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Original article

The single mandibular implant study – Short-term effects of the loading protocol on Oral Health-related Quality of Life

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ABSTRACT

Purpose: A single implant can be placed to retain an overdenture in the edentulous mandible. This study aimed at the development of Oral Health-related Quality of Life comparing immediate and delayed implant loading, i.e., loading after 3 months of submerged healing.

Methods: In a randomized controlled trial, 158 participants received a single mandibular implant in the midline. Quality of life was measured using the summary score of the German 49-item Oral Health Impact Profile at baseline, one month after implant placement (direct loading group) as well as one and four months after loading.

Results: Mean scores at baseline were comparable. Four months after implantation, a decrease of mean scores was recognized for both groups, indicating a significantly enhanced quality of life after treatment. When comparing the groups after both 1 and 4 months of loading, quality of life was insignificantly higher in the delayed loading group (1 month: 42.1 vs. 32.3; 4 months: 33.6 vs. 27.7). For immediate loading, an insignificant tendency to an earlier improvement was recognized ($\Delta_{1\text{ month-baseline}}$: 9.7, compared to $\Delta_{1\text{ month-baseline}}$: 6.4).

Conclusions: The single mandibular implant concept was associated with a positive impact on quality of life. However, no statistically significant influence of implant loading on quality of life was found.

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1. Introduction

Placing a single implant in the mandibular midline (SMI) to retain a complete denture has been introduced for the treatment of patients with an edentulous mandible [1]. Obvious advantages of the SMI concept in contrast to classical concepts using two or more implants are reduced costs and reduced surgery

time. High implant survival rates and significant improvements in patient satisfaction have already been reported for delayed [2] and early loading protocols [3,4] with the SMI concept. For immediate loading, however, information is scarce – especially regarding patient-reported outcomes such as Oral Health-related Quality of Life (OHRQoL). The available, preliminary evidence suggests that SMI treatment improves OHRQoL in edentulous patients [5].

A multicenter study was designed to compare two loading concepts: immediate loading and delayed loading with a re-entry after 3 months [6]. Trial data were analyzed to assess the development of OHRQoL over time for both loading concepts, hypothesizing no significant differences between both concepts.

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2. Materials and methods

A comprehensive description of the trial design has been published [7,8]. The study design was approved by each of the locally responsible institutional review boards at the nine participating universities. All participants signed an informed consent. A total of 163 edentulous participants received one dental implant (Camlog Screw Line, Promote Plus, Camlog Biotechnologies, Basel, Switzerland) in the mandibular midline. Of these, 158 were randomly assigned to either the immediate loading group (ILG: $n = 81$) or the delayed loading group (DLG: $n = 77$) (age: 60–86 years, median: 70 years) with a submerged healing protocol (Table 1). Participants were only included in this trial with a minimum mandibular bone height of 11 mm (Classes II or III according to McGarry et al. [9]), and a minimum height of 13 mm in the midline of the mandible. To determine the alveolar bone height, panoramic X-rays were taken. For standardization of the measurements, a steel ball with a diameter of 3 mm was polymerized into the denture base for the X-ray, and removed afterwards. For denture retention, ball attachments (Dalbo-Plus Elliptic, Cendres Métaux, Biel, Switzerland) were used. The respective housings were intra-orally luted into the existing mandibular overdenture of the patient, which had been worn for at least 3 months before study start to allow adaptation. The participants were only included into the study when the dentures were technically acceptable in both mandible and maxilla and had a bilaterally balanced occlusal scheme. The maxillary denture required adequate retention and stability. Finally, minimum denture height between base and central anterior denture teeth was chosen to be at least 6 mm. Self-perceived OHRQoL was assessed using the summary score of the German version of the Oral Health Impact Profile (OHIP) with 49 items [8]. Low OHIP scores (possible range 0–196) represent a high level of OHRQoL. The OHIP was administered at baseline, at one month after implant placement (only in DLG), at one month after loading, and at four months after loading as shown in Fig. 1. The OHIP sum score was used for further analyses. The non-parametric Wilcoxon rank-sum test and Friedman test were used to identify significant inter- and intra-group differences statistically. To eliminate confounding a multivariate regression analysis was carried out. The target variables of this linear regression model were the OHIP-difference between baseline and one month after loading (Table 2) and between baseline and four months after loading (Table 3). Following variables were included: age, baseline OHIP, gender, income, and (former) profession. The level of significance was set to $p \leq 0.05$, not adjusted for multiple testing. Statistical analyses were conducted using R (URL <https://www.R-project.org>) version 3.2.3.

3. Results

At baseline before treatment, mean OHIP sum score was 51.8 (SD: 29.7, range: 5–132) in the immediate and 50.7 (SD: 29.5,

Table 1
Baseline characteristics of the study groups.

	Immediate loading ($n = 81$)	Delayed loading ($n = 77$)
Mean age (years, SD)	70.4 ± 5.9	69.1 ± 6.4
Gender		
Male (%)	48 (59.3)	44 (57.1)
Female (%)	33 (40.7)	33 (42.9)
Minimum mandibular bone height according to McGarry et al. [9]		
Class II (16–20 mm)	33 (52.4)	48 (50.5)
Class III (11–15 mm)	48 (47.6)	47 (49.5)

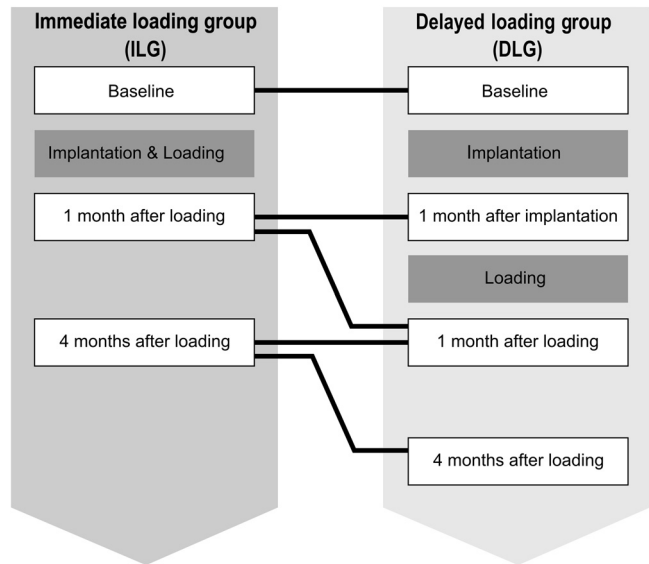


Fig. 1. Course of treatment and respective study examination visits (white) for both groups. Relevant comparisons between the groups are marked with a thick black line.

Table 2
Results of multiple regression analysis of OHIP-difference ($\Delta\text{OHIP}_{1\text{ month after loading-baseline}}$) and potential confounders. The level of significance was set to $p \leq 0.05$.

Variable	Estimate	Std. Error	t-Value	p-Value
Group	8.315	4.621	1.799	0.074
OHIP at baseline	0.522	0.078	6.700	<0.001*
Age	-0.434	0.358	-1.211	0.228
Gender	0.987	4.810	0.205	0.838
Profession				
Technician/employee	-0.174	5.027	-0.035	0.972
Craftsman	2.483	6.573	0.378	0.706
Un-/half skilled	16.016	14.092	1.137	0.258
Unemployed	16.549	19.371	0.854	0.395
Not specified	14.176	14.188	0.999	0.320
Income				
1000–2000 € p.m.	4.512	6.461	0.698	0.486
>2000 € p.m.	5.075	8.028	0.632	0.528
Not specified	7.607	8.648	0.880	0.381

* Bold values indicate a significant influence of confounder on OHIP difference.

Table 3
Results of multiple regression analysis of OHIP-difference ($\text{OHIP}_{4\text{ months after loading-baseline}}$) and potential confounders. The level of significance was set to $p \leq 0.05$.

Variable	Estimate	Std. Error	t-Value	p-Value
Group	4.841	4.163	1.163	0.247
OHIP at baseline	0.572	0.07	8.176	<0.001*
Age	0.003	0.321	0.008	0.993
Gender	3.757	4.374	0.859	0.392
Profession				
Technician/employee	1.496	4.521	0.331	0.741
Craftsman	0.929	5.990	0.155	0.877
Un-/half skilled	-2.441	14.395	-0.170	0.866
Unemployed	-2.309	17.407	-0.133	0.895
Not specified	17.840	12.759	1.398	0.164
Income				
1000–2000 € p.m.	0.024	5.808	0.004	0.997
>2000 € p.m.	-1.783	7.281	-0.245	0.807
Not specified	4.467	7.759	0.576	0.566

* Bold values indicate a significant influence of confounder on OHIP difference.

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