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THE POROACCESSIBILITY PARAMETERS FOR THREE-DIMENSIONAL CHARACTERIZATION OF ORTHOPAEDIC IMPLANTS POROUS COATINGS*

The ability of formation of the proper bone-porous implant fixation depends, among others, on the structural-osteoinductive properties of the porous coating covering the orthopaedic implant surface. These properties, describing the poroaccessibility of porous biomaterial, are one of co-factors conditioning the promotion of bone tissue ingrowth into pore space of implant porous coating. So far the structural-osteoinductive properties of implants porous coatings are described by the traditional two-dimensional roughness parameters obtained with contact or non-contact roughness profile measurement (mostly standard surface roughness amplitude parameters e.g.: R_a, R_q, R_{max}) or with the average pore size, which is, in the authors opinion, inadequate and unsatisfactory for porous coating characterization in respect of its poroaccessibility. The lack of proper directives on porous structure characterization of titanium and hydroxyapatite coatings on orthopaedic implants is the reason to work them out. In connection with the development of methods for surface texture analysis in three dimensions, the authors have perceived new possibilities for porous coatings microstructure analysis and on this base a set of parameters of poroaccessibility of implant porous coating for bone tissue ingrowth has been proposed: 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. With this set of parameters one can characterize the structural-osteoinductive properties of porous biomaterial. In this paper a new set of poroaccessibility parameters of implant porous coatings and a method of calculation of these parameters on the basis of three-dimensional roughness measurements are presented.

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Keywords: Surface topography, joint replacement, biologic fixation of implants, bone tissue ingrowth, porous coating poroaccessibility

1. INTRODUCTION

The problem of total hip arthroplasty reliability comprises three fundamental problems: 1) the fixation of the acetabular element to the periacetabular pelvis, 2) unfailing work of articulation elements (femoral head and acetabular socket), and 3) the fixation of femoral stem. Various mechanisms of fixation (mechanical - by press-fitting [1], with bony cement as a binding factor [2], with threaded elements [3]; biological – by adaptive ingrowth of bone tissue into the gaps of the implant texture or into the porous coating on implant surface [4]; and direct – by mechano-physico-chemical fixation of the bone and the implant layer covered with porous calcium hydroxyapatite [$Ca_{10}(PO_4)_6(OH)_2$], the mineral structure of which is similar to the inorganic part of the bone [5]) are used to customize load transfer to structural-biomechanical requirements of different regions of the bone. Loosening, unlocking, or de-bonding between implant and bone constitute some of most important mechanisms of endoprosthetic failure [6].

The fixation of particular endoprosthesis elements is generally divided into two categories, i.e.: cemented and cementless. In case of cementless implants, the factor playing an important role in this task, is the adaptive bone tissue ingrowth into porous microstructure designed for this purpose, coated on the implant substrate with various technologies e.g.: by plasma spraying [7, 8], sintering powder, fiber or beads on implant surface [9], wire mesh diffusion bonding [10], powder metallurgy [7, 11], etc. It provides the proper formation and stability of bone-porous implant fixation. The implant porous coating constitutes a microstructure built of a three-dimensional interconnected array of canalicular pores. The volumetric porosity of porous coatings is variable throughout the depth of the coating. The coating porosity is graded from highly porous surface layer usually open for penetrating bone tissue to dense and closed in contact with the implant metal substrate providing appropriate strength to sustain loading. Different types of porous coatings available for biologic ingrowth are presented in Fig. 1.

The porous implant osseointegration with bone is affected by many factors, including implant metal substrate, HA coating, surface topography, patient age, health state host-bone, surgical technique and initial implant stability [13]. According to many authors of all the investigated factors, the surface structure, biomechanical factors and biologic response have been demonstrated to have the greatest influence on implant osseointegration [14, 15]. A deeper understanding of the mechanism of bone bonding could lead to improvement in design of porous coatings, leading to enhanced performance and survival of orthopaedic implants [16]. In author's opinion, the design of endoosseous implant porous coatings should be oriented to promote the effective

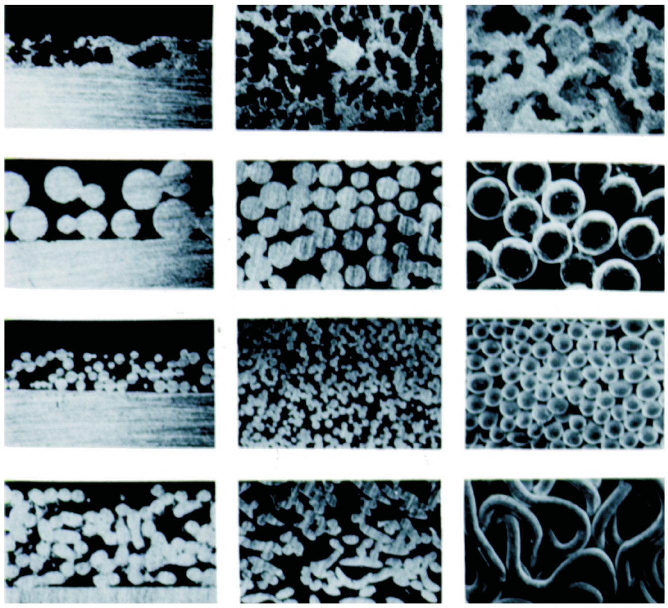

Fig. 1. Different types of porous coatings available for biologic ingrowth. From top to bottom: plasma sprayed surfaces, sintered beaded surfaces with large spheres, sintered beaded surfaces with small spheres, and diffusion-bonded fiber-metal surfaces. From left to right in each column there are presented representative cross-sections through the porous coating [12].

bone tissue ingrowth while maintaining enough biomechanical strength of bone-porous implant fixation.

So far the structural-osteoinductive properties of porous coatings are described by traditional two-dimensional roughness parameters obtained with contact or non-contact roughness profile measurement. Many researchers characterize the microstructure of a porous coating only by roughness amplitude parameter $\mathrm{R_a}$, see e.g. [17–23]. Giavaresi et al. [24] use for porous implants analysis six surface profile parameters: R_a, R_{max}, R_{Sm}, R_{ku} (kurtosis), R_{sk} (skewness) and M_{r1}. (R_{Sm} is the roughness spacing parameter measuring the mean spacing between peaks whereas R_{ku}, R_{sk}, and M_{r1} are statistical parameters describing the amplitude distribution function – for details see [25]). Other parameters like the average pore size and percent porosity of porous coatings are most often evaluated, usually with standard methods used in quantitative metallography, cf. e.g. [20, 26]). The application of the standard surface roughness parameters of amplitude: R_a, R_q, R_{max} is, in the authors opinion, inadequate and unsatisfactory for porous coating characterization in respect to its poroaccessibility.

There are still no well-defined criteria of structural-adaptive compatibility of the bone-implant fixation on the basis of the modern two-phase poroelastic biomechanical model of bone tissue and of implant coatings. For more information about the modern two-phase poroelastic biomechanical model of bone tissue introduced to the clinical orthopaedic biomechanics in Poland in 2002 and in Europe in 2004 by Rogala, Uklejewski and Styła see [27, 28, 29] (cf. also in earlier works by Uklejewski, 1992 [30], and Cowin, 1999 [31]). For more details about the problem of structural-adaptive compatibility of the bone-implant fixation stated by Uklejewski, Winiecki and Rogala on the basis of this model see [32]. This problem is also the subject of work [33] and has been presented at the 5th World Congress in Biomechanics in Munich, Germany, in July 2006 [34]). The achievement of proper stability of implants, when it depends on the efficiency of adaptive bone ingrowth into the implant porous coating, is determined by the configuration of the porous coating surface microgeometry, i.e. the osteoinductive properties of the porous coating. Therefore the identification of the parameters characterizing the microstructure of porous coatings from the point of view of formation of proper bone-implant fixation is important and necessary. Proper coating microstructure is still a matter of research, though there are a lot of types of microstructures of porous coatings on the market. In the literature on the subject it is widely accepted that optimum bone tissue ingrowth is possible in case of porous biomaterials with average pore size between 100-500 μm [35]. The quoted range of pore sizes recognized as an optimum from the point of view of the effective bone tissue ingrowth was established as a result of various postoperative observations performed on the basis of a one-phase biomechanical model of bone. This criterion of structural-adaptive compatibility described only by one quantity (i.e. pore size) should be, in our opinion, supplemented with the quantity/-ties connected with the rate of bone tissue ingrowth into pore space of implant porous coatings. In connection with the development of methods for characterization of roughness in three dimensions [36], authors have perceived new possibilities to porous coatings analysis and on the basis of this a normalization of description methods has been proposed for evaluation of the structural-osteoinductive properties of an endoosseous implant porous coating. A set of parameters describing the microgeometry of porous coatings on implants is proposed below. There is also a method of its a calculation presented, based on the analysis of three-dimensional roughness. It was also referred in part at the 11th International Conference on Metrology and Properties of Engineering Surfaces in Huddersfield, UK, in July 2007 [37] and in the 6th Seminar: "*Surface Stereometry: Measurement, Research, Applications*" in Poznan, Poland, 2006 [38].

2. THE EVALUATION OF POROACCESSIBILITY PARAMETERS

2.1. The porous coating effective pore depth

The three-dimensional topography measurements of the porous coating allow to obtain a discrete function $z = f(x, y)$. For every measured fragment of the porous coating a matrix of roughness height points can be created. Then the surface roughness mean plane $z_m = f(x, y)$ has to be estimated with the least squares method. The next step is the determination of the average pore size – $p_S = f(h)$ and the surface porosity – $\phi_S = f(h)$, both as a function of height of roughness h. The curves of the areal pores fraction and the average pore size in function of height of roughness can be presented in diagrams as presented in Fig. 2. The boundary values of average pore size p_{Smin}

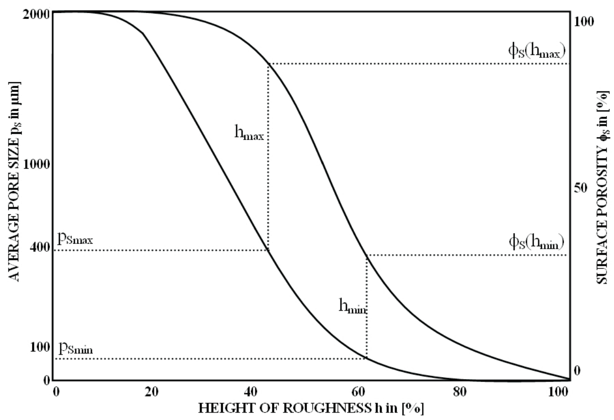

Fig. 2. The curves of the surface porosity and the average pore size in function of the roughness height.

and p_{Smax} determine the boundary levels of height of roughness h_{min} and h_{max}. The difference of the boundary levels of roughness height is assumed as the effective pore depth p_{def}. The assumption of the levels of height of roughness assigning the effective pore depth was predetermined as the levels on which the average pore size of 100 μm (p_{Smin}) and 400 μm (p_{Smax}) can be found [39]. This means that the bone tissue penetrating into this pore space is able to mineralize and create a biomechanically functional (effective) fixation between bone and implant. That is why the parameters related to pore space being filled with bone tissue are called the effective ones. This also means the effective pore depth p_{def} and defined below the effective volumetric porosity of implant porous coating are not quantities equivalent to the geometrical quantities. By the representative quantities the authors mean the quantities which are characteristic for the effective part of a porous coating being able to accommodate penetrating bone tissue. From the diagram presented in Fig. 2 there can be read e.g.: the surface porosities $\phi_S(h_{min})$ and $\phi_S(h_{max})$ corresponding to the levels of roughness height h_{min} and h_{max}.

2.2. The porous coating effective volumetric porosity

The effective volumetric porosity ϕ_{Vef} of the considered porous coating on an implant is defined as the ratio of the volume of the pore fraction in the examined fragment of porous coating to the total volume of the examined fragment of porous coating between the levels of roughness height h_{min} and h_{max}. It can be calculated from the formula:

$$\phi_{Vef} = \frac{V_P(h_{\max}) - V_P(h_{\min})}{p_{def}(M-1)\Delta x(N-1)\Delta y}, \tag{1}$$

where: V_P $(h_{max}) - V_P(h_{min})$ is the volume of the representative pore space on the examined fragment of the porous coating, M, N – the number of profiles; Δx, Δy – sampling intervals in directions x and y respectively.

2.3. The index of the porous coating space capacity

Among the standard parameters of the three-dimensional roughness, the group of functional parameters connected with the bearing and the fluid retention properties can be distinguished. To this group of parameters belong: the surface bearing index S_{bi}, the core fluid retention index S_{ci} and valley fluid retention index S_{vi} [35]. To establish a derivative parameter to effective volumetric porosity ϕ_{Vef} the authors have used the following modification of core fluid retention index S_{ci}. The value of the modified core fluid retention index S_{ci-mod} can be calculated from Eq. (2). It is the ratio of representative pore volume of the measured fragment of the porous coating to the root mean square deviation of the investigated topographic surface:

$$S_{ci-\text{ mod}} = \frac{\frac{V_P(h_{\max})-V_P(h_{\min})}{(M-1)\Delta x(N-1)\Delta y}}{S_q}, \tag{2}$$

where: S_q is the root-mean-square deviation of the roughness surface from its mean plane. The comparison of the Eqs. (1) and (2) allows separating the common part which can be named the index of the porous coating space capacity. The index of the porous coating space capacity V_{PM} [mm^3/cm^2] is a quantity that lets to specify the volume of the penetrating medium (e.g. the ingrowing bone tissue) which is able to fill the pore space on the investigated surface of the implant porous coating. It can be calculated from the formula:

$$V_{PM} = \frac{V_P(h_{\max}) - V_P(h_{\min})}{(M-1)\Delta x(N-1)\Delta y}. \tag{3}$$

2.4. The porous coating surface porosity

The surface porosity $\phi_S(h)$ corresponding with the particular roughness height level is defined as the ratio of the area of the pore fraction in the examined fragment of the porous coating to the total area of the examined fragment of porous coating. It can be calculated from the formula:

$$\phi_S(h) = \frac{\sum_{j=1}^{N-1}\sum_{i=1}^{M-1} P_{ij}}{(M-1)\Delta x(N-1)\Delta y}, \tag{4}$$

where: $P_{ij} = \Delta x \Delta y$ is the area of an infinitesimal element of the examined fragment of porous coating interpreted as a pore ($i = 1, 2, \ldots, M-1$; $j = 1, 2, \ldots, N-1$). As the representative surface porosity ϕ_{Srep} it is proposed to take the arithmetic mean of the surface porosities taken from the established roughness height levels, e.g.:

$$\phi_{Srep} = [\phi_S(h_{0,25}) + \phi_S(h_{0,5}) + \phi_S(h_{0,75})]/3, \tag{5}$$

where: $h_{0,25} = 0,25p_{def}$, $h_{0,5} = 0,5p_{def}$ and $h_{0,75} = 0,75p_{def}$.

2.5. The average pore size of a porous coating

The average pore size $p_S(h)$ corresponding with a particular roughness level can be calculated from the formula:

$$p_S = \frac{1}{2}\left(\frac{L_x(h)\Delta x}{NoP_x} + \frac{L_y(h)\Delta y}{NoP_y}\right), \tag{6}$$

where: $L_x(h)$ and $L_y(h)$ are the lengths of the linear elements of the particular roughness profile interpreted as a pore in x and y directions respectively; NoP_x, NoP_y – the number of pores counted in x and y direction respectively. As the representative pore size p_{Srep} there is proposed the arithmetic mean of the average pore sizes taken from the established roughness height levels, e.g.:

$$p_{Srep} = [p_S(h_{0,25}) + p_S(h_{0,5}) + p_S(h_{0,75})]/3. \tag{7}$$

2.6. The representative angle of poroaccessibility in a porous coating

The quantity of the representative angle of poroaccessibility Ω_{rep} is also proposed to be taken as the arithmetic mean of the poroaccessibility angles $\Omega_r(h)$ taken from the established roughness height levels, e.g.:

$$\Omega_{\mathrm{rep}} = [\Omega(h_{0,25}) + \Omega(h_{0,5}) + \Omega(h_{0,75})]/3. \tag{8}$$

The angles $\Omega(\mathrm{h}_{0,25})$, $\Omega(\mathrm{h}_{0,5})$, \$$Omega(\mathrm{h}_{0,75})$ are the arithmetic means of the individual angles Ω_i. Ω_i is the angle between the tangent to element of lateral pore surface $z(x, y)$, lying on the intersection of the porous surface with the reference plane $z_r(x, y)$, and this reference plane (see Fig. 3). The reference planes lie in the established pore depth and are parallel to the surface mean plane $z_m(x, y)$ estimated with the method of least squares. The tangent to the lateral pore surface element in point $P(x, y)$ is plotted in the direction of maximum inclination of the lateral pore surface i.e. in the direction shown by the gradient vector **g**. The method of estimation of the individual angle of poroaccessibility Ω_i of a porous coating is presented in Fig. 3.

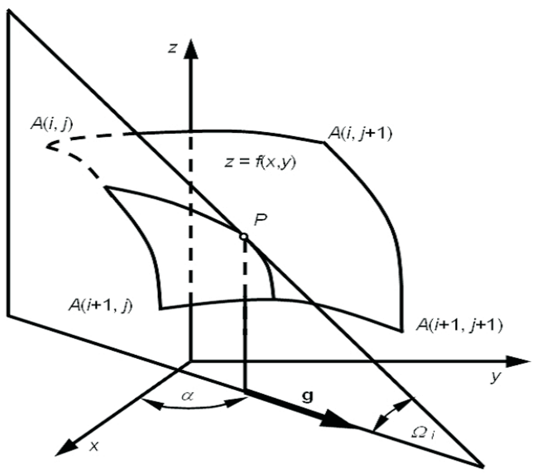

Fig. 3. The sketch illustrating the individual angle Ω_i estimation; **g** – the gradient vector.

The value of the individual angle of poroaccessibility Ω_i is estimated from the formula:

$$\Omega_i = arctg(\sqrt{p_x^2 + p_y^2}), \tag{9}$$

where: $p_x = \Delta z/\Delta x$ and $p_y = \Delta z/\Delta y$ can be computed from the Eqs. (10) and (11):

$$p_x = \frac{A\,(i+1, j+1) - A\,(i, j+1)}{2\Delta x} + \frac{A\,(i+1, j) - A\,(i, j)}{2\Delta x}, \tag{10}$$

$$p_y = \frac{A\,(i+1, j+1) - A\,(i+1, j)}{2\Delta y} + \frac{A\,(i, j+1) - A\,(i, j)}{2\Delta y}. \tag{11}$$

The presented procedure of estimation of the individual angles Ω_i was inspired by the method of estimation of surface anisotropy presented by Wieczorowski, Cellary and Chajda in [40].

2.7. The adhesive surface enlargement index

Roughening of the implant surface with porous coating increases the interface area with bone tissue which permits the transmission of various kinds of mechanical loads and increases the resistance to shear forces. It also produces resistance to relative motion between bone and implant, what improves conditions of adaptive bone tissue ingrowth. Roughening of the implant surface also causes an augmentation of the adhesive properties of the implant surface [10]. The enlargement of the adhesive surface improves biomechanical conditions for load-carrying conditions between the implant and ingrowing bone tissue and substantially improves conditions of creeping substitution - the manner of penetration of bone remodelling process [24, 27, 28]. The mathematical evaluation of the adhesive poroaccessibility of bone-implant interface is possible by means of the index of the enlargement of the adhesive surface of bone-implant interface , which can be calculated from the following formula:

$$1 < \psi = \frac{\sum\limits_{j=1}^{N-1} \sum\limits_{i=1}^{M-1} A_{ij}}{(M-1)\Delta x(N-1)\Delta y}, \tag{12}$$

where: A_{ij} ($i = 1, 2, \ldots, M-1$; $j = 1, 2, \ldots, N-1$) is the area of the infinitesimal element of lateral pore surface $z(x, y)$ approximately calculated with the formula:

$$A_{ij} = 1/4\left(\sqrt{\Delta y^2 + (A(i,j) - A(i,j+1))^2} + \sqrt{\Delta y^2 + (A(i+1,j+1), -A(i+1,j)^2}\right)\times .$$
$$\times\left(\sqrt{\Delta x^2 + (A(i,j) - A(i+1,j))^2} + \sqrt{\Delta x^2 + (A(i,j+1), -A(i+1,j+1)^2}\right) \tag{13}$$

The adhesive surface enlargement index ψ indicates the improvement of implant adhesive properties by roughening its surface with porous coating in comparison with a smooth implant.

3. SUMMARY

The stability of porous implants is determined among others by the microgeometry of the porous surface. The structural-adaptive compatibility of bone-implant fixation considered on the basis of the modern two-phase poroelastic model of bone tissue describes the compatibility of porous coating microtexture with the microstructure of the remodeling bone tissue and of the mineralized bone tissue. Every porous biomaterial possessing the poroaccessibility parameters compatible with the microstructure of the remodeling bone tissue and the mineralized bone tissue can be called a structural-osteoinductive biomaterial. The compatibility of appropriate parameters of the microgeometry of an implant porous coating with the overall dimensions of remodeling bone tissue unit warrants the presence of suitable conditions for fully mineralized new bone formation in the pore space of the implant coating. This ensures the formation of the proper bone-porous implant fixation [32, 33, 36].

The proposed set of implant porous coating poroaccessibility parameters for bone tissue ingrowth is: 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 can be applied to the biostructural evaluation of the porous coated orthopaedic implants. It makes the characterization of porous coated implants from the point of view of their poroaccessibility possible, i.e. 1) the ability to induce adaptive bone tissue ingrowth and 2) the capability to accommodate the penetrating bone tissue into pores of the porous coating following the proper bone-porous implant fixation formation. In the authors opinion the analysis of structural-adaptive compatibility of bone tissue and porous coatings on the implant might require additional knowledge for increasing artificial joint reliability and extension of its vitality. The analysis of the various porous coatings connected with *in vivo* observation of bone tissue ingrowth planned in the future may also allow to optimize the processing parameters in order to obtain porous coatings that meet the requirements of structural-adaptive compatibility of bone implant fixation.

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