A one-year clinical evaluation of IPS E.max press versus CERASMART endocrowns in anterior endodontically treated teeth: a randomised clinical study

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ABSTRACT

Objective: The purpose of this study was to evaluate and compare gross fracture, patient satisfaction and marginal adaptation of anterior endocrowns restoring endodontically treated anterior teeth fabricated from IPS e.max press and CERASMART hybrid ceramics. Material and Methods: A total of 24 patients were selected to receive an aesthetic endocrown for an upper tooth in the aesthetic zone (central incisor, lateral and canine). The 24 patients were divided into two groups (n = 12 each), where Group 1, the control group, received an IPS e.max press anterior endocrown and Group 2, the intervention group, received a CERASMART anterior endocrown. After cementation all patients were followed up at 3, 6, 9 and 12 months. During each follow-up examination, United States Public Health Service criteria were adopted for clinical evaluation to score margin integrity and gross fracture. Questionnaires were also used to evaluate the patients' satisfaction and potential postoperative discomfort. The X² or Fisher's Exact test were used to compare qualitative variables in the two groups and Friedman's test was used to study the changes over time within each group. The significance level was set at P≤ 0.05. Results: With regard to gross fracture and marginal integrity, there was no statistically significant difference at any interval of time between the endocrowns IPS e.max.
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INTRODUCTION

Endodontic treatment causes the loss of a considerable amount of tooth structure due to the central destruction created by the access preparation, in addition to the existing trauma or caries. This usually leaves the tooth with an insufficiently sound structure, resulting in increased cuspal deflection during loading; this in turn increases the occurrence of crown fractures and microleakages at the margins. In such cases treatment should be designed to protect and strengthen the remaining amount of endotreated teeth. The material and prosthetic treatment choices thus play an important role in the longevity of such restorations [1–4].

There are a number of different treatment modalities for restoring Endodontically Treated Teeth (ETT): Direct restoration, a crowns retained using a post and core, amalcore, inlay and onlay, and anterior endocrowns. Endodontic posts and core are the classic approach for restoring endodontically treated teeth, as they have physical properties very similar to natural dentine. Before the introduction of adhesion technology in dentistry, the coronal restoration of ETT was most often performed using metallic and macro-mechanically retained posts. Cast-metal posts and cores have a high elastic modulus compared to root dentin, creating a more rigid restorative complex which causes high stress concentrations in the root and leads to a high incidence of vertical root fractures [5–7]. Ceramic, glass and zirconium posts have gained popularity because they are tooth-coloured and avoid aesthetic problems in the anterior teeth; however, the only way to remove non-metallic posts is to grind them out with a bur, which is a tedious and dangerous procedure. These posts should be avoided because they may make retreatment impossible even if it becomes necessary [8].

Stress analysis has shown that cast-metal posts and cores create high stress concentrations inside the root canal. Such high stress concentrations can initiate vertical fracture and micro gaps in the cement-dentin or cement-post interfaces, resulting in bacterial colonisation and periapical lesions. Preparation of the canal has also been shown to weaken the root and decrease its ability to withstand force [3]. To avoid these problems and to increase patient’s aesthetic expectations, post materials have been improved in many ways, including the use of high flexural strength and elastic modulus close to the dentine. A wide range of natural-tooth-coloured and metal-free post materials, such as fibre reinforced composite posts with mechanical characteristics similar to those of dental tissues, have also been developed [9].

Several studies [10,11] have reported that the process of applying posts weakens the roots,
in addition to the risk of perforation during the preparation of the post space. Today posts are no longer mandatory for restoring non-vital teeth unless there is evident insufficient core retention[12]. A tooth with substantial coronal structure loss requires core build-up and a crown[13]. The purpose of the core restoration, with or without a post, is to replace lost dentine, provide internal support and retention for the crown, and ensure resistance against cervical tooth fracture. The presence of adequate tooth structure (ferrule) at the crown-root interface is critical for the long-term success of the crowned endodontically treated tooth[14]. A minimum sound dentine height of 1.5–2 mm is required between the core and crown margins. The final restoration provides a bracing, casing or hugging action to improve the integrity of the endodontically treated tooth. Optimal ferrule length transmits occlusal forces to the periodontium in normal physiological fashion[15].

In modern conservative dentistry, the retention of restorations is based primarily on adhesion, so the use of macro-retentive elements is no longer required in every case. Over the last 30 years, the development of adhesive systems has led dentists to question the indications for crown restorations. Modern clinical procedures to restore ETT are instead based on the principles of minimally invasive dentistry, which attempts to conserve sound tissues without the need for aggressive macroretentive techniques[13].

In 1995 Pissis [16] introduced the heat-pressed ceramic monoblock technique, which utilised the pulp chamber to increase the macromechanical retention of the crown. In 1999 Bindl and Mörmann[17] modified Pissis’s procedure and used the term ‘endocrown’ to describe a CAD/CAM all ceramic crown which was macromechanically anchored to the internal portion of the pulp chamber and adhesively cemented to the remaining tooth structure, thereby improving micromechanical retention. These techniques offer full occlusal coverage and take advantage of the pulp chamber to increase the available adhesive surface[18,19].

Endocrowns are another alternative method of restoration, better suited to teeth with short clinical crowns or curved or short root canals, which make post construction challenging[1,20]. Endocrowns have recently been suggested as a replacement for traditional metal posts and cores. This type of restoration helps preserve pulp canals and healthy coronal tooth structures. Decreasing the number of clinical procedures needed for one tooth also decreases the stress which accumulates at the interfaces of the different materials, thus decreasing the likelihood of root fracture[3,21].

A finite element analysis showed that teeth restored with endocrowns are potentially more resistant to failure than those restored with fibre posts[22]. However, Weibull analysis suggested that the likelihood of individual failure of dentin and luting cement was reduced more with endocrowns than with traditional crowns. Other clinical studies have also confirmed the functional longevity of endocrowns[18].

A systematic review conducted in 2016 of three clinical trials[23] found that the success rate of the endocrowns was reported to be between 94 per cent and 100 per cent. Moreover, according to in vitro studies[24,25], there are no statistically significant differences between endocrowns and conventional treatments, but endocrown restorations do have higher fracture strength values than conventional restorations in anterior and posterior areas.

Recent advances in digital technology and computer-aided imaging, designing and manufacturing system (CAI, CAD and CAM, respectively) have expanded existing opportunities for improving the delivery of restorative dentistry. A number of different materials have been developed for CAD/CAM procedures, including ceramics, composites and alloys. These advances have allowed for the
The type of material used may also affect the performance of endocrowns. According to the literature, glass ceramics reinforced with either leucite or high-strength lithium disilicate enhance flexibility and fracture resistance to 400 MPa. This is therefore the best option for fabricating endocrowns, as it is able to withstand occlusal force during mastication[1,26]. Hybrid CAD/CAM materials such as resin ceramic and polymer-infiltrated ceramic[9] have physical and mechanical properties similar to those of natural teeth. CERASMART is a flexible nano-ceramic CAD/CAM block with high-density ultrafine glass particles 71 wt. per cent filled nanocomposite. This material combines high-strength 230 Mpa, unique aesthetics with an acceptable level of marginal adaptation, and a modulus of elasticity (12.8 GPa) similar to that of dentin[27].

Previous studies have shown that resin nano-ceramic endocrowns have significantly higher fracture resistance and more favourable fracture mode than lithium disilicate ceramics[28–30]. Studies have also shown that endocrowns with different preparation designs showed a clinical acceptable range of marginal and internal fit (≤150 μm)[31,32]. However, it is marginal adaptation that is one of the most important factors for the longevity of aesthetic crowns[1]. In this regard, Dalloul and Nassar [33] found that the marginal fit of endocrowns was also better than that of conventional crowns. Five-year clinical observations revealed that 87.1 percent of endocrowns in posterior teeth functioned well without fracturing or debonding[34]. Ceramic endocrowns are thus recommended for anterior teeth restoration.

It was determined to be worthwhile to evaluate CERASMART and IPS e.max press anterior endocrowns in terms of gross fracture, marginal integrity and patient satisfaction. The null hypothesis for this study is there is no significant difference between IPS e.max press endocrowns and CERASMART endocrowns in terms of gross fracture, patient satisfaction or marginal integrity.

**MATERIAL AND METHODS**

The materials used in the study are described below in Table I.

**Table I - The brand names, materials, manufacturers and lot numbers used in this study**

| Brand Name | Material Description | Manufacturer |
|------------|----------------------|--------------|
| IPS e.max Press | Lithium disilicate glass-ceramic (LS2) ingots for the press technique | Ivoclar Vivadent AG, Schaan, Liechtenstein |
| CERASMART | A resin nano-ceramic material | GC dental products, Europe |
| Porcelain Etchant | Buffered Hydrofluoric Acid Gel, composed of (50–75 per cent poly-acryl-amido-methylpropane sulfonic acid and 10–30 per cent hydrofluoric acid) | Schaumburg, Bisco, United States |
| Porcelain Primer | A single component pre-hydrolysed no-mix silane primer | Schaumburg, Bisco, United States |
| BisCem | A dual-cured self-adhesive resin cement requiring no etching, priming or bonding of the prepared surface | Schaumburg, Bisco, United States |
| Build-It FR fibre-reinforced core material | A dual-cured, auto-mixed | Pentron Clinical Technologies LLC, Wallingford, CT, United States |

**Ethical considerations and approval**

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

**Registration**

This trial was registered at the ClinicalTrials.gov registry under registration number NCT03298152 on 12 October, 2017.

**Study design**

This study was a double-blind randomised controlled clinical trial with a 1:1 allocation ratio.
Participants

All participants were recruited from the outpatient clinic of Cairo University's Department of Fixed Prosthodontics in the Faculty of Dentistry. Potential participants were selected in person according to the patient's need for an aesthetic endocrown restoration for upper tooth in aesthetic zone (central incisor, lateral and canine) and invited to take part in the study. A total of 24 participants agreed to join the study from July to September 2018. The study was completed in January 2020. A full medical and dental history was obtained from each participant and the treatment plan was explained. Each participant then signed an informed consent form before the clinical work was conducted.

Eligibility

The inclusion criteria were as follows: 1) The participants ranged in age from 20 to 60 years, and had to be able to read and sign the informed consent document; 2) the patients had to be willing to return for follow-up examinations and evaluation; 3) the patients could not be diagnosed with another medical condition or controlled systemic disease; 4) no active periodontal disease could be present; and finally 5) any patients with upper anterior teeth indicated for endodontic treatment must have at least 2–3 mm of tooth structure above the cement-enamel junction.

The following exclusion criteria were used: 1) Patients diagnosed with psychiatric problems or expressing unrealistic expectations; 2) patients with missing teeth opposing the area intended for restoration; and 3) patients with parafunctional habits (clenching/bruxism).

Sample size

A total of 24 endocrowns (12 in each group) was sufficient, with 80 per cent power and at 5 per cent significance. The sample size was calculated using PS: Power and Sample Size Calculation Software (version 3.1.2).

Randomisation

Randomisation was carried out using computerised sequence generation (https://www.randomizer.org/) at Cairo University's Centre of Evidence-Based Dentistry. The participants were divided into two groups (A and B) according to ceramic material used either IPS e.max or CERASMART. Each participant received a sealed opaque envelope with their randomisation number.

Allocation concealments

The number representing each member in each group was written on a large white paper sheet using an indelible pen. The sheet was folded eight times and sealed inside an opaque envelope so that the contents could not be seen with the naked eye.

Implementation

The candidate under supervision was responsible for providing allocation generation and dividing patients into two groups. The group lists concealed in the envelopes were then placed in a secure location until the date that the first procedure was performed.

Blinding

The study was double-blinded (both the patients and the statistics). The trial participants and outcome assessors were blinded throughout the series of procedures because the dentist practitioner was responsible for all clinical procedures.

Intervention

Two endocrown materials (IPS e.max press and CERASMART ceramics) were selected for this study. All treatment procedures were performed by the same clinician. Scaling and polishing were performed for each patient to remove any calculus and staining before shade selection in order to remove any dental plaque, as this could affect the accurate shade selection. The tooth colour was recorded visually using a Vita Easysmashade V digital spectrophotometer (VITA, Zahnfabrik, Germany). For each patient, two putty indices were obtained using condensation silicon impression material, either...
directly from the patient’s mouth or indirectly from a corrected cast. Corrected casts were obtained for cases with badly broken-down teeth.

Endodontic treatment was done using the Ni-Ti rotary system and a lateral condensation technique, and access cavities were blocked using a flowable composite (Filtek Z350, 3MESPE Dental products, St. Paul, MN, United States). At least 3 days were allowed to elapse before starting preparation for both groups.

**Endocrown preparation**

The flowable composite was removed from the canal orifice without further drilling inside the canal. To eliminate undercuts, the pulp chamber was prepared with a 10° coronal divergence using tapered round diamond stone, with an oval shape and a depth of 4–5 mm from the cavo-surface margin; this was checked with periodontal probe. The internal line angles were rounded and smoothened using finishing stones.

The preparation was performed with smooth, round contours and line-angles, deep chamfer finish lines of 1 mm in diameter with round internal angles, and incisal reduction of 2 mm [20,35] (Figure 1-2). The shade of the prepared abutment tooth was recorded visually using the IPS Natural Die Material shade guide (IvoclarVivadent) in order to fabricate a die that mimicked the oral situation to achieve the optimum desired final aesthetic results.

Vinyl polysiloxane elastomeric impressions (Elite HD+, Zhermack SpA – Via Bovazecchino, 100 – 45021 Badia Polesine (RO), Italy) were made, and provisional restorations (Structur 2 SC, VOCO, Germany) were cemented with non-eugenol provisional cement (RelyX Temp NE, 3MESPE, USA). The IPS e.max press endocrowns were constructed using a pressing furnace (Programat EP 3010, Ivoclar VivadentAG, Schaan/Liechtenstein); the CERASMART endocrowns were constructed using a 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 instructions and the abutment teeth were prepared with self-etch adhesive protocol using adhesive resin cement (BisCem, Bisco, United States) (Figures 3–6).
Clinical evaluation

The different outcomes for all patients were measured following bonding as a baseline; the patients were then contacted via phone and SMS messages were sent to remind them of each follow-up appointment every 3 months.

All patients were followed up at 3, 6, 9 and 12 months. During each follow-up examination, the evaluator performed a direct clinical evaluation using modified United States Public Health Service (USPHS) criteria for margin integrity and gross fracture. Patients’ satisfaction and potential postoperative discomfort was also evaluated using the Visual Analogue Scale (VAS).
Primary and secondary outcomes

For primary outcome ‘Gross Fracture’, two groups were assessed using the modified USPHS criteria. Alpha signified ‘Excellent’; Bravo signified ‘Acceptable’ and Charlie signified ‘Unacceptable’. While Secondary outcome ‘patient satisfaction and marginal integrity’ the two groups were assessed for patient satisfaction using the VAS and the following scale: 1 = yes; 2 = no; 3 = sometimes; and 4 = don’t know. Marginal integrity was assessed using the modified USPHS criteria.

Statistical analysis

The qualitative variables in the two groups were compared using the X² or Fisher’s Exact test. Friedman’s test was used to study the changes over time within each group. A Kaplan–Meier survival curve was constructed to calculate the mean survival estimates of the two groups. The significance level was set at P≤ 0.05. The necessary statistical analyses were performed using SPSS version 23.0 (IBM, Armonk, NY, United States).

RESULTS

Gross Fracture: The results of the comparison between the two groups are presented in Table II. After 3 months; all restorations in the two groups showed (Alpha) score. While after 6, 9 and 12 months there were significant differences between the two groups (P= 1.000, effect size= 0.209); (P= 1.000, effect size= 0.128) and (P= 0.387, effect size= 0.333), respectively. With regard to the changes over time within Group B, there was a statistically significant change in fracture scores during the study period (P= 0.016, effect size= 0.288). There was an increase in prevalence of Bravo and Charlie scores after 6 months and from 6 to 9 months. There was no change in all scores from 9 to 12 months. In Group A, there was a statistically significant change in fracture scores during the study period (P= 0.027, effect size= 0.255). At 6 months the prevalence of Bravo scores had increased; at 9 months the prevalence of both Bravo and Charlie scores had increased; and at 12 months the prevalence of Charlie scores had increased further, although that of Bravo scores decreased during this period.

Marginal integrity

The results of the comparison between the two groups are presented in Table III. After 3 months; all restorations in the two groups received an Alpha score. After 6, 9 and 12 months there was no statistically significant difference between the two groups (P= 1.000, effect size= 0.209; P= 1.000, effect size= 0.236; and P= 0.387, effect size= 0.394, respectively). With regard to the changes over time in each group, there were no statistically significant changes in marginal integrity scores during the study period (P= 0.112, effect size= 0.200; P= 0.392, effect size= 0.100).
Table III - Descriptive statistics and results of Friedman’s test comparing the fracture scores at different follow-up periods for each group

|                  | CERASMART (n = 12) | IPS e.max press (n = 12) |
|------------------|---------------------|--------------------------|
|                  | N %                 | N %                      |
| 3 months         |                     |                          |
| Alpha            | 12 100              | 12 100                   |
| 6 months         |                     |                          |
| Alpha            | 10 83.3             | 11 91.7                 |
| Bravo            | 1 8.3               | 1 8.3                    |
| Charlie          | 1 8.3               | 0 0                      |
| 9 months         |                     |                          |
| Alpha            | 8 66.7              | 9 75                     |
| Bravo            | 2 16.7              | 2 16.7                   |
| Charlie          | 2 16.7              | 1 8.3                    |
| 12 months        |                     |                          |
| Alpha            | 8 66.7              | 8 66.7                   |
| Bravo            | 2 16.7              | 0 0                      |
| Charlie          | 2 16.7              | 4 33.3                   |
| P                | 0.016*              | 0.027*                   |
| Effect size (w)  | 0.288               | 0.255                    |

Patient satisfaction

Results of the comparison between the two groups are presented in Figure 7. At 3 months all patients in both groups reported being satisfied. At 6 months, 91.7 per cent of the patients in Group B were satisfied and 8.3 per cent were dissatisfied, while in Group A 91.7 per cent were satisfied and 8.3 per cent were dissatisfied. There was no statistically significant difference between the two groups (P = 1.000, effect size = 0.000). After 9 months, 66.7 per cent of patients in Group B were satisfied and 33.3 per cent were dissatisfied. In Group A, 75 per cent of patients were satisfied and 25 per cent were dissatisfied. There was no statistically significant difference between the two groups (P = 1.000, effect size = 0.092). After 12 months, 66.7 per cent of patients in Group B were satisfied and 33.3 per cent were dissatisfied. In Group A, 66.7 per cent of patients were satisfied and 33.3 per cent were dissatisfied. There was no statistically significant difference between the two groups (P = 1.000, effect size = 0.000).

DISCUSSION

This study was a randomised, double-blinded clinical trial. Randomisation was carried out using computerised sequence generation to eliminate the risk of selection bias in choosing which patients were included.

The use of lithium disilicate restorations is documented in the literature as a successful method. Lithium-disilicate-based ceramics are considered among the best restorative materials for endocrowns because of their adhesive properties and their promotion of micromechanical interlocking with resin cement[35–37].

IPS e.max press is the most preferred option for manufacturing the highest-quality e.max restorations due to the lost wax process used in its manufacture and its ability to reproduce superior anatomic details. With regard to strength, both e.max processes offer some of the strongest restorations available. However,
e.max press is 11 per cent stronger than e.max CAD. E.max has high fracture toughness (2–3 MPa), high flexural strength (360–440 MPa) and high thermal shock resistance due to its low thermal expansion; furthermore, its lithium disilicate crystals minimise the propagation of microcracks. These qualities, combined with its high aesthetic properties and bonding availability, make it the gold standard of all glass ceramic restorations[38]. It provides more precise margin integrity, less chipping and a much smoother margin line with little or no post-processing work; it also reduces sintering shrinkage during ceramic firing, which further improves the marginal adaptation. The marginal fit for heat pressing ceramics was reported to range from 44–63μm [39]. Azar and Eckert [40] reported that heat-pressed lithium disilicate offers better internal fit and mechanical performance than CAD-CAM pre-crystallised blocks.

The unique composition of CERASMART gives the material a modulus of elasticity similar to that of dentin (18 ± 2 GPa) with 220–240 MPa flexural strength. This hybrid ceramic also exhibits high flexural strength and low flexural modulus, making it less brittle and more flexible and allowing it to absorb high stress loads[27,41,42].

Surface treatment of the intaglio surface of the endocrowns was done using 5 per cent hydrofluoric (HF) acid for approximately 20 seconds. This treatment increases surface area, micromechanical retention and the cleanliness of the surface [43]. It was followed by a coating of silane to increase the wettability of the resin cement and to interact chemically with both the resin matrix and the hydroxylated porcelain, yielding a greater resistance to water attack at the bonding interface[44,45].

All currently available in vitro studies of CERASMART have found HF acid etching in combination with silane to be a superior pre-treatment[46]. Applying HF acid partially dissolves the glass phase and provides undercuts in the micrometre scale for better micromechanical interlocking with composite cement.

Marginal fit was examined, as it seemed to be one of the most important technical factors for the long-term success of any restoration. Poor marginal fit can lead to cement dissolution, marginal discoloration, plaque retention and secondary caries[40]. Furthermore, variations in the adaptation of a restoration could lead to stress concentration, which in turn can reduce the strength of the restoration and lead to fracturing [47]. The marginal adaptation of restorations is usually assessed using either invasive techniques such as cross-sectioning and impression replicas or non-invasive techniques such as indirect viewing with a dental probe.

Previous studies[48,49] have reported that CAD-CAM ceramic restorations produce an inferior marginal fit compared to pressed restorations.

USPHS guidelines were used to document patients’ outcomes. Modified USPHS criteria are usually preferred in clinical trials because they enable the assessment of multiple parameters and provide reliable information regarding the overall long-term success of a restoration[50]. The USPHS criteria method can be used to investigate a tooth using visual inspection as well as tactile inspection using an explorer[51].

Patient satisfaction was also recorded as an outcome in this study, as several authors have reported discrepancies between the treatment needs perceived by patients and those assessed by dental professionals[52].

Gross fracture is another critical factor that determines the success and longevity of a restoration. After 3, 6, 9 and 12 months, there was no statistically significant difference between IPS e.max and CERASMART endocrowns with regard to gross fracture results. This finding is clinically relevant because it indicates that CERASMART endocrowns can be used instead of IPS e.max when restoring endodontically treated teeth.
There are several factors which may affect the performance and longevity of ceramic restorations, such as the strength and thickness of the ceramic and the compatibility of the elastic moduli of the ceramics and the tooth[1]. The high Alfa ratings for gross fracture generally confirm the beneficial clinical characteristics achieved with both IPS e.max press and CERASMART materials for endocrown fabrication. These comparable results may be due to the reduction of the effect of multiple interfaces, as adhesive interface failure and debonding are reduced in endocrowns. This finding confirms that of Liedberg and Norlen [53], but contradicts those of other studies[28,54]. The good adhesive properties and high resistance to displacement of both materials is due to the fact that they are acid-etched, which provides micro-mechanical interlocking with the resin cement[23,55]. Moreover, the amount of remaining ferrule and the modification in the butt joint preparation with complete encircling of the tooth structure increases the surface area for bonding, which reduces the transmitted stress and improves resistance to force[3,23,56].

With regard to marginal integrity results, after 3, 6, 9 and 12 months there was no statistically significant difference between IPS e.max and CERASMART endocrowns. This may be due in part to the strict and meticulous fabrication and cementation protocol followed for each material. This finding confirms that of Goujat and Abouelleil [57].

There are several factors that may affect the marginal adaptation of the restorations, including fabrication technique, preparation design, spacer thickness, the type of finish line, geometry of tooth preparation, the material used to create the crown, the fabrication technique and cementation[39]. A shallow intra-coronal cavity depth of endocrown preparation is attributed to the proper seating of the endocrown. The IPS e.max pressing technique reduces sintering shrinkage during ceramic firing, thus improving marginal adaptation, whereas CERASMART material has low hardness, which improves good machinability and reduces chipping in the restoration[58].

With regard to patient satisfaction, all patients reported being satisfied with their restorations after 3, 6, 9 and 12 months and there was no statistically significant difference between the two groups. We believe these results to be reasonable as they are a combined reflection of the best materials and bonding protocols available. No post-treatment discomfort was reported[59-60].

These findings confirm the hypothesis, as there was no significant difference in the clinical performance of IPS e.max press endocrowns compared to CERASMART endocrowns.

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Conflict of interest

The authors have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and policies of: yes

The approval code for this study is: 171010.

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