COMPUTER AIDED STEREOMETRIC EVALUATION OF POROSTRUCTURAL-OSTEOCONDUCTIVE PROPERTIES OF INTRA-OSSEOUS IMPLANT POROUS COATINGS

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Abstract

The proper interaction of bone tissue – the natural porous biomaterial – with a porous coated intra-osseous implant is conditioned, among others, by the implant porous coating poroaccessibility for bone tissue adaptive ingrowth. The poroaccessibility is the ability of implant porous coating outer layer to accommodate the ingrowing bone tissue filling in its pore space and effective new formed bone mineralizing in the pores to form a biomechanically functional bone-implant fixation. The functional features of the microtopography of intra-osseous implant porous surfaces together with the porosity of pore space of the outer layer of the porous coating are called by bioengineers the porostructural-osteoconductive properties of the porous coated implant. The properties are crucial for successful adaptive bone tissue ingrowth and further long-term (secondary) biomechanical stability of the bone-implant interface. The poroaccessibility of intra-osseous implants porous coating outer layers is characterized by – the introduced in our previous papers - set of stereometric parameters of poroaccessibility: the effective volumetric porosity ϕ_{Vef}, the index of the porous coating space capacity V_{PM}, the representative surface porosity ϕ_{Srep}, the representative pore size p_{Srep}, the representative angle of the poroaccessibility Ω_{rep} and the bone-implant interface adhesive surface enlargement index ψ. Presented in this paper, an original method of evaluation of the porostructural-osteoconductive properties of intra-osseous implant porous coatings outer layer by means of the parameters of poroaccessibility was preliminary verified during experimental tests performed on the representative examples of porous coated femoral stems and acetabular cups of various hip endoprostheses. The computer-aided stereometric evaluation of the microstructure of implant porous coatings outer layer can be now realized by the authoring application software PoroAccess_1.0 elaborated in our research team in Java programming language.

Keywords: surface topography, porous coating characterization, poroaccessibility, 3D measurement.

1. Introduction

The fixation of components of joint endoprostheses (or generally speaking – the orthopaedic intra-osseous implants) is divided into two categories, i.e.: cemented and cementless. In case of fixation of cementless implants, the factor playing an important role in this task is the adaptive bone tissue ingrowth into the porous coating on the implant substrate, designed for this purpose. The preferred technique of fabrication of implant porous coatings is the plasma-spray technique [1, 2, 3, 4]. Porous coatings can also be manufactured with other technologies e.g.: sintering powders, fibres or beads on implant surface [5], wire mesh diffusion bonding [6], powder metallurgy [7, 8], etc. The variety of types of porous coatings available for biologic ingrowth is presented in Figure 1. The long-term vitality and biomechanical strength of the porous implants inserted into the bone structure depends on: 1) the effectiveness of the adaptive bone tissue ingrowth into the porous coating outer

layer on the intra-osseous implant and 2) the proper stress-strain fields in bone tissue around the implant.
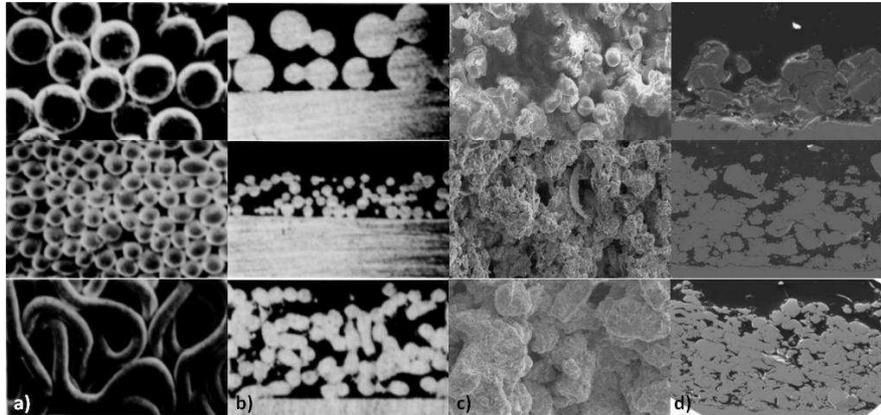

Fig. 1. Different types of porous coatings available for biologic ingrowth – from top to bottom:
in column a) – sintered beaded surfaces with large spheres, sintered beaded surfaces with small spheres and diffusion-bonded fibre-metal surfaces and in column c) – various plasma sprayed coatings;
in columns b) and d) there are presented representative cross-sections through the porous coatings presented respectively in columns a) and c).

The porous coatings constitute a microstructure built of a three-dimensional interconnected array of canalicular pores and are characterized by a gradual change in porosity from the substrate-coating interface to the coating outer layer surface. The coating outer layer is full of pores usually opened for penetrating bone tissue with diameter of many macro pores surpassing 150 μm, which is beneficial for the bone to grow into the porous coating [1, 10, 11]. The volumetric porosity of porous coatings is variable throughout the depth of the coating. The middle layer consists of a "mixture" of micro pores and macro pores. The inner layer varies into dense, tight and closed interface which includes mechanical, physical, and metallurgical bonding with the implant metal substrate providing appropriate strength to sustain loading. Figure 2 presents the cross section of the bone-implant interface created by adaptive ingrowth of bone tissue into the pore space of the porous coating and the cross section of typical porous coating with symbolically distinguished layers: outer layer, middle layer and inner layer, of which the outer layers porostructural-osteoconductive properties are the subject of our research.
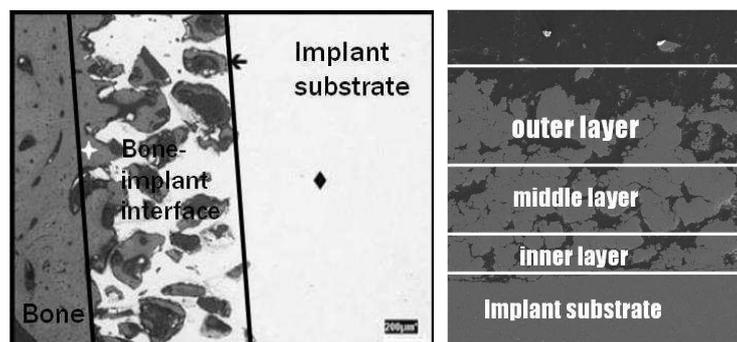

Fig. 2. (left) The cross section of the bone-implant interface created by adaptive ingrowth of bone tissue into pore space of the porous coating and (right) the cross section of a typical porous coating with symbolically distinguished layers: outer layer, middle layer and inner layer of which the outer layer is the subject of our research.

The configuration of microgeometrical properties of implant porous coatings outer layer has crucial influence on the bone-implant osteointegration [12, 13, 14]. Roughening of the implant surface by porous coating changes the physicochemical and biomechanical properties in bone-implant interface [15] (see Figure 3). It increases 1) the adhesive properties and the

interface area with bone tissue, what permits the transmission of various kinds of mechanical loads and increases resistance to shear forces, 2) constitutes the resistance to relative motion between the bone and implant, 3) improves conditions of adaptive bone tissue ingrowth by creating a porous microstructure with pores opened for penetration of the bone tissue, and 4) ensures the proper formation of the bone-implant fixation and stability of the porous implant in bone.
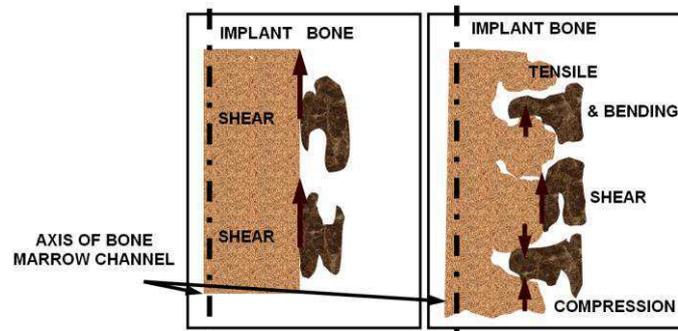

Fig. 3. Smooth vs. porous implant-bone interface.

Hence, the design of the porous coating porosity and its poroaccessibility should be oriented to obtain the microstructural properties promoting the effective bone tissue ingrowth into its pore space. The effective bone tissue ingrowth means the ingrowth which results in the accommodation of remineralized new bone tissue in the pore space of porous coating guaranteeing the formation of a biomechanically functional bone-porous implant fixation – i.e. the fixation being capable permanently to restore the biomechanically-reconstructional role of the components of the artificial joint.

The genesis of the set of poroaccessibility parameters, although its measurement is based on the 3D roughness profilometry [16], is independent and arises from the necessity of three-dimensional evaluation of the functional properties of the microstructure of the porous coatings outer layers. The problem of successful integration and long-term biomechanical vitality of the bone-implant interface as discussed on the basis of the modern two-phase poroelastic model of bone tissue [17, 18, 19] and the mechanics of porous materials applied to implant porous coating was stated as the problem of structural-biomechanical compatibility of bone-porous orthopedic implant interface and was presented at the 5th World Congress in Biomechanics in Munich, Germany, in July 2006 [20] in papers [21, 22] and the PhD dissertation [15]. In [15, 23, 24] there has been proposed a set of poroaccessibility parameters describing the functional properties of microgeometry of implant porous coatings outer layers, which are crucial for adaptive bone tissue ingrowth. The set contains: the effective volumetric porosity ϕ_{Vef}, the index of the porous coating space capacity V_{PM}, the representative surface porosity ϕ_{Srep}, the representative pores size p_{Srep}, the representative angle of the poroaccessibility Ω_{rep} and the bone-implant interface adhesive surface enlargement index ψ. The main performance requirements of an implant porous coating which can be characterized by the proposed set of parameters are: 1) the structural ability to induce adaptive bone tissue ingrowth (the structural osteoinduction) and 2) the capability to accommodate the penetrating bone tissue into pores of the porous coating (the poroaccessibility) following the proper bone-porous implant fixation formation.

The set of parameters was presented at the 11th International Conference on Metrology and Properties of Engineering Surfaces in Huddersfield, UK, in July 2007 [25] and later published in [23]. The results below were presented in part at the 13th International Conference on Metrology and Properties of Engineering Surfaces in London, UK, in April 2011 [26] and are exemplary of practical application of the poroaccessibility parameters as a specific research tool in our research on designing, manufacturing in additive technologies

and biostructural evaluation of implant porous coatings with functionally graded pore distribution and designed poroaccessibility.

2. The parametric evaluation of porous coating outer layers of representative orthopaedic implants

2.1. Materials

With the purpose of verification of the methodology of evaluation of implant porous coating outer layers with the use of the poroaccessibility parameters, and to discuss its utility on the basis of the obtained exemplary values, the preliminary experimental investigations have been performed on representative components of various total hip arthroplasty endoprostheses: 3 randomly chosen types of femoral stems types and 2 of acetabular cups described below,. The measurements were carried out on 1) the Johnson & Johnson Orthopaedics (Great Britain) stems with hydroxyapatite porous coating on the proximal section, 2) the Aesculap® (Germany) stems with a metallic porous coating on the proximal section, 3) the Biomet Merck Ltd. (Great Britain) stems completely covered with a metallic porous coating and 4) and 5) – two different Biomet Merck Ltd. (Great Britain) acetabular cups – both covered with the metallic porous coating. The examined components of the implants are presented in Figure 4.
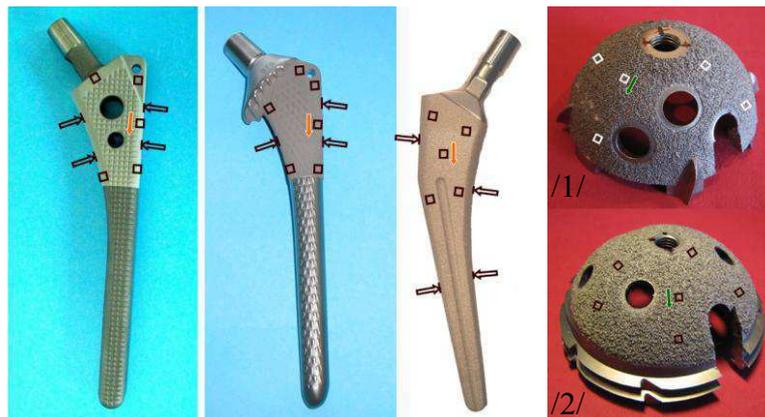

Fig. 4. The examined components of total hip arthroplasty endoprostheses: (from left to right) Johnson & Johnson Orthopaedics stem (Great Britain), Aesculap® stem, Biomet Merck Ltd. stem (Great Britain) and two acetabular Biomet Merck Ltd. cups /1/ & /2/ (Great Britain).

2.2. Methods

The investigations were made with a profile measurement gauge (Mahr S8P Perthometer, Perthen, Germany) equipped in case of stems with a RFHTB 250 pickup and contact stylus (diamond cone tip with 90 degrees vertical angle and 5 ± 2 μm nose radius) and in case of acetabular cups with FRW-250 pickup and contact stylus (diamond cone tip with a 90-degree vertical angle and 10 ± 2 μm nose radius). The measurement was subcontracted to the Laboratory of Surface Stereometry in the Department of Metrology and Measurement Systems at Poznan University of Technology
The method of contact profile measurement was chosen by the reason of 1) a similar shape of the conic gauging stylus with the „the cutting cone" of the remodelling unit of bone tissue, and 2) the analogy between the measurement gauge penetration and the manner of penetration of bone tissue called "creeping substitution" during the remodelling process. The examined stems and acetabular cups were fastened in a precisely-driven fixture enabling the registering

of data from measurements in parallel traversing lengths. The 3D representations of measured surfaces of porous coating outer layers were reconstructed by acquisition of 2D profiles. .

The stereometric evaluation of the porostructural-osteoconductive properties of implants porous coating outer layers was performed using a methodology similar to that used in the three-dimensional surface topography analysis [16]. This analysis was made to obtain a discrete function $z = f(x,y)$. For every measured fragment of the porous coating outer layer the matrix of roughness height points has been created. Then the surface roughness mean surface $z_m = f(x,y)$ has been estimated using the least squares method, and the cylindrical and spherical shapes: for respectively surfaces of stems and acetabular cups were computationally filtered to obtain a flat mean plane.

On the coating surface of each examined stem and acetabular cup there have been chosen representative regions to carry out the measurement. The preliminary standard 2D roughness measurement was carried out to determine the area of regions for examination and sampling intervals. In case of stems the measurement was performed in the direction parallel to the long stem axis on surface regions with no grooves and macrotextures and with small curve radius. In case of the acetabular component the measurements were performed in the direction lined up with the line of longitude. On each component of the endoprosthesis with porous coatings there were measured 7 to 12 regions (see Fig. 4) consisting of 361 profiles of roughness with traversing length 2,16 mm. The sampling intervals between the height points in matrix were 5,56 μm x 6 μm. Hence the area of the measured regions was 4,32 mm^2.

The following results were obtained with the use of the authorial application software PoroAccess_1.0 elaborated for our purposes by our research team in Java programming language. The screen of the application software is presented in Figure 5. The PoroAccess_1.0 software allows to perform a dynamic analysis of the surface porosity ϕ_S in function of the pores depth p_d which is illustrated by the map of porosity situated on the right side of the screen (see Figure 5) and an estimation of the selected standard 3D roughness parameters. The applications software has also a module enabling the 3D visualization of the measured region of porous coating outer layer as the isometric plot. The visualization opens as a new window and is shown on the screen in Figure 6.
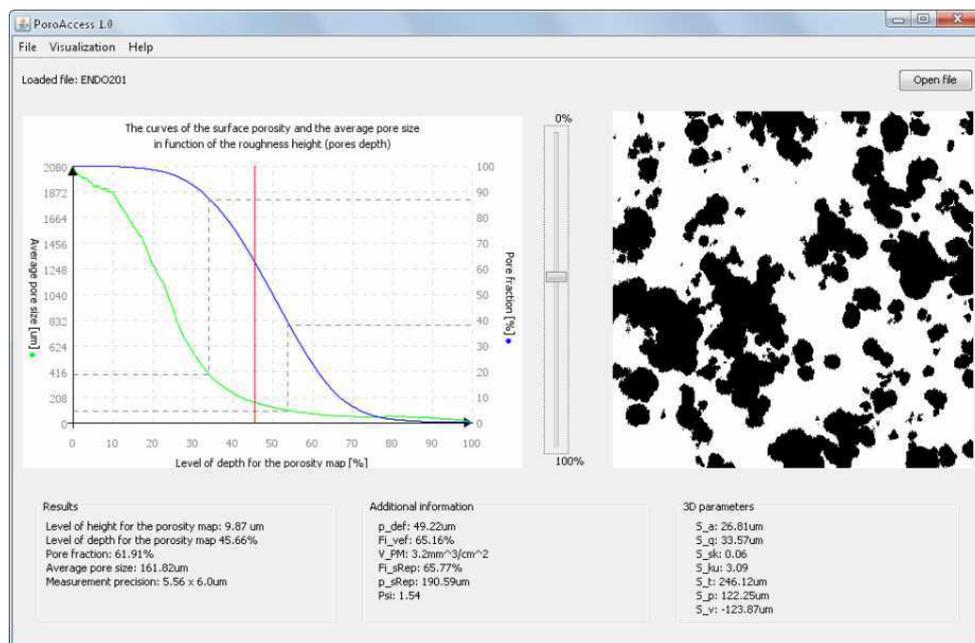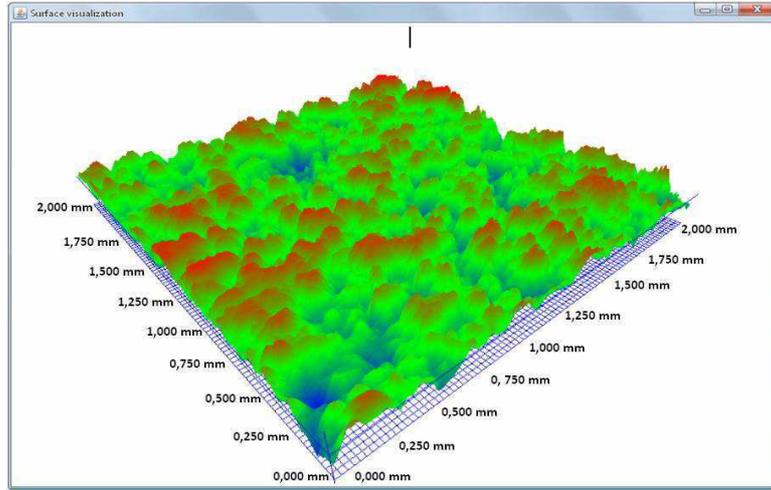

Fig. 5. Screen of PoroAccess_1.0.

Fig. 6. The isometric plot of the exemplary measured region.

The application software imports measurement results as 2D matrices in ASCII format and calculates the values of the average pore size p_S and the surface porosity ϕ_S, both in function of the height of roughness h. The curves of the areal pores fraction (APF) and the average pore size p_S in function of height of the roughness can be presented on diagrams as it is shown in Figure 6. The APF curve is analogous to the Abbott-Firestone bearing area curve [27]. Then the boundary values of average pores size p_{Smin} and p_{Smax} were determined on the boundary levels of height of roughness h_{min} and h_{max}. In this way the effective pore depth p_{def} is determined (Figure 7). The effective pore depth p_{def} is the difference between the boundary levels of roughness height h_{max} and h_{min}. The levels of height of roughness assigning the effective pores depth were assumed as the levels on which the average pores size of 100 µm (p_{Smin}) and 400 µm (p_{Smax}) can be found, which is justified by the results of the clinical research [28]. It is clinically confirmed that bone tissue penetrating into this compartment pore space is able to mineralize effectively and to create a biomechanically functional (effective) fixation between the bone and implant. From the diagram presented in Figure 6 there can be determined e.g.: the surface porosities $\phi_S(h_{min})$ and $\phi_S(h_{max})$ corresponding with the levels of roughness height h_{min} and h_{max} and the effective pore depth p_{def}.

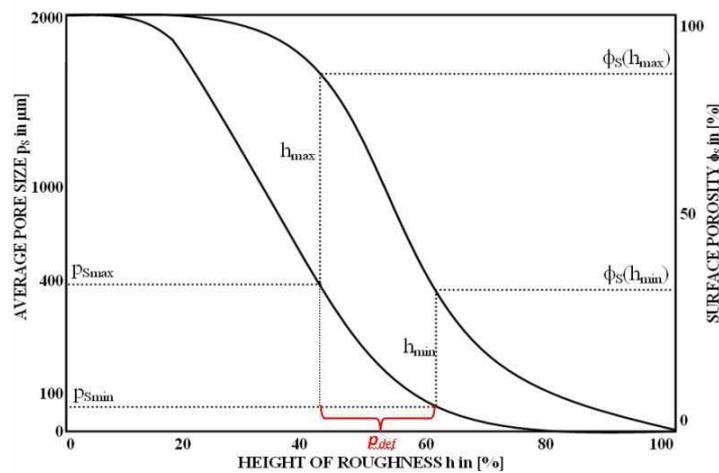Fig. 7. The curves of the surface porosity and the average pore size in function of the roughness height.

The values of the poroaccessibility parameters of porous coating for bone tissue ingrowth: the effective volumetric porosity ϕ_{Vef}, the index of the porous coating space capacity V_{PM}, the representative surface porosity ϕ_{Srep}, the representative pores size p_{Srep}, the representative

angle of the poroaccessibility Ω_{rep} and the bone-implant interface adhesive surface enlargement index ψ were calculated in PoroAccess_1.0 according to the mathematical formulas given in [23].

2.3. Results

Figure 8 presents a graphical illustration of the measurement results of surface of an implant porous coating obtained with the use of the PoroAccess_1.0 software. Exemplary data are presented for 40% and 55% of roughness height for an exemplary porous coating. The geometric model of a representative pore – the red circle/ellipse – is localized by the axis of average pores size. On the right side of Figure 8 there are presented maps of porosity corresponding with the level of roughness height, where pores are marked white. In Figure 9 there are shown isometric plots of the exemplary region measured on the porous coatings of particular endoprostheses components.
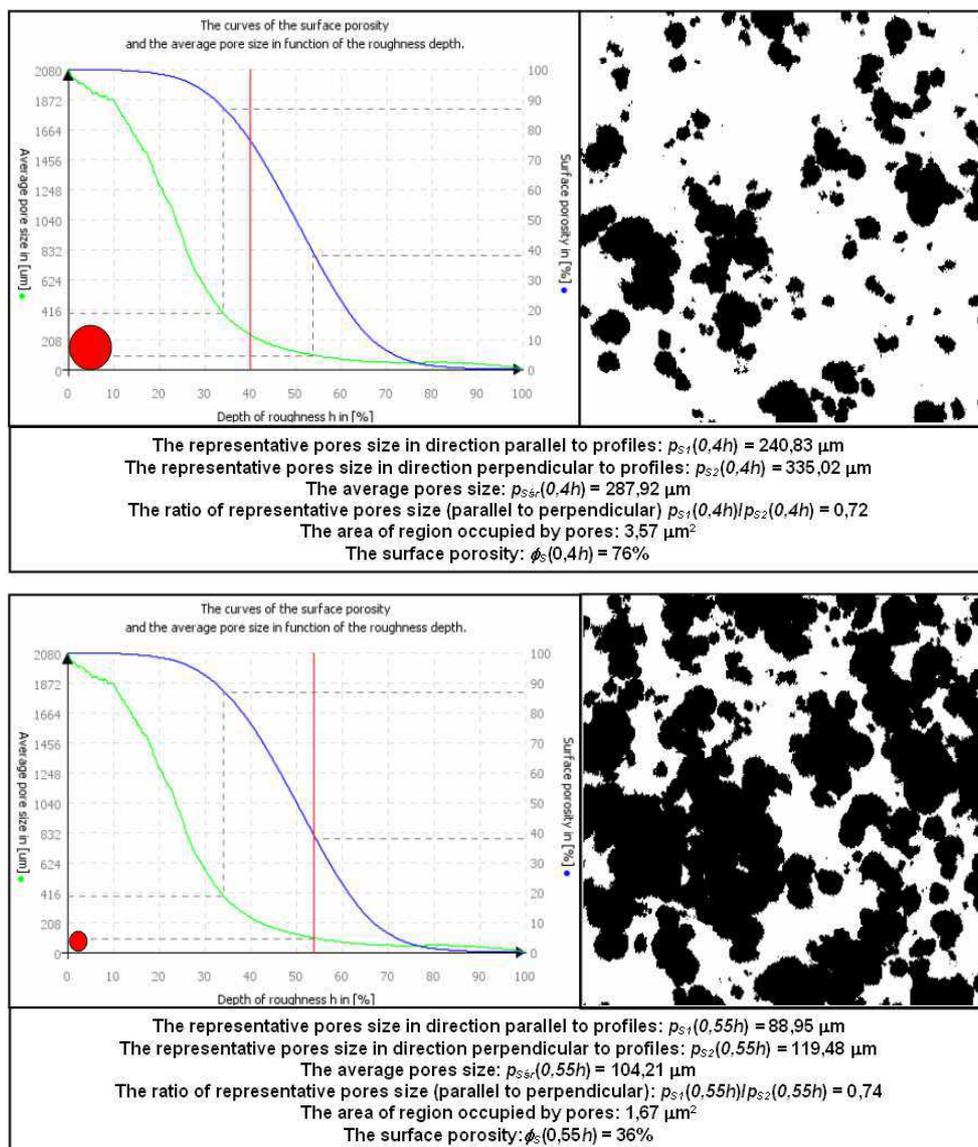

The representative pores size in direction parallel to profiles: $p_{S1}(0,4h) = 240{,}83$ μm
The representative pores size in direction perpendicular to profiles: $p_{S2}(0,4h) = 335{,}02$ μm
The average pores size: $p_{Sśr}(0,4h) = 287{,}92$ μm
The ratio of representative pores size (parallel to perpendicular) $p_{S1}(0,4h)/p_{S2}(0,4h) = 0{,}72$
The area of region occupied by pores: $3{,}57$ μm²
The surface porosity: $\phi_S(0,4h) = 76\%$

The representative pores size in direction parallel to profiles: $p_{S1}(0,55h) = 88{,}95$ μm
The representative pores size in direction perpendicular to profiles: $p_{S2}(0,55h) = 119{,}48$ μm
The average pores size: $p_{Sśr}(0,55h) = 104{,}21$ μm
The ratio of representative pores size (parallel to perpendicular): $p_{S1}(0,55h)/p_{S2}(0,55h) = 0{,}74$
The area of region occupied by pores: $1{,}67$ μm²
The surface porosity: $\phi_S(0,55h) = 36\%$

Fig. 8. The graphical illustration of exemplary readouts calculated by the PoroAccess_1.0 software.

The mean values (± standard deviations of the mean values) of the poroaccessibility parameters of porous coatings of examined endoprosthesis components are presented in Table 1. For all measurement data a comparative analysis between the parameters of

poroaccessibility has been performed. On diagrams in Figures 10 and 11 we have presented exemplary interrelations of the particular poroaccessibility parameters, both obtained for stems of Johnson & Johnson Orthopedics' endoprostheses. Figure 10 presents the interrelation between effective volumetric porosity ϕ_{Vef} and the representative surface porosity ϕ_{Srep}. In Figure 11 is presented the interrelation between the effective pores depth p_{def} and the index of the porous coating space capacity V_{PM}.
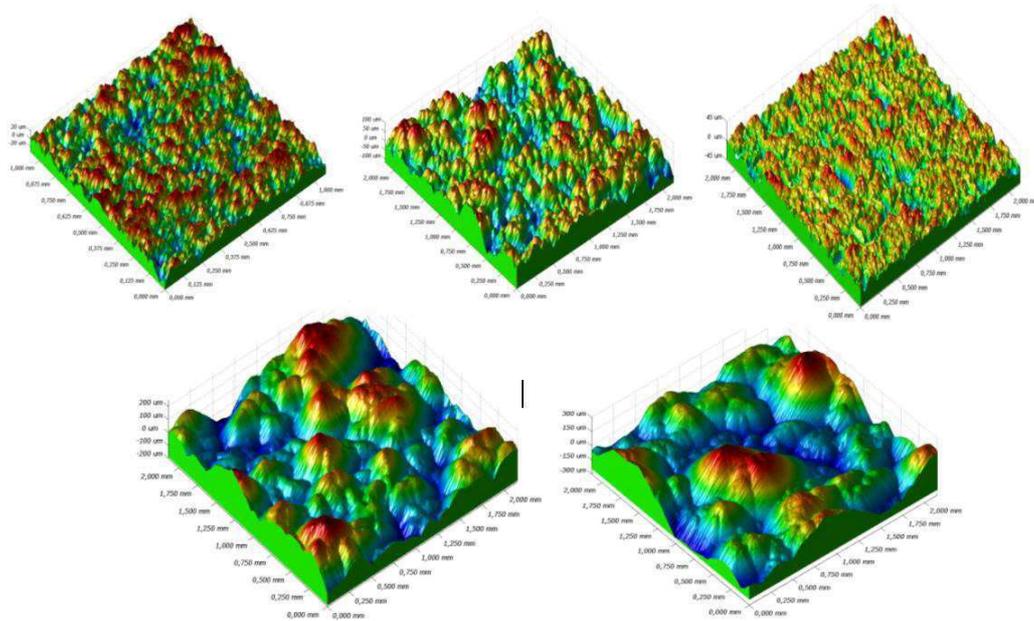

Fig. 9. The isometric plots of the exemplary region measured on the porous coatings of particular endoprosthesis components (from left to right): Johnson & Johnson Orthopaedics stem (Great Britain), Aesculap® stem, Biomet Merck Ltd. stem (Great Britain) and two acetabular Biomet Merck Ltd. cups (Great Britain), presented from Matlab 6.5.

Table 1. Mean values ± standard deviations of the poroaccessibility parameters of porous coatings of examined endoprosthesis components.

	Johnson & Johnson Orthopaedics stems	Aesculap® stems	Biomet Merck Ltd. stems	Biomet Merck Ltd. cups /1/	Biomet Merck Ltd. Cups /2/
ϕ_{Vef} [%]	92±1	65±1	86±2	28±6	32±5
V_{PM} [mm^3/cm^2]	0,7±02	3,3±0,2	0,8±0,1	4,5±0,3	4,9±0,5
p_{def} [µm]	8±2	50±4	9±1	162±37	160±35
ϕ_{Srep} [%]	92±1	66±1	86±2	27±7	31±5
p_{Srep} [µm]	195±9	191±10	201±8	191±17	220±12
Ω_{rep} [°]	44±2	47±1	36±2	47±1	48±1
ψ	1,44±0,04	1,55±0,04	1,21±0,03	1,51±0,05	1,53±0,02

2.4. Discussion

The mean values of the poroaccessibility parameters of porous coatings of examined endoprosthesis components presented in Table 1 demonstrate that values of the representative surface porosity ϕ_{Srep} are practically equal to the effective volumetric porosity ϕ_{Vef} in case of all measured implant porous coatings. The fact can be easy seen in the diagram in Figure 10. This indicates that we can use only one of these two parameters for general characterization of porosity of implant porous coatings, so we do in our following considerations using simply the term "the representative porosity".

Since,
   1) the volume or the capacity of a geometrical shape can be generally estimated as the product of the area of the base and the height (or depth),
   2) the direct interrelation of the effective pore depth p_{def} and the index of the porous coating space capacity V_{PM} was observed during the graphical comparison of the values distribution of these two parameters obtained for all measured endoprosthesis components (the example is presented in Figure 11),
   3) the practical equality of the representative pore size p_{Srep} was ascertained, as well as, the slight changes of the values of the representative angle of poroaccessibility Ω_{rep} for all endoprostheses components (see Table 1),

it can be concluded that in case of the measured porous coatings the value of the index of the porous coating space capacity V_{PM} mainly depends on the value of effective pore depth p_{def}. It indicates that for the proper evaluation of the poroaccessibility of the implant porous coatings the use of either one of these parameters or the other interchangeably is adequate.

The porous coatings on stems of Johnson & Johnson Orthopaedics endoprosthesis and Biomet Merck Ltd. endoprosthesis characterize with high values of the porosity (about 90%) and low values of effective pore depth p_{def} (less than 10 mm). This means that these coatings have shallow and vast pores with a smooth lateral surface and allows to conclude that the porostructure of these coatings is more open for adaptive bone tissue ingrowth. This is characteristic in case of ceramic (hydroxyapatite) porous coatings, having a different (from metallic coatings) manner of bonding with the bone tissue [21, 23], and for porous coatings manufactured to be in contact mostly with cortical bone – e.g. in case of completely covered stems of endoprostheses.

The porous coatings on stems of Aesculap[®] endoprostheses and on both measured acetabular cups are built with rough, shapeless and irregular forms with a steep and sharp lateral surface. This can be confirmed by the higher (than in case of Johnson & Johnson Orthopaedics endoprosthesis and Biomet Merck Ltd. endoprosthesis) values of the effective pore depth p_{def}. Also the relatively higher value of the capacity of pore space V_{PM} shows that in case of these implants their porous coating can access and accommodate more of penetrating bone tissue per area unit. This is typical in the case of metallic porous coatings having contact with a trabecular bone (mostly the acetabular cups and stems covered in the proximal part).

The values of the representative pore size p_{Srep} are similar for all measured porous coatings. It appears from the fact that the curve (see e.g. Fig 8) characterizing the pore size p_S in a function of height of roughness h is quasi-linear in the range between the levels of roughness height h_{min} and h_{max} for all measured regions. It also lets to assume that the value of the representative pore size is equal to the average pore size value in half of the range of the effective pore depth. Since the value of the representative pore size p_{Srep}, according to [21], is taken as the arithmetic mean of the average pore sizes from the established roughness height levels, thus, if more levels of height are established, a better measurement precision can be obtained.

The angle of poroaccessibility Ω gives information about the changes of the slope in lateral pore surface of the porous coating outer layer. We have observed very slight changes of the angle of poroaccessibility values in the range of effective pore depth p_{def} for all investigated implant surfaces.

The similar values of the adhesive surface enlargement index ψ, obtained for all the measured components of endoprostheses indicate a comparable level of the increase of the implant adhesive surface. For intra-osseous cementless orthopaedic implants it means an improvement in the range of about 50% of their adhesive properties, achieved by roughening their surface with a porous coating, in comparison to the smooth implants.

3. Summary

To date in characterization of the microgeometry of implant porous coatings there is in use only the quantity of the average pore space or alternatively only the basic amplitude 2D roughness parameter. In our opinion, such an approach does not take into account the functional features of the porous coating especially related to its porostructural-osteoconductive properties. The set of poroaccessibility parameters introduced in our previous papers characterizes some major aspects of porous coating features. The parameters describe spatial (ϕ_{Vef}, ϕ_{Srep}), volumetric (V_{PM}), hybrid and functional (p_{def}, Ω_{rep}, ψ) properties of implant porous coatings which can be interpreted in the aspect of their porostructural-osteoconductive properties.

It has been found that all the measured porous coatings of various applied hip endoprosthesis components have similar values of the following parameters: the representative angle of the poroaccessibility Ω_{rep}, the index of the enlargement of the adhesive surface ψ and the representative pore size p_{Srep}. As a conclusion, it is suggested that these new parameters are crucial for the determination of promotion conditions of bone tissue ingrowth, what is important for the proper fixation of the implant in bone.

The slight changes of the values of the angle of poroaccessibility Ω together with the linear or nearly linear changes of the values of pore size p_S and surface porosity in function of pore depth p_d in the range of the distinguished effective pore depth p_{def} justifies the methodology of estimating its representative values as the arithmetic means of the particular parameter values taken from the established roughness height (or identically pore depth) levels.

The presented methodology provides the characterization of the effective part of a porous coating – its outer layer, which is full of pores opened for penetrating bone tissue with the diameter of many macro pores surpassing 100 μm. The outer layer is related to the pore space of porous coating participating in creating a biomechanically functional bone-porous implant biological fixation. A wider investigation of implant porous coatings with use of this methodology is expected to provide information about the representative features of the coating microstructure and to characterize the most advantageous poroaccessibility of its pore space for potential bone tissue ingrowth as a major step forward into designing implant porous coatings with functionally graded pore distribution and designed poroaccessibility to be manufactured e.g. in additive technologies.

4. Future remarks

The presented methodology of characterization of implant porous coatings with use of the poroaccessibility parameters is going to be applied as a specific tool in research on designing implants porous coatings with functionally graded pore distribution and designed poroaccessibility. The current version of PoroAccess software is able to import data only from the stylus measurements. The extension of its functionality is under development, among others, to make possible importing and processing data from non-contact profilometers.

Nowadays, the best potential to manufacture implant porous coatings with designed poroaccessibility have Direct Metal Manufacturing (DMM) technologies like Selective Laser Sintering/Melting (SLS/M) or Electron Beam Melting (EBM). Hence, the next stage of this research is an investigation of the possibilities to manufacture the porous coating with designed poroaccessibility in one of DMM technologies. The porostructural properties of the porous coatings manufactured in additive laser technologies are going to be evaluated with the poroaccessibility parameters including research on the repeatability, reproducibility, measurement uncertainty of the raw surface topography data, as well as the derived

poroaccessibility parameters and comparison of the same area measured in 0° orientation and the 90° orientation.

The next step of the biostructural (porostructural-osteoconductive properties) evaluation of the manufactured porous coatings in DMM technologies together with its biological in vitro evaluation in NHOst cultures is expected to provide more information about the representative features of the microstructure of the porous coatings and allow to evaluate the most advantageous poroaccessibility of their pore spaces for potential bone tissue ingrowth to be verified on following in vivo tests on animal models. The presented approach to the evaluation of porostructural-osteoconductive properties of porous surfaces of intra-osseous implants with the poroaccessibility parameters is planned to be verified in the future with computer mictrotomography (µCT) data analysis, which could then be matched with the histological data, to be validated.

5. Acknowledgements

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