PROTOTYPE OF INNOVATING BONE TISSUE PRESERVING THRA ENDOPROSTHESIS WITH MULTI-SPIKED CONNECTING SCAFFOLD MANUFACTURED IN SELECTIVE LASER MELTING TECHNOLOGY

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Abstract

The paper presents the prototype of innovating bone tissue preserving THRA endoprosthesis with multi-spiked connecting scaffold – the main result of our research project: "Experimental investigation and design of the constructional properties of bone-porous implants fixations" (4T07C05629, Polish Ministry of Science, finished in February 2008) presented also as plenary lecture at the 18th International Conference "Biomaterials in Medicine and Veterinary Medicine" in Rytro (Poland), 2008. Three-dimensional selective laser melting (SLM), a direct metal manufacturing (DMM) technology from rapid prototyping/rapid manufacturing (PR/RM) group, was successfully applied to manufacture these prototypes of Ti6Al7Nb powder. We share our observations and remarks on the prototypes manufacturing in SLM laser additive technology.

[Engineering of Biomaterials, 87 (2009), 2-6]

Introduction

As it was announced in [29] the subject of our research project is a new kind of minimally invasive hip resurfacing arthroplasty (RA) endoprosthesis with original fixation system based on the concept by Rogala (European Patent No. 072418 B1: "Endoprothesis", US Patent No. 5,91,759: "Acetabulum endoprothesis and head", Canadian Patent No 2,200,064: "Method and endoprosthesis to apply this implantation") [13,14,22]. There is proposed the essential innovation in fixation technique of the RA endoprosthesis components in trabecular bone, i.e.: totally cementless fixation by means of the multi-spiked connecting scaffold. The concept of the THRA endoprosthesis was previously presented in [18,20,21]. Excerpts from CAD derived design process and modelling, early unsuccessful attempts of fabricating the endoprosthesis in traditional technology (Electrical Discharge Machining) and pre-prototyping the RA endoprosthesis and multi-spiked connecting scaffold (needle-palisade) fixation system samples in laser additive technologies are presented in previous papers [7,15,20].

The minimally invasive THRA endoprosthesis according Rogala's patents [13,14,22] includes an acetabulum and a head as shown in FIG. 1, while the bearing surfaces are located on round surfaces with projecting spikes forming multi-spiked connecting scaffold.

The multi-spiked connecting scaffold prototype was designed to mimic the interdigitations of articular subchondral bone (FIG. 2) which interpenetrate the trabeculaes of the periarticular cancellous bone. The connecting scaffold is expected to provide the biological anchorage in the trabecular bone via its ingrowth into the inter-spike space of the scaffold and in this way to fixate the components of RA endoprosthesis.

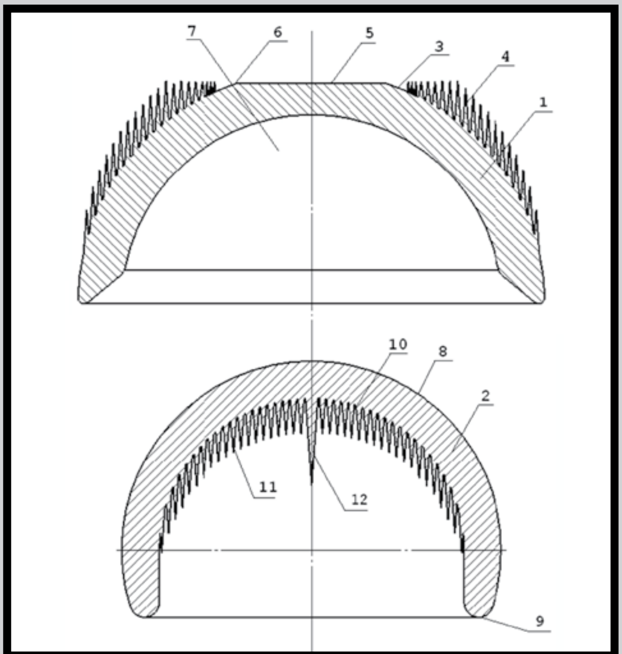

FIG. 1. Schematic drawing of prototype acetabulum and head of the innovating RA endoprosthesis in cross-section: (1) acetabulum, (2) head, (3) acetabulum spherical boundary surface, (4) acetabulum spikes, (5) circular surface, (6) edge lying in the plane perpendicular to acetabulum axis, (7) pan, (8) external head surface, (9) annular bearing surface, (10) spherical boundary surface, (11) head spikes, (12) central spike.

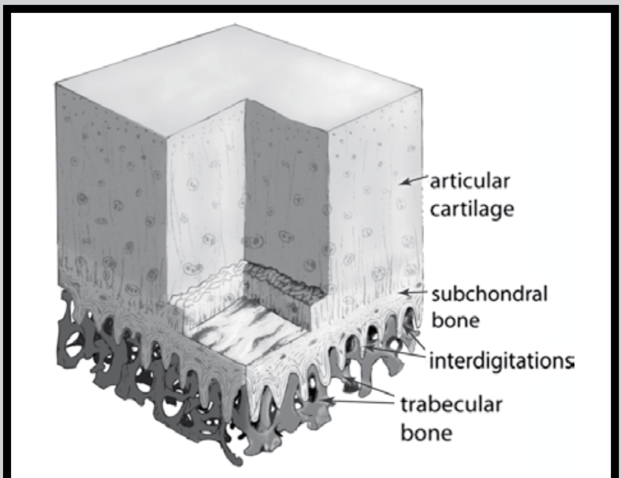

FIG. 2. The 3D diagram of articular hyaline cartilage and subchondral bone with its interdigitations interlocking with trabeculaes of cancellous bone; own diagram built on the base of the results of [9].

The fixation of the RA endoprosthesis will proceed in two steps: 1) the mechanical insertion of the endoprosthesis components into the periarticular trabecular bone by the operating surgeon and 2) the adaptive bone tissue ingrowth into the inter-spiked space of the connecting scaffold. From the bioengineering point of view we have here the interpenetration of the two porous biomaterials: the press-fit penetration of the multi-spiked connecting scaffold into the pore space of trabecular bone and the biological penetration of bone tissue during its ingrow into the connecting scaffold.

It is important to note, that the macrodimensions of the annular bearing part (9) (FIG. 1) of femoral head component of our cementless THRA endoprosthesis prototype are designed to preserve the main blood supply of the femoral head (FIG. 3), i.e. the subcapsular arteriae retinaculares: superior (3), anterior (4) and inferior (5). Consequently, the main physiological blood supply of femoral head and the suitable remodelling potential of its trabecular bone are preserved.

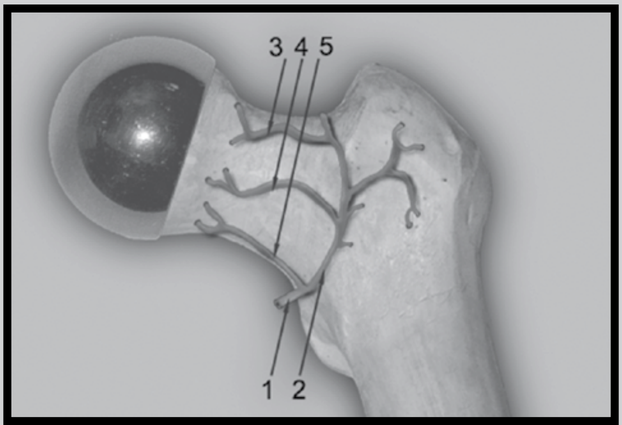

FIG. 3. The femoral head component of our prototype of innovating THRA endoprosthesis – designed to preserve the subcapsular *arteriae retinaculares: superior* (3), *anterior* (4) and *inferior* (5); (1) – *a.circumflexa femoris lateralis*, (2) – *ramus ascenens* of (1); auhor's scheme based on the blood supply diagram from [4].

The filling-up of the inter-spike pore space of connecting scaffold by ingrowing new formed bone tissue will allow for the effective biological fixation in trabecular bone of the femoral component of proposed innovaive THRA endoprosthesis. This multi-spiked connecting scaffold of proposed THRA endoprosthesis is believed to provide the close-to-natural load transmission in the hip joint and the proper implant fixation in the periarticular trabecular bone tissue, preventing the endoprosthesis from spraining and loosening.

Principles of bioengineering design of the prototype of innovating THRA endoprosthesis

The bioengineering design of the multi-spiked connecting scaffold being (like as the interdigitations of subchondral bone) the structural complement interlocking the trabecular bone architecture was performed on the basis of the modern two-phase poroelastic biomechanical bone model [2,16,17,25,34]. The model enables an alternative look, based on the mechanics of porous materials (the so-called poromechanics), on the problem of design of the constructional properties of porous scaffolds for orthopaedic implants. The new two-phase poroelastic bone model: a poroelastic solid filled with viscous ionic intraosseous fluid, enables to solve the biomechanical problem concerning the bone-porous implant fixation in the way that was not possible in the case of applying the traditional one-phase elastic model. It also enables more adequate interpretation of the conditions of the biodynamic process of adaptive bone tissue remodelling (remodelling of the external shape and the internal material properties) under the influence of their mechanical loading (and strain) history and takes into account the biomechanical and bioelectrophysiological role of fluid phase in this process [26-28,32].

During the design process of the multi-spiked connecting scaffold, to create beneficial conditions for the induction and stimulation of bone tissue response in the form of adaptive remodelling, there was assumed, that the bone tissue ingrowing into the scaffold inter-spike pore space will fix it in bone, increasing simultaneously its interface adhesive area with bone tissue and will adaptively optimize the stresses distribution due to the load transfer. The providing of the structural-osteoinductive and mechanical biocompatibility determined by the parameters set for quantitative evaluation of bone-porous implant interface properties (described for cortical bone in our previous papers [8,31-33,35,36]) has been the main criterion during the design of the our prototype of the multi-spiked connecting scaffold for THRA enoprosthesis.

The multi-spiked connecting scaffold, bearing on the periarticular trabecular bone, provides the possibly maximal reduction of micromotions between the implant and the bone owing the suitable enlargement of the adhesive contact surface between the bone and the implant. The total interface bearing surfaces should be advantageously more than seven times larger than the joint surface of the acetabulum and the head, and assume to allow the limb loading directly after the RA endoprosthesis implantation. To achieve this, the spikes advantageously have to be sized so that the ratio of the base radius to the height of the spike is at least than one to five [30].

Manufacturing of RA endoprosthesis prototypes

Selective Laser Melting

Contemporary the orthopaedic endoosseous implants (e.g. hip and knee implants) are fabricated from wrought or cast bar stock by 5axis or 6axis CNC, CADdriven machining, or powder metallurgy (PM) production methodologies; including hot isostatic pressing and powder injection molding of nearnetshape components [3,6,11]. In recent years, solid freeform fabrication (SFF) – also variously called rapid prototyping (RP), layered manufacturing (LM) or rapid manufacturing (RM) or direct digital manufacturing (DDM) – has provided a "renaissance in manufacturing" [11]. Solid freeform fabrication (SFF) is a family of one-step processes that involve the layer-wise shaping and consolidation of material (e.g.: powder, wire) in which tooling is eliminated thereby reducing production time and cost [23].

Due to the additive nature of SFF it can produce parts with a high freedom directly from a CAD model. These technologies are able to fabricate complex shapes of patient-fitted components using precursor powders to build these shapes by sintering or melting powder layers using either a laser or an electron beam. Only recently, these technologies are able to build components from biocompatible metals or alloys powders such as Stainless Steel, Ti, Ti6Al4V, and other Ti-alloys, and cobalt-chromium alloys. Furthermore, desirable monodispersed metal or alloy powders with uniform rapid solidification microstructure were also not generally available until early in this century [11].

There are several machines in the market that utilize different building methods, such as 3D printing, fused deposition modelling, laminated object manufacturing, selective laser melting (SLS), 3D laser cladding, electron beam melting (EBM) and selective laser melting (SLM) [23]. Among them the SLM presents great potential to manufacture metal components with microstructures and mechanical properties equivalent or superior to bulk materials and conventionally processed materials [1,5,11]. SLM development was driven by the need to produce near full dense objects, with mechanical properties comparable to those of bulk materials and by desire to avoid lengthy post processing cycles [5]. In SLM the powder particles are fully molten. It is a powder bed process that begins with the deposition of a thin layer of powder onto a substrate held in place by an adjustable platform. A laser then scans the surface of the powder, the heat generated by the laser causes powder particles to melt and form a melt pool [23]. As the laser beam moves away from the melt pool, the molten material is solidified forming a structure. Once a layer has been scanned the adjustable platform lowers in the z-axis, another layer of powder is deposited onto previous layer and is again melted by the laser. Schematic diagram of this process is shown in FIG. 4.

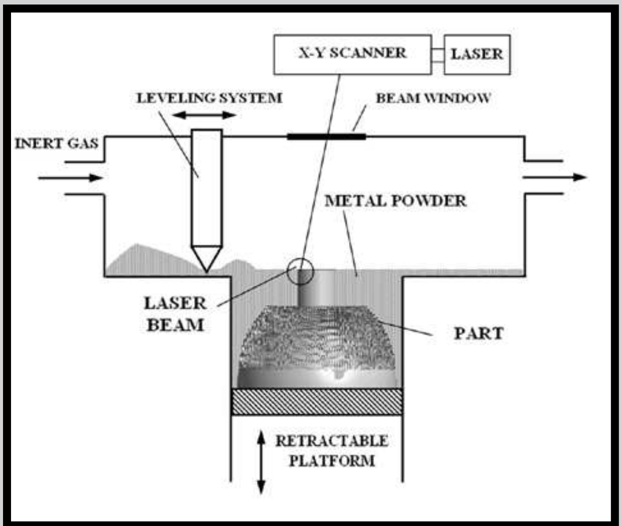

FIG. 4. Schematic diagram showing the principle of Selective Laser Melting (SLM) (Note that the real size proportions of the rapid prototyped element to the SLM machine differs from these presented in the diagram).

Prototypes of the minimally invasive RA endoprosthesis

The prototypes of the minimally invasive RA endoprosthesis with multi-spiked connecting scaffold were manufactured on the base of elaborated geometrical CAD models in SLM technology (the manufacturing was subcontracted to SLM Tech Center in Paderborn, MTT Technologies Group, Germany [10]). The CAD models were designed in size variant for swine (breed: Polish Large White), because our prototypes are going to be used in preclinical in vivo tests on animals. The swine femoral head dimensions were taken as mean values from the radiological examination performed on 47 animal individuals (age 0.5-1 year, weight 90-130 kg).

The prototypes were manufactured using the Ti6Al7Nb powder shown in FIG. 5 (grain size distribution from 5 to 50 μm; the mean grain size – 35 μm) on the MCP Realizer 100 SLM machine equipped in ND:YAG laser. Because of high reactivity of titanium to enviromental agents such as oxygen, nitrogen, carbon, and hydrogen, the SLM process was carried out in a closed chamber continuously flushed with argon gas to reduce the oxygen level below 0.1 percent.

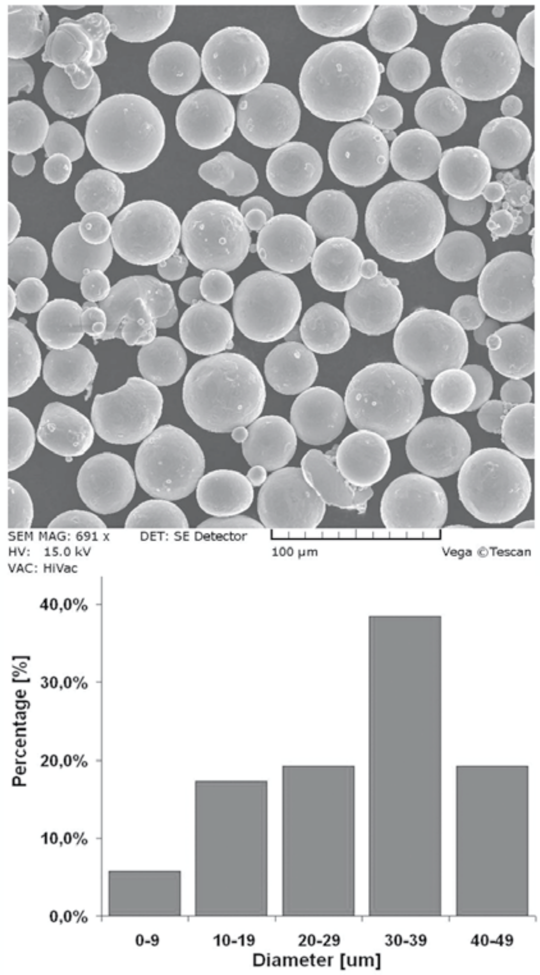

FIG. 5. SEM view of the Ti6Al7Nb powder particles and histogram of powder particle size (diameter) distribution from series of SEM images.

FIG. 6 presents our prototype of the innovating THRA endoprosthesis with the multi-spiked connecting scaffold, after grinding and polishing of the articular surfaces.

FIG. 6. a) The prototype of the innovating THRA endoprosthesis with the multi-spiked connecting scaffold after grinding and polishing. The process parameters applied during the SLM manufacturing of the prototype were: layer thickness – 50 μm, scan speed – 125 mm/s, built rate – 4 cm³/h, b) the THRA endoprosthesis prototype in situ: the socket (acetabular component) and the cup (femoral component).

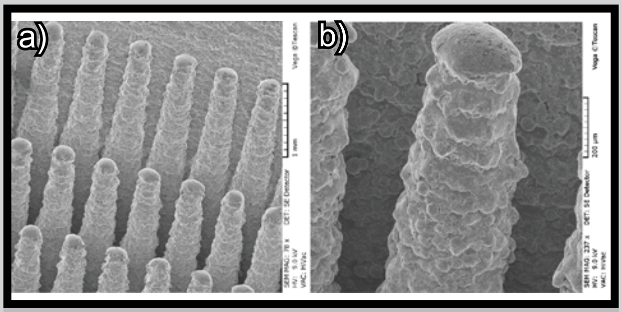

FIG. 7. a) The multi-spiked connecting scaffold of the endoprosthesis after pearl glass blasting treatment; b) singly spike in close-up.

FIG. 7a shows the spikes from the region marked with white square frame in FIG. 6, while in FIG. 7b there is singly spike in close-up. The spikes of the scaffold presented in FIG. 7 are after pearl glass blasting treatment. The rough surface of the spikes is expected to be advantageous factor affecting bone-implant integration.

A fragment of the endoprosthesis prototype was sectioned to investigate its density in cross section. In FIG. 8 several pores are evident. Such non-melted zones including unmelted powder particles are related to the fabrication parameters (e.g. laser beam power, scanning speed, layer thickness, scan stratedy particle size and distribution, etc.) are typical built defects in SLM processed structures [24]. The classification of the crucial parameters to the resulting quality attributes of the SLM manufactured parts are presented in FIG. 9.

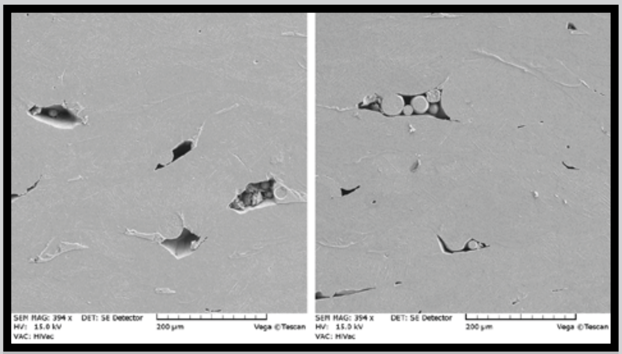

FIG. 8. The cross section of the RA endoprosthesis prototype showing non-melted zones (pores, cavities) including unmelted powder particles.

The presence of pores and cracks, as showed in FIG. 8 in SLM processed structure, particularly if appear on the polished articulate surfaces of the RA endoprosthesis, can disqualify the SLM-manufactured part to work as an articulate joint implant, because of the risk of catastrophic wear resulting in the enhanced wear particles migration to living organism. It indicates that some improvements have to be done in processing parameters selection area, so further investigation with wider spectra of processing parameters of SLM is going to be carried out to establish the optimal parameters to resist the porosity in cross section and to obtain the homogeneous, coherent and crack free microstructure.

The rough surface of the spikes is expected to be an advantageous factor improving bone cells adhesion to the scaffold. The termochemical modification (hydroxyapatite coating) of the multi-spiked connecting scaffold surfaces interfacing bone tissue to improve their osteoinductive and osteointegrative properties.

The research on microstructural properties and mechanical behaviour of SLM manufactured pre-prototypes and prototypes of the THRA endoprosthesis are planned following the optimization of the constructional properties and the processing directives for the scaffold manufacturing with SLM technology on the base of the preclinical in vivo tests results are the subject of our research next stages.

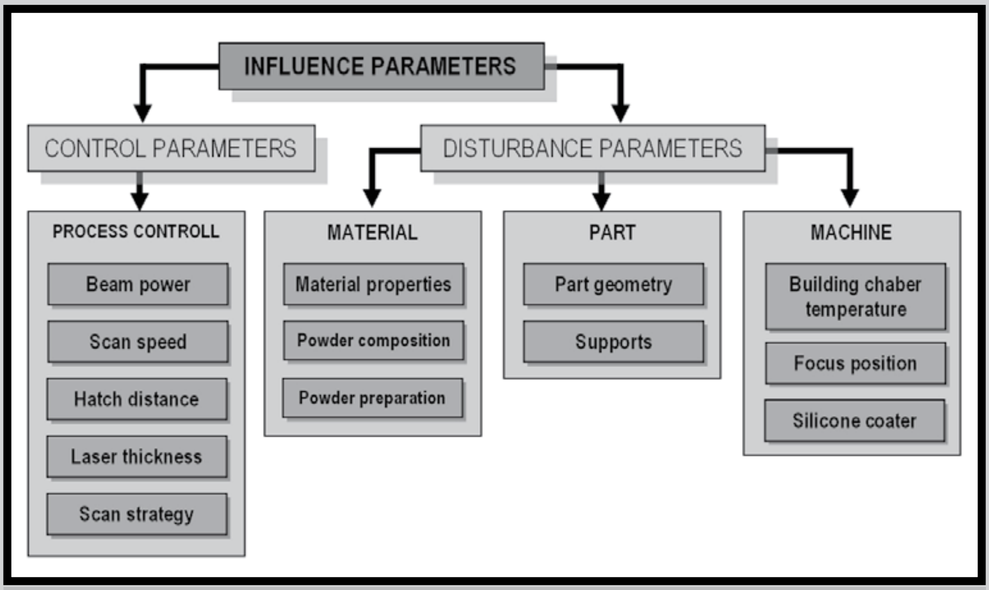

FIG. 9. Most dominant influence parameters on SLM, after [12].

Summary

The macroscopic and SEM microscopic evaluation of the SLM-manufactured THRA endoprosthesis prototype have demonstrated the evident advantage of this laser additive technology to manufacture the further prototypes and possible future serial product. Particularly the reproduction of multi-spiked connecting scaffold, which is designed by mimicking the interdigitations of articular subchondral bone have been judged as accurate regarding to its biological original.

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