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EVALUATION OF PATIENT SATISFACTION AND PERI-IMPLANT PARAMETERS OF TWO TYPES OF CUSTOM MADE ESTHETIC IMPLANT ABUTMENTS: A RANDOMISED CLINICAL TRIAL

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Abstract— **Aim:** to evaluate patient`s satisfaction and peri-implant parameters around dental implants restored with customized PEEK abutments compared to Zirconium abutments and loaded with PEEK superstructure. **Methodology:** 30 implants in the esthetic were restored with custom made hybrid abutments made from PEEK (n=15) and zirconium (n=15), both groups were loaded with PEEK crowns veneered with Visiolign., outcomes were assessed at time of superstructure insertion (T0), 3 months (T1), 6months (T2) and 12 months (T3) after loading. Patient`s satisfaction was measured using the visual analogue scale (VAS), Peri-implant parameters included bleeding on probing (BOP), plaque index (PI) and probing depth (PD) were measured using a graduated periodontal probe. **Results:** There was no statistically significant difference between PEEK and zirconium abutments regarding patient`s satisfaction, Plaque index, Probing depth, however PEEK abutments group showed statistically significant lower BOP results at T1. **Conclusions:** Within the limitation of the current study it was concluded that PEEK is a viable substitute to zirconium abutments when restoring dental implants, with the advantage of decreasing plaque accumulation.

Keywords: peri-implant, esthetic implants, PEEK superstructure.

Introduction:

The use of dental implant in the restoration of missing teeth became a routine treatment modality due to its high success rates and proven biological and mechanical advantages[1]. Recently dental implants placement and restoration became more patient centered and mainly with the esthetic outcome and pink dynamics around dental implants[2]**.** In the esthetic zone implant success is not only measured by the survival rate but also by the ability to mimic the soft tissue architecture of the adjacent dentition and restore the implant with a prosthesis which is in harmony with the adjacent teeth [3]**.**Such concerns are associated with the darkness of soft tissues around dental implants and the metallic color of titanium abutments under translucent all ceramic crowns, therefore the use of non-metallic abutments such as zirconium became common to improve esthetics and soft tissue response and emergence profile around dental implants[45]

Authors claimed that loading the implants with rigid metal abutments and frameworks can result in high impulse loading of the implant and supporting bone and that the use of resin based materials as an alternative can act as shock absorber and decrease the load falling on the implant and bone[67]. The materials most commonly used as a framework for the fixed dental prosthesis is either zirconium, Nobel metal or titanium, all characterized by having increased weight and a modulus of elasticity much higher than the alveolar bone around the

implant, which leads to the transmission of higher loads to the underlying implants with higher possibility of failure and bone resorption [8].

Recently with the development of new materials such as Polyetheretherketone (PEEK), a polymer having lighter weight than conventional framework materials and modulus of elasticity comparable to bone (18 GPa) [9], can significantly decrease the stresses falling on the underlying implants thus increasing the survival and clinical performance of dental implants [10]. Moreover, PEEK has good biocompatibility and causes no toxic or inflammatory side effects [11].

However there is no enough clinical evidence regarding the clinical performance of PEEK as an abutment or a restorative material over dental implants nor its expected benefits to the patient regarding esthetics and decreased peri-implant inflammatory response. So the aim of the current study is to evaluate the patients` satisfaction and the clinical and radiographic performance of PEEK material as an abutment and superstructure to restore dental implants.

Materials and Methods:

The trial was conducted in the outpatient clinic of the fixed prosthodontics department – faculty of dentistry- Cairo University. The main investigator selected the patients that fulfilled the inclusion criteria by screening of patients until the target population was reached

Inclusion Criteria:

1. Patients above 18 years old
2. Patients able to comprehend and legally competent to sign the informed consent.
3. Medically free patients or medically controlled.
4. Missing tooth in the esthetic zone
5. Minimum bucco-lingual bone width of 6mm, evaluated using CBCT.
6. Good oral hygiene and favourable occlusion.
7. Cooperative and motivated Patients.

Exclusion Criteria:

1. Patients over the age of 60
2. Patients who are unable to comprehend or sign the informed consent form
3. Uncontrolled diabetes, vitamin D deficiency and patients undergoing chemo/radiotherapy
4. Poor oral hygiene or unfavorable occlusion
5. Insufficient bone quantity or quality for implant placement.

The Sample size was calculated using the G*Power software version 3.1.9.2 :

$$Cohen's\ d = (M2 - M1) / SDpooled$$
$$SDpooled = \sqrt{((SD1 + SD2) / 2)}$$

Where M1= 4.4167, SD1= 0.88, M2=3.5 and SD2=0.51

Assuming an effect size of 1.28, a type I error of 0.05 and a power of 0.8, a sample of 22 subjects (11 for each group) is required to detect a significant difference between the two groups regarding the VAS. For a possible drop-out rate of approximately 25-30%, the sample size will be increased to 30 subjects (15 for each group)

Randomization and blinding:
A random sequence was generated using computer software (http://www.random.org/). The randomization table was printed where one column assigned for the intervention group (PEEK abutments) and one for the control (Zirconium abutment). The randomization table was kept with co-investigator.

30 folded numbered papers were packed in opaque sealed envelopes by the operator and were dragged by the patients. After the participant was confirmed eligible for the study, the participant dragged an envelope and was given a number. Based on this number the patient was allocated according to the generated random sequence to either intervention or control group.

Diagnosis:
Diagnosis was performed by accurate history taking to make sure that the patient was free from the aforementioned conditions that my lead to exclusion, clinical intra-oral examination of the edentulous site Peri-apical radiographs and a cone beam CT for accurate assessment of the bone volume and anatomy at the surgical site in both sagittal and coronal cuts. *(fig.1)*

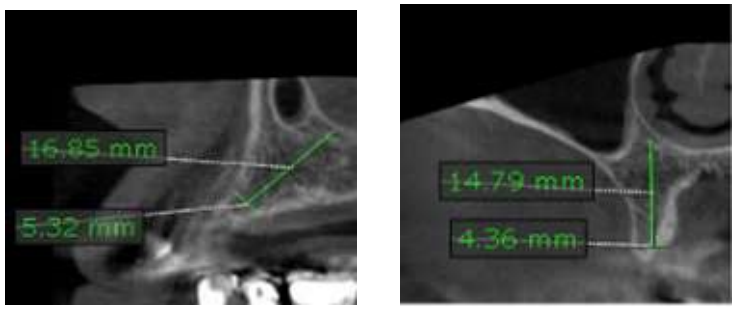

Figure 1:Measurement of bone volume on(A) Sagittal section of CBCT (B) Coronal section of CBCT

Implant insertion:
The surgical site was locally anaesthetized by local injection of Articaine 4% *(Septanest, France)*and left for 5 -10 minutes after which he/she was examined for subjective signs (prick with a sharp explorer) and objective signs (feeling of numbness)

A full thickness flap was elevated at the surgical site using #15 blade with a sub-crestal incision to expose the crest of the bone and two vertical releasing incisions. The flap was reflected using a muco-periosteal elevator. Sequential drilling was performed according to the desired implant diameter using the drills provided by the surgical kit (Osteocare implant system- UK) *(fig.2)*

The implants were inserted manually into the osteotomy using the ratchet wrench and driver until the platform was flush with the bone. The initial stability of the implant was tested with the torque wrench at 30 N. cm and the implant hex was closed using a cover screw *(fig.3)*. The Flap was repositioned using a tissue forceps and suturing was done to secure the flap in position using a 4-0 silk suture material and a peri-apical radiograph was taken to confirm the implant position and assure it is away from all vital structures by 2mm. *(fig.4)*.

The Patients were given post-operative instructions and hygiene measures and prescribed Augmentin 1gm / 12 hours for 7 days and analgesics to relieve pain (Brufen 400 mg tablets)

Figure 2: Intraoral photograph showing (A) osteotomy preparation using the pilot drill (B) osteotomy preparation using sequential drills

Figure 3:Intraoral photograph showing the implant in place with platform flush with the crestal bone and cover screw secured in

Figure 4: A periapical radioghraph showing the inserted implant with platform flush with the crestalcone

Re-entry

After three to four months, the patients were recalled for the 2nd stage surgery and implant exposure. Peri-apical radiographs and intra-oral photographs were taken. The patients were anaesthetized and the implant were exposed by a crestal incision using a #15 blade. The cover screws were removed using a 1.5 mm screw driver and replaced with a healing collars which were left for 2 weeks. *(fig.5)*

Impression making:

After 2 weeks the healing collars were removed *(fig.6)* and the impression transfers were placed for an open tray technique were screwed over the implant and a double mix single step impression (putty soft & light) was made*(fig.7)*, after setting the impression material the transfers were unscrewed from the implant and the impression tray was removed from the patient`s mouth, the implant analogueswere then fixed to the impression transfers (*fig. 8*).

Figure 5: Healing collar placed after crestal incision in the 2nd stage surgery

Figure 6: Healing collar removed after 2 weeks of healing

Figure 7: Impression transfer placed inside the patient`s mouth for an open tray impression

Figure 8: extra-oral photograph of the Final impression with impression transfer and implant

Secondary impressions were poured with scannable extra hard stone (Elite rock, extra hard stone type IV – Zhermack) into master casts with silicone soft tissue mimic material. Scan bodies were then fixed to the implant replicas with the flat surface facing buccal for scanning. The casts were placed in the 3-shape desktop scanner, a new order form was created and the scanning mode was set to customized abutment.

The implant library was loaded and the implant diameter was selected, the material of the abutment was set for zirconium/ PEEK according to the group *(fig. 9)*

Figure 9: scan bodies fixed to the master cast and scanning on 3-shape software

Theemerg
ence profile of the custom abutment was adjusted to follow the anatomical gingival contour. After that the anatomy of the final crown and the core of the custom made abutments were adjusted*(fig 10).*The abutment core was milled from either PEEKor Zirconium blank according to the group.The superstructures were milled in the form of PEEK copings and were later veneered with visiolign. The Abutment cores were cemented to the Ti-baseusing panavia-F.*(fig 11)*

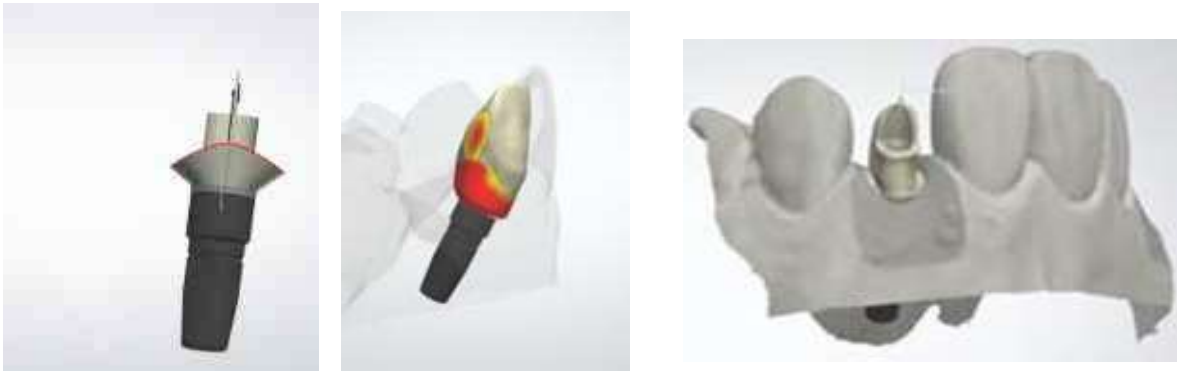

Figure10: Adjustment of the emergence profile of abutment core contour and the screw hole and crown anatomy

Figure 11: PEEK abutment with PEEK superstructure

the abutments were fixed on the implant using the abutment screw and the 1.5 screw driver and torqued *(fig. 12),*The final PEEK crown was then placed over the custom abutment and checked for the marginal adaptation and occlusal interferences *(fig.13)* Cementation was done using a dual cured, self-adhesive resin cement, light curing of the margins was done for 10 seconds(Tack curing) for removal of the excess cement then the curing was continued for 40 seconds on each surface.

Figure 12: Intra-oral photograph showing torquing of the customized abutment after fixation on the implant

Figure 13: Intraoral photographs showing the final PEEK superstructure in different regions of the mouth

Patients` satisfaction was assessed using the Visual analogue scale (VAS) ; a numerical scale from 0-10 with 0 being the lowest value (dis-satisfied) and 10 being the highest (highly satisfied). The patient was asked to fill the VAS at time of crown delivery (T0), 3months (T1), 6 months (T2) and 12 months (T3).

Bleeding on probing:

A periodontal probe was inserted in the sulcus of the patient with light pressure and removed, and the BOP score was recorded according to [12]*Table 1* and the procedure was repeated at T1, T2 and T3.

Table 1: Measurement scores of bleeding on probing (BOP)

Score	Clinical picture	Indication
0	No BOP	Normal ginigiva
1	Isolated bleeding spots visible with color change and minor edema	Mild inflammation
2	Blood forms a confluent red line on mucosal margin redness, edema, and glazing	Moderate inflammation
3	Heavy or profuse bleeding with redness, edema, ulceration, and spontaneous bleeding without probing	Severe inflammation

Probing depth:
A graduated periodontal probe was inserted inside the sulcus with light pressure at 6 different positions Mesio-buccal (MB), Mid-buccal (B), Disto-buccal (DB), Mesio-palatal (MP), Mid-palatal (P) and Diso-palatal (DP). The values were recorded in the patient`s chart and the procedure was repeated at T1, T2, and T3.

Plaque index:
Plaque accumulation was assessed visually and by running a smooth periodontal probe on the crown surface. Values were recorded according to ***Mombelli et al., 1987*** [12]and ***Lindquist et al., 1988*** [13]3-point scale (*Table 2)*, patients with visible plaque accumulation at the follow up visits were instructed to adhere to more strict oral hygiene measures. Records were repeated at T1, T2 and T3.

Table 2: Measurement scores of plaque index (PI)

Score	Clinical picture
0	No detection of plaque
1	Plaque only recognized by running a probe accross the smooth implant marginal
2	Visible plaque accumilated in the implant surface
3	Abundance of soft matter

Numerical data were explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). Patient satisfaction scores, PI scores as well as BOP scores showed non-normal (non-parametric) distribution while crestal bone loss data showed normal (parametric) distribution. Numerical 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 the groups. Friedman's test was used to study the changes by time within each group. Dunn's test was used for pair-wise comparisons when Friedman's test is significant. For parametric data; repeated measures ANOVA test was used to compare between the groups as well as to study the changes by time within each group. Bonferroni's post-hoc test was used for pair-wise comparisons when ANOVA test is significant.The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

Results:

Patient Satisfaction:

There was no statistically significant difference between median satisfaction scores in the two groups at T0, T1, T2 as well as T3. Within the same group; there was a statistically significant change in patient satisfaction from T0 to T1 as well as T1 to T2. However, there was a statistically significant decrease in scores from T2 to T3. *(fig.14)*

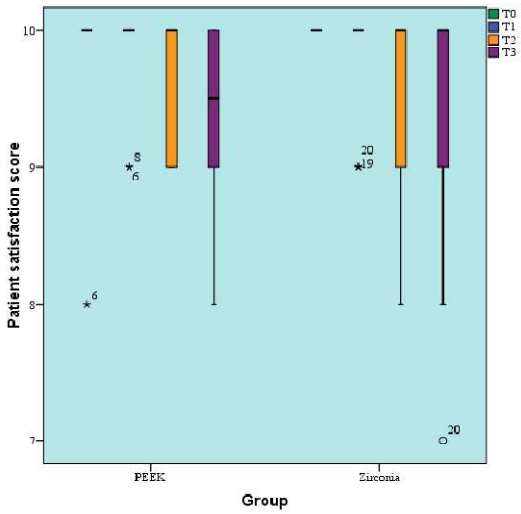

Figure 14: Box plot representing median and range values for patient satisfaction scores in the two groups (Circle and stars represent outliers)

Plaque Index (PI) scores:

At T0, T1, T2 as well as T3; there was no statistically significant difference between median PI scores in the two groups. Within the PEEK group there was no statistically significant change in PI scores from T0 to T1 followed by a statistically significant increase in scores from T1 to T2 then non-statistically significant change from T2 to T3.

Within the zirconium group there was a statistically significant increase in PI scores from T0 to T1 as well as T1 to T2 followed by non-statistically significant change from T2 to T3. *(fig.15)*

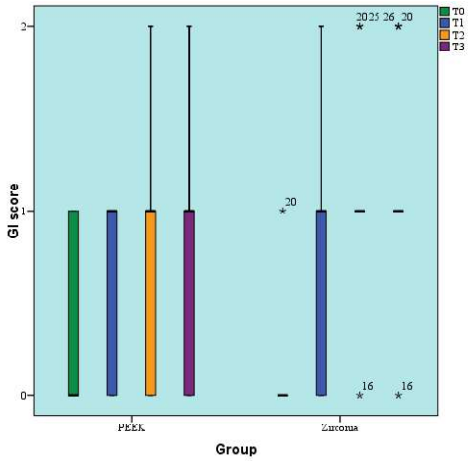

Figure 15: Box plot representing median and range values for PI scores in the two groups (Stars represent outliers)

Bleeding **on Probing (BOP) scores:**
At T0; PEEK group showed statistically significantly higher BOP score than Zirconia group.
At T1; PEEK group showed statistically significantly lower BOP score than Zirconia group.
At T2 as well as T3; there was no statistically significant difference between median BOP scores in the two groups

Within the PEEK group, there was a statistically significant increase in scores from T1 to T2 then non-statistically significant change from T2 to T3. Within the zirconium group, there was a statistically significant increase in BOP scores from T0 to T1 as well as T1 to T2 followed by non-statistically significant change from T2 to T3.*(fig.16)*

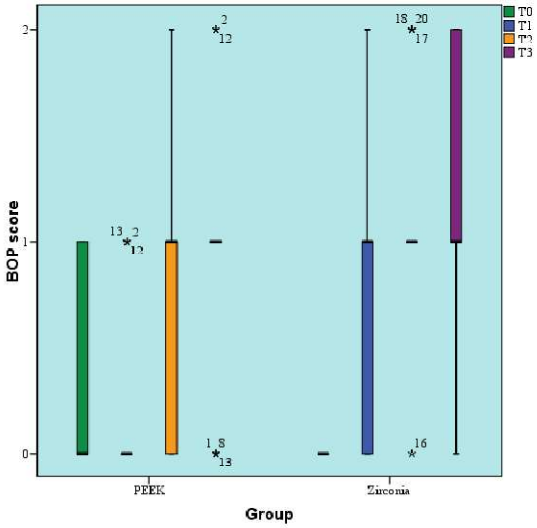

Figure 16: Box plot representing median and range values for BOP scores in the two groups (Stars represent outliers)

Probing Depth (PD) in mm:

There was no statistically significant difference between median PD measurements in the two groups throughout the follow up period. Within the PEEK group there was a statistically significant increase in PD from T1 to T2. Within the zirconium group there was a statistically significant increase in PD from T0 to T1 followed by non-statistically significant change from T1 to T2 then a statistically significant increase in PD measurements from T2 to T3.*(fig.17)*

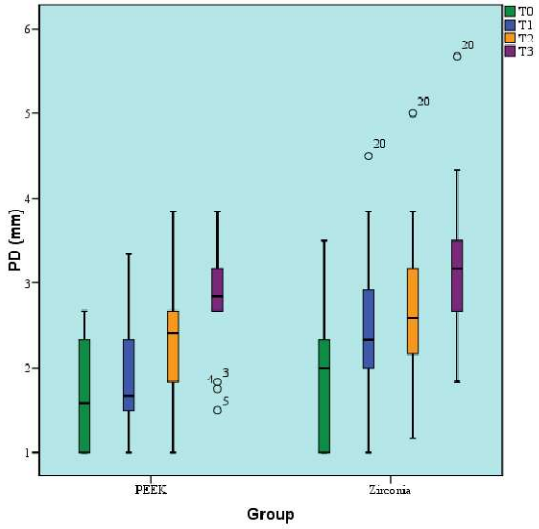

Figure 17: Box plot representing median and range values for PD measurements in the two groups (Circles represent outliers

Discussion:

The success of implant retained restorations is no longer dependent only on survival rates, but also on its ability to restore function and esthetics. The ability of the implant restoration to achieve an appearance that seems to be in harmony with the adjacent teeth and becomes hard to distinguish by the observer`s eyes is a challenging procedure that is highly dependent on the optical characteristics of the crown and the appearance of the surrounding soft tissue or what is known as white and pink esthetics [14]**.** Although titanium abutments have high survival rates attributed to their excellent biocompatibility and mechanical properties, yet they usually cause grayish discoloration of the peri-implant mucosa especially in patients with thin gingival biotype [15]several studies measured the change in color of peri-implant mucosa (ΔE) of titanium, gold plated and ceramic abutments, and found that the ΔE values for titanium abutments were significantly higher than gold plated and ceramic abutments [161718].

Therefore to overcome such esthetic problems, several alternatives to titanium abutments have been investigated and used over the years to produce maximum esthetical outcome such as zirconium, gold plated titanium, pink hued titanium and pink hued zirconium abutments [15]. Moreover metal abutments may have a negative influence on the final esthetic outcome of all ceramic superstructures [17].

In the present study PEEK abutments were used as an intervention. PEEK biomaterials can be considered as a viable option to replacing metals and conventional polymers due to their documented hypersensitivity and the increasing demand for metal free restorations [19] with a modulus of elasticity resembling the dentine and cortical bone, PEEK biomaterials exhibits less stress shielding when compared with their titanium rigid counterparts thus decreasing the incidence of failure [20]. It was found that implant superstructure fabricated from PEEK and veneered by composite produced less stresses in bone when compared to porcelain fused to metal crowns [21]. PEEK has also been found to reduce biofilm formation, bacterial accumulation and improve the soft tissue stability around dental implants [92223] Being biologically inert, having low density, un-obstructive gray coloring and low plaque accumulation has made PEEK a viable option for implant abutments and superstructure fabrication[2425].

The results of the present study showed no statistically significant difference in patient satisfaction results between PEEK and zirconium abutments . PEEK crowns showed no change from T0-T1, T1-T2 however it decreased from T1-T3 this may be attributed to minor chippings in the veneering composite, increased surface roughness and staining of the composite veneering as stated by [26]. This also comes in consensus with [27]who concluded that PEEK crowns showed less patient satisfaction than porcelain fused to metal crowns after 1 year follow up and that within PEEK group patient satisfaction with PEEK crowns decreased after 6 months of cementation.

Some patients in the PEEK group complained of change in the color in their PEEK crowns after 6 months saying it became darker than the initial color at the time of insertion. This might be due to the hydrophilic resin nature of the veneering composite which permits water and beverages sorption leading to darkening of the restoration color [27].

Plaque index results showed no statistically significant difference between both groups, these results comes in consensus with [23]who found that PEEK abutments showed similar or slightly lower plaque accumilation when compare to zirconium and titanium abutments invitro and [28]who stated that there was no statistically significant difference between PEEK and zirconium abutments in plaque accumulation where PEEK showed a slightly less plaque accumulation than zirconium, this has been attributed to the fact that the surface roughness and surface energy of PEEK is lower than that of other machined materials such as zirconium and titanium which contributes to less plaque accumulation and biofilm formation.

Within the PEEK group plaque accumulation showed no difference from baseline (T0) to 3 months (T1) which can be due to the low surface roughness and surface energy when compare to the Zirconium group that showed significant increase in the plaque accumulation from T0 – T1. Both groups showed significant increase in plaque accumulation from T1 – T2

which can be due to failure in maintaining proper oral hygiene measures by the subjects, however in the follow-up visits subjects were instructed to increase and maintain their oral hygiene regimen, which resulted in no significant difference in plaque accumulation from T2 – T3.

PEEK group showed a significantly higher bleeding on probing (BOP) values compared to zirconium group at T0, however after insertion of the superstructure, patients were instructed to adhere to strict oral hygiene measures, which resulted in a significantly lower BOP values at T1 due to the fact that plaque accumulation in PEEK is less than zirconium as stated by [23]. At T2 and T3 there was no statistically significant difference between both groups. These results are contradictory with **(Ayyadanveettil et al., 2021)** that found no statistically significant difference in BOP between PEEK and zirconium abutments from superstructure insertion and up to 5 years follow up.

Probing depth values showed no statistically significant difference between both groups, which is consistent with **(Ayyadanveettil et al., 2021),** and both groups showed a mean Probing depth after 1 year of prosthesis insertion that is within the normal range (PEEK = 2.79 ±0.68and Zirconium =3.24 ±0.93). [29] stated that mild peri-implantitis starts with a probing depth > 4mm, [30]stated that an implant is considered to be suffering from peri-implantitis if it shows a probing depth > 5mm, therefore the results of the current study indicate that both groups are within the normal readings.

Within the PEEK group, there was no differnce in the probing depth from T0 – T1 , however showed a significant increase from T1-T2, this can be due to the fact that T2 reprsent 9 months post-implant insertion which means it's the close to the end of the 1^{sst} year which exhibits the highest rate of bone resorption of 1mm – 1.5 mm and then the rate of resorption should decrease to 0.2 mm/ year according to many authors [313233]From T2-T3 the is no statistically significant difference in the probing depth values.

Zirconium group on the other hand shows a significant increase in the probing depth from T0 – T1 which can be explained by its higher affinity to plaque retention, resulting in more inflammation in the peri-implant mucosa.

CONCLUSIONS

Within the limitation of the current study it was concluded that:

1. PEEK crowns veneered by Visiolign showed high level of patient`s satisfaction and only minor incidents occurred such as veneer chipping, roughness and discolortion.
2. PEEK abutments showed reliable clinical performance after one year of loading, and its results were comparable to its zirconium counterpats.
3. PEEK abutments showed slightly better soft tissue response regarding plaque accumulation and bleading on probing when compared to zirconium abutments.

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