CLINICAL ORAL IMPLANTS RESEARCH

Jie Han Xiao Zhang Zhihui Tang Li Zhang Dong Shi Huanxin Meng A prospective, multicenter study assessing the DENTSPLY Implants, OsseoSpeed[™] TX, length 6 mm in the posterior maxilla and mandible: a 1-year follow-up study

Key words: early-loading, implant, marginal bone loss, periodontitis, posterior, short

Abstract

Objective: The aim of this multicenter study was to prospectively assess clinical and radiographic outcomes of short implants (length 6 mm) in the posterior region and early-loading with splinted-fixed dental prostheses.

Materials and methods: A total of 45 subjects (77.8% with chronic periodontitis) were enrolled at three study sites. In total, 95 implants (diameter 4 mm, length 6 mm; OsseoSpeed[™] 4.0 S; DENTSPLY Implants; Mölndal, Sweden) were placed, two or three implants per subject, using one-stage surgery and loaded with a screw-retained splinted ceramic-fixed prosthesis 6 weeks later. Clinical and radiographic examinations were performed preoperatively, post-surgery, at loading, and 6 and 12 months after prosthesis placement.

Results: Four implants failed before loading; all other implants showed favorable clinical and radiographic findings throughout the observation period (1-year survival and success rate: 95.8%). Postoperative pain and swelling were negligible. Mean changes in marginal bone levels measured from loading were minimal (0.01 ± 0.37 and -0.13 ± 0.46 mm after 6 months and 1 year, respectively). Bone loss less than 1.00 mm was found in 77.5% implants, and bone gain was found in 15.5% implants. Probing depth change less than 2 mm was found in 98.7% of the implants between loading and 1-year follow-up. Prosthetic complications included one ceramic veneer chipping.

Conclusion: One-year data indicate that the use of 6-mm-long implants is a predictable treatment. This provides a good treatment option in situations with limited bone height in posterior regions.

Treatment with endosseous titanium implants present high long-term success rates for the rehabilitation of edentulism and partial dentate situations. Implant success depends on several different factors, such as the anatomy of the host site, vertical and horizontal dimensions, and the quality of the bone (Watzek & Ulm 2001). Jemt & Lekholm (1995) reported that implant failures in the edentulous maxilla correlated significantly with bone quality and the use of 7-mm implants. Other studies (Friberg et al. 1991; Jaffin & Berman 1991) have reported low survival rates for short implants. However, all these studies describe implants with machined-made surface geometries, and implants placed in posterior areas where the chewing forces are higher than in anterior regions. Geckili et al. (2014) found that both

implant length and position influenced implant success, with lower success rate for short and maxillary implants. The general concept has so far been that only implants of a minimum of 12 mm should be inserted in "poor quality" bone in the posterior maxilla (Misch 2007).

In a multicenter study (ten Bruggenkate et al. 1998) evaluating 6-mm non-submerged dental implants, only 1 of 208 implants placed in the mandible was lost compared to 6 failures in 45 implants placed in the maxilla. The survival rates were 99.5% and 86.7%, respectively, after a 7-year follow-up period. Four of these 7 lost implants were lost during the healing phase. Two multicenter studies on ITI implants (Buser et al. 1997; Brocard et al. 2000) analyzed the survival and success rates of implants of different lengths. No significant

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difference was found between 8-, 10-, and 12-mm implants with rough surface geometries. The restrictions for the use of longer endosseous oral implants are more common in the posterior regions of the maxilla and the mandible because of the lack of sufficient bone volume, especially in patients with advanced periodontitis, which leads to reduced bone quantity and/or quality. Instead of using different challenging surgical techniques such as bone augmentation, or intra- or parasinus procedures, to increase the bone height, a short implant would be desirable. The advantage of using short implants is a reduction in the number of treatment procedures, treatment time, and morbidity. Recent clinical studies (Fugazzotto et al. 2004; Renouard & Nisand 2005) using short implants with rough surface morphologies, designed for high initial stability, reported survival rates of about 95%. This correlates with the survival rate reported for implants in general, placed under similar conditions (Berglundh et al. 2002).

The implant surface appearance is a major determinant in the performance of short implants, and for the success of osseointegration. Numerous pre-clinical and clinical studies in both animals and humans have demonstrated a positive correlation between the surface characteristic of the implants and the degree of osseointegration (Junker et al. 2009; Wennerberg & Albrektsson 2009, 2010). The OsseoSpeed[™] Implant (DENTS-PLY Implants) is a screw-shaped and self-tapping implant with a chemically modified moderately rough surface. These features lead to increased bone formation and stronger bone-to-implant bonding at shorter healing times (Ellingsen & Lyngstadaas 2003; Ellingsen et al. 2004; Berglundh et al. 2007).

This study was designed as an open, prospective, consecutive, 1-year follow-up, multicenter study, evaluating the use of the OsseoSpeedTM implant, 6 mm in length (OsseoSpeedTM 4.0 S; DENTSPLY Implants) in the posterior maxilla and mandible, in an earlyloading protocol with splinted-fixed dental prostheses. The primary objective of this study was to evaluate marginal bone level alteration, by radiological assessments, 1 year after loading. The secondary objectives of the study were to evaluate implant survival rates, condition of peri-implant mucosa, pocket depths, and safety in a Chinese population.

Material and methods

This was a multicenter study with three centers in China. At each center, up to three

clinicians performed the surgery and clinical observations.

Patient selection

The screening procedure included a clinical and radiographic examination (CBCT), and full-mouth periodontal chartings were recorded. Standardized professional periodontal treatments were undertaken before the implants were inserted in patients with periodontitis. Subjects fulfilling all of the inclusion criteria and none of the exclusion criteria were informed orally and in writing about the study and signed the informed consent form. The study protocol had been approved by the medical ethics committee of Peking University Medical Center.

Inclusion criteria

For inclusion in the study, subjects had to be between 20 and 75 years of age at the time of enrolment, be in good general condition, and in need of 2–3 implants in the posterior area of the upper or lower jaw. A history of edentulism in the study area of at least 4 months was another prerequisite, as was the presence of occlusal contacts in the opposing jaw, and natural tooth root(s) adjacent to the planned bridge/crowns. The bone height, as well as the width, should be at least 6 mm.

Earlier graft procedures in the study area, uncontrolled diabetes mellitus, smoking more than 10 cigarettes/day, present alcohol and/or drug abuse, and pregnancy were all regarded as criteria for study exclusion.

Treatment procedure

Surgical procedures

Implant surgery was performed following a standard one-stage protocol, according to the manufacturer. The surgical procedure was performed under local infiltration anesthesia. After a crestal incision and reflection of buccal and lingual/palatal flaps, two or three OsseoSpeed[™] implants 6 mm in length with a diameter of 4 mm were placed in each patient. To improve the situation with reduced bone support in the spongious bone area, a modified drilling protocol was performed by reducing the diameter of the final drill in the standard sequence. The final drill size was recorded. In cases of a small dehiscence, autologous bone particles, harvested in the bone area close to the implant site, could be used. No other graft material was allowed. Maximum torque used during implant installation was set according to DENTSPLY Implants' surgical manual, and primary implant stability was assessed

clinically through torque insertion measurements at placement and at later time points by manual mobility testing. Flaps were sutured, and intraoral radiographs and clinical photographs were obtained. The implants were left in a transmucosal position during the 6-week healing period. Postoperative treatment included a 0.12% chlorhexidine rinse twice daily for 14 days. Other medication, which was considered necessary for the subject's safety and well-being, was given when indicated. To avoid excessive loading of the implants during the initial healing period, the patients were advised to use a soft diet from implant placement (IP) until the delivery of the provisional prosthetic restoration.

Prosthetic procedures

One week after IP, a follow-up visit was scheduled for suture removal and review of the healing process. Adverse events and adverse device effects were recorded throughout all the visits. Five weeks after IP, implant stability was manually examined. Impressions at the abutment level were made for fabrication of the screw-retained temporary polymer-ceramic restoration, which was delivered 6 weeks following IP. The definitive screw-retained metal-ceramic prostheses were delivered 6 months after loading with the provisional prosthesis.

Clinical examination

An oral examination evaluating the presence of plaque, probing pocket depth (PD), and bleeding on probing (BOP) was performed at 6 weeks after IP and at 1, 6, and 12 months after temporary restoration (loading baseline). The presence of plaque, PD, and BOP was scored at four sites for each implant (mesial, distal, buccal, lingual/palatal). Implant stability was evaluated manually. If presence of plaque was noted, the subject was re-instructed in oral hygiene. Full-mouth periodontal chartings were recorded once again at the 12-month visit.

Radiographic evaluation

At 6 weeks when the provisional prosthesis was placed, and at 6 and 12 months after loading, digital peri-apical radiographs were taken with a paralleling technique, using film holders. The threaded profile of the implant, both mesially and distally, had to be clearly visible. An external radiologist, independent from the investigational team and DENTSPLY Implants evaluated all radiographs. Marginal bone level alteration was determined from radiographs and expressed as the change in distance from a reference point on the implant (the junction between the machined bevel and the microthreaded portion) to the most coronal bone-to-implant contact on the mesial and distal aspect of the implant. The distance was recorded to the nearest 0.1 mm using a $7 \times$ magnifying device. In cases where the implant reference point was below the margin of the crestal bone, the value was considered as zero. Bone loss was presented as the mean values for distal and mesial changes from baseline for each implant and each time point.

Statistical analysis

The main analysis was performed on marginal bone level alterations 1 year after implant loading with temporary restoration. Results were presented by descriptive methods, for example, mean, median, standard deviation (SD), and frequencies. For continuous data, a mean value was calculated per patient. Thus, probing depths were presented as the mean of all measurements on four sides of the implant. For bleeding, a patient was considered as "bleeding" if at least one site was "bleeding", otherwise the patient was considered as "non-bleeding".

Results

A total of 45 subjects (17 men and 28 women, mean age 53 years, range 26–73 years) were included in the study (Table 1). In total, 95 implants were placed. The first patient was enrolled in February 2011 and the last patient in February 2012. A total of 95.6% of the patients were non-smokers, and 77.8% were diagnosed with periodontitis. All patients completed the 1-year evaluation period.

Table 1. Study population

Patient characteristics	
Patients (n)	45
Age (years)	
Mean	53
Min	26
Median	53
Max	73
Gender	
Female	28
Male	17
Edentulism prior to treatment (months)	
Mean	74
Min	4
Median	72
Max	240
Nicotine use (%)	
Non-smokers	95.6
Smokers	4.4
Oral examination (%)	
Abnormal jaw relations	8.9
Periodontitis	77.8
Bruxism	4.4

Implant survival

Any removed implant was considered as a failure, regardless of reason(s) for removal. Primary stability was achieved in 96.8% of the implants during surgery. At 5 weeks after surgery, at the time of impression taking, five implants were detected unstable, including one implant that rotated when removing the Uni-Abutment carrier. After prolonging the healing period to 5 months, the rotated implant achieved osseointegration and a final restoration was delivered. No implant was lost after loading. This indicated a survival rate of 95.8% (91/95).

Radiographic bone levels and marginal bone level changes

Marginal bone levels (MBL) were analyzed by radiographs taken at surgery (IP), at 6 weeks when the provisional prosthesis was placed (loading baseline, T = 0), at 6 months (T = 6), and at 1 year (T = 12) after loading (Table 2). The mean bone level changes from IP to T = 0 and T = 12, T = 0 to T = 6 and T = 12 are shown in Table 3. The frequency of implants experiencing bone loss >1.00 mm between T = 0 and T = 12 was 7.0%. No bone loss (including bone loss less than 1.00 mm) was found in 77.5% of the implants, and bone gain was found in 15.5% (Fig. 1).

Soft tissue status

According to the full-mouth periodontal charting of the 35 subjects with chronic periodontitis at the initial examination, 28.6% patients presented PD \geq 5 mm in more than 20% sites and the mean BOP score was 91.6%. Bleeding index more than 3 was presented in 40.8% of the sites. And 40% of the patients presented BI \geq 3 in more than 30% sites (Table 4).

Probing depth was measured at time of loading (T = 0), 1 month, 6 months, and 1 year thereafter. The mean PD value of the four sites of the implants was calculated. Probing depth change in 98.7% implants was within 2 mm and 82.3% within 1 mm from loading to 1-year follow-up (Fig. 2).

The proportion of implants with BOP^+ is shown in Fig. 3. The proportion of implants with plaque was 42.2%, 55.6%, 43.3%, and 21.8%, respectively.

Adverse events

Besides four implant failures, one ceramic veneer fracture occurred during the follow-up period.

Discussion

This study showed that when placing two or three implants of 6 mm length and 4 mm diameter in the posterior region, restored with a splinted-fixed dental prosthesis at 6 weeks post-surgery, predictable clinical and radiographic outcomes after 1 year of loading was accomplished, thus offering a reasonable alternative to higher risk, more time-consuming, and costly treatment alternatives. Early failure occurred for 4 of 95 implants. No implant was lost after loading. Besides one ceramic veneer fracture, no further mechanical or biological complications were encountered during the 1-year follow-up. The 1-year implant survival rate was 95.8%.

Patients in the present study were treated under local anesthesia with a one-stage implant procedure. Few postoperative complications and no relevant side effects were observed, and most patients reported negligible pain and swelling after implant surgery, confirming the minimal invasiveness of 6-mm implant placement. When using short implants, more advanced treatments can be avoided, treatment time and cost can be reduced, all for the benefit of the patient.

Meta-analyses of Telleman et al. (2011) and Pommer et al. (2011) confirmed the high survival rate of implants shorter than 10 mm. As to the very short implants, as short as 6 mm, the results of the present study are comparable with published reports. In a prospective 2-year follow-up cohort study of SLActive 6 mm implants, Rossi et al. (2010), a survival rate of 95% and a mean marginal bone loss of 0.23 mm 1 year after loading were reported. Pieri et al. (2012) reported the treatment outcomes for 6-mm-long implants (OsseoSpeedTM 4.0 S) placed in posterior

Table 2. Marginal bone levels

Implants	Surgery	Loading	Loading +6 months	Loading +12 months
N	86*	78*	91*	84*
Mean	0.11	0.18	0.18	0.28
Std	0.32	0.44	0.34	0.45
Min	0.00	0.00	0.00	0.00
Median	0.00	0.00	0.00	0.03
Max	1.75	2.05	1.60	2.15

*Number of radiologically interpretable implants at each visit.

Table 3. Marginal bone level changes from implant placement/loading

MBL average (mm)	IP to $T = 0$	T = 0 to $T = 6$	T = 0 to $T = 12$	IP to <i>T</i> = 12
N	72*	78*	71*	75*
Mean	-0.09	0.01	-0.13	-0.20
Std	0.30	0.37	0.46	0.44
Min	-1.85	-1.60	-1.50	-2.15
Median	0.00	0.00	0.00	0.00
Max	0.60	1.45	1.35	0.80

*Number of radiologically interpretable implants at each visit.

atrophic mandibles. Implants were placed submerged according to a two-stage protocol and loaded 5–6 months later. Two-year survival and success rates were 96.8%, and the mean change in marginal bone levels was 0.51 ± 0.38 mm at the 1-year follow-up.

In a 1-year multicenter study carried out by Guljé et al. (2013), OsseoSpeedTM 4.0 S implants of 6 mm were placed in the posterior region and restored with a screw-retained splinted-fixed prosthesis after 6–7 weeks. The 1-year survival rate was 97%. Mean marginal bone gain around the 6 mm implants was 0.06 ± 0.27 mm after 1 year of function. There was an initial bone loss between placement and loading 6 weeks later, with a mean loss of 0.23 mm for the 6 mm implants.

In the present study, the marginal bone levels were stable during the whole observation period. There was only a mean of 0.09 mm initial bone loss between implant placement and loading 6 weeks later. The mean bone loss during the first year after loading was 0.13 mm. The frequency of implants experiencing no bone loss (including bone loss less than 1.0 mm) was 77.5%. Moreover, bone gain was found in 15.5% implants. This minimal bone loss could be due to the neck design of the implant with a platform switch and chemically modified surface roughness up to the neck of the implant, which lead to increased bone formation and stronger bone-to-implant bonding at shorter healing time (Van de Velde et al. 2010).

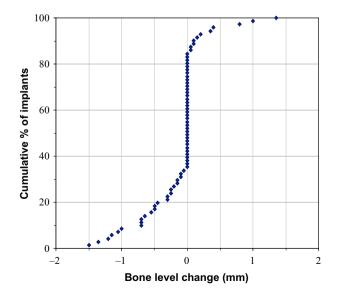


Fig. 1. MBL cumulative plot from loading to 1 year after loading.

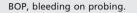
Previous studies suggested that short implants can achieve short-term clinical results similar to, if not better than, longer implants placed in augmented bone; however, surgeons have used short implants with wider bodies to compensate for the lack of implant height (Cannizzaro et al. 2009; Felice et al. 2009: Esposito et al. 2011). It remains uncertain whether this "compensation" is actually needed; however, the present study suggests that short implants with a conventional diameter perform well in 1-year loading period. It should be noted that the long-term prognosis is yet unknown and the follow-up will continue up to 3 years after loading in the current study.

In the present study, four early implant failures occurred and one implant rotated at 5 weeks post surgery. Poor bone quality caused by severe periodontitis and systemic factors that decrease vascularity or contribute to delayed wound healing, such as those seen in smokers and elderly patients, may have contributed to the failing of osseointegration formation in 6 weeks post IP. This implant failure pattern is consistent with the results of other long-term clinical studies of standard-length implants used in larger bone volumes and suggests that a low frequency of additional implant failures might be expected in subsequent years (Romeo et al. 2006; Cecchinato et al. 2008).

Although patients were subjected to a strict oral hygiene regime, the mean indices for plaque and bleeding on probing were shown to have a higher tendency during the 1-year evaluation when compared with the study of Guljé et al. (2013), in which the

Table 4. Periodontal status of the subjects with chronic periodontitis at the initial examination

Periodontal status			
Chronic periodontitis (<i>n</i>)	35		
(%)	77.8		
PD ≥5 (mm) sites ≥20%	10 patients, 28.6%		
BOP+	91.6%		
BI ≥3 (%)	40.8		
BI \geq 3 sites \geq 30%	14 patients, 40%		



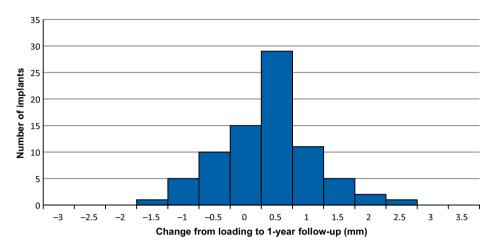


Fig. 2. Frequency of probing depth change from loading to 1 year after loading.

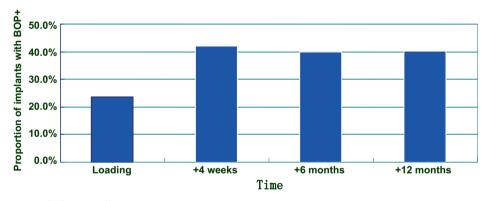


Fig. 3. Bleeding on probing.

same criteria were used. Probably the subject population could explain the difference. In the present study, 77.8% of the subjects were diagnosed with periodontitis, in which 28.6% were severe periodontitis patients. The mean BOP score was 91.6% before treatment. The periodontal condition was much worse than in other studies. All subjects received standardized professional periodontal treatment before implant insertion. After treatment, the mean BOP score decreased to 45.1% and

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there was no site with probing depth more

than 5 mm. Moreover, the mean probing

depth of the observed implants is 2.3 mm at

the 1-year follow-up after loading, which is

not different from what is reported in other

studies, and is accompanied by healthy peri-

implant soft tissues. This is most probably

due to the fact that all these patients received

periodontal treatment before implantation.

Considering the limited portion of the

implants engaged in bone, high prevalence of

periodontitis in Chinese population and relatively poor oral hygiene compared to Western people, the authors suggest proper professional periodontal treatment before implantation and strict follow-up and mandatory supportive periodontal treatment to reduce the risk of excessive marginal bone resorption, including peri-implantitis, in the long term.

Clinical implications

The results of this study indicate that the use of 6-mm-long implants was a predictable treatment also in patients with chronic periodontitis. This provides a good treatment option in situations with limited bone height in posterior regions, as short implants may offer greater simplicity and safety compared with bone augmentation procedures. However, long-term follow-up studies are required to confirm this, because ongoing remodeling of marginal bone around implants may be detected over longer follow-up periods, and the benefits of using short implants may be reversed by increasing failure rates after a few years of function. Considering the limited portion of the implants engaged in bone, high prevalence of periodontitis in the Chinese population and relatively poor oral hygiene compared to western people, a regular maintenance program is mandatory to reduce the risk of excessive marginal bone resorption, including peri-implantitis, in the long term.

Conclusion

One-year data indicate that treatment with 6mm-long implants is reliable when used to support FPD's in the posterior maxilla or mandible. Proper and necessary periodontal treatment before implant installation is mandatory for patients with periodontitis, and strict follow-up maintenance is a requisite for long-term success.

Conflict of interest

This multicentre study has been fully sponsored by DENTSPLY Implants. However, none of the researchers have any economical interest in the product related to this study or in the company.

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