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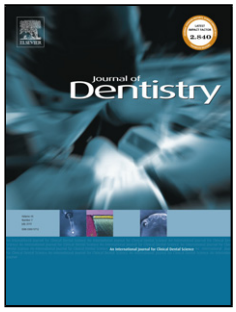


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# Influence of cervical margin relocation (CMR) on periodontal health: 12-month results of a controlled trial

Short Title: Periodontal health and cervical margin relocation

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Key words: Cervical Margin Relocation, Proximal Box Elevation, Indirect restorations, Peridontal health.

## ABSTRACT

**Objectives**: The concept of Cervical Margin Relocation (CMR) consists on placing a base layer of direct resin composite to elevate supra-gingivally the proximal indirect bonded restorations. The aims of this clinical study were to evaluate 1. Bleeding on Probing (BoP) on posterior indirect restorations with one interproximal margin relocated cervically, and 2. possible correlation between depth of the interproximal margins and BoP.

**Methods**: CMR (Group 1) and shoulder preparations (Group 2) were performed in 35 posterior teeth and evaluated after 12 months (T12). Cavities' margins were placed below the Cemento-Enamel-Junction (CEJ). CMR was applied in one interproximal box-slot preparation using G-Premio Bond, for dentin hybridization, and universal flow resin composite (GC Co. Tokyo, Japan). Pressed lithium disilicate crowns (LS2) (LiSi Press, GC Co. Tokyo, Japan) were made and placed with proprietary luting material. At baseline and after 12 months, clinical surrogate parameters were assessed; and measurements were recorded for the restorative margin position in relation to *margo gingivae* by probing, and radiographically, the distance from the bone crest was calculated (in mm). Statistical analysis was performed.

**Results**: CMR was associated with statistically significant increased BoP scores compared to shoulder preparation at T12 (53.0% vs. 31.5% per site, respectively) (p=0.10). Gingival Index (GI) and Plaque Index (PI) were not

statistically different between both groups. The linear distance between the bone crest and the restorative margin was 2 mm in 13 out of 19 experimental sites of Group 1, and 6 out of 11 of Group 2.

**Conclusions**: Higher incidence of BoP can be expected around teeth treated with the concept of CMR and in coincidence with deep margins placed at or closer than 2 mm from the bone crest.

1. Clinical Significance
CMR is a clinically sensitive-technique, especially when performed on deep subgingival margins.

Keywords: Cervical Margin Relocation, Proximal Box Elevation, Indirect restorations, Peridontal health

## 2. 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 interproximal cavity cannot be isolated with rubber dam alone, in alternative 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 4mm 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 alternatively 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).

## 3. 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 approval 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 to 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 (< 18 years); 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, < 1mm 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) language barriers; 15) plaque index higher than 20.

Patient Selection

After recruitment, oral hygiene instructions were given to the patients 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 operators: PPD at two different facial sites (mesial and distal) with a periodontal 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 probing (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 difference of 1 mm.

The inter-examiner agreement for the assessment of the variables was determined with the intra-class correlation coefficient (ICC). For the two examiners, t test ($\alpha = .05$) revealed no statistically 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 (Figs. 1a-1d). 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 Thickness (RDT) was evaluated on a periapical radiograph, and teeth with RDT thinner than 0.5 mm were excluded. Interproximal margins were located below

cementum-enamel junction into cementum-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) (Figs. 2a-2d). 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 (Link Force, GC Co., Tokyo, Japan) after being sandblasted, etched with fluoridric acid at 5 % for 60 seconds and a coat of multi primer being applied and left to evaporate for 1 minute.

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) (Figs.4a-4b).

At baseline, the restorative margin position in relation to the gingival margin was recorded quantifying by probing in mm [20], 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 percentage for continuous and categorical data, respectively. The baseline comparisons between study groups were performed using chi-square test (Fisher exact test with observed frequencies < 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 .05. SPSS version 21 software (IBM) was used for all calculations.

## 4. 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 different 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 2 mm (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.

## 5. 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.

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 radiographic 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 margins located in the root below the cementum-enamel junction cementum-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 standardize 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 2-3 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.

## 6. 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 subgingival margin is selected and bonding restorative procedures are performed on cementum dentin substrate below the cementum enamel margins.

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Figures

1a.2b. Old indirect restoration made with porcelain fused to metal in need to be replaced because secondary decay.

1c. X-ray of the cavity after the old restoration was removed.

1d. 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.

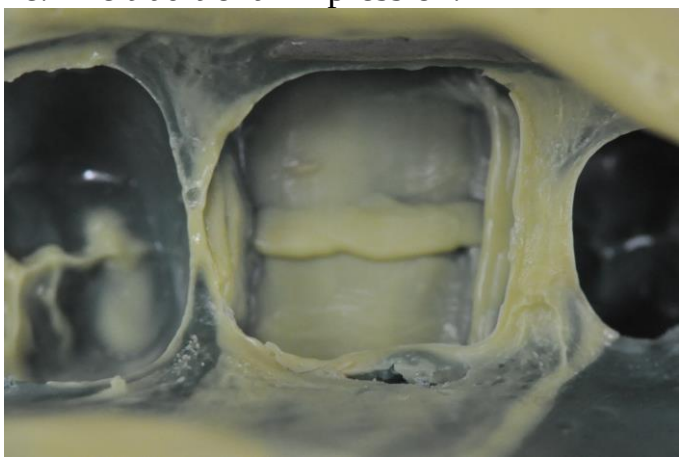
2a. Under rubber dam and after adaptating metal matrix and wedge to the emergence profile of the tooth, the procedure of immediate dentin sealing and cervical margin relocation are perfomed: the first layer of flowable resin composite is already light-cured.

2b. Complete build-up of the cavity.

2c. Immediately after the build up, still under rubber dam, the final preparation was made.

2d. The final preparation.

2e. The traditional impression.



3a. The final LiSi Press partial crown.

3b. The crown after being luted under rubber dam.

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

## Tables

| | |
|---|---|
| Age 42 (± 16.5) years | Sex (19F, 16M) |

**Table 1.** Demographic data of the included study participants.

| Variable | Baseline | 12 mo follow-up | P |
|---|---|---|---|
| Age (y)[x] | 45.1 (7.6) | | |
| Sex (men) | 19 | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

**GI (n[%])**
0 35 24
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] |

**Table 2 Sample characteristics at Baseline and 12 Months**

[a]Mean (SD).
[b]Paired t test (quantitative variables).
NA = not applicable; GI = Gingival Index; PI = Plaque Index; BoP = bleeding on probing; PPD = periodontal probing depth.

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

**Table 3 Pre-Post analysis by Study Group**

aMean (SD).
bNonpaired Student t test was used for comparisons between groups in baseline measures.
cChi-square test was used for comparisons between groups at 12 months.
dANCOVA (LS mean) was used for comparison of 12 months vs baseline (mean adjusted by baseline value and age).
NA = not applicable; GI = Gingival Index; PI = Plaque Index; BoP = bleeding on probing.
PPD=Periodonatl probing Depth