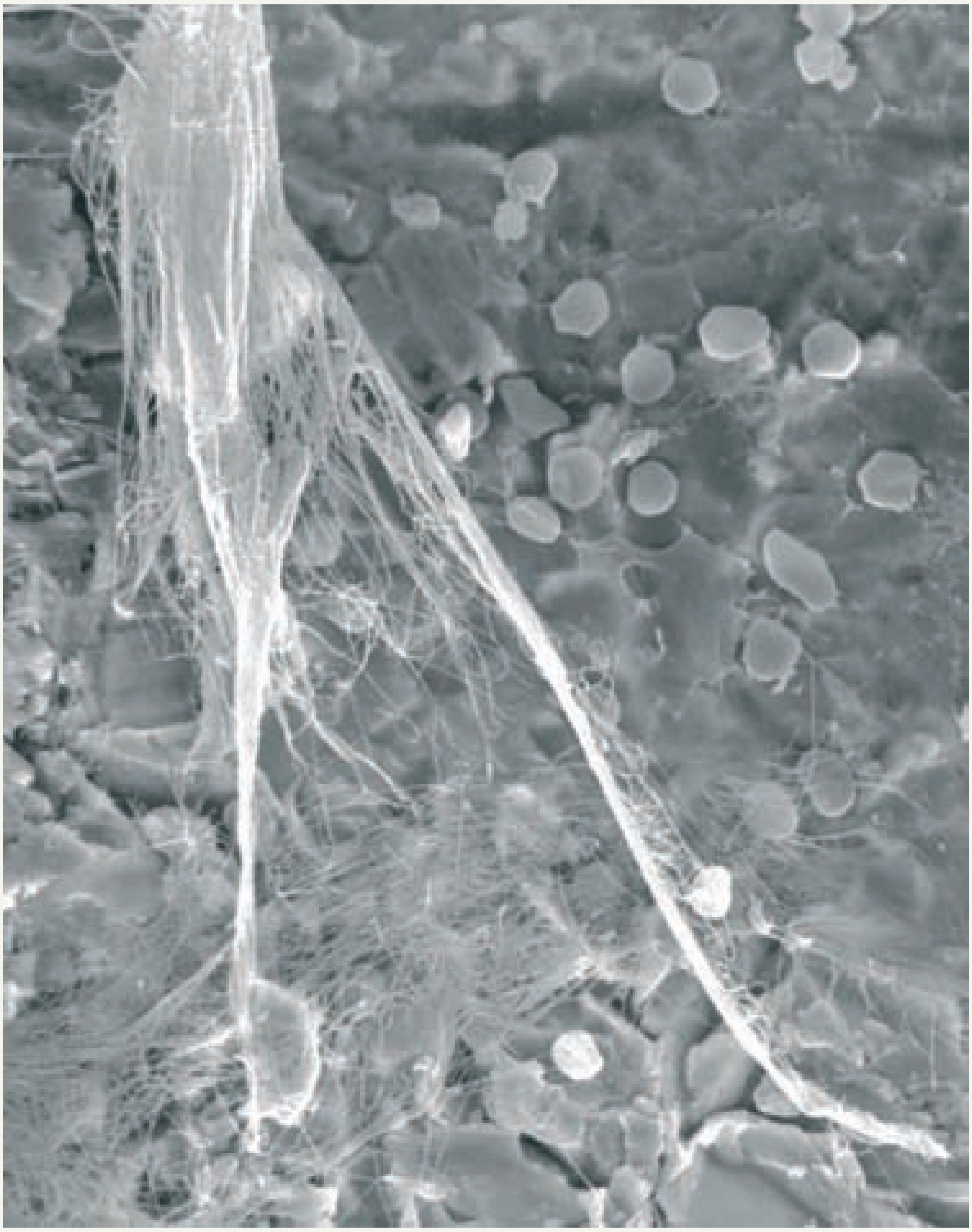

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STUDY OF IMPLANT MATERIALS AND THEIR BIOLOGICAL COMPATIBILITY CHARACTERISTICS

applying microscopy and microanalysis techniques

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Surface of the implant

Many studies have shown that a greater percentage of bone apposition occurs on implants that have a rough surface than on machined ones, so that there is correlation between **roughness** values and bone-implant contact. If we also consider that the early increase in bone apposition around the implant increases its primary stability, it should clearly be indicated that the **surface of the implant** must be rough, in order to optimize both the biological response to the implant and its own primary stability. Many rough surfaces are used with the approval of the FDA, EC and other bodies, but, in our judgment, the surface of the **GMI-Ilerimplant implant** has a series of properties that make it a very appropriate choice.

• Firstly, it is a pure **titanium oxide** surface, without the involvement of another series of factors in its manufacture that could lead to contamination.

• In addition, both the **roughness** and surface area are ideal, ensuring very good bone tissue apposition in accordance with the micromorphological topography.

• Finally, pores have been created on the surface of the implants in the form of **craters** with a diameter of 20 micrometres encouraging osteoblast cells to settle and fix, leading to synthesis in bone tissue formation.

Micromorphological study of the surface of Phoenix (GMI–Ilerimplant) dental implants

In this case, the Scanning Electron Microscopy – SEM – technique was applied. This technique has been used to view the exterior micromorphology of the implant.

Scanning Electron Microscope DSM 940A Zeiss, with (EDS) Oxford Link ISIS microanalysis system at the Electron Microscopy Service of the University of Lleida

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Front and back page pictures obtained by scanning electron microscopy. Direct contact is shown between the porous surface of the Phoenix implant and the recently formed bone cells. The growth of these cells causes rapid bone growth, better implant stability and perfect long-term osseointegration.

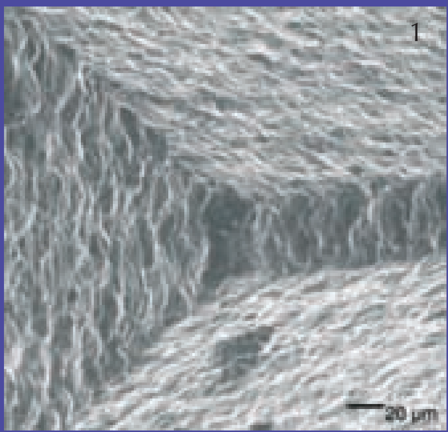
Note: Dr. J. Wierzchos holds a PhD in Chemical Science by the Polish Academy of Sciences, and is a collaborator-researcher in various national and international projects, including NASA and CSIC projects, among others.

Results of collaboration between:
Electron Microscopy Service,
University of Lleida, and GMI-Ilerimplant

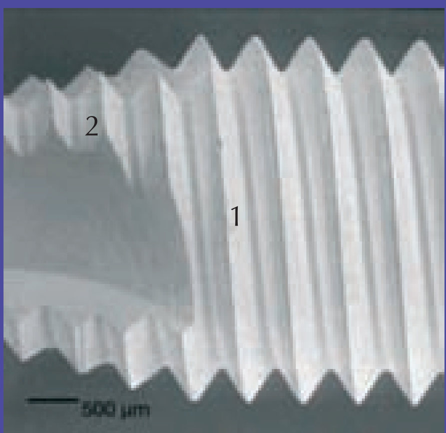
December 2005
Dr. Jacek Wierzchos
University of Lleida

SEM: view of the implant surface

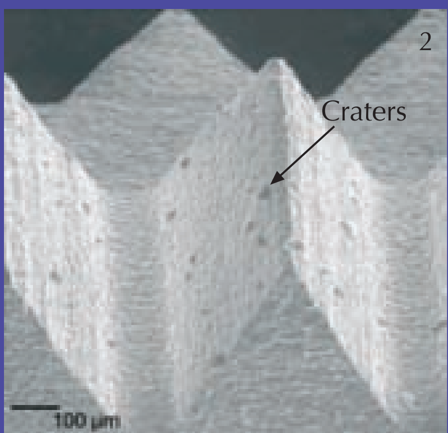
SEM microphotograph of the implant



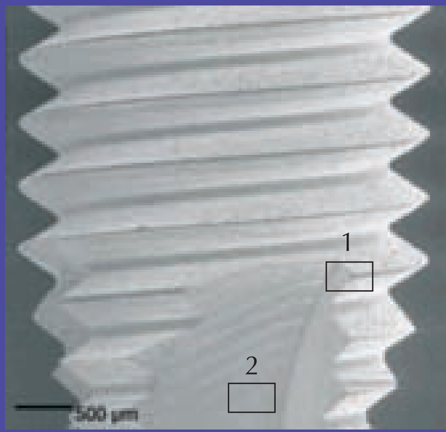
Detail of the implant surface



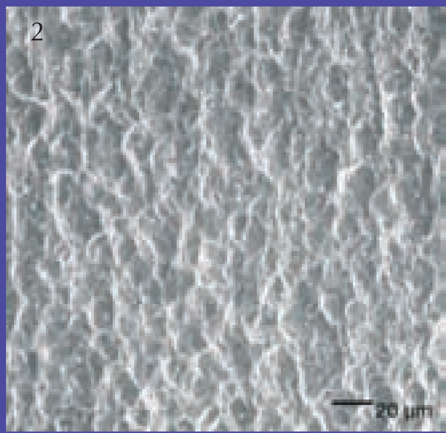
SEM microphotograph of the implant



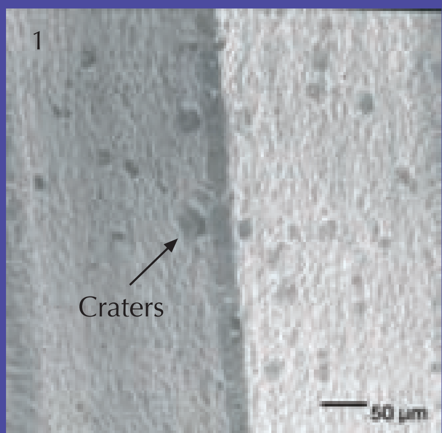
Detail of the surface



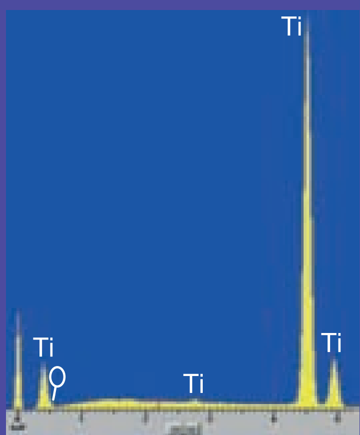
SEM microphotograph of the implant



Detail of the implant surface



Detail of the implant surface



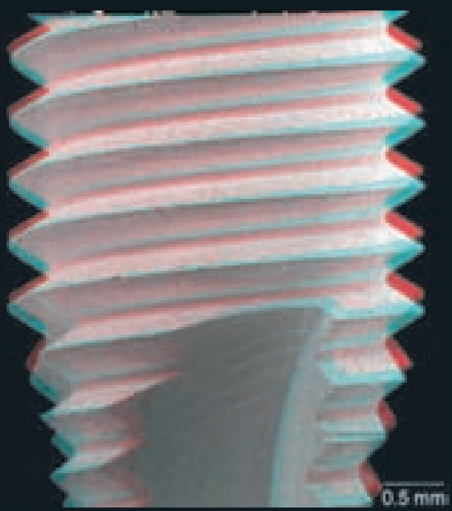
*Results of microanalysis using the energy dispersal X-ray (EDS) of the surface of an Ilerimplant implant. **Titanium oxide**.*

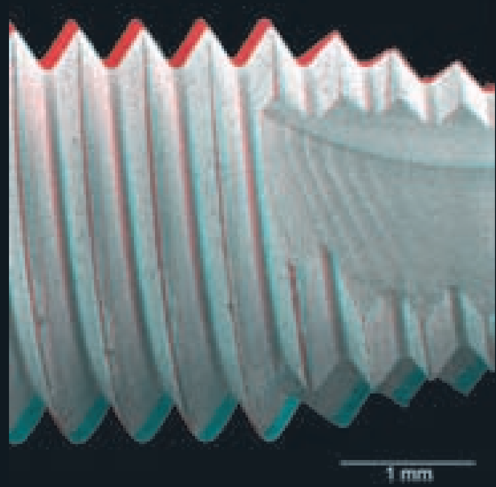
"Stereo" 3D images view of the implant surface obtained with the SEM technique

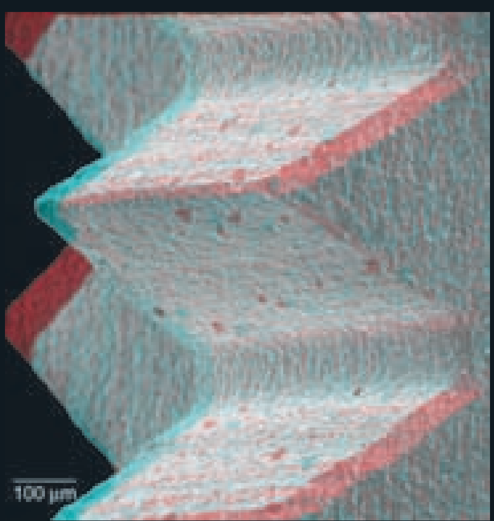
The new feature of this study has been to view the implant surface in “stereo” 3D image mode using coloured glasses.

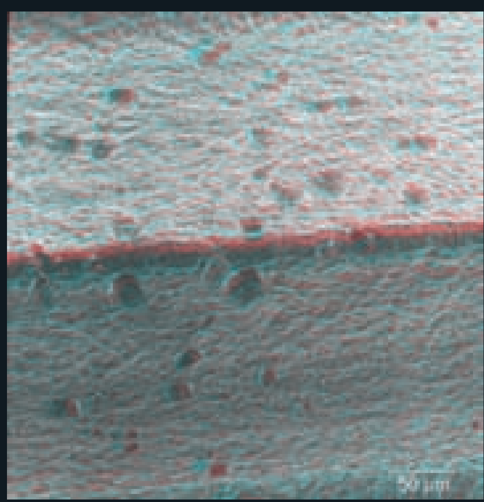
“Stereo” (3D) images

SEM microphotographs of the PHOENIX implant









SEM microphotographs of the PHOENIX implant. Surface roughness with craters

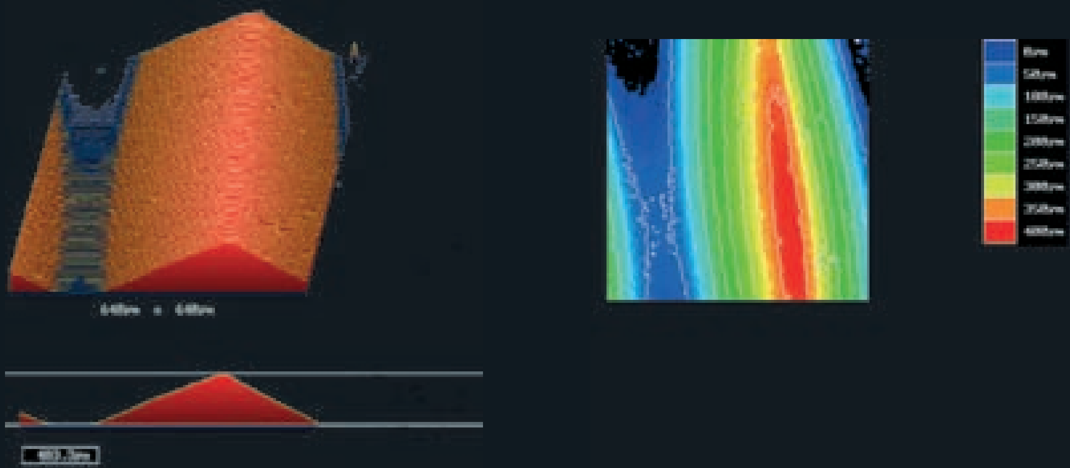
Study of the surface roughness of GMI–Ilerimplant implants

The Confocal Laser Scanning Microscopy (CLSM) technique was applied in this study.

Using the CLSM technique, it is possible to analyse and compare the roughness of the implants.

The values that describe the surface topography (roughness) of the implant are:
zm = average height
Rq = average roughness (standard deviation)
Rt = average roughness (deviation of the arithmetic mean)
Rmax = maximum surface roughness
Rz = average surface roughness

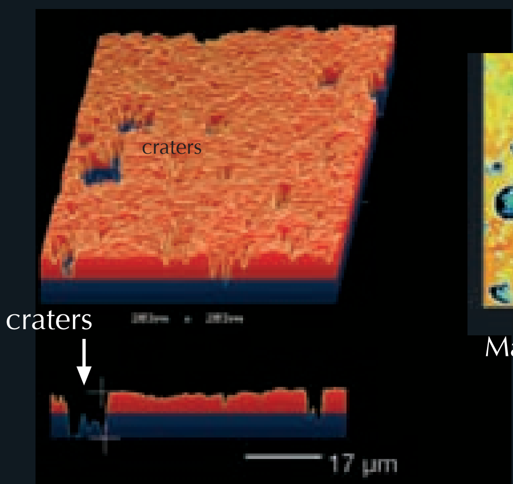
CLSM: topographical study of the surface of the implant. Lens: 20x

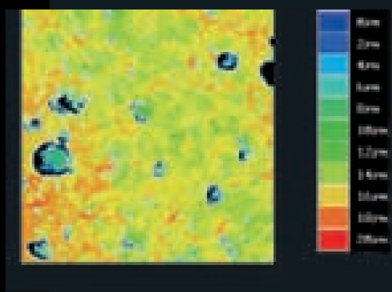


CLSM: topographical study of the surface of the implant. Lens: 63x

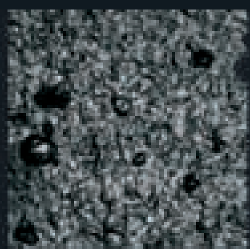
Roughness values

zm:	15.2 µm
Rq:	2.71 µm
Ra:	1.56 µm
Rt:	19.7 µm
Rmax:	19.4 µm
Rz:	18.7 µm





Map image



Gradient image - CLSM

Study of the osseointegration of GMI-Ilerimplant implants with bone tissue

GMI-Ilerimplant and the UdL's Electron Microscopy Service have established cooperation with the Department of Gastrointestinal Physiology the Kielanowski Institute of Animal Physiology and Nutrition the Polish Academy of Sciences, Poland. Head of tests in Poland: Dr. Adam Kiciak.

The main aim of this collaboration is a detailed study of the osseointegration of the implants produced by GMI-Ilerimplant in experiments with animals (pigs). Very few companies try to establish the quality of their products through clinical trials with animals. So far, the results obtained confirm that PHOENIX implants achieve perfect osseointegration.

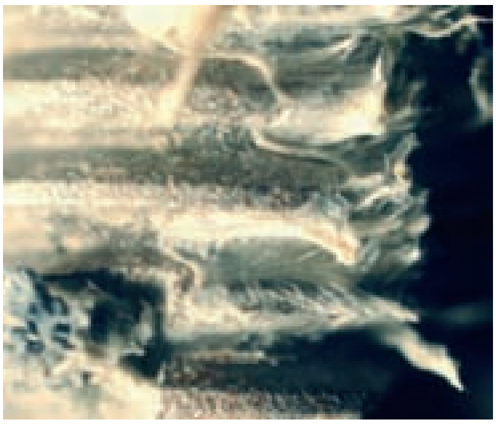
Here we show images of Phoenix implants covered with bone tissue obtained by the Scanning Electron Microscopy (SEM) technique.

The implants for this study were implanted in pigs and extracted after 8 weeks. After extraction, the implants with bone tissue were immediately processed and then observed using the SEM DSM940 Zeiss microscope.

In some cases, micro-analytical data have been obtained in the form of element distribution maps using the EDS microanalysis system (energy dispersive X-ray spectroscopy) Oxford Link ISIS.

Preparing for the operation - fitting implants at the facilities of the Institute of Animal Physiology and Nutrition (PAN), Poland.

Phoenix implant after fitting for the osseointegration study.



Phoenix implant recovered 8 weeks after fitting, to analyse its osseointegration. Image obtained by light microscopy. The new bone tissue formed can clearly be seen adhering to the implant surface.

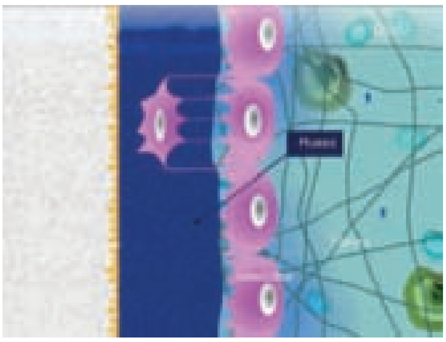
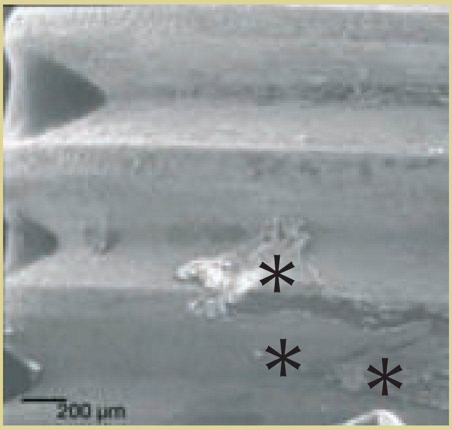
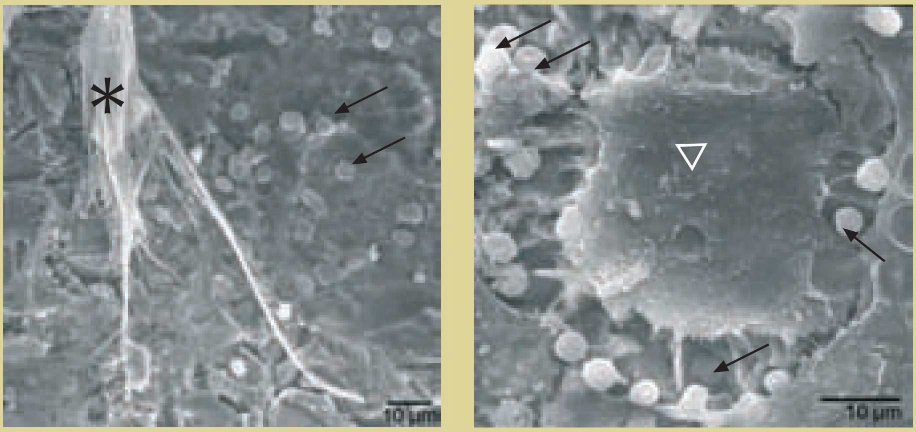


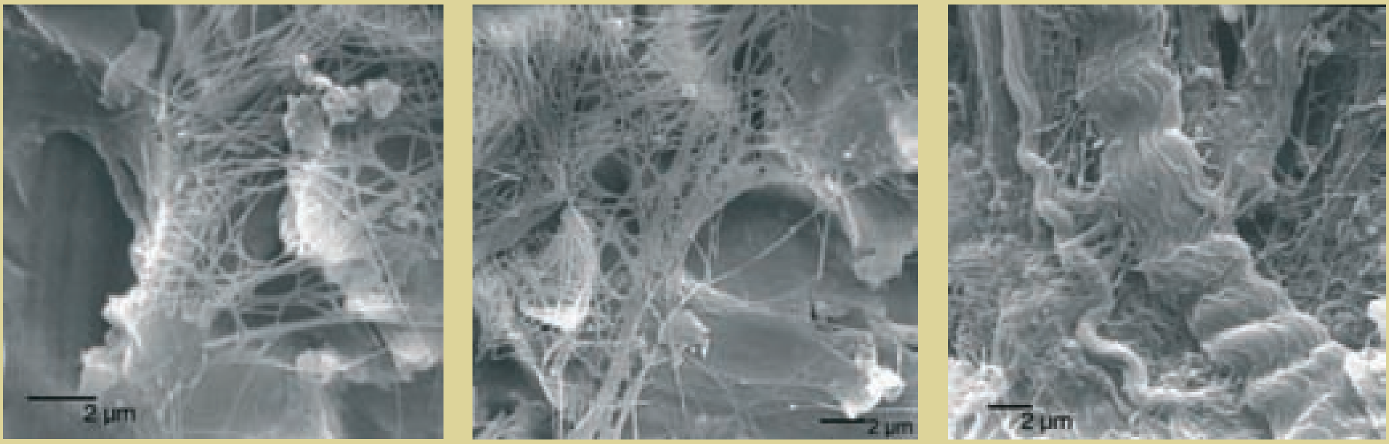
Diagram showing good osseointegration: new bone tissue formed on the implant: osteoblast cells, red blood cells and fibrin can be observed. The SEM images (right) confirm the good osseointegration of the Phoenix implants.



Formation of new bone tissue adhering to the implant surface (asterisks)

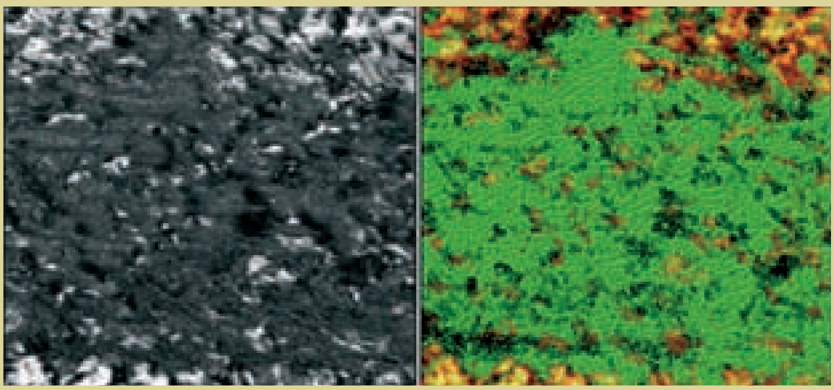


Formation of new bone tissue adhering to the implant surface; fibrin (asterisk), red blood cells (arrows) and an osteoblast (triangle).



Detailed image of fibrin adhering to the new bone tissue.

SEM microphotograph (left) and corresponding element distribution (right): titanium (orange) and calcium (green) on the surface of the Phoenix implant after 8 weeks of osseointegration. Note: the implant surface (Ti) is practically covered by the newly-formed bone tissue. The bone contains high concentrations of Ca, shown in the image in green. The image on the right is a microphotograph obtained using the EDS micro-analysis system (Oxford Link ISIS) in the form an element distribution map.



SEM microphotograph and titanium distribution map (EDS): implant (orange) and Ca: bone (green).