Evaluation of patient satisfaction and shade matching of Vita Suprinity versus lithium disilicate (E-max) ceramic crowns in the esthetic zone: a randomized controlled clinical trial [version 1; peer review: awaiting peer review]

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Abstract
Background: Optical impairments of teeth in the esthetic zone constitute a problem for many dentists and patients as several studies concluded that patients were dissatisfied of their dental appearance because of their restorations’ color. The purpose of this study was to assess patient satisfaction combined with shade matching of VITA SUPRINITY versus lithium disilicate (IPS e-max CAD) all-ceramic crowns in esthetic zone.

Methods: 26 patients with teeth problems indicated for full coverage restoration on one tooth in the esthetic zone (from upper central incisor to 1st premolar) were randomized into 2 equal groups (n=13) for which different CAD-CAM ceramic materials were used; (VITA SUPRINITY) a zirconia reinforced lithium silicate ceramic and (IPS e.max CAD) lithium disilicate glass ceramic. The crowns were fabricated to match the shade of the contra-lateral/ adjacent tooth and assessed using the modified USPHS criteria. Also patient satisfaction was assessed. The data obtained by evaluating each assessment criteria were statistically analyzed using the Chi-square test that was performed in categorical data.

Results: According to the modified USPHS criteria, 100% of the patients were Alpha score with 0% for Bravo, Charlie and Delta scores in both groups. While according to the visual analogue scale (VAS), 100% of the patients were satisfied while 0% were dissatisfied by the restoration in both groups.

Conclusions: The results for both materials in terms of patient satisfaction and shade matching were Alpha. This indicated that both materials are clinically accepted to be used as full coverage restorations for excellent esthetic outcome.

Registration: NCT0284611.

Keywords
E.max CAD, VITA SUPRINITY, shade matching, patient satisfaction, ceramic restorations, esthetic dentistry.
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Introduction
In dentistry, accurate and predictable shade matching between natural teeth and restorative materials represents a challenge for clinicians and laboratory technicians. For decades, visual shade matching was most commonly used for the shade selection in the dental clinics as it is easy and does not require expensive equipment. Several studies reported that the color of the shade tabs is uniformly distributed and the shade guide enables accurate shade matching with the natural teeth. Other studies stated that the number of correct matches might increase if the Vitapan 3D-Master shade guide is used. They also suggested the use of Vitapan 3D-Master along with shade mapping, as in this study, to eliminate the effect of operators’ experience on shade-matching process and to ensure correct placement of different shade effects and characterizations.

However, many factors may negatively affect the quality of shade matching clinically, including tooth texture, lighting conditions, the surroundings and background, as well as the subjective nature of human color observation, through color blindness or color perception defects. Differences in gender, variations in experience of the evaluators, lighting conditions, metamerism and eye fatigue that could affect proper shade selection. Additionally, factors such as tooth dehydration as result of chemical disinfection can cast a significant effect on the final shade matching.

Therefore, in order to eliminate the confounders during the color matching process, instrumental methods have been introduced. Greater correlation in several studies have been found between both the objective (spectrophotometer) and the subjective (visual) shade selection methods with respect to color dimension of value or lightness, followed by hue and finally chroma. It was concluded that combination of both methods should be used for a successful esthetic outcome. While other studies found that using a spectrophotometer for shade matching is more accurate than using a conventional shade guide. In other studies, instrumental color matching was suggested as a supplementary tool for a better esthetic outcome.

In addition, the final color of all-ceramic restorations is affected by different factors including the porcelain layering technique, dental ceramic type, ceramic brand, veneering ceramic thickness, and firing temperature and conditions. Moreover, clinical parameters, including type, color, and thickness of cement can also influence the final result.

Therefore, the esthetic needs of the patients during treatment should be taken into consideration, otherwise patient satisfaction will not be achieved, which has a significant effect on patient self-perception and quality of life. A survey looking at patient satisfaction with esthetic treatment found that the restoration color was the primary cause for patient dissatisfaction, as 89.3% of patients were not satisfied with their esthetic treatment because of the color of their restoration. Other studies found that tooth color and gender also affect patient satisfaction, with females more dissatisfied than males.

Newly introduced ceramic systems with improved optical properties may lead to improve clinical shade matching and patient satisfaction. VITA SUPRINITY, introduced by VITA Zahnfabrik, is a glass ceramic material enriched with approximately 10% zirconia by weight. This very fine homogenous dual microstructure resulted in high flexural strength while simultaneously providing a high percentage of glassy matrices. These structural effects provide the ceramic with good optical and polishing properties and allow delivery of restorations with excellent esthetics.

Lithium disilicate ceramic (such as IPS e.max CAD, manufactured by Ivoclar Vivadent) is considered one of the more esthetic ceramics due to the glass matrix embedded with needle-like lithium disilicate crystals that results in reduction of internal scattering of the light as it passes through the material. There are also other optical properties for better mimicking of adjacent natural teeth, which include the chameleon effect.

Therefore, this study was conducted to evaluate patient satisfaction according to the visual analogue scale (VAS) and shade-matching of VITA SUPRINITY versus (IPS e-max CAD) lithium disilicate all ceramic crowns in esthetic zone using the modified United States Public Health Service (USPHS) criteria in a prospective controlled randomized clinical trial. The null hypothesis of the study was that there would be difference in patient satisfaction and shade matching of VITA SUPRINITY if compared with lithium disilicate ceramic crown used in the esthetic zone.

Methods
Ethical considerations and approval
This study was approved by the Research Ethics Committee of the Faculty of Dentistry (approval no: 1082016). Written informed consent regarding treatment sequence, publishing of their images and results was obtained from all participants.

Registration
This trial was registered at the ClinicalTrials.gov registry under registration number NCT02846116 on July 27, 2016.

Study design
This study was a double blind randomized controlled clinical trial with a 1:1 allocation ratio. This article was written in concordance with the CONSORT checklist; a completed checklist is available on Open Science Framework.

Participants
All participants were recruited from the outpatient clinic of the Department of Fixed Prosthodontics of Faculty of Dentistry, Cairo University, Cairo, Egypt. A face-to-face participants’ selection was performed according to the patients’ need for a full coverage restoration on a tooth in esthetic zone. A total of 26 participants were recruited for this study during the time from July 2017 till September 2017. This study was completed by May 2018. Full medical and dental history were obtained from all participants. A CONSORT flow diagram is available as extended data.
Eligibility

Inclusion criteria. (1) Age ranging between 20 and 60 years old; (2) patients psychologically and physically able to tolerate the treatment procedures; (3) patients with no periodontal or pulpal diseases with acceptable restorations; (4) patients with teeth in esthetic zone indicated for all-ceramic crowns (e.g. mild-to-moderate discoloration, coronal fracture where partial coverage is not indicated); (5) patients with endodontic treated teeth requiring all-ceramic crowns.

Exclusion criteria. (1) Lack of patient motivation; (2) patients with psychiatric problems or unrealistic expectations; (3) patients with parafunctional habits; (4) teeth with increased incisal translucency; (5) severe discolored teeth; (6) no opposite occluding dentition.

Sample size
A total of 26 crowns (13 in each group) was sufficient with 80% power and at 5% significance. The sample size was calculated using G*power Version 3.0.10.48

Randomization
Randomization was carried out using computerized sequence generation (https://www.randomizer.org/) in the Center of Evidence Based Dentistry, Cairo University.

Participants were divided into two groups (A and B) according to the ceramic material used. Each participant received a sealed opaque envelope with their randomized number.

Allocation concealments
Number for each member in each group was written by indispensable pen on large white paper sheet. The sheet was folded eight times and saved inside opaque well sealed envelope.

Implementation
The candidate under supervision was responsible for providing allocation generation and dividing patients into two groups and save it in the envelopes in secured place until the date of performing procedure.

Blinding
The trial participants and outcome assessors were blinded throughout the whole procedures (double blind), as the dentist practitioner (S.A.) was responsible for all clinical procedures.

Intervention
Two crown systems (IPS e.max CAD and VITA SUPRINITY ceramics) were selected for this study (Table 1). All treatment procedures were performed by the same clinician (S.A.). Scaling and polishing were performed for each patient before shade selection in order to remove any dental plaque, calculus and staining, which will affect the accurate shade selection. The tooth color was recorded visually using VITA 3D-Master shade guide system (VITA, Zahnfabrik, Germany) in accordance to the contra-lateral/adjacent tooth under different light conditions: natural day light, incandescent light and color-corrected light (using Smile Lite, Smile Line, Switzerland) to avoid metamerism. This was done with the help of three prosthodontists, who had performed Ishihara’s test to determine deficiency in color vision. Their results showed no color blindness.

Visual shade selection was carried out within a standardized environment at midday, when incident daylight is most balanced with the visible light spectrum. While the patients were positioned on dental chair so that his/her mouth was at the same level and 40 cm apart from observers’ eyes. All bright colors were removed from the field of view (as makeup, tinted eye glasses) and a neutral gray patient bib masked clothing colors. Upper and lower teeth were separated with the tongue retracted. Both tooth (the contra-lateral/adjacent tooth) and shade tab were placed in the same plane with neutral gray background (Flexipalette Color Match, Smile line, Switzerland). Shade selections were done in three areas of the tooth (incisal, middle and cervical third) to match the subject’s maxillary contra-lateral/adjacent tooth5,51. (Figure 1)

The color-corrected light, with a color correlated temperature of 5,500K, 1,500 lux at a distance of approximately 10 cm and a color rendering index (CRI) of 92, was used as a confirmatory procedure. The evaluators were asked to stand opposite the targeted tooth so that shade matching was performed from the see-thru rectangular window (Figure 2).52–54.

Shade matching was also confirmed with Vita Easyshade V spectrophotometer (VITA, Zahnfabrik, Germany). It was calibrated before starting each measurement. As stated by the manufacturer, the measurement was acknowledged when three consecutive, identical readings were generated using tooth area measurement mode for shade selection (Figure 3).22 Vita Easyshade V was used as a confirmatory tool for better shade selection by

Table 1. The materials investigated in the study.

<table>
<thead>
<tr>
<th>Material name</th>
<th>Composition</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS e.max CAD</td>
<td>Lithium disilicate glass-ceramic</td>
<td>Ivoclar Vivadent (Germany)</td>
</tr>
<tr>
<td>VITA SUPRINITY</td>
<td>Zirconia reinforced lithium silicate ceramic</td>
<td>Vita Zahnfabrik (Germany)</td>
</tr>
</tbody>
</table>

Figure 1. Shade selection under natural day light of upper left central incisor.
Preparation of teeth for full coverage restoration were performed with smooth, round contours and line-angles, chamfer finish lines of 1 mm in diameter with round internal angles, and incisal reduction of 2 mm\(^46\),\(^55\),\(^56\). The shade of the prepared abutment tooth was recorded visually using the IPS Natural Die Material shade guide (Ivoclar Vivadent) under natural day light and color corrected light in order to fabricate a die mimicking the oral situation for optimum desired final esthetic results (Figure 4)\(^46\),\(^57\).

Vinyl polysiloxane elastomeric impressions (Honigum impression material, DMG, Germany) were made, and provisional restorations (Structur 2 SC, VOPO, Germany) were cemented with non-eugenol provisional cement (RelyX Temp NE, 3MESPE, USA)\(^55\).

The construction of the all-ceramic crowns was performed using CAD/CAM Cerec InLab MC X5 milling machine, with Cerec 15.0.0 software. The fitting surfaces of the all-ceramic crowns were treated and silanated according to the manufacturer’s instruction and abutment teeth were prepared where self-etch adhesive protocol was obeyed using adhesive resin cement (Bifix-QM, VOPO, Germany) (Figure 5)\(^53\),\(^59\).

**Clinical evaluation**

Patients were given a handheld mirror to view their teeth and definitive restoration in the clinic and evaluated their own restoration\(^57\). Patients were asked to fill in patient satisfaction chart for either satisfied or dissatisfied.

In addition, restorations were evaluated by three prosthodontists from the Department of Fixed Prosthodontics, Cairo University. A few minutes before the procedure, these evaluators entered the clinic in order to adapt to the environmental lighting conditions\(^51\),\(^54\),\(^59\),\(^61\). Evaluation was performed with the same sequence used for initial shade-matching (visually using VITA 3D-Master shade guide system (VITA, Zahnfabrik, Germany) in accordance to the contra-lateral/adjacent tooth under different light conditions (natural day light, incandescent light and color-corrected light). To avoid eye fatigue, evaluators were asked to rest their eyes by temporarily closing them or looking at a neutral grey zone every 10 seconds\(^54\),\(^55\). Evaluators were asked to fill in a clinical assessment chart with each patient number.

**Primary outcome (patient satisfaction)**

The two groups of patients were assessed using the Visual Analogue Scale (VAS)\(^40\),\(^42\),\(^57\) which is binary and documented in chart including number of satisfied and unsatisfied.

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**Figure 2.** Shade selection using color corrected light of upper left central incisor.

**Figure 3.** Shade selection corresponding to upper right central incisor.

**Figure 4.** Tooth stump shade selection of upper left central incisor.

**Figure 5.** After cementation of the crown of upper left central incisor. (A) Frontal view. (B) Palatal view.
Secondary outcome (shade match)

The two groups were assessed using the modified United States public health service (USPHS) criteria by the three evaluators\(^4\). Alpha (Excellent), Bravo (Acceptable), Charlie (Acceptable but modifications needed) and Delta (Unacceptable).

Statistical analysis

The results were analyzed using Graph Pad Instat (Graph Pad, Inc.) software for windows. A value of \( P \leq 0.05 \) was considered statistically significant. Data obtained by evaluating each assessment criteria were statistically analyzed using the Chi-square test that was performed in categorical data.

Results

The patient satisfaction associated with restorations for both groups is highlighted in Table 2 and Figure 6. Raw data are available on Open Science Framework\(^47\).

According to the visual analogue scale (VAS), 100% of patients were satisfied while 0% were dissatisfied by the restoration in both groups. This was statistically non-significant as verified by chi square test (\( p > 0.05 \)). Table 2 and Figure 6. No harms were recorded.

Regarding shade matching, no statistical difference was found between the two tested groups (\( p > 0.05 \)). According to the modified USPHS criteria, 100% of the patients were Alpha score with 0% for Bravo, Charlie and Delta scores in both groups (Table 3 and Figure 7).

Discussion

Concerning shade matching results, all patients recorded no color difference between their restorations and adjacent/contra-lateral teeth which might be attributed to the strict and meticulous shade matching protocol followed in respect to the staining procedure in accordance to each material used. In addition to the similarity in microstructure of both materials being lithium silicate-based glass-ceramics. This was in accordance with several studies that stated that in order to achieve a tooth-colored restoration, two different steps are required:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Outcome</th>
<th>e.max, n (%)</th>
<th>VITA SUPRINITY, n (%)</th>
<th>Chi</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient satisfaction</td>
<td>Satisfied</td>
<td>13 (100%)</td>
<td>13 (100%)</td>
<td>&lt;0.05</td>
<td>&gt;0.95</td>
</tr>
<tr>
<td></td>
<td>Dissatisfied</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>&lt;0.05</td>
<td>&gt;0.95</td>
</tr>
</tbody>
</table>

Figure 6. Column chart of aesthetics scores associated with restoration for both groups.

Table 2. Distribution of patient satisfaction with esthetics associated with restoration for both groups.
select the proper shade using a shade guide and/or an electronic shade-taking device, and reproduce this shade with a suitable dental material.\textsuperscript{37,63}

Concerning IPS e.max CAD all-ceramic crowns, Fasbinder et al.\textsuperscript{64} stated that no color change was noted for CAD/CAM lithium disilicate crowns after 2 years of service. Rauch et al.\textsuperscript{65} reported USPHS alpha scores for all monolithic lithium disilicate crowns in the posterior zone upon evaluation after 6 and 10 years. Contradicting to our results those found by Chaiyabutr et al.\textsuperscript{46}, who found color variation in CAD/CAM lithium disilicate glass-ceramic restorations. They explained that this may be due to the optical characteristics of the material, which allows the underlying tooth shade stump to affect the final color of the crown. They reported that the final color of 1 mm ceramic thickness in the cervical area combined with low-translucency ceramic blocks may be affected by intense discoloration of underlying abutment tooth color. This was avoided in our current study, as severely discolored abutments were among our exclusion criteria.

Rinke et al.\textsuperscript{66} found the excellent esthetic properties of VITA SUPRINITY may be related to the homogenous dual micro-structure, consisting of very fine lithium disilicate and lithium metasilicate crystals with average size of 0.5–0.7 \textmu m which are four to eight times smaller than lithium disilicate crystallites. The result is very fine microstructure that provides a higher ratio of glass matrix/zirconium oxide in solution.

However, contradicting our results, Jirajariyavej et al.\textsuperscript{29} found that the different ceramic materials affected the final esthetic outcome of the restoration. This color difference may be due to difference in translucency between the silicate-based glass-ceramic materials, with the IPS e.max CAD being more translucent than VITA SUPRINITY.

Concerning patient satisfaction results, all the patients were satisfied with their restorations. Additionally, there was no statistically significant difference between the two groups. This might be attributed to the meticulous shade matching protocol and laboratory procedure followed in this study. Ballard et al.\textsuperscript{55}

\begin{table}[h]
\centering
\caption{Distribution of shade match with aesthetics associated with restoration for both groups.}
\begin{tabular}{|c|c|c|c|c|c|}
\hline
Parameter & Outcome & e.max, n (%) & VITA SUPRINITY, n (%) & Chi & P value \\
\hline
Shade match & Alpha & 13 (100\%) & 13 (100\%) & <0.05 & >0.95 \\
& Bravo & 0 (0\%) & 0 (0\%) & <0.05 & >0.95 \\
& Charlie & 0 (0\%) & 0 (0\%) & <0.05 & >0.95 \\
& Delta & 0 (0\%) & 0 (0\%) & <0.05 & >0.95 \\
\hline
\end{tabular}
\end{table}
found that patients reporting high satisfaction ratings may have been affected by the high value of the restoration. Al-Wahadni et al. found that patients’ satisfaction increased when the restorations were received in an academic institution, denoting that patients’ confidence in the school or good relationship with the dental student may have elevated their opinions of the care received.

Contradicting our results are those by Shah et al. who found the overall rating of patient satisfaction was acceptable (USPHS Bravo and Charlie scores). They explained that patient level of education might affect the results. Well-educated patients tended to be more satisfied with their tooth color compared to patients with primary level of education. Samorodnitsky-Naveh et al. found discrepancies between overall satisfaction with tooth appearance and satisfaction with tooth color. They explained that age might have a significant effect on patient satisfaction, as the selected young cohort of subjects might have been excessively sensitive about the appearance of their teeth. This was avoided in our study by selecting large age range between 20 and 60 years old.

Finally, the hypothesis was rejected as no statistical difference was found between the two tested groups (IPS e.max CAD and VITA SUPRINITY).

Limitations
More clinical studies are required with prolonged follow-up periods to evaluate long-term esthetic clinical performance of the materials along with patient satisfaction in order to be used in different situations for better esthetic outcome.

Spectrophotometer (Vita Easyshade V) was used as clinical confirmatory tool only in this study by the operator and not for final outcome assessment. Further studies utilizing spectrophotometer as a main assessment tool are required.

Conclusions
VITA SUPRINITY and IPS e.max CAD full coverage restorations revealed excellent patient satisfaction and color matching. This indicates that both materials can be recommended as full coverage restorations in clinical situations for optimum esthetic outcome. The choice depends on the dentist’s preference.

Data availability

Underlying data

Underlying data for this study are available in file “Raw data. xlsx”.

Extended data

This project contains the following extended data:
- ResearchRandomizer.csv
- CONSORT flow diagram of experimental stages and group distribution.docx
- Trial protocol.doc

Reporting guidelines
Open Science Framework: CONSORT checklist for article “Evaluation of patient satisfaction and shade matching of Vita Suprinity versus lithium disilicate (E-max) ceramic crowns in esthetic zone: a randomized controlled clinical trial”. https://doi.org/10.17605/OSF.IO/ZH6SC86.

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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