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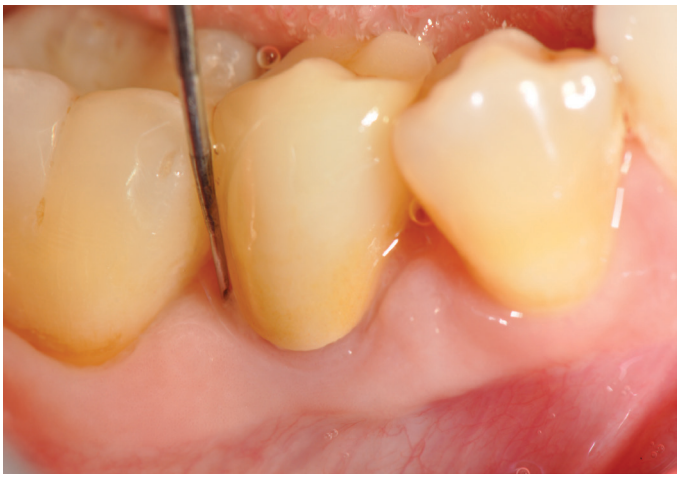
Periodontal evaluation of restorative and prosthodontic margins



Edoardo Ferrari Cagidiaco

UNIVERSITY OF SIENA

School of Dental Medicine

Department of Medical Biotechnologies

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Edoardo Ferrari Cagidiaco

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Periodontal evaluation of restorative and prosthodontic margins

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Committee

Promoter Prof. Simone Grandini

Prof. Francesco Dotta

Prof. Francesco Iannelli

Prof. Andrew Keeling

Prof. Lorenzo Leoncini

Prof. Teresa Marafioti

Prof. Teresa Mezza

Prof. Susanna Morano

Prof. Maurilio Ponzoni

Prof. Roberto Sorrentino

Prof. Fernando Zarone

CANDIDATE

Edoardo Ferrari Cagidiaco

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Chapter 1

Introduction

1.1 . Prosthodontic and periodontal correlation on teeth

In the daily dental practice 3 fundamental/empiric/clinical parameters have a role to establish the clinical success of prosthodontic treatment: function, aesthetic and longevity of the restorations. But, from a scientific point of view, how do we rate the success of the restorations?

When analyzing the existing literature, it can be noted that many authors focus their attention on the precision of the margin, to pursuit a small gap between the abutment and the crown, and to achieve the clinical success.

Christensen et al.[1] and Mc Lean & Von Fraunhofer[2] investigated the margins' clinical acceptability by dentists and asked to measure the gap between the abutment and the crown to a number of practitioners: it was shown that a clinician can clinically appreciate a gap not lower than 120 microns using a sharp explorer. This result may end in a not sure and sufficient seal between the crown and abutment, and consequently leakage at the margins.

This finding is not in agreement with the existing data coming from an in vitro study in which the acceptable marginal gap is lower than 50 microns[3] Sorensen[3] reported that small defects less or equal then 0,050 mm were associated with significantly less fluid flow and bone loss than defects exceeding this value.

Martignoni[4-5] reported that there are variable definitions regarding what constitutes a margin that cab ne clinically acceptable, and there is no definite threshold for the maximum marginal discrepancy that is clinically acceptable. Many authors accept the criteria established by McLean and Von Fraunhofer[2], they completed a 5-year examination of 1000 restorations and concluded that 120 microns should be considered the maximum marginal gap.

The adaptation, the precision and the quality of the restoration margin can be of greater significance in terms of gingival health, than the position of the margin[6].

According to Lang et al. [7] following the placement of restorations with overhanging margins, a subgingival flora was detected which closely resembled that of chronic periodontitis. Following the placement of the restorations with clinically perfect margins, a microflora characteristic for gingival health or initial gingivitis was observed.

In patients with suitable oral hygiene, tooth-supported and implant-supported crowns with intra-sul-

cular margins were not predisposed to unfavorable gingival and microbial responses[8].

Even among patients receiving regular preventive dental care, subgingival margins are associated with unfavorable periodontal reactions[9].

Ercoli and Caton[10], in a systematic review, describe how placement of restoration margins within the junctional epithelium and supracrestal connective tissue attachment can be associated with gingival inflammation and, potentially, recession or periodontal pocket. The presence of fixed prostheses finish line within the gingival sulcus or wearing of partial, removable dental prostheses does not cause gingivitis if the patients are complaint with self-performed plaque control and periodic maintenance. Procedures adopted for the fabrication of dental restorations and fixed prostheses have the potential to cause traumatic loss of the periodontal supporting tissue. They concluded that restoration margins located within the gingival sulcus do not cause gingivitis if the patients are complaint with self-performed plaque control and periodic maintenance.

Tooth-supported and/or tooth-retained restorations and their design, fabrication, delivery, and materials, have often been associated with plaque retention and loss of attachment. Restoration margins placed within the junctional epithelium and supracrestal connective tissue attachment can be associated with inflammation and, potentially, recession. Factors related to the presence, design, fabrication, delivery and materials of tooth-supported prostheses seem to influence the periodontium, generally related to localized increase in plaque accumulation and, less often, to traumatic and allergic reactions to dental materials[10].

Jansson showd that the influence of a marginal overhang on pocket depth and radiographic attachment decrease with increasing loss of periodontal attachment in periodontitis-prone patients, and the effect on pocket depth of a marginal overhang may act synergistically, potentiating the effect of poor oral hygiene[11].

Subgingival restorations with their apical borders still located subgingivally after periodontal treatment should be regarded as a risk factor in the progression of periodontitis[12]. Consequently, placement of the restoration margin supragingivally is recommended, especially in periodontitis-prone patients with an insufficient plaque control[12].

Dental restorations may be suggested as a risk indicator for periodontal disease and tooth loss. Routine SPT (Supportive Periodontal Therapy) was found to be associated with decrease in the prevalence of deep PPD over time, and it is of the utmost importance in maintaining periodontal health, especially adjacent to teeth with restorations. Finally, these findings may support the treatment of caries lesions and faulty restorations as part of a comprehensive cause-related therapy and

should be followed by a regular maintenance program[13].

The relationship between dental restorations and periodontal status has been examined for some time. Research has shown that overhanging dental restorations and subgingival margin placement play an important role providing an ecologic niche for periodontal pathogens[14].

An overhanging dental restoration is primarily found in the class II restoration, since access for interdental finishing and polishing of the restoration, and cleansing is often difficult in these areas, even for patients with good oral hygiene. Many studies have shown that there is more periodontal attachment loss and inflammation associated with teeth with overhangs than those without. Presences of overhangs may cause an increase in plaque formation[15-21] and a shift in the microbial composition from healthy flora to one characteristic of periodontal disease[14].

The location of the gingival margin of a restoration is directly related to the health status of the adjacent periodontium[8]. Numerous studies[8-12-25]

have shown that subgingival margins are associated with more plaque, more severe gingival inflammation and deeper periodontal pockets than supragingival ones. In a 26-year prospective cohort study, Schatzle et al. [25] followed middle class Scandinavian men for a period of 26 years. Gingival index, and attachment level were compared between those who did and those who did not have restorative margins greater than 1mm from the gingival margin. After 10 years, the cumulative mean loss of attachment was 0.5 mm more for the group with subgingival margins. This was statistically significant. At each examination during 26 years of the study, the degree of inflammation in the gingival tissue adjacent to subgingival restorations was much greater than in the gingiva adjacent to supragingival margins. This is the first study to document a time sequence between the placement of subgingival margins and periodontal attachment loss, confirming that the subgingival placement of margins is detrimental to gingival and periodontal health.

Plaque at apical margin of a subgingival restoration will cause periodontal inflammation that may in turn destroy connective tissue and bone approximately, 1-2 mm away from inflamed area[14].

Determination of the distance between the restorative margin and the alveolar crest is often done with bitewing radiographs; however, it is important to remember that a radiograph is a 2-dimensional representation of 3-dimensional anatomy and structure. Thus, clinical assessment and judgment are important adjuncts in determining if, and how much, bone should be removed to maintain adequate room for the dento-gingival supra crestal connective tissue height attachment[14].

Although surface textures of restorative materials differ in their capacity to retain plaque[26], all of them can be adequately maintained if they are correctly polished and accessible to patient care[27].

This includes underside of pontics. Composite resins are difficult to finish interproximally and may be more likely to show marginal defects than other materials[28]. As a result, they are more likely to harbor bacterial plaque[29]. Intra-subject comparisons of unilateral direct compositive “veneers” showed a statistically significant increase in plaque and gingival indices adjacent to the composites, 5-6 years after placement[28]. In addition, when a diastema is closed with composite, the restorations are often overcontoured in the cervical-interproximal area, leading to increased plaque retention[28]. As more plaque is retained, this could pose a significant problem for a patient with moderate to poor oral hygiene[14].

For that, in absence of more specific prosthodontic parameters to evaluate the integration of crowns in to the periodontal environment, another way to determine the success and health of the restoration is to use the periodontal parameters such as: PPD (Periodontal Probing Depth) that is the measurement of the periodontal sulcus/pocket between the gingival margin and the bottom of the sulcus/pocket; REC (Recession) is the apical migration of the gingival margin measured with the distance between the gingival margin and the CEJ (Cement-Enamel Junction); PI (Plaque Index) the index records the presence of supragingival plaque; BOP (Bleeding On Probing) the presence or not of bleeding on surfaces of the teeth during the probing.

The aim of this study/thesis was to propose a clinical procedure to evaluate single unit restorations and their relations with periodontal tissues by a new clinical score: the FIT (Functional Index for Teeth). FIT, that is a novel index for the assessment of the prosthetic results of lithium disilicate crowns, based on seven restorative-periodontal parameters, that evaluate crowns placed on natural abutments, and want to be a reliable and objective instrument in assessing single partial crown success and periodontal outcome as perceived by patients and dentists.

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Chapter 2

2.1 Differences on different types of preparations

In prosthodontics there are different kind of margins preparation (chamfer, knife edge, feather edge, shoulder, ecc.) that can be differently located in relation with the periodontal tissues, in accordance with the clinical situation and needs of the patients. All of them have the same goal: good sealing, function and maintenance of the prosthetics margins.

In fact, the precision of the margins, and their location are important to achieve a good clinical result but also the possibility to clean them by home (care) oral hygiene is mandatory.

The effect of different finish line designs on the fatigue, fracture resistance and failure modality of veneered zirconia restorations was evaluated in a study: a complete narrow chamfer, a narrow chamfer with a lingual ledge, and a complete ledge are the three finishing margins that were proposed and analyzed for zirconia crowns[1]. The study showed that the finish line design did not have any statistically significant influence on the fracture resistance or on the failure type of zirconia crowns. In another study it was showed that after experimentally induced veneering fracture the framework remained intact, independently of the finish line[2] .

Some evidence is growing that crowns fabricated with digital procedures exhibit better marginal fit compared to conventional techniques[3].

As to the overall fidelity, many authors reported that marginal discrepancy of single zirconia crowns is comprised in a clinical acceptable range of 0-78 microns[4-10] whilst FDPs exhibit worse openings, between 9-149 microns[11-13].

However several aspects are not clarified yet.

The studies on marginal discrepancy usually report about mean value of gaps that may be in a clinical acceptable range[14-18], but when all recorded values at the margins and the standard deviations are evaluated it is clear that if only the mean value is considered the conclusions can be misinterpreted. Also, when external margins fidelity (marginal fit) is compared to internal fit, usually the latter shows higher discrepancies[14].

Another open issue is how much marginal gap can be clinically accepted. Christensen[18] supported that a clinically detectable sub-gengival margin is between 34-119 microns, Mc Lean and von

Fraunhofer[19] pointed out 120 microns as a limit for clinically acceptable marginal discrepancies, Holmes et al. [20] placed the ideal marginal gap no more than 50 um, whilst Audenino et al., [21] found gaps between 50-300 microns for metal-free restorations, Cagidiaco et al. [22] reported a marginal gap of 20 microns with metal bevel margins and 120 microns with butt joint porcelain margins, but Jahangiri et al.[23] specified that with clinical devices, such as the explorer, an assessment marginal accuracy over 124 microns can be achieved.

Also, it must be pointed out that only few papers report about the value of clinically acceptable margins: how much discrepancy at the margins can be clinically accepted is still unclear[24].

Recently Navarra et al[25] showed that after one year of simulated chewing activity, feather edge, deep chanfer or slight chamfer zirconia crowns did not show any signs of t-m (temporo-mandibular) transformation, neither where the load was applied, neither at the margins.

In conclusions, although the chamfer is the most advocated finishing line of porcelain crowns, the choice of the marginal design of the preparation should be carefully evaluated, based on the condition of the specific restored tooth.

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2.2 RCT on single zirconia crowns with knife edge vs chamfer finish lines: four years results

Abstract

Objectives: To evaluate the influence of two finish lines on the fracture resistance and periodontal response of porcelain zirconia crowns. Materials and Methods: Fifty zirconia single crowns were placed in posterior regions. Ethical committee approval was obtained. Abutments were randomly distributed into 2 groups. Group 1: feather-edge preparation (FP) and Group 2 chamfer preparation, (CP). Patients recalled after 1, 6 months, 1, 2, 3, and 4 years. The function, esthetics and marginal adaptation of the restorations were evaluated. Bleeding on probing (BoP) and distance of margins from bone crest were recorded. Statistical analyses were performed about survival and success rates. Results: Group 1: Success 21/25 (80%); survival 24/25 (96%); (one not reparable fractures of ceramic layer); Group 2: Success 20/25 (76%); survival 25/25 (100%). Chippings of four crowns were noticed in Group 1 (one crown replacement). In Group 2 five chippings without any replacement. No statistical significant differences between the two groups.

BoP was found in 18 of the 25 crowns of Group 1 (72%) and in 12 of the 25 crowns of Group 2 (48%). A statistically significant correlation between BoP and the distance of the margin to the bone crest was found. Conclusions: 1. No differences on survival and success rates clinically; 2. Statistically significant correlation between BoP and the distance of the margin to the bone crest was found: margins should be placed at least at 3 mm from the bone crest; 3. In case of FP, higher probability of BoP can be faced.

Introduction

The clinical success in restorative/prosthodontic dentistry has been classically based on attainment of adequate function on occlusion precision and esthetics. These goals depend on many factors, such as the health of the periodontal tissues, the accuracy of the preparation margins, the precision and lack of fractures of the abutments, etc. [1,2].

In terms of periodontal health, it is clearly evidenced the preference for supra-gingivally placed restorations[3,4], however, this is not always possible in cases of high esthetic demands of in presence of dental disease[4]. In these situations, subgingivally located margins are indicated, although even slightly subgingival margins may affect periodontal health[5]. Due to this, the precision and type of finish line[6], its distance to the bone crest[6] and quality of oral hygiene by the patient[7-10] become key factors in clinical success.

One of the most controversial of these factors has been the type of finish line when preparing the margins on natural abutments. This finish line has been defined as the final margin that separates the prepared axial tooth surface and the remaining unprepared tooth surface. When this finish line is prepared vertically without a defined margin (feather-edge), the resulting vertical area is the margin of the preparation. Conversely, when the finish line is designed by a horizontal sharp line (chamfer), there is a clear margin outlining this finish line. Consequently, the feather-edge leaves an undefined margin, whilst the chamfer results in a defined clear margin. It has been argued that the choice of the finish line depends on the: type of tooth[4], crown length[11], existing restorations[11], distance between adjacent abutments/teeth[11] , location of the margin in relation with soft periodontal tissue[11], type of planned restorations[11], type of selected material to fabricate the crown(s) or bridge(s) [11], the periodontal health status[12-13] and skill, experience and preference of the operators[15]. However, there is no clear evidence from clinical trials on the superiority of a specific finish line[10-15]. Carnevale et al. [16-17] introduced the feather-edge preparation during periodontal surgery and reported retrospectively on the clinical success of this combined periodontal-prosthetic procedure. Paniz et al more recently designed a RCT to evaluate the 12-month periodontal response to two subgingival restorative margin designs reporting that the feather-edge in comparison with the chamfer was associated with a higher rate of bleeding on probing (BOP)[18]. Furthermore, other authors have reported that the type of finish line could also affect the fracture resistance of esthetic crowns[16,20].
It was, therefore, the objective of this randomized clinical trial to evaluate the influence of two margin finish lines on the periodontal health and fracture resistance of zirconia single crowns layered with dedicated ceramics. Furthermore, this RCT was designed to evaluate whether the distance between the margin and the bone crest had a direct influence on the periodontal parameters, independently from the type of finish line.

The following null hypotheses were tested: 1) no difference between two different finish lines (feather-edge vs chamfer) on fracture resistance; 2) no difference between two different finish lines on periodontal tissue health and 3) there is a direct influence of the distance of the margin to the bone crest on the periodontal parameters, independently from the type of finish line,

Material and Methods

Study Design

This study was designed as a parallel, randomized, single-center, clinical trial (RCT) to evaluate the

effect of two different finish lines of posterior natural abutments on periodontal outcomes and the resistance to fracture of the restoration when loading. This RCT was approved by the Institutional Ethics Committee of the University of Siena (clinicaltrials.gov #NCT020906567) and was conducted according to the revised 2008 Declaration of Helsinki on experimentations involving human subjects[20]. The results of this RCT are presented in fulfillment of the CONSORT guidelines[21].

Participants

Subjects were enrolled at the Department of Prosthodontics of the University of Siena (Italy) between September 2013 and December 2013.

Patients were selected for the study on the basis of the following inclusion criteria: age above 18 years with one tooth in need of crowning, no active intraoral or systemic disease, no pregnancy or lactation, smoking less than 10 cigarettes/day, in good general health, good oral hygiene, low caries activity, vital or satisfactory endodontically treated tooth with no pathological signs on the X-ray and without clinical symptoms of inflammation, no history of previous periodontal flap surgery, periodontal pocket depth less than 3 mm, Bleeding On Probing and Plaque Index inferior to 20%, no tooth mobility, occlusal function with a natural tooth, possibility to placer the margins on sound dental structure, lack of excessive parafunctional activity leading to an extensive loss of tooth structure, abfraction lesions or cracks.

Conversely, the following exclusion criteria were adopted: addiction to alcohol and/or drugs, psychologically unstable patients, patients with acute symptoms of parafunctional disorders with the necessity of functional pretreatment before prosthodontic therapy, patients with systemic life-threatening diseases (physical status corresponding to group IV or higher of the American Society of Anesthesiologists classification), patients requiring hard/soft tissue augmentation, patients with untreated periodontal disease/poor compliance, teeth with deep intrasulcular restoration.

Fifty consecutive patients (28 females and 22 males) with a mean age of 45.7 years (SD=10.2) and in need to receive 1 posterior layered zirconia single crown each in premolar and/or molar regions were selected for the study (Table 1). A total of 50 posterior teeth were selected: 30 molars (17 maxilla and 13 mandible) and 20 premolars (11 maxilla and 9 mandible). All the treated posterior teeth had natural dentition in the opposite arch.

An experienced dental hygienist prepared the patients from a periodontal point of view and a first impression was taken with an irreversible hydrocolloid (GC Aroma Fine Plus, GC, Tokyo Japan) in order to pour the study casts and fabricate the composite resin temporary crowns. The casts of

both dental arches were mounted into a semi-adjustable articulator (Artex, Ammann Girrbach AG, Koblach, Austria) .

Randomization, Allocation Concealment, Masking of Examiners

Each patient was randomly assigned to 1 of the 2 experimental groups.

Allocation concealment was performed by opaque sealed, sequentially numbered envelopes. The statistician generated the allocation sequence by means of a computer-generated random list and instructed a different operator to assign a sealed envelope containing the type of finish line (i.e., feather-edge vs chamfer). The opaque envelope was opened before finish line election and treatment assignment were communicated to the prosthodontist. Blinding of the examiners was maintained throughout all experimental procedures.

The abutment teeth were randomly distributed into 2 groups of 25 samples each, according to 2 different finish line designs, as follows (Fig. 1):

- Vertical Preparation (Knife edge)
- Horizontal Preparation (Chamfer)

Surgical and Prosthetic Procedures

A single, calibrated examiner, blinded to the experimental procedures, assessed all the clinical outcomes of the investigation both at the baseline and at the follow-up examinations.

A standardized tooth preparation was performed with occlusal and axial reduction of 1.5 mm and a chamfer or a knife edge finish line, that was placed juxta-gingivally. After one-two weeks, the temporary crowns were removed, a retraction suture silk cord (OOO) was placed into the sulcus and the tooth preparations refined using a stereomicroscope at 10x magnification placing the margins 0.5 mm into the sulcus (Zeiss OpMi1, Zeiss, Oberkochen, Germany). All internal line angles were rounded. All the preparations were made by the same experienced prosthodontist (MF). The interim restorations were relined intraorally on the prepared teeth; then, they were smoothed with soft rubbers and polishing cups to obtain an optimal marginal adaptation between the crowns and the soft tissues. Finally, the interim restorations were cemented in the same session with a eugenol-free temporary cement (Freegenol, GC). The interim restorations were worn by the patients for 3 weeks, so as to allow the soft tissues to recover from any possible preparation trauma and recover a complete health status.

One-step precision impressions were taken using vinyl polyether silicone impression materials

(EXA'lence, GC) with custom auto polymerizing acrylic resin trays (SR-Ivolen, Ivoclar Vivadent AG, Schaan, Liechtenstein) made by the same dental technician at least 24 hours before the impression. The impressions were poured using an extra-stone plaster type IV (Fuji Rock, GC) after 5 hours in order to allow the elastic return of the impression material. The composite resin temporary crowns were relined intraorally, polished and cemented as previously described.

In order to standardize as much as possible, the shape of the experimental copings, each framework was waxed-up by the same experienced dental technician with a minimum thickness of 0.5 mm; then, the copings were scanned by a Computer Aided Design-Computer Aided Manufacturing (CAD-CAM) software (Aadva, GC) and the zirconia cores were fabricated. The porcelain veneering was performed using a ceramic material dedicated to zirconia (Initial Zr-FS, GC), characterized by a special adaptation to the coefficient of thermal expansion (CTE) of the zirconia frameworks ($9.4x10^{-6}K^{-1}$). Slow cooling was made, in order to dissipate the residual stresses within the bi-layered restorations. The pressure layering technique was adopted following the manufacturer's instructions.

At the intraoral try-in of the bisquebake crown and the slight occlusal adjustments were made by a diamond bur when needed, carefully checking the occlusal contacts. The final restorations were finally glazed and then cemented using a glass ionomer cement (Fuji-Cem, GC) following the manufacturer's instructions. The luting agent was inserted into the crowns and the patients were requested to hold them under occlusal compression until cement set; then, excess cement was carefully removed.

Follow-up Examinations

The cementation time was considered the baseline to record data.

The patients were recalled for follow-up visits after 1 month, 6 months, 1, 2, 3 and 4 years of clinical service. The function and the esthetics were checked at the follow-up appointments by two independent examiners blinded to the group assignment and calibrated. In order to collect and classify the clinical outcomes, 'success' was defined by the percentage of restorations that remained in situ without any modification, 'survival' by the percentage of restorations that remained in situ with modifications but still under clinical acceptability, whilst 'failure' by the percentage of restorations that needed to be replaced[23,24].

Data collection

Data collection included clinical and radiographic measurements and photographs (horizontal for-

mat 1:1). 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.

The following clinical measurements at the baseline, immediately after luting the crown, were taken at the experimental sites by the blinded examiner: gingival bleeding on probing (BoP), at two different facial sites (mesial and distal), was reported as mean, according to Ainamo and Bay[24].

Radiographic measurements at the time of placement of definitive restoration and final follow-up were made in order to calculate the distance between the bone crest and the margin of the crown.

Bone level Mes: the distance from the tooth preparation to the bone at the mesial site.

Bone level Dis: the distance from the tooth preparation to the bone at the distal site.

The mean bone level was then calculated considering mesial and distal bone levels at the single dental abutment.

Statistical analysis

The patients' characteristics and clinical variables were balanced between groups. The Fisher's Exact Test was applied to assess the statistical significance of between-group differences in the 4-year success rate. The level of statistical significance was set at $p<0.05$.

A logistic regression analysis was applied to verify whether 4-year BoP at the interproximal level was significantly influenced by tooth type, preparation type, and distance of preparation margin from bone crest level. A separate logistic regression analysis was performed to assess whether 4-year BoP at the buccal site was significantly influenced by tooth type and preparation type.

The statistical analyses were performed using a statistical package software (IBM SPSS Statistics for Windows, Version 21.0, IBM Corp., Armonk, NY, USA).

Results

The following results were collected after the period of clinical service: Group 1: 80% success rates 21/25 (one not reparable fractures of ceramic layer) and 96% survival rate (24/25). Group 2: 76% success rate (20/25) and 100% survival rate (25/25). Four chippings were noticed in Group 1 but only 1 crown needed to be replaced after 4 years. In Group 2 five chippings were noted but no need for replacement was considered after 4 years of clinical service (Table 2). All chippings took place in coronal part of the sample crowns of patients with evident clinical signs of occlusal wear. One chipping (the catastrophic one) was recorded during the first year of clinical service, 2 were noted during the second year, 2 during the third and the other 4 during the fourth year of clinical service.

No chipping at the margins of both groups was noted.

Statistical analysis of survival and success rates did not show any statistically significant difference (Table 2).

Regarding the periodontal parameters, BoP at 4 years was present in 12 of 25 crowns of Group 1 (48%) and in 18 of the 25 crowns of Group 2 (55,5%) (Table 3). A statistically significant correlation was found between BoP and the distance of the margin to the bone crest. When the bone crest was less than 3 mm, a higher probability of BoP was detected. According to the regression analysis BOP at interproximal level was significantly dependent on the type of the preparation ($p=0.004$) and the distance between the bone crest and the crown margin (BC-CM) ($p<0.001$), while tooth type did not have a significant influence ($p=0.821$). Conversely, BOP at buccal sites, neither preparation type ($p=0.721$), nor tooth type ($p=0.399$) were statistically significant.

Discussion

The results of this study support rejection of the first null hypothesis: the survival rate of the zirconia crowns made with vertical or horizontal margins did not show statistically significant differences about survival and success rates after 4 years of clinical service. Within the limitations of this *in vivo* study, due to the limited number of specimens tested, it was concluded that all zirconia crowns created with feather-edge or chamfer demonstrated a similar and acceptable behavior with relation to the fracture resistance and periodontal response of zirconia single crowns layered with dedicated ceramics. Feather-edge would allow the use of precise zirconia restorations in abutments for fixed prostheses. Preserving a maximum amount of sound tooth structure during tooth preparation for fixed abutments, as it is commonly done in vertical preparations, might be a less invasive alternative to a chamfer margin. This would be true not only for periodontally treated teeth[16-18], but also in other clinical conditions such as endodontically treated teeth, vital teeth in young individuals, and teeth affected by caries at the cervical third of the clinical crown[25].

There were certain limitations to this study. Only one specific zirconium-oxide-based ceramic CAD/CAM system was evaluated with only one ceramic material dedicated to zirconia. Further clinical investigation is necessary to evaluate the influence on clinical behavior of different tooth preparation designs with different total occlusal convergence (TOC) angles[25-26]. It would be also necessary to undertake additional studies to determine the clinical risk of delamination of the veneering porcelain if different types of preparation are carried out.

One cement has been used: glass ionomer cement is very well-known luting material but it can be

speculated that other cements can reach similar clinical results of this study[27]. It should also be noted that all the crowns included in this study had 360° zirconium-oxide margins: the zirconia margins when a feather-edge was used are thinner than the zirconia margins obtained when a chamfer has been performed; therefore, it might be supposed that these thinner margins can be more easily altered during various clinical phases, for example during scaling procedures at oral hygiene recalls[28,29]. Further studies should be accomplished to verify if these small irregularities may influence the BoP of the two types of finish line. On the other hands a previous study showed that zirconia should not be altered during cementation and can be the material of choice to make esthetic crown with vertical finish line[30].

The second null hypothesis tested in this study, that there was no difference between two different finish lines on periodontal response was rejected. The evaluation of the recorded BoP showed statistically significant differences between the two groups and the highest score was recorded when feather-edge was used.

However, it should be noted that the deep position into the sulcus of this finish line and consequently its close position to bone crest may be a real reason of increased BoP: because of the revealed statistically significant correlation between BoP and the distance of the margin to the bone crest, it should be clinically advocated that the margins have to be placed at least 3 or more mm far away from the bone crest independently from the type of finish line. For that reasons the third null hypothesis tested, that there was a direct influence of the distance of the margin to the bone crest on the periodontal parameters, independently from the type of finish line, was accepted. Another factor that can influence the BoP scores of the two groups might be different levels of home oral hygiene of the patients, aspects that can not be completely controlled in all patients.

Within the limitations of this study, it can be stated that clinicians might decide what type of finish line have to be chosen when using zirconia single crowns.

Accordingly with previous articles CAD/CAM systems were used to achieve good *in vivo* marginal fit for single-unit crowns made with chamfer and feather-edge with the advantages of homogeneous standardized materials[31].

Clinicians should pay attention also on the periodontal parameters, as a matter of fact that the BoP can be correlated by the distance of the finish line from the bone crest as already demonstrated[32-37].

Recently Ercoli and Caton[10] evaluated if there was evidence in the literature that factors related to teeth and dental prostheses can play a role in the initiation and progression of gingivitis and periodontitis. Along their narrative review Ercoli and Caton wanted to summarize the current evidence

about the role that the fabrication and presence of dental prostheses and tooth-related factors have on the initiation and progression of gingivitis and periodontitis[10]. They pointed out once more that the placement of margins within the biological width causes gingival inflammation and possibly recession or pocket formation, and that the intraoral procedures to fabricate fixed prostheses can traumatize periodontal supporting tissue. However, it was evident that despite the existance of many clinical factors that can affect the periodontal tissue health, adequate periodontal assessment and treatment, appropriate instructions and motivation in self-performed plaque control and compliance to maintenance protocols appeared to be the most important factors to limit or avoid potential negative effects on the periodontium caused by fixed and removable prostheses[10]. Given the limited available evidence in humans, it was not possible to determine if the negative effects on the periodontium associated with a violation of the biologic width by restorative margins is caused by bacterial plaque, trauma or a combination of these factors[10], both factors can play an important role. For that the high rate of BoP recorded in the study can be related to the fact that when a margin is located slightly (0.5 mm) into the sulcus, in the interproximal area of posterior teeth, independently from the type of finish line was designed, the maintenance of healthy periodontal condition is mainly in the hands of the patient and his/her home plaque control[38-40]. The clinician must design the preferred margin in order to make easier to the patient all plaque control procedures and motivate the patient to properly and regularly perfom his/her oral hygien also interproximaly.

Another limitation of this study is that, after luting the sample crowns, was not possible to check the precision of the margin also based on the fact that a marginal gap of up 100-120 microns can be detected clinically[41]. For that reason, it can not be underestimated that the presence of a marginal overhang can act as a plaque retentive factor and cause a qualitative shift toward a subgingival cultivable microflora more characteristic of periodontitis[42].

Regarding the fact that 10% of both groups reported chipping of the crowns, a % of failures higher than that was expected; It might be observed that all crowns of this study were porcelain fused to zirconia crowns and all chipping were recorded in patients with signs of occlusal wear. Chipping of porcelain fused to zirconia crowns might be correlated to different factors such as the presence of natural opposing teeth and type of occlusal loading[42-43], coping/framework design[44-46], surface finishing[47-48], thermal misfit of veneering ceramic/zirconia composites[49-55], slow heating and slow cooling of porcelain on zirconia couping[56], internal surface treatment of coping, type of luting material and marginal gap[56-61], hydrothermal degradation[62], different clinical conditions and operators[63-69].

However, considering that all patients of this study that were reported with chipping showed differ-

ent degrees of wear, more clinical information are needed to point out limitations of using porcelain to fused zirconia crowns on bruxist patients.

However, further research must be carried out; for example, concerning the clinical outcomes of horizontal and vertical finish lines in the case of multiple dental restorations: in multiple abutments different results can be achieved because of the insertion of the bridge and because higher the number of abutments less precision can be expected.

Conclusions

According to the results of the present *in vivo* study and under its limitations, the following conclusions were draw:

- the clinical performance of the zirconia crowns made with vertical or horizontal margins showed no differences of survival and success rates after 4 years of clinical service.
- statistically significant correlation between BoP and the distance of the margin to the bone crest was found: for that margins, both vertical or horizontal, should be placed at least at 3 mm or more far away from the bone crest.
- it must be also considered that in case of a vertical prep a higher probability of BoP can be faced.

Clinical Significance

The results of the present clinical study would allow clinicians to make a vertical or/and a horizontal finish line when using zirconia single crowns. However, clinicians must focus their attention also on the periodontal parameters, suggesting that the type of prep and its distance from the bone crest are key clinical factors.

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Legends

Fig. 1 The 2 different finish line designs.

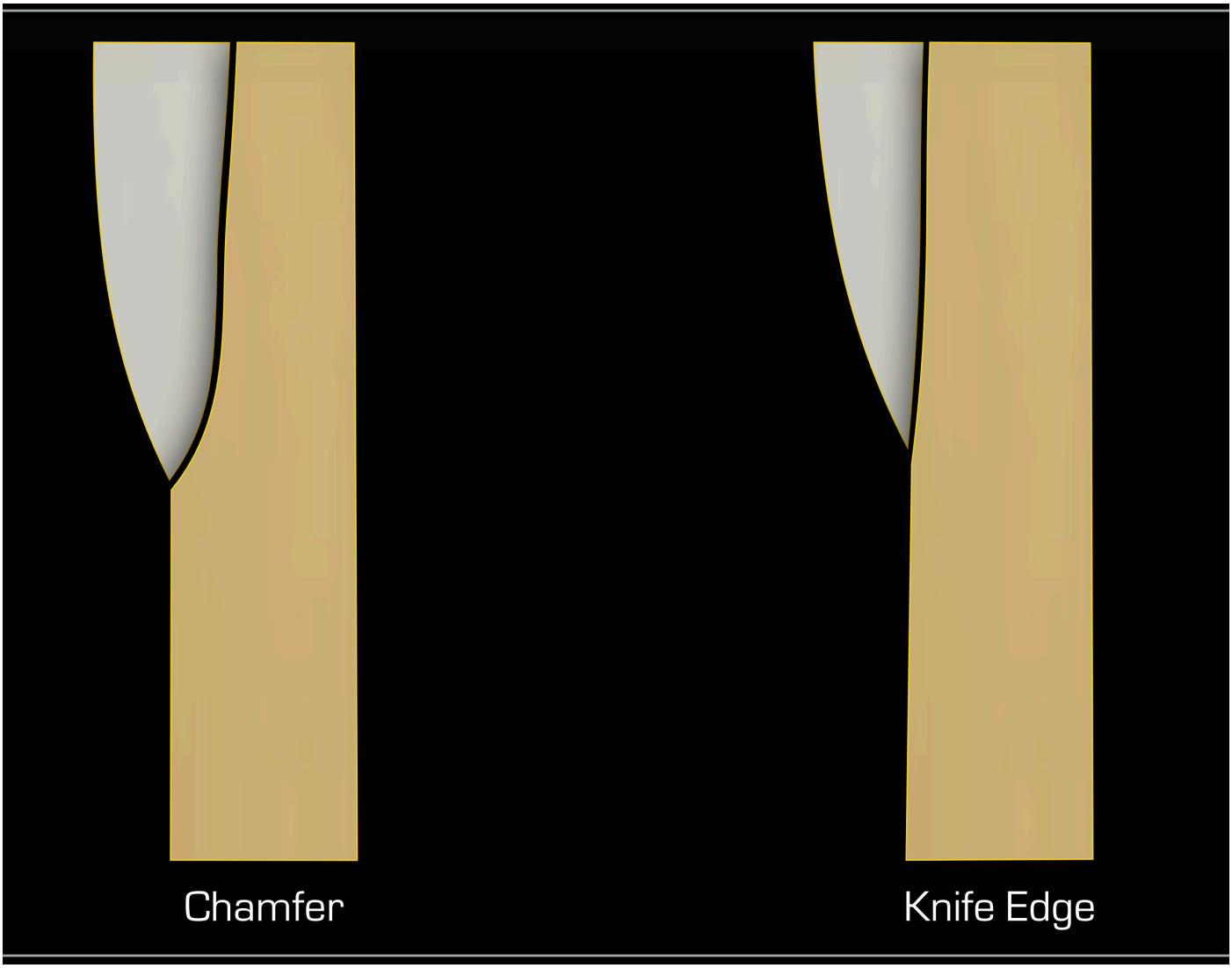


Fig. 2 (Group 1) x-Ray of a patient in need to restore the first premolar and to extract the second molar.

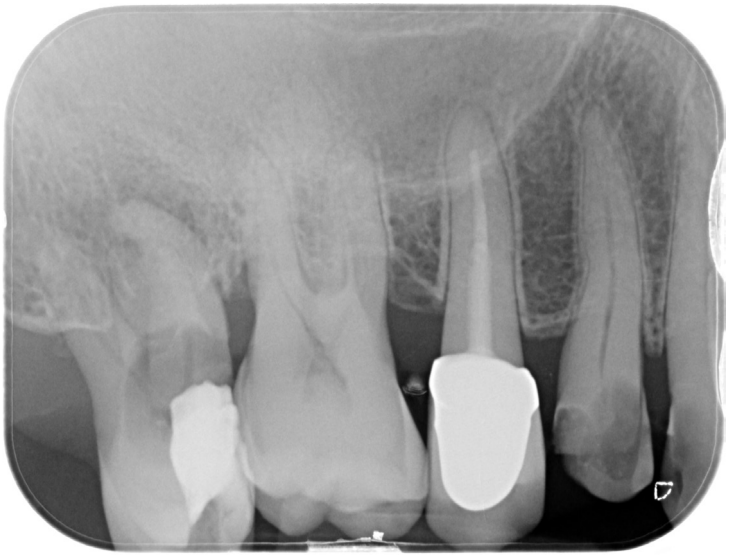
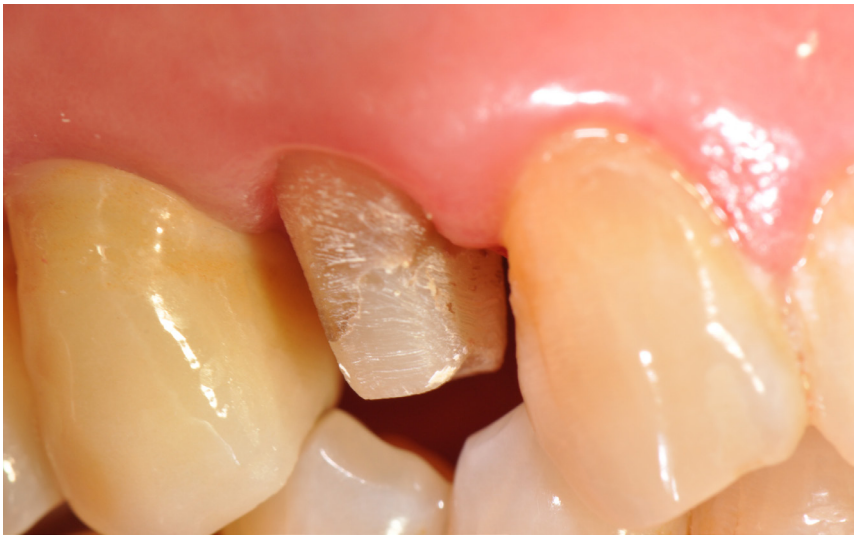


Fig. 3 and 4 After receiving a build up with resin composite, the premolar was prepared with feather edge.



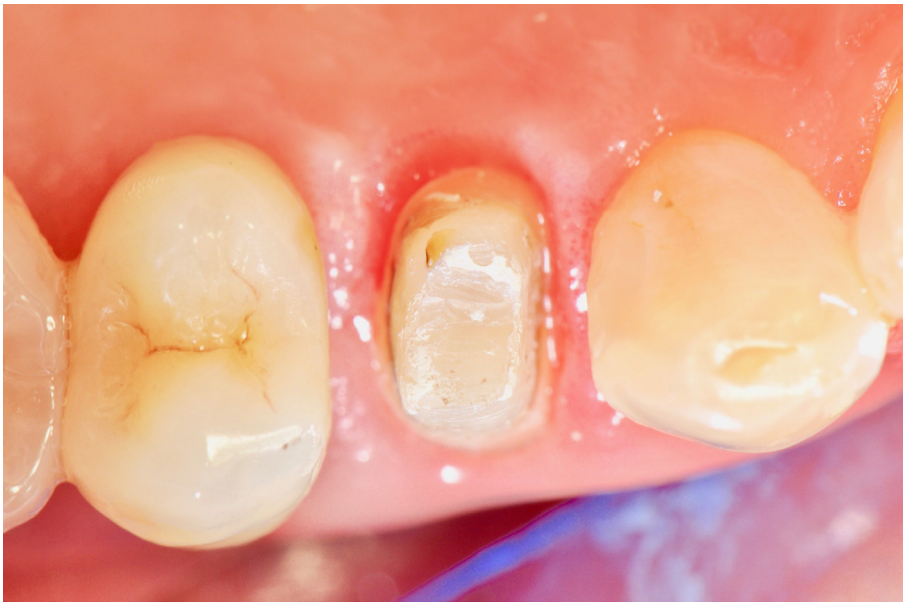
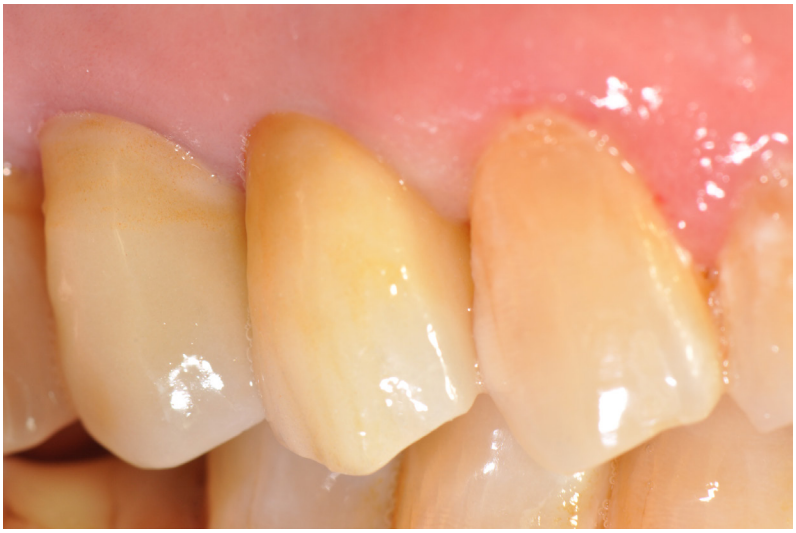
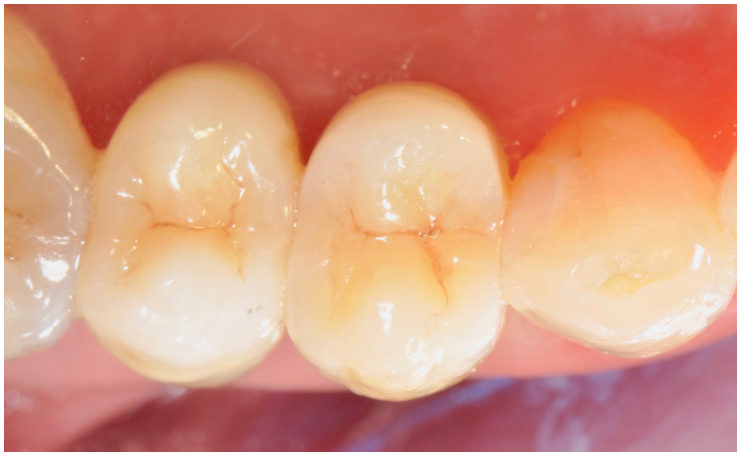


Fig. 5, 6 and 7 The premolar after being restored with a porcelain fused to zirconia crown. Buccal and occlusal view and x-Ray.





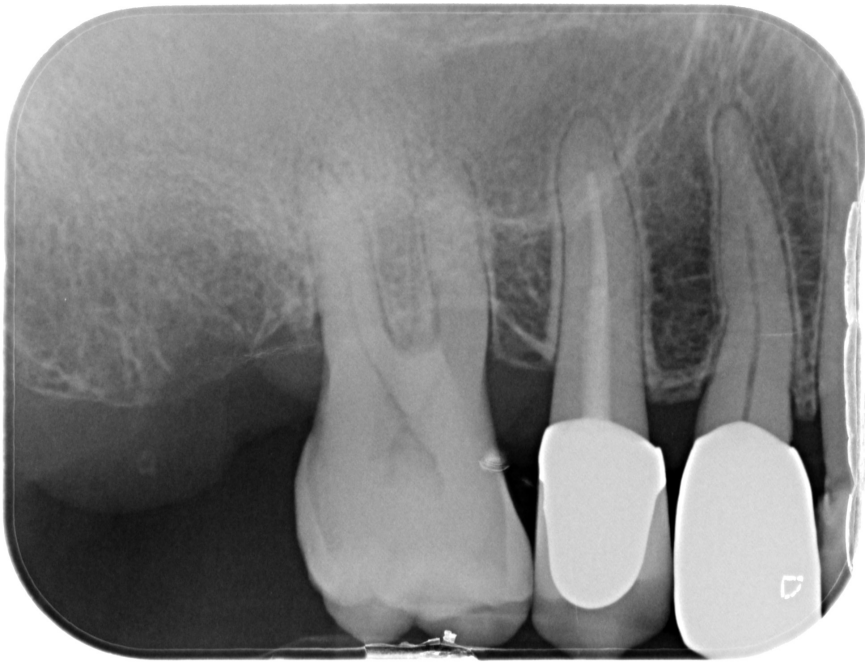


Fig. 8 (Group 2) x-Ray of a patient in need to remove an old crown on the second pre-molar made with a cantilever.

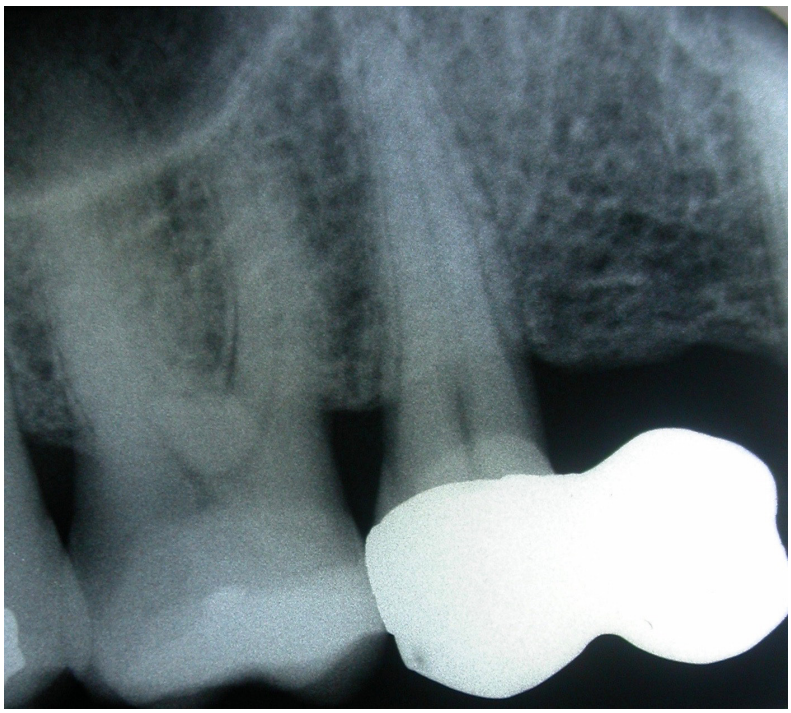


Fig. 9 The patient was treated with a fixture to replace the missed first premolar and with a single crown with a chamfer finishing line.

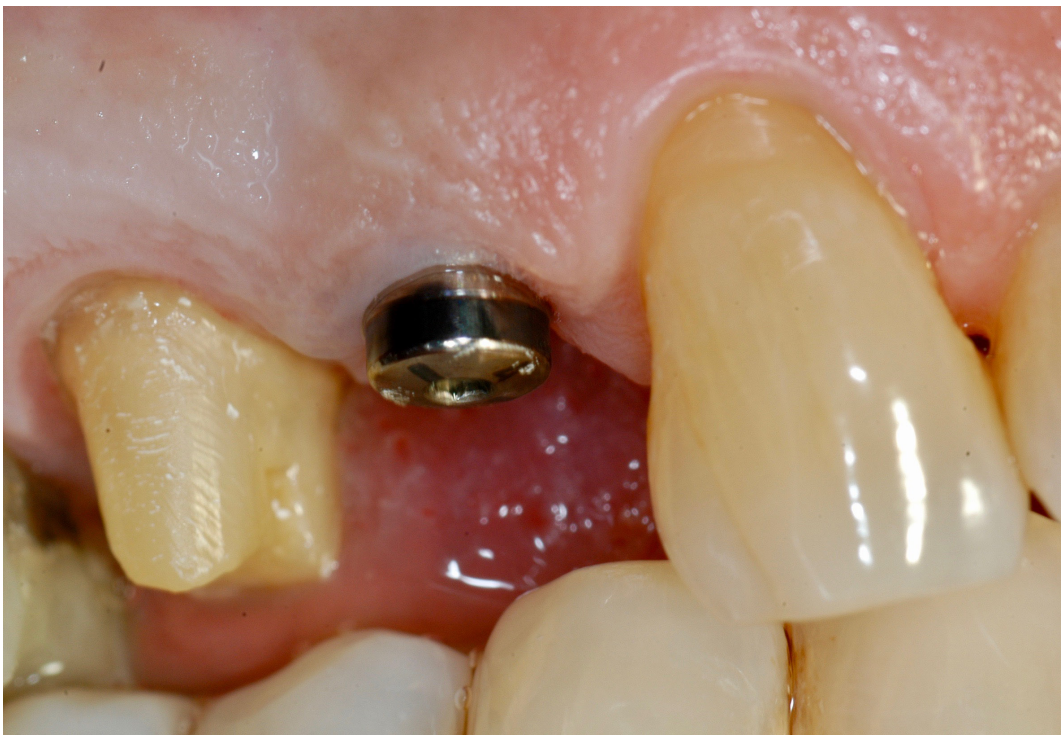


Fig. 10 Try-in of the two copings

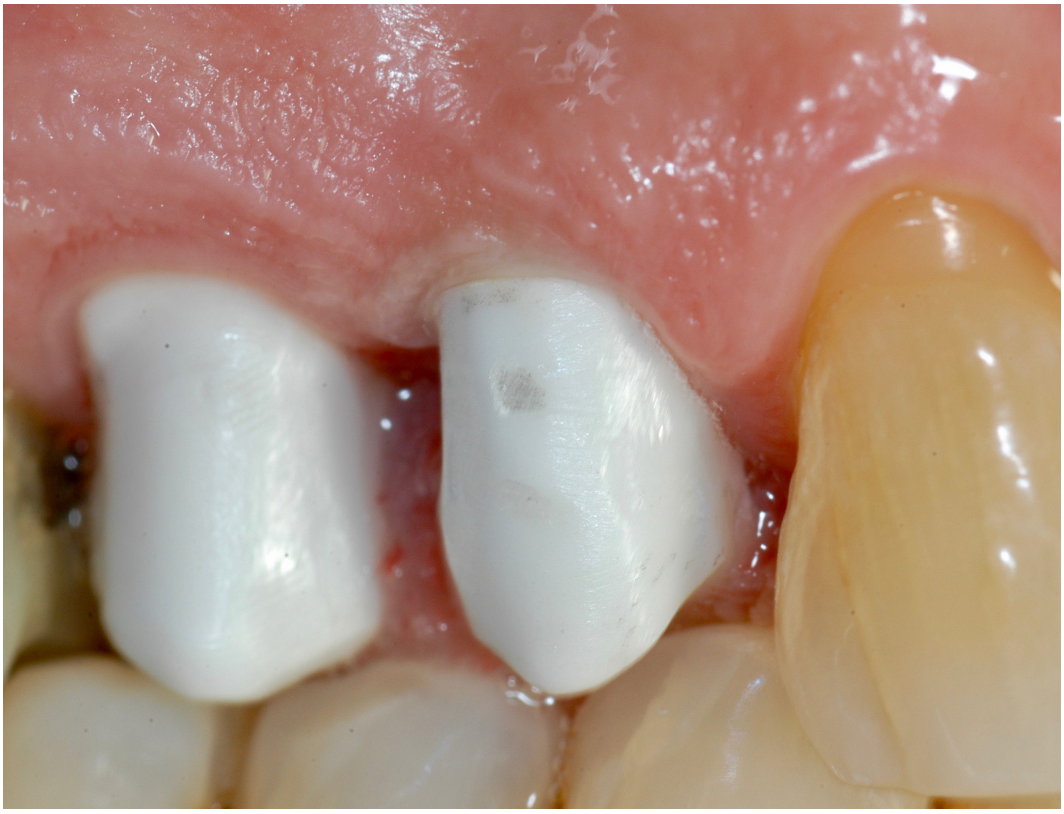
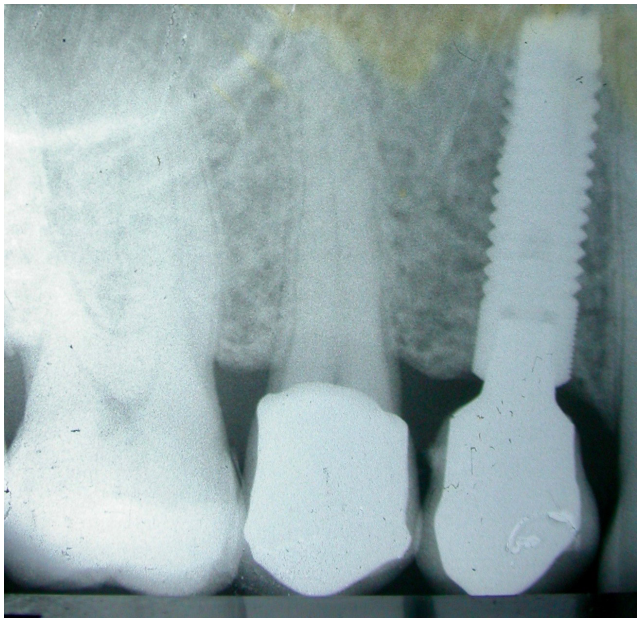
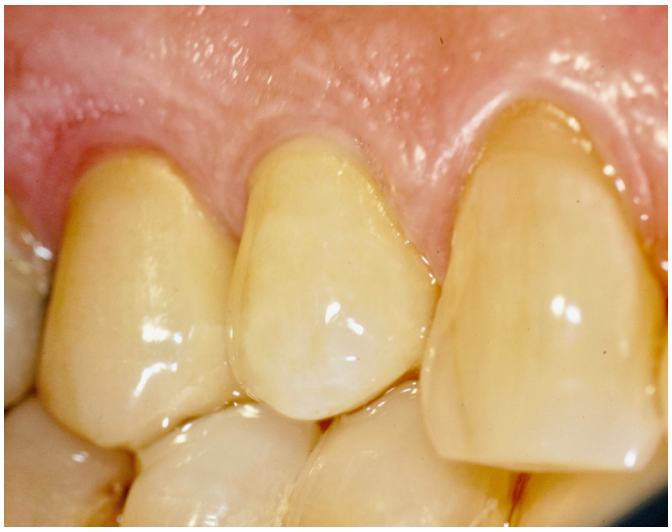


Fig. 11 and 12 Buccal view and x-Ray at last recall.





Chapter 3

3.1 Fit a new clinical score to evaluate single crowns

The aim of this study was to propose a clinical procedure to evaluate single restorations and their relations with periodontal tissues by a new clinical score: the FIT (Functional Index for Teeth). FIT, that is a novel index for the assessment of the prosthetic results of lithium disilicate crowns, based on seven restorative-periodontal parameters, that evaluate crowns placed on natural abutments, and want to be a reliable and objective instrument in assessing single partial crown success and periodontal outcome as perceived by patients and dentists.

The variables are the following: Interproximal Contacts and Papillae, Static and Dynamic Occlusion, Design Contour and Color, Quality and Quantity of Mucosa, Bone level in x-Ray, Biology related to Bleeding on Probing (BoP) and Plaque Index (PI) and Stain and Gap at Margins. Scoring for each variable from 0 to a maximum of 2, resulting a max score of 14.

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

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[1-3]]. 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. CAD/CAM technology is mainly used as chairside procedure, while the pressable technology is performed in the laboratory mainly using an analogic workflow. Pressed lithium disilicate results were very promising[6,7] and recently the evaluation of a new lithium disilicate material (Initial 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]; FIPS was based on 5 clinical variables evaluated crowns placed on implants with an oral radiograph and a buccal and an occlusal picture. its potential to serve as an objective and reliable instrument in assessing implant success and restoration and periodontal 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. Similarly, FIT, that is a novel index for the assessment of the prosthetic results of lithium disilicate crowns, based on seven restorative-periodontal parameters, that evaluate crowns placed on natural abutments, and want to be a reliable and objective instrument in assessing single partial crown success and periodontal outcome as perceived by patients and dentists.

The aim of this study was to clinically evaluate two lithium disilicate systems using the novel prosthodontic Functional Index for Teeth (FIT).

Materials and 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.

Functional Index for Teeth (FIT)

A novel Functional Index for Teeth (FIT) was used (Table 2). Seven clinical variables have been collected and main prosthodontic and periodontal parameters were evaluated simultaneously (Interproximal Contacts and Papillae, Static and Dynamic Occlusion, Design Contour and Color, Quality and Quantity of Mucosa, Bone level in x-Ray, Biology related to Bleeding on Probing (BoP) and Plaque Index (PI) and Stain and Gap at Margins).

The FIT evaluation was performed only at last recall (3-year follow-up) by an experienced operator (Figs. 1,2).

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 mean age of 37 (±7.5) years (between 18 and 70) (14F,16M). Exclusion criteria were: age <18 years, pregnancy, disabilities, prosthodontic restoration of the tooth, spontaneous sensitivity, pulpitic,

non-vital or endodontically treated teeth, (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 selection of the patients and masking of examiners

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, to be sure to have the radiogram in the same position at each recall.

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

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

Main characteristics of the two Lithium Disilicate materials were reported in Table 1.

Table 1 Mechanical properties of IPS e.max press and GC Initial™ LiSi press materials.

Properties (as provided by manufacturers)	Units	IPS e.max Press	Initial LiSi Press
Manufacturer	–	Ivoclar Vivadent	GC
Components	–	lithium disilicate crystals (approx. 70%), Li2Si2O5, embedded in a glassy matrix	lithium disilicate micro-crystals equally dispersed in a glass matrix
Crystal system	–	lithium disilicate - crystals measure 3 to 6 μm in length.	lithium disilicate - crystals measure 1.5 μm × 0.5 μm
Flexural Strength	MPa	433*	454*
Biaxial Flexural Strength	MPa	> 500	> 500
Vickers hardness		(HV10) 5900 ± 100 Mpa	600 HV
Chemical solubility	mg/cm2	40 ± 10	5.4 $\mu g/cm^2$
Liner thermal expansion CTE	× 10–6/K	Coefficient of thermal expansion (100–400 °C) 10.15 ± 0.4 $10^{-6} K^{-1}$ Coefficient of thermal expansion (100–500 °C) 10.55 ± 0.35 $10^{-6} K^{-1}$	Liner thermal expansion CTE (25–500 °C) $9{,}8 \times 10^{-6} K^{-1}$
Glass transition temperature	°C	560	520
Density	g/cm^3	2.5 ± 0.1	2,4

*Internal data, University of Siena.

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 for no more than 1 mm. At least one cusp was covered. Teeth were kept vital.

Hybridization of dentin with adhesive material was done using Adhese Bond Ivoclar-Vivadent, Schaan, Liechtenstein, in Group 1 and G-Premio Bond, GC Co., Tokyo, Japan in Group 2, and then a thin layer of flowable has been applied on top (Tetric Flow, Ivoclar-Vivadent in Group 1 and Genial Flow, GC Co, in Group 2). 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).

Outcome variables

"Success" was set when the restoration was in place at last recall without any biological or technical complication, whilst "Survival" when the restoration was still in place at last recall but with biological or technical complications that needed to be treated and/or the crown to be remade. "Failure" was set when the restoration was not in place anymore at last recall or, because of mechanical or biological complications, needed to be replaced.

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 of periodontal parameters showed mean scores for PI of 18.0 (SD 2.5; range: 16–21) at baseline and 17.5 (SD 1.0) (range: 16–20) at 1- year follow-up, PPD of 3.4 (SD 0.5 mm;

range: 1–4) and 3.2 (SD 0.5 mm; range: 1–4), and a mean score for BoP of 18.4 (SD 2.2; range: 17–24) and 16.6 (SD 1.4; range: 16–22), respectively. At last recall, scores of periodontal parameters showed a proper maintenance of periodontal health thanks to professional recall program and home maintenance of patients.

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).

Table 2 Functional Index for Teeth Prosthodontic (FIT)

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

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 result 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 (SD 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 (SD 0.2; range 1-2) in Group 2; “interproximal contacts and papillae” 1.73 (SD 0.7; range: 1–2) in Group 1 and 2 (range: 2–2) in Group 2; “biology” scored 1.93 (SD 0.3; range 1-2) in both Groups; and “stain and gap at margins” was 1.73 (SD 0.8; range 0-2) in Group 1 and 1.86 (SD 0.7; range 1-2) in Group 2 were the most challenging to satisfy (Table 3).

Table 3 Radiographic and clinical scores based on FIT for each group

Variables	Group 1 IPS e.max (n = 30) (total) (median)	Group 2 GC Initial™ 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)**	

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 as evaluation method of clinical trials. 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 and are the most used clinical criteria to evaluate direct restorations. 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 and is based on 7 clinical parameters: interproximal, occlusion, design, mucosa, bone, biology, margins. Although its targets resemble the ones of the modified FDI criteria, that is limited to the tooth and the restoration without evaluating the periodontal tissues, FIT can also evaluate the periodontal tissues behavior by 'Interproximal', 'Mucosa', 'Bone' and 'Biology' parameters and is a more user-friendly and straightforward

method for the clinician to be applied 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 novel proposed classifications (FIT for single crowns on natural abutments and FIPS for single crowns on fixtures) 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 restorations.

It must be considered that the operator's experience can be a key factor when a Randomized Controlled Trial (RCT) is done and FIT is applied; However, in order to explain the high success rate found in this pilot RCT, the oral hygiene maintenance (professional and at home) of the selected patients in combination with the experience and skill of the operator must be considered.

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 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 (Initial LiSi Press), can clinically perform as well as e.max pressed system (IPS e.max press), that has instead been marketed for many years.

It must be pointed out that about IPS e.max press several clinical studies are available in the literature[25-29]. There is consensus that IPS e.max press (also with the previous name of Empress 2) has good enough longevity when used to restore single tooth after 5 years (survival of 90%) [25,26] and 71% after 10 years of clinical service[27,28]. Particularly relevant is the recently published report by Malament[29] in which was found out that pressed lithium disilicate restorations (Empress 2) survived successfully over the 10.4 period studied with an overall failure rate below 0.2% per year and primarily confined to molar teeth. It can be speculated that also in this study[29] skill and knowledge of the operator and oral hygiene regime can contribute to the impressive success rate.

Regarding Initial-LiSi press, only one prospective clinical study is already available and showed 100% survival after 3 years [8]. Long term RCT results are need in order to evaluate longevity under

clinical function of Initial LiSi press.

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. Also, it must be point out that, accordingly with exclusion criteria, a category of patients without any health issue were really selected. This might be considered a partial limitation of this study.
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) in a wider number of patients 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 rate 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.

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Figure Legends

Figure 1a, 1b and 1c. are related to a clinical case of Group 1 (the second premolar received a IPS e.max press restoration) while figure 1d, 1e and 1f of Group 2 (the first molar received a GC Initial™ LiSi Press restoration). No technical or biological complications were observed at 3-year recall.

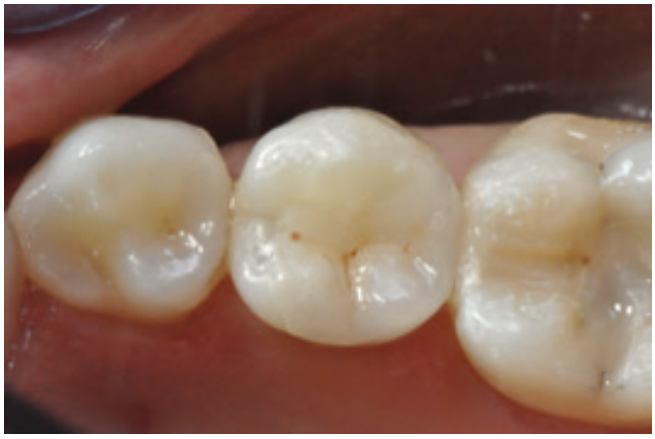


Fig. 1a

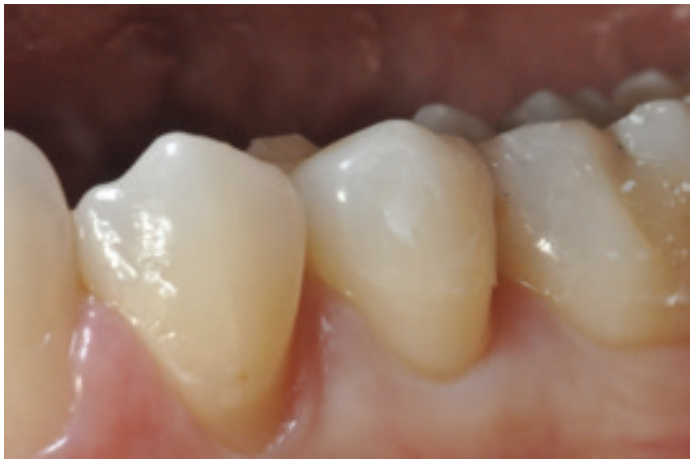


Fig. 1b

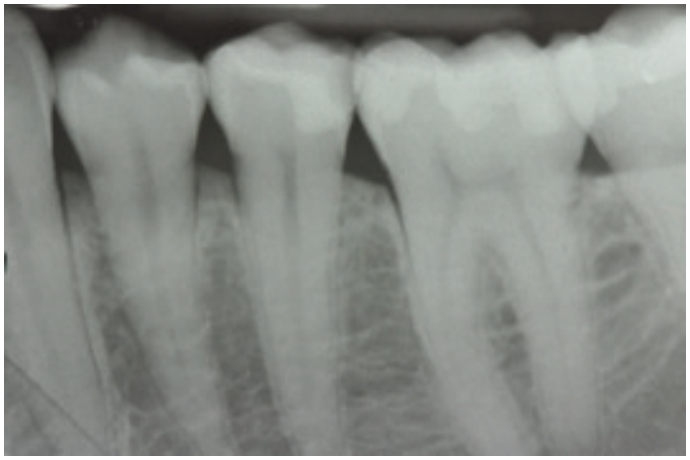
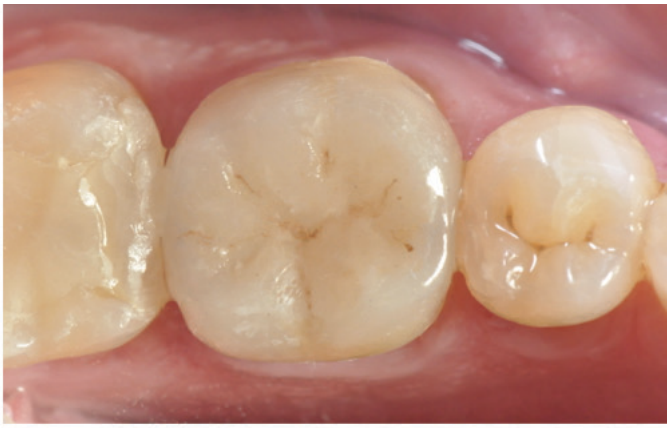
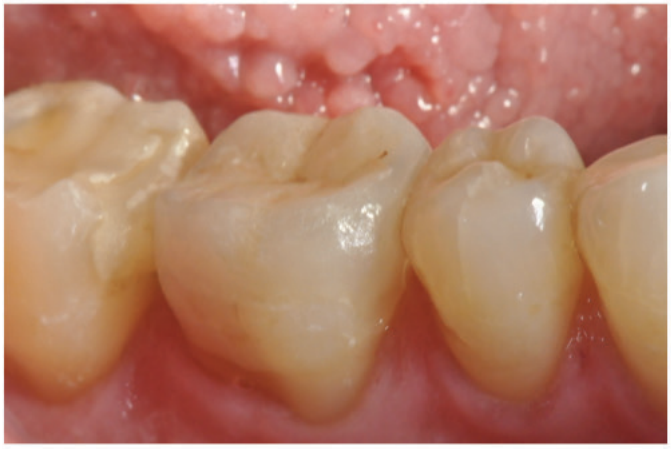
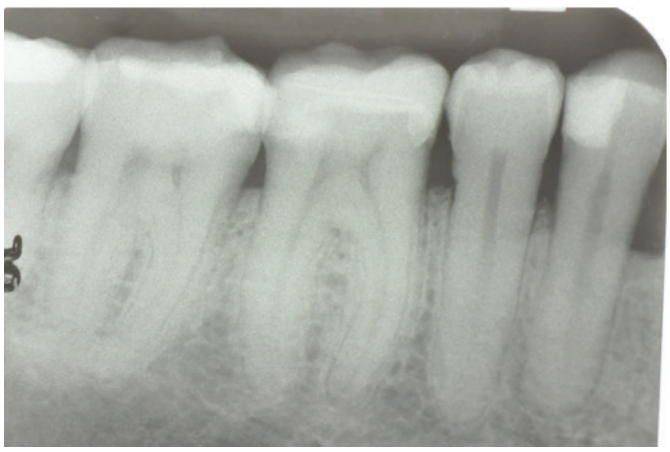


Fig. 1c







Figs. 1d,e,f

3.3 A randomized controlled clinical trial on two types of lithium disilicate partial crowns.

Introduction

In the last 20 years, lithium disilicate (LD) ceramics become widespread among both dentists and dental technicians to fabricate esthetic partial and full adhesive prostheses[1-5].

LD ceramics presents high flexural strength, fatigue resistance and fracture toughness when compared to other glass ceramics. These mechanical properties associated to excellent optical characteristics result in a highly versatile material for both anterior and posterior restorations[4-7].

The promising clinical and mechanical performances of LD crowns can be attributed to resistant clusters of interlocked needle-like crystals that represent 70% of 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]. Notwithstanding, clinical trials are the most reliable way to assess if mechanical properties of biomaterials will be translated into clinical longevity,

According to clinical studies, recent retrospective investigations on posterior LD single crowns up to 6 and 12 years reported overall survival rates of 95.46% and 97.93% respectively, highlighting bulk fractures of the material in the failed teeth[12-14]. Similar results were noticed in retrospective studies between 81.9% and 96.1% of survival for a time frame between 9 and 15 years of clinical service[15-17] and in a prospective study pointing out a 10-year survival rate of 83.4%[18]. In short, the use of LD restorations in fixed prosthodontics proved to be effective and reliable in the short, medium and long term[17,19,20].

More recently, different brands and configurations of LD materials were introduced into the market[21-23]. A recent paper reported very good clinical results after 3 years of clinical service using a novel LD material, Initial LiSi Press[a], when used to restore endodontically treated teeth[20].

During masticatory function, molars are subjected to mechanical fatigue with high loads in a wet environment; this fatigue process can lead to fractures or debonding, typically considered the worst case scenario[4-6].

The occlusal thickness of CAD-CAM monolithic LD crowns affects either the mode of failure and the fracture resistance of the prostheses; the occlusal area can be reduced up to a lower bound of 1.0 mm to retain sufficient strength to withstand occlusal forces; CAD-CAM monolithic LD crowns

showed satisfactory resistance to fracture to restore molar areas 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 score systems were proposed to clinically evaluate the performances of prosthetic restorations[24-26].

Recently, an innovative score named Functional Index for Teeth (FIT) was used to assess different clinical variables, proving to be easy and simple to be used[27]. FIT scores 7 parameters, combining radiographic and clinical examinations, and evaluates not only aspects strictly related to restorations but also periodontal issues that can influence the clinical outcome of prostheses; the possibility to score also periodontal parameters permits to evaluate not only the behavior of the restoration itself but also its biological integration in the periodontal tissues[27].

The aim of the present randomized controlled trial (RCT) was to evaluate the clinical performance of two pressed LD materials using an innovative Functional Index for Teeth (FIT).

The null hypothesis stated that there was no association between the LD brands and their clinical performances.

Materials and Methods

Study set-up

Between May 2015 and January 2016 a sample of 105 patients (for a total of 170 restorations) was included in the study due to their need of a single partial crown onto maxillary and mandibular premolars and molars. Patient age was 43 (±9.5) years (between 18 and 72) and the gender was 62F, 43M.

The criteria of inclusion were periodontally healthy or successfully treated posterior teeth in need of one indirect adhesive restoration. Exclusion criteria were: 1. Not proper age, 2. Pregnancy, 3. Disabilities, 4. Previous prosthodontic restorations of abutment teeth, 5. Spontaneous sensitivity, pulpitis, non-vital or endodontically treated teeth, 6. Sever and/or chronic periodontitis, 7. Deep defects (close to pulp, < 1mm distance on customized xRay) or pulp capping, 8. Heavy wear signs on occlusal surfaces due to bruxism, 9. Systemic disease or severe medical complications, 10. Allergic history concerning methacrylates, 11. Rampant caries, 12. Xerostomia, 13. Lack of compliance, 14. Language barriers, 15. Plaque index higher than 20.

The aim of the study had been previously explained to the patients in order to obtain their written consent.

The study protocol was approved by the Ethical Committee of University of Siena (#43/2015)(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.

Patients preparation and baseline examination

The patients, after being enrolled, were given instructions on how to achieve an optimal plaque and gum health.

Periodontal parameters such as periodontal probing depth (PPD)[28,] bleeding on probing (BoP)[29] and full-mouth plaque index (PI)[28], were recorded in order to determine the periodontal clinical assessment of each patient.

Before starting the treatment, it has been performed a standardized radiographic examination for each abutment tooth with X-ray individual trays in order to have the same projection of the tooth in the X-ray at each recall

An expert operator carried out all the restorative procedures under local anesthesia (articaine with 1:100.000 epinephrine).

The sample of 105 patients was divided and randomly assigned to two groups of 85 restorations each (maximum 3 restorations per patient), defined in accordance with the two different materials[27] used for the restoration:

- Group 1: e.max Press[b] - Group 2: Initial LiSi Press[a]

In Group 1, 54 patients were treated, 30 of them received one single crown, 17 patients 2 crowns and the last 7 patients 3 crowns. In Group 2, 51 patients were treated, 25 patients received one single crown, 20 patients 2 crowns and 6 patients 3 crowns.

Sample Size Calculation

Sample size was calculated in agreement with the recommendations for conducting controlled clinical studies. Considering a 5% alpha and 90% power value and an effect size of 0.5, the minimum sample size was calculated as 60 per group. The drop-out rate was set as an increase of 15%.

Randomization, allocation concealment and masking of examiners

Treatment assignment was performed by using opaque, sealed and sequentially numbered envelopes. The allocation sequence was made by means of a computer-generated random list. The corresponding opaque envelope to each patient was opened immediately before material selection and information were passed to the operator.

Clinical procedures

In order to eliminate or minimize the operator's bias all the clinical procedures were performed by two expert prosthodontists that were following the same protocol:
anesthesia, rubber dam placing, old restoration and eventual decayed tissue removal.
The cavity preparation, performed with diamond burs, was custom made because its shape depended on the extent of decay and on the pre-existing restoration, while the preparation guidelines were defined by the manufacturer of the restorative material.
By means of periapical X-ray examination, the residual dentin thickness (RDT) was evaluated and the elements with a dental thickness lower than 1.00 mm were excluded from the study while thicknesses of occlusal clearance ranged between 0.5-1 mm and 1-1,5 mm. All teeth were kept vital, at least one cusp was covered, margins were kept mainly into enamel (i.e. more than 50%) and placed iuxta- or supra-gingivally; only interproximal boxes had cervical margins below the cementum-enamel junction. Dentin was conditioned and hybridizated with bonding agents (Adhese Bondb in Group 1 and G-Premio Bonda in Group 2) and a thin layer of flowable composites (Tetric Flowb in Group 1 and Genial Flowa in Group 2) was applied on top of the bonding layer.
All preparations were finished and polished, after that the protocol required to perform impressions of the prepared teeth with an elastomeric material (Exa'lencea) then poured in extra-hard stone (FujiRocka). The restorations were then waxed and pressed in LD, strictly following the manufacturers' instructions. In order to protect the prepared teeth, temporary restorations made by a self-curing acrylic resin were cemented with a eugenol free temporary cement. After 7 days LD final restorations were delivered and luted following manufacturers' instructions. The intaglio surface of each restoration was etched with 10% hydrofluoric acid for 1 minute, silanized with Monobond Plusb in Group 1 and G-Multi Primera in Group 2 and then luted using MultiLink Sprintb in Group 1 and LinkForcea in Group 2. By placing rubber dam a proper tooth isolation was ensured.

Follow-up

The oral hygiene program for the patient provided one recall every 6 months, standardized intra oral radiographs and a clinical exam immediately after the cementation of the crowns (baseline), as well as after 1, 2, 3 and 4 years of clinical service (follow-up). The novel FIT was applied (Table 1) and recorded at the 4-year follow-up recall by a blinded experienced operator.

Outcome variables

At last recall the Success Criteria determined for this study were the ones listed below:
"Success "of a restoration was defined when it was in place without any technical and biological complication. "Survival" when the restoration was still in place at last recall but with a biological or technical complication that needed to be treated but without the need to remake the crown. "Failure" was set when the restoration was lost at last recall or, because of mechanical (failure of the restoration) or biological (failure of the tooth) complications, needed to be replaced.

2.9. Statistical analysis

The Mann-Whitney U test was used to evaluate the presence of statistically significant differences in the scores recorded for each assessed variable between the 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

A dropout rate of 4.25% (5 patients) in Group 1 and 3.4% (4 patients) in Group 2 was recorded, consequently the patients' recall rate was 95.75% in Group 1 and 96.6% in Group 2.
In group 1, three biological and two mechanical complications were recorded, whilst in Group 2 two biological and two mechanical complications were noted. In all cases in which a biological complication was recorded, the tooth was accordingly treated (Group 1: two endodontic treatments and one periodontal flap were made; Group 2: one endodontic treatment and one periodontal flap were performed) and all crowns were remade. When a mechanical complication was recorded (2 in each group) fracture of crowns was noted, and a new crown was remade. Consequently, failure rate corresponded and was 6.25% and 6.17% respectively for Group 1 and Group 2.
The FIT results were reported in Table 2. At baseline and 4-year follow-up, clinical examinations showed the following mean scores respectively: 18.5±2.5 (range: 16-21) and 16.5±1.0 (range: 16-19) for PI, 3.4±0.5 mm (range: 1-4) and 3±0.5 mm (range: 1-4) for PPD and18.6±2.3 (range: 17-24) and 16.2±1.2 (range: 16-21) for BoP.

At the 4-year follow up, the mean total FIT score was 13.08 and 13.49 for Group 1 and 2 (range: 10-14) respectively. All partial crowns showed a stable level of alveolar crest without signs of bone loss at the radiographic analysis; therefore, the variable “bone” regarding the 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 variable “occlusion (static and dynamic)” were 2 (range: 2-2) both in Group 1 and in Group 2. Regarding “mucosa (quality and quantity)”, the scores were 1.95 (range: 1-2) in Group 1 and 1.9 (range: 1-2) in Group 2. The mean scores for “design (contour and color)” were 1.8 (range: 1-2) in Group 1 and 1.9 (range: 1–2) in Group 2; for “interproximal (contacts and papillae)” they were 1.7 (range: 1-2) in Group 1 and 1.9 (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 1.7 (range 0-2) in Group 1 and 1.89 (range 1-2) in Group 2, proving to be the most challenging to satisfy.

No statistically significant differences were found between the experimental groups in any of the assessed variables ($p>0.05$) and for that no tables were reported.

Discussion

The laboratory procedures necessary to fabricate full and partial crowns using the tested brands of LD are comparable and consequently an RCT was mandatory to better understand the clinical behavior of the two products.

According to the results of the present investigation, the null hypothesis was accepted, since there were no statistically significant differences between the experimental groups. Each of the seven parameters of FIT did not show statistically significant differences. Two of them (Bone and Occlusion) showed the highest scores, whilst high clinical levels were recorded for the other variables (Table 2). It can be speculated that the high-quality score of ‘Bone’ can be related to the iuxta-and/or supra-gingival position of the prosthetic margins, combined with the professional recall and home oral hygiene regimes. Similarly, the top score of ‘Occlusion’ can be related to the proper wax-up made by the dental technician in combination with proper occlusal thickness and functional check of each restoration[6].

One of the parameters with the lowest score was ‘Interproximal’, that refers to the health and shape of papillae and to the interproximal contacts with adjacent teeth; it is worth noticing that such results 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. However, the three parameters evaluating periodontal aspects, such as Biology (BoP and PI), Bone (radiographic examination) and Mucosa (quality and quantity) were clinically satisfactory in both groups.

In absence of clear and documented indications about how to prepare partial crowns, the restoration design used in the present study provided a complete covering of at least one cusp and one or two interproximal boxes, so as to provide adequate contact areas, retain the temporary restoration and stabilize the partial crowns during cementation[30].

Correct seating and adhesion are mandatory for glassy ceramic materials and LD restorations as well[30]. In this study all the restorations were luted adhesively; dental substrates were etched and bonded, the internal surface of LD was etched and silanized and then the partial crowns were luted under rubber dam. The role of etching-bonding-luting procedures might be crucial to adsorb occlusal forces and seal the enamel margins[30].

The two types of LD materials tested in the present RCT are available also in CAD-CAM blocks[32] and further clinical studies comparing pressed LD versus chair-side blocks are on the road.

The evaluation of clinical outcomes of partial crowns luted onto posterior teeth might be performed following different clinical parameters and scores[25,26]. The assessment is usually made after luting 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[25,26]. Moreover, RCTs should be done by blinded, calibrated and experienced dentists that can perform follow-up evaluations[25-27].

It must be pointed out that modified FDI criteria[25-26] were born for direct restorations and there was a need of clinical criteria to evaluate indirect restorations with standardized procedures as well, easy to be calibrated and applied, available not only for clinical research but also in daily practice and reflecting the patients' perception of restorations.

Several attempts were made and a couple of classifications and prognosis evaluations of individual teeth were proposed, considering periodontal conditions as well, to make proper treatment planning easier and operator-friendly[31,33]. The use of the FIT score system permitted to evaluate restorative and periodontal parameters at the same time, providing a more comprehensive clinical view of each sample tooth[27,32].

It must be pointed out the possible limitations could have influenced the present study: the relatively short-term observation period and the selection of teeth with no periodontal disease and no evident parafunction.

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

the tested lithium disilicate materials presented comparable clinical outcomes and effectiveness after 4 years 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.

[a] GC Co, Tokyo, Japan

[b] Ivoclar-Vivadent, Schaan, Liecthenstein

[c] Kavo Kerr, Milano, Italy

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Table 1 - Functional Index for Teeth (FIT): definitions and scores.

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. No statistically significant differences were noticed between the two groups in any of the assessed variables (p>0.05).

Variables	**Group 1** (n=80) e.max (total) (median)	**Group 2** (n=81) LiSi (total) (median)
Interproximal Contacts & Papillae	136.8 (1.71)	153.9 (1.9)
Occlusion Static & Dynamic	160 (2)	162 (2)
Design Contour & Color	144 (1.8)	153.9 (1.9)
Mucosa Quality & Quantity	156 (1.95)	153.9 (1.9)
Bone X-Ray	160 (2)	162 (2)
Biology BoP -& PI	152 (1.9)	153.9 (1.9)
Margins Gap & Stain	137.6 (1.72)	153.1 (1.89)
Total Score of Each Group	1046.4 (149.48)	1092.7 (156,1)

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3.4 A randomized controlled clinical trial on press and block LiSi partial crowns: a pilot study.

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 permit 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 a 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 using a novel LD material, Initial LiSi Press (GC Co., Tokyo, Japan), when adhesive partial pressed crowns were made and luted on posterior endodontically treated teeth [26]. An experimental Initial LiSi in 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[32,33].

The FIT is composed of seven variables (Interproximal, Occlusion, Design, Mucosa, Bone, Biology and Margins), each of them are evaluated using a 0-1-2 scoring scheme 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) 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 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.

Patients preparation and baseline examination

After being recruited, all patients received an oral hygiene session and 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 X-ray individual 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.)

Treatment assignment was noted in the registration and the treatment assignment form was kept by the 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.) and a thin layer of flowable composite (Genial Flow, GC Co.) 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.) was used and then the impression was poured in extra-hard stone (FujiRock, GC Co.). 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 exam 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 novel FIT was applied (Table 2) and recorded at the baseline and the 1-year follow-up recall.

Outcome variables

The "Success" of a restoration was set when it was in place at last recall without any biological or technical complication, whilst "Survival" was given when the restoration was still in place at last recall but with a biological or technical complication that needed to be treated, without the need to remake the crown. "Failure" was set when the restoration was lost at last recall or, because of mechanical or biological complications, needed to be replaced.

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 respectively for Groups 1 and 2: 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 and 16.1±0.5 mm (range: 17-24) and 16.8±1.2 (range: 16-21) for BoP. The results are reported in Table 3.

At the baseline, the mean total FIT score was 13.46 for Group1, 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 (Tab.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.

Discussion

According to the results of the present investigation, 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 one 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 of 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) seems 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, under lab conditions, 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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Table 1 - Demographic data, inclusion and exclusion criteria.

Inclusion criteria

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

Exclusion criteria

Not proper age (< 18 years);
Pregnancy
Disabilities
Previous prosthodontic restorations of abutment teeth
Spontaneous sensitivity, pulpitis, non-vital or endodontically treated teeth
Sever 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 2 - Functional Index for Teeth (FIT): definitions and scores.

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 3 - Periodontal parameters. No statistically significant differences were found between the two Groups at 1-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]	16.0±1.2 [a]

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).

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 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).

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]

Chapter 4

4.1 Evaluation of clinical failure, survival and success

Many Authors focused their attention on the clinical evaluation of restorations and have tried to define 'Failure', 'Survival' and 'Success'.

Anusavice[1] proposed a method for reporting chipping and bulk fracture and defined the "success" as the achievement of treatment planning goals and expectations whilst "failure" as the inability of a restoration to perform as expected under typical clinical and patient conditions. In this view, grade 3 of Heinze and Rousson[2] classification was modified and the need of replacement of the entire restoration due to severe chipping as follow: 1. Fracture surface extends into a functional area and repair is not feasible. 2. Recontouring will result in a significant unacceptable alteration of the anatomic form from the original anatomy. 3. Recontouring will significantly increase the risk of pulp trauma by the generation of heat. 4. Repair with a resin composite will result in esthetic changes that are unacceptable by the patient. In summary, in order to avoid misunderstanding between definition of success and survival, "success" can be defined by percentage of restorations that remained in situ without any modification, "survival" can be defined by percentage of restorations that remained in situ with modifications but still under clinical acceptability, whilst "failure" can be defined by percentage of restorations that needed to be replaced.

In this view clinical trials and systematic reviews can be evaluated.

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4.2 Influence of cervical margin relocation (CMR) on periodontal health: 12-month results of a controlled trial.

Introduction

The Cervical Margin Relocation (CMR) was proposed more than 15 years ago, and in the last decade became more and more popular among dental practitioners[1,2].

CMR is indicated when the gingival margin of a Class II inter- proximal cavity cannot be isolated with rubber dam alone, in alter- native to perform surgical crown lengthening. CMR consists on placing a base of direct resin composite using a metal interproximal matrix to elevate the interproximal underneath indirect bonded restorations. Consequently, margins can be predictably caught by a conventional impression and/or intraoral optical scanning (IOS)[3].

A few trials described clinical steps of CMR[4–7] and others mainly evaluated 'quality margins' through SEM observations of the external margins relocated coronally at lower magnifications[8-10].

The clinical success in restorative/prosthodontic dentistry can be based on different technical parameters, such as esthetics, precision of the margins, proper function on occlusion, preservation of vitality and fractures of the abutments[11,12]. It seems mandatory, but beside this feature, healthy periodontal tissues, defined by a Probing Pocket Depth (PPD) less/equal than 4 mm without Bleeding on Probing (BoP).

It might be argued that even slightly subgingival located margins may affect the periodontal health[13]; and therefore, subgingivally located margins should be avoided whenever possible.

Therefore, it has to be emphasized that the extent of the biological width between the cervical aspect of the interproximal composite box and the alveolar bone should be respected[14].

Recently, Paniz et al.[15] evaluated in a 12 month clinical trial, the periodontal response (BoP and gingival recession) of different full crowns placed with subgingival margins, with teeth prepared alter- natively with feather edge or chamfer finishing lines. After one year, both experimental groups displayed more deep inflammation (BoP) in respect to baseline.

Unfortunately, the literature does not report any clinical trial evaluating periodontal tissue response on indirect adhesive restorations placed on posterior teeth with CMR[16].

Differently, the literature reports about the influence of approximal restorations extension on the development of secondary caries, showing that restorations ending below the CEJ showed significantly increased risk for failure[17,18].

The primary aim of this clinical trial was to evaluate BoP on single adhesive indirect restorations

made on posterior teeth with one interproximal margin relocated cervically; and secondary, to analyse the correlation between depth of the interproximal margins and BoP. The null hypothesis tested was that there is no statistically significant difference between margins with or without CMR regarding periodontal tissue inflammation (BoP).

Materials and methods

A consecutive sample of 35 restorations in 35 patients (Table 1) in need of one single partial crown (onlay) on posterior teeth was placed between January and April 2016. A partial restoration was performed from the pool of patients accessing the Department of Prosthodontics and Dental Materials of the University of Siena, Italy. All of them had an old restoration and some carious tissue to be replaced.

Patients written consent to the trial was obtained after having provided a complete explanation of the aim of the study. Ethical ap- proval was achieved beforehand by the University of Siena, Italy (ClinicalTrials.gov #NCT01835821).

Inclusion criteria

A total of 35 patients (19 men/16 women, aged 27–54 years, mean age of 45.1 years) received 35 partial-coverage restorations. All patients were periodontally healthy or have been treated successfully before rehabilitation with indirect restorations on posterior teeth (molars or premolars). Positive response to vitality testing by a one second application of air from a dental unit syringe (at 40–65 p.s.i. at approximately 20° C), directed perpendicularly to the root surface at a distance of 2 cm and by tactile stimuli with a sharp #5 explorer.

Exclusion criteria

Patients with the following factors were excluded from the clinical trial: 1) not proper age (< 18years); 2 pregnancy; 3) disabilities; 4) potential prosthodontic restoration of the tooth; 5) pulpitic, non-vital or endodontically treated teeth; 6) (profound, chronic) periodontitis; 7) deep defects (close to pulp, < 1 mm distance) or pulp capping;8) heavy occlusal contacts or history of bruxism; 9) systemic disease or severe medical complications;

10) allergic history concerning methacrylates; 11) rampant caries; 12) xerostomia; 13) lack of compliance; 14) lan- guage barriers; 15) plaque index higher than 20.

Patient selection

After recruitment, oral hygiene instructions were given to the pa- tients and prophylaxis was performed by a Periodontist to establish optimal plaque control and gingival health. After 1 week,

the following periodontal measurements were registered by two experienced opera- tors: PPD at two different facial sites (mesial and distal) with a peri- odontal probe (UNC periodontal probe, Hu-Friedy), rounding the measurements to the nearest millimetre, plaque index (PI), according to Löe and Silness[19]; gingival index (GI), according to Löe and Silness[20]; gingival bleeding on prob- ing (BoP), according to Ainamo and Bay[21]. Intra-examiner calibration took place before initiation of the study by examination of ten patients twice, hours apart[22]. The sequence of examiners was random. Measurements were accepted as calibrated if 90% of the recordings could be reproduced within a dif ference of 1 mm.

The inter-examiner agreement for the assessment of the variables was determined with the in- tra-class correlation coefficient (ICC). For the two examiners, t-test ($\alpha = 0.05$) revealed no statis- tically significant differences. All restorative procedures were performed under local anaesthesia (Articaine with 1:100.000 epinephrine) by a single experienced prosthodontist (Faculty member, MF). Intraoral X-rays were made before starting the treatment. Following anaesthesia, rubber dam was placed, caries detector was applied and all detected carious structures were excavated, and any restorative material was removed.

The 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 define by the manufacturer of the restorative materials (Fig. 1a and d). Cavities preparation must provide at least 1 mm space at the cervical margin and 1.0–1.5 clearance occlusaly. At least one occlusal cusp was covered. The Residual Dentin Thick- ness (RDT) was evaluated on a periapical radiograph, and teeth with RDT thinner than 0.5 mm were excluded. Interproximal margins were lo- cated below cementum-enamel junction into ce- mentum-dentin. The decision where to place CMR was taken flipping a coin for each tooth. Consequently, two groups were allocated: Group 1 corresponded to the interproximal margin in which CMR was performed and Group 2 to the other interproximal margin in which the crown was luting directly to dental structures.

Caries cleaning of the affected area was performed after placing a first matrix band to retract and simultaneously protect the soft tissue, the curvature of the metal matrix was properly adapted to the curvature of the tooth to achieve the best cervical fit was possible[5]. In one proximal box CMR procedure was performed using G-Premio Bond, simultaneously used to perform for hybridization of entire exposed dentin of the entire cavity, and universal flow resin composite applied in two or three thin layers depending the depth and size of the cavity (GC Co. Tokyo, Japan) (Fig. 2a and

d). After final cavity's preparation, an impression was taken (Ex'lance, GC Co., Tokyo, Japan) (Fig. 2e) and sent to the laboratory in order to make the restoration using lithium disilicate (LS2) press material (LiSi Press, GC Co. Tokyo, Japan) (Fig. 3a). A temporary restoration was made with heat-polymerizing polymethylmethacrylate (PMMA) acrylic resin and luted. Patients were instructed to use a 0.2% chlorhexidine gluconate solution for 7 days until they could perform regular oral hygiene and returned 12 weeks later for the impression procedures, giving enough time for soft tissue adaptation and maturation after teeth preparation. The restorations were milled made in the laboratory, then tried-in, and margins were examined and carefully verified for fit and extension. Rubber dam was always placed to isolate the abutment (Fig. 3b). The restorations were luted following manufacturer's instructions using proprietary's cement

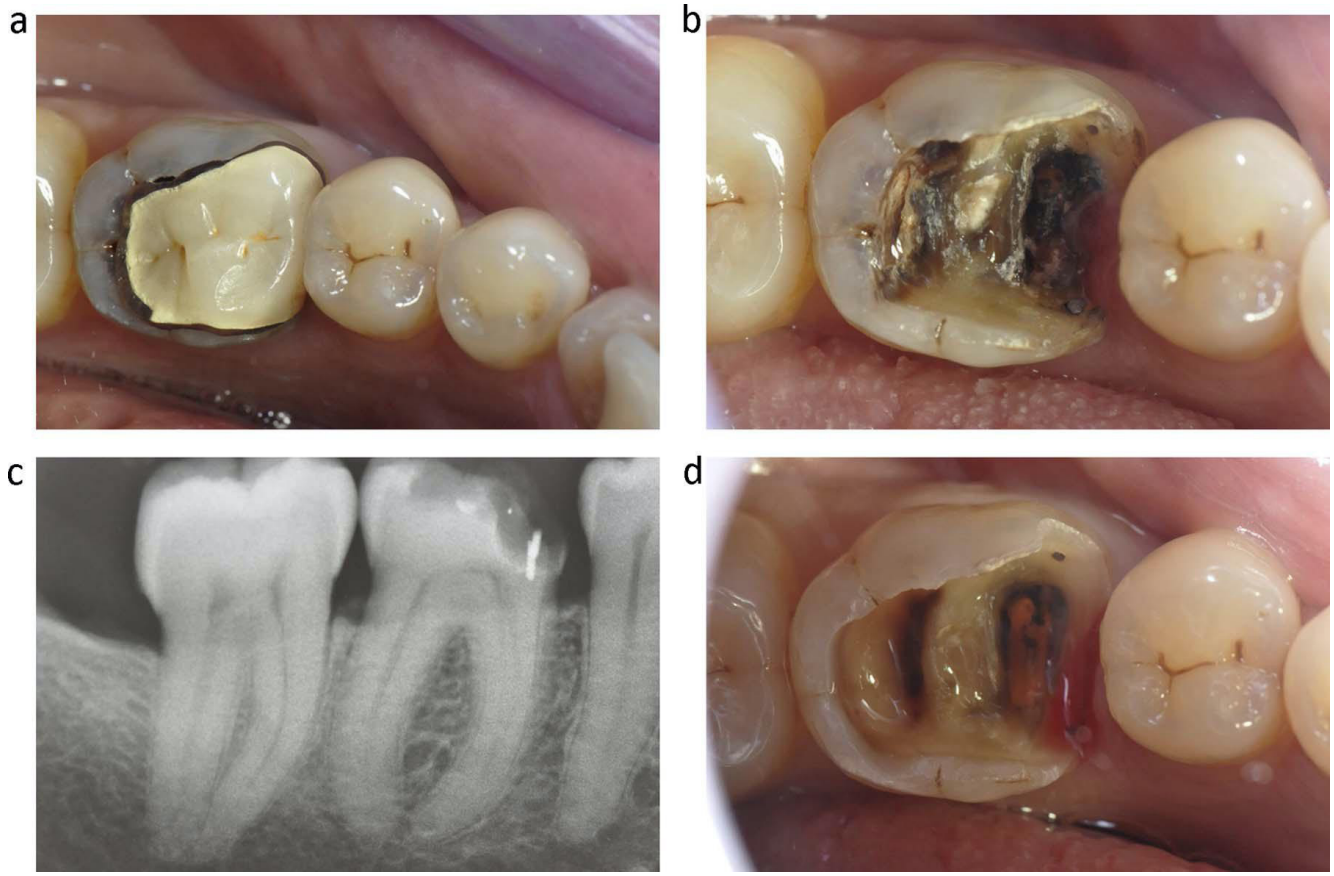

Fig. 1. a, b. Old indirect restoration made with porcelain fused to metal in need to be replaced because secondary decay. c. X-ray of the cavity after the old restoration was removed. d. The cavity after decay removal. The application of a metal matrix protected the soft tissue, although after removing the matrix the tissue is slightly bleeding.

(Link Force, GC Co., Tokyo, Japan) after being sandblasted, etched with fluoridric acid at 5% for 60 s and a coat of multi primer being applied and left to evaporate for 1 min.

Cement excess was carefully removed, and occlusion was slightly adjusted when needed. Intra-sulcular margin position was verified, and oral hygiene instructions were given to the patients. Patients were recalled 2 weeks later and then 3 months after for evaluation and oral hygiene measures reinforcement.

The restorations were placed in the time period between January 2016 and April 2016 and examined for (BoP) at baseline (cementation of the restorations), and after 12 months by two calibrated operators (EFC, ND) (Fig. 4a and b).

At baseline, the restorative margin position in relation to the gingival margin was recorded quantifying by probing in 20mm, and the linear distance from the bone crest was calculated in mm by intraoral x- ray. In addition, intraoral x-rays were made at the 12-month recall as well.

All clinical procedures were made using 3.5/4.5 magnification.

Data analysis

Descriptive statistics were expressed as mean (SD) and valid per- centage for continuous and categorical data, respectively. The baseline comparisons between study groups were performed using chi-square test (Fisher exact test with observed requencies < 5) for categorical variables whereas continuous variables were tested using t-test (U- Mann Whitney test if the variables were not normally distributed).

Outcomes were analysed using analysis of covariance (ANCOVA), once assumptions for the convenience were confirmed, with baseline values and age as covariates and study group as independent variable. Least square (LS) mean ± standard error (SE) was calculated for variables involving each outcome. Paired t-test or McNemara test (if applicable) was used to compare outcomes at baseline and 12 months. Level of significance was set at 0.05. SPSS version 21 software (IBM) was used for all calculations.

Results

Included participants completed the 12-month follow-up (Table 2).

At 12 months follow-up, changes from baseline were observed in GI, PI, and BoP: 20% of the sites of Group 1 (CMR) and 8.5% of Group 2 (shoulder preparation) presented dental plaque (PI), while at baseline dental plaque was not present. Teeth at baseline did not show any degree of gingival inflammation (GI) or BoP, while at 12 months 31.5% of Group 1 and 18.5% of Group 2, the

GI scoring ranged from 1 to 3, and BoP was presented in 53% of Group 1 and 31.5% of Group 2, respectively.

Statistically significant differences existed for PPD at mesial and distal sites at baseline (P = .001) (Table 2). Considering the two dif- ferent groups, differences were identified for PPD from baseline to 12 months (P = .340).

PI and GI at 12 months were similar in both groups (P = .250 and P = .465), respectively. Significantly more sites in Group 1 had BoP (53%) compared with group 2 (31.5%) (P = .010) (Table 3).

Evaluating Group 1 cases with positive BoP at one-year recall, the recorded margin-bone crest distance was mainly 2mm (13 of 19 margins) and similarly in 6 cases of 11 in Group 2.

No evident radiographic anomalies of recurrent decay were found after 1 year of clinical service.

Discussion

The CMR procedure is a popular restorative procedure but in need to be validated scientifically and clinically by randomized clinical trials. Because the CMR technique is usually made on posterior teeth that had an interproximal decay and/or an existing restoration to be replaced and in need to receive an adhesive partial restoration the present clinical trial focused on BoP of subgingival margins in the interproximal area.

Scientific publications available on CMR are mainly based on ‘marginal quality’[19,22-25]; however, neither leakage tests under laboratory conditions nor clinical investigations, such as randomized controlled trials, evaluating CMR are available yet.

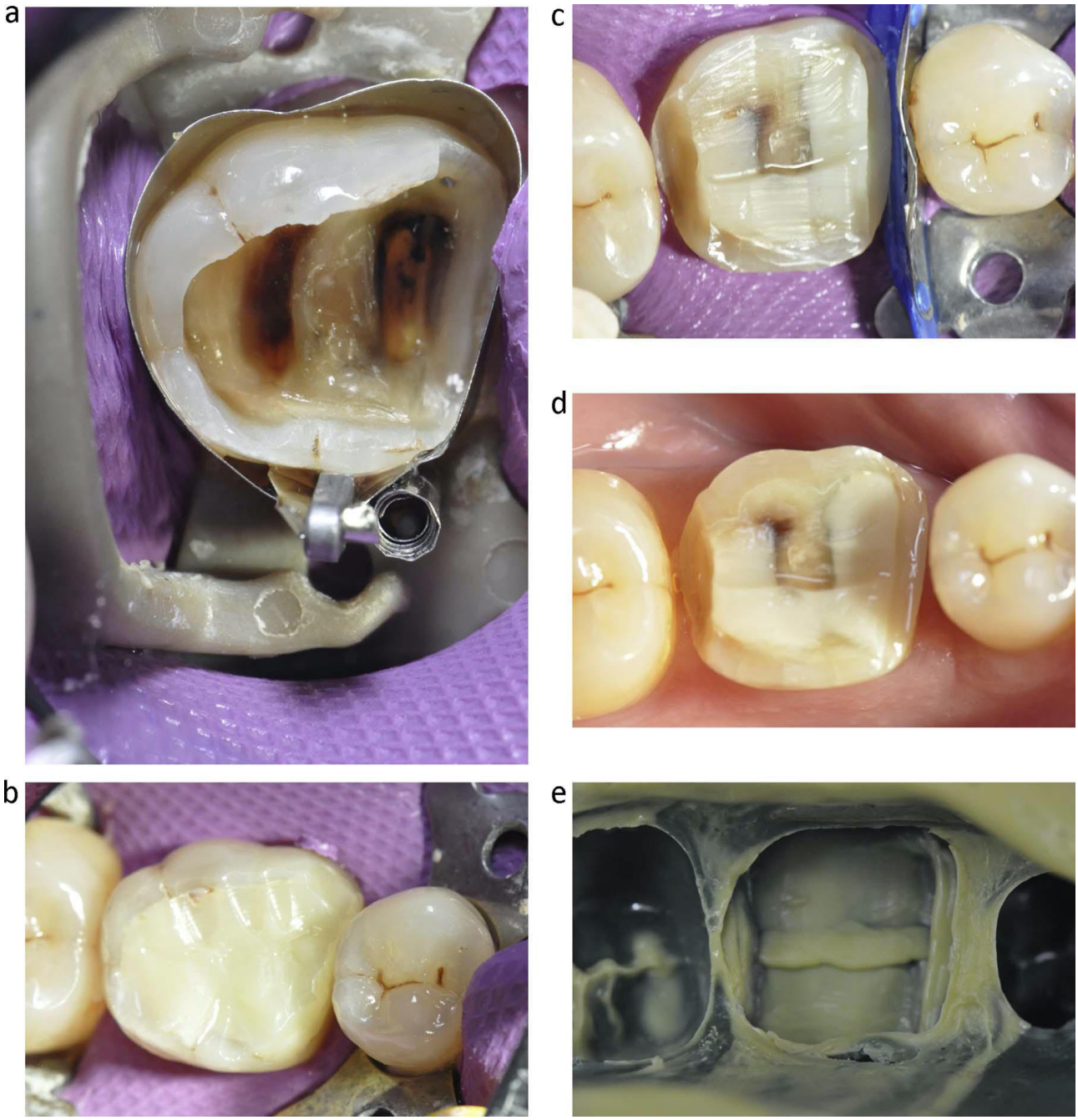

Fig. 2. a. Under rubber dam and after adaptating metal matrix and wedge to the emergence profile of the tooth, the procedure of immediate dentin sealing and cervical margin relocation are perfomed: the first layer of flowable resin composite is already light-cured. b. Complete build-up of the cavity. c. Immediately after the build up, still under rubber dam, the final preparation was made. d. The final preparation. e. The traditional impression.

Fig. 3. a. The final LiSi Press partial crown. b. The crown after being luted under rubber dam. 4

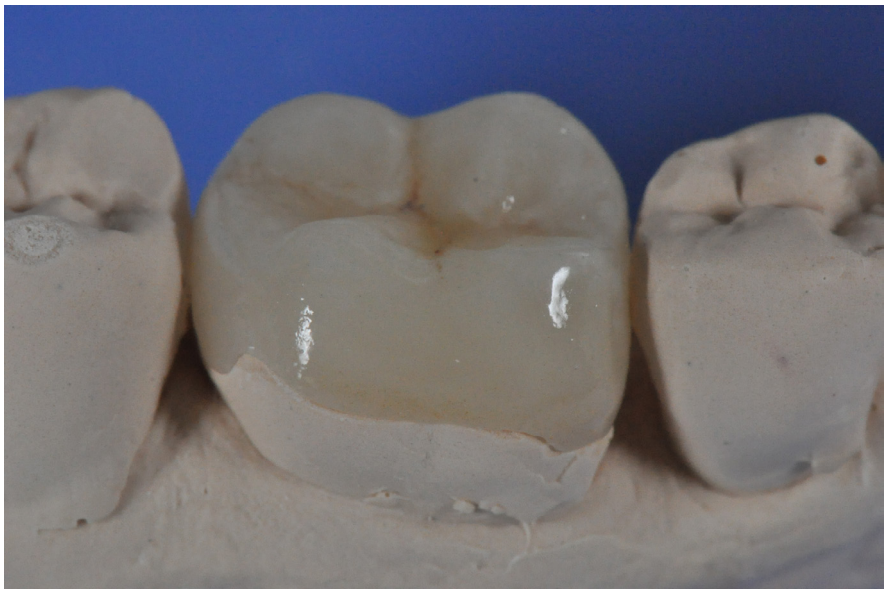

Fig. 3a

Fig. 3b

Fig. 4. a, b. Recall after 12 months; clinical and radiographic views.

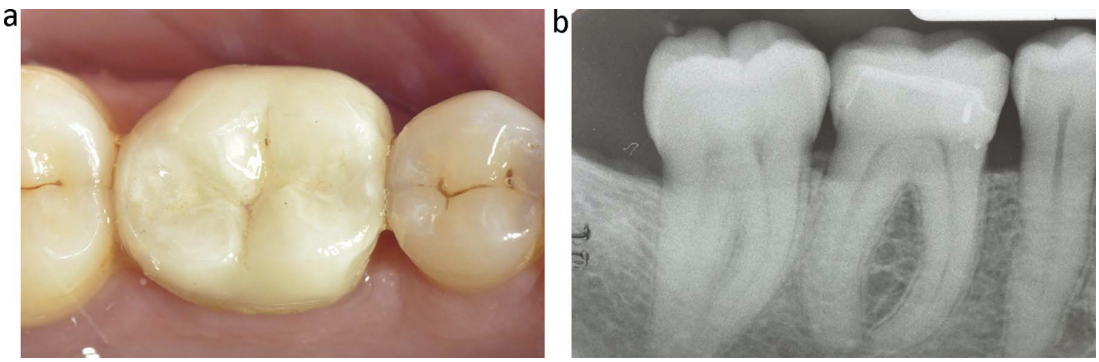

Table 2
Sample characteristics at Baseline and 12 Months.

Variable	Baseline	12 mo follow-up	P
Age (y)[x]	45.1 (7.6)		
Sex (men)	19		
GI (n[%])			
0	35	24	NA
1	/	7	
2	/	4	
3	/	0	
PI (n[%])			NA
0	35	28	
1	/	7	
BoP (n[%])			NA
0	35	16	
1	/	19	
PPD mesial/distal, mm[a]	2.3 (0.25)	3.1(0.70)	0.001[b]

NA = not applicable; GI = Gingival Index; PI = Plaque Index; BoP = bleeding on probing; PPD = periodontal probing depth.

[a] Mean (SD).

[b] Paired *t*-test (quantitative variables).

Table 3
Pre-Post analysis by Study Group.

Variable	Baseline Group 1 (CMR)	(n = 35) Group 2 (below CEJ)	P[b]	12 months Group 1 (CMR)	(n = 35) Group 2 (below CEJ)	P
Age (y)[x]	43.2(5.3)	48.5(3.7)	.001			
GI (n[%]) 0 1 2 3	35	35	NA	24 7 (20%) 4 (11.5%) 0	29 6 (18.5%) 0 0	.465[c]
PI (n[%]) 0 1	35	35	NA	28 7 (20%)	32 3 (8.3%)	.250[c]
BoP (n[%]) 0 1	35	35	NA	16 19 (53%)	24 11(31.5)	0.10[d]
PPD mesial/ distal, mm[a]	2.3 (0.40)	2.4 (0.25)		3.1 (0.25)	3.2 (0.35)	.340[d]

NA = not applicable; GI = Gingival Index; PI = Plaque Index; BoP = bleeding on probing. PPD = Periodontal probing Depth.

[a] Mean (SD).

[b] Nonpaired Student *t*-test was used for comparisons between groups in baseline measures.

[c] Chi-square test was used for comparisons between groups at 12 months.

[d] ANCOVA (LS mean) was used for comparison of 12 months vs baseline (mean adjusted by baseline value and age).

In vitro studies were mainly performed with thermal and/or mechanical-occlusal stress[9,10,22-24] and the main findings concluded that the quality of the external margins, under scanning electron microscopic observations, were very good but a significant decrease of margins' quality after thermal and mechanical stress was observed[10,23-25].

However, the evaluation of margins' quality under scanning electron microscopy (SEM) when conducted at low magnification can not clarify if the margins sealed efficiently: leakage to be present does not require an evident gap visible at low magnifications, and it can be clearly detected only using micro computerized tomographic analysis and/or cutting the samples after being processed for marginal leakage. Recently, no correspondence between SEM quality margin assessment and presence of nano-leakage was found[26].

From a clinical point of view, the effectiveness and the "bio-integration" of CMR of posterior indirect restoratives should be related to both BoP, as a measure of periodontal tissue stability, and to a radio- graphic examination, able to assess the marginal bone stability.

In the present trial, two different margin designs were compared in regard to periodontal tissue response in the same sample tooth (resin composite where cervical margins were relocated coronally and mar- gins located in the root below the cementum-enamel junction ce- mentum-dentin). At the 12-month evaluation, PI and GI were increased as in the previous literature with no statistically significant differences between the two types of margins (Table 2). This data is in agreement with previous investigations[15,27]. It must be noted that BoP refers to deep probing whilst GI to superficial probing and PI to the presence of plaque superficially.

When the two experimental groups were compared in terms of Bop, statistically significant differences were found, and consequently, the null hypothesis was rejected. Recent articles confirm how the presence of a deep subgingival margin is otherwise associated with an increase of bleeding after probing[15,28-30].

Lang et al. clearly described the periodontal inflammation mechanism that occur when overhanging margins are found interproximally[31]. However, in the same preclinical model, Lang and co. demonstrated how periodontal inflammation is a reversible process, and restitutio ad integrum can be again established if proper margin is present[31]. The periodontal inflammation experimentally provoked[31] can be similar to that took placed in the interproximal areas where CMR was applied in this study. The CMR clinical procedure is advocated to get a better control of margins of the indirect restoration at the time of preparation, impression and luting[1,2], but cannot improve quality of bonding to cementum-dentin substrates[32,33], and the progressive degradation of the hybrid layer at

the bonding interface can not avoided.[34,35].

The seal of the cervical margins below the CEJ remains an important unsolved issue.

While no differences were present between the groups at baseline, at the 12-month follow-up 53% of sites in Group 1 was positive to BoP versus 31.5% in Group 2 (P = .010) (Table 2).

When the margin-bone crest distance was considered, it was noticed that in Group 1 samples, 13 margins of 19 were located at a distance of 2 mm from the bone crest and in Group 2 in 6 of 11 cases. This figure can be prudently evaluated because no attempt was made to standar- dize the angulation of the x-ray. If it is considered that the recorded distance between the restorative margins and the bone crest of all cases with positive BoP (in both Groups 1 and 2) was between 2 and 3 mm, it can be speculated that one of the reason of the bleeding might be related to an invasion of the biological width[36,37]. This interpretation can be also supported by the fact that any resin composite material can have defects that formed as a result of the inclusion of air are liable to have a negative impact on their properties[38]. These defect within the resin composite material can alter its mechanical properties by reducing the conversion rate[39], can be the starting point of fractures that can propagate inside the material itself, with a potential reduction of the resistance to compression, flexion, traction and wear and can also increase the diffusion of water molecules inside them[40-45], It thus appears that porosity is a factor liable to have an impact on plaque retention, the durability and clinical performance of the restoration.

At the authors' best knowledge, the present investigation offers for the first time short-term clinical results about the periodontal tissues response to the CMR procedure. After one year of clinical service, there was no evidence of bone loss (BL) neither pathological interproximal PPD > 5 mm; this can be due to the fact that the time needed to develop an evident bone loss and pathological interproximal probing pocket depth can be longer than the 1-year observation time.

In addition, BoP was mainly related with a deeper radiographic location of the margin and in 9 cases out of 19, BoP was also present in the other marginal side, where the crown margin was luted directly to the sound dental structure.

However, BoP was evident in the majority of relocated margins. Among the clinical reasons that can justify the BoP positive sites in group 1, it' s worth to mention the difficulties to keep clean deep margins by the patients, overhangins and/or underhangins of the margins, roughness of the cervical resin margins, incomplete control of adhesive and resin composite flow in between the interproximal margin and the metal matrix in an amount that can not be visible in the x-ray.

However, especially in wide MOD-cavities, which often extend close or below the cemento-enamel

junction, rubber dam application as well as the adhesive cementation is often difficult to perform. In these situations, a surgical crown lengthening can be useful to allow proper placement of the indirect restoration, to ensure dry conditions during cementation with supragingival margins and to make the restorations more easily home maintainable by the patient[36,37].

Veneziani recently proposed a new classification based on the depth of the cervical margins related to periodontal tissue: a prudent approach on using CMR when the margins are too deep on the root surface was advocated and a traditional periodontal surgery, based on crown lengthening is still the most reliable procedure when the interproximal margin is placed into the sulcus, in order to expose and make it easily maintainable by the patient[7].

The results of this study and limited information of medium-long term clinical behaviour of CMR procedure suggest a prudent selection of clinical cases in which CMR can be made, and a periodic recall of patients in order to keep under control all periodontal parameters.

However, as increased BoP was observed, long-term data will be needed to rule out the (potential negative) effect of gingival inflammation in terms of tissue stability. For this reason, the results of the present study might be considered preliminary, as longer observational period studies are under evaluation to establish better correlations between the examined parameters.

Conclusions

Within the limitations of this study, higher incidence of BoP can be expected around CMR margins and in coincidence with deep margins. CMR of margins is a sensitive-technique, especially when deep sub- gingival margin is selected and bonding restorative procedures are performed on cementum dentin substrate below the cementum enamel margins.

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Summary

The goal of this Ph D thesis was to evaluate periodontally prosthodontic margins. That because in literature it is not possible to find clinical prosthodontic parameters that can be reliable and predictable. For that, it was decided to use periodontal parameters.

Firstly, two different types of full crown's finishing lines were evaluated under four-year clinical conditions, and it was evident how the location of the margin can affect the biological response of periodontal soft tissue. The vertical margins were more difficult to be free from marginal inflammation when were located into the sulcus.

Then, it was looked for and proposed a Functional Index for Teeth, in which periodontal and restorative/prosthodontic parameters were combined. This new index can be useful for practitioners in order to evaluate their own daily job and to reevaluated it at each recall as well.

The FIT was used in a pilot study to evaluate lithium disilicate partial crowns and it results to be reliable and easy to be used. Then, the FIT was applied in a randomized controlled clinical trial (RCT) on two types of pressed lithium disilicate partial crowns and finally in a randomized controlled clinical trial on press and block LiSi partial crowns. In all these RCT the FIT resulted to be very useful when there is the need to control clinical behavior of new prosthodontic matertials during a short period of clinical service.

Also, the evaluation of clinical failure, survival and success of RCT was explained. The evaluation of clinical behavior of new techniques and/or materials is a common need in dentistry. A proper understanding of failure, survival and success under clinical conditions is of a paramount importance and must be adapted to each clinical procedure in a well accepted modality.

The influence of cervical margin relocation (CMR) on periodontal health after one year of clinical service was made. This RCT showed that the distance of the interproximal margin from the bone crest is the parameter to predict if bleeding on probing will be present. This distance shoukd be at least 2 mm, better more, in order that the margin can not interfer with the connective attachment.

In summary, it was evident how periodontal clinical parameters are appropriate to evaluate relation between cervical margins of crowns/restorations. Three main factors are playing an important role: 1. Precision of the margins, 2. Position of the margin in relation to the periodontal tissues and 3. Oral hygiene of the patient. The precision of the margins is mainly based on the well made clinical and laboratory procedures, and it is accepted that a unprecise margin per se do not determine a periodontal disease. The position of the margins is mainly related to clinical and esthetic

needs and deeper the margin will be located into the sulcus, more difficult will be to be cleaned. The quality level of oral hygiene of each patient and to keep the patient in a oral hygiene recall is probably the key for a good lonbg term prognosis. A margin located buccaly in front teeth will be much easier cleaned than an interproximal margin, located into the sulcus, of a molar.

Conclusions

It can be concluded that all the three clinical aspects mentioned above are really important to achieve a long term clinical success but it should be kept in mind that any margin must be easibly cleanable.

Future Directions

In order to validate the results of this Ph D thesis and the results of each RCT, a long term recall of the patients is desirable, other similar RCTs with a wider number of patients per group and in multicenter modality are advocated.

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Curriculum Vitae

Name: Edoardo Ferrari Cagidiaco

Date of birth: 25-08-1991

Place of birth: Pisa, Italy

Citizenship: Italian

Telephone: +39 3338121517

E-mail: Edoardo.Ferrari.Cagidiaco@gmail.com

Academics

2015 Graduated at Universidad Europea de Madrid, in Valencia, School of Dental Medicine

2015 Attended full-time the department of Periodontology of Università Vita-Salute San Raffaele, in Milano, chaired by Prof. Massimo De Sanctis

2016 Attended the PerioCampus Course on “Non Surgical Periodontal Therapy “ (one week course) in Pisa, chaired by Prof. Filippo Graziani and Prof. Cristiano Tomasi

2017 Attended full-time the Master en Ciencias Odontologicas of Universidad Complutense de Madrid, in Madrid, and the Experto course of Master Propio Periodoncia, chaired by Prof. Mariano Sanz

2018-2020 Attended full-time the Master of Prosthodontics Sciences, in Siena, chaired by Prof. Marco Ferrari

2020 recognized as “Prosthodontics Specialist” by EPA (European Prosthodontics Association)

2020 attended the GSID Summer School “International TMD Camp”, in Marina di Carrara, chaired by Prof. Daniele Manfredini

Current Occupation

From 2015 Dentist, private practice at Studio Cagidiaco Associati, in Livorno, as coworker and from 2019 as associate

From 2018 PhD Student School of Dentistry at Università di Siena, in Siena, chaired by Prof Simone Grandini

From 2018 PhD Student School of Dentistry at Universidad Complutense de Madrid, in Madrid, chaired by Prof. Mariano Sanz

From 2021 Specializing in Oral Surgery at Università Vita-Salute San Raffaele, in Siena, chaired by Prof. Raffaele Vinci

Interntional Publications

D'Elia C, Baldini N, Ferrari Cagidiaco EF, Nofri G, Goracci C, de Sanctis M
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Abstract

Infelise M, Ferrari Cagidiaco E, Sorrentino R, Gherlone EF, Ferrari M

In vitro analysis of the fracture resistance of CAD-CAM monolithic zirconia molar crowns with different occlusal thickness.

Collegio dei docenti universitari discipline Odontostomatologiche, Rome, April 2016.

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A RCT on posterior teeth restored by disilicate partial crowns with or without posts: A three years clinical service.
AIOP, Bologna, October 2019

Ferrari Cagidiaco E, Goracci C, Joda T

Introduction of a novel functional index for teeth prosthodontic score (FIT): a prospective study analyzing single-unit natural abutment crowns after three years of loading.

AIOP, Bologna, October 2019

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