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The CE-certified Fixa Ti-Por acetabular cup.
Manufactured with an integrated trabecular structure for improved osseointegration.

THE PROBLEM

The ability to "Fit and Forget" is an essential requirement in many critical applications, and there is nothing 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 improving people's quality of life by relieving pain and restoring their physical independence.

An implant that doesn't provide long term fixation and needs to be replaced prematurely causes unnecessary trauma for the patient, as well as additional social costs that often aren't taken fully into account. It is therefore vital to reduce the risk of this occurring to a minimum.

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

The 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.

THE SOLUTION

Adler Ortho Group, the Italian manufacturer of orthopaedic implants, is known for its innovative product designs, e.g. femoral stems with modular interchangeable and adjustable necks, and with its new Fixa Ti-Por acetabular cup it has now introduced another groundbreaking implant.

Adler Ortho had been investigating alternative means to promote bone ingrowth for some time when it was introduced to Arcam's Electron Beam Melting (EBM) technology, and realized how it can be used to build orthopaedic implants with full material properties and an integrated trabecular structure for improved osseointegration. The EBM technology, developed by 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.

Fixa Ti-Por, acetabular cup with a continuous, engineered trabecular structure for improved osseointegration.

The vacuum environment makes the EBM process especially well suited to manufacture parts in reactive materials with a high affinity for oxygen. One such 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 continuous trabecular structures that enhance the osseointegration.

THE 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 to decide on the design of the acetabular cup's trabecular structure, which was done in cooperation with the network of orthopaedic surgeons that Adler Ortho works with.

Several different designs were proposed and evaluated, and the final one was a cup with a trabecular structure with interspaces of about 700 micron (Fig. A) throughout the outer surface. 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. B (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 macroporosity. The bone is directly attached to the metal without any fiber tissue interposition.

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

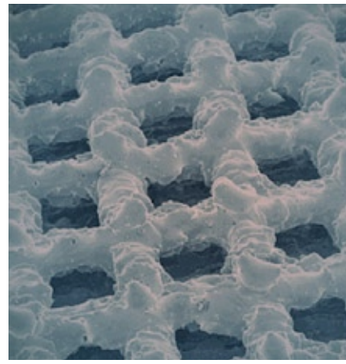

Fig. A. Trabecular structure, manufactured with EBM.

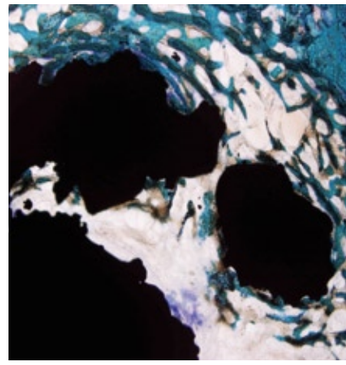

Fig. B. Spongy bone in the repair phase.

ARCAM EBM MACHINE TECHNICAL DATA

Build envelope	200 x 200 x 180 mm (W x D x H)
Build speed	Up to 60 cm^3/h
Layer thickness	0.05–0.20 mm
Vacuum pressure	$<5 \times 10^{-4}$ mBar
Electron Beam power	Up to 4000 W
Electron Beam accuracy	±0.05 mm
Electron Beam scan speed	~1000 m/s
Electrical connection:	3 x 400 V, 32 A
Certification	CE

THE PRODUCT

An Arcam EBM S12 machine was then installed at Adler Ortho's manufacturing facilities in Milan, forming an integral part of their production system, and the group was thus ready to start its own production of acetabular cups with trabecular structures.

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

The CE certificate was the final part of the group's product puzzle, and in July 2007 the new, groundbreaking acetabular cup was launched as a commercial product.

During its first year on the market more than 1.000 acetabular cups were implanted at several Italian reference centers. 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.

A post market clinical follow-up has also been put in place to fully evaluate the medium and long-term results of the product.

The Fixa Ti-Por cup is now in series production at Adler Ortho, and the group is ramping up the production volumes to meet the market demand. Adler Ortho's engineers have also started to investigate other new, innovative implant designs to be produced with Additive Manufacturing.

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