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A Randomized Controlled Clinical Trial on Press, Block Lithium Disilicate, and 3D Printed Partial Crowns in Posterior Teeth: One-Year Recall

Giulia Verniani [1,*], Alessio Casucci [1], Matteo Val [2], Gennaro Ruggiero [3], Daniele Manfredini [2], Marco Ferrari [1] and Edoardo Ferrari Cagidiaco [1]

[1] Department of Prosthodontics, University of Siena, 53100 Siena, Italy; alessio.casucci@gmail.com (A.C.); ferrarm@gmail.com (M.F.); edoardo.ferrari.cagidiaco@gmail.com (E.F.C.)
[2] Orofacial Pain Unit, University of Siena, 53100 Siena, Italy; matteo.val63@gmail.com (M.V.); daniele.manfredini75@gmail.com (D.M.)
[3] Department of Prosthodontics, University of Naples Federico II, 80131 Naples, Italy; gennaro_ruggiero@hotmail.it
* Correspondence: giuliaverniani96@gmail.com

Abstract: This study compares the clinical performances of two lithium disilicate (Initial LiSi press vs. Initial LiSi Block, GC Corp.) and a 3D printed resin (Temp Print, GC Corp.) partial crown using modified United States Public Health Service (USPHS) evaluation criteria and survival rates after one year of clinical service. Eighty-nine partial adhesive restorations on posterior teeth were realized using different materials: Group 1 used Initial LiSi press, Group 2 used Initial LiSi Block, and Group 3 used Temp Print. An analog workflow was used to realize the restoration of Group 1, while a fully digital workflow was used for Groups 2 and 3. The modified USPHS parameters, together with periodontal parameters, were collected at baseline and at the one-year recall. Contingency tables to assess for significant differences of success over time in each group were used. All modified USPHS parameters showed Alpha or Bravo; no Charlie was recorded. No statistically significant difference emerged between the three groups in any of the assessed variables ($p > 0.05$). All modified USPHS scores were compatible with the outcome of clinical success, no restoration was replaced or repaired, and the survival rate was 100% at the one-year recall. No difference was found between the traditional and digital workflows used to fabricate the restorations.

Keywords: randomized controlled trial; 3D printed restorations; posterior partial crowns; digital workflow; lithium disilicate

Citation: Verniani, G.; Casucci, A.; Val, M.; Ruggiero, G.; Manfredini, D.; Ferrari, M.; Ferrari Cagidiaco, E. A Randomized Controlled Clinical Trial on Press, Block Lithium Disilicate, and 3D Printed Partial Crowns in Posterior Teeth: One-Year Recall. *Prosthesis* **2024**, *6*, 887–895. https://doi.org/10.3390/prosthesis6040064

Academic Editor: Andrea Scribante

Received: 11 July 2024
Revised: 1 August 2024
Accepted: 5 August 2024
Published: 7 August 2024

1. Introduction

Partial coverage restorations are a viable option to restore teeth in case of a substantial loss of tooth substrate compared to the direct option, since it can ensure reduced polymerization shrinkage, prevention of tooth fracture, and better clinical performance over the years [1]. Partial coverage restorations can be realized using a wide range of materials such as ceramics, resin composites, and metal alloys [2].

Milled Cad-Cam resin composite blocks have been used for partial coverage restorations and have showed great clinical performance, since the indirect restoration demonstrates a higher degree of conversion, filler content, and chemical stability compared to the direct alternative [3].

Nowadays, 3D printing is rapidly spreading as a new technology that overcomes the limitations of subtractive manufacturing systems in dentistry, thanks to the current development of printable materials [4–8]. In prosthodontics, 3D printing is mainly used during the workflow to produce models, custom trays, silicone indices, surgical guides, tooth preparation guides, and interim restorations, but until now, it has rarely been used to realize the final restoration [9]. This can be attributed to the lower mechanical properties

of the 3D printable materials present on the market up to now. In fact, some in vitro studies pointed out lower values for fracture resistance when compared to the milled options [10–12].

Lately, new interesting materials have been launched on the market with the possibility to remain intraorally for a longer period of time due to their characteristics of occlusal stress dispersion and high durability under occlusal loading [13,14]. In recent in vitro studies, a new class 2, highly silica-filled, 3D printable composite resin reported high values for flexural strength comparable to the ones of different PMMA-milled resins [15], and good dimensional stability compared to others 3D printable materials [16]. As such, its use in producing restorations in vivo should be investigated. In recent in vitro studies, additive manufacturing onlay restorations showed high intaglio surface trueness and adaptation comparable to the subtractive-manufactured ones [17,18]. Additionally, 3D printing allows less waste of materials and has a lower cost of production when compared to subtractive manufacturing [19,20].

Lithium disilicate (LD) is a well-accepted prosthodontic material by both dentists and dental technicians [21], and it is available on the market in two different formulations: press and blocks. Pressed LD has to be manufactured in a laboratory, pressing the material at a high temperature into the final shape, and its clinical use to realize partial restorations has already been widely tested [22,23]. LD blocks are an attractive alternative for realizing restorations as they have good mechanical properties and allow for a reduction in the time and cost of being milled, as well as being chairside [24,25]. Recently a RCT study has demonstrated the good clinical performance of this method, also in vivo [26].

The aim of this short-term randomized clinical study (RCT) was to evaluate the clinical outcomes of two LD materials, press and block, and one 3D printed composite after one year of clinical service for partial posterior restorations. The null hypothesis was that there was no statistically significant difference between the two LD formulations and the 3D printed composite at the one-year follow-up.

2. Materials and Methods

Between October 2022 and January 2023, 89 restorations were placed in 49 periodontally healthy patients (18+ years). All patients were informed about the trial's scope, and after they provided written consent, they were enrolled in the present study as shown in Figure 1.

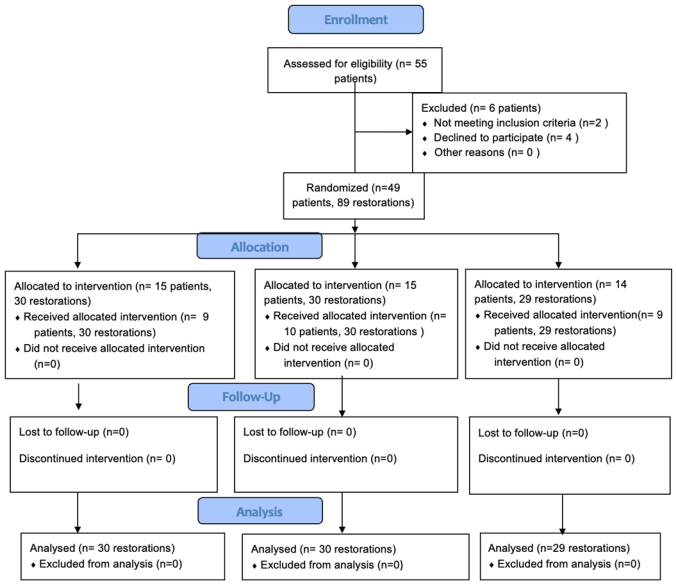

Figure 1. CONSORT 2010 flow diagram.

Patients were collected according to the following inclusion criteria:

Periodontally healthy or successfully treated adult patients (bleeding on probing (BoP) < 10%) in need of an overlay or onlay partial crown (one restoration each and not more than two) on a posterior tooth.

Patients were excluded from this study based on the following exclusion criteria: age < 18 years, disabilities, severe medical disease, pregnancy, insufficient compliance, previous indirect restorations of the abutment teeth, active periodontitis, bruxism, and endodontic treated abutment. Additionally, after cavity preparation, all teeth with a residual dentin thickness (RDT) lower than 0.5 mm between the bottom of the cavity and the pulp were excluded from the study.

The study protocol was approved by the Ethical Committee (clinicaltrial.gov #CT01932049). Also, the clinical treatment was performed 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.

Before starting the treatment, all patients underwent professional oral hygiene sessions, and the periodontal probing depth (PPD), bleeding on probing (BoP), and full-mouth plaque index (PI) were recorded. An individual X-ray tray was specifically fabricated for each abutment tooth to standardize radiographic examinations and allow the possibility for making the radiograph at baseline and in the same position at future recalls.

The same prosthodontics (M.F.) after anesthesia removed all carious lesions and previous direct restorations under rubber dam and prepared all the abutment. The preparation's design was made accordingly with the presence of caries and pre-existing restorations with a chamfer finish line. When possible, margins were kept equi- or supra-gingivally and into the enamel (i.e., more than 50%); only interproximal boxes had cervical margins below the cementum–enamel junction. A universal bonding agent (G-Premio Bond; GC Corp., Tokyo, Japan) and a thin layer of flowable composite (Genial Flow; GC Corp., Tokyo, Japan) were placed as a dentine sealing on the prepared dentine. Rubber points were used to finish and polish the preparations before the final impression.

The eighty-nine teeth were randomly divided into three experimental groups according to the materials used for the restoration: Initial LiSi Press (GC Corp., Tokyo, Japan); Initial LiSi Block (GC Corp., Tokyo, Japan); and Temp Print (GC Corp, Tokyo, Japan). Treatment assignment forms were kept for the study. Opaque, sealed, and sequentially numbered envelopes were used for allocation concealment. The allocation sequence was computer-generated, and the statistician assigned a sealed opaque envelope containing the type of restoration material to be used; the envelope was opened by the operator only before the impression was taken. Elastomeric material (Exa'lence; GC Corp., Tokyo, Japan) was used to take traditional final impressions for Initial LiSi Press (GC Co, Tokyo, Japan) restorations and a master model was realized using Type IV gypsum (FujiRock; GC Corp., Tokyo, Japan). For the other two groups, the final impressions were performed using an intraoral scanner (Aadva 200 iOS; GC Corp., Tokyo, Japan), resulting in a .stl file that was sent to the technician. The restorations were digitally waxed up and the final project was sent to a milling machine (n4 Plus; Vhf AG) or to a 3D printer (ASIGA MAX UV). In Group 2, the restorations were milled using LiSi Blocks (GC Corp., Tokyo, Japan), while in Group 3, the partial crowns were made with Temp Print resin (GC Corp., Tokyo, Japan). A self-curing acrylic resin for provisional crowns was temporarily cemented to protect the prepared teeth with no eugenol temporary cement (TempBond NE; Kerr Corp., Brea, CA, USA). After one week, all the restorations were delivered and tried in; some restorations needed minor adjustments, but no piece was remade. For the lithium disilicate restorations, the internal surface of the restoration was etched with 10% hydrofluoric acid for 20 s and silanized with G-Multi Primer (GC Corp., Tokyo, Japan). For the 3D printed restoration, the internal surface of the restoration was cleaned after the try-in, sandblasted, and a drop of G-Multi Primer (GC Corp., Tokyo, Japan) was applied for at least 1 min. All luting steps were performed after isolation with rubber dam. The abutment teeth were etched with

orthophosphoric acid, and a universal adhesive was applied (G-Premio Bond, GC Corp., Tokyo, Japan). Adhesive cementation was performed under rubber dam using G-Cem One (GC Corp., Tokyo, Japan) for all the restorations. The patients were recalled every 6 months for an oral hygiene session. A clinical examination was performed immediately after the seating of the crown as baseline, as well as after 6 and 12 months of clinical service. Modified USPHS scores were assessed and recorded (Table 1) at baseline and at the 1-year recall. A standardized intraoral radiograph was taken using a customized X-ray tray for each restoration. At the 1-year recall, two examiners (E.F.C. and G.V.), after being calibrated, blindly evaluated all the subjects and an assessment was taken by consensus. Also, periodontal parameters such as BoP, PI, stain, and gap at margins were recorded, as well at each recall. To clinically classify each single crown, "Success" was considered when it did not show any biological (such as pulpal or periodontal problems) or technical complications (such as debonding, chipping, or fractures of the restorations) 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; if the restoration was lost at the last recall or, because of mechanical or biological complications, needed to be replaced, it was classified as "Failure".

Table 1. Criteria of the modified United States Public Health Service method.

Topics	Score	Criteria
Marginal adaptation (MARA)	Alpha	Margin continuity (without prominence or crack)
	Bravo	Little discontinuity detectable by explorer, but does not require replacement
	Charlie	Prominence or crack; require replacement
Color Alteration (COA)	Alpha	No color alteration close to tooth structure
	Bravo	Little color alteration, clinically acceptable
	Charlie	Esthetically unacceptable
Marginal Discoloration (MARD)	Alpha	No marginal discoloration
	Bravo	Marginal discoloration
	Charlie	Deep discoloration
Restoration Fracture (RESF)	Alpha	No fracture
	Bravo	Small fracture fragments (1/4 of the restoration)
	Charlie	Severe fracture (3/4 of the restoration)
Tooth Fracture (TFRA)	Alpha	No tooth fracture
	Bravo	Small fracture fragments of tooth fracture (1/4)
	Charlie	Severe tooth fracture (1/2)
Restoration wear (RESW)	Alpha	No wear
	Bravo	Wear
Antagonist Tooth Wear (ANTW)	Alpha	No wear
	Bravo	Wear
Caries Presence (CARP)	Alpha	Absent
	Charlie	Present
Postoperative Sensitivity (POSTS)	Alpha	Absent
	Charlie	Present

Statistical Analysis

Contingency tables to assess for significant differences of success over time in each group were used, and the level of significance was set to $p < 0.05$. The Mann–Whitney 'U' test was used, and the level of significance was set to $p < 0.05$ to analyze the periodontal parameters. The statistical analysis was calculated using dedicated software (PASW Statistics 18). Modified USPHS scores were assessed and recorded after cementation (baseline) and after 1 year of clinical service, as reported in Table 2, together with periodontal parameters. At the 1-year follow-up appointment, X-rays were taken for each restoration.

Table 2. Modified USPHS scores for Lisi Press, Lisi Blocks, and Temp Print at baseline and 1 year.

Topics	Material	Baseline			Time 1		
		Alpha	Bravo	Charlie	Alpha	Bravo	Charlie
Marginal adaptation (MARA)	Lisi Press	30	/	/	29	1	/
	Lisi Blocks	30	/	/	29	1	/
	Temp Print	29	/	/	27	2	/
Color Alteration (COA)	Lisi Press	30	/	/	30	/	/
	Lisi Blocks	30	/	/	30	/	/
	Temp Print	27	2	/	26	3	/
Marginal Discoloration (MARD)	Lisi Press	30	/	/	29	1	/
	Lisi Blocks	30	/	/	29	1	/
	Temp Print	29	/	/	27	2	/
Restoration Fracture (RESF)	Lisi Press	30	/	/	29	1	/
	Lisi Blocks	30	/	/	29	1	/
	Temp Print	29	/	/	29	/	/
Tooth Fracture (TFRA)	Lisi Press	30	/	/	30	/	/
	Lisi Blocks	30	/	/	30	/	/
	Temp Print	29	/	/	29	/	/
Restoration wear (RESW)	Lisi Press	30	/	/	30	/	/
	Lisi Blocks	30	/	/	29	1	/
	Temp Print	29	/	/	29	/	/
Antagonist Tooth Wear (ANTW)	Lisi Press	30	/	/	30	/	/
	Lisi Blocks	30	/	/	29	1	/
	Temp Print	29	/	/	29	/	/
Caries Presence (CARP)	Lisi Press	30	/	/	30	/	/
	Lisi Blocks	30	/	/	30	/	/
	Temp Print	29	/	/	29	/	/
Postoperative Sensitivity (POSTS)	Lisi Press	30	/	/	30	/	/
	Lisi Blocks	30	/	/	30	/	/
	Temp Print	29	/	/	29	/	/

3. Results

The patients' recall rate was 100%. At the one-year recall, survival and success rates were 100%, since no major technical or biological complications were observed. Clinical parameters related to the restoration results are shown in Table 2. No Charlie scores were recorded at the one-year recall. At the one-year recall, only several restorations of each group showed a Bravo score for MARA, COA, MARD, RESF, RESW, and ANTW. Regarding

the COA score, three restorations of Group 3 (3D Printed onlays) showed Bravo, while in Groups 1 and 2, all restorations scored Alpha. Regarding MARA and MARD, two restorations of Group 3 scored Bravo, while in the two other groups, only one scored Bravo.

Periodontal parameters at baseline and the one-year follow up are reported in Tables 3 and 4. No statistically significant differences were found among the experimental groups in any of the assessed variables ($p > 0.05$) and between baseline and the one-year recall.

Table 3. Periodontal parameters at baseline.

	PI	PPD	BoP
Group 1 (Initial LD Press)	17.5 ± 2.5 [a]	2.9 ± 0.5 mm [a]	16.1 ± 0.5 [a]
Group 2 (Initial LD Block)	17.0 ± 1 [a]	2.8 ± 0.5 mm [a]	16.0 ± 1.2 [a]
Group 3 (Temp Print)	17.7 ± 1.5 [a]	2.9 ± 0.5 mm [a]	16.0 ± 1.7 [a]

Legend: PI: plaque index; PPD: periodontal probing depth; BoP: bleeding on probing. Same letters per table denote no statistically significant differences ($p > 0.05$).

Table 4. Periodontal parameters at one-year 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]	16.8 ± 1.2 [a]
Group 3 (Temp Print)	17.5 ± 1 [a]	2.6 ± 1 mm [a]	16.3 ± 0.5 [a]

Legend: PI: plaque index; PPD: periodontal probing depth; BoP: bleeding on probing. Same letters per table denote no statistically significant differences ($p > 0.05$).

4. Discussion

To the authors' knowledge, this RCT is the first that reports short-term clinical performances of definitive partial single units made using additive manufacturing methods. The use of 3D printing is rapidly spreading in dentistry with numerous applications, especially in prosthodontics [5–7]. But while the in vitro performances of these new printable materials have been investigated with promising results, scientific evidence for intraoral use concerning permanent restorations is still quantitatively limited [8].

This study reported 100% success and survival rates of 3D printed partial crowns at the one-year follow-up, with no statistically significant difference compared to milled lithium disilicate crowns, so the null hypothesis was accepted. With the modified USPHS scores, the null hypothesis was also accepted since there were no statistically significant differences among the groups and in any of the assessed variables at the one-year recall.

Cakmak et al. [17], in an in vitro study of 3D printed onlays, reported high intaglio surface trueness and adaptation, together with marginal integrity, and their results are in accordance with those of Canto Naves et al. [18], which reported significantly better adaptation of the additive-manufactured onlays compared to the subtractive-manufactured ones. In the present study, all the restorations reported a good marginal adaptation (MARA), and only two 3D printed onlays scored Bravo at the one-year follow-up. The data are not statistically different from the result obtained from Group 1, where the restorations were realized in LD using a traditional workflow, or Group 2, where the restorations were realized in LD but with a fully digital workflow. The good results reported in all the groups for marginal discoloration (MARD) can be related to the optimal marginal adaptation of the restoration resulting in a thin layer of adhesive cement between the two interfaces, and to the adhesive cementation protocol under rubber dam [27,28]. The latter, together

with immediate dentine sealing right after the preparation, probably influenced the good scores for the postoperative sensitivity (POSTS). Scores for caries presences (CARP) can be attributed to the strict oral hygiene program of the patients enrolled and to the limited observation time that also influenced the absence of the antagonist tooth wear (ANTW). Regarding restoration fracture (RESF) and restoration wear (RESW), no statistically significant difference was found between the three groups despite some of the in vitro studies reporting lower mechanical properties of the composite 3D printed restorations compared to the milled ones [10–12]. The in vivo results of this clinical study can be related to those of Rosentritt et al. [29], which reported acceptable in vitro performance and fracture force for clinical mid-term application, and also to those of Zimmermann et al. [13], which showed more significant results for 3D printed composite crowns compared to milled ceramic crowns after fatigue testing. It could be speculated that the three Bravo scores reported for color alteration (COA) can be attributed to the lower color stability of 3D printable resins compared to the subtractive-manufactured ones, as reported in vitro by Cakmak et al. [30] and by Daghrery et al. [31]. At the one-year recall, no statistically significant differences were found among the groups, probably thanks to the post-processing procedures applied to the printed restorations in the laboratory and the short follow-up time [32]. The limited observation time might have influenced the modified USPHS scores registered, and future recalling may confirm the high clinical performances that were recorded until now. Additionally, it must be taken into consideration that only one type of 3D printed material (Temp Print, GC Corp.) with a high silica filling was tested in this study, and the good clinical performance could be attributed to the high filler content of the tested material that may differ from other printable materials, as reported by Bauer et al. [33]. Three-dimensionally printed restorations can have a very limited lab cost when compared to lithium disilicate and consequently, it can be expected that they will become more and more popular in the future. The mechanical properties of 3D printed resins are much more similar to resin for direct restorations than lithium disilicate [20,34,35]. As such, randomized controlled trials also comparing 3D printed resins and resins for direct restorations are desirable. Longer randomized clinical trials are desirable to investigate the medium- and long-term results of 3D printed resin restorations, possibly compared to direct, lithium disilicate, porcelain, and/or resin-reinforced resin restorations for partial crowns.

5. Conclusions

Under the limitations of this clinical trial, the following conclusion can be drawn:

Since no significant difference was found among pressed, lithium disilicate blocks, and 3D printed resin restorations at the one-year follow up, 3D printed onlays can be considered a viable option for restoring posterior teeth.

Also, because no difference was found between the traditional and digital workflows, the latter can be considered a reliable clinical procedure and used in daily practice.

Author Contributions: Conceptualization, M.F. and E.F.C.; methodology, E.F.C.; validation, G.V. and A.C.; formal analysis, D.M.; investigation, M.F.; data curation, D.M.; writing—original draft preparation, G.V.; writing—review and editing, G.V., G.R., and M.V.; visualization, A.C.; supervision, E.F.C. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: This study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of the University of Siena (protocol code PP001, date of approval 20 October 2022).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available upon request from the corresponding author. The data are not publicly available due to the University of Siena's policy.

Conflicts of Interest: The authors declare no conflicts of interest.

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