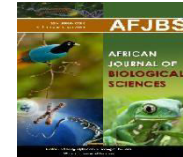




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Evaluation of Prosthetic Maintenance and Complication of Three Differently Constructed Bars on Two Implants Retaining Mandibular Overdenture - One Year Follow-up (A Randomized Controlled Clinical Trial)

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Abstract: **Aim of the study** This study assessed prosthetic maintenance and complications over a one-year period for three different construction Co-Cr bar-retained implants overdenture prosthesis. Three different types of Co-Cr construction bars: conventional casting, milling CAD/CAM techniques, and 3D printing CAD/CAM techniques.

Material and methods Thirty edentulous patients who needed bar-retained implants for mandibular overdentures were randomly assigned to one of three groups. Group I, consisting of 10 patients, received a Co-Cr conventional casting bar; Group II, also with 10 patients, received a Co-Cr CAD/CAM milled bar; and Group III, with 10 patients, received a Co-Cr CAD/CAM 3D-printed bar. All bars were attached between two implants located bilaterally in the canine region. Patients received their definitive prostheses within two weeks following implant placement. Prosthetic maintenance and complications were evaluated at 3, 6, and 12 months. The results were collected, tabulated, and statistically analyzed.

Results Thirty patients participated in this study, with a total of sixty implants inserted-two implants in the canine area on both sides for each of the 30 edentulous patients. The prosthetic maintenance was a statistically significant difference between the three groups regarding the need for replacement of retentive component (P-value = 0.003). The conventional bar group showed the highest percentage of need for replacement of retentive component followed by milled bar group while 3D printed bar group didn't need replacement of retentive component.

Conclusion. The conventional bar group had the highest percentage of cases requiring retentive component replacement, followed by the milled bar group, whereas the 3D printed bar group did not require any replacement of the retentive component

Keywords: Bar, Implants, Milled, 3D printed, Prosthetic maintenance and complications

Introduction

The development of implants and their diverse prosthetic solutions has significantly enhanced the oral rehabilitation of both fully and partially edentulous patients. Numerous clinical trials have consistently shown that placing implants to support or retain overdentures in the mandible leads to a greater quality of life when compared to conventional complete dentures [1-4].

Several challenges have been noted with conventional complete dentures, including issues with stability and retention of the prosthetic, discomfort during chewing, and reduced chewing effectiveness. Clinical studies have demonstrated that these challenges can be effectively managed by using dental prostheses in conjunction with dental implants, particularly in implant-supported or implant-retained overdentures [2-3].

The rehabilitation of edentulous patients with prosthetics continues to be a persistent area of focus. Increasingly, there is a demand for enhanced chewing function, aesthetic request, and prosthetic durability, leading to a rise in the utilization of implant-supported prostheses. Implant-supported overdentures have proven to be a practical, cost-effective, and successful treatment option for fully edentulous patients, particularly in older adults. Various attachment systems, such as ball, locator, or magnetic attachments, telescopic crowns, or bars connecting implants, have been successfully employed to retain implant overdentures [4-8].

Historically, dental laboratories have traditionally produced metallic restorations using the conventional cast method, which relies on the lost wax process [9-11].

Initially, the casting technique predominantly utilized gold-based alloys of choice, but over time, these were substituted with base-metal alloys like nickel-chromium (Ni-Cr) and cobalt-chromium (Co-Cr) alloys [11,12].

In the past, nickel-chromium (Ni-Cr) alloys with beryllium (Be) were frequently used but are now not recommended due to the risk of allergic reactions and the potential cancer risks associated with nickel and beryllium. As an alternative, Co-Cr alloys are commonly used for patients who are allergic to nickel [12-13].

Cobalt-chromium alloys are more cost-effective than noble alloys and offer material properties that are ideal for dental restorations, such as excellent strength, a high modulus of elasticity, and outstanding corrosion resistance. However, Co-Cr alloys have the highest melting points among casting alloys [12-14]. Additionally, the high hardness and low ductility of cobalt-chromium alloys present difficulties in finishing and polishing. To address these issues, the importance of advanced manufacturing methods, like computer-aided design/computer-aided manufacturing (CAD/CAM) technologies, has increased over the past decade for producing biomedical devices and dental prostheses. Cobalt-chromium (Co-Cr) dental restorations can be created using two main CAD/CAM techniques: subtractive manufacturing and additive manufacturing [12-17].

In subtractive CAD/CAM milling, a method used to produce metallic restorations, minimizing casting-induced flaws and porosities is achievable by using Co-Cr alloy blanks made under standardized industrial conditions. However, drawbacks include increased wear on tools and machinery due to the solid nature of the blank, as well as high costs associated with acquisition and maintenance of equipment [11-13,18].

Additive manufacturing aided by CAD/CAM technology offers another approach for creating metallic restorations. Selective laser melting (SLM) is an additive manufacturing process in which metal parts are created directly from a three-dimensional (3D) CAD model. This is done by melting successive layers of metal powder using a high-power, focused laser beam [11,19].

Implant-supported overdentures offer a viable treatment choice for patients with a mandibular edentulous condition, particularly when insufficient bone volume prevents the use of implants for a fixed prosthesis [20-22]. The two-implant overdenture is frequently recommended as a treatment option, and employing a bar and clip design can enhance retention and minimize prosthesis movement [23-30].

The maintenance of implant-assisted overdentures in prosthodontics has significant implications across clinical, laboratory, and economic aspects, impacting treatment success and patient satisfaction. Various factors influence prosthetic care for implant overdentures, including denture retention and stability, ridge atrophy severity, quality of the denture base, type of anchorage system (splinted versus non-splinted), and

patient expectations. Numerous studies, both prospective and retrospective, have investigated the prosthetic challenges associated with mandibular two-implant overdentures retained by a bar [31-33].

Hence, the goal of this randomized clinical study was to monitor prospectively prosthetic maintenance and complications outcomes in three differently constructed bars at a one-year follow-up period. The first bar was cast by a conventional method, the second was a milled bar (subtractive processes), and the third was a 3D printed bar (additive processes), both the second and third were fabricated by CAD/CAM Digital Technology.

The null hypothesis assumes that there will be no significant differences between the three groups regarding prosthetic maintenance and complications.

Materials and methods

The selected patients were allocated into three groups, each receiving two implant bar-retained mandibular overdentures. Group I received a conventional casting bar (control group), Group II received a milled CAD/CAM bar, and Group III received a 3D printed CAD/CAM bar. There were ten patients in each group.

Before securing informed consent, all participants were informed about the study protocol. The study was performed in accordance with the ethical standards of the Helsinki Declaration for clinical trials. The research also complied with the CONSORT guidelines for reporting clinical trials [34].

In this study, thirty edentulous patients (average age = 59.63 ± 8.4 years) who had difficulty adapting to conventional dentures were selected for a randomized trial. These patients were chosen from the outpatient clinic of the Prosthodontic Department at the Faculty of Dentistry, Minia University. The inclusion criteria were complete edentulism of both the maxilla and mandible, dissatisfaction with the retention and stability of mandibular dentures, adequate bone volume in the mandibular interforaminal area for receiving two implants of at least 13 mm in length and 3.7 mm in width, and a minimum of 15 mm of restorative space (the distance between the mandibular mucosa and the occlusal plane). Patients were excluded if they had bone metabolic disorders, had undergone radiation therapy to the head and neck area, or had detrimental habits such as clenching or smoking. The sample size of 30 patients (10 per group) was determined using block randomization performed in Microsoft Office Excel 2010 (Microsoft Corporation, Redmond, WA, USA), and the assignments were recorded in a printed table. All participants received new maxillary and mandibular complete dentures using standard procedures.

The existing mandibular denture was duplicated twice using clear self-cure acrylic resin: one copy was made to function as a radiographic stent, and the other was made to serve as a surgical template for implant placement, using agar-agar material in a duplicating flask.

Gutta-percha markers (Meta Biomed, Chungcheong Buk, South Korea) were applied to the fitting surface of the mandibular radiographic stent. A Cone Beam Computed Tomography (CBCT) scan was conducted on every patient while they wore the radiographic stent.

Implant placement surgery was conducted under local block anesthesia. To ensure proper placement of the osteotomy sites, a bleeding point was initially created through the surgical stent. Parallelism was verified using paralleling pins. Dental implants (Vitronix, TURATI, 38 20121 MILANO-ITALY) with a diameter of 3.7 mm and a length of 13 mm were placed into the osteotomy sites. The implants were positioned to be flush with the crestal bone and secured using a torque wrench set to 35-40 N/cm. The multiple unit abutments were manually installed and tightened with a torque wrench to 10-15 N/cm.

To enhance comfort during the healing phase and prior to delivering the definitive mandibular denture, relieve the mandibular denture on both sides opposite the surgical site and apply tissue conditioning material. This material should be changed every 72 hours to serve as a cushioning layer beneath the denture.

A week later, the open tray impression technique was made. Using Exocad software (Exocad GMBH, Germany), the 3D positioning of the implants in each cast was documented to design the bars using the OT Bar (OT Bar Rhein83, Bologna, Italy) design.

After verifying the try-in bar, a wax bar was 3D printed. This wax bar was then converted to a metal Co-Cr alloy (BEGO Medical GmbH, Bremen, Germany) bar (Group I) using a traditional casting method. The final bar was completed and polished according to the manufacturer's specifications.

After verifying the design, the Standard Tessellation Language (STL) file was sent to either the milling machine (ED5X-EMAR, Egypt) or the 3D printing machine (VULCANTECH, Germany) for processing with CAD/CAM techniques

Group II used a milled Co-Cr block (Mogucera C disc, Germany) to create the bar via a computer-aided milling machine (CAM) (Ceramal, Amann Girrbach, Austria). The milling process involved the gradual cutting away of excess material to shape the bar according to the CAD design.

Group III employed selective laser melting (SLM) for 3D printing. This method started with placing raw powdered Co-Cr material into a tray, where a laser beam (HBD 100D, Guangdong Hanbang 3D Tech Co. Ltd., China) was used to fuse the powder layer by layer into the desired bar shape.

All bars were secured to the implants, and the modification of the mandibular overdentures began using the rebasing techniques following standard procedures. The Co-Cr bar was placed two weeks post-operation following the immediate loading protocol (ILP). A plastic clip was picked up directly in the patient's mouth by creating a space in the fitting surface of the prosthesis opposite the clip. The mandibular overdenture was finally checked for occlusal discrepancies and delivered to the patient. Follow-up appointments were scheduled to address any issues or complaints.

Evaluation of prosthetic complications and maintenance

All patients attended regular follow-up appointments at 3, 6, and 12 months after the insertion of the definitive mandibular overdenture to assess prosthetic maintenance and any complications. The details of these follow-ups, including evaluations of prosthetic maintenance and complications, are summarized in the table (1) below: [35-36].

	At 3 months	At 6 months	At 12 months
A-Implant abutment components (ISO)			
1-Implant fracture			
2-Abutment/screw loosening			
3-Abutment/bar fracture			
B-Implant prosthetic maintenance (ISO)			
1-Wear/distortion of retentive components			
2-Replacement of retentive components			
3-Overdentures reline			
4- Overdenture fracture/remake			
5-Teeth wear			
6- Teeth separation /fracture			
7-Denture margin adaptation (reduction/reline)			
C- Opposite prosthodontic maintenance (OD)			
1-Dentures reline			
2-Denture fracture/remake			
3-Teeth wear			
4-Teeth separation/fracture			
5-Mucositis			
6-Soreness			
7-Hyperplasia			

Data analysis

Numerical data were evaluated for normality by examining their distribution and applying normality tests, specifically the Kolmogorov-Smirnov and Shapiro-Wilk tests. All data followed a normal (parametric) distribution. The data were reported as mean, standard deviation (SD), median, and range. For parametric data, a repeated measures ANOVA was used to compare the three groups and to examine changes over time within each group. When ANOVA indicated significant differences, Bonferroni's post-hoc test was used for pair-wise comparisons. For non-parametric data, the Kruskal-Wallis test was employed to compare the three groups, with Dunn's test used for pair-wise comparisons if the Kruskal-Wallis test showed significance. Qualitative data were presented as frequencies and percentages, and Fisher's Exact test was utilized for comparisons between the three groups. The significance threshold was set at $P \leq 0.05$.

Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

Results

Evaluation of maintenance and complications

A. Implant abutment components (ISO)

After 12 months, complications were observed in conventional bar group (P -value = 0.310) only in the form of biological failure and screw loosening. However, there was no statistically significant difference between the three groups for each complication, respectively. Table 2-Fig (1)

Table (2): Descriptive statistics and results of Fisher's Exact test for comparison between implant abutment component maintenance/complications in the three groups

Time	Type of maintenance/complication	Conventional bar (n = 10)		Milled bar (n = 10)		3D printed bar (n = 10)		P-value	Effect size (v)
		n	%	n	%	n	%		
12 months	Biological failure	2	20	0	0	0	0	0.310	0.378
	Abutment/screw loosening	2	20	0	0	0	0	0.310	0.378

*: Significant at $P \leq 0.05$

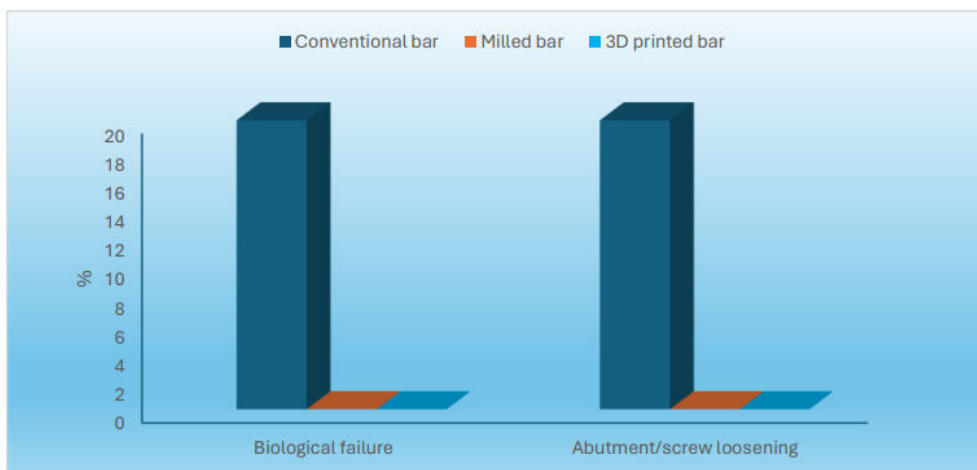


Figure (1): Bar chart representing prevalence of implant abutment component maintenance/complications in the three groups.

B. Implant prosthetic maintenance (ISO)

After three months, there was a statistically significant difference between the three groups regarding the need for denture margin adaptation (P -value = 0.040). Conventional bar group showed the highest percentage of need for adaptation followed by 3D printed bar group while milled bar group didn't need denture margin adaptation.

Regarding replacement of retentive component, after 12 months, there was a statistically significant difference between the three groups regarding the need for replacement of retentive component (P -value = 0.003). The conventional bar group showed the highest percentage of need for replacement of retentive component followed by milled bar group while 3D printed bar group didn't need replacement of retentive component (P -value = 0.507). Table 3-Fig (2)

Table (3): Descriptive statistics and results of Fisher's Exact test for comparison between implant prosthetic maintenance in the three groups

Time	Type of maintenance	Conventional bar (n = 10)		Milled bar (n = 10)		3D printed bar (n = 10)		P-value	Effect size (v)
		n	%	n	%	n	%		
3 months	Denture margin adaptation	5	50	0	0	2	20	0.040*	0.468
12 months	Replacement of retentive components	7	70	5	50	0	0	0.003*	0.601
	Denture margin adaptation	0	0	2	20	2	20	0.507	0.277

*: Significant at $P \leq 0.05$

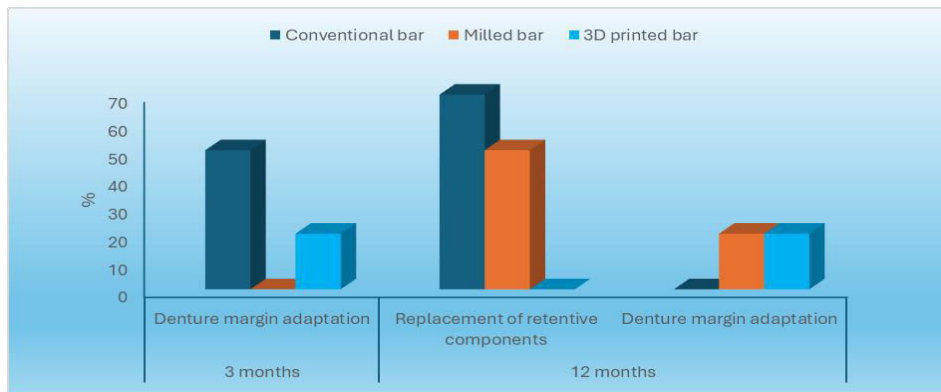


Figure (2): Bar chart representing prevalence of implant prosthetic maintenance in the three groups

C. Opposite prosthodontic maintenance (OD)

After three months, there was no statistically significant difference between the three groups regarding the need for denture reline and presence of mucositis (P -value = 0.348) for each type, respectively.

After six months, there was no statistically significant difference between the three groups regarding presence of mucositis (P -value = 0.321). Table 4-Fig (3)

Table (4): Descriptive statistics and results of Fisher's Exact test for comparison between opposite prosthodontic maintenance in the three groups

Time	Type of maintenance	Conventional bar (n = 10)		Milled bar (n = 10)		3D printed bar (n = 10)		P-value	Effect size (v)
		n	%	n	%	n	%		
3 months	Denture reline	5	50	2	20	5	50	0.348	0.289
	Mucositis	5	50	2	20	5	50	0.348	0.289
6 months	Mucositis	3	30	0	0	2	20	0.321	0.335

*: Significant at $P \leq 0.05$



Figure (3): Bar chart representing prevalence of opposite prosthodontic maintenance in the three groups

DISCUSSION

This study is a randomized control trial that evaluated prosthetic maintenance and complications outcomes for three different construction Co-Cr bar-retained implants overdenture prosthesis.

In this study, the prostheses achieved a high survival rate after 1 year of follow-up. This result is comparable to the 95.5% survival rate over 20 years reported in a previous retrospective study involving 425 implant overdentures (IODs) [37]. Additionally, another clinical study documented a 97.7% survival rate over 5 to 19 years. These results indicate that IOD is an effective and reliable treatment for edentulous patients, with minimal risks during the observation period [38].

Using a bar attachment improves the retention of overdentures, supports the implants by distributing forces evenly, and thereby reduces the stress experienced by the implants [39].

Many clinical studies have enhanced our understanding of intraoral corrosion processes and have provided a better basis for assessing the risks associated with biocompatibility. Considering the current knowledge about the use of base metal alloys in dentistry. (Geurtsen 2002 and Roach 2007), Given the shift towards milled frameworks using metal alloys instead of cast frameworks, the superior dimensional stability of cobalt-chromium compared to other alloys, and the findings from this study, the authors recommend that cobalt-chromium be prioritized as the metal alloy of choice for fabricating frameworks for implant-supported prostheses [40-41].

The increased occurrence of biological failure and screw loosening in the conventional bar group, relative to the milled and 3D printed bar groups, may be attributed to the use of materials in conventional bars that potentially have inferior mechanical properties or lower fatigue resistance, leading to these complications over time. Furthermore, the surface finish of conventional bars may be rougher compared to the smoother surfaces achieved through milling or 3D printing, which can negatively affect both biological compatibility and mechanical stability [42-43].

Several factors may explain why the conventional bar group had the highest percentage of retentive component replacements, followed by the milled bar group, while the 3D printed bar group required no replacements. Conventional bars might experience greater wear and tear over time, resulting in a higher need for component replacements. The materials used in conventional bars could be less durable compared to those in milled or 3D printed bars, leading to more frequent replacements. Additionally, the design and fit of conventional bars might be less precise, causing increased stress and failure of the retentive components. Although milled bars are more precise than conventional bars, they may still not match the high accuracy of 3D printed bars, resulting in a lower replacement rate but still higher than that of the 3D printed group [44-45].

The increased incidence of mucositis seen with conventional, and 3D printed bars, in comparison to milled bars, can be linked to factors such as potentially inferior fit precision. Poor fit may cause mucosal irritation and inflammation. Conventional and 3D printed bars might have rougher or less smooth surfaces compared

to the finely finished surfaces of milled bars, leading to mucosal irritation and a higher risk of mucositis. Additionally, conventional and 3D printed bars may be more challenging to clean and maintain, which can result in plaque accumulation and a greater risk of mucositis. Milled bars, with their smoother surfaces, typically allow for easier cleaning [43-47].

Multiple studies have shown that CAD/CAM bars improve both functional performance and aesthetic qualities, resulting in increased patient satisfaction and a lower rate of prosthetic complications. Supporting these results, our study found that CAD/CAM bars are linked to less complication than conventional bars [48-49].

CONCLUSIONS

Based on the outcomes and limitations of this randomized clinical trial, it was determined that:

1. Biological failure and screw loosening complications were observed in conventional bar group than another bar types.
2. The conventional bar group showed the highest percentage of need for replacement of retentive component followed by milled bar group while 3D printed bar group didn't need replacement of retentive component.

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