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EFFECT OF SUPERSTRUCTURE MATERIAL ON PINK ESTHETICS & MARGINAL BONE LOSS AROUND IMMEDIATE LOADING IMPLANT: A RANDOMIZED CONTROLLED TRIAL WITH 1 YEAR FOLLOW-UP

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ABSTRACT

Purpose: The purpose of the present study was to determine the marginal bone loss and analyze peri-implant soft tissue using PES around single immediate loading implant with different superstructure materials (PMMA, zirconia, PEEK).

Materials& Methods: A single center blind and parallel group study applied on 17 patients (17 implants) in the age group 25-40 years with a thick gingival biotype and intact buccal bone wall of healed extracted upper centrals or upper 1st premolar. All patients were receiving delayed implantation with immediate non-occlusal loading utilizing different superstructure material. Group (A) control: PMMA crowns for 6monthes followed by final zirconia crowns, group (B) Zirconia crowns and group (C) PEEK crowns. Patients were recalled for follow-up and PES was analyzed at 3, 6, and 12 months while marginal bone loss was determined at 6 and 12 months.

Results: The results of pink esthetic score (PES) and the marginal bone loss (mm) showed no significant difference between different groups at different follow-up intervals (P>0.05) while marginal bone loss for all groups recorded at 12 months a significantly higher mean bone loss value at 12 months than 6 months (P>0.05),

Conclusion: within the limitation of the current study, immediate loaded implants with zirconium and PEEK superstructure had a minor role on enhancing peri-implant soft tissue esthetics and decreasing the marginal bone loss.

KEYWORDS immediate loading, marginal bone loss, PES, peek superstructure, zirconia superstructure, PMMA.

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INTRODUCTION

Higher success rates of implant supported restorations have been documented by long term clinical trials in last years with subsequent wide acceptance of its use as a first restorative option in many clinical situations[1]. With these promising results, the esthetic outcome has become the main focus of interest during implant procedures especially when restoring single tooth loss at esthetic zone[2&3].

Planning optimal implant restoration in the aesthetic area requires a thorough communication between both the surgeon and the prosthodontist. It is influenced by many factors as the anatomical position, the various prosthetic materials and designs of the superstructure[4].

Esthetics is subjective and patients' opinion should be considered together with professional assessment using the objective factors. These objective factors can modify the success rate of single tooth implant restoration including the level of the peri-implant soft tissue with its effect on the crown length. Also, the similarity in color and texture of soft tissue surrounding implants with contralateral teeth are decisive for the 'natural' appearance. Albrektsson's criteria of implant success were extended by Smith and Zarb: 'To be considered a success, an implant must allow placement of a restoration with adequately esthetic appearance'[2, 5&6].

But the objective criteria of what can be considered as 'adequately esthetic' have so far not yet been clearly available in the field of esthetic implant dentistry. Many trials and studies were tried to organize the esthetic assessment in a standardized method. A systematic review by Benic et al 2014[7] analyzed the parameters and methods used for esthetic assessment in implant dentistry and concluded that scoring systems greatly differed between studies. On another hand, criteria assessing bone quality, bone loss and papilla score are widely used in implant dentistry[8].

Fürhauser et al[9] applied the pink esthetic score (PES) for soft tissue esthetic assessment. PES combined seven parameters; the mesial papilla; the distal papilla; level of soft tissue margin; soft tissue contour; alveolar process deficiencies; soft tissue color and texture. A score of 0-2 (0 is the worst while 2 is the best) was utilized for assessment resulting in a maximum score of 14.

Traditionally, dental implants required a healing period of 3 to 6 months before loading but this may increase patient burden especially when restoring an esthetic zone. Many studies have shown increased success rates of implants with immediate loading[10&11] with no changes in osseointegration process[12] or the level of bone loss[13]. In view of these, a meta-analysis by Zhang et al in 2017[14] compared clinical and radiographic outcomes of many recent randomized controlled trials evaluating loading protocols. Zhang et al supported the immediate loading protocol as a good selection in implant restoration reducing the treatment time without influencing marginal bone loss or osseointegration.

With the advent of CAD/CAM technology in of prosthetic dentistry, development of new materials for chair-side milling was increased. Zirconia had been the material of choice for last years with its unique biomechanical properties.[15]

PEEK is a thermoplastic polymer with high mechanical performance that has been used in general medicine since the 1980s. in the last years, its applications in dentistry had been increased. PEEK can be used as an implant material, milled framework and abutment material[15-17].

The aim of the present study was to analyze peri-implant soft tissue using PES score and the marginal bone loss around single immediate loading implant with different superstructure materials (PMMA, zirconia, Peek).

The 1st null hypothesis was that the PES score

will be significantly higher with PEEK than with the other groups and the 2nd one was that the marginal bone loss will be significantly lower than the other groups.

MATERIAL AND METHODS

The present study was a single center, prospective, randomized controlled and single blind clinical trials that carried on 17 patients (6 men and 11 women, taking into account 10% dropouts if present)) in a private practice, Cairo, Egypt. Patients were seeking prosthodontics treatment of their missing upper central or first premolar. The patients were in age group 25 to 40 years. All implants were inserted by same clinician between September 2015 and December 2016, patients were fully informed about the study design, follow-up and complications. A written consent was signed from the patient after discussing all the treatment options and required follow-ups. Study was conducted in accordance with Helsinky declaration of 1975 for medical study as revised in 2000.

Patient population

The inclusion criteria for patient enrolment in this study were:

1. Age between 25- 40 years.
2. Willingness to sign an informed consent.
3. Good medical health with good oral hygiene.
4. Needed one or more single-tooth implant-supported restorations in the maxillary 1st premolar area.
5. Had natural tooth on opposite side and adjacent to implant site without any ulceration or inflammation.
6. Had a stable favorable occlusion.
7. Had healed extraction socket with minimum three intact walls and need no graft.
8. Had the criteria of immediate temporization within 72 hours.

While the exclusion criteria included the followings:

1. Had history of alcohols or drug abuse.
2. Had any occlusion disorders or para-functional habits.
3. Had adjacent teeth with ongoing inflammation, endodontic treatment, periodontal problem or surgical problems.
4. Lack of adequate primary stability at implant insertion (implant insertion torque is 35Ncm).

Surgical and Prosthetic planning:

Full Arch impression was made in both arches. Casts were poured and mounted on articulator. A diagnostic wax up was made to represent the anatomy and ideal locations of the planned implants and prosthetic designs. Model was finally scanned using CBCT machine and the DICOM data was processed to obtain STL file for the model.

Standard CBCT scanning procedures with standardized setting of 90 kV, 6.3mA, an exposure time of 12 s and voxel size of 0.2 mm were followed for each patient. The scanning was performed by the same radiologist operating a CBCT machine (Planmeca promax 3D classic, Planmeca, Finland).

For virtual planning of implant surgical guide, the resultant CBCT were imported into the implant planning software (Blue Sky Plan® V3, Blue Sky Bio, LLC, USA). The digital image segmentation was performed and the virtual implant was placed in the most optimal position according to the surgical and prosthetic design.

Surgical Guide Printing:

The designed virtual template was transferred as STL files and printed with a three- dimensional printing machine (Form 1+, Formlabs, USA). The metal sleeves for guided surgery were manually pushed into the respective nots.

Surgical procedure

A full thickness muco-periosteal flap was elevated to expose the hard tissue. After the harvesting of the bone sample, the preparation of the bony bed was completed at the same site and a dental implant (TRI® implants, TRI Dental implants, Bösch, Germany) was placed according to the manufacturer's surgical protocol. Primary stability (≥35Ncm) was confirmed by torque controller for all cases.

Prosthetic procedures

Implant level impression was taken after flap suturing using polyvinyl siloxane impression material (Aquasil LV, Putty/Light Body, Dentsply, Germany) for all cases by same prosthodontist.

A healing abutment was placed till superstructure cementation. Patients were instructed to use 0.2% chlorhexidine digluconate twice daily for the first month after surgery with modified oral hygiene instructions.

Patients were randomly divided at site level into 3 groups using randomized trial software program (Researcher Randomizer), random allocation after impression taking was done by an investigator who was neither involved in the treatment nor outcome assessment, so as to make allocation concealment.

Group A (n=5): Control group, received PMMA crowns for 6 months followed by final zirconia crowns.

Group B (n=6): Zirconia group, received zirconia crowns.

Group C (n=6): PEEK group, received PEEK crowns.

Regarding group B & C, the crowns were designed milled using CAD/CAM zirconia and PEEK blanks by the same technician and veneered following manufactures instruction to standardize the procedure.

Group A (control), PMMA crowns were also designed and milled as the other groups. Six month later, PMMA crowns were replaced with final zirconia which were milled following same steps as group B and with same technician. Great attention was paid for this group to replicate accurately the emergence profile of the provisional PMMA crowns.

All crowns were designed with non-occluding surface. Final restoration was cemented to the implant within 72 hours after surgical procedure using provisional cement (Temp-Bond NE, Kerr,Scafati, Italy). All prosthetic steps were performed by same prosthodontist.

Follow-up examination

I- Esthetic assessment

Peri-implant soft tissue esthetic outcome was analyzed using the pink esthetic score (PES) based on the parameters defined by Fürhauser et al[9]. Seven variables were assessed, including the mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiency, soft tissue color, and soft tissue texture. A score of 2 (the best), 1 or 0 (the worst) was assigned to each PES parameter. The mesial and distal papillae were evaluated for completeness=2, incompleteness=1, or absence=0. All other variables were assessed by comparison with the contralateral tooth (anterior region) or neighboring teeth (premolar region).

For the overall PES score, the individual scores are summed, meaning the highest possible score is 14 which represented a close match of the peri-implant soft tissue conditions compared to the respective features present at the contralateral natural tooth site.

All implant crowns were photographed immediately after cementation and at 6 month and 12 month with a digital camera (Nikon D100®; Nikon, Tokyo, Japan) and a 105 mm lens (AF micro Nikkor 105 mm 1:2.8 D®; Nikon) with a ring flash (Nikon Macro Speedlight SB-29S®; Nikon).

For proper assessment with the contralateral tooth, the photographs were centered at the midline in order to facilitate the subsequent analysis, which was primarily based on symmetry. A photograph including adjacent teeth was taken to serve as a reference. In addition, standardized clinical photographs were taken of each implant site, as tools for a more detailed evaluation (fig 1).

The aesthetic analysis was performed by an independent periodontitis who had not been involved in the treatment of the patients.

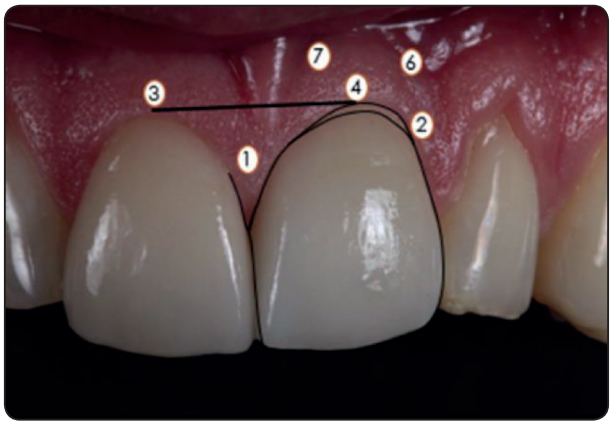

Fig. (1) A case with single implant zirconia crown at 12 month follow-up showing parameters of pink esthetic score (PES). 1, mesial papilla; 2, distal papilla; 3 soft tissue level; 4, soft tissue contour; 6 & 7 represent soft tissue color and texture.

II- Radiographic Evaluation for marginal bone loss:

The area of interest was identified in accordance with the site of dental implants. Axial correction of the view was performed in conformity with angulation of the alveolar ridge.

Patients in all groups received CBCT immediately after the implant placement, 6 months and 12 months postoperatively. Each implant was evaluated for the marginal bone level. The implant shoulder was used as a reference point, and the distance to the first bone contact mesially and distally was measured from the CBCT using Invivo 5 software (version 5.3 Anatomage, San Jose, USA) (Figure 2). All the measurement was performed using software of Planmeca (Romexis Planmeca, Planmeca, Finland.) and same radiologist.

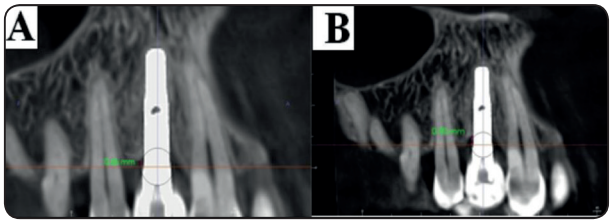

Fig. (2) CBCT of implant loaded by zirconia superstructure showing measurements of distal marginal bone loss at (A) 6 months and (B) 12 months.

Statistical analysis:

Numerical data were explored for normality by checking the data distribution, calculating the mean and median values and using Kolmogorov-Smirnov and Shapiro-Wilk tests. Data showed parametric distribution so; it was represented by mean and standard deviation (SD) values. Intergroup comparisons were done using One-way ANOVA followed by Tukey's post hoc test when the ANOVA test was significant. Intragroup comparisons were done using repeated measures ANOVA followed by Bonferroni's post hoc test when the ANOVA test was significant. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM (Corporation, NY, USA) SPSS (Inc., an IBM Company). Statistics Version 25 for Windows.

RESULTS

In this study 17 patients were recruited at the start of the study, two cases were not reported during follow up period which was well within our estimated dropout percentage

The results of pink esthetic score (PES) showed no significant difference between different groups at different follow-up intervals ($P>0.05$) with the

highest mean score recorded by group (C) and the lowest mean was scored by group (A). For all tested groups, 12 months had the highest mean value and the lowest mean value was found at 3 months with no significant difference between different follow-up intervals for all groups (P>0.05), (Table :1).

Regarding the marginal bone loss (mm), there were no significant difference between different tested groups at different follow-up intervals (P>0.05). Group (A) had the highest mean bone loss while the lowest mean was scored by group (C) at 6 month follow-up. Moreover at 12 months, group (A) had the highest mean bone loss followed by group (C) and the lowest mean was scored by group (B). For all groups, (12 months) had significantly higher mean bone loss value than (6 months) (P>0.05), (Table:2).

Percentage change (%) of increase from baseline to final measurements was calculated using the following formula; (Figure 3 & 4)

A scatter plot of the values of (PES) scores and marginal bone loss (mm) at (6 and 12 months) showed no linear correlation between the two measurements.

TABLE (1): Mean& standard deviation (SD) of pink esthetics score (PES) for different groups at different follow-up intervals

Follow-up intervals	**(PES) [Mean (SD)]**			**P-value**
	Group (A)	**Group (B)**	**Group (C)**	
3 months	9.40 (0.89)	11.20 (2.16)	11.40 (1.14)	0.109ns
6 months	10.20 (1.64)	11.60 (1.14)	12.40 (1.81)	0.120ns
12 months	10.40 (1.94)	12.00 (2.00)	12.60 (1.16)	0.161ns
P-value	0.321ns	0.186ns	0.367ns	

; significant (p ≤ 0.05) ns; non-significant (p>0.05)

TABLE (2): Mean& standard deviation (SD) of marginal bone loss (mm) for different groups at different follow-up intervals

Follow-up intervals	**Marginal bone loss [Mean (SD)]**			**P-value**
	Group (A)	**Group (B)**	**Group (C)**	
6 months	0.61 (0.20)	0.47 (0.19)	0.45 (0.24)	0.595ns
12 months	1.22 (0.40)	0.92 (0.35)	1.02 (0.39)	0.478ns
P-value	0.002*	0.20*	0.003*	

; significant (p ≤ 0.05) ns; non-significant (p>0.05)

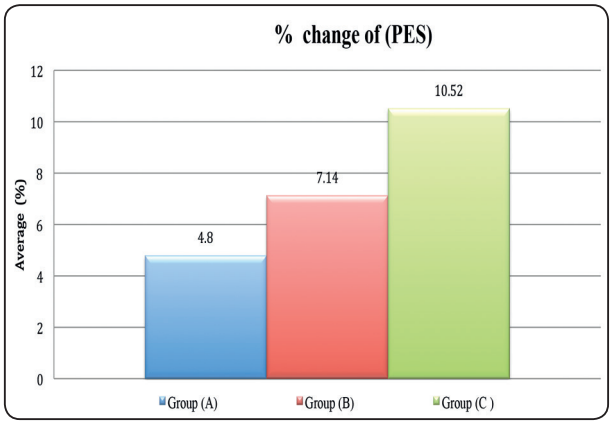

Fig. (3): Bar chart showing average percentage change (%) of pink esthetics score (PES) for different groups.

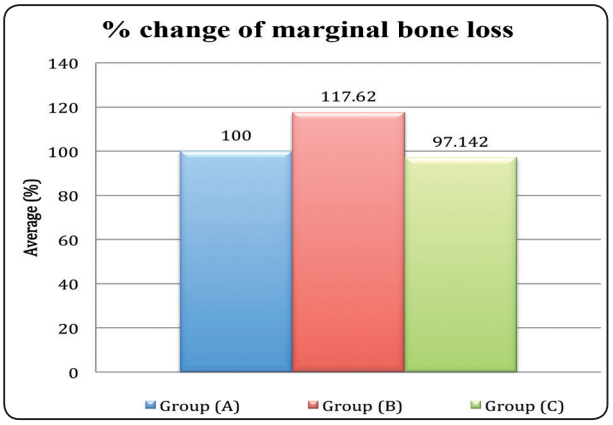

Fig. (4): Bar chart showing average percentage change (%) of marginal bone loss for different groups

DISCUSSION

The rehabilitation of single tooth loss in esthetic zone with implant supported restoration is a common restorative option nowadays with continuous challenges for surgeons and prosthodontists. Esthetics has become a success key in implant dentistry. Ideal esthetic implant prosthesis is described by visually accepted restoration with healthy, harmoniously scalloped soft tissue[5, 18].

The assessment of the esthetic outcomes has become an imperative part of clinical studies with reference to many trials using objective parameters as papilla presence or absence, level of mucosal margin as well as the color, shape and texture of contralateral tooth[2, 6]. Esthetic index can facilitate analyzing the outcomes and act as a checklist for improving the final treatment[19].

The PES integrates the soft tissue height, level with the color and texture of the peri-implant soft tissue and so PES based on seven variables for a more practice-oriented evaluation using a simple rating system. It is mainly rated by three categories (good, fair, poor) because more detailed ratings are problematic in the intermediate category. PES is a score of several single variables with less sensitivity to misjudgments than a single-variable score which has a more dramatic effect (100%) than one of seven variables (14.2%)[9, 18]. Barris et al in 2016 mentioned that PES score is a good tool for analyzing esthetic around single implant restoration with a better reproducibility[19].

Conventionally, a healing period of three to six months is needed for proper implant osseointegration but the longer treatment procedures may increase the patient discomfort[8]. However, many studies[11-13] and meta-analysis[14,20,21] reported that osseointegration was not influenced by the loading time. Moreover, randomized controlled trials compared the early and immediate loading reported inconsistent results regarding implant stability and bone loss[22]. On another level, the loading time has been concerned to affect the final esthetics.

It's important to mention that in the current study, the implants were restored with immediate restoration but not immediate loading as any contact in centric occlusion or lateral excursion with the opposing dentation was removed to avoid early risk of occlusal overload.

Zirconia has been considered one of the best materials for implant superstructure due to its well-documented biocompatibility and mechanical properties[23] while PEEK have an elastic modulus almost 60 times lower than that of zirconia demonstrating expected low stress values within the structure[15-17].

The relationship between load factors and pink esthetics cannot be ignored any longer because of the high incidence of marginal bone loss and loss of osseo-integration in situations of compromised prosthetic reconstruction and/or extreme load conditions[24].

According to the present results, both null hypotheses were rejected. Generally, the results of the current study reported that there were no statistically significant differences in PES score between different superstructure materials at different follow-ups (Table 1). Based on different clinical studies[25-29], superstructure materials had no significant changes in PES score and alveolar bone loss. On the other hand, it is inspiring to note that Brakel et al [30] found significantly higher PES around zirconium superstructure in comparison with non-ceramic superstructure.

The surface roughness of zirconia and PEEK superstructure may play an important role in PES and marginal bone loss. In-vitro studies showed that the surface roughness of the different superstructure materials has a significant value on cell performance with superstructure materials[31]. It was stated that comparing polished zirconia surfaces with PEEK surfaces will resulted in a better lower adhesion media for attachment cells. It could be speculated that decrease pocket probing depth around implant superstructure is greatly affected by the well adherence of the gingival cells to the superstructure materials[32&33].

Furthermore, oral biofilm of different superstructure materials reported that the PEEK and PMMA materials showed a high concentration of microorganism numbers and biofilm mass. This was explained by increase in surface roughness of these materials with increase their bacterial adhesion. Oppositely, zirconia superstructure showed free energy surface which lead to decrease bacterial adhesion on its surface. Decreasing bacterial adhesion and consequently biofilm formation on implant superstructure surface is considered as a main approach on clinical practice to preserve the soft tissue integrity and improve the peri-implantitis treatment[31&34].

Moreover, PEEK and zirconium superstructure showed hydrophobic activity due to thick peptidoglycan layer that attract immediately the gram-positive bacteria. In the opposite hand gram-negative bacteria will be fend off. Although the hydrophobicity of PEEK and zirconium superstructure play an important role for bacterial adhesion but the bioactive layer PEEK shows semiconductor structures, and this may explain debated results in the results[35].

Usually the margin of the implant superstructure is placed 1-1.5 mm sub-gingival below the gingival crest for better emergence profile. But this sub-gingival location may adversely affect the removal of excess cement. As a result of extreme difficult to remove the cement, biological complication was speculated.

Therefore, this complication is not only related to cementation procedures only but the superstructure materials in form of surface energy were also a main issue[36, 37].

AS for marginal bone loss (Tablel: 2), the results of the present study revealed that group (A) had the highest mean marginal bone loss while the lowest mean was scored by group (C) at 6 month follow-up with no significant differences. Moreover at 12 months, group (B) had non-significant lowest marginal bone loss.

Kaleli et al in 2018[38] mentioned that the change in prosthesis materials does not lead to major differences on the stress patterns. Many studies reported that the difference in superstructure and abutment materials had no effect on stress distribution and peripheral bone loss with similar biomechanical behavior[39-41].

On another way, the PEEK customized abutments, which have an elastic modulus almost 60 times lower than that of zirconia customized

abutments, demonstrated low stress values within the structure but also generated great stress in restorative crowns[16, 42]. Another study showed that abutment material had no effect on stress distribution in implants and peripheral bone, but the zirconia customized abutments resulted in favorable stress values in the restorative crowns[38].

It was suggested that the low level of the elastic modulus of PEEK material is thought to provide insufficient support and generate more stress on the surrounding structure[42].

Wang et al stated that there were no differences on the total energy transferred to the implant-bone interface with changes in superstructure materials and displacement. This total energy was passed through the abutment-implant interface first before transferred to the implant-bone interface. Some of the transmitted energy is thought to be absorbed by the intermediate structures. This may explain the similar biomechanical responses in implants with different superstructure materials[41].

Finally, PEEK superstructure is a promising restorative option in recent years, but it is scarcely reported in researches. It is a more economic material than zirconia. Moreover, the correlation between peri-implant soft tissue esthetics and marginal bone loss with different materials is still not clearly determined.

CONCLUSIONS

Within the limitations of the present study,

1- Immediate loaded implants with PMMA before final zirconium crowns had no effect on enhancing peri-implant soft tissue esthetics or marginal bone loss.

2- PEEK superstructure is a promising restorative option enhancing peri-implant soft tissue esthetics and decreasing the marginal bone loss.

3- Marginal bone loss increased with time regardless of the superstructure material.

Finally, there are insufficient randomized clinical trials assessing both peri-implant soft tissue and marginal bone loss of PEEK. Subsequently more clinical trials are required to study and assess the correlation between soft tissue esthetics and marginal bone loss with different materials. Further studies are required with increased sample size and follow-up period to evaluate the long term clinical success.

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