Orthobion – a titanium coated plastic for the spinal column

The number of spinal disc herniations and back problems are increasing due to lack of exercise or incorrect movement. In many cases, artificial spinal discs need to be implanted to fill the space previously occupied by a removed herniated disc or to help repair another injury. Increasing life expectancy not only requires larger numbers of artificial spinal implants, but also increases the demand for improved material properties. In order to overcome the weaknesses of existing implants, Orthobion GmbH has recombined different materials into TSC (titanium sputter coated PEEK), which stimulates the formation of bone and makes a considerable contribution to the formation of a stable and dense bone bridge. TSC is the result of a cooperative project between Orthobion GmbH and the University of Konstanz, which was initiated by BioLAGO.

Dr. Dietmar Schaffarczyk, CEO of Orthobion GmbH, works on the optimisation of spinal column implants, notably plastics implants covered with a titanium layer.

The first ever metal screw was implanted into a human individual as far back as the 18th century. Since then, metal (e.g. titanium) or plastics implants have become an integral part of routine spinal column surgery. Both materials have their advantages and disadvantages. Titanium is characterised by excellent cell adhesion properties and has mechanical properties superior to those of steel. "On the other hand, titanium is a relatively stiff material and the implants run the risk of subsiding into the endplates of the vertebras, which is rather painful for the patient," said Dr. Dietmar Schaffarczyk, CEO of the Konstanz-based medical technology company Orthobion GmbH.

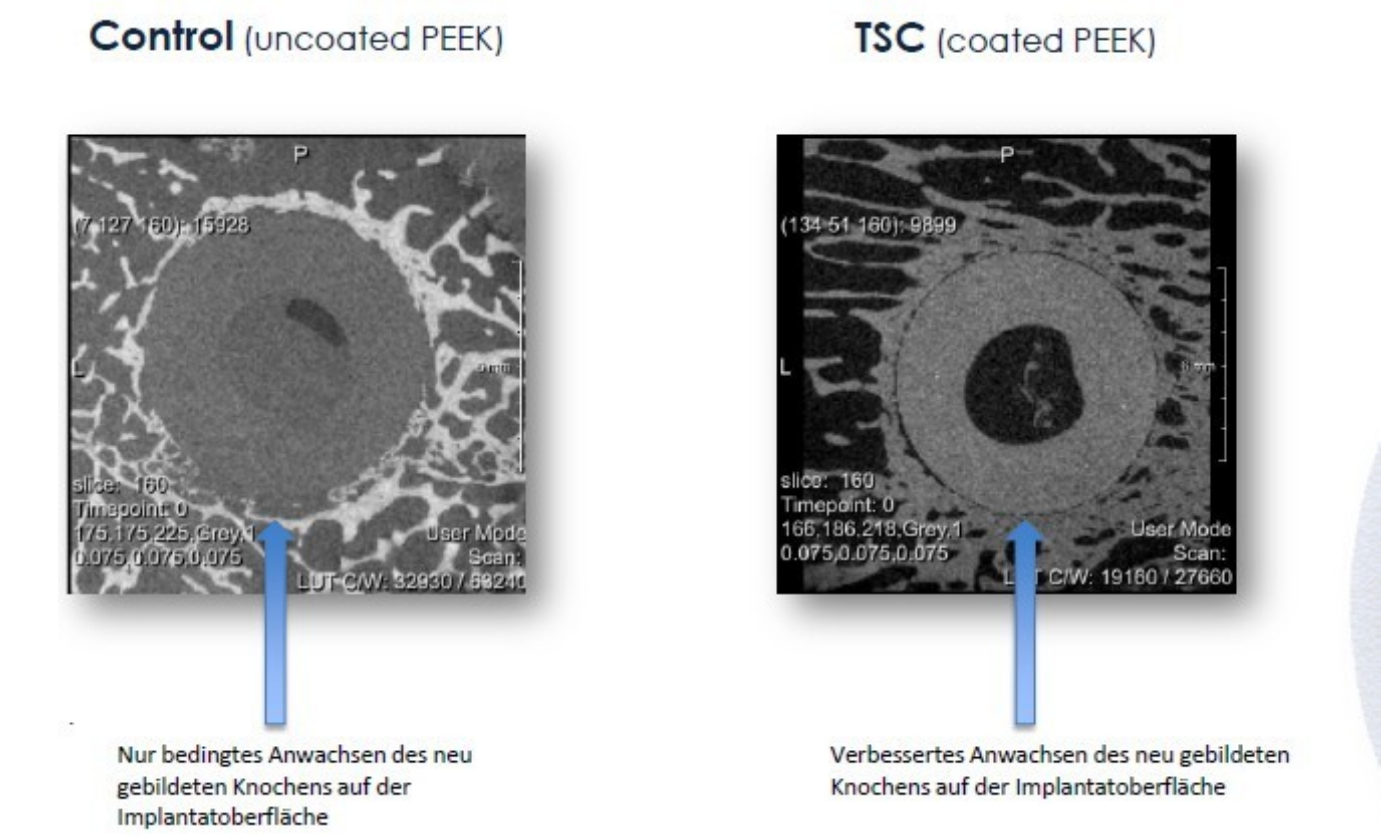
Moreover, the osseointegration of titanium implants is difficult to assess using X-ray-based imaging

methods. This is due to the impermeability of titanium to X-rays. The polymer thermoplastic PEEK (polyetheretherketone) has been used as a biomaterial for the production of artificial spinal discs since the 1980s. PEEK has far better mechanical properties than titanium and is permeable to X-rays. “X-rays can therefore be used post operation to find out whether a bone bridge has been formed,” said Schaffarczyk. PEEK is softer than titanium at the same time as being relatively inert. Therefore, the cells do not attach so well to the implant and the integration of the implant into the bone proceeds slowly.

The solution: plastics coated with a titanium layer

Orthobion’s TSC brings together the positive properties of titanium and PEEK. “The key to success is that the company was able to coat PEEK with a thin layer of titanium. The innovative material now combines the excellent mechanical properties of the thermoplastic as well as the cell-growth promoting properties of titanium. In contrast to pure titanium implants, the extremely thin titanium layer does not impede X-ray transparency either,” said Schaffarczyk. The titanium layer is only 250 nanometres thick; therefore, the implant is only perceived as a light shade on X-ray films. X-ray analyses are therefore suitable for visualising the formation of bone bridges and the concrete position of the TSC-based implant.

Rapid formation of bone bridges



TSC implants have several positive properties. One is that they are superior to pure plastics implants in their ability to adhere to cells, thereby promoting the integration of the implant.

“The use of the innovative material for the development of artificial spinal discs leads to the faster healing of bone fractures due to improved implant integration,” said Felix Kraeft from Orthobion GmbH. The integration of the implant consists of three stages: osteoinduction, osteoconduction and

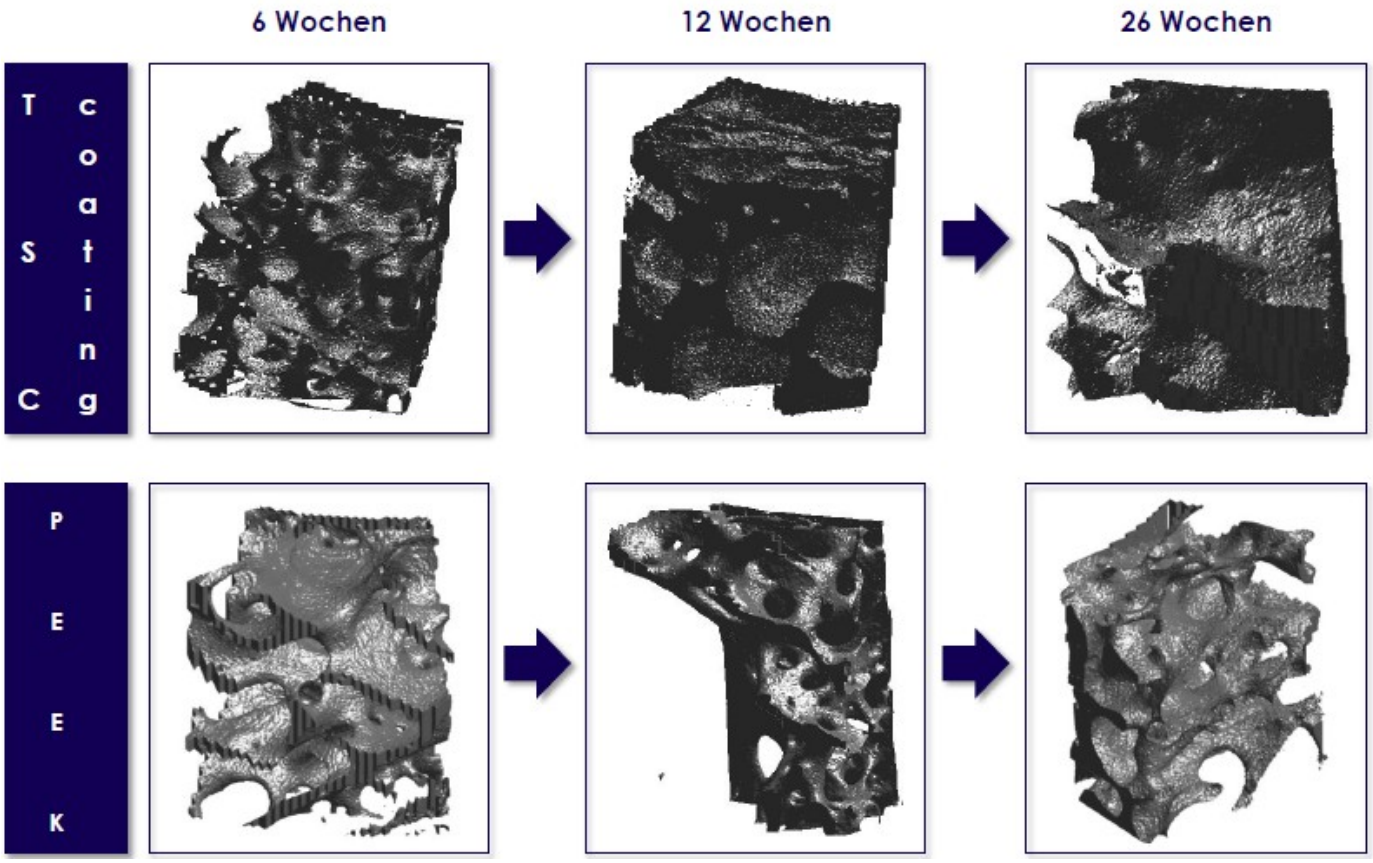
finally osseointegration. Osteoinduction is the stimulation of pluripotent cells to differentiate into bone cells (osteoblasts) that are responsible for forming new bone. Osteoconduction implies the growth of the osteoblasts on the surface of the implant. Osseointegration is the presence of a solid bond between a titanium implant and bone; this solid bond is a prerequisite for the successful integration of the implant. A mechanically structured implant area, which is not covered by the titanium layer, has a decisive influence on the ability of osteoblasts to attach to the surface. "Cells find it difficult to attach to implants made of pure PEEK as the surface is too smooth; a far more unstable bone bridge forms," said Kraeft.

How is titanium applied to the plastic?

The biggest challenge associated with the development of TSC was the development of a method that enabled the researchers to apply the thin titanium layer to the plastic. Research always has an uncertain outcome, and it often takes quite a while to achieve a successful result, if at all. This was also the case here: Orthobion was not sure whether it would be possible to apply a titanium layer to PEEK. Prior to Orthobion's innovative development, plasma spraying was used to apply titanium to surfaces. However, this method leads to layers that are too thick for the intended application," said Kraeft and Schaffarczyk.

The company wanted to produce an implant with a titanium layer that was only a few nanometres thick. "This seemed to be possible, at least in theory; so we had to find ways to turn the theoretical possibility into practice," said Kraeft. In order to speed up the development process, Orthobion contacted BioLAGO for assistance in putting the company into contact with potential cooperation partners. BioLAGO set up a meeting between Orthobion and Professor Schatz from the University of Konstanz whose major focus is the field of nanotechnology. Kraeft, Schaffarczyk and Schatz joined forces and eventually took the new coating method to the industrial application stage.

PEEK can also be coated with calcium phosphate



TSC combines the positive properties of PEEK and titanium – cells adhere well to the material, which also contributes to greater bone volume.

The cooperation partners also tested the suitability of calcium phosphate as coating. Calcium phosphate also has a positive influence on cell growth. TSC and calcium phosphate coatings have led to similar results. "It is up to the surgeon to decide which implant to select," said Schaffarczyk.

The coating process is the only significant difference between the two implants. The TSC coating method involves purely physical processes such as the plasma sputtering of thin titanium films on the PEEK surface. "Calcium phosphate involves a chemical process; it is dissolved in brine into which the implant is immersed," said Schaffarczyk. Orthobion has received CE marking for both methods.

Further research projects with the University of Konstanz are ongoing. These projects focus primarily on the functionalisation of plastics surfaces. "An implant is never perfect. We are investigating how much the chemical structures of PEEK can be modified in order to optimise the implant further," said Kraeft, in conclusion.

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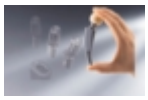

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