# Micrometric characterization of implant surfaces of the five largest companies in the Brazilian market. Part II: Biomet 3i BoneLike 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 S<sub>a</sub> between 1 to 2 $\mu$ m, 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. **Objective:** The aims of this study are to evaluate and characterize numerically the surface of the implants BoneLike, of Biomet 3i do Brasil 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 (BoneLike-HE and BoneLike-CM) 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<sub>a</sub> values of 0.47 $\mu$ m for BoneLike-HE and 1.01 $\mu$ m for BoneLike-CM. Comparing the batches, both designs showed statistically significant differences between them. **Conclusions:** The roughness values found herein categorize the surfaces of BoneLike-HE implants as smooth, and BoneLike-CM implants as moderately rough, with S<sub>a</sub> values quite close to a smooth surface.

Keywords: Dental implant. Brazilian implants. BoneLike 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<sup>1,2</sup>. The quality of the bone-implant interface is directly influenced by the roughness of the implant surface<sup>3-8</sup> 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.<sup>3</sup>

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.<sup>8,9</sup> 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.<sup>10</sup>

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.<sup>8</sup> Moreover, roughnesses do not only facilitate the retention of osteogenic cells, but they allow them to migrate on the implant surface by osseoconductivity.<sup>11</sup> A faster and stronger bone formation provides higher stability during the repair process, allowing even a faster loading of the implant.<sup>5,6,7</sup>

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

So far, the certainties are limited to the influence of implant design and roughness in micrometric scale. A screwshaped design and a surface with a mean roughness, Sa of 1-2 $\mu$ m show better results.<sup>6,7,8,12</sup> Studies have shown titanium implants with appropriate roughness can improve the bone-implant contact<sup>19</sup> and also increase the force of the extraction torque.<sup>19,20</sup> On the other hand, increasing the surface roughness higher than 2 $\mu$ m of S<sub>a</sub> causes an impaired and unreinforced bone response.<sup>5-8</sup>

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

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). Biomet 3i do Brasil (São Paulo, Brazil), 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 Bonelike implants designs (external hex and morse taper) and describe them within the international standard developed by Wennerberg and Albrektsson<sup>5</sup>. Data found will bee described and evaluated with the expectation for the treatment utilized, comparing them with SLA<sup>®</sup> implants, made by Straumann, used as reference since they use the same type of treatment and have solid publishing in worldwide literature.

#### **Material and Methods**

Methodology used to evaluate the implant surface was proposed by Albrektsson and Wennerberg in 2000<sup>5</sup>, and became a worldwide pattern 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 Biomet 3i do Brasil, were purchased directly in the market: BoneLike-HE, external hex (Fig 2) and Bone-Like-CM, morse taper (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.

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

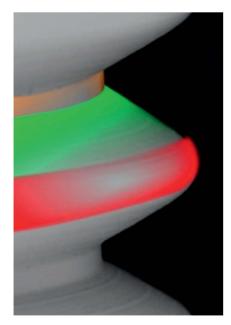


Figure 1 - Red = top; green= flank; orange= valley



**Figure 2** - 3i BoneLike-HE (external hex) implant (Lot I – 6653 JB; Lot 2 – 8489KB/I; Lot 3 – 2659KB).



Figure 3 - 3i BoneLike-CM (Morse Taper) implant (Lot I - 03064LB, Lot 2 - 04963LB, Lot 3 - 03079LB).

#### Surface treatment

The surfaces of BoneLike implants 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.<sup>6</sup>

Surface characteristics obtained by deformation depend on the type of particle used, its hardness, its size and impact velocity. Blasting process usually per- formed by titanium (TiO<sub>2</sub>) or alumina ( $AI_2O_3$ ) particles allows a good control on the size of microcavities obtained. However, some remaining particles may be embedded and contaminate the implant surface.<sup>8</sup>

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.<sup>6,8</sup>

3i BoneLike implants are manufactured using  $Ti_6AL_4V$  titanium alloy, considered grade 5. The type of titanium directly influences the roughness values obtained by

surface treatments since metal hardness affects treatment efficiency.

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.<sup>21</sup>

#### Surface analysis

Implant surfaces were evaluated using a light Interferometer (MicroXAMTM, Phaseshift, USA) is indicated to evaluate roughness of the implant with threads at micrometric level<sup>5</sup>. We use an objective of 50X and a zoom of 0.62. The measured area was 264 X 200µm, while the average height of measures ranged between 80µm and 100µm. The maximum resolution of this technique is 0.30µm horizontally and 0.05µm 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<sub>a</sub>: Represents the arithmetic mean for height of peaks and valleys, surface roughness in the median plane.
- b) S<sub>ds</sub>: Represents the density, in other words, number of peaks per area unit.
- c) S<sub>dr</sub>: 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<sub>a</sub>: 12 smooth (S<sub>a</sub> <  $0.5\mu$ m); minimally rough (S<sub>a</sub> between 0.5-1.0µm), moderately rough (Sa between 1.0-2.0µm); Rough (S<sub>a</sub> >2.0µm).

## **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 the surface

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.<sup>14</sup>

In Figures 5 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.

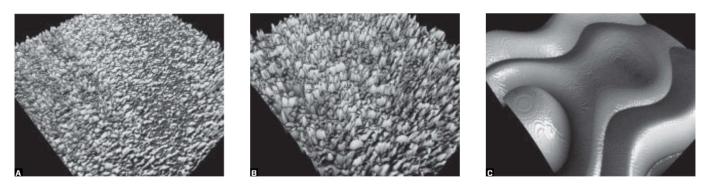
The Figures 7 to 9 are detailed SEM images, at three different magnifications, of the three evaluated BoneLike implants made by Biomet 3i do Brasil, as well as of the Straumann SLA® implant used as reference.

# 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  $S_{dr}$ .

# BoneLike-HE

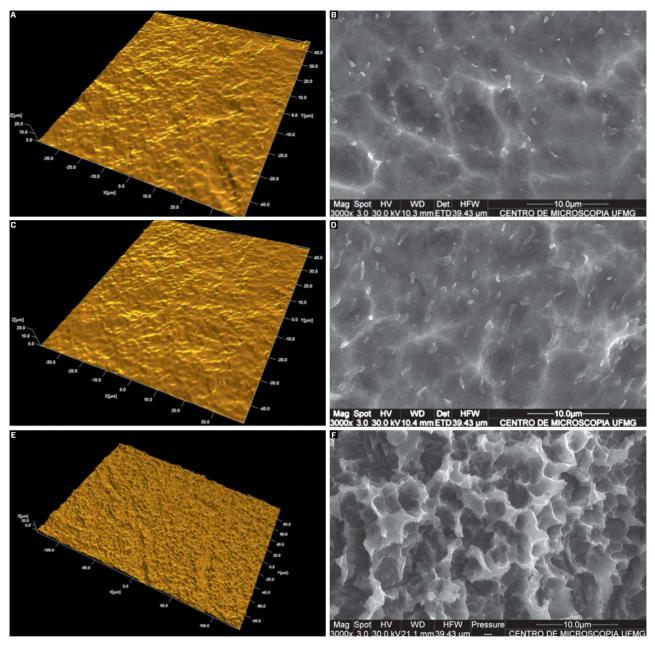
These implants showed statistically significant differences in S<sub>a</sub> values between Lot 01 (S<sub>a</sub> = 0.41 $\mu$ m), and Lot 03 (S<sub>a</sub> = 0.53 $\mu$ m) (Fig 10). Despite considerable numerical



**Figure 4** - Sequence of filters in which the undulations and shapes are removed. **A**) Original Nanotite, **B**) Nanotite with 50X50µm Gaussian filter, **C**) Nanotite with 50X50µm Gaussian filter (low pass)<sup>14</sup>.

 Table 1 - Numerical description of the surface topography of 3i implants BoneLike in micrometer level.

	S <sub>a</sub> (μm)	S <sub>ds</sub> (mm²)	S <sub>dr</sub> (%)
3i BoneLike – HE	0.47 ± 0.06	187.053 ± 37.143	33.98 ± 21.61
3i BoneLike – CM	0.53 ± 0.12	174.539 ± 30.456	40.20 ± 41.56
SLA <sup>®</sup> Straumann	1.53 ± 0.19	129.04 ± 22.67	74.52 ± 33.34



**Figure 5** - **A**, **B**) BoneLike–HE; **C**, **D**) BoneLike–CM; **E**, **F**) SLA<sup>®</sup> Straumann.

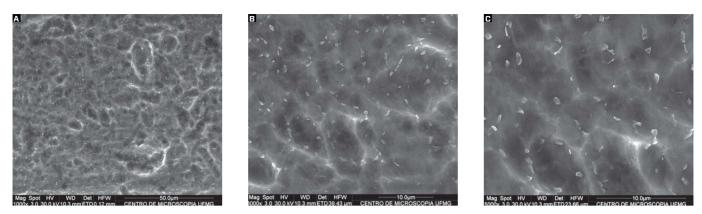


Figure 6 - SEM images of BoneLike implants - CM (A: 1000x, B: 3000x e C: 5000x).

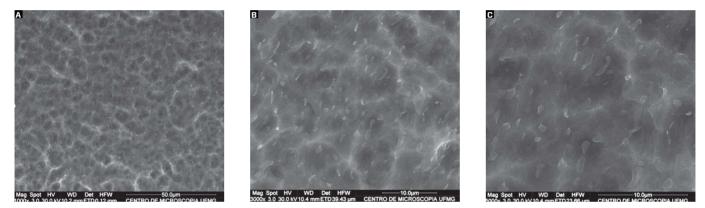


Figure 7 - SEM images of BoneLike implants – HE (A: 1000x, B: 3000x e C: 5000x).

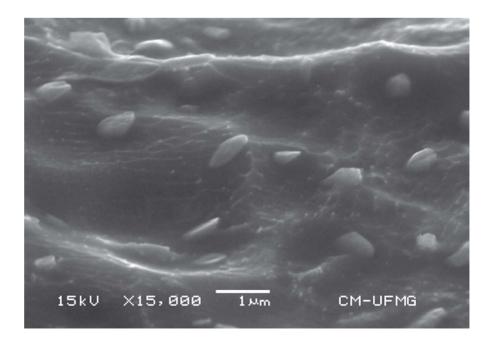


Figure 8 - Image with highest magnification (15000x) showing the particles present on the surface of the BoneLike implants. differences between values for Sdr - 27% for Lot 01, 38% for Lot 02 and 36% for Lot 03 (Fig 11), no statistically significant differences were found in this parameter.

## BoneLike-CM

This implant design displayed statistically significant differences in S<sub>a</sub> values between Lot 02, with 0,39 $\mu$ m, and Lot 03, with 0.67 $\mu$ m (Fig 12). Despite the significant numerical differences between S<sub>dr</sub> values, especially in Lot 03, with 72%, Lot 01, with 28%, and Lot 02, with only 19% (Flg 13), no statistically significant differences were found in this parameter.

#### **EDS of the implants**

The EDS analysis results for both implant designs from Biomet 3i do Brasil showed an identical pattern and indicated the use of titanium alloy  $\text{Ti}_6\text{AI}_4\text{V}$  grade-5 (ASTM F-136), which is fully in accordance with the specifications given in the product description. Figure 14 presents the spectrum of the BoneLike-HE implant, and will serve

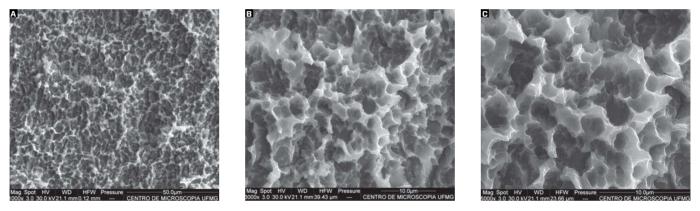


Figure 9 - SEM images of Straumann SLA® implants (A: 1000x, B: 3000x and C: 5000x).

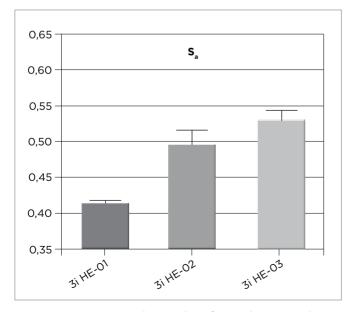
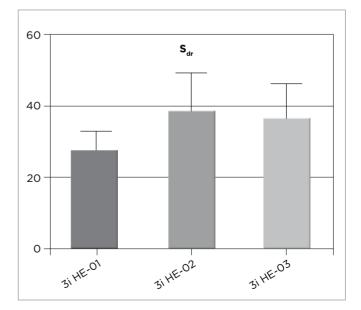
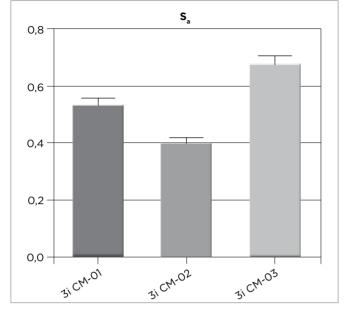


Figure 10 - S<sub>2</sub> comparison between lots of BoneLike – HE implants.



**Figure 11** - S<sub>dr</sub> comparison between lots of BoneLike – HE implants



**Figure 12** - S<sub>a</sub> comparison between lots of BoneLike–CM implants.

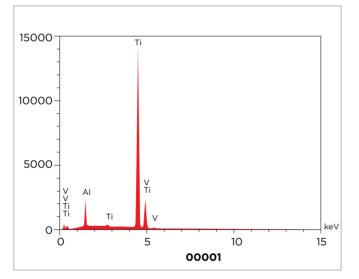


Figure 14 - EDS analysis of the sample of 3i BoneLike-HE implants, evidencing the use of titanium alloy Ti<sub>6</sub>Al<sub>4</sub>V.

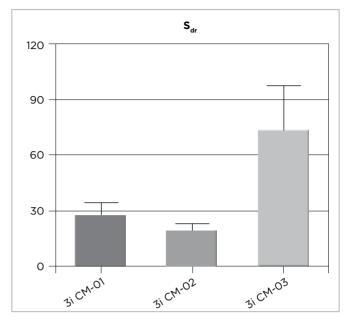


Figure 13 - S<sub>dr</sub> comparison between lots of BoneLike–CM implants.

to demonstrate the chemical composition of both evaluated implants from Biomet 3i.

## 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. Although its U.S. headquarters used only acid etching to treat the surfaces of its implants, Biomet 3i do Brasil chose to use blasting followed by acid etching as the standard treatment for its implants manufactured in Brazil 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. In this case, Straumann SLA® implants were used as reference, as they apply 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.<sup>7,12,22</sup>

Generally, in blasting treatments followed by acid at- tack, moderately rough surfaces with  $S_a$ , between 1.0 and 2.0µm<sup>12</sup>, are obtained. These two types of treat ment, even alone, have many variables and may have 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.<sup>8</sup>

The surface of BoneLike-HE implants presented an  $S_a$  of 0.47µm, being therefore considered a smooth surface<sup>12</sup>, whereas the BoneLike-CM had  $S_a$  of 0.53µm, making it theoretically a minimally rough surface. The SLA implants, from Straumann, used as reference for this type of treatment, have a  $S_a$  of 1.53µm, and they are considered to be moderately rough.<sup>12</sup> 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, <sup>12</sup> presenting a  $S_a$  of 0.90µm.<sup>7</sup>

The use of  $Ti_6Al_4V$  titanium alloy in the manufacture of BoneLike implants, classified as grade 5 and harder than the others and certainly resulted in the low roughness obtained. Nevertheless, the treatments employed must be adequate for the material used, in order to obtain the desired roughness. When analyzing the  $S_{dr}$  values, in other words, increased surface area obtained, 34% for

BoneLike-HE and 40% for BoneLike-CM were found. Reference SLA implant provides a  $S_{dr}$  of 74%.<sup>14</sup>  $S_{dr}$  values of around 50% provide and produce a stronger contact between bone and implant.<sup>12,23-26</sup> Therefore, the implants from Biomet 3i showed values below what is considered ideal for this parameter as well.

Analyzing both the interferometer and SEM images, it is evident a surface of low roughness, especially when compared images of the Straumann SLA® implant (Fig. 9). The SEM analysis showed the presence of particles smaller than 1µm spread throughout the implant surface (Fig 8). Due to its size and characteristic, these particles are not from the process of blasting. A more detailed analysis, through appropriate equipment or a company's position on the subject, would be appointed to ensure greater security for its users. Since these particles are not related to the primary purpose of this study, and in evaluate the standard of the surface roughness, as yet not been made any more specific analysis on them. The company was contacted, but despite having knowledge of the presence of these particles, further alleged to be investigating their origin and composition.

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 alloy,  $Ti_6AI_4V$ (ASTMF F-136), grade 5 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. contamination or any metal or material on the surface of the implants.

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. According to the methods employed, the assessment of two more samples from the batch 01 of the BoneLike-HE implant and from batch 02 of the Bonelike-CM 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 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<sub>2</sub> and  $S_{dr}$  values between the new batches evaluated, for all two designs. Mean S<sub>2</sub> values were 0.50µm for Bone-Like-CM implants and 0.46µm for BoneLike-HE. For Sdr values, BoneLike-CM implants showed 34% and BoneLike-HE, 35%. These values are consistent and showed no statistically significant differences compared to the values found in the first assessment.

To know what these differences really may represent, further investigations are required. It can state the similar treatments do not show the same results.<sup>7</sup> Even only machined surfaces may vary considerably in roughness, as well as blasted surfaces with acid conditioning or anodized. 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.<sup>6,7</sup>

As it was already stated,<sup>67</sup> 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.

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

# Conclusions

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, especially when there are changes not only in the design but also in the type of titanium used.

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.

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