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Clinical performance of lithium disilicate crowns restoring endodontically treated teeth with two occlusal preparation schemes: Randomized clinical trial

Marwa Salem
PhD candidate, Division of Fixed Prosthodontics, Faculty of Dentistry, Cairo University, Egypt and Assistant lecturer, Division of Fixed prosthodontics, Faculty of Dentistry, New Giza University, Egypt

Omnia Nabil
Lecturer, Division of Fixed Prosthodontics, Faculty of Dentistry, Cairo University, Egypt

Maha Taymour
Associate Professor, Division of Fixed Prosthodontics, Faculty of Dentistry, Cairo University, Egypt

***Abstract*---**Aim: To evaluate the clinical performance of lithium disilicate crowns restoring endodontically treated teeth with two occlusal preparation schemes. Materials and methods: Forty full coverage lithium disilicate restorations were fabricated for posterior endodontically treated teeth. Patients were divided into two groups according to the preparation design, Group PO (control group): Planar occlusal design and Group FO (intervention group): Flat occlusal design. The preparation was standardized with deep chamfer finish line for all teeth. The restorations were milled from e.max CAD blocks and proper adhesive protocol was followed. After final cementation, the clinical performance of the restorations was evaluated according to the USPHS criteria in terms of fracture, marginal adaptation, marginal discoloration and secondary caries. These measurements were recorded at baseline, after 3, 6, 9 and 12 months respectively. Results: No statistically significant difference was detected between both groups for all tested outcomes (Fracture, marginal adaptation, secondary caries and marginal discoloration) over one year. While comparison between follow-up periods revealed statistically significant difference within the PO group, regarding marginal discoloration ($P \leq 0.05$). Conclusions: Both planar and flat occlusal design revealed

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***Corresponding author**: Salem, M.; Email: marwasalem107@gmail.com*
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successful clinical performance with lithium disilicate full coverage restorations.

***Keywords*---**Lithium disilicate, endodontically treated teeth, occlusal design, clinical evaluation, fracture, marginal adaptation, marginal discoloration, secondary caries.

Introduction

The completion of root canal treatment does not signal the end of patient management. The restoration of the tooth back to its normal form, function and esthetics is the actual goal. This is achieved by protecting the weakened teeth from future failure, with the help of a well-fitted restoration[1].

Restoration of endodontically treated teeth is challenging when compared to vital teeth which is understandable due to the structural variations between them. Current literature suggests that successful management of root canal treated teeth depends on two main factors: an effective coronal seal against any microorganisms and the preservation of the remaining tooth structure for better prognosis to resist occlusal loads[2]**.** Monolithic ceramic crowns offer the clinician superior aesthetic results while being conservative for the fabrication of full coverage crowns[1]**.**

The successful clinical performance of glass ceramics is documented in multiple researches which explains their global spread and acceptance[3]. The structural durability of any ceramic restoration is influenced by its mechanical properties, thickness and underlying amount of preparation[4]**.**

Tooth preparation is considered a fundamental step for the success of any tooth-supported fixed restoration. Therefore, studying the effect of tooth preparation on withstanding functional stresses to prevent crown and/or tooth fracture, is necessary[5]**.**

Guidelines for tooth preparation to receive a full coverage restoration, have always been following the anatomical geometry. However, a different concept of using the non-anatomical preparation designs emerged to decrease the stresses and allow better distribution of the loads. Planar occlusal design is used in case of non-vital teeth, as well as the flat occlusal design which provided better qualitative and quantitative stress distribution when compared to an anatomically prepared surface[6]**.**

The long-term success of ceramic restorations is affected by various factors that should be inspected closely to avoid the risk of failure. Clinically, precise marginal fitting of the restorations is crucial for good long-term prognosis and avoiding early failure, which can be presented as fracture or secondary caries[7]**.**

A gap was found in literature due to the lack of clinical studies evaluating the effect of non- anatomic occlusal preparation on the success of final restorations. This is important because the mechanical forces, as well as the geometric outline

of the underlying tooth structure, play a major role on the prognosis of these fragile teeth.
The aim of this study was to evaluate the clinical performance of lithium disilicate crowns restoring endodontically treated teeth with two occlusal preparation schemes, the planar occlusal preparation and the flat occlusal preparation, every 3 month for 1year as follow-up periods.

The first null hypothesis of this study was that there would be no significant difference between the clinical performance of endodontically treated posterior teeth with flat occlusal design and those with planar occlusal design restored by lithium disilicate crowns. The second null hypothesis was that there would be no statistically significant difference between different follow-up periods, for each outcome, in both groups.

Materials and Methods

This randomized clinical study was performed in Fixed Prosthodontics' clinics of the Faculty of Dentistry, Cairo University, Egypt. It was approved by the University's Ethics Committee of Scientific Research in July 2019. Medical and dental history as well as a written informed consent, were obtained from all participants who were selected according to their need for a full coverage restoration on an endodontically treated tooth.

The inclusion criteria: Age range between 21-40 years old, absence of periapical pathosis, absence of tooth mobility or furcation involvement, patients with endodontically treated teeth requiring full coverage restorations and patients with sufficient occluso-gingival height.
Exclusion criteria: Poor oral hygiene, pregnant patients or patients unwilling to attend follow-up visits, absence of opposing dentition, patients with improper root canal treatment and presence of parafunctional habits.

To avoid selection bias in our study, randomization was done using (www.randomizer.org). For allocation concealment, opaque sealed envelopes containing the grouping generated previously, were released to the patient in the 2nd visit before tooth preparation, with allocation ratio 1:1. This study was triple blinded: the outcome assessors (two experienced doctors), the participants and the statistician were blinded[8].

The calculated sample size was 17 in each group, however, to compensate for anticipated missing data, the number was increased to 20. So, a total sample size of 40 restorations was sufficient with power 80% and 5% significance level which was calculated by the G power program[9].

The participants were divided into two groups according to the employed occlusal preparation design. Group PO (control group) represented the planar occlusal design and group FO (intervention group) represented the flat occlusal design.

Clinical and radiographic examination were carried out before proceeding with the treatment. All procedures were performed by the main researcher. Scaling and polishing were performed for each patient then a silicon index was done before

tooth preparation and was used to evaluate the amount of preparation done in the occlusal, buccal and palatal/lingual surfaces[10]. The central groove was taken as a reference point to standardize and compare the tooth removal between 2 groups. For the control group, 1.5 mm was removed from the central groove, the buccal cusps were prepared in one plane and the palatal/lingual cusps were prepared in another plane. For the intervention group, 1.5 mm was removed from the central groove and slightly more at the cusp tips to reach a flat non- anatomic occlusal surface[6]. Figures (1-2)

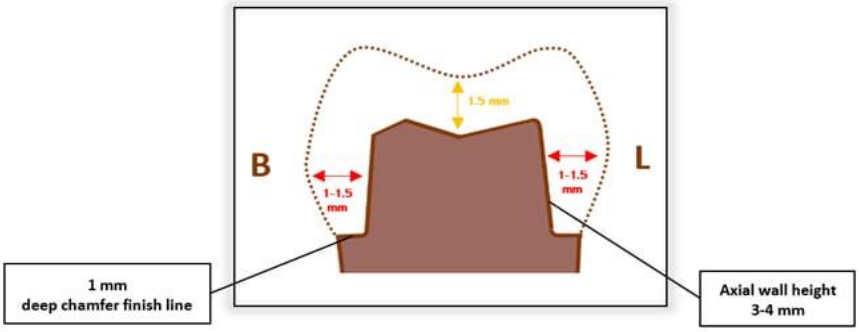

Figure 1. Schematic diagram representing the guidelines for planar tooth preparation

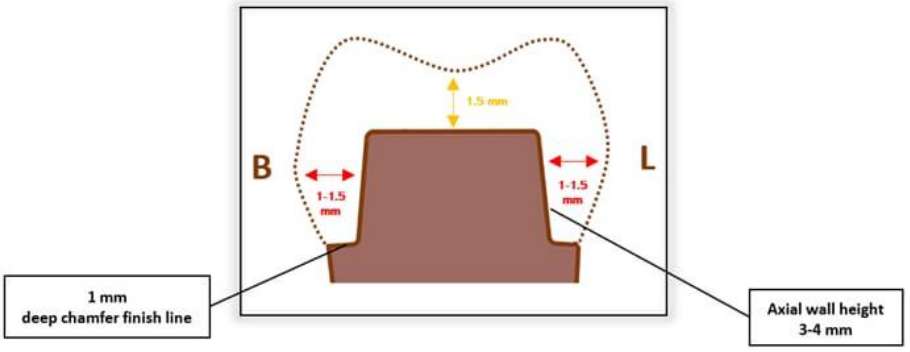

Figure 2. Schematic diagram representing the guidelines for flat tooth preparation

Depth cutters of known depth were used for occlusal and buccal preparation then the preparation was verified with the silicon index. The remaining axial wall height must be a minimum 3-4 mm. A deep chamfer finish line of thickness 1 mm, was created supra-gingivally, to reach a continuous circumferential finish line[10,11]. Figure (3)

Figure 3. Silicon index to verify preparation of axial surfaces

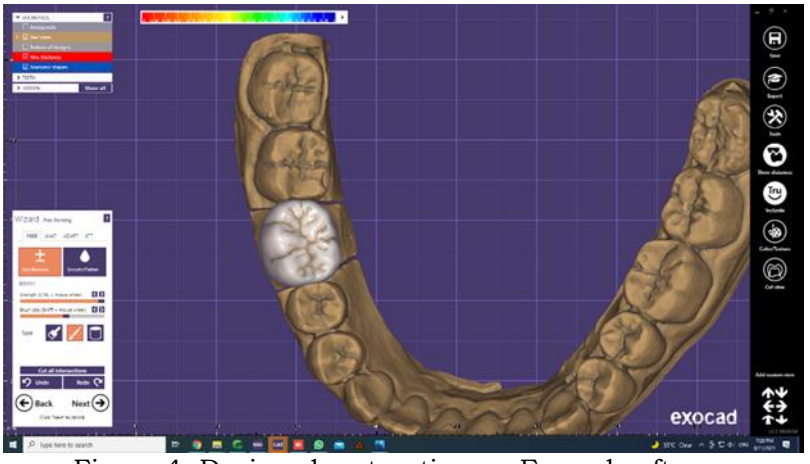

Figure 4. Designed restoration on Exocad software

Vinyl polysiloxane elastomeric impressions (Panasil, Kettenbach, Germany) were made, poured and master casts were fabricated. An extra oral scanner (Medit Identica T500) was used to scan the master cast from different aspects. Designing was carried out on Exocad software Figure (4).

Sequential CAD steps were followed: starting with the selection of restorative material, margin determination, selection of suitable path of insertion and then adjusting the restoration design. The cement space was set to 50 microns[13]. Chairside provisional restorations (Structur 2, VOCO, Germany) were cemented with non-eugenol provisional cement (Rely X temp NE, 3MESPE, USA) till the fabrication of another milled PMMA restorations. The construction of the final e.max crowns was performed using 5-axis milling machine (Arum Mill 5X-400).

During bonding, the fitting surfaces of the e.max crowns were treated according to the manufacturer's instructions. After rubber dam isolation, dual cured self-adhesive resin cement (Breeze, Pentron, USA) was used for bonding[14]. Then excess cement was removed inter-proximally using dental floss, and an articulating paper was used to check for any occlusal interference. Figure (5)

Figure 5. Lateral view post operatively

Since the main researcher performed all the procedures during this study, then, outcomes' evaluation had to be performed by experienced evaluators who did not know the patients belonged to which group[8]. The clinical performance was determined using USPHS criteria and follow-up visits were carried out every 3, 6, 9 and 12 months[9,15]. A sharp explorer was used for inspection under magnification, using tactile sensation. Any cracks or fracture was detected visually, as well, any discoloration or stains at the margins of the restoration were recorded (Table 1).

Table 1
USPHS criteria for outcomes' evaluation

Primary outcome	Fracture	**Alpha (A)** Smooth surface of the restoration, No evidence of fracture **Bravo (B)** Dull surface and/or chipping of porcelain that does not impair function, Minor fracture **Charlie (C)** Chipping of veneering material impairing esthetics and function, Moderate fracture **Delta (D)** Major fracture
Secondary outcomes	Marginal adaptation	**Alpha (A)** Restoration is continuous, 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
	Marginal discoloration	**Alpha(A)** No discoloration **Bravo (B)** Superficial staining (removable, localized) **Charlie (C)** Deep staining (not removable, generalized)
	Secondary caries	**Alpha (A)** No evidence of caries continuous with the margin of the restoration **Bravo (B)** Caries is evident, continuous with the margin of the restoration

After data collection, it was recorded that 3 participants, from the control group, did not show-up in the last follow-up period and were considered as dropouts from the study.

Results

All qualitative data were presented as frequency & percentages. All comparisons were performed by using Chi square test. Statistical analysis was performed with SPSS 20®, Graph Pad Prism®, and Microsoft Excel 2016. Comparison of the results between the control and intervention groups in terms of: fracture, marginal adaptation, marginal discoloration and secondary caries, revealed absolute insignificant difference in alpha score as they were (100%) at different follow-up periods.

Comparison between different follow-up periods for each score separately was performed, for both groups. Regarding the following outcomes: fracture, marginal adaptation and secondary caries, results revealed an insignificant difference in alpha score as it was the only recorded score (100%) as $P > 0.05$. However, regarding the marginal discoloration outcome in the PO group, comparison revealed a statistically significant difference between alpha (A) & bravo(B) scores, as $P < 0.05$ (Table 2)(Figure 6). The survival analysis done for the restorations of the two groups was 100% since all restorations showed alpha or bravo scores and there was no failure.

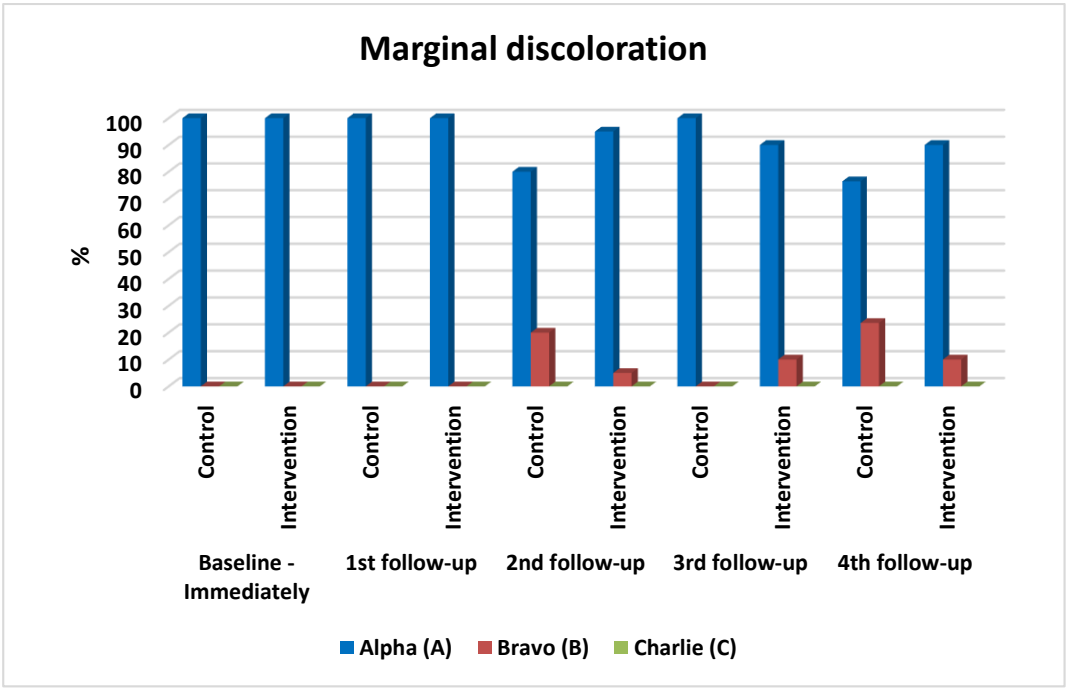

Figure 6. Comparison between control & intervention groups regarding marginal discoloration

Table 2
Comparison between control & intervention groups regarding marginal discoloration

Marginal discoloration		Alpha (A)		Bravo (B)		Charlie (C)	
		N	%	N	%	N	%
Baseline - Immediately post-cementation	Control	20	100	0	0	0	0
	Intervention	20	100	0	0	0	0
	P value	1.0000		--------		--------	
1st follow-up after 3 months	Control	20	100	0	0	0	0
	Intervention	20	100	0	0	0	0
	P value	1.0000		--------		--------	
2nd follow-up after 6 month	Control	16	80	4	20	0	0
	Intervention	19	95	1	5	0	0
	P value	0.15		0.15		--------	
3rd follow-up after 9 month	Control	20	100	0	0	0	0
	Intervention	18	90	2	10	0	0
	P value	0.15		0.15		--------	
4th follow-up after 12 month	Control	13	76.4	4	23.6	0	0
	Intervention	18	90	2	10	0	0
	P value	0.21		0.28		------	
N= number		%= percentage				*p*-value ≤ 0.05	

Discussion

This study was a randomized, triple blinded clinical trial where randomization was carried to eliminate the risk of selection bias of the included patients[8]. For standardization, all teeth included were first molars, with good obturation and limited coronal loss. They were mainly selected because they are the first teeth to erupt in the oral cavity, thus, the most liable to decay and exposed to high occlusal forces[10].

The choice of endodontically treated teeth was based on their fragility after treatment. Usually, anatomical preparation is crucial in vital teeth to preserve pulp vitality while in non-vital teeth, the main goal is to protect tooth from fracture[10].

The material used for fabrication of the final restoration in this study was lithium disilicate glass ceramic as it is one of the most popular materials in dentistry with outstanding performance in terms of optimum esthetic and adequate mechanical properties to withstand occlusal forces[12]. Using IPS e.max CAD allowed easier laboratory construction compared to the traditional laboratory process with comparable accuracy[16].

In order to standardize the preparation and preserve tooth structure, depth cutter diamond stones, of known diameter and depth, were used for the preparation of occlusal and buccal surfaces. All teeth were prepared with 1 mm supragingival deep chamfer finish line, to simplify visualization, impression taking and final bonding of the restoration. Axial preparation was a range between 1-1.5 mm [14]. Deep chamfer configuration showed accurate marginal adaptation, better internal fit and stress distribution than shoulder finish line[17].

The amount of occlusal preparation was set to 1.5 mm from the central groove as a reference point, to give sufficient thickness for glass ceramics to resist occlusal forces in posterior areas. The accepted axial wall height was 3-4 mm to allow proper retention and resistance of the restoration while the total occlusal convergence was up to 20° [10,11].

The variation of the occlusal scheme can affect the stress distribution in ceramic restorations as well as the ability of the tooth to resist fracture better, especially in case of fragile teeth like endodontically treated teeth[6,14]. The USPHS criteria were chosen to standardize and document the different studied outcomes according to previous studies using a mirror and sharp explorer under magnification[9].

Outcomes were evaluated immediately after cementation, after 3, 6, 9 and 12 month. Any required polishing for the marginal discoloration was done using nylon polishing brushes (Nylon Prophy Brushes, Pegasus, UK) and polishing paste (prophylaxis paste, Defend, USA). The drop-out patients, who didn't complete the follow-up visits, were 15 % and they were all from the control group. This didn't affect the results of the study, so, attrition bias was non-significant because this was already considered during sample size calculation[18]. The drop-out may be justified due to the inability of the patients to come in the COVID-19 critical conditions and lock-down.

Based on the collected data from this study, no statistically significant difference was detected between the clinical performance of both tested groups in all evaluated outcomes. This is presented as 100 % survival rate for both groups in this period of one year. Thus, the 1st null hypothesis was accepted.

The 2nd null hypothesis was partially rejected. This was evident in the variation between the marginal discoloration scores, through the different follow-up visits. Regarding the fracture results, alpha scores were recorded for all restorations during follow-up periods. This may be explained by the satisfactory thickness of the restoration to withstand masticatory forces[19].

The flat occlusal design may have a positive effect on the improvement of the fracture resistance of glass ceramics which is in agreement with the results of other in-vitro studies[6,20,21]. On the other hand, some studies still consider the anatomical preparation as the gold standard for tooth preparation with the best results in terms of resistance, retention, fracture resistance and marginal adaptation[4,5,22].

Regarding the marginal adaptation results, alpha scores were recorded for all restorations during the follow-up periods. The marginal adaptation of any restoration may be influenced by multiple factors, including the preparation design, the optical scanner used, the interface parameters defined in the design software, the manufacturing process, and the type of material used during fabrication[5]. Therefore, in this study, meticulous attention to all the previously mentioned details was done to reach the best results.

Simple preparation design will ensure proper marginal fitting of the restoration when compared to more sophisticated occlusal designs[23]. This was in accordance with the results concluding that the flat occlusal scheme provided good marginal fit[7]. The fabrication technique using CAD/CAM technology, is known to create marginal discrepancy values within clinically accepted range (120 μm), improved marginal and internal fit in comparison to other fabrication techniques[13,24].

Regarding the marginal discoloration results, there was no statistically significant difference between both groups, as the majority of the restorations recorded alpha scores. However, during the follow-up periods, the restorations showed alpha and bravo scores.

These marginal discolorations were removed after scaling and polishing which was the normal protocol followed by Petridis et al 2012[25]. Although, they improved in the next follow-up visit, they re-occurred in the final follow-up at 12-month which may be justified because the patients didn't follow the proper oral hygiene protocol.

Rauch et al 2017 stated that discoloration is noticeable at the adhesive gap while using self-adhesive resin cements which may be caused by the wear of the luting material[26]. Although there was no significant difference in the marginal adaptation of the restorations between both groups during clinical examination, there might be some variations in the marginal adaptation of these restorations on a microscopic scale.

A purely digital workflow may have an effect on the marginal adaptation, as concerns regarding scanning accuracy of the anatomically prepared cusps, as well as the milling inaccuracies of the intaglio surface of milled restorations, were raised[27].

Therefore, planar occlusal design needs more attention during scanning and seating when compared to the flat design[19,26,27]. Majeed, M.A. & Al-Adel, S.K. 2016 stated that higher internal gap values were recorded in the planar preparation compared to flat preparation which is accompanied by the increase in marginal gap. Inaccuracies in scanning may be based on the principle" not on the same plane surface"[28].

On the other hand, other studies showed lower performance of the flat occlusal preparation[5,29]. Nevertheless, the visual-tactile assessment of all tested groups, showed adequate and successful marginal integrity. This explains that there

could be difference between clinical examination results and the microscopic ones.

Regarding the results of secondary caries, the scores recorded were alpha for all groups during the follow-up periods. This may be explained by following the strict adhesive bonding protocol. This was in agreement with Sorrentino et al 2018 and Liebermann et al 2020 who studied and proved the importance and effectiveness of adhesive bonding on the decrease of microleakage risk and subsequent complications[19,30]. Limitations of this study include short follow-up period, so, long-term randomized clinical trials are recommended.

Conclusions

Within the limitations of this study, the following conclusion could be drawn:

- The clinical performance of lithium disilicate CAD crowns, in terms of fracture, marginal adaptation, secondary caries and marginal discoloration, is successful over a period of one year.
- Flat occlusal preparation and planar occlusal preparation could be used for the restoration of endodontically treated teeth with good clinical results. The choice is based on other clinical factors, such as the remaining tooth structure, anatomic tooth form, occluso-gingival height and the restorative material.
- Regular recall visits are essential to assess the restorations and the need for any modifications especially with planar preparation design.

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