RADIOGRAPHIC EVALUATION OF MARGINAL BONE LOSS AROUND IMPLANTS RETAINING MANDIBULAR OVERDENTURE WITH COBALT-CHROMIUM VERSUS POLYETHERETHERKETONE BAR: RANDOMIZED CLINICAL TRIAL

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Abstract

Background: Implant-supported overdentures play a pivotal role in restoring function and improving the quality of life for edentulous patients. While cobalt-chromium (Co-Cr) is a commonly used bar material, polyetheretherketone (PEEK) has been introduced as an alternative. However, its influence on marginal bone loss remains a critical consideration.

Objective: the aim of this study was to investigate the influence of bar materials, cobalt-chromium (Co-Cr) and polyetheretherketone (PEEK) on marginal bone loss around implants retaining mandibular overdentures.

Materials and methods: Twenty edentulous patients were enrolled, each receiving implants with either Co-Cr or PEEK bars. Overdentures were constructed and marginal bone loss around the implants was evaluated after 6 months of prosthetic loading. Data analysis was conducted using the Shapiro-Wilk and Kolmogorov-Smirnov tests to confirm data normality. The independent t-tests compared marginal bone loss between Co-Cr and PEEK groups, Statistical significance was set at $P \leq 0.05$.

Result: Data was normally distributed in both groups. Although marginal bone loss around Co-Cr bars was slightly higher than PEEK bars, yet it was not statistically significant ($P>0.05$).

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Conclusion: Within the limitations of this study, it can be concluded that Co-Cr and PEEK may have a comparable effect on marginal bone loss around implants retaining mandibular overdenture after 6 months of follow up.

Keywords: Polyetheretherketone (PEEK), Implant-retained overdenture, Marginal bone loss, Cobalt-Chromium

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Introduction

For over a century, complete dentures have served as the standard of care for the rehabilitation of edentulous patients. Despite the high level of satisfaction reported by the majority of patients using maxillary dentures in terms of speech, esthetics, mastication, and retention, retention of mandibular dentures is often more problematic due to various factors. These factors include the thin mucosal coverage of the edentulous ridge, reduced support area, and the mobility of the floor of the mouth, mandible, and tongue. As a result, over 20% of patients experience little to no satisfaction and a diminished quality of life. [1–3]

In order to overcome the problems of mandibular dentures, implant overdentures have been proposed because of their significantly improved retention, stability, and patient satisfaction. Implant overdenture (IOD) is a removable partial or complete denture retained by a superstructure secured to implants usually positioned in the anterior area of the mandible. [4–7]

The two-implant overdenture has been shown to be a reliable treatment option for edentulous mandibles. [8] A wide range of retention mechanisms has been utilized to retain implant overdentures, which are classified into two main groups, Free-standing single attachment systems, and splinted anchorage systems. [9–11]

Bar-retained overdentures represent the most ideal option particularly in the cases of an atrophied mandible since they offer improved horizontal stability, retention, and support of the prosthesis compared to other attachment systems. [12]

Studies suggest that bar attachments are more advantageous than non-splinted attachments, particularly in cases where implants are improperly positioned, as bar attachments are convenient for correcting the insertion path of the prosthesis, resulting in reduced incidence of maintenance and complications; providing a relatively constant patient's satisfaction with retention and stability, while it appears to decrease over time when using non-splinted attachment systems. [13–15]

The selection of suitable materials for the fabrication of bars and implant frameworks is crucial for achieving optimal biomechanical performance. The material chosen can significantly impact the distribution of stresses within the bone surrounding the implants, as well as the overall functionality and durability of restorations. [16]Metal frameworks are commonly used in prosthesis design due to their good mechanical properties, with cobalt-chromium being the most predominant metal in commercially available alloys, followed by titanium. [17,18] However, recent demands for esthetic and biomimetic materials, coupled with an increase in metal allergies among patients, have spurred the development of new metal-free materials. [16,19]

Zirconia has emerged as an attractive alternative due to its excellent biocompatibility, corrosion resistance, and good mechanical properties, making it an excellent option for achieving esthetic outcomes while benefiting from computer-assisted design/computed-assisted manufacture (CAD/CAM) techniques. [20–22]

The literature revealed that a rigid framework is essential to absorb and distribute stresses evenly, preventing any deformations. However, Studies have suggested that stiffer materials tend to exhibit higher stress values in the prosthetic framework compared to less rigid materials. [23] Materials with higher elastic modulus values resist deformation, thus increasing stress concentration. In contrast, a framework material with a lower modulus of elasticity could effectively reduce occlusal forces and evenly distribute the load. [24]

Polyetheretherketone (PEEK), is a relatively novel material that is increasingly being utilized in various dental applications. PEEK is a high-performance polymer that possesses numerous desirable traits, such as biocompatibility, biostability, and compatibility with medical diagnostic imaging. [25]

One of the most remarkable features of PEEK is its outstanding mechanical properties. This material offers superior chemical stability, mechanical behavior, creep, and wear resistance, making it highly sought-after in the fabrication of removable dentures, fixed restorations, dental implants, implant abutments, and implant frameworks. [26]This characteristic, coupled with its shock-absorbing properties, makes PEEK an attractive option for use as an implant prosthesis. PEEK's low modulus of elasticity creates a cushioning effect that can decrease the stress transfer and it can help to reduce the risk of implant failure due to stress concentration. [27,28]

The aim of the present study was to evaluate the effect of Co-Cr and PEEK bar materials on the marginal bone around two implants retaining mandibular overdenture.

Materials and methods

I. Patient selection

The study enrolled a twenty completely edentulous patients, who were meticulously assessed to fulfill 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. participants were randomly assigned to two equal groups. The allocation was determined by the type of the bar material. The control group (A) received mandibular implant overdentures with a cobalt-chromium bar, while the intervention group (B) received mandibular implant overdentures with a PEEK bar.

II.

III. Surgical and prosthetic phase

Each patient received a complete denture fabricated with bilateral balanced occlusal contact. A radiographic stent was fabricated by duplicating the lower denture using a clear auto-polymerized acrylic resin with two radiopaque markers between the canine and lateral incisor acrylic area. Patients were instructed to wear the stent for radiographic imaging. Pre-operative Cone Beam Computed Tomography (CBCT) was performed on each patient, the width and height of bone in these sections were then measured and examined.

After radiographic examination the radiographic stent was converted to surgical stent and used for implant placement, the stent was firmly fixed to the lower arch, and the positions of the two implants were marked by an indelible pencil through holes made at the planned implant sites.

Two separate crestral incisions were performed, bisecting the mucosa and periosteum and reaching the bone of the ridge crest at the lateral incisor-canine region followed by two anterior vertical incisions were also made, Two implants (IS-II Active, CMI implant system; neobiotech, Seoul, Korea) with 11.5 mm length, and 3.5 mm width were inserted at crestal bone level, The mucoperiosteal flap was repositioned, approximated without tension, and sutured by a 4-0 non-resorbable horizontal and interrupted mattress. and the denture was relined with a tissue conditioner material.

After 3 months of implant placement patients were recalled for the second stage surgery, the surgical stent was used to relocate implant sites, and keyhole access expansion excisions of approximately 2 mm of soft tissue were performed directly over the implant head on both sides to retrieve the cover screw, and two healing abutments were tightened to the implants. Patients were then recalled one week later for the prosthetic phase.

Lower preliminary impressions were obtained using Alginate impression material in a properly selected stock tray. The impression was poured using dental stone, and a study cast was obtained, A lower acrylic resin special tray was constructed on the study cast, and two holes were prepared and adjusted to the multi-unit abutments.

The healing abutments were unscrewed, and two multi-unit abutments were tightened to 30 Ncm, using a calibrated torque wrench, Pick-up impression copings were screwed onto the multi-unit abutments, and the special tray was fitted with these copings.

Vinyl siloxanether (IDENTIUM® MEDIUM, Kettenbach GmbH & Co. KG, Eschenburg, Germany) impression material was mixed and loaded into the tray. Once set, the screws of the copings were loosened, the impression was carefully separated, and the implant analogs were screwed onto the impression copings. Impression was obtained and poured with a type IV dental stone. After 1 hour, the cast was separated from the impression, trimmed, labeled, and stored at room temperature for 24 hours before scanning. The Cast was sprayed and scanned using a desktop scanner (CS.NEO; CAD star GmbH, Bischofshofen, Austria), 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.

Bar design and fabrication

The Co-Cr bar was designed based on a standard bar type from the software library (Exocad DentalCAD 3.1; exocad GmbH, Darmstadt, Germany), with 2.0 mm thickness, 2.4 mm height with preservation of 1mm supragingival hygienic space, and 1.0 mm thickness at the abutments, The STL digital file was exported to fabricate a cobalt-chromium bar using selective laser melting (SLM) machine using an IPG photonics 200W air-cooling fiber laser system. After the sintering process was completed, the bar was finished, and polished (Fig 1).

Figure (1): SLM Co-Cr screwed to the multi-unit abutments

Figure (2): PEEK bar screwed to the multi-unit abutment

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, the STL file was exported to the milling machine to mill the bar assembly, from PEEK blanks (Fig 2). The marginal fit of the bars was assessed by tightening the bar at 10 Ncm onto one multiunit abutment, and a digital periapical radiograph was obtained to the unscrewed side.

the patient was closing in light-centric occlusion with minimal pressure then the denture was carefully removed, the excess material was removed

Recall appointments were scheduled for the patients one week after implant loading and follow-up visits at 6 and 12 months after prosthetic loading for loss data were collected at the time of prosthetic loading (T0), 6 months (T6) after prosthetic loading.

IV. Radiographic Evaluation

A standardized radiographic evaluation was performed using a digital periapical radiograph, standardized radiographic parameters were used, with the x-ray machine set to 70 kVp, 7 mA, and an exposure time of 0.2 seconds.

The software's (ImageJ; National Institute of Health, Maryland, USA) measurement scale was set according to the length and the width of the implant, Version 22.0., IBM Corp., NY, USA), and checked for normality by examining their distribution and using the Kolmogorov-Smirnov and Shapiro-Wilk tests.

The p-values were greater than 0.05, indicating that the data were normally distributed. The independent t-tests were used to compare the mean marginal bone loss between the Co-Cr and PEEK groups at 6 months. The significance level was set at $P \leq 0.05$.

Results

Effect of Bar material on average marginal

Mandibular over denture was constructed for each participant ,the bar was tightened to the multi-unit abutments, plastic clips were attached to it and any undercuts beneath the bar was blocked out. The pickup was done by self-cured acrylic resin with the denture seated completely, the material was left to polymerize while

and the overdenture was finished, polished, and delivered to the patient, occlusion was checked and errors were detected and adjusted.

clinical and radiographic evaluation of the implants, Marginal bone

the measurement tool was utilized to measure the distance between the implant shoulder and the first bone-to-implant contact (Fig 5).

Marginal bone loss was then measured by subtracting bone levels at T6 from values at T0. This measurement was taken at both the mesial and distal surfaces of each implant, and the mean value was subjected to statistical analysis.

V. Statistical Analysis

Data were analyzed using IBM® SPSS® (Released 2013. IBM SPSS Statistics for Windows,

bone loss (mm)

Means and standard deviation values of average marginal bone loss around two implants connected by Co-Cr and PEEK bars after 6 months of prosthetic loading were (0.57±0.19) and (0.51±0.17) respectively as shown in (Table 1) and (Fig 3)

This result revealed that the mean of marginal bone loss around implants in the Co-Cr bar group was higher than in the PEEK bar group; however, the difference between them was statistically insignificant (P>0.05).

Table 1: Mean and standard deviation (SD) of marginal bone loss (mm) for different bar materials at 6 months.

Bar material	n	Mean	Std. deviation	*p*-value	Effect size (Cohen's d)
Co-Cr	10	0.57	0.19	0.447 NS	0.356
PEEK	10	0.51	0.17		

*=significant, NS= non-Significant

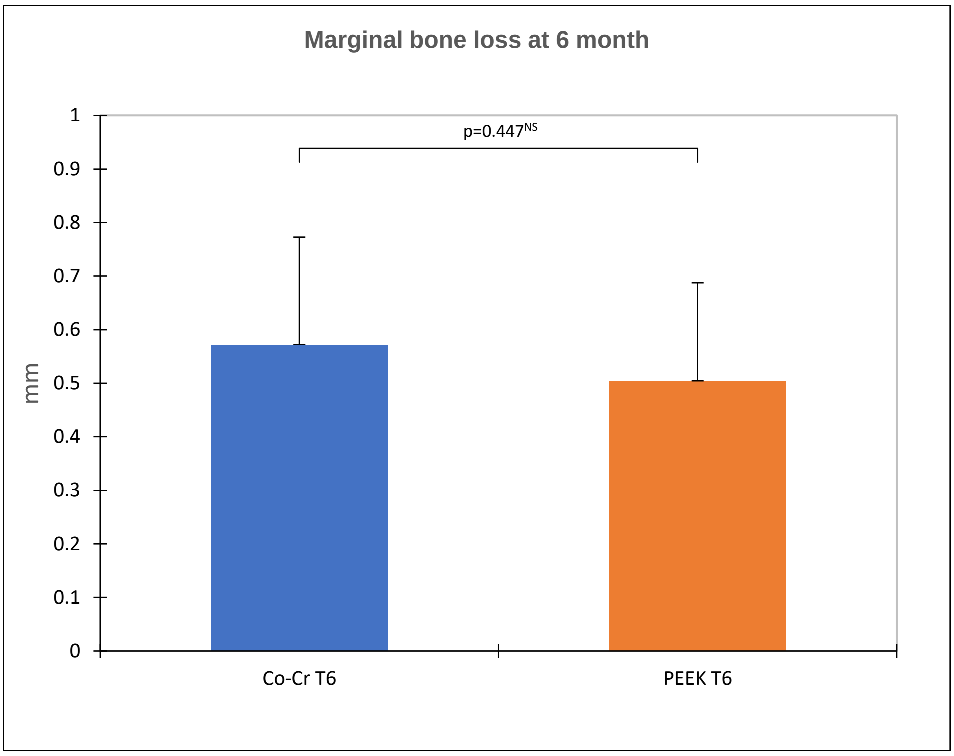

Figure (3): Bar chart showing the average marginal bone loss (mm) for different bar materials after 6 months

Discussion

Many materials have been utilized for bar attachment fabrication, and the impact of the biomechanical behavior of the material on stress distribution around the prosthesis as well as the implant-bone interface has been identified as a critical factor in achieving implant success and longevity.[29]

While a rigid framework is essential for absorbing and distributing stresses evenly, studies have revealed that stiffer materials tend to exhibit higher stress values in the prosthetic framework compared to less rigid materials.[23] Materials with a higher elastic modulus value resist deformation, leading to increased stress concentration. In contrast, a framework material with a lower modulus of elasticity can effectively reduce occlusal forces and evenly distribute the load.[24]

The present study aimed to evaluate the effect of different bar materials on marginal bone loss around implants, The results showed that after 6 months of prosthetic loading, the average marginal bone loss around implants connected by Co-Cr bars was higher than that of PEEK bars, although the difference between the two was statistically insignificant. The effect size for this difference was moderate, indicating that the Co-Cr bar may lead to slightly higher marginal bone loss than the PEEK bar after 6 months of loading.

The lack of significant difference in marginal bone loss between Co-Cr and PEEK bars indicates that both materials are capable of maintaining peri-implant bone levels when used for implant overdenture frameworks. The comparable bone loss values suggest that these materials have suitable mechanical properties to prevent excessive loading that could jeopardize osseointegration within the 6-month follow-up period. While PEEK exhibited marginally less mean bone loss, the difference was not statistically significant.

PEEK material is distinguished by its exceptional biocompatibility and remarkable physical and chemical properties, including outstanding toughness, hardness, and elasticity. In terms of the load cushioning capacity of prosthetic components, PEEK exhibits a modulus of elasticity (4GPa) comparable to that of bone (4.2GPa). As a result, PEEK may promote bone stimulation, favoring its natural remodeling process without causing excessive loading. [30]

Conclusion and recommendation

Within the limitations of this study, it can be concluded that Co-Cr and PEEK may have a comparable effect on marginal bone loss around implants retaining mandibular overdenture after 6 months of follow up.

Further long-term clinical studies with larger sample sizes are recommended to validate these findings and better understand the influence of different bar materials on peri-implant bone loss in implant-supported overdentures. However, within the follow-up period evaluated, both Co-Cr and PEEK appear to be viable options as bar framework materials for implant overdentures without any significant differences in marginal bone loss.

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