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*Corresponding author

Ricardo Lillo E, Universidad Mayor, School of Dentistry, Santiago de Chile

E-mail: ricardo.lillo@umayor.cl

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Research Article

Application of Early Loading on Surface Implants with Nanostructured Hydroxyapatite Coating

Ricardo Lillo E*, Felipe Marti C, Stephanie Bohmann, Johannes Ilge, Claudia Delgado

Universidad Mayor, School of Dentistry, Santiago de Chile

Abstract

The objective of this work was to describe the variation in the stability of nanostructured HA coatied implants installed in the upper premolar area by means of resonance frequency analysis (RFA, measured in ISQ) during the first 4 weeks, in partially edentulous patients. The study design is quantitative, observational, descriptive, longitudinal and prospective. The implants used were the UNITITE line of S.I.N Implant System® of 3.5 mm x 11.5 mm, which have HAnano® surface. These implants have a surface treatment with a nanostructured hydroxyapatite coating, which increases hydrophilicity and would accelerate the process of new bone formation and remodeling after installation. The surgeries were carried out by students of the Oral Maxillofacial Implantology department, at Universidad Mayor, Santiago. A descriptive analysis was performed on a sample of 8 implants, resulting in a variation of 1 to 2 ISQ points during the four weeks studied. The results suggest that as the stability of the implants keeps constant, it would be possible to carry out early loading at 4 weeks in the implants studied, however, a greater number of samples, comparative studies and longer-term studies are required to generate more robust conclusions on this subject.

Introduction

Since Professor Branemark and his collaborators began using dental implants in humans, they have become a fundamental tool in the field of oral rehabilitation when treating patients with different degrees of edentulism. It was from his studies that the first protocols began to be established regarding the time it was necessary to wait before generating functional loads on an implant, in order to allow its osseointegration [1]. When we talk about loading an implant, we mean subjecting it to functional loads, either occlusal, generated by the musculature and soft tissues, or by the interposition of the food bolus. In the past, multiple loading time protocols for implants have been proposed, which has generated confusion and problems in comparing data from different studies, however, in the last decade publications have been considering definitions generated by consensus (Weber et al., 2009 - ITI Consensus Conferences). Which will be used for this study [2,3].

i. **Immediate loading:** a prosthesis is attached to the dental implant within a week of implant installation.

ii. **Early loading:** a prosthesis is connected to the dental implant between 1 week to 2 months after the implant is installed.

iii. **Conventional loading:** it is carried out after 2 months, after the installation of the implant [4,5].

It is necessary to point out that there are two major concepts that are fundamental and are closely associated with the moment in which we can generate the load on an implant. These are primary and secondary stability. Primary stability is that which is achieved through the mechanical lock that is generated between the bone and the dental implant at the time of its installation, and is mainly defined by the macro design of the implant and the type and quality of bone [6]. Secondary stability, on the other hand, refers to biological stability, which is the result of new bone formation and remodeling in the osseointegration process, and results in the biological fixation of the implant to the bone tissue. The micro design of the implant and the surface properties are factors that contribute to the osseointegration process [7]. While conventional loading involves a large window of time that allows the implant to develop this secondary stability before being loaded and immediate loading requires, among other factors, reaching significant progressive primary stability in order to be carried out, early loading has had its boom due to technological advances in relation to surface treatments applied to the implant, which allow the process of neoformation and bone remodeling to occur faster and earlier in time, thus facilitating the achievement of secondary stability in a period of time less than time [8] For implant surface treatments, it is possible to modify the physical and topographic characteristics of the implant surface, as well as to make changes in its chemical composition, surface energy and wettability [9,10] (Table 1).

The surface energy and the wettability of the implant participate in the process of osteogenesis. According to these elements we can find a classic hydrophobic or hydrophilic surface, which has been developed later. The hydrophilic surface is positively charged allowing some of the essential plasma proteins to establish initial osteogenic interactions, which, unlike the hydrophobic surface, favors the initial stages of wound healing and during the cascade of events that occurs during osseointegration [9]. For the present study, implants from the UNITITE line of SIN Implant System® have been used, which present a surface treatment consisting of a nano-structured coating of hydroxyapatite, which increases the hydrophilicity of the surface and would have greater adhesion to bone tissue. compared to the use of other conventional surface treatments. This is because when implants with this surface treatment come into contact with the body's biological fluids, they are capable of causing ionic saturation of the medium and generating the precipitation of biological apatite towards the surface of the implant. This biological apatite matrix acts as a scaffold for bone regeneration in addition to containing endogenous proteins that allow the migration, differentiation and proliferation of osteogenic cells [11].

Table 1: Surface treatments on dental implants [6,19].

Methods	Characteristics	Methods	Characteristics
Self-assembly of monolayers	The exposed functional end group could be a molecule with different functions (an osteoinductive or cell adhesive molecule).	Peroxidation	Produces a titania gel layer. Both chemical and topography changes are imparted.
sandblasted	High pressure propulsion of a fluid or abrasive material that generates topographic changes and removes surface contaminants.	Alkali treatment (NaOH)	Produces a sodium titanate gel layer allowing hydroxyapatite deposition. Both chemical and topographic changes are imparted.
Ion beam deposition	Can impart nanofeatures to the surface based on the material used.	Anodization	Can impart nanofeatures to the surface creating a new oxide layer (based on the material used).
Acid etching	Combined with other methods (sandblasting and/or peroxidation) can impart nanofeatures to the surface and remove contaminants.	Sol–gel (colloidal particle adsorption)	Creates a thin-film of controlled chemical characteristics. Atomic-scale interactions display strong physical interactions
Discrete crystalline deposition	Superimposes a nanoscale surface topographical complexity on the surface	Lithography and contact printing technique	Many different shapes and materials can be applied over the surface. Approaches are labor intensive and require considerable development prior to clinical translation and application on implant surface.
Photo-induced Surface treatment	Increase the bioactivity and osteocnductivity of titanium, thus inducing increased adsorption of protein, increased osteoblast proliferation, migration, differentiation, attachment and enhanced osteoblast speed.	Laser	Studies reported a 200-300 nm of thick titanium oxide layer. Bone growth into the nanoindentation of the titanium and the gradual inclusion of Ca and P ions into de the titanium oxide layer.

This work seeks to describe the stability of implants with an early loading protocol using the mentioned implants. There are various methods to quantify the stability of osseointegrated implants. For example, methods such as histological and microscopic methods that represent the Gold Standard, but lack clinical reproducibility, and others such as insertion torque, removal torque, and response to percussion, but which are highly invasive and inaccurate. There is also resonance frequency analysis (RFA), which consists of a test to assess the stability of implants by measuring the frequency of its oscillation within the bone tissue [12-14]. For two decades now, this method has been used because it is reliable, predictable, and objective to measure the stability of osseointegrated implants, determine the effects of immediate or early loading, and assess changes that occur during the period. of osseointegration [14, 15]. The measurement is made using a metal device called a Smartpeg (similar to a prosthetic abutment), which acts as a transducer. In its upper portion, it has a magnet that is excited by magnetic impulses produced by the same measuring device. This resonance frequency is expressed electromagnetically as an implant stability quotient (ISQ) with units ranging from 1 to 100, where low values indicate instability and high values greater stability. This value represents the stiffness of the implant-bone interface. According to the manufacturer, a successful implant is associated with ISQ values greater than 65, while loading implants with ISQ values less than 50 indicates a higher risk of failure [12,16]. In this case, the Ostell™ system was used to measure the stability of the implants studied, using RFA.

General objective

To describe the stability of an implant with a surface treated with nanostructured hydroxyapatite by means of resonance frequency analysis (RFA), for four weeks from its installation.

Specific objectives:

a. Measure the final insertion torque of the implant with the torque wrench.

b. Measure the stability of the implant with hydrophilic surface by Resonance Frequency Analysis once a week for four weeks.

c. To determine the variation in the stability of the implants during the period of the first four weeks.

Material and Methods

Design: the study is quantitative, observational, descriptive, longitudinal, prospective.

Operationalization of variables:

Specific goal	Variable	concept definition	Dimensions	Indicators	Coding	Variable Type	Measurement Scale
measure RFA	Implant stability hydrophilic surface	Mechanical or biological lock	1-100	Implant Stability Quotient	numerical	Dependent	<60: low stability; 61-70: medium stability; >70: High stability.
Measure RFA for 4 weeks.	Weather	Time elapsed between implant installation and each measurement.	0-4	Weeks	numerical	Independent	0 to 4 weeks.

Sample

a. **Universe:** Patients candidates for surgical intervention for implant installation.

Partially edentulous patients were selected, who underwent rehabilitation based on upper premolar implants, using PRIME hydrophilic surface implants from the UNITITE line of SIN Implant System®.

Inclusion criteria:

a. Patients of legal age between 18 - 75 years, self-employed who have signed the informed consent.

b. Partial edentulous in the upper premolar area with available or previously regenerated bone (at least 3 months before).

c. Patients who, in the event of having undergone extraction of an upper premolar, that this, together with alveolar preservation (if applicable) had been performed at least 4 months before.

d. Correspond to the ASA I and II classification of the American Association of Anesthesiologists.

Exclusion criteria:

a. Patients with psychiatric disorders.

b. Patients with untreated bone pathologies in the jaws.

c. Heavy smokers (more than 10 cigarettes/day).

d. Active periodontal disease.

e. Patients with non-prescribed consumption of medicines and drugs.

Process

After having explained the procedure, benefits and risks to each patient, and they had signed the informed consent, preoperative imaging tests such as Cone-Beam computed tomography were requested. For this step, a preoperative radiographic guide was made that should be used simultaneously with the Cone-Beam Computed Tomography, to better plan the position in which the implants will be installed at the time of surgery. The surgeries were performed by students of the specialty of Oral and Maxillofacial Implantology in the pavilion of the School of Dentistry, Universidad Mayor, Santiago. Preoperative premedication was indicated, Amoxicillin 1g every 12 hours for seven days starting the day before surgery and Ketoprofen 100mg every 12 hours for three days starting after surgery. Under aseptic conditions and local anesthesia with 2% lidocaine with epinephrine 1:100,000, a mucoperiosteal incision was made and a full-thickness flap was raised over the edentulous alveolar ridge. Subsequently, the bed was made by means of progressive osteotomy with a drill protocol under irrigation as indicated by the manufacturer. We proceeded with the installation of a 3.5 X 11.5 mm UNITITE PRIME™ SIN Implant System® implant, at which time the achieved insertion torque was recorded with the torque wrench or Torquemeter. A SIN® conical abutment (torqued to 20Ncm, according to manufacturer) was immediately connected and a "Type A3" SmartPeg was attached to it to perform the first stability measurement with the Ostell™ system. Finally, the Smartpeg was removed to place a protective cap over the tapered abutment.Every week, and for four weeks, the protection cap was removed and the connection of the SmartPeg on the conical abutment for resonance frequency measurement and analysis (RFA). The data were entered into a data collection table (Annex two).

The installation of the definitive prosthesis began at the sixth week. The success criteria for a dental implant [17,18] were the following:

a. Absence of pain, discomfort or paresthesia.

b. Absence of mobility.

c. Absence of radiolucent image around the implant.

d. It allows the installation of a crown or prosthesis with a satisfactory appearance for both the patient and the dentist.

e. That meets the aesthetic requirements of the patient.

Data analysis plan: A descriptive analysis was performed with the data obtained from the sample using the Stata v16 software for Windows.

Results

A total of 8 patients participated in the study, in which the implants were installed according to the defined protocol in 11 sites to be studied. Two implants did not achieve sufficient initial stability to be connected and measured (insertion torque <30Ncm), one implant suffered rotation when removing the protection cap from the conical abutment in the first week control, therefore, they were included for the analysis. final a total of 8 implants. All the implants considered in the analysis were installed in type III bone and without surgical complications of any kind. Of the total, four implants were installed in tooth zone 2.5, three in tooth zone 1.5 and one in tooth zone 2.4. The two implants that did not achieve sufficient initial stability were installed in zone 2.5, while the implant that suffered rotation in the first control had been installed in zone 1.4. In the control of the first week, suture removal was performed together with the corresponding measurement [19-22]

Table 2: Summary of the data.

Variable	show	average	Dev. Standard	Min	Max
Torque	8	31,25	2,165	30	35
ISQ Clinical	8	56,625	8,158	37	62
ISQ 1	8	54,875	7,12	39	61
ISQ 2	8	55,375	8,146	35	61
ISQ 3	8	54,625	7,963	36	60
ISQ 4	8	54,625	7,424	38	61

With the exception of one case, whose RFA values remained between 35 and 40 ISQ, all the cases studied had values between 55 and 62 ISQ during the four weeks recorded, remaining constant in their stability with respect to the beginning.

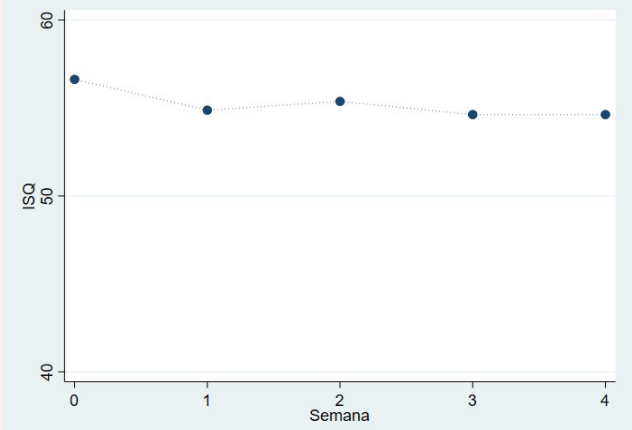

Figure 1: Variation of the ISQ averages during 4 weeks.

The lowest average ISQ was observed in the third week, however this number is only one point or even less than one point lower than the first, second or fourth week, and two points less than the initial post-installation record.

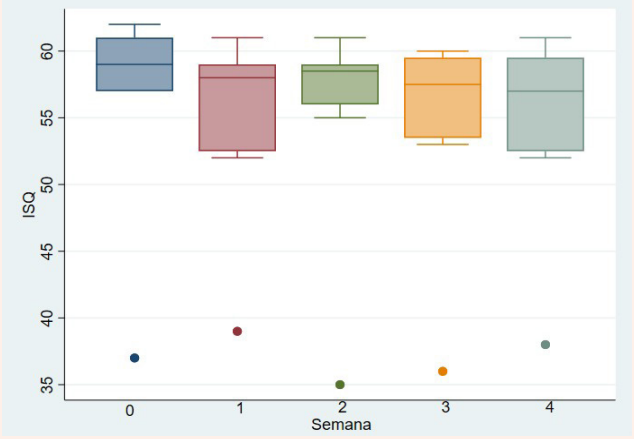

Figure 2: Summary of the data.

Regarding the installation of the definitive prosthesis on the implants, the loading was carried out at the sixth week and the absence of pain, discomfort or mobility was evaluated in all cases and complying with the aesthetic requirements of the operator and according to the criteria of each patient [22-34].

Discussion

The intention of this work was to describe the stability of implants with a hydrophilic surface with NanoHA - Unitite Prime technology from SIN Implant System for four weeks after their installation, with the aim of generating evidence that helps validate early loading in these implants. For this, the stability of the implants was evaluated by means of resonance frequency analysis (RFA) and measured in ISQ), recording the variation of the stability of the implants with respect to their initial stability. The results reflected a minimal variation of the ISQ in all cases week after week, which seems to agree with what is indicated in the theory regarding the hydrophilic surface and its ability to shorten the time of the osseointegration processes, maintaining, in In this case, the constant stability during the process of passing from primary or mechanical stability to secondary or biological stability. The latter contrasts with what studies show us regarding traditional surface treatments (hydrophobic) where a significant decrease in implant stability is seen after installation and mainly around the second and third week [35].

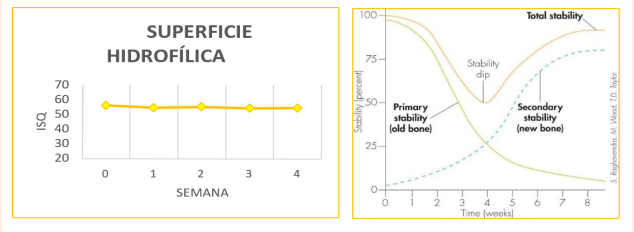

Figure 3: (35) Schematic comparison between the stability achieved by an implant with a traditional surface and the stability achieved in the cases studied.

When comparing the results with similar studies [36-38], we can note that the trend of constant stability is maintained or in some cases with a minimal decrease in the second or third week, but completely far from the levels to which the hydrophobic surface. What, if it differs to some extent from our results with respect to other similar studies, are the ISQ values as such, where in other studies [36-38] values above 60, 70 and even more ISQ can be seen. Although what was important in this case was the comparison between the initial ISQ value with the subsequent values, this difference with other studies could be due to the fact that in all the cases of the present study the measurement was made on an intermediate abutment, and not directly on the implant. as in most peer-reviewed publications. This translates into an increase in the distance between the measurement point (SmartPeg) and the bone crest, which implies a greater oscillation and therefore a lower ISQ value than if the procedure were performed directly on the implant [39]. Our reason for deciding to perform the measurements on an intermediate abutment was to avoid multiple connections and disconnections, favoring adequate peri-implant health [40,41].

Another important point to highlight about carrying out measurements on an intermediate abutment is that it must be torqued according to the manufacturer's instructions and it is essential to ensure that it is firmly adapted and without interference, since this could greatly alter the ISQ values obtained. We emphasize this since, when looking at the results, it can be seen that one of the cases obtained ISQ values lower than 40 despite the fact that it had a sufficient final insertion torque for the connection of the abutment immediately upon installation. As there was no greater variation in stability from installation to the fourth week, we believe that the reason for this low ISQ was possibly interference or maladaptation of the conical abutment. Due to this, the use of periapical radiography is recommended to ensure the intimate seating between the abutment and the implant. Another factor to take into consideration is the operator variable. Being in a university environment and surgeries being performed by students in training, it can be assumed that the inexperience of the surgeon may play an unquantified role in this study. Despite this possibility, the result is successful since osseointegration of all the implants is achieved except 1, which rotated in the first measurement. It opens the debate on the real need for high levels of insertion torque to achieve clinical success. The SIN Implant System's Unitite Prime implant system suggests for early loading, that this be done from day 28, and the intention of this study is to help validate this premise by providing evidence and specific data regarding the stability of the implant. and, although the sample is small, the results obtained show us that since there is practically no decrease in the stability of the implant since its installation, loading could be carried out without major inconveniences.

Conclusion

The results of this work suggest that Unitite Prime implants could apparently be subjected to early loading with definitive rehabilitation, thus providing a safe and predictable solution, greater patient satisfaction and reduction in treatment times and costs. This is because there was no DIP or decrease in implant stability during the first 4 weeks. This benefit, as mentioned above, is thanks to its HA nano ® surface treatment, which accelerates the osseointegration processes. This work has allowed us to simply present the information in a broad or general way, describe a trend and generate evidence, data and information that can be used in future studies of greater complexity. Despite this, and also due to the type of study presented, together with the small size of the sample, it is suggested in subsequent studies to carry out a longer follow-up time for the ISQ values to evaluate the long-term stability behavior of the implants. term, along with larger samples and comparative study designs that provide more scientific evidence.

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