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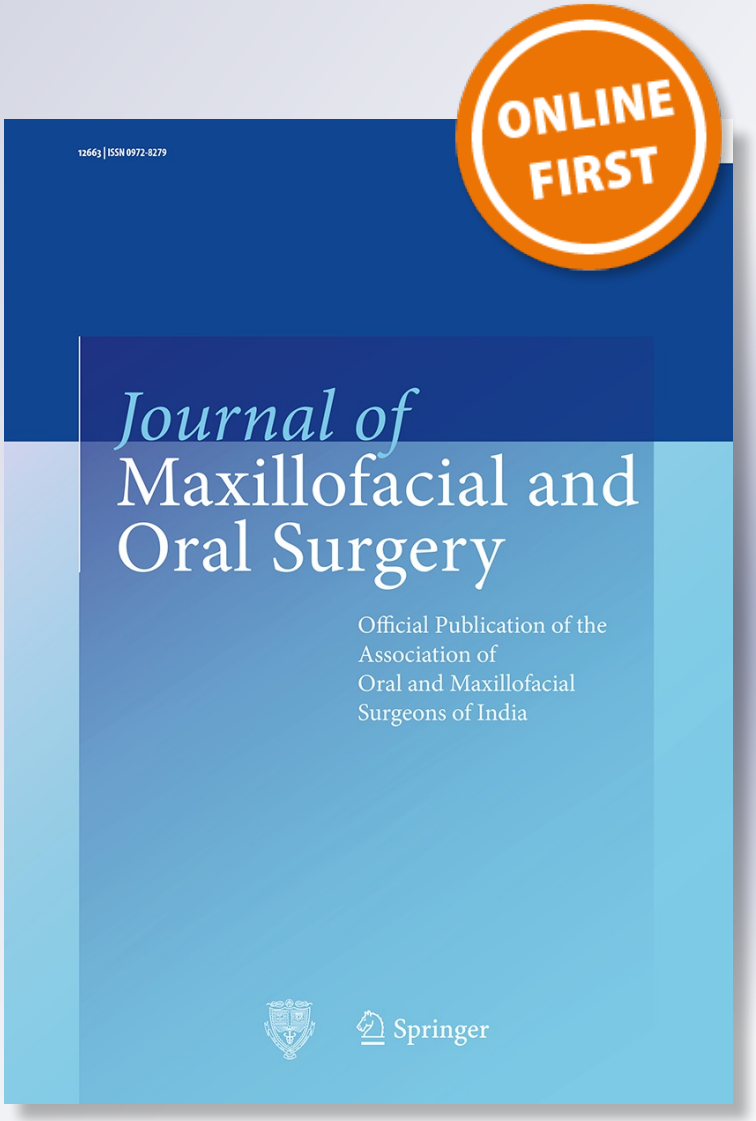

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CLINICAL PAPER

Clinical Evaluation of Anodized Surface Implants Submitted to a Counter Torque of 25 Ncm After 60 Days of Osseointegration: Study in Humans

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Abstract
Introduction Decreasing the time needed for osseointegration has always been a big challenge for modern implantodontics. The main factor which helps to decrease the time needed for osseointegration is the newly 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 The anodized surfaces in humans, following a 60 days-period of osseointegration.
Methodology Forty-Five implants were placed in different kinds of bones, according to the technique recommended by the manufacturer. Those implants were opened after 60 days of osseointegration. The success of evaluation was made through assessing the counter torque resistance of 25 Ncm. The implants which could withstand the applied torque were considered osseointegrated.
Results Of the forty-five implants made in different kinds of bones, only one failed to present osseointegration, resulting in a success rate of 97.7 %.
Conclusions With this methodology it was possible to conclude that anodized surface implants present primary osseointegration after 60 days of healing, after which they can function normally.

Keywords Dental implants · Osseointegration · Surfaces

R. Manfro · V. Fabris
Post Graduation Program on Implantodontics, UNOESC, Joaçaba, Brazil

R. Manfro
Post Graduation Program on Implantodontics, SOEBRÁS, Passo Fundo, Floianópolis, Brazil

R. Manfro (✉)
Presidente Coutinho 264/903, Florianópolis, SC CEP 88015-230, Brazil
e-mail: manfroimplante@hotmail.com

M. C. Bortoluzzi
Post Graduation Program in Bucomaxillofacial Surgery, UNOESC, Joaçaba, Brazil

M. C. Bortoluzzi · V. Fabris
Faculty of Dentistry, Universidade Estadual de Ponta Grossa, Ponta Grossa, Paraná, Brazil

C. N. Elias
Mechanical Engineering and Material Science Department, Military Institute of Engineering (IME), Rio de Janeiro, RJ, Brazil

V. C. de Araújo
Post Graduation Program, SLMANDIC, Campinas, SP, Brazil

Introduction

The conventional protocol proposed by Bränemark for treatment utilizing dental implants requires implant procedures to be performed in two phases, maintaining an interval between procedures of 3 months for mandibular treatment and 6 months for maxillary treatment to ensure osseointegration [1–3].

Implant surfaces allow for the acceleration of osseointegration. The morphology, topography, surface roughness, surface energy, and chemical composition and potential have a significant influence on the reaction of the bone tissue during osseointegration [2–7].

A surface roughness of up to 0.5 μm is necessary for fibroblast adhesion, while a roughness ranging from 0.5 to 1.5 μm allows for osteoblast adhesion [8, 9]. As

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technology has developed, these special surfaces have diminished the time needed for osseointegration while maintaining an acceptable success rate. To ensure the migration of osteogenic cells to the implant surface, fibrin retention must occur [10]. 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 [7, 11]. Further, anodization is another important factor for faster osseointegration because it incorporates Ca and P ions on the implant surface [3–5, 12–19].

Vulcano Surface Actives® implants, produced by Connection, utilize an anodization treatment. This treatment, which produces a roughness of 1.26 μm [20], allows for the incorporation of Ca and P [21, 22]. This surface treatment increases the wettability capacity by increasing the contact surface area by 10 % relative to surfaces treated with acid [23] (fig.1).

The main anodized surface in the market is TiUnite (Nobel Biocare), which was clinically shown to last 10 years with 97.96 % survival [24]. In a recent study, the structure of the Vulcan Actives' surface was compared to that of TiUnite via electron microscopy. The study concluded that while the roughness of the two was similar, the treatment area obtained by the Vulcan Actives surface was significantly greater [20]. The authors noted that although these values suggest good clinical performance, such performance was not found by studies evaluating Vulcan Actives' surface. This work is presented to address this issue and examine the clinical performance of Vulcan Actives' surface, a topic not yet addressed by the present literature [20].

This work seeks to clinically assess the level of osseointegration of Vulcano Actives® implants 60 days after their placement in patients.

Methodology

Selection of patients and number of implants

The sample was selected from those patients attending a clinic for a specialization course on implantology at UNOESC, Joaçaba campus, who required implant rehabilitation of up to a maximum of three implants in each hemi-arch, provided that they did not have any systemic problems that could contraindicate implant rehabilitation. Further, the patients must not have been treated through the immediate load technique or have been in need of bone grafting. All patients were required to accept the terms of the research agreement. Forty-five Connection ARs and Morse ARs Vulcano Actives® surfaces were placed over the course of the study.

Pre-surgical preparation

Patients were evaluated 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 was administered orally 1 h before the surgical procedure, and the patients gargled with chlorhexidine digluconate 0.12 % twice a day, beginning 1 day before the surgery. Patients who were allergic to penicillin were medicated with clindamycin 600 mg 1 h before surgery. Post-surgery, 750 mg of paracetamol was administered every 6 h for 24 h to control pain. Patients continued to gargle with chlorhexidine digluconate 0.12 % twice a day for 7 days after the procedure, as prescribed.

Surgical technique

The implants were selected on a case-by-case basis, as determined by recommendations according to the length, thickness, and type of connection. The insertion 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 record.

Assessment

After 60 days of osseointegration, reopenings were performed. During this procedure, a torque test was performed so as to assess the osseointegration, with the help of a ratchet extender for the placement of implants, which was assembled in a prosthetic ratchet made by the Conexão Sistema de Próteses®. The implants were submitted to a torque of 25 Ncm.

The implants which did not withstand the counter torque test were removed, and prosthetic procedures were performed in a conventional way for the remaining implants.

Results

From September 2008 to December 2008, 45 implants were placed in 25 patients. The distribution of the implant locations in the maxilla and the mandible are given in Figs. 2, 3 and 4 respectively.

Of the 45 implant placements, only one placement failed to achieve osseointegration, thus yielding a 97.7 % success rate. Table 1 presents data referring to the 45 implant placements' location, insertion torque, reopening time, and result.

Bone quality and primary stability, which are two of the main factors that influence the success of osseointegration, are given in Tables 2 and 3, respectively.

Discussion

When osseointegrated implant treatments were first introduced, the initial goal was to discover a metal that would bind well to bone. The material originally considered to be most promising was commercially pure titanium [3, 5, 24]. Today, other materials, such as tantalum, niobium, and titanium alloys, are known to have the capacity to achieve osseointegration [25]. Further, ceramics are known to permit greater bone bonding with the implant than titanium [26, 27].

Several surface treatments have been described in the literature. Initially, with the aim of increasing the bone/implant contact area, hydroxyapatite and titanium etchings were used [24]. Acid conditioning was also employed to create roughness in the implants and to increase the bone/implant contact area [28].

The difference in texturization is directly responsible for the cell behavior on the implant surface [8]. It influences not only the quality and the quantity of bone formation but also the speed of both bone formation and implant binding [29]. The main factors that allow for faster osseointegration are the nano-topography of the surfaces and the chemical modification resulting from the incorporation of calcium and phosphate ions [3–5, 12–19].

Albrektsson and Wennenberg [4, 5] 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 [12, 18, 19], and they improve cicatrization in the first 5 weeks [30]. To diminish osseointegration time, thus altering the biological behavior of implant, it is necessary to maintain the implant in an isotonic surface to eliminate the titanium oxide layer [31–33]. Maintaining both the implant and those surfaces bio-activated by bisphosphonates in an isotonic solution in animals presented significant differences in neither the quantity of bone formation nor the percentage of bone/implant contact [34].

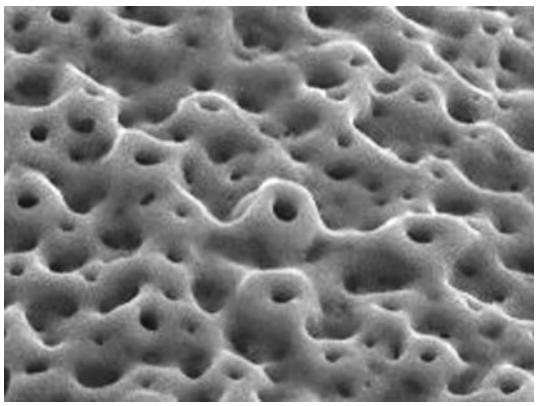

Fig. 1 Vulcano Actives surface (magnification 5.000×)

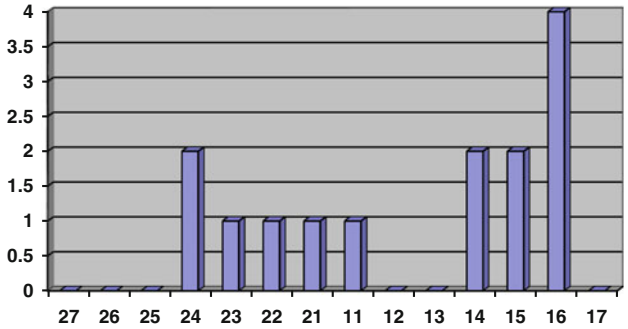

Fig. 2 Distribution of implants according to their location in the maxilla

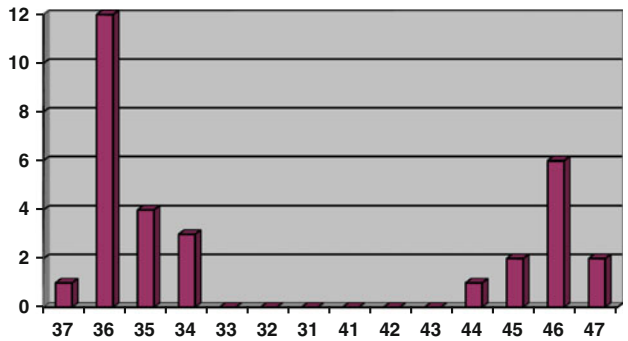

Fig. 3 Distribution of implants according to their location in the mandible

This study used anodized surfaces, which showed 97.96 % success. This treatment produces a roughness of 1.26 μm, yielding a surface with nanometric features [20]; moreover, its shape diminishes 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 [22]. 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 [22, 34, 35].

When compared to implants treated with etching and acid conditioning placed in rabbits' tibias, the anodized surfaces showed a smaller contact angle between the bone and the implant, and they required a greater removal torque after 12 weeks of osseointegration [34]. In humans, 2 months following implant placement, the surface presented greater bone/implant contact than machined surface implants [35].

Table 1 Distribution of implants according to location, size of implant, type of prosthetic connection, bone quality, initial stability, and result

	Location	Size of implant	Connection	Bone quality	Reopening period (days)	Initial stability	Result
1	46	3.75 × 11.5	HI	II	60	70 Ncm	Success
2	35	3.75 × 13	HI	I	58	60 Ncm	Success
3	35	3.75 × 13	HI	I	58	70 Ncm	Success
4	36	4.0 × 10	CM	II	62	50 Ncm	Success
5	46	4.0 × 10	HI	I	60	60 Ncm	Success
6	36	3.75 × 11.5	HI	I	60	60 Ncm	Success
7	45	3.75 × 10	HI	I	60	50 Ncm	Success
8	35	3.75 × 11.5	HI	I	60	55 Ncm	Success
9	24	3.75 × 13	CM	III	60	50 Ncm	Success
10	36	4.0 × 11.5	HI	II	59	40 Ncm	Success
11	36	4.0 × 13	HI	II	60	60 Ncm	Success
12	14	3.75 × 11.5	HI	III	60	50 Ncm	Success
13	15	3.75 × 10	HI	III	60	35 Ncm	Success
14	16	3.5 × 10	HI	III	60	60 Ncm	Success
15	34	3.75 × 11.5	HI	II	59	45 Ncm	Success
16	46	3.75 × 13	HI	I	60	50 Ncm	Failure
17	36	3.75 × 10	CM	II	60	40 Ncm	Success
18	34	3.75 × 10	HI	II	60	60 Ncm	Success
19	36	4.0 × 13	HI	II	60	30 Ncm	Success
20	44	3.75 × 10	HI	II	60	70 Ncm	Success
21	46	4.0 × 11.5	HI	II	60	30 Ncm	Success
22	36	4.0 × 11.5	HI	II	61	50 Ncm	Success
23	34	3.75 × 15	HI	II	60	55 Ncm	Success
24	36	4.0 × 13	HI	II	60	40 Ncm	Success
25	36	3.75 × 11.5	CM	II	58	60 Ncm	Success
26	47	3.75 × 11.5	CM	II	58	70 Ncm	Success
27	24	3.75 × 13	HI	III	61	30 Ncm	Success
28	15	3.75 × 11.5	HI	IV	61	25 Ncm	Success
29	16	4.0 × 10	HI	IV	61	50 Ncm	Success
30	22	3.75 × 11.5	HI	III	61	50 Ncm	Success
31	16	4.0 × 13	HI	II	61	70 Ncm	Success
32	45	4.0 × 13	HI	II	61	60 Ncm	Success
33	47	3.75 × 13	HI	II	61	70 Ncm	Success
34	36	3.75 × 11.5	HI	II	60	80 Ncm	Success
35	36	3.75 × 11.5	HI	III	61	40 Ncm	Success
36	11	3.75 × 11.5	CM	III	60	40 Ncm	Success
37	21	3.75 × 10	CM	III	60	30 Ncm	Success
38	23	3.75 × 11.5	CM	III	60	40 Ncm	Success
39	36	3.75 × 10	CM	II	60	50 Ncm	Success
40	46	3.75 × 10	CM	II	60	40 Ncm	Success
41	14	3.75 × 13	CM	III	60	50 Ncm	Success
42	16	3.75 × 10	CM	IV	60	30 Ncm	Success
43	35	3.75 × 13	HI	III	60	40 Ncm	Success
44	37	3.75 × 15	HI	II	60	70 Ncm	Success
45	46	3.75 × 11.5	HI	II	60	50 Ncm	Success

There are many works in the relevant literature on animals that address the aspect of speed of osseointegration on bioactive surfaces [14, 18, 31, 36–38], but there are few works on humans defining the necessary amount of time needed before placing a load on such implants [3]. Therefore, in this study, we chose to verify the secondary stability of implants

Table 2 Distribution of implants according to bone quality and their respective success rate

Bone quality	Number of implants	Failed implants	% of success
Type I	07	1	85.7
Type II	23	0	100
Type III	12	0	100
Type IV	3	0	100

Table 3 Distribution of implants according to primary stability of implants and their respective success rates

Primary stability (N/cm2)	Number of implants	Failed implants	% of success
20 a 35	07	0	100
40 a 55	22	1	95.4
60 a 80	16	0	100

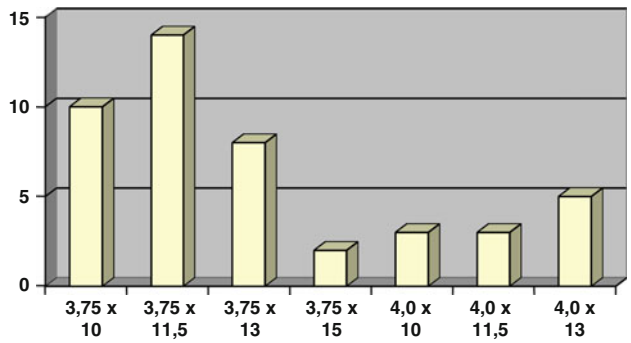

Fig. 4 Distribution of implants according to size and thickness

produced by the company Connection, using a Vulcano surface (anodization) in humans. A torque of 25 N/cm was considered for this technique. In conventional implants, the insertion torque for the prosthetic component is 20 N/cm. Because it was 25 N/cm, it was possible to perform the prosthetic procedures following the manufacturer's instructions. Despite only making assessments during the reopening procedure, no fixation was lost during the prosthetic stabilization and placement procedures.

Primary osseointegration was obtained regardless of the bone quality, insertion torque, and implant location. The only implant that did not present osseointegration had been placed in the posterior part of the mandible, in type I bone. We believe that the failure to establish osseointegration was due to problems that occurred during the implant placement, contamination, or prosthetic denaturation through the milling process, which, considered in the context of this work, does not impact the positive results obtained.

We believe that this methodology allows for the safe use of tested implants, regardless of the type of bone or implant placement location, resulting in a 60-days osseointegration period and confirming the expectation reported by the authors in the assessment of surface electronic microscopy [20].

Conclusions

The proposed methodology led us to conclude that the primary osseointegration success rate, tested using a counter torque of 25 N/cm on the Vulcano surface implants, was 97.7 % after 60 days of cicatrization.

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