ORIGINAL RESEARCH

# Gingival Health Around Cervical Carious Lesions Restored with Calcium Silicate-based Cement (Biodentine™) Compared with Glass-ionomer Cement: A Randomized Clinical Trial

Rola Al Habashneh[1], Malik Qabaha[2], Yousef Khader[3], Iya Ghassib[4], Amre Atmeh[5]

## Abstract

**Aim:** The study aims to assess the gingival health around cervical lesions restored with calcium silicate-based cement (Biodentine™) compared to treatment with glass-ionomer cement (GIC).

**Materials and methods:** A total of 28 healthy subjects with carious lesions on the cervical third of the buccal surfaces of posterior teeth (class V—Black's classification) have participated and were distributed over two equal groups. The participants in each group received one type of the tested cements: Biodentine™ or GIC. The oral hygiene and the gingival health of the restored teeth were evaluated clinically at 1, 3, and 6 month intervals.

**Results:** Comparing clinical parameters of gingival and periodontal tissues adjacent to cervical restorations indicated significant differences. Plaque index (PI) and gingival index (GI) were higher in the Biodentine™ group at 1, 3, and 6 months of evaluation with a significant difference ($p < 0.05$), a rise in pocket depth has been noticed at 3 and 6 months ($p < 005$). Gingival recession (GR) did not show any difference between groups ($p > 0.05$). Moreover, bleeding on probing (BOP) values were higher for Biodentine™ restorations compared with GIC with a significant difference ($p < 0.05$).

**Conclusion:** Cervical restorations of Biodentine™ were associated with more plaque accumulation with a higher degree of gingival inflammation in comparison with GIC.

**Keywords:** Biodentine, Calcium silicate, Cervical carious lesions, Dental plaque, Gingival health, Glass ionomer.

*The Journal of Contemporary Dental Practice* (2019): 10.5005/jp-journals-10024-2583

## Introduction

Carious cervical lesions (class V) are very challenging to restore. These lesions could extend deep subgingivally and compromise the health and stability of gingival and periodontal tissues. Studies that investigated the periodontal health near subgingival restorations found that these restorations have led to gingival inflammation and contributed to gingival recession (GR), increased probing depth (PD), bleeding on probing (BOP), and loss of attachment.[1–4] These changes are attributed to plaque accumulation around the subgingival restoration, altering the local microflora.[5]

Different restorative materials have been used for the restoration of cervical lesions, such as amalgam, composite resin, and glass-ionomer cement (GIC). Clinicians should be able to make informative decisions and investigate gingival parameters to develop better awareness of periodontal health in reference to restorative treatment. Amalgam and composite are not regarded the "optimal" materials for gingival health.[6,7] GIC constitutes aluminosilicate polyacrylate cement and has good mechanical and esthetic properties. Well-adapted GIC restorations showed less marginal leakage and a retention of Gram-positive bacteria.[8] Inflammatory markers were not enhanced by class V restorations with GIC.[9]

A new calcium silicate-based dental cement has been recently introduced to the market as a coronal restorative material called Biodentine™ (Septodont®—Saint-Maur-des-Fossés). This material has several properties that resemble those of natural dentin, such as elastic modulus (22 GPa) and compressive strengths (220 MPa). Biodentine™ has a relatively short setting time for the convenience of clinicians.[10] Its anti-bacterial effects are largely attributed to high alkalinity, i.e., the pH is 12.5. A recent clinical trial reported very promising results when Biodentine™ was placed as an indirect pulp cap in deep carious lesions in teeth with clinical signs of reversible pulpitis.[11] Calcium silicate-based dental

[1,2]Department of Preventive Dentistry, Faculty of Dentistry, Jordan University of Science and Technology, Irbid, Jordan

[3]Department of Community Medicine, Public Health and Family Medicine, Faculty of Medicine, Jordan University of Science and Technology, Irbid, Jordan

[4]Private Practice, Amman, Jordan

[5]Department of Restorative Dental Sciences, College of Dentistry, Imam Abdulrahman Bin Faisal University, Dammam, Saudi Arabia

**Corresponding Author:** Rola Al Habashneh, Department of Preventive Dentistry, Faculty of Dentistry, Jordan University of Science and Technology, Irbid, Jordan, e-mail: rolaperio@yahoo.com

**How to cite this article:** Al Habashneh R, Qabaha M, *et al*. Gingival Health Around Cervical Carious Lesions Restored with Calcium Silicate-based Cement (Biodentine™) Compared with Glass-ionomer Cement: A Randomized Clinical Trial. J Contemp Dent Pract 2019;20(6):702–706.

**Source of support:** This study was supported by the Jordan University of Science and Technology/Deanship of Research Fund

**Conflict of interest:** None

materials, such as mineral trioxide aggregate (MTA), have shown good biocompatibility with tissues and less cytotoxicity as well as good remineralization potential of demineralized tissues, compared with GIC.[10,12,13] Constituents of Biodentine™ were found to attract fibroblasts and induce the formation of different tissues such as cementum and may even induce regeneration and reattachment of periodontal tissues.[14] Thus, this material could be suitable for application close to the gingival tissues with fair durability of up to 6 months.[15]

Cervical restoration can affect the health of adjacent periodontium depending on the type, adequacy, adaptation of restorations, as well as the position of their margins.[16] The impact of these factors can be justified by their tendency to accumulate plaque that is responsible to elicit gingival inflammation. This comparative prospective clinical study aimed to assess the gingival health around cervical restorations and to examine any significant difference in the effect of Biodentine™ and GIC restorations on gingival parameters, namely probing pocket depth (PPD), gingival index (GI), plaque index (PI), BOP, and GR, under controlled variables.

## Materials and Methods

All healthy subjects from December 2014 to February 2015 attending Jordan University of Science and Technology Dental Health Center with carious lesions on the cervical third of buccal/labial surfaces (class V—Black's classification) were invited to participate in the study. The sample size was randomly arranged into two groups to detect a difference of 0.5 in average PI. The assigned postoperative period was 6 months at a level of significance of 0.05 and a power of 80%, which resulted in 14. Therefore, a total of 28 subjects were needed for the two study groups.

The study was approved by the Institutional Review Board of Jordan University of Science and Technology. Only those who informed verbal and written consent were included. Participants were assured about confidentiality of all information obtained. Patients included in the study had (1) good general health, (2) good oral hygiene, and (3) age range of 18–60 years old. Patients with the following criteria were excluded: (1) current smokers; (2) pregnant females; (3) or patient with periodontal diseases; and (4) those who had a history of poorly controlled diabetes, liver disease, malignancy, and radiotherapy. The participants received comprehensive oral hygiene instructions 14 days before treatment. Only patients who demonstrated good oral hygiene were included in the study.

### Patients' Preparations and Instructions

All subjects had a full mouth examination conducted by the same dental practitioner, followed by professional mechanical full mouth cleaning using ultrasonic scalers and abrasive pastes with a brush or a rubber cup. Oral hygiene instructions were given to all the patients as follows:

- Demonstration of modified Stillman's tooth brushing technique.
- Tooth brushing with soft tooth brush and fluoridated toothpastes (1500 ppm) twice a day.
- Instructions for flossing (once a day).

Standardization was carried out by examining 10 patients, not included in the study population, on two occasions, PI and PPD were recorded. The $\kappa$ value was 89% of the replications for PI and 96% for PPD.

### Groups of the Study and Cavities Preparation

Participants were distributed using flip a coin into the following:

- *Group 1: GIC (Fuji IX, Japan) to restore prepared cavities (14 subjects)
- *Group 2: Biodentine™ (Biodentine from Septodont, France) to restore prepared cavities (14 subjects)

Cervical carious lesions were minimally prepared by the same clinician by removing unsupported enamel as well as soft carious dentin. For hemostatic control, merely a cotton pellet with pressure was applied. Both Biodentine™ and GIC were mixed per manufacturers' instructions for 30 and 15 seconds, respectively, using an amalgamator. Mixed cements were applied and adapted gently to the prepared cavities using a plastic instrument.

### Period of Evaluation and Clinical Parameters

For each restored tooth, PDs and GR were measured at three sites (mesial, distal, and middle sites of the buccal) using a Williams periodontal probe. Recession was measured from the middle of the reference line to gingival margin (GR).

The reference line was a horizontal line that was created from the most superior edge of the restoration where it was easily detected through a slight change in color between the natural enamel and the restoration that was used as a reference (Fig. 1). The percentage of sites with BOP was calculated too. Additional assessments of gingival status included the PI of Silness and Loe and the GI of Loe and Silness. These parameters were evaluated at four sites (mesial, distal, buccal, and lingual) on each tooth.

The clinical examination of all parameters was recorded before placing the restoration (baseline), and after 4, 12, and 24 weeks.

### Data Management and Analysis

Data were analyzed using the Statistical Package for Social Sciences software (SPSS Inc., version 11.5, Chicago, IL, USA). Difference between two means was analyzed using an independent *t* test. The change over time in each group was analyzed using the general linear model (GLM) with repeated measures. A *p* value of less than 0.05 was considered statistically significant.

## Results

A total of 28 subjects had successfully completed the study period of 6 months. All participants maintained the recall visits at 1, 3, and 6

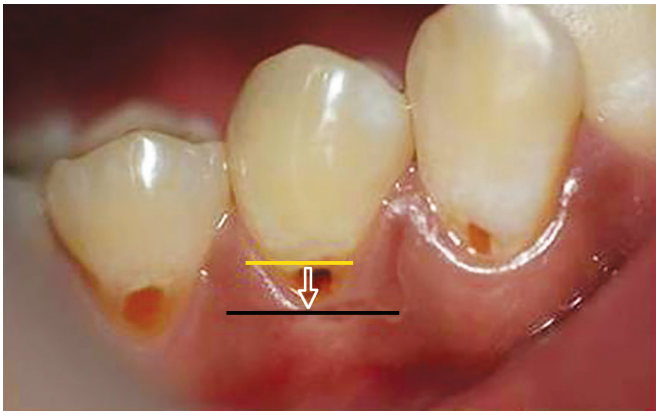

**Fig. 1:** A cervical carious lesion with reference point of PD measurement. The PD was measured from a horizontal reference line (yellow) that was created at the superior margin of the restoration

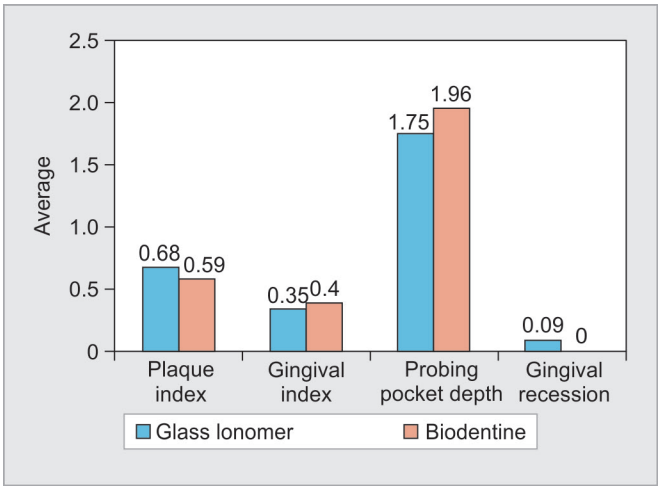


**Fig. 2:** Comparison of the changes in gingival parameters adjacent to cervical restorations of glass ionomer and calcium silicate-based cements

months. The mean age was 31.1 years for patients in the Biodentine™ group and 31.2 years for patients who had GIC restorations, with no significant difference between the two groups. Male to female ratios were 10:4 and 6:11 in patients who had Biodentine™ and GIC restorations, respectively ($p$ value = 0.049). For the baseline measurements, there were no significant differences between the two restorative materials used (Fig. 2).

As shown in Table 1, the average PI was higher in patients with Biodentine™ restorations over time until it platitude at month 3 with no significant trend. For patients with GIC, the PI scored lower after 1 month and then increased slightly with no significant trend. At each time point after the baseline, the mean was significantly higher for the Biodentine™ group. The change in GI followed almost the same trend as PI. However, it increased significantly in the Biodentine™ group and its mean remained significantly higher compared to the GIC group at all follow-up time points. The average pocket depth increased significantly over time near Biodentine™ restorations and remained significantly higher after 3 and 6 months compared with the GIC. The percentage of sites with bleeding increased after 3 months, but decreased after 6 months. The percentage was higher in patients with the Biodentine™ restorations at all time-points of follow up (Fig. 2). Repeated measures' analysis showed that there were significant interactions between the type of restoration and the time ($p$ values: 0.014 for PI, 0.030 for GI, and 0.036 for PPD) (Table 2).

**Table 2:** Changes in clinical parameters according to material, time, and both material and time

| | *PI* | *GI* | *PD* |
|---|---|---|---|
| Material | 0.000 | 0.000 | 0.000 |
| Time | 0.014 | 0.002 | 0.005 |
| Time × material | 0.238 | 0.030 | 0.036 |

## Discussion

Failure of dental restorations is a major concern in dental practice and their replacement constitutes the majority of operative work. Beside recurrent caries and leakage, cervical restorations may impose additional concern on the health of adjacent tissues. Therefore, it is imperative to fully understand the influence of restorative materials on dental and gingival tissues when deciding to restore a defective tooth segment. While calcium silicate cement has been known for its compatibility and ability to induce dentin repair and remineralization,[10] it was only recently used as coronal restorations. Biodentine™ seemed suitable for restoring cervical carious lesions close to gingival tissues as a substituent to GIC, which have also been widely used due to the ease of application and a low incidence of caries reoccurrence.[17]

All the participants in this study had a strict program of oral hygiene during the 6 months study, comprising of daily brushing, twice a day and flossing once daily, which rendered full mouth scores at or around the level of baseline records. Patients' compliance was regarded a controlled variable, which allowed investigating restorations independent of oral hygiene changes and of consequences of patients' cleaning habits. The cervical carious lesions that were involved in the study were selected based on the similarity in size, where the size of defect did not exceed 5 mm and not less than 2 mm in mesiodistal dimensions. Coronally, lesions had to be more than 3 mm above the marginal gingiva but at least 2 mm subgingivally. Complete field isolation was attempted during the placement of restorations; however, this was difficult considering the location of lesions where the rubber dam may impede the operative field.

Using calcium silicate-based restorative material Biodentine™ to restore cervical carious lesions showed significant differences in their clinical behavior on gingival and periodontal tissues in

**Table 1:** Repeated measures analysis of clinical parameters according to the time of follow-up and type of restoration

| | | *Mean (SD)* | | | | | |
|---|---|---|---|---|---|---|---|
| *Parameter* | *Material* | *Baseline* | *1 month* | *3 months* | *6 months* | *p value linear trend* | *p value quadratic trend* |
| PI | Biodentine | 0.59 (0.3) | 0.9 (0.9) | 1.4 (0.5) | 1.4 (0.5) | 0.180 | 0.095 |
| | Glass ionomer | 0.6 (1.2) | 0.2 (0.4) | 0.3 (0.5) | 0.4 (0.5) | 0.073 | 1.00 |
| | *p* value | 0.165 | 0.007 | 0.000 | 0.000 | | |
| GI | Biodentine | 0.40 (0.4) | 1.1 (0.8) | 1.6 (0.7) | 1.7 (0.5) | 0.045 | 0.321 |
| | Glass ionomer | 0.35 (0.4) | 0.2 (0.4) | 0.5 (0.8) | 0.4 (0.5) | 0.188 | 0.095 |
| | *p* value | 0.912 | 0.000 | 0.001 | 0.000 | | |
| PD | Biodentine | 2.0 (0.6) | 2.0 (0.6) | 2.3 (0.5) | 2.4 (0.6) | 0.027 | 1.000 |
| | Glass ionomer | 1.7 (0.4) | 1.8 (0.4) | 1.8 (0.4) | 1.9 (0.5) | 0.431 | 0.541 |
| | *p* value | 0.219 | 0.152 | 0.008 | 0.016 | | |
| BOP% | Biodentine | 0 | 35.7% | 80.0% | 71.4% | 1.000 | 0.470 |
| | Glass ionomer | 0 | 0.0% | 17.6% | 5.9% | 0.431 | 0.541 |
| | *p* value | | 0.007 | 0.001 | 0.001 | | |

comparison with GIC. Biodentine™ demonstrated increased plaque scores, GI, BOP, and PPDs. These differences could be partially attributed to the surface properties of both restorative materials, which is related to the handling and adaptation properties of the cements and, therefore, can imply the smoothness of their surfaces. Upon placement, GIC can be conveniently adapted using an alcohol wetted plastic instrument that can create a regular surface that sets within a few minutes. Biodentine™, however, needs around 20 minutes for initial setting, which may lead to surface loss and irregularities during this period considering the location and the thickness of class-V restorations close to salivary flow within the buccal vestibule. As reported in previous studies, worn and roughened surfaces, in addition to subgingival margins, could provide favorable niche for plaque accumulation and for attachment and colonization of oral bacteria. Subsequently, this might have worsened the PI and affected the gingival health of adjacent tissues.[18–21]

The choice of time periods was made in accordance with thorough knowledge of time required for significant changes to occur in the health of periodontium.[22] Statistically significant difference was observed in PI in patients with Biodentine™ restorations compared with patients with GIC ($p < 0.05$), at all recall visits. After the first recall visit (1 month), it was noticed that Biodentine™ restorations yielded a gradual loss from their external surfaces that may have resulted in roughened surfaces. Better gingival health adjacent to GIC restorations was documented. PI merely increased from 0.2 to 0.4, at last recall visit. This could be because of good marginal adaptation, reduced surface roughness, and fluoride release, interfering with early adherence of bacteria to restoration and teeth surfaces.[23,24]

GI and BOP scores at 1, 3, and 6 months were higher adjacent to Biodentine™ restorations in comparison with GIC. More specifically, GI of the former increased from 1.1 to 1.7, while those of GIC restorations increased from 0.2 to 0.4. BOP percentage values markedly increased from 35.7 to 71.4% with Biodentine™ and only from 0.0 to 5.9% with GIC restorations. A statistically significant difference ($p < 0.05$) in the GI was seen at all recall visits. One can expect that an increase in plaque, which is composed of various microorganisms, could cause gingival inflammation in these areas. Therefore, the high PI among Biodentine™ cases can justify the increase in GI noticed. Waerhaug[25] proposed that subgingival dental materials may favor the initiation of gingivitis or periodontitis by local plaque. His results partially match our findings in this study. A healthy gingiva is always associated with good adaptation and good finished restorative margins, whereby marginal integrity is affected.[20–25]

Results in this study partially agreed with previous reports which showed that the placement of equigingival and subgingival restorations leads to increased pocket depths as opposed to supragingival restorations.[18,26,27] Higher PPDs were measured around Biodentine™ restorations than with GIC, whereby the latter remained almost similar to baseline records and did not affect the periodontal health significantly. This was in accordance with earlier studies that supported the efficacy of GIC as a cervical restoration with no significant difference between restored and non-restored teeth in terms of periodontal health.[28]

According to our best knowledge, no previous comparative studies have been published on Biodentine™ and GIC. This imposes limitations to direct comparisons with published papers. Although several studies have been published on the longevity of different restorative materials, especially composite and amalgam, most are difficult to compare with our study because they diverse based on the (1) number of patients, (2) time of follow-up, (3) number of clinicians evaluating treatment and their level of experience, (4) number of restorations per patient, (5) type and size of restorations, and, finally, (6) the type of statistical methods used.

In summary, within the limitations of this study, teeth restored with Bio showed increased PI, GI, PPD, and BOP in comparison with those of GIC-restored teeth. High BOP scores resulted as a consequence of increased PI, GI, and PPD. GIC is employed because of its great longevity, ease of use, and versatility. In contrast, Bio restorations depicted several limitations as suggested by their short longevity, higher cost, higher technique sensitivity, as well as higher consumption of time.

Further investigations are still needed to evaluate the longevity of tested cements under different clinical situations and for longer periods of time. Additionally, further efforts are needed to improve the handling properties of calcium silicate cements to invest their superior biological properties for this clinical application.

## Clinical Significance

Applying calcium silicate cements to restore cervical carious lesions might adversely affect the gingival health due to increased plaque accumulation in comparison with conventionally used GIC.

## Ethical Approval

The study was approved by the Institutional Review Board of Jordan University of Science and Technology. All procedures performed in studies involving human participants were in accordance with the Ethical Standards of the Institutional and/or National Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## Informed Consent

After informed verbal and written consent was obtained, eligible patients were included in the study.

## References


1. Schätzle M, Lang NP, et al. The influence of margins of restorations on the periodontal tissues over 26 years. J Clin Periodontol 2001;28(1):57–64.
2. Padbury Jr A, Eber R, et al. Interactions between the gingiva and the margin of restorations. J Clin Periodontol 2003;30(5):379–385.
3. Ferrari M, Koken S, et al. Influence of cervical margin relocation (CMR) on periodontal health: 12 month results of a controlled trial. J Dent 2018;69:70–76. DOI: 10.1016/j.jdent.2017.10.008.
4. Gurgel C, Solera NG, et al. Evaluation of the periodontal conditions of teeth with restored and non-restored non-carious cervical lesions. Quintessence Int 2016;47(10):825–831. DOI: 10.3290/j.qi.a36885.
5. Nassar U, Meyer AE, et al. The effect of restorative and prosthetic materials on dental plaque. Periodontol 2000 1995;8(1):114–124.
6. Wang J, Liu Z. Influence of amalgam on the growth of mutans streptococcus: an in vivo study. Chin J Dent Res 2000;3(2):33–37.
7. Larato DC. Influence of a composite resin restoration on the gingiva. J Prosthet Dent 1972;28(4):402–404.
8. Santos VR, Lucchesi JA, et al. Effects of glass ionomer and microfilled composite subgingival restorations on periodontal tissue and subgingival biofilm: a 6 month evaluation. J Periodontol 2007;78(8):1522–1528. DOI: 10.1902/jop.2007.070032.
9. Willershausen B, Köttgen C, et al. The influence of restorative materials on marginal gingiva. Eur J Med Res 2001;6(10):433–439.

10. Atmeh AR, Chong EZ, et al. Calcium silicate cement-induced remineralisation of totally demineralised dentine in comparison with glass ionomer cement: tetracycline labelling and two-photon fluorescence microscopy. J Microsc 2015;257(2):151–160. DOI: 10.1111/jmi.12197.
11. Hashem DF, Foxton R, et al. The physical characteristics of resin composite–calcium silicate interface as part of a layered/laminate adhesive restoration. Dent Mater 2014;30(3):343–349. DOI: 10.1016/j.dental.2013.12.010.
12. Camilleri J, Montesin FE, et al. The constitution of mineral trioxide aggregate. Dent Mater 2005;21(4):297–303. DOI: 10.1016/j.dental.2004.05.010.
13. Zhou HM, Shen Y, et al. In vitro cytotoxicity evaluation of a novel root repair material. J Endod 2013;39(4):478–483. DOI: 10.1016/j.joen.2012.11.026.
14. Zanini M, Sautier JM, et al. Biodentine induces immortalized murine pulp cell differentiation into odontoblast-like cells and stimulates biomineralization. J Endod 2012;38(9):1220–1226. DOI: 10.1016/j.joen.2012.04.018.
15. Koubi G, Colon P, et al. Clinical evaluation of the performance and safety of a new dentine substitute, Biodentine, in the restoration of posterior teeth—a prospective study. Clin Oral Investig 2013;17(1):243–249. DOI: 10.1007/s00784-012-0701-9.
16. Broadbent JM, Williams KB, et al. Dental restorations: a risk factor for periodontal attachment loss? J Clin Periodontol 2006;33(11):803–810. DOI: 10.1111/j.1600-051X.2006.00988.x.
17. Nicholson JW. Chemistry of glass-ionomer cements: a review. Biomaterials 1998;19:485–494.
18. Renggli HH, Regolati B. Gingival inflammation and plaque accumulation by well-adapted supragingival and subgingival proximal restorations. Helv Odontol Acta 1972;16(2):99–101.
19. Leon AR. Amalgam restorations and periodontal disease. Br Dent J 1976;140(11):377.
20. Valderhaugw J, Birkeland JM. Periodontal conditions in patients 5 years following insertion of fixed prostheses: pocket depth and loss of attachment. J Oral Rehabil 1976;3(3):237–243.
21. Valderhaug J. Periodontal conditions and carious lesions following the insertion of fixed prostheses: a 10 year follow-up study. Int Dent J 1980;30(4):296–304.
22. Reitemeier B, Hänsel K, et al. Effect of posterior crown margin placement on gingival health. J Prosthet Dent 2002;87(2):167–172.
23. Reeves WG. Restorative margin placement and periodontal health. J Prosthet Dent 1991;66(6):733–736.
24. Van Dijken JW, Sjöström S. The effect of glass ionomer cement and composite resin fillings on marginal gingiva. J Clin Periodontol 1991;18(3):200–203.
25. Waerhaug J. Presence or absence of plaque on subgingival restorations. Eur J Oral Sci 1975;83(4):193–201.
26. Richter WA, Ueno H. Relationship of crown margin placement to gingival inflammation. J Prosthet Dent 1973;30(2):156–161.
27. Lang NP, Kiel RA, et al. Clinical and microbiological effects of subgingival restorations with overhanging or clinically perfect margins. J Clin Periodontol 1983;10(6):563–578.
28. Garcia R, Caffesse RG, et al. Gingival tissue response to restoration of deficient cervical contours using a glass-ionomer material. A 12 month report. J Prosthet Dent 1981;46(4):393–398.