Research manuscript

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Immediate and Early Loading of Hydrothermally Treated, Hydroxyapatite-Coated Dental Implants: 7-Year Prospective Study

Background:

Endosseous dental implants are currently a widely accepted treatment option for the replacement of missing teeth. The original protocol for treatment with implants proposed by Branemark advocates a waiting period of at least 3 months for osseointegration before loading the implant (1). However, more recently, immediate or early loading protocols have been successfully implemented (2–5). Restoring implants immediately or soon after placement is appealing to both patients and clinicians, due to the shortened treatment time required.
Esposito et al. defined 3 protocols for implant load timing: immediate loading implants, within 1 week from implant placement; early loading implants, between 1 week and 2 months; and conventional loading implants, after 2 months from implant placement (3).
Although some systematic reviews (6) have shown no convincing evidence of implant failure or bone loss associated with different loading times of implants, other meta-analyses (7,8) have shown a greater risk for implant failure when compared to conventionally loaded implants.
One of the main factors that has been evaluated as a determinant of success is primary stability of implants at placement.

The clinical success of immediate loading is dependent on many factors such as bone quality and quantity, implant number and design, implant primary stability, occlusal loading and clinician's surgical ability. Among these, implant primary stability is considered the most important (2).
Osstell® (Gothenburg, Sweden) is an electronic instrument designed to measure implant vibrations in response to resonance frequency analysis (RFA). This device measures the resonance frequency of a transductor attached to the implant body (9). The result of the measurement is the Implant Stability Quotient (ISQ), which corresponds to the hardness of the implant-bone connection (10).

The determinant and most accessible parameter to assess the primary stability is thought to be the implant insertion torque value. However, research has shown strong correlations among primary implant stability, IT values, and RFA's proprietary ISQ (Osstell®) (11).
Certain levels of IT and ISQ values have been reported to be suitable indicators for immediate (IT=35–45 N.cm; ISQ ≥70) or early (IT = 30–45 N.cm; ISQ = 40–70) loading of dental implants (12,13).

Factors such as implant surface characteristics and diameter have also been shown to influence primary stability: rough implant surfaces create more surface area for implant-bone contact (14). Therefore, implant design and surface also play a role in implant outcomes when loaded immediately or soon after placement.

In the human body, Hydroxy apatite (HA) forms 98% of the enamel, 77% of the dentin,70% of the cementum, and 60–70% of bone by weight (15,16). Synthetic HA is a calcium phosphate ceramic that is chemically similar to the HA and forms naturally in the human body. After implantation, it has been reported that calcium phosphate from the implant surface is released into the peri-implant region, which increases the saturation of body fluids and results in the precipitation of a biological apatite layer on the implant surface (17). Other researchers have reported increased adhesion and proliferation of bone-forming cells at the bone-HA interface in both animal (18) and human (19) models (20,21), which results in accelerated bone formation, maturation, and union between HA-coated implants and the surrounding bone (17).
The research on marginal bone stability around HA-coated implants often lack adequate follow-up to substantiate the reported clinical findings. Consequently, it remains unclear to what extent simply having a rougher surface may have contributed to the reported differences between HA-coated and uncoated implants in some studies conducted over the past 2 decades.

Long-term research is needed on the subject of clinical efficacy of plasma-sprayed HA-coated implants with different loading times.

The purpose of this prospective study was to evaluate the 7-year outcome of patients with immediate and early loaded single-tooth restorations supported by implants with plasma-sprayed, partially HA-coated surfaces.

Methods:

Study population:
Forty-two patients in need for 51 single implants were treated in in the Postgraduate Periodontics Clinic of Louisiana State University School of Dentistry. The 2-year results of this prospective randomized clinical study were published previously (22). The current study is a 7-year recall of the same patient population, in order to follow-up these implants. This protocol was approved by the LSUHSC-NO Institutional Review Board (IRB #). The study was conducted in accordance with international standards for health, safety, and good clinical practices, and was adhered to the patient privacy rules of the US Health Insurance Portability and Accountability Act of 1996.

Dental implants were randomly divided into two groups by the study coordinator: In group A, immediately loaded (implants to be loaded at the day of placement) and in group B, early loaded (implants to be loaded 3 weeks after placement).

Surgical Procedure:

All implants (Tapered Screw-Vent MP-1 HA, Zimmer Dental Inc, Carlsbad, CA) were placed in healed extraction sites with or without prior augmentation by periodontal residents (22). Implant placement was performed manually using a gauged insertion calibrated torque wrench. The IT value of each implant was recorded in the patient's chart. Bone density was evaluated by tactile feedback during surgery according to the Lekholm and Zarb (23) scale. RFA (Osstell®) assessment was immediately conducted after implant placement. Two readings were taken with the probe pointing toward the abutment from 2 different directions. An average of the 2 ISQ values was obtained and recorded in the patient's chart.

Provisionalization:

Patients in group A received a provisional restoration the day of surgery, loading the implant. Patients in group B received a healing abutment the day of surgery and returned in 3 weeks. At this time, a provisional restoration was placed, and the implant was loaded. Definitive prosthesis RFA was conducted at six months and 12 months of provisionalized loading. After one year of provisionalized function, a final impression was made for a computer-aided designed and computer-aided manufactured custom abutment, which was delivered with a definitive, cement-retained crown. Provisional and final restorations were placed by an implant restorative fellow in training.

Follow-up care:

Phase I Follow up (6 months – 2 years)

Continuous follow-up with periodic maintenance care was performed every 6 months for 2 years following implant placement. During these periodic follow-up appointments, clinical and radiographic evaluation was performed along with oral hygiene prophylaxis. At every appointment, oral hygiene was reinforced. If patients presented with any problems, they were advised on and issues were assessed. Periodontal parameters were assessed by clinical evaluation and standardized digital radiographs (Schick, Sirona Dental Systems, Inc, New York, NY), which were performed using a prefabricated template made for each patient. After this point, patients continued their visits in the periodontics department if any other ongoing treatments existed. Patients with no additional dental treatments at LSUHSC dental clinic, were guided to continue receiving oral hygiene prophylaxes elsewhere.

Phase II Follow up (at 7 years)

Seven years after the initiation of the study, all participants were contacted and followed up for a 7-year evaluation of the implants. At this follow-up appointment, clinical parameters and restorative complications were assessed by clinical exams and radiographic imaging. Efforts were made to mimic the previous angulations as much as possible for each radiograph image. Clinical and prosthetic evaluations were done at this appointment. All patients were educated with tailored oral hygiene instructions at the end of follow-up visits.

Evaluation of the bone level changes:

Radiographs were taken at 3 different time points; immediately after (baseline), 2 years and 7 years after implant placement. The radiographic images were imported into the ImageJ image processing software. ImageJ is an open source image processing program designed to analyze scientific multidimensional images (24). Using ImagJ, we measured mesial and distal bone level changes. To calibrate for potential differences in angulation between the radiographs, a known vertical distance which was constant in all subjects (distance from the platform to the first thread of the implant was chosen as reference. All mesial and distal bone levels were corrected using the reference measure (distance from the platform to the first thread of the implant).

Statistical analysis

Implant survival was the primary outcome of the study**.** Secondary study outcome consisted of peri-implant crestal bone level changes (measured from a fixed point on the implant to the area of first bone contact with the implant surface). Peri-implant crestal bone change was measured at 2 years and 7 years follow-up visits. Data on age, sex, bone quality (type 1, 2, 3, or 4) (23), implant location (mandible or maxilla), length and diameter, and prior augmentation of the site were collected. The baseline characteristics of participants were compared between two groups using two-sided t-student test and Fisher's exact test.

Outcome variables were summarized using descriptive statistics. A bivariate analysis was performed to show the distribution of the outcome in different groups. Multiple regression analyses were conducted to determine whether the independent variables were associated with bone loss. Predictors that, based on the available literature, are potentially associated to bone loss were considered in the full regression model. The predictors included in the full models were (a) type of bone (clinical), (b) location (mandible or maxilla), (c) implant diameter, (d) implant length, (e) load time (immediate or early), (f) augmented or non-augmented bone, (g) ISQ values, (h) participant age (years), and (i) participant gender. A separate regression model was fit for each outcome variable.

Participant confidentiality was protected at all stages of the study. participants' unique identifiers were used for the analysis.

Results:

A total of 42 subjects with 51 dental implants were initially enrolled in this study. One implant failed to maintain stability and was removed at 3 weeks. Forty patients (48 implants) were available for the 2-year follow up appointment. However, only 34 patients (14 males, 20 females with a total of 42 implants) were reached and completed the 7-year follow up visit (Table 1). The average time at follow-up was 6.6 years. The average age of patients was 53 years, ranging between 29 and 73 years. Patients had previously been randomly assigned to immediate loading group (group A), or early loading group (group B). Distribution of the implants based on various variables and study groups is summarized in Table 2.
Of all implants initially assigned to group A, 20 finished the 7-year follow-up. Whereas, 22 implants initially assigned to group B completed the 7-year follow-up.
No significant difference was observed regarding gender and age distribution between the two groups. No significant difference was detected in distribution of implant locations, types of bone in which implants are placed, implant length, implant diameter, and augmentation status of the bone between two groups (P-values > 0.05, Table 2)

Table 1: Patient Demographics

Gender	Total (Number)	Group A (Number)	Group B (Number)	P-value*
Female	22	10	10	0.681
Male	20	6	8	
total	42	16	18	

* Fisher's exact test

Group	Age (mean)	P-value*
A	50.75 ±10.61	0.285
B	55.11 ± 12.54	
total	52.93 ± 11.35	

* independent t-test

Table 2: Implant-related Variables

		Number of implants			
Variable		Total	Group A	Group B	P-value
Loading time		42	20	22	
Location	Maxilla	14	5	9	0.275
	Mandible	28	15	13	
Bone Augmentation Status	Augmented	12	7	5	0.499
	Non-Augmented	30	13	17	
Implant Length	8 mm	1	1	0	0.76
	10 mm	13	5	8	
	11.5 mm	17	8	9	
	13 mm	11	6	5	
Implant Diameter	3.7 mm	5	3	2	0.074
	4.1 mm	14	7	7	
	4.7 mm	17	10	7	
	6.0 mm	6	0	6	
Bone Type	Type I	0	0	0	0.717
	Type II	27	12	15	
	Type III	14	7	7	
	Type IV	1	1	0	

* Fisher's exact test

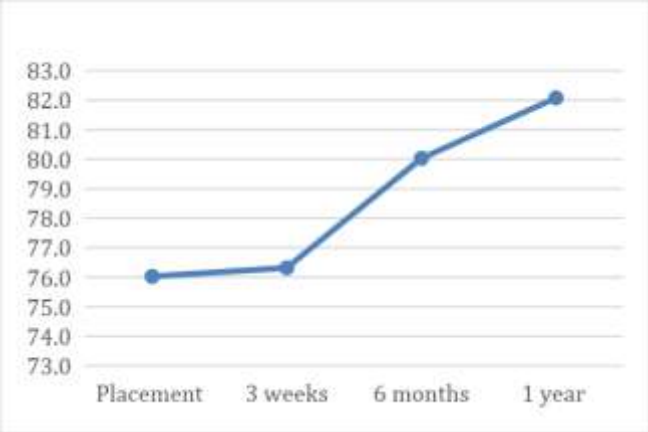
After 7 years of functioning, cumulative implant survival rate was 97.62% (n = 41/42) (group A = 100%, n = 20/20; group B = 95.45%, n = 21/22).

Implant Stability:

ISQ values and IT values were measured at the day of implant placement. ISQ values were acquired again at 3 weeks, 6 months and 1 year after implant placement. Table 3. shows the average ISQ values at different time points and mean IT values at placement, for groups A and B. Mean ISQ values are presented in Figure 1, which show an ascending trend over time.

Figure 1. Group A and B Mean ISQ values

Group A



Group B

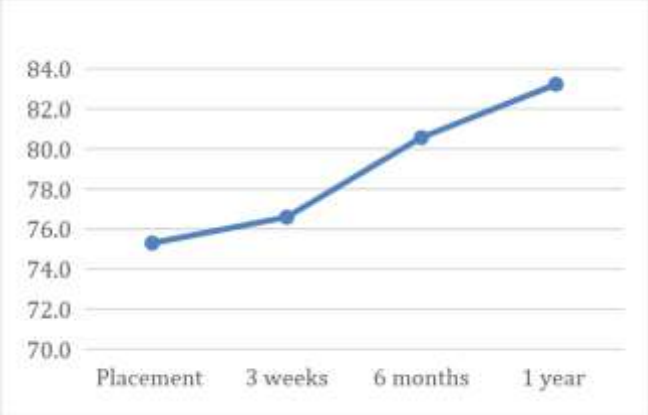


Table 3. Mean ISQ values at different time points.

Mean (SD) ISQ Values	Placement	3 weeks	6 months	1 year
Group A ±SD	76.0 ±4.790	76.3 ±3.791	80.0 ±6.034	82.1 ±3.150
Group B ±SD	75.3 ±4.488	76.6 ±4.655	80.6 ±6.729	83.2 ±5.149

	Mean IT Values at Placement (Ncm)
Group A ±SD	42.85 ±9.080
Group B ±SD	43.81 ±7.222

Marginal Bone Loss:

Table 4. describes the marginal bone loss at two years and seven years follow-up compared to baseline, and between two- and seven-year follow-ups.

The cumulative mean radiographic marginal bone loss around the implants after 2 and 7 years in function was 0.414±0.055 mm and 0.498±0.057 mm, respectively. When comparing radiographic bone levels of 2-year and 7-year follow-ups, 0.084 ±0.039 mm bone loss was found.

Table 4: Marginal bone loss on different follow-up times.

Variable		Total	Group A	Group B	P-value*
2^y Bone Loss (Mean ± Sd)	Mesial	0.433 ± 0.067	0.428 ± 0.077	0.438 ± 0.110	0.944
	Distal	0.395 ± 0.058	0.395 ± 0.093	0.395 ± 0.075	0.993
	Cumulative	0.414 ± 0.055	0.411 ± 0.076	0.417 ± 0.081	0.962
7^y Bone Loss (Mean ± Sd)	Mesial	0.479 ± 0.072	0.446 ± 0.090	0.510 ± 0.113	0.662
	Distal	0.516 ± 0.053	0.520 ± 0.065	0.512 ± 0.084	0.945
	Cumulative	0.498 ± 0.057	0.483 ± 0.064	0.511 ± 0.094	0.806
2-7^y Bone Loss (Mean ± Sd)	Mesial	0.046 ± 0.041	0.018 ± 0.072	0.073 ± 0.045	0.513
	Distal	0.121 ± 0.049	0.125 ± 0.088	0.117 ± 0.052	0.935
	Cumulative	0.084 ± 0.039	0.072 ± 0.071	0.095 ± 0.038	0.768

*Based on t-test

Table 5. provides information regarding the test of difference between the mean mesial and distal bone loss in two groups. The analysis confirms that there is no significant difference between mesial bone loss and distal bone loss at any point of follow-up time in both groups.

Table 5. Comparison Between Mesial and Distal Bone Loss in the Two Groups

	2y Bone Loss (Mean ± Sd)			7y Bone Loss (Mean ± Sd)			2-7y Bone Loss (Mean ± Sd)		
	Mesial	Distal	P-value	Mesial	Distal	P-value	Mesial	Distal	P-value*
Group A	0.428 ± 0.077	0.395 ± 0.093	0.669	0.446 ± 0.090	0.520 ± 0.065	0.427	0.018 ± 0.072	0.125 ± 0.088	0.169
Group B	0.438 ± 0.110	0.395 ± 0.075	0.659	0.510 ± 0.113	0.512 ± 0.084	0.974	0.073 ± 0.045	0.117 ± 0.052	0.474

*Based on T-test

The distribution of distal and mesial bone loss at different levels of gender, bone augmentation status, implant length, implant diameter, and bone type is shown in Table 6.

Table 6: Bone Loss at 7 Years Based on Study Variables

Variable		Mesial (Mean ± Sd)	Distal (Mean ± Sd)	Average (Mean ± Sd)
Gender	Male	0.500 ± 0.439	0.503 ± 0.371	0.501 ± 0.387
	Female	0.461 ± 0.504	0.528 ± 0.329	0.495 ± 0.363
Bone Augmentation Status	Augmented	0.305 ± 0.426	0.498 ± 0.383	0.402 ± 0.370
	Non- Augmented	0.549 ± 0.474	0.523 ± 0.336	0.536 ± 0.370
Location	Maxilla	0.348 ± 0.537	0.540 ± 0.308	0.444 ± 0.375
	Mandible	0.545 ± 0.426	0.504 ± 0.367	0.524 ± 0.371
Implant Length	8 mm	0.430 ± 0.000	0.529 ± 0.000	0.480 ± 0.000
	10 mm	0.463 ± 0.380	0.486 ± 0.363	0.475 ± 0.366
	11.5 mm	0.559 ± 0.540	0.562 ± 0.395	0.561 ± 0.422
	13 mm	0.380 ± 0.489	0.478 ± 0.269	0.429 ± 0.320
Implant Diameter	3.7 mm	0.628 ± 0.694	0.702 ± 0.210	0.665 ± 0.447
	4.1 mm	0.370 ± 0.435	0.497 ± 0.340	0.433 ± 0.334
	4.7 mm	0.495 ± 0.451	0.481 ± 0.377	0.488 ± 0.379
	6.0 mm	0.565 ± 0.459	0.503 ± 0.384	0.534 ± 0.413
Bone Type	Type I			
	Type II	0.524 ± 0.492	0.522 ± 0.372	0.523 ± 0.400
	Type III	0.358 ± 0.415	0.480 ± 0.298	0.419 ± 0.300
	Type IV	0.959 ± 0.000	0.840 ± 0.000	0.899 ± 0.000
Cumulative		0.480 ± 0.469	0.516 ± 0. 345	0.497 ± 0.370

Multivariate regression analysis (Table 7) was applied to analyze the predictors of four outcome variables (two-year distal bone loss, two-year mesial bone loss, seven-year distal bone loss,

seven-year mesial bone loss). Regression analysis of marginal bone loss indicates that having bone augmentation is correlated with increased distal bone loss at two years (p=0.034). No other predictor was significantly correlated with distal bone loss at two-year time point. The analysis indicates that having bone augmentation is also significantly correlated with mesial bone loss at two-year time point (p=0.007). Furthermore, average ISQ was correlated to mesial bone loss at two years at 0.1 significance level. Placing a 11.5 mm implant was negatively correlated to mesial bone loss at two years point of time (p=0.04). This finding indicates that the 11.5 mm length of implant might be a predictor for lesser mesial bone loss. Also, 4.1 mm diameter was significantly correlated to mesial bone loss at two years (p=0.022) compared to smaller diameter (3.7 mm).
However, no significant predictor was detected in multivariate regression on distal and mesial bone loss at seven-year point of time.

Table 7. Multivariate regression analysis on bone loss variables

Outcome	**Two year distal**		**P-value**
4.1 diameter	0.175	0.121	0.155
Bone augmentation	0.279	0.127	0.034
Outcome	**Two year mesial**		**P-value**
4.7 diameter	0.224	0.167	0.190
Mean ISQ	0.034	0.020	0.095
Bone type 4	-0.689	0.465	0.149
Group B	0.195	0.142	0.182
Female	0.232	0.148	0.127
Bone augmentation	0.494	0.172	0.007
10 mm length	-0.795	0.499	0.121

11.5 mm length	-1.068	0.508	0.044
13 mm length	-0.850	0.513	0.108
4.1 diameter	0.509	0.210	0.022
Outcome	**Seven year distal**		**P-value**
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Outcome	**Seven year mesial**		**P-value**
40-60 years old	0.456	0.275	0.106
>60 years age	0.451	0.285	0.123
4.1 diameter	0.229	0.153	0.144
Bone type 4	-0.631	0.455	0.174
Bone augmentation	0.258	0.157	0.109
Bone type 3	0.192	0.122	0.123

Discussion:

To the authors knowledge, this study was the first comparing the HA coated Zimmer Tapered Screw vent Implant survival rates and marginal bone stability, when loaded immediately to loading in 3 weeks. There has been a reluctance to manipulate implants in 3 weeks due to fear of disrupting osseointegration. By using resonance frequency analysis, we were able to dispel this myth. With this implant after 7 years in function, we found no significant loss of stability and were able to get a survival rate of 97.62%. This was equal or better than other immediate loading studies (6,12,23,24). It has been theorized that the layer of apatite that forms of the implant surface during the early stages of osseointegration may (or may not) contain endogenous proteins and serve as a matrix for osteogenic cell attachment and growth on the implant surface (17).

Because the biologic fixation of bone tissue to implant surfaces has been reported in some studies to be faster with a calcium phosphate coating than with uncoated titanium surfaces, (18,19) some clinicians have assumed that the bone healing process around the implant may be enhanced by the formation of the biological apatite layer, which may result in better early stability (17). All of the implants in the study were stable enough to load at the time of placement. In group B, all of the implants were stable enough to load at 3 weeks. Stability of all implants increased over the 12-month period.

During the 1990s, the US government conducted a prospective, randomized, multicenter study of HA-coated (n=1725) and uncoated (n=1070) implants placed in participants and monitored for 36–71 months of clinical follow up (25). More than 85 dentists in 30 study sites participated, and an independent external review committee composed of experts internationally recognized in their respective fields closely monitored the study (25). The researchers concluded that HA coating might offer some clinical advantages up to 36 months over uncoated surfaces when placed in poor-quality bone (26), smokers, or when implants were mobile at the time of placement but cautioned that further prospective research was needed to verify these findings. Other researchers in the same study reported that there was no clinically significant difference between in periodontal-type measurements between HA coated and uncoated dental implants. Nonetheless, the dissolution behaviors of HA coatings with amorphous calcium phosphate phases resulted in relatively isolated reports of possible coating delamination and particle release from the implant surface, which resulted in the clinical failure of the implants (17). A meta-analysis of clinical trials of HA coated implants published in 1990 through 1999 conducted at the time, however, found that HA-coated and uncoated implants exhibited no significant differences in survival and success rates (27). During the mid-1990s, shifting of the calcium phosphate phase was addressed by subjecting HA-coated implants to a hydrothermal treatment that caused their calcium phosphate phase to revert from amorphous to highly crystalline, which significantly helped to resist dissolution (28,29). Despite many years of clinical use as a dental implant surface coating, long-term data has remained very limited (17). A subsequent meta-analysis of clinical trials on HA coated implants published in 2013 reported that annual failure rates and cumulative survival rates of HA-coated dental implants were comparable to those of non-coated implants(17).

Implant survival rates (97.62%, n= 41/42) of the present study at the 7-year follow-up period were consistent with earlier outcomes (5,28) of the same highly crystalline HA-coated surface used on cylindrical rather than threaded implant designs.

Conclusion:

After 7 years in function, implants partially coated with plasma sprayed and hydrothermally treated HA were clinically predictable when restored in occlusion immediately after or after 3 weeks of implant placement.

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