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ABOUT FAILURE UNCEMENTED HIP REPLACEMENTS FROM FRACTURE STEM PROSTHESIS

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ABSTRACT

This research refers to a prosthesis made of CoCr with porous area "Madrepore macro", recovered during a revision surgical intervention due to femoral stem's fracture. Such a fracture appears to prosthesis distally well fixed, but proximally mobile, leading to fracture through stem's middle or proximal third. In the case of this prosthesis, object of the present study, the goal is to find the cause leading to the implant's failure. The macroscopic observations showed that the stem's fracture occurred on a transversal plan, proximally close to the distal area of the porous zone, due to bending efforts, not preceded by a plastic strain. Based upon microscopic observations, this research shows that this process manifested itself as a fragile fracture with highlight on a pronounced trans-crystallization.

In the fracture area and in its adjacency there were detected conspicuous oxidation aspects (corrosion). Therewith, during microscopic observation performed on both pieces (the femoral head being assembled through a shrinking-on process on the flange femoral stem) it was detected that they have the same type of microstructure, made of a solid solution δ, and a relatively coarse compounds network, wich represents the structure as it was casted. In the stem's marginal area as well as middle area, numerous casting defects were identified, like microporosities and microfissures. These defects communicated with the stem's exterior, and after the implant, they allowed body's organic components diffusion, which leaded to tribocorrosion. The present research highlights also the existence of a major casting defect around the tiredness efforts' action area, a defect that facilitated the stem's fracture.

KEYWORDS: uncementless hip prosthesis, stem stability, porous implant surfaces, breakage.

INTRODUCTION

Bone tissue ingrowth within the open porous microstructure leads to improvement of the transfer forces, avoiding at the same time stress concentrations, by producing a permanent secondary contact. One of the main parameters of the implant's surface is to establish the optimal pores dimension to facilitate bone growth. From a historical point of view, French researchers started by producing structures similar to cancelleous bone by means of a coarse structure made of a CoCrMo alloy. For example, the Judet prosthesis, with "porometal" (porous metal) surface, as well as many other models so-called "mandrapore" surfaces (coarse surfaces, with only one layer) produced through balls (coating), like in the case of Lord prosthesis.

Subsequently, these ideas were developed in Germanic countries and USA by replacing the unique layer with a multilayer structure, with open pores – an interconnected porous structure. For example, the LUBECK hip prosthesis surfaces made of spongy metal (spongy metal) and "mini-mandrapores" structures (resembling corals), retrievable in PCA prosthesis (Tab.1, Fig.1) [1].

As the use grew, microporous coating surfaces was also taken into account. In comparison with coarse porous surfaces and those resembling corals, for this prosthesis, it can be reached a growing rate of the contact surface of the bone several times higher. Casting processes, possible only for coarse structures and cobalt alloys, must face the comparison with the sintering processes which can be used for cobalt alloys as well as for titanium alloys.

New achievements (executions, performances) were obtained applying metal fibers and Ti balls on stems made of wrought titanium alloy, with the help of diffusion contacts. Moreover, prosthesis models with porous surfaces obtained through plasma and powder blasting were also tested.

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Table.1. Implants' porous metal surfaces [1].

Porous covering (coating)	Material	Deposit technique	Pores' size	Porosity
1. a "Porometal" (porous metal)	Cast CoCr	Adhesion of spongy material on a wax model	0,5 ÷ 1,5 mm	> 50 ÷75%
b." Spongy Metal"	Cast CoCr	Adhesion of plastic balls on a wax model	400 ÷ 500 μm (ball diameter approx. 1,5 mm)	> 35 ÷50%
2. "Madrepore" macro (coarse , one layer)	Cast CoCr	Metal balls sintered in a mould	200 ÷ 300 μm (ball diameter approx. 0,8 mm)	approx. 35%
- "Madrepore" mini (fine, multilayer)				
4. "Madrepore" mini/micro (one layer /multilayer)	Ti	Metal ball sintering on raw wrought stems	200 ÷ 300 μm (ball diameter approx. 0,8 mm)	approx. 35%
5. "Metal fibres"	Ti	Contact through diffusion of wrought alloy fibres	400 μm (ball diameter approx. 0,5 mm)	50%
6. "Plasmapore"	Ti	Deposits through plasma atomization of Ti powder on Ti wrought alloy	20 ÷ 200 μm	25 ÷ 50%

Microporous implant surfaces with active transfer processes are carried through plasma coating (for endoprosthesis). Pores' sizes afferent to the structures mentioned above enter the range of approximately 400 μm to 1.5 mm for macroporous surfaces with a porosity higher than 50%, between 200 and 400 μm for microporous surfaces and between 20 ÷ 200 μm for microporous surfaces with a porosity between 25 and 50%.

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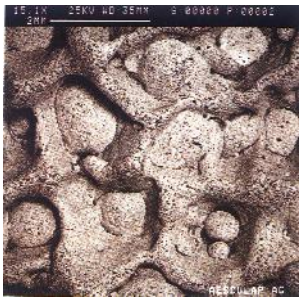
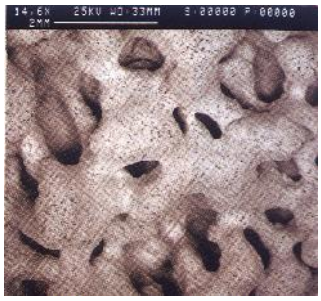
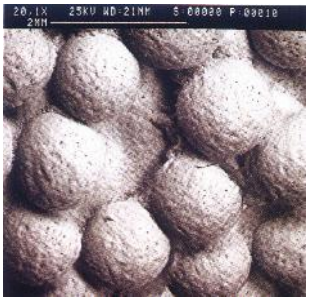
Fig.1. Images obtained through microscopy with electronic scan of certain porous metal coatings [1].



a. Porous metal



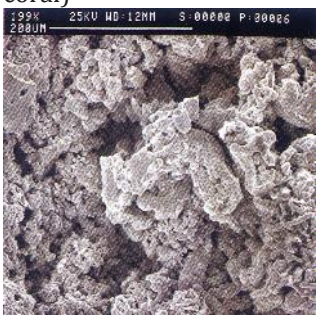
b. Spongy metal



c. Madrepore macro (resembling coral)

d. Madrepore mini (resembling coral)

e. Metal fibres coating (armour)



f. Plasmapore

High expectations are expected from material engineering for porous coating of metal prosthesis. On one side, the coating material must be compatible and stable within the organism. Because of the surface growth, the corrosive products quantity, which toxic reaction may inhibit the formation of new bone, may increase. On other side, coating layers must adhere so well on the prosthesis body and it must be that stable so that it will not shatter and the particles will not detach themselves during press or after the contact with the bone. Mechanical characteristics of the prosthesis components under effort must not be significantly affected by the coating method. A peculiar importance has also the resistance to weariness.

When applying the porous coating one must take into account both medical aspect and technical aspect. The necessary profile must be elaborated based upon clinical experiments as well as tests made on animals. The success of the uncemented prosthesis models depends particularly on the bone / implant interface's capacity to bear mechanic efforts.

If we follow the experiments on animals done in USA and in other countries starting with 1970, it results the necessity to take into account pores' size, porosity, bone growth kinetics, micro and macro movements and the contact resistance after a certain period, based upon histologic examinations and shearing stress measurements.

Hulbert experiments s.a., [2], performed on porous ceramic material made of calcium alumina with a pores' size varying between 11 μm and 200 μm, showed that:

- There is a significant growth of the binding tissue only in the pores that have a dimension between 44 μm and 75 μm;
- The vascularization starts in the pores whose dimensions vary between 75 μm and 100 μm with un-mineralized bone formation within concentric lamella and with tissue calcification at the surface;
- Infiltration with mineralized bone starts in the pores having between 100 and 150 μm;
- Osteon formation takes place in the pores having between 150 and 200 μm.

Hence, the conclusion that the minimum pore size to have a significant growth of the natural bone is approximately 70-100 μm.

These results are in accordance to those obtained by Klawitter s.a., [3], while using polyethylene with high molecular density, porous. He drew the conclusion that pores that have 40 μm allow the

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bone to grow, but the optimum growth speed is obtained when the size of the pores is between 100 and 135 μm, even trough for larger pores there is no significant growth acceleration. Cameron s.a., [4] reached the same conclusion. According to their experiments, where they employed screws with balls coated with CoCr, apparently, the stabilization speed of implants with porous coverage and pores size up to 100 μm is similar to those whose size is larger than 100 μm.

There are few data in the specialized literature that rely on appropriate experiments referring to optimum porosity, particularly referring to the fact that pores' size and porosity are not independent one from another. According to Hahn and Palich [5], there is an ideal value, 20-40%, which allows the osteoblasts to grow. Below 20%, there is neither direct growth, nor blood circulation. Above 60%, the pores' growth becomes incomplete (Galante s.a. [6]).

Most authors accept the pores size as being higher than 200 μm. They investigated a large variety of materials (porous polyethylene, calcium aluminate, stainless steel, titanium, Ti fibers network). For example, Predecki's s.a. very detailed work, [9], tackles the kinetics of bone growth within deep cylindrical channels produced in ceramic materials with alumina and in titanium. Authors reached the conclusion that:

- Tissue calcification can be observed in channels with 95 μm diameter;
- A significant growth of bone tissue, with continuous growing process – for a long period of time– can be registered starting with 195 μm diameter.

Particularly it was demonstrated that:

- deep bone penetration takes place far more rapidly during the first 4 weeks for channels with 400 μm diameter than for those with diameters smaller than 400 μm, but
- the larger the channel's diameter, the less complete will be the filling
- growth speed decreases significantly after 8 weeks within the channels with diameters of 500 μm to 1000 μm. Many of these types of implants, after these 8 weeks, lost their bondage.
- on the other hand, bone growth was evidently accelerated after 8 or even 18 months in the case of implants with channels whose diameters decreased from 400 μm to 195 μm.

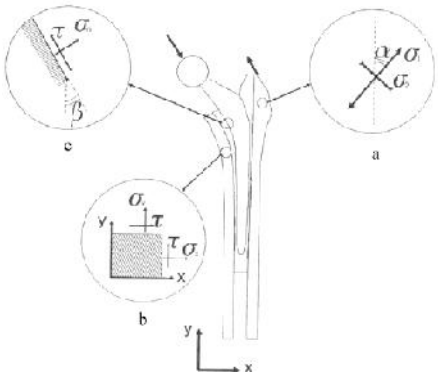
Consequently, growth behavior in the case of pores smaller than 400 μm should be evaluated as being more favorable considering the fast, permanent contacts. Because of the results' highly variance, authors reached the conclusion that the movements at the implant – bone interface have a negative effect over the contacts' growth and certain roughness is needed in order to ensure the primary implant stability. During their experiments, a minimum roughness R_a was determined of approximately 6.5 μm. This roughness corresponds to the top-bottom height R_t of approximately 20 μm for a sandblasted surface.

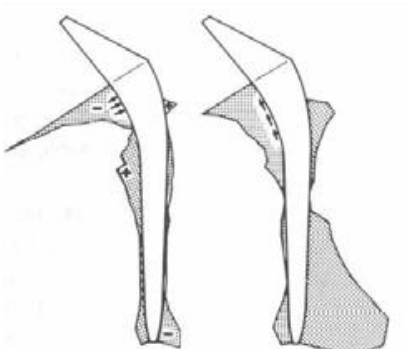
Cameron s.a., [4] and Pillar s.a., [10] verified the fact that new bone formation may appear during micro-movements that have a maximum value of 28 μm. For example, contrarily to such phenomenon only binding tissue can form itself during macro-movements of about 150 μm. In this sense, large interstitial *spaces* between implant and bone need extensive movements. For example, Harris' s.a. [11] experiment made on a pelvis model, determined that an interstitial space of 0.5 mm is already too large to ensure the implant's fixation into the bone. The importance of primary stability and of the surfaces in direct contact is also confirmed by the experiences related to fractures' healing. Damaging influence of the local interstitial spaces formation between implant and surrounding bone must be avoided by using the appropriate implant model, instruments used during implant and a very attentive operating technique. If the porous coating is in direct contact with the bone, it is highly expectable to have a firm anchorage of the implant after approximately 3 weeks and to reach the maximum critical shear stress of the area between the implant and tissue after 4 weeks. According to Heck [12], considering his animal experiments, when decreasing the stress that the implant is subject to, for 3 weeks in row, a positive effect on improvement of the biomechanical performances of the implants with porous coatings is registred, in comparison with the situation when implants are subject to maximum stress.

Looking at the measurements of the critical shear stress within dogs' cortex layer, on samples with mandreporous surfaces consisting of CoCr balls with groups of pores A: between 20-50 μm, B: between 50-200 μm, C: between 200-400 μm and D: between 400-800 μm, as they were carried out by Bobyn s.a. [13], they might lead to a maximum critical shear stress of 17 N/mm^2. Groups of pores between 50-200 μm as well as those between 200-400 μm register the fastest implant stabilization. Authors explain this fast stabilization through the plurality of the bone's contact points existing in the groups of pores A and B.

Stresses status of the prosthesis stem is dully described by six stress components. As a whole, the stress status is known as stress tensor. Even though

components may vary according to the chosen specific references system, stress status remains the same. In other words, stress status along an object does not depend on the chosen references system (for example observer). It depends only on the load, geometry and features of the material. The simplest way to represent stress status is within the main references system and through three main stress components of normal stress. Structures bone/prosthesis often require information related to the "interface" loadings, where different materials are connected. These interfaces do not always align with the references external system, and generally, they do not align with the main directions of the loadings [14]. To reach this goal, the local system of coordinates at the interest points may be relatively introduced. Relate to it the normal interface and shear stresses are expressed. The three methods to represent the loading (coordinates, main efforts, and interface) are illustrated in Figure 2 (A), for a bi-dimensional example, where (a) main stress (σ_1, σ_2) in main direction α, relative to *x-y* coordinates system; (b) stress components (σ_x, σ_y and τ) within *x-y* coordinates system; (c) stress components (σ_n and τ) normal and parallel to a chosen surface, for example an interface at a β orientation towards *y* axis. The distribution of tension, compression and shearing stresses at the interface stem/cement for a THA cemented stem, simulated though a FE model, is illustrated in Fig. 2 (B) [15].





(A) (B)

Fig. 2. (A) The illustration of three representation of the stress status and (B) the distribution of tension, compression and shearing stress at the interface stem/bone for a THA stem, simulated through a FE model. Left: normal efforts at the interface (tension/compression); Right: shearing efforts [15].

Maximum stress (elastic limit) of a material is usually measured through uniaxial compression and tension tests or through shear test made on samples of material with simple geometries. The arising question is how to relate a stress status calculated in 2D or 3D, characterized through six components, to those resulted from the uniaxial tests in order to obtain an estimation of the failure probabilities. To reach such a goal, it is necessary to calculate an equivalent stress (or an effective stress) by using a particular resistance criterion.

For example the von Mises resistence criterion assumes that the material will fail (plastic deformation) when distortion energy will rise for a certain value. Von Mises stress can be calculated from the equation:

$$\sigma_m = \left\{ \frac{1}{2} \cdot \left[(\sigma_1 - \sigma_2)^2 + (\sigma_1 - \sigma_3)^2 + (\sigma_2 - \sigma_3)^2 \right] \right\}^{\frac{1}{2}} \quad (1)$$

where σ_1, σ_2 and σ_3 are the main efforts in the interest point in the material. These values of the von Mises equivalent loadings can be simply compared to the values of failure effort obtained from samples of the same material, tested in laboratory for uniaxial stresses and compressions with the goal of obtaining an estimation of the failure probabilities. They offer reasonable predictions for isotropic materials. In the case of anisotropic elastic materials (as bone) or in the case of viscoelastic materials, such comparisons are less satisfactory. Nevertheless, they are often used for such materials as well [15].

The density of the deformation energy represents as well the deformation status of a material but it was not directly related to a failure criterion. This quantity can be calculated using the following equation:

$$U = \frac{1}{2} \cdot \left(\varepsilon_1 \cdot \sigma_1 + \varepsilon_2 \cdot \sigma_2 + \varepsilon_3 \cdot \sigma_3 \right) \quad (2)$$

where ε_1, ε_2, ε_3, σ_1, σ_2, and σ_3 are the specific deformations and main efforts, respectively. This formula is valid only for isotropic materials where the directions of main forces and main efforts are parallel. The function of the density of the deformation energy is used usually to formulate constitutive equations of the non-linear elasticity. It is also used within the theory of bone remodeling that adapts to effort [15].

Most medical devices implanted serve their patients well, during the entire use period, which sometimes can be quite long (decades, in case of permanent implants, following certain accidents suffered by young patients). The performance of such a device when it is in use, can be evaluated only after it is retrieved from the organism, intervention performed if there is any damage suffered by the device or if the implant's duration has expired.

If the extraction is imposed by a certain type of damage (fracture, deformation, detachment) or by certain complications suffered by the organism, such an analysis of the damaged medical devices is absolutely necessary in order to explain the failure's causes. In the cases of implants for bone system, most clinic complications that can be indicated through the analysis of damaged medical devices can be grouped in a series of well-defined categories [15]:

- structural damage due to materials' degeneracy (wear; fracture; calcification; sectioning);
- adverse interaction of the local tissue (inflammation and infection; toxicity; tumors' formation; tissue overgrowth)
- migration (displacing of the entire device; embolism or lymphatic dispersion of material fragments);
- systemic effects or others (allergy).

The analysis performed may refer either to design and test processes, that potentially affect all devices of a certain batch, or to the particular conditions that damaged the device in the case of that particular patient. Determining the causes and mechanisms contributing to the damage of an implant or device following the retrieval and evaluation procedures of the implants may lead to a series of conclusions that might result in the following effects [16, 17]:

- patient management modification, by choosing a different type of prosthesis, modifying the existent one or modification of the medication dosage used during patient's therapy, patient closer monitoring through non-invasive therapy (bone scanning);
- revealing the vulnerabilities of a certain prosthesis type, of a manner or particular damaging mechanism, which in their turn lead to the intervention of regulating agencies, in the sense of retiring from usage of that type of prosthesis, detailed examination of a group of patients having that particular type of device, design modification, materials or production selection;
- influencing litigations regarding the liability related to the respective product, as an individual case or with the involvement of several patients.

Retrieved implants' analysis may accurately indicate several aspects of the damaging mechanism:

- presence of model deficiency;
- choosing inappropriate materials;
- damage that might appear due to the fact that preclinical tests of that device did not indicate certain manufacturing or material flaws, but which become evident after their clinic use on large-scale;
- the time when the defect appeared (in production or during the implantation);
- patient's physiological abnormal response to the implant (for example, hypersensitivity or blood clotting tendency).

Implant's evaluation without taking into consideration also the tissue represents an incomplete evaluation, without the understanding of the host medium's response. It may be anticipated that implants and new materials may impose the use of advanced techniques in the assessment of interactions between host medium and biomaterials, and the development of new analytical techniques for these particular situations [18].

MATERALS AND METHODS

Protocols and analytical techniques to evaluate the implant can be specified only after appropriate consultation, cataloguing and identification, including a complete overview of the patient's medical antecedents, and after the radiography [16]. ASTM and ISO [19, 20], implants' retrieval standards, established an assessment approach in

three stages. Stage I supposes the routine device identification and its description. Stage II of the assessment (more detailed, time consuming and costly) includes photographing and not destructive evaluation of the damage. The protocols for Stage I and II are identical for different types of materials, and can be found in ASRM F561-05a. Stage III protocols include destructive analytic techniques, a lot of them being specific for particular types of materials and they suppose separate techniques for metal, polymeric and ceramic materials. The combination of such protocols results in guides helpful in the analysis of different compounds and materials components. The assessment of an implant and its surrounding host tissue, when the implant is located into the bone, takes place in the conditions where around the implant there is grown bone, and the local tissue calcifies. There are a series of standards regulating the issues intervening during bone implants' analysis retrieved for assessment, such as: ASTM F561-05a: Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids; ISO/NP 12891-1:2007 Retrieval and analysis of surgical implants - Part 1: Retrieval and handling; ISO 12891-2: 2005 Retrieval and analysis of surgical implants - Part 2: Analysis of retrieved metallic surgical implants; ISO 12891-3: 2005 Retrieval and analysis of surgical implants - Part 3: Analysis of retrieved polymeric surgical implants; ISO 12891-4: 2005 Retrieval and analysis of surgical implants - Part 4: Analysis of retrieved ceramic surgical implants.

The techniques to assess the implant are in most cases typical destructive, which means that the implant or a part of it must be destroyed or modified in order to obtain the needed data in what its features or those of the material out of which the implant was manufactured [21] are concerned.

Stress analysis in solids' mechanics involves a particular structure with a given geometry, created for a certain material, whose elastic properties are known (Young modulus and Poisson coefficient). The structure is under the influence of external forces and/or moments and connected to the environment through a certain shape. The objective of a stress analysis is to determine the loading and forces field within the structure and to see whether the structure produces excessive deformations or loadings, which might cause the mechanical failure. Stress analysis may be achieved either numerical on a computer or using mathematic solutions. In the first case, a model simulated on the computer is used, for example the method with finite element. In the second case, the solution is obtained through explicit mathematic formulae. These solutions, with similar shapes, are available only for particular structures, with regulated shapes, such as prismatic bars and beams. Solutions with similar applicable shape are always preferred to the numerical ones due to their numerical results. They offer an understanding of the relationships between structural parameters, materials features, efforts and effort-force models. Finally, as a rule, all calculated loadings and forces must be verified through experiments. Forces acting on the surface of a structure can be experimentally determined either directly, through measurements, or indirectly using a testing model.

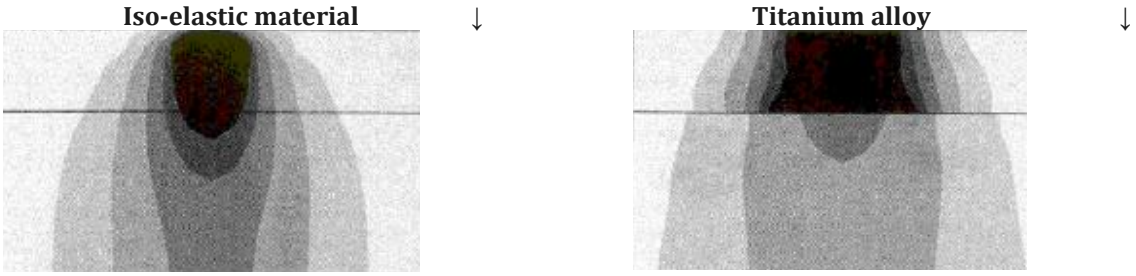
Mention must be made that the results of a stress analysis, experimental or analytical, depend very much on the model built to recreate the structure. The accuracy of the calculations of force and effort depend very much on the model's realism (for example geometry, constitutive equations for the material, material's coefficients, loading conditions and boundary conditions). Models are abstract forms of the reality and are used to simplify the current issue. The essence of modeling is that each model must include issue's main features, as close to its needs as possible. Complex models are not always better than the simple ones. There are no fixed rules regarding these modeling processes. The questions are when is an assumed model real (almost never) and when a simplification is justified regarding the issue definition [15].

Surface bondage

To bond the femoral stem surface of a hip prosthesis is taken into consideration a very simple model of a solid layer (prosthesis) bonded on a sub-layer (bone) (Figure 3). It is assumed that both materials, taken separately, have uniform elastic properties and that the layer above it is rigidly bonded on the sub-layer. Figure 3 shows a von Mises model of stresses within the materials for the case in which the prosthesis is loaded through a force *F* that acts in only one place. For example, the resistance criterion von Misses supposes that the material will cede (plastic deformation) the moment when the distorting energy will increase above a certain value. Von Misses stress can be calculated from the equation (1)

Fig. 3.A presents the case in which the prosthesis has the same elastic properties as the bone ("isoelastic material"), while in Fig. 3.B the prosthesis is made of metal, assuming it is titanium, which is far more rigid than bone.

Fig. 3. Stresses distribution calculated for a FE simple model of an elastic sub-layer and upon which an *F* force acts. A: von Mises stresses distribution, equation 3, is presented for the case in which the layer from above (prosthesis) has the same elastic properties as its foundation (bone); B: von Mises stresses distribution for the case in which the prosthesis is made out of a more rigid material (ex. titanium) than its base (bone).



A **B**

From these results we note the following characteristics:

1. Stresses are not essentially uniform, mostly concentrated on a central band within the structure, directly below the applied effort.
2. When the modules of the two materials are equal (Fig. 3.A), efforts are continuous along the surface; when materials are different (Fig. 3.B), stresses are discontinuous along the surface.
3. Stresses' models are more uniformly distributed in the case of rigid prosthesis (Fig. 3.B) in comparison with the case of soft prosthesis (Fig. 3.A). As a result, efforts' intensities are higher in the case of the prosthesis made of a softer material.

These characteristics are central for the understanding of the stresses' transfer during the surface_bondage. Normal stress (compression) σ_y at the interface must balance the applied force on direction *y*. Stress σ_y is not uniform and must satisfy the balance conditions. Thus, there is a simple relation, which establishes the link between the stresses' average and the current stress.

Even though the stresses' average may be used in certain situations, when there are doubts related to the existence of a number of loadings concentrations within the composite structure, the loadings average should not be taken as representative for the maximum stress value. As the stress distribution σ_y should always balance the applied force *F*, a composite structure that leads to the stresses distribution contraction will have a maximum value higher (Fig 3.A), than in the case of Fig. 3.B.

Such a situation indicates that, even though, according to the intuitive expectancies that a material having similar elastic properties with the bone might be ideal for implants, in fact it might not be the ideal choice from the point of view of stresses distribution.

Generally, stresses models of a surface bondage structure depend, not only, on the features of the articular stresses (amplitude, direction, contact area and contact area increment) but also on the bending rigidity (elasticity modules and component's dimensions), the elastic characteristics of the support bone and the characteristics of the joint type. The bending rigidity of the prosthesis is a design parameter that can be adjusted so that it influences the stresses models. It is the product of the elastic module and of the second module of inertia (proportional with width *x* depth). As well, the effects of rigidity onto the osseous sub-layer have to be taken into account, as, in general, they are not uniform [15].

As a rule, local concentration of efforts appears where the rigidity of the support bone is relatively high. Rigid area tends to attract the loading transfer, and the flexible area tends to become a shield against stresses. In fact, all mechanisms discussed above play a role in the stresses transfer within this composite structure. Because of the structure's complexity and bone's lack of homogeneity, they are not easily recognizable in the stresses models.

The principles of stresses transfer during the inter-marrow fixation rely on the participation of stresses and are very similar to the mechanism illustrated in Fig. 3. As simplified model, a metallic stem was chosen (femoral stem) fixed within a tubular bone. The stem is under stress through an axial force that has to be transferred to the bone. Once again, the

transfer of loadings between stem and bone is carried out through shear stresses localized at the interface. In fact, the diagram of the stem's free body indicates that these shear stresses should balance the external loading. Therefore, the shear stresses average multiplied by the stem's surface area should be equal to the axial force. However, once again, these shear stresses are not uniformly distributed. Stresses concentrations appear in the proximal and distal zones.

When the stem suffers a bending stress, a mechanism appears which is similar to the stresses transfer. This time, the bending moment is transferred from the stem to the bone through the interface loadings (stress, compression, and tangential shear) that carry out this transfer of moment. These stresses are not uniform and are concentrated mostly in the proximal and distal zone.

Principles of the stresses transfer

The most important principles of the stresses transfer during the intra-marrow fixation for artificial articulations are:

1. The structure can be divided in three regions zones: medial zone where the stresses participation appears and two stresses transfer zones in the proximal and distal zone.
2. Within medial zone there is a pure participation of the stresses, while the stem carries ε_n ×100% of the axial force or ε_t ×100% of the bending moment; here ε_n and ε_t are the relative rigidities, axial and bending defined as:

$$\varepsilon_n = \frac{A_s \cdot E_s}{A_s \cdot E_s + A_b \cdot E_b} \quad (3)$$

$$\varepsilon_t = \frac{I_s \cdot E_s}{I_s \cdot E_s + I_b \cdot E_b} \quad (4)$$

where E, A and I represent the elasticity module, the plan areas and the second moment of stem's inertia (s) and bone's inertia (b).

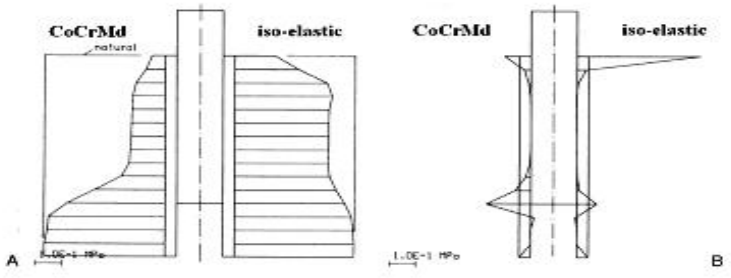
3. In a normal situation the loading are taken over only by the bone, but in this case the loadings are taken over by stem and bone, the bone is protected against stresses by the stem. The higher ε_n and ε_t are the higher percentage of the stress taken over by the stem and the more extensive the stress shielding effect.
4. The higher is the percentage of stress taken over by the stem within medial zone the smaller will be the transfer within proximal zone and the bigger it will be in the distal zone and the other way round. The stress transfer in the proximal zone is proportional with $(1 - \varepsilon_n)$, respectively $(1 - \varepsilon_t)$ and the transfer in the distal zone is proportional with ε_n, respectively ε_t. Hence, the more rigid the stem is, the bigger the tensor of the proximal interface is.
5. The length of the distal and proximal areas of stresses transfer and the peak of the stresses interface on the distal and proximal zone, depend on the parameters λ_n and λ_t, and on the fixation exponents for axial and shear stresses. These parameters depend not only on the axial and bending rigidity of the stem and bone, but also, mostly on the elasticity modules and depth of the middle layer (acrylic cement and trabecular bone). A rigid middle layer (large module and /or thin layer) reduces the length of the efforts transfer zones, increasing in this way the gradients of the interface's stresses.
6. Stresses' peak at the interface is not necessarily reduces when the stem is longer. In this case, the notion "stresses is the loading on the available area" is erroneous. When the stem is longer, only the regions of the transfer of loading change. When the stem is shorter (shorter than π/λ_n or π/λ_t), the region in the middle disappears, and a further reduction of the stem affecting the interface stress.
7. If a collar in the proximal region of the stem is bonded to the proximal bone, the proximal region of the transfer of loadings is deviated. Hence, conceptually, none of the stresses will be transferred in the proximal part along the interface.

The above considerations represent basic principles derived from a generalized simplified model, and they are actually very useful as an information data base for the prosthesis design. In reality the stresses transfer mechanism and stresses models are far more complex. The loadings do not appear as isolated axial compressions or bendings, stems are not usually straight, interfaces are not always bonded rigidly, and the bone has features and shapes far more complex than in this model.

Stem's rigidity plays a major role in inter-marrow fixation, and as such, it is an important parameter in the design process. The considerations about the major effects of the rigidity lead to the main design conflict for uncemented prosthesis (Fig. 4). When a stem is manufactured from metal (rigid stem in comparison to bone), in the bone appears a low stress value, possibly resulting, as a long-term effect, in a bone resorption (Fig. 4 A). The stresses at the interface are relatively small (Fig. 4B). When the

stem is manufactured from a flexible material (isoelastic material), the stress amplitude is only moderate but the proximal shear stresses are extremely high (fig. 4B), and in such case thessolution of the bondages implant interface/ bone may appear.

Fig. 4. Stresses models for a simple FE model of inter-marrow fixation that compares the effects of a CoCrMd stem (left) with those of a isoelastic flexible stem (right). A: Periostal osseous stresses compared to natural efforts. B: Interface shear's stressess. The stem suffers an stress while bending [15].



This will show again that a prosthesis material having the same elastic properties as the bone, cannot necessarily represent the ideal solution. Finding the optimum design for the stem's shape and the right material that will protect the bone and guarantee the interface's long-term integrity represents a challenge in the contemporary design of artificial articulations [15].

Methods of morphological quantitative analysis

Artificial articulations' design is usually created in two phases. First phase is the conceptual design, when the specialist's philosophy is transformed into shape. The designer may be an engineer, an orthopedist or an entire team composed of engineers and surgeons. Second phase is very difficult to carry out and to analyze due to the difficulties that appear while trying to obtain samples of human tissue and due to the large variety of osseous shapes. The designer can use databases containing the most encountered osseous dimensions from different patients' populations. However, such situations are rarely available in the accessible literature. Some data may belong to implants' manufacturers. Anthropometric data retrievable in the specialized literature are, in general, limited in what the bones' extreme dimensions characterization is concerned, and it is not detailed enough to serve as basis for the prosthesis design.

The morphological quantitative analysis on large scale of the bones' shape and with a statistics basis is very important to develop the implantology, and for the moment, there are not very popular research projects in this field. Some researchers deployed extended geometrical analysis of the proximal femur with the help of digital analysis with *X* rays. They obtained few significant correlations for the femur, which is a very important step in the prosthesis design of THA. On the other hand, they managed to define dimensional classes for the endosteum shapes. Such a system based on dimensional classes can be used to code the essential geometric models to achieve an order within the large variation of bones' dimensions.

A more precise method of geometric analysis is achievable by sectioning the osseous samples and through the digital analysis of photos and radiographic contacts. Such tasks are dull in comparison to conventional methods with *X* rays. Following this analysis, the first issue arising is the collection of a sufficient number of bones and to be sure that the collection represents a well-defined population. Second issue is to define an external reference system so that each osseous section can be reported to it. Due to it, the reference system can rely only on the very varied external geometry of the bone, which is not an easy task [15].

Analysis of the relative movements

Implant's micro-motions related to the bone in conditions of dynamic stresss prevents the bone to grow within the porous coatings. The same micro-motions may lead to bone resorbtion at the interface with the prosthesis stem and to the creation of a fibred tissue membrane. Therefore, it is important, in the case of uncemented stems, to have an adequate "initial stability". Micromotions can be measured experimentally in vitro by placing sensors on the prosthesis, in one or in several

points, to measure its motions related to the bone [16, 17, 18].
Sometimes, only the particular components of the motion are measured, for example femoral stems' deformation in case of axial or angular stresses or rotary bending stresses. A complete evaluation of prosthesis motions is trivial. The rigid body motion of the prosthesis component towards the bone can be described through 3 translations of a chosen basic point (superior / inferior motion or deformation, anteroposterior translation and medial-lateral translation) and 3 rotations around the perpendicular axis, alternatively (axial rotation, flexion and varus/valgus rotation). To determine these 6 motions of rigid body, at least 6 relative motions of 3 points must be determined (the motion on *x, y* and *z* of a point, the motion on *x, y* and *z* of a second point, the motion on *z* axis of a third point). Often, the motions of a rigid body are not enough to define the prosthesis motions. At the physiological levels of stresses, certain components bear deformations, which cannot be neglected when they are under stress. For example, the femoral stem suffers significant deformation while bending [15].

Experimental analysis to determine the stress

The experimental analysis of stress is usually deployed on laboratory models, using osseous samples or osseous substitutes. In each case the deformation are measured, and then interpreted visually, or measurements are used to calculate the stress using the elasticity theory. The common methods used to measure deformations in biomechanics are the analysis with the extensometer, holography, photo-elastic analysis, etc. The most used method is the analysis with the strain gauge, where this electric instrument is attached to a blank surface of an object. The instrument contains one or more filaments, which deform at the same time with the surface to which they are attached. Strain gauge functions according the following principle: a filament's deformation is proportional to its electric resistance modification. Thus, the force that acts over a material sample on the point where the strain gauge was applied can be easily measured by evaluating the difference of electric resistance. To determine the complete force status (two linear forces and a shear force) on a blank surface, a rosette-tensometer can be used. A rosette contains three filaments (usually oriented at 30-45^{o} one against the other) that measure three linear forces in the application point. These three linear forces can be used to calculate the complete force status as well as the values of main force and main directions. When the elastic features of an object are known, forces can be calculated by using Hooke's generalized law.

Finite element analysis

The finite element method (FEM) became a very used instrument in orthopedic mechanics. It represents a computerized simulation method used to determine stresses and forces in any given point within a structure with geometric complexity and a material's complexity arbitrarily chosen. The model relies on modeling constitutive accuracy of the material and on material coefficients (Hooke generalized law is the most used), 3D geometric data, stresses features and interface conditions. To develop a FEM model, the form and structure is divided in small finite elements. In case of 3D analysis, volume elements with particular shapes (parallelepipeds and tetrahedrons) are used and for 2D analysis, area elements with particular shapes (triangles and tetragons) are used. Each element has joint points, regular at the elements' corners. For each joint point three movement components and three force components are identified (in case of 2D analysis only two by two).
When there is a need of information about structures which are too small to be taken into account, in FE models, local model may be used instead of general one (Fig. 5).

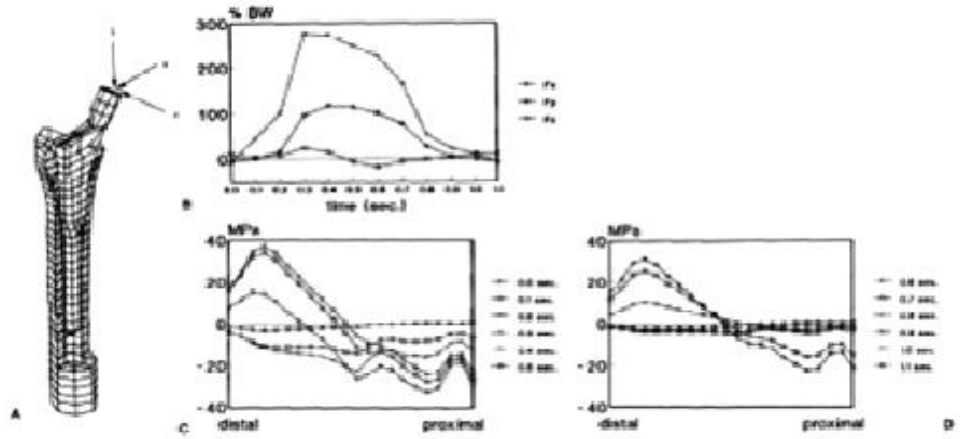


Fig. 5. A: a FE model of a composite structure femoral stem - bone. B: hip articulation forces are determined with an instrumented prosthesis in vitro. C and D: bending stresses distribution at the medial part of the frontal plan of the prosthesis, from 0 to 0.5 seconds and from 0.6 to 1 second

In this case, a local region from the entire (global) surface is modeled in a secondary FE model, with a finer surface. Boundary conditions of the secondary model (stresses, motions) are then derived from the results of the global model. This secondary model needs boundary conditions independent of the micro-structural details that have to be analyzed. In other words, micro-structural details are small enough not to produce a notable effect on the mechanic behavior of a larger structure.

FE analysis demands numeric descriptions of external forces applied to the structure (application point, amplitude, direction). These loads are usually variable and not always accurately known, so the issue related to the FE analysis is often linked to the approach that has to be followed in order to obtain the necessary information. One consideration that is always helpful is that FE analysis is accessible for small parameters variations. Therefore, stresses may vary and studies' results may be defined in the idea of determining relations and situations of the "worst case scenario" type. Often the critical case configuration is initially selected in the case of different stresses. In such cases it is recommendable to investigate the stress modes sensitivity at small deviations of external forces. Fig. 5 shovs an example of variable stresses effect from hip joint during walking, at the bending stress modes from a femoral THA structure. A critical case loading for the proximal stem appears 0.5 seconds after the start of the walking phase. Anyhow, the distal stem's loading's will reach a maximum value of 0.3 seconds. This situation indicates that a critical case loading for one part of the structure does not necessarily imply a critical case loading for another part.

Another approach to select the efforts is to use the loadings representative cases. This approach is useful especially when the effects of the construction of a particular prosthesis design are to be studied in a comparative analysis, or when the stress transfer's mechanism is to be studied. For example, regarding the femoral component THA, the effects of the hip articulation force can be separated in those resulted out of axial force, and out of bending and rotary bending moments. The issue may be then analyzed from the point of view of the three perspectives or from the point of view of the main perspective. Finally, it is important to realize that most FE models of prosthesis structures use the linear infinitesimal elasticity theory and as such surfaces are perfectly bonded to their interface. For these models the superposition principle was used. Therefore, stress models resulting from the force application in the hip articulation together with muscular forces can be found by adding the results obtained from the separate approach of these forces [15].

When the interfaces are not bonded, meaning they are destabilized without friction or destabilized with friction, the issue becomes nonlinear and must be solved by using stresses increments. In order to achieve that, FE packages use the so-called "gap" elements to take into account the surfaces separation or untying. Load transfer for inter-marrow implants (femoral stems) are affected by

the interface conditions more severely than by any other structural parameter, in particular when a completely bonded case is compared with a completely untied case (Fig. 6).

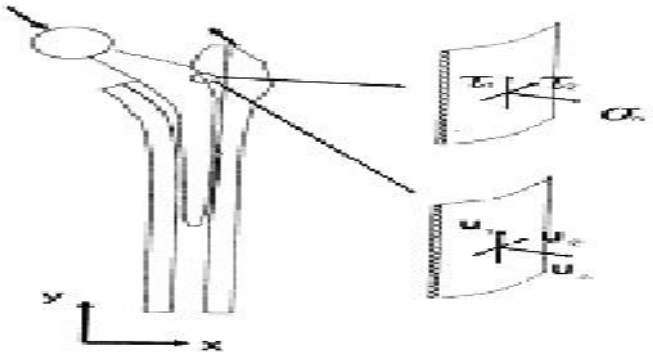


Fig. 6. Components of normal stress (σn) and shear stresses (τ_1 şi τ_2), transferred through the liaison interface; Normal (u_n) and tangential (u_1 and u_2) motion componentss are relative movements that may appear at the interface if it is not bonded.

This is the effect described previously due to the penetration of stem into the bone. When an interface is bonded, the compressive axial load acting on the stem is balanced by shear stresses from the interface. When the stem is unbonded and there is no friction, the shear stresses cannot exist. Stem should afterwards penetrate into the tubular bone developing a compression effort at the interface with the bone. The smaller the angle, the more necessary is to have a deeper penetration into the bone to balance the applied axial force. For a real stem, this mechanism is far more complex due to the stem's curve, ununiformed elastic features of the bone, and friction appearing at the interface.

Parametric analysis

There are two major benefits in using the FE analysis. Firstly, such analysis can be used to determine a stress, a force and a particular movement anywhere within the object, which otherwise, in theory, will be impossible to obtain by using other experimental or analytical methods. Secondly, this type of analysis can be used as an instrument for parametric analysis. This means that structural parameter can be modified and their results rapidly established. An example of such parametric analysis applied along the stem of a THA component is presented in Figure 7.

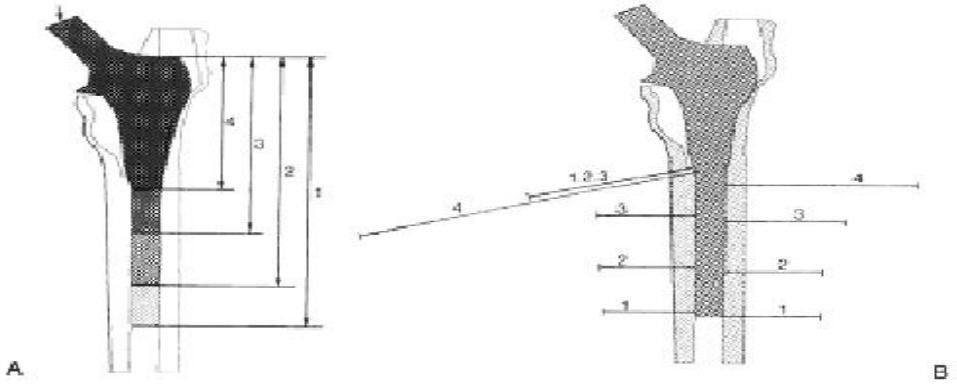


Fig. 7. Parametric analysis with a FE 2D model, lateral lamella of an uncemented femoral stem with variable stem lengths (A) and (B) normal maximum (right) and the shear stresses (left) peak at the interface are presented for variations of the length. To be noted that differences are visible when the stem is very short (case 4).

The parametric analysis is useful not only during the design phase of the prosthesis, but also when defining experiments and explaining clinical observations.

The current research refers to a monobloc type prosthesis (Figure 8), whose femoral stem suffered a fracture during service time, surgery being necessary to remove and to replace it.

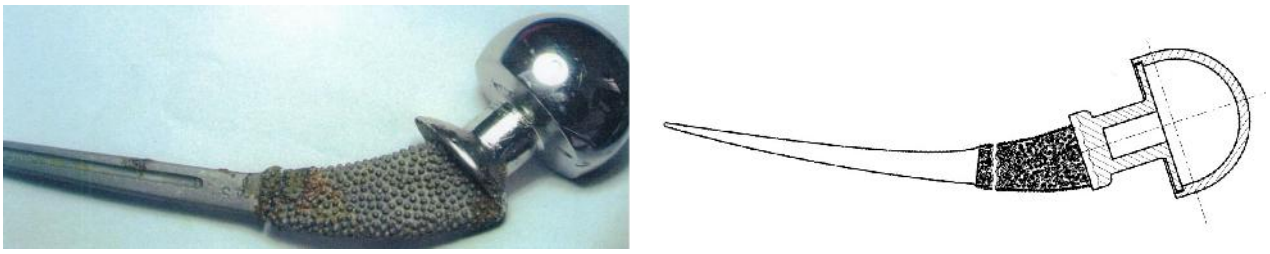


Fig. 8. Hip prosthesis submitted to investigation

RESULTS AND DISCUSSIONS

Investigations were performed in compliance with the international norms previsions ASTM F561-05a, Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluid [19]; ISO/NP 12891-1: 2007 Retrieval and analysis of surgical implants - Part 1: Retrieval and handling [20]; ASTM F1903-98(2003) Standard Practice for Testing for Biological Responses to Particles in Vitro [21]; ASTM F1904-98(2003) Standard Practice for Testing the Biological Responses to Particles in Vivo [22]; ISO 17853: 2003 Wear of implant materials - Polymer and metal wear particles - Isolation, characterization and quantification [23]; ISO 17853: 2003 Wear of implant materials - Polymer and metal wear particles - Isolation, characterization and quantification [24], as well as in compliance with the Romanian standards SR EN ISO 10993-13: 2003 Biological evaluation of medical devices. Part 13: Identification and quantification of degrading products within medical devices based upon polymers [25]; SR EN ISO 10993-14: 2003: Biological evaluation of medical devices. Part 14: Identification and quantification of degrading products from ceramic [26]; SR EN ISO 10993-15: 2002 Biological evaluation of medical devices. Part 15: Identification and quantification of degrading products from metal and alloy [27]; SR EN ISO 10993-16: 2003 Biological evaluation of medical devices. Part 16: Identification and quantification of degrading products and extractible substance [28]; SR EN ISO 10993-17: 2003 Biological evaluation of medical devices. Part 17: Establishing the admissible limits for extractible substances [29] and SR EN ISO 10993-9: 2003 Biological evaluation of medical devices. Part 9: The frame to identify and quantify the potential degrading products [30].

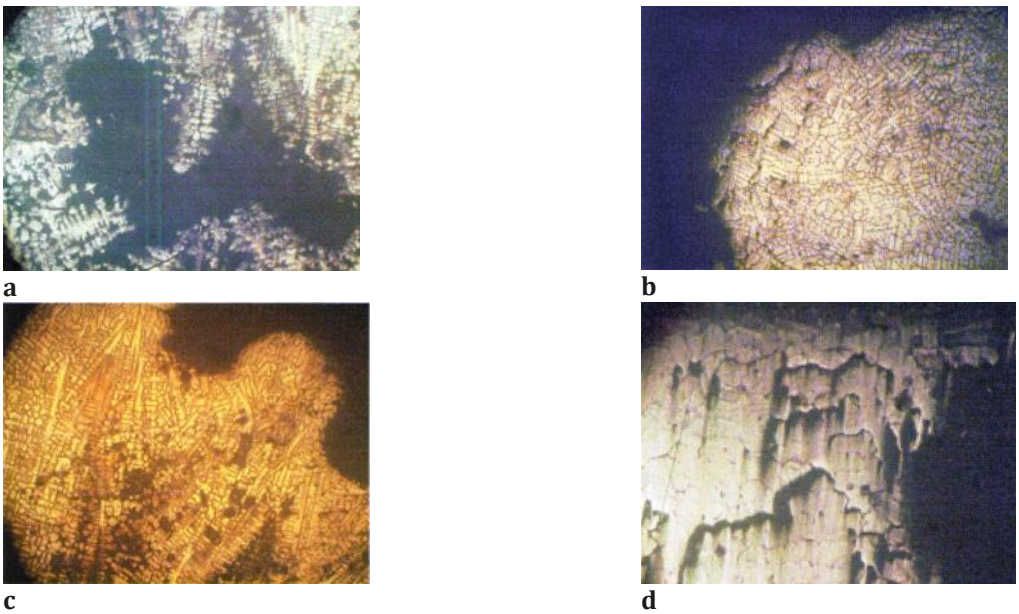
In compliance with these standards, the investigations included three stages. During stage I, routine stage, of macroscopic inspection, the implant was identified as being a monobloc femoral prosthesis, with femoral head of 40 mm diameter (Fig 8). The femoral stem was manufactured through casting, and the proximal area covered with semi-spheres with 1.5 mm diameter, manufactured during casting, resembling to a coarse “Mandrepore macro” coating, presented in Fig. 1 c. The stem was fractured on a transversal plan on the porous area, at approximately 5 mm from its distal area. During Stage II, non-destructive, digital photographs of the two prosthesis fragments were made, of the fracture, highlighting the fracture’s aspect, where a possible casting defect is indicated. The fracture was not preceded by a plastic deformation; it was a fragile fracture, indicating a pronounced trans-crystallization (Fig 9 a, and b). On the stem, in the fracture area, there were visible rust corrosion.

(a) **(b)**

Fig. 9. Photographs (a) and (b) of the two surfaces if the fractured femoral stem.

The fractured area of the femoral stem was submitted to microscopic investigation, indicating a casting defect near the middle of the area. Images from Fig 9 illustrate the sections of the two fractured stem pieces, where a casting defect can be observed almost in the middle of the fracture, of approximately 4 mm (natural size), but also reddish corrosion traces, from the contour towards the middle. This evident observation proves that the femoral stem broke exactly where is the maximum bending (shear) stresses area (see. Fig. 2).

During the microscopic observation performed on both pieces (spherical head, and collar stem, shrunken-on), it was observed that they have the same type of microstructure, composed of a solid solution δ, and a network of relatively coarse compounds, rough casting structure.In marginal areas as well as in the middle of the stem, numerous casting defects were identified such as micro-porosities and fissures. These defects communicate with the piece's exterior. They are illustrated in Fig. 10 a, b, c and d (x50).



a **b**

c **d**

Fig. 10. Casting defects, micro-porosities (a, and b) and fissures (c, and d). These defects communicate with the stem's exterior.

Mention must be made that the femoral head structure (Fig. 11) did not present any casting defects.

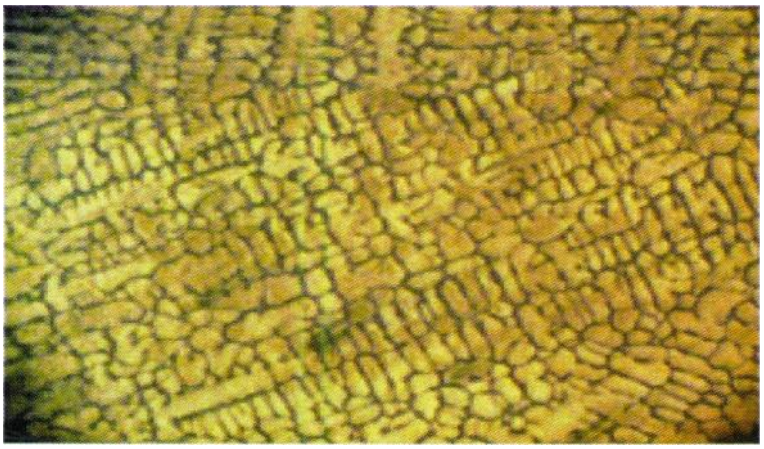


Fig. 11. Image of the femoral head structure, without casting defects

During stage III of the evaluation, femoral head as well as stem sections were submitted to hardness investigations. For the stem the following values were identified HV_{10} of 235; 232, the equivalent of ~ 21 *HRC*, that is an average resistance of R_m ~ 790 N/mm^2, and for the femoral head HV_{10} of 206 – 207 , the equivalent of ~ 18 *HRC*; R_m ~ 700 N/mm^2. The values of the stem's and femoral head's hardness are compliant with the range of values for different types of his endo-prosthesis.

CONCLUSIONS

Following theoretical studies and experimental investigations presented above, the following conclusions can be drawn:
- The prosthesis was manufactured from a stainless alloy (not magnetic) casted (CoCr), without further metallurgical processing.
- Glossy parts of the two components were carefully mechanically processed.
- The curved stem that is introduced in the marrow channel, with rounded prominences obtained through casting, presents a rusty aspect, due to the bio-tribo-corrosion within human organism.
- The entire stem presents numerous micro-porosities and fissures, where organic components diffused after the implant.
- The technological variant chosen to manufacture this prosthesis is not compliant, and as such the imposing action should be the manufacturing interdiction (and consequently its use).
- The fracture appeared most probably due to bending efforts that the stem was subject to, their maximum acting exactly in the area weakened by the casting defect highlighted during our investigations.

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