Prototype of a non-cemented resurfacing hip arthroplasty endoprosthesis with multispiked connecting scaffold – bioengineering design, manufacturing and preliminary results in animal model

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SUMMARY
The minimally invasive RHA endoprosthesis invented by Rogala offers totally cementless and bone tissue preserving fixation of both components of RHA endoprosthesis by means of the multi-spiked connecting scaffold (MSC-Scaffold). The bioengineering design and the manufacturing in selective laser melting (SLM) technology of the prototype of this TRHA endoprosthesis, together with preliminary results with this prototype in animal model (swine) are presented.

INTRODUCTION
The resurfacing hip arthroplasty (RHA) is the epiphyseal trabecular bone preserving alternative to commonly used long-stem total hip arthroplasty (THA). The high invasiveness of traditional long-stem endoprostheses and arthroplasties leads to non-physiological load transmission (stress shielding phenomenon) resulting in atrophy and extensive destruction of the surrounding bone tissue. RHA endoprostheses allows transferring load in the artificial hip joint in the way close-to-natural: through the preserved head and the neck of the femur and then along the femoral shaft. The hip arthroplasty with application of a stemless RHA femoral component saves the proximal femur for an eventual later revision THA with the use of a short-stem or a traditional long-stem endoprosthesis. Currently implanted RHA endoprostheses (e.g. Birmingham Hip Implant®, Wright Conserve Plus Implant®, Cormet 2000 Implant®, Zimmer DUROM Implant®, ICON Implant®; Biomet ReCap Implant®, DePuy ASR Implant®, ESKA resurfacing Implants®) generally have the femoral component fixed in the bone with polymethylacrylate cement. Applied cements never guaranteed proper and long-lasting RHA endoprostheses fixation. Bone resorption, loosening in bone-cement-implant interface and migration of the endoprosthesis components were observed in many clinical studies in the past (Howie et al., 1990). Cement, penetrating deeply into the trabecular bone of femoral head, occupies more than 1/3 of its volume (Howald et al., 2006). This situation causes regional blood supply insufficiency (see Beaulé et al., 2008) which leads to the weakening of the internal bone microstructure and can result in failures. The loosening and migration of the femoral component, as well as the femoral neck fracture, are still problems in the current generation of “cemented” RHA endoprostheses (Daniel et al., 2004; Amstutz, 2004, Spencer et al., 2008; Morgan et al., 2008).

The minimally invasive RHA endoprosthesis invented by Rogala [3] offers a major breakthrough in fixation technique of RHA endoprosthesis components in the bone – totally cementless and bone tissue preserving fixation of both components of RHA endoprosthesis by means of the multi-spiked connecting scaffold (MSC-Scaffold). The aim of this contribution is to present the main results of our two research projects (sponsored by the Polish Ministry of Science) concerned with: the bioengineering design and the manufacturing in selective laser melting (SLM) technology of the prototype of this new kind of non-cemented TRHA endoprosthesis, together with preliminary results of the investigation performed with this prototype in animal model (swine). Our previous attempts performed in pre-Direct Metal Manufacturing (DMM) era demonstrated that it was impossible to manufacture suitable prototypes of this RHA endoprosthesis (especially of the MSC-Scaffold) using traditional machining technologies. Owing to an extensive development of DMM technologies observed in recent years the effective bioengineering design connected with manufacturing of such prototypes has become possible.

BIOENGINEERING DESIGN AND SLM MANUFACTURING OF THE PROTOTYPE OF TRHA ENDOPROSTHESIS
The bioengineering design of the MSC-Scaffold, being structural complement to the trabeculae porous architecture, was prepared on the basis of the modern two-phase poroelastic biomechanical bone model (Uklejewski, 1992; Cowin, 1999; Rogala, Uklejewski and Stryła, 2002a, 2002b; Stryla, Uklejewski and Rogala, 2004a, 2004b). It enables an alternative look, based on the mechanics of porous materials at...
the problem of design of the constructional properties of porous scaffolds for orthopaedic implants. The spikes of the MSC-Scaffold were designed to mimic the interdigitations of articular subchondral bone which interpenetrate the trabeculae of the periarticular trabecular bone (Milz & Putz, 1994). In this biomechanical approach the MSC-Scaffold and the trabecular bone can be treated as two interpenetrating porous structures. The CAD models of the pre-prototypes and the prototype of the RHA endoprosthesis with MSC-Scaffold were designed and initially optimized within the claims and the general assumptions of international patents by Rogala (Rogala, 1999a, 1999b, 2002); prototyping in SLM technology of Ti6Al7Nb alloy powder was subcontracted to SLM Tech Center (Paderborn, Germany), Fig.1.

![Figure 1. A: Schematic drawing of acetabulum component and femoral head component of the RHA endoprosthesis in cross-section: (1) - acetabulum component, (2) - femoral head component, (3) - acetabulum spherical boundary surface, (4) - acetabulum neighbouring 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 neighbouring spikes, (12) - head central spike; B: The 3D diagram of articular hyaline cartilage and subchondral bone with interdigitations interlocking with trabeculae of cancellous bone; C: The prototype of the RHA endoprosthesis with the MSC-Scaffold after grinding and polishing. D: the RHA endoprosthesis prototype in situ: the socket (acetabular component) and the cup (femoral component).](image)

PRELIMINARY RESULTS IN ANIMAL MODEL
Animal model (swine, 72 kg) preliminary investigations results of our prototype of the non-cemented RHA endoprosthesis with MSC-Scaffold are shown in Fig.2.

![Figure 2. Our prototype of the non-cemented RHA endoprosthesis with MSC-Scaffold implanted to swine hip: a) the postoperative radiograph; b) after 4-weeks of the surgery. We have found that the femoral component of the prototype of THRA endoprosthesis is well-situated inside the hip. No early complications after the surgery were observed.](image)

DISCUSSION
For the first time, largely owing to slm technology, it was possible to manufacture the prototype of the original non-cemented rha endoprosthesis with msc-scaffold suitable for further research. The thermochemical modification of the msc-scaffold surfaces interfacing bone tissue to improve their osteoinductive and osteointegrative properties together with the optimization of the constructional properties and the technological directives for the msc-scaffold manufacturing in slm technology on the base of the preclinical in vivo tests on animal models are the subject of our current (starting in 2010) research project (Polish Min.Sci. No nn518412638; head: R. Uklejewski).

REFERENCES
[3] P. Rogala, European patent nr 072418 B1: Endoprosthesis (1999); US patent nr 5,91,759; Acetabulum endoprosthesis and head (1999); Canadian patent nr 2,200,064: Method and endoprosthesis to apply this implantation (2002).