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PATIENT SATISFACTION AND SOFT TISSUE CHANGES AROUND BIOHPP® BAR COMPARED TO COBALT CHROMIUM BAR RETAINING MANDIBULAR IMPLANT-OVER DENTURES: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objective: To assess patient satisfaction and peri-implant soft tissue changes of PEEK (BioHPP®) bar compared to cobalt chromium (Co-Cr) bar retaining four implants mandibular overdenture. **Subjects and methods:** Ten completely edentulous participants received four implants and were allocated into two groups. Group I: Co-Cr-bar attachment, Group II: BioHPP® -bar attachment. Mucosal recession (MR), probing depth (PD), modified plaque index (mPI) and modified bleeding index (mBI) were assessed at the time of overdentures insertion (T0), and after twelve months (T12). Patient satisfaction was also evaluated at (T12). **Results:** Co-cr bars showed significant increase in all studied peri-soft tissue parameters' readings. In addition, BioHPP® bars recorded significant better patient satisfaction scores regarding patient comfort, taste of food, esthetics than Co-Cr bars. **Conclusion**: Both Co-Cr bar and BioHPP® bar connecting implants supporting mandibular overdenture are considered potential treatment options. BioHPP® bar presented better results than Co-Cr bar concerning soft tissue changes and patient satisfaction.

KEY WORDS: BioHPP, Co-Cr, implant-over denture, patient satisfaction, soft tissue

INTRODUCTION

Complete dentures have been the selected treatment for edentulous patients for a long time. Though, patients usually complain from the mandibular denture stability and retention. The use of implant-supported overdenture (ISOD) was directed to overcome those complaints and enhance the oral function in the elderly[(1)]. Implant splinting with bar attachments is recommended to intensify the support and the stability of the overdenture under functional loading[(2)]. Bar attachments are classified based on their resiliency, component retentive mechanism, and mode of attachment to the implant [(3)].

Earlier, gold alloys were favored but, because of its flexibility and expensiveness, gold material is not preferred anymore. For metal bar frameworks construction, alternative materials such as silver-palladium (Ag-Pd) alloys, titanium (Ti), cobalt-chromium (Co-Cr) were favored [(4)].

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BioHPP® is a partially high-performance crystalline and thermoplastic polymer that modifies PEEK developed by Bredent GmbH. Their strength is attributed to a unique ceramic filler of 20%, which optimizes its mechanical properties. Because of the tiny grain size, consistent homogeneity can be achieved. This homogeneity is critical to material properties and is the foundation for consistent quality[5]. Due to its excellent mechanical properties BioHPP® was introduced in dentistry offering a metal free restoration for the patients for removable partial denture (RPD) framework construction [6] [7].

Patient-reported outcome has a significant influence on dental treatment success and the assessment of the treatment should rely on the patient's own assessment instead of on the clinical evaluation [8] [9].

Data discussing the effect of using different bar materials on oral soft tissue are insufficient, therefore this research was aimed to compare the peri-implant soft tissue changes of Co-Cr bar and BioHPP® bar retaining mandibular overdenture and evaluating the patients' satisfaction.

SUBJECTS AND METHODS

Ten completely edentulous participants (7 males & 4 females) aging between 50 to 70 years old were selected from the outpatient clinic of the Prosthodontic Department, Faculty of oral and dental medicine, Future University in Egypt to join this study according to the following criteria:

- Completely edentulous patients for at least 6 months prior to implants placement.
- Systemically free patients as stated by the modified Cornell Medical Index[10].
- Patients who with no temporomandibular joint disorders and a normal maxillo-mandibular relationship (Skeletal Angle's class I maxillo-mandibular relationship).
- The mandibular ridge had sufficient height and width with adequate inter-arch space and was covered by a firm, dense, fibrous mucoperiosteum.
- The alveolar ridges of the patients were either rounded or U-shaped.

Patients with V-shaped ridges or history of parafunctional habits including clenching or bruxism were excluded from the current study. Patients signed informed consent forms after being given information about the procedure, including the surgical and prosthetic steps, potential risks, and advantages. The approval of the Research Ethic Committee (REC) in the faculty of Oral and Dental Medicine, Future University in Egypt was obtained (FUE.REC-(27)/10-2022).

Examination:

Extra oral examination:

The vertical dimension of the face was evaluated, as well as the maxillary-mandibular relation. Examining the temporomandibular joint (TMJ) was directed to spot disorders including dislocation, clicking, or discomfort.

Intraoral examination:

Digital and visual examinations were utterly carried out to evaluate the intra-oral tissues condition and confirm if the patients were appropriate for the upcoming surgical and prosthetic procedures. In addition, the edentulous mandibular ridge was examined to eliminate the presence of any bony undercuts, abnormal bony exostosis, mandibular tori, and sharp bony spicules.

Diagnostic cast evaluation:

Maxillary and mandibular Alginate impressions (Cavex alginate, Holland) were made in selected trays and were poured with dental stone to make casts. Following the making up of the upper and lower occlusion blocks, a temporary jaw relation

recording was assembled at the decided occlusal vertical dimension. The upper and lower casts were mounted on a Mean Value Articulator (Detrey, Rational, Germany) to guarantee parallelism between the maxillary and mandibular ridges and the availability of a minimum of 15 mm inter-arch space.

Radiographic evaluation:

Preoperative radiographs were conducted via Cone-beam computed tomography (CBCT) to detect the location of the mental foramina, the level of the inferior alveolar canal, and the anterior looping of the mental nerve.

Virtual implant planning:

Dual scan protocol was carried out by adjusting participant's lower denture into radiographic guide through adding multiple sphere-shaped radiographic composite markers (Z 350 composite 3M ESPE, Germany) on the buccal and lingual denture flanges. The software allows rotation of the 3D images to view the treatment plane from all angles to allow selection of the proper location and number of the implants in relation to the existing bone and anatomical landmarks.

Stereolithographic surgical guide fabrication:

Four metallic sleeves were included in a stereolithographic tissue-supported surgical guide to help the virtual insertion of the implants with the exact angulation, depth, mesio-distal and bucco-lingual inclination as planned.

Surgical procedures:

The surgical guides were disinfected according to the manufacture instructions and the patients were advised to use chlorohexidine mouth wash (Hexitol mouthwash, Arab Drug company, Cairo, Egypt). The surgical procedures were operated under nerve block anesthesia and the tissue supported surgical guide was stabilized in its place by a rubber base occlusal index (Neobiotech dental implant, Korea) during centric relation bite with upper the denture and secured to the mandibular bone using anchor pins. Occlusal index and the upper denture were removed from the mouth then the osteotomy preparation was carried out via the surgical kit provided by the guide manufacturer.

After complete drilling of the implant sites, the surgical guide was removed, and parallel pins were inserted to confirm proper implant positioning. Implants with diameter 3.5 mm and length 11.5 mm (Neobiotech dental implant, Korea) were opened and inserted in implant sites. A manual ratchet wrench was used to tighten the implant in position followed by screwing of the cover screws. After three months, the patients were scheduled to uncover submerged fixtures and the surgical guide was used to relocate the implant positions. Implants were uncovered, and the healing abutments replaced the cover screws to allow the soft tissue healing. One week later, impression copings with long retention screw replaced the healing abutments and were splinted together firmly allowing a free space between the splinting connection and mucosa to permit impression material injection.

Vinyl polysiloxane medium body impression material (Panasil monophase medium impression material, Kettenbach, Germany) in special tray was used to obtain open tray impression and after its seating the impression copings were unscrewed and removed with the tray as a single unit then poured to obtain a master cast.

Patients were allocated into two groups based on the type of bar construction:

Group I (Co-Cr): The patients were rehabilitated with four inter-foramina implants, and a Co-Cr bar supporting and retaining overdentures.

Group II (BioHPP®): The patients were rehabilitated with four inter-foramina implants, and a BioHPP® bar supporting and retaining overdentures.

For group I: A verification jig was made to assure the impression precision, then UCLA abutments (University of California at Los Angeles Abutment) were connected onto the implant analogues on the cast and connected with a bar (OT Bar Rhein83, Italy) with width of 4 mm, height of 5 mm, and 1 to 2 mm space beneath the bar to ease oral hygiene. Subsequently, the plastic part of the abutments and the bar wax pattern were burned, and molten alloy was then casted into the mold developing a framework pattern providing cast interface which directly match with the implants. (Figure 1a)

For group II: The BioHPP® (Bredent, Germany) was created using the design of a standard bar type included in the software library (Dolder bar). The bar was designed, with a height of 5 mm, a width of 3.5 mm, and a 1-2 mm clearance for oral hygiene to assistance. Following plan finalization, the computer added manufacture (CAM) milled the PMMA verification jig and tested it in the patient's mouth to verify passive fitting. The BioHPP blank was then clamped to the milling fixture and milled in an exact 5-axis milling unit. (Figure 1b)

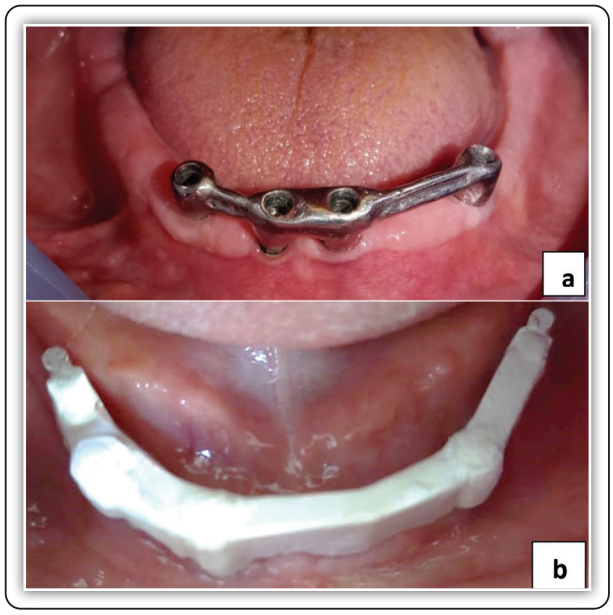

FIG (1) a; Co-Cr bar intraoral b; BioHPP® bar intraoral.

New complete lower dentures were constructed in the usual manner by taking secondary impression in acrylic resin special tray with rubber base impression material (Thixoflex, Oranwash L, C-silicone impression material, Zhermack. Italy), followed by jaw relation record, try-in, final denture insertion.

Assessment of peri-implant soft tissue changes and patient satisfaction:

Modified plaque index (mPI), and modified sulcular bleeding index (mBI) according to Mombeli et al., 1987 [11], mucosal recession and peri-implant probing depth measurements using a color-coded plastic periodontal probe were evaluated at time of overdenture insertion (T0) and twelve months follow up (T12). All measurements were done at four sites (Labial, lingual, mesial & distal) for each implant.

In addition, patients' satisfaction was evaluated at T12 on a scale from 1 to 10 according to the following criteria: (A) physical (stability and retention of denture), (B) Functional (chewing ability, speech ability, Pain, Comfort, Occlusion, Easiness of denture cleaning& taste of food) and (C) Aesthetic factors (Appearance of dentures & Self-image).

Statistical analysis

Numerical numbers were introduced as mean and standard deviation (SD). Parametric data were analyzed using paired t-test for intergroup differences and independent t-test to compare the two studied groups. Nonparametric data were analyzed statistically using Mann-Whitney U test to compare between the two studied groups and Wilcoxon signed rank test for intergroup differences. The significance level was adjusted at $p \leq 0.05$. Statistical analyses were performed using Statistical Package for Social Sciences (IBM SPSS Statistics version 26).

RESULTS

At baseline (BL), no significant difference was noticed between both groups regarding mucosal recession (MR), probing depth (PD), modified plaque index (mPI) and bleeding index (mBI). By the end of the study at T12, a significant increase in all parameters was shown on both groups.

Comparing the two groups, a significant difference regarding MR, PD, mPI and mBI in favor of BioHPP® group at T12 was reported. (Table 1) (Table 2)

Patient satisfaction was evaluated using VAS method that presented a significant difference in favor of group II regarding patient comfort, taste of food, appearance of denture and self-image. The other parameters showed no significant difference between both groups. (Table 3) (Figure 2)

TABLE (1) Comparing the soft tissue changes between groups and observation times regarding mucosal recession & probing depth.

Point of comparison		Group I (Co-cr)		Group II (BioHpp)		95% confidence interval	*P-value*
		Mean	SD	Mean	SD		
Mucosal Recession (MR)	BL	0.261	± 0.08	0.187	± 0.04	(-0.0319 to 0.1795)	0.1461
	T12	0.962	± 0.22	0.352	± 0.16	(0.3249 to 0.8951)	0.0011*
	P-value = 0.0003*			***P-value = 0.0302****			
Probing Depth (PD)	BL	0.561	± 0.02	0.528	± 0.04	(-0.0227 to 0.0887)	0.2097
	T12	0.772	± 0.09	0.593	± 0.02	(0.07442 to 0.28318)	0.0042*
	P-value* = 0.0031			***P-value* = 0.0035***			

: statistically significant at p≤ 0.05

TABLE (2) Comparing the soft tissue changes between groups and observation times regarding modified plaque index and bleeding index.

Point of comparison	Time	Group I (Co-Cr)			Group II (BioHPP)			Mann-Whitney test (p value)
		M	Min	Max	M	Min	Max	
Plaque Index (PI)	**BL**	**0**	**0**	**1**	**0**	**0**	**1**	**0.6744**
	12 months follow up	**3**	**2**	**3**	**2**	**1**	**2**	**0.3662***
	P value*= 0.0109				***P value*= 0.0327***			
Gingival Index (GI)	**BL**	**0**	**0**	**1**	**0**	**0**	**0**	**0.6744**
	12 months follow up	**1**	**1**	**2**	**1**	**0**	**1**	**0.3662***
	P value < 0.0039*				***P value*= 0.0161***			

*M; median, min; minimum, max; maximum, * p is significant at 5% level.*

TABLE (3) Comparing group I and II regarding the 10 points evaluating patient satisfaction

Point of comparison	Group I (Co-cr)		Group II (BioHpp)		95% confidence interval	*P-value*
	Mean	SD	Mean	SD		
Retention & stability of denture	10.00	± 0.00	9.80	± 0.45	(-0.66 to 0.26)	0.346
Ability of chewing	9.60	± 0.55	9.80	± 0.45	(-0.93 to 0.53)	0.5447
Ability of speech	9.60	± 0.55	9.60	± 0.55	(-0.80 to 0.80)	1.000
Occlusion	9.60	± 0.55	9.80	± 0.45	(-0.93 to 0.53)	0.5447
Comfort	8.20	± 0.84	9.80	± 0.45	(2.58 to 0.62)	0.005*
Pain	9.60	± 0.55	9.40	± 0.55	(-0.60 to 1.00)	0.579
Ease of cleaning	8.40	± 0.40	8.20	± 0.84	(-1.06 to 1.46)	0.724
Taste of food	8.00	± 0.71	9.80	± 0.45	(-2.66 to -0.94)	0.0013*
Appearance of dentures	8.60	± 0.55	9.80	± 0.45	(-1.93 to- 0.47)	0.0053*
Self-image	8.80	± 0.45	9.60	± 0.55	(-1.53 to -0.07)	0.035*

**: statistically significant at p≤ 0.05*

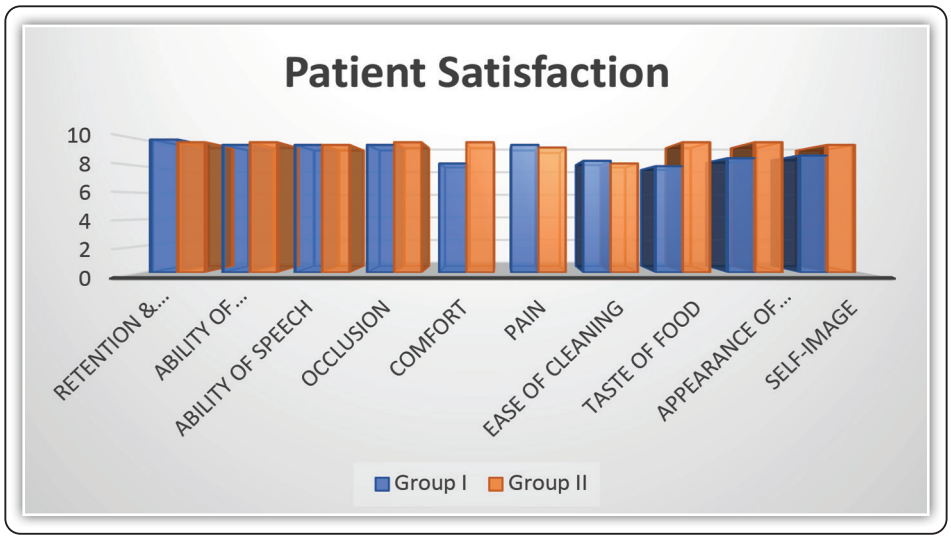

FIG (2) Multiple comparison of mean domain scores of patient satisfaction between both groups.

DISCUSSION

Only limited controlled clinical studies on the soft tissue responses to BioHPP® -based superstructures and patients' satisfaction are available. For these reasons, the effects of BioHPP® bar versus Co–Cr bar on peri-implant soft tissues were investigated in this study.

Bar attachments help improving the overdenture retention. In addition, implant splinting, distribute the forces and results in fewer stresses on implants [(12)]. Compared to subjects with ball attachments, the mean bone loss values seem to be lower in in bar attachments [(13)]. The reason for this bone loss was speculated to be linked to loading patterns

differences or bone conditions [14]. Therefore, bar attachments were used in the current study.

Despite that some studies mentioned that implant number has no influence on the soft tissue in implant supported overdenture cases, the All-on-Four treatment concept was established to intensify the use of existing remnant bone in atrophic jaws, which permits instant function and evades regenerative procedures [15] [16]. Adding to that an efficient prosthetic basis can be established from the well-spread implants [17].

The ceramic fillers in BioHPP® upgrade their strength and abrasion properties which allow BioHPP® to be the first material to attain the perfect balance between rigidity and elasticity, in addition of being veneered which is considered an important aesthetic characteristic of this material [18].

Compared to titanium, zirconium, and ceramics, the BioHPP® prosthesis significantly diminishes the maximum values of vertical and lateral masticatory forces distributed on the bone and on the prosthetic structures acting similarly to Sharpey fibers [18][19] [20].

Different studies have reported the promising advantages of BioHPP® over Co-Cr in terms of soft tissue health, vertical bone loss (VBL), retentive forces and patient satisfaction [21] [22] [23].

Regarding the current study, a significant mucosal recession was reported in both groups at T12 however the mucosal recession was more significant in group I (Co-Cr). Mucosal recession with dental implants is common especially in the first 3 months following implant placement and 80% of mucosal recession occurs buccally[24]. Mucosal recession usually follows marginal bone loss around implants supported overdentures which is common in the first year due to bone remodeling and is not influenced by the attachment design [25].

In addition to other peri-implant soft-tissue parameters, probing depth was reported as a factor affecting implant survival in cases of implant supported overdentures[26]. While other studies have reported that the peri-implant PD may not be significantly correlated with bone loss, the changes in probing depth and other soft tissue peri-implant parameters aid as a valuable sign in peri-implantitis diagnosis, which affects the implant survival in implant supported over dentures [16].

With advancement of time probing depth (PD) significantly increased in both groups with median of 0.77 & 0.562 in group I and group II respectively. This goes in accordance with several studies that reported increase in probing depth in implants supporting "All on four" prosthesis [27] [28]. However, other studies reported shallow periodontal pockets and more stable soft tissues with no significant midfacial recession [29] [30].

In bar overdentures, increased PD has been associated with gingival hyperplasia in the denture gaps around the bar and abutment [31]. Comparing the two groups, a statistically significant difference in PD was noticed after 12 months from insertion (T12). PD was higher in group I (Co-Cr) than that in group II (BioHPP®). This may suggest that the Co-Cr bar has encouraged gingival hyperplasia more than the BioHPP® bar.

Regarding modified plaque index (mPI) and modified sulcular bleeding index (mBI), there was significant increase of the readings in both measures in both groups at T12. Comparing both groups, a significant difference was noticed in mPI and mBI in favor of group II (BioHPP®) which may be explained by the reduced affinity of PEEK to plaque accumulation. The increase in mPI readings may be correlated to the significant increase in gingival index and may be associated with the obstacle of cleaning beneath the bar due to constrained access and reduced hand abilities in the elderly patients. This goes in agreement with Krennmair et al., 2012, Kappel et al., 2016 who reported that higher plaque and gingival scores are found in bar attachments compared to single attachments [32] [33].

By the end of the study, patient satisfaction was evaluated in both groups according to physical, functional, and aesthetic factors using visual analog scale (VAS). Patients in group II (BioHPP®) were more satisfied than patients in group I (Co-Cr). This goes in accordance with Ragheb & Elgamal 2022 who compared patient satisfaction in group of patients receiving extracoronal attachment removable partial denture (RPD) framework fabricated from BioHPP and a group receiving the extracoronal attachment RPD made out of Co-Cr and reported that BioHPP® group were more satisfied in terms of esthetic and comfort than Co-Cr group [34]. In the present study the comfort was greater in group II, and this could be attributed to the minimal bar weight of BioHPP® that usually has a major impact on patient's comfort and satisfaction. It was reported that PEEK removable partial dentures could weight 27.5% less than Co-Cr RPD [35]. Added to that taste of food and esthetics were superior in group II compared to group I as BioHPP® achieves patients' satisfaction with metal free overdentures.

CONCLUSION

Within the constraints of the present study, it could be concluded that BioHPP® bar was superior to Co-Cr bar in terms of soft tissue changes and patient satisfaction.

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