Characterization of implants surface of the five largest companies in the Brazilian market, on micrometric level. Part III: SIN implants

Márcio Borges **ROSA***
Tomas **ALBREKTSSON****
Carlos Eduardo **FRANCISCHONE*****
Humberto Osvaldo **SCHWARTZ FILHO******
Ann **WENNERBERG*******

Abstract

Introduction: The quality of the bone-implant interface is directly influenced by implant surface roughness and a roughness average, with the S_a between 1 to 2 µm, has demonstrated better clinical and laboratory results. In Brazil, more than two million implants per year are installed, where 79% are manufactured by domestic companies. However, very little is known or published about the characterization of surfaces of these implants, on the micrometer level. The aims of this study are to evaluate and characterize numerically the surface of the implants of SIN (Sistema de Implante Nacional) company, one of the five largest companies in the Brazilian market. **Methods:** Were evaluated a total of 6 implants, purchased directly on the market, of two different designs (Tryon-HE and Strong-SW) and different batches, using light interferometry. Were performed 9 measurements randomly chosen for each unit, 3 on the tops, 3 on the valleys and 3 on the flanks of the threads. The same pattern was followed for evaluation by scanning electron microscope. **Results:** The analyzed implants from this company showed S_a values of 0.84µm for Tryon-HE and 1.01 µm for Strong SW. Comparing the batches, only the SW design showed statistically significant differences between them. **Conclusions:** The roughness values found herein categorize the surfaces of Tryon-HE as minimally rough, and Strong-SW implants as moderately rough.

Keywords: Dental implant. Brazilian implants. SIN implants. Implant surface. Roughness.

How to cite this article: Rosa MB, Albrektsson T, Francischone CE, Schwartz Filho HO, Wennerberg A. Characterization of implants surface of the five largest companies in the Brazilian market, on micrometric level. Part III: SIN implants. Dental Press Implantol. 2012 July-Sept;6(3):60-70.

» The authors inform that they have no associative, commercial, intellectual property, or financial interests representing a conflict of interest in products and companies described in this article.

Contact address

Márcio Borges Rosa
Av. do Contorno 4849, 4º andar – Bairro Serra
Zip Code: 30.110-100 – Belo Horizonte/MG – Brazil
E-mail: marcio@implantare.com.br

Submitted on: July 13, 2012
Reviewed and received on: July 15, 2012

* PhD student of Implantology, São Leopoldo Mandic.
** Head, Department of Biomaterials, University of Gothenburg, Sweden.
*** Full Professor, FOB–USP. Coordinator of the PhD Course in Implantology, São Leopoldo Mandic.
**** PhD student of Implantology, Unesp.
***** Head, Department of Prosthetic Dentistry, Malmö University of Odontology, Sweden.

Introduction

An important parameter for the clinical success of osseointegrated implants is the formation of direct contact between implant and surrounding bone.[1,2] The quality of the bone-implant interface is directly influenced by the roughness of the implant surface[3-8] which was identified as one of six particularly important factors for the incorporation of implant into the bone from the beginning of the 80's.[3]

Both morphology and surface roughness have an influence on the proliferation, cell differentiation, extracellular matrix synthesis, local production factors and even on the cell shape.[8,9] Fixing mechanisms used by cells on the implant surface determine its shape and the transmission of signals through their cytoskeleton resulting in the expression of specific phenotypes. Furthermore, the shape of the cell regulates the growth, gene expression, protein secretion, differentiation and apoptosis.[10]

The osteoblast adhesion on the implant surface is not sufficient for obtaining the osseointegration, or even improves it, but it is necessary particularly for the cell to receive signals in order to induce their proliferation.[8] Moreover, roughness do not only facilitate the retention of osteogenic cells, but they allow them to migrate on the implant surface by osseoconductivity.[11] A faster and stronger bone formation provides higher stability during the repair process, allowing even a faster loading of the implant.[5,6,7]

The oral implants surfaces have measurable structures in macrometric scale in millimeters (mm), micrometric scale in micrometers (μm) and nanometric scale in nanometers (nm).[5,7,8,12,13,14] The objective of several publications and studies in this recent years is how these structures influence the repair.[6,13,15-18]

So far, the certainties are limited to the influence of implant design and roughness in micrometric scale. A screw-shaped design and a surface with a mean roughness, S_a of 1-2μm , show better results.[6,7,8,12] Studies have shown titanium implants with appropriate roughness can improve the bone-implant contact[19] and also increase the force of the extraction torque.[19,20] On the other hand, increasing the surface roughness higher than 2μm of S_a causes an impaired and unreinforced bone response.[5-8]

Over the past 20 years, a high number of implant systems with different surface topographies was added.[17] Oral implants are an example of the close binding between research and industry, as the laboratory findings often become clinical applications.[1]

Brazil is currently one of the largest implant markets of the world with an annual consumption estimated at 2.000,000 (two million) units which 79% are manufactured by national companies (Survey on the Status of Implantology in Brazil — Implant News, Survey 2010). SIN (São Paulo) is one of the five largest companies in Brazil.

But it is disclosed or known very little about the physicochemical characteristics of the surface of their implants, thus limiting the information contained in the leaflet and in its catalog.

This study aims to characterize the surfaces of two different SIN designs: Tryon-HE and Strong-SW, and describe them within the international standard developed by Wennerberg and Albrektsson[5]. Data found are described and evaluated with the expectation in the treatment used, comparing them with Osseotite® implants, made by Biomet 3i, used as reference since they use the same type of treatment and have solid publishing in worldwide literature.

Material and Methods

Methods used to evaluate the implant surface was proposed by Albrektsson and Wennerberg in 2000[5], and became a worldwide standard for evaluating the implant surfaces.

Therefore, three measurements were carried out in different areas for each implant, from the tops, valleys and flanks of the threads (Fig 1), with a total of nine measurements for each unit. Furthermore, three samples were evaluated in different batches for each implant to permit evaluation of the regularity of production process, and they are separated in samples 1, 2 and 3. Following this pattern, three implants of each of the following designs made by SIN, were purchased directly in the market: Tryon-HE (Fig 2) and Strong-SW (Fig 3).

Scanning electron microscopy images were also performed (Quanta 200) from top, flank and valley of threads in the upper, middle and lower thirds, with a total of 9 areas assessed. Magnifications of 65X, 350X, 1,000X, 3,000X and 5,000X were used.

The objective of those images was to undertake a qualitative analysis of the modifications achieved by the surface treatments, by observing the roughness characteristics and whether they upheld the same pattern throughout the entire body of the implant.

Then, one of implants sample was cut transversely for polishing metal and underwent the EDS analysis, the energy dispersive spectroscopy, used to identify elements present in the surface to ensure the titanium used by the company, checked that described in the leaflet.

Surface treatment

SIN implants surfaces are treated by acid etching, that removes the outer layer of titanium oxide from

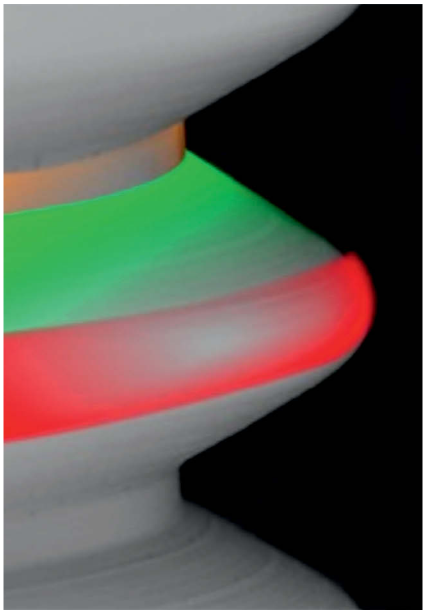

Figure 1 - Red = top; green= flank; orange= valley.

Figure 2 - SIN Tryon-HE Implant. Lots evaluated: Lot 01 – IO0173; Lot 02 – H71070; Lot 03 – G60337.

Figure 3 - SIN Strong-SW Implant. Lots evaluated: Lot 01 – I10960; Lot 02 – I90543; Lot 03 – H80750.

the surface and portions of the layer immediately below the surface, creating microcavities of different depths, with a new oxide layer being immediately formed on the new surface. The amount of removed material and the characteristics of the irregularities that are created depend on the type and concentration of the acid as well as on its temperature and treatment time, and obviously, on the type of titanium employed.[6,8]

Acid etching usually leads to a slight increase in roughness. It should be noted, however, that different features may increase or decrease the irregularities.[6]

Each manufacturer has a unique method to carry out this treatment. Usually, double acid etching is performed by first immersing the implant in acidic solutions, among which are: HCl, H_2SO_4, HNO_3, HF or any combination of these. Then, the implant is immersed in an aqueous solution of HNO_3 to stabilize an oxide layer.[6,8]

Surface analysis

Implant surfaces were evaluated using a light Interferometer (MicroXAM™, Phaseshift, USA) is indicated to evaluate roughness of the implant with threads at micrometric level.[5] We use an objective of 50X and a zoom of 0.62. The measured area was 264 X 200 µm, while the average height of measures ranged between 80 µm and 100 µm. The maximum resolution of this technique is 0,30 µm horizontally and 0.05 µm vertically.

To be able to adequately describe the roughness obtained with the treatment, the undulations of machining process and shape are considered separately. A standard filtering process using a Gaussian Filter of 50 X 50µm was used to perform this separation and assessment of the micrometric roughness (Fig 4-7). For this, the Surfascan software (Somicronic Instrument, Lyon, France) is used, which also provides visual images and numerical descriptions. For the numerical description of the surface topography which should preferably be in 3D, the following parameters are used:

a) S_a: Represents the arithmetic mean for height of peaks and valleys, surface roughness in the median plane.
b) S_{ds}: Represents the density, in other words, number of peaks per area unit.
c) S_{dr}: Hybrid parameter representing the increase in area obtained.

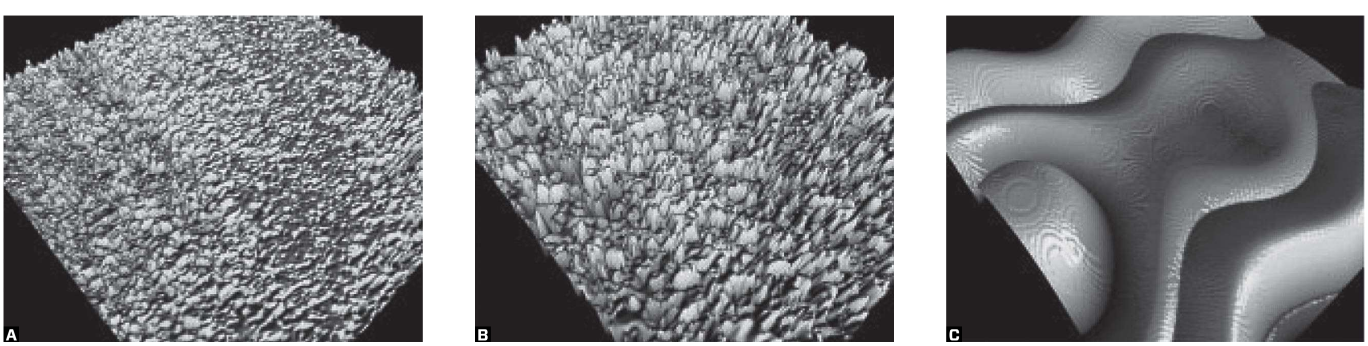

Figure 4 - **A**) Original Nanotite, **B**) Nanotite with 50X50Ÿm Gaussian filter, **C**) Nanotite with 50X50Ÿm Gaussian filter (low pass)14. Sequence of filters in which the undulations and shapes are removed.

Implants can be divided into 4 different categories, depending on the surface roughness measured by the value of S_a:[12] smooth ($S_a < 0.5$ µm); minimally rough (S_a between 0.5–1.0 µm), moderately rough (S_a between 1.0–2.0 µm); Rough ($S_a > 2.0$ µm).

Statistical analysis

Implants were evaluated for significant differences in surface topography at micrometric level. Statistical analyzes were performed using GraphPad Prism 5,0 (GraphPad Software, San Diego, USA). Results were analyzed using Kruskall-Wallis test with significance level of $p < 0.05$, and Dunn's multiple comparison test was applied, also at a significance level of $p < 0.05$.

Results

Characterization of surface

Table 1 shows the values obtained, as well as the implant used as reference for comparison to the values found and published by Svanborget al.[14]

In Figure 5, images of interferometer analysis generated by the Surfascan were observed along with the obtained in the SEM with a magnification of 3,000X. Images were selected from the flanks of the thread in the middle third of the implants. Following detailed images of scanning electron microscopy in 3 different magnifications of Tryon-HE (Fig 6) and Strong-SW (Fig 7) implants evaluated, as well as the Osseotite implant surface used as reference (Fig 8).

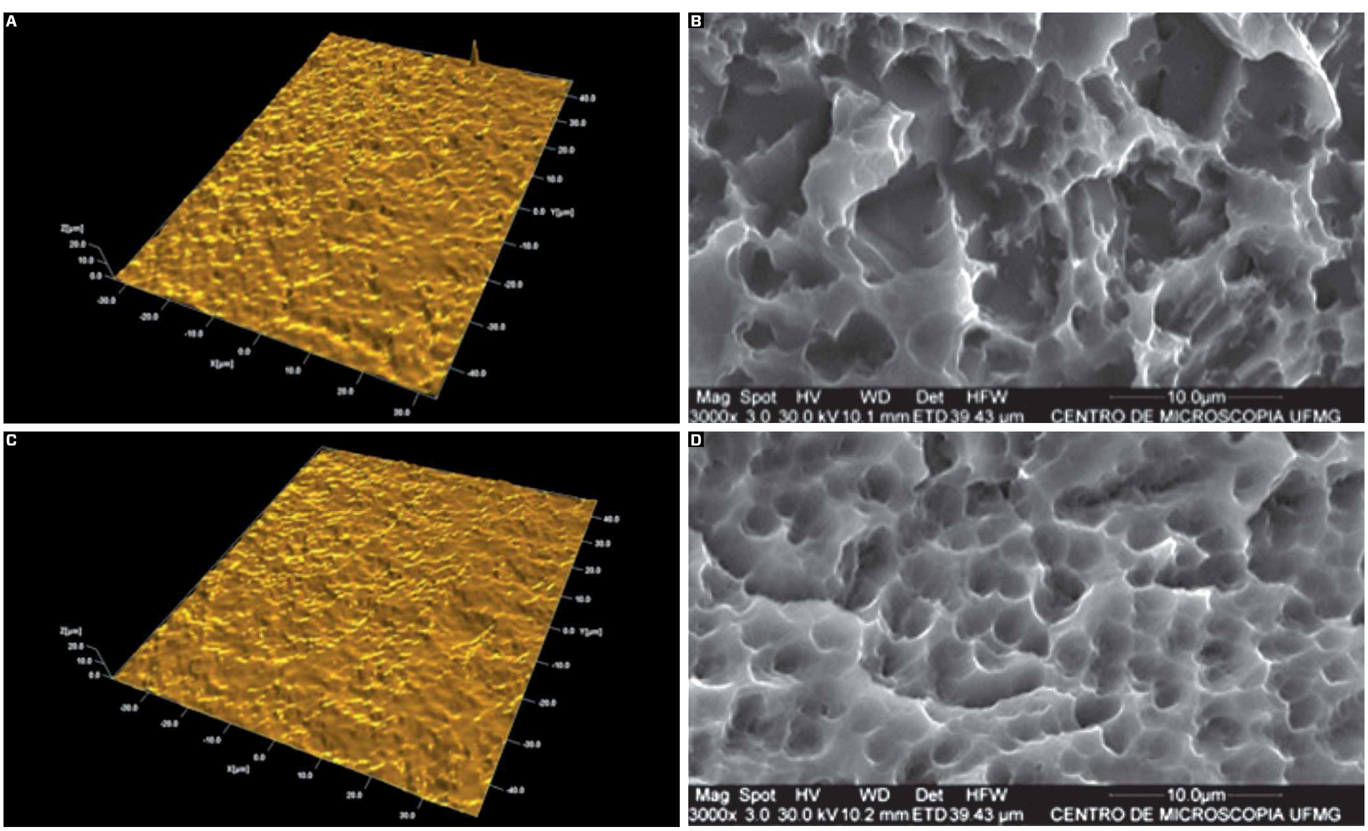

Figure 5 - Images of the interferometer (left) and SEM (right), 3,000x magnification. **A**, **B**) SIN Strong-SW; **C**, **D**) SIN Tryon-HE

Table 1 - Numerical description of the SIN implant surface topography, in micrometric level.

	S_a µm	S_{ds}/mm²	S_{dr}%
SIN Tryon-HE	0.84 ± 0.23	164.463 ± 8.680	47.47 ± 17.68
SIN Strong-SW	1.01 ± 0.35	165.051 ± 15.426	92.67 ± 41.73
3i Osseotite®	**0.66 ± 0.05**	**140.441 ± 8.321**	**26.80 ± 4.02**

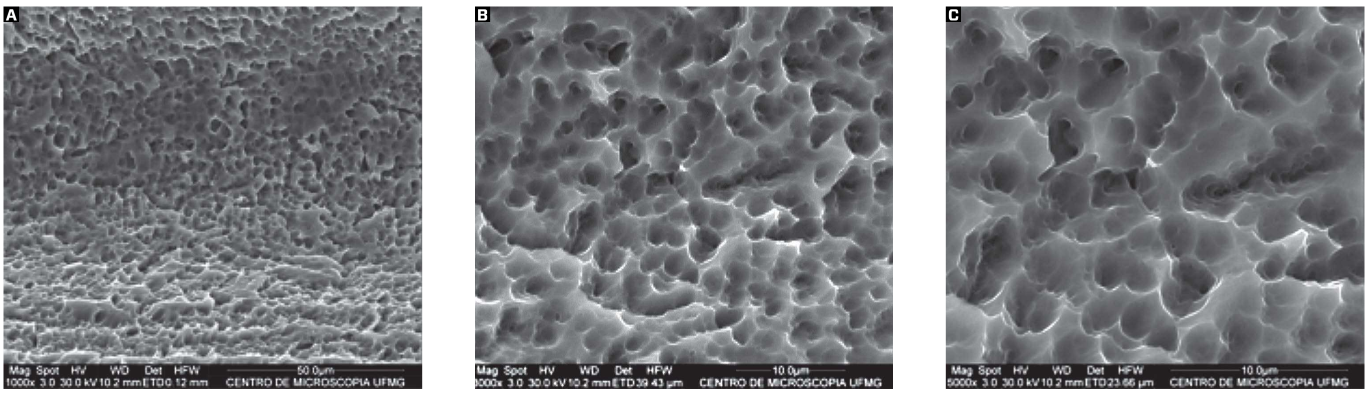

Figure 6 - SEM images of Tryon-HE implants (**A**: 1,000x, **B**: 3,000x, and **C**: 5,000x).

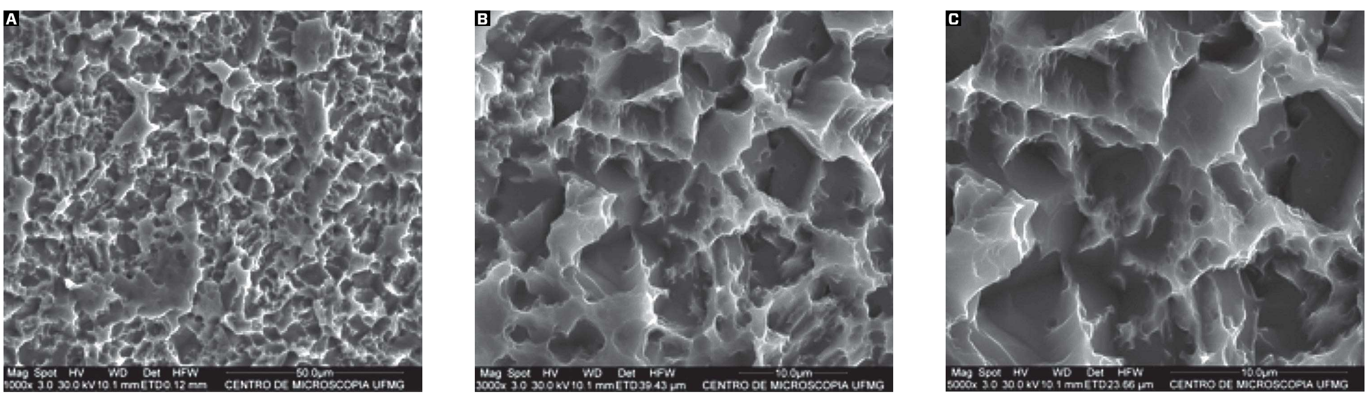

Figure 7 - SEM images of Strong-SW implants (**A**: 1,000x, **B**: 3,000x, and **C**: 5,000x).

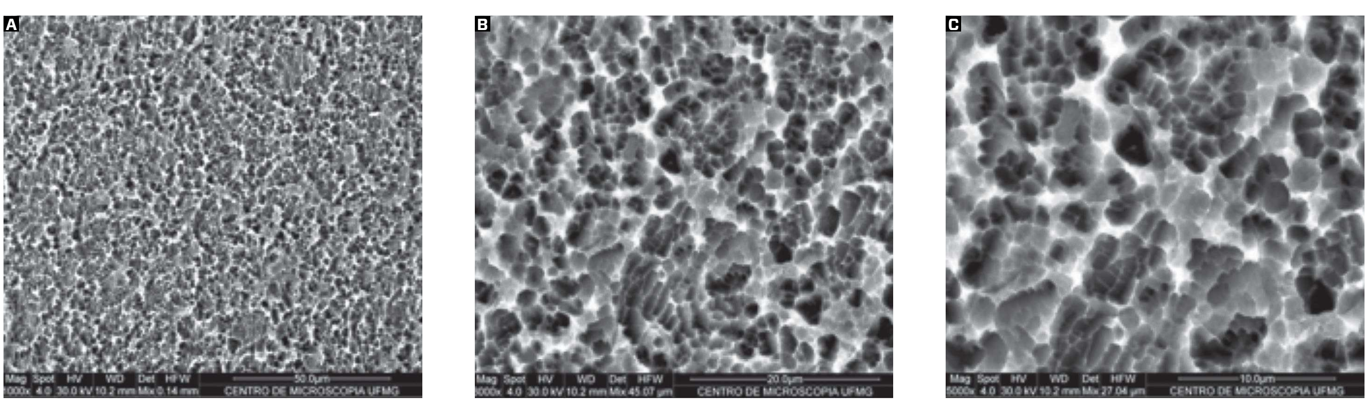

Figure 8 - SEM images of Osseotite® implants, by Biomet 3i (**A**: 1,000x, **B**: 3,000x, and **C**: 5,000x).

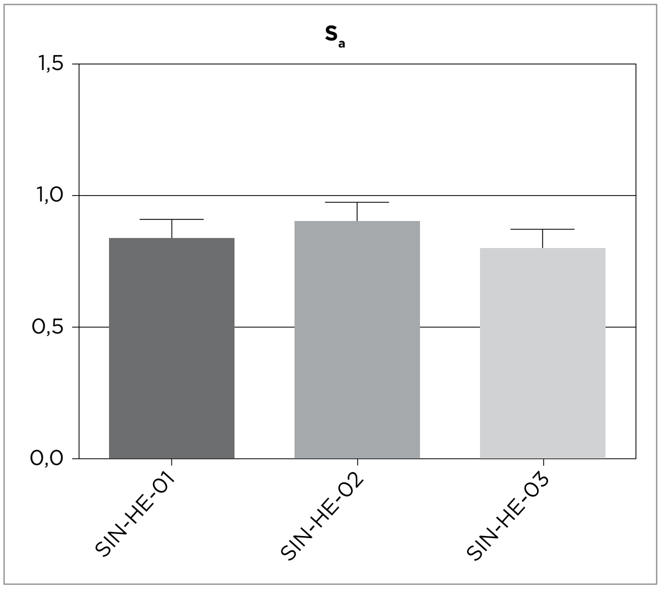

Figure 9 - Representation of S_a values for Tryon-HE implants.

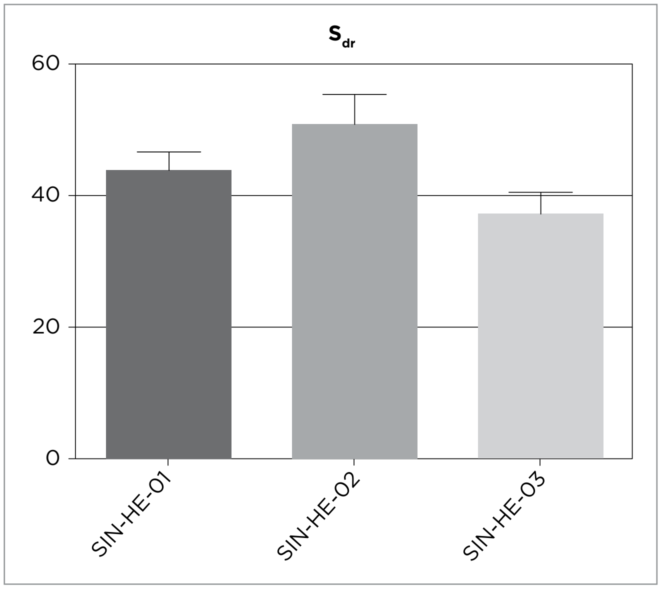

Figure 10 - Representation of de S_{dr} values for Tryon-HE implants.

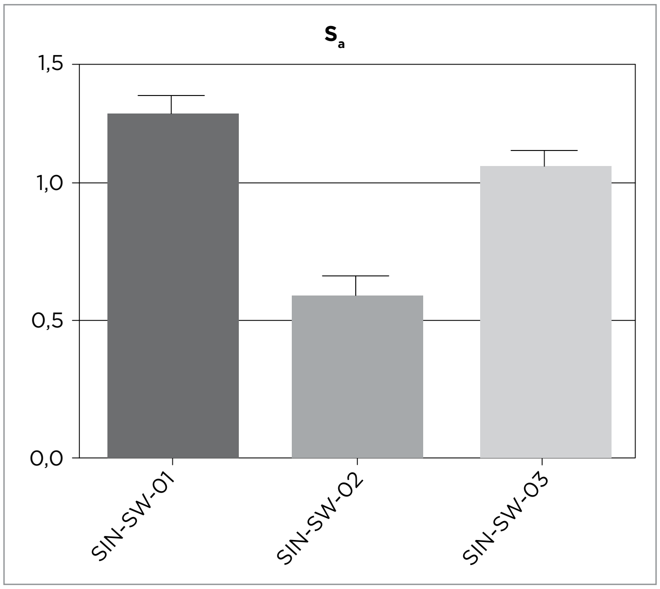

Figure 11 - RRepresentation of S_a values for Strong-SW implants.

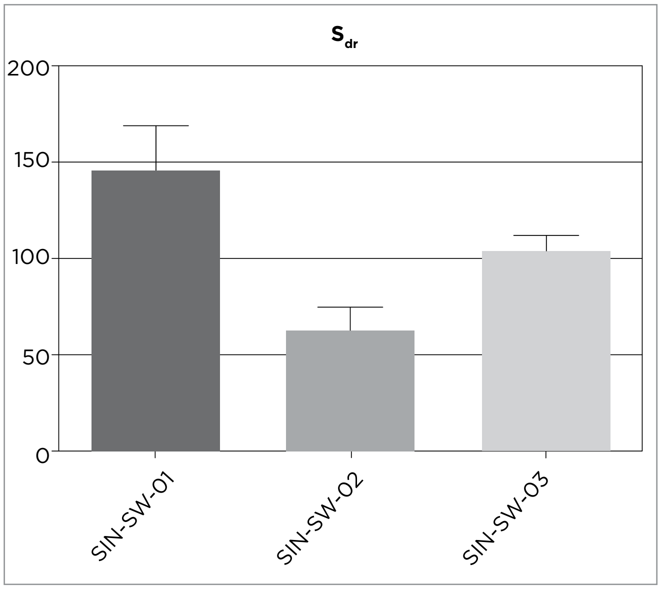

Figure 12 - Representation of S_{dr} values for Strong-SW implants.

Comparing the different lots

Analysis was performed separately for each design, because herein does not fit any comparison between them. In addition to this, comparison will be made only regarding the S_a and S_{dr}. For statistical analysis, the Prism software was used, and as the distribution was not normal, we applied the Kruskal-Wallis test ($p < 0.05$) as well as Dunn's multiple comparison test, also at a significance level of $p < 0.05$.

Tryon-HE

These implants displayed a fairly regular pattern between lots, with S_a values of 0.83 µm for Lot 01, 0.89 µm for Lot 02, and finally 0.79 µm for Lot 03 (Fig 9). Likewise, S_{dr} values were very close to each other, with 44% in lot 01, 50% in Lot 02, and 37% in lot 03 (Fig 10). Therefore, there were no statistically significant differences between the values in both parameters.

Strong-SW

This implant design displayed statistically significant differences between S_a values for Lot 02, with 0.62 µm, and Lots 01, with 1.30 µm, and 03, with 1.08 µm (Fig 11), as well as in S_{dr} values between Lots 01, with 117%, and 02, with 62% (Figure 12).

EDS of the implants

The EDS analysis results for both SIN implant designs indicated the use of titanium grade-4 (ASTM F67),which is fully in accordance with the specifications given in the product description. Figure 13 presents the spectrum of the Strong-SW implant and will serve to demonstrate the chemical composition of both evaluated implants from SIN.

Discussion

When the implants started to be manufactured in Brazil, most companies chosen designs and implant surface treatments established, with extensive scientific publication and strong presence in the Brazilian market. SIN was chosen dual acid etching as the surface treatment, in the manner of Osseotite® surface, of Biomet 3i, USA. One way to evaluate the obtained results is to compare them with the values obtained from reference implants, using the same standards and backed by vast scientific evidence. Certainly, these considerations led SIN to use the Osseotite® implants as reference, and follow their model.

Among the parameters evaluated, the most representative ones for the analysis of a surface are S_a, representing the arithmetic mean of peak and valley heights of the surface roughness in 3D and S_{dr} representing the increase in surface area obtained with treatment. Analysis of these factors and previous knowledge of its influence on the repair processes allows a behavior signaling of certain surface.[7,12,22]

The SIN implants, that use grade-4 titanium, showed an S_a of 0.84 µm for Tryon-HE and 1.01 µm for Strong-SW — therefore, displayed by the reference implant,

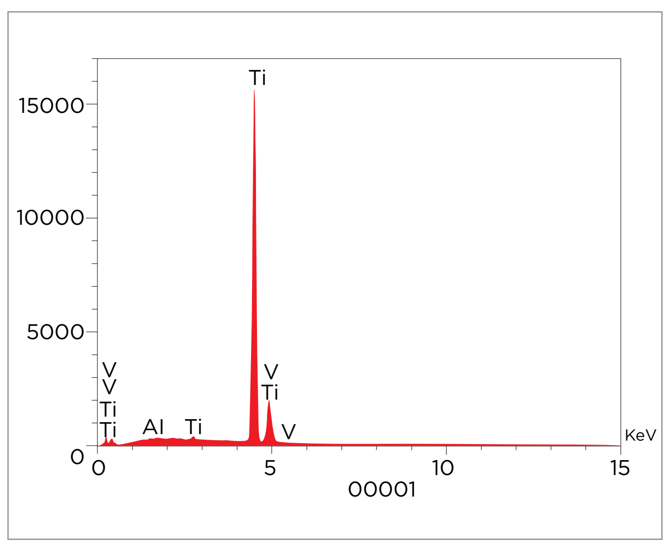

Figure 13 - EDS spectrum showing the elements present in the sample of the SIN Strong-SW implant. The x-axis represents the energy of the corresponding element, and the y-axis, the x-ray photon count.

i.e., Osseotite,® at 0.66 μm,[14] but however, uses grade 2 titanium in its manufacture, which favors the quality of repair. Nevertheless, it should be highlighted that not even the reference implant features the roughness regarded as ideal (between 1.0 and 2,0 μm) following acid etching. In general, this etching leads to a slight increase in roughness and, in fact, many consider Osseotite® implants to be too smooth to be ideal.

A similar result was found in evaluating S_{dr}, with SIN implants achieving higher values than Osseotite®, which displayed an S_{dr} of 27%,[14] while Tryon-HE showed 47%, and Strong-SW, 92%. Theoretically, this combined increase of roughness and surface area benefits repair, but should be further investigated through comparative clinical studies.

For both evaluated SIN designs, the values of S_a and S_{dr} alike, as well as the topographic characteristics observed in SEM images (Figs 8 and 9), were quite different from one another. Since the company employs the same surface treatment process for both implant designs, the difference found is due to the influence of the macro design of the implant obtained by microtopography. As demonstrated by Wennerberg and Albrektsson,[6] when the macrometric topography of a given surface is changed, its micrometric characteristics may also undergo concurrent changes, even if accidentally.[7,19,23,24,25]

An analysis of the SEM images evidences topography typical of a surface submitted to acid etching. In addition to the previously mentioned differences between the two evaluated SIN implants, both also proved to be topographically different from the Osseotite® implant (Fig 10), which reinforces the variability inherent to acid etching.

As with the methodology employed, EDS analysis allows to state only on the percentage of chemical elements found, which are fully consistent with the leaflet of the implants, and they point to the use of Titanium ASTMF F67 grade 4 in their manufacture. In this analysis, it is not possible to make any consideration on the existence or absence of contamination or any metal or material on the surface of the implants.

In comparing among batches, there was a statistically significant difference only among Strong-SW implants. According to the method employed, the assessment of two more samples from the batch 02 of this implant. For this, the company was contacted in order to concede these implants for further analysis. However, as those stock batches were no longer found, the company sent three new samples from the same batch for each design distinct from those first evaluated. Herein, it is noteworthy that the implants of the first assessment were acquired directly in the market. In the subsequent analysis of the new samples, there was a statistically significant difference between the evaluated implants for S_a values of sample 3 (0.89 μm) compared to samples 1 (0.45 μm) and 2 (0.43 μm). This also occurred for the values of S_{dr}, which samples 1, 2 and 3 presented, respectively, 25%, 26% and 39% of S_{dr}. Moreover, there was a statistically significant difference between the mean values of S_a and S_{dr}, presented by the first group of implants to be evaluated (S_a of 1.01 μm and S_{dr} of 92%) compared to that obtained by the other group in the second analysis (S_a 0.61 μm and S_{dr} 30%). These differences indicate that the company must reassess the level of control of its process of surface treatment.

To know what these differences really may represent, further investigations are required. It can state the similar treatments do not show the same results.[6,7] Even only machined surfaces may vary considerably in roughness, as well as blasted surfaces with acid conditioning or anodized.[6,7] Many studies and companies omit the topographic characterization of the surface because they believe the treatment alone will determine the optimum roughness of this surface.[6]

As it was already stated,[6,7] when the macrometric topography of a certain surface is changed, the micrometric and chemical characteristics may be changed at the same time, even accidentally. Therefore, it is essential the surface treatments are appropriate for each implant design in order to obtain the desired roughness.

Conclusions

Even if companies use consecrated techniques of surface treatments, it is important to invest in ongoing laboratory experiments to evaluate the results, its standardization and regularity.

In addition of course, to conduct clinical studies both prior as to subsequent releases of their implants, to validate its effectiveness and evaluate their influence on osseointegration, success rate and longevity.

REFERENCES

1. Shalabi MM, Wolke JG, Jansen JA. The effects of implant surface roughness and surgical technique on implant fixation in an in vitro model. Clin Oral Implants Res. 2006 Apr;17(2):172-8.
2. Fröjd V. On Ca 2+ Incorporation and nanoporosity of titanium surfaces and effect on implant performance. Malmo- Sweden: Malmo University; 2010.
3. Albrektsson T, Branemark PI, Hansson HA, Lindstrom J. Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man. Acta Orthop Scand. 1981;52(2):155-70.
4. Cooper LF. A role for surface topography in creating and maintaining bone at titanium endosseous implants. J Prosthet Dent. 2000 Nov;84(5):522-34.
5. Wennerberg A, Albrektsson T. Suggested guidelines for the topographic evaluation of implant surfaces. Int J Oral Maxillofac Implants. 2000 May-Jun;15(3):331-44.
6. Wennerberg A, Albrektsson T. Effects of titanium surface topography on bone integration: a systematic review. Clin Oral Implants Res. 2009 Sep;20 Suppl 4:172-84.
7. Wennerberg A, Albrektsson T. On implant surfaces: a review of current knowledge and opinions. Int J Oral Maxillofac Implants. 2010 Jan-Feb;25(1):63-74.
8. Elias CN, Meirelles L. Improving osseointegration of dental implants. Expert Rev Med Devices. 2010 Mar;7(2):241-56.
9. Anselme K, Bigerelle M. Topography effects of pure titanium substrates on human osteoblast long-term adhesion. Acta Biomater. 2005 Mar;1(2):211-22.
10. Brunette MD. Principle of cell behaviour on titanium surfaces and their application to implanted devices. In: Brunette DM TP, Textor M, Thomsen P, editor. Titanium in Medicine. Berlin (DE): Spinger Verlag; 2001. p. 485–512.
11. Braceras I, De Maeztu MA, Alava JI, Gay-Escoda C. In vivo low-density bone apposition on different implant surface materials. Int J Oral Maxillofac Surg. 2009 Mar;38(3):274-8.
12. Albrektsson T, Wennerberg A. Oral implant surfaces: Part 1--review focusing on topographic and chemical properties of different surfaces and in vivo responses to them. Int J Prosthodont. 2004 Sep-Oct;17(5):536-43.
13. Albrektsson T, Wennerberg A. Oral implant surfaces: Part 2--review focusing on clinical knowledge of different surfaces. Int J Prosthodont. 2004 Sep-Oct;17(5):544-64.
14. Svanborg LM, Andersson M, Wennerberg A. Surface characterization of commercial oral implants on the nanometer level. J Biomed Mater Res B Appl Biomater. 2010 Feb;92(2):462-9.
15. Elias CN, Oshida Y, Lima JH, Muller CA. Relationship between surface properties (roughness, wettability and morphology) of titanium and dental implant removal torque. J Mech Behav Biomed Mater. 2008 Jul;1(3):234-42.
16. Mendonca G, Mendonca DB, Aragao FJ, Cooper LF. Advancing dental implant surface technology--from micron- to nanotopography. Biomaterials. 2008 Oct;29(28):3822-35.
17. Sul YT, Johansson C, Albrektsson T. Which surface properties enhance bone response to implants? Comparison of oxidized magnesium, TiUnite, and Osseotite implant surfaces. Int J Prosthodont. 2006 Jul-Aug;19(4):319-28.
18. Chang PC, Lang NP, Giannobile WV. Evaluation of functional dynamics during osseointegration and regeneration associated with oral implants. Clin Oral Implants Res. 2010 Jan;21(1):1-12.
19. Wennerberg A. On Surface Roughness and Implant Incorporation. Göteborg: University of Göteborg; 1996.
20. Sul YT, Johansson CB, Jeong Y, Wennerberg A, Albrektsson T. Resonance frequency and removal torque analysis of implants with turned and anodized surface oxides. Clin Oral Implants Res. 2002 Jun;13(3):252-9.
21. Bornstein MM, Schmid B, Belser UC, Lussi A, Buser D. Early loading of non-submerged titanium implants with a sandblasted and acid-etched surface. 5-year results of a prospective study in partially edentulous patients. Clin Oral Implants Res. 2005 Dec;16(6):631-8.
22. Shalabi MM, Gortemaker A, Van't Hof MA, Jansen JA, Creugers NH. Implant surface roughness and bone healing: a systematic review. J Dent Res. 2006 Jun;85(6):496-500.
23. Wennerberg A, Albrektsson T, Andersson B. Bone tissue response to commercially pure titanium implants blasted with fine and coarse particles of aluminum oxide. Int J Oral Maxillofac Implants. 1996 Jan-Feb;11(1):38-45.
24. Wennerberg A, Albrektsson T, Andersson B, Krol JJ. A histomorphometric and removal torque study of screw-shaped titanium implants with three different surface topographies. Clin Oral Implants Res. 1995 Mar;6(1):24-30.
25. Wennerberg A, Albrektsson T, Johansson C, Andersson B. Experimental study of turned and grit-blasted screw-shaped implants with special emphasis on effects of blasting material and surface topography. Biomaterials. 1996 Jan;17(1):15-22.
26. Wennerberg A, Albrektsson T, Lausmaa J. Torque and histomorphometric evaluation of c.p. titanium screws blasted with 25- and 75-microns-sized particles of Al2O3. J Biomed Mater Res. 1996 Feb;30(2):251-60.