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Clinical Study of the effect of two different types of attachments of implant supported obturators – Pilot Study

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Abstract:
The surgical removal of head and neck tumors frequently results in significant abnormalities, functional impairment, and deformity. The provision of a prosthesis is a crucial strategy for regaining physical and mental function. For patients with missing teeth, it has been claimed that the use of Osseo-integrated implants will increase retention and stability in the traditional obturator prosthesis. At the end of the follow-up periods, the clinical observations showed that inflammation had increased around implants with magnet attachments more than it had around implants with ball and socket attachments.
Key words: *Acquired maxillary defects, obturator, implant, attachments*

A subspecialty of prosthetic dentistry called maxillofacial prosthetics uses artificial substitutes to restore facial anatomy that has been destroyed or impaired due to trauma, pathological disorders, malignancies, or birth abnormalities [(1).] Patients with head and neck cancer may be arbitrarily divided into intra-oral acquired maxillary and mandibular defects and extra-oral face defects based on their post-treatment surgical defects and morbidities. Surgery to remove head and neck tumors frequently leaves behind sizable deformities, along with dysfunction and deformity [(2).] The provision of a prosthesis is a crucial strategy for regaining physical and mental function (3). With edentulous patients, retention and stability of the obturator prosthesis are significant issues that depend on the accurate fabrication of the prosthesis and the satisfactory resolution of the presented condition (4). Following partial or complete maxillectomy, the retention of the prosthesis has been described using Osseo-integrated implants placed in the remaining maxillary alveolar ridge (5). For patients who are edentulous, the use of Osseo-integrated implants has been recommended to increase retention and stability in the traditional obturator prosthesis (6,7).

Aim of the study:
The purpose of this study is to assess the clinical performance of maxillary obturators supported by Osseo-integrated implants and held in place by either magnetic or ball-and-socket attachments. The goal of this study is to evaluate the clinical performance of maxillary obturators that are fixed in place using either magnetic attachments or ball-and-socket devices and supported by Osseo-integrated implants.

Material and methods:
The intraoral soft and hard tissues examination was done both digitally and visually to detect any inflammatory reactions, stomatitis or ulcers of the lips, remaining part of the palate, alveolar ridge, cheeks or tongue. Also, presence of any attached mucosa at the prospective implant site. Only class I maxillary mandibular relationship were considered. Bone density of the intact part of the premaxilla was division (D3) and the available bone height and width was division (A) for all selected cases.

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The selected cases' defect side met the following requirements:
A. Split thickness skin graft was used to line the reflected check flap.
B. Nasal mucosa on the sinus side of the orbit's floor was removed before a skin graft was applied.
C. The soft palate's remaining location allowed it to influence velopharyngeal closure and did not obstruct access to the correct level of the closure.
D. During surgery, tissues like the turbinate and bands of oral mucosa were removed.
Sincerity of the patient: The patients and the rehabilitation strategy were addressed. Patients received a thorough explanation of implant treatment that covered the procedure's dangers, advantages, aftercare requirements, and follow-up instructions.
All of the chosen patients showed evidence of being driven to seek therapy and of being willing to follow the clinician's advice. Prior to the experiment, the human subjects participating were fully informed of the procedures, any potential discomforts or hazards, as well as any potential advantages.

Implant choice: Titanium root form Advent implant system with implant extender that can be used to keep tissue opening even when top of implant is positioned below the soft tissue, measuring 10 mm in length and 3.7 mm in diameter. *The implants have an apical vent and are SMB-blasted screen-shaped.
When the surgical stent was created, palatal support was included for when the patient's mouth received the stent. The lateral surface of the palate's defect-side provided additional support. To make it simple to transfer the implants to the bony ridge after surgery, the implant positions were noted on the template.
Patient grouping: Five patients from each of two equal groups were randomly selected from the patient population.
I Group:
*The AVBA2 ball and socket attachment which was created for the long advent implant, will be used to attach the five patients' removable maxillary obturator prostheses to the implants. The female part of the metal housing with a rubber nylon lining is joined to the obturator base, and the male ball is fastened to the implant. The AVBA2 ball attachment's reduced vertical height is due to the absence of a straight insert.
*Paragon implant company USA 1158211/ENTTURA Boulevard-RO, SUITE 420, ENCINO.
AVBA2, ball attachment for advent division- venture Boulevard,

Group II: The five patients will have a removable axillary obturator prosthesis attached to the implant using *the Dyna magnet system.
The magnet system, which consists of a keeper attached to the implant and magnet (60% palladium, 2% platinum, and 38% cobalt), was processed into the obturator fitting surface.
Pick-up technique for the attachments: After relining, the obturators' fitting surface exhibited voids against the abutment. The depth and width of these voids were altered. Auto polymerizing acrylic resin was applied to the dry stainless-steel housing and the voids of the fitting surface of the obturator for the ball and socket retained obturators group. The patient's mouth was introduced with the obturator, and they were told to close for 20 minutes into centric occlusion. The maxillary obturator was removed perpendicular to the implant and attachment once the acrylic had dried. The obturator's fitting surface took up the metal housing with rubber ring lining. A smooth surface was achieved by removing the extra acrylic and polishing its surface. The obturator was examined for retention in the patient's mouth.
In relation to the magnets retained group, each implant's keeper received a magnet by attraction. Each implant had its keeper and magnet attracted to it, then auto polymerizing acrylic resin was put to the base of the magnet and to the opposing voids for each implant. The patient was told to close in centric and remain that way for 20 minutes. The maxillary obturator was removed and polished to a flat surface once the acrylic had had time to set.
Patients were taught how to insert and remove the maxillary obturator for both groups of attachments, and they were advised never to use metal objects to clean the abutments.
After every meal and before bedtime each night, brush the implants using a soft nylon brush with a tufted end. cleaning the defect with a plastic syringe and a solution of saline, hydrogen peroxide, and chlorohexidine mouth washes. After every meal, gently brush the obturator's polished and fitted surface. removing the obturator before going to bed and keeping it submerged in water while not in use. For the immersion of the prosthesis, use a 4% chlorhexidine gluconate, 1% sodium hypochlorite, and saline solution.
Following final adjustments, the following follow-up records were created:
a. One week (starting point)
b. three months.
c. Six months
d. Nine months
e. Twelve months (follow-up period's end)
For at least 30 minutes before to the evaluation, patients were requested to abstain from eating, drinking, brushing their abutments, and cleaning their obturators.

*Dyna, Prostbus 70, 4600 AB Bergen OP Zoom, the Netherlands.
The following parameters were recorded at each follow-up visit one week after loading (baseline), and then every three months until the end of the study period after a year:
Test of mobility
A. Gingival index
B. Plaque index
C. Crevicular fluid
D. Deep pocket
A) Gingival bleeding index: Using the Loe and Silness gingival index [(8).] the status of the gingiva was evaluated. Four gingival scoring Units, including the distofacial papilla, the facial margin, the mesiofacial papilla, and the complete palatal margin, were created from the tissues surrounding each implant.
0: Adequate gingiva
1: minimal bleeding on probing, minimal color change, minimal oedema, and minimal inflammation.

2: mild swelling, erythema, edema, glazing, and bleeding with probing
3. severe inflammation, noticeable redness, oedema, ulceration, and a propensity for spontaneous bleeding.
By inserting a periodontal probe parallel to the edge of the soft tissue surrounding the gums and along the perimeter of the implant at four-line angles,
the bleeding propensity of the gingiva or alveolar mucosa surrounding the titanium implants was evaluated.
Units were the entire palatal margin, the distofacial papilla, the facial margin, the mesiofacial papilla, and the location
By advancing a periodontal probe parallel to the edge of the soft tissues and along the perimeter of the implant, into the gingival pocket, and into the alveolar mucosa surrounding the titanium implants, the bleeding tendency of the gingiva or alveolar mucosa was evaluated at four-line and noticed bleeding within 20 seconds. The relevant location received a positive score.
B) Pocket depth: At the mid-buccal, mid-palatal, mid-mesial, and mid-distal, the loss of attachment around the abutments was measured.
Using a standardized periodontal probe with a 0.7 mm thickness*(Sensor probe) the distance between the base of the gingival sulcus and the gingival edge was measured.
*Vivacare, Vivadent, Schann/leichtent ein. Switzerland
c) Mobility: The implant's mobility was evaluated by pressing a blunt wooden dowel against it while applying buccolingual and mesiodistal stresses. When rotating or depressing implants were checked, the failed implants displayed movement and produced a dull sound when percussion was applied.
D) Plaque index: This was calculated by evaluating how much of the implants were coated by plaque after dyeing the obturator implants with 5% erythrosine disclosing
E) Crevicular fluid: on strips of filter paper, crevicular fluid was collected from the buccal, palatal, and mesial surfaces of the three abutments. The *filter sheets were gently inserted into gingival fissure after the implant's abutments were isolated and dried.
After three minutes, the filter sheets were removed, immediately submerged in 2% ninehydrine solution for one minute, and then left to dry. On transparent square millimeter graduated paper, a dark purple stain caused by the collected gingival fluid was used to trace the wet area. A rough estimate of the number of squares to the nearest half square millimeter was made.
Analyses of descriptive statistics and data management. [9] To be tabulate and graphically display the results, an Excel computer program was employed.
Mesial and distal mean values were calculated.
A statistical analysis was subsequently performed on the difference between the baseline (one week after insertion) and each of the follow-up periods (3 months, 6 months, 9 months, and 12 months). natively distributed quantitative variables were expressed as mean S.D.
Results:
Implant supported maxillary obturators were used in ten patients' class I hemi maxillectomy. *Three lengthy advent implants were given to each patient almost the edentulous intact premaxilla's central, canine and second premolar Lower full dentures were the opposition for the maxillary obturators in all cases. The opposing for the maxillary obturators were lower complete dentures for all patients
The follow-up intervals were one week following loading (baseline), three, six, nine, and twelve months after the study's completion.
Two groups of patients were formed; group I had five patients who received a maxillary obturator attached to three implants using three ball and socket attachments.
The maxillary obturator was placed in five patients in Group I, and it was secured to the three implants with three ball and socket attachments.
Three magnet and keeper attachments held five members of Group II, who were getting maxillary obturators, in place.
*1.5 X 10 mm from Whatman No. 1
*Vivacare, Vivadent, Ets. Schann/leichtent ein. Switzerland- with plastic blade
Clinical Analysis:
A) Prosthetic evaluation:
Throughout the study period, a number of prosthetic or technical issues, as well as upkeep requirements, were noticed. One patient from each group reported that the opposing lower denture had issues with retention and stability.
Additionally, complaints of poor fit, poor retention, and obturator cracking were made in one case of the ball and socket group, and two cases of the magnet and keeper group. Table 1 and Graph
One instance had two of the three implants fail prematurely, and the case was removed from the research.
Two instances of the magnet and keeper group saw screw decreasing. Table 2 and Figure 2
During the follow up periods, all patients of group I and group II
Were satisfied with their prosthesis.

The peri-implant soft tissue reactions after loading through the 12 months study period were illustrated. All parameters were examined for descriptive analysis.

B) Plaque index:

Buccal, palatal, mesial, and distal sites are included. Superstructures and abutments for (group I) were clinically examined, and it was determined that they were mainly free of any calculus or plaque deposits.

93.3%, 86.7%, 86.1%, and 86.3% of the four locations displayed a plaque index of (0) after one week of loading. Nearly no change after three months of loading. 86.7%, 83.0%, 82.8%, and 81.9% of the sites displayed a plaque index of (0) after six months of loading. 80%, 80.1%, 81.0%, and 80.9% of the sites displayed a plaque index of (0) after nine months of loading.

At the end of the follow-up period after a year, 73.3%, 74.8%, 71.9%, and 72.0% of the locations displayed a plaque index of (0).

Within group II,

A week after loading (baseline), they were generally free of any calculus or plaque deposits. A plaque index of (0) was present at 93.3%, 93%, 89.8%, and 88.9% of the locations, respectively. 80%, 73.3%, 74.1%, and 73.8% of the locations revealed a plaque index of (0) after three months of loading. 66.7%, 62.9%, 65.1%, and 67.3% of the locations displayed a plaque index of (0) after six months of loading. 60%, 61.2%, 60%, 60%, and 60.1% of the sites displayed a plaque index of (0) after nine months of loading. A plaque index of (0) was present at 58.2%, 53.1%, 50.1%, and 51.3% of the locations at the conclusion of the follow-up period of twelve months.

By comparing the variation in the number of surfaces that display the plaque index of One week after of (0) in the ball and socket and magnet groups from the beginning of the follow-up period showed that the number of surfaces showing plaque index of (0) were significantly reduced in the second group, they were generally free of any calculus or plaque deposits. Table 3 and graph 3

C) Mobility:

During the follow-up intervals, the implants in both groups did not exhibit any mobility.

D) Gingival index:

Each group of three implants' three surfaces' gingival index scores were compiled. As a result, 60 surfaces in each group (15 implants x 4 surfaces) were assessed during all follow-up periods, with scores ranging from 0 to 1.

Group I: A week after the obturator was delivered, 55 out of 60 surfaces had G.I + 0 (91.7%), while 5 surfaces had G.I = 1 (8.33%). At the three-month checkpoint, 7 surfaces had G.I = 1 (11.7%), while 53 out of 60 surfaces had G.I = 0 (88.3%).

52 surfaces had G.I = 0 (86.7%) after the six-month follow-up period, while 8 surfaces had G.I = 1 (13.3%). 50 surfaces had G.I = 0 (83.3%) at the end of the nine-month follow-up period, while ten surfaces had G.I = 1 (16.3%). It was the same as the nine-month follow-up period at the conclusion of the twelve-month follow-up period.

Group II: Three surfaces had G.I =1 (5%), and 57 out of 60 surfaces had G.I =0 (95%) in the first week following the delivery of the obturator. Eight surfaces had G.I = 1 (13.3%) and eight surfaces had G.I = 0 (86.7%) during a three-month follow-up period. After a six-month follow-up period, 14 surfaces had a G. I=1 (23.3%) and 46 surfaces out of 60 had a G.I=0 (76.7%). Twenty surfaces had G. I=1 (33.3%) and 40 surfaces had G.I=0 (66.7%) during a nine-month follow-up period. 18 surfaces had G. I=0 (63.3%) and 22 surfaces had G.I=1 (36.7%) at the end of the follow-up period after a year.

The average number of implant surfaces with GI = 0 was calculated using the mean and standard deviations for both groups at the various follow-up times were displayed.

Table (4) compares the variation in the proportion of implant surfaces in the ball and socket and magnet groups that display gingival index = 0. In the magnet group, there was a decrease in the proportion of surfaces with a gingival index of 0 (Graph 4).

D) The volume of the crevicular fluid:

For group I (the ball and socket):

At the end of the year, the mean would have varied from 1.6 mm to 2.4 mm, with a constant rate of change of 0.066/month.

At the end of the year, group II (Magnet) showed a consistent rate of change of 0.092mm/month for a mean ranging from 1.7 to 2.8mm.

The change in crevicular fluid between the baseline and the end of the follow-up period for the ball and socket and magnet groups is compared in Table (5) (Graph 5).

G). Sulcular depth:

The values of the crevicular depth at each group's four implant surfaces were measured. For each patient in both groups during the follow-up intervals, the mean values and standard deviation of the four surfaces of the three implants are tabulated.

The mean values of the crevicular depth around the implants in Group I (Ball and Socket) were 2.1mm at the baseline (one week after loading), 2.33mm at the three-month follow-up period, an increase of 0.23mm.

The mean sulcular depth at six months after the follow-up period was 2.29mm, which was 0.04mm less than the value at three months.

At nine months after the follow-up period, the mean sulcular depth increased by 0.21mm to 2.5mm.
The mean sulcular depth was 2.73mm at the end of the follow-up period after a year, a rise of 0.23mm.
From the start of the study period to the end after twelve months, the total crevicular depth change increased by 0.62mm.
The mean values of the crevicular depth around the implants in Group II (Magnet) were 2.2mm at baseline after one week of loading.
The mean sulcular depth at three months after the follow-up period was 2.4mm. It revealed an increase in sulcular depth of 0.2mm.
The average sulcular depth at the end of the six-month follow-up period was 2.7mm, with a 0.3mm rise.
The mean sulcular depth at nine months after the event was 2.78mm, a little increase of 0.08mm over the sulcular depth at six months after the event.
The mean sulcular depth at the conclusion of the follow-up period after a year increased by 0.32mm to 3.1mm.
The overall crevicular depth variation from baseline (after one week of loading) The loading (base line) was raised by 0.9mm till the end of the follow-up after a year. Table (6) and Graph 6 compare the change in sulcular depth of the ball and socket and magnet groups and demonstrate that the magnet group saw a greater rise in sulcular depth surrounding the implants than did the ball and socket group.

Discussion:

The obturators were well received by all patients who were chosen. Some of the elements that contribute to the success of implants in this study are careful planning of the course of therapy, aseptic delicate surgical procedures, and postoperative care [3,10].
Increases in biological parameters as the gingival index, crevicular fluid, plaque index, and sulcular depth are all indicators of inflammation [11].
From the baseline to the various follow-up intervals and the study's conclusion, all these periodontal markers increased higher surrounding implants in the magnet group than in the ball and socket group.
The ball and socket attachment retained more plaque than the magnetic attachments, which decreased comfort and chewing effectiveness [12, 13].
Despite non-corroding coatings and seals, the corrosion issues that were initially connected to magnetic retainers still exist in many overdentures that have magnetic attachments [14].
The ball and socket attachment, on the other hand, are more hygienic, harbor less plaque, and are easier for patients to clean. When implants are placed very far away, it is a sign [15].
The system of ball attachment the ball attachment approach is ideally suited to the treatment's overarching goals of simplification and minimal complications for increased implant retained overdenture use [12, 16].

Conclusion:

All of the chosen patients were happy with their obturators, in sum. Comparing the clinical evaluation of groups, I with ball and socket attachments and groups II with magnet attachments revealed that group II had a lower gingival index of zero and a higher gingival index of one than group I at the conclusion of the follow-up periods. Additionally, the sulcular depth, plaque index, and crevicular fluid were all increased in group II. These clinical observations showed that, at the conclusion of the follow-up periods, inflammation had risen around implants of group II with magnet attachments compared to implants of group I with ball and socket attachments.

Table (1) the assessment of the prosthetical quality by a grade scale expressed by the number of patients of group 1 (Graph1)

Quality Control	Score (1) perfect	Score (2) acceptable	Score (3) to be acceptable	Score (4) unacceptable
Design	0 (0 %)	4 (80%)	1(20%)	0 (0 %)
Fit	0 (0 %)	4 (80%)	1(20%)	0 (0 %)
Esthetics	0 (0 %)	3 (60%)	2 (40%)	0 (0 %)
Occlusion	0 (0 %)	3 (60%)	2 (40%)	0 (0 %)

Graph 1,

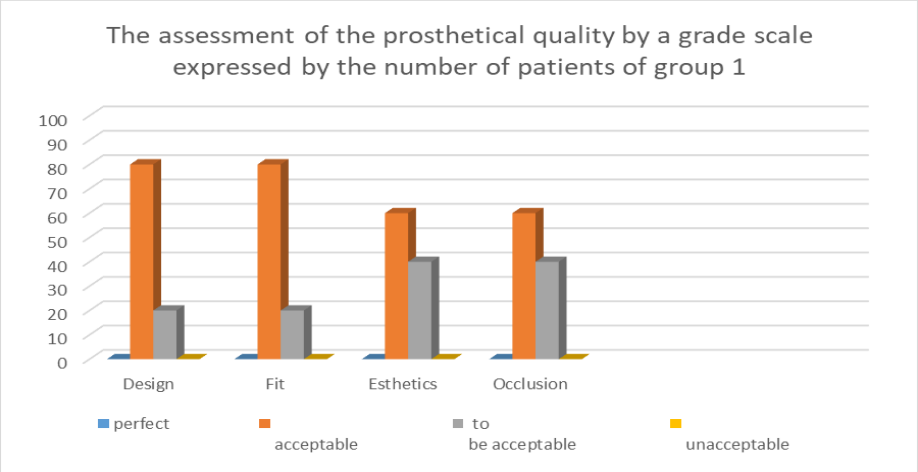


Table (2) the assessment of the prosthetical quality by a grade scale expressed by the number of patients of group 2 (Graph 2)

Quality Control	Score (1) perfect	Score (2) acceptable	Score (3) to be acceptable	Score (4) unacceptable
Design	0 (0 %)	3 (60%)	2(40%)	0 (0 %)
Fit	0 (0 %)	4 (80%)	1(20%)	0 (0 %)
Esthetics	0 (0 %)	3 (60%)	2 (40%)	0 (0 %)
Occlusion	0 (0 %)	3 (60%)	2 (40%)	0 (0 %)

Graph 2,

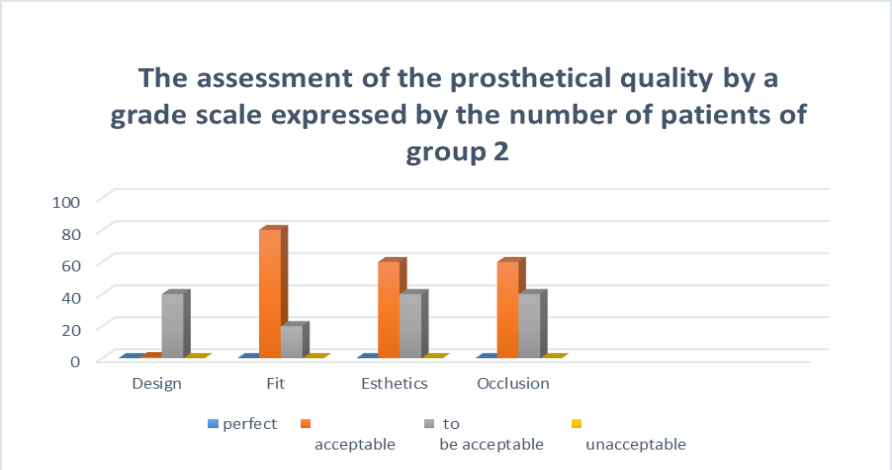


Table (3): Comparison of the change of plaque index between the base line and end of the follow up period between the two groups.

Surface	Ball and socket	Magnet	t-value
Mesial	-8.93±1.87	-24.13±2.39	19.42
Distal	-9.00±1.85	-22.00±1.81	19.43
Buccal	-10.00±2.73	-21.13±1.81	13.19
Palatal	-6.93±2.54	-24.00±2.85	17.28

Graph 3,

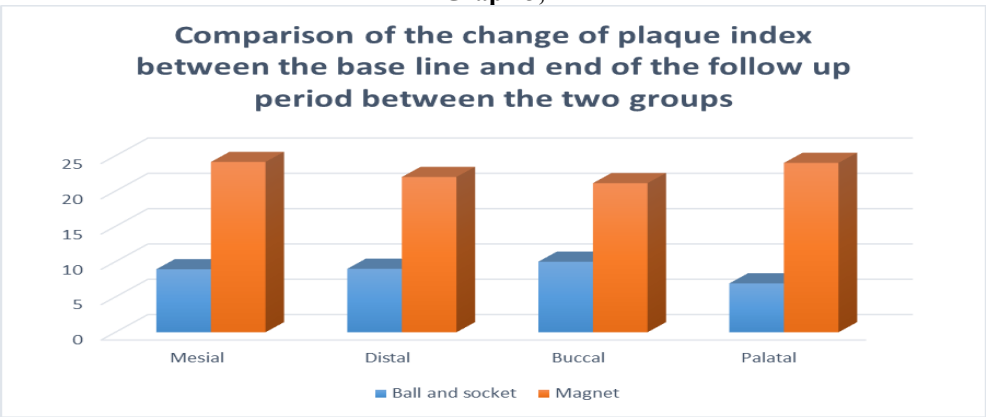


Table (4) Comparison of the gingival index between the base line and end of follow-up period between the two groups

Surfaces	Ball and Socket	Magnet	t-value
Mesial	-5.93±1.79	-19.00±3.07	14.24
Distal	-6.00±3.09	-18.87±2.92	11.71
Buccal	-7.07±2.74	-18.87±3.09	11.07
Palatal	-7.07±2.22	-19.00±2.33	14.36

Graph 4,

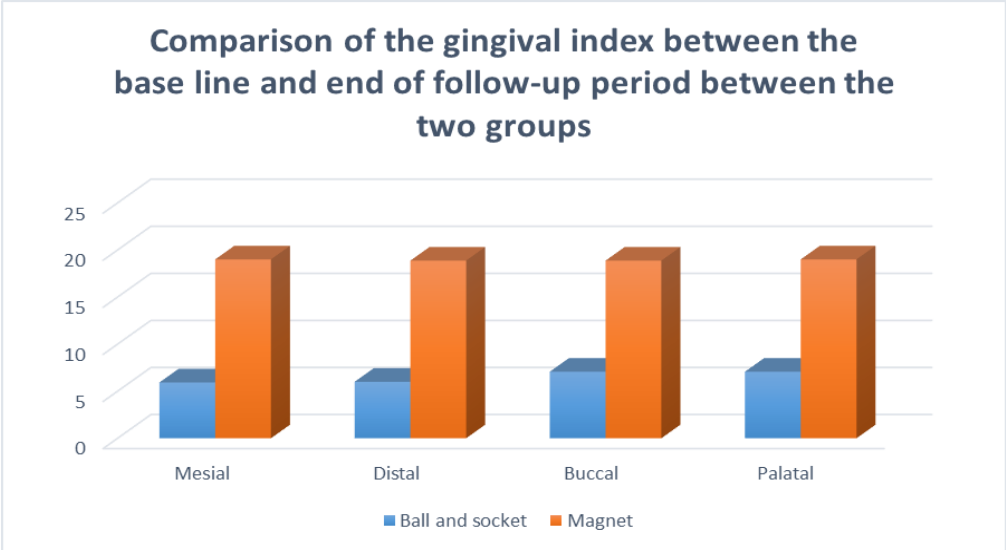


Table (5) Comparison of the change of crevicular fluid between the base line and end of follow up between the two groups.

Surface	Ball and Socket	Magnet	t-value
Mesial	0.80±o.28	1.30±0.19	5.59
Buccal	0.65±0.21	1.33±0.04	11.76
Palatal	0.86±0.28	1.52±0.15	8.07

Graph 5,

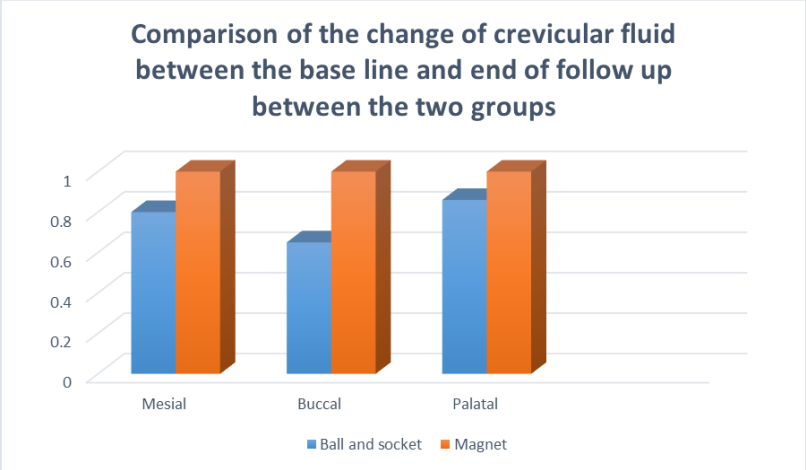
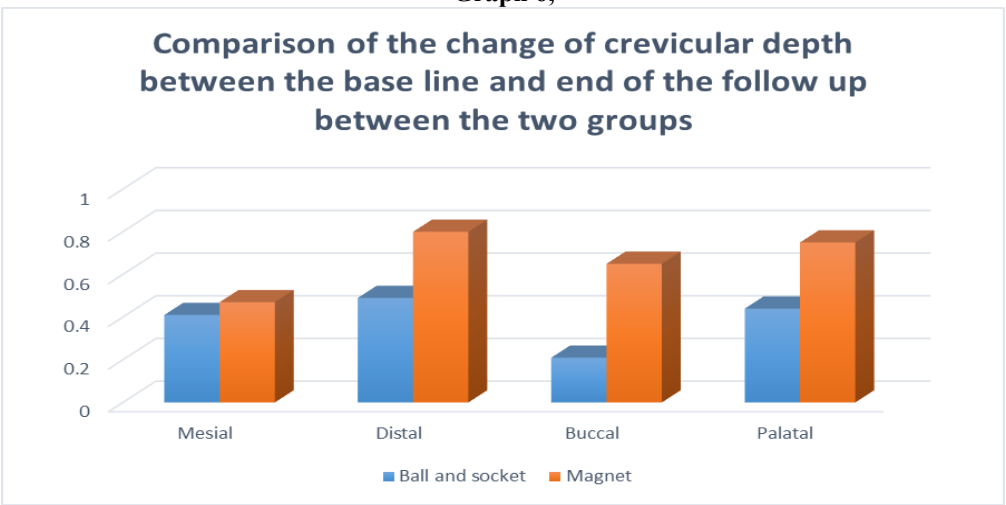


Table (6) Comparison of the change of crevicular depth between the base line and end of the follow up between the two groups.

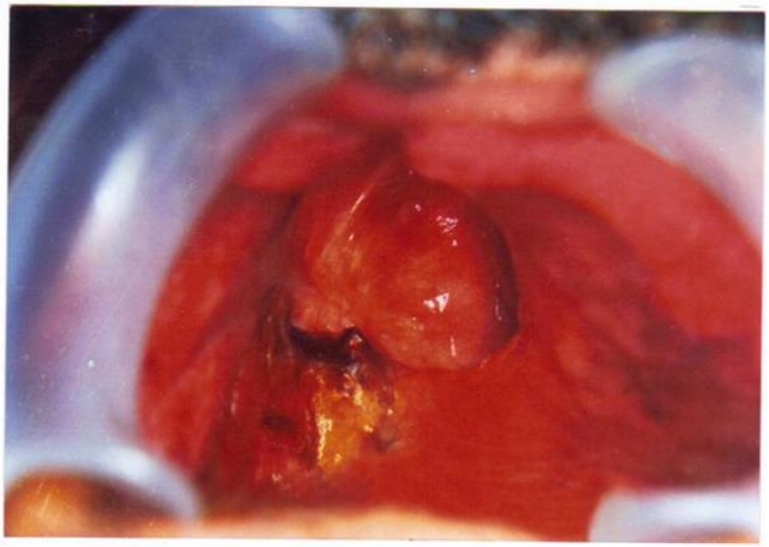
Surface	Ball and socket	Magnet	t-value
Mesial	0.41±0.013	0.47±0.19	2.55
Distal	0.49±0.19	0.80±0.11	5.46
Buccal	0.21±0.07	0.65±0.07	8.85
Palatal	0.44±0.14	0.75±0.08	7.12

Graph 6,

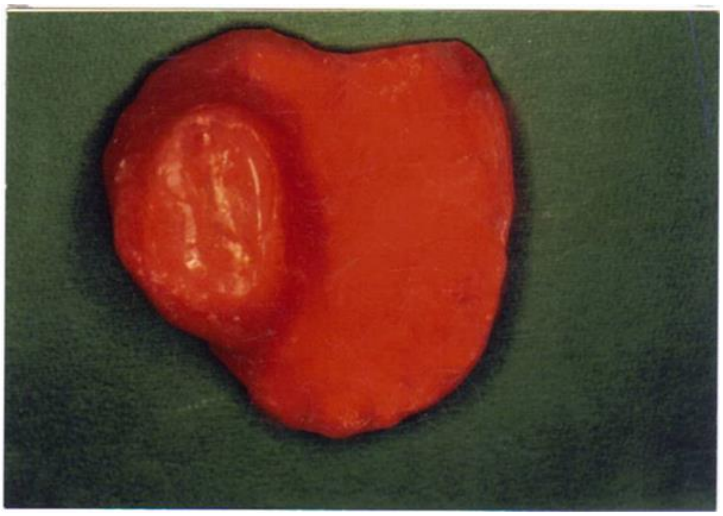


All values represented as Mean ± Standard deviation

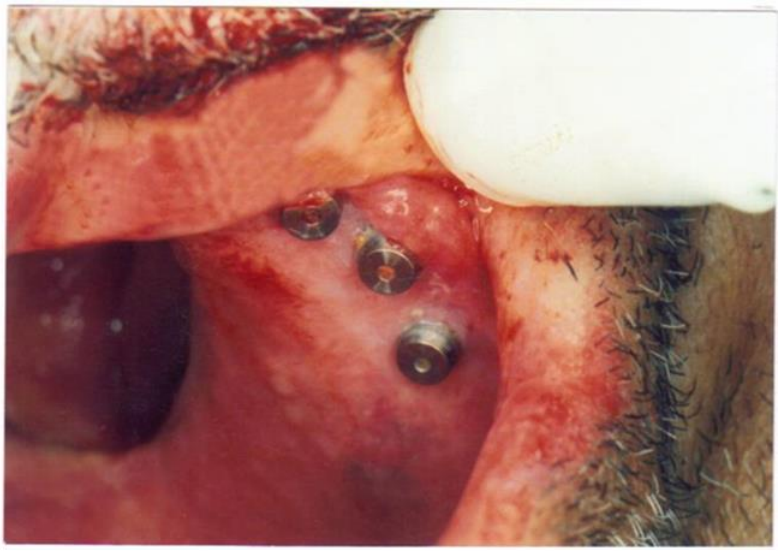
FIGURES:



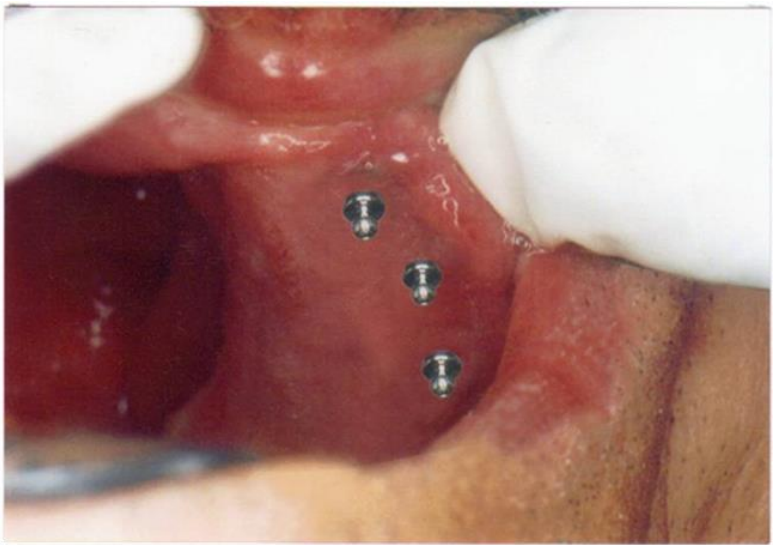
(Fig. 1) The site of surgery was healed completely



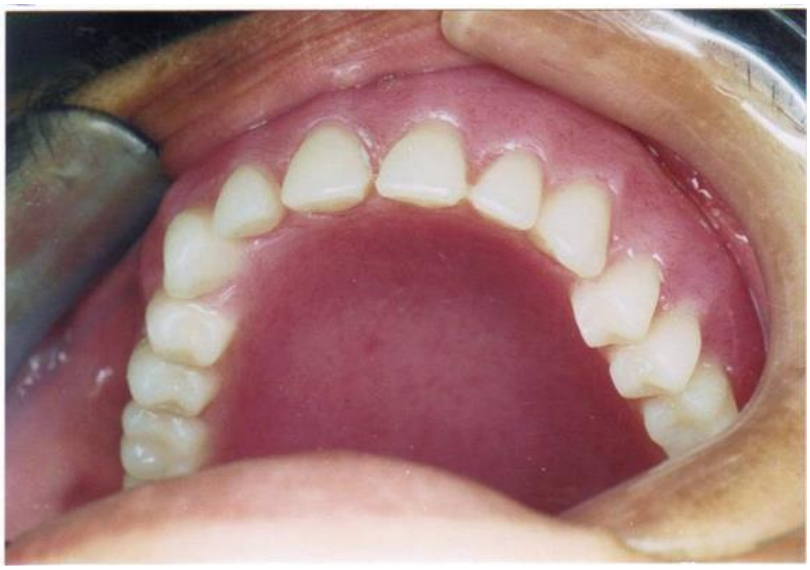
(Fig. 2) Hollow acrylic obturator



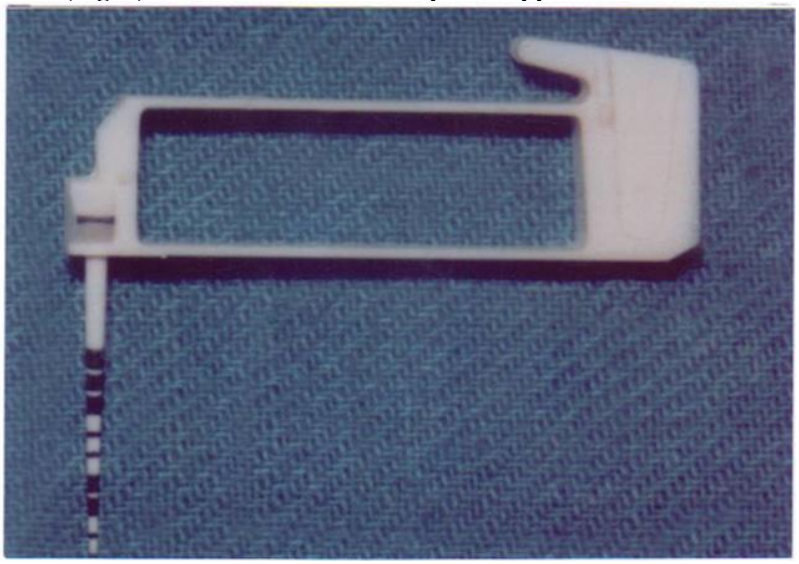
(Fig. 3) Intra oral view showing keeper of the magnetic attachment on the implants



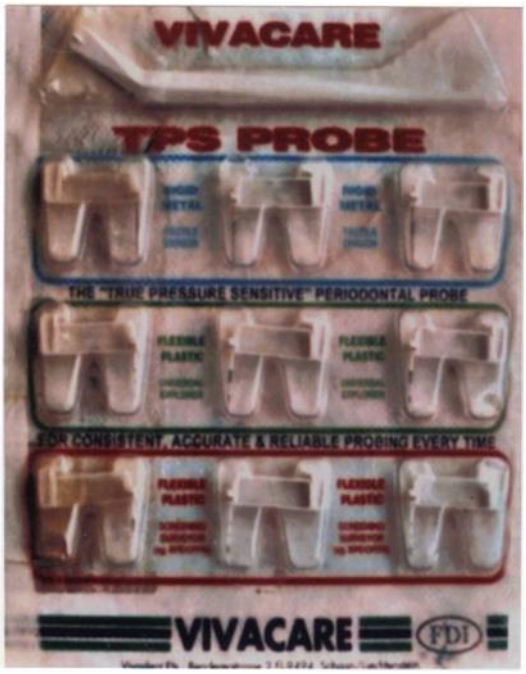
(Fig. 4) Intra oral view showing ball attachment on the implants



(Fig. 5) Intra oral view of the implant supported obturator



(Fig. 6) Sensor probe



(Fig. 7) Plastic tip of the sensor probe

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