Acta of Bioengineering and Biomechanics
Vol. 11, No. 2, 2009

Short communication

Prototype of minimally invasive hip resurfacing endoprosthesis – bioengineering design and manufacturing

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The resurfacing arthroplasty (RA) has become at present the most developed minimally invasive kind of all total arthroplasties, which is a result of the progress in biomaterials engineering, biomechanical design and surgical fixation methods achieved over the past decade. Despite the raising popularity of RA, which undergoes at present its renaissance, it still causes several clinical complications. In this paper, we present the most important result our research project (4T07C05629), finished in February 2008, which is the prototype of original minimally invasive endoprosthesis for total hip resurfacing arthroplasty (THRA). We propose the essential innovation in fixation technique of the RA endoprosthesis components in trabecular bone by means of the multi-spiked connecting scaffold, offering the possibility of totally cementless fixation and the physiological blood supply in trabecular bone of femoral head, which is not possible in contemporary used cemented RA endoprostheses. Moreover, the femoral component is designed to preserve the femoral neck and head blood vessels. The prototype of the new kind of hip resurfacing endoprosthesis was CAD-designed in the frames of the Rogala's international patent general assumptions [1]–[3], optimized on the basis of the preliminary biomechanical tests on the pre-prototypes, and manufactured in the Selective Laser Melting (SLM) of both CoCrMo powder and Ti6Al7Nb powder.

Key words: *total hip resurfacing arthroplasty endoprosthesis, minimally invasive endoprosthesis, multi-spiked connecting scaffold*

1. Hip resurfacing – introduction

The total hip resurfacing arthroplasty (THRA) is the epiphyseal trabecular bone preserving alternative to the 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 [4]. THRA endoprosthesis 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 overall stability of the hip joint is improved as compared to the traditional THA and, moreover, the stemless THRA femoral component application saves the proximal femur for an eventual later revision THA with the use of a short-stem or a long-stem endoprosthesis. Resurfacing arthroplasty (RA) is usually considered for patients with osteoarthritis, post-traumatic arthritis, juvenile rheumatoid arthritis and developmental dysplasia and patients who are likely to outlive a THA, for example, patients under the age of 65 years.

The early RA endoprostheses models (e.g., Smith's, 1917; Smith-Petersen's, 1923; Willey's, 1938; Albee and Pearson's, 1940–1944; Urist's, 1951; Laing's, 1960, Müller, 1968; Wagner and Freeman, 1976) have been made of various materials and vari-

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Received: April 8th, 2009
Accepted for publication: August 28th, 2009

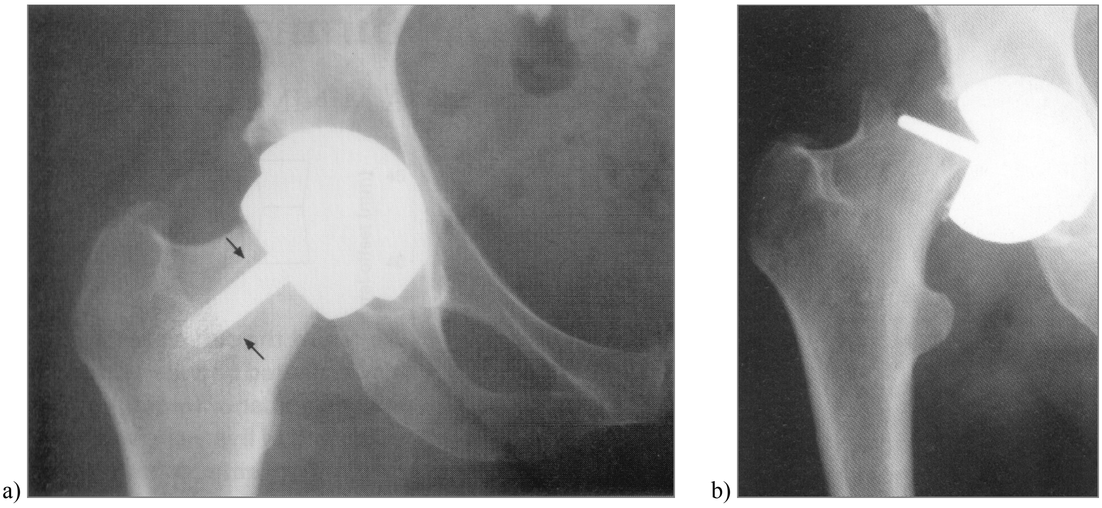

Fig. 1. Roentgenograms illustrating typical failures in Birmingham Hip Resurfacing (BHR) Implant (UK): a) femoral component loosening and migration and b) femoral neck fracture [12]

ous bearing surfaces like: metal-on-metal, plastic- or ceramic-on-metal and ceramic-on-ceramic [5]. However, all these models failed due to a weak biocompatibility of early biomaterials (Teflon®, celluloid, bakelite, Pyrex® glass and polyethylene), the lack of good long-term fixation or the loosening of the endoprosthesis components, necrosis, and deformation connected with high friction, rapid wear and intense tissue reaction to wear particles. Because of the poor clinical results this generation of hip resurfacing endoprostheses was abandoned in a short time.

The RA has its renaissance since the 1990's. These contemporary used RA endoprostheses differ from their predecessors in terms of materials, fixation technique, component thickness and size options. The advantages of those implants lie in their stronger fixation, lower wear bearing, lower invasiveness and lower risk of complications, especially fractures and dislocations. Several clinical studies carried out on those implants reported interesting and promising data on RA follow-ups and surface implant survival [6], [7]. However, the other studies showed the examples of THRA complications [8]–[12]. The loosening and migration of the femoral component, as well as the femoral neck fracture, are still problems in the contemporary generation of RA endoprostheses (see figure 1).

In all currently implanted THRA endoprostheses, the femoral component is fixed on bone with a polymethacrylate cement. The cements applied never guaranteed a proper and long-term THRA endoprosthesis fixation – bone resorption, the loosening in bone-cement-implant interface and migration of the endoprosthesis components were observed in many clinical studies [13]. On the one hand the use of cement provides firm primary fixation of RA endoprosthesis femoral component, but on the other one (as shown in figure 2) the cement penetrating deep into the trabecular bone of femoral head causes regional blood supply insufficiency, which leads to the internal bone microctructure weakening and results in failures (as, e.g., in figure 1).

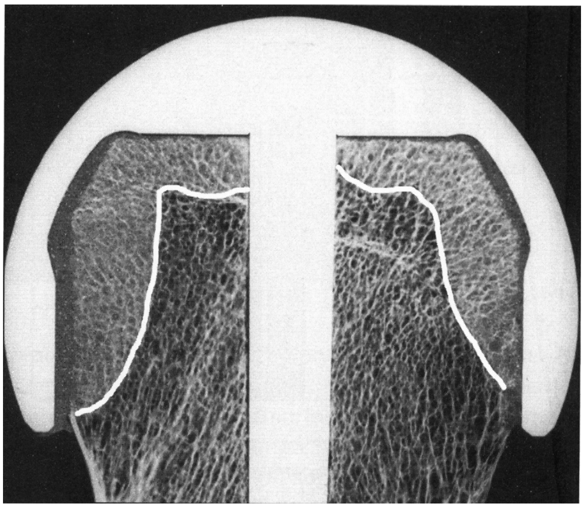

Fig. 2. Section showing cement penetration zone in femoral head occupying more than 1/3 of its volume; Durom Hip Resurfacing (DHR) Implant (Switzerland) [14]

We propose the essential innovation in fixation technique of RA endoprostheses – totally cementless fixation of both RA endoprosthesis components by means of the innovative multi-spiked connecting scaffold described below.

2. New RA endoprosthesis: structurally-biomechanical principles

The RA endoprosthesis invented by Rogala [1]–[3] and previously presented in [15]–[17] includes an acetabulum and a head (figure 3), while the bearing surfaces are located on round surfaces which include projecting spikes forming multi-spiked connecting scaffold. The edges of the bases of adjacent spikes contact each other and their axes are perpendicular to the surface in which the bearing edge of the acetabulum and the bearing surface of the head lie. Peaks of the projecting spikes of the acetabular cap do not extend beyond the circular plane boundary surface determined by the edge lying on the plane perpendicular to the acetabular axis; however, the head has a bearing surface in annular form with an outer diameter smaller than a diameter of round bowl, which constitutes a spherical cap of the external surface of the head. The length of the acetabulum spikes measured from the base on the boundary surface determines a theoretical spherical surface, concentric to the boundary surface, which crosses the peaks of the spikes.

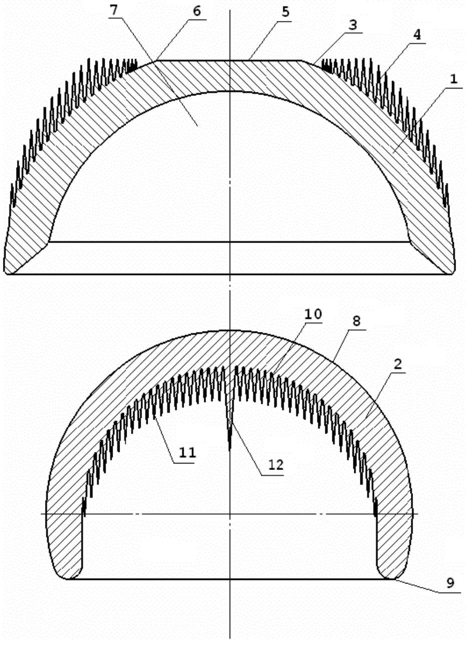

Fig. 3. Schematic drawing of acetabulum and head of the endoprosthesis in cross-section: (1) – acetabulum, (2) – head, (3) – acetabulum spherical boundary surface, (4) – acetabulum spikes, (5) – circular surface, (6) – edge lying in the plane perpendicular to acetabulum axis, (7) – pan, (8) – external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

The endoprosthesis acetabulum ((1) in figure 3) possesses a pan (7) to place the endoprosthesis head (2), which constitutes a part of spherical cap of the external head surface (8). The head has annular bearing surface lying below the transverse axis of the head. On the head spherical boundary surface there are spikes arranged around the central spike with parallel axes to each other, whereas a central spike is coincident with the axis of the head.

The implantation method involves the press fit insertion of spikes into the trabecular bone to the depth determined in the preliminary biomechanical “press-in and loading tests” performed on the SLM manufacture pre-prototypes shown in figure 4a on the Universal Testing Machine (TIRAtest, Germany). The pre-prototypes were manufactured as fragments of connecting scaffold with various sizes of spikes and arrangement variants, representing the middle area of femoral component around the central spike.

The spikes of the connecting scaffold mimic the interdigitations of articular subchondral bone, which interpenetrate the trabeculae of the periarticular cancellous bone. During their penetration into trabecular bone marrow lacunaes the spikes of the scaffold will cause the controlled destruction of cancellous bone trabeculae on at the desired osteoinductive level, allowing the effective promotion of bone tissue ingrowth into the remaining free space between the spikes (scaffolding effect) (figure 4b). After new bone formation, the boundary surface of the acetabulum and the boundary surface of the head, the circular surface, head annular bearing surface, and the surfaces of the spikes become the bearing surfaces of the endoprosthesis.

The multi-spiked connecting scaffold that bears the periarticular trabecular bone was designed to provide the possibly maximal reduction of micromotions between the implant and the bone owing to the optimal enlargement of the adhesive contact surface between the bone and the implant. The total interface of 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 one to five.

The macrodimensions of the annular bearing part (9) of femoral head component (see figure 3) are designed to preserve the posterolateral and medial epiphyseal femoral arteries (subcapsular *aa. retinaculares*) for femoral head. Consequently, the physiological blood supply and the optimal remodelling potential of the trabecular bone of femoral head are preserved. The filling-up of the inter-spike pore

Fig. 4. Variety of connecting scaffold fragments manufactured in SLM (a);
the SLM-manufactured scaffold fragment under crosshead of Universal Testing Machine (b);
pre-prototype of the multi-spiked connecting scaffold inserted into the animal femur head to the defined depth
– the remaining free space between spikes (indicated by arrows) can be filled-up by the ingrowing newly formed bone tissue (c)

space of connecting scaffold by an ingrowing newly formed bone tissue will allow the effective biological fixation in trabecular bone of the femoral component of the THRA endoprosthesis proposed.

This multi-spiked connecting scaffold of the THRA endoprosthesis provides 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.

3. Rapid prototyping of RA endoprosthesis

The prototypes of the RA endoprosthesis were manufactured on the basis of designed geometrical CAD models in Selective Laser Melting (SLM) technology owned by MTT Technologies Group, Germany (former MCP HEK, Germany). SLM is a layer-wise material addition technique that allows generating complex 3D parts by a selective melting of the successive layers of metal powder on the top of each other, using the thermal energy supplied by a focused and computer controlled laser beam. The powder particles have a statistical distribution of size from 5 to 70 μm. In each layer, the laser beam generates the outline of the part that is being built by melting the powder particles, before the building platform is lowered and coated with a new layer of powder. SLM is one of the possible processes to manufacture 3D metallic structures using a variety of material options, including biocompatible titanium and chromium-cobalt alloys with full serial characteristics and typically great variety of geometric design.

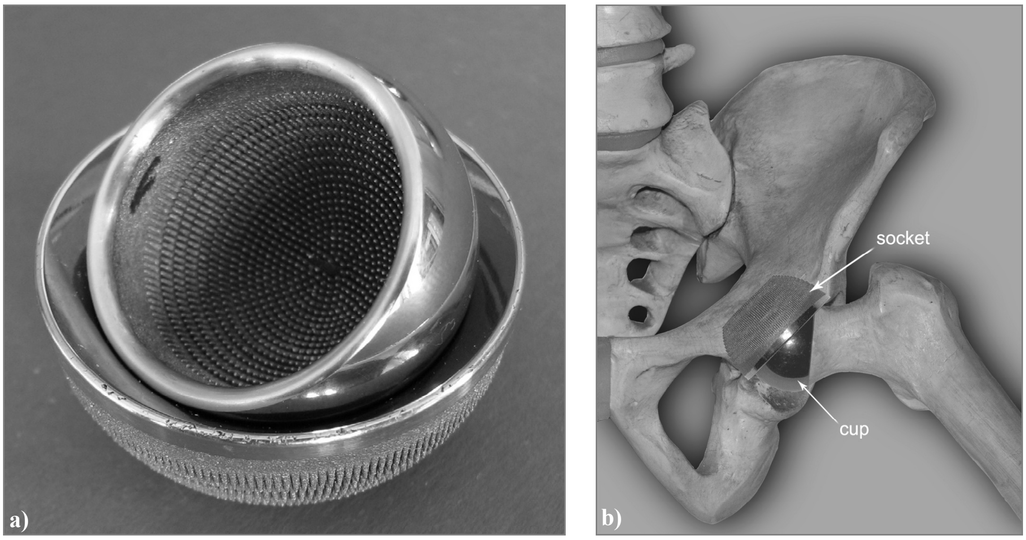

Fig. 5. Prototype of THRA endoprosthesis with the multi-spiked connecting scaffold after grinding and polishing (a); THRA endoprosthesis prototype in situ: the socket and the cup (b)

The geometrical CAD models of the total THRA endoprosthesis with multi-spiked connecting scaffold were designed in Autodesk Inventor® Professional 9 CAD software. 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 manufacturing of SLM prototypes of the THRA endoprosthesis on the basis of those CAD models was subcontracted to SLM Tech Center in Paderborn (MTT Technologies Group, Germany). The prototypes were made of CoCrMo powder, as well as of Ti6Al7Nb powder on the MCP Realizer 100 SLM machine.

Figure 5 presents the prototype of THRA endoprosthesis with the multi-spiked connecting scaffold after the grinding and polishing of the articular surfaces.

The manufacturing of the endoprosthesis prototypes has allowed us to investigate in a laboratory the biomechanical conditions of inserting endoprosthesis components (the determining of required implant insertion forces) and then to prepare the preclinical in vivo investigations of the endoprosthesis prototypes on animal models.

4. Final remarks

The termochemical modification of the multi-spiked connecting 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 scaffold manufacturing with SLM technology on the basis of the preclinical in vivo tests results are the subject of our next research project submitted (in January 2009) to the Polish Ministry of Science for financial support.

Acknowledgements

This research was supported by Polish Ministry of Science by research project no 4 T07C 056 29: *Experimental investigation and design of the constructional properties of bone–porous implants fixations* (Head of the project: R. Uklejewski). We are thankful to Mr. M. Ambroziak (WADIM Plast Narojek Co., Poland) and Mr. S. Ritt (MTT Technologies Group, Germany) for their kind support during the talks and preparations concerning the manufacturing of SLM parts.

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