PATIENT SATISFACTION AND ORAL HEALTH–RELATED QUALITY OF LIFE FOR SINGLE-IMPLANT MANDIBULAR OVERDENTURES REINFORCED BY COBALT CHROMIUM OR PEEK FRAMEWORK VERSUS CONVENTIONAL COMPLETE DENTURE: A CROSSOVER TRIAL.

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ABSTRACT

BACKGROUND: Edentulous mandible rehabilitation via single implant mandibular overdenture (SIMO) became mundane as a facile therapy averred promising results. SIMO was reported to prone to fracture thus, represented a concern for the clinicians.

OBJECTIVES: This study targeted at assessing satisfaction of the patient and Oral Health–Related Quality of Life OHRQoL referring to (SIMO) reinforced by metal or PEEK frameworks in comparison to conventional complete denture CD.

MATERIALS AND METHODS: Eighteen complete dentures were delivered for the eligible participants (group I). Three months later, they were evaluated for satisfaction of patient and OHRQoL. Patient satisfaction was performed employing the visual analog scale (VAS). Assessment of OHRQoL by oral health impact profile (OHIP-14) was accomplished. Through pursuing the delayed loading protocol, in the midline region of the mandible, single implant was inserted. Each patient received two overdentures utilizing a crossover design; metal reinforced (Group II) and PEEK reinforced overdentures (Group III). Patient Satisfaction and OHRQoL for groups (II and III) were carried out following three months of using each overdenture. Questions of VAS and OHIP-14 were evaluated for both overdentures.

RESULTS: SIMOs revealed statistically significant improvement compared to traditional dentures. Non-significant difference between SIMOs reinforced with metal or PEEK was demonstrated except for denture stability and retention in favor of PEEK reinforced SIMOs.

CONCLUSION: SIMOs ameliorated patient satisfaction together with OHRQoL when compared with CDs no matter the involved reinforcement material was. SIMOs reinforced with PEEK are deemed advantageous over the metal ones in terms of denture stability and retention.

KEYWORDS: Single-implant overdenture SIMO, OHRQoL, satisfaction.

INTRODUCTION

Edentulism is rendered a chronic plight for which CDs were regarded as the palliative treatment. Considering the global increase in the expectancy of life combined with rising in elderly population, seekers for this modality would be expanded. Despite being a privilege on the economic ground, CDs have assertive flaws. The denture wearers utter difficulties while crunching hard foods, likely hastened resorption of bone, besides, continuity in the clinical morbidity appertaining to CD (1).

The diminished stability and retention of mandibular CDs give rise to various troubles for those patients. Of these, issues of mastication, reduced satisfaction, quality of life, self-assurance along with more restricted social communication (2). To conquer these obstacles; implant-assisted overdentures were endorsed for boosting retention, stability together with psychosocial well-being (3).

Current prospective research advocated usage of a single implant for supporting mandibular overdentures (4-7). Originally, this approach was proposed for older patients complaining discomfort and functional problems with their CDs (2). In the region of midline mandibular symphysis, one implant is inserted for overdenture anchorage thorough surgical diagnoses (8). This less pricey and less invasive intervention helps more patients having general health concerns benefit from this modality (9).
SIMO is presumed to be simpler than overdentures retained by 2 implants and the fixed implant treatment as well. It is considered an easier option for geriatric patients, who cannot afford the complex implant interventions. That is owing to its less functional demands and favorable condition of bone in symphyseal area, which assures acceptable primary stability of dental implant (2).

Earlier reports elaborated satisfactory clinical outcomes of SIMO as; marginal bone loss, implant survival rate along with implant stability by time, improved quality of life as well as patient satisfaction (10). OHRQoL defined as a person’s assessment of how psychological, functional, social factors, pain, or discomfort affect his/her well-being in the context of oral health (11).

SIMOs enhance patient reported consequences compared to CDs respecting satisfaction, measures of the quality of life regardless to variance in protocols of the implant treatment and the retention systems. Even though attainable evidence proclaimed remarkable enhancement in reported outcomes of patients following SIMOs insertion, further comparative studies between SIMOs and complete dentures are inevitably requisite to advocate SIMOs in routine practice (12).

Attachments were verily used with SIMOs as, ball, magnet, and locator. Ball attachment enables much easier oral hygiene procedure and provides favored esthetics and phonetics in cases comprising advanced -ridge resorption (13). Ball and socket attachments were declared to distribute and minimize transmission of loads from the implant to alveolar bone. They permit multi-directional movements of the prosthesis, eventually, work as shock absorbers thus decrease loads on the abutment (14).

Patients’ satisfaction with their overdentures can be frankly affected by the attachment used to retain overdentures, since patients prefer attachments which are more retentive (2). SIMO with ball attachments was much simpler in fabrication, decreased demanded homecare to keep the gingiva healthier and the clinical results exhibited satisfactory reports.

Howbeit, susceptibility of denture base fracture in the area adjacent to implant thus factually represents a point of concern (15, 17). The fracture was supposed to be relevant to the acrylic resin thickness around the attachment which is being inadequate. This occurs primarily following denture base relieving for attachment inclusion. Moreover, during masticatory movements, the single implant functions as a fulcrum of the overdenture, thereon, its deformation and further fracture would be anticipated (18).

Accordingly, many approaches were proposed for reinforcement of the denture base. These implied; metal, rubber reinforced polymethyl methacrylate, fillers, hydroxyapatite, and Nano scale reinforcement materials (19). Interestingly, poly ether-ether ketone (PEEK), a new material, was efficaciously introduced in the field of medical and orthopedics during past years. PEEK has both better electrical and mechanical properties as resistance to both hydrolysis and high temperature added to high biocompatibility. PEEK has been widely availed in the field of dentistry and deemed to be an alternate to conventional materials (20).

Through reviewing the current literatures, numerous studies concerning SIMOs were available, but little is known spotlighting the influence of reinforcing SIMO base with CO-CR or PEEK. Thence, the present work aimed to clinically assess patient satisfaction and OHRQoL for CO-CR and PEEK reinforced SIMO versus conventional CD. The null hypothesis was that no difference will be present among the overdentures having either metal or PEEK reinforcement frameworks and conventional CDs.

**MATERIALS AND METHODS**

**Patient selection**

Eighteen edentate's patients were eligible for this study from the outpatients’ clinic, Faculty of Dentistry ,Mansoura University, Egypt. The present work has been accepted by Ethics Committee (No, A16011122), Faculty of Dentistry, Mansoura University. All participants informed about all treatment plan and recall visits then signed consents were obtained.

The inclusion criteria dictated that; all participants were completely edentulous at least six months from the last extraction, had adequate residual alveolar bone quantity and quality at the region anterior to mental foramen and covered with healthy mucosa (confirmed by cone beam CT), the patients were of Angle's class I maxilla-mandibular relation with acceptable inter-arch space (verified by a tentative jaw relation).

Exclusion criteria implied; the selected patients had no systemic disorders impeding Osseo-integration e.g., diabetes being uncontrolled, osteoporosis or hemophilia, history of chronic TMJ disorders or impaired neuromuscular control, head and neck radiation, Para functional habits such as bruxism, heavy smoking, and alcoholism.

**Pre-surgical procedures:**

- For all participants, traditional complete dentures were designed.
- Construction of complete dentures: Mandibular and maxillary preliminary impressions
were made by using irreversible hydrocolloid impression materials (Cavex, Holland, normal set). Final impressions were made from zinc oxide impression material (Cavex Outline ZOE). Then impressions were boxed and poured in dental stone to gain master casts on which record blocks were constructed, after adjusting maxillary occlusion rim its transferred to semi adjustable articulator (Dentatus) by means of maxillary face bow (Dentatus), mandibular occlusal rim was then mounted using wax intermaxillary record, then setting of acrylic artificial teeth (Viva dent) with lingualized balanced occlusal scheme, try in was made then flasking, packing with heat cured acrylic resin and denture was delivered to patient.

The patients were allowed to wear their dentures for one week and then being recalled for any further adjustments. Thereafter, three months later, they have been called back for recording the pre-surgical measurements (patient satisfaction & OHRQoL) (group I) together with planning of implant placement surgery.

The mandibular denture was duplicated with a clear vacuum formed matrix to fabricate the mandibular surgical template. Surgical and prosthetic procedures:

For each patient, a single implant (T6 implant from Nucleoss, Turkey, 13 mm length×3.2 mm diameter) was surgically inserted in the mandibular midline area following the two-stage surgical protocol. Corresponding to the implant, the mandibular denture has been relieved and relined by applying a tissue conditioning material (Viscogel, Dentsply).

Each participant in the current crossover study design was provided with two mandibular overdentures: one was metal reinforced (Group II), and the other was PEEK reinforced (Group III).

Three months afterward, the patients were recalled. The implants were exposed using a tissue punch. The cover screws were then replaced by healing abutments which were left in place for two weeks until the gingival tissue properly healed. After 2 weeks, the ball abutments were threaded in place and the gingival tissue was properly healed. After healing abutments were being removed (Figure 1). The implanms were exposed using a tissue punch. The cover screws were then replaced by healing abutments which were left in place for two weeks until the gingival tissue properly healed. After 2 weeks, the ball abutments were threaded in place and the gingival tissue was properly healed. After healing abutments were being removed (Figure 1). The implanms were exposed using a tissue punch. The cover screws were then replaced by healing abutments which were left in place for two weeks until the gingival tissue properly healed. After 2 weeks, the ball abutments were threaded in place and the gingival tissue was properly healed. After healing abutments were being removed (Figure 1).

The open tray definitive impression was completed, poured and the master cast was gained. Duplication of the mater cast was carried out (one cast for each prosthesis). The definitive mandibular cast of each patient was secured to the scanner (3Shape 3D Dental Scanners) and scanned to obtain the standard Triangulation Language file (STL). Consequently, STL file was transferred to the designing software (3Shape A/S, Copenhagen, Denmark) to start designing process of framework. A tentative stereolithographic 3D printed resin framework was constructed for each case by employing rapid prototyping technology. This was to check and validate the tentative framework intra-orally.

Metal frameworks were fabricated by conventional casting techniques while injection molding techniques was utilized for making PEEK frameworks for each patient, both frameworks were tried intra- orally.

Construction of metal framework by conventional lost wax casting technique as following: The 3D printed resin framework was tried intra-orally to make sure that it was well fitted. Then it was imported into CAD/CAM milling machine (Ceramill map 400, Amann Girrbach, Koblach, Ausstria) to obtain wax model. The wax pattern was invested and casted with CO-CR alloy, metallic framework was obtained. The metallic framework was finished, polished and being tried intra-orally (Figure 2).

Construction of PEEK framework by injection mold technique as following:

The 3D printed resin framework was tried intra-orally and then was imported into CAD/CAM milling machine (Ceramill map 400, Amann Girrbach, Koblach, Ausstria) to obtain wax model. The wax model was fitted to the master cast and invested in special silicon ring with a special phosphate-bond investment material (Brevest investment material for 2 press). The mold was heated between 630°C-850°C in a pre-heating oven, for melting the wax away and controlling expansion of the investment material and then cooled at 400°C.

At this temperature, PEEK granules (BioHPP, Bredent GmbH, granular form) have been brought to the cylindrical reservoir of investment mold, the melting procedure is carried out. The melting temperature of 400°C (20 min. and no longer) must be observed exactly and controlled. After complete melting of PEEK granules, press plunger was inserted in the cylindrical reservoir. The pressing procedure (PEEK press system & blue light of press system) was fully automatically completed. The mold was cooled down to room temperature and then was devested.

The framework was then disconnected from sprues and finished in the usual manner.

The PEEK framework was tried intra-orally (Figure 3).

Maxilla-mandibular relations were recorded. Mounting the casts on articulator (Dentatus, semi-adjustable articulator) and setting of artificial teeth (Viva dent) with lingualized balanced occlusal scheme was done. The polished and occlusal surfaces...
of mandibular complete dentures were replicated with aid of a silicone key (Coltoflax; Coltene AG, Altstatten, Switzerland). The silicone key was repositioned against the final cast. Acrylic resin teeth of the same size were replaced into the mold in their respective positions, and molten base plate wax was poured into the intervening space to form a similar contour and bulk in the duplicate denture.

After processing, the final single implant retained mandibular overdentures were delivered to patients and adjustment of occlusion was done. A transferable mark on top of each ball abutment was placed with an indelible pencil and the denture was seated to determine the ideal location for the attachment housings in the denture. Recesses in fitting surface of denture were prepared to accommodate housings. No contact between denture and housings should be found. Pick-up of the ball abutment to the overdenture intaglio surface was accomplished using an auto polymerized acrylic resin (Acroston, cold-cure acrylic resin, Egypt) (Figure 4 and Figure 5).

Each participant in the current crossover study design was provided with two mandibular overdentures: one was metal reinforced (Group II), and the other was PEEK reinforced (Group III). Each overdenture was delivered to patient and used for 3 months with 2 weeks rest period in between two overdentures. After that, patient satisfaction and OHRQoL were evaluated for each group.

Measurement of satisfaction and OHRQoL:
Participant satisfaction was assessed by applying questionnaire using Visual Analog Scale (VAS) which was given to the patients in Arabic. These questions are feeling of patient toward prosthesis, dentures comfortability, chewing difficulty, hygiene procedure easily or not, dentures retention and stability, speaking difficulty, ease of handling of denture, satisfaction with healing, biting difficulty, effect on socializing, and avoid any activities due to embarrassment. The amount of satisfaction was marked by participant on a 100 mm length line (0 = no satisfaction all and 100 = complete satisfaction) (21). This instrument was established to be valid for those wearing implant overdentures (22, 23).

Quality of Life (OHRQoL) was assessed by oral health impact profile (OHIP-14) questions. These questions consist of 7 domains: physical pains, functional limitations, physical disabilities (unsatisfactory diet, interrupting meals), psychologic discomforts (self-consciousness, feeling tense), psychologic disabilities (difficult to relax, embarrassment), social disabilities. The queries have been translated into Arabic language (24). Translation was performed by two independent dentists and bilingual translators who produced one common translation. Hence, revision of OHIP-14 Arabic version was executed and used in the current work. Scores of questions responses were never (= 1), hardly ever (= 2), occasionally (=3), fairly often (= 4), and very often (= 5). Lower scores indicate higher satisfaction, higher scores indicate lower satisfaction.

Statistical analysis:
Data analysis was carried out using the Statistical Package of Social Science (SPSS) program for Windows (Standard version 21). Shapiro test was used to test the normality of data. Continuous variables were presented as mean ± SD (standard deviation) for normally distributed data. The 2 groups were compared with independent t-test. The threshold of significance is fixed at 5% level. The results were considered significant when p ≤ 0.05. The smaller the p-value obtained, the more significant are the results.
RESULTS

Table 1 presented the results of VAS (in mm) for all types of studied denture. A statistically significant difference was revealed between group (I & II) except for ease of hygiene procedure. Also, there was a statistically significant difference between group (I & III) except for ease of hygiene procedure. On the other hand, a statistically insignificant difference was noted between group (II & III) except for stability/retention of mandibular denture.

Table 2 presented the results of OHIP-14 for the different denture types. There was a statistical significance demonstrated between group (I & II). A statistically significant difference was noticed between group (I & III). Howbeit, there is no statistically significant difference between group (II & III) was noted.

Table 1: Outcomes of Visual Analog Scale (in mm) for all denture type.

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Table 2: Outcomes of OHIP-14 for the different denture types

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T: Independent t-test, *significant p≤0.05

Group (I): Conventional complete denture
Group (II): Metal reinforced overdenture
Group (III): PEEK reinforced overdenture

The tables and figures provide detailed comparisons and outcomes for the different types of mandibular overdentures, highlighting the advantages and disadvantages of each method.
Group (I): conventional complete denture  
Group (II): metal reinforced overdenture  
Group (III): PEEK reinforced overdenture

DISCUSSION
Contrasting to other study designs, the crossover study let the participants to experience all therapeutic approaches and to personally compare them. Additionally, both subject and denture factors standardization could be permitted by crossover design. Furthermore, respecting satisfaction of patient with different prosthesis, the crossover study design enables more precise comparing between the prostheses. Thereupon, all patients received new traditional complete dentures to represent the control group.

In this current study, implant overdentures exhibited significantly superior patient satisfaction relating to VAS and OHQoL compared to conventional complete dentures. This finding is coping with the reports proclaimed by Yunus et al (25).

The increased patient satisfaction with overdentures may be due to implying single-implant overdenture (SIMO). This explanation is in consonance with Nogueir et al (3). They declared that SIMO treatment seemed advantageous pertaining to the reported outcomes of the patient’s consequent to single implant that inserted to retain the mandibular overdenture in CD patients. Significant increase in patient satisfaction and lower OHQoL impacts have been advocated by overall results. An obvious superiority of SIMO when compared to complete denture was determined.

SIMO is well thought out a more utilizable alternative for elderly. That is ascribed to less likely to comply with complex implant involvements, attributable to its less functional requirements combined with the favorable symphyseal region concerning its local bone condition that guarantee the satisfactory primary stability of the implant. This is in line with Alqutaibi et al (26). This is also conforming to Cordioli et al (14). They announced adequate and acceptable findings of SIMO relating to clinical outcomes like stability of dental implant over time, survival rate of implant and marginal bone resorption, as well as assuring improved both patient satisfaction and quality of life.

Moreover, patients’ satisfaction with their dentures might be affected by the attachment system used for implant overdentures retention, given that patients have a robust priority for potent retentive attachments (27).

Accordingly, denture instability induces irritation of soft tissue and thus reduced satisfaction.

In keeping with this observance, Sharka et al (28). They postulated that implant overdentures have a positive impact in comparison to CDs relating to OHQoL and satisfaction of the patient. This is especially evident for patients who were in need for implant treatment or those cannot conform to traditional denture treatment.

Upon using implant overdentures, increased the satisfaction of the patient while they chewed both soft and hard foods was recorded. That is factually went along with the findings of Awad et al (22). They declared that, chewing foods with different consistencies significantly enhanced by implant treatment. The improved stability and retention decrease discomfort, patients’ occlusal forces increased, eventually, boosting the capability of mastication of food. Notwithstanding, the denture bearing mucosa being compressed and the CD instability because of resorbed ridges results in ache throughout mastication and biting, muscle activity decreases, and influences masticatory performance . This was affirmed by Mahanna et al (29). Likewise, the amount of dentures stability and retention afforded via the attachment system impacted degree of patient satisfaction (30).

The present study valued incorporating the metallic CO-CR and PEEK frameworks in the intaglio surfaces of mandibular SIMOs, given the comprehensive knowledge about these issues concerning single-implant mandibular overdentures (31). While evaluating mandibular overdentures, denture fracture was a repeated complaint. This is principally obvious for single implant overdentures. That is on the ground that reduced and thin acrylic resin base in the midline area for conforming the attachment (32).

For this reason, inclusion of a metallic framework in the anterior region was performed to decrease stress concentration and minimize fracture of mandibular overdenture (33). Eventually, a metallic framework averted the propagation of the cracks and fracture of prostheses, thereby, being a clinical success (34).

The findings of the current work cleared a statistically significant difference in stability and retention for PEEK reinforced mandibular overdentures as opposed to those reinforced by CO-CR. This may be attributed to different modulus of elasticity of CO-CR and PEEK. The low modulus of elasticity of the thermoplastic resins presents superior flexibility compared to the conventional CO-CR. PEEK has a low modulus of elasticity of 4GPa, whereas CO-CR has a much higher modulus of elasticity (211GPa) (35). Also, mechanical properties of PEEK are conformable to those of enamel and
dentin. Upon that, PEEK was confirmed to be highly resisting loads and fracture (36).

Harb et al (37). The authors postulated that PEEK having decreased specific weight enables lighter prostheses construction with good functionality. That is asssented to the results of this study which recorded superior satisfaction of patients in favor of PEEK than metal group regarding retention and stability.

Ibrahim et al (38). The authors inferred that the ridge base relations of overdentures reinforced with PEEK were superior to those reinforced with CO-CR. The probable explanation was related to plasticity properties of PEEK.

Concerning other questions of VAS and OHIP, no statistically significant difference in satisfaction of patient was detected between metal or PEEK reinforced overdentures. Nonetheless, in current work, the short evaluation time (three months) may be the reason accountable for the statistical insignificant difference in the satisfaction of patient between the two reinforced overdenture groups. Overall, the null hypothesis was rejected in this study.

CONCLUSIONS
On the light of the current work results besides the limits of this short-term crossover study, one could conclude that:

Regarding the single implant mandibular overdentures (SIMOs) either metal or PEEK reinforcement are recommended to be used compared conventional complete denture.

PEEK reinforced mandibular overdentures are seemingly advantageous over the metal reinforced ones with relevance to (Stability/retention of mandibular denture) domain of VAS. Future long-term studies of variant evaluation methods are thus crucially required to validate the results of the current work.

CONFLICT OF INTEREST
No conflicts of interest in connection with this article have been explicitly stated by the authors.

REFERENCES


