

# Clinical and Radiographic Evaluation of Rehabilitated Implants with Overdenture with Two Ball Abutments in the Mandible and Submitted to Immediate Load: One Year of Observation

Evaluación Clínica y Radiográfica de Implantes Rehabilitados con Sobredentadura con dos Pilares de Bola en la Mandíbula y Sometidos a Carga Inmediata: Un Año de Observación

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ARISTIZABAL, H. J. A.; BURBANO, L. J. G.; SANDOVAL, R. A.; RAMÍREZ, T. J. J.; CHACÓN, A. P. T.; GONZÁLEZ, O. S. & ARANGO, G. C. E. Clinical and radiographic evaluation of rehabilitated implants with overdenture with two ball abutments in the mandible and submitted to immediate load: One year of observation. *Int. J. Odontostomat.*, 11(4):451-459, 2017.

**ABSTRACT:** The purpose of this prospective clinical study was to evaluate the clinical and radiographic survival of two non-splinted implants immediately loaded with ball abutments for supporting mandibular overdentures. Thirty edentulous patients using full dentures (22 women and 8 men) with a mean age of 64 years were included in this study. Each patient received two inter-foraminal implants in the mandible, near the canine, with an insertion torque greater than 45 Ncm. Non-splinted ball abutments were connected to the implants, and the overdenture was immediately loaded. The success of the implants was clinically and radiographically evaluated; along with the satisfaction level of the patients, after the first year of having placed the implants. One patient withdrew from the study. After 12 months the implants were loaded, the survival rate was of 98.27 %, one implant failed. The average bone loss was of 0.34 mm. No surgical complications were observed, minor prosthetic maintenance appointments were required. The satisfaction of the patients was of 89.3 %. The immediate loading of two non-splinted implants in the inter-foraminal area of the mandible retaining an overdenture by means of ball abutments is a predictable treatment, with a high success rate of survival and a favorable response of the peri-implant tissues. The patients showed good satisfaction with this treatment modality.

**KEY WORDS:** immediate dental implant loading, denture, overlay, mouth rehabilitation.

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## INTRODUCTION

Consensus between McGill (2003) and York (Thomason *et al.*, 2009), as well as a large body of scientific evidence, have suggested that two implants supporting a mandibular overdenture should be offered as the first option for the treatment of edentulous patients. The overdentures on implants in the mandible increases the satisfaction and the quality of life of the edentulous people (Awad *et al.*, 2003; Stoker *et al.*, 2007).

The possibility of a direct connection of the prosthesis to the osseointegrated dental implants, and the transmission of forces of the artificial teeth to the mandible, secures the retention and stability of the prosthesis, and decreases the trauma to the oral soft tissues. This allows patients to feel that their artificial teeth are an integral part of themselves, which increases their quality of life (Johns *et al.*, 1990).

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When implants are used to support a removable overdenture, an optimum distribution of stress is desirable to minimize the forces on the implants and the denture movements (Tokuhisa *et al.*, 2006). The types of abutments used for overdentures include bar systems, splinting the implants with different designs and individual adjustments as locator, balls, and magnetic adjustments (Feine *et al.*, 2002). Consistent differences in the patients' satisfaction rate have not been reported regarding the type of adjustments used on muco-supported implant-retained dentures (Lachmann *et al.*, 2007; Nogueira *et al.*, 2009) or regarding the use of splinted or non-splinted modalities (van Kampen *et al.* 2003).

Different studies have concluded that two-splinted or non-splinted implants in the inter-foraminal region of the mandible are enough to support an overdenture (Mericske, 1990; Mericske & Zarb, 1993; Feine & Carlsson, 2003; Attard & Zarb, 2004; Alfadda *et al.*, 2009; Cehreli *et al.*, 2010).

In a conventional protocol after the implant surgery, it is considered mandatory that the patient should not wear his/her prosthesis for 2-4 weeks (Albrektsson, 1983).

It has been suggested that the implant-prosthesis connection is to be carried out after a critical scarring period, so the bone-implant osseointegration is usually given a 3-month period for the mandible (Brånemark *et al.*, 1985). Most patients perceive such period from the implant placement until the final rehabilitation, as traumatic and uncomfortable, as the provisional prosthesis compromise function, aesthetics and is not comfortable (Esposito *et al.*, 2007).

Different authors (Babbush *et al.*, 1986; Buser *et al.*, 1988; Romeo *et al.*, 2002) have shown the benefits of an immediate loading technique with four implants in the mandibular symphysis with an overdenture. The implants are rigidly splinted with a metal bar, after two or three days of their placement. The splinting of the immediately placed implants was advocated in order to avoid force peaks in the bone-implant interface during the healing period, thus improving the survival rate (Chiapasco & Lanza 2002).

Prospective studies have reported survival rates between 94.4 % and 100 % for immediately loaded and splinted implants in observation periods between 12 and 96 months (Gatti *et al.*, 2000; Stricker *et al.*, 2004; Degidi & Piatelli, 2005).

For a long time, the immediate loading with less than four implants had been considered harmful for osseointegration. However, more recent researches are showing positive results regarding the possibility of immediately loading of the overdentures on one (Liddel & Henry, 2007; Liddel & Henry, 2010) or two non-splinted, inter-foraminal implants (Turkylmaz *et al.*, 2006; Kawai & Taylor 2007; Marzola *et al.*, 2007; Kronstrom *et al.*, 2010; Liao *et al.*, 2010; Roe *et al.*, 2011; Elsyad *et al.*, 2012; Grandi *et al.*, 2012; Lahori *et al.*, 2012; Shayegh *et al.*, 2012; Turkylmaz *et al.*, 2012).

The immediate loading of the implants has been considered, since it has many advantages: a minor surgical procedure (Hobo *et al.*, 1989), is substantially less expensive (Heydence *et al.*, 1989), the immediate restoration of aesthetics and function, decreased number of visits of the patient for treatment, reduced morbidity of a second surgical intervention (Roe *et al.*, 2010) and good levels of patients satisfaction.

A recent meta-analysis (Schimmel *et al.*, 2014) regarding the loading protocols for mandibular overdentures conclude that although the three loading protocols (Immediate, early, conventional) provide a high rate of survival, the protocols of early and conventional loading are better documented than the protocol for immediate loading, therefore, further knowledge would be required regarding this aspect. The purpose of this study was to evaluate clinically and radiographically the behavior of two non-splinted implants with ball-type abutments rehabilitated with overdentures, in the mandible and loaded immediately after one year of function in the mouth.

## MATERIAL AND METHOD

**Selection of Patients:** Thirty bimaxillary edentulous patients using full prosthesis with a mean age of 64 years, 22 women and 8 men were included in this study. In order to be included, they should have osseous availability to allow the placement of two inter-foraminal implants of 3.8 x 15 or 3.8 x 12 mm. The patients excluded were those who had received previous mandibular bone regeneration, heavy bruxers, irradiated patients, patients with mental disorders, with severe systemic disease that prevented surgery, patients who received injectable bisphosphonates, and heavy smokers.

The research was approved by the Bioethics Committee (Act 12 of 2010), and informed consent was

requested for all patients according to Resolution 8430 of the Ministry of Health of Colombia.

**Surgical procedure:** Antibiotic prophylaxis was prescribed with 2 g of amoxicillin, 1 hour before the surgical procedure. All surgeries were carried out by the same surgeon. Two implants (BIOHORIZONS TAPERED INTERNAL IMPLANT SYSTEM) of 3.8 x 15 or 3.8 x 12 mm, with prosthetic platform of 3.5 and hexagonal internal connection were inter-foraminally inserted under local anesthesia (2 % lidocaine with epinephrine, Ropsohn therapeutics inc.). A crestal incision was made, a flap was raised at total thickness, involving only the lingual portion to reduce post-surgical edema in the passage area and to allow surgical access to the lingual surface of the mandible. The bone was prepared using systematic drilling with abundant irrigation (with the surgical kit of internal connection Biohorizons®) using the 3.2 mm diameter drill as the final drilling and with the desired depth). The operator used parallel straight pins between drill and drill, in order to avoid distortion of parallelism required for the overdentures system. The implant with the surgical unit with maximum insertion torque of 45 Nm was placed, however, the final torque was achieved with manual ratchet until the implant was at crestal level. The position of the implant was performed by means of analyzing a panoramic radiography with a radiographic/surgical guide based on the duplicate of the existing full denture. After the insertion of the implant, the ball abutments were connected.

**Prosthetic treatment:** All prostheses were created by an only prosthodontist. The ball abutments were torqued at 20 Ncm. The prostheses were flared to create the space for the abutments and in the vestibular side, two holes were done to allow the visualization of adequate space and without interferences. Once the passive seating of the prosthesis was achieved, the capturing of the housings or retentive attachments (Biohorizons) in the oral cavity with self-curing acrylic (Kooliner) was performed.

Two circular portions of sterile rubber dam over the ball abutments were placed to avoid undesirable acrylic retentions. Afterwards, the occlusion was checked.

As postoperative measures, patients were asked to continue for additional seven days under antibiotic therapy, not removing the prosthesis in a week, following soft diet, and doing mouthwashes with chlorhexidine solution 0.12 % (Clorhexol, FarPag) twice

a day for one minute during 14 days. The pain was controlled with acetaminophen 500 mg, one every 8 hours during three days, Nimesulide 100 mg, one every 12 hours during three days. Soft diet was recommended during the first weeks.

**Follow-up visits:** Weekly clinical controls were performed during the first month, and at 2, 3, 6, and 12 months. Periapical and panoramic radiographs were taken as a baseline for the third week after the surgery. One year after surgery, a new clinical and radiographic control was performed. From this control, the results for this research were obtained.

**Evaluation: During the controls, it was observed:**

**Survival of the implants:** The success criteria of Ahlqvist *et al.* (1990) were taken into account: the implant should be functioning and clinically stable, there should be no pain, peri-implant tissues should be clinically healthy or show signs of mild inflammation; X-rays should not show radiolucency or other pathological conditions adjacent to the implant.

**Changes in the bone level:** The changes in the bone level were measured by means of periapical x-ray with the standardized technique of parallelism. A calibrated examiner performed the measurement of the bone height, Image Analysis software (Sopro Imagin) was used to measure the distance between the implant platform and the most apical bone level in contact with the implant body, at mesial and distal level. The distortion of each X-ray was calculated, taking into account the length of the implant in position.

A calibrated examiner performed the measurements, first, at the third week, and then, one year after the implants' placement, with the difference between them and the average loss for all the implants was calculated.

Comparative measurements were performed with another calibrated examiner in a different university in order to confirm the results.

**Evaluation of the peri-implant conditions:** Depth assessment to the probing in millimeters, plaque index, bleeding index, and presence of calculus was included. The plaque and bleeding were evaluated according to the indexes of Mombelli & Lang (1994). For the plaque: 0: When plaque 1 is not detected: The bacterial plaque is detected only by passing the periodontal probe through the marginal surface of the implant, 2: The

bacterial plaque is visible, 3: Abundant bacterial plaque. For bleeding index 0: No bleeding on tour with the probe, 1: Bleeding in isolated points, 2: In line bleeding around the mucosa of the implant margin 3: Profuse bleeding (46). The probing depth was defined as an average value of measurements of 4 sites (mesial, distal, oral and lingual) using a calibrated periodontal probe (Hu-Fryde). The presence 1, or the absence 2 of dental calculus was also measured.

**Prosthetic aspects:** It was assessed if the overdenture retention, stability, static and dynamic occlusion, presence of fissures and fractures, as well as the state of the retentive elements were intact and fulfilled its retention function and need of relines.

**Level of Satisfaction:** Patient satisfaction was assessed using the survey validated by Bergendal & Engquist (1998), through the use of questionnaires and a quantitative scale about the treatment.

**Statistical Analysis:** The patients and implants data were recorded in the statistical program SPSS version 19. Descriptive statistics, absolute and relative frequencies of each variable, averages, percentage and distribution among the sample were used to analyze the information.

## RESULTS

The initial sample consisted of thirty patients with an average age of 64 years. 60 implants were placed in the mandible to support 30 immediately loaded overdentures. Each patient received two interforaminal implants, approximately, at the canine position. One patient was excluded from the research, since it was impossible to conduct assessments because he moved his permanent residence abroad.

**Survival of the Implants:** The survival rate after 1 year of function was of 98.27 %. One of the implants failed. Later, it was placed back and the implant immediately loaded. However, this patient was not taken into account for the study. (Table I).

The bone loss in the first year was averaged 0.34 mm. (Table II). The distribution of the bone level changes is reported in Table III.

Peri-implant assessment. 62.5 % of the implants did not show bacterial plaque. 3.57 % in the inspection showed abundant plaque (Table IV).

Table I. One-year survival rate of the implants.

Time	n patients	n successful implants	n failed implants	Survival rate
0 months	30	60		
12 months	29	57	1	98.27%

Table II. One-year average peri-implant osseous loss.

(mm)	Right implant		Left implant		Patients average
	Mesial	Distal	Mesial	Distal	
	0.248	0.368	0.475	0.296	
Implant average	0.308		0.385		0.347

Table III. One-year values of peri-implant osseous loss per loss.

(mm)	Right implant				Left implant			
	Mesial		Distal		Mesial		Distal	
	N	%	n	%	N	%	n	%
_ 0.5	22	78.57	22	78.57	18	64.29	23	82.14
0.5 -1	5	17.86	3	10.71	7	25.00	4	14.29
_ 1-1.5	1	3.57	2	7.14	1	3.57	1	3.57
_ 1.5-2			1	3.57	2	7.14		
_ 2								

Regarding the bleeding index, 92.86 % of the implants did not show bleeding. Instead, 1.79 % showed bleeding around the mucosa of the implant margin (Table V).

The increase in the probing depth was seen in 4 of the 56 implants assessed. These values were related to problems such as screw loosening and ball-type pillars (Table VI).

Table IV. Presence of bacterial plaque.

Plaque index.	Implants n	Percentage
0	35	62.5
1	13	23.22
2	6	10.71
3	2	3.57

Table V. Bleeding index.

Bleeding	Implants	
	n	%
0	52	92.86
1	3	5.36
2	1	1.79
3		

Table VI. Increased probing.

Increased probing	Implants	
	n	%
Yes	4	7.1
No	52	92.9

Table VII. One-year prosthetic assessment.

	Yes		No	
	n	%	n	%
Active retention	23	82.1	5	17.9
Stay in place	25	89.3	3	10.7
Acceptable stability	23	82.1	5	17.9
Work when speaking	25	89.3	3	10.7
Static occlusion	23	82.1	5	17.9
Dynamic	22	78.6	6	21.4
Work when chewing	23	82.1	5	17.9
Presence of fissures	1	3.6	27	96.4
Presence of fractures	1	3.6	27	96.4
Intact retention elements	16	57.1	12	42.9
Functional elements	23	82.1	5	17.9

**Prosthetic.** The greater percentage of prostheses had active retention, remained in place, worked when speaking and chewing, and the static and dynamic occlusion was acceptable.

The retentive elements "O-ring" of the prosthetics were worn at 42.9 %. 17.9 % of them did not fulfill their function. One prosthesis was accidentally fractured. (Table VII)

**Prosthetic complications.** Prosthetic complications are described below in Table VIII. Fractures were not related to the functioning of the prosthesis, but to accidental rupture.

**Satisfaction subjective assessment.** This assessment was performed through the satisfaction survey applied to the annual control appointment. A satisfaction of 89.3 % was found. The dissatisfaction of 10.7 % in general was related to the lack of retention that prevented talking or chewing.

100 % considered their prosthesis as pretty (Table IX). On the subjective scale, the average was of 9.14.

Table VIII. Prosthetic complications.

	n	%
Loosening of the abutment	2	3.57
Fracture of the overdenture	1	3.57
Relines	1	3.57
Housing	2	3.57
O-ring wear	1	42.85
Hyperplasia	1	3.57
Need to change housing due to other procedures	6	10.71

Table IX. Percentage of patient satisfaction with the overdenture.

	Yes		No	
	n	%	n	%
Satisfied	25	89.3	3	10.7
It stays in place	25	89.3	3	10.7
It works when chewing	24	85.7	4	14.3
His/her prosthesis is pretty.	28	100	0	0
It works when speaking	25	89.3	3	10.7

## DISCUSSION

The implant survival in this study was 98.27 % (57 of 58 implants observed at the first year of control). The bone loss at the first year was averaged 0.34 mm. Turkyilmaz *et al.* (2006) reported success and implant survival of 100 % and average of bone loss of  $0.3 \pm 0.2$  mm. Marzola *et al.* observed 100 % of success and implant survival, and the percentage for bone loss was 0.7 mm +/- 0,5 mm after a year of observation. Konstrom *et al.* (2010) found that the implant survival was of 81.8 % and the average of peri-implant bone loss was of  $0.44 \pm 0.4$  mm. Liao *et al.* obtained an implant survival of 94 %, and when considering the loss on the smooth- and rough-surface of the implant, the average bone loss was of 0.73 mm. At one year of observation, Roe *et al.* (2011) found a 100 % survival and showed an average marginal bone change of  $-0.36 \pm 0.29$  mm. Elsyad *et al.* observed a 93 % survival for immediate loading implants and found greater vertical loss in the group with immediate loading. Lahori *et al.* compared late loading and immediate loading and found no significant differences in either implant survival, or percentage of bone loss between the two groups. Shayegh *et al.* reported after 12 months of observation, an implant survival of 100 % and average bone loss of  $0.84 \pm 0.03$  mm. Grandi *et al.* observed a survival rate of 100 % and a marginal bone loss of 0.298 mm after a year of observation.

When considering the success of an implant, several aspects must be taken into account, including the primary stability. It is believed that the primary stability of the implant plays an essential role in the success of the osseointegration. The primary stability is given in function of the quality and quantity of the local bone, the geometry and the composition of the used implant and the implant placement technique (Meredith, 1998). A good primary stability of the implant after surgery has been highlighted as one of the most important clinical parameters when trying to succeed with immediate loading (Attard & Zarb, 2005). A high torque in the implant placement is also associated with the primary stability (Marzola *et al.*). In this study, all implants were placed at more than 45 Ncm, which could be identified as one of the factors favoring the success. In contrast, Kronstrom *et al.* reported a 22 % failure and insertion values between 30 and 40 Ncm. Another study (Elsyad *et al.*), which showed a survival rate of 93 %, did not report torque values during the implant insertion. Grandi *et al.* used an insertion torque of at least 40 Ncm on 42 patients; in this study the survival

rate was of 100 % at one year of observation. Another study (Shayegh *et al.*), that reports a placement torque of the implants of more than 45 Ncm, obtained a survival of 100 %.

Another factor that must be considered to achieve a high implant survival is related to the skills of the surgeon and the expertise of the prosthodontist. In this case, the specialists were highly qualified. Prosthetic assessment:

There are studies that have compared splinted implants and non-splinted implants. They suggest that there are no differences in clinical behavior of prostheses or implants (Payne & Solomos, 2000; Heydenrijk *et al.*, 2003). Turkyilmaz (2006) citing other authors stated that the number of adjustments and repairs required for the maintenance of mandibular implant-supported overdentures are considerable and are usually needed within the first year. It also reported difficulties including fractures of the retentive gold caps, acrylic resin and denture teeth, as well as frequent reactivation of the retentive elements. This same author did not report statistically significant differences in the number of appointments for making an overdenture immediately loaded or loaded conventionally. There were also no statistically significant differences in the adjustment or repair of prostheses and in both types of load (Turkyilmaz *et al.*).

Schimmel *et al.* (2014) in a systematic review of the literature, says that when placing the overdenture the day of the surgery, the tissues are still traumatized and morphological changes will occur in the weeks following intervention. Therefore, relines will be necessary during the adaptive period. In this study, it was exceeded only 1 of 28 prostheses during a year of observation. Schimmel's study also states that immediate loading is necessary to make an impression when sutures are still at the surgical site and the material could contaminate the wound. In this study, the prostheses were previously manufactured and it was not necessary to take impressions in surgical sites that are still healing.

This study shows similarities with the results reported by Marzola *et al.*, where minimal interventions on prostheses that cannot be attributable to the immediate loading of the prosthesis were needed. As in the study of Marzola, this research agrees that the use of ball adjustments allows for a very slight modification of the prosthesis compared to a design of bar and clip that needs more space to be adapted to

the prosthesis and consequently can weaken complete denture, so the risk of prosthesis fracture was reduced. Several studies (Shayegh *et al.*; Liao *et al.*; Kronstrom *et al.*; Roe *et al.*, 2010) agree with this study that the most frequent maintenance on dentures was the need to replace the O-ring to improve retention.

**Satisfaction:** In this study, the overall patient satisfaction with treatment with the overdentures was high. Some studies have highlighted the satisfaction and quality of life of the patients with overdentures on two dental implants (Naert *et al.*, 2004). This satisfaction is consistent with the findings of Naert *et al.*, which concludes that the group with ball-retained overdenture had a high vertical retention and satisfaction with mandibular overdentures was similar for groups on non-splinted and splinted implants.

## CONCLUSIONS

After a year of observation, it can be concluded that the immediate loading of two non-splinted interforaminal implants in the mandible retaining an overdenture with ball abutments achieves high patient satisfaction and is a predictable treatment for edentulous patients that have a high survival rate of implants and a favorable response of the peri-implant tissues.

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**RESUMEN:** El propósito de este estudio clínico prospectivo fue evaluar la supervivencia de manera clínica y radiográfica de dos implantes no ferulizados cargados inmediatamente con pilares tipo bola para soportar sobredentaduras mandibulares. Treinta pacientes desdentados totales usuarios de prótesis total (22 mujeres y 8 hombres) con una edad promedio de 64 años se incluyeron en este estudio. Cada paciente recibió dos implantes interforaminales en la mandíbula aproximadamente en posición de canino con un torque mayor a los 45 Ncm. Pilares no ferulizados tipo bola se conectaron a los implantes y se cargó inmediatamente la sobredentadura. El éxito de los implantes se evaluó clínica y radiográficamente; así como el nivel de satisfacción de los pacientes al año de haber sido colocados los implantes. Una paciente se retiró del estudio.

Después de 12 meses de cargados los implantes la tasa de supervivencia fue del 98,27 %, un implante fracasó. El promedio de pérdida ósea fue de 0.34 mm. No se observaron complicaciones quirúrgicas, se requirieron citas de mantenimiento protésicas menores. La satisfacción de los pacientes fue del 89,3 %. La carga inmediata de dos implantes no ferulizados en el área interforaminal de la mandíbula reteniendo una sobredentadura a través de pilares en bola es un tratamiento predecible, con un alta tasa de éxito de supervivencia, y respuesta favorable de los tejidos periimplantares. Los pacientes muestran una buena satisfacción ante ésta modalidad de tratamiento.

**PALABRAS CLAVE:** carga inmediata del implante dental, sobre-dentadura, rehabilitación oral.

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Received: 12-07-2017

Accepted: 13-09-2017