Assessment of Peri-Implant Tissues Surrounding PEEK and Porcelain Fused to Metal Superstructures in Posterior Region

A Randomized Controlled Clinical Trial

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Abstract

Purpose: to compare the clinical and radiographic outcomes of PEEK and PFM implant supported crowns.

Methods: This study was designed as randomized controlled study. Twenty-three single implants in posterior region were restored randomly either with PFM or PEEK crowns. Peri implant soft tissue parameters were evaluated using the modified plaque index (mPI), bleeding on probing (BOP), probing depth (PD), modified gingival index (mGI), and crestal bone loss was measured (CBL). Clinical data were collected at crown delivery, after 6 months, and after one year of function.
Results: there was no statistical significant difference between the mean of the modified plaque index (mPl), bleeding on probing (BOP), probing depth (PD), modified gingival index (mGI) in the two groups, while the mean crestal bone loss was statistically less in PEEK group than that of the PFM one.

Conclusion: PEEK implant supported crowns appeared to reduce the amount of CBL in the posterior region. Regarding the peri-implant soft tissue parameters both PEEK and PFM crowns showed comparable results.

Keywords: Randomized controlled trial, posterior PEEK implant crown, soft tissue parameters, crestal bone loss, extra-oral cementation.

1. INTRODUCTION

Dental implant therapy affords a favorable treatment option with long-term predictability (1). The success of such treatment is related not only to the implant osseointegration but also to interrelationship of the final prosthesis with soft and hard tissues (2).

Advancement of implant materials and surface modifications has increased the outcome measures of implant prosthodontics (3). The material used for conventional tooth-supported restoration influences periodontal health (4). In the same way, the material used for implant-supported restoration may also affect peri-implant health and esthetics (5).

Implant supported restorations are commonly made from porcelain fused to metal (PFM) and all ceramic materials. PFM have excellent mechanical properties, however, the metal framework causes allergic reactions and discoloration to the surrounding mucosa. Consequently, PFM restorations are gradually substituted with all ceramic restorations. Nonetheless, PFM crowns are still the gold standard. (6).

Due to lack of periodontal ligaments and absence of micro-movement at the implant-bone interface, concentrated loads could result in crestal bone resorption (7). Restorative materials having low modulus of elasticity, including acrylics or composite resins, might absorb high occlusal forces and distribute less energy to the underlying bone-implant surface and the nearby
bone (8). In contrast, materials having high modulus of elasticity, including metals, zirconia and ceramics, can transmit a greater force to the bone (9).

Polyetheretherketone (PEEK) is a semi-crystalline high performance polymer, lately used in dental practice as a non-metallic framework for both tooth and implant supported restorations. It has been also used for constructing dental implants, implant abutments, healing abutments and occlusal splints (10).

**Tekin 2019** evaluated PFM and PEEK restorations on titanium implants using FEA. They observed that the PEEK material reduced all the applied stresses. So, they revealed that stresses on the implant system can be changed through the usage of different prosthetic materials (11).

**Mourya 2021** evaluated the stress distribution around titanium and carbon fiber-reinforced polyetheretherketone (CFR-PEEK) implant with 2 different prosthetic crowns (PFM and PEEK) under parafunctional loading through FEA. They found that both implants transmitted comparable stresses in bone. While PFM crowns transmitted higher stresses than PEEK ones under oblique as well as vertical loads. Thus they recommended the use of PEEK crowns to decrease stresses absorbed by peri-implant bone (12).

The proper integration of the implants in the soft and hard tissues has a crucial role in the success of implant therapy. Thorough evaluation of clinical parameters (plaque index, bleeding on probing, probing depth) and radiographic crestal bone loss (CBL), at the base line and every 6 months follow up visit, is recommended to exclude the risk of peri-implant mucositis/implantitis. Therefore, this randomized clinical study was aimed to evaluate the peri-implant tissues around PEEK restorations in posterior region.

**2. MATERIAL AND METHODS**

**2.1. Participant characteristics**

The present study was randomized clinical trial. This double blinded study was undertaken in the Prosthodontic Department of Cairo University, and participants were recruited from the out-patient clinic, the ethical approval was obtained from Ethics Committee of Scientific Research - Faculty of Dentistry – Cairo University.
Adults who needed only a single posterior implant crown with proper bone, thick gingival biotype and medically free were eligible. Patients with parafunction habits as well as noncompliant participants, were excluded from the study. Before inclusion, informed consent was obtained. This clinical trial was registered with the Clinical Trials.gov. The sample size was 24 implant supported restorations obtained with 80% power and 5% significance level using a power analysis. Sample size calculation was achieved using PS Power and Sample Size Calculation software Version 3.1.2.

2.2. Funding and Conflict of interest:

The trial was totally self-funded. There were no conflicts of interest for any of the authors.

2.3. Clinical procedures:

2.3.1. The surgical protocol:

A full-thickness flap was elevated drilling was performed sequentially until the decided diameter and length of the implant was reached by the final drill. Then the implant (Superline Dentium, Seoul, Korea) was inserted flushed with the crest of the bone and the flap was sutured. Post-operatively, patients were prescribed systemic antibiotic, mouthwash rinse and an analgesic.

2.3.2. The prosthetic protocol:

Six months after implant placement, definitive crowns were fabricated. The frameworks were designed using a CAD program, the first group was restored with PFM crowns, the metal frameworks (MAGNUM SOLARE Co-Cr blank) were milled using CAM, then coated with feldspathic porcelain (VITA Zahnfabri, Germany). While the second group was restored with the PEEK frameworks, which milled from (Biohpp blank Bredent Germany) and coated with Visiolink primer followed by layering with composite (Crea lign Bredent. Germany)

To obtain the minimum amount of cement required for crown cementation, copy abutment analogues were fabricated from bis acrylic composite material (Ivoclar Vivadent GmbH & Co.KG, Germany), and the crowns were loaded with the cement (Dento temp ITENA, France) then placed

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on the substrate prior to intraorally to remove the excess cement. The crowns were then seated intraorally onto the implant abutments with firm pressure for final cementation. **Figure (1)**

**Figure (1):** The flow of Excess cement around the margin of the bis-acrylic abutment.

### 2.3.3. The outcome measures:

#### 2.3.3.1. Soft tissue examination:

The following parameters were recorded using a millimeter graduated plastic periodontal probe (Helmut ZEPF, Medizintechik GMBH, Germany)

1. **Presence of bacterial plaque according to Modified plaque index (mPLI):** 4 sites per implant were assessed (mesiobuccal, distobuccal, mid-buccal, and mid-lingual) and scored.

2. **Modified bleeding index; bleeding on probing (BOP):** 4 sites per implant (mesiobuccal, distobuccal, mid-buccal, and mid-lingual) were assessed for positive bleeding or suppuration up to 30 s after probing and scored. **Figure (2)**

3. **Probing depth (PD):** was evaluated at 6 sites per each implant (mesiobuccal, mid-buccal, distobuccal, mesiolingual, mid-lingual, distolingual). The probe was used to measure the distance between the peri-implant mucosal margin and the bottom of sulcus to the nearest millimeter. **Figure (3)**

4. **Modified Gingival index (mGI):** the peri-implant mucosal tissues around the implants were assessed using the modified, non-invasive (no probing) technique and scored
2.3.3.2. The radiographic assessment:

Radiographs were taken by the mean of parallel cone technique using a Rinn alignment system (Rinn system XCP, Dentsply Sirona), individualized radiographic stents were used to retain the plastic film holders. The radiographs were then taken in high-resolution mode with a dental x-ray
machine (Densply Sirona USA) equipped with a long tube that was operated at A 70 kVp, 7 mA, and 0.02 sec. exposure time, with an approximately 30 cm focal film distance. Then the sensor was inserted into the laser scanner (Soredex, Kavo, Finland) for digital processing. Specialized software (CLINIVIEW™11.4.Ink, Soredex, Kavo, Finland) was used for the linear measurement of crestal bone changes.

To correct the dimensional distortion in the radiograph, the software was calibrated with the true implant length. The distance (mm) between the line linking the implant shoulder and the first contact of the crestal bone on both mesial and distal sides of the implant was considered the baseline reference. The radiographic CBL was measured as the difference between mesial/distal values at baseline and at each follow-up visit. **Figure (4)-(5)**

**Figure (4):** Radiographic bone loss of PEEK implant crowns. **A:** Base line reading; **B:** At 6 months readings; **C:** At 12 months readings.

**Figure (5):** Radiographic bone loss of PFM implant crowns. **A:** Base line reading; **B:** At 6 months readings; **C:** At 12 months readings.
3. STATISTICAL ANALYSIS

Numerical data were explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). All data showed non-normal (non-parametric) distribution except for age data. Data were presented as mean, standard deviation (SD), median and range values. For non-parametric data; Mann-Whitney U test was used to compare between two groups. Friedman’s test was used to study the changes by time within each group. The significance level was set at $P \leq 0.05$.

4. RESULTS

One participant was dropped out from the trial during the follow up period.

4.1. modified Plaque Index (mPI)

There was no statistically significant difference between the mean ±SD of mPI scores in the two groups, at the base line (0.64 ± 0.67, 0.5 ± 0.52), after 6 months (0.91±0.7, 067± 0.49), and after 12 months for PEEK and PFM respectively. (Figure 6, Table1)

Table (1): Descriptive statistical results of Mann-Whitney U test for comparing the PI scores in the two groups and Friedman’s test for comparing the PI scores at different time intervals within each group.

<table>
<thead>
<tr>
<th>Time</th>
<th>PEEK (n = 11 restorations)</th>
<th></th>
<th>PFM (n = 12 restorations)</th>
<th></th>
<th>Effect size (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>±SD</td>
<td>Median (Range)</td>
<td>Mean</td>
<td>±SD</td>
</tr>
<tr>
<td>Base line</td>
<td>0</td>
<td>±0</td>
<td>0 (0-0) B</td>
<td>0</td>
<td>±0</td>
</tr>
<tr>
<td>6 months</td>
<td>0.64</td>
<td>±0.67</td>
<td>1 (0-2) A</td>
<td>0.5</td>
<td>±0.52</td>
</tr>
<tr>
<td>12 months</td>
<td>0.91</td>
<td>±0.7</td>
<td>1 (0-2) A</td>
<td>0.67</td>
<td>±0.49</td>
</tr>
<tr>
<td>$P$-value</td>
<td>0.003*</td>
<td></td>
<td></td>
<td>0.002*</td>
<td></td>
</tr>
<tr>
<td>Effect size (w)</td>
<td>0.529</td>
<td></td>
<td></td>
<td>0.542</td>
<td></td>
</tr>
</tbody>
</table>
**: Significant at P ≤ 0.05, Different superscripts in the same column indicate statistically significant change by time

4.2. Bleeding on probing (BOP)

There was no statistically significant difference between mean ±SD of the BOP scores after 6 months (55 ±0.69, 0.58 ±0.51), as well as 12 months (1 ±1, 0.67 ±0.49) in the PEEK and PFM groups respectively. (Figure 7, Table 2)

Table (2): Descriptive statistical results of Mann-Whitney U test for comparing BOP scores in the two groups and Friedman’s test for comparing BOP scores at different time intervals within each group.

<table>
<thead>
<tr>
<th>Time</th>
<th>PEEK (n = 11 restorations)</th>
<th>PFM (n = 12 restorations)</th>
<th>P-value</th>
<th>Effect size (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ±SD</td>
<td>Median (Range)</td>
<td>Mean ±SD</td>
<td>Median (Range)</td>
</tr>
<tr>
<td>Base line</td>
<td>0 ±0</td>
<td>0 (0-0) B</td>
<td>0 ±0</td>
<td>0 (0-0) B</td>
</tr>
<tr>
<td>6 months</td>
<td>0.55 ±0.69</td>
<td>1 (0-2) A</td>
<td>0.58 ±0.51</td>
<td>1 (0-1) A</td>
</tr>
</tbody>
</table>

Figure (6): Bar chart representing mean ± SD values for PI scores in the two groups (Circles represent outliers).
12 months | 1 | ±1 | 1 (0-2) \(^A\) | 0.67 | ±0.49 | 1 (0-1) \(^A\) | 0.429 | 0.312

\(P\)-value | 0.004* | 0.001*  

Effect size (\(w\)) | 0.5 | 0.594

*: Significant at \(P \leq 0.05\), Different superscripts in the same column indicate statistically significant change by time

**Figure (7)**: Bar chart representing mean ±SD values for BOP scores in the two groups.

### 4.3. Probing Depth (PD)

There was no statistically significant difference between mean ±SD value of PD measurements (mm) at base line (1.48 ±0.47, 1.63 ±0.76), after six months (2.02 ±0.54, 1.83 ±0.48) as well as 12 months (2.58 ±0.63, 2.6±0.58) in the PEEK and PFM groups respectively. (**Figure 8, Table 3**)
Table (3): Descriptive statistics and results of Mann-Whitney U test for comparing PD measurements (mm) in the two groups and Friedman’s test for comparing PD measurements at different time intervals within each group.

<table>
<thead>
<tr>
<th>Time</th>
<th>PEEK (n = 11 restorations)</th>
<th></th>
<th>PFM (n = 12 restorations)</th>
<th></th>
<th>P-value</th>
<th>Effect size (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ±SD</td>
<td>Median (Range)</td>
<td>Mean ±SD</td>
<td>Median (Range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Base line</td>
<td>1 ±0.47</td>
<td>1.33 (1-2.67)</td>
<td>1.63 ±0.76</td>
<td>1.42 (1-3.33)</td>
<td>B</td>
<td>0.950</td>
</tr>
<tr>
<td>6 months</td>
<td>2.02 ±0.2</td>
<td>1.83 (1.17-3)</td>
<td>1.83 ±0.48</td>
<td>1.75 (1-2.83)</td>
<td>B</td>
<td>0.385</td>
</tr>
<tr>
<td>12 months</td>
<td>2.58 ±0.63</td>
<td>2.5 (1.5-3.5)</td>
<td>2.6 ±0.58</td>
<td>2.67 (1.67-3.33)</td>
<td>A</td>
<td>0.975</td>
</tr>
<tr>
<td><em>P-value</em></td>
<td>&lt;0.001*</td>
<td></td>
<td>0.001*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Effect size (w)</em></td>
<td>0.872</td>
<td></td>
<td>0.576</td>
<td></td>
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</tr>
</tbody>
</table>

*: Significant at P ≤ 0.05, Different superscripts in the same column indicate statistically significant change by time

![Probing Depth (PD)](image-url)
Figure (8): Bar chart representing mean ± SD values for PD measurements (mm) in the two groups (Circles and stars represent outliers).

4.4. Gingival Index (GI)

There was no statistically significant difference between mean ± SD of GI scores, after six months (0.27 ± 0.65, 0) as well as 12 months (0.45 ± 0.82, 0.08 ± 0.29) in PEEK and PFM groups respectively. (Figure 9, Table 4)

Table (4): Descriptive statistical results of Mann-Whitney U test for comparison between GI scores in the two groups and Friedman’s test for comparing the GI scores at different time intervals within each group.

<table>
<thead>
<tr>
<th>Time</th>
<th>PEEK (n = 11 restorations)</th>
<th>PFM (n = 12 restorations)</th>
<th>P-value</th>
<th>Effect size (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ±SD</td>
<td>Median (Range)</td>
<td>Mean ±SD</td>
<td>Median (Range)</td>
</tr>
<tr>
<td>Base line</td>
<td>0 ± 0</td>
<td>0 (0-0)</td>
<td>0 ± 0</td>
<td>0 (0-0)</td>
</tr>
<tr>
<td>6 months</td>
<td>0.27 ± 0.65</td>
<td>0 (0-2)</td>
<td>0 ± 0</td>
<td>0 (0-0)</td>
</tr>
<tr>
<td>12 months</td>
<td>0.45 ± 0.82</td>
<td>0 (0-2)</td>
<td>0.08 ± 0.29</td>
<td>0 (0-1)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.082</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effect size (w)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*: Significant at P ≤ 0.05.
Figure (9): Bar chart representing mean ±SD values for GI scores in the two groups (Circles and stars represent outliers).

4.5. Amount of crestal bone changes (mm)

At the mesial side; there was no statistically significant difference between Mean ±SD for the amounts of bone changes (mm) at 6 months (0.36 ±0.07, 0.39 ±0.17) in the PEEK and PFM groups respectively. While at 12 months; PEEK group showed statistically significantly lower Mean ±SD bone changes than PFM (0.34 ±0.15, 0.62 ±0.15) (P-value <0.001, Effect size = 2.13)

At the distal side; there was no statistically significant difference between Mean ±SD amounts of bone changes (mm) at 6 months (0.34 ±0.15, 0.30 ±0.13) in the PEEK and PFM groups respectively. While at 12 months; PEEK group showed statistically significantly lower Mean ±SD bone changes than PFM (0.35±0.14, 0.64 ±0.18) (P-value = 0.001, Effect size = 1.83). (Figure 10, Table 5)

Table (5): Descriptive statistics and results of Mann-Whitney U test for comparing crestal bone changes (mm) in the two groups.
<table>
<thead>
<tr>
<th>Side</th>
<th>Time</th>
<th>PEEK (n = 11 restorations)</th>
<th>PFM (n = 12 restorations)</th>
<th>P-value</th>
<th>Effect size (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean ±SD</td>
<td>Median (Range)</td>
<td>Mean ±SD</td>
<td>Median (Range)</td>
</tr>
<tr>
<td>Mesial</td>
<td>6 months</td>
<td>0.36 ±0.07</td>
<td>0.40 (0.20-0.42)</td>
<td>0.39 ±0.17</td>
<td>0.33 (0.20-0.80)</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td>0.34 ±0.15</td>
<td>0.30 (0.20-0.60)</td>
<td>0.62 ±0.15</td>
<td>0.60 (0.40-0.83)</td>
</tr>
<tr>
<td>Distal</td>
<td>6 months</td>
<td>0.34 ±0.15</td>
<td>0.30 (0.20-0.60)</td>
<td>0.30 ±0.13</td>
<td>0.23 (0.20-0.60)</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td>0.35 ±0.14</td>
<td>0.40 (0.10-0.50)</td>
<td>0.64 ±0.18</td>
<td>0.70 (0.30-0.90)</td>
</tr>
</tbody>
</table>

*: Significant at P ≤ 0.05.

**Figure (10):** Bar chart representing mean ±SD values for amount of marginal bone changes (mm) in the two groups (Circles represent outliers).

5. **DISCUSSION**

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Dental implant therapy is a predictable treatment option for missing dentition rehabilitation and has been documented as an appropriate tool for dental reconstruction (13)\textsuperscript{(14)}.

Alterations in the peri-implant tissues status were investigated in terms of, modified plaque index (mPI), bleeding on probing (BOP), probing depth (PD) and modified gingival index (mGI) values for both implant supported crown groups in this study. Results showed that no statistical significant differences in all measured peri-abutment soft tissue parameters after 6 months and 12 months follow-up intervals.

Studies have shown that there is a direct positive correlation between surface characteristics of dental materials, in terms of surface roughness, chemical compositions, surface free energy, and bacterial adhesion (15)(16). Therefore, the use of highly polished Nano-hybrid composite, and glazed porcelain surfaces in this study might be the reason that peri implant soft tissue parameters were comparable in both groups.

Regarding the similarity of (BOP) scores in PEEK implant crowns when compared to PFM ones. These results could be related to high surface polishability of both materials, the gingival finish line which placed within 1 mm of the gingival sulcus, and to the use of extra oral cementation technique that facilitated the removal of excess luting cement Frisch et al. (2016); . (19) W. Wang et al. (2020);(20)

The results of this study showed that the average probing depths was (2.58 ± 63 and 2.6 ± 58) mm for PEEK and PFM implant supported crowns respectively after one year follow-up period. These results were in agreement with Mombelli 2002 (21) who claimed that successful implants normally permit a probe penetration of approximately 3 mm.

The results of this study were also consistent with many studies by Rossi 2015,2016, (22,23), Gulje’ 2019 (24) who reported 2.6 mm probing depth. They assumed that healthy peri-implant tissues were confirmed when the patients are following a firm oral hygiene regime.

In this study the decreased plaque accumulation, resulted in lack of difference in mGI between PEEK and PFM crowns. The causal relation between plaque buildup and increased gingival inflammation was previously reported by Salvi 2012 (25), Malo 2018 (26), AbdulAzeez 2021 (27).

The results of this study showed that the amount of bone changes after 12 months in PEEK
group showed statistically significant lower mean bone changes than PFM.

These results could be explained by PEEK’s cushioning effect, the fact that the low modulus of elasticity of PEEK copings could have absorbed more energy from the functional occlusal loads than PFM ones, and transferred less energy to the supporting structures. Therefore, PEEK might absorbed the occlusal forces, and thus decreased its effect on the bone implant interface (28,29).

The results were in agreement with Taha & Sabet 2021 (31) reported that the force damping is mostly material dependent, as per implant-supported crowns fabricated from resilient materials such as polymer-infiltrated ceramics and PEEK showed better force absorption than rigid materials such as zirconia and lithium disilicate ceramics.

In line with the results of the present study, Canto´-Nave´s 2021 (32) evaluated the stresses in crown, abutment, and cortical bone under dynamic impact loading when using different materials for single implant supported crowns through finite element analysis (FEA). They found that Composite veneered PEEK implant supported crowns generated lower stress peaks at the cortical bone than ceramic veneered Co-Cr crowns. They stated that the use of Composite veneered PEEK can absorb and dissipate the stresses transferred to the implant. So, it diminished the risk of having bone resorption around the implant.

However, these findings were in disagreement with the data reported in previous randomized clinical trial by Mahrous 2018 (33) who found no statistical significant difference between PEEK and zirconia implant supported crowns. They related the comparable biomechanical responses of different implant crown materials to the implant abutment being the main structure that can absorb the total applied energy (34).

The results of this study were in disagreement with the result of randomized clinical trial by Elwan 2021 (35) who evaluated the use of titanium and PEEK abutment restored with PEEK and VITA Enamic crowns radiographically using paralleling technique at baseline, 3, 6 and 12 months. They concluded that PEEK abutment was considered a better alternative to titanium abutment in relation to hard tissue response, in addition to having a good role in occlusal force distribution. They also stated that the marginal bone loss was reduced when PEEK abutments were used compared to titanium abutments regardless the type of superstructure crown.
In literature, the amount of crestal bone loss (CBL) was reported to be 1.0 – 1.2 mm in the first year of implant insertion and 0.1 – 0.2 mm for each succeeding year. Which was considered a normal physiologic bone remodeling (36). However, recently new implant designs with novel surface characteristics showed lower CBL rates than the earlier reports (37–39).

LIMITATIONS

The present study has some limitations. Firstly, the follow up period which was one year after implant loading. Secondly, a larger sample size may possibly increase the statistical power of the multivariate analysis. Thirdly, the use of periapical radiographs which allowed bone tissue visualization only in mesial and distal sides. Where 3D radiographic imaging couldn’t be achieved.

6. CONCLUSIONS

Within the limitation of this randomized clinical study, the following conclusions were pointed out:

1. PEEK implant supported crowns appeared to reduce the amount of CBL compared to PFM crowns in the posterior region.
2. The peri implant soft tissue parameters around PEEK crowns were comparable to PFM crowns.

7. CLINICAL IMPLICATIONS:

1- Strict polishing protocol for the veneering composite is mandatory, for achieving healthy peri-implant soft tissues.

2- Firm oral hygiene measures must be maintained along with regular follow up visit, for avoiding peri implant diseases, and preservation of crestal bone loss.

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