A pilot trial on lithium disilicate partial crowns using a novel prosthodontic Functional Index for Teeth (FIT)

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Abstract

Background Lithium disilicate is now a well accepted material for indirect restorations. The aim of this trial was to evaluate two lithium disilicate systems using a novel prosthodontic Functional Index for Teeth (FIT).

Methods Partial adhesive crowns on natural abutment posterior teeth were made on sixty patients (clinicaltrial.gov # NCT 01835821). Patients were divided into two groups: Group 1 e.max press (Ivoclar), Group 2 LiSi press (GC Co.). The restorations were followed-up for 3 years. The FIT is composed of seven variables (Interproximal, Occlusion, Design, Mucosa, Bone, Biology and Margins), each of them to be evaluated using a 0-1-2 scoring scheme. The Mann-Whitney 'U' test was applied. The level of significance was set at $p<0,05$.

Results Survival rate was 100%, without any biological or technical complication. No statistically significant difference emerged between the two groups in any of the assessed variables ($p>0.05$).

Conclusions The results showed that it is possible to evaluate the clinical performance of partial crowns using FIT. The FIT proved to be an effective tool to foresee the possible risk of failures and to monitor the performance of the restorations at each recall. The two lithium dislocate materials showed same results after 3 years of clinical service.

Background

Due to the specific properties of lithium disilicate, particularly flexural strength, this restorative material is mainly indicated for single full and/or partial crowns (1, 2,3). Lithium disilicate provides high aesthetic results and, in comparison with porcelain and reinforced resin composites, its higher flexural strength makes it be preferable whenever the tooth defect exceeds a certain dimension (4,5).

Lithium disilicate can be obtained using two different production processes: press technology and CAD/CAM technology. Pressed lithium disilicate results were very promising (6,7) and recently the evaluation of a new lithium disilicate material (LiSi press, GC) has been reported (8). Only few clinical trials are available on lithium disilicate partial crowns, the majority of them being retrospective studies (9–11) and only one being a randomized controlled trial (RCT)(8).

Evaluation of clinical results of partial crowns on posterior teeth is usually performed following standardized parameters, such as Ryge and Snyder clinical parameters (12) or the modified FDI criteria (13). The evaluation is usually performed after luting at baseline, and then at recalls after 1,6,12, 24, or 36 months. The modified FDI criteria evaluate several categories with some sub-categories (13). Also, RCTs are done by blinded, calibrated and experienced dentists that can perform the follow-up evaluation (14,15).

It must be pointed out that Ryge and Snyder clinical parameters and modified FDI criteria were initially defined for direct restorations, therefore there is the need to determine clinical criteria adequate to evaluate indirect restorations. Clinical criteria should reflect the patients' perception of the restorations, fulfilling teaching purposes and being easily applicable in daily practice. In order to ease the process of drafting a proper treatment plan (16,17), some classifications and prognosis evaluations have been proposed.

Recently, a novel Functional Implant Prosthodontic Score (FIPS) was proposed (18–21); its potential to serve as an objective and reliable instrument in assessing implant success and restoration outcome as perceived by patients,

as well as identifying the possible risk of failure, comparing follow-up observations, providing an effective teaching tool was demonstrated.

Methods

The aim of this RCT was to evaluate the clinical performance of two lithium disilicate pressed systems using a novel Functional Index for Teeth (FIT), which is made up of seven clinical variables showing, among other things, the possible correlation with the level of appreciation perceived by the patients.

The null hypothesis tested in this clinical study was that there was no statistically significant difference in the clinical performance of the two lithium disilicate systems. A sample of 60 patients in need of a single partial crown on posterior teeth (upper and lower premolars and molars), accessing the Department of Prosthodontics and Dental Materials of the University of Siena, Italy, in the time period between September 2015 and January 2016 were included in the study. Selected patients, periodontally healthy or successfully treated in need for one posterior restoration, had a media age of 37 (±7.5) years (between 18 and 70) (14F, 16M). Exclusion criteria were: no proper age (< 18 years), pregnancy, disabilities, prosthodontic restoration of the tooth, spontaneous sensitivity, pulpitic, non-vital or endodontically treated teeth, (profound, chronic) periodontitis, deep defects (close to pulp, < 1mm distance) or pulp capping, heavy occlusal contacts or history of bruxism, systemic disease or severe medical complications, allergic history concerning methacrylates, rampant caries, xerostomia, lack of compliance, language barriers, plaque index higher than 20.

Patients written consent to the trial was obtained after having provided a complete explanation of the aim of the study. The study protocol was approved by the Ethical Committee of University of Siena (clinicaltrial.gov # NCT 01835821). All procedures performed in this study involving human participants were in accordance with the ethical standards of the Institutional and National Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study adheres to CONSORT guidelines.

Randomization and selection of the patients

After recruitment, oral hygiene instructions were given to the patients and prophylaxis was performed to establish optimal plaque control and gingival health.

The clinical assessment of periodontal parameters such as probing pocket depths (PPD)(22), bleeding on probing (BoP)(23), and full-mouth plaque index (PI)(22) was performed.

All restorative procedures were carried out under local anesthesia (Articaine with 1:100.000 epinephrine) by the same experienced operator. Intraoral radiographs were also taken before starting the treatment. In order to standardize the radiographic examination, X-ray individual tray was made for each sample tooth of each patient, in order to be sure to have the radiogram in the same position at each recall.

Randomization, allocation concealment and masking of examiners

Each participating patient was randomly assigned to one of the two experimental groups (n = 30), that were defined based on the material to be used for the restorative treatment:

Group 1: e.max press (Ivoclar-Vivadent, Schaan, Lichtenstein)

Group 2: LiSi press (GC Co., Tokyo, Japan)

Treatment assignment was noted in the registration and treatment assignment form that was kept by the study. Allocation concealment was performed by using opaque sealed, sequentially numbered envelopes. The statistician made the allocation sequence by means of a computer-generated random list and instructed a different subject to assign a sealed envelope containing the type of lithium disilicate material to be used. The opaque envelope has been opened before material selection and communicated to the operator. At the 3-year recall blinding of the examiner has been applied.

Clinical Procedure

For standardization purposes, all clinical procedures were performed by the same trained operator. Following anesthesia, rubber dam was placed, all carious lesions were excavated, and any restorative material was removed. Preparation was performed using conventional diamond burs in a high-speed hand piece, with no bevel on margins. The preparation design was dictated by the extent of decay, pre-existing restorations and the preparation guidelines defined by the manufacturer of the restorative materials. The Residual Dentin Thickness (RDT) was evaluated on a periapical radiograph, and teeth with RDT thinner than 0.5 mm were excluded. Cavities' preparation provided at least 0.5–1 mm space at the margin and 1.0–1.5 mm of clearance occlusally. Margins were mainly into enamel and only interproximal boxes had cervical margin below the cementum-enamel junction. At least one cusp was covered. Teeth were kept vital.

Hybridization of dentin with adhesive material (Adhese Bond Ivoclar-Vivadent, Schaan, Liechtenstein, in Group 1 and G-Premio Bond, (GC Co., Tokyo, Japan) in Group 2) and a thin layer of flowable has been applied on top (Tetric Flow (Ivoclar-Vivadent) and Genial Flow, (GC Co). After the final preparation, an impression of the prepared tooth was taken with an elastomeric material (Exa'lence, GC Co.), and poured in stone (FujiRock, GC Co.). The restoration was then waxed and pressed in lithium disilicate, strictly following the manufacturer's instructions. A temporary restoration of the prepared tooth was provided and after one week the lithium disilicate restoration was luted following manufacturer's instructions. The intaglio surface of the restoration was etched with 10% hydrofluoric acid for 1 minute, silanized with Monobond Plus (Ivoclar-Vivadent, Schaan, Lietchtenstein) in Group 1 and G-Multi Primer (GC Co.) in Group 2, and then luted using MultiLink Sprint (Ivoclar-Vivadent) in Group 1 and LinkForce (GC Co.) in Group 2. During cementation proper tooth isolation was provided by rubber dam.

Follow-up

All patients were enrolled in a dental hygiene program in which recalls were planned every 6 months. A clinical exam and standardized intraoral radiographs were performed immediately after the seating of the crowns (baseline), as well as after 1, 2, and 3 years of clinical service (follow-up).

A novel Functional Index for Teeth (FIT) was applied (Table 1). The FIT evaluation was performed at last recall (3-year follow-up) by an experienced operator (Figs 1–2).

Statistical analysis

The Mann-Whitney 'U' test was applied to verify the statistical significance of the difference between the two groups in the scores recorded for each assessed variable. The level of significance was set at $p<0,05$. The statistical analysis was handled by the PASW Statistics 18 software (IBM, Armonk, NY, USA).

Results

The recall rate of patients was 100% and for that no loss to follow up was recorded. Survival and success rates were 100%. No technical or biological complications were observed during follow-up.

Clinical examinations showed mean scores for PI of 18.0 +−2.5 (range: 16–21) at baseline and 17.5+−1.0 (range: 16–20) at 1- year follow-up, PPD of 3.4 +−0.5 mm (range: 1–4) and 3.2+- 0.5 mm (range: 1–4), and a mean score for BoP of 18.4-+2.2 (range: 17–24) and 16.6+−1.4 (range: 16–22), respectively.

At the 3-year follow up, the mean total FIT score was 13.26 and 13.66 for Group 1 and 2 (range: 10–14) respectively (Table 2). All partial crowns showed a stable level of alveolar crest without signs of bone loss at the radiographic analysis. Therefore, the variable “radiographic bone level” demonstrated the most consistent results and the highest scores, with a mean value of 2 (range: 2–2) in both groups. Similarly, the mean scores recorded for the variables “static and dynamic occlusion” and “quality and quantity of mucosa” were 2 (range: 2–2) in Group 1 and 1.9 in Group 2 (range: 1–2). In contrast, mean scores for “design contour and color” were 1.86+−0.7 in group 1 (range: 1–2), and 2 (range: 2–2) in Group 2; “mucosa” 2 (range: 2–2) in Group 1 and 1,93+−0.2 (range 1–2) in Group 2; “interproximal contacts and papillae” 1.73+−0.7 (range: 1–2) in Group 1 and 2 (range: 2–2) in Group 2; “biology” scored 1.93+−0.3 (range 1–2) in both Groups; and “stain and gap at margins” was 1.73+−0.8 (range 0–2) in Group 1 and 1.86+−0.7 (range 1–2) in group 2 were the most challenging to satisfy (Table 2). Table 3 reports the descriptive statistics of all the recorded scores along with the statistical significance of the difference between the two groups.

No statistically significant difference emerged between the two groups in any of the assessed variables ($p>0.05$).

Discussion

Some clinical parameters such as Ryge and Snyder criteria (12) or the modified FDI criteria (13–15,24) are commonly used. The Ryge and Snyder parameters evaluate post-operative sensitivity, retention, marginal gap, marginal discoloration, fracture, interproximal contacts and secondary caries, scoring each parameter in alpha, beta, charlie and delta. The modified FDI criteria evaluate several categories such as aesthetic, functional and biological properties with four sub-categories each. Each sub-category is then divided into 5 quality scores from clinically excellent/very good to clinically poor, for a total of 16 criteria that might not be all used in the same case (13). A calibration by e-calib system of the FDI criteria is available and its main goals were to efficiently train and calibrate clinical dental research workers using e-learning tools, to reduce the variability of the outcome of dental restorations in clinical studies using standardized assessment criteria, to better compare the results of clinical trials on dental restorations among different clinics in the world, to render clinical calibration programs more efficient, to improve daily clinical practice and to be used as a teaching tool in dental schools (15).

The FIT evaluation was proposed for the first time in the present study. Although its targets resemble the ones of the modified FDI criteria, FIT is a more user-friendly and straightforward method for the clinician to be used in everyday practice.

The fact that RCTs are carried out by blinded, calibrated, and experienced dentists that perform the follow-up evaluations in specialized centers (24) might be considered as a limit. In fact, it is still under discussion in the dental scientific community whether thus conducted RCTs accurately represent the reality of daily practice. One of

the main goals of FIT is to make practitioners more familiar with the core idea of RCTs by getting them into the habit of scoring their restorations, following the evolution of clinical parameters at each recall.

The two proposed classifications evaluate individual teeth with special regard to their periodontal conditions in order to formulate an appropriate treatment plan (16,17). FIT, on the other hand, was conceived for single restorations and, consequently, it can be applied to any indirect restoration.

The FIT scores recorded in this RCT were high for all parameters and no statistically significant differences were found between the two tested lithium disilicate materials. Such findings lead to acceptance of the first formulated null hypothesis. The lack of differences between the two pressed lithium disilicate materials showed that the new system, which has been recently launched into the market (LiSi Press, GC), can clinically perform as well as e.max pressed system (Ivoclar), that has instead been marketed for some years.

The limited number of restorations for each group and the relatively short time of observation might be considered as a shortcoming of this study, possibly affecting the power of the statistical tests. RCTs are being conducted on larger samples, also comparing Ryge and Snyder clinical parameters with the modified FDI and FIT scores. Another possible limitation of the present RCT is the reduced number of tested materials; a similar RCT comparing several restorative materials (e.g reinforced resins in different formulations) is ongoing.

Conclusions

The findings of this study showed that FIT score can be a reliable tool to rate the clinical outcome of posterior partial crowns over time. FIT score can also be useful to monitor any possible early failure and to standardize follow-up recalls. Furthermore, the two lithium disilicate materials tested in this RCT showed comparable clinical performances, with high success and survival rates after 3-year of service.

Abbreviations

FIT: Functional Index for Teeth; RCT: Randomized Controlled Trial; FIPS: Functional Implant Prosthodontic Score; PPD: probing pocket depths; BoP: bleeding on probing; PI: full-mouth plaque index; RTD: Residual Dentin Thickness; FDI: Federation Dental International.

Declarations

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‘Not applicable’

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Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Authors' contributions

All authors, EFC, TJ, SG and CG have: 1. made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data; 2. been involved in drafting the manuscript and revising it critically for important intellectual content; 3. given final approval of the version to be published; 4. agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Patients written consent to the trial was obtained after having provided a complete explanation of the aim of the study. The study protocol was approved by the Ethical Committee of University of Siena (clinicaltrial.gov # NCT 01835821). All procedures performed in this study involving human participants were in accordance with the ethical standards of the Institutional and National Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent for publication

The authors have given their consent to publish.

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1 Functional Index for Teeth Prosthodontic (FIT).

Scoring Scheme	0	1	2
Interproximal Contacts & Papillae	major discrepancy (2x incomplete)	minor discrepancy (1x complete)	no discrepancy (2x complete)
Occlusion Static & Dynamic	major discrepancy (supra-contact)	minor discrepancy (infra-occlusion)	no discrepancy
Design Contour & Color	major discrepancy (contour)	minor discrepancy (color)	no discrepancy
Mucosa Quality & Quantity	non-keratinized non-attached	non-keratinized attached	keratinized attached
Bone X-Ray	radiographic bone loss >1.5 mm	radiographic bone loss <1.5 mm	radiographic bone loss not detectable
Biology BoP & PI	BoP and PI present	BoP present	no clinical impairment
Margins Gap & Stain	detectable gap and visible stain	detectable gap or visible stain	no clinical impairment
Max Score			**14**

Table 2 Radiographic and clinical scores based on FIT for each group.

Variables	Group 1 e.max (n=30) (total) (median)	Group 2 LiSi (n=30) (total) (median)	Total Score Each Outcome
Interproximal Contacts & Papillae	26 (1.73)	30 (2)	**(56)**
Occlusion Static & Dynamic	30 (2)	29 (1.93)	**(59)**
Design Contour & Color	28 (1.86)	30 (2)	**(58)**
Mucosa Quality & Quantity	30 (2)	29 (1.93)	**(59)**
Bone X-Ray	30 (2)	30 (2)	**(60)**
Biology BoP -& PI	29 (1.93)	29 (1.93)	**(58)**
Margins Gap & Stain	26 (1.73)	28 (1.86)	**(54)**
Total Score Each Group	**199 (13.26)**	**205 (13.66)**	

Figures

Figure 1.

Variables	0	1	2
Interproximal Contacts & Papillae			x
Occlusion Static & Dynamic			x
Design Contour & Color			x
Mucosa Quality & Quantity			x
Bone X-Ray			x
Biology BoP & PI			x
Margins Gap & Stain			x
Max Score			14

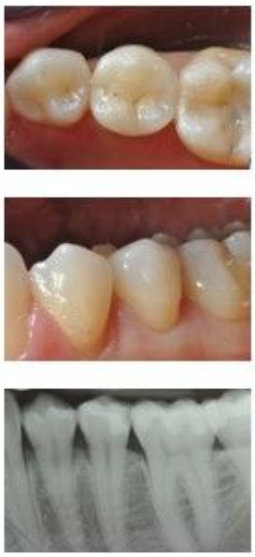

Figure 1

Pictures are related to a clinical case of Group 1 (the second premolar received a e.max Press restoration). No technical or biological complications were observed at 3-year recall.

Figure 2

Variables	0	1	2
Interproximal Contacts & Papillae			X
Occlusion Static & Dynamic			X
Design Contour & Color			X
Mucosa Quality & Quantity			X
Bone X-Ray			X
Biology BoP & PI			X
Margins Gap & Stain			X
Max Score			14

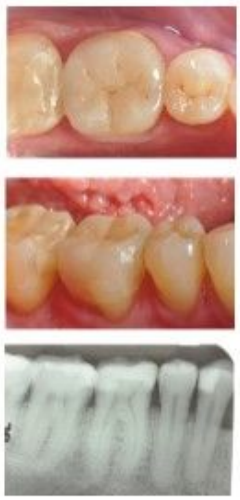

Figure 2

Pictures are related to a clinical case of Group 2 (The first molar received a LiSi Press restoration). No technical or biological complications were observed at 3-year recall.

Supplementary Files

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- supplement1.docx