Early Loaded Implant Overdenture

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Implants were placed in the interforaminal region of the mandible according to a one-stage approach. Any brand of implants that provide OT-Equator OT attachments (Rhein83, Bologna, Italy) was placed according to the manufacturer suggestions, in order to achieve an insertion torque of at least 35 N cm. The implant lengths were dictated by the preoperative radiographs.

Keywords: overdenture ; attachment systems ; OT Equator ; implant number ; dental implant ; complete removable prosthesis

1. Introduction

Today completely edentulous patients with atrophic mandible or maxilla more frequently ask for fixed rehabilitations. Nevertheless, overdenture with implants retentions represent one of the best solutions to achieve an optimal masticatory and phonetic function and to satisfy the higher esthetic request. According to McGill consensus statement, implant-retained overdentures (IRO) have become a standard option for the prosthetic treatment of the edentulous jaws, both with immediate and the delayed loading protocols [1]. The stable anchoring of implant overdenture contributes importantly to these successful results. Two- to four-implant–retained mandibular overdentures have been proven to be a successful treatment option for edentulous patients, allowing sufficient retention and support [2][3]. Placement of three or more implants should increases retention and constitutes an angular relationship instead of a straight-line relationship. Despite that, there is a lack of studies evaluating the ideal number of implants to retaining an overdenture [2].

A recent meta-analysis demonstrated no statistically significant differences between splinted and unsplinted attachment systems with regard to marginal bone loss, complications, and implant survival rate [4]. For the latter, unsplinted implants should be considered the gold standard. Several attachment systems have been developed [5][6]. Among these, retentive anchor with titanium matrix and locator may be a better choice from a financial point of view, taking into consideration the initial low cost of the components and also the reduced number of complications. In a long term retrospective analysis, implant overdenture showed high implant and prosthetic survival rates, low complications, high patient satisfaction, and good biological parameters. Within these, low-profile attachments showed lower number of complications [5].

The purpose of this randomized controlled trial, is to compare implant and prosthetic success and survival rates, biological and technical complications, marginal bone loss, patient satisfaction, and peri-implant tissue health between two or three non-splinted implant-supported overdentures. The hypothesis was that there were no differences between the groups.

2. 1 Year RCT Preliminary Data

Exclusion criteria were general contraindications to oral surgery, pregnancy, or lactation, intravenous bisphosphonate therapy, alcohol or drug abuse, heavy smoking (≥20 cigarettes/day), radiation therapy to the head or neck region within the past five years, parafunctional activity, untreated periodontitis, psychiatric therapy, or unrealistic expectations, immunosuppressed or immunocompromised, lack of opposing teeth/occluding dentition in the area intended for implant placement, acute infection in the area intended for bone augmentation and implant placement, poor oral hygiene and motivation, patients participating in other studies, and allergy or adverse reaction to restorative materials.

Severely compromised tooth elements were extracted three months prior to implant placement and finalization of the new temporary complete removable denture.

On the day of surgery, a single dose of an antibiotic (2 g amoxicillin or 600 mg clindamycin or 500 mg azithromycin or clarithromycin if allergic to penicillin) was administered 1 h before implant placement.

In both groups, the occlusion was developed to provide a lingualized occlusion with balanced contacts during function, avoiding any premature contact. However, when the opposing arch was a removable complete denture, the over-jet had to be left deliberately wide, two to five mm to avoid interference during function. Instructions were given to patients and recall visits were scheduled for occlusal adjustments and oral hygiene quality control every six months and, for retentive cap replacement, every year.

3. OT-Equator® Attachments Comparison for Retaining an Early Loaded Implant Overdenture on Two or Three Implants

Thirty-seven patients were screened for eligibility, but only 34 participants were consecutively enrolled in the trial by the seven participating centers. Three patients refused to participate. Each center was supposed to enroll six patients (three patients in each group), but five centers out of seven did not enroll all the patients. In particular, two centers recruited six patients; two centers recruited five patients; two centers recruited four patients; and only one center recruited three patients. Finally, 14 patients were randomized in the test group (42 implants) and 20 patients were randomized in the control group (40 implants). No patients dropped out after randomization at the one-year examination. The main baseline patients' and implants' characteristics of the 34 patients that were actually randomized are presented in **Table 1** .

Table 1. Main patients and implants characteristics.

	Test Group (*n* = 14)	Control Group (*n* = 20)	*p* Value
Numero of implants	**42**	**40**	**-**
Sex (M/F)	**6/8**	**3/17**	**0.1157**
Age (years)	**70.9**	**68.7**	**0.0152**
Smoke	**4**	**2**	**0.2022**
Bone quality Type I/II	**7/7**	**10/10**	**0.7290**
Mean implant length (I)	**10.0**	**9.7**	**0.6497**
Mean implant diameter (I)	**3.8**	**3.8**	**0.7954**
Mean implant length (II)	**10.1**	**9.8**	**0.6604**
Mean implant diameter (II)	**3.9**	**3.8**	**0.4323**
Mean implant length (I)	**9.7**	**-**	**NA**
Mean implant diameter (I)	**3.9**	**-**	**NA**

There were no significant baseline imbalances between the two groups.

At the one-year follow-up, two implants failed in the test group, one at each center, while no implants were lost in the control group. The difference was not statistically significant (p = 0.4941). Both patients lost the middle implant before loading (failed osseointegration). The implants were replaced 3 months later with no other complications/failures. In the meantime, the patient wore the prosthesis attached to the other two implants/attachments. At the one-year follow-up, no prostheses failed in both groups (p = 1.0).

At the one-year follow-up, three complications were experienced in the control group, while, only one complication was experienced in the test group. In the control groups, three complications were experienced at two centers. All of these complications were early loss of retention of the caps (first month). At the center two and seven, one patient each showed an early loss of retention of the caps (first two weeks). The yellow retentive caps were replaced chairside with a stronger type. In the control group, one patient showed an early loss of retention of the middle cap that was treated for the control group. Comparison of complications were not statistically significant (0.6272). Comparison of mean marginal bone loss, OHIP, mean BI, and PI are reported in **Table 2** . There were no statistically significant differences between groups in any of the tested secondary outcomes.

Table 2. Comparison of MBL, OHIP, BI, and PI between groups.

Mean Value	Groups	Baseline Mean ± SD	1-Year Mean ± SD	Difference Mean ± SD
MBL (mm)	Test (*n* = 14)	0.04 ± 0.07	0.14 ± 0.13	0.10 ± 0.08
	Control (*n* = 20)	0.01 ± 0.02	0.11 ± 0.07	0.10 ± 0.07
p Value		0.052	0.374	0.890
OHIP	Test (*n* = 14)	61.8 ± 5.8	26.4 ± 5.5	38.1 ± 9.9
	Control (*n* = 20)	60.4 ± 7.6	22.3 ± 6.2	35.36 ± 6.97
Difference		0.567	0.051	0.378
BI	Test (*n* = 14)	-	0.11 ± 0.14	-
	Control (*n* = 20)	-	0.06 ± 0.10	
p Value			0.183	-
PI	Test (*n* = 14)		0.15 ± 0.13	-
	Control (*n* = 20)		0.12 ± 0.12	
p Value			0.485	-

4. Conclusions

There are no differences in all the investigated outcomes. Waiting for further studies, it is possible to conclude that adjunctive implant besides the two to retain an implant overdenture are not needed.

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