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METAL VERSUS POLY ETHER-ETHER KETONE SECONDARY COPINGS FOR RIGID TELESCOPIC RETAINED IMPLANT SUPPORTED MANDIBULAR OVERDENTURES. RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Purpose: The aim of this study was to evaluate and compare clinical retention values of metal and poly ether-ether Ketone secondary copings for rigid telescopic retained implant supported mandibular overdentures

Material and methods: Eight edentulous patients (4 males and 4 females) who were unsatisfied with the retention of mandibular dentures were randomly assigned equally into 2 groups then received 4 implants in the interforaminal region of the mandible. Group I received telescopic overdentures with metal secondary coping (control group), Group II received telescopic overdentures with Poly ether-ether secondary copings (PEEK) (test group). Measurement of clinical retention forces (in Newton) were performed by digital force meter device attached to a special device that ensure application of vertical dislodging perpendicular to the patient's occlusal plan. Measurements were performed at time of overdenture insertion, 3 months and 6 months after insertion.

Results: For all times of measurements, PEEK secondary copings were associated with significant higher clinical retention values than metal secondary copings. For metal and PEEK groups, retention values at base line were the highest values followed by retention values after 3 months and the least retention forces were noted after 6 months.

Conclusion: Within the limitations of this study caused by small patient sample and short evaluation period, PEEK secondary copings for telescopic attachments of mandibular implant overdentures is recommended than cobalt chromium secondary copings as it was associated with increased clinical retention values even after 6 months of clinical use.

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INTRODUCTION

Mandibular implant-supported overdentures can provide an effective treatment modality for edentulous patients and, in particular, those who have persistent problems using a conventional mandibular prosthesis[1]. The high success rate of interforaminal implants used to support mandibular overdentures is well documented with longitudinal studies[2]. The use of 4 interforaminal implants to support a mandibular overdenture optimizes the stress distribution and improve denture stability and retention and reduce mucosal support [3]. It also reduce posterior mandibular bone resorption [4], decreases the need for prosthodontic maintenance[5] and avoids problems of high muscle attachments and prominent mylohyoid ridges[6]. It can restore both dental and alveolar tissues, to satisfy esthetic demands, improve oral hygiene and reduce noctural parafunction compared to fixed restorations[7]. Various types of attachments could be used to retain, support, and stabilize these overdentures. The splinted attachment systems are the bar attachments while the unsplinted systems comprise spherical/ball-types, magnets, telescopic crowns or stud-type attachments[8]

Telescopic attachments are composed of primary (inner) and secondary (outer) crowns. Telescopic attachments may be rigid ones which include friction parallel walls or the conical, and the non-rigid (resilient) ones. Rigid telescopic crowns direct occlusal contact between inner and outer copings. They achieve retention using friction of parallel-sided milled surfaces of the inner and outer crowns during insertion and removal. Conical (tapered) telescope crowns exhibit friction only when completely seated using a "wedging effect." [9-11]. Telescopic attachments provide several advantages compared to bar attachments such as easier oral hygiene, self-insertion ability in patients with handling problems, high retention by friction, excellent denture support and stability especially in patients with atrophied ridges, and minimal restriction of tongue space[11-13]. They also provide self-seating mechanism that facilitates prosthesis insertion especially for geriatric patients with reduced manual dexterity[13]. Telescopic crowns can provide indirect retention preventing the dislodgment of the distal extension base away from the edentulous ridge. Moreover, they provide high horizontal stability due to the parallel walls of non-rigid telescope type which is very beneficial in case of alveolar ridge atrophy [11].

The available materials used for construction of the inner and outer crowns of the telescopic attachments include gold alloys, chrome cobalt metal alloys, titanium, and zirconia.[14] Secondary copings of telescopic crowns can be fabricated by several methods such as conventional one-piece castings, casting and laser welding, casting and spark erosion, copy milling, and computer-aided design/computer-aided manufacturing (CAD/CAM) [15]. The later provide fast construction. High precision and passive seating [16]. Rapid prototyping provide automatic wax-up of the copings which later converted into metal copings by traditional lost-wax process [17].

Cobalt-chromium (CoCr) is very well suited for the double crown technique due to its precise fitting, high elastic modulus, mechanical strength, lower weight compared to gold alloys, high biocompatibility and corrosion resistance[18]. Poly ether ether ketone (PEEK) represents a modification of the thermoplastic high-performance polymer group polyetherarylketone (PEAK) [19]. It possess several advantages as thermal stability, high hardness, lower water absorption and solubility[20-22]. Also biofilm formation on the surface of PEEK is equal to or even lower than on prosthodontic materials such as zirconia and titanium[20]. PEEK can be utilized as a metal substitute for fixed and removable restoration[20-22]. Moreover, it has good mechanical behavior, creep, wear resistance and shock absorbing ability[23, 24]. PEEK has also a low specific weight that allow construction of lighter prostheses, providing high patient satisfaction and comfort during function[25]. The manufacturing methods of PEEK include; milling, pressing from pellets, and pressing from granules[26]. The use of PEEK material in construction of telescopic attachments for natural teeth was previously reported in several invitro studies[18, 19, 26]

Retention of overdentures is of high importance clinically as it determines patients' satisfaction. Overall, patients are more satisfied with implant-retained prostheses than with conventional complete dentures[27]. Clinical retention forces of different attachments used to retain implant mandibular overdentures was previously investigated in several studies[27-30]. Retention of telescopic crown fabricated from PEEK for natural teeth with different taper angles was previously investigated in several invitro studies[18, 19, 26]. However, the clinical measurements of retention of telescopic crowns and the change of retention values over time was not sufficiently investigated. Accordingly, the aim of the present study was to evaluate, within patient, the effect of metal versus poly ether-ether Ketone secondary copings on the clinical retention values of telescopic retained implant supported mandibular overdentures

MATERIALS AND METHODS

Patient selection

A convenient sample of eight edentulous patients (4 males and 4 females, mean age=58.5±3.5 years) were selected from outpatient clinic of prosthodontic department for this investigation. The patient were included based on the following inclusion characteristics 1) un-satisfaction with the retention of mandibular dentures due to mandibular ridge atrophy and desired to have more stable prosthesis, 2) sufficient remaining bone in height, width and thickness in the interforaminal area to allow installation of at least 3.7mm diameter implants. 3) Adequate amount of interarch space of at least 12mm from the occlusal plane of the mandibular denture to the mucosa of the ridge. Patients with the following conditions were excluded: 1) systemic and metabolic diseases that may affect osseointegration such as diabetes mellitus and hyperparathyroidism, 2) blood disorders, 3) patients under radiotherapy or chemotherapy. The patients instructed about the treatment protocol and objectives prior to obtain an informed consent. The study was approved by the faculty ethical committee (Approval no FDBSUREC/26042020/MS). The patients were categorized by age, gender, and bone height in the canine region of the mandible and were randomly assigned into 2 groups using balanced randomization, then comparison of baseline criteria between groups was made to ensure that was no difference in age, gender, and bone height between groups to avoid selection bias. Patients were randomly allocated into one of 2 groups using random numbers generated using Excel program. Group I included 4 patients (2 males and 2 females) who received 4 implants and telescopic overdentures with metal secondary coping (control group), Group II included 4 patients (2 males and 2 females) who received 4 implants and telescopic overdentures with Poly ether-ether secondary copings (PEEK) secondary coping (test group). Allocation was performed using a dentist blinded to treatment groups. All patients signed an informed consent.

Surgical and prothetic protocols

The mandibular denture was duplicated using clear acrylic resin to produce a radiographic template. Gutta percha markers were attached to the template at the region of lateral incisor and first premolar teeth. Each patient was instructed to wear the template during cone beam radiographic evaluation to evaluate proposed implant sites regarding bone height and thickness, and approximation to vital structures (mental foramen). Radiographic template was then converted to surgical template by attachments of metal tubes in the desired position. The tubes are made parallel to each other's in mesiodistal dimension, and attempt was made to make it parallel in buccolingual dimension. If inclination of the implants is inevitable buccally or lingually due to mandibular concavities, tubes are inclined to the desired direction and the inclination will be compensated later during waxing of telescopic primary copings. A crestal incision was made from first molar area on one side to first molar area on the other side and mucoperiosteal flap was reflected. Four implants (Tiologic, Dentaurm, Germany) were inserted in the lateral incisor and first premolar using the standardized 2-stage surgical protocol. The flap was closed with interrupted sutures. The mandibular denture was relined and used during the 3 months healing period. After osseointegration, implants were exposed and healing abutments were threaded to the implants.

After 2 weeks of gingival healing around the abutments, Open tray direct impression procedure was started. Custom acrylic tray was constructed with perforations on the implant positions. Long impression posts were threaded to the implants and splinted in patient mouth using a special resin with minimal dimensional changes (Duralay, Reliance Dental MFG Co, Worth, IL, USA) to prevent movement of the impression posts during impression removal. Light consistency rubber base impression was loaded around the impression posts and the overall impression was made using putty material (Zhermack®, Badia Polesine, Rovigo, Italy). Implant analogues were attached to the impression posts and the impression was poured using hard stone. On the model, 4 precious metal abutments (TioLogic, Dentaurum, Germany) were threaded to the implant analogues. The plastic portions of the abutments were waxed and the wax was milled with special burs (which have 2^{o} inclination) using a milling device (Confident, Bangalore, India) to give the primary (inner) copings (6mm in height and 5mm in diameter). The 4 wax patterns were milled to make their circumferential walls parallel to each other's in mesiodistal and buccolingual direction regardless implant inclination. The wax was invested, cast in cobalt chromium alloy[31-33] (Heraenium Pw, Heraeus-Kulzer GmbH, Hanau, Germany) and refined by milling again and tried in patient mouth (Fig 1).

Fig. (1) Milled primary coping of telescopic attachment screwed in place in patient mouth

The cast with primary copings in place was scanned using CAD/CAM device (Ceramill Map400, Amann Girrbach AG. Koblach, Austria). Using the software of the device, four secondary copings were designed with a 1.0 mm-thickness to cover the primary copings and saved as STL file. The designed copings were printed (using additive method) in castable resin (GC Pattern Resin, GC Corp, Tokyo, Japan) using a laser sintering device (EOSINT, Germany). The castable resin patterns were invested and casted with cobalt chromium alloy (group I, fig 2a). In group II, the designed copings were milled in PEEK discs (BioHPP, high performance polymer, Bredent GmbH & Co.KG, Weißenhorner Str. 2, 89250 Senden, Germany) (fig 2b). PEEK secondary copings were painted with Visio.link Adhesive to facilitate bonding of PEEK to acrylic resin of the denture base. Record blocks were made on the master casts and Jaw relationship were recorded. The secondary copings were placed over the primary copings on the master cast and packing of acrylic resin and denture processing were performed in usual manner. The overdentures were finished and delivered to the patients with emphasis on oral hygiene procedure, the occlusion was refined and follow up visits were scheduled with patients on 3 months regular recalls.

Fig. (2) Fitting surface of the overdentures with secondary copings a; Cobalt chromium metallic secondary copings (group I), b, PEEK secondary copings (group II)

Evaluation of overdenture retention

Force meter device was used to measure the retention of the mandibular overdenture in Newton (fig 3). Measurement of retention was recorded in vertical direction perpendicular to the patient's occlusal plan using a special device for measurement of clinical retention values of overdentures previously described by Refaat and Elsyad[34]. For all overdentures, four hooks were attached to the buccal flange at the canine and first molar areas using autopolymerized acrylic resin at the same height. The mandibular overdenture was completely seated in the patient's mouth. Force gauge was attached to the measurement device perpendicularly to ensure movement with the device as one unit in a vertical direction. The patient was asked to sit keeping the mandibular occlusal plane parallel to the floor. The hooks would engage intra-orally to the fork of the force meter at the pull end. The wheel in the stand of the device was used to move the force gauge in vertical direction which is absolutely perpendicular to the base of the device and to the patient's mandibular occlusal plane. The force gauge was used to measure the pull force (in N) needed to dislodge the mandibular overdenture from its place. Measurement of retention forces were made immediately after overdenture insertion, 3 months and 6 months after insertion by independent dental personnel blinded to treatment groups.

Fig. (3) Retention measuring device

Statistical analysis

A blind statistician performed statistical analysis. Independent samples t-test was applied to test possible differences in retention force between groups. Repeated measures ANOVA was used to compare retention forces between different observation times (at insertion, 3 months and 6 months after insertion). P values for comparisons were adjusted for simultaneous hypothesis testing according to the Bonferroni method of multiple comparisons. The overall threshold value for significance (α) was set at .050. The data were analyzed using SPSS® software version 22 (SPSS Inc., Chicago, IL, USA).

RESULTS

The data were parametric and met the normal distribution. Therefore, the retentive forces were presented by mean and standard deviation. No drop out occurred to the participants and all patients completed the analysis. No implant failures occurred and the survival rate was 100% in both groups. Comparison of retentive forces between metal and PEEK groups are presented in table 1 and fig 3. There was a significant difference in retentive forces between groups at all times of measurements (base line, 3 months after insertion and 6 months after insertion ($p<.001$). For all times of measurements, PEEK secondary copings were associated with significant higher clinical retention values than metal secondary copings.

Comparison of retentive forces between measurements times are presented in table 2. There was a significant difference in retentive forces between measurement times for metal ($p=.035$) and PEEK ($p=.003$) groups. For metal and PEEK groups, retention values at base line were the highest values followed by retention values after 3 months and the least retention forces were noted after 6 months. Multiple comparison between each 2 measurement times is presented in the same table. There was a significant difference between each 2 measurement times for both groups

TABLE (1) Comparison of retentive forces between groups at different measurement times

	At insertion		**3 months after insertion**		**6 months after insertion**	
	X	SD	X	SD	X	SD
Group I (metal)	27.18	3.74	24.53	3.26	19.97	4.1
Group II (PEEK)	58.13	4.62	43.87	5.40	31.57	3.54
Independent samples t-test (p value)	<.001*		<.001*		<.001*	

X: mean, SD: standard deviation. * p is significant at 5% level.

TABLE (2) Comparison of retentive forces between measurement times for each group

	Group I (metal)		**Group II (PEEK)**	
	X	SD	X	SD
T0	27.18a	3.74	58.13a	4.62
T1	24.53b	3.26	43.87b	5.40
T2	19.97c	4.1	31.57c	3.54
Repeated ANOVA P value	.035*		.003*	

X: mean, SD: standard deviation. * p is significant at 5% level. Different letters in the same column indicate a significant difference between measurement times (Bonferroni, p<.05)

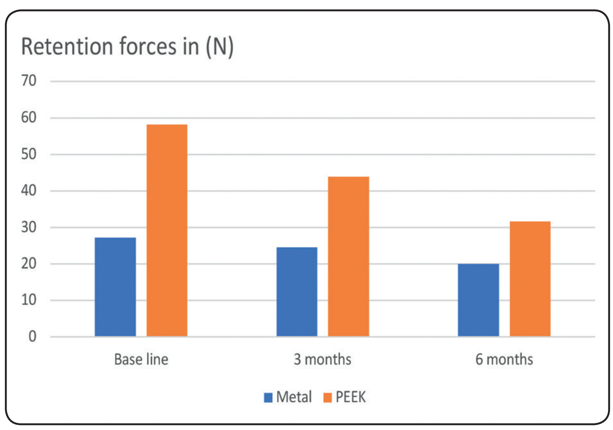

Fig. (4) Retention forces in N for both groups at different observation times

DISCUSSION

In this study it was decided to standardize taper angle at 2° to provide a slight resiliency, facilitate prosthesis insertion and to avoid excessive implant loading. The reason for choosing 2° degree was that Ohkawa et al.[32] noted that retention was rapidly lost when the taper angle of telescopic crowns exceeded 2°. Moreover, construction of PEEK secondary copings was made using milling rather than pressing as pressed PEEK has a lower elasticity modulus, are softer more deformable), compared to milled PEEK material which may affect retention values. Moreover, pressed PEEK has more difficult sequence with a higher number of potential sources for errors such as unpredictable expansion coefficient of the investment, pre-heating process and contraction of the material

during the cooling which changes the fitting of the copings even at the inner surface. Also, the inner surface of the pressed PEEK may be roughened by airborne particles to remove the investment material which may have an effect on retention forces[19]. On the other hand, the milling process may be influenced only by the software program, which provides small path differences of the milling machine[19]

Most of studies evaluating retention forces of implant overdenture attachments performed in laboratory setting to facilitate application of pure vertical dislodging forces and avoid non axial dislodging of the dentures if the retention was measured clinically. In clinical situation, it is difficult to apply the dislodging forces perpendicular to the occlusal plane from the center of the dentures due to presence of opposing jaw. Therefore, non-axial dislodging usually occurred which does not represent retention forces but stability forces instead. In this study, the device used for measuring the clinical retention combines the advantages of the in vitro and in vivo measurement of the retention. This device ensures application of pure vertical force perpendicular to occlusal plane in presence of oral environment like humidity, saliva, and temperature.[25, 26]

Moreover, invitro evaluation of retention forces does not simulate clinical conditions as presence of saliva and the way that the overdenture is loaded during function which may influence the attachment friction, and wear and thus affecting the retention values. In addition, simulation of occlusal wear in laboratory studies made by cyclic dislodging which apply dislodging forces of the same magnitude and direction that differs completely from clinical setting as implant overdentures, when it placed in the oral environment, move in complex ways in several directions (occlusal, gingival, mesial, distal, facial, and lingual). While true unidirectional dislodging forces rarely occur in clinical scenarios.[31–33]

The design and the material of the secondary copings are important factors in determining the retention and stability of the telescopic attachments. In This study, PEEK secondary copings were associated with significant higher clinical retention values than metal secondary copings at all times of measurements. This could be attributed to the higher retention forces of PEEK material when used as an attachment for removable restorations [19,35]. Another explanation may be due to the technique and the taper used in construction of the PEEK secondary copings. Copings were constructed with milling from PEEK discs with a 2-degree occlusal taper to provide a slight resiliency, facilitate prosthesis insertion and to avoid excessive implant loading. In line with this explanation, Stock, et al.[19] evaluated the retention force between primary and secondary PEEK crowns made by different tapers (0°, 1°, and 2°) and different fabrication techniques (milling from PEEK blanks, pressed from pellets or granules). They found that milled PEEK secondary crowns of telescopic attachments constructed on 2° tapered primary crowns displayed significantly higher retention values compared to granular pressed crowns. They added that 0° tapered crowns milled secondary crowns showed lower retention forces compared to pressed pellet crowns. On the other hand, Wagner et al. [26] evaluated the retention of PEEK secondary telescopic copings on cobalt-chromium primary crowns with different tapers (0°, 1°, and 2° tapers) and different fabrication methods (milling, pressing from pellets, and pressing from granules). They found no effect of manufacturing method on the retention was observed within 1° and 2° groups. They concluded that telescopic crowns made of PEEK seem to show stable retention load values. Therefore, in clinical settings, milled PEEK may be a suitable material for removable prosthesis and telescopic crowns [35] as it provided higher degree of retention even after 6 months of denture use. In contrast, the reduced retention of metal secondary copings may be attributed to the wear of the casting nodules and scratches caused by casting process[36, 37]. The reduced retention with metal copings may be also attributed to the relief provided in the fitting surface of the metal secondary copings. This relief was made by the dental technician using a disclosing media to facilitate the prosthesis seating and remove casting nodules[36, 37].

The retention force decreased with passage of time in both groups. This observation was not surprising and is in line with several in vitro studies[38,39]. The significant decrease in retention forces of both telescopic attachments after clinical use was in line with other studies[32, 33, 36]. Elsyad et al.[36] found a significant decrease in retention of telescopic attachments used to retain mandibular overdentures after repeated insertions and removals (540 times) that simulate denture use of about 6 months. This could be attributed to the nature of the retention mechanism of telescopic crowns which is based on the adhesive friction between joining surfaces[33]. The internal surfaces of the inner and outer crowns show nodules due to the casting process. Such nodules create wear tracks (scratches) on the surface of the metal crowns[33]. Interlocked surfaces at wear tracks may result in an increase in the initial retentive force. However, abrasion of the surfaces by wear caused replacement of the wedged contact by a gap and retentive force is reduced. Similarly, Ohkawa et al. [32] found that for telescopic crown with 4 mm height and 0-2 degree axial convergence, retentive force decreased by approximately one half of the first cycle value after repeated insertions and removals.

The limitations of the study included small patient sample and the short follow up period. Finally, future long term randomized clinical trials are required to evaluate the clinical retention and patient satisfaction and oral health related quality of life of metal and PEEK telescopic attachments used to retain implant overdentures.

CONCLUSION

Within the limitations of this study caused by small patient sample and short evaluation period, PEEK secondary copings for telescopic attachments of mandibular implant overdentures is recommended than cobalt chromium secondary copings as it was associated with increased clinical retention values even after 6 months of clinical use.

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