THE IMPACT OF MANDIBULAR COBALT-CHROMIUM AND PEEK BAR IMPLANT-SUPPORTED OVERDENTURES ON ORAL HEALTH AND QUALITY OF LIFE: A RANDOMIZED CLINICAL TRIAL

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Abstract

Background: Oral health profoundly influences the overall quality of life, including functions, aesthetics, and emotional well-being. Optimal soft tissue health around implants is essential for long-term success and enhanced quality of life.

Objectives: The aim of this study was to evaluate the Modified gingival index (MGI) at the time of overdenture insertion (T0), six months (T6) and twelve months (T12) later. In addition, patients filled out a standard version of the Oral Health Impact Profile (OHIP-14) questionnaire pre-treatment which was repeated at 6- and 12-months post-treatment.

Materials and methods: twenty patients received two implants in the canine area, the patients were classified into two groups: the control group (A) received mandibular implant overdentures supported by a cobalt-chromium bar and the intervention group (B) received mandibular implant overdentures supported by a PEEK bar. Data analysis was performed using Shapiro-Wilk test and Kolmogorov-Smirnov test for normality which revealed non-parametric data for MGI scores and parametric data for OHIP-14. Mann–Whitney test was used to compare MGI at (T0), (T6) and (T12) after prosthetic loading. Freidman test and Wilcoxon signed ranks test for pairwise comparisons. Paired t-test was conducted to evaluate the OHIP scores before and after treatment, in addition to an independent t-test to assess the impact of bar material on OHIP-14 scores at (T0), (T6) and (T12) after prosthetic loading.

Results: revealed a statistically insignificant difference in modified gingival index between the two groups after 6 months while the PEEK group showed a statistically significant decrease in MGI values after 12 months. In addition, a statistically significant difference was observed between the pre-treatment OHIP scores and after 6 months of prosthetic loading. However, no significant difference was found between the OHIP scores at 6 months and at 12 months after prosthetic loading in both Co-Cr and PEEK bar groups.

Conflict of interest declaration: The authors declare that they have no conflicts of interest.

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Conclusion: Both Co-Cr and PEEK bar groups exhibited comparable OHIP scores while PEEK material has the potential to improve long-term gingival health, which in turn contributes to enhancing the overall quality of life related to oral health.

Keywords: PEEK, Cobalt-Chromium, implant overdenture, modified gingival index, OHIP-14

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Introduction

Edentulism is known as the condition of being toothless, but nowadays is more than that, it involves a biochemical complex where both bone changes and inflammation of soft tissues play crucial roles. Furthermore, the World Health Organization (WHO) has categorized edentulism as a physical handicap,[1] it is commonly recognized that it can significantly affect functionality and trigger unfavorable changes in appearance and emotions for

individuals. Problems include restrictions in diet and reduced ability to eat certain foods,[2–4] difficulties in speech, weakening of facial muscle support, and a decrease in the vertical dimension.[5]

The clinical indexes used to describe the oral health status of populations following standard methodologies of WHO do not encompass details about an individual's ability to carry out daily activities or their overall physical, psychological, and emotional welfare, including their quality of life. [6]

In dentistry, the development of tools designed to measure the quality of life is relatively recent.[7–10] Therefore, this has become of great interest to the patient's perspective and the benefits of various treatment options. [11–13]

Dental implants have been used in edentulous jaws to improve the retention and stability of complete dentures. Attachment to the implants improves the stability and function of the prostheses and increases patient satisfaction.[14–16]

The implant connection also improves neuromuscular activity and adaptation and thereby substantially improves masticatory function in edentulous patients.[12,17] In addition, it has been shown that those with implant treatment can achieve nearly double maximum forces compared with those who have conventional dentures.[16,18]

The use of two osseointegrated implants to carry an overdenture in the lower jaw is normally well accepted by patients.30 The increased stability of the conventional denture, added to the low costs involved, makes this a much-appreciated treatment. [19,20]

The selection of the appropriate overdenture attachment system greatly influences patient satisfaction, because of its direct association with the stability of the denture and retentive force.[20,21]

Currently, the cobalt-chromium (Co-Cr) alloy is commonly used for dental prosthesis superstructures. The alloy has a reasonable cost and biocompatibility, as well as exhibiting good mechanical properties. [22,23]

PEEK can be a promising alternative to metallic frameworks to use in various clinical situations in dental practice due to its high-quality mechanical properties such as favorable elastic modulus, strength, rigidity, and lightweight.[24–27]

The health and stability of peri-implant soft tissues are essential clinical parameters for the long-term success of implant-supported prosthetic restorations. Maintaining the health and stability of peri-implant soft tissues, as well as their successful integration, is crucial for preventing future inflammation and bone resorption ultimately leading to an improved quality of life. [28–30]

Quality of life is affected in some way by oral health in the majority of people. The type and quality of prosthetic constructions, and nowadays more often implant-supported prostheses, can be considered one aspect of oral health. The oral health impact profile index (OHIP- 14)[31] has been used as a shortened 14-item questionnaire to evaluate the impact of oral health on the quality of life. The index measures people's perception of the social impact of oral disorders on their well-being.[32]

The OHIP-14 captures only negative impacts, whereas some other oral health-dependent quality-of-life instruments capture both positive and negative impacts. However, the OHIP is the most frequently used and best-documented instrument nowadays. [33,34]

This study aimed to evaluate the peri-implant modified gingival index of two implants retained mandibular overdenture using Poly-etheretherketone (PEEK) and Cobalt chromium bar materials. In addition, assessment of oral health impact profile (OHIP-14) pre-treatment and post-treatment after 6 and 12 months.

Materials and Methods

Patient's selection

This randomized clinical trial was conducted in strict adherence to the Declaration of Helsinki and CONSORT guidelines. Ethical approval was granted by the Faculty of Dentistry's Ethical Committee at Minia University.

The study enrolled twenty completely edentulous patients, who were meticulously assessed to fulfil specific inclusion criteria: age between 45 and 70 years, healthy and firm mucosa covering edentulous ridges, sound general health devoid of systemic conditions affecting bone or osseointegration, absence of Temporomandibular joint disorders confirmed through clinical examination, no history of para-functional habits, normal maxillo-mandibular relationship categorized as Angel's class I ridge relationship, and adequate inter-arch space not less than 14 mm.

Individuals with uncontrolled diabetes, including those with a medical history of bisphosphonate therapy, poor oral hygiene, and heavy smokers were excluded, Furthermore, we excluded patients who were undergoing chemotherapy or had previously received local radiotherapy to the head and neck region.

Patients' randomization

Patients were randomly allocated into two equal groups using Minitab software to receive maxillary complete dentures and bar-retained mandibular implant overdentures. Assigning was done according to the material of the retaining bar:

- The control group (A) received mandibular implant overdentures supported by a cobalt-chromium bar.
- The intervention group (B) received mandibular implant overdentures supported by a PEEK bar.

Before starting treatment procedures, both groups participated in a quality-of-life assessment. This assessment involved using the Oral Health Impact Profile OHIP-14 questionnaire, a tool designed to evaluate various aspects of individuals'

quality of life. The scores obtained from this questionnaire were then designated as pre-treatment scores, serving as a baseline measure of participants' quality of life before any interventions were administered.

Surgical and prosthetic procedures

Upper and lower Complete dentures were constructed for all patients, the lower denture was duplicated, and radiographic markers were inserted into the canine region to be used as a radiographic stent and later as a surgical stent.

Patients received two mandibular root form implants with standardized diameters of 3.4 mm and 11.5 mm length, placed at the canine region. After 3 months, patients were recalled for placing healing abutment and left in place for 1 week.

***Figure 1**: Pick-up impression copings* ***Figure 2:** Open tray final impression using VSXE impression material*

Patients were then recalled for the prosthetic phase, the healing abutments were unscrewed, two multi-unit abutments were then connected into position, pick-up impression copings were screwed onto the multi-unit abutments, and the special tray was fitted with these copings. Once set, the screws of the copings were loosened, the impression was carefully separated, and the implant analogues were screwed onto the impression copings. (Fig 1,2)

After 1 hour, the cast was separated from the impression, trimmed, labelled, and stored at room temperature for 24 hours before scanning. The Cast was sprayed and scanned using a desktop scanner, scan bodies were screwed to the multi-unit abutment, tightened at 10 Ncm and the cast was rescanned to obtain digital casts. The STL digital file was exported to CAD software for bar design.

Cobalt chromium bar design and fabrication: The virtual bar was designed based on a standard bar type from the software library, with 2.0 mm thickness, 2.4 mm height with preservation of 1mm supragingival hygienic space and 1.0 mm thickness at the abutments.

STL file of the bar was then exported and printed in 3D using a proprietary transparent resin, to obtain a replica of the bar, this bar was tested in the patient's mouth, to check the adaptation, precision, and passivity.

After checking the passivity of the 3D printed bar, The STL digital file was exported to nesting and slicing software to fabricate a cobalt-chromium bar using SLM machine using an IPG photonics 200W air-cooling fiber laser system. After the sintering process was completed, homogenization treatment was performed at 1150°C for 30 minutes and the bar was cooled, finished, and polished.

PEEK bar design and fabrication: The PEEK bar was designed to have a 2.5 mm thickness, 4.0 mm height with preservation of 1mm supragingival hygienic space, and 1.5 mm thickness at the abutment.

STL file of the bar was then exported and printed in 3D using a proprietary transparent resin, to obtain a replica of the bar, this bar was tested in the patient's mouth, to check the adaptation, precision, and passivity. The STL file was exported to the milling machine to mill the bar assembly, from PEEK blanks.

Bar try-in and evaluation of marginal fit

The bar's marginal fit was tested by securing it at 10 Ncm on a multiunit abutment. A periapical radiograph was taken on the unscrewed side and assessed for misfit. If a marginal misfit was found, the bar was replaced, and the fabrication process was repeated following the previously mentioned steps.

Mandibular overdenture clips pick up

Undercut areas below the bar were blocked with a gingival barrier material, and escape holes were created in the denture for excess material. Using self-cured acrylic resin, the pickup of plastic clips was performed with the denture fully seated. The material polymerized while the patient maintained light-centric occlusion. (Fig 3)

After careful removal, excess material was eliminated, and the denture underwent finishing,

polishing, and delivery. The occlusion was assessed, and any identified errors were adjusted.

Figure 3: Fitting surface of the finished denture with bar clips and denture in centric occlusion

Evaluation of peri-implant modified gingival index (MGI)

The modified gingival index was evaluated at the time of overdenture insertion (T0), six months (T6) and twelve months (T12) later. (Fig 4,5) The modified gingival index was scored 0 to 3 based on a non-invasive visual scale according to the following criteria:

0 **Score 0:** No bleeding when a periodontal probe is passed along the mucosal margin adjacent to the implant.

Score 1: Isolated bleeding spots visible (slight change in color and slight oedema)

Score 2: Blood forms a confluent red line on the mucosal margin (redness, oedema and glazing)

Score 3: Heavy or profuse bleeding (marked redness, oedema and ulceration).

Figure 4: Co-Cr bar screwed to multiunit abutments

Figure 5: PEEK bar screwed to multiunit abutments

Statistical analysis: was performed with SPSS 20®, Graph Pad Prism® and Microsoft Excel 2016, exploration of the given data was performed using Shapiro-Wilk test and Kolmogorov-Smirnov test for normality which revealed a significance as P-value ≤ 0.05 which indicated data were non-parametric and not normally distributed.

Mann–Whitney test was used to compare gingival scores between groups at the time of prosthetic loading (T0), 6 months (T6) and 12 months (T12) after prosthetic loading. Freidman test was used to compare gingival scores between observation times followed by Wilcoxon signed ranks test for pairwise comparisons.

Assessment of the Oral Health Impact Profile (OHRQoL) with OHIP-14 modified version

A standard version of the Oral Health Impact Profile OHIP-14 questionnaire was used. The questionnaire was filled out by patients after treatment and the quality-of-life assessment was repeated at 6 and 12 months after the placement of the prosthetic restoration.

Statistical analysis: was performed with SPSS 20®, Graph Pad Prism® and Microsoft Excel 2016, exploration of the given data was performed using Shapiro-Wilk test and Kolmogorov-Smirnov test for normality which revealed that the significant level (P-value) was insignificant as P-value > 0.05 which indicated data originated from normal distribution (parametric data) resembling normal Bell curve.

An independent t-test was utilized to assess the impact of bar material on OHIP-14 scores at three

different time points: pretreatment, 6 months, and 12 months after prosthetic loading. Additionally, paired t-test was conducted to evaluate the OHIP scores before and after treatment.

Results

1. Modified Gingival Index

i. Effect of Bar Material on Modified Gingival Index

a. After 6 months of prosthetic loading (T6)

The mean and standard deviation values of the modified gingival index around implants connected by Co-Cr and PEEK bars were (0.89 ± 0.55) and (0.56 ± 0.53) respectively. These findings indicate that the modified gingival index was slightly higher in the Co-Cr bar group compared to the PEEK bar group. However, the difference between the two groups was found to be statistically insignificant (P=0.187) as presented in Table (1) and Fig (6)

Table 1: Mean and standard deviation (SD) of Modified Gingival Index for different bar materials at 6 months

Bar material	n	Mean	Std. deviation	p-value
Co-Cr	10	0.89	0.55	0.996 NS
PEEK	10	0.56	0.53	

*=significant, NS= non-Significant

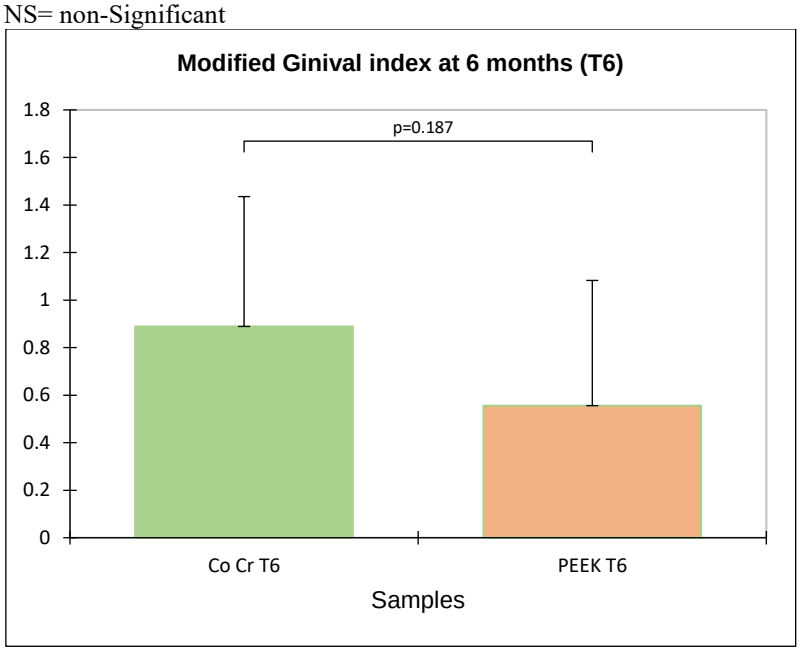

Figure 6: Bar chart showing the modified gingival index for different bar materials at 6 months.

b. After 12 months of prosthetic loading (T12)

Means and standard deviation values of the modified gingival index around two implants connected by Co-Cr and PEEK bars after 12 months of prosthetic loading were (1.5 ± 0.9) and (0.44 ±0.68) respectively. This result showed that there was a statistically significant difference (P=**0.012**) between the Co-Cr bar group and the PEEK bar as shown in Table (2) and Fig (7)

Table 2: Mean and standard deviation (SD) of the modified gingival index for different bar materials at 12 months.

Bar material	n	Mean	Std. deviation	p-value
Co-Cr	10	1.5	0.9	0.012*
PEEK	10	0.44	0.68	

*=significant, NS= non-Significant

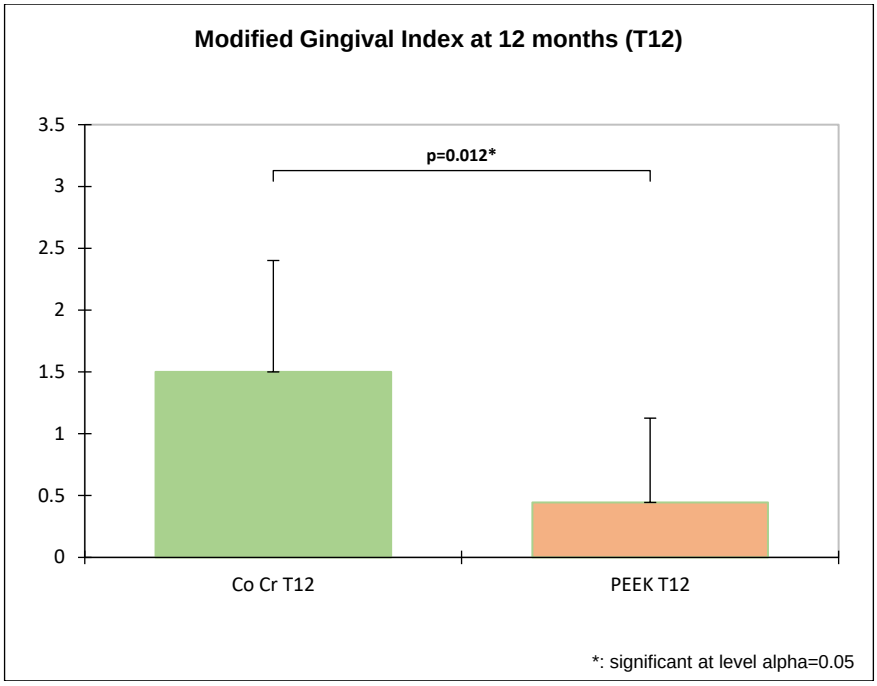

Figure 7: Bar chart showing the modified gingival index for different bar materials at 12 months.

Effect of different Follow-up periods on the modified gingival index

A. Co-Cr bar groups

To detect the difference in tested outcomes between observation times, Friedman test was utilized. During the 12-month follow-up period, the analysis of the data revealed a statistically significant difference (P=**0.016**) around implants connected by Co-Cr bars as shown in Table (3)

Table 3: Mean and standard deviation (SD) of the modified gingival index for Co-Cr bar at different follow-up periods

Time Interval	n	Mean	Std. deviation	Freidman test (p value)
Co-Cr (T0)	10	0.44	0.68	0.016*
Co-Cr (T6)	10	0.89	0.55	
Co-Cr (T12)	10	1.5	0.9	

*=significant, NS= non-Significant

To test the significant difference between time intervals, Wilcoxon signed ranks test was used for pairwise comparison, it revealed that there was no statistically significant difference in the modified gingival index between the time of prosthetic loading (T0) and 6 months (T6), as well as between 6 months (T6) and 12 months (T12), however, there was a statistically significant difference between T0 and T12 where (P= **0.027**) as shown in Fig (8).

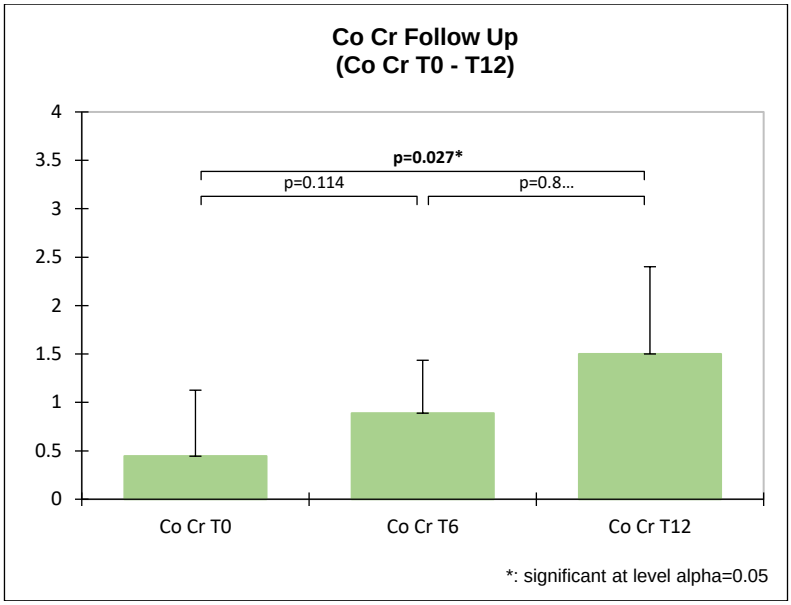

Figure 8: Bar chart showing the modified gingival index for Co-Cr bar at different follow-up periods.

B. PEEK bar groups

The results showed a slight increase in the modified plaque index from the time of prosthetic loading (T0) to 6 months after loading (T6), while there was a minimal change from (T6) to (T12) months after loading, however, the difference was statistically insignificant (P=0.34) as shown in Table (4)

Table 4: Mean and standard deviation (SD) of the modified gingival index for PEEK bar at different follow-up periods

Time Interval	n	Mean	Std. deviation	Freidman test (p-value)
PEEK (T0)	10	0.33	0.7	0.34^{NS}
PEEK (T6)	10	0.56	0.53	
PEEK (T12)	10	0.44	0.68	

*=significant, NS= non-Significant

OHIP-14 outcome

i. Effect of different follow-up periods on OHIP-14

A statistically significant difference was observed between the pre-treatment period and the OHIP scores after 6 months of prosthetic loading. However, no significant difference was found between the OHIP scores at 6 months and 12 months after prosthetic loading in both Co-Cr and PEEK bar groups as shown in Table (5)

Table 5: Mean and standard deviation (SD) of OHIP-14 scores of different bar materials pre-treatment and post-treatment

		Mean	**SD**	***p*-value**
Co-Cr	Pre-treatment	34.40	7.975	.001*
	T6	9.40	5.400	
	T12	8.50	4.478	.134 ^{NS}
PEEK	Pre-treatment	34.40	7.975	.001*
	T6	10.70	7.379	
	T12	7.70	6.848	.151 ^{NS}

Effect of different bar materials on OHIP-14

The study results revealed that there was no statistically significant difference between patients who had Co-Cr and PEEK bars supported overdentures. However, the PEEK group demonstrated a slightly lower score compared to the Co-Cr group's score after 12 months follow up as shown in Table (6) and Fig (9).

Table 6: Range, mean and standard deviation (SD) of different bar materials on OHIP-14 scores

	Group	Range	Mean	Std. Deviation	P-value
T6	Co-Cr	1-21	9.40	5.400	.658 NS
	PEEK	1-20	10.70	7.379	
T12	Co-Cr	1-18	8.50	4.478	.761 NS
	PEEK	0-19	7.70	6.848	

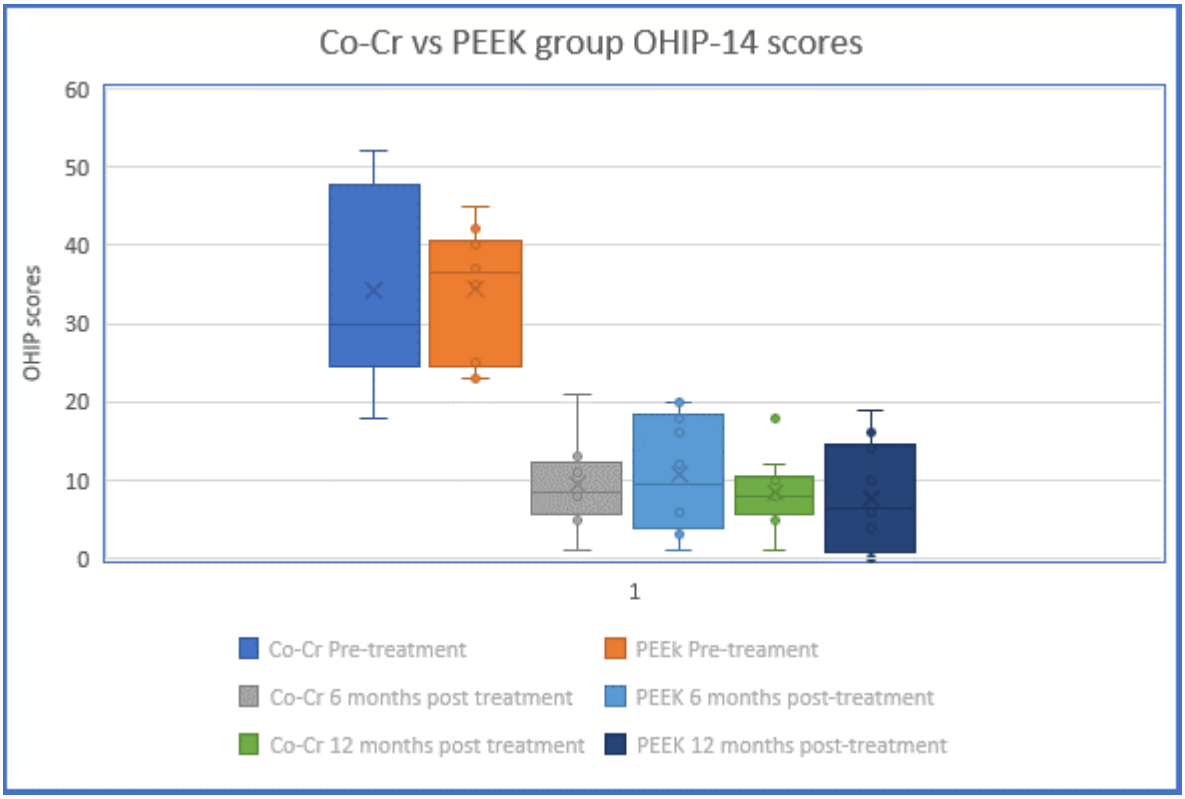

Figure 9: Box-and-whisker plots of OHIP questionnaire for patients represent Pre-treatment and post-treatment OHIP-14 score of Co-Cr and PEEK groups after 6 months and 12 months. In the box-and-whisker plot, the central box represents the values from the lower to upper quartile (25th –75th percentile). The middle line represents the median. The horizontal line extends from the minimum to the maximum value, excluding "outside" and "far out" values, which are displayed as separate points

Discussion

In this study, the chosen approach was using bar attachments. The rationale behind this choice was based on the observation that dental implants connected with bars for support demonstrate more effective stress distribution and necessitate less frequent prosthetic maintenance when contrasted with individual, non-connected implants[35]

PEEK bar was used in this study as, PEEK is considered as a viable alternative to standard alloy and ceramic dental materials due to its high hardness, minimal water absorption, chemical inertness, better biocompatibility, and solubility. Moreover, biofilm development is low and mechanical characteristics are excellent. [36,37]

The Gingival Index modified (MGI) by Mombelli [38] is a non-invasive index that is based on visual assessment of changes in colour, texture and oedema which reveal the characteristic inflammatory changes at the gingival margin. [39]

Using a periodontal probe to assess modified gingival index on the basis of bleeding on probing

has been considered by some authors to be unreliable because of the mechanical trauma caused by the periodontal probe, this could be effective in the diagnosis and monitoring of active periodontal diseases, but when used as a stand-alone test, it can be inaccurate. [40,41]

The results of the present study revealed a statistically insignificant increase in the modified gingival index (MGI) within the Co-Cr group after a 6-month follow-up period. In contrast, a statistically significant elevation in MGI values was observed around implants that were linked by Co-Cr bars throughout a 12-month follow-up duration. This could be explained by the increased surface roughness of Laser-sintered Co-Cr copings compared to copings produced by milling or milled wax/lost wax technique.[42]

These findings are consistent with a study that found that Co-Cr alloy exhibits micro defects in the form of undulation and pitting, even on polished surfaces which enhance the microbial colonization for Co-Cr, the results demonstrated an increased number of species and their concentrations among the Co-Cr denture bases so bacterial retention was substantial on all surfaces.[43]

In a study conducted to find out the influence of surface roughness and surface-free energy on supra- and subgingival plaque formation, it has revealed that rough surfaces will promote plaque formation and maturation, and high-energy surfaces are known to collect more plaque, to bind the plaque more strongly which increases micro- organism binding, resisting mechanical removal and so increases plaque accumulation and maturation.[44,45]

Furthermore, multiple studies have previously reported the causal relationship between plaque buildup and increased gingival inflammation as evidenced by the works of Salvi 2012, Malo 2018 and AbdulAzeez 2021.[46–48]

The results of the present study showed a statistically significant difference in the MGI values around implants connected by Co-Cr and PEEK bars during 12 months of follow-up, where the PEEK group demonstrated a lower MGI score than the Co-Cr group, this could be explained by the reduced affinity of PEEK material to plaque accumulation with favourable chemical stability.[49]

In a study conducted to investigate the formation of biofilms on the surface of PEEK, titanium and zirconia materials applied for the fabrication of implant abutments, it was found that biofilm formation on the surface of PEEK is lower than on the surface of materials such as zirconia and titanium.[50] These results are in alignment with the outcomes of the current study, which observed a decreased modified gingival index (MGI) in the PEEK bars group.

In a recent study conducted by Othman M. (2023) [51] to evaluate the plaque affinity in comparison to titanium and zirconium dioxide, it was found that the PEEK material had the lowest bacterial adhesion and plaque affinity, which was found to be in line with the results of the present study.

The results of OHIP-14 questionnaire scores revealed a statistically significant difference between the pre-treatment period and 6 months post-treatment. However, no significant difference was found between the OHIP scores at 6 months and at 12 months after prosthetic loading in both Co-Cr and PEEK bar groups.

The questionnaire used in the present study has been validated in several studies both in its complete form (with 49 items) and its short one (14 items).[52,53] In the present study, a significant improvement in the quality of life has been reported by all patients post-treatment, and it was often associated with the early improvement of dietary habits. These results are consistent with Toia M. [54] who evaluated the patient satisfaction and the clinical outcomes of edentulous arches rehabilitated with overdentures retained by CAD-CAM milled titanium bars.

A study conducted by Kouppala and Raustia in 2015 found excellent OHIP-14 results after treatment with full-arch maxillary restorations which is in line with the present study.

The present study results revealed that there was no statistically significant difference between patients who had Co-Cr and PEEK bars supported overdentures. However, the PEEK group demonstrated a slightly better score compared to the Co-Cr group after 12 months of follow-up, these results are in line with a study that reported high patient satisfaction with function and esthetics after 6 months.[55]

Another study described the use of milled PEEK frameworks for the fabrication of a removable maxillary obturator prosthesis. It has reported high patient satisfaction regarding esthetics, retention and comfort.[56]

In addition, a study evaluated the patients' satisfaction with conventionally manufactured metal RPD framework versus milled PEEK framework, the results revealed that PEEK material increases patients' satisfaction with RPDs than the conventional metal framework material, thus decreasing patients' complaints from removable appliances.[57]

Within the limitation of this clinical study, it could be recommended to utilize larger sample sizes in future research to validate these outcomes comprehensively. This will facilitate a deeper comprehension of how various bar materials impact peri-implant soft tissues in implant-supported overdentures. Additionally, further studies should specifically examine how both Cobalt Chromium and PEEK bar materials impact the peri-implant soft tissue health.

Conclusion: Within the limitations of this study, it can be concluded that both Co-Cr and PEEK bar groups exhibited comparable OHIP scores while PEEK material has the potential to improve long-term gingival health, which in turn contributes to enhancing the overall quality of life related to oral health.

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