Prosthetic Maintenance Assessment for Two Implant-Retained Overdentures Reinforced with PEKK Versus Co-Cr Framework: A Randomized Controlled Clinical Trial

Keywords

Dental Implants
Overdenture
Maintenance/Standards
Computer-Aided Design-Computer-Aided Manufacturing

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Received: 18.04.2024
Accepted: 28.06.2024

doi: 10.1922/EJPRD_2715Salama09

ABSTRACT

Introduction: The primary challenge associated with implant overdentures lies in the occurrence of denture fractures around the attachments. Hence, it is recommended to enhance flexural strength through reinforcement frameworks. This study aimed to assess and compare the prosthetic maintenance of mandibular implant overdentures reinforced with Co-Cr and PEKK frameworks. Methods: Twenty-four participants with completely edentulous ridges were selected, and two implants were placed at the mandibular canine areas. After osseointegration period, ball attachments were installed. Participants were randomly assigned into two groups: Group I received a mandibular implant overdenture reinforced with a Co-Cr framework, while Group II received a mandibular implant overdenture reinforced with a PEKK framework. Prosthetic maintenance evaluations were conducted in both groups twelve months post-denture insertion. Categorical data were analyzed, and results were presented as frequency and percentage values. Results: Group II exhibited a significantly higher percentage of cases with screw looseness, denture relining, and tooth separation compared to Group I. Although Group II cases showed a non-significant increase in the percentage of insert wear and retention loss. Conclusion: Within the limitations of this study, the findings suggest that Co-Cr, in contrast to PEKK frameworks, offers a more reliable reinforcement of the implant-retained overdentures.

INTRODUCTION

Complete denture rehabilitation remains one of the most prevalent conventional prosthodontic treatment options for edentulous patients with systemic, anatomic, or socioeconomic constraints.[1] Complaints from complete denture wearers typically concern the insufficient retention and stability of the mandibular complete denture, which are attributed to the absence of a peripheral seal, reduced surface area, and the presence of the tongue.[2] To address these issues, dental implants are currently regarded as one of the crucial treatment modalities for rehabilitating partially and completely

edentulous patients.[3] Implementing implant-supported overdentures (ISODs) has become a favored treatment option for completely edentulous patients, offering advantages such as enhanced function, stability, and retention, particularly in the mandible.[4] The two-implant-retained overdenture is recognized as a treatment option for completely edentulous patients due to it is several advantages, such as cost-effectiveness, patient satisfaction, and the increased retention of the mandibular denture, which is deemed acceptable for many patients.[5]

However, one of the significant challenges with using two-implant-retained overdentures is the susceptibility of the denture base material, typically polymethyl methacrylate (PMMA), to distortion during mastication due to its low mechanical strength. This often leads to denture fractures, especially in the anterior region where stress is concentrated over the implants. The fractures usually begin with a crack and propagate along the entire denture base.[6] To mitigate this issue and enhance flexural strength, denture bases can be reinforced with metal frameworks to protect against implant overdenture fractures, reduce deformation, and increase rigidity.[7] Despite these benefits, the insertion of metal frameworks into the denture base to reinforce it presents several drawbacks. These include increased weight, higher costs, and a more complicated treatment process.[7] the metal frameworks, often made from Co-Cr and nickel-chromium (Ni-Cr) alloys, can cause allergic reactions in the underlying tissues.[8]

Given these limitations of metal frameworks, researchers and clinicians have used alternative materials such as polyaryletherketones (PAEKs). PAEKs, including polyetheretherketone (PEEK) and PEKK, are used for their exceptional mechanical properties and biocompatibility.[9,10] PEEK offers high chemical resistance and mechanical stability, making it a compelling choice as a framework material for patients with metal allergies.[11] However, studies have highlighted that while PEEK exhibits excellent biocompatibility and mechanical performance, its higher deformation under stress compared to metal alloys can lead to increased stress transfer to the supporting structures of dentures.[11] On the other hand, PEKK emerges as a promising alternative with even greater mechanical strength and durability. For instance, Pekkton® ivory, a PEKK variant, demonstrates significantly higher compressive strength compared to unreinforced PEEK. Furthermore, the incorporation of titanium dioxide (TiO_2) in PEKK enhances its hardness, wear resistance, and shock absorbance.[12] A Study comparing PEKK and PEEK frameworks in full-arch prostheses has shown that PEKK's superior shock absorbance results in lower stress concentrations on prosthetic screws and bases, thereby reducing the risk of acrylic base fractures and screw loosening compared to PEEK. Conversely, lower stress concentration was observed on PEEK frameworks.[13]

In addition to selecting the appropriate material for frameworks, the type of attachment used to connect the overdentures to the dental implants plays a crucial role in the overall success and performance of the prosthesis. Different types of attachments, such as bar, ball, and magnetic attachments, along with telescopic crowns, have been suggested.[15] Ball attachments are the simplest and easiest treatment used in implant-retained overdentures. They offer high retention, can be used with unparalleled implants, and reduce the load transferred to the implants.[14]

The most important factors in determining prosthetic survival are the evaluation of implant survival and the complication rate of mandibular implant-retained overdentures.[15,16] There are two common types of complications in implant prostheses: biological and prosthetic. Biological complications refer to disorders in implant function that disturb the supporting peri-implant tissues, resulting in mucositis or peri-implantitis in severe conditions. Technical complications refer to damage to the implant, implant parts, and/or the superstructures, such as screw loosening, attachment wear, and fractures of the prosthesis or its teeth.[17]

In this context, this study aimed to evaluate and compare the prosthetic maintenance of mandibular implant-retained overdentures reinforced with Co-Cr and PEKK frameworks. The null hypothesis set for this clinical trial was that there would be no differences between mandibular implant-retained overdentures reinforced with Co-Cr and those reinforced with PEKK frameworks regarding prosthetic maintenance.

MATERIALS AND METHODS

This randomized clinical trial. was approved by the Faculty of Dentistry, Ain Shams University (approval number: FDASU-Rec PC 122352). It was retrospectively registered and published on https://clinicaltrials.gov/ with the NCT number (NCT06219811) on 23/01/2024.

A power analysis was designed to have adequate power to apply a statistical test of the null hypothesis that there is no difference between different tested groups regarding prosthetic maintenance. By adopting an alpha (α) level of (0.05), a beta (β) level of (0.2) (i.e., power=80%), and an effect size (ω) of (0.646) calculated based on the results of a previous study;[18] the total required sample size (n) was found to be (20) cases (i.e., 10 cases per group). Sample size was increased by (20%) to account for dropouts during follow-up intervals to be (24) cases (i.e., 12 cases per group) Sample size calculation was performed using R statistical analysis software version 4.3.2 for Windows.[19]

PATIENT SELECTION

Twenty-four completely edentulous patients were selected from the outpatient clinic of the prosthodontics department at a dental institution. The flow of participants during the study is shown in the CONSORT 2010 flow diagram *(Figure 1)*.

Patients were asked about their personal, medical, and dental history. Patients were gathered according to the selected inclusion: male patients aged 50 to 70 years, completely edentulous,

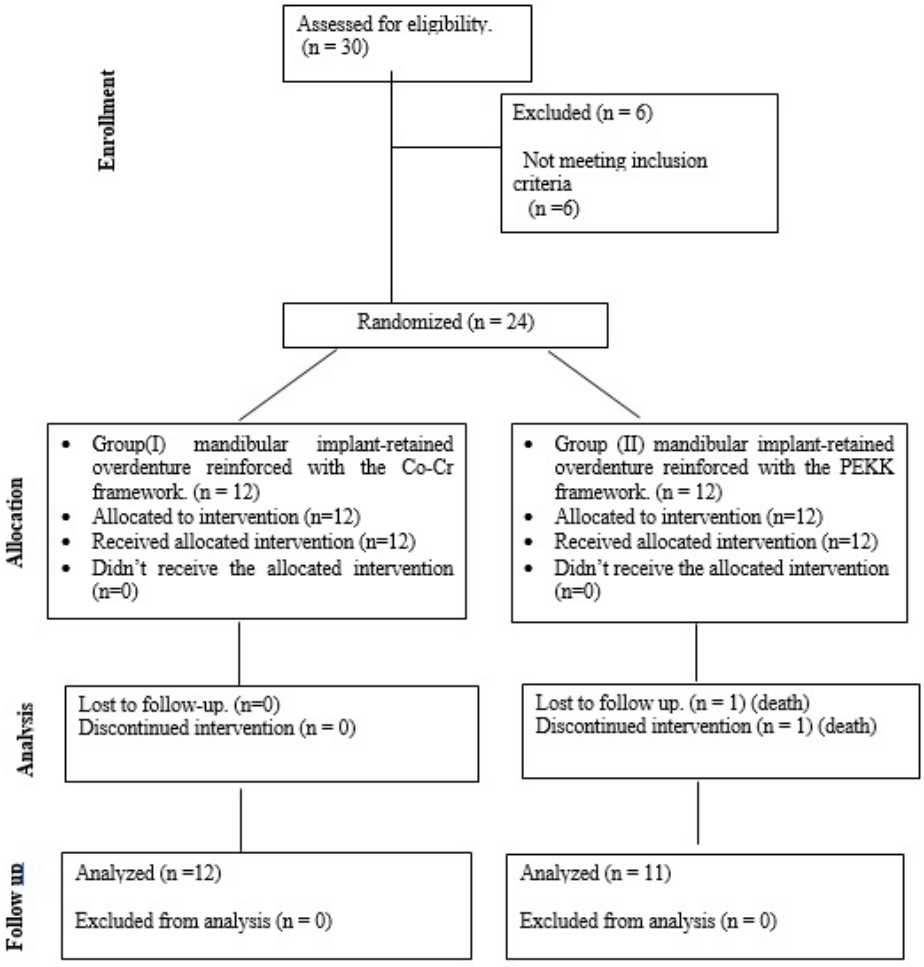

Figure 1: Participant CONSORT Flowchart Detailing Patient Progression Through Each Stage of the Randomized Controlled Trial.

systemically free from diseases contraindicating implant placement, a minimum of 12 mm bone height and 6 mm bone width at the canine areas as diagnosed by pre-operative Cone Beam Computerized Tomography (CBCT), and sufficient inter-arch space (12-15 mm) to accommodate the reinforced mandibular implant-retained overdentures.[20,21] heavy smokers, patients with uncontrolled metabolic disorders such as diabetes mellitus, bone or mucosal diseases, parafunctional habits, irradiated patients,[22] and conditions complicating treatment, such as a severe gag reflex or limited mouth opening.

Extraoral and intraoral examinations were conducted to identify any abnormalities in the temporomandibular joint (TMJ) and any bony or tissue irregularities. The patients' existing removable complete dentures were assessed for retention, vertical dimension, centric occluding relation, and interarch distance. These dentures were duplicated to a radiographic stent and Gutta-percha was fixed as radiopaque markers on the buccal and labial surfaces, extending from the occlusal surface to the lower border of the stent.[23] New ones were fabricated if the existing dentures were inadequate or absent. Cone Beam Computed Tomography (CBCT) (i-CAT Vision®, Imaging Sciences International, Hatfield, PA, USA) was performed while the patient wore the radiographic stent in centric occluding relation to the opposing maxillary removable complete denture. The implant width and length were calculated and planned for placement in the canine region.

SURGICAL PROCEDURES

All patients signed informed consent before surgical procedures, detailing all surgical and prosthetic steps. Patients were instructed to rinse with chlorhexidine mouthwash (Hexitol, Kahira Pharma and Chemical Co., Cairo, Egypt) three times daily for two days before the surgery and to take a prophylactic dose of amoxicillin-clavulanate (Augmentin 1 g, Glaxo-SmithKline Pharmaceutical Nigeria Ltd., Lagos, Nigeria) one hour before the procedure. The radiographic stent was modified to serve as a surgical guide by creating two holes in the canine area to locate the implant sites. Bilateral mental and lingual nerve blocks (LIGNOSPAN®, Septodont, United Kingdom) were administered. A periodontal probe was used to mark the proposed implant sites, followed by an intraoral crestal incision between the marked points, extending posteriorly with buccal releasing incisions to facilitate flap reflection. A full-thickness mucoperiosteal flap was reflected buccally and lingually to expose the bone completely. Sequential drilling was performed at the planned implant sites, and parallelism was checked using parallel pins. Two implants (SuperLine, Dentium, Katella Avenue, USA) measuring 3.6 mm x 12 mm were inserted with a torque of 35 Ncm.[24] Single interrupted sutures were used to close the surgical flap with resorbable sutures. All participants were instructed to complete the

course of amoxicillin-clavulanate every twelve hours for seven days post-surgery. An analgesic (Ibuprofen 600 mg, Knoll AG, Ludwigshafen, Germany) was prescribed every eight hours for three days to manage post-operative pain and inflammation. Additionally, patients were advised to maintain strict oral hygiene and to rinse with chlorhexidine mouthwash three times daily for seven days starting the day after surgery. A follow-up visit was scheduled for a one-week post-surgery for relining of the relieved removable complete denture with a soft liner (MUCOPREN® SOFT, Kettenbach GmbH & Co. KG, California, USA) over the surgical site.

PROSTHETIC PROCEDURE

Before proceeding with the prosthetic procedure, Participants were randomly assigned to one of two groups (I or II) by a practitioner not involved in the treatment process, who coordinated with the laboratory technician. Randomization was performed using Research Randomizer (https://www.randomizer.org/), which generated a list of random codes. These codes were printed and placed in opaque, sealed envelopes. The randomization list was stored on a password-protected laptop, accessible only to the practitioner. Patients were asked to select an envelope, and the practitioner determined the group assignments accordingly.

Group I received mandibular implant-retained overdentures reinforced with a Co-Cr framework. Group II received mandibular implant-retained overdentures reinforced with a PEKK framework.

After three months of osseointegration, patients were recalled, and healing abutments were reconnected to the dental implants using the previous stent to relocate the implant sites. One week later, preliminary maxillary and mandibular impressions were taken using an irreversible hydrocolloid (CA37, Cavex Holland BV, Haarlem, Netherlands). Special trays for maxillary and mandibular impressions were constructed from auto-polymerizing acrylic resin (Acrostone Cold Cure, Acrostone Dental & Medical Supplies, Cairo, Egypt) with two holes aligned with the mandibular implants on the study cast. Secondary impressions were taken by border molding the special trays with green stick compound (Hiflex Green Sticks, Prevest DenPro, USA) and making the maxillary secondary impression with medium rubber base impression material (Thixoflex M, Zhermack, Badia Polesine, Italy). Long impression copings were connected to the implants, and open tray mandibular impressions were performed using medium rubber base impression material. Implant analogs were attached to the copings before pouring the master cast. Identical Ball abutments were utilized for both groups and connected to the implant analogs on the master cast, and occlusion blocks were fabricated. A face-bow record (Bio-Art Elite Face Bow, Bio-Art, São Carlos, Brazil) was taken for mounting the maxillary cast on a semi-adjustable articulator (A7 Plus Articulator, Bio-Art, São Carlos, Brazil). An interocclusal record was obtained using the wax wafer technique (CAVEX SET UP WAX, CAVEX, Haarlem, Netherlands) for mounting the mandibular cast. Setting up of acrylic teeth in a lingualized balanced occlusion, waxing up, and try-in procedures were subsequently performed.

Metal housings were connected to the ball abutments on the master cast, which was then scanned using a desktop scanner (Medit IdenticaT500, MEDIT, Seoul, South Korea) both with and without the trial denture base to obtain standard tessellation language (STL) files. These STL files were overlapped and imported into the design software (Exocad DentalCAD 2.4 Plovdiv, exocad GmbH, Darmstadt, Germany) to design the frameworks according to the group specifications. All undercuts were blocked on the virtual model. The framework was outlined and positioned on the virtual model to cover the crest of the ridge, allowing space over the metal housings, with a thickness of 1 mm for Co-Cr frameworks and 2 mm for PEKK frameworks, based on the recommended minimum thickness from previous studies.[25,26] A 2 mm relief was designed under the frameworks, which were checked and smoothed on all surfaces *(Figure 2)*.

The STL file was imported into a milling machine (K5, vhf cam-facture AG, Ammerbuch, Germany) to mill the framework according to the group assignment. For Group I, the framework was initially milled from polymethylmethacrylate (PMMA) (PMMA disk, YAMAHACHI, Japan). Afterward, it was cast to Co-Cr alloy using a conventional casting technique. *(Figure 3)*.[27] For Group II, the framework was milled directly from PEKK blanks (Pekkton® ivory, Cendres + Métaux SA, Biel/Bienne, Switzerland).

The frameworks were checked on the master cast *(Figures 4* and 5) and intraorally to ensure proper adaptation. Both frameworks underwent surface treatment by air abrasion with alumina oxide 110 µm particle size at 2 bar pressure for 15 seconds, maintaining 10 mm distance using a specially designed holder for standardization. They were then ultrasonically cleaned with deionized water for 10 minutes and dried with air.[28] Subsequently, the maxillary and mandibular overdentures were processed using heat-cured acrylic resin (Vertex Rapid Simplified, Vertex Dental, Soesterberg, Netherlands) via a conventional long polymerization cycle, followed by the usual finishing and polishing procedures.

The denture was assessed for retention, stability, and support, and necessary adjustments were made. Ball abutments were connected to the dental implants, after which the undercuts were blocked out, block-out shims were inserted, and metal housings were connected intraorally to the abutments. The housings were directly picked up to the fitting surfaces of the overdenture using auto-polymerizing acrylic resin (Dura Liner II Denture Reline, Reliance Dental Manufacturing LLC, United States). Patients were instructed to bite in centric relation until the acrylic resin was set. The excess acrylic resin was removed, and the denture was finished, polished, and checked intraorally *(Figure 6)*.[29,30] Patients were advised to follow strict oral hygiene practices.

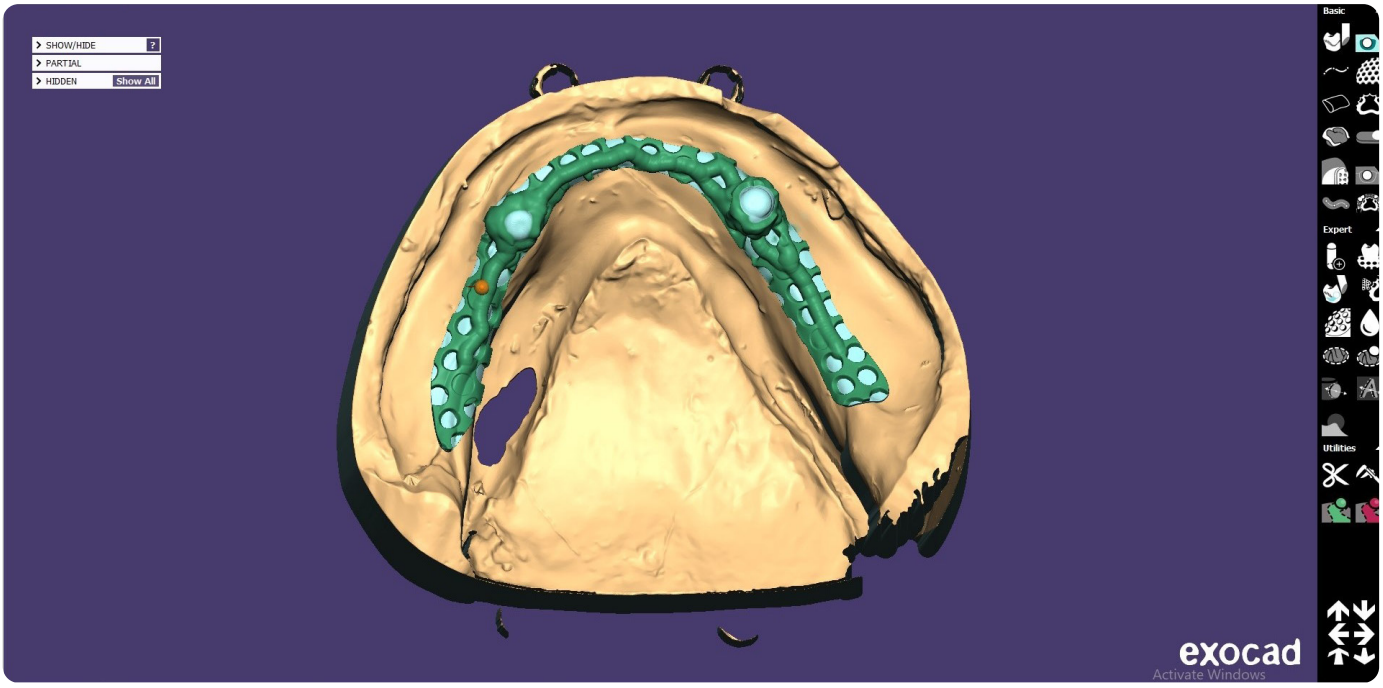

Figure 2: Digital Designing of PMMA framework on virtual model. using Exocad software.

Figure 3: Conventional casting technique used to cast PMMA framework into a Co-Cr framework.

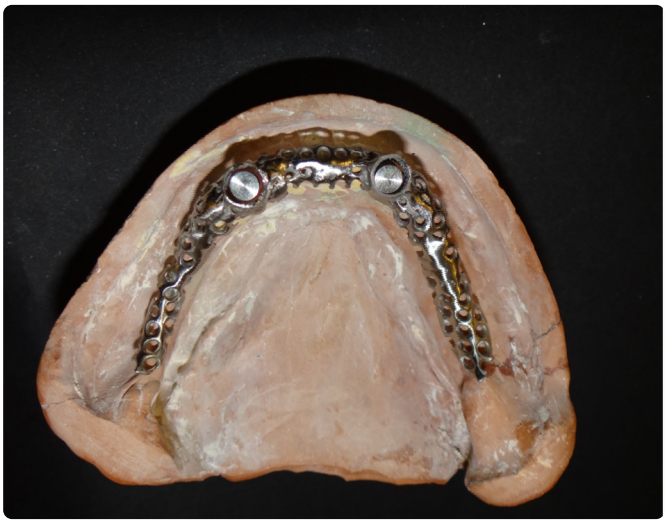

Figure 4: Checking the metal framework on the master cast before processing within the denture.

Figure 5: Checking the PEKK framework on the master cast before processing within the denture.

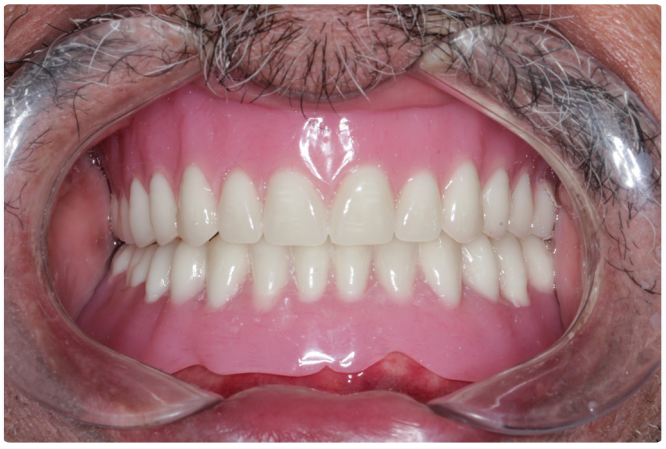

Figure 6: Delivery of the implant-retained overdenture after pickup of attachment housings.

Prosthetic maintenance for mandibular implant-retained overdentures in both groups was assessed twelve months after clinical functional use. The evaluation concentrated on identifying screw-related problems (such as loosening or fracture), attachment-related issues (including wear, distortion, fracture, or replacement), and overdenture-related concerns (such as fracture, need for relining or remake, and issues with teeth wear separation or fracture). Each complication was documented as either present or absent by a single researcher, who also noted the frequency and percentage of occurrence for each issue.[18,24]

Categorical data were presented as frequency and percentage values and were analyzed using Fisher's exact test. The significance level was set at $p<0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.3.2 for Windows.[19]

RESULTS

The study included 12 patients in Group I and 11 patients in Group II. After a 12-month follow-up, the collected data were tabulated and analyzed statistically. Summary statistics and intergroup comparisons of prosthetic maintenance are presented in Table 1.

No fractures of abutments or screws were observed in either group. However, screw looseness was significantly more common in Group II (n=6, 54.55%) compared to Group I (n=1, 8.33%) (p=0.027).

Group II also had higher percentages of insert wear (n=9, 81.82%) and loss of retention (n=9, 81.82%) than Group I (n=6, 50.00% and n=5, 41.67%, respectively), these differences were not statistically significant (p >0.05). Additionally, all patients in both groups required nylon insert replacements after twelve months, and there were no instances of housing fractures.

Teeth wear was more prevalent in Group II (n=3, 27.27%) than in Group I (n=2, 16.67%), but this difference was not statistically significant (p >0.05). Conversely, Group II had a significantly higher percentage of denture relining (n=9, 81.82%) and tooth separations (n=4, 36.36%) compared to Group I (n=4, 33.33% and n=0, 0.00%, respectively) (p<0.05).

DISCUSSION

A primary issue with implant-retained overdentures is the occurrence of denture fractures around the attachment area. To mitigate this issue, it is recommended to reinforce the denture to enhance its flexural strength.[6,31] In this study, ball attachments were employed, given that denture base fractures are

Table 1. Summary statistics and intergroup comparisons of prosthetic maintenance.

Parameter	Complication	n (%)		χ^2	p-value	Odds ratio (95% CI)
		Group (I) (n=12)	Group (II) (n=11)			
Ball abutment	Abutment fracture	0 (0.00%)	0 (0.00%)	NA	NA	NA
	Screw loosening	1 (8.33%)	6 (54.55%)	5.79	0.027*	13.20 (1.24:140.69) *
	Screw fracture	0 (0.00%)	0 (0.00%)	NA	NA	NA
Housing and Nylon Insert	Nylon Insert wear	6 (50.00%)	9 (81.82%)	2.56	0.193	1.09 (0.02:59.4)
	Nylon Insert replacement	12 (100.00%)	11 (100.00%)	NA	NA	NA
	Loss of retention	5 (41.67%)	9 (81.82%)	3.88	0.089	6.30 (0.93:42.73)
	Fracture of housing	0 (0.00%)	0 (0.00%)	NA	NA	NA
Overdenture	Dentures reline	4 (33.33%)	9 (81.82%)	5.49	0.036*	9.00 (1.29:63.03) *
	Denture fracture	0 (0.00%)	0 (0.00%)	NA	NA	NA
	Teeth wear	2 (16.67%)	3 (27.27%)	0.38	0.640	1.88 (0.25:14.08)
	Teeth separation	0 (0.00%)	4 (36.36%)	5.28	0.037*	15.00 (0.7:319.54)
	Teeth fracture	0 (0.00%)	0 (0.00%)	NA	NA	NA

NA: Not Applicable, CI: Confidence interval, *Significant (p<0.05).

a prevalent complication with implant-retained overdentures utilizing these attachments. Consequently, strengthening the denture base is advised to improve fracture resistance.[32,33]

The null hypothesis of this study was partially rejected, as a significant difference was observed between implant-retained overdentures reinforced with Co-Cr and PEKK frameworks in terms of screw loosening, denture relining, and teeth separation. At the same time, there was no significant difference between the two groups regarding insert wear and replacement, retention loss, and teeth wear.

Only male patients aged 50-70 years were included in this study. Female patients in this age range were excluded due to known factors such as estrogen deficiency and qualitative bone changes related to menopause, which have been linked to potential challenges in the osseointegration of dental implants.[34] Additionally, the mean age of menopause in Egypt is 46.7 years, which is lower than in many other countries, although this age has been increasing recently. Egyptian women experience a higher incidence of menopause-associated symptoms compared to women in Western countries, likely due to differing sociocultural attitudes towards menopause. Bone mineral density charts for Egyptian women indicate that they generally have lower bone mineral density compared to their Western counterparts, and post-menopausal women often suffer from osteoporosis.[35]

The use of Exocad software to perform a virtual design of PEKK and Co-Cr frameworks was to standardize their thickness. In Group I, Co-Cr frameworks were initially milled from PMMA and subsequently cast using conventional casting techniques. This approach was chosen to mitigate the high costs of milling precious metals and minimize wear on milling burs.[36]

Before applying heat-cured acrylic resin, both frameworks underwent surface treatment by air abrasion. This treatment involved the use of airborne particles to create a suitable surface condition and improve bond strength. The air abrasion process effectively removed any contaminated layers, debris, and metal oxides from the surface. Additionally, it increased the surface area by producing micromechanical roughness, which is essential for enhancing mechanical bonding. This treatment also improved the wettability of the material surface, further aiding in the adhesion of the acrylic resin.[28,37,38]

Abutment screw loosening occurred in both groups, likely due to the transmission of masticatory forces to the implant-abutment interface, which subsequently affects the screws, leading to their loosening.[24] A previous study reported screw loosening in 7.2% of 1928 implants within six months of loading due to masticatory forces.[39]

Screw loosening was significantly more frequent in group II compared to group I. This finding contradicts the expectation that PEKK, known for its shock-absorbing properties,[12,40] would transmit more stress to the supporting implant over time compared to Co-Cr. This phenomenon is due to the tendency of PEKK frameworks to undergo permanent deformation under dynamic stresses, as demonstrated by previous studies.[41,42] Another study indicated that while a PEKK framework showed lower stress transmission to the implant and simulated adjacent tissue under dominant compressive stress, it experienced increased stress transmission under tensile conditions.[43] Additionally, studies have shown that the increased rigidity of metal frameworks leads to a more even load distribution, this is because the high rigidity and strength of these materials allow them to withstand significant forces without deformation, ensuring that the stress is evenly distributed across the entire structure.[42,45] This study's results regarding screw loosening are consistent with another study comparing Co-Cr framework incorporation in implant overdentures with the PEEK framework in terms of strain analysis during maximal clenching. The findings indicate that overdentures with Co-Cr frameworks experienced significantly lower strains across all channels compared to those reinforced with PEEK. This suggests that Co-Cr frameworks may effectively manage dynamic stresses, potentially leading to fewer instances of screw loosening and reduced overall prosthetic maintenance issues.[46] In contrast, our study results contradict a study that compared PEKK and PEEK frameworks for implant-supported full arch fixed prostheses, which showed that the superior shock absorbance of PEKK resulted in a lower stress concentration on the prosthetic screw and prosthetic base.[14]

The wear of the nylon insert was observed to be substantial in both groups, with no significant difference noted. Factors contributing to this wear include cyclic and dynamic loading, denture cleansing practices, and exposure to saliva, which can lead to swelling of the insert over time.[47-49] A previous *in-vitro* study investigated a two-implant overdenture with ball attachments by subjecting it to cyclic fatigue testing. The study aimed to assess retention and observe surface changes in nylon inserts using a Scanning Electron Microscope (SEM). Results showed that new nylon inserts had smooth surfaces, while those tested displayed significant flaking and sloughing due to cyclic loading. These surface degradations led to a notable decrease in retention and these results are consistent with our study results regarding wear of nylon insert and loss of retention by time.[50]

The incidence of dentures requiring relining was notably high in both groups. This is commonly associated with elevated stress on the distal flange of mandibular implant overdentures, which can lead to localized bone resorption. However, implants may play a role in mitigating this resorption in the adjacent bone.[51,52] The findings of our study indicated a significant increase in denture relining within group II. This increase can be attributed to the permanent deformation of PEKK under load, resulting in flexure of the denture base and subsequent heightened stress on the distal portion of the residual ridge.[41,42]

Significant teeth separation was noted in group II, which may be attributed to the PEKK framework's increased thickness. As previous research suggested, this greater thickness reduced

the available space for acrylic resin and teeth, likely contributing to the observed teeth separation.[26] Additionally, the inert nature of PAEK polymers, characterized by low surface energy and minimal surface modification properties, complicates the bonding of acrylic resin.[53,54]

Finally, the limitations of this study include the need for a larger sample size and a longer investigation period exceeding twelve months. These identified limitations highlight the need for future research endeavors to address these factors. Recommendations for further investigation include conducting randomized and well-controlled clinical trials with a large investigation period and sample size to strengthen the reliability and applicability of the findings.

CONCLUSION

Within the limitations of this study, findings suggest that two implant-retained overdentures reinforced with Co-Cr demonstrated superior clinical performance and required less prosthetic maintenance after 12 months than those reinforced with PEKK frameworks.

RELEVANCE TO CLINICAL PRACTICE

Reinforcing the denture base in implant-retained overdentures is important for reducing the risk of denture fractures and prosthetic complications.

DECLARATIONS

ETHICS APPROVAL

This research was approved by the Faculty of Dentistry Ain Shams University Research Ethics (number of approvals: FDASU-Rec PC 122352).

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

COMPETING OF INTEREST

The authors declare that they have no conflict of interest.

FUNDING OF THE STUDY.

This study was self-funded.

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