ISSN: 2230-9926

Available online at http://www.journalijdr.com

IJDR

International Journal of Development Research
Vol. 12, Issue, 11, pp. 59942-59946, November, 2022
https://doi.org/10.37118/ijdr.25500.11.2022

RESEARCH ARTICLE

OPEN ACCESS

CLINICAL EVALUATION OF ANODIZED SURFACE IMPLANTS SUBMITTED TO A COUNTER TORQUE OF 25 NCM AFTER 45 DAYS OF OSSEOINTEGRATION: STUDY IN HUMANS

***Rafael Manfro, Vinicius Fabris, Marcelo Carlos Bortoluzzi, Carlos Nelson Elias, Vera Cavalcanti de Araújo, Gislaine Garcia and Márcio de Carvalho Formiga**

[1,2]Post Graduation Program on Implantodontics, UNOESC, Joaçaba, Brazil
[3]Post Graduation Program in Bucomaxillofacial Surgery, UNOESC, Joaçaba, Brazil
[4]Post GraduationProgram, SLMANDIC, Campinas, SP, Brazil
[5]Department of Periodontology and Oral Surgery, Unisul, Palhoça, SC, Brazil
[6]DepartmentofPeriodontologyand Oral Implantology, Unisul, Palhoça 88137-270, SC, Brazil

ARTICLE INFO

Article History:
Received 24th August, 2022
Received in revised form
20th September, 2022
Accepted 14th October, 2022
Published online 30th November, 2022

Key Words:

Dental Implants;
Osseointegration;
Implant Surface.

Corresponding author:
Rafael Manfro

ABSTRACT

Introduction: Decreasing the time needed for osseointegration has always been a big challenge for modern implantodontists. The main factor which helps to decrease thetime needed for osseointegrationis the developed surfaces being used, as well as their microstructures, in relation to their osseoinductive properties. The aim of this work is to clinically evaluate the osseointegration of the implants when using ananodized surfaces in humans, following a 45 days-period of osseointegration. ***Methodology:*** Forty-Five implants were placed in different kinds of bones, according to the technique recommendedby the manufacturer. Those implants were openedafter 45 days of osseointegration. The success of evaluationwas made through assessing the counter torque resistance of 25 Ncm. The implants which could with stand the applied torque were considered osseointegrated. ***Results:*** Of the forty-five implants made in different kindsof bones, only four failed to present osseointegration, resulting in a success rate of 91.11 %. ***Conclusions:*** With this methodology it was possible to conclude that anodized surface implants present primary osseointegration after 45 days of healing, after which they can function normally.

Citation: ***Rafael Manfro, Vinicius Fabris, Marcelo Carlos Bortoluzzi, Carlos Nelson Elias, Vera Cavalcanti de Araújo, Gislaine Garcia and Márcio de Carvalho Formiga.*** "Clinical evaluation of anodized surface implants submittedto a counter torque of 25 ncm after 45 days of osseointegration: Study in humans*",* *International Journal of Development Research*, 12, (11), 59942-59946.

INTRODUCTION

Implants macro, micro and Nano geometry had been evolved meaningly since the protocol proposed by Bränemark(1) for treatment full arch edentulism, with machined implants. Nowadays, depending on the bone density and the technique for its instrumentation, we no longer need to place implants and wait from 3 to 4 months in the mandibular treatment and 6 months for maxillary treatment to ensure osseointegration, depending also on the primary stability of the implants (Albrekson *et al*., 1981; Elias, 2010; Albreksson, 2008). Implants Surfaces can accelerate osseointegration process. The morphology, topography, surface roughness, chemical composition, surface energy, and chemical potential of the implant surface have significant influence on the reactions of bone tissue (Elias, 210; Albreksson, 2000; Albrektsson, 2004; Albrektsson, 2004; Esposito, 2005). It has been proved that a surface roughness of up to 0.5 µm is necessary for fibroblast adhesion, while a roughness ranging from 0,5 to 2,0 µm allows for osteoblast adhesion (Joos, 2006; Inonue, 1987). As technology have been developing these special surfaces, the time needed for osseointegration have diminished, but without decreasing the success rate. To ensure the migration of osseogenic cells to the implant surface, fibrin retention must occur (Kunrath, 2020). To ensure fibrin retention, several texturization techniques may be utilized, such as etching, etching followed by acid texturing, acid texturing associated with fluorine deposition and anodization (Esposito, 2005; Testori, 1997). Further, anodization is another important factor for faster osseointegration because it incorporates C and P ions on the implant surface

(Albreksson, 2000; Albrektsson, 2004; Ferguson *et al*., 2008; Marin, 2008; Guehennec *et al*. 2008; Schliephake, 2006). The Vulcano Surface Actives® implants, produced by Conexão (São Paulo SP/ Brazil), is an example of implant that utilize an surface anodization treatment. This treatment produces a roughness of 1,26 µm (Rosa, 2013), and allows the incorporation of Ca and P (McAlamery, 1996; Bathamarco, 2004). In a recent study, the structure of the Vulcan Actives' surface was compared to that of TiUnite via electron microscopy. They evaluated that the two implants had similar roughness, nevertheless the treatment area obtained by the Vulcan Actives surface was significantly higher (Rosa, 2013). Many studies had demonstrated excellent clinical results with anodized surface implants, placed in immediate or late load protocol period (Glauser, 2017; Calandriello, 2011; Degidi, 2012). One study submitted a counter-torque 25Ncm after 60 days of osseointegration in humans in implantswith anodized surface (Vulcano Actives – Conexão Sistema de Próteses), with a survival rate of 97,7% (Manfro, 2015), suggesting that the osseointegration period could be shorter then. This study aims to clinically assess the level of osseointegration of anodized surfaces (Vulcano Actives® - Conexão Sistema de Prótese – Arujá/SP-Brazil) implants 45 days after their placement in human patients.

MATERIALS AND METHODS

Ethical Approvals: All participants have read and signed an informed consent form. The use of human subjects in this study has been reviewed and approved by the Ethics Committee of UNOESC/Joaçaba-SC, protocol number 071/2008.

Selection of patients and number of implants: The selection was made among patients attending the post-graduations clinic at UNOESC, Joaçaba/SC and SOEBRÁS Passo Fundo/RS, requiring implant rehabilitation of up to a maximum of 3 implants in each hemi-arch, with age 18 older at least, without any systemic problems that could contraindicate implant rehabilitation, non-smokers.Just cases that not required bone grafts, without immediate load were selected. All patients were asked to read and accept the terms of the research agreement.

Pre-operatory preparation: Patients were evaluated clinically and through imaging (X-ray and tomography), and plaster models were made. A final diagnosis was then made to determine the number and position of implants to be placed. The patients' systemic condition was evaluated by blood tests, including complete blood count and fasting glucose. Two grams of amoxicillin were administered orally 1 hour before the surgical procedure, and the patients mouth-rinsed with chlorhexidine digluconate 0.12% twice a day, beginning one day before the surgery. Patients who were allergic to penicillin were medicated with clindamycin 600 mg one hour before surgery. Post-surgery, Paracetamol 750mg was administered every 6 hours for 24 hours for pain control. Patients continued to rinse with chlorhexidine digluconate 0.12% twice a day for seven days after the procedure, as prescribed. Patients were instructed to put ice bags on the local of the surgery, and to have soft meals within the next 7 days after the procedures. Oral hygiene was made carefully, with extra soft teeth brushes, regarding the surgery area, where the chlorhexidine was been applied in order to biofilm control. After 10 days the sutures were removed.

Surgical technique: The implants Connection AR (Figure 1) with Vulcano Surfaces (Figure 2) were selected on a case-by-case basis, as determined by recommendations according to the length, thickness, and type of connection. The bone instrumentation technique was performed as recommended by the manufacturer. The implant placement data, including positioning, bone quality, and insertion torque, were noted on the patient's prontuary.

Assessment: After a 45 days period, second surgeries were performed to asses the submerged implants.

Figure 1. Connection AR, Conexão(São Paulo, SP/ Brazil)

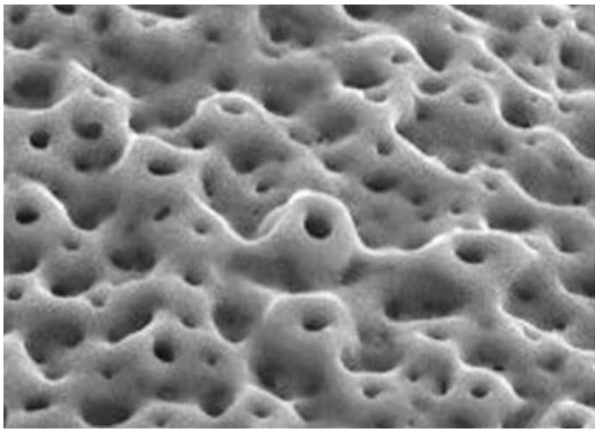

Figure 2. Vulcano Activessurface (magnification 5.000x)

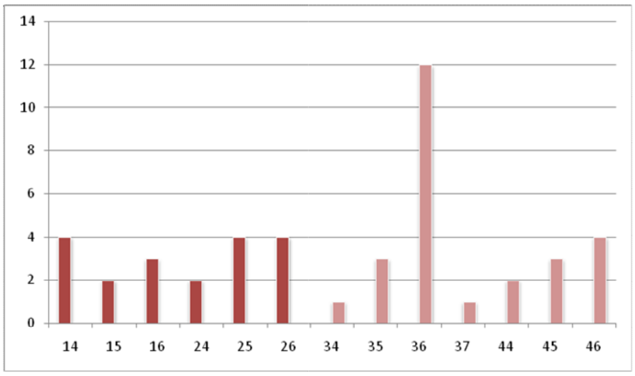

Figure 3. Number of implants considering the location of the installation

During this procedure, a counter torque test was performed to assess the osseointegration by utilizing a ratchet extender to place the implants. The ratchet used in the procedure was a prosthetic ratchet made by Conexão Sistema de Próteses® (São Paulo, SP/Brazil). The implants were submitted to a counter torque of 25 N/cm. The implants that did not withstand the counter torque test were removed and replaced at this moment, but counted as failure. The implants that remained stable were rehabilitated 15 days after these procedures.

RESULTS

From January 2009 to July 2009, 45implants Connection ARs Vulcano Actives® surfaces were placed over the course of the study in 32 patients. The distribution of the implant locations is given in Table 1.

Table 1. Description of the 45 implants installed according to the size, primary stability, bone type and implant installation location and results after 45 days of osseointegration

Implant	Diameter and lenght	Initial torque	Bone type / Region	Result
1	3.75 X10	40 Ncm	III / 26	Success
2	3.75 X10	35 Ncm	III / 36	Success
3	3.75 X 10	60 Ncm	II/ 44	Success
4	4.0 X 11.5	80 Ncm	II/ 36	Success
5	3.75 X 10	45 Ncm	II/ 25	Success
6	3.75 X10	60 Ncm	III / 44	Success
7	4.0 X 10	40 Ncm	III / 15	Success
8	4.0 X 10	40 Ncm	III / 16	Success
9	4.0 X 10	60 Ncm	II/ 46	Success
10	4.0 X 11.5	60 Ncm	II/ 45	Success
11	3.75 X 10	30Ncm	II/ 35	Success
12	3.75 X 10	60 Ncm	II/ 36	Success
13	3.75 X11.5	40 Ncm	III / 14	Success
14	4.0 X 10	15 Ncm	IV/ 26	Failure
15	3.75 X 10	10 Ncm	IV/ 16	Failure
16	3.75X 11.5	15 Ncm	IV/ 15	Failure
17	3.75 X 11.5	50 Ncm	IV/ 24	Success
18	3.75 X 11.5	80 Ncm	II/ 36	Success
19	4.0 X 11.5	40 Ncm	II/ 36	Success
20	4.0 X 11.5	80 Ncm	I / 35	Success
21	3.75 X10	25 Ncm	III / 14	Failure
22	3.75 X10	70 Ncm	III / 25	Success
23	3.75 X11.5	40 Ncm	III / 24	Success
24	4.0 X 11.5	40 Ncm	II/ 36	Success
25	4.0 X 11.5	25 Ncm	III / 46	Success
26	3.75 X 10	50 Ncm	II/ 36	Success
27	4.0 X 11.5	50 Ncm	II/ 37	Success
28	3.75 X 10	70 Ncm	II/ 34	Success
29	3.75 X 13	80 Ncm	II/ 36	Success
30	3.75 X 10	60 Ncm	III / 16	Success
31	3.75 X 11.5	50 Ncm	III / 25	Success
32	3.75 X 15	80 Ncm	I/ 46	Success
33	3.75 X 10	60 Ncm	II/ 14	Success
34	3.75 X 11.5	40 Ncm	III / 26	Success
35	3.75 X 10	50 Ncm	II/ 36	Success
36	3.75 X 10	40 Ncm	II/ 36	Success
37	3.75 X 10	50 Ncm	II/35	Success
38	3.75 X 10	60 Ncm	II/36	Success
39	3.75 X 10	60 Ncm	II/46	Success
40	3.75 X 11.5	30 Ncm	III/26	Success
41	3.75 X 13	30 Ncm	III/25	Success
42	3.75 X 11.5	80 Ncm	I / 36	Success
43	3.75 X 11.5	40 Ncm	III/14	Success
44	3.75 X 10	60 Ncm	II/45	Success
45	3.75 X 10	30 Ncm	II/45	Success

Table 2. Implants installed in accordance with bone quality and the respective success rate

Bone quality	Number of implants	Failed implants	% of success
Type I	03	0	100
Type II	22	0	100
Type III	16	1	93.75
Type IV	4	3	25

Table 3. Implants installed in accordance with primary stability and the respective success rate

Initial torque (Ncm)	Number of implants	Failed implants	% of success
10 to 25	05	4	20
30 to 55	22	0	100
60 to 80	18	0	100

Of the 45 implant placed, only four failed, did not resist the 25N/cm counter torque, with an overall 91.11% success rate, according to the proposed methodology. Bone quality and primary stability measured by Initial torque, which are two of the main factors that influence the success of osseointegration, are demonstrated in Tables 2 and 3, respectively, with the success rate of each, whereas Figure 3 shows the number of implants placed on each region.

DISCUSSION

The implant surface is the key to improve the quality and speed of osseointegration (Albrekson, 1981; Elias, 2010; Albreksson, 2000). As said before, the Vulcano Actives treatment produces a roughness of 1.26 µm, yielding a surface with nanometric features (Rosa, 2013); moreover, its shape decreases the surface energy and increases the wettability capacity, improving the contact between the bone and the implant by 10% compared to the surfaces obtained by double acid treatment (Degidi, 2012). This topography is associated with the incorporation of calcium and phosphate ions; in addition to improving the bone/implant contact, it brings about faster results and diminishes osseointegration time. Thus, we can characterize this surface as being bioactive and having medium roughness (Bathamarco, 2004; Elias, 2009; Shibli, 2007). These characteristics may have influenced the results obtained in our study. Initially, hydroxyapatite and titanium etchings were tested to increase bone to implant contact (BIC) area (Karabuda, 1999). Acid conditioning was also used to create roughness in the implants surface and with that, to increase the bone/implant contact area (Testori, 2001). The difference in texturization is directly responsible for the cell behavior on the implant surface (Joos, 2006). It influences not only the quality and the quantity of new bone formed in contact with the implant but also the speed of both bone formation and implant binding[24].

The main factors that allow for faster osseointegration are the Nano-topography of the surfaces and the chemical modification resulted from the incorporation of calcium and phosphate ions (Albreksson, 2000; Albrektsson, 2004; Albrektsson, 2005). Albrekson *et al*. (2004) stated that moderate roughness presented little or statistically insignificant advantages and that the anticipated performance should originate from the bioactive surfaces. Superficial changes with bisphosphonates and collagen seem to precociously reinforce peri-implant bone formation (Ferguson, 2008; Guehennec, 2008; Schliephake, 2006), and they improve bone repair in the first 5 weeks (Stmad, 2008). To diminish osseointegration period, thus altering the biological behavior of implant, it is necessary to maintain the implant in an isotonic surface to eliminate the titanium oxide layer. Maintaining both the implant and those surfaces bio-activated by bisphosphonates in an isotonic solution in animals presented significant differences in either the quantity of bone formed and the percentage of bone/implant contact (Vicente, 2006).

When compared to implants treated with etching and acid conditioning placed in rabbits' tibias, the anodized surfaces as Vulcano Actives showed a smaller contact angle between the bone and the implant, and they required a greater removal torque after 12 weeks of osseointegration (Elias, 2008). There are many studies in the relevant literature on animals that address the aspect of time of osseointegration on bioactive surfaces (Marin, 2008; Guehennec, 2008; Schwarz, 2007; Schliephake, 2009; Schliephake, 2009; Lai, 2009), but there are few studiesin humans defining the necessary period of time needed before loadingthese implants (Albreksson, 2000). In humans, two months after implant placement, the Vulvanosurface presented greater bone/implant contact than machined surface implants. When subjected to counter-torque in humans after 60 days, 97.7% implants survived a 25N/cm counter-torque regardless of primary stability and bone quality. In the present study implants with Vulcane Actives were subjected to 25 N/cm counter-torque after 45 days in order to verify the secondary stability (osseointegration). The insertion torque of the prosthetic abutment recommended by the manufacter is 20 N/cm. Because the test was done with 25 N/cm, it was possible to initiate the prosthetic procedures following the manufacturer's instructions after that.

Despite only making assessments during the reopening procedure, no implants were lost during the prosthetic rehabilitation. Secondary stability in 45 days was obtained in implants installed in bone type I, II and III and they presented primary stability greater than 25N/cm. The 4 implants without these requirements suffered movement in the counter torque application and were considered failures.All implants considered lost resisted a torque of 20 N/cm, only presenting mobility when the torque meter was near 25 N/cm. After presenting mobility, they were removed and a new implant was placed in the same site, and waited for another 60 days to reopening. After this period, they all presented osseointegration and were submitted to conventional prosthetic procedures, but were counted as failures on the study. We believe this methodology allows the clinician to safely restoreVulcano Active implants after 45 days of osseointegration, when they present primary stability higher than 25 N/cm and are not placed in type IV bone. In situations where the primary stability of implants were lower than 25N/cm or bone quality is type IV we suggest to wait at least 60 days submerged before rehabilitation.

CONCLUSIONS

Within the limitations of this study, we can conclude that the osseointegration period of 45 days for theVulcano Active surface implants can be stated, but the bone quality and the level of primary stability are fundamental for the success within this period of osseointegration.

REFERENCES

Albrekson T, Branemark P-I, Hansson HÁ, Lindstöm J. 1981. Osseointegrated titanium implants. Requirements for ensuring long-lasting direct bone-to-implant anchorage in man. *Acta OrthopScan.,* 52: 155-70.

Albreksson T, Sennerby L, Wennerberg A. 2008. State of the art of oral implants. Periodontology 2000 47: 15-26.

Albrektsson, T., Wennenberg, A. 2004. Oral implant surfaces: Part 1 – review focusing on clinical knowledge of different surface. *Int. J. Prosthodont.,* n. 17, p. 536-543.

Albrektsson, T., Wennenberg, A. Oral implant surfaces: Part 2 – review focusing on clinical knowledge of different surface. *Int. J. Prosthodont.,* n. 17, p. 544-564, 2004.

Bathamarco RV, Solorzano G, Elias CN, Prioli R. 2004. Anatomic force microscopy analysis of the different surface treatments of Ti dental implant surfaces. *Applied Surface Science*., 233: 29-34.

Brunski JB. Biomechanical factors affecting the bone-dental implant interface. Clin Mater. 1992; 10: 153, 201.

Calandriello R, Tomatis M. 2011. Immediate occlusal loading of single lower molars using Brånemark System® Wide Plat- form TiUnite implants: a 5-year follow-up report of a pro- spective clinical multicenter study. *Clin Implant Dent Relat Res.,* 13:311–318.

Degidi M, Nardi D, Piatelli A. 2012. 10-year follow-up of immediately loaded implants with TiUnite porous anodizes surface. *Clin Implant Dent Relat Res*., 14: 828-838.

Elias CN, Meirelles L. 2010. Improving osseointegration of dental implants. *Expert Rev Med Devices*. 7: 241-256.

Elias CN, Oshida Y, Cavalcanti JH, Muller CA. 2008. Relationship between surfaces properties (roughness, wettability and morphology) of titanium and dental implant removal torque. *J of Mech Behavior Biomed Mat.,* 1; 234-42

Esposito M, Coulthard P, Thomsen P, Worthington HV. 2005. The role of implant surface modifications shape and material on the success of osseointegrated dental implants. A Cochrane systematic review. *European Journal of Prosthodontic and Restorative Dentistry*. 13: 15-31.

Ferguson SJ, Langhoff JD, Voelter K, Rechenberg B, Scharnweber D, Bierbaum S, Schnabelrauch M, Kautz AR, Frauchiger VM, Mueller TL, Lenthe H, Schlottig F. 2008. Biomechanical comparison of different surface modifications for dental implants. *J Oral MaxillofacImplants*., 23: 1037-46.

Glauser R, Zembic A, Ruhstaller P, Windisch S. 2007. Five-year results of implants with an oxidized surface placed predominantly in soft quality bone and subjected to immediate occlusal loading. *J Prosthet Dent*., 97:59–68.

Guehennec LL, Goyenvalle E, Lopez-Heredia MA, Weiss P, Amouriq Y, Layrolle P. 2008. Histomorphometric analysis of the osseointegration of four different implant surfaces in the femoral epiphyses of rabbits. *Clin Oral Impl Res.,* 19: 1103-10.

Inonue T, *et al*. 1987. Effect of the surface geometry of smooth and porous coated. Titanium alloy on the orientation of fibroblasts in vitro. *J Biomed Mater Res*., 21: 107-126.

Joos U, Wiesmann HP, Szuwart T, Meyer U. 2006. Mineralization at the interface of implants. *Int J Oral Maxillofac Surg*., 35: 783-90

Karabuda C, *et al*., 1999. Histologic and histomorphometric comparison of immediately placed hydroxyapatite-coated and titanium plasma-sprayed implants: a pilot study in dogs. *Int J Oral Maxillofac Implants.*, 14: 510-515.

Kunrath MF, Santos RP, Oliveira SD, Hubler R, Sesterheim P, Teixeira ER. 2020. Osteoblastics Cell Behavior and early basterial adhesion on macro, micro and nanostructured titanium surfaces for biomedical implant applications. *Int J Oral Maxillofac Implants.,* 35: 773-81.

Lai HC, Zhuang LF, Zhang ZY, Wieland M, Liu X. 2009. Bone apposition around two different sandblasted, large-grit and acid-etched implant surfaces at sites with coronal circumference defects: an experimental study in dogs. *Clin. Oral Impl. Res*., 20; 247-253.

Manfro R, Bortoluzzi MC, Fabris V, Elias CN, Araújo VC. 2015. Clinical Evaluation of Anodized Surface Implants Submitted to a Counter Torque of 25 N.cm after 60 Days of Osseointegration - Study in Humans. *Journal of Maxillofacial and Oral Surgery*., 15; 14: 1-6.

Marin C, Granato R, Suzuki M, Gil JN, Piatelli A, Coelho PG. 2008. Removal torque and histomorphometric evaluation of bioceramic grit-blasted/acid-etched and dual acid-etched implant surfaces: An experimental study in dogs. *J Periodontol*., 79: 1942-1949.

McAlamery ME, Oshiro MA, McAlarney CV. 1996. Effects of titanium dioxide passive film cystal structure, thickness and crystallinity on C3 adsorption. *Int J Oral Maxillofac Implants.,* 11: 73-80.

Oates T, Valderrama P, Bischof M, Nedir R, Jones A, Simpson J, Toutenburg H, Cochran. 2007. Enhanced Implant Stability with a chemically modified SLA Surface: A randomized pilot study. *J Oral Maxillofac Implants.,* 22: 755-60.

Rosa MG, Albrekson T, Francischone CE, Schwartz Filho HO, Wennerberg A. Micrometric characterization of the implant surfaces from the five largest companies in Brazil, the second largest worldwide implant market. *Int J Oral Maxillofac Implants.* 2013; 28: 358-365.

Schliephake H, Aref A, Scharnweber D, Bierbaum S, Sewing A. 2009. Effect of modifications of dual acid-etched implant surfaces on peri-implant bone formation. Part I: organiccoatings. *Clin. Oral Impl. Res.,* 20; 31–37.

Schliephake H, Aref A, Scharnweber D, Bierbaum S, Sewing A. 2009. Effect of modifications of dual acid-etched implant surfaces on peri-implant bone formation. Part II: Calciumphosphatecoating. *Clin. Oral Impl. Res*., 20; 38–44.

Schliephake H, Scharnweber D, Roesseler S, Dard M, Sewing A, Aref A. 2006. Biomimetic calcium phosphate composite coating of dental implants. *Int j Oral Maxillofac Implants*., 21: 738-46.

Schwarz F, Herten M, Sager M, Wieland M, Dard M, Becker J. 2007. Bone regeneration in dehiscence-type defects at chemically modified (SLActive) and Conventional SLA titanium implants: a pilot study in dogs. *Journal of clinical periodontology*., 34: 78-86.

Shibli JA, Grassi S, Figueiredo LC, Feres M, Marcantonio Jr. E, Lezzi G, Piatelli A. 2007. Influence of implant surface topography on early osseointegration: A histological study in human jaws. J Biomed Mater Res Part B: *Appl Biomater* 2007; 80: 377-85.

Stmad J, Urban K, Povysil C, Stmad Z. 2008. Secondary stability assessment of titanium implants with an Alkali-etched surface: A resonance frequency analysis study in beagle dogs. J Oral Maxillofac Implants., 23: 502-12.

Testori T, Del Fabbro M, Szmukler-Moncler S, Francetti L, Weinstein RL. 1997. Immediate occlusal loading of Osseotite implants in the completely edentulous mandible. *Int J Oral Maxillofac implants*. 12: 319-24.

Testori T, Wiseman L, Woolfe S, Porter S. 2001A prospective multicenter clinical study of the osseotite implant: four-year interim report. Int J Oral Maxillofac Implants. 2001; 16: 193-200.

Vicente JC, Recio O, Martin-Villa L, Junquera LM, Lopez-Arranz JS. 2006. Histomorphometric evaluation of guided bone regeneration around implants with SLA surface: an experimental study in beagle dogs. *Int J Oral Maxillofac Surg*., 35: 1047-1053.

****