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THREE YEARS CLINICAL EVALUATION OF LITHIUM DISILICATE AND HYBRID NANO-CERAMIC CAD/CAM ENDOCROWNS (RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

Purpose: To compare marginal adaptation, fracture, retention, shade matching, and patient satisfaction between lithium disilicate (e.max) and hybrid nano-ceramic (Grandio) CAD/CAM endocrowns.

Methods: A total of 20 CAD/CAM endocrowns (10 e.max (E group) and 10 Grandio (G group)) were randomly inserted in 20 participants. Shade selection, cavity preparation, and digital impression were performed. Then, restorations were designed, milled, and checked clinically before cementation using resin cement. The restorations underwent baseline and annual evaluations for three years using Modified United States Public Health Service (USPHS) criteria, along with patient satisfaction. With a p-value of (p=0.05), the data obtained was statistically evaluated with IBM SPSS Statistics for Windows.

Results: Regarding marginal adaptation, retention and fracture, all restorations in both groups had Alpha scores; at baseline, and during the follow-ups. While for shade matching and patient satisfaction, regarding the changes by time within the E group all restorations revealed (100%) Alpha scores and satisfaction respectively at base line, and during the follow-ups. While in G group, all restorations revealed (100%) Alpha scores and (100%) satisfaction at baseline, after 12, and 24 months. However, after 36 months, Alpha scores and satisfaction insignificantly decreased to (80%) while Bravo scores and unsatisfaction insignificantly increased to (20%) as P= 0.31 with 0.51 effect size.

Conclusion: Lithium disilicate endocrowns offer higher clinical outcomes in terms of shade matching and patient satisfaction than Grandio endocrowns, which offer a good clinical solution for the teeth that have undergone endodontic treatment. The study was registered at ClinicalTrials.gov (NCT04757428).

KEY WORDS: Endocrowns, Lithium Disilicate, hybrid Nano-ceramic, CAD/CAM, USPHS criteria.

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INTRODUCTION

Digital dentistry is considered worldwide as the future of the dental field, with wide clinical acceptance among clinicians. The CAD/CAM technology is considered as an advanced predictable approach in the restorative and prosthetic dentistry, which appeared in 1985 with continuous uprising modification and development till now. Different available software provides the clinicians with the advantage of accurately achieving complex procedures rapidly together with optimum adjustment of occlusal morphology.[1] Thus permitting the constructions of precise final simple and complex restorations when compared to traditional techniques. [2] The CAD/CAM technology delivers a customized production of 3-D images for different preparation designs obtained through digital scanning of the impression or even intraoral scanning. The restoration is designed virtually and sent to the milling machine to manufacture the restoration from different blocks of restorative material. The clinician should make the optimum choice of the material based, not only on the esthetics, but also on the intended durability of the restorations. [3]

The restoration of root canal treated teeth with variable amount of destruction coronally remains a controversial topic. The ideal post-endodontic restoration for those teeth may vary, especially after combining the CAD/CAM technology with the excelling adhesive systems. [4] In a systematic review published in 2020, it could be noticed that the clinical decision to practice traditional post and core restoration systems is stepped-back with the introduction of alternative endocrowns.[5] Many studies proved the great clinical performance of endocrown restorations both functionally and esthetically, in addition to the longevity of such restorations, along with their cost effectiveness and less time consumption.[6,7]

E.max restorations composed mainly of lithium disilicate crystals, were commonly used as a glass ceramic material for restorations such as crowns, veneers and endocrowns due to the ability to combine both esthetics and adhesion to the natural tooth structure. [5] In addition its excellent shade matching characteristics, and similar translucency to the natural tooth structure provide an optimum esthetic outcome compared to the adjacent natural teeth. When it is bonded, glass ceramic has excellent long-term durability and strength.[8] Dartora et al. in 2017, reported that lithium disilicate CAD\CAM endocrown restorations were a successful substitute for rehabilitation of teeth with endodontic treatment. Being conservative; it offers proper mechanical behavior and durability besides its cost effectiveness and quicker constructional steps. Also, it exhibited better bonding and higher compressive strength than endodontic treated teeth restored with conventional crowns. [2] However, it still suffers from some drawbacks attributed to its modulus of elasticity (67.2 GPa), [9,10] which is higher than the tooth structure (18.6 GPa). [11] This might disturb the marginal adaptation [9] and lead to unbalanced stress transmission to the restored weakened tooth, resulting in a negative impact on the biological and mechanical functionality of the restorative system employed to restore the destroyed dentin.[12]

Grandio blocks were introduced in the market as nano-ceramic hybrid CAD/CAM blocks containing high filler content of 86 % by weight that make a perfect similarity to natural teeth, enhanced physical properties for flexural strength, and the ease of polishability. In addition to accurate grinding properties of restorations with thin margins, it allows optimum repairability in case of minor fractures.[13] The accuracy of fit as well as the type of luting cement have great impact on the longevity of ceramic-based hybrid material. Thus, retentive preparations and small gap widths (<100μm) should be maintained while using adhesive resin cements. [14]

The introduction of hybrid ceramics combined with nanotechnology may enhance the clinical effectiveness of endocrowns. Therefore, the aim of this clinical trial was to compare the marginal

adaptation, fracture, retention, shade matching and patient satisfaction between lithium disilicate (e.max) and hybrid nano-ceramic (Grandio) CAD/CAM endocrowns after one, two- and three-years of clinical service. The null hypothesis of the study was that there would be no significant difference in the marginal adaptation, fracture, retention, shade matching and patient satisfaction between lithium disilicate (e.max) and hybrid nano-ceramic (Grandio) CAD/CAM endocrowns.

MATERIALS AND METHODS

This randomized clinical trial was triple blinded with an allocation ratio 1:1. It has been approved by the Research Ethics Committee of the Faculty of Dentistry, Cairo University. Each participant signed an informed consent form in the native language of the patients before participating in the trial.

Study setting and study design

All participants who met the inclusion criteria were collected until the required sample size was reached. The selection criteria for the recruited patients were male or female between the ages of 20 and 50 who maintained good oral hygiene and had endodontically treated molars in need of prosthetic restoration. Participants should approve to participate in the trial. There should be enough tooth structure in the included molars to receive endocrown restoration with three walls, at least 1.5mm thick, and supragingival margin. In addition, the tooth should be completely erupted with a healthy periodontium, have a successful endodontic treatment with lack of developmental flaws or periapical pathosis. Patients with poor dental hygiene, active periodontal disease, missing teeth opposite the area planned for restoration, parafunctional habits, psychological issues, unrealistic expectations, and lack of cooperation were rejected. Detailed medical and dental records were taken before taking part in the study.

Sample size

With 80% power and at 5% significance, a total of 20 CAD/CAM endocrown restorations (10 in each group) were sufficient. To evaluate the clinical relevance of this study, power analysis employed Modified United States Public Health Service (USPHS) criteria addressing marginal adaption, fracture, retention, shade matching, and patient satisfaction as outcomes. PS: Power and Sample Size Calculation Software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA) was used to calculate sample size. [15–17]

Allocation concealments and implementation

On a white piece of paper using a blue ink, a number was inscribed for each participant in each group. The paper was securely sealed, pleated, and stored in a safe location until the time the procedure was carried out.

Randomization

The randomization was done using an automated sequence generator (https://www.randomizer.org/). Group E was given e.max endocrowns (lithium disilicate ceramic blocks, IPS e.max CAD), while group G was given Grandio endocrowns (nano-hybrid composite blocks, Grandio, VOCO), according to the kind of restorative material used.

Blinding

This study was a triple blinded study since the participants, the outcome assessors, and the statistician were blinded. However, the main operator, who oversaw all clinical operations, was not.

Restorative procedure

Grandio and e.max CAD/CAM blocks were the two materials chosen for this trial. All clinical procedures were completed by the same operator to ensure consistency in restorative procedures. Each participant received scaling and polishing prior to shade selection to remove calculus, plaque, or

stains.[2] Vitapan's 3D Master shade guide (VITA, Zahnfabrik, Germany) was used to choose tooth's shade visually by matching the shade with the adjacent teeth using 3 different light sources; (i) day light at mid-day where there is a balance between incident daylight with visible light spectrum and then checked with (ii) incandescent light of the dental unit, and (iii) Color-corrected light (Smile Lite, Smile Line, Switzerland) was utilized by three prosthodontist to prevent metamerism. A color rendering index (CRI) of 92, 1.500 lux at about 10 cm, and a color correlated temperature of 5500K were all characteristics of this light.

Any pre-existing restoration was removed, and then occlusal surface was reduced from 1.5 - 2 mm using wheel diamond stone to make butt margin design. Cavity depth should be a minimum of 3mm. Any undercut in the preparation was eliminated, using a round end tapered stone, by holding the stone parallel to the tooth. The width of butt margin should not be less than 2 mm. Immediate dentin seal was performed to all dentin walls and pulp chamber floor using universal bonding agent and flowable composite (Te-Econom, Ivoclar Vivadent) was applied to block any undercuts in the pulpal floor and axial walls to avoid weakening of the remaining tooth structure (Fig. 1A and B).

Digital impression was made using an intraoral scanner (Medit i500, Medit, Korea), and Exocad software was used to design the endocrown. Afterwards, a 5-axis milling machine (Arum 400 milling machine, Arum Gmbh, Germany) was used to mill the restoration from prefabricated blocks.

Before bonding, each endocrown was intraorally examined for interproximal contact, marginal adaptation, and occlusal contact. Using a rubber dam to effectively isolate the tooth, universal adhesive agent was then applied, air thinned, and light-cured for 20 seconds. The fitting surface of the endocrown restoration, on the other hand, was treated with 9.5% hydrofluoric acid for 20 seconds, thoroughly rinsed with water, and then air dried. After 60 seconds of application, silane was allowed to air dry. After applying dual-cured self-adhesive resin cement (BisCem, Bisco, USA) to the fitting surfaces of the endocrown and the cavity, the restoration was carefully placed inside the cavity while being gently pressed by finger pressure against the occlusal surface of the restoration. Tack curing for three seconds was done first to remove the excess cement using probe and dental floss. The curing procedure was then completed for 40 seconds from each surface using LED light cure unit perpendicular as close as possible to the margins and surface of the restoration. [5–7] After bonding of endocrowns, occlusal interferences were checked and eliminated. Then finishing and polishing were performed to obtain a luster surface and maximum esthetic appearance (Fig. 2A and B).

A. Occlusal view B. Lateral view

Fig. 1. Finished preparation of upper first molar (occlusal view)

Assessors' calibration for clinical evaluation

To standardize the shade selecting process, three qualified and experienced staff members were chosen as the evaluators of the shade chosen compared to the contra-lateral/adjacent tooth. They have all undergone Ishihara's test to discover whether they are color deficient.[17] Their findings excluded color blindness. Each endocrown was evaluated, using Modified United States Public Health Service (USPHS) criteria. (Table 1), at base line, after 12, 24 and 36 months of clinical service (Fig. 2,3, and 4).

Statistical analysis

Through the evaluation of each assessment criterion, data were collected. Frequencies and percentages were used to present qualitative data. The two groups were compared using Fisher's Exact test. To examine the alterations over time within each group, Friedman's test was applied. The cutoff for significance was chosen at P 0.05. Statistical analysis was carried out with IBM SPSS Statistics for Windows, Version 23.0, IBM Corp., Armonk, New York.

TABLE (1). USPHS criteria for direct clinical evaluation of restorations

Outcome	Measuring device	Measuring unit
Marginal adaptation	According to modified USPHS criteria	Alpha(A): No visible evidence of crevice along the margins; no catch or penetration of the explorer. -Bravo(B): Visible evidence of crevice and/or catch of explorer; no penetration of the explorer. -Charlie(C): Visible evidence of crevice and penetration of the explorer
Fracture	According to modified USPHS criteria	Alpha(A): None -Bravo(B): Small accepted -Charlie(C): Moderate\unaccepted
Retention	According to modified USPHS criteria	-Alpha(A): Retained. -Bravo(B): N/A*. -Charlie(C): Mobile\Missing
Shade matching	According to modified USPHS criteria	-Alpha (Excellent): Ideal. -Bravo (Acceptable): Less than ideal but no modifications required -Charlie (Acceptable but modifications needed): Staining or other shade modifications required. -Delta (Unacceptable): Remake
Patient satisfaction	Visual Analogue scale (VAS)	Satisfied or not satisfied.

N/A: not applicable

A. Lateral view B. Occlusal view

Fig. 2. Endocrown immediately after cementation

Fig. (3). Checking shade matching during the follow-up after 3 years

A. Before polishing B. After polishing

Fig. (4). Upper first molar showing Bravo score after 3 years

RESULTS

Demographic data

The mean age values in both groups did not differ statistically significantly. Additionally, there was no statistically significant variation in the gender distributions between the two groups. (Table 2)

Evaluation of marginal adaptation, retention, and fracture

Regarding marginal adaptation, retention, and fracture, all restorations in both groups had Alpha scores; at base line, after 12, 24 and 36 months.

Evaluation of shade matching

For shade matching, in group E (e.max) all restorations revealed Alpha scores (100%) at base line, after 12, 24, and 36 months. While in group G (Grandio) all restorations revealed Alpha scores (100%) at base line, after 12, and 24 months. However, after 36 months Alpha scores insignificantly decreased to (80%) and Bravo scores insignificantly increased to (20%) as P= 0.31 with 0.51 effect size. (Table 3) (Fig. 5)

Evaluation of patient satisfaction

Concerning patient satisfaction, in group E (e.max) all restorations revealed (100%) satisfaction at base line, after 12, 24, and 36 months. While in group G (Grandio) all restorations revealed (100%) satisfaction at base line, after 12, 24 months. However, after 36 months satisfaction insignificantly decreased to (80%) and unsatisfaction insignificantly increased to (20%) as P= 0.31 with 0.51 effect size. (Table 3) (Fig. 5)

TABLE (2) Mean, standard deviation (SD), frequencies (n), percentages and results of Student's t-test and Chi-square test for comparison between demographic data in the two groups

Demographic data		Experimental (n = 10)	Control (n = 10)	*P*-value
Age (Years) M (SD)		32.6 (5.8)	34.4 (7.5)	0.792 ns
Gender n (%)	Male	2 (20)	3 (30)	0.465 ns
	Female	8 (80)	7 (70)	

NS: Non-significant difference as P > 0.05

TABLE (3) Descriptive statistics and results of Fisher's Exact test for comparison between shade matching scores in the two groups and Friedman's test for the changes by time within each group

Parameter	**Follow up**	**Score**	**Group E (e.max)**		**Group G (Grandio)**		**P value**	**Effect size**
			N	%	N	%		
Shade matching	**Baseline**	Alpha	10	100	10	100	----	----
		Bravo	0	0	0	0		
		Charlie	0	0	0	0		
	12 months	Alpha	10	100	10	100	----	----
		Bravo	0	0	0	0		
		Charlie	0	0	0	0		
	24 months	Alpha	10	100	10	100	----	----
		Bravo	0	0	0	0		
		Charlie	0	0	0	0		
	36 months	Alpha	10	100	8	80	0.31	0.51
		Bravo	0	0	2	20		
		Charlie	0	0	0	0		
Patients' satisfaction	**Baseline**	Satisfied	10	100	10	100	----	----
		Unsatisfied	0	0	0	0		
	12 months	Satisfied	10	100	10	100	----	----
		Unsatisfied	0	0	0	0		
	24 months	Satisfied	10	100	10	100	----	----
		Unsatisfied	0	0	0	0		
	36 months	Satisfied	10	100	8	80	0.31	0.51
		Unsatisfied	0	0	2	20		

N: frequency ***%: percentage*** ***Ns: non-significant at P > 0.05***

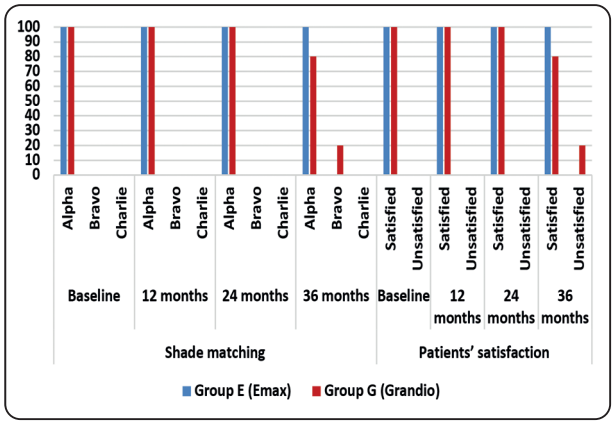

Fig. (5). Bar chart representing different scores of Shade matching and Patients' satisfaction in both groups at different intervals.

DISCUSSION

The root canal treated teeth are mechanically weakened structures, frequently subjected to fracture or loss of structural integrity which resulted from foregoing caries attack, elimination of old restoration, in addition to root canal cleaning and shaping procedure during endodontic treatment. All these integrated factors will lead to more brittle weakened teeth that require rapid reinforcement and support of their remaining structures to be able to restore their function in the oral cavity and prevent fracture.[4] Previously, the post and core systems were the commonly used line of treatment to support these endodontically treated teeth. However, many studies revealed that some post and core systems might contrarily weaken the remaining tooth structure rather than reinforcement, as they require further removal of the radicular structure for post space preparation. [6,18,19] The majority of research highly recommended tooth structure preservation with a more conservative preparation like endocrowns. These restorations conserve the tooth structure because they include supragingival borders on peripheral enamel without requiring root-canal preparation which leads to preservation of tooth structures, improvement in bonding capability and decreasing the concentration of stresses along the interface of cement/root dentin. [5,7,20,21]

Lithium disilicate endocrown restorations possess high fracture toughness, flexural strength, and thermal shock resistance. This is attributed to the presence of lithium disilicate crystals which resist crack propagation and enhance the esthetic properties and bonding, together with decreased thermal expansion scale that marks it as a gold standard between all glass ceramic restorations. [22,23]

Grandio blocks being a hybrid nano-ceramic offer good properties such as flexural strength close to the natural teeth, optimum performance under heavy occlusal loads and the possibility of intra-oral repairability. [13]

Endocrown restorations were fabricated using CAD/CAM technique to minimize human error as well as eliminate many variables to enhance their marginal and internal fit. [24–26]

In our clinical trial, shade was selected after scaling and polishing to match the correct shade with patients' natural teeth. Repeatability for color matching was crucial with 3D master shade guide by using color corrected light and daylight to avoid metamerism. [17,27]

According to several studies, the fracture resistance of all-ceramic restorations increases as the occlusal thickness does. Additionally, endocrowns that are 5.5 mm thick have twice as much fracture resistance as ceramic restorations that are 1.5 mm thick at the occlusal surface. Therefore, in this study, the cavity depth was kept at least of 3 mm pulp chamber depth because of the improved mechanical properties. (28,29).

Concerning this study's patient satisfaction and shade matching results, no statistically significant difference between the study groups were found. This might be because of the two tested materials' excellent mechanical and esthetic characteristics as well as the meticulous construction procedure combined with a strict bonding protocol to each corresponding material used. However, a couple of Bravo scores were recorded in the Grandio group after 36 months, this may be due to the smoking habit of the patients and surface staining of the restoration

over time, which was managed by proper polishing to restore the original shade.

In accordance with our results, Tzimas et al. in 2018 stated that all evaluated criteria of resin composite endocrowns, after 12 months, were recorded as Alfa, showing high success. However, the shade match was rated as Bravo, because of the pre-existing crack and the periodontal mobility of the teeth, respectively. [28] Also, Carlos et al. in 2018 found that after 2-5 years of clinical evaluation, margin discoloration of resin composite endocrowns was noticed due to natural pigmentation of composite over time. This discoloration can be managed by simple polishing. [29]

In 2017 Dartora et al. concluded that lithium disilicate endocrown restorations seem to be a good substitute for reconstruction of endodontic treated teeth since it presents maximum tooth preservation, longevity, faster clinical procedures and exhibits higher fracture strength and improved bond strength to tooth.[2]

Concerning CAD/CAM lithium disilicate endocrowns, Da Cunha et al in 2017 pointed out that the 12-year success rate with 90.5% for molars and 75% for premolars might be due to increased degradation resistance of the reported restoration. [1] Altier et al. revealed in 2018 that compared to resin composite, e.max endocrowns showed greater fracture strength. [30] In addition, Belleflamme M. et al. in 2017 discovered that after 44 months of service, lithium-disilicate glass-ceramic material had higher survival and success rates than Polymer Infiltrated Ceramic Network material. They found that this may be due to high strength and fracture resistance of lithium-disilicate glass-ceramic. [31]

In 2016, Sedrez-Porto et al revealed that the excellent survival rate of lithium disilicate endocrowns used for indirect restorations after 36 months might be due to the high structural durability and reasonable longevity of this material. [32]

In 2019, according to Furtado de Mendonca. et al e.max endocrowns and polymer-infiltrated ceramic network or direct resin composite restorations both revealed equivalent biomechanical performance. This was in accordance with several previous studies. They highlighted how these similar materials behave, due to these materials' superior mechanical characteristics and high flexural strength of up to 250 MPa. (35).

Contradicting our results, a clinical study performed by Otto and Mormann in 2015 who found lower success rate of molar endocrowns. They explained the failure of molars in their study by insufficient stabilization and lack of retention in the pulp chamber. [33]

Finally, the hypothesis was accepted as there was no statistically significant difference in the marginal adaptation, fracture, retention, shade matching and patient satisfaction between lithium disilicate (e.max) and hybrid nano-ceramic (Grandio) CAD/CAM endocrowns.

CONCLUSION

Within the limitations of this clinical trial, it is possible to withdraw the following conclusions:

1. Lithium disilicate endocrowns offer higher clinical outcomes in terms of shade matching and patient satisfaction.
2. Grandio endocrowns are a good clinical solution for the teeth that have undergone endodontic treatment.

CLINICAL IMPLICATION

For teeth with endodontic treatment, Grandio and e.max could be used as endocrown restorations with good prognosis. The selection between both materials is reliant on the dentist's predilection and clinical condition.

CLINICAL RECOMMENDATION

Further randomized clinical trials are recommended for long-term evaluation of the clinical behavior and patient satisfaction of Grandio to enable its usage in different clinical situations.

CONFLICT OF INTEREST

The authors do not have any conflicts of interest to disclose.

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