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Evaluation of retention and patient satisfaction with implant retained mandibular dentures: A clinical study

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Abstract---Objective The aim of this clinical study was to compare the overall satisfaction and retention values of two types of commonly used attachment systems in implant supported mandibular overdentures. Materials and methods: : Prior to implant installation, conventional complete dentures were fabricated for 22 completely edentulous individuals. Two implants were placed in the canine region following the two-stage flapless implant surgical protocol. After 4 months of healing, patients were randomly allocated into two groups: group 1 received ball and socket attachments and group 2 received bar and clip attachments. Patient satisfaction was assessed by VAS questionnaire and retention values were recorded using custom made testing device attached to a force meter at baseline (at the pick-up visit), three, six and twelve months after implant supported prostheses insertion. Result: The study showed significant superior retention values for bar attachment than ball attachment. Patient's satisfaction scores showed no significant difference between both type of prostheses throughout the study period; however, patients' satisfaction rates were improved while retention values were reduced significantly by time. Conclusion: The selection of a specific type of implant attachment for implant supported overdentures is dependent on multiple dentist as well as patient related factors.

Keywords---Implant Overdenture, Attachment, Retention, Patient Satisfaction.

Introduction

Truthfully, tooth loss is considered an outcome of a complex interaction between disease entities such as caries and periodontal disease and non-disease entities as economy, oral healthcare system, access to dental services, dental awareness, cultural tradition and education.^[1] Edentulism is a public health concern presenting an irreversible medical condition described as the final marker of disease burden for oral health.^[2,3] Its prevalence is high in developing countries as well as all over the world. ^[4,5] It has several deleterious consequences on oral, general, mental and social well-being thus compromising the quality of life.^[1,3,6-8]

Conventional complete dentures were and still the treatment of choice in many cases for both economical and biological reasons. However, the primary goal in treating edentulous patients with any prosthodontic treatment is patient satisfaction.^[9] The lack of adequate retention and stability of mandibular conventional denture bases does not only cause loss of patient trust in dentists and treatment, it conveys into complaints and biological complications as it might affect the integrity of the denture bearing tissues and associated structures.^[6,10] Therefore, the treatment of edentulous mandibles with two implant-supported overdenture became the standard of care.^[11]

Implant retained mandibular overdentures provide enhanced esthetic, retention and stability through their different attachment mechanism.^[12] They proved themselves to be logical alternatives to conventional mandibular dentures with improve oral functionality and chewing efficiency up to 20% more thus maintaining alveolar bone and delaying or eliminating future oral rehabilitation problems.^[13-15] In addition, implant overdentures are well-accepted by patient and have shown to provide long-term clinical success and patient satisfaction rates.^[16,17] However, these prostheses require thorough initial case evaluation, frequent oral hygiene recall and maintenance expenses.^[18-20]

The implants in the implant supported overdentures can be splinted together with bars or unsplinted with individual attachments of different designs.^[21-23] Studies that compared between the two retention concepts, namely the splinted and non-splinted, showed that splinted designs have superior retention.^[24,25] However, the biological and technical complications are much higher with the splinted design.^[26] The fabrication of implant supported prosthesis retained by bar attachment is technique sensitive and more challenging to construct and repair than removable restorations supported by individual attachments.^[24-27] The most common biological problem associated with the bar design is overgrowth of tissues beneath the bar causing gingival inflammation and patient dissatisfaction.^[26,28]

A plethora of attachment systems for mandibular two-implant overdentures is currently available and more are being produced by implant manufacturers, often without evidence-based support for their design, material selection, long-term

maintenance or repair.^[29] Clinicians often base their selection of attachment system for mandibular implant overdentures empirically on their presumed retentive qualities. This is evident in the mandibular implant overdenture literature, where adequate retention has been correlated with improved levels of patient satisfaction.^[30,31] Unfortunately, a definition as to what is an “acceptable”. Therefore, this study aimed to evaluate patients’ satisfaction and retention of two attachment designs retaining mandibular overdenture: individual (ball and socket attachment) implant overdentures compared to splinted (bar and clip attachment) implant overdentures over 12-month period.

Material and Methods

The study was conducted after approval was obtained from the Research Ethics Committee (REC 15-11-22). Twenty-two completely edentulous patients with age range between 40 to 70 years old signed informed consent to participate in the study. For inclusion in the study, participants has to be completely edentulous for a minimum period of one year, seeking prosthodontic treatment at the prosthodontics out patients clinic of the university with sufficient inter arch space (22 mm or more), normal maxillomandibular relationship (Class I Angle Classification) and adequate buccolingual width of keratinized attached gingiva mucosa over the crest of the mandibular ridge (5 mm or more). Individuals with systemic conditions that interfere with implant placement and/or osseointegration or those who requires hard or soft tissue grafting of the proposed implant sites, patients with parafunctional habits and/or temporomandibular joint disorders were excluded from participation.

At the initial visit, all patient’s personal information, past and present medical history, as well as, dental history were recorded. Patients were examined thoroughly; extra and intra-orally, radiographic and laboratory investigations were done as needed.

I- Prosthetic treatment

Before implant installation, all patients received a set of conventional complete denture. The complete dentures were fabricated according to the conventional five appointment protocol: preliminary impressions using irreversible hydrocolloid (Cavex Holland B.V, P.O.Box 852-2006 R W Harrlem, Holland) were made in the first visit. Study casts were obtained by pouring the impressions according to manufacturer instructions. Custom trays were constructed from Triad light polymerized Materials and trimmed 2 mm shorted than the sulcus depth (Tru Tray Sheet; Dentsply Intl). In the second visit, border molding and definitive impressions using green stick compound (green stick compound care, green stick compound kerrHawe SA, Via Strecce 4, 6934 Bioggio, Switzerland) and ZnO/Eugenol (ZnO/Eugenol cavex Holland BV fustweg 6, 2031 CJ Haarlem, Netherlands) were completed. Selective impression technique was used during final impression following Passamonti’s technique.^[32] Impressions were boxed and poured in Type III hard dental stone (type M gypsum, Zeta Industria, Italy) and records blocks were fabricated. Interocclusal records and teeth selection were completed in the third appointment. Record blocks were mounted on semi adjustable articulator (A7 plus semi adjustable articulator, Bio art, Brazil) by the

help of arbitrary face bow (Bio-Art Equipmentos Odontologicos Ltda) and centric occlusion relation record at the proper vertical dimension of occlusion. After artificial teeth setting, trial dentures were tried in the perspective patient mouth in the fourth visit. The waxed trial dentures were processed into heat polymerizing acrylic resin (Lucitone 199; Dentsply Intl). The denture bases were fabricated through the lost wax technique and processed using the long polymerization cycle (9 hours in water bath at 73°C followed by 30 min in boiling water). Laboratory remounting were done to restore vertical dimension of occlusion and refinement of occlusion before insertion. In the fifth and last visit, dentures were inserted in the patient mouth and further occlusal adjustments were made to achieve cross-arch bilateral balanced occlusion .

II-Implant surgery

Two to three appointments followed denture insertion visits to assure patients' comfort with the prostheses. Then, the mandibular dentures were duplicated into radiographic stents using an orthodontic plastic box and putty consistency rubber base (ZetaPlus, Zhermack SpA, Italy). Cold cure acrylic resin (Acrostone Dental & Medical Supplies, Egypt) was mixed with radiopaque material (barium sulphate) and packed in the molds. Ideal implant proposal site has been prepared in the stents as holes. Cone Beam Computed Tomography (CBCT) were obtained with stents stabilized in the patients mouth in opposition with the upper dentures. The virtual planning for implant placement was made using CBCT Software (In2Guide Module of Ondemand 3D, Cybermed Inc., Seoul, Korea) to plan implants geometry and site and the computer guided stents were constructed using 3D printing (3D printer, Envision tech, Envision TEC Inc.).

Antibiotics and non-steroidal anti-inflammatory drug (Augmentin 1g/12 hours & Ketoptofen 50 mg/ 8 hours) were prescribed for patients 24 hours before surgery and continued for a week after the surgery. In addition, Chlorohexidine mouthwash was prescribed two times daily for chemical plaque control for two weeks after the surgery.

Following the two-stage flapless surgical protocol of implant placement, two implants (Dentium, Super Line, Korea, size is 3.6 mm x 12.0mm) were placed at the canine region in all patients with the aid of the computer guided surgical stents. The surgical stents were stabilized in the patients' mouths using anchor pins. The drilling sequence of the implants followed the manufacture instructions in vertical direction with copious external irrigation at a speed of 800 RPM. The implants were slowly threaded manually into the osteomy using torque wrench at 35 Ncm till complete insertion and sealed with cover screws . Patients were advised to eat soft diet for one week after the surgery and report any complications. After 4 months, the uncovering surgeries were completed through punch technique using the previous surgical stents and healing abutments replaced the cover screws.

III-Implant supported denture fabrication

Two weeks after the uncovering surgery, patients were randomly allocated into two groups using coin toss. For group 1 (Stud attachment group), Ball attachments were chosen in respect to gingival cuff height, placed and torqued according to manufacturer's recommendations at 35 Ncm. Direct technique was performed to pick-up the stud attachments into the existing dentures; sufficient relief was done in the fitting surface of the dentures, metal housings were placed over the ball attachments after blocking the undercut and cold cure acrylic resin (Lucitone 199; Dentsply Intl) was used to attach the housings to the denture fitting surfaces. Regular blue nylon was used for all patients (Dentium ball and socket, Dentium attachment system, Korea) and occlusion refinement was completed (Figure 1). For group 2 (Bar attachment), implant level impression using open tray impression technique with polyvinyl siloxane impression material (Aquasil Ultra Heavy, Dentsply Caulk, Milford, DE) was done. Definitive casts with lab analogs were obtained. Plastic abutments were secured to the implant analogues and connected to the plastic bar (Castable bar OT, RHEIN83, Italy) using duralay. The bars were positioned 2 mm above the surface of the gingiva using the surveyor. The whole assemblies were casted into white gold alloy. Casted bars were tried in the patients mouths to assure passivity using one screw test and radiographs were taken for confirmation. Pick up of the clips was done in the lab after blocking the undercut. Upon denture delivery, occlusion was adjusted to ensure refinement of the planned balanced occlusal scheme (Figure 2).



Fig 1: Ball attachment inside patient's mouth (up), Blue retentive cap for ball attachment in the fitting surface of denture (down).



Fig 2g: Bar attachment inside patient's (up), clips of bar attachment in the fitting surface of the denture

IV-Assessment of patient satisfaction

Patient satisfaction was assessed by face to face questionnaire (Table 1) and measured with visual analogue scale (100 mm VAS) on the day before the insertion of the implant supported prostheses and three, six, nine and twelve month after the pick-up and delivery of the implant supported overdentures.^[33] In each visit, patients were asked face to face, by the principal researcher, the questions covering the different items of the patient satisfaction questionnaire.

Table (1): Questionnaire given to patients.

Statement	Criteria
Describe the extent of discomfort with your upper denture	Comfort of Dentures
Describe the extent of discomfort with your lower denture	
How would you rate the fit of your upper denture?	Fit of Dentures
How would you rate the fit of your lower denture?	
Do you have difficulties speaking with your prosthesis?	Speech and Phonetics
How often does your prosthesis affect your socializing?	Social Activities
Are there activities you avoid because of the possibility of being embarrassed by your prosthesis?	
How often does your prosthesis affect your work?	
To what extent has your implant-supported prosthesis improved your social and work relationships with other people?	
How difficult is it for you to bite off soft food?	Chewing Efficiency
How difficult is it for you to bite off hard food?	
How difficult is it for you to chew soft food?	
How difficult is it for you to chew hard food?	
How satisfied are you with the healing since your implant surgery?	Psychological Impact
Do you think your implant-supported prosthesis is actually part of you?	

V-Measurement of retention

A stainless-steel snap hook wires were fixed and attached to the center of the mandibular denture base using cold cure acrylic resin (Lucitone 199; Dentsply Intl). The center of the denture bases was located by marking the distance halfway between the center of both implants. Evaluation of retention was assessed using retention measuring device (Force meter) upon insertion, three months, six months and twelve months after implant supported overdenture delivery for all patients in the two groups.

Patients were seated in upright position so that the inferior border of the mandible was parallel to the floor. Patients heads were well supported. Each denture base was checked to ensure proper seating intraorally. Dentures were

inserted into the patients mouths and checked intra orally for proper seating, tongue freedom, loop position and denture stability before testing. Retention was measured by the force meter machine, which is a digital device that can apply vertical force gradually in upward direction at a definite point. Three measurements were taken for each patient at 10-minute intervals. Between measurements, the patients were allowed to rest, and full seating of the overdentures was secured in their places firmly before repeating the measurement. The measurements were recorded many times to determine accuracy and the mean was calculated. The retention values were recorded by the digital force meter in Newton.

VI-Sample size calculation

The minimum sample size ($n=11$) was calculated based on Nitish Varshney et al, 2019.^[34] In a previous study, the response within each subject group was normally distributed with standard deviation (2.9). If the true difference in the experimental and control means is (3.7), 11 study subjects were needed in each group to be able to reject the null hypothesis that the population means of the experimental and control groups were equal with probability (power=0.8). The Type I error probability associated with this test for this null hypothesis is (0.05)

VII-Statistical analyses

Data from the two groups were analyzed using a SPSS statistical package (Version 19, Chicago, IL, U.S.A.). Mean values were compared by independent T-test to compare between the two groups and paired T-test to compare the effect of time in each group. The level of significance was set at 5% for all statistical analyses.

Results

The samples of twenty-two patients, with a mean age of 59.8 years participated in this study. A total of 44 implants were placed and 22 attachment retained implant supported mandibular overdentures were delivered (11 ball retained and 11 bar retained). No drop out, all patients completed the 12-month follow-up. Demographic data extrapolated from the questionnaire is summarized in table 2 (Table 2).

Patient satisfaction was measure by visual analogue scale (VAS) using scale 1 – 100 mm. Patients' responses from 70 – 100 was recorded as satisfied, 50 – 60 as neutral and 40 and below as dis-satisfied. In reference to the criteria evaluated through the questionnaire on patient satisfaction, 68.2% of patients were pleased with the comfort of both type of overdentures; 68.2% were pleased with the fit of the ball retained implant supported overdentures and 72.72% were pleased with the fit of the bar retained implant supported overdentures; 72.72% were satisfied with their speech using the ball retained implant supported prostheses while 81.81% were satisfied with their speech using the bar retained implant supported prostheses; 75% agreed that their new ball retained implant supported dentures improved their socialization skills compared to 79.54% with the bar retained implant supported overdentures; 77.27% of both groups agreed that their implant supported overdentures has improved their chewing efficiency and 81.81% were

satisfied psychologically with their implant supported overdentures (Figure 3). T test results revealed no statistical significance difference ($p > 0.05$) in these rating between both type of prostheses.

Regarding patients' overall satisfaction, from the baseline (before delivery of implant overdenture) to the different follow-up period there were statistically significant ($p < 0.05$) improvement of patient satisfaction in the ball and bar retained implant supported overdentures. The great improvement was noticed between baseline and after 12 months (Figure 4). There were no statistically significant differences ($p > 0.05$) regarding patient satisfaction recorded at baseline, three, six- and twelve-months follow-up periods when compared ball retained overdenture to bar overdenture group (Table 3a)

The average retention values for the ball and bar retained implant supported overdentures at baseline, three, six and twelve months follow up periods were illustrated in table 3B (Table 3b). Significantly more retention values at baseline, three, six and twelve months follow up periods ($p < .0001$) was noted in the retention of bar retained implant supported overdentures when compared to ball retained implant supported overdentures. From the baseline (at the time of pick-up) to the different follow-up period, there were statistically significant ($p < 0.05$) reduction in the retention of ball and bar retained implant supported overdentures (Figure 8). Error! Reference source not found. The great reduction was noticed between baseline` and after 12 months of loading. The p value indicates statistically differences between baseline and different follow-ups periods ($p < 0.05$).

Table 2: Patients demographics data summarized from self-questionnaire.

Participants	Group 1 (ball attachment) Participants				Group 2 (Bar Attachment) Participants			
	Age (year)	Sex	Marital Status	Employment Status	Age (years)	Sex	Marital Status	Employment Status
1	59	male	married	working	40	male	single	working
2	64	male	married	retired	52	female	married	not working
3	67	male	widow	retired	65	male	married	retired
4	58	male	married	working	48	male	married	working
5	62	male	married	working	63	male	married	retired
6	53	female	married	working	70	male	widow	retired
7	60	male	married	working	62	female	married	not working
8	62	male	divorced	retired	59	male	married	working
9	57	male	married	working	61	male	married	working
10	60	male	married	working	59	male	married	working
11	62	male	married	working	64	male	married	retired

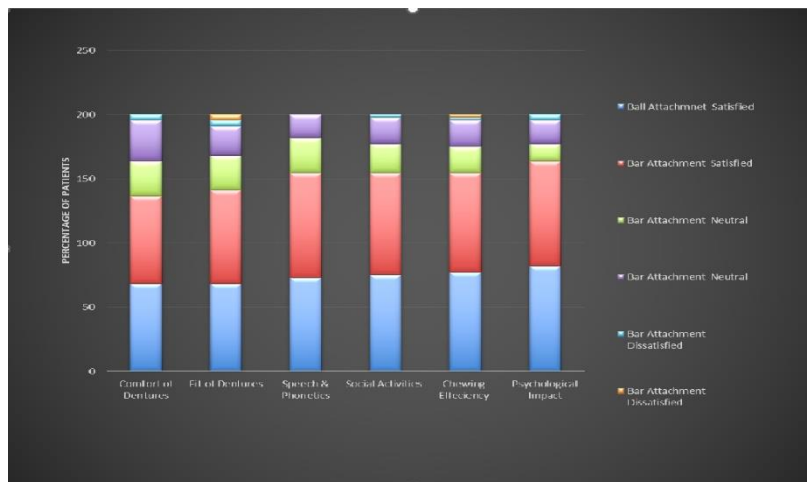


Fig 3: Comparison between group 1 & group 2 in patient satisfaction which measured by VAS Scale.

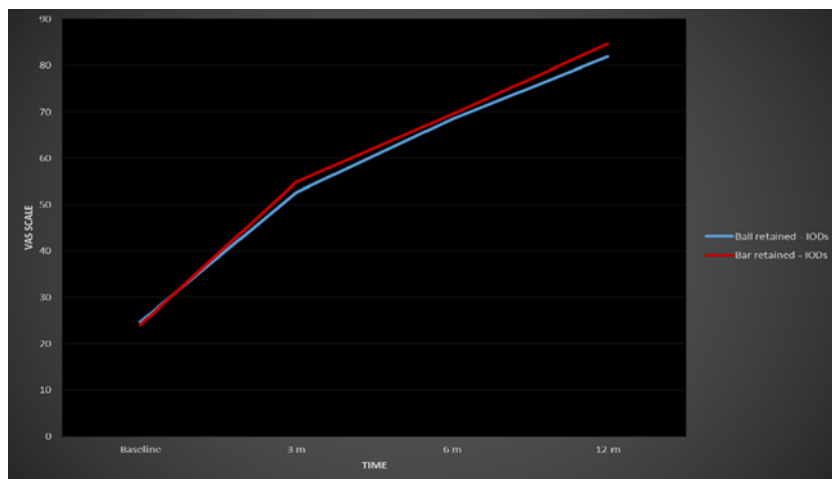


Fig 4: Comparison between group 1 & group 2 in patient's overall satisfaction

Table 3: A. Comparison between Patient satisfaction of Ball and Bar retained implant supported overdentures s regarding

Follow-up periods	Ball retained implant supported overdentures		Bar retained implant supported overdentures		P value
	Mean	SD	Mean	SD	
Baseline	24.72	4.54	24.09	2.25	0.68
3 m	52.63	6.18	54.90	5.10	0.36
6 m	68.45	4.98	69.5	5.64	0.64
12 m	81.90	7.09	84.72	7.28	0.37

SD= standard deviation, P value <0.05 show statistically significant

Table 3: B.Comparison between retention of Ball and Bar retained implant supported overdentures

Follow-up periods	Ball retained implant supported overdentures		Bar retained implant supported overdentures		P value
	Mean	SD	Mean	SD	
Baseline	23.18	2.92	32.3	1.96	<0.0001*
3 m	19.36	2.54	29.9	1.92	<0.0001*
6 m	13.36	2.11	26.81	1.66	<0.0001*
12 m	8.90	1.814	22.6	1.96	<0.0001*

SD= standard deviation, P value <0.05 show statistically significant

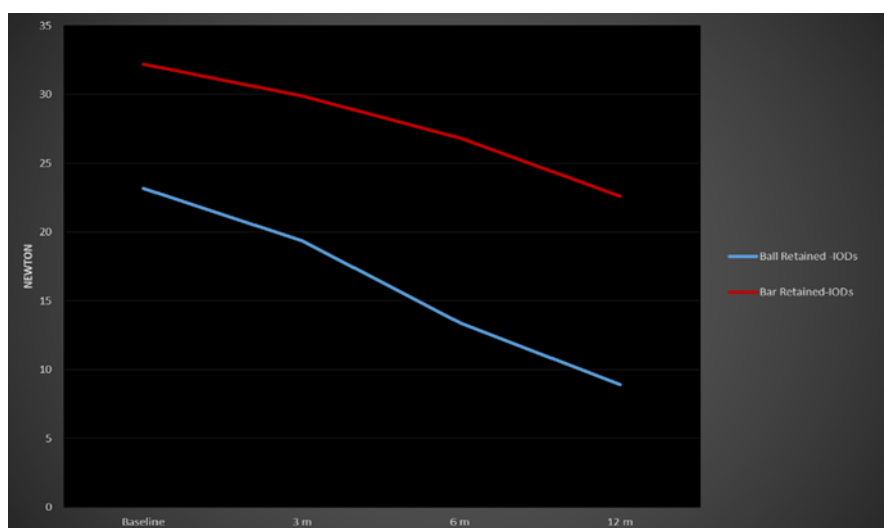


Fig 5: The average retention values for group 1 & bar retained implant supported overdentures at baseline, three, six and twelve months follow up periods.

Discussion

In highly industrialized countries, where optimum healthcare services are present, the percentage of edentulous individuals over 65 years of age is projected to decrease considerably; however, the absolute number of individuals over 65 years is expected to double by the year of 2030, and thus the actual number of those individuals needing complete denture therapy will remain constant.^[34] The removable prosthodontics needs for this elderly population is not only significant, but poses unique challenges not commonly seen in younger population. Many elderly patients demonstrate progressively decreasing neurophysiological adaptive capacity for wearing conventional complete dentures with increasing age.^[36] They often have difficulty adapting to complete dentures and have problems attaining comfortable and efficient denture function.^[36] According to this study, the introduction of implants in completely edentulous patients have proven again and again their success in providing the denture wearer satisfaction and confidence in their implant supported overdenture.^[1,30,37]

The standardization of methods was an important aspect of this investigation; therefore, all factors regarding implant selection and surgical procedures were carefully considered to assure standardization of the results of the study.^[38] The direct pick up technique was performed in this study as it is simple, economic, quick, and allow patient to retain the same prosthesis.^[39] Meticulous oral hygiene regimen including plaque control and frequent recall visits were followed throughout the study to ensure the success of the implant supported overdentures.^[40]

The null hypothesis of this study that no differences would be found in retention values between individual (ball) and splinted (bar) implant supported mandibular overdentures was rejected. The retention value for the splinted (bar) attachment was significantly higher than the retentive values for the unsplinted (ball) attachments at dentures' insertion, three, six and twelve month of denture use. This could be explained by the different designs of both attachments, where the bar limited base due to its cross-section. On the other hand, the ball attachment usually shows more flexibility in several directions.^[25,29] However, these differences in retentive values didn't affect the overall patients' satisfaction.

Regarding patients' satisfaction with the implant supported overdentures, the literature established the fact that satisfaction depends on multiple factors, like patient preferences, chewing comfort, phonetics, and esthetics. There is also the direct relationship with the retention of the overdenture.^[41] In the current study, patients' satisfaction questionnaire results showed statistically significant increase in patient satisfaction regarding all aspects. The significant increase in patients' satisfaction could be related to the significant retention obtained by either the ball or the bar attachments. Effective retention and stability of the prosthesis can help the patient to use the denture regularly, thus improving patient confidence for speech, function and even esthetics.^[42] The patients showed continuous satisfaction throughout the study period, although the retentive properties of the retentive caps of both attachment designs showed loss of retention. This could be justified by the fact that patients usually have amazing adaptive qualities, that although the dentures became less retentive, they can still control and adapt by musculoskeletal. The use of denture regularly in function will aid in the development of orofacial muscle adaptation that can compensate for the reduced retention value later^[43,44]

Previous investigations of attachments are in general agreement that loss of retentive force over time is inevitable.^[29] The obtained results from the current study confirmed the loss of retentive values of both type of attachment designs during the use of implant supported overdenture overtime. This loss of retention has been attributed to wear of attachment components which may be related to deformation that occurs during insertion and removal of the prosthesis.^[29,45-46]

According to the current study, the higher retention value of the splinted (bar attachment) as compared to the individual (ball attachment) implant supported overdenture and the reduction in the retentive value of both attachment designs overtime was not related to patients experience and satisfaction of the outcome. Nevertheless, patient satisfaction could be multicausal process involving objective and subjective factors.^[41,48] These results are not surprising because literatures

confirm that patient reported that the retentive quality is less important than other clinical parameters in determining the success of treatment outcome. Other factors such as individual treatment preference and satisfaction with the prosthesis functional aspects, tissue health, maintenance aspects, and complications outweigh the higher retention. When these factors were weighed together, prosthesis retention was only one aspect of the entire process.^[16]

Although bar attachment showed higher retentive values than ball attachment, patient satisfaction was improved by both type of attachments over time. The one-year follow-up precludes further conclusions on the long-term satisfaction and attachments retention. Maintenance of the prostheses was kept to the minimum as needed. In further studies, larger sample size would increase the power of the study, compensate for drop out over longer follow up period and allow the investigation of other outcomes such as maintenance relevance on patient as well as dentist satisfaction.

Conclusion

Within the limitation of the study, we may conclude that; although bar attachment showed higher retentive values than ball attachment during fabrication of implant supported overdenture, patient satisfaction was improved by both attachments design over time. Reduction in the retention of both attachments design with denture use did not affect the improvement in patients' satisfaction with time. The selection of a specific type of implant attachment for implant supported overdentures is dependent on many factors. Some of these factors include patient preference, implant and attachment angulation, inter-implant distance, the direction of applied dislodging forces, material, design, dimension, and mode of retention of attachment systems.^[49]

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