

Clinical Evaluation of Peri-Implant Tissues in CAD/CAM versus Conventional Implant-Assisted Overdentures: A Randomized Clinical Trial

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Aim: This study assessed the impact of different materials; CAD/CAM- milled poly-ether-etherketone (PEEK), poly-methyl-methacrylate (PMMA), and conventional PMMA for mandibular implant-assisted overdenture bases on peri-implant soft tissue health.

Materials and Methods: 30 completely edentulous participants were enrolled in this randomized clinical study. They received mandibular implant-assisted overdentures, each constructed using one of 3 denture-base materials, opposing a single-maxillary denture. They were randomly allocated to one of 3 groups as follows: CAD/CAM-milled PEEK, CAD/CAM- milled PMMA, and conventional PMMA. Peri-implant tissue health was evaluated immediately after insertion, at 1, 3, 6, and 12 months later.

Results: Peri-implant parameters showed a significant increase over time across all groups ($P < 0.001$), except for calculus formation in CAD/CAM-milled PEEK and PMMA groups ($P = 1.00$). Significant differences were noticed among the 3 groups in bleeding scores and plaque index at 3, 6, and 12 months ($P < 0.000$). Significant differences in pocket depth revealed among groups at 1 and 3 months ($P = 0.001$), and at 6 and 12 months ($P < 0.000$) in favor of CAD/CAM-milled PEEK group. Respecting calculus, non-significant difference showed among groups after 1 and 3 months. However, it was observed after 6 and 12 months ($P < 0.000$). Calculus score displayed non-significant difference with time in all groups ($P = 1.00$) except for conventional PMMA ($P < 0.000$).

Conclusion: Within the limitations of this study, both CAD/CAM- milled PEEK and PMMA were advantageous as implant-assisted overdenture bases over conventional PMMA regarding peri-implant soft tissue health. However, CAD/CAM- milled PEEK provided better outcomes respecting bleeding, plaque and pocket depth indices.

Keywords: PEEK, PMMA, CAD/CAM, implant-assisted mandibular overdentures, peri-implant soft tissue health

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Introduction

An implant-assisted overdenture is an excellent choice for rehabilitating edentulous patients, offering obvious advantages in stability, retention, comfort, and quality of life compared to traditional dentures. Interestingly, implant installation in the anterior mandible notably improves functionality and patient satisfaction.¹⁻⁴ However, dental implant therapy does come with drawbacks. Complications like peri-implantitis, marked by connective tissue inflammation and bone loss around the implant, present a challenge.^{5,6} Consequently, many studies focused on enhancing treatment outcomes and reducing failure risk.⁷⁻¹⁰

The implant design, host reaction, bone quantity and quality, biomechanical and microbiological factors influenced the longevity of implants.^{7,11,12} No clear superiority among various attachment types or implant numbers regarding peri-implant health in mandibular implant overdentures was observed.^{11,13,14} Identical patient/clinical outcomes for implant overdentures with splint or no-splint attachment systems were reported.^{11,15} Immediate loading appeared to be an encouraging substitute for delayed loading for unsplinted mandibular implant-retained overdentures.¹⁶ Nonetheless, occlusal loading and uncorrected occlusion can affect long-term implant durability and promote marginal bone loss.^{12,17} The intense patient care and routine follow-up can reduce the failure rate of implant-retained overdentures.⁸

The implementation of CAD/CAM systems in removable denture construction offers benefits over conventional methods.¹⁸ These include fewer clinical visits, enhancements in the mechanical properties of dental materials developed by these technologies, shorter treatment times, and maintaining high precision and aesthetic standards. The digital nature of CAD/CAM allows for fast replication, data backup, prosthetic duplication, and research standardization.¹⁹⁻²¹ Milled

dentures made from exceptionally dense, pre-polymerized resin pucks created under high pressure and temperature resulted in reduced monomer content, better mechanical properties, enhanced denture retention, adaptation, and patient comfort, and reduced post-delivery complaints.²²⁻²⁴ Moreover, CAD/CAM-manufactured materials have smoother surfaces than conventional ones with more surface hydrophilicity that helps reduce microbial adherence.²⁵

Clinical trials comparing CAD/CAM implant-assisted overdenture-milled bases to conventionally fabricated ones emphasized favorable outcomes in terms of tissue surface adaptation,²⁶ denture deformation,²⁷ masticatory and bite force efficiency,²⁸ as well as satisfaction of the patient.²⁹ Advances in CAD-CAM technology developed new machinable materials like polyetheretherketone (PEEK), a polymer of high-performance that has lately become commonplace in dentistry. It is a semi-crystalline thermoplastic, linear, and aromatic material that offers several advantages. Of these, it has a high strength-to-weight ratio, chemical stability, biocompatibility and medical imaging compatibility, excellent mechanical properties, resistance to creep and wear, shock absorption,^{30,31} and low plaque affinity.³²

PEEK with a low elasticity modulus of 4 GPa closely matches that of bone, providing a cushioning effect and reducing the loads on the abutment teeth, unlike stiff framework materials like metal alloys and zirconium oxide.^{31,33} Thence, PEEK is explored as a potential alternative for fixed and removable dental prostheses.^{28,29,33-35} Besides, it was utilized to construct dental implants and implant abutments,³⁶ occlusal splints,³⁷ retentive components for implant overdentures,³⁸ and onlay implants to improve local mandibular contour deformities.³⁹ PEEK was used for denture bases via injection-molding technique to protect the implant-supporting structures in overdentures,⁴⁰ besides, PEEK framework

could diminish the pressure sores.³² All-on-Four CAD/CAM PEEK framework was endorsed as a suitable strategy for managing mandibular edentulous arches.^{41,42} However, the authors emphasized periodic monitoring for peri-implant soft tissues and marginal bone levels.

Despite extensive research on CAD/CAM technology's benefits, limited evidence exists regarding the peri-implant tissue health associated with CAD/CAM PEEK or PMMA overdenture bases. Hence, this clinical study aimed to evaluate the effects of CAD/CAM -milled (PEEK and PMMA) bases for 4- implant-assisted mandibular overdentures, focusing on assessing the peri-implant tissues in comparison to conventional PMMA overdenture bases.

The null hypothesis of this clinical trial stated that there would be no significant differences in peri-implant soft tissue parameters when using CAD-CAM-milled PEEK or PMMA mandibular overdenture bases and the conventional heat-polymerized PMMA ones throughout the different evaluation periods of the study.

Materials and methods

The study was approved by the Local Dental Research Ethics Committee, number A25061222. ClinicalTrials.gov Identifier: NCT06647199. All participants in the current study provided informed consent after receiving a thorough explanation about the details of the study's procedures and protocol. The guidelines for clinical studies were followed. Two different researchers carried out the treatment steps and follow-up. Both the researchers and patients were blinded to the group assignments. The study was described in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines (Fig. 1).

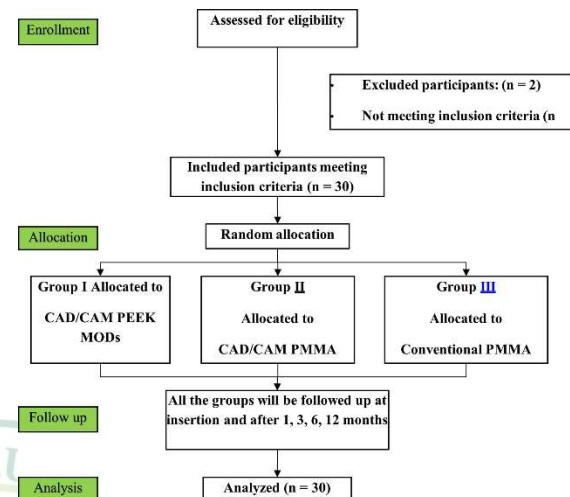


Figure 1: CONSORT flow diagram. n: number

Calculating the sample size was performed using G*Power 3.1 for Mac with $\alpha = 0.05$ and power = 0.95. ANOVA repeated measures, including within- and between-group interactions, were used. An effect size of 0.3 was assumed, determined by the anticipated mean differences in clinical evaluation parameters measured 12 months after implant insertion, as reported by Mourad et al.⁴¹ The mean probing depths were 0.37 mm and 0.62 mm, the mean bleeding score was 0.00, and the mean plaque score was 1.00 after 12 months. The anticipated improvement in clinical parameters was estimated at 10% based on the recommendations of Sharaf et al.³⁸ The total calculated sample size for the three groups was 30.

A total of 30 healthy, completely edentulous individuals (18 men and 12 women), with an average age of 60 years were chosen. These participants had previously experienced inadequate stability and retention with their conventional mandibular dentures and were seeking implant placement for improved retention in their prostheses. The following criteria were fulfilled for each selected subject: all subjects reported unsatisfactory stability and retention of their mandibular dentures at the time of presentation; they had sufficient mandibular bone quantity and quality in the areas of lateral and canine to accommodate standard implants (14 mm in length and 3.6 mm in diameter), as confirmed by cone beam computed

tomography(CBCT); they had a class I maxillomandibular relationship, healthy keratinized mucosa, and adequate interarch space. Conditions such as diabetes, osteoporosis, and immunodeficiency were all excluded, as were subjects with a history of radiation therapy in the head and neck or those using anticoagulant medications. Subjects with a temporomandibular joint dysfunction history which could impede the appropriate function or those who smoked heavily were also excluded. To meet the aforementioned criteria, subjects' medical histories, clinical assessments, and radiographic investigations were conducted.

The participants eligible in this study were allocated to one of 3 studied groups randomly depending on their mandibular overdenture base material. The researcher, who was not involved in the treatment or follow-up, has performed the randomization using an Excel-generated random number sequence. This sequence was securely stored in sealed, opaque envelopes that were only opened immediately before the mandibular overdentures were delivered. The same researcher received the overdentures from the dental laboratory and distributed them according to the randomization sequence to the clinical investigator, who remained blinded to the type of overdenture.

Surgical and Prosthetic Procedures

All participants were provided with a new set of traditional complete dentures that implied a scheme of bilateral balanced occlusion. They were thoroughly instructed to wear their dentures consistently for 3 months prior to placement of implants ascribed to enhancement of the neuromuscular adaptation. Clear autopolymerizing acrylic resin was used to duplicate the mandibular denture for each patient, enabling the fabrication of the mandibular surgical template with gutta-percha markers. By employing CBC3D imaging software program (OnDemand 3D; Cybermed Inc.), all patients underwent

imaging following the dual scan protocol.⁴² Virtual placement of the implants was planned to ensure they were aligned parallel to one another and perpendicular to the occlusal plane at the sites of the canines and lateral incisors. This procedure was performed using 3D imaging software program. The surgical stent with four sleeves was fabricated via rapid prototyping (In2Guide; Cybermed Inc.) and placed over the proposed implant locations. Four dental implants (14 mm in length and 3.6 mm in width) (Dentium Co.) were surgically placed in the anterior mandible. Two implants were positioned bilaterally in the lateral incisor regions, while the remaining two were placed in the canine areas. A flapless surgical technique and a conventional loading protocol were employed. The surgical stent was stabilized on the underlying bone with anchor pins before inserting the implant fixtures. Cover screws were secured to the implants, and the wound was closed. To accommodate the implants, the mandibular denture was relieved and relined using tissue conditioning material (Visco-gel; Dentsply Sirona) and served as a provisional denture. Three months afterward, registering the mandibular impression was performed. The primary impression was recorded, then poured to get the primary cast, upon which fabricating a closed custom tray was executed. Positioner attachments (Dentium Co.) were attached to the implants (Fig. 2), and processing caps along with metal housings were placed over them. By using silicone impression material (Silaxil Light Body;LASCOD), a definitive impression was made at the abutment level after the custom tray was border-molded. The processing caps and metal housings were removed from the impression. Extra-hard scannable dental stone (Kimberlit Extra Hard High-Density Die Stone; Girona) was utilized to pour the impression to make the master cast. Maxillomandibular relations were registered. This was accomplished using traditional mandibular record blocks opposed by the existent maxillary complete

denture. Semi-anatomical acrylic teeth (Ruthinium acrylic teeth; Acry Rock Co.) were set employing the bilateral balanced occlusion. Finally, trying the waxed overdentures in the patient's mouth was performed.



Figure 2: Four implant fixtures with positioning abutments were screwed in place.

Based on the material of mandibular denture bases and the processing technique used, the participants were categorized into 3 equal groups: (CAD/CAM PEEK MODs) whose mandibular overdentures were fabricated using pre-polymerized PEEK discs through CAD/CAM milling, (CAD/CAM PMMA MODs) whose mandibular overdentures were made by milling pre-polymerized PMMA resin discs and (conventional PMMA MODs) who received conventionally manufactured heat-polymerized PMMA overdentures. For (CAD/CAM PEEK MODs) group, scanning of mandibular master cast and trial denture, and maxillary denture have been separately performed and upon occlusion. This was accomplished employing an intraoral digital scanner (Medit i500;MEDIT CO.) (Fig. 3A, B). The scan data were saved in Standard Tessellation Language (STL) format and imported into the design software (EXOCAD Dental CAD DB 2.2 Valletta, exocad; GmbH). The mandibular denture base and tooth setup were virtually designed (Fig. 3C).

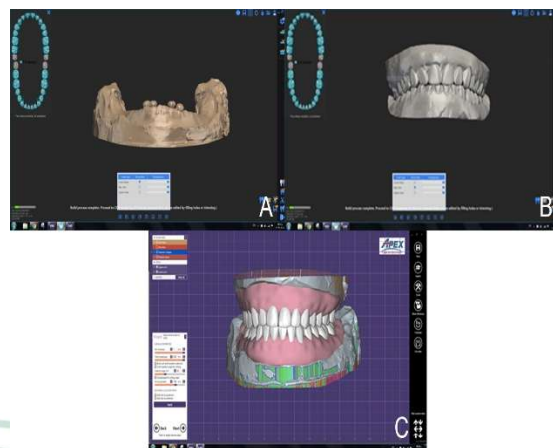


Figure 3: The virtual master cast (A, B) and virtual trial denture (C).

Using the digitally created mandibular denture base, the STL file was transferred to a 5-axis milling machine with a precision of ± 5 mm (MILL Box 2018, ARUM 400). Pre-polymerized PEEK discs (Cupra Peek Rose; Kuraray Noritake Dental Inc.) were milled to fabricate the CAD/CAM PEEK MOD base (Fig. 4).



Figure 4: PEEK overdenture base milling.

Milling of the denture teeth was also done and then bonded to the PEEK-milled overdenture base using a methacrylate-based bonding agent (Visio Lign; Bredent). For (CAD/CAM PMMA MODs) group, importing the STL file of the designed denture base into the milling machine was done for milling the PMMA

MOD base. The virtual designing of the mandibular denture base and tooth setup were accomplished. The PMMA MOD base was milled from gingival-colored prepolymerized PMMA blocks (PMMA Disc;Bio HPP Bredent GmbH & Co.KG) using the virtually created mandibular denture base with the same milling machine used for CAD/CAM PEEK MOD group. Milling of denture teeth, scanned and virtually modeled, was performed from tooth-colored prepolymerized PMMA blocks, then finished, polished, and bonded into the PMMA milled base with a methacrylate-based bonding agent as described for before.

For (conventional PMMA MOD) group, the traditional heat-cured PMMA overdenture was constructed. Processing of the waxed-up overdenture with heat-polymerized PMMA resin (Resin;Major Prodotti Dentari SPA) was performed using the compression molding technique.

For each subject, picking up of the attachments' metal housings into the mandibular overdenture bases was done. A block-out spacer was positioned on the head of each positioner abutment. The metal housings along with the white processing caps were snapped over the abutments. A relief was made in the mandibular overdenture opposing each metal housing to avoid contact with the denture base. Lingual vents were drilled to allow for escapement of excess acrylic resin while picking up procedure. With auto-polymerizing acrylic resin (Repair Material; Dentsply, Sirona), the metal housings were picked up into the fitting surface while subjects were led into centric occlusion gently. Finishing and polishing procedures were done soon after refinement of occlusion. The processing caps were replaced by color-coded retention plastic inserts. Blue extra-light retention caps were used for all attachments (Fig. 5).

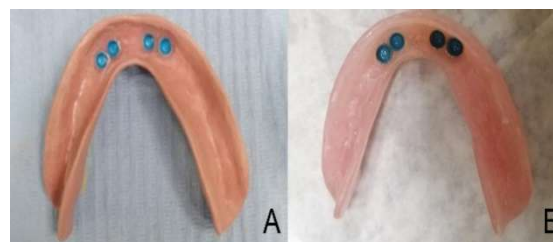


Figure 5: Fitting surface with picked-up attachments of mandibular overdentures. (A) CAD/CAM-milled PEEK. (B) CAD/CAM-milled PMMA.

All patients received their dentures after the necessary adjustments were performed. Strict instructions on oral hygiene were given, along with scheduled periodic visits of follow-up to monitor peri-implant tissue health.

Peri-implant tissue health was evaluated using clinical parameters commonly employed in daily clinical practice and epidemiological studies.⁴⁴ These parameters include bleeding tendency, probing depth, plaque, and calculus formation at the insertion time of mandibular overdenture (T0), at 1 month (T1), 3 months (T2), 6 months (T3), and 12 months (T4) after overdenture insertion. The bleeding index (BI) and plaque index (PI) were evaluated in accordance with Mombelli et al.⁴³ Measurements were taken from the buccal, lingual, mesial, and distal aspects of each implant. All clinical parameters were measured from these four aspects using a graduated periodontal probe (Hawe Perio-Probe; Kerr), and the sum total of the four readings was divided by four to get the mean value (Fig. 6).



Figure 6 : A periodontal probe was used to measure pocket depth (PD) around each implant.

The bleeding index, based on Mombelli et al,⁴³ was used with a Merritt-B periodontal probe. The level of bleeding was measured on a scale from 0 to 3: Score 0: No bleeding, Score 1: Isolated bleeding spots visible, Score 2: Blood forms a confluent red line along the mucosal margin, Score 3: Heavy or profuse bleeding

The modified PI, according to the criteria of Mombelli et al,⁴³ was employed. A score from 0 to 3 was assigned: Score 0: No plaque detected, Score 1: Plaque only recognized by running a probe across the smooth marginal surface of the implant, Score 2: Plaque visible to the naked eye, Score 3: Abundant soft plaque accumulation.

The pocket depth (PD) probing around dental implants was conducted using a light force of approximately 0.25 N with a rounded-tip periodontal probe. The probe was carefully inserted parallel to the long axis of the implant to measure the distance from the gingival margin to the maximum values, followed by analysis using the Mann-Whitney test. To compare different observation times within the same group, the Friedman test was applied. Pairwise comparisons were made using the Wilcoxon signed-rank test. P value was considered significant if equal to or less than 0.05.

Results

A total of thirty healthy, completely edentulous participants (18 men and 12 women) with an average age of 60 years were enrolled in this study. Because of their motivation during the relatively short period of evaluation, all participants attended their scheduled visits without any dropouts. The results indicated that the clinical peri-implant tissue health parameters increased significantly over time in all groups ($P < 0.001$) across the evaluation periods, except for the CAD/CAM- groups (Groups I and II) in terms of calculus formation ($P=1.00$) (Table 1).

base of the sulcus or pocket, recorded in millimeters. Measurements were taken at six key points around the implant: mesial, distal, buccal, lingual, and their interproximal sites. Excessive force was deliberately avoided to ensure patient comfort and prevent damage to the soft tissues.⁴³

A score of 0 or 1 was assigned depending on the presence of calculus: Score 0 indicates no calculus, while Score 1 indicates the presence of calculus.

Data were collected, tabulated, and then statistically analyzed using the Statistical Package of Social Science (SPSS) program, Windows (Standard version 27). Normality of the data was assessed using the Shapiro-Wilk test. Based on the data's normality, the appropriate statistical test was chosen. For comparing mandibular overdentures across the three groups, nonparametric data were tabulated, and descriptive analysis was conducted using the median, minimum, and

With regard to the bleeding index, significant differences were observed among the three groups at 3, 6, and 12 months ($P<0.000$). While no significant differences were found in the other time intervals. The median (range) scores were as follows: 0.00 (0.00 - 0.00) for the CAD/CAM-milled PEEK group, 1.00 (0.00 - 1.00) for the CAD/CAM-milled PMMA group and 2.00 (0.00 - 2.00) for the conventional PMMA group, respectively (Table 1) With respect to the plaque index, significant differences were observed among the three groups at 3, 6, and 12 months ($P < .000$). However, no significant differences were found in the other time intervals. The median (range) scores were: 0.00 (0.00 - 0.00) for the CAD/CAM-milled PEEK group, 1.00 (0.00 - 1.00) for the CAD/CAM-milled PMMA group and 2.00 (0.00 - 2.00) for the traditional PMMA group, respectively (Table 1). Regarding the pocket depth, significant differences were observed among the three groups at 1 and 3 months ($P = 0.001$), and at 6 and 12 months ($P < 0.000$). The median (range) scores

were as follows: at (T1), 0.10 (0.05 - 0.15), 0.19 (0.07 - 0.23), 0.21 (0.13 - 0.25); at (T2), 0.12 (0.10 - 0.17), 0.22 (0.17 - 0.31), 0.37 (0.22 - 0.55); at (T3), 0.17 (0.11 - 0.19), 0.24 (0.19 - 0.37), 0.46 (0.31 - 0.57); and at (T4), 0.17 (0.11 - 0.19), 0.26 (0.20 - 0.41), 0.51 (0.26 - 0.66) for the CAD/CAM-milled PEEK group, CAD/CAM-milled PMMA group, and the conventional PMMA group, respectively (Table 1). As for calculus formation, significant differences were noted among the three groups at both 6 and 12 months ($P < .000$). When comparing the change in calculus formation over time within each group, a significant increase was shown only in the conventional PMMA group ($P < .000$) (Table 1).

Discussion

Successfully monitoring soft tissues around dental implants for implant-assisted prostheses entails clinicians having comprehensive cognition of proper placement of implant, prosthesis design, and tissue management, in addition to advanced surgical and technical skills. The health of peri-implant tissue was known as one of the most crucial factors impacting management success. Emerging advancements like reconstructive digital dentistry involving digital tools implied in treatment planning, surgical techniques that are minimally invasive and novel biomaterials can all lead to more satisfying outcomes and can help achieve both functional and aesthetic excellence in implant-based oral rehabilitation.⁴⁴⁻⁴⁷

Implant-assisted overdentures have become a popular and effective treatment choice for edentulous patients, particularly for individuals facing issues with traditional complete dentures. This study utilized four implants to assist mandibular overdentures rather than the more commonly used two implants, since current studies indicated that employing four implants provides greater consequences for rehabilitating the edentulous mandibles than two.^{29,48,49} Nonetheless, to the best of

the authors' knowledge, relatively little information is available in the literature regarding the use of innovative, digitally fabricated PEEK or PMMA base materials in four implant-assisted mandibular overdentures upon rehabilitating the edentulous patients. Thence, the current study was designed to elaborate on how these new base materials impact the health of peri-implant soft tissues compared to the conventional PMMA.

The findings of the current study revealed that the clinical peri-implant parameters increased significantly over time in all groups ($P < .001$) across the evaluation periods, except for the CAD/CAM-milled PEEK and CAD/CAM-milled PMMA groups in terms of calculus formation ($P=1.00$). Also, the results showed that the CAD/CAM-milled PEEK and PMMA mandibular overdentures displayed overall better peri-implant soft tissue scores compared to the conventional heat-cured PMMA mandibular overdenture (Conventional PMMA MOD). Therefore, the null hypothesis has been rejected.

The explanation could be owing to the more precise bases adaptation of the delivered CAD/CAM overdentures, higher patient satisfaction, accordingly, superior clinical performance than the compression mold technique as announced in previous studies.^{26-29,50} These studies emphasized that employing CAD/CAM-milled PEEK or PMMA for mandibular overdentures resulted in less denture deformation, greater fit of the denture, improved biting force and patient satisfaction compared to conventional PMMA. This finding also concurred with Felton et al.,⁵¹ who demonstrated that properly fitted dentures offered greater initial wearing comfort and decreased the occurrence of traumatic ulcers.

Table 1: Comparison of different clinical parameters (bleeding, plaque, pocket depth and calculus) at different observation times in 3 groups

	CAD/CAM-milled PEEK Median (Min-Max)	CAD/CAM-milled PMMA Median (Min-Max)	Conventional PMMA Median (Min-Max)	P value
Bleeding index				
At insertion (T0)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	1.00
One month (T1)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	1.00
3 months (T2)	0.00 ^{bc} (0.00 - 0.00)	1.00 ^{ac} (0.00 - 1.00)	2.00 ^{ab} (0.00 - 2.00)	< 0.000*
6 months (T3)	0.00 ^{bc} (0.00 - 1.00)	1.00 ^{ac} (0.00 - 1.00)	2.00 ^{ab} (0.00 - 3.00)	< 0.000*
One year (T4)	0.00 ^{bc} (0.00 - 1.00)	1.00 ^{ac} (0.00 - 2.00)	3.00 ^{ab} (0.00 - 3.00)	< 0.000*
P value	< 0.000*	< 0.000*	< 0.000*	
Plaque index				
At insertion (T0)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	1.00
One month (T1)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	1.00
3 months (T2)	0.00 ^{bc} (0.00 - 0.00)	1.00 ^{ac} (0.00 - 1.00)	2.00 ^{ab} (0.00 - 2.00)	< 0.000*
6 months (T3)	0.00 ^{bc} (0.00 - 1.00)	1.00 ^{ac} (0.00 - 1.00)	2.00 ^{ab} (0.00 - 3.00)	< 0.000*
One year (T4)	0.00 ^{bc} (0.00 - 1.00)	1.00 ^{ac} (0.00 - 2.00)	3.00 ^{ab} (0.00 - 3.00)	< 0.000*
P value	< 0.000*	< 0.000*	< 0.000*	
Pocket depth				
At insertion (T0)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	1.00
One month (T1)	0.10 ^{bc} (0.05 - 0.15)	0.19 ^c (0.07 - 0.23)	0.21 ^{ab} (0.13 - 0.25)	0.001*
3 months (T2)	0.12 ^{bc} (0.10 - 0.17)	0.22 ^c (0.17 - 0.31)	0.37 ^{ab} (0.22 - 0.55)	0.001*
6 months (T3)	0.17 ^{bc} (0.11 - 0.19)	0.24 ^{ac} (0.19 - 0.37)	0.46 ^{ab} (0.31 - 0.57)	< 0.000*
One year (T4)	0.17 ^{bc} (0.11 - 0.19)	0.26 ^{ac} (0.20 - 0.41)	0.51 ^{ab} (0.26 - 0.66)	< 0.000*
P value	0.001*	< 0.000*	< 0.000*	
Presence of calculus				
At insertion (T0)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	1.00
One month (T1)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	1.00
3 months (T2)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	0.00 (0.00 - 0.00)	1.00
6 months (T3)	0.00 ^c (0.00 - 0.00)	0.00 ^c (0.00 - 0.00)	1.00 ^{bc} (0.00 - 1.00)	< 0.000*
One year (T4)	0.00 ^c (0.00 - 0.00)	0.00 ^c (0.00 - 0.00)	1.00 ^{bc} (0.00 - 2.00)	< 0.000*
P value	1.00	1.00	< 0.000*	

*Significant if $P \leq 0.05$. Max: maximum; Min: minimum. (T0): at the time of insertion; (T1): one month after insertion; (T2): three months after insertion; (T3): six months after insertion; (T4): twelve months after insertion. (a) CAD/CAM-milled PEEK; (b) CAD/CAM-milled PMMA; (c) conventional PMMA. Superscript abbreviations in the same row indicate significance with this group.

In this sense, the results are in line with AlHelal and colleagues.²⁴ They reported that milled PMMA complete denture bases exhibited significantly better retention compared with traditional heat-polymerized denture bases. Besides, enhanced fit of the denture base was also proclaimed with PEEK denture base material.⁵² Notwithstanding, complete denture bases manufactured using CAD/CAM techniques showed comparable fit and retention to those of traditionally manufactured bases, as stated by Maniewicz et al.⁵³ Meanwhile, Ohara et al,⁵⁴ declared that digital dentures may be somewhat comparable to or inferior to conventional dentures, contrary to our findings. The inconsistency in results could be due to the differing manufacturing processes used for digital dentures made with a milling machine compared to those fabricated with a 3D printer, as demonstrated in their study.⁵⁴

The better peri-implant tissue scores observed in the CAD/CAM overdenture groups, compared to the conventional group, in the present study may be due to the prostheses' characteristics including a smooth surface, lower porosity, and reduced shrinkage of polymerization, as confirmed in previous research.^{19,20,22,55,56} It was established early that a smooth surface is requisite in all restorative procedures to prevent biofilm development, which consequently enhances therapeutic outcomes and patient acceptance.^{57,58} Traditional dentures were found to have greater *Candida* adhesion than CAD/CAM dentures, even when carefully finished and polished.⁵⁹ Additionally, some researchers also observed that materials produced using CAD/CAM technology have notable surface hydrophilicity, which may lead to decreased microbial colonization.^{60,61}

Moreover, the findings of the current study demonstrated that bleeding tendency, plaque scores, along with probing depth increased significantly over

time in the 3 groups ($P < 0.001$) across the evaluation periods, except for calculus, which was significant only in the conventional PMMA group with advancement of time ($P < .000$). These findings could be attributed to the challenges of cleaning the narrow space beneath the prosthesis, such as the relieved areas created surrounding the metal copings to prevent gingival trauma. Additionally, it could be related to the geometry of the positioner attachments, which had areas prone to plaque accumulation and difficult to clean. This aligns with the observations announced by Dörsam et al,³² However, Bakker et al,⁶² noted in their study that poor oral hygiene practices were prevalent among elderly participants.

Based on the study's findings, comparisons among the three groups over various evaluation periods showed significant differences in bleeding scores and pocket depth at 1 month, 3 months ($P = .001$), 6 months, and 12 months ($P < .000$) following overdenture insertion, with the CAD/CAM-milled PEEK group showing better outcomes. The explanation can be ascribed to PEEK's peculiar properties, which include high biocompatibility, hypoallergenic nature, strong mechanical performance, resistance to temperature and wear, as well as chemical stability.⁶³⁻⁶⁵

Within this framework, unlike rigid materials, for instance metal alloys and zirconium oxide, PEEK has a lower modulus of elasticity (4 GPa), making it as elastic as bone and capable of reducing stress on abutment teeth through a cushioning effect. PEEK's low specific weight allows for the fabrication of lightweight prostheses, enhancing patient satisfaction and comfort. Additionally, PEEK is advantageous due to its metallic taste-free composition and can serve as an alternative material for removable partial denture frameworks upon combining with acrylic denture teeth and base materials.³³⁻³⁶ Moreover, PEEK's excellent polishability and low plaque affinity, traits that contribute to its effectiveness, have been

linked with enhancement of peri-implant soft tissue outcomes.^{32,61,66-68}

The study is limited by its small sample size and relatively short period of follow-up. More outcomes on long-term evaluation, such as bone resorption, should be considered. Therefore, future randomized clinical trials with a larger sample size and longer follow-up periods are required to validate the findings of the present study.

Conclusion

Based on inferences from this study, CAD/CAM-milled PEEK and PMMA are suggested for mandibular implant overdenture bases with regard to peri-implant tissue health outcomes, as they exhibited better peri-implant tissue health compared to conventionally constructed bases. However, CAD/CAM-milled PEEK overdenture bases are seemingly advantageous.

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Availability of data and materials

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Consent for publication

Not applicable

Ethics approval and consent to participate

The patients were fully informed about the purpose and procedures of this study and provided written informed consent. The study was approved by the Local Dental Research Ethics Committee of the Faculty of Dentistry, Mansoura University, number A25061222. ClinicalTrials.gov Identifier: NCT06647199.

Competing interests

The authors have no conflicts of interest to declare.

Author Contribution

Fatma Ahmad El Waseef: Formulated the study concept, performed the randomization and validation, contributed to the writing, critically revised the manuscript, and conducted editing procedures. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved.

Rabab I. Salama: Collected data, performed formal analysis, and contributed to the writing of the manuscript. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved.

Amira Mohammed Gomaa Faramawy: Designed and planned the research, conceptualized the study, performed the prosthetic procedures, and participated in writing and revising the manuscript. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved.

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