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Dear Biotec implant GmbH,

We inform you from the Department of Biomaterials of the University of Barcelona about the Preliminar study made on the BIOTEC samples in terms of roughness and surface analysis at the microscale.

In order to situate the treatment surface among different known companies, you can see further a table with the Roughness Parameter S_a and $Sdr_{\%}$ (Table 1). Also, you can see what is the correct definition of a treatment surface in relation to his S_a value in the next (Table 2).

The S_a parameter represents the average of the roughness of the surface; the ideal surface roughness for osseointegration is from minimally rough to moderately rough. Also, the parameter $Sdr_{\%}$ represents the surface exposed to the media, and it's directly related with the adhesion of the first line of glycoprotein and thus the subsequent cellular response.

	Sa (µm)	Sdr (%)
Osseotite	0.68	27
Nanotite	0.5	40
Prevail Ti-6Al-4V	0.3	24
TiOblast	1.1	31
OsseoSpeed	1.4	37
TiUnite	1.1	37
SLA old batch	1.5	34
SLA new batch	1.78	97
SLActive	1.75	143

*Table 1: Surface Topography of Implants from the 4 major companies in the **microscale.***

Roughness	**Smooth**	**Minimally rough**	**Moderately rough**	**Rough**
Sa	$S_a < 0.5$ µm	0.5 µm $< S_a <$ 1.0 µm	1.0 µm $< S_a <$ 2.0 µm	$S_a > 2.0$ µm

Table 2: Surface roughness.

The Biotec surface was **minimally rough** and **homogeneous** all over the implant (Fig. 1 and 2).

The treatment surface was made on a grade 5 titanium core through blasting with hydroxyapatite particles and etching with Nitric Acid 70% at 50°c for 20 min. After cleansing the surface was impregnated with low levels of calcium phosphate.

The treatment surface of the **BIOTEC** samples follows the MTX™ surface treatment of the ZIMMER Biomet implant in terms of roughness and surface analysis. The mean values of surface roughness S_a and the exposed surface to the media in percent $Sdr_{\%}$ were, in the microscale, of **0,9 μm and 57%** respectively. Theses results were even better than the **MTX** treatment reported in the literature of **0,78 μm and 38%.**

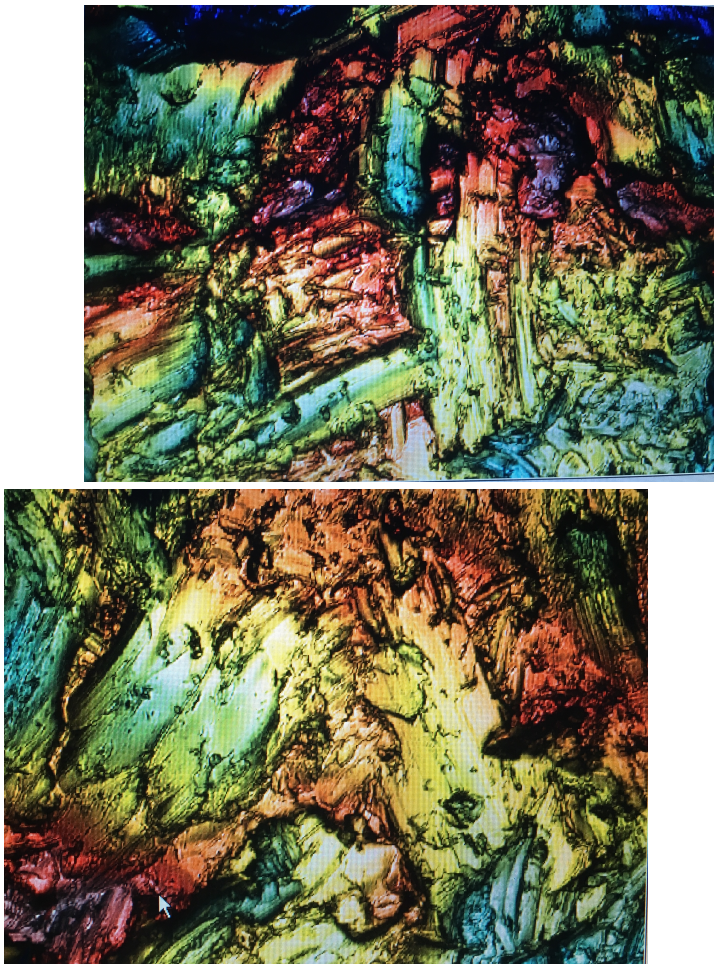

Fig. 1 and 2: Images taken with Confocal interferometry at 50X.

At the Nanoscale, little data is available in the literature, and you might find incoherent results in terms of nanoroughness. When we study in the nanoscale, all the parameters of roughness decrease directly, although, the mean values of the nanoroughness S_a and $Sdr_{\%}$ were of **0,16 μm and 17%** respectively. (We can increase theses parameters up to **0,38 μm and 41%** respectively after one week of treatment in our solution).

The BIOTEC treatment surface is realized by blasting with hidroxyapatite (HA) particles, which are biocompatible, but also by an etching process that remove the rests of it. The final result is a homogeneous surface with a lower roughness compared to Alumina oxide blasting and Acid-etched treatments, but a surface highly biocompatible and free of contaminants proceeding from the treatment surface itself.

In conclusion, the roughness and the surface analysis showed that the BIOTEC treatment surface is much favourable to accomplish an osseointegration process.

Sincerely,

Prof.Dr. Angel Espías *Dr. Luis Sánchez Soler* *Dr. Frederic Parahy* *Dr. Santiago Masip*