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DESIGN AND MANUFACTURING OF THE HUMAN BONE ENDOPROSTHESES USING COMPUTER-AIDED SYSTEMS

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Basing on the results obtained previously, the authors present both research and application issues of modern computer-aided design and manufacturing of human bone replacements (endoprostheses). The first stage of the procedure consists in identifying the geometry (dimensions, shapes) and material (composition of the tissue, i.e. cortical and cancellous bone fractions) of the elements of human bone to be replaced with implants. For this purpose, the X-ray Computerized Tomography (CT) and Coordinate Measuring Machine (CMM) are used. In the second stage by means of a Computer-Aided Design (CAD) system, a geometrical model of the bone under consideration is constructed, representing both external and internal (marrow cavity) shapes and areas of cortical and cancellous bones. At this stage it is possible to change the shape of the endoprosthesis to fit exactly the patient's anatomic features. Also, the strength can be estimated, using the Finite Element Method package included in the Computer-Aided Engineering (CAE) system, and the system can be modified if necessary. At the third stage, using the Computer-Aided Manufacturing (CAM) system, the technological process is designed and then the endoprosthesis, e.g. using a Computer Numerical Controlled (CNC) machine, is manufactured.

Key words: endoprosthesis, computer aided design of implants, custom-design, geometrical modelling of bones

1. Introduction

Nowadays, one of the most effective medical treatment procedures performed in order to restore movement in joints damaged due to congenital defects illness, traffic accident etc., is implanting either artificial joints or their elements; i.e. the so-called alloplasty.

The most popular is the hip replacement operation. According to different sources data, the total number of such operations performed world wide has been estimated at between 800 000 and 1 200 000 per year (Huiskes, 1988), not to mention other replacements, e.g. the radial bone head, elbow joint, knee joint, finger joints, etc. In Poland the number of hip replacements ranges about 17 thousand per year, though this is estimated as covering only about 50% of what is required.

Such treatment is quite expensive, even according to the standards of so-called developed nations. The cost of surgery becomes much higher if the operation has to be repeated because of a bad-quality junction between the implant and the bone, resulting usually from a bad selection of implant or a badly performed operation. This is why the main effort of many research centres is concentrated on the improvement of the whole treatment process and on reducing its cost.

Considerable progress has been made recently in the field of orthopaedic engineering, due to the application of up-to-date computer-assisted methods of measuring (such as CT (cf Fager and Peddanarappagani, 1993; Harris, 1993; Strong et al., 1990; Woolson et al., 1989), CMM (cf Pfeifer and Hemdt, 1990), designing (CAD) (cf McDonald et al., 1989; Saito et al., 1995; Werner et al., 1998), stress analysis (CAE) (cf Kang et al., 1993; Keyak and Skinner, 1992; Rubin et al., 1993) and manufacturing (CAM) (cf Elber and Cohen, 1996; Werner et al., 1998).

This work aims at presenting a general approach to a modern computer-aided design and manufacturing process of human bone replacements developed recently at our group.

2. Procedure of bone implants designing and manufacturing

In most cases the endoprostheses of standard sizes are designed and manufactured by well-known producers. However, there is a group of patients who show individual, unique anatomic features or whose bones are subjected to serious pathological changes. Such patients need custom designed implants (cf Huo, 1993; Werner et al., 1997).

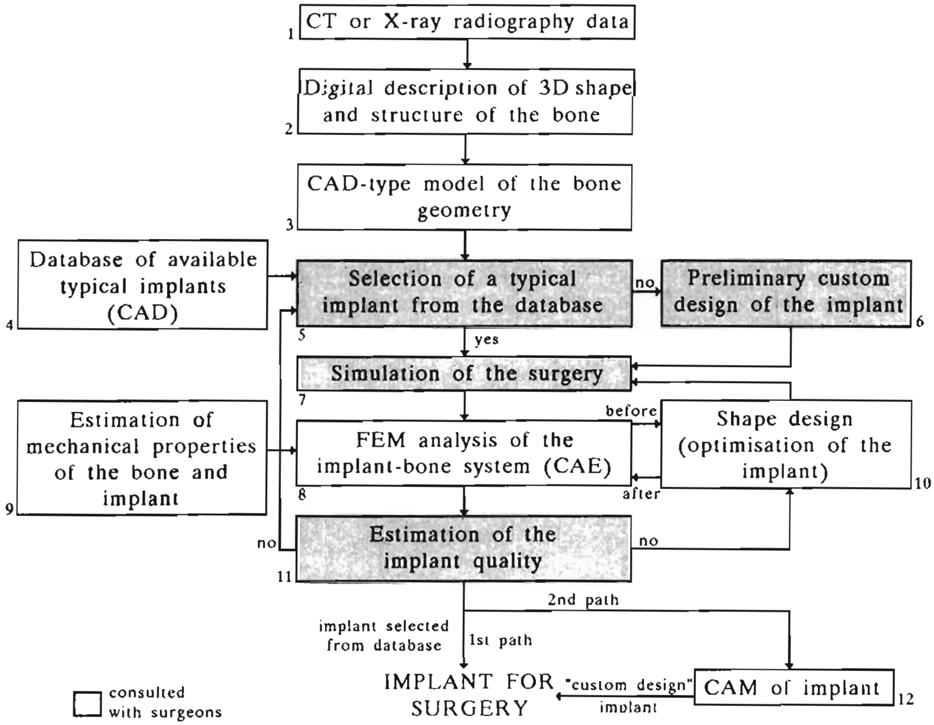


Fig. 1. Flowchart of the computer-aided process of endoprosthesis design and manufacturing

The flow diagram shown in Fig.1 presents the modern bone replacement procedure. It includes the following main steps:

1. In the first step identification of the bone shape is performed. Precise measurement of geometrical parameters is the most difficult problem arising in 3D bone modelling. Currently, two alternative methods of data collection for construction of the geometric database can be applied. In the first one typical X-ray images are used, while the second is based on the Computerized Tomography (CT). The X-ray images, however, are useful only in collecting geometric data for one or just a few cross-sections of a given bone and such information is inadequate for a good quality 3D reproduction of the bone shape. The CT is much more effective tool because of its specific features:
   - acceptably small differences between CT images and the real object
   - elimination of the analog-to-digital conversion because the CT images have a digital form

- possibility of estimating the mechanical properties of the bone on the basis of CT image parameters corresponding to the given bone density.

2. In the next step the digital description of the object based on CT technique is formulated. This digital description forms the input database for the CAD system.
3. After the database generation the bone geometrical model is constructed using the CAD system.
4. A database of implants available on the market also has to be created. It contains the geometrical and material description of standard commercial implants.
5. In the following step the database of standard implants is selected for the preliminary choice of the implant for a given patient, which matches the previously-identified (block 4) and modelled shape of the bone into which the implant is to be fixed. If the preliminary selection is satisfactory (yes), one may proceed to the next step: simulation of surgery (block 7).
6. If none of the standard implants fits the model of the bone (no), a so-called "custom design" implant should be designed.
7. After typical selection or preliminary custom design of implant computer simulation of the operation to be performed by surgeons opens up the possibility of surgery planning.
8. Before the implant manufacturing (block 12) the Computer-Aided Engineering (CAE) is applied, based on the Finite Element Method analysis of the bone-implant system to determination of the stress and strain distribution for typical loads of the bone-implant system resulting from various patient activities after the surgery. The long-term effects of implantation, such as the functional adaptation of the bone (cf Van Rietbergen et al., 1993), can be also taken into account.
9. Of course, for such an analysis to be carried out, the mechanical properties of both the bone and implant should be defined, as well.
10. From the results of the strength analysis the optimal shape and the material suitable for the designed implant are determined.
11. If estimation of the implant quality, is not satisfactory (no), the steps $5 \div 11$ for the typical implant or, alternatively, the block 10 and block 8 for the design are repeated. Then the two paths can be taken:
    - 1st final selection and acceptance of typical implant

- 2nd final decision of manufacturing of atypical implant (custom design).

12. At the final stage of computer-aided process a "custom design" will be done using a Computer-Aided Manufacturing (CAM) system, which usually means manufacturing on Computer Numerical Control (CNC) machines.

These twelve stages can be seen in Fig.1, and only four of them are shaded, the shading means "in consultation with surgeons".

3. Sample design and manufacturing processes

In order to illustrate the above mentioned steps of implantation procedure some examples are presented below.

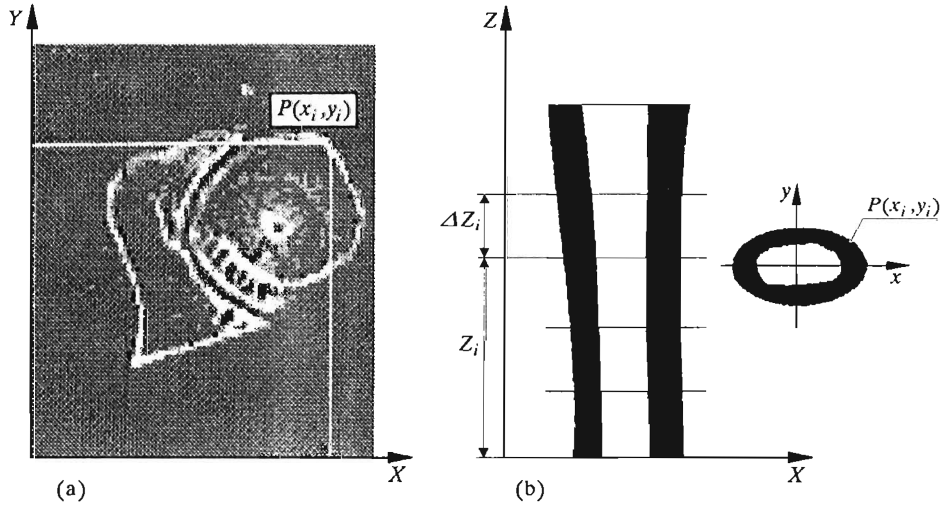


Fig. 2. Scheme of 3D reconstruction based on the CT scans of the bone: (a) 2D CT image of a single scan taken perpendicularly to the long axis Z of the femur, (b) the procedure of reconstruction of the bone shape; X,Y,Z – global and x,y – local coordinates

A typical CT image is presented in Fig.2 (cf Brzeski et al., 1998; Święszkowski et al., 1998; Woolson et al., 1989). Fig.2a shows a CT image of a cross-section through the parts of pelvis and femur head. The idea of 3D reconstruction is shown in Fig.2b. The CT image is composed of the so-called

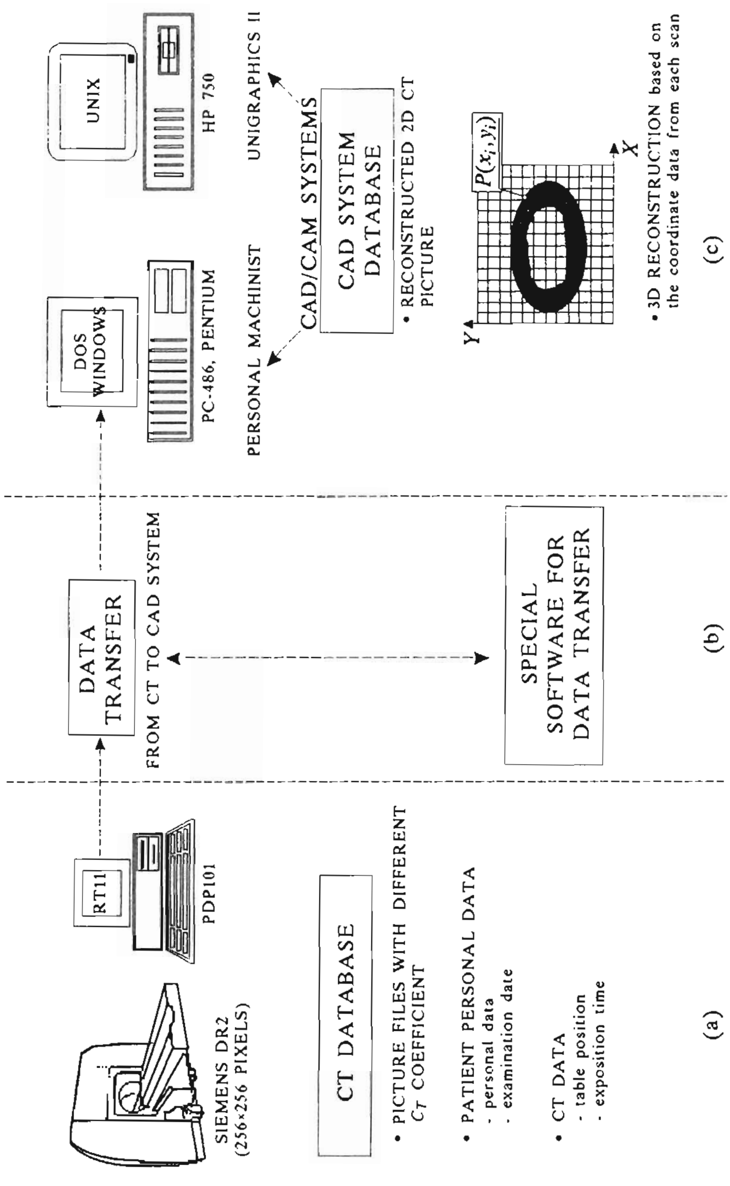


Fig. 3. Scheme of the data format conversion and CT pictures reconstruction: (a) CT database, (b) data transfer, (c) CAD system database

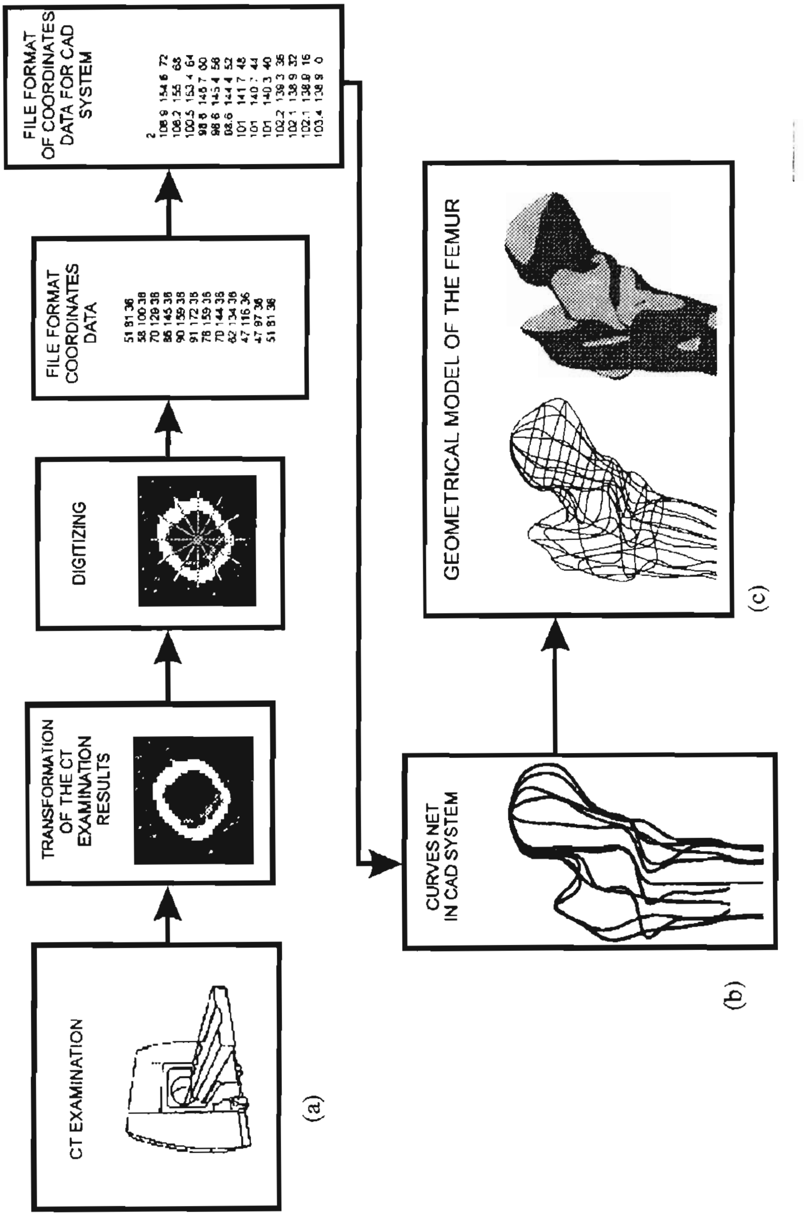


Fig. 4. Scheme of the geometrical modelling of the femur using CT and CAD systems: (a) reconstruction of 2D scans, (b) curves net, (c) geometrical model of the femur

pixels. Typical dimensions (cf Fager and Peddanarappagani, 1993) of each pixel in modern equipment of CT machine are about $0.2\text{mm} \times 0.2\text{mm}$. A typical distance ΔZ between consecutive parallel scans is of 0.5 to 3 mm.

The set of CT scans contains the information on different bone layers (Fig.3a). For further use, the most important part of the data is associated with the 2D scans which have the form of picture files, the so called "bit maps" composed of different X-ray intensity coefficients stored in the computer memory of the CT machine. Unfortunately, due to the format, usually they cannot be used directly as the input data in a typical CAD system. They have to be processed using special software (Fig.3b) for the format adaptation and picture reconstruction applicable to a typical CAD system. In such a way the CAD system database for a given case can be created (Fig.3c). Such specialized software (Image Processing Software) is available nowadays on the market. In our investigations we have used the software developed by the research group from the Institute of Radioelectronics of Warsaw University of Technology. As the platform for the CAD software we use both Personal Computers with Pro-Engineer, Solid Works software and HP Work Stations with Unigraphics software.

Fig.4 shows a typical process of geometrical modelling of a human bone identified "in situ" using the CT (Siemens-Somaton HiQ) and processed by the CAD system. In order to create a 3D picture of the bone, the reconstructed 2D pictures (Fig.4a), in a digital form, have to be transformed to the 3D database suitable for 3D geometric presentation using the curve segments (Fig.4b) in the first approximation, and the surface patches in the final form (Fig.4c). The accuracy of geometric approximation, i.e. dimensional and shape reconstruction based on the CT scans is about ±0.5 mm, if a modern CT equipment is used.

Much more accurate results may be achieved using a computerized Coordinate Measuring Machine (CMM) (Fig.5) (Skalski et al., 1998). The example below presents this method when applied to identification of the geometric properties of the human radial head by using the Koordynator XYZ-VIS machine (Święszkowski et al., 1996). Fig.5a presents the measurement stand for measuring the Cartesian coordinates of technical or biomechanical objects. A stiff frame is fixed to a rigid foundation. The stand is equipped with rotating table, specimen holder, and measuring head with a sensor tip (Fig.5b). The accuracy of the measurement is $\pm 2\mu\text{m}$. This method can be applied only to "in vitro" measurements, and clearly, cannot be combined with the "custom design" technique. But owing to its almost perfect accuracy, the method provides a very good database for identification of dimensions and shapes of a large number of bones, which is necessary for creating of a set of standard endoprostheses.


(a) (b)

Fig. 5. Coordinate Measuring Machine: (a) general view of the stand, (b) radial bone head and the measurement probe

Basing on the CT or CMM measurement results, one can proceed with the geometrical modelling of a bone using the CAD systems (McDonald et al., 1989).

In order to describe the curve segments or surface patches in a form applicable to the CAD systems, special parametric methods are commonly used; e.g., Bežier, B-spine and NURBS (cf Barry et al., 1992; Dietrich et al., 1998, Lin and Hewitt, 1994; Piegl, 1991; Sarkar and Meng, 1991). Graphic representations of these methods are shown in Fig.6. Bežier curves (Fig.6a) are suitable for typical regular shapes such as prosthesis heads. However, this method does not yield good results for complex and irregular shapes. Due to its specific properties the B-spline method (Fig.6b) can be successfully applied to the modelling of complex shapes. The main advantage consists in the fact that the change of one vertex of a control polygon affects only the neighbouring curve area. However, some undesirable distortion can result from the irregularity of interpolation points. The representation of the NURBS method (Non-Uniform Rational B-spline) is shown in Fig.6c. This method appears to be the most effective one for very complex 3D shapes. It can provide a good approximation of the curve in the case of non-uniformly distributed interpolation points (e.a., known from measurements); this feature results from the type of rational functions used in the method.

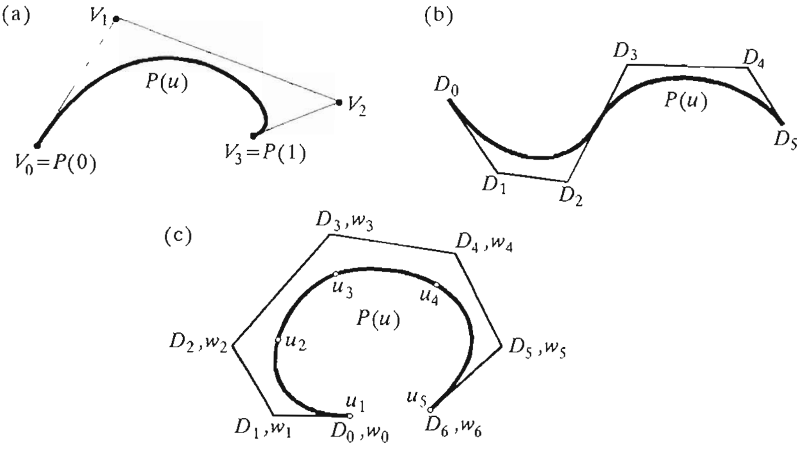


Fig. 6. Curve approximation methods: (a) Bežier, (b) B-spline, (c) NURBS: $P(u)$ – approximation curve, $V_0, V_1, \ldots$; $D_0, D_1, \ldots$ – control points of the approximating polygon; $w_1, w_2, \ldots$ – weights

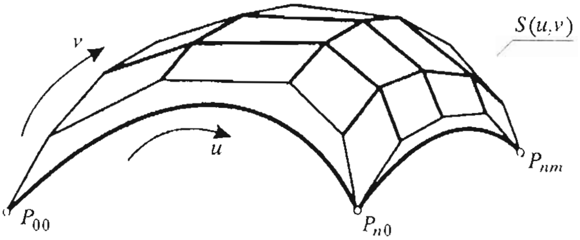


Fig. 7. Geometric interpretation of the two-parameters (u, v) approximation of the surface: $S(u, v)$ – approximating surface; $P_{00}, \ldots, P_{nm}$ – control points

The same rules are applied to the surface definition, but here, the two directions of interpolation have to be taken into account. The geometric interpolation of two parameters (u, v) describing 3D surface is shown in Fig.7. On the base of the NURBS mesh generated in the CAD-Solid Works system surface models of the femur (Fig.4c, Fig.8) have been created (Dietrich et al., 1998). One can notice that the shapes of biological objects are much more complex than those of technical ones. The geometrical models of bones create the input data for the process of endoprosthesis design.

The block diagram of the next step, i.e. Computer-Aided Engineering (CAE), is shown in Fig.9 (Piszczatowski, 1998). The physical model of the bone-implant system under different conditions (Weinans et al., 1992) follo-

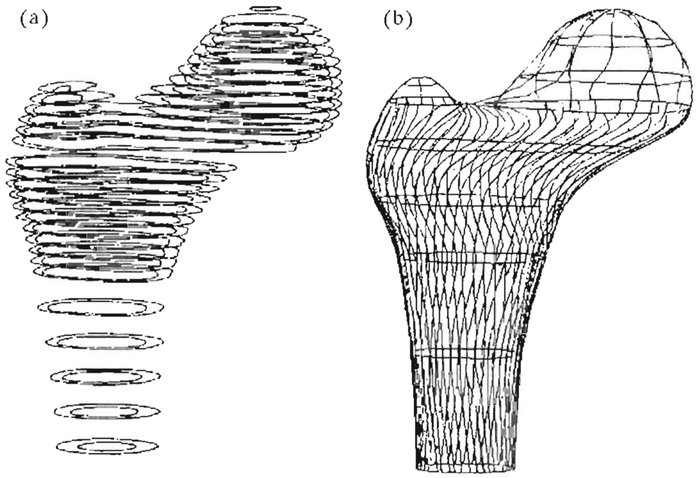


Fig. 8. Geometrical models of the proximal femur

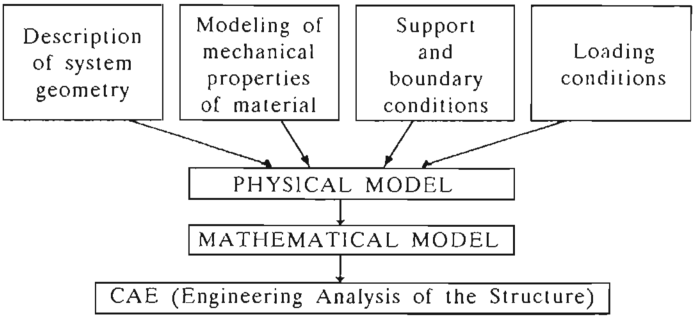
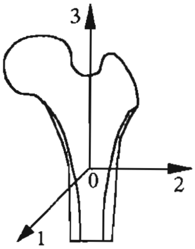


Fig. 9. Block diagram of the CAE

wed by the mathematical one has to be created. This allows the numerical engineering analysis of the system to be carried out.

The geometrical model required for this purpose is already known; it has been generated by the CAD. The material of the implant data are well-known and reliable (Keaveny and Hayes, 1993).

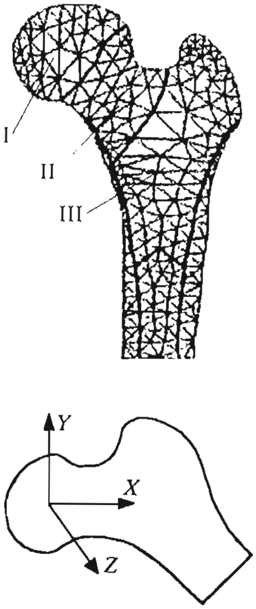
When dealing with bone material, basic properties such as heterogeneity, anisotropy and viscoeleasticy (cf Deligianni et al., 1994; Keaveny and Hayes, 1993; Knets, 1987; Natali and Meroi, 1989) should be taken into account. Fig.10 presents the mechanical properties of the femur cortical bone in terms of: the Young modulus E, Kirchoff modulus G and Poisson ratio η, which are needed for the engineering analysis (cf Knets, 1987; Natali and Meroi, 1989). One can notice the material anisotropy and the wide range of values the parameters take.



	Minimum	Maximum
E_1	6.25 GPa	12.0 GPa
E_2	7.95 GPa	13.4 GPa
E_3	13.14 GPa	20.58 GPa
G_{12}	2.26 GPa	4.53 GPa
G_{13}	3.12 GPa	5.61 GPa
G_{23}	3.28 GPa	6.23 GPa
η_{12}	0.302	0.580
η_{13}	0.092	0.310
η_{23}	0.118	0.310
η_{21}	0.422	0.767
η_{31}	0.306	0.460
η_{32}	0.295	0.460

Fig. 10. Properties of the cortical bone

Fig.11 shows the same parameters for the cancellous bone, revealing the material heterogeneity (Natali and Meroi, 1989).



	Zone	Young modulus E [MPa]	Standard deviation [MPa]
X	I	900	710
	II	616	707
	III	263	170
Y	I	811	604
	II	174	84
	III	317	293
Z	I	403	66
	II	63	7
	III	12	6

Fig. 11. Properties of the cancellous bone

The viscoelastic properties of biological materials are illustrated in Fig.12 for the cortical bone and cartilage, respectively, in terms of a set of so-called creep curves. The creep curve describes the relation between elongation ε (or strain $\bar{\varepsilon}$) and time t (Knets, 1987).

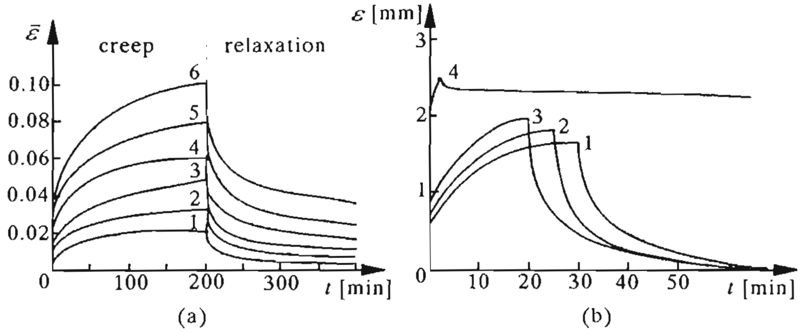


Fig. 12. Creep-relaxation curves for different loads 1,2,3,...: (a) cortical bone, (b) cartilage

One can notice that the time-course of the elongation (or strain) depends on the magnitude of the load applied. This means that the bone-implant system is non-linear and strongly time-dependent, making engineering analysis very complicated.

The time scale is of crucial importance in these investigations. Sasaki et al. (1993) postulated using the following combination of the Debye exponential function with dependent Kirchhoff $G(t)$ and Young $E(t)$ moduli when describing the process of relaxation

$$
\begin{aligned}
\frac{G(t)}{G(0)} &= a_0 \exp\Big[-\Big(\frac{t}{\tau_1}\Big)^{a_1}\Big] + a_2 \exp\Big(-\frac{t}{\tau_2}\Big)\\
\frac{E(t)}{E(0)} &= b_0 \exp\Big[-\Big(\frac{t}{\tau_1}\Big)^{b_1}\Big] + b_2 \exp\Big(-\frac{t}{\tau_2}\Big)
\end{aligned}
\tag{3.1}
$$

where

$G(0), E(0)$ – initial values of moduli

a_i, b_i – constants, $i = 1, 2, 3$

τ_1, τ_2 – relaxation times.

The analysis of relaxation of spongy bone properties on the microstructural scale allows one to associate the increase of Young modulus with the bone density as well as with the rate of elongation using the general model

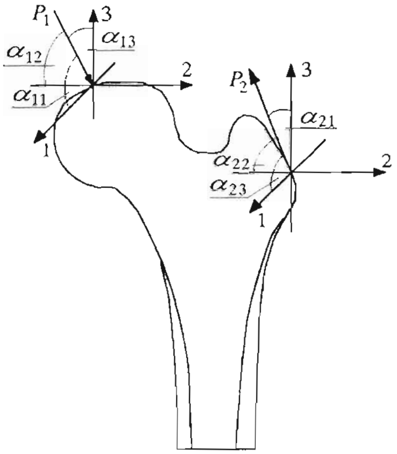
$$
\varDelta E(t) = \alpha\Big[\dot{\varepsilon}(t)\Big]^{\alpha_1}\Big[\rho(t)\Big]^{\alpha_2} \tag{3.2}
$$

where

α_i – constants, $i = 0, 1, 2$

ρ – density.

The appropriate conditions for engineering analysis are available in the literature. Fig.13 presents sample loads acting upon the human femur.



Authors	Activity	P_1 [N]	P_2 [N]	α_{11} [deg]	α_{12} [deg]	α_{13} [deg]	α_{21} [deg]	α_{22} [deg]	α_{23} [deg]
Keyak [12]	standing on one leg	1730	1270	79.67	80.01	15.13	75.87	76.33	20.44
Kang [10]	standing on one leg	1914	1325	-	78	22	-	71	29
Rubin [25]	standing on one leg	1160	-	58.85	69.82	30.45	-	-	-
Rubin [25]	entering step	1450	-	67.71	71.08	32.71	-	-	-

Fig. 13. Typical loads acting on the human femur

Because of its effectiveness, the most popular method of engineering analysis is the Finite Element Method (FEM). Sample ANSYS package applications to the analysis of strain and stress distributions in the bone-implant system (cf Kędzior et al., 1995; Krzesiński, 1995; Skalski et al., 1997), including rheological phenomena (cf Piszczatowski et al., 1998a,b; Piszczatowski, 1998) are presented in Fig.14 and Fig.15.

The process of attenuation of spongy bone relaxation is rapid, taking about 10^2 seconds compared to about 10^4 seconds for the cortical bone. An example percentage increase in stresses, strains and strain energies at characteristic points of the femur-implant system is shown in Fig.15.

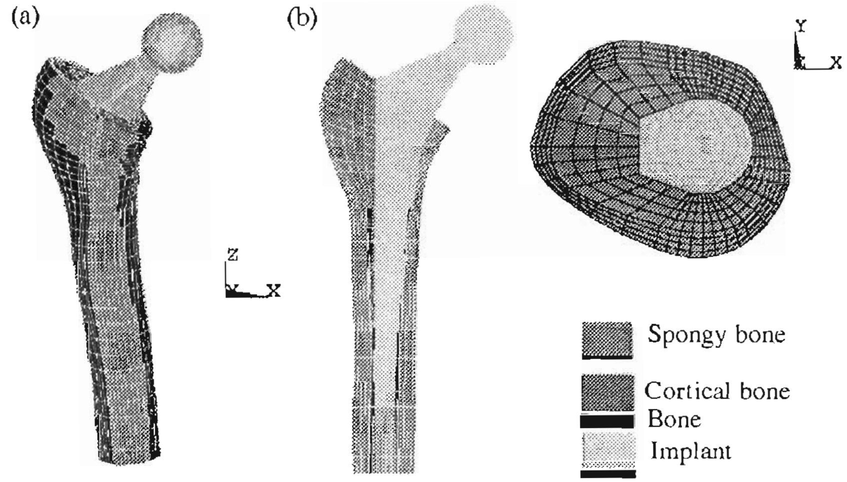


Fig. 14. FEM mesh of the femur-implant system: (a) axonometric view, (b) vertical section along the implant axis, (c) cross section

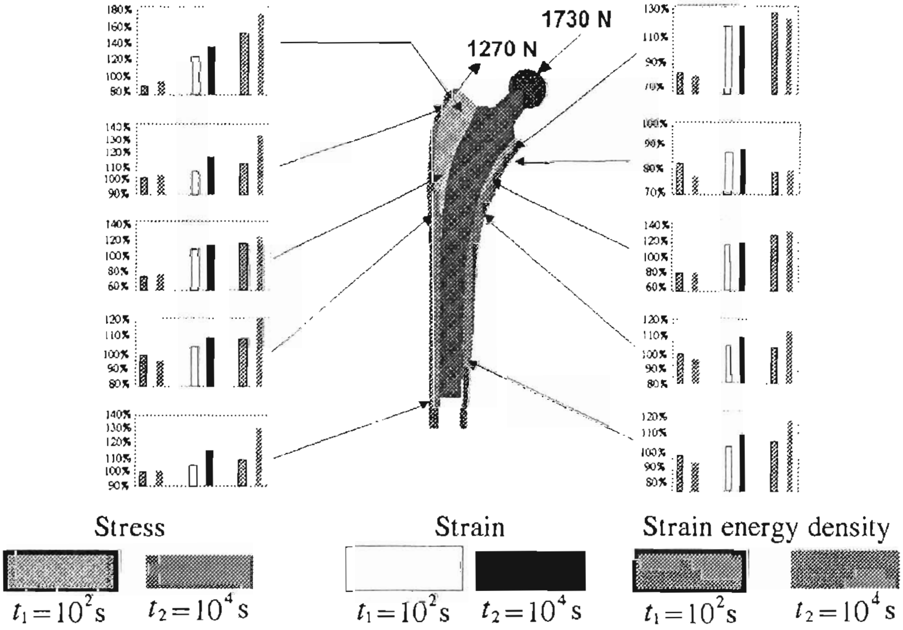


Fig. 15. Percent change of equivalent stresses and strains as well as strain energy density for times of 100 s and 10 000 s in relation to their values at $t_0 = 0$

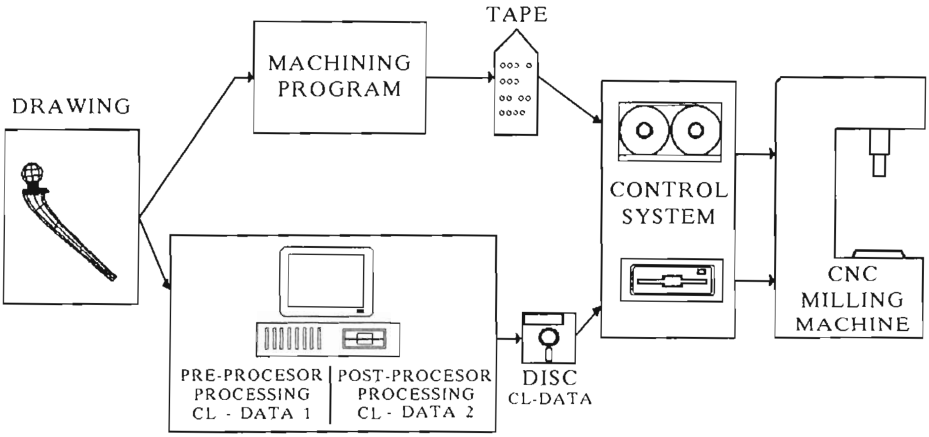


Fig. 16. Scheme of the machining process

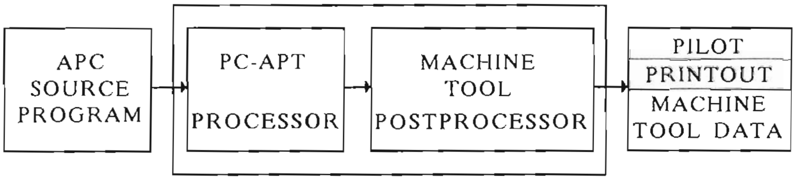


Fig. 17. Concept of the APT Programming

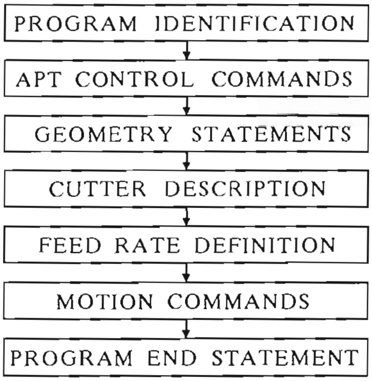


Fig. 18. Typical structure of the APT Source Program

The geometric and material models of the designed and optimised (using the FEM) implant are finally transmitted to the CAM system – the last step of the procedure (Fig.1). In this system the procedure of numerical control of the CNC machine necessary for manufacturing the implant should be created. The idea of the process of implant machining is presented in Fig.16 (Werner, 1996). Due to very complex shapes of the prosthesis the program controlling the CNC machine (FYS-16N), with the error compensation included (Lechniak, 1998), has to be prepared in the PC-APT (Automatic Programm Tool) system, Fig.17. The APT program is completed in the following four (see Fig.18) phases:

- Translation of the APT; programming statements are created
- Calculation of the tool path (Fig.19); the CL (Cutter Location) DATA-1 is created
- Generation of the tool motion; the CL DATA-2 is created
- Post-processor transformation; the both CL DATA sets are processed yielding the set of blocks for the numerical control system of the CNC machine.

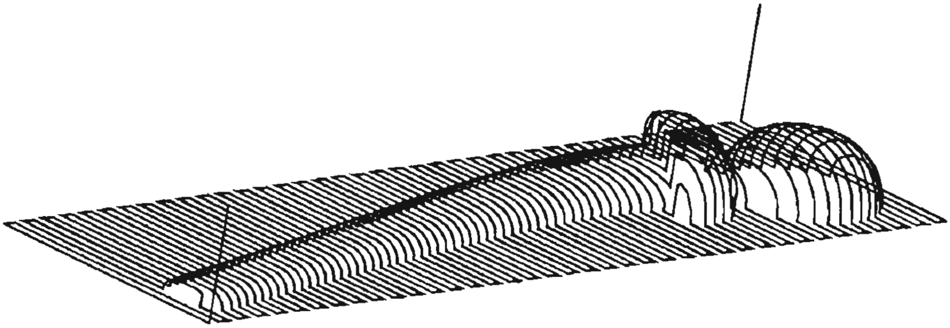


Fig. 19. The toolpath for the femur head endoprosthesis manufacturing

Finally, the integrated CAD/CAM system offers the possibility of creating a program for manufacturing the prosthesis. A sample endoprosthesis manufactured on the CNC milling machine is shown in Fig.20. Machining accuracy can then be measured on the CMM-stand (Fig.21).

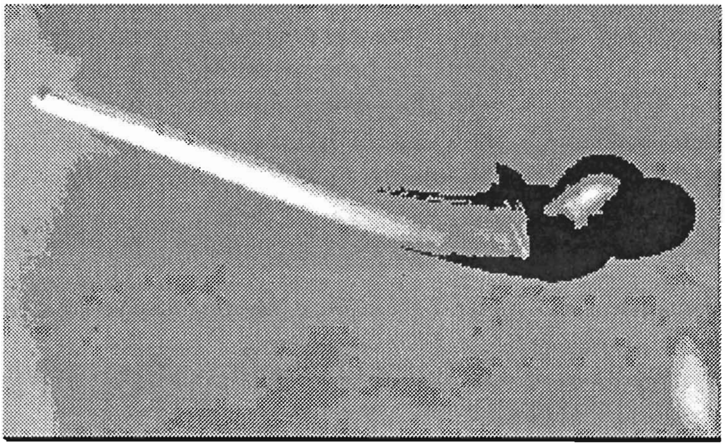


Fig. 20. The endoprosthesis manufactured using the CNC milling machine

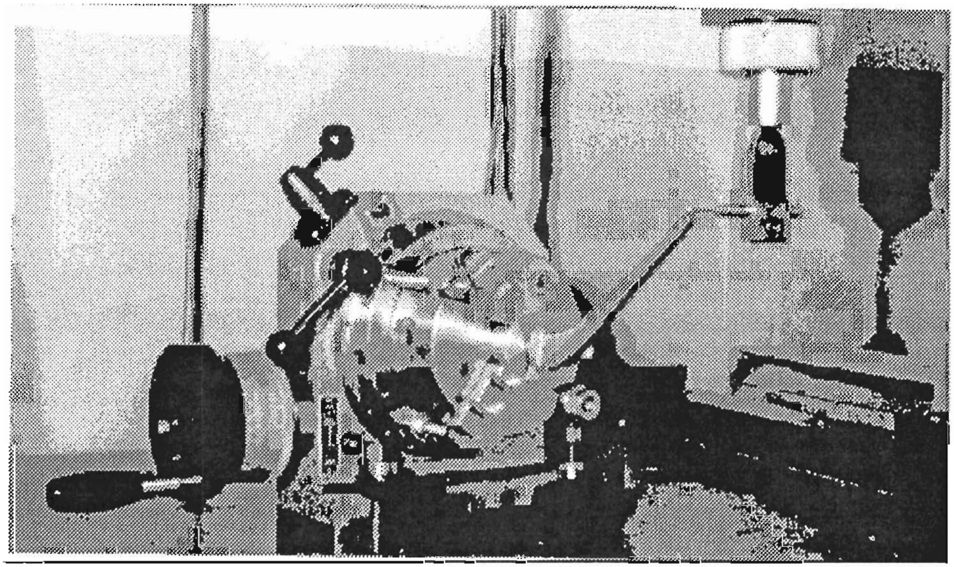


Fig. 21. Measurement of machining accuracy of the endoprosthesis on the CMM

4. Conclusions

The main trends of alloplasty development are directed towards raising the quality of implants (fitting, durability) and reducing the cost of manufacturing. These goals can be achieved by using modern methods of integrating the CT/CMM/CAD/CAE/CAM systems. This means that engineers and technicians supported by modern technology perform a major part of the process of modern alloplasty.

The most important tools used nowadays in this process are:

- The NURBS method of geometrical modelling
- Rheological analysis of the bone-implant system into the design process
- Numerically-controlled machines application to the implants manufacturing.

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Wspomaganie projektowania i wytwarzania endoprotez kości człowieka za pomocą systemów komputerowych

Streszczenie

Na podstawie wyników prac własnych przedstawiono zastosowanie współczesnych inżynierskich systemów komputerowych do wspomagania projektowania i wytwarzania endoprotez elementów kości człowieka.

Pierwszy etap zintegrowanego procesu projektowo-wytwórczego obejmuje identyfikację własności geometrycznych (wymiary, kształt) i materiałowych tych elementów kości człowieka, które na skutek choroby lub uszkodzenia mają być zastąpione implantowaną na ich miejsce endoprotezą. Stosuje się do tego rentgenowską tomografię komputerową (CT) i skomputeryzowane współrzędnościowe maszyny pomiarowe (CMM).

W drugim etapie za pomocą systemu do komputerowo wspomaganego projektowania (CAD) tworzy się model geometryczny powierzchni zewnętrznej i wewnętrznej (jamy szpikowej) zidentyfikowanej w poprzednim etapie kości. Ten etap obejmuje także dobór typowej (spośród dostępnych na rynku implantów) lub zaprojektowanie indywidualnej, anatomicznie dopasowanej endoprotezy. Drugi przypadek dotyczy pacjentów o nietypowych, np. ze względu na zaawansowane zmiany chorobowe, własnościach geometrycznych kości. Następnym krokiem w tym etapie jest komputerowo wspomagana analiza inżynierska (CAE) układu kość-implant metodą elementów skończonych, której wyniki mogą doprowadzić do zmian w doborze typowego lub w konstrukcji indywidualnego implantu. System CAD umożliwia także symulację zabiegu chirurgicznego wszczepienia dobranej lub nowozaprojektowanej endoprotezy. Ułatwia to przeprowadzenie zabiegu wszczepienia i zmniejsza ryzyko powikłań pooperacyjnych.

W trzecim etapie, za pomocą systemu do komputerowo wspomaganego wytwarzania (CAM) projektuje się proces obróbki endoprotezy, a następnie steruje się jej wytwarzaniem na sterowanej numerycznie (CNC) obrabiarce.

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