Randomized clinical trial on clinical performance of sectional non – invasive laminate veneers using the modified US Public Health System criteria

Abstract

Purpose
To compare the clinical performance of Sectional non – invasive laminate veneers (SNIVs) in patients with tooth diastemas in the frontal area.

Methods
Ten patients with tooth diastema in the frontal area were included in this study. Each tooth diastema was treated with one feldspathic and one lithium disilicate sectional non-invasive laminate veneer. The veneers were evaluated by two investigators at baseline, immediately after cementation, at four and at twelve months of function according to the modified United States Public Health Service (USPHS) criteria. The parameters under evaluation included: anatomical form, marginal discoloration, marginal integrity, restoration color stability, secondary caries and surface texture.

Results
Based on the clinical evaluation by the investigators, both groups had alterations in their anatomical form, developed marginal discoloration and loss of marginal integrity. On the other hand, the color of the restorations and the surface texture had no significant changes and no secondary caries were detected.

Conclusions
Both groups of SNIVs had an acceptable clinical performance within 12 months of function in the oral cavity.

Authors

P. Papanagiotou[1]
P. Kamposiora[2]
G. Papavasiliou[3]

[1]National and Kapodistrian University of Athens, Greece

[2]Associate Professor, Head of Department of Prosthodontics, Dental School, National and Kapodistrian University of Athens, Athens, Greece

[3]Associate Professor, Department of Prosthodontics, Dental School, National and Kapodistrian University of Athens, Athens, Greece

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INTRODUCTION

The presence of tooth diastema is a common esthetic concern of patients. Tooth diastema, especially in the frontal area, can be a challenge to resolve by clinicians. Since porcelain laminate veneers were introduced (1,2), they have become a popular method to correct such problems and deliver an esthetic result to patients. Nowadays, minimally invasive dentistry gains more field in daily practice by means of minimally invasive or non – invasive veneers and clinicians tend to introduce this concept to treat tooth diastemas keeping as a second choice the placement of a single crown (3-8). The non – invasive approach has many advantages. There is no need to sacrifice intact tooth structure while anesthesia and impression cords in the gingival region are unnecessary during the treatment. Non - invasive veneers are biocompatible with dental substrates, are gentle to the periodontium and can be reversible in case of removal or reintervention (9-11).

Feldspathic porcelain and lithium disilicate glass ceramics are materials commonly used to fabricate veneers and treat tooth diastemas. Both materials have adequate abrasion resistance, can imitate the optical properties of enamel, retain color stability, achieve high survival rates and deliver an esthetic result (12-14). Nowadays, sectional non – invasive veneers (SNIV) seem to attract more attention in the dental field and clinicians are more eager to shift their treatment decision towards that direction. The treatment of tooth diastemas via minimally invasive or non – invasive veneers, has been described in various studies and case series, involving patients of all ages with acceptable results (15-19). However, there are no studies to compare different materials of SNIVs.

The aim of this in vivo study was to compare feldspathic and lithium disilicate SNIVs and evaluate their clinical performance according to the modified United States Public Health Service (USPHS) criteria. The evaluation will take place at baseline, immediately after cementation, after 4 months of function and after 12 months of function. The null hypothesis dictates primarily that the clinical performance of SNIVs is within acceptable clinical level and secondarily, both materials will perform in a similar manner.

METHODS

This study was addressed to patients who were admitted in the undergraduate clinic of Dental School of Athens for dental treatment and whose common concern was the presence of tooth diastemas in the frontal area of maxilla or mandible. The study was approved by ethics committee (Dental School Faculty Committee, number: 295- 09/03/2016). Upon clinical examination, the patients who presented tooth diastema in the frontal area were identified as possible candidates and a brief introduction of the research project was presented to them. The patients who showed interest to participate in the study were scheduled for a second appointment at which detailed information of the study together with an incentive offer (no treatment cost until the completion of the study) was submitted to them. Ten patients (seven women and three men), reviewed and signed a written consent form and thus committed to participate in the study.

The inclusion criteria were:

1. All patients were required to be at least 18 years old
2. All patients must be skeletal classification I
3. The diastema must be located in the frontal area of maxilla or mandible
4. Teeth involved must have intact tooth structure
5. Patients willing to participate in follow-up examinations.

The exclusion criteria were:

1. Teeth with caries
2. Presence of composite or any other restorative material on the tooth surface
3. Presence of periodontal disease
4. Presence of extensive tooth ware
5. Parafunctional habits or bruxism
6. Poor oral hygiene.

The color of each veneer was selected by comparing the color of each tooth with a shade guide (Ivoclar Vivadent Dental Teeth Shade Guide A-D 20/ND1-9 Porcelain Color Chart) and with patients approval was used as reference for the fabrication of the veneers.

The occlusal scheme of the patients was evaluated during protrusion and excursive movements. Main concern was to place sectional non – invasive veneers in a position which will avoid any tooth contact during static occlusion or during excursive movements and thus protect the integrity of the veneer and prolong its life expectancy. Twenty sectional non – invasive veneers were used in the study divided into two groups. Group C1 including veneers made by feldspathic porcelain (IPS e.max Ceram; Ivoclar Vivadent AG, Schaan, Liechtenstein). Group C2 including veneers made by lithium disilicate IPS e.max Press ingots (Ivoclar Vivadent AG).

Polyvinylsiloxane impressions of each patient were obtained (Aquasil Ultra+, Dentsply Sirona) and a duplicate model was fabricated. A single dental technician fabricated all the necessary veneers. All the materials used in this comparative study were acquired by one manufacturer and were handled under the manufacturer's protocols. The materials used are presented in Table1. The refractory dyes technique (Nori-Vest; Kuraray Noritake Dental Inc., Hattersheim am Main, Germany) was used to manufacture feldspathic veneers. This technique permits the use of layers with multiple levels of opacity, resulting in optimum esthetics (20). Feldspathic porcelain behaves similar to the enamel, has very good bonding strength with the

enamel, it can be very thin and delivers a high esthetic result (21,22).

Pressed lithium disilicate (IPS e.max Press ingots manually generated with staining) was used to fabricate the veneers for group C2. Following the instructions of the manufacturer, pressed lithium disilicate is recommended for laminate veneers with minimum thickness of 0.6mm. Considering this recommendation, the decision was made to fabricate both groups with 0.6mm of thickness. One of the challenges in this study was to find patients whose tooth diastema could accommodate two veneers, one from each group, and at the same time the restorations do not interfere in the occlusion or compromise the esthetics.

Each patient's diastema was treated by cementing a sectional non-invasive laminate veneer on each tooth adjacent to the diastema. The distribution of veneers per patient and fabrication method is presented in Table 2 (according to the International Tooth Numbering System).

The cementation procedure was conducted by a single clinician following the manufacturer protocol. Before cementation, the teeth were cleaned with a micromotor brush using a Fluoride free cleaning paste (Proxyt, RDA 36, by Ivoclar Vivadent AG, Schaan/Liechtenstein). The paste was removed with water spray and oil free air. A self-etching glass - ceramic primer (Monobond, by Ivoclar Vivadent AG, Schaan/Liechtenstein) was applied on the intaglio surface of the veneer with a micro brush for twenty seconds and left to react for forty seconds. Then, the primer was removed with water spray and oil free air for ten seconds. A phosphoric acid gel (Total Etch, by Ivoclar Vivadent AG, Schaan/Liechtenstein) was applied on the designated labial area of the tooth and reacted for thirty seconds. The gel was removed with water spray and oil free air. On the same area, a light cured adhesive (Adhese Universal Vivapen, by Ivoclar Vivadent AG) was applied for twenty seconds. Excess adhesive was removed with gentle air spray. The adhesive was then light cured for ten seconds. A light-curing luting composite, (Variolink Esthetic LC by Ivoclar Vivadent AG) of translucent color, was applied on the intaglio surface of the veneer and the restoration was seated on the designated area of the tooth by means of an adhesive tip applicator (Optra Stick by Ivoclar Vivadent AG). While seated the excess cement was light cured following the margin line and was removed with a scaler without damaging the veneer. To prevent oxygen-inhibition, a glycerine gel (Liquid Strip, by Ivoclar Vivadent AG) was applied on the margin. The gel was rinsed with water spray. Finally, the margin of the veneer was polished with a diamond polishing system (OptraFine, by Ivoclar Vivadent AG, Schaan/Liechtenstein). At baseline observation (immediately after cementation), the veneers were evaluated by two independent clinicians (investigators) with long experience in the field of Prosthodontics. The two investigators were calibrated according to the modified United States Public Health Service/ Ryge criteria (modified USPHS/Ryge criteria) and evaluated the veneers at baseline, after four months of function in the oral cavity and finally after twelve months of function. The modified USPHS criteria included: surface texture, anatomical form, marginal integrity, marginal discoloration, secondary caries, and restoration color stability. Clinical interpretation of the ratings was based on the Ryge criteria, an ordinal scale that rates restorations as Alfa, Bravo, Charlie, or Delta (Table 3). The veneers were clinically examined by the investigators by applying mild dry air, using visual inspection under magnification (4x) and an explorer. To avoid favoritism during the evaluation period, the investigators had no information in regards to the materials used to fabricate the veneers they were evaluating. Intraoral and extraoral photographs were taken from each participant before cementation, at baseline, at 4 and 12 months.

Statistical Analysis

Categorical and ordinal variables were expressed as absolute (n) and relative (%) frequencies. For the comparison of qualitative variables between C1 and C2, Fisher's exact tests were used. Wilcoxon signed rank tests and McNemar tests were used for time comparisons regarding ordinal and categorical variables respectively. In order to evaluate the degree of change in ordinal variables through time and if this degree differs significantly between C1 and C2, repeated measures analysis of variance (ANOVA) was adopted, with the use of logarithmic transformations of the dependent variables. All reported p values are two-tailed. Statistical significance was set at $p<0.05$ and analyses were conducted using SPSS statistical software (version 26.0).

RESULTS

In this study ten patients agreed to participate and twenty veneers were fabricated divided in two groups. Each patient received two veneers to treat their diastema, one veneer from each group (C1 and C2) and a single operator was responsible to deliver these veneers to the patients. Two independent investigators evaluated the veneers using the Modified USPHS parameters at baseline, after 4 months of intraoral function and finally after 12 months. Overall there was a significant agreement between the two investigators (ICC=0.91; 95% CI: 0.88-0.92; $p<0.001$). The parameters evaluated were anatomical form, marginal discoloration, marginal integrity, color stability of the restoration, secondary caries and surface texture. The results of the clinical evaluation showed that anatomical form, and marginal integrity deteriorated more than the other factors. Patients' anatomical form by material and timepoint is presented in table 4. From baseline to 4 months as well from 4 to 12 months no significant changes were found

in neither material. Overall, from baseline to 12 months anatomical form deteriorated in both materials, in a similar degree (p=0.456).
The marginal discoloration of veneer of patients by material and timepoint is presented in table 5. No significant differences were found between C1 and C2 at all timepoints. From baseline to 4 months as well from 4 to 12 months no significant changes were found in neither material. Overall, from baseline to 12 months marginal discoloration of veneer deteriorated in both materials, in a similar degree (p=0.959).
Patients' marginal integrity of veneer by material and timepoint is presented in table 6. No significant differences were found between C1 and C2 at all timepoints. From baseline to 4 months, marginal integrity of veneer worsened only in C2. From 4 to 12 months as well as from baseline to 12 months, marginal integrity of veneer deteriorated significantly in both materials. The degree of overall deterioration was similar in C1 and C2 (p=0.443).
Color stability and surface texture remained unchanged from the baseline till the final evaluation, while no caries were detected in any group. Overall, no significant differences were detected between the groups in any evaluation factor.

DISCUSSION

In this randomized clinical trial, the clinical performance of sectional non – invasive laminate veneers were evaluated using the modified USPHS criteria.
The patients selected for the study had a convenient profile, they were eager to treat the diastema in the frontal area and agreed to follow the recall schedule. The clinical observation had a duration of 12 months of clinical function in which instructions were given to the patients to preserve their oral hygiene and to avoid excessive biting force on the treated area. The two groups were evaluated by two investigators. The results of the study confirm the null hypothesis primarily because both groups showed adequate clinical performance through the whole evaluation period and secondarily because both materials had a similar behavior with no significant differences between them. (Figure 1 and 2)

Immediately after the cementation of the veneers, the anatomical form of the teeth involved in the treatment is reformed and is subject to alterations due to function. Both groups were subject to alterations due to function but these minor discrepancies did not have an impact on their clinical performance. D' Arcangelo et al. suggest that the margin of non – invasive veneers should correspond to the line of maximum convexity of the tooth's labial surface. Such an area of maximum convexity behaves as a natural finish line for the veneer, avoiding over-contour and maintaining a physiologic emergence profile after cementation (23). This concept was adopted in this study in order to avoid bulky margins or overhangs and achieve a natural result as much as possible. At the same time, by avoiding occlusal load or biting force on the treated area seemed to be beneficial for preserving the anatomical form of the non – invasive veneers (24).

Marginal discoloration is anticipated through time (25), yet short- to medium-term investigations have reported a high percentage of veneers exhibiting minimum or no marginal discoloration (8,26-28). Similar results with the present study were found in a split-mouth randomized clinical trial by Marchionatti et al (29). In their study, laminate veneers with no preparation were cemented on patients' buccal surface and after twelve months of observation no marginal discoloration was detected. A reason for marginal discoloration might be related to minor marginal defects observed over time or due to degradation of the cement, which in turn, can create voids or defects, leading to accumulation of biofilms and food particles, thereby increasing marginal staining (11). Repolishing of the marginal interface is a simple and efficient way to answer the problem and extend their clinical service (24, 28). In this study, only one patient complained about the marginal discoloration at the last recall appointment, which was resolved by repolishing the adhesive interface with a polishing kit.

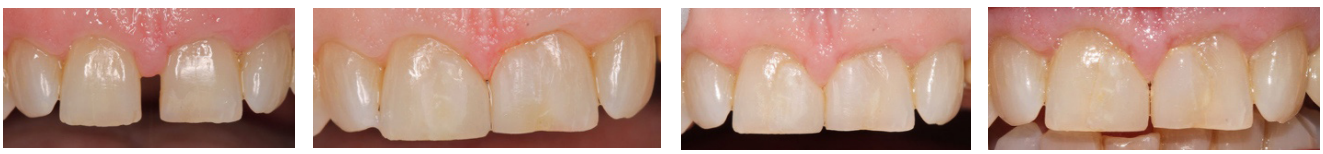

Figure 1. Intraoral pictures of upper central incisors at initial stage, at baseline, after 4 months and 12 months of function.

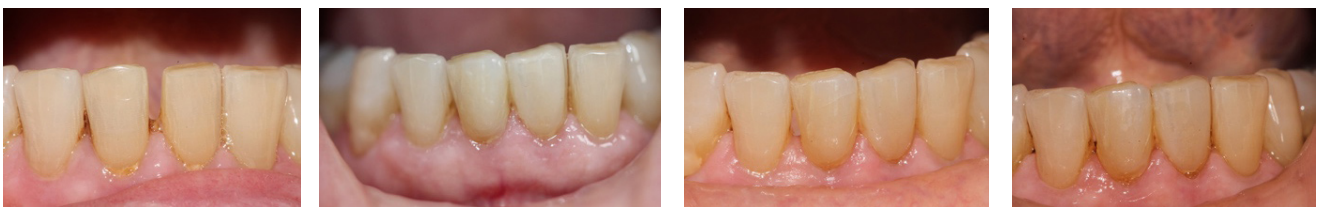

Figure 2. Intraoral pictures of lower central incisors at initial stage, at baseline, after 4 months and 12 months of function.

MATERIALS	LOT	MANUFACTURER
IPS e.max ceram	684725	Ivoclar Vivadent AG, Schaan/ Liechtenstein
IPS e.max press ingots HT	626320	
Proxyt, RDA 36	701472	
Monobond plus	626221AN	
Total Etch	550588AN	
Adhese Universal Vivapen	663720WW	
Variolink Esthetic LC cement	666127WW	
Liquid Strip	532505AN	
Optrafine paste	602289AN	

Tab. 1. List of materials used in the study. All materials are provided by Ivoclar Vivadent.

Patient	Number of Veneers	Teeth	Fabrication Method
1	2	21,22	e.max/feldspathic
2	2	11,21	Feldspathic/e.max
3	2	31,41	e.max/feldspathic
4	2	41,42	e.max/feldspathic
5	2	31,41	Feldspathic/e.max
6	2	12,22	Feldspathic/e.max
7	2	41,42	Feldspathic/e.max
8	2	31,41	e.max/feldspathic
9	2	41,42	Feldspathic/e.max
10	2	31,41	e.max/feldspathic

Tab. 2. Distribution of laminate veneers per patient according to tooth position and fabrication method (International Tooth Numbering System)

Marginal integrity of the veneers was changed due to function. Still, these alterations were not detected by the patients, required no repairs and did not have an impact on the veneers' clinical performance. One of the reasons for high Bravo scores in this study, could be the absence of a prepared margin. When veneer preparation is performed, the presence of a distinct margin always helps the clinician to orient the veneer in place and verify the marginal closure by removing the cement excess during the sitting. Sectional non – invasive veneers don't provide this advantage during cementation and thus, cement excess can hide discrepancies or create bulks between the margin and the tooth surface (8). Restoration color stability remained unchanged during the evaluation period. One of the reasons for that can be attributed to the color of the cement used. The shade of the cement must be carefully selected by the clinician because wrong matching can create deviations in the color of veneers after cementation leading to anesthetic results. Some authors suggest that the color of the cement can affect the final color of the veneers and thus transparent cement is recommended (30,31). In this study, transparent cement was used for the cementation of all the veneers. Immediately after cementation both investigators gave 100% Alpha scores to both groups and all the patients were satisfied with the esthetic outcome of the veneers. Through the whole evaluation period, both groups retained a satisfying esthetic level, while none of the veneers received Charlie scores, which is a visual evidence of discoloration of the restoration.

	Alpha	Bravo	Charlie	Delta
Surface texture	Sound	Rough	-	-
Anatomical form	Sound	Slight loss of material (chipping, clefts), superficial	Strong loss of material (chipping, clefts), profound	Total or partial loss of the buld
Marginal integrity	Sound	Positive step, removable by finishing	Slight negative step not removable, localized	Strong negative step in major parts of the margin, not removable
Marginal discoloration	None	Slight discoloration, removable by finishing	Discoloration, localized not removable	Strong discoloration in major parts of the margin not removable
Secondary caries	None	Caries present	-	-
Restoration color stability	No change	Change of color compared to baseline condition	-	-

Tab. 3.. Modified United States Public Health Service/ Ryge criteria (modified USPHS/Ryge criteria) used for the evaluation.

Group	Anatomical form	Baseline n (%)	4months n (%)	12months n (%)	P+ Baseline vs 4 months	P+ 4 months vs 12 months	P+ Baseline vs 12 months
C1	Sound	9 (90.0)	6 (60.0)	5 (50.0)	0.083	0.157	0.025
	Slight loss of material	1 (10.0)	4 (40.0)	4 (40.0)			
	Strong loss of material	0 (0.0)	0 (0.0)	1 (10.0)			
	Total or partial loss of the buld	0 (0.0)	0 (0.0)	0 (0.0)			
C2	Sound	9 (90.0)	8 (80.0)	4 (40.0)	0.317	0.046	0.025
	Slight loss of material	1 (10.0)	2 (20.0)	6 (60.0)			
	Strong loss of material	0 (0.0)	0 (0.0)	0 (0.0)			
	Total or partial loss of the buld	0 (0.0)	0 (0.0)	0 (0.0)			
P++ C1 vs C2		>0.999	0.628	0.656			

+Wilcoxon signed-rank test ++Fisher's exact test

Tab. 4. Patients' anatomical form by material and timepoint

Group	Marginal discoloration of veneer	Baseline n (%)	4months n (%)	12months n (%)	P+ Baseline vs 4 months	P+ 4 months vs 12 months	P+ Baseline vs 12 months
C1	None	10 (100.0)	8 (80.0)	5 (50.0)	0.180	0.083	0.034
	Slight discoloration. removable by finishing	0 (0.0)	1 (10.0)	4 (40.0)			
	Discoloration. localized not removable	0 (0.0)	1 (10.0)	1 (10.0)			
	Strong discoloration in major parts of the margin not removable	0 (0.0)	0 (0.0)	0 (0.0)			
C2	None	10 (100.0)	8 (80.0)	5 (50.0)	0.157	0.083	0.025
	Slight decoloration. removable by finishing	0 (0.0)	2 (20.0)	5 (50.0)			
	Discoloration. localized not removable	0 (0.0)	0 (0.0)	0 (0.0)			
	Strong discoloration in major parts of the margin not removable	0 (0.0)	0 (0.0)	0 (0.0)			
P++ C1 vs C2		-	>0.999	>0.999			

+Wilcoxon signed-rank test ++Fisher's exact test

Tab. 5. Patients' marginal discoloration of veneer by material and timepoint

Alhekier et al. reported that the major cause of color change was human error, such as removal of the glazed layer after finishing and polishing the prosthesis (32). In this study, in order to minimize the human factor only one clinician was responsible for the cementation and finishing of the veneers.

Other factors that can alter the color of the veneers include hot and cold beverages, acids from foods, saliva effects, oral biofilm, and the influence of brushing. All these factors can affect the restorations color stability (29, 33, 34). Definitely patient selection was a key factor for this study because none of the patients were heavy smokers or had a preference to acidic diet or alcohol and beverages.

All the patients were instructed to be consistent with their oral hygiene. During the evaluation period of twelve months, patients followed the oral hygiene instructions and were consistent to the recall schedule.

		Baseline	4months	12months	P+ Baseline vs 4 months	P+ 4 months vs 12 months	P+ Baseline vs 12 months
Group	Marginal integrity of veneer	n (%)	n (%)	n (%)			
C1	Sound	6 (60.0)	3 (30.0)	0 (0.0)	0.083	0.025	0.005
	Positive step. removable by finishing	4 (40.0)	7 (70.0)	8 (80.0)			
	Slight negative step not removable. localized	0 (0.0)	0 (0.0)	2 (20.0)			
	Strong negative step in major parts of the margin. not removable	0 (0.0)	0 (0.0)	0 (0.0)			
C2	Sound	7 (70.0)	2 (20.0)	0 (0.0)	0.014	0.046	0.004
	Positive step. removable by finishing	3 (30.0)	7 (70.0)	7 (70.0)			
	Slight negative step not removable. localized	0 (0.0)	1 (10.0)	3 (30.0)			
	Strong negative step in major parts of the margin. not removable	0 (0.0)	0 (0.0)	0 (0.0)			
P++ C1 vs C2		>0.999	>0.999	>0.999			

+Wilcoxon signed-rank test ++Fisher's exact test

Tab.6. Patients' Marginal integrity of veneer by material and timepoint

The sectional veneers were in the frontal area, an area which can be reached and cleaned easily by the patients. This can explain why no secondary carries were found in any of the groups at all timepoints. Short and medium - term investigations had similar results no secondary carries detected which is in accordance with the present study (11,14,24,35).

From baseline till the final evaluation the patients were instructed to maintain their oral hygiene and to avoid vigorous brushing on the veneers. This can explain the high Alpha scores of surface texture on both groups. After twelve months of function the veneers' surface was practically unchanged which is in accordance with other studies (10,36-38). On clinical level, none of the patients reported any complain regarding the texture of the veneers throughout the whole evaluation period.

This randomized clinical trial showed that sectional non-invasive veneers can be a solution for closing tooth diastemas in the frontal area and achieve an acceptable clinical performance after twelve months of function in the oral cavity. Both materials used, feldspathic porcelain and lithium disilicate, had a similar clinical behavior with non-significant differences between them. Of course, proper case selection, delicate handling by the clinician and commitment to oral hygiene by the patient are essential for clinical success. However, small patient number and short-term evaluation limits the extension of the results. Thus, further investigation is required with long term follow up periods.

CONCLUSIONS

Based on the findings of this randomized clinical study of SNIVs, the following conclusions were drawn:

The clinical performance of SNIVs is acceptable within 12 months of function in the oral cavity.

Feldspathic porcelain SNIVs and lithium disilicate SNIVs behaved in a similar manner with no significant differences.

Proper case selection, high oral hygiene and absence of parafunctional habits are factors of paramount importance that contribute to the success of the treatment.

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Declaration of interests

None.

Conflicts of interest

There are no conflicts of interest.

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