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A 5-year prospective clinical trial on short implants (6 mm) for single tooth replacement in the posterior maxilla: immediate versus delayed loading

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Abstract

The aim of this paper was to demonstrate the treatment outcomes following immediate functional loading concept of short implants inserted for single tooth replacement in the posterior maxilla. The study was performed on 63 patients who received short (6 mm) implants for single tooth replacement in the posterior maxilla. Forty-eight patients underwent immediate functional concept, whereas 15 of the implants were loaded 3 months after insertion. The patients were evaluated for up to 5 years after prosthesis completion. The endpoints included the evaluation of implant survival rate, crown length, bone resorption, plaque accumulation (PI), bleeding on probing (BOP), periodontal probing depth (PPD) and assessment of oral health impact profile (OHIP). At the end of the follow-up period of 5 years, three implants (6.3%) from the immediate loading group have failed during the observation period. Bone loss was significantly lower in the delayed loading group compared to the immediately loaded implants. At the end of the second year, BOP values were higher in the immediately loaded group. Throughout the observation period, PI values in the group with immediate loading were higher. PPD increased consistently and during the first 3 years in the immediate loading group. As a conclusion, short implants inserted for single tooth replacement at the posterior maxilla presented with satisfactory clinical outcomes in both immediate and delayed loading concepts. However, immediately loaded implants presented with an increased bone loss and higher BOP values. As assessed by the OHIP score, a subjective improvement was observed in both groups without significant differences.

Keywords Delayed · Immediate · Implant · Maxilla · Temporary

Introduction

Despite recent advances in oral and maxillofacial surgery for optimizing bone volume at the implant recipient sites such as the use of novel bone substitutes [1], guided bone

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regeneration techniques [2] and mesenchymal stem cell applications [3], implant-supported prosthetic rehabilitation of patients with poor residual bone volume at the edentulous posterior maxilla remains still challenging. In addition to the limited bone volume secondary to the sinus pneumatization, several studies have suggested that the implants are most to prone to failure in the posterior maxilla, thus the bone volume at this region presents often with an insufficent bone quality [4–6].

Short implants (\leq 8.5 mm) were introduced as an alternative treatment option to maxillary sinus bone grafting with promising clinical results considering their survival rates and three times lesser intraoperative complications compared to the standard implants [7]. Thoma et al. [8] have also highlighted their superiority to bone grafting options regarding their cost and time effectiveness. In addition, several studies have investigated the clinical outcomes of short implants under different loading conditions.

To instantly meet the patient functional demands and esthetic expectations by shortening the treatment duration and reducing the number of surgical interventions, immediate functional loading concept gained its popularity as an accepted treatment modality in well-selected cases. It is obvious that achieving the requisite implant stability for immediate functional loading depends on the bone quality at the implant recipient site and surgical technique as well as the macro-topography of the implant used [9]. The lack of initial stability in lower quality bone results in lower success rates, which is especially critical for immediate loading [10]. In addition, it is well known that implant insertion in the posterior maxilla poses a great challenge for dental professionals, thus more than 80% of the edentulous posterior maxillae consisted of porous cortical crest or no cortical bone, which might present an increased risk for the implant survival. Nowadays, short implants are frequently placed in the posterior area to avoid complementary surgical procedures. However, it has been suggested that the clinicians need to be aware that short implants with length less than 8 mm present greater risk to failures in the posterior maxilla [11].

Treatment outcomes of immediately functionally loaded short implants have been rarely studied. Therefore, there is a need for determining the patient selection and management guidelines to improve the knowledge regarding the potential benefits and pitfalls at each distinct implant recipient site. Current study aimed to compare the treatment outcomes of immediate versus delayed functional loading concepts of short implants inserted for single tooth replacement in the posterior maxilla.

Materials and Methods

Between January and July 2010, patients which were randomly assigned to receive one short implant (6 mm) for single tooth replacement at their posterior maxilla (first or second molar) were screened for participation. All implants were examined during a period of 5 years.

The inclusion criteria were as follows:

- Loss of the first or second molar at the posterior maxilla with a residual bone height between 6.5 and 8 mm, and bone width of > 8 mm.
- Opposing natural dentition or natural tooth or implantbased prosthesis.
- Completely healed, at least 6 months postextraction socket.
- Favorable periodontal health status according to community periodontal index [12].

The exclusion criteria were as follows [13]:

- General systemic contraindications against implant surgery (psychiatric disorders, pregnancy, metabolic bone diseases, etc.).
- The presence of systemic diseases which may jeopardize the success of implant integration (uncontrolled diabetes [Hba₁c < 8], osteoporosis, etc.).
- The use of drugs which may negatively affect the osseointegration process (bisphosphonates, antiresorptive agents, corticosteroids, etc.).
- Active inflammation or neighboring pathologies in the areas intended for implant placement.
- Radiation therapy to the head and/or neck region in the preceding 12 months.
- Requirement of bone augmentation during implant placement.
- Clinically significant parafunction.
- Tobacco and alcohol abuse.
- Poor oral hygiene and/or compliance.

The study was approved by the Ethics Review Committee (#GMMA/12.15.2015-498) Eligible patients, which have to pay for their surgical and prosthetic treatments, were informed orally and in writing about the goals and the duration of the study (observation period of 5 years) and the pertinent risks and benefits of the procedure and of the respective superstructures.

A total of sixty-three patients were enrolled the study. Prior to the surgical procedure, standard dental volumetric tomography scans (iCat[®], Imaging Sciences International, LLC, http://www.i-cat.com) were obtained from the implant recipient site.

Surgical procedure

All procedures were performed by the same dental surgeons (MA and AG). The patients were consecutively treated with internal-hexed self-tapping titanium implants with large grit, sand-blasted and acid-etched surfaces (LGI plus, Hi-Tec Implant Ltd. Herzliva Israel) according to a standardized surgical procedure under local anesthesia (articaine chlorohydrate [72 mg/1.8ml] with epinephrine [0.018 mg/1.8ml] 1:100,000). All implant sites were free from clinical signs of inflammation. Briefly, a full thickness muco-periosteal incision was placed at the mid-crest and the flap was elevated with mini-vertical releasing incisions. Considering the residual bone width, implants in 6 mm length with either 5 or 6 mm in diameter were inserted according to the manufacturers' guidelines. Antibiotics (amoxicillin 875 mg+clavulanic acid 125 mg) were given 1 h prior to surgery and two times a day for 6 days thereafter. Antiinflammatory medication (ibuprofen, 600 mg) was administered for 5 days.

According to the peak insertion torque values, the patients with their torque value of ≥ 35 N cm were assigned

for immediate functional loading, whereas patients having implants with lesser then 35 N cm were conducted for delayed loading after 3 months.

Prosthetic procedure

All prosthetic procedures were accomplished by M.A. and A.G. The laboratory phases were performed by the same dental technician at the same dental laboratory.

Immediate loading concept

In the immediate loading group, the implants were immediately functionally loaded with a screw-retained temporary crowns. The provisional suprastructures of bis-methacrylatecomposite resin were (Luxatemp DMG Chemisch-Pahrmazeutische Fabrik GmbH, Hamburg—Germany) mounted on temporary polyetheretherketone (PEEK) abutments (Fig. 1a) and were adjusted to a light centric contact and free from eccentric contacts with the opposing teeth before the polishing procedures. The restorations were tightened to 20 N cm and the mucoperiostal flaps were adapted to the provisional suprastructure before performing the wound closure. The patients were instructed to avoid exerting force on the temporary restoration and oral hygiene instructions were given.

Delayed loading concept

In the delayed loading group, the patients underwent a twostage surgery procedure with a healing period of 3 months. The definitive crown consisted of a standard titanium abutment (Hi-Tec Implant Ltd. Herzliya Israel), with a screwretained metal-supported ceramic veneer suprastructure (Fig. 1b). Prosthetic procedures for definitive crowns were initiated after 3 months in the immediate loading group in the same manner (Figs. 2, 3).

Outcome parameters

Measurement of bone resorption

Bone crest levels around the implants were measured with a standard right-angle parallel technique, based on single digital X rays. The radiographs were scanned at 600 dpi (Trophy RVG UI USB Sensor, KODAK 5.0



Fig. 1 a Vestibular and occlusal views of the provisional suprastructures of methacrylate-composite material (left) and definitive ceramic veneer crowns (right)



Fig. 2 a Immediate loading with provisional crown. b Soft tissue profile during replacement of the provisional prosthesis after 3 months c. Definitive ceramic veneer suprastructure in situ

Fig. 3 OPTG with **a** provisional acrylic suprastructure on PEEK abutment, **b** definitive ceramic crown



software, Carestream, Stuttgart, Germany), and image analysis software was used to assess bone level (UTH-SCSA Image Tool version 3.00 for Windows, University of Texas Health Science Center, San Antonio, Texas USA) (Fig. 4a, b). The linear distance between the implant neck and the most coronal bone-to-implant contact at the mesial and distal aspect was measured for each implant [13–15] immediately after implant insertion and at the end of each year throughout the 5-year observation period, bone loss was calculated using the bone level immediately after implantation as a reference.

Probing pocket depth (PPD) and bleeding on probing (BOP)

Probing pocket depth was measured in mm at six periimplant sites at each year for 5 years postoperatively. BOP was measured at four sites every year. The deepest pocket was considered in the analysis, and any bleeding on probing was recorded as affirmative.

Plaque accumulation

Plaque accumulation was evaluated using the plaque Index according to Mombelli et al. [16]. The examination was performed every year throughout the follow-up period.

Crown length

The crown length was determined by measuring the distance between the highest extension of the cusps of the crown and the most coronal bone-to-implant contact.

Oral health impact profile (OHIP)

The impact of the reconstruction on the quality of life was assessed using the German version of the OHIP, [13, 17] which was applied before surgery, immediately after implantation and at 1, 5 and 7 years after denture integration. OHIP considers 14 metrics in seven domains using a five-point verbal rating scale ranging from "never" (coded 0) to "very often" (coded 4).

Fig. 4 Measurement of bone resorption was measured with a standard right-angle parallel technique, based on single digital X rays. a Provisional acrylic suprastructure on PEEK abutment, b definitive ceramic crown



Table 1Peak insertion torquevalues for both groups

	п	Mean	Median	Minimum	Maximum	St.d.
Delayed loading	g					
Peak inser- tion torque (Nm)	15	24.46667	25.00000	14.00000	31.00000	4.703595
Immediate load	ing					
Peak inser- tion torque (Nm)	48	60.85417	61.50000	38.00000	78.00000	11.19838

(St.d.: standard deviation) The peak insertion torque values in the immediate-loading group $(60.9 \pm 11.2 \text{ Nm})$ were significantly higher then the delayed loading group $(24.5 \pm 4.7 \text{ Nm})$ (p < 0.001)

Table 2Distribution of theimplant recipient sites

n	Ratio%
21	33.33
16	25.39
13	20.63
13	20.63
63	100
	n 21 16 13 13 63

Statistical analysis

The data were analyzed using the software package SPSS 20. The following non-parametric methods were used: the Wilcoxon test for differences over time and Mann–Whitney U test for group differences and for discrete parameters. The level of significance was set at p < 0.05. The Spearman correlation coefficient was calculated to analyze the relationship between scale variables. Exact Fisher test was used to calculate the effect strength of the variables at a significance level of p > 0.3.

Results

A total of 63 patients with a mean age of 54.68 ± 8.63 were enrolled in the study. The female/male ratio was 33-30. None of the patients were smokers as a part of the study design. There were no statistically significant differences in the demographics and the baseline data between the two groups. Totally, 63 implants (*n*: 40 in 5 mm and *n*: 23 in 6 mm diameter) were placed according to the peak insertion torque values (Table 1). Forty-eight implants were loaded immediately and 15 were loaded 3 months after insertion. The distribution regarding the recipient sites is shown in Table 2.



Fig. 5 Bone loss was significantly lower in the delayed loading group compared to the immediately loaded implants (p < 0.001)

Implant survival rates

Three of the implants failed during the observation period (*n*: 2 at the end of the second year and *n*: 1 at the end of the first year.). All three documented implant failures occurred in the immediate loading group. The rate of failure was 6.3% (3 out of 48). The difference between immediate loading and delayed loading groups was statistically insignificant (exact Fisher test, p = 1.00). Since only 3 losses were recorded, consideration of the implant failures with regard to the parameters assessed (insertion torque, plaque accumulation, implant width, bone resorption) could not be statistically evaluated.

Bone loss

In both groups, a uniform, albeit slight, a progression of bone loss was observed over the 5-year observation period which remained well within the limits for 'success', as defined by the 2007 Pisa consensus [18] (< 2 mm). Nevertheless, bone loss was significantly lower in the delayed loading group compared to the immediately loaded

 Table 3
 In both groups, a uniform, albeit slight, a progression of bone loss was observed over the 5-year observation period

Bone loss (mm) Year	t value	n (delayed loading)	<i>n</i> (immedi- ate load- ing)	р	р
1	5.01795	15	48	61	0.000005*
2	6.47145	15	46	59	0.000000*
3	8.16883	15	46	59	0.000000*
4	10.07387	15	45	58	0.000000*
5	10.08171	15	45	58	0.000000*

Bone loss was significantly lower in the delayed loading group compared to the immediately loaded implants. The t test yielded p values below 0.001 throughout the observation period

*Statistically significant differences (p < 0.05) were obtained in the first- and second-year observations

Table 4 At the end of the second year, 53.3% of the implants in the delayed loading group (8 out of 15) and 97.9% of the immediately loaded group (46 out of 47) were positive to bleeding on probing (BOP) and the difference was statistically significant (p < 0.001)

BOP (+/-)	п	n (%) +	n (%) _	р
Delayed loading	15	8 (53.33%)	7 (46.67%)	p=0.00009
Immediate loading	48	46 (97.87%)	1 (2.13%)	

implants (Fig. 5). The t test yielded p values below 0.001 throughout the observation period (Table 3).

Bleeding on probing

At the end of the first year, BOP was positive in 86.7% (13 of 15) of the cases in the delayed loading group, whereas all 48 cases in the immediate loading group presented with positive results. The difference between the study groups was not statistically significant (exact Fisher test, p=0.054). At the end of the second year, 53.3% of the implants in the delayed loading group (8 out of 15) and 97.9% of the immediately loaded group (46 out of 47) were positive to BOP and the difference was statistically significant (p < 0.001) (Table 4). Further evaluations in the 3rd, 4th and 5th years revealed no differences (Fig. 6).

Plaque index

Plaque index values of ≥ 1 in both groups were included for analysis and compared using the exact Fisher test. Throughout the observation period, PI values in the group with immediate loading were higher than that in the delayed loading group (Fig. 7). Statistically significant differences (p < 0.05) were obtained in the first- and second-year observations (Table 5). Moreover, among all selected parameters,



Fig. 6 At the end of the second year, 53.3% of the implants in the delayed loading group (8 out of 15) and 97.9% of the immediately loaded group (46 out of 47) was positive to BOP and the difference was statistically significant (p < 0.001)



Fig. 7 Throughout the observation period, PI values in the group with immediate loading was higher than that in the delayed loading group. Statistically significant differences (p < 0.05) were obtained for the first- and second-year observations

only the plaque index at the the end of the second year was found to have a weak effect on implant failure (Table 6).

Probing pocket depth

Periodontal probing depth increased consistently and during the first 3 years in the immediate loading group. There was a tendency towards shallower pockets for the delayed loading group, which was persistent following the second year of examination (Fig. 8) (p < 0.001).

Crown length

Crown lengths overall the study sample are shown in Table 7. No statistically significant differences were found in distribution between two groups. Crown length had no effect on any of the parameters evaluated.

PI 1st year	n	≥1	<1	р
Delayed loading	15	2 (13.33%)	13 (86.67%)	p=0.0006*
Immediate loading	48	35 (72.92%)	13 (27.03%)	
PI 2nd year	n	≥1	<1	р
Delayed loading	15	0 (0.00%)	100 (100.00%)	p=0.00016*
Immediate loading	48	25 (52.08%)	23 (47.92%)	

Table 5 Plaque index (PI) values of ≥ 1 in both groups were compared using the exact Fisher test

*Statistically significant differences (p < 0.05) were obtained in the first- and second-year observations

 Table 6
 The effect of plaque accumulation on implant loss was calcu lated as 0.28, which could be considered as weak (p < 0.3)

Implant failures	Plaque index	Implants total			
	<1	≥1			
+	38	22	60		
Rate %	100.00%	88.00%			
_	0	3	3		
Rate %	0.00%	12.00%			
Total	38	25	63		



Fig.8 Probing pocket depth increased consistently and during the first 3 years in the immediate loading group. There was a tendency towards shallower pockets for the delayed loading group, which was significant after second year of examination (p < 0.001)

Oral health impact profile

There was a subjective improvement, as assessed by the Oral Health Impact Profile (OHIP) score in both groups immediately after prosthetic treatment. However, there were no differences in the OHIP scores between both groups (Fig. 9).

Complications

All prostheses were easily mended and served. No mechanical complications were registered throughout the observation period.

Discussion

The number of studies on clinical aspects following single tooth replacement using short implants with immediate functional loading concept is limited [7, 19-21]. Anitua et al. [7] have demonstrated that immediate loading of short implants is not a risk factor for treatment success and concluded that the satisfactory outcomes could be related to the good bone quality and the achievement of adequate primary stability. Along with that, in a review performed by Esposito et al. [22], it has been proclaimed that the immediate loading correlates neither with an increased risk failure nor peri-implant bone loss; however,

Fable 7 The comparative analysis of the crown length in both groups was statistically insignificant		Rg Delayed loading	Rg Immediate loading	U	n Delayed loading	n Immediate loading	p
	Crown length (mm)	395.5000	1620.500	275.5	15	48	0.174512*

Mann–Whitney U test has provided a p value of 0.175 (p > 0.05)



Fig.9 There was a subjective improvement, as assessed by the Oral Health Impact Profile (OHIP) score in both groups after prosthetic treatment. No differences was observed between both groups

an insertion torque of ≥ 35 N cm is recommended. The same value was also highlighted later by Schrott et al. [23]. Similarly, an insertion torque value of 35 N cm was selected as a descriptive parameter to decide on the loading concept for the current study.

In the present study, three out of 48 implants of the immediate loading group have failed during the observation period. Alvira-Gonzales et al. [24] compared the survival rates of immediately and delayed loaded short implants and stated that immediate loading of short implants placed on free ends could be considered as a successful treatment option. Boni et al. [25] have evaluated the survival rates of short implants and reported 10 failures out of 161 immediate loaded implants compared to 11 failures out of 626 delayed loaded fixtures. In addition, Muelas-Jimenez et al. [26] have reported higher failure rates with single crowns for immediate loading concept. A recent literature review stated that implants of ≤ 8 mm length presented with failure rates between 0 and 14.5%, 0 and 37.5% and 0 and 22.9% for 6-, 7-, and 8-mm implants in length, respectively [27]. In the present study, the implant failure rate was 6.3%. It was remarkable that the implant faliures were observed only in the immediate loading group; however, it was not possible to define a correlation between the implant failure and immediate loading concept, due to the limited sample size of the delayed loading group. Regarding all parameters evaluated, plaque accumulation was found to be the unique statistically significant factor which might effect the implant survival.

In the literature, there are controversies regarding the implant survival rates following immediate loading in single tooth replacement. Mangano et al. [28] have evaluated the outcomes of single, 3.5×10.0 -mm implants subjected to immediate functional loading during a period of 24 months and suggested that immediate functional loading of single implants seems to represent a safe and successful procedure. Similar results have been also presented by Sethi and Kaus

[29]. Moy et al. [30] have stated that the prognosis for single molar implants provides a viable treatment option for replacing a single missing tooth in the posterior quadrants of the maxilla; however, the success rates were slightly higher with delayed loading protocols than immediate loading protocols. Gjelvold et al. [31] have evaluated the clinical and radiographic outcomes following immediate and delayed loading of single tooth implants in the maxillary premolar region and suggested that single implants in the maxilla can present satisfactory results with respect to either immediate or delayed loading after 12 months. The mean time of implant failure in the current study was 20 ± 6.9 months after implant placement. Therefore, it might be concluded that the studies focusing on the survival rates should have longer follow-up periods than 24 months.

In addition to the implant survival rates, stability of the peri-implant bone and adjacent soft tissues determine the clinical success of the dental implant treatment [32]. Previous systematic reviews including studies evaluating both single and splinted implants revealed that the loading protocol does not influence the marginal bone loss. Similar results were also presented by Benic et al. [32], who have recently reviewed the marginal bone loss of single implant crowns under different loading conditions. Despite being within the limits determined for 'success', as defined by the 2007 Pisa consensus [18] (< 2 mm), a uniform, albeit slight, a progression of bone loss was observed in both groups. However, the immediate loading group presented with higher values of bone loss and probing pocket depth throughout the observation period. In addition, plaque accumulation and bleeding on probing was significantly higher in the immediate loading group compared to the delayed loaded implants within the first 2 and 3 years, respectively. It is obvious that plaque accumulation could be effected by the oral hygiene status of the patients; however, the study sample was already conducted from the patients with advanced periodontal health status. In the literature, it has been shown that bacterial adhesion and formation of dental plaque on provisional fixed prosthodontic materials resulting from variable surface roughness values could cause gingival inflammation [33–35]. Bisacrylate composite resins might have significantly lower adhesion potentials than improved methacrylates [36]; however, current differences described during the the first years of examination could be attributed to the resistance of the material used for the bacterial adhesion which might occur during the first 3 months of immediate loading.

Despite the fact that all implants were definitively loaded after 3 months and should behave similarly once osseointegration occurred, there is a longlasting difference between both groups in terms of peri-implant health status. In a recent meta-analysis, Zhu et al. [37] have stated that, loading protocols could present different results in terms of attachment loss and probing depth. It might be hypothesized that the increased probing depth might be responsible for the progression of peri-implant inflammation in the immediate loading group.

Crown length of the suprastuctures were also measured to determine a possible relation between the crown/implant ratio and the marginal bone loss and/or implant survival; however, it was observed that the crown length had no influences on any of the above-mentioned parameters. From this point of view, current study was in agreement with statements reported by Blanes et al. [38] and later by Rossi et al. [39], in which it was concluded that the crown/implant ratio had no relevance to the prognostic outcomes.

Patients' expectations, the level of satisfaction, and the oral health-related quality of life with regard to the immediate loading protocol have been studied by several researchers [13, 40–42]. In the current paper, OHIP instrument was used to assess subjective treatment outcomes; however, no statistically significant differences were found between two groups. This could have been resulted from the limited negative effect of a single tooth failure on functional status of masticatory system.

Conclusion

Short implants inserted for single tooth replacement at the posterior maxilla presented with satisfactory clinical outcomes in both immediate and delayed loading concepts. However, immediately loaded implants presented with an increased bone loss which was statistically significant during the whole examination period and higher BOP values which differ especially between second and third years of examination from the immediate loading group. Further studies with greater sample size are needed to exactly clarify the potential risks and treatment guidelines.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no confict of interest.

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