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EXPERIMENTAL INVESTIGATIONS OF THE INFLUENCE OF THE MICROGEOMETRICAL CONSTRUCTIONAL PROPERTIES OF POROUS ENDOOSSEOUS IMPLANTS ON THE STRENGTH OF THE BONE-IMPLANT MODEL FIXATION

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ABSTRACT: In this paper authors deal with the problem of the examination of ultimate shear strength of bone-porous implant fixation. There is presented the experimental verification of influence of the implant porous coating microgeometric properties on the bone-implant fixation shear strength with use of substitute model of the fixation. The microgeometric properties of implant porous coating are described with the set of original parameters of implant porous coatings poroaccessibility: the effective volumetric porosity ϕ_{Vef}, the index of the porous coating space capacity V_{PM}, the effective pore depth p_{def}, the representative surface porosity ϕ_{Srep}, the representative pore size p_{Srep}, the representative angle of the poroaccessibility Ω_{rep}, the index of the enlargement of the adhesive surface of bone-implant interface ψ, presented by authors in previous papers [6, 12, 13, 15, 16]. On the basis of the results of the preliminary experimental investigations performed on the porous implant-bone substitute model with push out tests the most significant influence of the representative surface porosity ϕ_{Srep} on the ultimate shear strength of bone-porous implant fixation has been demonstrated. Authors also propose the formula for evaluating the interfacial shear stress in bone-porous implant fixation.

KEY WORDS: porous implant-bone fixation, structural-biomechanical compatibility in bone-implant interface

1. INTRODUCTION

The microstructure of porous coating is the one of biomechanical factors having the biggest influence on the strength (the ultimate mechanical strength and the fatigue strength) of porous bone-implant fixation [5]). In seventies of 20th century Weish et al. (1971, [14]) and Robertson et al. (1976 [10]) found the correlation between the augmentation of fixation strength and the pore size increase. Clemow et al. (1981, [2]) show the fixation stability weakens with the growth of the pore size from 175 to 325 μm. Pilliar (1987, [9]) comparing the implants samples with sintered bead porous coatings and diffusion bonded wire mesh porous coating suggests, that the flexibility (deformability) of wire mesh porous coating generates lower mechanical stress in porous implant-bone fixation. Noble et al. (1997, [7]) found the plasma sprayed porous coatings having the higher fatigue strength than sintered bead porous coatings and fiber-metal porous coating. Søballe et al. (1993, [11]) performed a comprehensive study on bone tissue ingrowth into the composite biomaterial coated with hydroxyapatite ceramics. He compared the bone integration with metallic and ceramic coating and he proved, that the smoother ceramic coating with smaller pores and smaller contact surface between the bone and the implant has the ultimate shear strength (obtained from push-out tests) similar to implants with metallic coating, which have more rough topography. It results from the fact, the bone-implant fixation in metallic porous implants is a mainly mechanical fixation. However, in porous hydroxyapatite ceramic the fixation has mechano-physico-chemical character, which is conditioned also by other factors, e.g.: calcium phosphate coating quality i.e. its chemical composition, purity, trace elements content, Ca/P ratio, crystallinity, solubility, density, porosity, etc) [8]. Friedman et al. (1996, [3]) comparing results of push-out tests performed on implants with various porous coatings have demonstrated differences of the ultimate shear strength for particular coatings types, see Fig. 1.

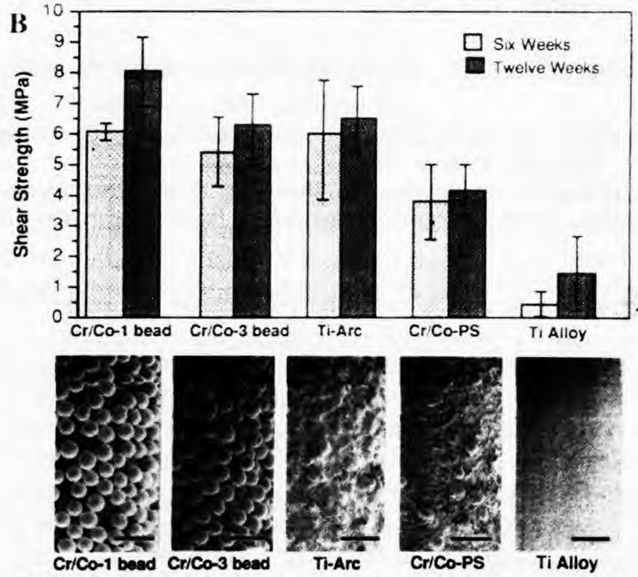

Fig. 1: Shear strength of the implants with various porous coatings at 6 and 12 weeks and SEM of the porous coatings. Bar denotes SD of mean. Cr/Co-1 = one layer of cobalt-chromium beads, Cr/Co-3 = 3 layers of cobalt chromium beads, Ti-Arc = arc-deposited titanium, Cr/Co-PS = plasma sprayed cobalt chromium, Ti alloy = grit blasted titanium alloy – no porous coating [3]

Since there were no well-defined method of porous coating structure characterization from the point of view of the biomaterial structural-osteoinductive properties (the present criterion of structural-biomechanical compatibility of bone-porous implant is still described only by one quantity, i.e. pore size) authors have proposed, on the basis of the two-phase poroelastic biomechanical model of bone tissue and theory of porous materials, the set of original parameters of implant porous coating poroaccessibility for bone tissue ingrowth. The set incorporates the 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 index of the enlargement of the adhesive surface of bone-implant interface ψ. The new poroparameters and the original method of its calculation based on the analysis of areal roughness with contact profile measurement gauge were presented in [6, 12, 13, 15, 16]. With the new parameters set characterizing the porous coating structural-osteoinductive properties there can be analyzed the influence of the porous coating microstructure for strength of bone-porous implant fixation.

2. EXAMINATION OF THE INFLUENCE OF THE POROUS COATING MICROGEOMETRY ON THE SHEAR STRENGTH OF THE BONE-IMPLANT FIXATION

To demonstrate the influence of the porous coating microgeometry on the porous implant-bone fixation shear strength the bone substitute-porous implant model fixations were put into the pushout test. Implant push out test is usually applied to periodical evaluation of the bone tissue ingrowth effectiveness during pre-clinical test of biomaterials. During the experiment the cylindrical implants are put into the osseous system of sheep, goat, dog or rabbit and left in organism for some time. After specified time bonė is removed from animal to *in vitro* tests. For more about push out test seep in [5].

The implant samples for the pushout tests were manufactured in Institute of Precision Mechanics (Warsaw, Poland) on arc device OSU Machinenbau LD/V2 with closed spraying system. Implants for tests ware covered with porous coating made by stainless steel arc-deposition on stainless steel cylindrical shafts 4 cm long and 16 mm in diameter. There were obtained five variants (W1-W5) of porous coating differed from each other in S_a and S_q surface roughness parameters as specified in Tab. 1. The diversification of the roughness parameters was obtained by change of spraying air pressure from 0,01 to 0,45 MPa (the wire feeding pressure – 0,6 MPa, distance of spraying – ±200 mm, wire – stainless steel, ∅ = 1,6 mm, brass plated, current voltage – 23V, current intensity – 100÷150 A).

In the described below pushout tests bone tissue was replaced with substitute material. Epoxy resin (SpeciFix-20, Struers) was chosen as bone tissue substitute. The epoxy resin is widely used in biomechanics substitute material for cortical bone [1]. It was also chosen because of its very good penetration capability, which allowed to get accurate pore space filling with the penetrating material. The model implant was put coaxially in the mould in form of cylinder with diameter fitting to hole in the support jig and clamped. The resin was mixed in volumetric proportions 5:1 with hardener (mixing time – about 3 minutes) and left for 2 minutes to remove intrinsic air bubbles. After that the moulds were filled with resin and left in 20°C for 24 hours (**Fig. 2**). Before the model fixations preparation all cylindrical implant samples have been measured to evaluate the poroaccessibility parameters.

Tab.1: Mean values of the S_a and S_q surface roughness parameters

Sample / Parameter	W1	W2	W3	W4	W5
S_a [μm]	12±1	14±1	16±1	18±1	20±2
S_q [μm]	15±1	17±1	21±1	22±2	26±2

The model fixation of porous implant-bone substitute prepared this way was put into the push out tests. The pushout test were realized on the Universal Testing Machine (TIRAtest 24250, Germany). The criteria of the particular test termination was relative decrease (at least 20%) of the push force corresponding to permanent destruction of the fixation.

Fig. 2: The porous implant-bone substitute model fixation preparation for later push out tests

The force was applied with a constant displacement speed 1.0 mm/min to implant by mandrel clamped in testing machine support jig (Fig. 3). The resulting forces and displacement between implant and bone substitute were registered. The peak force load-displacement curve was considered as the pushout force and it was the force at which the implant started move in the surrounding bone substitute. Since from a theoretical standpoint this was the shear force, subsequently and interface shear strength was calculated with formula:

$$\sigma_u = \frac{F_u}{A}, \tag{1}$$

where: σ_u is the interface shear strength, F_u is the ultimate load and A is the area of the implant being in contact with bone surface.

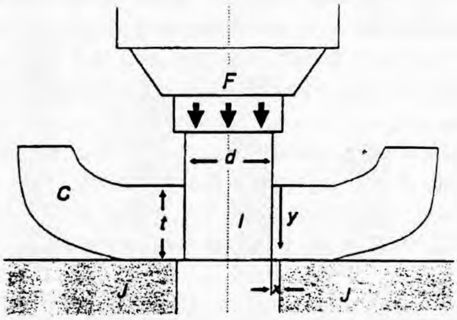

Fig. 3. Schematic drawing of the pushout test. F = force applied on implant; C = cortical bone; J = support jig; y = position along interface; t = cortical thickness; d = implant diameter; x = clearance of hole in support jig [5]

Mean values of the poroaccessibility parameters are presented in Tab. 2. Mean values of the ultimate shear stress received from pushout tests are presented in Tab. 3.

Tab.2: Mean values of the poroaccessibility parameters

Parameter \ Sample	W1	W2	W3	W4	W5
ϕ_{Vef} [%]	20,1±0,6	17,9±0,7	15,8±0,2	15,3±0,3	14,4±0,2
V_{PM} [mm3/cm2]	$3{,}3\pm0{,}2\cdot10^{-2}$	$3{,}6\pm0{,}4\cdot10^{-2}$	$3{,}9\pm0{,}3\cdot10^{-2}$	$4{,}0\pm0{,}4\cdot10^{-2}$	$5{,}0\pm0{,}6\cdot10^{-2}$
p_{def} [mm]	17±1	20±2	22±2	26±3	35±2
ϕ_{Srep} [%]	36±2	40±1	43±2	44±2	48±1
p_{Srep} [μm]	222±18	198±32	202±15	199±16	190±11
Ω_{rep} [°]	31±1	32±1	33±1	31±1	33±1
ψ	1,54±0,04	1,52±0,02	1,53±0,08	1,62±0,06	1,59±0,02

Tab. 3: Mean values of the ultimate shear stress received from pushout tests

Parameter \ Sample	W1	W2	W3	W4	W5
σ_u [MPa]	35,7±0,9	39,8±0,9	37,3±0,8	41,2±0,9	40,0±0,5

In Fig. 4 there is presented diagram with mean values of the poroaccessibility parameters from Tab. 2 put together with the S_a and S_q surface roughness parameters from Tab. 1, for all samples with porous coating variants W1-W5. As it can be seen on the diagram the values of the representative surface porosity ϕ_{Srep}, the effective pore size p_{def}, and the index of the porous coating space capacity V_{PM} shows the same increasing tendency as the surface roughness parameters S_a and S_q. Revaluation of the representative pore size p_{Srep}, the representative angle of poroaccessibility Ω_{rep} and the index of the enlargement of the adhesive surface of bone-implant interface is insignificant. It was found the decrease of the effective volumetric porosity ϕ_{Vef}. In connection with these facts there was analyzed the relationship between the porous implant-bone substitute fixation ultimate shear stress and the parameters demonstrating distinctly increasing tendency (at least 30% increase of the maximum value relatively to minimum). Fig 5 presents the dependence of the ultimate shear stress received from pushout tests of porous implant-bone substitute model fixation on the representative surface porosity ϕ_{Srep}.

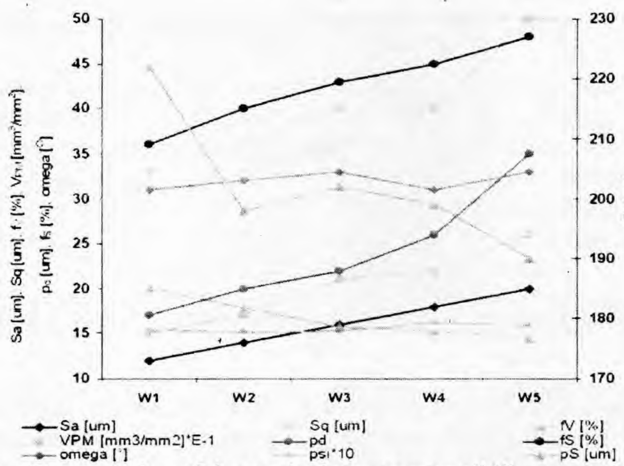

Fig. 4: The diagram of interrelation of the particular poroaccessibility parameters of implant porous coating with S_a and S_q surface roughness parameters. $f_{Vef} = \phi_{Vef}$, $f_{Srep} = \phi_{Srep}$, $W_{rep} = \Omega_{rep}$, $psi = \psi$

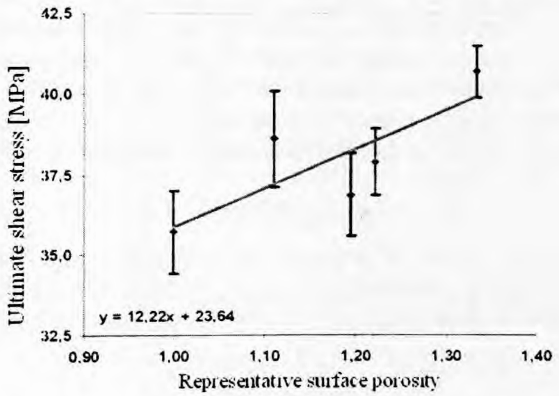

Fig. 5: The model fixation ultimate shear stress in function of the representative surface porosity ϕ_{Srep} presented in relative units

The values of the relative units was received by division of the adequate poroaccessibility parameters of particular porous coating types W1-W5 by adequate the parameters of W1 type of porous coating. On the basis of the received results than can be observed an increase of the ultimate shear strength σ_u in porous implant-bone substitute fixation in function of the representative surface porosity ϕ_{Srep}. The representative surface porosity ϕ_{Srep} of bone porous coating appears to be the most influencing parameter for ultimate shear stress of bone-porous implant fixation. The influence of other parameters (p_{def}, V_{PM}) on the strength of the bone-porous implant fixation have been also observed (in adequatly lower proportions – 60% i 30%, see [16] – because of the limited paper content we do not present this results).

3. THE INTERFACIAL SHEAR STRESS IN POROUS BONE-IMPLANT FIXATION

The porous implant-bone substitute model fixation was destroyed during the pushout test by shear of the bone filling the pore as there is shown on geometrical model in Fig 6. Sum of all pores area on fracture face gives the effective shear section in considered fixation. The ratio of the effective shear section area to fracture face area of implant is the representative surface porosity of the porous implant.

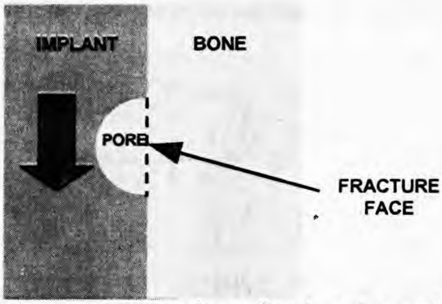

Fig. 6: The geometrical model of porous implant-bone fixation. A pore is in the shape of a half sphere.

According to the geometrical model presented in Fig. 6 and referring to the results of the pushout test performed on the porous implant-bone substitute model fixation authors propose the formula for evaluating the interfacial shear stress τ_i in bone-porous implant fixation:

$$\tau_i = \phi_{Srep} \tau_b , \qquad (2)$$

where: τ_b is the shear strength of the surrounding mineralized bone. The confirmation of the validity of the proposed formula (2) can be given on the basis of the model presented by Hansson and Norton in [4]. In this model there were introduced the following factors characterizing the porous surface of implant: f_{pe} – pit (pore) effectivity factor, connected with pore shape size; $0 < f_{pe} < 1$, and f_{pd} – pit (pore) density factor, connected with density of pore spacing; $0 < f_{pd} < 1$. These factors are taken into account in Hansson's theoretical formula for evaluation of interfacial shear stress in porous implant-bone fixation:

$$\tau_i = f_{pe} f_{pd} \tau_b . \qquad (3)$$

The formula (3) is right in porous implant structure built with regularly arranged pores of uniform shape and uniform size. It can be generalized to cover the case with different kinds of pores on the implant surface with different pore effectivity factors f_{pe}, and arranged with different pore density factors f_{pd}:

$$\tau_i = \tau_b \sum_j (f_{pej} f_{pdj}) . \qquad (4)$$

In case of the implant porous coating manufactured for example by plasma spraying the evaluating of the interfacial shear stress with formula (4) is impossible. The difficulty is in measurement of all pores sizes and measurement of all distances between the pores. The formula (2) haven't got this kind of deficiency.

4. CONCLUSIONS

The result of the experimental investigations of the influence of the implant porous coating microgemetrical properties on the interfacial shear strength of the bone-implant model fixation presents the representative surface porosity ϕ_{Srep} as the most influencing factor. This justifies the possibility of the preliminary evaluation of the interfacial shear stress in porous implant-bone fixation with the proposed formula (2). The fact of the other poroaccessibility parameters (p_{def}, V_{PM}) influence on the shear stress in the considered fixation indicates, in the authors opinion, the necessity of further research on the bone-porous implant fixation strength on the basis of the mechanics of porous media.

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