Functional Evaluation of Ceramic Onlay Restorations with Different Preparation Designs
(Randomized clinical trial)

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ABSTRACT

Aim: The aim of this study is to evaluate the clinical functional performance of ceramic onlay restorations with butt joint preparation design and compare them to shoulder preparation design in posterior teeth cases constructed from heat pressed lithium disilicate (IPS-Emax press) using MUSPHS.

Materials and methods: Thirty eight onlay ceramic restorations were fabricated for posterior teeth. Scaling and polishing were performed for all the patients two weeks before preparation. The patients were divided into two groups according to the preparation designs. Group1: shoulder design and Group 2: butt joint design. Wax pattern (CAD/CAM wax pattern) was used for the try in stage using CAD/CAM (DWX-50) milling machine with software (Exocad) and monolithic lithium disilicate (IPS, E.max press) was used for the final restorations. The try-in and the final restorations were performed using heat pressing technique. The restoration surfaces were treated using hydrofluoric acid etching and saline coupling agent and the cementation was done by using dual cure-adhesive resin cement (I. Fix Due resin cement). Fracture, marginal adaptation and patient satisfaction were assessed immediately after cementation using the modified United States Public Health Service for restoration clinical assessments (MUSPHS standards). These measurements were repeated after one, three, six, nine, and twelve months respectively.
Results: Results showed there was no significant difference between the two groups regarding all tested aspects. Since all restorations showed (Alpha) or (Bravo) scores in the two groups, then there was no failure and survival of the two types of restorations is 100%. Moreover, clinical evaluation showed that the two groups were clinically and functionally successful during one year follow up.

Conclusions: Both designs of onlay ceramic restorations revealed successful clinical performance in terms of fracture resistance, marginal adaptation and patient satisfaction.

Clinical significance: Heat pressed lithium-disilicate glass ceramic partial coverage restoration (IPS emax press) revealed successful clinical performance and can be considered as a reliable treatment option for the restoration of larger defects in the posterior dentition. With two onlay designs (shoulder design and butt joint design) which showed comparable results within the 12 months research period.

Keywords: onlays, partial coverage restoration, Heat pressed lithium-disilicate glass ceramic, cavity design, different design, IPS Emax press, clinical evaluation.

INTRODUCTION

Partial coverage restorations are an alternative to conventional crowns, in view of the growing demand for minimally invasive restorations, since crowns or complete coverage restorations imply an important loss of tooth structure. In this regard, partial coverage restorations have become a conservative treatment option thanks to their good aesthetic outcomes, durability, color stability, biocompatibility and high long-term survival rates. [1]

When an indirect Partial coverage restoration is selected as the treatment option for posterior teeth, the clinician must determine the configuration of the cavity preparation. Several designs have been proposed for preparing all-ceramic resin-bonded posterior restorations, as guided by the particular mechanical and structural characteristics of ceramic restorative materials.

In the early 1990s, a pressable ceramic system, IPS-Empress (Ivoclar-Vivadent, Schaan, Leichtenstein), was introduced as an innovative processing method for all-ceramic restorations. IPS-Empress system consists of a heat pressed ceramic fabricated by the traditional lost-wax technique. The main advantage of the Empress ceramic is that the glass ceramic ingot is fabricated under controlled conditions and heated to a temperature at which it becomes a highly viscous liquid to allow the material to flow under pressure into the lost wax mold. [2]
Although encouraging data have been published for pressable systems, a few prospective clinical studies have provided long-term evidence of clinical performance of inlay and onlay ceramic systems. And the most common failures observed on the clinical trials are related to fracture of the ceramic restoration and degradation of adhesive interface which led to deterioration of the marginal integrity. [2]

Therefore, this is study aimed to analyze the biomechanical performance of onlays made from heat pressed lithium disilicate-reinforced ceramics restorations associated with both shoulder cavity preparations and butt joint preparations according to MUSPHS criteria over 1 year. The null hypotheses of this study is there would be no significant differences in the clinical performance among the ceramic restorations made with two different designs and as well as there would be no significant differences in the clinical performance of ceramic restorations between baseline and 1 year.

MATERIALS AND METHODS

Study Design:

This study was a double blind randomized controlled clinical trial with a 1:1 allocation ratio.

Sample size estimation:

According to the results of Maria Santos et al 2016[3], in which the probabilities of alpha and bravo scores in the control group were (0.99) and (0.01) respectively- and based on the expert’s opinion which estimated the probabilities of both scores in the intervention to be (0.80) and (0.20) respectively- By adopting an alpha (α) level of 0.05 (5%), a Beta (β) level of 0.20 (20%) i.e. power=80%, and an effect sizes (w) of (0.98) and (0.600); the predicted sample size (n) was a total of (31) cases. Sample size was increased by (20%) to compensate for possible drop-outs during follow-up periods to be (38) cases i.e. (19) cases per group. Sample size calculation was performed using G*Power version 3.1.9.4

Participant’s selection:

A total of 38 onlay restorations were placed in patients with an age range between 25 to 45 years old. Fulfilled the following inclusion criteria, the patients in this study have no active periodontal or pulpal diseases, have teeth with good restorations, psychologically and physically able to withstand conventional dental procedures, patients with teeth problems indicated for posterior onlay like decayed teeth, teeth restored with large filling
restorations, able to return for follow-up examinations and evaluation. Each participant received onlay restoration for replacement of the caries in posterior tooth. Their chief complaint was to enhance chewing efficiency and esthetics. Information was given to each patient regarding the alternative treatment options. The treatment plan was explained for each patient. Then, they agreed to sign the informed consent before proceeding to clinical work. They were able and willing to maintain good oral hygiene measures. They were recruited during the time from November 2019 till June 2020 from the outpatient clinic of Fixed Prosthodontics Department, Faculty of Dentistry, Cairo University, and Cairo, Egypt. Screenings of patients were carried out until target number was reached. This study was completed by July 2021.

The clinical study:
It started with an extra oral, intraoral examination, and radiographic examination. pre-operative photographs for each patient were taken using Canon 650D DSLR camera (Nikon D7100 DSLR camera, Japan). Full mouth scaling, primary and shade selection were made before teeth preparation.

Teeth preparations phase:

After diagnosis and selection of appropriate cases, the cases were divided into two groups:

1- Group 1: cases prepared to receive shoulder design group

Onlay preparations were done according to the standardized guidelines. The isthmus width was established between 1.5 to 2.0 mm, the pulpal floor depth was between 1.5 to 2.0 mm, the axial wall depth was 1.5 mm, the internal line angles were rounded, and the divergence angle of the cavity was approximately 10 to 15°, with no bevel. Minimum occlusal reduction of 1.5 to 2.0 mm was established. The undercuts were covered with flowable composite (Nexcomp Flow- Nano Hybrid) to achieve the cavity form by removing the build-up material in order to preserve sound tooth structure. The tooth was prepared by means of a tapered, rounded diamond tip in high speed1 with water spray. The enamel margins were subsequently finished using hand instruments2. The depth was 2 mm measured from central groove. Proximal cavities were extended with flared buccal and lingual walls (5 mm). The proximal box was 4 mm long and 1.5 mm deep. Occlusal divergence angle was set at 10°-12°. Cavosurface margins were finished in butt joints (90°) with no bevels. Internal line and point angles were rounded. Cusps to be onlayed
with 1 mm cusp shoulder for shoulder design. [3]. For conservative shoulder design onlay designs, cusps to be onlayed were prepared with the shoulder finish line. **Figure (1)**

2- **Group two: cases prepared to receive butt joint design group**

In butt joint design the cusps to be onlayed were 2 mm occlusally reduced with butt joint design for conventional onlay design. After preparation, if there were caries remained extended beyond the preparation margin, the case was excluded and referred to the conservative department for filling. [3]

The preparations were done using inlay and crown preparation kit (Diatech swiss dental instruments, Switzerland) by the same operator for both designs and were finished and smoothened so that no sharp angles were left. Before preparation, silicone impressions (putty indices) were made for teeth and then were sectioned in a buccolingual and mesiodistal direction to control tooth structure removal during preparation. **Figure (2)**[4] After the preparation was finished, the final impression was taken using addition silicon impression material )Express™ Impression Material, 3M ESPE, U.S( and perforated stock tray (two -step/ double mix putty wash impression technique) [3]

Polyvinyl siloxane bite registration material (Occlufast,Zhermack, Italy) was used to obtain the interocclusal records from the patient. The final impressions were poured using ascannable type IV stone (Esthetic-base gold, Dentona AG,Dortmund Germany) according to the manufacturer instructions with using vacuum mixing to avoid voids formation. [5] The master cast was mounted on a simple hinge articulator with the aid of the interocclusal record.
Fabrication of the all-ceramic restorations

**CAD/CAM wax fabrication.** For the scanning process, Medit Identica Hybrid 3D dental scanner (Medit Identica Hybrid 3D scanner, on dent, Turkey) was used with ColLab 2017 Scan Software (ColLab 2017 Scan Software). Both the arches were scanned separately and in occlusion. Merge was performed for each cast scanned with the corresponding one in the occlusion scan. The prepared teeth of group (I), and group (II), were assigned for CAD/ CAM wax pattern technique. All the teeth on master cast were layered with spray powder (Renfert)
Scanspray, Renfert, Germany) to be able to be scanned using CAD/CAM scanner (Medit Identica Hybrid 3D scanner, on dent, Turkey). The wax pattern design was created using CAD/CAM software (Exocad software, exocad DentalCAD, exocad GmbH, Germany), the marginal discrepancy was set to 0 μm. The replicated die spacer was set to 30 μm, starting away from by 0.5mm from the margin. And patterns were designed in the software. Then exocad software² was used to analyze the entire image and uses the results to calculate the restoration proposal after making the preparation margin and adjustment cement space at 30 μm as supported by (Sharma et al., 2020, Saleh et al., 2016, Alikhasi et al., 2018). Figures (3, 4, 5) [6,7,8]

Figure (3): Software designing for CAD/CAM wax pattern (margin detection)
Milling process

The wax patterns for onlays were milled using 5-axis CAD/CAM milling machine (‘DooWon ARUM 5X-400) from CAD wax discs (Wax-On, On dent, Turkey) and then repositioned on the cast. After careful checking of wax pattern in the patient mouth, the lithium disilicate heat pressed onlays (IPS e.max PressMT, IvoclarVivadent) were made and eventually polished by flowing steps.[9,10]
Try in for the wax pattern restoration

The wax restoration was checked first on the master cast then in the patient mouth for the seating, occlusion, and marginal fitting then the temporary restoration was removed using a manual excavator, and the abutment teeth were cleaned with pumice paste over a rotating brush and gently air-dried, after completion of the try-in stage. [11]

Pressing technique

The final wax restoration was sprued and invested in IPS PressVEST Speed (Ivoclar Vivadent, Schaan, Liechtenstein) investment material and pressed with IPS e.max Press LT A2 ingots in a press furnace (Ivoclar Vivadent, Schaan, Liechtenstein) EP 600 using the firing parameters recommended by the manufacturer. The programed press temperature was 915°C and the dwell time was 15 mins. The press procedure was activated at the press temperature and the then viscous glass-ceramic ingot was pressed (0.4 MPa) into the mold.

The press process was performed in a vacuum; both the pressure and vacuum were maintained until the completion of the dwell time. The glass-ceramic restorations were divested by immersing pressed parts in an aqueous solution containing 0.6% hydrofluoric acid and 1.7% sulphuric acid followed by blasting with Al₂O₃ particles (100 μm at 0.2 MPa pressure).

The divested restorations were then glazed with IPS e.max Ceram Glaze Liquid. Two glaze firings were performed in a Programat P200 furnace at 770°C with a dwell time of 1:30 mins and 1 min, respectively. [12, 13]

The final restoration was checked for seating, stability, marginal adaptation, retention, proximal contacts and occlusion.

Final cementation of the restoration

The operative field was isolated with rubber dam. The intraoral fit was evaluated and the internal adjustments performed using diamond burs with low speed. Following adjustments, these surfaces were then etched with 9.5 % hydrofluoric (Bisco, Inc.Schaumburg,Chicago,USA )acid for 20 s, washed in an ultrasonic cleaner (Shenzhen Codyson Electrical Co) for one minute, then dried with air spray. And the silane agent (Bisco, Inc.Schaumburg,Chicago,USA )was applied for 60 s and dried, The cavity was cleaned with pumice slurry and etched with 35 % phosphoric acid gel for 15 s, rinsed with water and gently air dried, taking care to avoid desiccation of the tooth substrate.
The dentinal surfaces were treated with a dentin-bonding agent (DentsplySirona, Konstanz GERMANY). Subsequently, the cavity preparation and intaglio surface of the ceramic onlays were covered with a layer of bonding agent that was air thinned then light cured. The dual-cured resin luting material i-FIXES Duo (i-DENTAL, UAB „Medicinoslinija“ Karaliauciaus str. 29 LT-78348 Siauliai Lithuania). Adhesive Resin Cement was used for the luting procedures of all onlays according to the manufacturer’s instructions. The onlay restorations were placed on their respective teeth with finger pressure. Excess resin cement was carefully removed using a brush and dental floss. Glycerine gel was applied at the margins to prevent an oxygen inhibition layer at the interface; subsequently, Polymerization of the luting agent was performed by light curing (XL2500, 3 M Dental Products, St. Paul, MN, USA; 570 mW/cm2) the restoration from different positions—occlusal, buccal, lingual. And proximal surfaces for 60 s in each direction. Excess luting resin cement was removed and the occlusal contacts were adjusted with diamond finishing burs \(^1\) under water cooling. \([14, 3, 15]\)

The surfaces were carefully polished with rubber tips and the final polishing was conducted using felt disks with diamond polishing gel (KG Sorensen Ind Com Ltda, São Paulo, SP, Brazil). \([16]\) Figure (6)

![Figure (6a, b): onlay restoration after the final cementation, lower arch (a) upper arch (b).](image)
Postoperative instructions and care
The patients were instructed to perform brushing and flossing regularly, using non-abrasive fluoridated toothpaste and a soft brush

Follow up procedure:
Evaluation of the restoration fracture, marginal adaptation, and patient satisfaction was done immediately after cementation, one month, three months, six months, nine months, and twelve month. This was done by using the MUSPHS criteria. In addition to evaluating the patients’ satisfaction via a questionnaire. [17]
Fracture: evaluation of fracture determined if the restoration was intact or not
Marginal adaptation: evaluation was done by sharp explorer
Patient satisfaction: via a questionnaire

Statistical Analysis

Qualitative data were presented as frequencies and percentages. Fisher’s Exact test was used to compare between the two groups. Friedman’s test was used to study the changes by time within each group. Numerical data were explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). Age data showed normal (parametric) distribution while patient satisfaction scores showed non-normal (non-parametric) distribution. Data were presented as mean, standard deviation (SD), median and range values. For parametric data, Student’s t-test was used to compare between mean age values in the two groups. For non-parametric data, Mann-Whitney U test was used to compare between satisfaction scores of the two groups. Friedman’s test was used to study the changes by time within each group. Dunn’s test was used for pair-wise comparisons when Friedman’s test is significant. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

RESULTS
Regarding fracture:
Immediately post-operative, after 1, 3, 6 as well as 9 months; all restorations in the two groups showed (Alpha) score, so no statistical comparison could be done. After 12 months; all restorations in shoulder group showed (Alpha) score while only 94.7% of onlays in Butt joint group showed (Alpha) score. Yet there was no statistically significant difference between the two groups ($P$-value = 1, Effect size = 0.486). Figure (7)
Regarding marginal adaptation:
Immediately post-operative, after 1, 3, 6 as well as 9 months; all restorations in the two groups showed (Alpha) score, so no statistical comparison could be done. After 12 months; all restorations in shoulder group showed (Alpha) score while only 89.5% of analyses in Butt joint group showed (Alpha) score. Yet there was no statistically significant difference between the two groups (P-value = 0.486, Effect size = 0.472). Figure (8)
Patient satisfaction scores

Immediately post-operative, after 1, 3, 6, 9 as well as 12 months; there was no statistically significant difference between the two groups ($P$-value = 0.422, Effect size = 0.214), ($P$-value = 0.469, Effect size = 0.287), ($P$-value = 0.469, Effect size = 0.287), ($P$-value = 0.469, Effect size = 0.287), ($P$-value = 0.469, Effect size = 0.287) and ($P$-value = 0.337, Effect size = 0.385), respectively. As regards the overall satisfaction score; there was also no statistically significant difference between the two groups ($P$-value = 0.442, Effect size = 0.311). Figure (9)

![Figure (9): Box plot representing median and range values for patients' satisfaction scores in the two groups (Circles and stars represent outliers)](image)

Survival analysis

Since all restorations showed (Alpha) or (Bravo) scores in the two groups, then there was no failure and survival of the two types of restorations was 100%.

DISCUSSION

Due to Partial coverage, restorations are considered less invasive and more conservative than full coverage restorations. Moreover, they have good aesthetic outcomes, durability, color stability, biocompatibility and high long-term survival rates so this treatment option
were taken in our study which allowed lesser tooth reduction during preparation of the restoration, thus preserving the vitality and the dental tissues of the tooth and reduce postoperative sensitivity. [1]

With the presentation of highly esthetic materials as heat-pressed lithium disilicate glass-ceramic (IPS-E-max press) and recent adhesive techniques it was proved that it might even have increased probability of success of partial coverage restorations more than full coverage restorations. [1]

At this study it was investigated the use of bonded onlay ceramic restorations in posterior teeth with extensive loss of tooth substance. Tooth substance was saved as much as possible during the preparation in order to minimize the risk of pulpal complications. To avoid complication of traditional full crown treatments this resulted from more sacrificing of tooth structure. Other advantages of the investigated technique were good esthetics and a higher frequency of supra-gingivally placed cervical margins with excellent adaptation. [18]

And enhancing fracture and retention resistance, particularly with onlays to safeguard the weaker tooth structure, cuspal covering is recommended. The advantage of a full cuspal covering design (onlay) can be explained by the quantity of surviving tooth structure, which results in a more favourable stress distribution in teeth and lowers the risk of fracture. [18]

Also according to Edelhoff and Sorensen [19], onlay preparation removes 39% of the total tooth structure, whereas preparation for a complete crown requires removal of between 72.3% and 75.6%. So onlay ceramic restorations were chosen in this study. [19]

According to Bustamante-Hernández, N et al 2020 [1] they showed that onlays in the posterior region have a survival rate of 94.2% with a prediction interval of 84.0-100%. This high survival rate confirms the capacity of onlay indirect partial restorations to repair dental structural defects in the posterior region in a conservative and predictable way.

So following a general trend towards better esthetic restorations and increased biocompatibility, ceramic restoration (heat-pressed lithium disilicate glass-ceramic (IPS-E-max press) was chosen to be used in this study as material for restoration when high aesthetics is required. But this material needs an accurate wax pattern to gain an accurate final restoration. [13,20]

During an observation period of 3 years, according to van den Breemer, et al 2019 [21] to IPS e.max Press ceramic partial coverage restorations showed promising survival rates of 100%. All IPS e.max Press restorations remained in situ in good function. So in our study, onlay ceramic restorations were fabricated from heat pressed lithium disilicate glass-ceramic (IPS-E-max press) and recent adhesive techniques it was proved that it might even have increased probability of success of partial coverage restorations more than full coverage restorations. [1]
from IPS-E-max press ingots which had been used in heat pressing technique for the construction of final onlay ceramic restorations.

Correct preparation is crucial to the success of bonded onlays and partial crowns. Due to it is considered one of the important factors affect long term survival rate or longevity of onlays ceramic restoration. [1]

Moreover, there is great variation in what is suggested to be the “ideal” onlay preparation. Some suggest modifications to geometric preparations such as conventional preparation with heavy chamfer, shoulder preparation, butt joint, butt joint with bevel and modified shoulder preparations. The size of these preparation features would depend on the tooth size and suggested that more needs to be known about the consequences of such variation on fracture resistance and marginal adaptation of bonded ceramic onlay restoration. [22, 23, 9, 10]

So in our study, two designs were assessed (shoulder design and butt joint) as the shoulder design was the control, and the butt joint design is one to be the intervention. The preparations were done regarding the guidelines mentioned in the literature and those preparations were done by the same operator for standardization. [9,10]

For the cementation, the internal surfaces of empressed restorations were etched with 9.5 % buffered hydrofluoric acid for 20s, washed in an ultrasonic cleaner for one minute, the utilization of a cleaning procedure after the conditioning with hydrofluoric acid is extremely important. These procedures increased the bond strength between lithium disilicate and resin cement, especially after ultrasound cleaning. Since it was proved that the most effective surface treatment for glass ceramic is hydrofluoric acid etching followed by the silane agent applied for 20 s and dried. [15]

Dual-cure resin cement was used for the final cementation of the onlay restorations. In a study by Stamatakos C, et al., 2013 [24] they reveal that these cements are used for metal-free restorations where light-curing may be performed to quickly seal margins, in accessible areas, while the chemical cure part would insure the full polymerization of the entire restoration in inaccessible areas so ensure better marginal adaptation and fracture resistance. [24] Evaluation of onlay restoration was based on modified USPHS criteria which was proved to be reliable for the tooth-colored restorations as previously reported by Frankenberger et al., 2000 [25] As it provided a practical and logical approach to the assessment of the clinical performance of the restorations, moreover, it is widely used for the long-term assessment of the restorations and are considered to be valid for
comparison purposes at different observation periods and provide a systematic approach that is now known to be universally accepted.[26,27]

Based on the results of this study, the null hypothesis proposed was accepted, since both onlay design showed non-significant difference clinically.

**Regards fracture results**, there was no significant difference in fracture resistance between two designs tested, and both were proved to be clinically acceptable and can withstand masticatory forces. This could be attributed to the ideal preparation designs and restorations thickness followed in this study, together with high mechanical preparation of the IPS _ EMAX press material.

The satisfying clinical outcome of the presently investigated materials may be related to the enhanced mechanical properties of IPS e.max Press material. As result of the lithium disilicate microstructure, the pressable glass-ceramic IPS e.max Press material reveals flexural strength of up to 400 MPa (manufacturer's information). In our study, none of the partial coverage restorations detached after an observation period of 12 months. [28]

So in our study, it was shown that there was no difference in the occurrence of fracture of the onlay ceramic restorations either with shoulder design or butt joint design in all stages, until 12 months of cementation. This might be related to the better strength of the heat pressed lithium disilicate (IPS E-MAX press) which is less than the zirconia material but still within the biting force limit and due to the use of a total-etch technique with duel cure resin cement for bonding of restoration, which increased fracture strength of the restorations.[29]

The results of this study were in agreement with van den Breemer, et al. 2019[21], who conducted a study to evaluate the survival and success rate and the quality of survival of partial ceramic restorations bonded employing immediate (IDS) or delayed dentin sealing (DDS) in vital molar teeth. They found that adhesively luted partial ceramic restorations made from lithium disilicate ceramic (IPS-e.max press, IvoclarVivadent) in vital molar teeth have a good prognosis. With the survival rate of the restorations in this study (98.3%) after 3 years of function. [21] The results of this study were not in agreement with the Vianna, A et al. 2018 [2], they evaluated effect of cavity preparation design and ceramic type on the stress distribution, strain and fracture resistance of CAD/CAM onlays in molars, they found that
ceramic onlays with conservative preparation without occlusal and proximal boxes demonstrated better biomechanical performance than conventionally prepared ceramic onlay restorations. [2]

The difference in these results may be related to different preparation designs, different materials, techniques, cementation protocols, and extend of observation period which in this study was limited to one year.

Regards marginal adaptation results, there was no significant difference in marginal adaptation between two designs tested, and both were proved to be clinically acceptable. This could be attributed to the ideal preparation designs and restorations thickness followed in this study, together with high mechanical preparation of the IPS _ EMAX press material.

Marginal fit is one of the most important criteria of dental restoration assessment and is one of the most important preconditions for ceramic restoration long-term success. The great marginal discrepancy leads to a high plaque index with subsequent gingiva inflammation and increased exposure to the oral environment of luting materials. Also, failure of the cement seal could lead to bacterial percolation, secondary caries, pulpal inflammation, and eventual pulpal necrosis. [30]

The key factors that could affect the marginal adaptation of inlay/onlays are the type of preparation design, impression accuracy the type of material, the choice of intrinsic parameters for the CAD process for CAD/CAM wax pattern, the type and shape of milling instruments, and machine accuracy which will mill the CAD /CAM wax pattern for final restoration. [31]

In our study, it was shown that the difference in the marginal adaptation of the shoulder design and the butt joint design was statistically insignificant in all tested stages, until12months of cementation they were both clinically accepted and showed high marginal accuracy.

It was shown that the overall marginal adaptation was excellent immediately after placement, and after 1, 3, 6 as well as 9 months; all restorations in the two groups showed (Alpha) score, so no statistical comparison could be done. After 12 months; all restorations in shoulder group showed (Alpha) score while 89.5% of onlays in Butt joint group showed (Alpha) score. There was no statistically significant difference between the two groups.

It was shown that after one year, the shoulder design showed the best marginal adaptation and the butt joint showed clinically accepted results except for two cases which
showed during the examination by explorer negative step, that would be repaired by composite filling but the restorations were not mobile and in function.

The clinically accepted results might be related to an accurate impression using the addition silicon, scanning the master cast rather than the impression, utilizing a scanner with blue light technology, milling wax pattern or using of CAD/CAM wax pattern, type of preparation design, the type of material, the type and shape of milling instruments, and the behavior of the material (lithium-disilicate glass-ceramic (IPS e.max Press, Ivoclar Vivadent) as material chosen for restoration. [11, 32, 3, 33]

The results of this study were in agreement with the study performed by Roggendorf M. J , etal ,2012 [34] they found A total of 96.4% of the restorations revealed sufficient ratings for marginal discoloration," and "marginal integrity" after 4 years in their study. [34]

The results of this study were in agreement with the preceding laboratory studies on the investigated all ceramic systems and preparation design, marginal accuracies for IPS e.max partial coverage restorations that were obtained after 5-year artificial aging and met the clinical requirements and -lithium-disilicate glass-ceramic (IPS e.max Press, Ivoclar Vivadent) showed good marginal adaptation. [31]

The results of this study were not in agreement with the studies by Petra C. Guessa,etal 2009 , Maria Santos et al 2016 [35,3] ,they revealed that IPS Empress system showed significant differences in relation to, marginal discoloration, and marginal integrity between the baseline and 12-year recall for both ceramic systems. Also Petra C. Guessa,etal 2009) [35] , revealed that marginal discoloration showed most significant change over time for ceramic materials, showing a statistically significant difference after 1-3 years when compared to baseline data. And they are conflicting with our findings and stated that poor marginal adaptation during the observation period related to the difference in the observation period, bonding protocol, and material difference, which may lead to micromovement of the restoration with loss of marginal fit.
Regarding patient satisfaction

As regards the overall satisfaction score; there was also no statistically significant difference between the two groups ($P$-value = 0.442, Effect size = 0.311). Immediately post-operative, after 1, 3, 6, 9 as well as 12 months; there was no statistically significant difference between the two. These results might be reasonable due to the 1 year duration of this study. So more studies with longer durations. Also, satisfaction was strongly related to communication, approach, and involvement and not always directly related with the clinical outcome. Moreover, not all satisfaction items were relevant when comparing differences between the test and control group.

The results of this study were in agreement with the studies by van den Breemer c, 2019 [36], they concluded Patient satisfaction with regard to the color and shape of the partial ceramic indirect restorations of lithium disilicate ceramic (IPS-e.max press, Ivoclar Viva- and the ability to chew were not significantly different between two groups at all-time.

Limitation of the study

Furthermore studies with longer follow up period are required to evaluate clinical performance of onlay ceramic restoration with monolithic Heat pressed lithium-disilicate glass ceramic and compared it with another material.

Conclusion

Based on the results of this randomized clinical study covering an observation period of up to 12 months, and within the limitations of this study.

1- Heat pressed lithium-disilicate glass ceramic partial coverage restoration (IPS emax press s) revealed successful clinical performance in terms of fracture resistance, marginal adaptation, patient satisfaction can be considered as a reliable treatment option for the restoration of larger defects in the posterior dentition.

2- Patient satisfaction with regard to the color and shape of the restorations and the ability to chew were not significantly different between groups (shoulder design and butt joint design) at all-time points.

3- Both tested onlay restoration designs (shoulder design and butt joint design) showed comparable results within the 12months research period.
RECOMMENDATIONS

1. The ongoing randomized clinical study is recommended to expand the observation period up to 5 then 10 years to monitor the clinical outcome of the tested groups over a longer period.

2. Further studies are required to evaluate the clinical assessment with a different tool as (FDI tool)

Ethical considerations and approval

This randomized clinical trial was conducted in the Department of Fixed Prosthodontics in Faculty of Dentistry, Cairo University. The ethical approval for the study was obtained from the Ethics Committee of Scientific Research - Faculty of Dentistry – Cairo University (approval no: 190773). Participation in the study was voluntary and informed consent was obtained from all of them before starting the treatment regarding treatment sequence, publishing of their images and results.

Consent for Publication

I declare that the article is original and has not been published in any other journal.

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Registration

This trial was registered at the Clinical Trials.gov registry under registration number ClinicalTrials.gov ID: NCT04274959, on February 17, 2020.

Reference


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