Survival of Hybrid Laminate Veneers using two different tooth preparation techniques: Randomized Clinical Trial

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The aim of this study was to evaluate the survival of laminate veneers constructed using a recent polymer-infiltrated ceramic network material following the aesthetic pre-evaluative temporary (APT) technique of tooth preparation in comparison to traditional technique. Six patients received 54 laminate veneers. They were divided into two equal groups (n=27) according to the technique of tooth preparation: group T: traditional technique and group A: aesthetic pre-evaluative temporary technique. VITA ENAMIC material was used for CAD/CAM construction of laminate veneers. Cementation was performed using a light cured resin cement. The laminate veneers were evaluated at baseline, after 3, 6 and 12 months according to the modified United States Public Health Service (USPHS) criteriea. The data was collected, tabulated and statistically analyzed. Secondary caries, endodontic complications, cracks and loss of retention were not noted in any laminate veneer. Extensive fractures were not detected in both study groups through the study period. There was a statistically significant decrease of color match criteria between the two groups at the 6 and 12 months recalls. Based on this study, both preparation techniques resulted in successful clinical performance. After 12 months, all the veneers in both groups showed no post-operative sensitivity and all patients were highly satisfied regarding their veneers. However, there was a deterioration in color match criteria through the study period in both study groups.

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Introduction

Laminate veneers are a minimally invasive esthetic restorative option with a high rate of long-term success (1-3). They can provide esthetic improvement in case of discolored, fractured, worn, congenitally malformed teeth or in case of diastemas (4).

Although early protocols suggested no tooth preparation, current opinion supports enamel reduction to remove the aprismatic enamel surface, which reportedly has a reduced retention capacity. Thus, tooth preparation improves laminate veneers bonding to the tooth surface (5). However, mechanical interlocking with enamel is more stable than the bond to dentin, which is more humid, has a less homogenous nature, and may have areas of sclerosis. Larger quantity of remaining enamel results in less tooth flexion and reduced fractures and debonding (6) Thus, tooth preparation involving only the enamel surface may improve the success of laminate veneers (1, 5, 7).

There are two techniques for tooth preparation for laminate veneers; the traditional technique and the aesthetic preevaluative temporary technique (APT). In the traditional technique, tooth preparation is performed directly on the tooth structure. In the aesthetic preevaluative temporary (APT) technique, tooth preparation is performed through the APT which represents the final volume of the restoration (6). This will ensure more enamel preservation and may improve the clinical performance of laminate veneers(7–9).

Numerous CAD/CAM materials with varying shades and translucency have been introduced for the construction of laminate veneers. A polymer infiltrated ceramic network material with dual network structure has properties that imitate natural teeth. This material has high flexural strength, similar abrasion resistance and elasticity close to dentin. In addition, it is characterized by high edge stability during CAD/CAM milling. Therefore, hybrid ceramics are ideal materials for minimally invasive restorations (10).

There are limited clinical studies regarding the success of hybrid laminate veneers using the APT technique. Therefore, in this study, the survival of laminate veneers constructed using a recent polymer-infiltrated ceramic network material following the APT technique of tooth preparation was evaluated in comparison to traditional technique. The null hypothesis was that there would be no difference in survival of polymer infiltrated ceramic network veneers fabricated using the APT technique of tooth preparation in comparison to the traditional technique.

Materials and methods

The material used in this study is VITA ENAMIC (Vita Zahnfabrik, Bad Sackingen, Germany) which is a hybrid ceramic material formed of interpenetrating network of ceramic (75% vol) and acrylate polymer (25% vol)(11).

Study Design

This trial is registered at ClinicalTrials.gov, number NCT04515069. The protocol of this clinical study was approved and given a number 151021 by the Ethics Committee of Faculty of Dentistry, Cairo University. The clinical study was performed in the outpatient clinic of the Fixed Prothodontics Department, Faculty of Dentistry, Cairo University. This clinical trial is a Parallel group study with allocation Ratio 1:1

Sample Size Calculation

Based on a previous study(5), 98% of laminate veneers scored alfa. A total sample size of 54 laminate veneers (27 in each group) was sufficient to reject the null hypothesis that the failure rate for experimental and control subjects are equal with probability (power) 0.8. The type I error probability associated with this test of this null hypothesis is 0.05. Sample size was calculated by PS (power and sample size).

Patient's selection

Six recruited patients (4 females, 2 males; ranging from: 20–30 years old and with mean age 24.6 years), who needed indirect laminate veneer restorations were included in this study. Patients were selected from the outpatient clinic of the Department of Fixed Prosthodontics, Faculty of Dentistry, Cairo University The participants received a total of 54 laminate veneers between April 2017 and February 2018. Written informed consent was acquired from all participating patients. Inclusion criteria were as follows: slightly malaligned teeth, malformed teeth, multiple spacing, diastema, slightly and moderately discolored teeth. Patients who were medically compromised, had poor oral hygiene or parafunctional habits were excluded from the study. Also, previously restored teeth were precluded from the study. A meticulous clinical procedure was carried out by one operator (the researcher) to complete all the laminate veneer restorations.

Diagnosis and Treatment planning

After comprehensive clinical examination, standard preoperative patients photographs, primary upper and lower impressions were obtained using alginate impression material (CA 37, Cavex; Haarlem, The Netherlands) to prepare the study casts. Digital smile design (DSD) was used for smile analysis using DSD templates in power point presentation (Microsoft Office Power Point) following DSD protocol (12) (Figure 1).



Figure 1. (A) Pre-operative frontal smile. (B)Pre-operative frontal retracted view showing multiple spacing. (C)Digital smile design: drawing upper anterior teeth outlines. (D) Final result of the digital smile design.

Sample grouping

A total of 54 laminate veneers were divided into two groups (n=27) according to the technique of tooth preparation:

Group T: Traditional technique for tooth preparation.

Group A: Aesthetic preevaluative temporary technique for tooth preparation.

Randomization was done using a computer generated 2-column list by the aid of Random.org with allocation ratio 1:1. Allocation concealment was achieved using numbered cards in opaque sealed envelopes. Aluminum foil was placed inside the envelope to render the envelope impermeable to intense light. These envelopes were placed in a box and each participant was allowed to grasp one envelop the day of operation. An investigator with no involvement in the trial performed allocation concealment. This study is a single blinded study as the assessor was blinded to the assigned study groups. Blinding of the participants was not applicable as one of the techniques required extra visits. Blinding of the operator was not applicable as one clinician performed the tooth preparation in both techniques.

Construction of Hybrid Ceramic Veneers

1. Diagnostic wax up:

According to the data obtained from the digital smile design, the diagnostic wax up was fabricated using Renfert wax (GEO Classic - Renfert, USA) in the anterior region.

In case of group T, teeth were first prepared on the study cast as to be prepared in the patient's mouth. Then, the diagnostic wax up was constructed. In case of group A, additive technique of wax up was used for construction of the wax-up according to the digital smile design. Wax was added to the study casts without tooth preparation (Figure 2A). Aesthetic pre-recontouring (APR) was used when there were tooth areas in extreme labial position. These areas needed to be prepared on the study casts before wax up construction to keep the finished veneers in one level with the rest of the arch (Figure 2B).



Figure 2. Construction of Group A veneers (A) Additive wax-up (B) Reductive Wax up: Tooth areas in extreme labial position that needed to be removed before construction of diagnostic wax-up (C) Spot etching (D) Silicon matrix filled with Bis-acrylic material seated inside patient's mouth (E) Finished Aesthetic Preevaluative Temporary (APT) (F) Depth Grooves performed through the APT (G) Finished tooth preparation (H) Cheek retracted view after cementation and finishing (I) Post operative Patient's smile

2. Silicon Matrix Construction:

Three silicone impressions (Speedex, Coltene, USA) were taken from the diagnostic wax-up:

- 2.a. Silicone matrix for provisional restoration and the aesthetic pre-evaluative temporary.
- 2.b. Vertical Silicone index for determination of the amount of tooth reduction was formed by sectioning the index in vertical direction inciso-gingivally.
- 2.c. Horizontal Silicone index was made by creating a palatal window using #11 blade (Delta Med Surgical, Pakistan) which was cut and removed. This palatal part is used to determine the amount of incisal reduction. The remaining buccal index was sliced into three horizontal layers to evaluate the amount of reduction at the incisal, middle and cervical thirds of the labial surface. Figure 3.



Figure 3. Horizontal index sliced into incisal, Middle and cervical layers

3. Tooth Preparation:

3.a. Tooth Preparation for Group T:

Depth cutter wheels of predetermined depths (Komet, Germany) were used to perform the preparation directly on the tooth structure. (Figure 4)



Figure 4. Tooth preparation for Group T veneers (A) Pre-operative photograph showing diastema. (B) Depth cuts performed directly on the tooth structure (C) Final Tooth preparation carried out directly on the tooth structure

The labial reduction

Depth cuts were performed using depth cutter wheels (Komet, Germany) with radius of 0.3 mm and 0.5 mm which is directly related to the thickness of the laminate veneers in the cervical and incisal one thirds respectively. Using tapered stone with round end (Mani, Japan), islands of tooth structure between depth orientation grooves were removed. The labial reduction was carried out at three different angles in order to conform to the facial convexity of the tooth structure and to achieve consistent thickness of laminate veneer. A supragingival chamfer finish line 0.3 mm deep was created. The horizontal silicone index was used to check the facial clearance.

Proximal reduction

The interproximal reduction was completed just labial to the contact areas using a round end tapered diamond stone (Mani, Japan), and polishing was performed using polishing strips (Sof-Lex, 3M ESPE, Seefeld, Germany) to create smooth and even surfaces.

In cases of diastemas, proximal slot preparation was performed where the proximal surface was flattened and the proximal margin was placed at the proximo-palatal line angle.

Incisal reduction

Vertical depth grooves were created. Then, the round end tapered diamond stone (Mani, Japan) was placed parallel to the incisal edge creating 1.5 mm incisal butt joint preparation. The palatal index was used to assess incisal clearance.

Finishing and polishing of tooth preparation

Fine-grit round-end tapered diamond stone (Mani, Japan) was used for finishing of the preparation and roundation of sharp line and point angles. The polishing of the preparation was done using sequential disks (Sof-Lex, 3M ESPE, Seefeld, Germany).

3.b. Tooth Preparation for Group A:

In Group A, tooth preparation was performed through the Aesthetic Pre-evaluative temporary. The APT was used as a precise guide to prepare the tooth structure based on the planned final tooth contours.

Before construction of the Aesthetic Pre-evaluative Temporary, spot etching was performed on the teeth to be prepared (Figure 2C). Then, the silicon matrix was filled with Bis-acrylic material (Protemp, 3M ESPE, Seefeld, Germany) and seated rapidly in the patient's mouth (Figure 2D). After setting of bis-acrylic material, the putty matrix was removed and the mockup was finished and polished (Figure 2E).

The Aesthetic Pre-evaluative temporary was then evaluated esthetically and functionally by the operator and the patient. Different lip positions were evaluated to confirm incisal length during smiling and at rest. Phonetic tests were carried out to evaluate the incisal edge position vertically and buccolingually in relation to the vermilion border of the lower lip in F,V sounds. The patient was allowed to try the mock up for two weeks, which is the minimal time, required for the patient to be deprogrammed from the preoperative situation. After two weeks, necessary adjustments were performed until the mockup was approved by the operator and the patient.

Intraoral and extraoral photographs were obtained to be used as a reference during veneers construction. Before teeth preparation, the Aesthetic Pre-evaluative temporary was scanned using Cerec Omnicam (Sirona Dental System, Bensheim, Germany) to be used later on as a reference during the design phase of the CAD/CAM fabrication of laminate veneers.

The labial reduction

Depth cuts were performed similar to those performed in the traditional preparation with the difference of being prepared on the aesthetic pre-evaluative temporary instead of directly on the dental structure (Figure 2F). Using tapered stone with round end (Mani, Japan), islands of tooth structure between depth orientation grooves were removed. The tooth structure underwent only the minimal necessary preparation or even no preparation in certain areas. The remaining parts of the APT restoration were removed for the final detailed preparation and finishing of the 0.3 mm deep cervical finish line (Figure 2G). The horizontally sectioned silicone index from the wax up was used to check the facial clearance.

Proximal reduction, Incisal reduction Finishing and polishing of tooth preparation were carried out using the same technique as in group T.

4. Construction of Provisional Veneers:

Temporary veneers were made chair-side using an auto-polymerized Bis-acrylic composite temporary material. (Protemp II, 3M ESPE, Germany) Enamel was spot etched with 37% phosphoric acid (Scotchbond Universal Etchant, 3M ESPE) for 30 seconds before application of the temporary material.

5. Fabrication of Hybrid Ceramics Veneers:

The CAD/CAM system CEREC Premium CAM SW 4.4 (Sirona Dental System, Bensheim, Germany) was used for construction of laminate veneers (Figure 4). In the adminstration phase, the mode biogeneric copy was selected. Cerec omnicam (Sirona Dental System, Bensheim, Germany) was used for intraoral scanning. In case of group T, an optical impression of the wax up was obtained to allow veneer designing similar to the wax up. In case of group A, the approved aesthetic preevaluative temporary was scanned to be used in designing similar veneer restorations. After tooth preparation, prepared teeth in both arches were scanned (Figure 5A). Then, the patient's bite was also scanned. During the design phase, the copy line was adjusted. Veneer parameters were defined such as 40 μ m spacer thickness. (13) MC XL milling machine was chosen to perform the milling process using extra fine mode (Figure 5D).

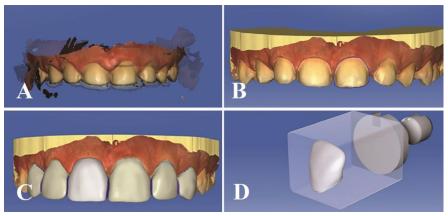


Figure 5. (A) Intra-oral scanning using Cerec Omnicam (B) Marking of prepation finish line(C) Veneers designed according to the scanned APT (D) Designed veneer ready for milling.

Try-in

The veneers were carefully tried in without pressure to confirm their fit. To determine the correct luting shade, veneers were tried in using RelyX Veneer try-in paste (3M ESPE, Seefeld, Germany) without isolation of the working field as teeth drying temporarily lightens the tooth structure.

Finishing and polishing of VITA ENAMIC veneers

Laminate veneers were finished and polished using 2-step VITA ENAMIC technical Kit (Vita Zahnfabrik, Bad Sackingen, Germany) as suggested by the manufacturer.

Surface Pretreatment of VITA ENAMIC Veneers

The internal surfaces were treated with 5 % hydrofluoric acid etching gel (VITA CERAMICS ETCH, Vita Zahnfabrik, Germany) for 60 seconds followed by application of the silane coupling agent (Monobond Plus, Ivoclar Vivadent AG) that was allowed to evaporate for 3 minutes and air dried for 30 seconds.

Cementation of Laminate Veneers

37% Phosphoric acid etchant was applied over the enamel surfaces for 15 seconds. Then, it was rinsed for 10 seconds. Two successive layers of adhesive (Adper Single Bond Plus) were applied to the tooth preparation. Then, they were gently air dried. Light cured resin cement (RelyX Veneer Cement, 3M ESPE, Seefeld, Germany) was used for veneer cementation. Veneers were cervically pre-cured for 5 seconds and excess resin cement was removed using hand instruments and dental floss. Then, each surface was cured for 40 seconds with a light-emitting diode polymerizing unit.(Elipar II, light-curing device) Vita Enamic clinical polishing set (Vita Zahnfabrik, Bad Sackingen, Germany) was used for finishing and polishing of veneer margins. The cement in the interproximal areas was removed using interproximal polishing strips (Soft-Lex Finishing Strips, 3M ESPE; Seefeld, Germany). A final check of occlusion was performed in lateral and protrusive movements.

Evaluation of Survival of VITA ENAMIC Laminate veneers

Patients were called back after 1 week as the baseline to assess the veneer restorations. Assessment was carried out by an experienced observer blinded to the assigned study group for each patient. Laminate veneers were examined at baseline, after 3, 6 and 12 months according to the modified United States Public Health Service (USPHS) criteriae (13–16) and the USPHS scores of Alfa, Bravo and Charlie were used for rating Table 1. Patients were also questioned about possible post-operative complaints. Digital photographs were made after placement of the veneers and during follow-up sessions.

Table 1. Modified United States Public Health Service Criteria

Outcome	Measuring Device	Score	Characteristics
Secondary caries	Visual inspection, explorer	-Alfa -Bravo -Charlie	-No evidence of caries at margin of restoration -Caries at the margin of restoration -N/A
Marginal adaptation	Visual inspection, explorer	-Alfa -Bravo -Charlie	 -No visible evidence of crevice along margin, no catch or penetration of explorer -visible evidence of crevice and/or catch of explorer, no penetration of explorer -visible evidence of crevice and explorer penetration
Marginal discoloration	Visual inspection	-Alfa -Bravo -Charlie	 -No discoloration at the margin -Superficial discoloration at the margin, does not penetrate in pulpal direction -Discoloration has penetrated along the margin in pulpal direction
Color match	Visual inspection, VITA shade guide, VITA Zahnbabrik	-Alfa -Bravo -Charlie	 -No mismatch in color, shade, and/ or translucency between restoration and adjacent tooth -Mismatch between the restoration and tooth structure within normal range of color, shade and/ or translucency (<1 shade off) - Mismatch between the restoration and tooth structure outside normal range of color, shade and/ or translucency (>1 shade off)
Endodontic complications	Cold vitality test	Yes/No	-Vitality Negative -Percussion positive
Fracture	Modified USPHS criteria	-Alfa -Bravo -Charlie	-None -Minimal/acceptable -Extensive/unacceptable
Crack	Visual inspection, explorer	-Alfa -Bravo -Charlie	-None -Minimal/acceptable -Extensive/unacceptable
Retention of the veneer	Modified USPHS criteria	-Alfa -Bravo -Charlie	-Bonded -Rebonded -Lost
Gingival Response	Visual inspection, periodontal probe	-Alfa -Bravo -Charlie	-Healthy -Calculus or gingivitis -Pocketing and bleeding present
Postoperative sensitivity	Explorer	-Alfa -Bravo -Charlie	-No symptoms -Slight sensitivity -Moderate pain
Patient satisfaction	Modified USPHS criteria	-Alfa -Bravo -Charlie	-High -Moderate -Not satisfied

Statistical Analysis

Qualitative data were provided as frequencies and percentages. Comparison between the two groups was excuted using Fisher's Exact test. Cochran's Q test was employed to study the changes by time within each group. The significance level was specified at $P \le 0.05$. Statistical analysis was achieved using IBM (IBM Corporation, NY, USA) SPSS (SPSS, Inc., an IBM Company) Statistics Version 20 for Window.

Results

The study was conducted on 6 patients; 4 females (66.7%) and 2 males (33.3%). The mean (SD) values for age were 24.6 (2.2) years old with a minimum of 20 and a maximum of 30 years old. Participant recruitment and allocation are represented in Figure 6.

Results of USPHS criteria for evaluation of Group T and Group A veneers at baseline, 3 months, 6 months and 12 months are outlined in table 2.

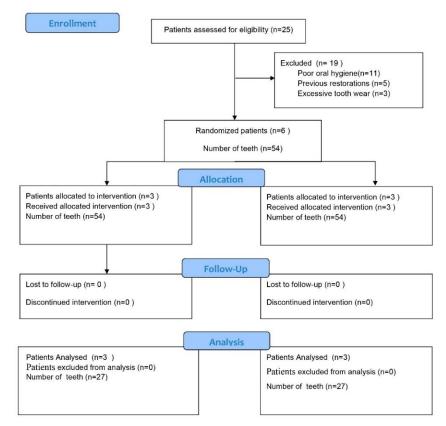


Figure 6. Patients flow diagram including detailed information on the excluded participants.

Table 2. Results of USPHS criteria for evaluation of Group T and Group A veneers

		Baseline				3 months			6 months			12 months					
Criteria	Score		Т	A	١		T		A		T		А		T		А
		n	0/0	n	0/0	n	0/0	n	0/0	n	0/0	n	0/0	n	0/0	n	%
Secondary	Alfa	27	100	27	100	27	100	27	100	27	100	27	100	27	100	27	100
caries	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
carics	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Marginal	Alfa	27	100	27	100	27	100	27	100	26	96.3	24	88.9	26	96.3	24	88.9
adaptation	Bravo	0	0	0	0	0	0	0	0	1	3.7	3	11.1	1	3.7%	3	11.1
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Marginal	Alfa	27	100	27	100	27	100	27	100	27	100	25	92.6	26	96.3	26	96.3
discoloration	Bravo	0	0	0	0	0	0	0	0	0	0	2	7.4	1	3.7	1	3.7
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.1	Alfa	27	100	27	100	27	100	27	100	27	100	21	77.8	7	25.9	23	85.2
Color match	Bravo	0	0	0	0	0	0	0	0	0	0	6	22.2	20	74.1	4	14.8
Franka da satia	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Endodontic complications	Yes/No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
	Alfa	27	100	27	100	26	96.3	27	100	26	96.3	26	96.3	26	96.3	26	96.3
Fracture	Bravo	0	0	0	0	1	3.7	0	0	1	3.7	1	3.7	1	3.7	1	3.7
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Alfa	27	100	27	100	27	100	27	100	27	100	27	100	27	100	27	100
Crack	Bravo	0	0			0	0	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Retention of	Alfa	27	100	27	100	27	100	27	100	27	100	27	100	27	100	27	100
the veneer	Bravo	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Gingival	Alfa	27	100	27	100	23	85.2	22	81.5	23	85.2	23	85.2	23	85.2	24	88.9
Response	Bravo	0	0	0	0	4	14.8	5	18.5	4	14.8	4	14.8	4	14.8	3	11.1
	Charlie Alfa	0 27	0 100	0 27	0 100	0 25	0 92.6	0 27	0 100	0 25	0 92.6	0 27	0 100	0 27	0 100	0 27	0 100
Postoperative	Bravo	0	0	0	0	25 2	92.6 7.4	0	0	25 2	92.6 7.4	0	0	0	0	0	0
sensitivity	Charlie	0	0	0	0	0	7.4 0	0	0	0	7. 4 0	0	0	0	0	0	0
	Alfa	27	100	27	100	27	100	27	100	25	92.6	24	88.9	27	100	27	100
Patient	Bravo	0	0	0	0	0	0	0	0	23	7.4	3	11.1	0	0	0	0
satisfaction	Charlie	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C	cnariie	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U	U

Marginal adaptation

Comparison between group T and group A regarding marginal adaptation is represented in Table 3 and Figure 7. At base line as well as after 3 months; all veneers in the two groups showed no visible evidence of crevice, catch or penetration of explorer along the margin (Alpha score). At the 6 months and 12 months recalls, 3.7% of veneers in Group T (n=1) and 11.1% (n=3) of veneers in Group A showed visible evidence of crevice and/or catch of explorer, but no penetration of explorer (Bravo score). However, there was no statistically significant difference between the two groups (P-value = 0.610, Effect size = 0.141). For Group A; there was a statistically significant change in marginal adaptation criteriea through the study period (P-value = 0.029)

Table 3. Descriptive statistics and results of Fisher's Exact test for comparison between marginal adaptation in the two groups

Time		Group T (n = 27)		ıp A 27)	<i>P</i> -value	Effect size (v)
	n	0/0	n	0/0		
Base line Alpha	27	100	27	100	NC ⁺	
3 months Alpha	27	100	27	100		NC ⁺
6 months Alpha Bravo	26 1	96.3 3.7	24 3	88.9 11.1	0.610	0.141
12 months Alpha Bravo	26 1	96.3 3.7	24 3	88.9 11.1	0.610	0.141

^{*:} Significant at $P \le 0.05$, NC*: Not Computed because the variable is constant

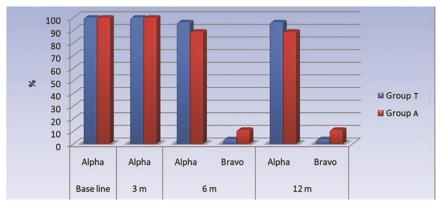


Figure 7. Bar chart representing marginal adaptation scores in the two groups.

Marginal discoloration

Comparison between group T and group A regarding marginal discoloration is represented in Table 4 and Figure 8. At base line as well as after 3 months; all veneers in the two groups showed no marginal discoloration (Alpha score). After 6 months, 100% of veneers in Group T and 92.6% of the veneers in Group A (n=25) showed no marginal discoloration (Alpha score). However, there was no statistically significant difference between the two groups (P-value = 0.491, Effect size = 0.196). After 12 months, 96.3% of veneers (n=26) in Group T and Group A showed no marginal discoloration (Alpha score). Within each group, there was no statistically significant change in the marginal discoloration criteria through the study period (for group T P-value = 0.392 and for goup A P-value = 0.194).

Table 4. Descriptive statistics and results of Fisher's Exact test for comparison between marginal discoloration in

the two groups

Time		Group T (n = 27)		ıp A 27)	P-value	Effect size (v)
	n	0/0	n	0/0		
Base line Alpha	27	100	27	100		NC ⁺
3 months Alpha	27	100	27	100		NC ⁺
6 months Alpha Bravo	27 0	100 0	25 0	92.5 7.4	0.491	0.196
12 months Alpha Bravo	26 1	96.3 3.7	26 1	96.3 3.7	1.000	0.000

^{*:} Significant at $P \le 0.05$, NC*: Not Computed because the variable is constant

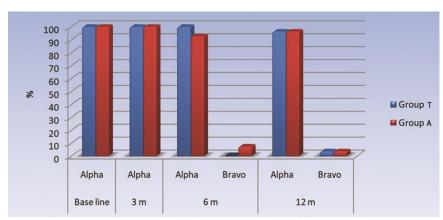


Figure 8. Bar chart representing marginal discoloration scores in the two groups

Color match

Comparison between group T and group A regarding color match is represented in Table 5 and Figure 9. At base line as well as after 3 months; all veneers in the two groups showed no mismatch in color, shade, and/ or translucency between the veneer and adjacent tooth (Alpha score). After 6 months, 100% of veneers in Group T (n=27) and 77.8% of the veneers in Group A (n=21) showed (Alpha score). Group T showed statistically significantly higher prevalence of (Alpha) score than Group A (P-value = 0.023, Effect size = 0.354). After 12 months, 25.9% of veneers (n=7) in Group T and 85.2% of the veneers (n=23) in Group A showed (Alpha) score. Group T showed statistically significantly lower prevalence of (Alpha) score than Group A (P-value <0.001, Effect size = 0.596). As for Group T; the prevalence of (Bravo) score was statistically significantly higher at the 12 months recall (P-value <0.001) (Table 9, Figure 11) while for Group A; there was statistically significant increase in incidence of (Bravo) score at the 6 months as well as 12 months recalls. (P-value = 0.002)

Table 5. Descriptive statistics and results of Fisher's Exact test for comparison between color match in the two groups

Time		Group T (n = 27)		ıp A 27)	<i>P</i> -value	Effect size (v)
	n	0/0	n	0/0		
Base line Alpha	27	100	27	100		NC [†]
3 months Alpha	27	100	27	100		NC [†]
6 months Alpha Bravo	27 0	100 0	21 6	77.8 22.2	0.023*	0.354
12 months Alpha Bravo	7 20	25.9 74.1	23 4	85.2 14.8	<0.001	0.5996

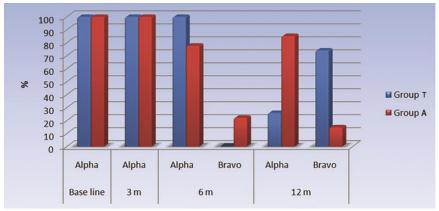


Figure 9. Bar chart representing color match scores in the two groups

The deterioration in color match criteria was in the form of generalized discoloration. Two step finishing and polishing was performed using Vita Enamic clinical polishing set (Vita Zahnfabrik, Bad Sackingen, Germany) as suggested by the manufacturer. In the first step, the pre-polishing pink rubber disc was applied with a speed of 10,000 rpm. For the second step, the high gloss polishing grey disc was used with a speed of 5000 rpm.

Fracture

Comparison between group T and group A regarding veneer fracture is represented in Table 6 and Figure 10. At base line; all veneers in the two groups showed no fracture (Alpha score). After 3 months, 96.3% (n=26) of veneers in Group T and 100% of the veneers in Group A showed no fracture (Alpha score). However, there was no statistically significant difference between the two groups (P-value = 1.000, Effect size = 0.137). At the 6 months and 12 months recalls, 96.3% (n=26) of veneers in Group T and Group A, showed (Alpha) score. Within each group, there was no statistically significant change in the fracture criteria through the study period. (For group T, P-value = 0.792 and for group A, P-value = 0.410)

Table 6. Descriptive statistics and results of Fisher's Exact test for comparison between fracture in the two groups

Time		Group T (n = 27)		ıp A 27)	<i>P</i> -value	Effect size (v)
	n	0/0	n	0/0		
Base line Alpha	27	100	27	100		NC ⁺
3 months Alpha Bravo	26 1	96.3 3.7	27 0	100 0		NC ⁺
6 months Alpha Bravo	26 1	96.3 3.7	26 1	96.3 3.7	1.000	0.000
12 months Alpha Bravo	26 1	96.3 3.7	26 1	96.3 3.7	1.000	0.000

^{*:} Significant at $P \le 0.05$, NC*: Not Computed because the variable is constant

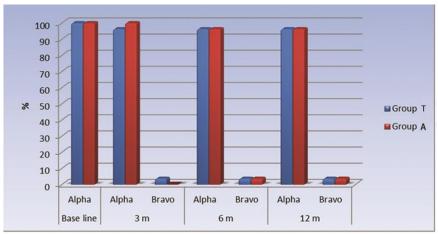


Figure 10. Bar chart representing fracture scores in the two groups

A total of three veneer fractures were observed during the follow-up period. Two veneers exhibited clinically acceptable cohesive fractures (Bravo score) in the incisal edge that required only finishing and polishing (Figures 14A and B).

Another veneer fracture was observed at the incisal angle of upper lateral incisor during the 3 months recall. It was noted that the patient developed a parafunctional habit of bruxing in a lateroanterior excursive movement. Upon relief of the occlusal contacts in this position, finishing, polishing and providing a nightguard, no further fractures were observed for this patient until the end of the follow-up period.

Gingival response

Comparison between group T and group A regarding gingival response is represented in Table 7 and Figure 11. At base line; all veneers in the two groups showed healthy gingiva (Alpha score). After 3 months, 85.2% (n=23) of the veneers in Group T and 81.5% (n=22) of the veneers in Group A showed (Alpha score) However, there was no statistically significant difference between the two groups (P-value = 1.000, Effect size = 0.050). After 6 months, 85.2% (n=23) of veneers in both study groups showed (Alpha score). After 12 months, 85.2% (n=23) of the veneers in Group T and 88.9% (n=24) of the veneers in Group A showed healthy gingiva (Alpha score). However, there was no statistically significant difference between the two groups (P-value = 1.000, Effect size = 0.055).

Table 7. Descriptive statistics and results of Fisher's Exact test for comparison between gingival response in the two groups

Time		Group T (n = 27)		ıp A 27)	<i>P</i> -value	Effect size (v)
	n	0/0	n	0/0		
Base line Alpha	27	100	27	100		NC ⁺
3 months Alpha Bravo	23 4	85.2 14.8	22 5	81.5 18.5		NC ⁺
6 months Alpha Bravo	23 4	85.2 14.8	23 4	85.2 14.8	0.491	0.196
12 months Alpha Bravo	23 4	85.2 14.8	24 3	88.9 11.1	1.000	0.000

^{*:} Significant at $P \le 0.05$, NC^{\dagger} : Not Computed because the variable is constant

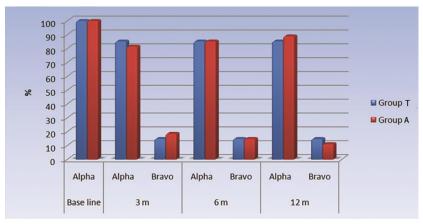


Figure 11. Bar chart representing gingival response scores in the two groups

Post-operative Sensitivity

Comparison between group T and group A regarding post-operative sensitivity is represented in Table 8 and Figure 12. At base line; all veneers in the two groups showed no symptoms of post-operative hypersensitivity (Alpha score). At the 3 months and the 6 months recall, 92.6% (n=25) of veneers in Group T and 100% of the veneers in Group A showed no post-operative hypersensitivity (Alpha score) However, there was no statistically significant difference between the two groups (*P*-value = 0.491, Effect size = 0.196). After 12 months, all veneers in the two groups showed (Alpha) score. As regards Group T; there was no statistically significant change in post-operative sensitivity criteria through the study period (*P*-value = 0.261). In Group A; all veneers presented with an (Alpha) score through the course of the study.

Table 8. Descriptive statistics and results of Fisher's Exact test for comparison between post-operative sensitivity in the two groups

Time		Group T (n = 27)		ıp A 27)	<i>P</i> -value	Effect size (v)
	n	0/0	n	0/0		_
Base line Alpha	27	100	27	100		NC ⁺
3 months Alpha Bravo	25 2	92.6 7.4	27 0	100 0		NC ⁺
6 months Alpha Bravo	25 2	92.6 7.4	27 0	100 0	0.491	0.196
12 months Alpha Bravo	27	100	27	100	1.000	0.000

^{*:} Significant at $P \le 0.05$, NC^{\dagger} : Not Computed because the variable is constant

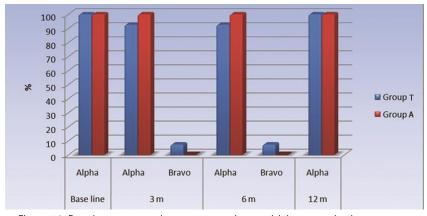


Figure 12. Bar chart representing post-operative sensitivity scores in the two groups

Patient satisfaction

Comparison between the two groups regarding patient satisfaction is displayed in Table 9 and Figure 13. At base line as well as after 3 months, all the patients in the two groups were highly satisfied regarding their veneers. (Alpha score). After 6 months, patients were highly satisfied regarding 92.6% (n=25) of veneers in Group T and 88.9% (n=24) of the veneers in Group A (Alpha score) and were moderately satisfied regarding the rest of the veneers. However, the difference between both groups wasn't statistically significant. (P-value = 1.000, Effect size = 0.064). After 12 months, all the patients in the two groups were highly satisfied regarding their veneers. (Alpha score).

Table 9. Descriptive statistics and results of Fisher's Exact test for comparison between post-operative sensitivity	' in
the two groups	

Time	Group T (n = 27)		Grou (n =		<i>P</i> -value	Effect size (v)	
	n	0/0	n	0/0			
Base line Alpha	27	100	27	100		NC ⁺	
3 months Alpha	27	100	27	100		NC ⁺	
6 months Alpha Bravo	25 2	92.6 7.4	24 3	88.9 11.1	1.000	0.064	
12 months Alpha	27	100	27	100		NC ⁺	

^{*:} Significant at $P \le 0.05$, NC^{\dagger} : Not Computed because the variable is constant

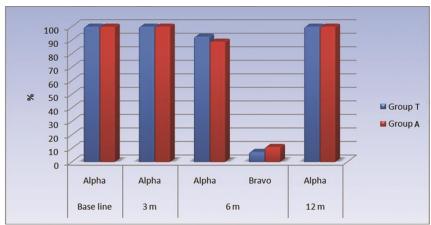


Figure 13: Bar chart representing patient satisfaction scores in the two groups

Secondary caries, Endodontic complications, Cracks and Retention of the veneers criteria At base line, after 3, 6 as well as 12 months; all veneers in the two groups had (Alpha) score.

Harms

Harms and adverse effects that occurred in this clinical trial included post-operative sensitivity, fracture of veneers and discoloration and were managed as previously explained. All potential harms were explained to the patients before start of the trial and were included in the written informed consent.

Discussion

In the present study, the null hypothesis was partially accepted as there was no statistical significant difference in the survival of polymer-infiltrated ceramic network laminate veneers constructed using aesthetic pre-evaluative temporary technique and those constructed using the traditional technique regarding secondary caries, marginal adaptation, marginal discoloration, endodontic complications, fracture, crack, retention, gingival response, post-operative sensitivity and patient satisfaction criteria during the whole study period. However, there was a statistically significant difference between the two groups regarding the color match criteria during the 6 and 12 months recalls.

Laminate veneers represent an aesthetic treatment modality with high success rate.

However, the success of laminate veneers depends on the choice of material and tooth preparation(17).

In the present study, VITA ENAMIC material was selected for construction of laminate veneers. VITA ENAMIC material combines the advantages of both ceramics and composite resins and can be milled in very thin sections (0.2– 0.5mm). This makes it suitable for minimally-invasive veneers (10). The Weibull modulus, which describes the range of fracture, the reliability and strength of a material, is remarkably high (11). Therefore, PICN materials can prevent cracks which are stopped by the interpenetrating polymer within the hybrid network (10).

Another factor that affects the success of laminate veneers is the tooth preparation. Incisal butt joint design and incisal overlap preparation are highly preferred because they increase the bonding surface area, provide better load distribution, characterization of the incisal region and seating of the restoration (18). However, butt joint design may lead to restorations with higher strength and more simplified tooth preparation (19). Therefore, in this study, butt joint incisal reduction was used.

In the current study, the aesthetic pre-evaluative temporary (APT) technique was used in one study group as described by Gurel et al. (6). The APT represents the final veneer contours. Tooth preparation was performed through the APT. Therefore, only necessary amount of reduction was performed allowing more enamel preservation (6). However, there are limited clinical studies regarding the success of hybrid laminate veneers using the APT technique.

The clinical evaluation parameters in this study were modified from the United States Public Health Service Criteria (Modified USPHS Criteria) as they are preferred by many authors (13-16) for documenting clinical outcomes. These criteria enable the assessment of multiple parameters and provide reliable information regarding the overall long-term success of the restoration. (20) Moreover, they are simplified criteria, making it easy to evaluate the veneers clinically and analyze the results. However, they do not cover all aspects of successful restoration. On the other hand, World Dental Federation (FDI) criteria for indirect restoration include an aesthetic, mechanical and biological evaluation. However, the criteria are difficult to apply clinically (9). Moreover, some of the FDI criteria are considered confusing and inconsistent (21). In most cases, radiographic examination (criterion 9) was not used for ethical reasons (with a poor risk-benefit ratio for patients) except when clinically indicated (21, 22).

Secondary caries was not observed in any laminate veneer during the 12 months follow-up period. This was in agreement with Guess et al (14). This may be due to the fact that the finish line was left within enamel in all cases (9).

The results of the present study regarding marginal adaptation revealed that at base line as well as after 3 months; all veneers in both groups showed Alfa score. While, at the 6 months and 12 months recalls, 96.3% of veneers in Group T (n=25) and 88.9% of the veneers (n=21) in Group A showed Alpha score (Table 3, Figure 6). These results are consistent with results obtained by Fradeani et al. (23) who reported that adequate marginal adaptation may be related to the supragingival margin preparation. This may have facilitated intra oral scanning, veneer cementation and oral hygiene measures (24). Adequate marginal adaptation may also be due to the polymer content in VITA ENAMIC resulting in milling of restorations with superior marginal fit. However, the decrease in marginal adaptation over time (table 4) was in agreement with Guess et al (14). This may be due to aging of the adhesive resin cement (14). However, the marginal deterioration did not require clinical intervention or replacement of the restorations.

In the current study, excellent success of the marginal discoloration criteria was observed. (table 4), (figure 7). This was in agreement with Calamia and Calamia (25). They attributed their findings to the supragingival margins which are accessible for oral hygiene measures (25).

Regarding the color match criteria, there was a statistically significant deterioration in color match by time in the two study groups. (table 5), (figure 8). This is consistent with results obtained by Kazakova et al. (15) Da Cunha et al. (26). This is also in agreement with Sarıkaya et al. (27) who reported discoloration of Vita Enamic after storage in cola, tea and coffee. This may be attributed to the high water sorption of trithylene glycol dimethacrylate (TEGDMA) content of VITA ENAMIC. Thus, staining agents can easily penetrate the material causing discoloration (27).

Regarding fracture parameter, clinically unacceptable extensive fractures (Charlie score) were not detected in both study groups during the follow-up period (table 6), (figure 9). This is in agreement with Magne et al (28).

According to Gurel (29), extensive fractures in laminate veneers with only small part of the veneer adhering to the tooth structure result from adhesive failure. However, small chipping fractures are due to cohesive failure (29). In the current study, the lack of extensive adhesive failures in both study groups during the follow up period could be related to performing the preparation entirely within enamel, (6) and surface treatment of VITA ENAMIC using hydrofluoric acid etching and silane coupling agent. It may also be attributed to the use of total etch technique. Adequate bonding reduces crack propagation initiated at the internal surface of laminate veneers (30). Moreover, VITA ENAMIC hybrid ceramic material is characterized by high Weibull modulus that causes inhibition of crack propagation by the interpenetrating polymer within the hybrid network (10). Two veneers exhibited clinically acceptable cohesive fractures (Bravo score) in the incisal edge that required only finishing and polishing (Figures 13A and B). This was in agreement with Ozturk (31) and Guess et al. (14).

In one of the patients who developed minimal veneer fracture, it was observed at the 3 months recall that the patient developed a parafunctional habit of bruxing in a lateroanterior excursive movement. Upon relief of the occlusal contacts in this position and providing a nightguard, no further fractures were observed during follow-up. This was in agreement with Granell et al (24) who noted that parafunctional habits play a major role in veneers fracture. According to Gresnigt et al (32), the cause of the minimal fracture observed in the other patient at the 6 months recall may be multifactorial. It may have resulted from either masticatory forces or thin parts of the hybrid material.

The fair success rate of the Gingival response criteria was in agreement with the findings of Leevailoj et al. (9) who attributed their results to the supragingival tooth preparation and the improvement in the oral hygiene of patients (20). The smooth surface texture of polished hybrid ceramics also decreased bacterial colonisation and growth, and facilitated plaque removal (9). However, gingivitis on the gingival margins of veneers occurred in patients who reported that they did not brush their teeth regularly. After periodontal treatment and patient education, the gingival tissues healed. Gingivitis was occasionally observed at the gingival papilla which was consistent with the results obtained by Aykor et al. (20). Gingival embrasure shape was modified in these cases using extra fine diamond stone (Diamond burs, Mani, INC, Japan). This led to healing of the gingival tissues.

In the current study, the excellent results of the postoperative sensitivity criteria (table 8), (figure 11) may be attributed to the adequate curing procedure which results in polymerization shrinkage (20), together with the use of the total-etch technique (20). Mild post-operative sensitivity (Bravo score) was noted in 2 veneers in Group T during the 3 months recall and in 2 veneers in Group T during the 6 months recall. These results were in agreement with the results obtained by Leevailo and Monaraks (9) who noted that the patients pain threshold might have played a role in the described sensitivity. Upon application of potassium nitrate desensitizing agent, post-operative sensitivity subsided and was not observed for the same patient on the following recall appointment. However, in group A, all veneers showed no post-operative sensitivity (Alfa score) during the study period. This was in agreement with Gurel et al. (6) and might be due to the use of the aesthetic preevaluative temporary technique of tooth preparation which resulted in more enamel preservation leading to superior adhesive bonding and reduced post-operative sensitivity (6, 24).

At the 12 months recall, all the patients in the two groups were highly satisfied with their veneers (Alpha score) (Table 9, Figure 12). This high success for patient satisfaction criteria was in agreement with Granell-Ruiz et al. (24), and could be due to the choice of recent materials and techniques, proper patient communication during diagnosis, digital smile design and wax-up construction. It may also be due to the use of the aesthetic preevaluative temporary in Group A which allowed the patient to visualize the end result before veneers construction.

The present clinical trial extend the work of other authors (5, 7, 9, 33) and the results are consistent with previous studies (5, 7, 14, 27). This indicates that the treatment provided in this study can be delivered in different settings by clinicians outside of the group who originally developed the intervention.

In the current study, the follow-up period is moderately short which, is a limitation of the study. However, this overcomes some problems such as the withdrawal of some dental materials and loss of a number of patients by time (34). Also, when reporting over short observation periods as 6 or 12 months, changes in the evaluation scores can indicate the behavior of dental restorations and indicate the weak points in particular materials or restorative technique (22). Moreover, the age range in this clinical study is relatively small with more female participants.

Patients willing to perform aesthetic treatment modalities are predominantly young female patients. The number of the patients in the study is small, which is a limitation of the study. However, the number of the veneers was determined according to sample size calculation. It will be necessary to

conduct future clinical studies with more extended follow-up periods, greater participant's number, age range and more equal gender distribution.

Proper control and maintenance through periodontal treatment, patient education, proper oral hygiene and adequate intervention during follow-up is mandatory for the success of polymer- infiltrated ceramic network laminate veneers constructed using traditional or aesthetic preevaluative temporary technique for tooth preparation.

Conclusion

Within the limitations of this clinical study, the following could be concluded: Polymer infiltrated ceramic network laminate veneers provided a successful clinical performance in terms of crack formation, secondary caries, endodontic complications, anatomical form and veneer retention in the two study groups during the follow-up period. After 12 months, all the veneers in both groups showed absence of post-operative sensitivity and all patients were highly satisfied regarding their veneers. VITA ENAMIC laminate veneers presented a deterioration in color match criteria over time regardless of the preparation technique used.

Funding

This clinical trial is self-funded.

Resumo

O objetivo deste estudo foi avaliar a sobrevivência de facetas laminadas construídas utilizando um material recente de rede de cerâmica impregnada de polímero, seguindo a técnica estética pré-avaliadora temporária (APT) de preparação de dentes em comparação com a técnica tradicional. Seis pacientes receberam 54 facetas de laminados. Foram divididos em dois grupos iguais (n=27) de acordo com a técnica de preparação do dente; grupo T; técnica tradicional e grupo A; técnica temporária pré-avaliativa estética. O material VITA ENAMIC foi utilizado para a construção de facetas de CAD/CAM de laminados. A cimentação foi realizada utilizando um cimento de resina fotopolimerizável. Os laminados foram avaliados na linha de base, após 3, 6 e 12 meses de acordo com os critérios modificados do Serviço de Saúde Pública dos Estados Unidos (USPHS). Os dados foram recolhidos, tabulados e analisados estatisticamente. Cáries secundárias, complicações endodônticas, fissuras e perda de retenção não foram observadas em nenhuma faceta laminada. Não foram detectadas fraturas extensas em ambos os grupos de estudo durante o período do estudo. Verificou-se uma diminuição estatisticamente significativa dos critérios de correspondência de cor entre os dois grupos nos 6 e 12 meses. Com base neste estudo, ambas as técnicas de preparação resultaram num desempenho clínico bem sucedido. Após 12 meses, todos os laminados de ambos os grupos não mostraram qualquer sensibilidade pós-operatória e todos os pacientes ficaram altamente satisfeitos com os seus laminados. No entanto, houve uma deterioração dos critérios de correspondência de cor durante o período de estudo em ambos os grupos de estudo.

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