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EVALUATION OF IMPLANT-RETAINED OBTURATORS USING SPLINTED VERSUS NON-SPLINTED ATTACHMENTS FOR MAXILLECTOMY PATIENTS: IN-VITRO STUDY

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ABSTRACT

INTRODUCTION: After maxillectomy, patients suffer a significant loss of bone as well as soft tissue, leading to ailing retention of traditional obturators. Therefore, for patients who have undergone a maxillectomy, an implant-retained obturator may be a preferable alternative achieving sufficient retention and restoring oral function. For retaining obturators, splinted or non-splinted attachment systems can be used; each having unique stress transmission pattern in alveolar bone surrounding implants under load of mastication and functional forces.

OBJECTIVES: In this study, two distinct attachment designs—ball and socket (non-splinted) attachment and Hader bar and clip (splinted) attachment—were used to assess stress distribution in peri-implant tissues of implant-retained obturators.

MATERIALS AND METHODS: An epoxy resin maxillary model of completely edentulous patient with unilateral maxillary defect (Brown's class IIA) was used in which two parallel dental implants were positioned at the canine and second premolar regions on the intact side. Thirty obturators were constructed representing two groups; each using distinct attachment system. Group I received 15 pair of ball (non-splinted) attachment and Group II received 15 Hader bar-clip (splinted) attachment. Using the universal testing machine, vertical and oblique loads (30^0 and 45^0) of 50 and 100 N were applied bilaterally on the central occlusal fossae of maxillary first molars, and stress distribution was computed using strain gauges and compared between the two groups.

RESULTS: There was statistically significant difference in strain value between group I (Ball) and group II (Bar-clip) after application of vertical loading 50 N and 100 N with p value < 0.0001 and after application of 30^o oblique loading 100 N and 45^o oblique loading 100 N with p value < 0.001, as group I exhibited lower strain values.

CONCLUSIONS: Ball (non-splinted) attachment showed less strain values with favorable stress distribution when compared to bar-clip (splinted) attachment.

KEYWORDS: Implant-retained obturator, Hader bar and clip, ball and socket, maxillectomy, strain gauges.

RUNNING TITLE: Splinting effect on stress distribution of implant-retained obturators.

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INTRODUCTION

Congenital deformity, trauma, benign or malignant neoplastic growth, and others all warrant the need for a maxillectomy (1,2); Which may encourage oral-nasal-sinus communication, facilitating movement of food, liquid, and air between these chambers. This can have an adverse effect on swallowing, mastication, and speaking, lowering quality of life (2-4).

The importance of the patient's rehabilitation following a maxillectomy varies depending on the patient's age and medical history. Due to the invasiveness and complexity of restorative plastic operations, obturator prostheses are usually used for rehabilitation. The purpose of this prosthesis is to restore speech and mastication by preventing oral-nasal-sinus communication (5). Maxillectomy defects are categorised in a variety of ways. The maxillofacial surgeon and the maxillofacial prosthodontist can utilise these classifications to guide them during the reconstruction and rehabilitation phases in addition to using them for descriptive purposes. Among these classifications are Brown (6), Aramany (7) and Cordeiro's (8) classifications. The current study relied on Brown's classification which is adopted extensively by the maxillofacial community.

Patients who undergo a maxillectomy suffer significant loss of bone as well as soft tissue (3), which makes traditional obturator dentures unstable during routine activities like mastication

(4). In such scenarios, implants and attachments have facilitated restoration (1,2). In implant-retained obturators, prior research had demonstrated that the survival rate of the implants might reach 96% or higher (2).

The attachment technique directly affects the prostheses' retention and stability (9). Attachment systems that involve two or more implants can be classified according to whether they act as splints or not (10). In splinted systems, one or more bars are used to fasten the prosthesis to the implants in a stiff manner (bar-clip system) (11). Individual non-splinted attachment systems employed over the implant can provide connection using balls, Locators, extra coronal resilient attachments, magnets, and crowns (12).

It might be challenging for dentists to choose the best attachment system since both splinted and non-splinted attachment methods have certain benefits and drawbacks and have a direct impact on clinical factors. Non-splinted systems are less sensitive to the technique used and easier to operate in terms of maintaining hygiene (12,13). Bar-based solutions, however, produce more stability and retention (14). Also, each attachment system has unique stress transmission pattern in alveolar bone surrounding implants under load of mastication and functional forces (15). Both attachment systems were rarely discussed with maxillectomy obturators in literature.

Masticatory forces result in vertical and transverse load components. These loads may induce axial stresses and bending moments leading to stress gradients in the implant & bone. The majority of implant-retained prosthetic failures are caused by excessive stress being applied to the implants and attachment devices. The systems' wear and tear might lead to bone tissue overload, implant component fractures, loss of osseointegration, instability of the prosthetic device, and loss of retention (16). An effective method for figuring out the stress distribution patterns in implants and the implant/bone contact is strain gauge analysis (17).

Consequently, the purpose of this study was to assess the stress distribution of implant-retained obturators with ball and socket (non-splinted) attachment system versus Hader bar and clip (splinted) attachment system in completely edentulous maxillectomy (Brown's class IIA) patients using strain gauge analysis.

This study's null hypothesis was that there would be no significant difference in stress distribution between ball and socket (non-splinted) attachment system and Hader bar and clip (splinted) attachment system.

MATERIALS AND METHODS

A set of maxillary and mandibular models of completely edentulous arches were used. The maxillary arch had maxillectomy class IIA according to Brown's classification (Fig. 1-A) (6). Those models were made of epoxy resin coated with a mucosa-simulating polyurethane substance of 1.5 mm thickness (Ramses medical products factory, Alexandria, Egypt). The models were duplicated into 30 stone casts for fabrication of closed hollow-bulb overdenture obturators (Fig. 1-B).

Fabrication of the overdenture obturators (18,19)

Trial obturator base and mandibular trial denture base with wax occlusion rims were constructed on one set of the duplicated stone models and mounted on mean value articulator; on which maxillary and mandibular acrylic teeth were arranged and carefully adjusted. Thirty trial obturator bases were constructed on 30 duplicated maxillary stone models. The same size maxillary acrylic teeth (Acrostone cross-linked acrylic teeth, Cairo, Egypt) were arranged on all the trial obturator bases utilizing the opposing mandibular trial denture with the same mounting to ensure standardization of all the trial obturators.

The obturator part was made following Elshimy's (18) modifications to the conventional closed hollow-bulb technique as in the following procedures:

On each cast, two layers of base plate wax were adapted to the defect walls till the margins of the palate (Fig. 1-C), then flasked and washed out to leave a space for the obturator part. The space was packed with heat polymerized acrylic resin (Acrostone heat-cure material, Cairo, Egypt) and processed following manufacturer's instructions.

After careful deflasking to keep the cast intact, lateral defect walls were sectioned to help retrieve the obturator part without damaging the cast (Fig. 1-D). The interior space of the obturator part was filled with a lump of soft plaster and was contoured to take the shape of the normal palatal contour without covering the margins of the obturator part (Fig. 1-E).

Two layers of base plate wax were then used to make a lid for the obturator part. The waxed part was flasked and washed out to leave a space for the lid part. A wet cellophane paper was adapted to the margins of the obturator part. The space was packed with heat-cured acrylic resin and processed following manufacturer's instructions.

The obturator part and the lid were then assembled together and adapted to the cast. The waxed-up obturator base was adapted to the cast after trimming the acrylic extension into the surgical defect of the trial obturator base and leaving the oral part with the waxed-up artificial teeth previously arranged.

Flasking and packing using heat polymerized acrylic resin material (Acrostone heat-cure material, Cairo, Egypt) were performed for the thirty obturator trial bases. Finishing and polishing were done for all the obturators using the conventional method.

Drilling template fabrication and implant installation (17)

A clear acrylic resin maxillary denture base was fabricated to get the drilling guide for implant position (Fig. 2-A, B). Two drilling holes were made in it to guarantee exact drilling position at the canine and second premolar regions on the intact side of the maxillary reference model.

Drilling was done in the following order: cortical drill, pilot drill, body drill (core drill), head drill, and lastly body drill again to remove debris. The parallelism of the two implants was checked by the paralleling pin during drilling the second implant (Fig. 2-C, D). Two implants (Dentium, Dentium Co. Ltd., Korea) of 10 mm length and 3.5 mm diameter each were inserted in the drilled holes using torque wrench with 35N primary stability.

Pick-up of ball attachment [group I] (20)

Two ball attachments were screwed to each implant under torque of 20 N using torque wrench, then caps were seated on the attachments. The overdenture obturator was placed over the maxillary model. The positions of the attachments were marked in order to be relieved until the obturator was fully seated. Two holes were drilled into the obturator's surface at the locations of the attachments to allow excess self-cure acrylic resin used for attachment cap pick-up to escape (Fig. 3-A).

A separating medium (Acrostone separating medium, Cairo, Egypt) was applied on the model (Fig. 3-B) and monomer was applied on the relieved area. Cold-cure polymethyl methacrylate was mixed. The mixture was applied to the obturator's fitting surface after it had reached the dough stage. To pick up the attachments' caps, the obturator was seated over the model. The caps emerged from setting placed in the obturator's fitting surface (Fig. 3-C). Finally, finishing and polishing of the acrylic resin was done. The same steps were made for fifteen obturators.

Pick-up of Hader bar and clip attachment (Group II) (21)

On the same reference model, Casted Hader bar (Rhein 83, Bologna, Italy) was screwed to the implants under torque of 20 N using torque wrench (Fig 4-A, B). The obturator was placed over the model. The position of the bar was marked in order to be relieved as spaces were created for the bar, metal housing and plastic clip until the obturator was fully seated. Holes were drilled into the obturator's surface correlating to the location of the bar to allow surplus self-cure acrylic resin used for pick-up of the metal housing and the plastic clip to escape.

A separating medium (Acrostone separating medium, Cairo, Egypt) was applied on the model and monomer was applied on the relieved area. Cold-cure polymethyl methacrylate was mixed. The mixture was applied to the obturator's fitting surface after it had reached the dough-stage. To pick-up the metal housing and the plastic clip, the obturator was positioned over the model. After setting, the plastic clip came out fixed in the fitting surface of the obturator (Fig 4-C). Finally, finishing and polishing of the acrylic resin was done. The same steps were made for fifteen obturators.

Preparation of the model and installation of strain gauges (17)

Eight self-protected linear strain gauges (KFG-1-120-C1-11L1M2R, KYOWA strain gauges, Tokyo, Japan) of a gauge factor 2.13 ± 1%, a gauge length 1 mm and a gauge resistance of 119.6 ± 0.4Ω were used in this study.

To receive the strain gauges, eight channels were constructed in the epoxy reference model (Fig. 5-A). Each implant has four channels constructed at its labial, lingual, mesial, and distal ends. There was 2 mm of epoxy resin thickness between the strain gauge and the implant, and the channels were in the crestal area and parallel to the long axis of the implant. The walls of the channels were flattened, particularly the wall that ran parallel to the implant and was used to mount the strain gauge.

To gauge the strain in the tissues surrounding the implant, strain gauges were placed on the correspondingly prepared areas in the epoxy resin model (Fig. 5-B). The strain gauges were adhered parallel to the long axis of each implant using a cyanoacrylate adhesive (CC-33A, Kyowa, Japan). To verify that the adhesive had fully cured, the strain gauges were left unattended for 24 hours.

To prevent unintended wire displacement that may impair the accuracy of the readings, the strain gauge wires were inserted in specially prepared grooves that were made in the base of the model. All of the cables had labels on them designating the measurement surface. A multichannel strain meter was attached to the wire terminals of the 8 strain gauges (Data Logger model TDS-150, Japan).

Loading application and strain measurement (22)

A universal testing machine (Mecmesin, Multi Test5-XT (5KN), USA) connected to a computer was used to apply vertical and oblique (30º, 45º) loading. The load was applied in compression mode by two metal rods with cross-head speed set at 10 mm/min (Fig. 5-C, D).

Bilateral loading was used, as metal rods were used to apply the force to the first molars' right and left central occlusal fossae, respectively. The magnitude of load was 50 N and 100 N which simulates the average amount of biting force of completely edentulous patient on an implant-assisted overdenture (15).

Prior to loading, all strain gauges were zeroed and calibrated. The strain gauge sensors were linked to a strain meter (Japan Data Logger model TDS-150) that was linked to another computer to measure the stresses caused by the applied load.

Under the same circumstances, this technique was performed for each overdenture obturator in groups I and II. There was a five-minute break interval between each loading to allow for heat to dissipate from the strain gauge sensors.

Due to the use of variable materials with different modulus of elasticity (young modulus), it was difficult to obtain an equation to convert strain to stress. Moreover, there is direct correlation between strain and stress; when strain increases, this means there is high stress (23).

Statistical analysis

The normal distribution of data was approved using the Shapiro Wilk test, box plots, and descriptives. Mean and standard deviation was used to present the strain values. Comparison between groups was done using an independent t-test. Three Way ANOVA was applied to assess the effect of attachment, inclination, and applied force on strain values. Regression Coefficient, 95% Confidence Intervals, Partial Eta Squared, and Adjusted R square were reported. The significance level was set at a p-value of 0.05. all tests were two-tailed. Data were analyzed using IBM SPSS Statistics for Macintosh, Version 28.0. Armonk, NY: IBM Corp (24).

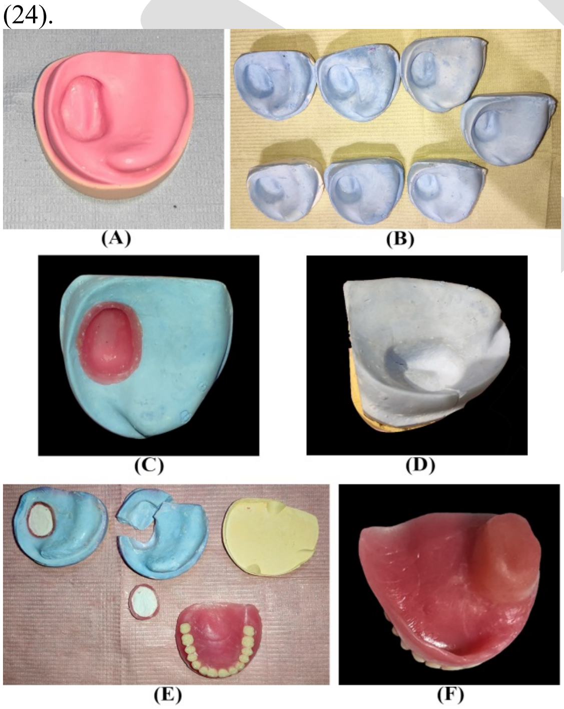

Figure (1): A. Maxillary epoxy model with maxillectomy class IIA. **B.** duplicated stone casts. **C.** Two layers of base plate wax were adapted to the defect part.
D. Lateral defect walls were sectioned. **E.** The interior part of the obturator was filled with soft plaster. **F.** Fitting surface of the obturator.

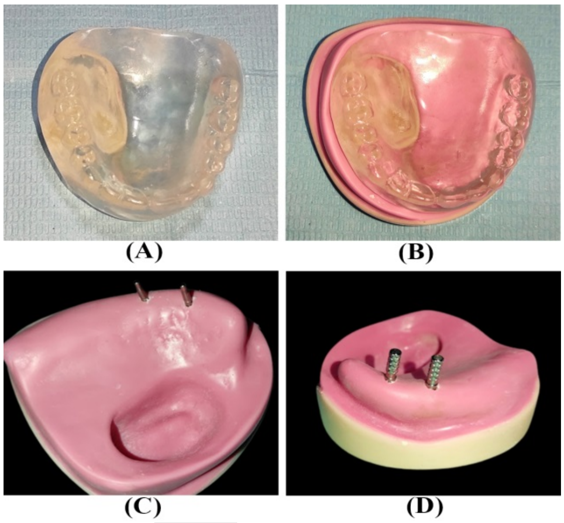

Figure (2): A,B. Clear acrylic resin maxillary denture base. **C, D.** The parallelism of the two implants was checked by the paralleling pin.

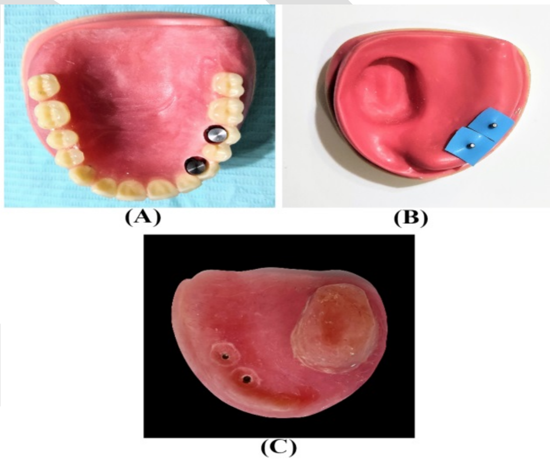

Figure (3): A. Two holes were made corresponding to ball attachments. **B.** Separating medium was applied on the model. **C.** Fitting surface of the obturator with ball attachment.

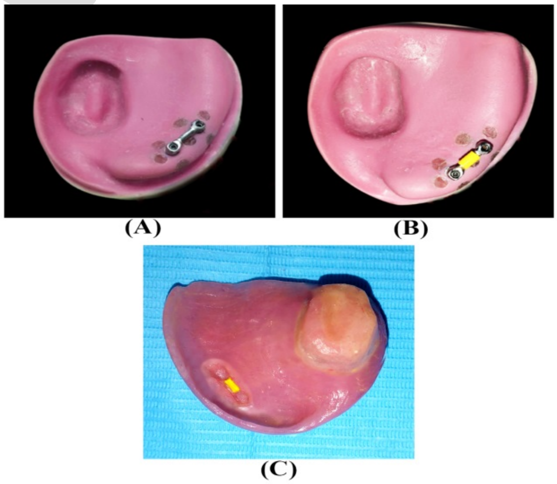

Figure (4): A. Casted Hader Bar. **B.** Casted Hader bar with retentive clip. **C.** Fitting surface of the obturator with bar attachment.

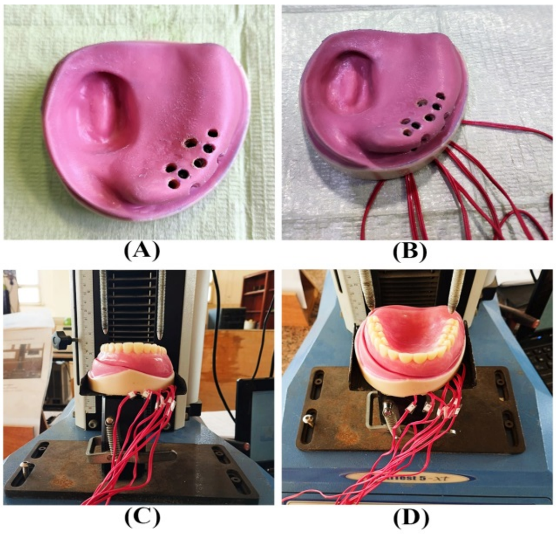

Figure (5): A. Eight channels were made in the epoxy model. **B.** Strain gauges were installed on their corresponding prepared sites. **C,D.** Applying load with universal testing machine.

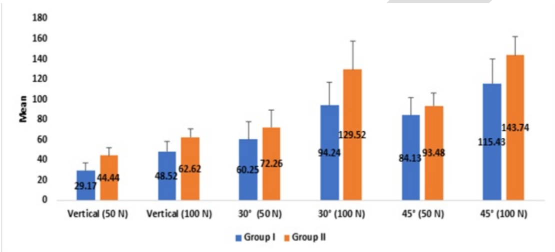

Figure (6): Mean of strain values for the study groups.

RESULTS

Sample size was estimated based on assuming 95% confidence level and 90% study power. Based on Goiato et.al (3), the mean ± SD strain of obturators attachment system was 23.04 ± 10.57 microstrains for Bar type whereas for Ball type, it was 33.7 ± 9.49 microstrains. The minimal sample size was calculated to be 14 obturators. This will be increased to 15 to make up for laboratory processing errors per group, with total sample of 30 obturators. Software Sample size was based on Rosner's method (25) calculated by Brant's sample size calculator at the University of British Columbia (26).

A power analysis was done as shown in table 1, and it shows that the study had enough power to find statistical effect on outcomes as reported in the results.

Stress analysis at peri-implant tissues of implant-retained obturator by measuring the strain distribution using strain gauges was compared between the two studied groups as shown in table 2 and graph 1.

The values of strains developed after load application in the labial, lingual, mesial and distal aspects of the implants were summed and compared between the two studied groups. There was statistically significant difference in the value of the sum of strains between group I (ball) and group II (bar-clip) after application of vertical loading 50 N and 100 N, as group I showed lower strain value with mean = 29.17 and 48.52 respectively as compared to group II whose mean = 44.44 and 62.62 respectively with p value < 0.0001.

Also, there was statistically significant difference in the value of the sum of strains between group I (ball) and group II (bar-clip) respectively after application of 30° oblique loading 100 N, 45° oblique loading 100 N, as group I showed lower strain value with mean = 94.24 and 115.23 respectively as compared to group II whose mean = 129.52 and 143.74 respectively with p value < 0.001.

However, there was no statistically significant difference in the value of the sum of strains developed at peri-implant tissues in the implant-assisted obturator between group I (ball) and group II (bar-clip) after application of 30^0 oblique loading 50 N and 45^0 oblique loading 50 N with p = 0.066 and p = 0.105 respectively.

Table (1): Power analysis for each variable assessed in the study

	Group I (n=15)	**Group II (n=15)**	**Power**
	Mean (SD)		
Vertical loading (50 N)	29.17 (7.72)	44.44 (7.74)	0.991
Vertical loading (100 N)	48.52 (9.97)	62.62 (8.02)	0.971
30° loading (50 N)	60.25 (17.55)	72.26 (16.87)	0.761
30° loading (100 N)	94.24 (23.02)	129.52 (28.08)	0.951
45° loading (50 N)	84.13 (17.33)	93.48 (12.89)	0.721
45° loading (100 N)	115.43 (24.65)	143.74 (18.32)	0.941

n: Number of implant-retained obturators
SD: Standard deviation

Table (2): Comparison of strain values between the study groups

	Group I (n=15)	**Group II (n=15)**	**Test (P value)**
	Mean (SD)		
Vertical loading (50 N)	29.17 (7.72)	44.44 (7.74)	**5.410 (<0.0001*)**
Vertical loading (100 N)	48.52 (9.97)	62.62 (8.02)	**4.267 (<0.0001*)**
30° loading (50 N)	60.25 (17.55)	72.26 (16.87)	1.910 (0.066)
30° loading (100 N)	94.24 (23.02)	129.52 (28.08)	**3.763 (0.001*)**
45° loading (50 N)	84.13 (17.33)	93.48 (12.89)	1.677 (0.105)
45° loading (100 N)	115.43 (24.65)	143.74 (18.32)	**3.570 (0.001*)**

n: Number of implant-retained obturators
SD: Standard deviation
*Statistically significant difference at p value<0.05

DISCUSSION

This study was carried out in vitro to overcome the constraints of stress analysis studies undertaken clinically owing to accuracy in the evaluation of stress distribution and due to difficulties in standardization and reproducibility of the acquired values for strain measurement in-vivo (27).

A set of maxillary and mandibular models of completely edentulous arches were used. The maxillary arch chosen had maxillectomy class IIA according to Brown's classification (6) as previous studies showed that class II is the most common maxillectomy defect (28). These models were created using epoxy resin, which has a suitable elastic property for a bone replica material (about 20 GPa) (29).

Only two implants were chosen to be placed in the canine and premolar regions in the intact side as was reported in the literature with high success rate and satisfactory results (30). However, using three implants also was reported (1).

Each implant was 10 mm length and 3.5 mm diameter. The 10 mm length was chosen as it is considered as an adequate length to obtain optimum stress distribution around the implants. According to Georgiopoulos et al (31), implant length greater than 10 mm resulted in strain reduction on bone tissue during immediate and delayed implant loading. Moreover, the 3.5 mm diameter was used as it was reported that there should be at least 1 mm of bone along the buccal and lingual borders of the proposed implant location to provide enough bone thickness and blood supply surrounding the implant for a predicted survival rate (32).

Strain gauges were installed in epoxy resin on flat surfaces that had been prepared, perpendicular to the crest of the ridge and parallel to the implant's long axis. To reduce the risk of acquiring incremental apparent strain as a result of fixing the strain gauge on curved surface, it is preferable to install the strain gauge on a perfectly flat surface (33,34).

Moreover, Strain gauges were attached to the crest of the ridge surrounding the implants since peri-implant stresses and bone loss frequently begin at the alveolar crest around the implant's neck and compression of cortical bone at the alveolar crest may result in stress overloading (35).

It was observed that, the average biting force of completely edentulous patients wearing implant-retained overdentures was in range of 50-100N (15,36). Thus, it was selected as the magnitude of load directed to the overdentures.

In this study, because the first molar frequently experiences the greatest occlusal stresses and the strongest activation of the elevator muscles, it was chosen for loading (37). Additionally, first molars' central fossae were subjected to bilaterally applied vertical and oblique static stresses. This is in line with the findings of Tokuhisa et al. (15), who noted that the occlusal force was frequently centred in the area around the molars, where the obturator moved most pronouncedly. Bilaterally applying the load simulated central occlusion in vivo.

Furthermore, loading was applied vertically parallel to the long axis of the implants and oblique (30º and 45º). This oblique loading application was done in accordance to Lin et al (38) who reported that forces of mastication are more oblique due to inclination of artificial tooth cusps and strains from oblique forces are more important to be recorded since they are more detrimental than vertical forces.

In the present study, when compared to the bar-clip (splinted) attachment method for implant-retained obturator prosthesis, the ball (non-splinted) attachment system displayed lower stress values as there was statistically significant difference in stress values upon application of vertical loading 50 N and 100 N, 30º oblique loading 100 N and 45º oblique loading 100N (Table 2). According to the authors' theory, the ball system's socket typically has a rubber ring inside of a metallic capsule, which may absorb or evenly distribute the stress they are subjected to.

These results agree with most previous studies such as Pesqueira et al (1) who used the photoelastic method and documented the best results with ball attachment system during compressive occlusal stresses applied to implant-retained obturators. Chun et al. (39) used finite element analysis to confirm these findings and discovered that ball systems experience less stress than bar-clip systems.

However, other investigations indicated that bar-clip subjected to compressive occlusal stresses had lower strain values than ball. According to Vafaei et al. (40), bar-clip has a better design for distributing loads than ball especially when force is applied unilaterally as the bar distribute stresses to the non-working side. According to the authors, as the implant-retained obturator uses only implants close to each other on one side (the intact side) so the obturator prosthesis cannot benefit from this bar advantage of distributing stresses.

Both the ball and bar attachment systems have advantages and disadvantages that directly affect clinical outcomes. When it comes to maintaining hygiene, the ball attachment method is less sensitive to the technique used and simpler to apply (12,13). Nevertheless, bar-based methods result in greater stability and retention (14).

This study results showed that ball and socket (non-splinted) attachment system had lesser stresses generated at peri-implant level than the bar (splinted) attachment system when applying forces imitating masticatory forces. This is a crucial factor to consider when choosing the convenient attachment system as most implant-retained prosthetic failures including implant component fractures, loss of osseointegration, instability of the prosthetic device, and loss of retention are caused by excessive stress being applied to the implants and attachment devices (16). This finding suggests using ball and socket (non-splinted) attachment system for achieving favorable stress distribution.

However, amongst limitations of this study is that it might not be applicable to generalize the results on all maxillectomy classes as there is a great variety in the extent and severity of bone and soft tissue loss between different classes (6); Therefore, the results might only be applicable for maxillectomy class II. Also, this study only measured strains while applying forces that simulate mastication and chewing functions, but not while dislodging the obturator which might have other patterns of strain distribution that might affect the longevity of the obturator and the attachments used (3). Another limitation is that strain gauge only registers stresses at the exact spot it is placed on, which means it might not be possible to observe the stress patterns in the whole model as it would be observable when using photoelasticity analysis (3). This in vitro study also did not completely replicate the oral cavity and clinical evaluations are necessary.

CONCLUSION

Based on the findings and taking into account the constraints of the study, it was determined that the ball and socket (non-splinted) attachment method had superior biomechanical performance with the lowest strain values surrounding the dental implants when exposed to forces imitating mastication and functional forces.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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