Micrometric characterization of implant surfaces of the five largest companies in the Brazilian market. Part I: Neodent implants

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Abstract

Introduction: The quality of the bone-implant interface is directly influenced by implant surface roughness and a roughness average, with the Sa between 1 to 2 µm, has demonstrated better clinical and laboratory results. In Brazil, are installed more than two million implants per year, 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 Neodent company, one of the five largest companies in the Brazilian market. **Methods:** Were evaluated a total of 9 implants, purchased directly on the market, of 3 different designs and different batches of the company, using a light interferometer. 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: In general, implants analyzed in this company, showed Sa values of 0.75 µm, 0.67 µm and 0.65 µm, respectively, for each design. Comparing the batches, all designs presented statistically significant differences between at least one batches in relation to other. **Conclusions:** The roughness values found, classify the surfaces of the three implants evaluated as minimally rough.

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

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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.[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, roughnesses 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 1-2 μm, 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 2 μm 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 — ImplantNews, Survey 2010). Neodent (Curitiba – PR) is one of the five largest companies in Brazil, which also exports its implants to most of Latin America countries, United States, Canada, some countries of Europe, no longer being a company dedicated only to the internal market.

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 implant surfaces from three different designs of Neodent, and describes them within the international standard developed by Wenneberg and Albrektsson.[5] Data found are described and evaluated with the expectation in the treatment used, comparing them to implants with the same treatment type and those which have solid publishing in worldwide literature.

Material and Methods

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

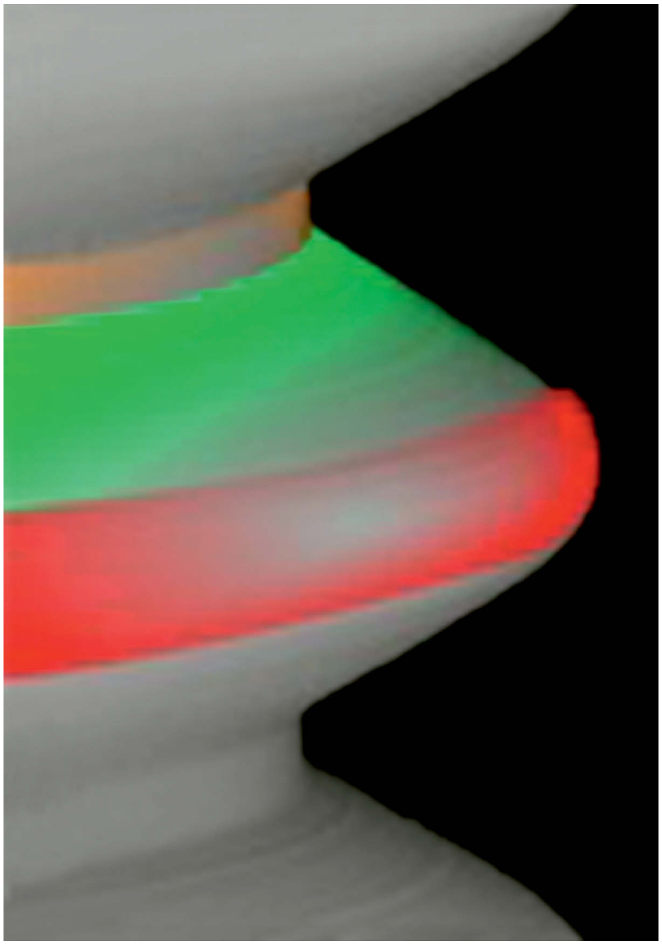


Figure 1 - Red = top; green= flank; orange= valley.

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 each of the following Neodent designs were compared directly in the market: Titamax Cortical (Fig. 2) Titamax Medular (Fig. 3) and Titamax EX (Fig. 4).

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.

A qualitative analysis of the changes obtained by surface treatment is performed on the images by viewing the roughness and maintenance characteristics of its pattern around the implant body.

In addition, one of samples of the implants was cut transversely for polishing metal and underwent the

Figure 2 - Neodent Titamax Cortical (Batch 01 – 8008; Batch 02 – 800015707; Batch 03 – 800011755).

Figure 3 - Neodent Titamax Medular (Batch 01 – 800012724; Batch 02 -800016680; Batch 03 – 800016665).

Figure 4 - Neodent Titamax EX (Batch 01 – 80002874; Batch 02 – 8097; Batch 03 – 80016700).

EDS analysis, the energy dispersive spectroscopy, which is used to identify the elements present in the surface and was used to ensure the titanium used by the company, checked that described in the leaflet.

Surface treatment

Neodent Implant surfaces are treated by a blasting combination followed by acid conditioning which has a commonly used technique for the surface treatment during recent years. The reason for the combination of methods is the blasting process hypothetically reaches an optimal roughness and mechanical fixing, while the conditioning softens some peaks and may add a high frequency component in the implant surface, with potential importance to the protein adhesion which is considered important to the early bone healing process.[6]

Surface characteristics obtained by deformation depend on the type of particle used, its hardness, its size and impact velocity. Blasting process usually performed by titanium (TiO_2) or alumina (Al_2O_3) particles allows a good control on the size of microcavities obtained. However, some remaining particles may be embedded and contaminate the implant surface.[8]

The acid conditioning removes some atomic layers from the deformed surface and part of the residual tension in surface reduces the possibility of contamination of the surface by remaining blasting particles because it also acts in cleaning the surface. These processes create microcavities superposed on the pre-blasted rough surface.

Each manufacturer has its own acid conditioning method for concentration and temperature of acids, as well as the exposure time which is a trade secret and we have no access. In general, we have the double acid conditioning which is performed by the first immersion of implants in $HCl + H_2SO_4$, $HNO_3 + HF$ or HNO_3 solutions. Then, implant is again immersed in an aqueous HNO_3 solution for stabilizing the titanium oxide layer.[6,8]

We will use the SLA surface as reference to compare Straumann documented clinically with positive results with 5-years follow-up by Bornstein et al.[21]

Surface analysis

Implant surfaces were evaluated using a light Interferometer (MicroXAMTM, Phaseshift, USA) is indicated to evaluate roughnesses 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 50 µm 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.

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 ANOVA test (Kruskall-Wallis Test) with significance level of $p < 0.05$.

RESULTS

Surface characterization

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

In Figures 8A-C, images of interferometer analysis generated by the Surfascan Software were observed along with the obtained in the scanning electron microscope with a magnification of 3,000X. Images were selected from the flanks of the thread in the middle third of the implants.

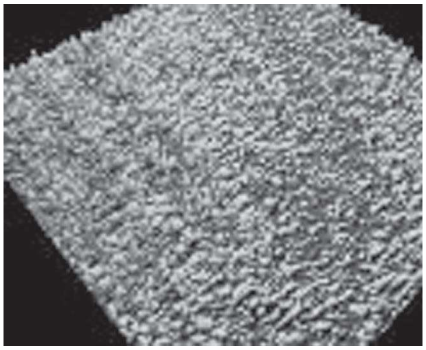


Figure 5 - Sequence of filters in which undulations and forms are removed. Original nanotite.

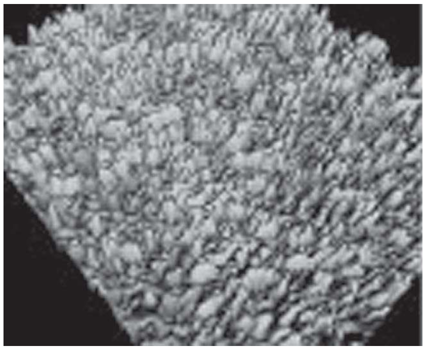


Figure 6 - Sequence of filters in which undulations and forms are removed. Nanotite with Gaussian filter of 50 X 50 µm.

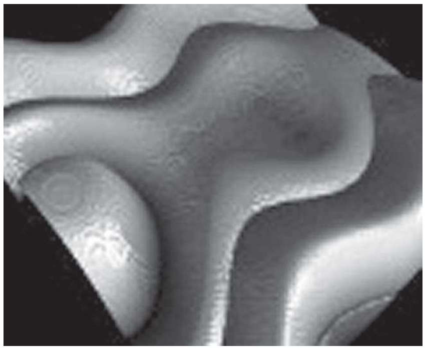


Figure 7 - Sequence of filters in which undulations and forms are removed. Nanotite with Gaussian filter of 50 X 50 µm

Table 1 - Numerical description of the surface topography for Neodent implants at micrometer level.

	S_a µm	S_{ds} /mm²	S_{dr} %
Neodent Cortical	0.75 ± 0.34	153.66 ± 11.32	41.36 ± 25.69
Neodent EX	0.67 ± 0.16	155.72 ± 15.72	52.33 ± 48.12
Neodent Medular	0.66 ± 0.24	154.98 ± 14.11	36.42 ± 13.80
Straumann SLA	1.53 ± 0.19	129.04 ± 22.67	74.52 ± 33.34

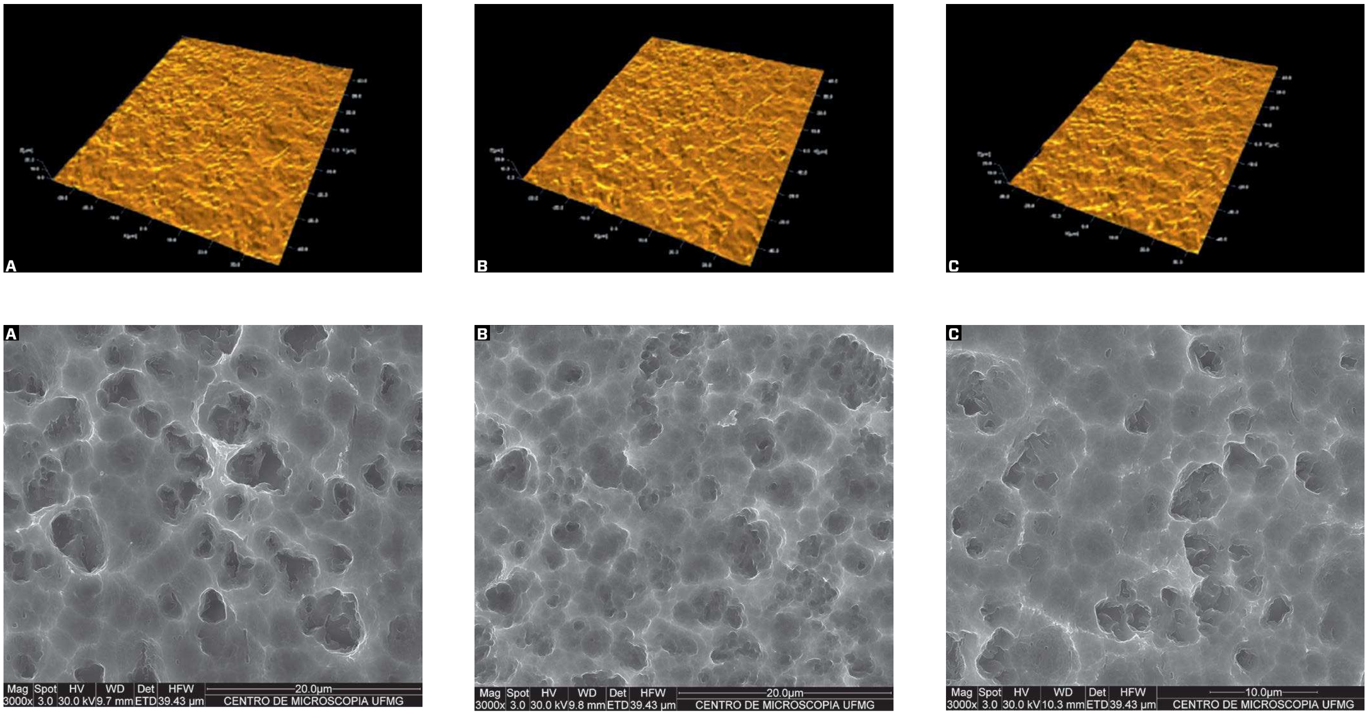


Figure 8 - Interferometer and MEV Images – **A**) Neodent Titamax Cortical. **B**) Neodent Titamax Medular. **C**) Neodent Titamax EX.

Following detailed images of scanning electron microscopy in 3 different magnifications from three Neodent implants evaluated, as well as the Straumann implant with SLA surface used as reference (Fig. 9A, 9B, 9C; 10A, 10B, 10C; 11A, 11B, 11C; 12A, 12B, 12C).

Comparison between batches

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,

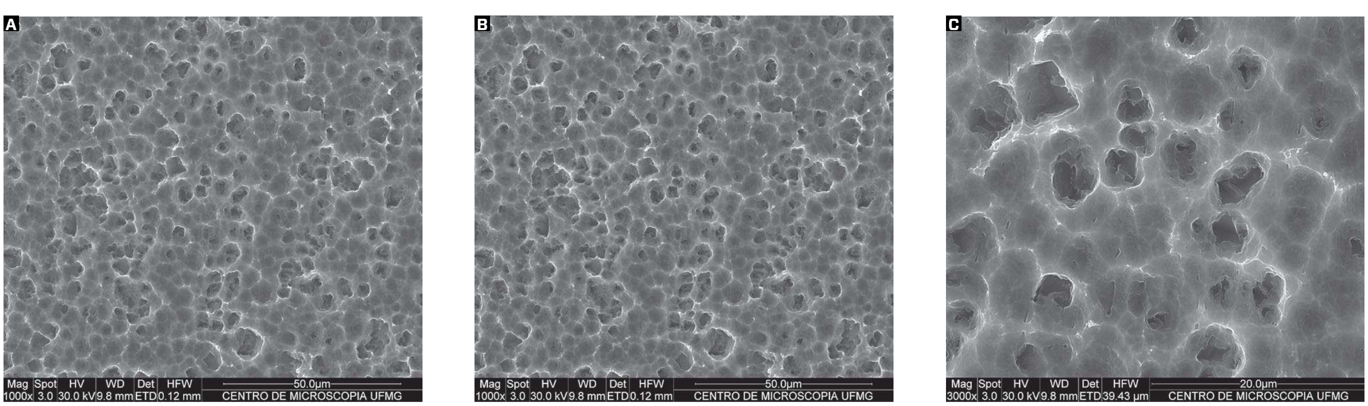


Figure 9 - MEV Images of Neodent Titamax Medular implants. **A**) 1,000x. **B**) 3,000x. **C**) 5,000x.

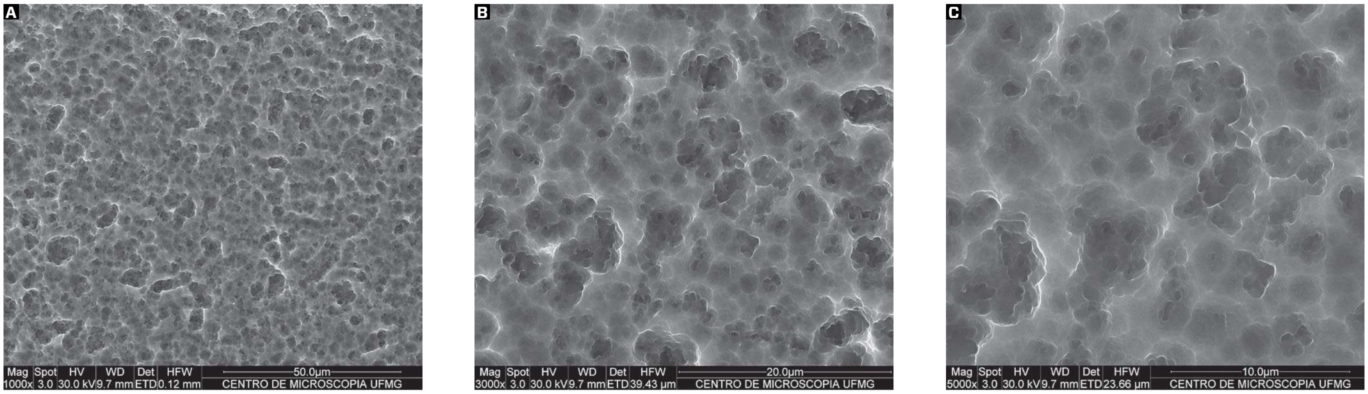


Figure 10 - MEV Images of Neodent Titamax Cortical implants. **A**) 1,000x. **B**) 3,000x. **C**) 5,000x.

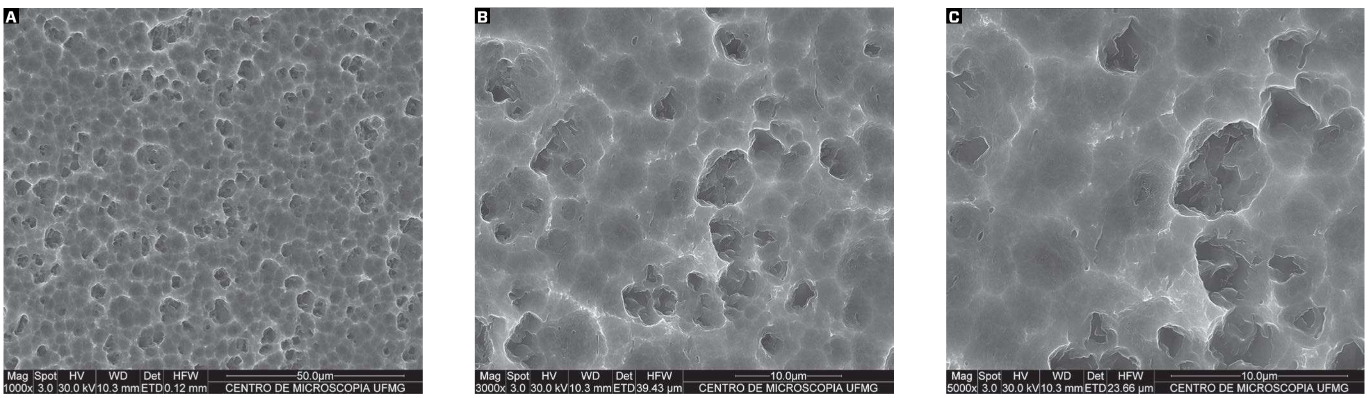


Figure 11 -MEV Images of Neodent Titamax EX implants. **A**) 1,000x. **B**) 3,000x. **C**) 5,000x.

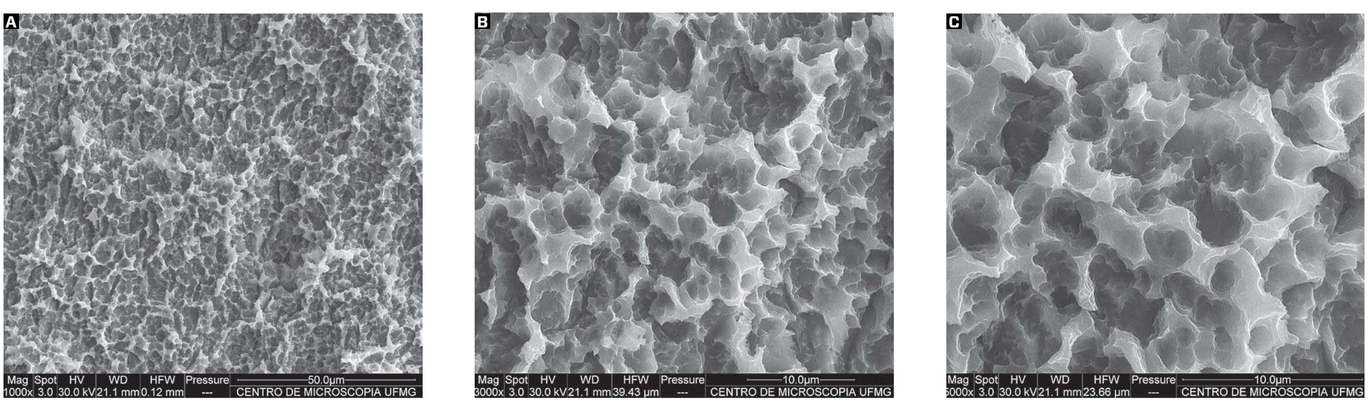


Figure 12 -MEV Images of SLA implants, from Straumann. **A**) 1,000x. **B**) 3,000x. **C**) 5,000x.

the Prism software was used, and as the distribution was not normal, we applied the Kruskal-Wallis test ($p < 0.05$).

a) Neodent Titamax Cortical

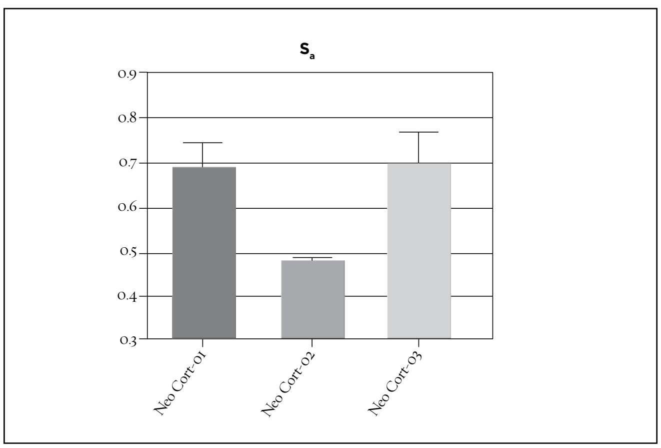
As we can observe in Graph 1, there is a statistically significant difference in the measures of batch 02, with S_a of 0.47 µm, regarding the batch 01 with 0.68 µm and batch 03 with 0.69 µm. The measures of S_{dr} (Graph 2) show statistically significant differences between batches 01 and 02, with 54% and 28% respectively, in addition to a very high standard deviation for Batch 01, with S_{dr} of 54437%.

b) Neodent Titamax Medular

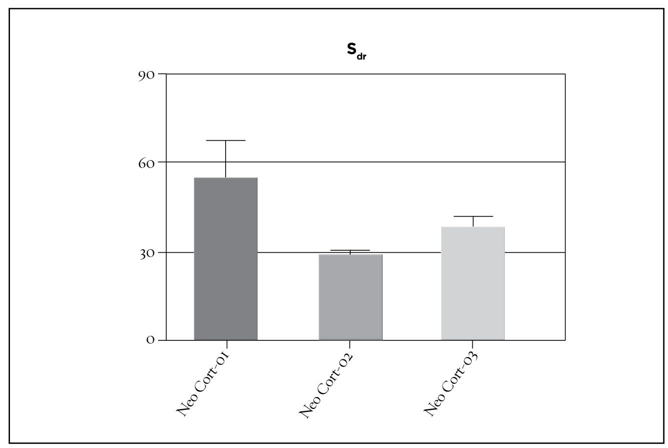
Statistically significant differences were observed in S_a values of batch 01, with 0.50 µm, compared to batch 02 with 0.72 µm and batch 03 with 0.77 µm (Graph 3). For S_{dr} values (Graph 4), although they are numerically different, 29%, 44% and 35%, respectively, no statistically significant differences were showed.

c) Neodent Titamax EX

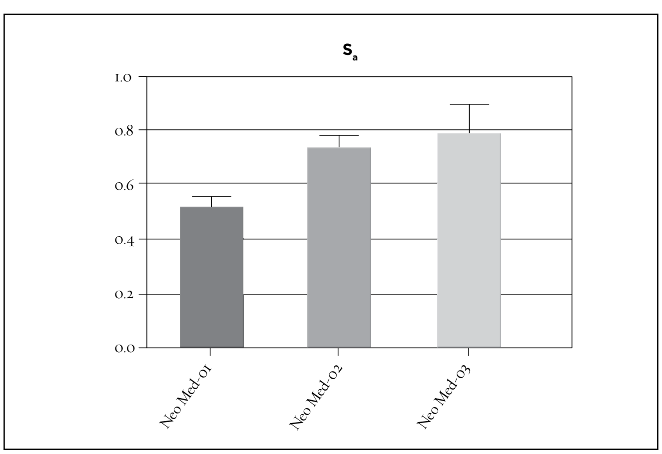
For this design, statistically significant difference were found in Sa values between the batch 02, with 1.01 µm compared to batch 01 with 0.74 µm and batch 03 with



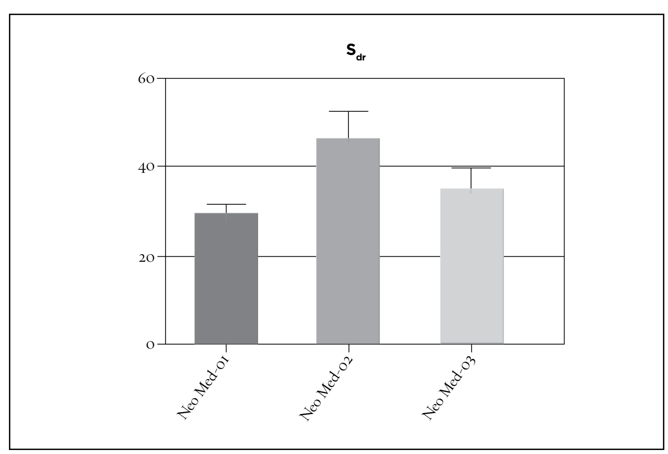
Graph 1 - Comparison of S_a for batches of Titamax Cortical implants.



Graph 2 - Comparison of S_{dr} for batches of Titamax Cortical implants.



Graph 3 - Comparison of S_a for batches of Titamax Medular implants.



Graph 4 - Comparison of S_{dr} for batches of Titamax Medular implants.

0.60 µm (Graph 5). For S_{dr} values, although they have values ranging from 66% to 34% in batches 01 and 03, respectively, we had no statistically significant differences (Graph 6).

EDS of the implants

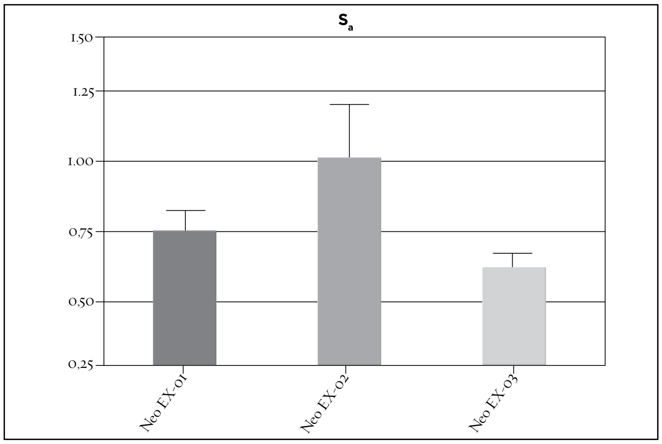
Results of EDS analysis from three Neodent implant designs showed an identical pattern compatible with titanium ASTMF F67 grade 4, as described in the leaflet. Therefore, Graph 7 which represents a Titamax Medular implant, will serve for chemical constitution to all Neodent implants evaluated.

DISCUSSION

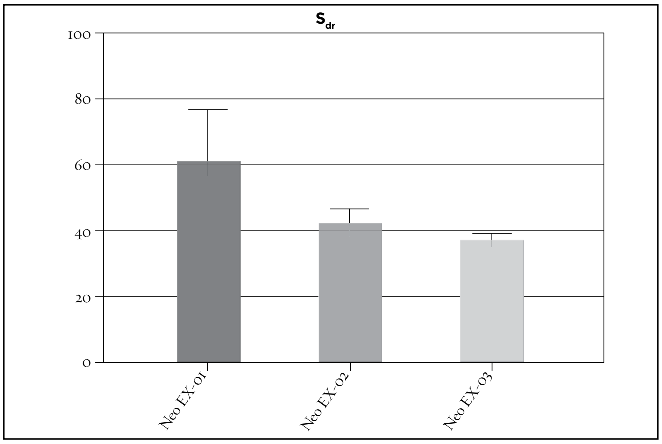
When the implants started to be manufactured in Brazil, most companies chosen designs and implant surface treatments established, with extensive scientific publication and strong presence in the Brazilian market. The surface characteristics, and their actual similarity compared to actual reference used, need to be tested and evaluated independently, as well as comparative clinical studies should be performed in order to prove adequate clinical performance. One way to discuss the results found is through comparison with those obtained by reference implants to the same type of treatment.

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]

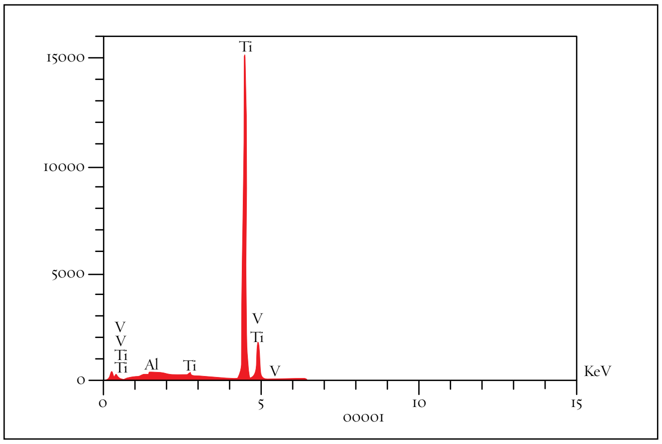
Generally, in blasting treatments followed by acid attack, moderately rough surfaces with Sa, between 1.0 and 2.0 µm, 12 are obtained. These two types of treatment, even alone, have many variables and may have



Graph 5 - Comparison of S_a for batches of Titamax Medular implants.



Graph 6 - Comparison of S_{dr} for batches of Titamax Medular implants.



Graph 7 - EDS analysis for the sample of Neodent Titamax Medular implant, showing the presence of 99.69% titanium.

different surfaces according to patterns adopted. In blasting, both the type of particle used, such as its size, and impact velocity are directly responsible for the results obtained. In acid conditioning, type of acid, exposure time and temperature are critical factors for the characterization of the surface.[8]

Neodent implants evaluated had Sa values of 0.75 µm for Titamax Cortical, 0.67 µm for Titamax EX, and 0.66 µm for Titamax Medular and they are therefore considered to be minimally rough surfaces.[12] The SLA implants, from Straumann, used as reference for this type of treatment, have a S_a of 1.53 µm, and they are considered to be moderately rough.[12] It should be noted these values are lower than even those found in machined Brånemark implants whose surface was previously considered to be smooth, but after the development of surface assessment technology and significant increase in capacity of the equipment used showed in fact to be a minimally rough surface, 12 representing a S_a of 0.90 µm.[7]

When analyzing the S_{dr} values, in other words, increased surface area obtained, 41.36% for Titamax Cortical, 52.33% for Titamax EX and 36.42% for Titamax Medular were found. Reference SLA implant provides a S_{dr} of 74.52%. S_{dr} values of around 50% provide and produce a stronger contact between bone and implant.[12,23-26]

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.

In comparing among batches, as parameter for the regularity of the surface treatment process, the statistical difference found confirms the variability of this type of treatment, as well as the need of characterization of each design and each implant trademark to check the result obtained. However, due to the reduced number of samples, the statistical differences observed are not conclusive, thus indicating the need for further studies with these batches which showed statistical differences compared to others. According to the methodology employed, the assessment of two more samples from the batch 02 for Titamax Cortical design, batch 01 for Titamax Cortical design and, finally, batch 02 for Titamax EX would be indicated. 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 03 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. The results showed no significant differences in S_a and S_{dr} values between the new batches evaluated from the three designs. Mean S_a values were 0.67 µm for Titamax Cortical implants, 0.69 µm for Titamax EX and 0.64 µm for Titamax Medular. For S_{dr} values, Titamax Cortical implants showed 36.67%, Titamax EX 43.54% and Titamax Medular 35.57%. These values are consistent and showed no statistically significant differences compared to the values found in the first assessment.

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.

CONCLUSIONS

The values and variations found in micrometric characterizations of the implant surface evaluated showed how sensitive are the techniques used for this treatment.

Therefore, even companies use surface treatment techniques devoted, it is important to invest in continuous laboratory and clinical experiments to validate the effectiveness of their implants and maintain standardization and regularity of the surface treatment performed, as well as to evaluate their influence on the osseointegration, success rate and their longevity.

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