Munck et al. 2005**)³³. Hence all the groups provided clinically similar and acceptable marginal integrity.

The findings of the present study are in accordance with the study conducted by **Hussainy et al. (2017)** who stated that the ratings of marginal discoloration corresponded within certain limits to that of the marginal adaptation⁹⁵. This provided evidence that the poor marginal adaptation can predispose to marginal discoloration.

3] Retention:

It refers to the ability of the composite material to sustain the tooth jewel for a particular period of time.

The retention was checked by the presence or absence of the tooth jewel at 1st, 3rd and 6th months and was scored accordingly.

At the first month evaluation, all the tooth jewels were retained in the oral cavity.

At the third month evaluation, 100% (25) samples were retained in case of Group A, whereas 72% (18) samples were retained for Group 2 and Group 3.

At the sixth month evaluation, again 100% (25) samples were retained in case of Group A, whereas 56% (14) samples were retained for Group 2 and Group 3.

The difference between the three groups was highly significant (p-value < 0.0001). These findings can be attributed to the difference in the composition of the resin matrix of the respective composites used in the trial. (**Khokar et al.**)⁶¹ Group 1 (G-aenial Universal Flo) is a UDMA based flowable composite whereas Group 2 (Filtek Supreme Flow Plus) and 3 (Tetric Evoflow) primarily contain Bis-GMA.

According to the studies by **Pearson, Malekipour and Bagheri et al.**, UDMA shows lower water sorption than Bis-GMA. Water sorption directly affects the retention of composites as it causes expansion and plasticizing of the resin, inducing microcrack formation, all of which leads to reduced longevity of the composites. It is apparent that this fluid uptake and dissolution results in the breakdown of the material, all of which results in the failure of a restoration.^{20,42,94}

At the end of six months, it was observed that the clinical performance of Group 1 (G-aenial Universal Flo) was clinically better than Group 2 (Filtek Supreme Flow Plus) and group 3 (Tetric Evoflow) in regards to marginal discoloration, marginal integrity and retention. This gives us an insight into the bonding milieu and it's direct impact on the clinical performance. It is apparent that marginal discoloration and loss of marginal integrity contribute to the loss of retention of the tooth jewel.

The results obtained from the present study have clinical relevance and provide clinicians with information about the staining potential, integrity of composites and durability of the tooth jewel when luted with these composites.

The null hypothesis was that there will be no difference in the clinical performance of tooth jewel luted with three commercially available flowable composites-G-aenial Universal Flo, Filtek Supreme Flow Plus, Tetric EvoFlow. This was rejected as the tooth jewel performed differently when luted with the three different flowable composites.

Within the limitations of this study, it can be concluded that the tooth jewel had

an acceptable clinical performance when luted with the nanohybrid flowable composites. But further long term studies are required on this topic for better elucidation of the tooth jewel and its clinical behaviour.

The results of this study would help in the better understanding of the interaction of the tooth jewel, flowable composites and the oral environment. The study also highlights the importance of patient education with regards to the tooth jewel. The esthetics and longevity of the tooth jewel is dependent on the marginal discoloration and marginal integrity of the bonding complex used. Efforts should be taken by the responsible clinician to make the patient aware about the possibility of debonding and failure of this expensive cosmetic procedure. It is advisable for the patient to turn up for regular follow ups and report to the dentist in case of any roughness or discoloration circumscribing the tooth jewel. This study also widens the scope for the improvement of present commercial materials and the development of better luting materials in the future.

LIMITATIONS

Limitations

1. Though even at six months , clinical trials offer meaningful information regarding the early changes in the flowable composites and predict it's future performance, further studies are required to evaluate the long term follow up of tooth jewel luted with the nanohybrid flowable composites.
2. Though the post operative oral hygiene and diet instructions were given to the patient, standardization of the oral environment was practically impossible.

SUMMARY & CONCLUSION

Tooth jewel is a cosmetic procedure which has gained popularity in the recent times. There are a plethora of luting agents that are available in the market, but flowable composites offer the best combination of esthetics, flow , adhesion and adaptation. However , there are no studies highlighting the clinical behaviour of tooth jewel when luted with flowable composites. There is till date no conclusive evidence of the durability , discoloration and marginal integrity of the recently introduced nanohybrid flowable composites .

Hence , the aim of the present study was to assess and compare the clinical performance of the tooth jewel when luted with three nanohybrid flowable composites through a prospective randomized clinical trial.

Subjects included in the study were recruited from the regular pool of patients visiting the Department of Conservative Dentistry And Endodontics. Total of seventy five patients interested in getting a tooth jewel were considered for the study. Patients which fulfilled the selection criteria were identified as suitable for the study and were asked to give their consent to be involved.

Three treatment groups included:

Group I : G-aenial Universal Flow

Group II : Filtek Supreme Flow

Group III : Tetric Evoflow

They were further divided according to the parameters which were to be evaluated :

Sub Group A : Marginal Discoloration

Sub Group B : Marginal Integrity

Sub Group C : Retention

Luting of the tooth jewel was performed using the same bonding protocol in three treatment groups except for the use of the different flowable composites.

Post operative evaluation was done as per the modified Ryge criteria with the help of visual inspection and explorer by two blinded investigators. The results were statistically compared and following conclusions were drawn :

1. Post operative comparison of marginal discoloration with respect to the three flowable composites was found to be statistically insignificant .
2. Post operative comparison of marginal integrity with respect to the three flowable composites was found to be statistically insignificant.
3. The mean retention period of G-aenial Universal Flo was found to be

statistically more than Filtek Supreme Flow and Tetric Evoflow.

4. There was slight degradation of the properties among all flowable composites over the study period.

Taking into considerations the limitations of this study, it can be concluded that all the flowable composites exhibited a clinically satisfactory performance. Further long term studies are required for better understanding of the clinical behavior of tooth jewel. Newer luting agents can be explored and other properties can be studied for a more predictable performance of the tooth jewel.

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TABLES & GRAPHS

Table 1: Descriptive Statistics for Age of the Patients Among Three Groups

| Composite | Age (in years) | | | | |
|---------------------------------|----------------|------|--------|-------|-------|
| | Mean | SD | Median | Min. | Max. |
| G-aenial Universal Flo (n=25) | 21.68 | 2.75 | 21.00 | 18.00 | 28.00 |
| Filtek Supreme Flow Plus (n=25) | 21.52 | 2.96 | 21.00 | 16.00 | 29.00 |
| Tetric EvoFlow (n=25) | 22.68 | 3.65 | 23.00 | 18.00 | 33.00 |

P-value: 0.3728(NS); Obtained using Student's t test; NS: Non Significant

Table 2: Descriptive Statistics for Gender of the Patients Among Three Groups

| Composite | Gender [No. (%)] | |
|---------------------------------|------------------|---------|
| | Male | Female |
| G-aenial Universal Flo (n=25) | 7 (28) | 18 (72) |
| Filtek Supreme Flow Plus (n=25) | 8 (32) | 17 (68) |
| Tetric EvoFlow (n=25) | 6 (24) | 19 (76) |

P-value: 0.8200(NS); Obtained using Pearson's Chi-square test; NS: Non Significant

Table 3: Inter-Investigator Agreement For Different Post Treatment

Parameters:

Marginal Discoloration

| CRITERIA AT FOLLOW UPS | KAPPA CO-EFFICIENT | P-VALUE |
|---------------------------|--------------------|---------------|
| USPHS Criteria : 1 month | 0.993 | < 0.0001 (HS) |
| USPHS Criteria : 3 months | 0.965 | < 0.0001 (HS) |
| USPHS Criteria : 6 months | 0.980 | < 0.0001 (HS) |

HS: Highly Significant

Table 4: Inter-Investigator Agreement For Different Post Treatment

Parameters:

Marginal Integrity

| CRITERIA AT FOLLOW UPS | KAPPA CO-EFFICIENT | P-VALUE |
|---------------------------|--------------------|---------------|
| USPHS Criteria : 1 month | 1.000 | < 0.0001 (HS) |
| USPHS Criteria : 3 months | 0.960 | < 0.0001 (HS) |
| USPHS Criteria : 6 months | 0.973 | < 0.0001 (HS) |

HS: Highly Significant

Table 5: Descriptive Statistics for Retention Among Three Groups

| Composite | Retention | | | | |
|---------------------------------|-------------------|------|--------|---------|---------|
| | Mean | SD | Median | Minimum | Maximum |
| G-aenial Universal Flo (n=25) | 6.00 ^a | 0.00 | 6.00 | 6.00 | 6.00 |
| Filtek Supreme Flow Plus (n=25) | 4.12 ^b | 2.26 | 6.00 | 1.00 | 6.00 |
| Tetric EvoFlow (n=25) | 3.92 ^b | 2.31 | 6.00 | 1.00 | 6.00 |

P-value < 0.0001(HS); Obtained using Kruskal-Wallis test;

HS: Highly Significant; Means with different superscripts shows statistical significance

Table 6: Comparison of Marginal Discoloration around Tooth Jewel across Three Groups At

1st MONTH

| USPHS Criteria | Composite Group [No. (%)] | | | P-value* |
|-------------------------------|---------------------------|--------------------------|----------------|-------------|
| | G-aenial Universal flo | Filtek Supreme Flow Plus | Tetric EvoFlow | |
| Marginal Discoloration | | | | |
| Alpha (A) | 25 (100) | 24 (96) | 25 (100) | 0.3629 (NS) |
| Bravo (B) | 0 | 1 (4) | 0 | |

*Obtained using Pearson's Chi-square test; NS: Non-Significant

Table 7: Comparison of Marginal Integrity around Tooth Jewel across Three Groups At 1st MONTH

| USPHS Criteria | Composite Group [No. (%)] | | | P-value* |
|---------------------------|---------------------------|--------------------------|----------------|----------------|
| | G-aenial Universal flo | Filtek Supreme Flow Plus | Tetric EvoFlow | |
| Marginal Integrity | | | | |
| Alpha (A) | 25 (100) | 25 (100) | 24 (96) | 0.3629 (NS) |
| Bravo (B) | 0 | 0 | 1 (4) | |

*Obtained using Pearson’s Chi-square test; NS: Non-Significant

Table 8: Comparison of Marginal Discoloration around Tooth Jewel across Three Groups At 3rd MONTH

| USPHS Criteria | Composite Group [No. (%)] | | | P-value* |
|-------------------------------|---------------------------|--------------------------|----------------|---------------|
| | G-aenial Universal flo | Filtek Supreme Flow Plus | Tetric EvoFlow | |
| Marginal Discoloration | | | | |
| Alpha (A) | 25 (100) | 15 (60) | 18 (72) | 0.0231 (S) |
| Bravo (B) | 0 | 3 (12) | 0 | |
| Loss of retention | 0 | 7 (28) | 7 (28) | |

*Obtained using Pearson’s Chi-square test; S: Significant; NS: Non-Significant

Table 9: Comparison of Marginal Integrity around Tooth Jewel across Three Groups At 3rd MONTH

| USPHS Criteria | Composite Group [No. (%)] | | | P-value* |
|---------------------------|---------------------------|--------------------------|----------------|----------------|
| | G-aenial Universal flo | Filtek Supreme Flow Plus | Tetric EvoFlow | |
| Marginal Integrity | | | | |
| Alpha (A) | 25 (100) | 17 (68) | 18 (72) | 0.2969 (NS) |
| Bravo (B) | 0 | 1 (4) | 0 | |
| Loss of retention | 0 | 7 (28) | 7 (28) | |

*Obtained using Pearson’s Chi-square test; S: Significant; NS: Non-Significant

Table 10: Comparison of Marginal Discoloration around Tooth Jewel across Three Groups At 6th MONTH

| USPHS Criteria | Composite Group [No. (%)] | | | P-value* |
|-------------------------------|---------------------------|--------------------------|----------------|-------------|
| | G-aenial Universal flo | Filtek Supreme Flow Plus | Tetric EvoFlow | |
| Marginal Discoloration | | | | |
| Alpha (A) | 23 (92) | 12 (48) | 12 (48) | 0.7711 (NS) |
| Bravo (B) | 2 (8) | 2 (8) | 2 (8) | |
| Loss of retention | 0 | 11 (44) | 11 (44) | |

*Obtained using Pearson's Chi-square test; S: Significant; NS: Non-Significant

Table 11: Comparison of Marginal Integrity around Tooth Jewel across Three Groups At 6th MONTH

| USPHS RYGE Criteria | Composite Group [No. (%)] | | | P-value* |
|---------------------------|---------------------------|--------------------------|----------------|-------------|
| | G-aenial Universal flo | Filtek Supreme Flow Plus | Tetric EvoFlow | |
| Marginal Integrity | | | | |
| Alpha (A) | 23 (92) | 12 (48) | 13 (52) | 0.7665 (NS) |
| Bravo (B) | 2 (8) | 2 (8) | 1 (4) | |
| Loss of retention | 0 | 11 (44) | 11 (44) | |

*Obtained using Pearson's Chi-square test; S: Significant; NS: Non-Significant

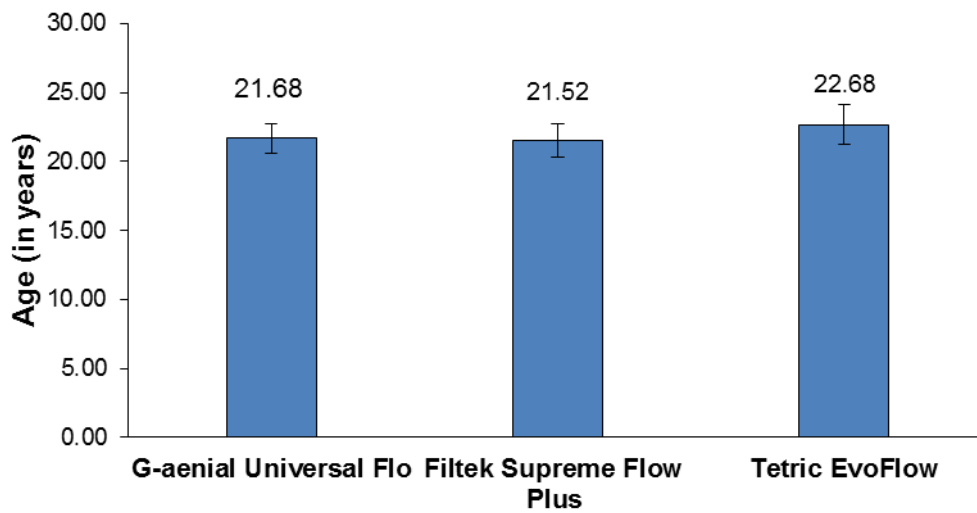


Figure 1: Column chart with error bar showing mean age parameter in three groups

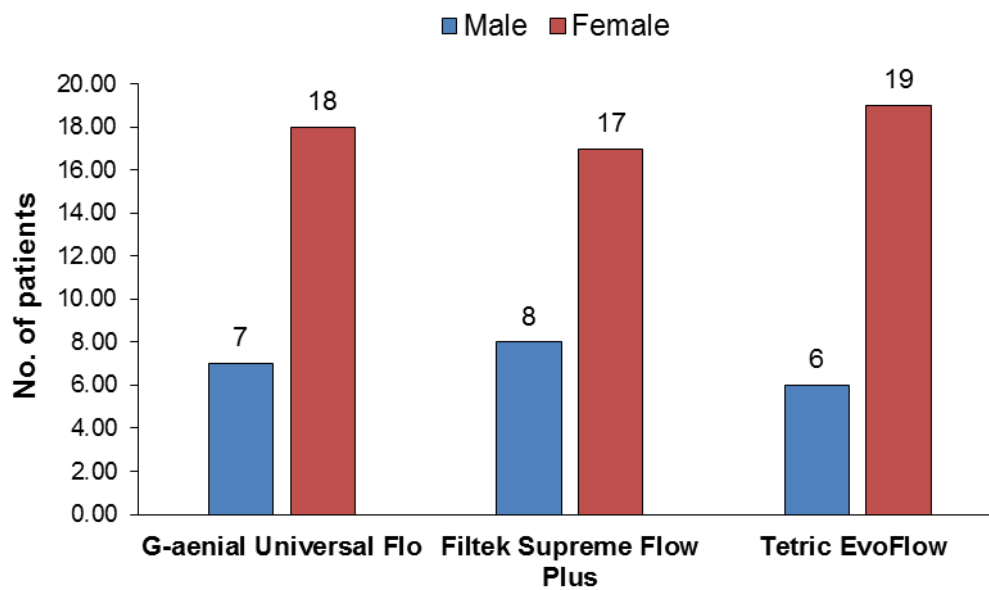


Figure 2: Distribution of patients as per gender in three groups

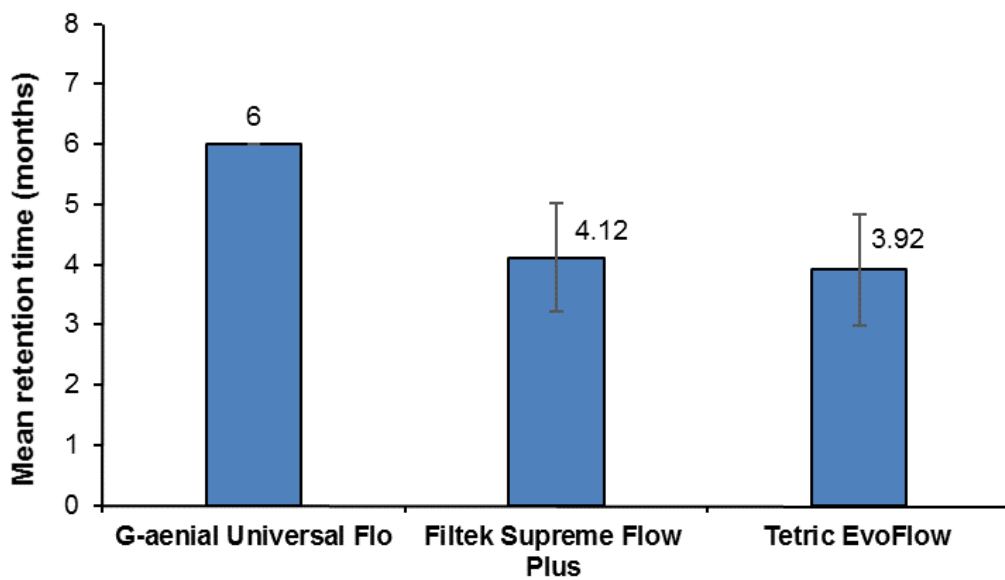


Figure 3: Column chart with error bar showing mean retention time in three groups

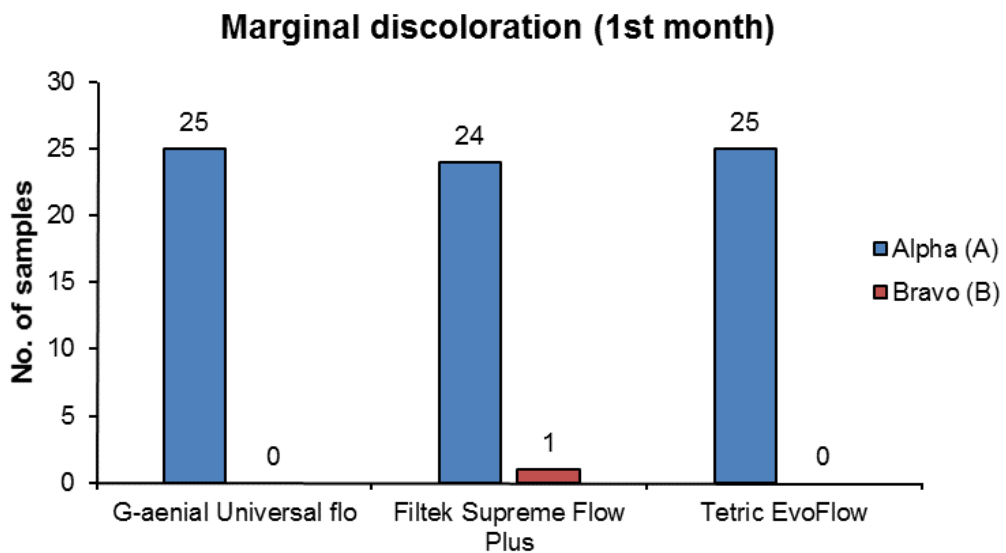


Figure 4: Column chart showing number of samples according to levels of marginal discoloration in each study group at 1st month

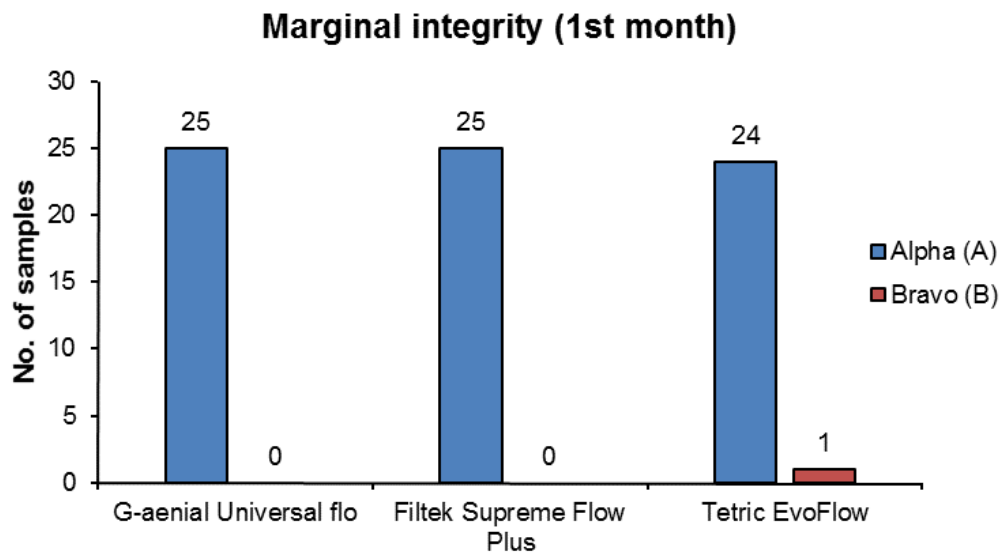


Figure 5: Column chart showing number of samples according to levels of marginal integrity in each study group at 1st month

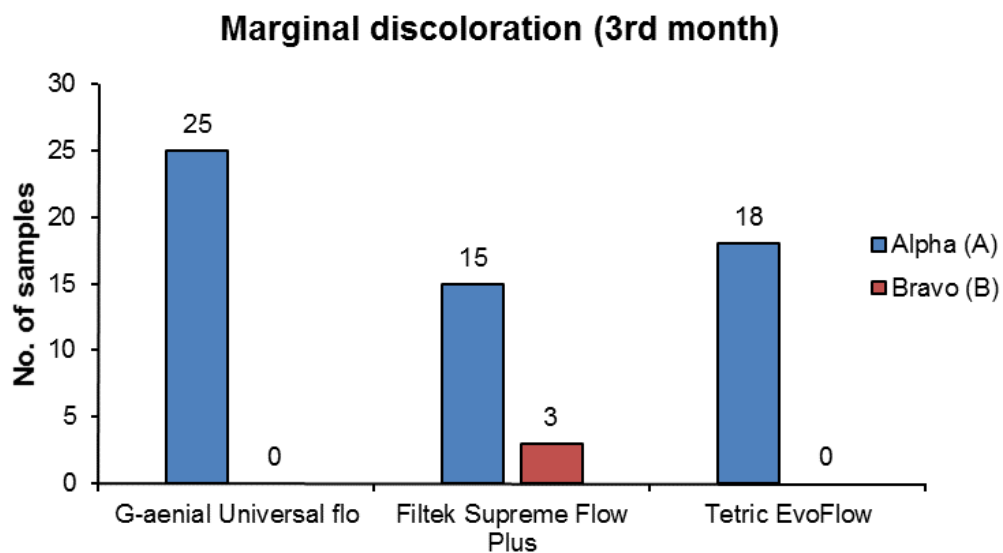


Figure 6: Column chart showing number of samples according to levels of marginal discoloration in each study group at 3rd month

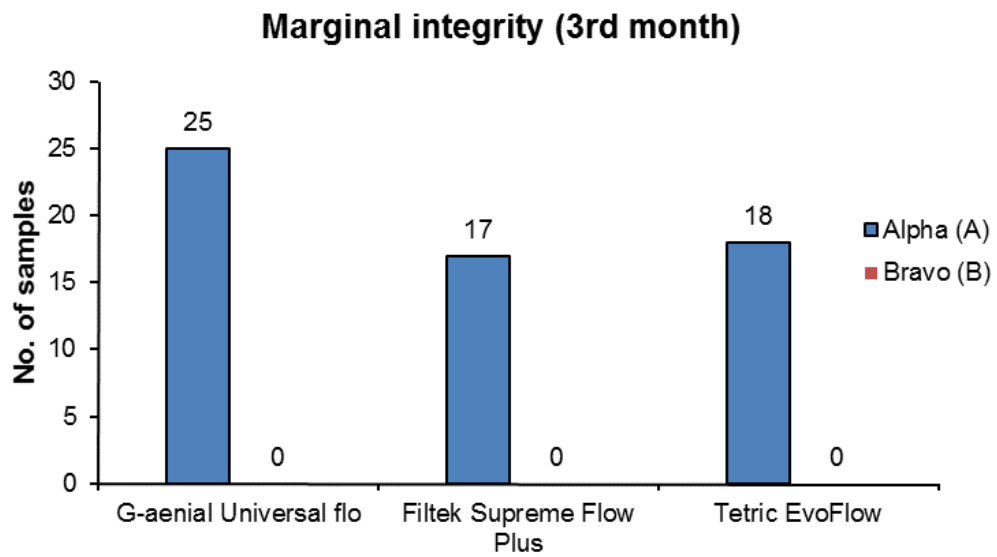


Figure 7: Column chart showing number of samples according to levels of marginal integrity in each study group at 3rd month

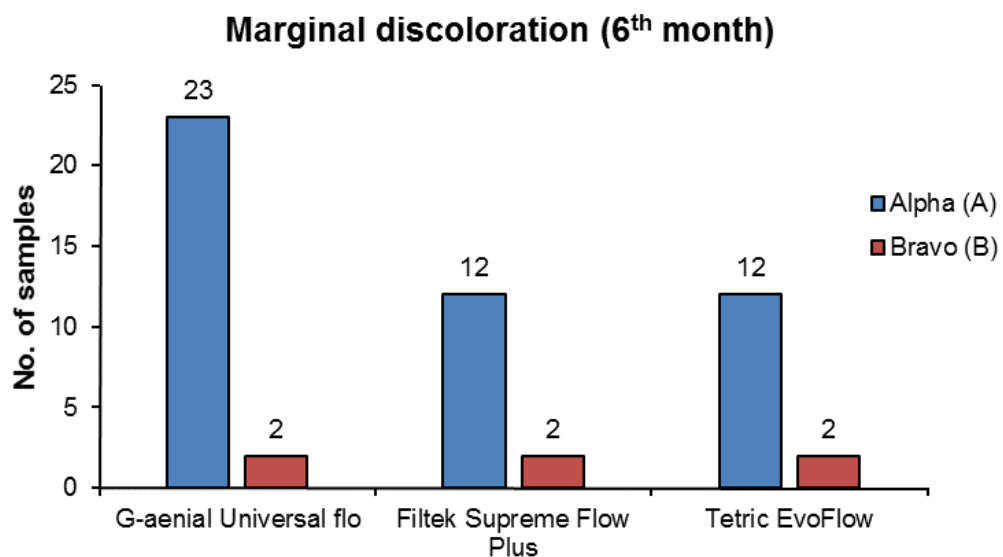


Figure 8: Column chart showing number of samples according to levels of marginal discoloration in each study group at 6th month

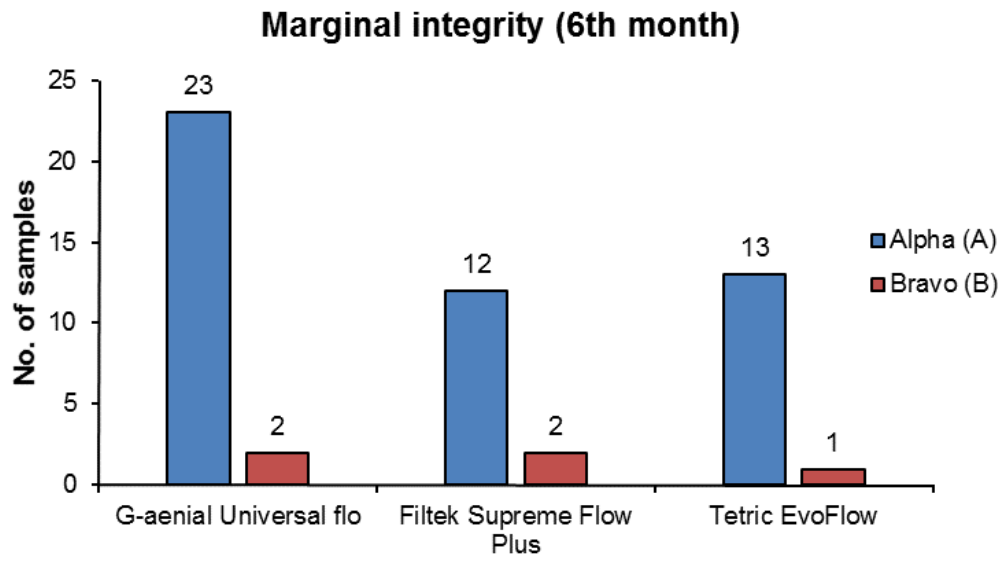


Figure 9: Column chart showing number of samples according to levels of marginal integrity in each study group at 6th month

ANNEXURE I

CASE RECORD FORM

Registration no. :

Date:

Name :

Age/Sex :

Address :

Contact no.:

Education : Illiterate / Literate

Occupation:

Economic status : low/ moderate / high

Chief complaint:

History of present illness :

Medical history:

H/O major illness :

H/O allergy:

Current medical treatment if any:

Past dental history :

Food habits :

Diet: Vegetarian / non vegetarian / mixed

Beverages : Tea/Coffee/Cola/others. Habits :

| Habits | Frequency | Quantity | Since | Location if any |
|----------------|-----------|----------|-------|-----------------|
| Chewing | | | | |
| Areca Nut | | | | |
| Kharra | | | | |
| Tobacco | | | | |
| Tobacco+ | | | | |
| Lime Others | | | | |
| Smoking | | | | |
| Bidi | | | | |
| Cigarette | | | | |
| Chutta | | | | |
| Alcohol | | | | |

Oral hygiene habits:

Cleaning teeth with: tobacco / toothpaste/ coal/ snuff / powder / salt/

ash/other With tooth brush / finger / datoon

Parafunctional habits : Bruxism / Nail biting.

Intraoral examination :

Hard tissue examination :

Teeth present:

Attrition:

Erosion:

Abrasion:

Caries:

Fracture:

Restored teeth :

Prosthesis:

Post operative Evaluation :

Syringe no. :

| Clinical Performance | Score | | |
|------------------------|-----------------------|-----------------------|-----------------------|
| | 1 st Month | 3 rd Month | 6 th Month |
| Marginal Integrity | | | |
| Marginal Discoloration | | | |
| Longevity | | | |

Signature of Patient

Signature of Operator

ANNEXURE II-A

CONSENT FORM IN VERNACULAR LANGUAGE (MARATHI)

(Confidential)

Informed Consent Form

TO ASSESS AND COMPARE THE CLINICAL PERFORMANCE OF TOOTH JEWEL LUTED WITH
THREE COMMERCIALY AVAILABLE FLOWABLE COMPOSITES IN YOUNG ADULTS –

A RANDOMISED CONTROLLED TRIAL

मी, श्री / मस्टर / श्री. / मिस _____ निवासी:
_____, वय _____ वर्ष, माझ्या
कोणत्याही इच्छेचा कोणत्याही प्रकारचा दबाव / प्रलोभन न करता, माझी मोफत इच्छा / निवड
वापरून, संशोधन प्रकल्पासाठी माझी संमती / संमती देऊन.

मी कबूल करतो की डॉक्टरांनी मला या संशोधन प्रकल्पाबद्दल समाधानकारक माहिती
दिली आहे. मी माझ्या छायाचित्रे आणि आवश्यकतेनुसार अन्य तपासण्या करण्यास सहमत
आहे. मी या प्रकल्पात भाग घेण्यास सहमती देतो आणि या चाचणीच्या कालावधीत कोणतेही
अन्य प्रकल्प एकत्रित करणार नाही. मला डेन्टल हॉस्पिटल किंवा इतर ठिकाणी दिलेल्या भेटीची
तारीख आणि वेळ सांगितली आहे. मी डॉक्टर आणि पॅरामेडिकल कर्मचा-यांना सर्व बाबतीत
सहकार्य करेल. या अभ्यासात मी माझ्या सहभागाचे निकाल प्रकाशित करण्यास परवानगी देतो.
मला कोणतीही नुकसान भरपाई दिली जाणार नाही. असे करण्यासाठी कोणतेही कारण न देता
मला कोणत्याही वेळी या संशोधन प्रकल्पातून बाहेर पडण्याचा अधिकार मिळालेला आहे. मी या
अन्वये केलेल्या चाचणीत सहभागासाठी माझी संमती नोंदवित आहे.

1. _____
रुग्णांच्या नाव स्वाक्षरी / अंगठा मुद्रण तारीख वेळ
2. _____
साक्षीदार नाव सही तारीख वेळ
3. _____
अन्वेषणकर्त्याचे नाव स्वाक्षरी तारीख वेळ

ANNEXURE – IIB

CONSENT FORM IN VERNACULAR LANGUAGE (HINDI)

(Confidential)

Informed Consent Form

TO ASSESS AND COMPARE THE CLINICAL PERFORMANCE OF TOOTH JEWEL LUTED WITH
THREE COMMERCIALY AVAILABLE FLOWABLE COMPOSITES IN YOUNG ADULTS –

A RANDOMISED CONTROLLED TRIAL

में, श्री / मस्टर / श्रीमती / मिस _____, का/ की निवासी :
_____ आयु _____ वर्ष, किसी भी रूप में
प्रोत्साहन / प्रलोभन के बिना, मेरी स्वतंत्र इच्छा / पसंद से इस प्रकार के अनुसंधान परियोजना
के लिए मेरी सहमति देता /देती हु

में मानता हूं कि चिकित्सक ने मुझे इस शोध परियोजना के बारे में उपयुक्त और
पर्याप्त रूप से मेरी संतुष्टि के बारे में बताया है। मैं अपने फोटो और अन्य जांचों को जरूरी
के रूप में लेने के लिए सहमत हूं। मैं इस परियोजना में भाग लेने के लिए सहमत हूं और इस
परीक्षण की अवधिके दौरान किसी भी अन्य परियोजनाओंको मिला नहीं करेगा। मैं सभी मामलों
में डॉक्टरों और पैरामेडिकल स्टाफ के साथ मिलकर काम करेगा। मैं इस अध्ययन में अपनी
भाग्यदारी के परिणामोंको प्रकाशित करने की अनुमति देता हूं। मुझे कोई प्रतिपूर्ति या क्षतिपूर्ति
नहीं दी जाएगी। मुझे ऐसा करने के लिए किसी भी कारण के बिना किसी भी समय इस
शोधपरियोजनासे ऑप्टआउट करने का मेरे अधिकार के बारे में सूचित किया गया है। मैं
एतद्वारा परीक्षण में भाग लेने के लिए मेरी सहमति रिकॉर्ड करता हूं।

1. _____
रोगी का नाम हस्ताक्षर / अंगूठे का निशान दिनांक समय
2. _____
गवाह का नाम हस्ताक्षर दिनांक समय
3. _____
अन्वेषक का नाम हस्ताक्षर दिनांक समय

ANNEXURE II-C

INFORMED CONSENT FORM :

(Confidential)

**TO ASSESS AND COMPARE THE CLINICAL PERFORMANCE OF TOOTH JEWEL LUTED WITH
THREE COMMERCIALY AVAILABLE FLOWABLE COMPOSITES IN YOUNG ADULTS –**

A RANDOMISED CONTROLLED TRIAL.

I, Mr./Master/Mrs./Miss. _____

Resident of: _____

_____ aged _____ years, exercising my free will/choice, without any pressure/lure of incentive in any form, hereby give my consent/consent for the research project.

I acknowledge that doctor has informed me about this research project suitably and sufficiently to my satisfaction. I agree to let my photographs and other investigations to be taken as required. I agree to take part in this project and will not mix any other projects during the period of this trial. I shall report to the dental hospital or other place where called on given appointment dates and time. I shall inform the doctor on any adverse effects or unusual symptoms noticed by me. I shall co-operate with the doctors and paramedical staff, in all respects. I permit to publishing the results of my participation in this study. I shall not be given any reimbursement or compensation. I have been informed of my right to opt out of this research project at any time without giving any reason for doing so. I hereby record my consent for participation in the said trial.

1. _____

Patient's name Signature/thumbprint Date Time

2. _____

Witness name Signature Date Time

3. _____

Investigator's name Signature Date Time

Annexure- III

| MASTER CHART | | | |
|---------------------|-------------------|--------------|-------------------|
| Descriptive data | | | |
| SR.NO | AGE/GENDER | SR.NO | AGE/GENDER |
| 1 | 23/F | 41 | 19/M |
| 2 | 27/F | 42 | 19/F |
| 3 | 18/F | 43 | 23/F |
| 4 | 20/F | 44 | 21/M |
| 5 | 18/F | 45 | 21/M |
| 6 | 21/F | 46 | 19/M |
| 7 | 19/F | 47 | 19/M |
| 8 | 19/F | 48 | 20/M |
| 9 | 23/F | 49 | 19/F |
| 10 | 20/M | 50 | 23/F |
| 11 | 23/F | 51 | 18/M |
| 12 | 20/F | 52 | 26/M |
| 13 | 25/F | 53 | 25/F |
| 14 | 21/F | 54 | 21/F |
| 15 | 19/F | 55 | 23/F |
| 16 | 22/M | 56 | 18/F |
| 17 | 18/M | 57 | 21/F |
| 18 | 23/F | 58 | 23/F |
| 19 | 25/F | 59 | 20/F |
| 20 | 26/F | 60 | 23/M |
| 21 | 21/M | 61 | 24/F |
| 22 | 24/F | 62 | 23/F |
| 23 | 21/F | 63 | 23/F |
| 24 | 29/M | 64 | 25/F |
| 25 | 23/F | 65 | 21/F |
| 26 | 16/M | 66 | 25/F |
| 27 | 27/F | 67 | 20/F |
| 28 | 20/F | 68 | 23/F |
| 29 | 19/M | 69 | 26/F |
| 30 | 20/M | 70 | 19/M |
| 31 | 21/F | 71 | 20/F |
| 32 | 23/F | 72 | 24/F |
| 33 | 28/F | 73 | 20/F |
| 34 | 20/F | 74 | 19/F |
| 35 | 18/M | 75 | 26/M |
| 36 | 21/F | | |
| 37 | 21/F | | |
| 38 | 24/F | | |
| 39 | 33/F | | |
| 40 | 29/M | | |

Annexure- IV

| RETENTION OF TOOTH JEWEL AMONG THREE GROUPS | | | | | |
|---|-----------|-----------|-------|-----------|-----------|
| SR.NO | COMPOSITE | RETENTION | SR.NO | COMPOSITE | RETENTION |
| 1 | B | 6 | 41 | B | 6 |
| 2 | B | 3 | 42 | C | 6 |
| 3 | C | 1 | 43 | A | 6 |
| 4 | A | 6 | 44 | A | 6 |
| 5 | C | 6 | 45 | B | 1 |
| 6 | B | 1 | 46 | B | 1 |
| 7 | A | 6 | 47 | C | 1 |
| 8 | B | 1 | 48 | B | 3 |
| 9 | C | 6 | 49 | B | 6 |
| 10 | B | 6 | 50 | A | 6 |
| 11 | B | 1 | 51 | A | 6 |
| 12 | C | 6 | 52 | B | 3 |
| 13 | A | 6 | 53 | A | 6 |
| 14 | B | 6 | 54 | B | 6 |
| 15 | C | 1 | 55 | A | 6 |
| 16 | C | 6 | 56 | A | 6 |
| 17 | A | 6 | 57 | A | 6 |
| 18 | C | 6 | 58 | C | 1 |
| 19 | B | 1 | 59 | B | 6 |
| 20 | C | 6 | 60 | A | 6 |
| 21 | C | 3 | 61 | C | 6 |
| 22 | A | 6 | 62 | B | 1 |
| 23 | A | 6 | 63 | C | 3 |
| 24 | B | 3 | 64 | C | 1 |
| 25 | A | 6 | 65 | A | 6 |
| 26 | B | 6 | 66 | C | 6 |
| 27 | C | 1 | 67 | B | 6 |
| 28 | B | 6 | 68 | C | 6 |
| 29 | A | 6 | 69 | A | 6 |
| 30 | C | 6 | 70 | A | 6 |
| 31 | A | 6 | 71 | C | 1 |
| 32 | B | 6 | 72 | B | 6 |
| 33 | A | 6 | 73 | C | 3 |
| 34 | B | 6 | 74 | B | 6 |
| 35 | A | 6 | 75 | C | 6 |
| 36 | C | 6 | | | |
| 37 | A | 6 | | | |
| 38 | A | 6 | | | |
| 39 | C | 1 | | | |
| 40 | C | 3 | | | |

Annexure- V

| GRADING OF MARGINAL DISCOLORATION AMONG THREE GROUPS | | | | | | | | | |
|--|-----------|-----|-------|-------|-------|-----------|-----|-------|-------|
| SR.NO | COMPOSITE | MD1 | MD3 | MD6 | SR.NO | COMPOSITE | MD1 | MD3 | MD6 |
| 1 | B | A | A | A | 41 | B | A | A | A |
| 2 | B | A | A | ----- | 42 | C | A | A | A |
| 3 | C | A | ----- | | 43 | A | A | A | A |
| 4 | A | A | A | A | 44 | A | A | A | A |
| 5 | C | A | A | A | 45 | B | A | ----- | ----- |
| 6 | B | A | ----- | ----- | 46 | B | A | ----- | ----- |
| 7 | A | A | A | A | 47 | C | A | ----- | ----- |
| 8 | B | A | ----- | ----- | 48 | B | A | A | ----- |
| 9 | C | A | A | A | 49 | B | A | A | A |
| 10 | B | A | B | B | 50 | A | A | A | A |
| 11 | B | A | ----- | ----- | 51 | A | A | A | A |
| 12 | C | A | A | A | 52 | B | A | B | ----- |
| 13 | A | A | A | A | 53 | A | A | A | A |
| 14 | B | A | A | A | 54 | B | A | A | A |
| 15 | C | A | ----- | ----- | 55 | A | A | A | A |
| 16 | C | A | A | B | 56 | A | A | A | A |
| 17 | A | A | A | A | 57 | A | A | A | A |
| 18 | C | A | A | A | 58 | C | A | A | A |
| 19 | B | A | ----- | ----- | 59 | B | A | A | B |
| 20 | C | A | A | A | 60 | A | A | A | A |
| 21 | C | A | A | ----- | 61 | C | A | A | A |
| 22 | A | A | A | B | 62 | B | A | ----- | ----- |
| 23 | A | A | A | A | 63 | C | A | A | ----- |
| 24 | B | A | B | ----- | 64 | C | A | ----- | ----- |
| 25 | A | A | A | A | 65 | A | A | A | A |
| 26 | B | B | A | A | 66 | C | A | A | A |
| 27 | C | A | ----- | ----- | 67 | B | A | A | A |
| 28 | B | A | A | A | 68 | C | A | A | A |
| 29 | A | A | A | A | 69 | A | A | A | A |
| 30 | C | A | A | B | 70 | A | A | A | A |
| 31 | A | A | A | A | 71 | C | A | ----- | ----- |
| 32 | B | A | A | A | 72 | B | A | A | A |
| 33 | A | A | A | A | 73 | C | A | A | ----- |
| 34 | B | A | A | A | 74 | B | A | A | A |
| 35 | A | A | A | B | 75 | C | A | A | A |
| 36 | C | A | A | A | | | | | |
| 37 | A | A | A | A | | | | | |
| 38 | A | A | A | A | | | | | |
| 39 | C | A | ----- | ----- | | | | | |
| 40 | C | A | A | ----- | | | | | |

Annexure- VI

| GRADING OF MARGINAL INTEGRITY AMONG THREE GROUPS | | | | | | | | | |
|--|-----------|------|-------|-------|-------|-----------|------|-------|-------|
| SR.NO | COMPOSITE | MI 1 | MI 3 | MI 6 | SR.NO | COMPOSITE | MI 1 | MI 3 | MI 6 |
| 1 | B | A | A | A | 41 | B | A | A | A |
| 2 | B | A | A | ----- | 42 | C | A | A | A |
| 3 | C | B | ----- | ----- | 43 | A | A | A | B |
| 4 | A | A | A | A | 44 | A | A | A | A |
| 5 | C | A | A | A | 45 | B | A | ----- | ----- |
| 6 | B | A | ----- | ----- | 46 | B | A | ----- | ----- |
| 7 | A | A | A | A | 47 | C | A | ----- | ----- |
| 8 | B | A | ----- | ----- | 48 | B | A | A | ----- |
| 9 | C | A | A | A | 49 | B | A | A | A |
| 10 | B | A | B | B | 50 | A | A | A | A |
| 11 | B | A | ----- | ----- | 51 | A | A | A | A |
| 12 | C | A | A | A | 52 | B | A | A | ----- |
| 13 | A | A | A | A | 53 | A | A | A | A |
| 14 | B | A | A | A | 54 | B | A | A | A |
| 15 | C | A | ----- | ----- | 55 | A | A | A | A |
| 16 | C | A | A | B | 56 | A | A | A | A |
| 17 | A | A | A | A | 57 | A | A | A | A |
| 18 | C | A | A | A | 58 | C | A | A | A |
| 19 | B | A | ----- | ----- | 59 | B | A | A | A |
| 20 | C | A | A | A | 60 | A | A | A | A |
| 21 | C | A | A | ----- | 61 | C | A | A | A |
| 22 | A | A | A | A | 62 | B | A | ----- | ----- |
| 23 | A | A | A | A | 63 | C | A | A | ----- |
| 24 | B | A | A | ----- | 64 | C | A | ----- | ----- |
| 25 | A | A | A | A | 65 | A | A | A | A |
| 26 | B | A | A | A | 66 | C | A | A | A |
| 27 | C | A | ----- | ----- | 67 | B | A | A | A |
| 28 | B | A | A | A | 68 | C | A | A | A |
| 29 | A | A | A | A | 69 | A | A | A | A |
| 30 | C | A | A | A | 70 | A | A | A | A |
| 31 | A | A | A | A | 71 | C | A | ----- | ----- |
| 32 | B | A | A | B | 72 | B | A | A | A |
| 33 | A | A | A | A | 73 | C | A | A | ----- |
| 34 | B | A | A | A | 74 | B | A | A | A |
| 35 | A | A | A | A | 75 | C | A | A | A |
| 36 | C | A | A | A | | | | | |
| 37 | A | A | A | A | | | | | |
| 38 | A | A | A | B | | | | | |
| 39 | C | A | ----- | ----- | | | | | |
| 40 | C | A | A | ----- | | | | | |