Medical implants by using RP and investment casting technologies

***Milan Horáček, Ondřej Charvát, Tomáš Pavelka, Josef Sedlák, Martin Madaj, Jindřich Nejedlý, and Jan Dvořáček**

(Faculty of Mechanical Engineering, Institute of Manufacturing Technology- Department of Foundry Engineering, Brno University of Technology, Technická 2896/2, 616 69 Brno, Czech Republic)

Abstract: The paper deals with the production technology of knee joint replacement by using rapid prototyping technology. The aim of the work is to outline the manufacturing technology intended for prototype production with the use of rapid prototyping and investment casting technology for use in orthopaedics and the surgery of knee joint replacement. The research results should make an effective contribution in the attempts to minimize the invasive surgical procedure, shorten the production of knee joint replacement as well as reduce the cost. At present, the research is focused on the preparation of STL data from CT (Computed Tomography) and verification of the production technology of prototypes made using available RP technology and its evaluation.

Key words: rapid prototyping; investment casting; knee joint replacement; computed tomography

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Rapid Prototyping (RP) technology is a procedure of direct prototype production by means of the gradual addition of individual material layers. The procedure, based on data of CAD (Computer Aided Design) file, is relatively known nowadays.

Rapid prototyping is basically used for the production of prototypes and patterns as soon as possible. The production of prototypes and patterns using classical technologies is very demanding and time-consuming [1].

Improving the quality of patient care, saving time spent by the patient in treatment, and the prevention of possible complications is a current trend in modern medicine. It is important that the patient is treated as soon as possible and that he undergoes necessary examinations and avoided interventions in so far as possible [2]. The production of total knee joint replacements seems to be a very interesting area for the RP methods application. In principle, a total knee joint replacement is a replacement of a diseased joint by a suitable implant. Nowadays around 800,000 knee joint replacements are implanted per year. Current replacements are designed with respect to human anatomy. In gennenal, each individual has a unique knee shape. So the objective should be to adapt the knee joint replacement to the original shape of the particular patient as much as possible. It is possible to produce a specific type of knee joint replacement using data gained from CT or MRI (Magnetic Resonance Imaging) [2].

***Milan Horáček**

Male, born in 1948, Ph.D, Prof. Over the past 30 years he has worked in the field of metallurgy and foundry technology at the Brno University of Technology. His research interests mainly focus on thermo-physical properties of sand mixtures (1970–1974), gating systems for grey iron castings (1974–1980), problems of hot spots solidification (1980-1985), filtration of foundry alloys in ceramic shells (1985–1990), TQM in foundries (1990–1995), and investment casting technology and RP (after 1996). He has published 90 papers at the international and domestic conferences, 25 articles in foundry periodicals, and 8 student text books. During 1978–1990 he served as the Scientific Secretary of Czech Foundrymen Society, since 1992 Vice-President of the CFS, since 1995 Vice-Chairman of the Czech Investment Casting Association. He has been a member of the executive committee of WFO (World Foundry Organization) since 2002, president in 2009.

E-mail: milan.horacek@iol.cz

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1 Problems of a total knee joint replacement

The problems of RP methods in the foundry industry have been researched at the Faculty of Mechanical Engineering, Brno University of Technology in the last two years. From the partial experiments and measurements various questions have been raised. An application of combined RP technologies and precision casting for the production of prototype parts has been an issue in several foundries in particular. The following question arose in relation to that: How best to benefit from promising results of RP methods in their application in the foundry industry; and which foundry product in particular could benefit most significantly from the specific know-how gained up to now? It has been determined that it could be the production of knee joint replacements; and possibly other implants.

2 Knee joint anatomy

A knee ranks among the most complex joints in the body. Joint areas of three bones are in contact here; the femur, tibia, and patella. The femur transfers the body weight through the knee joint to the tibia. Large muscles (quadriceps) running on the femur's anterior side straighten the knee (extension). Large muscles on the femur's posterior side (hamstrings) bend the knee (flexion). The patella acts as a lever for the quadriceps, increasing their effect. Areas of the tibia and femur glide on each other during the movement in the joint. The patella moves up and down in the groove on the femur's anterior area. Front and side X-ray images of a healthy knee are shown in Fig. 1. The space between the joint cartilages is called the joint cleft [3].

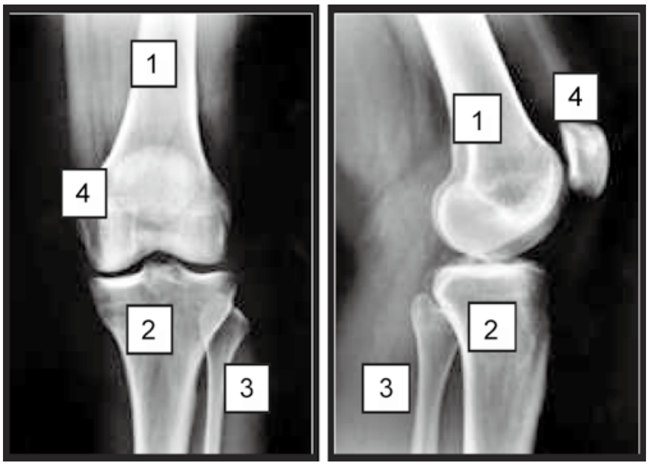

Fig. 1: X-ray images of a knee joint in the front (left) and side (right) views
(1-femur, 2-tibia, 3-fibula, 4-patella)

There are quite a number of causes that can result in knee joint disease. After all conservative treatment (physiotherapy, bandage treatment, baths, and analgesics or anti-inflammatory drugs) has been exhausted; the implantation of an artificial knee joint – also called a total knee joint replacement – helps to improve the patient's quality of life significantly (the mobility restoration, the pain relief) [4].

3 Total knee joint replacement

Specially treated components (prostheses), produced from biologically compatible metal and plastic materials of a high strength, are used for the total knee joint replacement. Cobalt, chromium, and molybdenum alloys are the metals used most frequently. Plastic materials are made from a high-molecular polyethylene. Total implants have been used for around 30 years and the body's tolerance to them has been very good. High requirements are imposed on the components' production, their surface must have identical properties all the time and it must be smooth and glossy [3].

Only damaged areas of the joint, not the entire knee, are replaced in a total knee replacement in modern medicine. In principle, the surgery lies in the replacement of the joint surface and joint cartilage only. Just a small part of the bone is removed; original ligaments, tendons and muscles are retained and re-fixed. Various axial deviations (bandy or knock knees) can be corrected by a correct bone trimming, osteophytes can be removed, and ligament lengths can be adjusted during the surgery. Front and side knee views after the total knee joint replacement are shown in Fig. 2. Polyethylene is used to fill to the joint cleft [3].

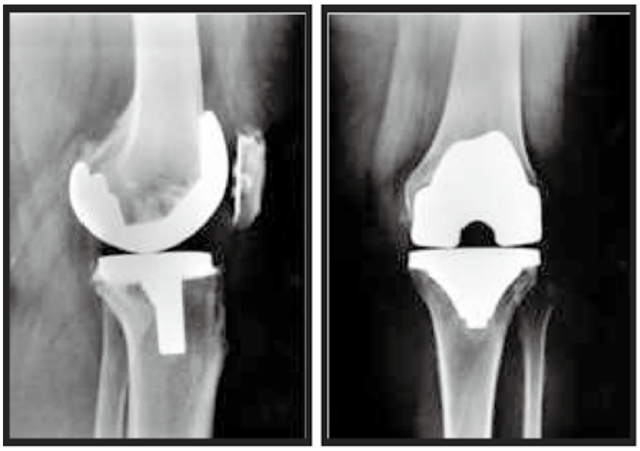

Fig. 2: X-ray images of an implanted knee joint replacement in the side (left) and front (right) views

The metal femoral component is the same size and shape as the femur end. The tibial component placed on the apex of the tibia has a metal base but the upper surface is always made from polyethylene. Part of the patella surface may be cut off and also be covered by polyethylene. Configuration of the joint replacement is shown in Fig. 3.

Fig. 3: Examples of joint replacement configurations

Components are frequently fixed to the bone by a special substance (polymethacrylate), a so-called "bone cement". Alternatively some components have a porous surface into which the bone can grow [3].

There is a wide range of models produced in different sizes for all prostheses types. The bone shape, the weight, the physical activity of the patient and the surgeon's experience and philosophy determine the selection of the prostheses[4].

4 CT imaging technology

For the uninitiated, a CT image does not differ from a common X-ray image. Tissues inside a body are visible in both of them. Hard tissues (bones, cartilages) are displayed in white and light grey colours in images. Softer tissues (muscles, brain) are of a grey up to dark grey colour. Spaces (lungs, bowels or ventricles) are almost black. The tissues on both X-ray and CT images have the same colour scheme, because the computed tomography method uses X-ray as its base.

The problem of making the 3D model from the CT image has not yet been finalised. It is still being studied by experts, research teams, and companies. It is due to the complexity of a human body, which contains many structures of irregular shapes and sizes that are often positioned differently, and to the presence of foreign bodies (fillings, implants) at scans. The principle of making a 3D model from the CT data is outlined in Fig. 4 [5].

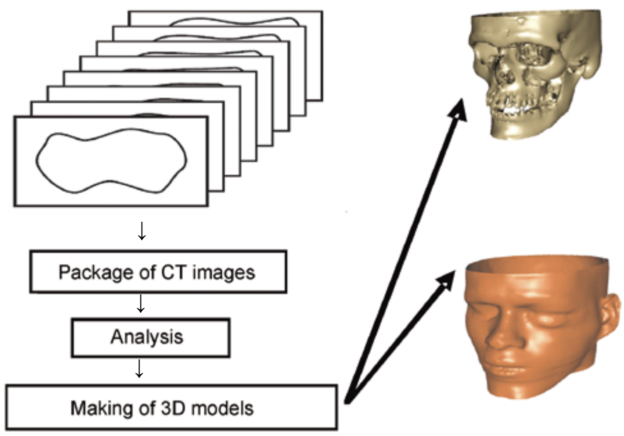

Fig. 4: CT data conversion

5 Materials for the production of implants

Metals absolutely prevail as the initial materials for the production of implants at present. This is the case, even though the research has been looking for an optimum use of composites and plastics in implants production for decades already. These substances have not been used widely except for the use of polyethylene as an articular insert. Of the non-metallic materials only ceramics are being used in the day-to-day work, e.g. hip implant heads (however even this material is not yet predominant)[6].

The implant materials of all three world producers are derived from three basic metals: iron, cobalt and titanium in the form of alloys that have the necessary mechanical and anticorrosive properties. The most widely used alloys are chromium-nickel austenitic corrosion resisting steels, a chromium-molybdenum alloy of cobalt and an aluminium-vanadium alloy of titanium. These metals predominate, and they will continue to do so as the material base for artificial joints from most producers for a long time.

Of the many viewpoints that are applied during the selection of a metal material for an implant, the biological compatibility aspect is being stressed more and more. If we assess the biological compatibility pursuant to the behaviour of the bone tissue to the implant material, we can classify the known materials roughly into three groups listed in the Table 1[6].

Table 1: Bio-properties of material

Bio - property	Metals	Ceramics, plastics
Biological tolerance	Corrosion resisting steel Cobalt alloy CoCrMo	Polymethyl methacrylate (cement)
Biologically inert	Titanium Ti - alloy	Carbon, Al-oxide, zirconium-oxide and Ti-oxide, TiN, Si3N4
Biologically active		Bio glass, bio ceramic

The biological compatibility is a property that is verified at the implant surface and live tissue interface. That is why the zone of interface between an implant and surrounding tissues is the most important place for determining the biological reaction to the implant and reaction of the implant material to the body's environment. The metal material does not directly make this interface all the time. Its surface is treated in various ways. Only some biologically inert and non-biologically active materials can be used for the production of implants so these chemical compounds must be coated onto the implant surface. That is the reason why so much research is being carried out all over the world to investigate how coatings of various layers influencing the parent base metal quality of the piece [6].

6 Proposal of a new approach to problems in the area of foundry industry

There are several companies producing knee joint replacements using titanium alloys in the Czech market. This production is mainly carried out by machining. During the machining there are up to 80% material losses. Cobalt alloys are used more in the area of knee joint replacements production in the foundry industry at present. A very strict certification regarding the material quality causes problems to foundries.

Joint replacements are produced in 6 sizes, for the left and right knee joint separately. Producers are trying to satisfy each individual patient's needs at a surgery.

The research activities of the foundry engineering branch at the Brno University of Technology focus on finding a metal implant for a knee joint replacement designed for a particular patient. The knee joint replacement will be adapted to each patient individualy. The data for the production of such an original would be based on the CT data of the patient.

7 Detailed analyses of individual stages

We have commenced a close cooperation with the Faculty of Information Technologies at the Brno University of Technology. They have been engaged in the editing of CT and MRI data and 3D model creating for a long time (3D model of knee joint is shown in Fig. 5). 3D data acquired in this way should facilitate an essentially different view of using RP technologies in the construction of knee joint replacements.

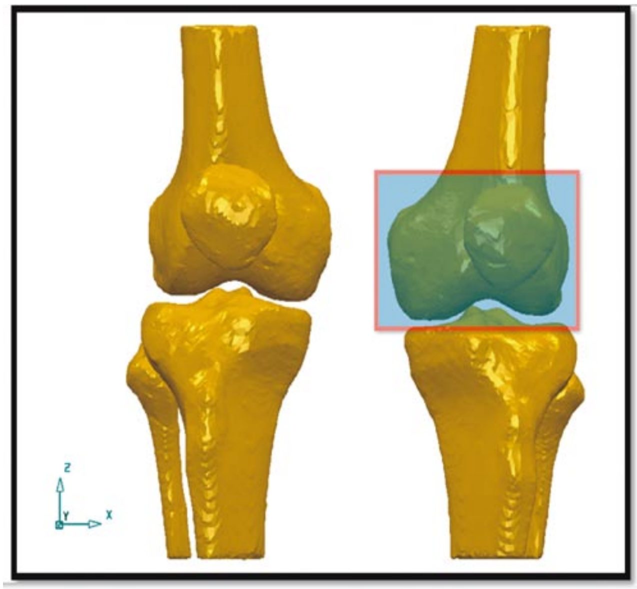

Fig. 5: 3D data of knee joint

The aim is to make a new of femoral part for a knee joint replacement, mainly in terms of creating an STL file of knee joint replacements. It should preserve partially the shape of a total knee joint replacement of the SVL type produced by Beznoska Company (Fig. 6) as standard; and get a new surface shape particularly in the area of contact of the femoral part of the implant with an affected bone. It especially concerns cases when the bone is damaged due to a car accident or a tumour (an oncogenous disease). This part should be adjusted according to the specific shape of the femur end depending on a CT image of the particular patient.

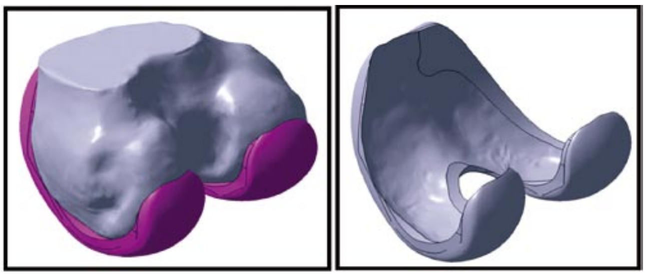

Fig. 6: Reconstructed STL model of knee joint replacement (SVL Beznoska)

The 3D file (STL) made and edited in this way is used for the production of the ABS pattern by applying the FDM (Fused Deposition Modelling) method. The use of this semi-finished product is double. Firstly, it is possible to use this pattern directly for the precision casting technology. Basically, it is a wax pattern replacement. A risk of the ABS pattern or the subsequent shell mould being destroyed is a disadvantage because it is necessary to reprint the ABS pattern, which prolongs the production process and makes it more expensive. Secondly, by using the ABS patterns it is possible to make a silicon mould and with it cast the wax patterns in the vacuum chamber. An ABS model is shown in Fig. 7. Precision casting technology is applied hereafter. We get a knee joint replacement from the required biologically compatible material after casting in both cases. A subsequent verification, measurement and financial evaluation should help to find out whether this method of knee joint replacement production is feasible.

Fig. 7: Printed ABS model of knee joint replacement (left) and silicon mould (right)

The technology of wax pattern production using a silicon mould and an ABS pattern will be verified also for other artificial replacements besides a total knee joint replacement, with respect to the very strict requirements concerning the use of new technologies in medicine. Patterns produced in foundries as a standard will be tested to get data characterizing the quality of production as precise as possible. Very promising results have been achieved in this area in the Institute of Manufacturing Technology (Department of Foundry Technology) from the point of view of dimensional accuracy of the wax patterns (prototype shown in Fig. 8) [8].

Fig. 8: Prototype of wax pattern for investment casting technology

Some castings or wax patterns made using a Reverse Engineering method will be digitalized as a loop check of total changes, not only in dimensions but also in shapes. The above-mentioned technology will also be applied in the production of other replacements, e.g. an acetabulum. This problem (the issue of shape and fixing the implant to the bone) is being solved in cooperation with St. Ann's Hospital at present.

Figure 9 show the Prototype of a new metal knee joint replacement.

Fig. 9: Prototype of a new metal knee joint replacement

8 Conclusions

The main effort of the work was to produce a total knee joint replacement using a different approach to the usual one. This research was based on real CT data of the patient. Thanks to the CT data it is possible to make a new implant more suitable for the patient. If the mechanical and material properties of the replacement part are comparable with a replacement produced using standard technologies then the total knee replacement can be produced. It could also provide advantageous financial conditions.

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