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# A randomized controlled clinical trial on press and block lithium disilicate partial crowns: a pilot study

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## ABSTRACT

**Aim** Lithium disilicate is available in two formulations: press and block. The first requires an analog workflow, the latter a full digital workflow. The aim of this study was to evaluate clinical performance of two lithium disilicate systems by means of the novel Functional Index for Teeth (FIT) after one year of clinical service.

**Materials and methods** Partial adhesive crowns on posterior teeth were made on 60 patients, who were randomly divided into two groups: Group 1 Initial LiSi Press and Group 2 Initial LiSi Block (GC Co., Tokyo, Japan), which therefore followed full analog and digital workflows respectively. The restorations were followed-up for 1 year, and the FIT evaluation was performed at baseline and at last recall. The FIT includes 7 variables: Interproximal, Occlusion, Design, Mucosa, Bone, Biology and Margins, that are investigated using an intraoral radiograph and occlusal and buccal pictures and evaluated using a 0-1-2 score as follows. The presence or not of major, minor or no discrepancy ('Interproximal', 'Occlusion' and 'Design'), presence or not of keratinized and attached gingiva ('Mucosa'), presence of bone loss >1.5 mm, <1.5 mm or not detectable ('Bone'), presence or not of Bleeding on Probing and or Plaque Index ('Biology'), presence of detectable gap and marginal stain or not ('Margins'). The Mann-Whitney 'U' test was used and a level of significance at $p<0.05$. Also, "success" of the crowns (restoration in place without any biological or technical complication) and "survival" (restoration still in place with biological or technical complication) were evaluated.

**Results** All FIT parameters had high scores, between 1.85 and 2, and no statistically significant differences between the two groups were found ($p>0.05$). No statistically significant difference was found between baseline and recall scores. All FIT scores were compatible with the clinical success and not one restoration was replaced or repaired. The success rate at 1 year was 100%.

**Conclusions** The FIT can be a viable standardized evaluation of the quality of prosthodontic therapy. The two materials showed similar results at 1 year. Longer observation times are needed to confirm these preliminary results.

## INTRODUCTION

Lithium disilicate (LD) ceramic is a well-accepted restorative material by both dentists and dental technicians for creating highly aesthetic partial and full crowns (1-5). LD has mechanical and optical properties that allow fabrication of aesthetic crowns which are stiffer than ceramics. This improves the natural look and function, making the material suitable for both anterior and posterior restorations (4-7).

The high mechanical properties of LD under clinical loading are directly related to clusters of interlocked needle-like crystals that represent 70% by volume of this reinforced glass ceramic. Crystalline arrangement and compressive stresses generated around crystals contribute to crack deflection (4,5,8), while the reduction of glassy matrix reduces its fatigue susceptibility (4,5,9); this results in the highest flexural strength and fracture toughness among glass ceramics (4,5,9-12).

LD is available in two different formulations: pressed and blocks. The two materials do not have the same composition, and consequently their mechanical and optical properties might be different: that determines completely different ceramic surface characteristics and affects crown adaptation at the margin and at the occluso-axial angles (13,14). Whilst promising results on medium and long term clinical trials are available for the pressed type (12-22), no clinical data are available on LD blocks. Recently, a new LD material was introduced into the market (23-25) and good clinical results were reported after 3 years of clinical service (Initial LiSi Press; GC Co., Tokyo, Japan), when adhesive partial pressed crowns were made and luted on posterior endodontically treated teeth (26). An experimental study on Initial LiSi Block is now available, but to date no clinical trial has been undertaken with this material.

Because of occlusal loading, posterior crowns undergo greater mechanical stresses and might present signs of mechanical fatigue that can lead to fractures or debonding (4-6).
In order to withstand occlusal loading under normal function, the thickness of CAD-CAM monolithic LD crowns must be at least 1.0 mm occlusally (6); Sorrentino et al. showed that CAD-CAM monolithic LD crowns can have sufficient resistance to fracture to restore posterior teeth, but not in an ultra-thin configuration (0.5 mm) (6). Consequently, abutment preparation guidelines must respect the minimum thickness recommended for LD restorations.
In the past, different scoring systems have been proposed to clinically evaluate the performance of prosthetic restorations (27-31). Recently, a Functional Index for Teeth (FIT) was proposed for evaluating clinical parameters within Randomized Clinical Trials (RCT), and was shown to be reliable and easy to use (31,32).
The FIT is composed of seven variables (Interproximal, Occlusion, Design, Mucosa, Bone, Biology and Margins), each of them is evaluated using a 0-1-2 score and is investigated using an intraoral radiograph and occlusal and buccal pictures. More specifically, the variables are scored as follows: the presence or not of major, minor or no discrepancy ('Interproximal', 'Occlusion' and 'Design'), presence or not of keratinized and attached gingiva ('Mucosa'), presence of bone loss >1.5 mm, <1.5 mm or not detectable ('Bone'), presence or not of Bleeding on Probing and or Plaque Index ('Biology'), presence of detectable gap and marginal stain or not ('Margins') (32, 33).
The aim of this short term randomized controlled trial (RCT) was to evaluate the clinical performance of two LD materials, press and block (Initial LiSi Press and Initial LiSi Block; GC Co., Tokyo, Japan) using FIT.
The null hypothesis stated that there were no differences between clinical behavior of the two LD formulations.

## MATERIALS AND METHODS

### Study set-up

Sixty patients in need of a single posterior partial crown (i.e. maxillary and mandibular premolars and molars) between July 2018 and October 2018 were selected for the study. Demographic data, inclusion and exclusion criteria are reported in Table 1.
The patients' written consent to the trial was obtained after providing a comprehensive explanation of the aim of the study. The study protocol was approved by the Ethical Committee (clinicaltrial.gov # NCT 01835821). All procedures performed in this study were in accordance with the ethical standards of the Institutional and National Research Committee and with the Declaration of Helsinki of 1964 and its later amendments or comparable ethical standards. This study adheres to CONSORT guidelines.

Inclusion criteria

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|---|
| Age: 34 (±7.5) years (range 18 to 62) |
| Sex: 35F, 25M |
| Periodontally healthy or successfully treated patients |
| In need of one restoration each on a posterior tooth |

Exclusion criteria

| |
|---|
| Not adult age (< 18 years); |
| Pregnancy |
| Disabilities |
| Previous prosthodontic restorations of abutment teeth |
| Spontaneous sensitivity, pulpitis, non-vital or endodontically treated teeth |
| Severe and/or 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 |

TABLE 1 - Demographic data, inclusion and exclusion criteria.

### Patients preparation and baseline examination

After being recruited, all patients underwent oral hygiene with instructions of prophylaxis in order to establish optimal plaque control and gingival health.
The clinical assessment of periodontal parameters such as periodontal probing depth (PPD) (34), bleeding on probing (BoP) (35) and full-mouth plaque index (PI) (34) was performed.
All restorative procedures were carried out under local anesthesia (articaine with 1:100.000 epinephrine) by the same expert operator. Intraoral radiographs were taken before starting the treatment; in order to standardize radiographic examinations, an individual X-ray tray was made for each abutment tooth, so as to have the radiograph in the same position at each recall.

### Randomization, allocation concealment and masking of examiners

Each patient was randomly assigned to one of the two experimental groups (n=30), that were defined according to the material to be used.
- Group 1: Initial LiSi Press (GC Co, Tokyo, Japan).
- Group 2: Initial LiSi Block (GC Co., Tokyo, Japan).

Treatment assignment was noted in the registration and the treatment assignment form was kept by the

| 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 Functional Index for Teeth (FIT): definitions and scores.

study. Allocation concealment was performed by using opaque, sealed and 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 LD material to be used. The opaque envelope was opened immediately before material selection and communicated to the operator.
At the 1-year recall, blinding of the examiner was applied.

## Clinical procedures

For standardization purposes, all clinical procedures were performed by the same trained prosthodontist. Following anesthesia, rubber dam was placed, all carious lesions were completely removed and any restorative material was removed. Preparation was performed using conventional diamond burs with a high-speed handpiece, with no bevel on margins. The preparation design was dictated by the extent of decay, pre-existing restorations and preparation guidelines defined by the manufacturer of the restorative material. Residual dentin thickness (RDT) was evaluated on periapical radiographs and teeth with RDT thinner than 0.5 mm were excluded from the study. Cavity preparations provided margin thicknesses ranging between 0.5-1 mm and 1.0-1.5 mm of occlusal clearance. Margins were kept mainly into enamel (i.e. more than 50%) and placed equi- or supra-gingivally; only interproximal boxes had cervical margins below the cementum-enamel junction. At least one cusp was covered and teeth were kept vital.
Hybridization of dentin with a universal bonding agent (G-Premio Bond, GC Co., Tokyo, Japan) and a thin layer of flowable composite (Genial Flow, GC Co., Tokyo, Japan) was placed to seal the adhesive layer, fill undercuts and make the base of the cavity more uniform. After preparations were finished and polished, precision impressions of the prepared teeth were taken. In Group 1, an elastomeric material (Exa'lence, GC Co., Tokyo, Japan) was used and then the impression was poured in extra-hard stone (FujiRock, GC Co., Tokyo, Japan). The crowns were then waxed and pressed in LD, strictly following the manufacturers' instructions.
In Group 2 an intraoral impression was made (Aadva iOS) and the crowns were digitally waxed-up and then cut from Initial LiSi blocks in a milling machine.
Temporary restorations made in self-curing acrylic resin were cemented to protect the prepared teeth and LD final restorations were delivered after one week and cemented following manufacturers' instructions. The intaglio surface of each restoration was etched with 10% hydrofluoric acid for 1 minute, silanized with G-Multi Primer (GC Co.) and then cemented using LinkForce (GC Co.) in both groups. 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 examination and standardized intraoral radiographs were performed immediately after the seating of crowns (baseline), as well as after 6 and 12 months of clinical service.
The FIT was assessed (Table 2) and recorded at baseline and at the 1-year follow-up.

### Outcome variables

A restoration was defined as "Success" when it did not show any biological or technical complication at the last recall, and "Survival" when it was still in place at the last recall but with a biological or technical complication that needed to be treated, without the need to remake the crown; whereas when the restoration was lost at last recall or, because of mechanical or biological complications, needed to be replaced it wa defined as "Failure".

### Statistical analysis

The Mann-Whitney U test was applied to verify possible statistically significant differences in the scores recorded for each assessed variable between the experimental groups. The level of significance was set at $p<0.05$. The statistical analysis was calculated by a dedicated software (PASW Statistics 18, IBM, Armonk, NY, USA).

## RESULTS

No loss at follow-up was recorded, consequently the patients' recall rate was 100%. Both survival and success rates were 100%, since no technical or biological complications were observed.

At 1-year follow-up, clinical examination of periodontal parameters showed the following mean scores for Groups 1 and 2 respectively: 17.5±2.5 (range: 15-20) and 17.0±1.0 (range: 15-19) for PI; 2.9±0.5 mm (range: 1-4) and 2.8±0.5 mm (range: 1-4) for PPD; 16.1±0.5 mm (range: 17-24) and 16.8±1.2 (range: 16-21) for BoP (Table 3).

At the baseline, the mean total FIT score was 13.46 for Group 1, and 13.26 for Group 2 (range: 12-14) respectively (Tab. 4). All samples showed very high clinical performance when scored with FIT. The level of the alveolar crest never showed signs of bone loss at the radiographic evaluation and the variable "Bone" scored a mean value of 2 (range: 2-2) in both groups. Similarly, the mean scores recorded for the variable "Occlusion (static and dynamic)" were 2 (range: 2-2) in both in Groups. Regarding the parameter "Mucosa (quantity and quality)", the scores were 1.96 (range: 1-2) in Group 1 and 1.8 (range: 1-2) in Group 2. The mean scores for "Design (contour and color)" were 1.9 (range: 1-2) in Group 1 and 1.8 (range: 1–2) in Group 2; for "Interproximal (contacts and papillae)" they were 1.8 (range: 1-2) in Group 1 and 1.8 (range: 1-2) in Group 2; "Biology (BoP and PI)" scored 1.9 (range 1-2) in both Groups 1 and 2; finally, the mean scores for "Margins (gap and stain)" were 1.9 (range 0-2) in Group 1 and 1.8 (range 1-2) in Group 2.

At 1-year recall, the mean total FIT score was slightly increased, 13.53 and 13.46 for Group 1 and 2 (range: 12-14) respectively (Table 5). Parameters 'Occlusion', 'Bone' and Biology did not show any change. For the parameter "Mucosa (quantity and quality)", the score in Group 2 increased to 1.9 (range: 1-2). The mean scores for "Design (contour and color)" decreased to 1.8 (range: 1-2) in Group 1 and remained 1.8 (range: 1–2) in Group 2; for "Interproximal (contacts and papillae)" both Groups increased to 1.9 (range: 1-2; finally, the mean scores for "Margins (gap and stain)" were 1.9 (range 0-2) in Group 1 and 1.9 (range 1-2) in Group 2, a little improved over that at the baseline.

No statistically significant differences were found between the experimental groups in any of the assessed variables ($p>0.05$) and between baseline and recall.

| | PI | PPD | BoP |
|---|---|---|---|
| Group 1 (Initial LiSi Press) | 17.5±2.5 a | 2.9±0.5 mm a | 16.1±0.5 a |
| Group 2 (Initial LiSi Block) | 17.0±1 a | 2.8±0.5 mm a | 16.0±1.2 a |

TABLE 3 Peridoontal parameters. No statistically significant differences were found between the two Groups at 1-year recall.

| Variables | Group 1 (n=30) Initial LiSi Press (total) (media of each sample) | Group 2 (n=30) Initial LiSi Block (total) (media of each sample) |
|---|---|---|
| Interproximal Contacts & Papillae | 54(1.8) a | 54(1.8) a |
| Occlusion Static & Dynamic | 60(2) a | 60 (2) a |
| Design Contour & Color | 57(1.9) a | 54(1.8) a |
| Mucosa Quality & Quantity | 59(1.96) a | 54(1.8) a |
| Bone X-Ray | 60 (2) a | 60 (2) a |
| Biology BoP -& PI | 57(1.9) a | 57(1.9) a |
| Margins Gap & Stain | 57(1.9) a | 59(1.96) a |
| Total Score of Each Group | 404 (158.81) (13.46) | 398 (163) (13,26) |

TABLE 4 Radiographic and clinical scores based on FIT for each group at baseline. No statistically significant differences were noticed between the two groups in any of the assessed variables ($p>0.05$).

## DISCUSSION

According to the results of the present investigation,

| Variables | Group 1 (n=30) Initial LiSi Press (total) (media of each sample) | Group 2 (n=30) Initial LiSi Block (total) (media of each sample) |
|---|---|---|
| Interproximal Contacts & Papillae | 57(1.9) a | 57(1.9) a |
| Occlusion Static & Dynamic | 60(2) a | 60 (2) a |
| Design Contour & Color | 55(1.8) a | 54(1.8) a |
| Mucosa Quality & Quantity | 59(1.96) a | 57(1.9) a |
| Bone X-Ray | 60 (2) a | 60 (2) a |
| Biology BoP -& PI | 57(1.9) a | 57(1.9) a |
| Margins Gap & Stain | 58 (1.93) a | 59(1.96) a |
| Total Score of Each Group | 406 (13.53) a | 404 (13,46) a |

TABLE 5 Radiographic and clinical scores based on FIT for each group at 1-year recall. No statistically significant differences were noticed between the two groups in any of the assessed variables and between the baseline and recall data($p>0.05$).

the null hypothesis was accepted, since there were no statistically significant differences between the experimental groups. None of the seven parameters of FIT showed statistically significant differences. Two of the FIT parameters (Bone and Occlusion) showed the highest scores, whilst high scores were always recorded for the other variables (Tables 4,5). It can be considered that the generally high scores recorded in both groups for all parameters could be due to the limited time the restorations stayed under clinical service. However, the high scores of 'Bone' could be related to the equi-and/or supra-gingival position of the prosthetic margins, combined with the professional recall and home oral hygiene regimes. Similarly, the high score of 'Occlusion' could be related to the skill of lab technician on properly waxing-up, with both analog and digital workflows, in combination with proper occlusal thickness and functional check of each restoration (6).

Regarding the 'Interproximal' variable, that refers to the health and shape of papillae and to the interproximal contacts with adjacent teeth, the fact that the top score was not reached can be explained by the difficulty to clean this area during home oral hygiene (strictly related to patients' compliance and manual skill) and/or the presence of light contact areas between restorations and adjacent teeth. Despite this, it should be pointed out that the three parameters evaluating periodontal aspects; The FIT scoring system was very useful for monitoring the crowns at baseline and after 1-year of clinical service and might be routinely used on randomized controlled trials and in daily dentistry by practitioners, to monitor the clinical behavior of crowns.

When the type of abutment preparation is considered, it is clear that there is no way to standardize them, being determined by needs of single tooth. For that, in the present study partial crowns were designed in order to provide a complete covering at least one cusp and one or two interproximal boxes, in order to create adequate contact areas, retain the temporary restoration and stabilize the partial crowns during cementation (35, 36).

Correct seating and adhesion are mandatory for glassy ceramic materials and LD restorations as well (33). In this study all the restorations were cemented adhesively; dental substrates were etched and bonded, the internal surface of LD was etched and silanized and then the partial crowns were cemented under rubber dam. The role of etching-bonding-cementing procedures might be crucial to absorb occlusal forces and seal the enamel margins (35) and both tested materials (pressed and CAD/CAM block) seem to be very effective, at least up to 1-year of clinical service.

The LD materials available in the market are pressed and CAD-CAM blocks (13,14,37) and this is the first RCT comparing pressed LD versus the same LD material in chairside blocks. More RCTs and also monitoring clinical behavior of CAD/CAM made versus pressed partial crowns are needed and with a longer observation time. However, according to the results of this clinical study, both workflows can provide clinically acceptable partial crowns.

Also, it must be pointed out that, although the clinical procedures were standardized in both groups, the procedures to take impression were different, analog impression in Group 1 and digital in Group 2. That permitted to compare the analog lab workflow with the full digital workflow. The results of this study showed that there were no differences between the analog and digital workflow on making LD partial crowns after 1 year of clinical service. These results are not in agreement with those reported by Schestatsky et al. (13) that recently evaluated, *in vitro*, the effect of two worflows (pressing-analog and digital-CAD/CAM) to make LD crowns also on internal and marginal adaptation and reported that pressing technique leads to better marginal and internal fit than the complete CAD-CAM workflow. For that, it can be speculated that visible and cleanable margins of LD partial crowns can be very well tolerated although the marginal gap can be 100 microns or more (13). This finding must be confirmed by a longer observation time.

Traditionally, the clinical evaluation of partial crowns is performed following different clinical parameters and scores (27-30). The assessment is usually made after

cementation as baseline and then at different recall appointments, such as 1, 6, 12, 24 and 36 months. The modified FDI criteria evaluate several categories with some sub-categories (27-30). However, modified FDI criteria are indicated to evaluate direct restorations, while FIT is indicated for indirect restorations. Being a standardized procedure, and easily calibrated, it could be useful in daily practice and that might reflect the patients' perception of restorations (38,39).

The use of the FIT score system permitted the evaluation of restorative and periodontal parameters simultaneously, providing a more comprehensive clinical view of each sample tooth. Also, it was very useful to monitor the clinical behavior of sample restorations comparing baseline and 1-year results. It was noted that at 1-year recall FIT parameters were slightly improved and crowns made with analog and/or digital workflow performed similarly.

No mechanical and/or biological complications were observed at 1-year recall, and thus 100% success was reported.

These findings must be confirmed by a longer clinical observation time, possibly in a wider number of sample teeth. Another limitation that might have affected the results of this RCT is related to the selection of teeth with no periodontal disease and no parafunctions.

## CONCLUSIONS

Within the limitations of the present RCT, the following conclusions can be drawn.

- The tested lithium disilicate materials presented comparable clinical outcomes and effectiveness, as measured using the FIT criteria, at the baseline and 1-year recall; crowns made with both analog and digital workflow showed 100% success after 1 year of clinical service.
- The FIT proved to be easy and operator-friendly to make a comprehensive periodontal and prosthetic evaluation of the clinical performances of adhesive partial crowns over time.
- Longer observation times are needed to confirm the findings of this RCT.

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