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Amitha M Shagale
Lecturer, Department of
Pedodontics and Preventive
Dentistry, Bapuji Dental College
and Hospital, Davangere,
Karnataka, India

Hexeba Aby
Consultant Pedodontist and
Preventive Dentist, Kottayam,
Kerala, India

AR Prabhakar
Retired Head of Department,
Department of Pedodontics and
Preventive Dentistry, Bapuji
Dental College and Hospital,
Davangere, Karnataka, India

Deepak BM
Reader, Department of
Pedodontics and Preventive
Dentistry, Bapuji Dental College
and Hospital, Davangere,
Karnataka, India

Gudla Sreeja Reddy
Senior Lecturer, Department of
Pedodontics, Panineeya Dental
College, Hyderabad, India

Corresponding Author:
Hexeba Aby
Consultant Pedodontist and
Preventive Dentist, Kottayam,
Kerala, India

Clinical performance of Equia Forte: A glass hybrid GIC versus Tetric N Ceram; a bulk fill composite in class II carious primary molars: A 12 month split mouth clinical trial

Amitha M Shagale, Hexeba Aby, AR Prabhakar, Deepak BM and Gudla Sreeja Reddy

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Abstract

The present study aims to clinically evaluate the performance of a glass hybrid glass ionomer cement (GIC), Equia forte (GC India) and a bulk fill composite, Tetric N Ceram (Ivoclar Vivadent) in restoration of class II carious lesions in primary molars for a period of 12 months. A total of 39 patients of 5-9 years with occlusoproximal carious lesion on primary maxillary or mandibular molars were selected and randomly allotted into two groups i.e Group A (Equia Forte) and Group B (Tetric N Ceram). A total of 78 restorations (39 teeth for each group) was placed using Equia Forte and Tetric N Ceram using a split mouth design and were evaluated for a period of 12 months at regular time intervals using FDI criteria by two blinded examiners for esthetic, functional and biological properties. The data were analyzed using one way ANOVA for intragroup comparison and student t test for intergroup comparison. There was no statistically significant difference seen at baseline, 3, 6, 9 and 12 months for esthetic, functional and biological properties within the group. On inter group comparison, there was no statistically significant result observed except for functional property at 6 months with a p value of 0.02. The current study suggests that both Equia Forte and Tetric N Ceram can be a choice of restorative material in class II carious lesions in primary molars.

Keywords: Bulk fill composite, Equia Forte, FDI criteria, occlusoproximal caries, primary molars, split mouth study

1. Introduction

Dental caries is one of the most common chronic infections of childhood. Early carious involvement of primary teeth can have a negative impact on normal growth and development of a child^[1]. The pattern of dental caries varies between the primary and permanent dentition owing to morphological and histological differences. The less coalesced and deep fissure topography in primary molars makes these more susceptible to caries. They have broad flat contact, which leads to food impaction at the smooth surface and increases the incidence of the proximal cavity. Tal *et al* states that class II restorations are one of the common type of restoration in primary teeth. Timely diagnosis and treatment plan for infected primary teeth is important since it reduces unpleasant complications in a growing child^[2, 3, 4].

Since, the introduction of the concept of MID and increasing demand on esthetics, tooth colored materials enables conservative tooth preparation. GIC and resin composites, which satisfy these criteria, are the most commonly used materials in management of dental caries in primary teeth. The ability of resin composites to bond to the tooth surface and their superior esthetics made them an instant choice, but they are time consuming and the need for efficient moisture control makes it difficult to use in cases of an uncooperative child thereby compromising the success and longevity of the restoration^[5, 6].

The unique properties of GIC *viz.*, biocompatibility, adhesion to tooth structure, coefficient of thermal expansion almost equal to dental tissues, ability to release fluoride ions over a period makes this a near to an ideal material in pediatric dentistry. However, they have high occlusal wear, low fracture toughness and moisture sensitivity.

The success of GIC has been evaluated through various clinical studies and it is shown to be successful in non stress bearing areas. Even though there is an array of dental materials available, the paucity of standardized clinical studies make it difficult for the clinician to select the most appropriate material [5, 6].

The ability to work with speed and accuracy is the most important quality of a pediatric dentist. This can be possible only if we have materials that are easy to manipulate, reduce working time and give dependable results [6].

Recently, a glass ionomer system called Equia Forte (a combination of Equia Forte Fil and Equia Forte Coat- GC corp) which uses a special hybrid technology with fillers of different size was introduced with increased flexural strength, wear resistance, optimal marginal seal, high translucency and esthetics. Equia Forte with its tougher resin matrix and short setting time claims to be a better option in stress bearing restorations [7, 8, 9].

Considering, the lack of data regarding the clinical performance of Equia Forte on primary molars, the study was conducted to compare and evaluate Equia Forte (GC India) with composite resins in class II restorations in primary molars in a split mouth study design for a period of 12 months.

2. Materials and Methods

After obtaining ethical approval from IERB –Institutional Ethical Review board with the reference code BDC/Exam/383/2017-18. A total of 39 patients of 5-9 years satisfying the inclusion criteria was selected from outpatient department of Pedodontics and Preventive Dentistry, Bapuji dental college and hospital, Davangere to participate in this clinical trial. Informed written consent was taken from patient's parent / guardian after explaining about the purpose, procedure and time period of the study.

The inclusion criteria of the study comprised of patients presenting with proximal carious lesion on primary maxillary or mandibular molars on either side (bilateral / contralateral) of the mouth with definitively positive and positive behavior rating based on Frankel's behavior rating scale. [4, 10] Teeth with deep caries lesion, soft tissue abscess/sinus tract and grossly decayed and non-vital tooth were excluded from the study [10, 11].

After obtaining a detailed case history including patient's demographic details, medical history, and dental history, clinical evaluation was done by visual and tactile examination, palpation, percussion, mobility and periodontal examination for selection. Patients who satisfy inclusion criteria were selected to participate in the present split mouth study. After the selection of case, primary molars were randomly allotted to either of the groups using table of

random numbers [10].

The study groups include - Group A: glass ionomer cement (Equia Forte Fil and Equia Forte Coat) Group B: Resin composite (Tetric N Ceram)

Initial intra oral periapical radiographs of the teeth to be treated were taken before procedure.

After obtaining adequate isolation using rubber dam and saliva ejector, caries excavation and removal of undermined enamel was done using high speed diamond burs with water cooling and hand instruments. The cavity was aimed to be approximately with a depth of 0.5 mm in dentin and width of at least one-third of the occlusal table. Outline of the cavity was determined by the extent of the carious lesion. The prepared cavities were medium to large size with none of them involving any cusps. No beveling was done in any of the cavities. After finishing the cavity, a matrix band was placed with inter proximal wedge [12]. The prepared cavities was restored using Equia Forte on one side and bulk fill composite resin on another side of the mouth according to manufacturer's instructions.

For Group A, Equia Forte fil capsule was activated by plunging the capsule and mixed for 10 seconds in the amalgamator and was expressed from the capsule onto the cavity using an applicator gun. The restoration was trimmed and polished after proper setting of cement. Light curing of Equia Forte coat which was applied after gentle drying of the surface of restoration was done for 20 seconds using a visible light curing unit [13].

For Group B, The enamel and dentin were conditioned using 37 % phosphoric acid for 15 seconds and bonding agent was applied using a micro tip applicator and light curing was done for 20 seconds. Tetric N Ceram Bulk fill composite resin was applied in increments of max 4 mm and adapted to the cavity walls with a suitable instrument and light-cured for 20 seconds. Finally, the restoration was shaped and finished with diamond burs and finishing strips or discs [14].

Both the restorations were evaluated for occlusal high points and were corrected if any. Post-operative instructions was given to all the patients and all the restorations was clinically evaluated using FDI criteria for esthetic, biological and functional properties at baseline i.e. after one week and thereafter 3, 6, 9 and 12 months respectively. (Figure 1, 2, 3, 4) Recall examination was comprised of clinical examination by two independent blinded examiners, which included photographing the treated teeth and radiographs if necessary [15, 16]. In case of restorations with unsatisfactory results, details of the mode of failure were recorded and necessary treatment was carried out.

Clinical picture showing 3, 6, 9 and 12 month follow up of restoration done i.r.t 54 and 64 with Tetric N Ceram (Ivoclar Vivadent) and Equia Forte (GC India) respectively.



Fig 1: 3 months follow up



Fig 2: 6 months follow up



Fig 3: 9 months follow up



Fig 4: 12 months follow up

3. Statistics

The data obtained were tabulated and statistical analysis was done using SPSS software version 19. Mean and mean difference were obtained for evaluation of data within groups and between groups respectively. One - way ANOVA were used to compare the mean, while student t-test were used to compare the mean difference followed by Post Hoc Tukey test for pairwise comparisons at the different time intervals for all the test groups. Inter examiner variability was assessed by Wilcoxon signed ranks test. Probability value of less than 0.05 was considered for statistical significance.

4. Results

Intragroup comparison of esthetic, functional and biological properties at baseline, 3, 6, 9 and 12 months showed no significant difference in Group A with a p value of 0.20, 0.19

and 0.46 respectively (Table 1). Similar results were observed in Group B with a p value of 0.59, 0.30, and 0.59 respectively (Table 1).

Inter group comparison of esthetic property at baseline, 3, 6, 9 and 12 months showed no significant difference with a p value of 0.85, 0.80, 0.15, 0.90 and 0.15 respectively (Table 2). There was no statistical significant difference noted between groups for functional property at baseline, 3, 9 and 12 months with p values 0.32, 0.67, 0.60, 0.07 respectively (Table 3). Similar results were noted between groups at baseline, 3, 6, 9 and 12 months for biological properties with p values 0.41, 0.15, 0.32, 0.15, 0.56 respectively (Table 4). But a significant statistical significance were observed between the groups for functional property at 6 months with a p value of 0.023 (Table 3). No statistically significant change was observed in inter examiner variability with a p value of 0.52 (Graph 1).

Table 1: Descriptive statistics showing comparison of esthetic, functional and biological properties within Group A and Group B at baseline, 3, 6, 9 and 12 months

| Parameter | | Mean ± SD | | | | | f value | p value |
|-----------|------------|-----------|-----------|-------------|-------------|------------|---------|---------|
| | | Baseline | 3 months | 6 months | 9 months | 12 months | | |
| Group A | Esthetic | 1.33 ±.52 | 1.43 ±.78 | 1.66 ± 1.13 | 1.61 ±.93 | 1.76 ±.98 | 1.51 | 0.20 |
| Group B | | 1.30 ±.65 | 1.48±1.02 | 1.35 ±.70 | 1.58 ± 1.01 | 1.48 ±.72 | .70 | 0.59 |
| Group A | Functional | 1.20 ±.57 | 1.38 ±.93 | 1.76 ± 1.42 | 1.46 ± 1.12 | 1.61± 1.20 | 1.5 | 0.19 |
| Group B | | 1.10 ±.30 | 1.48±1.18 | 1.20 ±.52 | 1.33 ± 1.08 | 1.20 ±.73 | 1.5 | 0.30 |
| Group A | Biological | 1.02 ±.16 | 1 ±.0 | 1.10 ±.64 | 1.20 ±.89 | 1.20 ±.89 | .89 | 0.46 |
| Group B | | 1.07 ±.35 | 1.05 ±.22 | 1 ±.0 | 1 ±.0 | 1.10 ±.64 | .70 | 0.59 |

SD denotes standard deviation

p value represents the probability value $p < 0.05$ is considered significant

Table 2: Descriptive Statistics showing comparison of esthetic property between two groups at baseline, 3, 6, 9 and 12 months

| Parameter – Esthetic property | Baseline | 3 months | 6 months | 9 months | 12 months |
|-------------------------------|----------|----------|----------|----------|-----------|
| Mean difference | -0.025 | 0.051 | -0.307 | -0.025 | -0.282 |
| t value | -0.190 | 0.248 | -1.440 | -0.116 | -1.442 |
| p value | 0.850 | 0.805 | 0.154 | 0.908 | 0.153 |

SD denotes standard deviation

p value represents the probability value $p < 0.05$ is considered significant

Table 3: Descriptive statistics showing comparison of functional property between two groups at baseline, 3, 6, 9 and 12 months

| Parameter – functional property | Baseline | 3 months | 6 months | 9 months | 12 months |
|---------------------------------|----------|----------|----------|----------|-----------|
| Mean difference | -0.102 | 0.102 | -0.564 | -0.128 | -0.410 |
| t value | -0.989 | 0.423 | -2.32 | -0.514 | -1.81 |
| p value | 0.326 | 0.673 | 0.023* | 0.609 | 0.073 |

SD denotes standard deviation

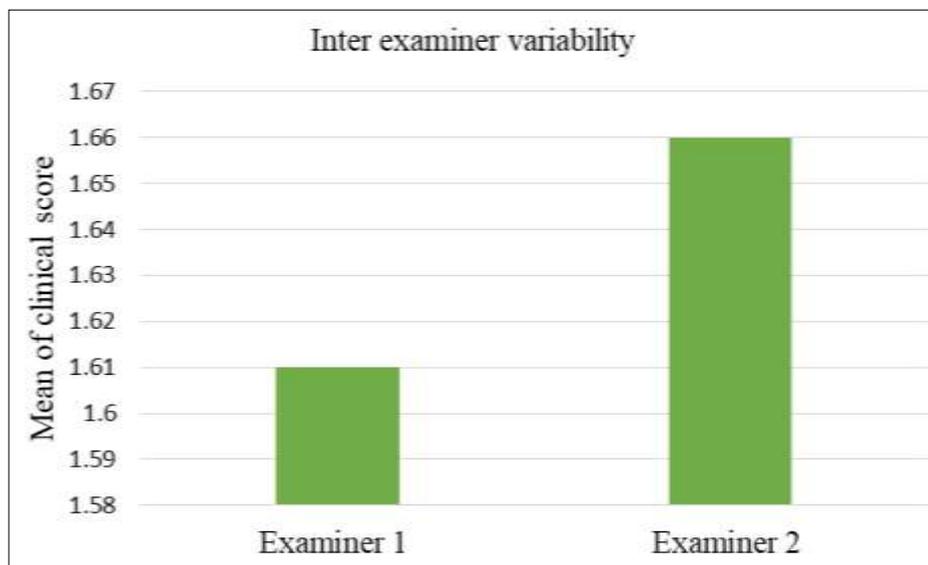
*p value represents the probability value $p < 0.05$ is considered significant

Table 4: Descriptive Statistics showing comparison of biological property between two groups at baseline, 3, 6, 9 and 12 months

| Parameter – biological property | Baseline | 3 months | 6 months | 9 months | 12 months |
|---------------------------------|----------|----------|----------|----------|-----------|
| Mean difference | 0.051 | 0.051 | -0.102 | -0.205 | -0.102 |
| t value | 0.824 | 1.43 | -1.0 | -1.43 | -0.58 |
| p value | 0.413 | 0.156 | 0.320 | 0.156 | 0.56 |

SD denotes standard deviation

p value represents the probability value $p < 0.05$ is considered significant



Graph 1: depicts inter examiner variability

5. Discussion

Caries management in a pediatric patient is an eclectic treatment procedure as it is affected by various factors such as cooperation of child, anatomical differences and individual caries risk. Based on the newer concepts and revised guidelines of pediatric restorative dentistry, caries management is not merely the restoration but also considering progression and prevention of lesion^[17]. Hence, selection of an appropriate restorative material should be based on sealing ability, adhesive, hydrophilic, physical, mechanical and bioactive properties^[18, 19].

Occlusoproximal surface, being the most common area affected by caries and the major site of load bearing area in primary molars shows high failure rate of restorations. Even though wide varieties of materials are available in dentistry there is a lack of an ideal material in restoration of load bearing areas^[20, 21]. Yengopal *et al* found that there is a lack of well designed clinical trials and lack of evidence for drawing conclusion regarding the type of restorative material in primary teeth^[22]. Pires *et al* had found high failure rate of conventional GIC in restoration of proximal lesions in primary molars^[23].

Equia forte a new encapsulated GIC with glass hybrid technology with improved physical and mechanical properties becomes an apt material of choice in restoration of load bearing areas. Moreover, application of Equia Forte Coat, a clear self adhesive light cured resin coat increases surface hardness and wear resistance^[24]. *In vitro* studies done by Poornima *et al* and Kutuk *et al* had shown improved compressive strength and fracture resistance of Equia Forte over others^[8, 9].

In this clinical trial, the clinical performance of Equia Forte was compared with a bulk fill composite in proximal carious lesions in primary molars. In order to provide an identical oral environment and to eliminate confounding variables and potential bias a randomized split mouth study design was adopted in the present clinical trial^[25, 26]. The use of FDI criteria for the assessment of clinical performance by two independent trained examiners aided in providing a standardized data for easy comparison of materials^[16].

5.1 Esthetic property

The findings of the present study had showed no significant difference in the clinical performance within the groups and

between the groups for esthetic property from baseline to 12 months. Improved clinical results of glass ionomer cement i.e., Equia Forte could be due to the application of Equia Forte coat which resulted in improved surface gloss and protection from external environment. This is supported by Davis *et al* who stated that the color changes in a restoration can be reduced by the use of protective coating over restorations^[27]. Similar findings were observed by Gurgun *et al* on comparison of Equia Fil and a micro hybrid composite in permanent teeth for a period of 5 years^[10].

In contrast to the findings of the present study, Balkaya *et al* and Diem *et al* stated significant difference in color match of Equia Forte and Equia Fil on comparison to composite in permanent teeth. However, Diem *et al* stated a steady increase in color match after 12 months and he stated that an improvement in translucency occurs as the cement matures^[28, 29].

5.2 Functional property

The present study showed no statistical significant difference between the functional property at baseline, 3, 6, 9 and 12 months interval among the scores in both the groups. Also no statistical significance was noted between groups at baseline, 3, and 9 months.

However, a significant difference was seen at 6 months as the p value was 0.02 and a considerable clinical difference at 12 months as the p value obtained was 0.07. This significant difference at 6 months can be attributed to loss of retention, marginal adaption and fracture of restoration with partial loss of restoration in Group A and due to chip fracture and marginal fracture of restoration in one case in Group B. Whereas at 12 months, the difference noted could be due to the loss of retention and chip fracture in group A and due to periapical pathology in one case in Group B even when the restoration was functionally intact. One possible reason for this could be due to presence of marginal gap in restoration tooth interface contributing to the micro or nano leakage which though can't be assessed clinically in the present study^[30]. The findings of the present study regarding functional properties of both groups are consistent with the observations done by Balkaya *et al* in permanent teeth after a period of 12 months^[28].

The reason for poor clinical performance in Group A can be due to ineffective application of resin coat at proximal surface

due to poor accessibility, chemical adhesion of GIC to metal matrix band leading to formation of microcrack while removal as reported by Tal *et al* and Balkaya *et al*.^[4, 28] Hence, Equia Forte can be used with a survival rate of 6 months considering its functional properties.

5.3 Biological property

No statistical significance was observed with respect to biological properties within the groups and between the groups at baseline, 3,6, 9 and 12 months. There was a failure of only 2 cases and one case in group A and group B respectively. Periapical pathology was the reason for failure in both groups.

There is a scarcity of literature regarding the clinical evaluation of EQUIA Forte and Tetric N Ceram in class II restorations in primary molars using the FDI criteria for esthetic, functional and biological properties. Therefore, the findings in the present study was compared with those studies wherein the USPHS criteria and other modified criterias were used. Hence, it is difficult to correlate the results of the present study with the existing literature.

Thereby the present clinical study emphasizes the need for future clinical studies with longer observation period with standardized evaluation criteria.

6. Conclusion

1. Restoration of load bearing areas in primary molars using EQUIA Forte and Tetric N Ceram showed no significant difference in clinical performance for a period of 12 months.
2. EQUIA Forte can be an acceptable restorative material in small to medium sized class II cavities in primary molars considering the ease of application in pediatric patients.
3. EQUIA Forte can be the choice of restoration in carious primary molars, which are expected to exfoliate within 6 months.

7. Clinical recommendation

The use of composite resin can be an alternative option in restoration of primary molars in children with better cooperation ability and low caries risk because of its superior functional property.

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