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SERIES PRODUCTION OF CE-CERTIFIED ORTHOPEDIC IMPLANTS WITH INTEGRATED POROUS STRUCTURES FOR IMPROVED BONE INGROWTH

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Abstract: *The CE-certified Fixa Ti-Por and DELTA TT acetabular cups from the orthopedic implant manufacturers Adler Ortho and Lima-Lto both have an integrated porous structure for improved bone ingrowth. The feedback from more than 5.000 performed surgeries is excellent, verifying that the strong surface grip of the cup design supports the primary fixation granted by the hemispherical press-fit. The acetabular cups are produced in Ti6Al4V with Additive Manufacturing, using the Electron Beam Melting technology from Arcam.*
Keywords: *CE-certified, implants, production, additive manufacturing*

1. THE CHALLENGE

The ability to "Fit and Forget" is an essential requirement in many critical applications, and nothing is more challenging in this respect than implants in the human body.

The number of people who undergo joint replacement surgery, e.g. total hip and knee replacement, is steadily increasing as people live longer. Higher quality of life expectations also produce an increasing number of younger patients.

Major joint replacement is the only treatment option for many patients with high levels of immobility and pain, dramatically improvingpeople's quality of life by relieving pain and restoring their physical independence.

An implant that does not provide long-term fixation and needs to be replaced prematurely causes unnecessary trauma for the patient, as well as additional social costs that often are not taken fully into account. Therefore, it is vital to reduce the risk of this occurring to a minimum.

One of the major "Fit and Forget" factors for orthopedic implants is the implant's ability to attach itself to the hosting bone, by enabling the bone to grow into the implant and make it almost an integral part of the body.

Conventional methods to improve bone ingrowth, by adding a porous coating of titanium beads or hydroxyapatite to the implant's surface, work well but still do not provide the optimum conditions for osseointegration.

2. THE SOLUTION

The orthopedic implant manufacturers Adler Ortho and Lima-Lto are known for their innovative product designs, e.g. femoral stems with modular interchangeable and adjustable necks, and with their Fixa Ti-Por and DELTA TT acetabular cups they have taken this innovativeness one step further.

They had both been investigating alternative means to promote bone ingrowth for some time when they discovered Arcam's Electron Beam Melting (EBM) technology, and realized how it can be used to build orthopedic implants with full material properties and an integrated, engineered porous structure for improved osseointegration.

The EBM technology, developed by the Swedish company Arcam and proven in other demanding mechanical applications, manufactures parts by melting thin layers of metal powder. The energy source is an electron beam gun and the process takes place in a vacuum chamber.

The vacuum environment makes the EBM process especially well suited to manufacture parts in reactive materials with a high affinity for oxygen.

One example is titanium, the most widely used material for implants because of its biocompatibility, whose material properties alter when the oxygen content increases.

The vacuum thus ensures very high purity of the material which is imperative in implant manufacture. The combination of vacuum and a high power energy source also yields high strength properties of the material.

Implants produced with EBM accordingly feature a chemical composition within stipulated standards, fully dense material with fine microstructure, high ductility and good fatigue characteristics.

The additive, layer-based nature of the EBM process also makes it possible to manufacture implants with the integrated trabecular structures that enhance the osseointegration.

3. THE ADLER ORTHO PROJECT

Adler Ortho therefore decided to develop a completely new acetabular cup, able to take advantage of the full range of possibilities that the EBM technology offers. The material of choice was Ti6Al4V with its combination of strength and excellent biocompatibility.

The first project step was the design of the acetabular cup's trabecular structure, which was done in cooperation with the group of orthopedic surgeons that Adler Ortho work with.

Several different designs were proposed and evaluated. The one selected is a cup with a trabecular structure with interspaces of about 700 micron (Fig. 1) throughout the outer surface.

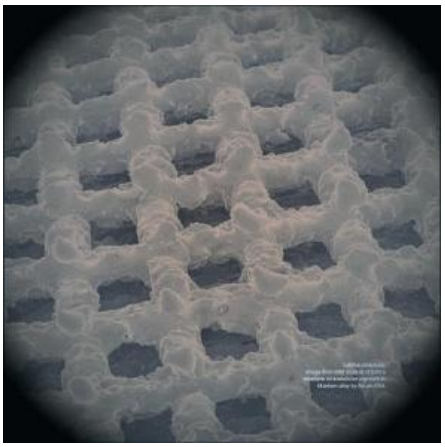

Fig. 1. Trabecular structure

This dimension enables the bony trabeculae to bring about excellent grafting, favoring the ingrowth of new bony tissue.

A pilot study was also conducted at the Laboratory of Surgical Preclinical Studies of the Istituto Ortopedico Rizzoli directed by Prof. Roberto Giardino, in collaboration with the VII Division of Traumatologic Orthopaedic Surgery directed by Prof. Armando Giunti.

Fig. 2 (taken two weeks after surgery) illustrates spongy bone observed in the repair phase with thin and dense trabeculae surrounding the implant, penetrating into the space created by the structure's macro-porosity. The bone attaches directly to the metal without any fiber tissue interposition.

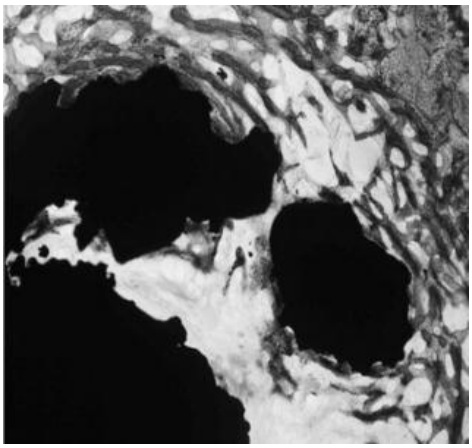

Fig. 2. Spongy bone and implant

Arcam produced the first batches of acetabular cups, allowing their engineers to optimize the production process while Adler Ortho concurrently initiated the clinical and biomedical trials.

Arcam then installed an EBM machine at Adler Ortho's manufacturing facilities in Milan, forming an integral part of their production system, and they were thus ready to start their own production of acetabular cups with trabecular structures.

4. THE PRODUCTS

Adler Ortho subsequently commenced the process to certify the new Fixa Ti-Por acetabular cup in accordance with the European regulations for orthopedic implants, covering also the EBM production process and the Arcam-supplied materials, and they were awarded the CE certification in January 2007.

The CE certificate was the final part of the group's product puzzle, and in July 2007 they launched the new, ground-breaking Fixa Ti-Por acetabular cup as a commercial product.

Fig. 3. Fixa Ti-Por acetabular cup

Lima-Lto were also hot on Adler Ortho's heels, and they launched their DELTA TT cup a few months later.

More than 5.000 EBM-manufactured acetabular cups have been implanted since the market introductions in 2007.

The surgeons' post-op feedback is excellent: the primary fixation granted by the hemispherical press-fit is supported by the strong surface grip of the cup design. Lima reports a BIC (Bone Implant Contact) factor of 95% in 26 weeks.

Post market clinical follow-ups are also in place to fully evaluate the medium and long-term results of the products.

The Fixa Ti-Por and DELTA TT acetabular cups are now in series production at Adler Ortho and Lima-Lto, and the two companies are ramping up their production volumes in order to meet the market demand.

Adler Ortho's and Lima-Lto's engineers are also working on other new and innovative implant designs to be produced with Additive Manufacturing.

5. OTHER MEDICAL EBM APPLICATIONS

In addition to the above mentioned application, the German spinal implant manufacturer Advanced Medical Technologies uses the EBM technology for the production of lumbar cages. Their FUSE cage was launched in October 2009.

The EBM technology is also being used to produce light-weight CMF implants, consisting almost entirely of porous structures. More than 50 such patient-specific skull implants have been implanted to date at the Walter Reed Army Medical Center in Washington, D.C., USA.

Moreover, the Swedish dental manufacturer Implantix uses the EBM technology for the production of implant bridges. Their Durobridge implant bridge was launched in 2009.