

Feasibility of Low Profile Attachments to Improve Quality of Life on Patients with Implant-Retained Mandibular Overdenture: 1-Year Preliminary Results of a Multicenter Prospective Case Series Study

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Abstract

Aim: The purpose of this multicenter prospective case series study evaluated peri-implant marginal bone loss, complications, oral health impact profile, and soft tissue parameters in patients with mandible implant overdenture retained on two low profile attachments. **Methods:** This study was designed as a multicenter prospective case series study conducted according to the Declaration of Helsinki of 1975, as revised in 2008. Patients that required an implant-retained overdenture to rehabilitate a complete edentulous mandible were considered eligible for this research. Patients were consecutively enrolled and treated in seven centers in Italy between February 2012 and March 2017. The last follow-up was in May 2018. **Results:** A total of 40 mandibular implant-retained overdentures were delivered on 40 participants (26 females and 14 males) with a mean age of 67.5 years. All the participants were followed for at least one year (mean 21.3 months, range 12 to 60) after implant loading. At the one-year follow-up examination, no implants and no prostheses failed. Three mechanical complications were experienced at two different centers. One fully acrylic implant-retained overdenture fractured 8 months after its delivery in a patient with brachycephalic facial type. **Conclusions:** It may be concluded that implant overdenture showed high implant and prosthetic survival rates, low complications, high patient satisfaction, and good biological parameters after one year of follow-up.

Key Words: Overdenture, Prosthesis, Low-profile attachments, Implant

Introduction

With the increase of an elderly population, there is a growing number of edentulous. Edentulism can lead to significant functional impairment, and unfavorable esthetic and psychological changes in patients [1]. Restrictions in diet, speech impairment, loss of soft-tissue support directly or indirectly contribute to the global burden of disease.

The conventional method for treating edentulism is to provide complete dentures. However, progressive loss of alveolar bone may contribute to loss of retention and stability, and hence masticatory function, patient discomfort and pain [2]. To overcome these problems, when a fixed implant-supported prosthesis is not indicated (e.g. excessive inter-arch discrepancy, financial problems, etc.) the use of Implant-Retained Overdentures (IOD) were shown to be successful in rehabilitating the edentulous patients, with a high implant success rate [3-8].

The attachment systems for dental implant overdentures can be classified into the self-standing type and bar-type. Self-standing type attachments, such as ball attachment, magnet attachment, and Locator, have advantages such as easiness in oral hygiene maintenance and the possibility of using in a narrow inter-arch space. On the other hand, limits could be found in parallel implant placement requirement, and stability of the implant overdentures lesser to that of bar-type [9,10].

Implant-retained overdentures have become a well establish option for the prosthetic treatment of the complete edentulous mandible, both with immediate and the delayed loading protocols. Nevertheless, the inter-arch space required for an

implant-retained overdenture, measured from the implant platform to the incisal edge is approximately 12-14 mm.

Inadequate inter-arch space may improve the risk of mechanical complications. Several attachment systems have been introduced to retain an implant overdenture. Among these, low profile attachment system may be a better choice to safe inter-arch space and also to potentially reduce number of complications.

The aim of this multicenters prospective case series study was to evaluate peri-implant marginal bone loss, complications, oral health impact profile, and soft tissue parameters in patients with mandible implant overdenture retained on two low profile attachments. The study was written according to the STROBE guidelines [11].

Materials and Methods

This study was designed as a multicenter prospective case series study conducted according to the Declaration of Helsinki of 1975, as revised in 2008. Patients that required an implant-retained overdenture to rehabilitate a complete edentulous mandible were considered eligible for this research. Patients were consecutive enrolled and treated in seven centers in Italy between February 2012 and March 2017. The last follow-up was in May 2018. The eligibility criteria were reported in (Table 1). Study protocol was designed to collect data up to the five years after implant loading. This manuscript presents the preliminary data at one-year after loading examination.

Table 1. Eligibility criteria adopted for this study.

Inclusion and exclusion criteria	
Complete edentulous mandible	General contraindications to oral surgery
ASA I and II	Pregnancy or nursing
Aged 18 years or older	Intravenous bisphosphonate therapy
Provided written consent to this research	Alcohol or drug abuse
	Heavy smoking (≥ 20 cigarettes/day)
	Radiation therapy to the head or neck region within the last five years
	Parafunctional activity
	Untreated periodontitis
	Allergy or adverse reactions to the restorative materials
	Absence of teeth/denture in the opposite jaw

Surgical Protocol

A single dose of an antibiotic (2 g of amoxicillin or 600 mg of clindamycin if allergic to penicillin) was administered one hour before implant placement.



Figure 1. Post-op x-ray with two implant.



Figure 2. Soft tissue healing.

Local anesthesia was administered and a mucoperiosteal flaps elevated. Non submerged implants were placed, as parallel as possible, in the interforaminal region maintaining an inter-implant distance ranging between 15 mm and 25 mm (Figures 1 and 2).

After surgery, patients received medication and oral hygiene instructions. A cold and soft diet was recommended for ten days. Smokers were encouraged to stop smoking for three days postoperatively. Patients were divided into three groups based on their facial type assessment: brachycephalic, dolichocephalic and mesocephalic. Cephalic index was used to assess the facial type measuring the ratio of the maximum head breadth to the maximum head length [12].

Prosthetic Protocol

Two months after implant placement, low-profile attachments (OT Equator, Rhein83, Bologna, Italy) were screwed onto the implants, with a torque of 22-25 Ncm (Figures 3 and 4). The cuff heights of the low-profile attachments ranged from 0.5 mm to 7.0 mm, based on the height of the peri-implant soft tissue, measured with the color-coded millimeter Cuff Height Measurer Gauge (Rhein 83), immediately after healing abutment removal.

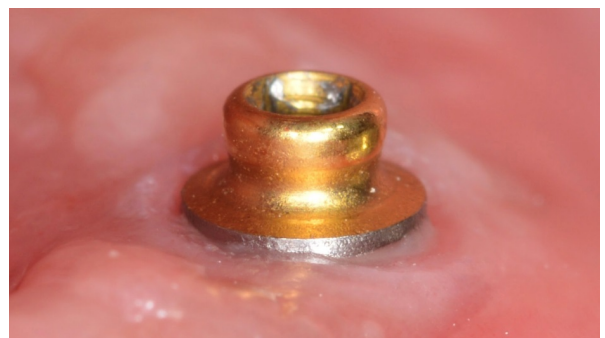


Figure 3. Clinical intraoral image of two mandibular low profile attachments.

All the patients received a new complete removable denture. Nevertheless, the operators were free to deliver the complete removable denture in the way they considered most appropriate. The research protocol did not affect individual operator preference regarding how to deliver the implant-

retained overdenture. However, variabilities between operators were collected and analyzed (Table 2).



Figure 4. Magnification of the Equator (Rhein83) low profile attachment after 1 year of function.

Table 2. Variability's between operators

Variability's between operators	
Metal-reinforced overdenture	Yes or No
Restorative material (teeth portion)	Composite, resin or ceramic
Occlusion	Anterior guidance, group function, bilateral balanced
Steel housing fixing	Dental laboratory or patient's mouth

After delivery of the implant-retained overdenture, the occlusion was adjusted and clinical pictures and standardized periapical radiographs of the implants were made. Patients were recalled for maintenance every 6 months for the entire study period. Operators could decide to recall patients more frequently (every 3 to 4 months) if necessary.

Patients were divided into three groups based on their facial type assessment: brachycephalic, dolichocephalic and mesocephalic.

Outcome Measures

- Implants and prosthesis failures: an implant was considered a failure if it was presented with any mobility, progressive marginal bone loss and suppuration or any mechanical complications rendering the implant unusable (i.e. implant fracture). A prosthesis was considered a failure if it needed to be replaced with another prosthesis for any reason.
- Complications: any biological (pain, swelling, suppuration, etc.) and/or mechanical (screw loosening, fracture of the framework and/or the veneering material, etc.) complications were considered. Implants and prosthesis failures and complications were assessed and treated by the treating clinicians in each center.
- Marginal bone loss: digital periapical radiographs were made with the paralleling technique using commercially available film holders. Mesial and distal bone level changes were measured as the distance from the implant

shoulder and the most coronal bone to implant contact, and then averaged. Radiographs were taken at the definitive prosthesis delivery (implant loading) and then yearly. Difference between each follow-up and baseline were taken as marginal bone loss. An independent outcome assessor measured all the radiographs using calibrated software (DFW2.8 for Windows, Soredex, Tuusula, Finland).

- Oral Health Impact Profile (OHIP-21) A questionnaire with 21 questions, divided in seven subscales (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap), with two to four questions each, was completed by patients. Patients were instructed to choose from five possible responses ranging from 1 (never) to 5 (very often). The questionnaire was administered by an independent dentist before treatment and yearly after definitive prosthesis delivery.
- Bleeding index and plaque index were evaluated yearly around each implant-abutment interface using a periodontal probe (PCPUNC156, Hu-Friedly, Milan, Italy) by an independent blinded dental hygienist. Four sites were evaluated (yes=1 / no=0) at each implant-abutment complex, and averaged between them.

All data analysis was carried out according to a pre-established analysis plan using SPSS Statistics for Macintosh (Version 22.0, IBM, Armonk, N.Y., U.S.). Descriptive analysis was performed using means, standard deviations and a 95% confidence interval, as well as median and interquartile ranges (IQR: first quartile; median; third quartile). Fisher exact test four count data was used to evaluate statistically significant differences between centers for implant and prosthetic failures and complications. Comparison of the means for OHIP scores between the baseline and the follow-ups was performed by paired tests. The mean differences in MBL and OHIP between different facial type assessments were compared using a mixed-model repeated-measures analysis of variance (ANOVA). Fisher exact test four count data was used to evaluate statistically significant differences between centers for implant and prosthetic failures and complications.

Results

Initially, 49 patients were selected, but only 40 were included in this single cohort prospective study. Six patients were excluded because of the presence of hopeless teeth that needed to be extracted at the same time as implant placement. Two patients were heavy smokers and one patient presented parafunctional habits. Finally, a total of 40 mandibular implant-retained overdentures were delivered on 40 participants (26 females and 14 males) with a mean age of 67.5 years. All patients presented natural teeth, fixed or removable prosthesis in the opposite arch, with stable occlusion. Participants were followed for at least one year (mean 21.3 months, range 12 to 60) after implant loading. At the one-year follow-up examination, no implants and no prostheses failed. Three mechanical complications were experienced at two different centers. One fully acrylic implant-retained overdenture fractured 8 months after its delivery in a patient with brachycephalic facial type. The

prosthesis was repaired chairside and a metal-reinforcement was applied. In two different patients of the same centre, early replacement of the retentive caps was needed. Extra-soft (yellow, 600 g) retentive caps were replaced chairside with stronger retentive caps, both in patients with mesocephalic facial type. There was no statistically significant differences between centers ($P=0.2530$), as well as, between different facial type ($P=0.3978$)

One year after implant loading, mean marginal bone loss of 0.29 ± 0.51 mm (95% CI 0.00 to 0.35). OHIP score at baseline was 76.9 ± 6.3 (95% CI from 76.0 to 78.0). One year after delivery of the implant-retained overdenture, OHIP was 22.5 ± 4.5 (95% CI from 20.6 to 23.4). The difference was statistically significant (54.4 ± 6.7 ; 95% CI from 53.9 to 58.1; $P=0.0000$) with better value at the one-year follow-up examination.

At the one-year follow-up session, bleeding index was 0.08 ± 0.07 (0.00; 0.08; 0.13); while the plaque index was 0.13 ± 0.14 (0.00; 0.10; 0.20).

Among 44 patients, 5 were with brachycephalic facial type, 9 with dolichocephalic facial type, and the others 30 with mesocephalic facial type.

At the one-year follow-up examination, the differences in MBL and OHIP between different facial type assessments were not statistically significant. The mean MBL was 0.21 ± 0.17 mm (brachycephalic); 0.6 mm- 1.1 mm (dolichocephalic); and 0.2 - 0.14 mm (mesocephalic). The P value was 0.1922. The mean OHIP difference between baseline and one year follow-up examination was 51 ± 3.2 (brachycephalic); 56.9 - 5.5 (dolichocephalic); and 54.2 - 7.4 (mesocephalic). The P value was 0.2887.

Discussion

This multicenter prospective case series study evaluated peri-implant marginal bone loss, complications, oral health impact profile, and soft tissue parameters in patients with mandible implant overdenture retained on two low profile attachments. In the present study, high implant cumulative survival rate was found after one year of loading. In fact, no implant failure occurred during the first year of function. This data is in agreement with implant survival rates of locator-retained overdentures, experienced by Elsyad et al. (96.9% after one year) [13].

In the present study, only three mechanical complications were experienced at two different centers using low profile attachments. All of these patients were easily treated with short chairside procedures. One fully acrylic implant-retained overdenture fractured eight months after its delivery in a brachycephalic patient. The prosthesis was repaired chairside and a metal-reinforcement was applied. In two different patients of the same centre, early replacement of the retentive caps was needed. In accordance with the international literature, the few studies that mentioned aspects of prosthetic aftercare provided to implant-retained overdentures reported similar or higher complications with other attachment components [14-16]. Among these, fractures of the acrylic resin or teeth [17,18], and overdenture adjustments [15,16] were the most frequent.

In the present study, one year after delivery of the implant-retained overdenture, all patients were highly satisfied. Considering OHIP score, the difference found during this prospective study was statistically significant with better value at the one-year follow-up examination. Implant attachments could positively contribute to the retention of the mandibular dentures and consequently led to higher rates of patient satisfaction. Furthermore, statistically significant improvement in all the OHIP categories was reported in all of the patients, after one-year of function; according to Awad et al. [19], high patient satisfaction was reported during the follow-up, mainly due to improved denture stability and masticatory function.

Nowadays, implant-retained overdentures can be considered a viable treatment option when bone volume is reduced. The IODs increase the masticatory function and improve satisfaction by making up for insufficient retention and stability of a conventional denture.

In the present study, one year after implant loading, a mean marginal bone loss of 0.29 ± 0.51 mm occurred (95% CI 0.00 to 0.35). This result is in line with recent literature data [20]. This phenomenon of up to one mm bone loss has been described previously and is related to maturation of bone after implant placement and adaptation of bone to withstand functional forces [21].

At the one-year follow-up session, bleeding index was 0.08 ± 0.07 (0.00; 0.08; 0.13); while the plaque index was 0.13 ± 0.14 (0.00; 0.10; 0.20). A plaque scores was reported in other studies for locator attachments [22,23]. This may be due to the resiliency of both attachments, which allow for denture movements, accumulation of food particles and plaque under the denture [23].

Although there were no statistical differences between facial types, the limited amount of patients as well as the short follow-up could have hidden some differences. For this reason, RCT studies conducted specifically in these patients or a longer follow-up will help to evaluate if there is any correlation.

Conclusions

Within the limitations of this study, it may be concluded that implant overdenture showed high implant and prosthetic survival rates, low complications, high patient satisfaction, and good biological parameters after a one year follow-up. Additional prospective clinical studies with larger samples and RCT will be needed to better understand these preliminary results.

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