

Early loading of splinted implants in the posterior mandible: a prospective multicentre case series

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Abstract

Aim: To evaluate the 12-months clinical and radiological outcomes with the OsseoSpeed™ TX implant using an early loading protocol in patients with missing teeth in the posterior mandible.

Material and Methods: Forty-five subjects, with Kennedy class I or II edentulism in the mandible, were enrolled at three centres in China. Two or three implants were placed in one edentulous region using a one-stage procedure. Patients received a screw-retained splinted fixed permanent restoration in one edentulous region 6–8 weeks after surgery. Follow-up took place at 6 and 12 months after loading. Marginal bone level alteration, implant survival and clinical findings were assessed using descriptive statistics. The data were analysed on a patient level, implying that the mean overall implants by patient was used as the statistical unit. The data from the three centres were pooled in the statistical analyses.

Results: A total of 107 implants were inserted in 45 patients. Twelve months after loading, the implant survival rate was 100%, with a mean (\pm std) marginal bone gain of 0.08 ± 0.411 mm and healthy soft tissue status.

Conclusions: Early loading of splinted OsseoSpeed™ TX implants was an effective and safe treatment for partial edentulism of the posterior mandible.

Clinical trial registration number on clinicaltrials.gov: NCT01346683.

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Treatment with endosseous titanium implants gives excellent long-term success rates for the rehabilitation of total and partial edentulism. Various implant systems are available, differing in both their design

and technological features. The continued development of new materials and components to improve dental implants has been of benefit to both patients and dental professionals.

One significant improvement has been a reduction in the healing time for osseointegration (Malo et al. 2003, Ma et al. 2010, Alsabeeha et al. 2011). Successful early loading of dental implants was first described in 1990 (Schnitman et al. 1990). Since then, several studies have confirmed that using immediate and early loading protocols for dental implants can have high survival rates and good clinical outcomes (Fuh et al. 2010, Haverstock et al. 2012,

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Blanco et al. 2013). However, these studies used different implant systems with different surface characteristics and different topographic structures, in different clinical situations. Whether the early loading protocol can routinely be used for all implant systems and in all clinical situations remains unclear. This is particularly so in the posterior jaws, where the occlusal forces are much higher than they are in the anterior jaws; consequently, traditional loading remains the choice of most clinicians.

Manufacturers and researchers have both been attempting to reduce the healing time for osseointegration. The Osseospeed™ TX is an implant produced by DENTSPLY Implants (formerly Astra Tech). It has a fluoride ion modified surface, with small amounts of fluoride ions bonded to the titanium oxide layer. It has been shown *in vivo* to enhance bone formation and bone-to-implant bonding, with a shorter healing time (Cooper et al. 2006, Abrahamsson et al. 2008, Monjo et al. 2008). It also has a tapered apex design, which allows for easier implant installation. A reduced osteotomy diameter means that an increased torque resistance can be achieved. Other design features of the system are the MicroThread and conical seal, which it is hoped will help maintain the marginal bone levels (Abrahamsson & Berglundh 2006, Schrottenboer et al. 2008, Yun et al. 2011, Kwon et al. 2013, Guerra et al. 2014).

The Osseospeed™ TX implant system has been thoroughly evaluated. The different components of it, together referred to as the BioManagement Complex, have been investigated both individually and together (Galindo-Moreno et al. 2012, Aguirrebeitia et al. 2013, Freitas-Junior et al. 2013, Limmer et al. 2014). However, whether it results in better clinical outcomes, such as reduced healing times and maintained marginal bone levels, still needs to be fully evaluated, in order to provide a solid clinical evidence base.

We hypothesized that using an early loading protocol and splinted dental implants (with a fluoride ion modified surface, a platform switching design, a MicroThread design, a conical seal design and a tapered

apex design) would maintain the marginal bone level (MBL) and have beneficial clinical outcomes. We carried out this pilot study in order to evaluate the 12-month clinical efficacy of early loading of two or three splinted implants by assessing the MBL alteration, implant survival rate and clinical outcomes in patients with edentulism of the posterior mandible.

Materials and Methods

Study design

This was an open, prospective and multicentre study, evaluating the Osseospeed™ TX implants (ASTRA TECH Implant System, DENTSPLY Implants, Mölndal, Sweden) with an early loading protocol and a 12-month follow-up. In total, 45 patients aged 20–75 years with partial dentition in the posterior region of the mandible were enrolled. The primary objective was to evaluate marginal bone level alteration by radiological assessments 1 year after loading. Implant survival, clinical assessment and safety were also evaluated.

The treatment included a one-stage implant and abutment installation, loading of the implants after 6–8 weeks of healing and follow-up at 6 and 12 months after loading. Each subject was treated with two or three splinted implants.

The three centres that participated in this clinical study were: Department of Prosthodontics, Peking University School and Hospital of Stomatology, Beijing, China; Department of Prosthodontics, Sun Yat-sen University, Hospital of Stomatology, Guangzhou, China; and Department of Prosthodontics, Ninth People's Hospital affiliated to Shanghai Jiaotong University, Shanghai, China. All three centres adopted the same eligibility criteria (Table 1) and clinical variables. Prior to the commencement of the study, a meeting was held at each centre and appropriate relevant training was given to all investigators.

The study was approved by the relevant Ethics Committees at the three universities. The subjects were given verbal and written information about the study. An informed consent form was signed by the subjects

and the study doctors prior to all study related procedures.

Implant placement

The subjects were given antibiotic prophylaxis prior to surgery. If the patients were not allergic to penicillin, they were asked to take amoxicillin or cephalosporins orally half an hour before the surgery. If the patients were allergic to penicillin, roxithromycin or other macrolide antibiotics were prescribed. The surgical procedure was performed under local anaesthesia, usually block anaesthesia of the inferior alveolar nerve and/or local infiltration anaesthesia. The surgery followed the guidelines for a one-stage procedure described in the Manufacturer's Manual for the implant. Implants 8–17 mm in length and 3.5–5.0 mm in diameter were permitted. Two or three implants were installed and healing abutments or Uni-abutments with ProHeal Cap (DENTSPLY Implants, Mölndal, Sweden) were connected. The peri-implant mucosa was sutured and closely adapted around the abutments. Immediately after implant placement and abutment connection, intra-oral radiographs of the implants were taken. Primary stability was assessed manually using a torque wrench.

The implant sites were allowed to heal for 6 weeks. To avoid overloading of the implants, the subjects were instructed not to wear any removable prosthesis over the implants during the healing phase and to avoid chewy food. Subjects were instructed to use chlorhexidine rinse twice daily during the healing phase. No other oral hygiene measures of the implant sites were allowed during the first 10–14 days. Two weeks after implant placement, the subjects returned to the clinic for post-operative control and removal of sutures.

In cases where primary implant stability was not reached (less than 15 Ncm), the patient was treated with a conventional two-stage approach (i.e. submerged healing in combination with an extended healing period of 3 months before loading of the implants). These patients were not excluded from the study, but followed up for the full course of the study. However, these

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1 Aged 20–75 years at enrolment;	1 Earlier graft procedures in the study area;
2 History of edentulism in the posterior mandible, Kennedy classes I or II for at least 4 months, and the last natural tooth in function is canine or first bicuspid;	2 Current need for pre-surgical bone or soft tissue augmentation in the planned implant area;
3 Neighbouring tooth to the planned bridge must have natural root;	3 Uncontrolled pathologic processes in the oral cavity;
4 Presence of natural teeth, partial prosthesis and/or implants in the opposite jaw in contact with the planned bridge;	4 History of radiation therapy in the head and neck region;
5 Deemed by the investigator to have adequate bone height and a bone width of minimum 5.5 mm;	5 History of chemotherapy within 5 years prior to surgery;
6 Deemed by the investigator as likely to present an initially stable implant situation.	6 Systemic or local disease or condition that could compromise post-operative healing and/or osseointegration;
	7 Uncontrolled diabetes mellitus;
	8 Corticosteroids or any other medication that could influence post-operative healing and/or osseointegration;
	9 Smoking more than 10 cigarettes/day;
	10 Present alcohol and/or drug abuse.

implants were excluded from the final analysis.

Permanent restoration and follow-ups

Approximately 6 weeks after implant placement, the subjects returned to the clinics and dental impressions were taken. The permanent restoration (splinted porcelain fused to metal crowns) was attached approximately a week after the dental impression was taken (Loading). Restorations were screw retained on the Uni-abutments in all cases.

The primary outcome measurement: marginal bone level alteration assessment

Marginal bone levels (MBLs) were evaluated from intra-oral radiographs, taken after surgery, at loading, and at the 6 and 12 months follow-up visits. MBLs were expressed as the distance from the reference point on the implant to the most coronal bone-to-implant contact on the mesial and distal aspect of the implant. To ensure reproducibility between the examinations, radiographs were taken with a parallel technique using commercially available film holders whenever possible. An external radiologist at the University of Gothenburg in Sweden, independent from the investigational team, evaluated all the radiographs taken in the study. The

precision measurement of radiological analyses was not done in this study, however, it has already been done in one of their previous studies (Wennstrom et al. 2004), in which the mean difference between two readings was only 0.04 mm.

The secondary outcome measurement: implant survival rate

Survival rate was defined as the percentage of implants in a study or treatment group that are still present in the mouth. The implant survival rate was calculated 12 months after loading.

The secondary outcome measurement: clinical assessments

The condition of the soft tissue was assessed immediately after loading, and at 6 and 12 months post-loading. Presence or absence of plaque was evaluated by visual inspection or with an explorer as detectable or non-detectable. Condition of the peri-implant mucosa was evaluated by assessment of bleeding on probing (BoP) and measurement of probing pocket depth (PPD). All variables were measured on four surfaces (mesial, distal, buccal and lingual). The proportion of surfaces that showed presence of plaque and BoP were presented on a subject level. The mean PPD was calculated for each implant.

Statistical considerations

General aspects

Results were presented by descriptive statistics, e.g. subject number (N), mean, median, standard deviation (Std), range (minimum, maximum) and frequency tables. No covariates were judged to influence the outcome of the primary or any of the secondary variables. The statistical software packages used were IBM SPSS Statistics for Windows, Version 22.0 (SPSS Inc., Chicago, IL, USA), and Microsoft Excel 2010.

In cases where only one side of the implant was readable on radiographs, the MBL was expressed as either the mesial or the distal value, whichever was evaluable.

Taking the dependency within patients into consideration, the data were analysed on a patient level implying that the mean over all implants by patient was used as the statistical unit. The study was not designed to investigate inter-centre differences. Consequently, if there was no statistical difference between centres, the data from different centres would be pooled for further analyses. If there were significant differences, the results from each centre would be analysed separately.

Sample size determination

The sample size calculation was performed “post hoc”. At the beginning of this study, we determined the sample size according to some previously published articles (Makkonen et al. 1997, Schliephake et al. 2012) and we chose the sample size as large as possible (15 patients per centre). After the study, when we got the standard deviation, we calculated the sample size using the following formula:

$$n = \left[\frac{(u_\alpha + u_\beta)\sigma_\alpha}{\delta} \right]^2,$$

where u_α represents the critical value when $\alpha = 0.05$, which is 1.96. u_β represents the critical value when the power of the study $(1 - \beta) = 0.9$, which is 1.282. As this study was self-controlled, δ was 1. σ_α is the standard deviation (0.417 mm at 6-month follow-up and 0.411 mm at 12-month follow-up). Accordingly, the calculated minimum sample size was two patients per centre, much

less than that we actually determined. Certainly, there are risks and limitations if the sample size was determined “post hoc” like we did in this study. If the final standard deviation is too large or there are some patients dropping out, the whole study might fail because of inadequate sample size.

Results

According to the inclusion and exclusion criteria (Table 1), 45 patients (15 patients from each centre) were enrolled and 107 implants were placed. The patient characteristics are shown in Table 2. The implant length ranged from 8 mm to 13 mm and the diameter of the implants ranged from 3.5 mm to 5.0 mm. Five study implants in two patients were excluded from the analysis due to prolonged healing times. As a consequence, a total of 102 implants in 43 patients were followed and analysed in this report. Nine subjects had a history of periodontitis and were controlled at the time of surgery. One subject had bruxism. One subject with three implants failed to return to the clinic for the 12-month follow-up visit as

the subject had moved to another city for business, while we were informed that the three crowns on the three implants were still in function through a telephone conversation. This patient was registered as lost to follow-up. All other implants were examined and analysed.

The implant survival rate 12 months after loading was 100%. During the bone-remodelling period (i.e. after surgery but before loading), there was a slight decrease in mean \pm std MBL of 0.24 ± 0.675 mm. At 6 and 12 months after loading, the MBL increased by a mean \pm std of 0.04 ± 0.417 mm and 0.08 ± 0.411 mm respectively (Table 3).

There was no difference of the mean MBL alteration among each centre when the comparison was made on a patient level. Therefore, we pooled the data from the three centres for further analysis.

For the clinical assessment, plaque existed in 27.9% of subjects at loading, in 18.6% of subjects at 6-month follow-up and in 21.4% of subjects at 12-month follow-up (Table 4). The mean change in PPD in all subjects from loading to 12 months was 0.38 mm (Fig. 1). BoP occurred in 23.3% of subjects at loading, in 27.9% of subjects at 6 month follow-up and in 31.0% of subjects at 12-month follow-up (Table 4). Only two

subjects experienced loose bridge screws. No other safety issues related to the dental implants were reported.

Discussion

This study assessed early loading of an OsseoSpeed™ implant system in the partially dentate posterior mandibles. In our patients, we observed a mean marginal bone gain (our primary outcome measure) of 0.08 ± 0.411 mm. In terms of our secondary outcomes, the implant survival rate was 100%, and positive clinical assessments, such as healthy soft tissue, were obtained 12 months after loading. In addition, no safety issues related to the dental implants were reported and only two subjects experienced loose bridge screws.

The results of this study using an early loading protocol are comparable with, or even better than, the results in many previously reported studies obtained using conventional

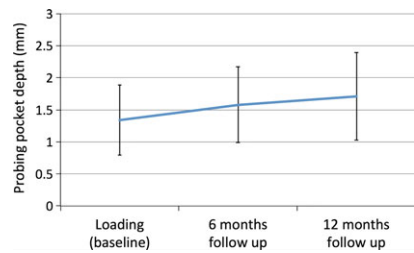


Fig. 1. Probing pocket depth (PPD).

Table 2. Patient characteristics

Patients (n)	45
Age (years)	
Mean	56
Min	34
Max	72
Gender (%)	
Female	58
Male	42
Edentulism (months)	
Mean	64
Min	3*
Max	396
Reason for edentulism (%)	
Caries/Endodontic	74.8
Periodontic	19.6
Trauma	0.9
Other	4.7
Nicotine use (%)	
Non-smoker	84.4
Ex-smoker	6.7
Habitual smoker	4.4
Occasional smoker	4.4
Oral examination (%)	
Abnormal jaw relations	2.2
Periodontitis	20.0
Bruxism	2.2

*Four months edentulism at the time of surgery.

Table 3. Marginal bone level (MBL) change (in mm) from loading (baseline), patient level

	Loading (baseline) – 6 months	Loading (baseline) – 12 months
N (patients)	39	38
Mean (mm)	0.04	0.08
SD (mm)	0.417	0.411
Min (mm)	-0.60	-1.30
Median (mm)	0.00	0.06
Max (mm)	1.83	1.08

Table 4. Plaque and bleeding on probing (BoP) for each patient at loading, and at 6- and 12-month follow-up

	Loading		6-month follow-up		12-month follow-up	
	Count	(%)	Count	(%)	Count	(%)
Plaque						
No	31	72.1%	35	81.4%	33	78.6%
Yes	12	27.9%	8	18.6%	9	21.4%
BoP						
No	33	76.7%	31	72.1%	29	69.0%
Yes	10	23.3%	12	27.9%	13	31.0%

loading protocols in the posterior mandible (Barewal et al. 2012, Palarie et al. 2012, Guljé et al. 2013, Guljé et al. 2015). In a previous study, which also used the OsseoSpeed™ implant system, a mean marginal bone gain of 0.02 mm was obtained using conventional loading (Guljé et al. 2013). There are two similar studies published recently using the same implant system. One evaluated the early loading protocol in the anterior region using narrow diameter implants (3 mm) (Maiorana et al. 2015). The other evaluated an early loading protocol in the posterior mandible or maxilla using splinted short implants 6 mm in length (Han et al. 2015). Both reported minimal MBL loss (0.11 mm and 0.13 mm respectively) after one-year loading. Because early loading of posterior single implants greatly increases the risk of failure, it is hard to compare the use of splinted implants and single implant used posteriorly.

When the implants are splinted, it becomes hard to evaluate the implant mobility individually. In this case, we used other criteria such as peri-implant radiolucency and clinical signs and symptoms to estimate the implant survival. Survival rate has quite a different meaning compared with success rate. Survival rate is a part of survival analysis, indicating the percentage of implants in a study or treatment group that are still in function for a given period of time after treatment. Success rate has many strict criteria as described in (Albrektsson et al. 1986). As 1-year follow-up was not long enough to adequately observe implant failure, we did not evaluate the success rate in this study. Therefore, we did not use the survival rate as the primary outcome measurement. Instead, we used the marginal bone level alteration.

It is believed that smoking and the amount of cigarette consumption has a statistically significant detrimental effect on implant survival (Renvert & Polyzois 2015). Therefore, patients enrolled in our study were strictly restricted to a maximum of 10 cigarettes per day. Additionally, as periodontitis also directly influences long-term implant survival (Meyle et al. 2014), a careful periodontal examination was performed before implant placement for every

patient. Systemic periodontal therapy was performed if the patients were found to have periodontal problems.

One important consideration for the success of early loaded implants is adequate implant stability. Implant stability is divided into two stages: primary stability, which mostly comes from mechanical engagement with cortical bone, and secondary stability, which offers biological stability through bone regeneration and remodelling (Meredith et al. 1998). In this study, we choose an implant system with a tapered apex design, which facilitates the entrance of the implant into the drilled osteotomy. This allows for minimal preparation of the implant site and increases primary stability. On the other hand, to get enough implant stability at the early loading phase, we splinted the two or three implants together in one edentulous region. It has been reported that splinting of implants could reduce initial bone tissue strains in comparison with the use of non-splinted implants (Akça et al. 2007) and that splinted crowns had significantly less abutment displacement than non-splinted crowns (Yilmaz et al. 2014).

The gain in MBL in this study might be partially due to the newly developed implant design concepts, including: (1) chemically modified implant surfaces, (2) platform switching design, (3) MicroThread design and (4) conical seal design. These four design features have a number of advantages. Firstly, the implants used in this study have a fluoride ion modified surface, which was previously found to improve bone-to-implant contact during the early healing stage (Cooper et al. 2006, Abrahamsson et al. 2008, Monjo et al. 2008). Secondly, the platform switching concept is believed to reduce the inflammatory cell infiltrate (Luongo et al. 2008), and shift the maximum biomechanical stress towards the central axis of the implant (Degidi et al. 2008). A large number of studies have shown higher levels of bone preservation with wider platforms (Canullo et al. 2010, Annibali et al. 2012, Telleman et al. 2012). Thirdly, the MicroThread design, which refers to minute threads on the implant neck, reduces the peak stress forces in the

coronal bone (Schrotenboer et al. 2008). Fourthly, the conical seal design has the inner conus inside the implant and the outer conus on the abutment. The connection between the implant and abutment is therefore located below the marginal bone level, transferring the load deeper down in the bone and reducing peak stress forces between the bone and the implant (Norton 2006, Harder et al. 2010). In the light of these previous studies, it is not surprising that patients in our study had maintained MBLs and good clinical outcomes following an early loading protocol using these newly designed implants.

There were some limitations to the study. Firstly, this was not a randomized controlled trial. If it had been, the findings would have been of a higher level of evidence. Randomized controlled trials comparing early loaded implants to conventionally loaded ones are required. Secondly, as all the implants were splinted, it was difficult to evaluate individual implant mobility. Thirdly, since this study was conducted only in a Chinese population, the generalizability of this study could be questioned. Although there is no direct evidence indicating that the implant clinical performance will differ among ethnic groups, the diversity of dental arch anatomy (Kook et al. 2004, Patil et al. 2013), bone density (Morton et al. 2003, Conradie et al. 2014), masticatory force (Shinogaya et al. 2001) and dietary pattern (Wahlqvist 2005) has been reported to be existing among different ethnic groups. Therefore, the potential difference of implant clinical performance among ethnic groups may exist.

Within the limits of this prospective multicentre study, we can conclude that early loading of splinted implants with a fluoride modified nanostructure surface and a tapered apex design in the healed posterior region of the mandible provides a safe and effective treatment. However, these results must be confirmed in future studies with a longer follow-up time.

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Clinical Relevance

Scientific rationale for the study: Whether the early loading protocol can routinely be used remains unclear, especially in the posterior jaws, where the occlusal forces are much higher than they are in the anterior jaws. We studied the 12-

month clinical outcome of splinted implants using an early loading protocol.

Principal findings: We observed a mean marginal bone gain of 0.08 mm after 12 months using an early loading protocol, which is

comparable to previous studies using conventional loading techniques.

Practical implications: The early loading of splinted implants can be safely used for treating patients with partial edentulism of the posterior mandible.