Journal of Achievements in Materials and Manufacturing Engineering
VOLUME 24
ISSUE 1
September
2007

Investigation and implantation of endo-prosthesis in biological experiment on animals

M. Žitňanský [a,*]
co-operating with
Ľ. Čaplovič [a], **Ľ. Rehák** [b], **F. Makai** [b]
[a] Institute of Materials Science, Faculty of Materials Science and Technology, Slovak University of Technology, J.Bottu 25, 917 24 Trnava, Slovakia
[b] Faculty of Medicine, Comenius University, Špitálska 24, 813 72 Bratislava, Slovakia
* Corresponding author: E-mail address: zitnanskymarcel@stonline.sk

Received 19.04.2007; published in revised form 01.09.2007

Materials

ABSTRACT

Purpose: Purpose of this paper is to inform professional public about our research activities and results in the area of development of implants.
Design/methodology/approach: Method used in the present study, was the computer design of 3D virtual model, rapid milling, rapid turning and special testing, to produce a new total endo-prosthesis for dogs.
Findings: Results of these activities are eight complete total endo-prostheses for dog implantation and for test preparing in vitro and in vivo and finally, for biological experiments on animals – dogs.
Research limitations/implications: This paper is the result of partly primary and partly applied research. The achieved results will be used for preparing of the total endo-prostheses into the human skeleton.
Keywords: Biomaterials; Analysis and modelling; CAD/CAM; Engineering design

1. Introduction

A team of scientific researchers from the Slovak University of Technology and the Comenius University, both in Bratislava, were engaged in the research and development of biocompatible materials. Their endeavours finally lead to a usable result, by creating a non-cement total endo-prosthesis of the hip-joint.

In the area of implants of the hip-joint, there are produced – in the developed countries of the world – many types of high quality total endo-prostheses. On medical conference in Antipo, France, it was published that in 1991 were implanted 1,9 million of knee and hip joints. It is really a remarkable number. We undertook to develop a non-cement total endo-prosthesis, which would reach the quality on a European, or even World-wide level.

In the course of preparing the design of such TEP, we utilised the life-long experiences of a mechanical engineer – Professor Marcel Žitňanský – in the field of scientific research of materials with special useful properties and – at the same time – the life-long experiences of an orthopaedist – Professor MUDr. František Makai, DrSc, the chief of the I-st Orthopaedic Hospital in Bratislava, who is active until his old age. Further, we utilised also multi-annual practical experiences of a Docent - orthopaedist, who grew scientifically and professionally under guidance of his Professor. We can declare justly, that the good results were achieved only thanks to enormous creative energy, of the authors and the main collaborators of the scientific and research team – invested into the implementation of granted patents. By this paper, we intend to inform the professional public about the results of our combined efforts.

2. Description of the approach, work methodology, materials for research, assumptions, experiments etc.

In the Slovak Republic, at present, there are not produced the TEP. In a long development sequence, we researched all possible manufacturing technologies, smelting and refining in the vacuum inductive furnace [1,2,6], rolling [6,7,8], smelting and refining in plasma furnace [9], isostatically pressing [10], creation special coatings [16,17,18]. We experimented also with many possible – metal and non-metal – biocompatible materials [1,2,6,11,12,13,14].

At the beginning of our research, we looked for and developed the idea into an utilisable, however original design. The research period advanced from the 20th century into the 21st century, what brought along also many novelties in technology and medical practice. In this way, there was offered the possibility of utilisation of the newest scientific knowledge. We utilised also the new possibilities of designing by progressive graphic software and of transfer of the design data into a special modern machine tool, using perspectively the most modern High Tec processes. This stage of development removed the individual human influence – during the traditional cutting and various other types of shaping and finishing. In this way, there is fully utilised the latest level of knowledge – both in science and technology. To these possibilities we adapted the whole development process from the idea, up to the implanting of the developed TEP into the human skeleton. On Figure 1, there is shown the way of creating a more complicated section in the plane (x – y), [1,2].

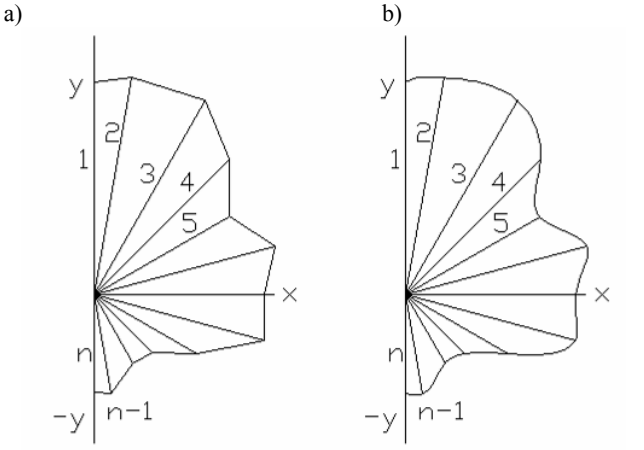

Fig. 1. Schematic representation of creation a figure in the plane, (x – y): a) line-segments, b) spline segments

By connecting of end-points of rays 1, 2, ...(n-1) to n, by simple line-segments, or better by splines, we receive one half of the created profile of a certain component. In this way, we have shown the first steps of a high number of further steps, during the creation of the virtual 3D model. In a similar way, it is possible to create the femoral component (FC), the acetabular component (AC), or any other part of a certain unit. For the creation of the design of necessary models, we utilised the program INVENTOR 11. For such a task it is excellent software.

On Figure 2, there is shown the section of the femur of a dog, drawn according to the actual size of the dog's femur. On Figure 3, there is the design of a TEP, which was made for biotests on experimental animals [1].

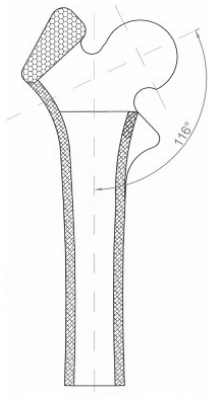

Fig. 2. Section of the femur of a dog [1]

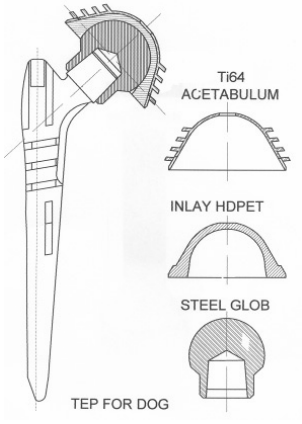

Fig. 3. Design of a TEP for im-, planting into experimental animals [1]

On Figure 4, there is shown the actual shape of the TEP [1], created for biotests. There was utilised a combination of different biomaterials. The head was made of chirurgical steel; the inlay of biocompatible high-molecular density polyethylene; the femoral component (FC) and the acetabular component (AC) were made of an alloy Ti64 ELI. The TEP for the dog was designed in such a way, to remain after implanting in the desired position, without shiftings or turnings, until the end of experiment. The time of the experiment was chosen – in accordance with the regulations – to 6 months. On Figure 4, there is shown the view on the model of the third iteration of the TEP for a dog. The surface of the FC and AC of models assigned for implantation was created of a nanocrystallic diamond [16].

Fig. 4. TEP for a dog, in a disassembled state [1]

2.1. Preparation of an experiment of implantation in vitro

Such experiment served for the preparation of the design of a TEP for a dog. It was necessary to take into account the small size of the dog's bones. Only in the third iteration, we succeeded in creation of the 3D model of the TEP, which was utilisable. We had the rtg. pictures of the dog and cleaned bones, as it are shown on Figures 5 and 6. These served for the graphic software INVENTOR 11, to make models of the necessary parts of the TEP for the dog. It was a very laborious task, but it was utilised for the preparation of the implant of the TEP for a dog.

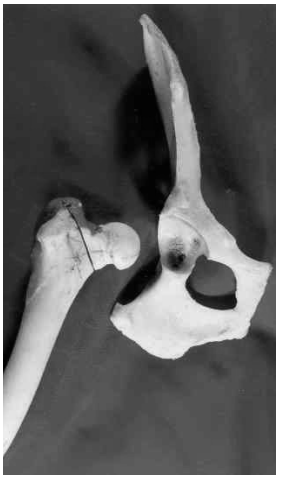

Fig. 5. Femur and the pelvis bone of a dog [1]

On Figures 5 and 6, there are shown the results of the study experiments "in vitro". The aim was, to assure the optimal anchoring of the TEP in the femoral and the pelvis bones of a dog. On Figures 7 and 8, there is shown a series of AC for a dog and a series of polyethylene inlays, inserted into the AC of a dog.

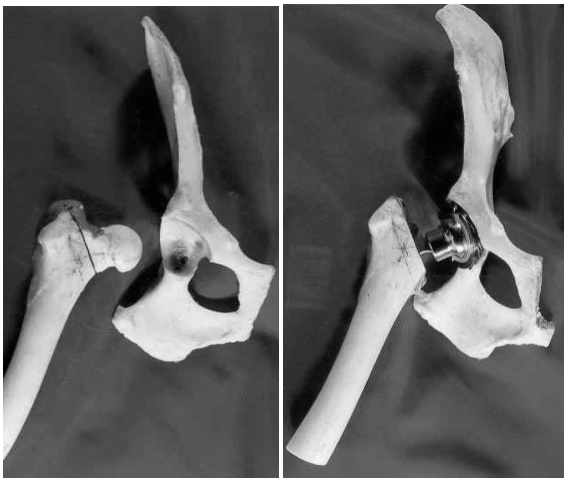

Fig. 6. Experiment TEP in vitro [1]

Fig. 7. View of the AC for dog [1]

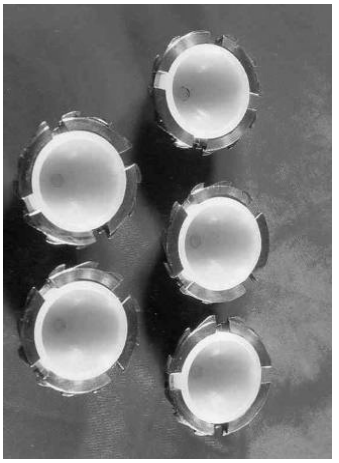

Fig. 8. View of the PET inlay in the AC [1]

2.2. Preparation of biological experiments on experimental animals

The aim of the biological experiments was mainly the monitoring of interactions following after the implanting into the experimental animals:

1. Biological experiment – preparation of the implantation of the developed TEP.
2. Testing period of 6 months.
3. Evaluation of the biological compatibility.
4. Evaluation of the inflammatory or allergic reactions.
5. Reactions of soft tissues in the vicinity.
6. The function of the prosthesis in a living organism.
7. Study of the anatomy and of the dimensions of the acetabula.
8. Study of morphology proximal femur.
9. Study of the anatomy of the narrow cavity.
10. Comparing of morphology on rtg.
11. Study of anatomic approach.

As can be seen from the preparation of the experiment, the bio-tests on animals were performed with a maximal orthopaedic skill. The experimental animals were carefully chosen from certified breeders. In Table 1, there are shown the main data about the experimental animals.

Table 1.
Experimental animal – a German sheep-dog

Item Nr	Sex	Age [m]	Weight [kg]
1	masc.	27	34
2	masc.	38	35
3	masc.	16	27
4	masc.	30	32
5	masc.	36	35
6	fem.	42	25

2.3. Results of the experimental study of implanting of the developed total endo-prosthesis

In 2004, we performed the implanting of the model TEP of the hip bone into the experimental animals. The whole experiment lasted 6 months, while in this time there was monitored also the reaction of the bone surrounding the implant and the pathologic reactions of the living bone tissue and of the soft tissues in the vicinity of the implant.

The aim of the experiment was the implantation of a new total non-cement endo-prosthesis in a biological experiment, into the hip joints of six German sheep-dogs, in a period of six months. Then we monitored the biologic compatibility, the inflammatory and allergic reactions, the reaction of the soft tissues in the vicinity of implants and the function of the prosthesis at walk and run of the tested animals.

At first, we performed a pilot experiment on one dog, where we tested the anatomic shapes, the dimensions of the marrow cave of the femur, the size of acetabula, the morphology of the proximal femur and we compared the morphology on the rtg. pictures and in vivo. At the same time, we studied the anatomic approach. After this pilot experiment, we performed the main experiment with six German sheep-dogs. There were five masculine dogs and one feminine (Table 1).

At the beginning of the operation, the experiment animal received medicines before the anaesthesia, the intravenous anaesthetics and it was it was introduced, properly connected to the monitoring of EKG and of the breath functions, what was properly documented for each animal. The operation process was lateral (from the side) in the reach of the left hip bone, Figure 10, after shaving the skin, antiseptic treatment, then by incision from the lateral approach, we penetrated through the skin by preparation of fascia, the muscles, until we reached the hip bone. Then we gradually implanted the hip bone pit, Figures 7 and 8. Consecutively, after the rasping of the marrow cave, we implanted the femoral component, Figure 4 and anchored its head, Figure 4. In the last stage we made the reposition and sewed the soft tissues and the skin above the hip bone, Figure 9. [1].

Fig. 9. Nicely sewed cut [1]

After the operation we monitored the vital functions of the experimental dogs, the temperature of their body and the healing of the operation wound, Figure 10. During the after-operation period, we monitored also the urination and the stool. After the healing of the operation wound, we evaluated the loading of the limb, the movement activity and the feeding of the experimental animals.

Fig. 10. Dog on the 3-rd day after implantation [1]

The experiment terminated by the destroying of the animals, taking of samples and by fixation of samples by a special fixation agent. There was evaluated the implant and the relation of the bone with the implant. We evaluated also samples of the parenchymatosic organs, whether some small particles of the metallic parts of the implanted TEP were not transported into the cells of organs as liver, kidneys, or lungs. There were no micro-particles from the TEP found in these organs.

After the complete processing and evaluation of results, we made the following conclusions:

Implanting of AC, after overcoming problems connected with the small size of biologic acetabula of dogs, was evaluated as good. After the pilot study, we achieved good anchoring of AC in the pits of experimental dogs, what was confirmed also by rtg. pictures of the post-operational monitoring, Figure 11. The compatibility of the implant in the region of implant was good, without rejection reaction. The histological evaluation of bones and of soft tissues in the vicinity of implants was without inflammation or allergic reactions, with a good overgrowing of the implant.

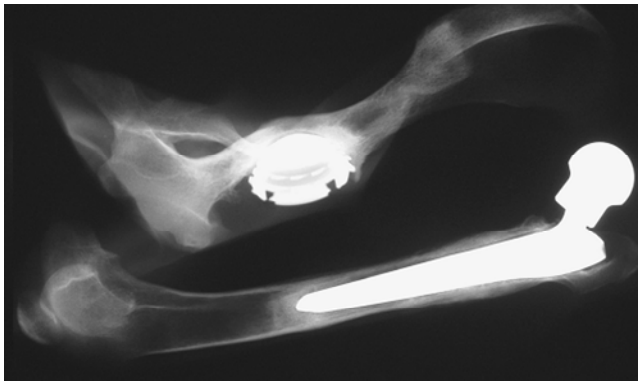

Fig. 11. Rtg. picture 6 months after the implantation [1]

After the evaluation of the biologic implants, there did not appear any negative or unexpected reaction of the soft tissue with the metallic parts of implants. After the evaluation of these important results, we started to prepare the implants into the human skeleton. In the paper we show only one developed model of FC and AC. It is non-cement TEP, assigned for the human skeleton.

2.4. Creation of the design of a human TEP

This is a very demanding stage, in the frame of the whole grant project. On the way from the idea to its realisation, it was necessary to solve a wide range of scientific problems. In this paper, we show only one developed model of FC and AC. It is non-cement TEP, assigned for the human skeleton.

On Figure 12, there are shown new human developed types of FC and AC into the human skeleton. At present, the parts of the developed TEP are being tested. Such testing is very demanding on the machinery equipment of the certified testing laboratory. Until now, five different tests were performed, with good results achieved. At present, there is being made the last one of the prescribed tests. After reaching favourable results of all tests, the researching team will receive the certificate valid in the EU. Only then may start the last stage of the development – the implantation of the TEP into the human skeleton.

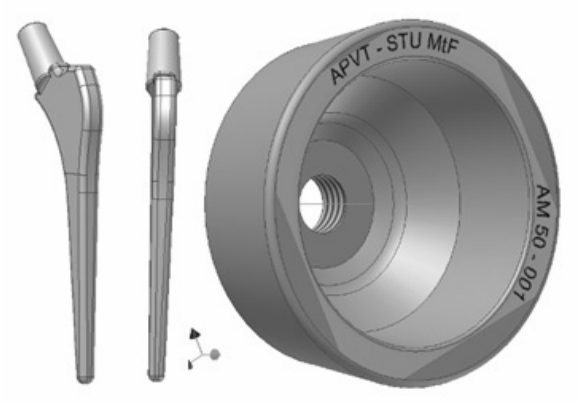

Fig. 12. View of the developed virtual 3D model of the FC and AC, [1,2]

2.5. Strength analysis of the implants

For the strength analysis, the element SOLID186 was utilised. The material of the implant is the alloy Ti64 ELI, which has the following properties: module of elasticity E = 114GPa, Poisson number m = 0, 33, limit of sliding at tension $\sigma_{TENSIL\ E}$ = 830MPa, limit of sliding at pressure $\sigma_{COMPRESSIBL\ E}$ = 860MPa.

Loading: concentrated force in the knot on the axis of the cone-tap in a distance of 40mm from the vertical axis of the implant (Figure 13). The magnitude of the static force is equal to the quintuple of the average weight of a human: F = 5.m.g = 5.(80kg).(9, 81ms^{-2}) = 4170N.

Border conditions: the surfaces of the implant, inserted into the bone have no degree of freedom.

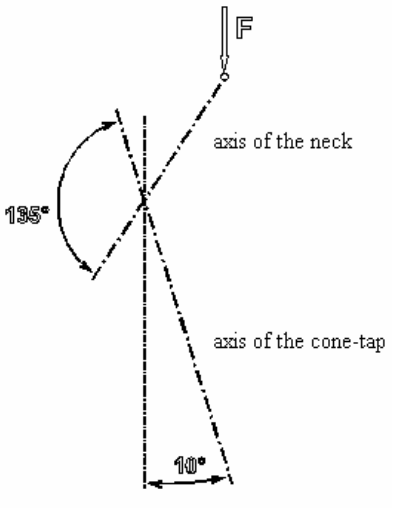

Fig. 13. Loading scheme of the implant model

The developed TEP should serve in the human skeleton during a supposed period of 15 to 20 years. Therefore, the FC has to be tested also by a strength-toughness analysis. For this purpose, we prepared two different FC, Figure 14a and 14b. We

introduce the results of the strength-toughness analysis only very briefly. On Figure 13, there is shown the standard loading scheme of the FC by a force F. On Figure 14a, there is shown the induced strength in the FC tailored to the measures of the patient. On Figure 14b, is the same, but in an FC of anatomic type. In both cases, there was very carefully elaborated the design of the corresponding FC-s.

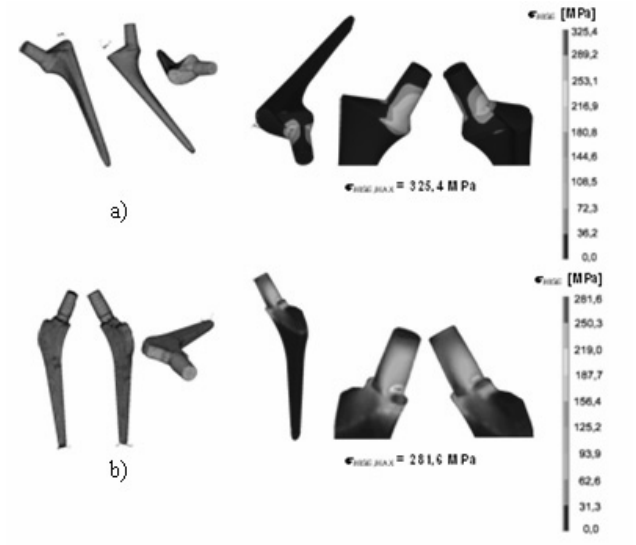

Fig. 14. Computationally analysis - Stronghold of analysis [3]

Maximal values of the reduced Misses tensions are lower as the limit of sliding of the material, therefore, the strain of the joint-replacements remains in the elastic area [3,4,5,6].

$$\sigma_{COMPRESSIBL\,E} = 860\ MPa \quad . << \quad \sigma_{MISE,MAX} = 325{,}4$$

From the Figures 14a, b, can be concluded that, the $\sigma_{MISE,MAX}$ during the straining of the FC, will be evoked in the place, where the cone passes into the shoulder of the FC. Such state can be further reduced, when in this transition there would be realised the greatest possible radius. This strength-toughness analysis has to be verified also by a weariness test of cycle load fatigue.

2.7. Metallographic evaluation of the structural properties of the utilised alloy Ti64 ELI

For the preparation of the developed TEP for implantation, there was used exclusively the certified alloy Ti64 ELI. Very briefly, we introduce the metallographic analysis of the utilised alloy.

Experiences from our previous experiments, confirmed clearly the very decisive influence of the micro-structural aggregate of the titanium alloy on the resulting mechanical characteristics [6,7,8,9,10]. It was proven that, the determining criterion is the share and morphology of the co-existing α, α´ and β phases, while the critical structural formation was not always the martensitic α´ phase, but mainly the location of the α phase, segregated along the borders of the primary grains of the β phase, due to insufficient rapidity of cooling, Figure 15 .

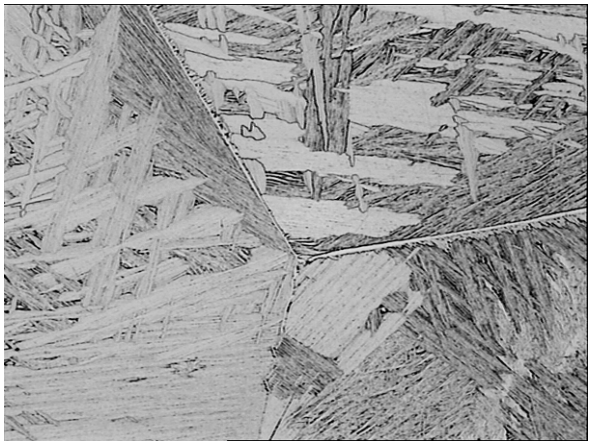

Fig. 15. Microstructure of a cast, after melting the Ti64 alloy in a v plasma furnace [1,2,6,9]

During the traditional way of manufacturing the half-products from the titanium alloys for demanding applications (casting and rolling of the hot material), there is created a relatively homogeneous microstructure, which eliminates the unfavourable influence of the primary crystallisation and the following phase transformation, Figure 16. The technology proposed by us – of casting the TEP in a plasma furnace, into a copper crystalliser – creates a complex crystallisation and transformation processes, which proceed in a short time interval (approximately 30 to 60 sec) and which modify significantly the microstructure into a thermo-dynamically non-steady state, created mainly by an ordered lamellar structure with a typical crystallographic orientation α´ and β phases, Figure 17.

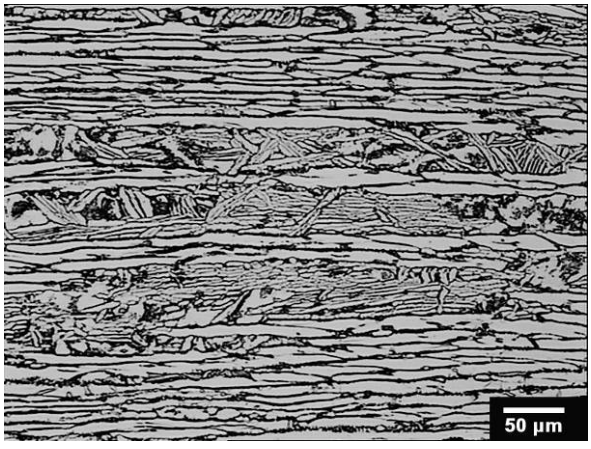

Fig. 16. Microstructure of rolling shaped component of certified alloy Ti64 [1,2,6,7,8]

From this reason, it was necessary to introduce a supplementary heat processing, which assured a high homogeneity of structure and which simultaneously lowered the

value of internal strains in the cast. For these purposes, the method HIP was utilised, which assures also that, in the cast, during the heat processing, there is achieved also elimination of possible porousnes, as well as the method of thermocyclic processing (Figure 18).

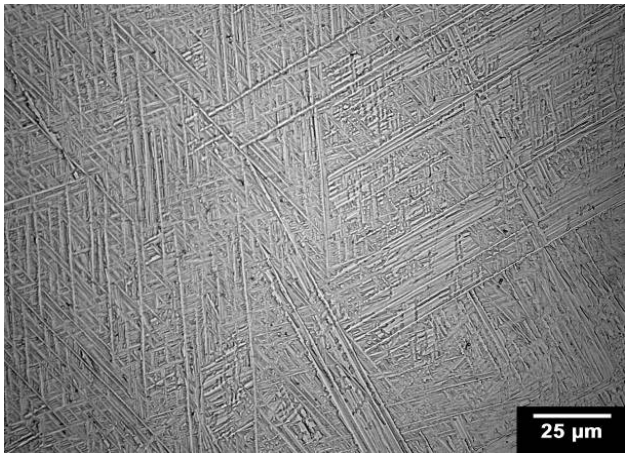

Fig. 17. Microstructure of a cast of the Ti64 alloy, into a copper crystalliser [1,2,6,9]

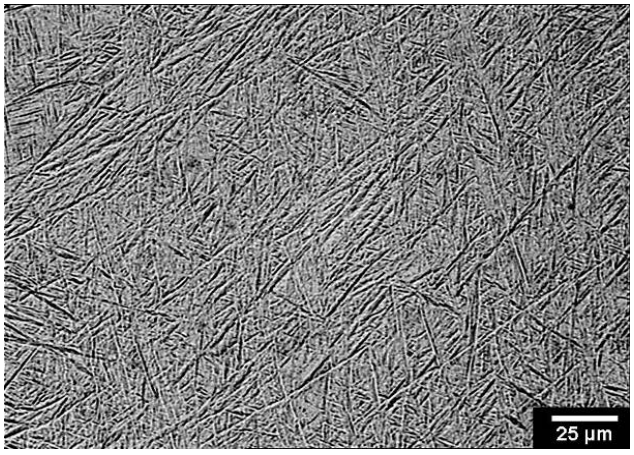

Fig. 18. Microstructure of a cast from the Ti64 alloy, after the heat processing [1,2,6,10]

3. Conclusions

This paper presents some of the results achieved during the scientific research activities, performed on two Slovak universities. These activities concerned the development of a TEP at conditions available in the Slovak republic, but with quality properties reaching the European and World-wide standard. The achieved results in the shown (but also in the still not shown) extent confirm that, they were achieved in a quite original solution. The developed TEP is being patented in the Slovak and Czech republics, in the EU and in USA. The developed TEP has a fully Slovak provenience.

Acknowledgements

The described activities were supported by VEGA, Ministry of Education of the Slovak republic and by the Slovak Academy of Sciences, under the contract No. 1/108/04No. Prof. Dr. Ing. Marcel Žitňanský, DrSc, was the responsible leader of the research team.

The research was supported particularly by the Science and Technology Assistance Agency, under the contract No. APVT-20-050702. Prof. Dr. Ing. Marcel Žitňanský, DrSc, was the responsible leader also of this research.

References

[1] M. Žitňanský, Contract, No. 1/108/04No, VEGA, Office of Education, SR.
[2] Contract, No. APVT-20-050702, Government, SR.
[3] ANSYS 10.0 - Theory Manual, SAS IP, 2005.
[4] http://www.matweb.com/index.asp?ckck=1
[5] M. Kutz, Standard Handbook of Biomedical Engineering and Design, McGraw-Hill, 2003.
[6] M. Žitňanský, L. Caplovic, Research and development of titanium alloy for implants, Office of Education, SR, VEGA, 1/1081/04-06.
[7] M. Žitňanský, M. Marek, I. Schindler, L. Caplovic, The influence of rolling parameter of Ti 6Al 4V alloy on notch toughness. Forming (2002), International Scientific Conference, Plasticity of materials Luhacovice (2002) 339-344.
[8] M. Žitňanský, M. Kursa, L. Caplovic, Influence of melting by plasma treatment on microstructure of Ti6AI4V, Tytan and its alloys, Czestochowa 12 (2002) 211-220.
[9] M. Žitňanský, L. Caplovic, Effect of the thermomechanical treatment on the structure of titanium alloy Ti6AI4V, Journal of Materials Processing Technology 157-158 (2004) 643-649.
[10] M. Jr. Donachi, Titanium. A technical guide, ASM International, The Materials Information Society, 225.
[11] D.M. Brunette, P. Tengvall, M. Textor, P. Thomse, Titanium in Medicine. Springer-Verlag, Berlin, Heidelberg, (2001).
[12] B.D. Ratner, A.S. Hoffman, F. J. Schoen, I.E. Lemons, Biomaterials Science, Elsevier Academia Press, California - London, (2004).
[13] M. Long, H. I. Rack, Titanium alloys in total joint replacement – a materials science perspective, Biomaterials 19 (1998) 1621-1639.
[14] W. Kajzer, M. Kaczmarek, J. Marciniak, Biomechanical analisis of stent –oesophagus system Journal of Materials Processing Technology 162–163 (2005) 209-214.
[15] M. Žitňanský, L. Caplovic, M. Greger, The influence of rolling on the structure of Ti 6Al 4V, Proceedings of the 10th Scientific International Conference, "Achievements in Mechanical and Materials Engineering" AMME'2002, Gliwice – Zakopane, 2002, 631-636.
[16] W.M. Smith, Surface Materials Processing, Backmann Verlag, Berlin–London–Paris–Warsaw, 2006.