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CUSTOMISED PROSTHESES OF HUMAN JOINTS AND ORTHOSIS DEVICES

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In the paper, a review of achievements of Inter-Faculty Laboratory of Biomedical Engineering[1] (IFLBE) at Warsaw University of Technology is presented to commemorate Prof. Marek Dietrich who was one of the pioneers of researches in the field of biomechanics and biomedical engineering in Poland. Thus, the paper deals with two sets of problems that the members of IFLBE focused their attention on, i.e. prostheses of human joints and orthosis devices. A detailed process of a custom-made prosthesis manufacturing together with problems related to implantation will be shown as well as some new constructions of orthoses designed at Warsaw University of Technology. In the framework of the first problem, i.e. customised prostheses of human joints, the following joints are considered: hip joint, lumbar spine, elbow joint, knee joint.

Key words: customised prosthesis, bone adaptation, orthosis device

1. Introduction

Recently, in the so-called developed countries, the diseases and injuries of hip joint have definitely become a civilization-related problem. The main causes observed are: aging of societies involving, e.g. osteoporosis, degenerations, material wear, etc.; the way of life, especially traffic crashes that are of crucial importance as well. Also the evolution gave us the vertical position which causes larger loads acting upon these joints.

[1]Workers of the Laboratory: Borkowski Paweł, Borkowski Piotr, Dąbrowska Tkaczyk A., Domański J., Floriańczyk A., Grygoruk R., Haraburda M., Kędzior K., Kuberacki B., Mianowski K., Pawlikowski M., Skalski K. – head of the Laboratory, Skoworodko J., Wróblewski G.

According to the World Health Organization data about 500 million people all over the world suffer from chronic diseases of bones and joints. This number includes about 200 millions suffering from osteoporosis. It is estimated that in 2020 about 400 millions will suffer from osteoporosis.

According to European Union data in 2010 every 3rd woman and every 9th man above 60 will suffer from femur neck fracture. It has also been estimated that about 1 million operations of alloplasty are performed per year all over the world, but in that number as many as quarter of million are performed in the USA. The last two numbers reveal the next problem, a very serious one, namely these diseases can be treated only in rich countries.

The needs for hip joint replacement in Poland are estimated 30 000 a year, however, only approximately 10 000 surgeries a year are performed. This is because the alloplasty is rather expensive compared to the average income. The patient must wait sometimes over 2-3 years for Social Security Service. This is typical situation for many countries being at the same stage of development.

Lumbar spine damages constitute a group of most common diseases the modern civilisation suffer from. Those damages are mostly related to intervertebral discs. The role of the disc is to absorb shocks. It protects the spine against daily activities. It also protects the spine during straining activities, such as running, jumping or lifting weights. The most common disease of the disc is discopathy when the nucleus herniates toward the spinal cord.

Each year, only in Poland, approx. 200 people suffer from multifragmental fractures of the radial head in elbow joint. In the case of a single fracture, the typical surgical procedure consists in osteosynthesis by means of a surgical nail which is impossible for multifragmental fractures (Fig. 1). Usually such a damage was, and in most cases still is, treated in a very simple way, i.e. cutting out the damaged bone part, detoriating substantially the patient's life quality.

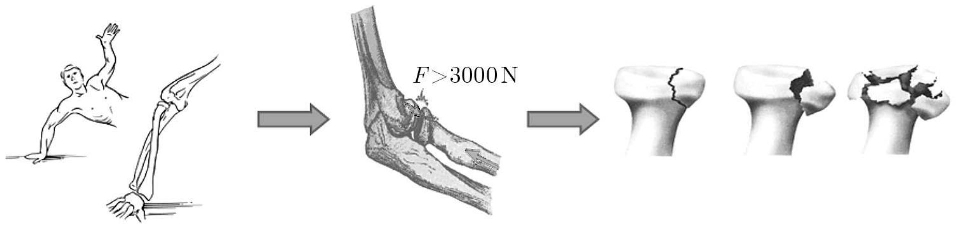

Fig. 1. Multifragmental fracture of radial head

Patients who suffer from bone cancer undergo traditional treatments involving chemotherapy, radiotherapy and surgery. Surgery, until very recently, consisted in cancerous limb amputation. However, the progress reached thanks to associated treatment pointed out a new role for the oncological surgery and caused development of so called sparing surgical techniques. Surgeons have begun performing less maiming amputations and, in the cases where it is possible, tumour resection together with a part of the bone. This contributed to the development of new reconstruction techniques. The aim of those techniques is to replace large bone loss applying not only oncological prostheses but also bone grafts and other reconstruction methods. The fact that bone cancer concerns mainly children, who are in the process of growing, makes the problem even more difficult as the limb with a prosthesis implanted in the place of diseased bone will be shorter after a certain time. Thus, a sophisticated prosthesis must be applied, i.e. an expandable prosthesis.

In the world approx. 500 cases of pediatric bone cancer are annually reported. As for the most common types of bone cancer at children, 963 cases of osteosarcoma and 576 cases of Ewing's sarcoma were reported worldwide between 1994 and 1998 for ages 0-19 (Li *et al.*, 2002). Thus, the potential global market of expandable prosthesis application is approximately 300 patients per year. Although the number is somewhat small, considering huge improvement of the patients' quality of life and, in many cases, possibility to give the patients hope for longer life if an expandable prosthesis is successfully applied, the problem of high-quality expandable prosthesis design becomes crucial.

There are approximately 1200 cancer cases being detected yearly by children in Poland. The amount covers about 100 bone cancers, out of what approx. 90 are located in the region of knee joint. Approximately 70 may be cured by surgeries and prosthesis implementation. In about 25 cases, the applied prosthesis should be the one of expandable capability due to the growing process of the patient's body. The best type of such an expandable prosthesis are those not needing systematic interventions resulting in additional surgeries. A cost of such an anti-interventional expandable prosthesis is approximately 15 000 €. The high cost causes that only few such solutions are being used yearly. This is the reason why we decided to focus on this issue.

As a result of accidents and various diseases, a large number of patients – including young people – suffer from parapleghia or tetrapleghia (quadripleghia). These people have to spent their lifes in beds or – best of all – in wheelchairs with no possibility of taking vertical position. This lack influences badly not only the quality of their life but also shortens it dramatically mainly due to disfunctions of digestive and circulatory systems. A kind of a solution to this problem consists in special orthotic devices.

2. Hip joint prostheses

Within the scope of hip joint prostheses, we have focused on the customized ones. The necessity of customised prostheses results from the fact that in about 5% of cases of hip joint diseases and injuries the common available on the market prostheses cannot be applied. Since the number of all cases over the world is very large and still growing these 5% deserves dealing with the problem. Many researchers all over the world have investigated the problem (Little *et al.*, 2006; Sridhar *et al.*, 2010). Basing on their results as well as on our own experience we have developed the procedure presented in Fig. 2.

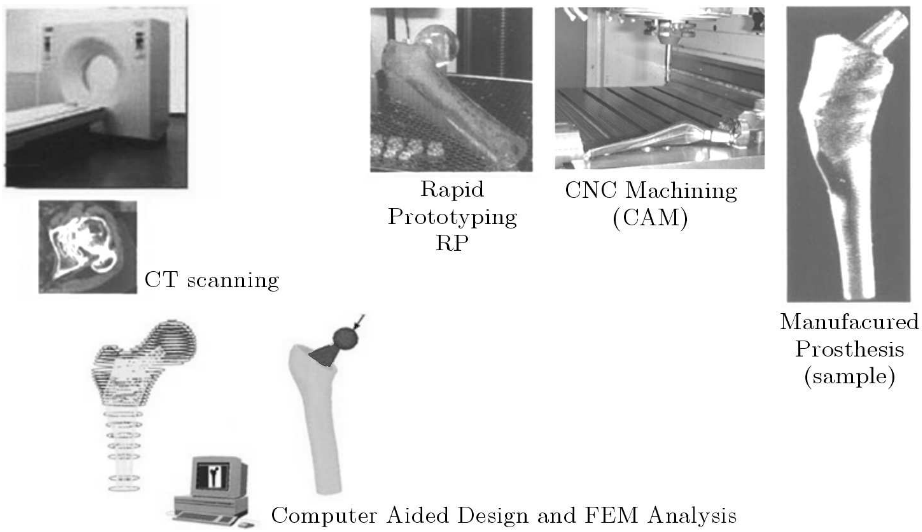

Fig. 2. The process of customised prosthesis design

The figure shows the main stages of the method: CT scanning, data transfer to the CAD system for implant design and engineering analysis, rapid prototyping for design examination and surgery planning and finally CNC machining.

The first step of the procedure consists in geometrical identification of the damaged or deformed joint, and sometimes even some neighbouring joints, using the CT technology. It consists in 3D bone shape reconstruction based on 2D scans – at first glance this task seems to be very simple. However there are some fundamental difficulties we were confronted with, especially when dealing with very damaged joints, e.g. caused by osteporosis, sever mechanical damages of bones, etc. This 42 years old patient (Fig. 3), a woman, had a normal right hip joint, however the left one was completely damaged due to the congenital dislocation of the hip joint which had been never treated. As a result, the natural joint as well as the femur head were completely damaged because of wear. That caused also changes in the knee joint orientation. Therefore, a very difficult decision had to be made at this stage of the method. In fact, the preoperative planning of surgery started here. We should have in mind that surgical reconstruction of the damaged hip joint to its normal shape – like the right-hand one – could involve unacceptable changes in the knee joint or even necessity for knee joint alloplasty. In the shown case surgical reconstruction of the hip joint reached only the level allowing the patient to walk without crutches.

Fig. 3. Clinical case; (a) hip joints (X-ray picture) – frontal view; transverse sections: (b) through hips, (c) through both knees at the condyle

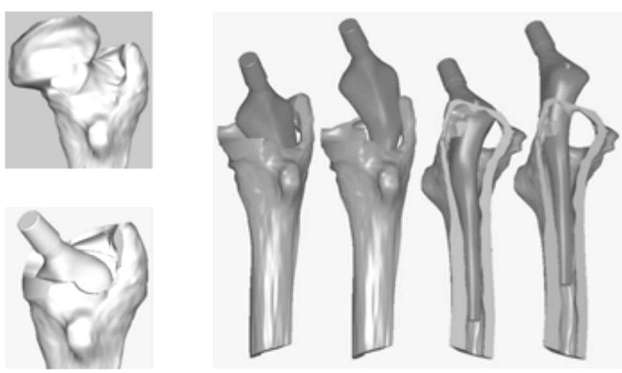

Fig. 4. Solid models of the bone and prosthesis

The CT measurement results create the input data to a common CAD system which generates the solid model of bones (Fig. 4). The first problem consists in proper identification of the bone contour, especially in the vicinity of marrow cavity. This obstacle can be overcome by means of the proper Hounsfield coefficient adjustment in the course of contour identification. A special software acting as an interface is required. There are packages available on the market – they are good, but very expensive. For this reason, the researchers sometimes write their own programs.

The second problem consists in the lack of compatibility between CT and CAD systems. Using the same CAD system one can design the individual prosthesis fitted to the marrow cavity of the patient bone. One can also plan the surgical procedure. So, a very important issue of the design process consists in proper designing of the implant stem to ensure the best matching with the marrow cavity, especially in the case of a cementless prosthesis.

During the whole process of the prosthesis design in the CAD system, consultations with the surgeon who was to perform the alloplasty operation were indispensable. The surgeon's advices and remarks on the shape of the prosthesis stem allowed us to create a set of stem designs from which we were to select a medically optimal anatomical hip joint prosthesis. In Fig. 5, two stem designs are shown, i.e. the first design, which was the initial design of the prosthesis (Fig. 5a), and the optimal design (Fig. 5b). The magnified cross sections presented in Fig. 5 allow one to distinguish the differences in the stem shape. The differences greatly influence the bond between the bone and prosthesis and, consequently, stability of the implanted prosthesis in the medullary canal. The criteria of the selection were mainly the degree of medullary canal filling by the stem and possibility of prosthesis insertion into the femur. The CAD system is able to generate cross-sections by means of which we could analyse to what degree the designed prostheses fit the medullary canal. Moreover, we could also simulate the alloplasty operation by performing virtual femoral head resection and virtually inserting prosthesis into the bone (Pawlikowski *et al.*, 2003).

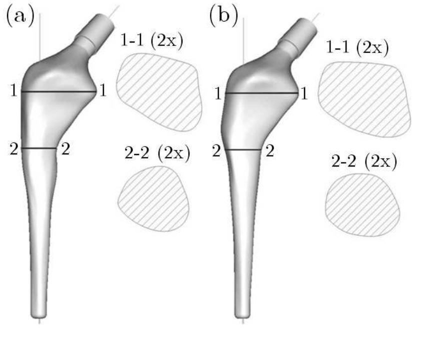

Fig. 5. Two selected designs of the prosthesis: the first one (Prosthesis 1) (a) and the optimal one (Prosthesis 2) (b)

Another important problem we should solve consists in designing the implant neck in the way ensuring proper cooperation with the artificial cup as well as proper orientation of the leg, especially the knee joint.

The FEM analysis is then applied for verification of the strength properties of the bone-implant system. In the FEM simulations, the phenomenon of bone adaptation was taken into account. It was simulated by means of kinetics equation (2.1). Bone adaptation, which is also called bone remodelling, was considered as a change of bone density with time. In equation (2.1) signifies the bone apparent density (Weinans *et al.*, 1992), S – bone remodelling stimulator, S_0 – reference bone remodelling stimulator, C – constant, s – width of the so called "dead zone" (Fig. 6).

$$\frac{d\rho_a}{dt} = \begin{cases} C[S-(1-s)S_0] & S \leqslant (1-s)S_0 & \text{bone resorption} \\ 0 & (1-s)S_0 < S < (1+s)S_0 & \text{dead zone} \\ C[S-(1+s)S_0] & S \geqslant (1+s)S_0 & \text{bone apposition} \end{cases} \tag{2.1}$$

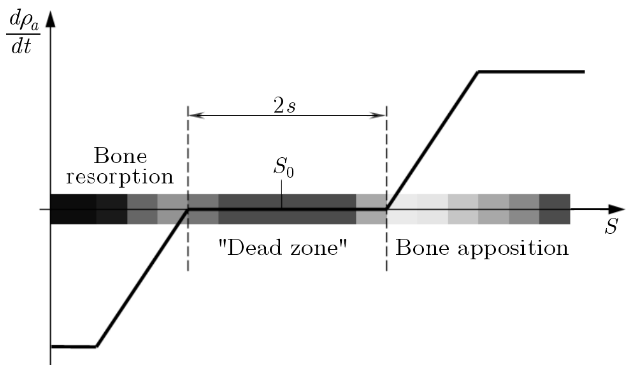

Fig. 6. Graphical interpretation of kinetics equation (2.1)

The geometrical models of the femur and prostheses were utilised to generate discrete models in the FEM system. The discrete models of the bone-implant systems consisted of about 7000 elements. The bone was simulated as a visco-elastic material. The initial value of bone density was 1.5 g/cm^3 and was homogenous in the whole bone volume. The material properties of the bone in the first time step depended on the initial value of bone density; in the next time steps the properties changed with bone density change. The initial Young modulus corresponded to the initial bone density and was equal to 14 000 MPa. Poisson's ratio was assumed to be equal $\nu = 0.4$ and was constant during the whole process of deformation. The prostheses were defined as an elastic material of the following properties: Young's modulus $E = 200\,000$ MPa, Poisson's ratio $\nu = 0.3$. The equation relating Young's modulus with bone density was assumed to be of the form: $E = 4249\rho^3$ (Weinans *et al.*, 2000). If the density is expressed in g/cm^3, the Young modulus is calculated in MPa. The load conditions of the bone-implant systems corresponded to the one-leg standing position. The reaction force acting on the prosthesis head and the force of abductor muscles were considered. Perfect bonding between the prostheses and femur was assumed. Selected results of FEM simulations, in the form of bone density distributions in femur, are shown in Fig. 7. The results indicate that the initial design of the prosthesis would cause significant bone resorption in the proximal part of the femur. On the other hand, the final design seems to be the optimal one since the bone density distribution after implantation is more advantageous.

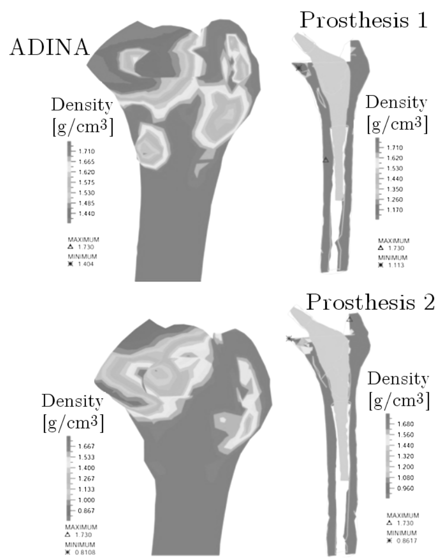

Fig. 7. Bone density distribution in femur for Prosthesis 1 and Prosthesis 2

In order to design an anatomical prosthesis of extended durability, it is essential to conduct the design process of the prosthesis as it was shown above, i.e. to begin with CT data acquisition, then to model the femur and design a custom-made prosthesis in a CAD system and finally to verify the new-designed prosthesis numerically in a FEM system. The factor of including the bone remodelling phenomenon in the process is of significant importance. It is obvious that during the design process consultations with a surgeon must be carried out.

At the final stage of the process the implant was covered first with a powdered pure titanium and a selected part of it was covered with hydroxyapatite using the plasma spraying technology (Skalski *et al.*, 2001). However, the custom design procedure of the implant forces the necessity for custom design surgical tools, e.g. the rasp. It rises the cost of surgery. The rasp is made of a cheaper material, however due to technological reasons, i.e. file cutting and polishing, it is also very expensive (Fig. 8).

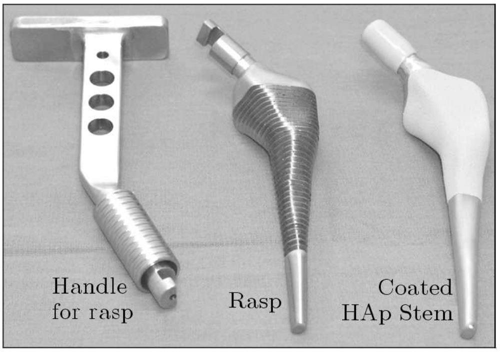

Fig. 8. Instrumentation for customized prosthesis implantation

Several operations were performed using the developed procedure. The patients have been observed for several years proving that the method can be used in clinical practice.

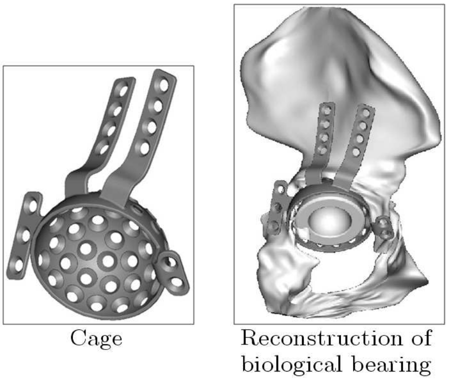

Fig. 9. Customised prosthesis of hip joint acetabulum

Exactly the same methodology of designing and manufacturing can be used in the case of pelvis bone reconstruction (Skalski *et al.*, 2006). It applies to the case when the level of bone damage makes it impossible to implant a standard artificial cap. Such a case can be seen in Fig. 9. Following the procedure, a new joint was designed using the CAD system. The damaged part of pelvis bone was replaced with a special customized acetabular cage which allows for fixing an artificial joint cup. The surgery set was made also using a CNC machine. It contains also a test cage used at the first step of operation to prepare the matching area like the rasp in the previous case (Fig. 10). In this case however, the extra material was added using a minced bone taken from bone bank. Finally, we arrive at the crucial moment of the whole process, i.e. the moment of truth when during the surgery the applicability of the implant is proved. In this case, as well as in the others we dealt with so far, the artificial joint was designed and manufactured properly (Fig. 11).

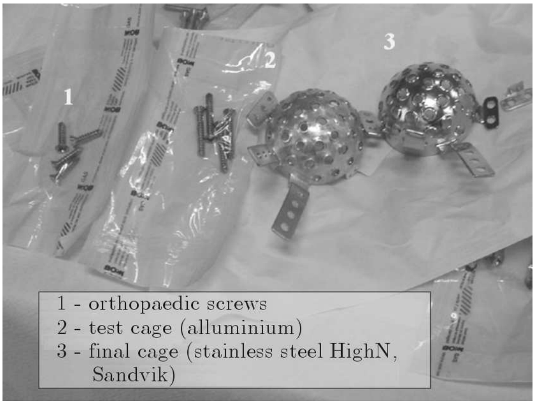

Fig. 10. Customised prosthesis of hip joint acetabulum


Fig. 11. X-ray picture of an implanted hip joint

The surgical procedure however does not end the treatment procedure. A long lasting rehabilitation process supported by periodic biomechanical analysis should be performed as well (Fig. 12).

Fig. 12. Biomechanical analysis of the surgery effect on Vicon system

3. Lumbar spine

Lumbar spine damages constitute a group of most common diseases the modern civilisation suffers from. Since computer advanced methods and technologies are now available, modern bioengineering can attempt at solving these problems. Following the procedure presented before, the first stage consists in reconstruction of the vertebra system using the Computer Tomography and the CAD system (Fig. 13).

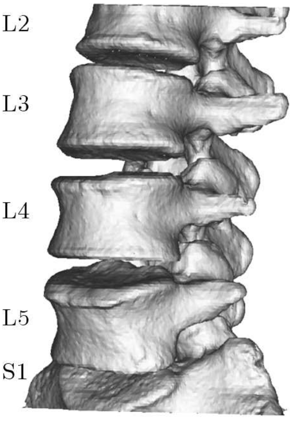

Fig. 13. Geometrical model of the lumbar segment of spine

We have proposed a three-element prototype which substitutes for a majority of functions of the natural disc, i.e. rotation and bending (Fig. 14). The most important factor affecting the designing process of the artificial disc con-

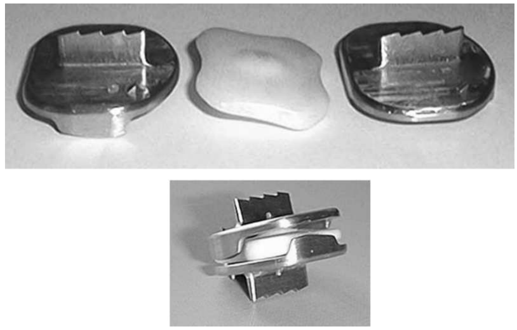

Fig. 14. Prosthesis of intervertebral disc

sists in ensuring that the stress distribution, after implementation, remains the same or almost the same as in the case of the natural disc. It can be achieved using FEM modelling (Fig. 15). It should be noted that the polyethylene pad provides also certain compressibility (Borkowski *et al.*, 2004). A few prototypes have been constructed which are now under testing on the experimental stand shown in Fig. 16. The measurement results obtained so far are promising (Dietrich *et al.*, 2005).

	E [MPa]	ν	Type of element
Cortical bone	12000	0.3	SHELL 43
Cancellous bone	100	0.4	SOLID 45
HMWP	1200	0.35	SOLID 45
Co-Cr-Mo	210000	0.3	SOLID 45

Number of elements: 36790
Number of nodes: 7361

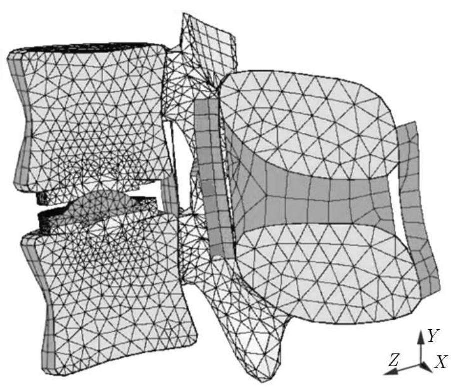

Fig. 15. FEM model of the lumbar segment (Borkowski *et al.*, 2004)

4. Elbow joint

Each year – only in Poland – about 200 people suffer from multifragmental fractures of the radial head. In the case of a single fracture, a typical surgical procedure consists in osteosynthesis by means of a surgical nail which is impossible for multifragmental fractures. Usually such a damage was, and in

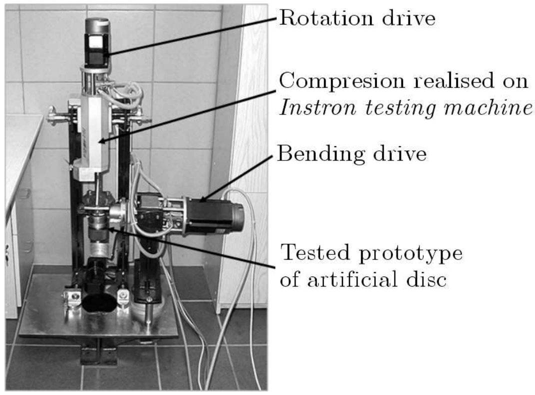

Fig. 16. Experimental stand for testing intervertebral disc prostheses

most cases still is, treated in a very simple way, i.e. cutting out the damaged bone part, deteriorating substantially the patient's life quality. We have decided therefore to design a new type of prosthesis. Upon application of our procedure, i.e. from CT to manufacturing including reconstruction of geometrical features of bone structures, we have obtained the prosthesis better fitted to the real joint. The new design comprises two or three elements (Fig. 17). It should be noted that the design is provided with an additional spherical joint not presented in nature, which allows for better adaptation of the prosthesis to the anatomy of the elbow joint (Pomianowski *et al.*, 2003). This feature is visible in the picture which presents the result of one of over hundred successful radial head prosthesis implantations performed so far (Fig. 18).

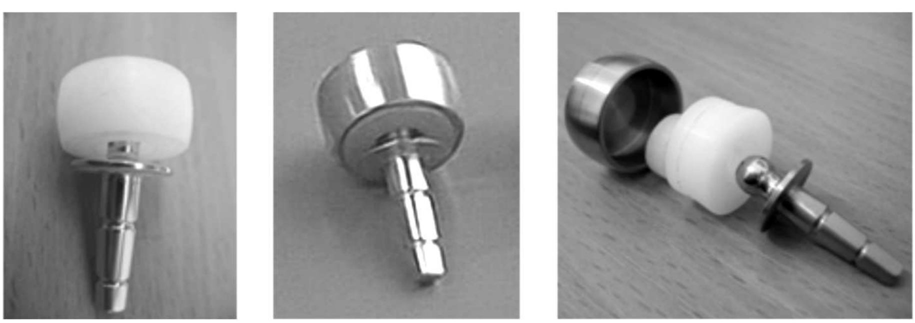

Fig. 17. New designs of the radial head prosthesis

We emphasize also the necessity for supplying the surgeon with special surgical instruments allowing for making more reliable intro-operative connections of prosthesis elements (Fig. 18). The promising results or clinical and technical tests allowed for industrial implementation of the design. The prosthesis is available on the market.

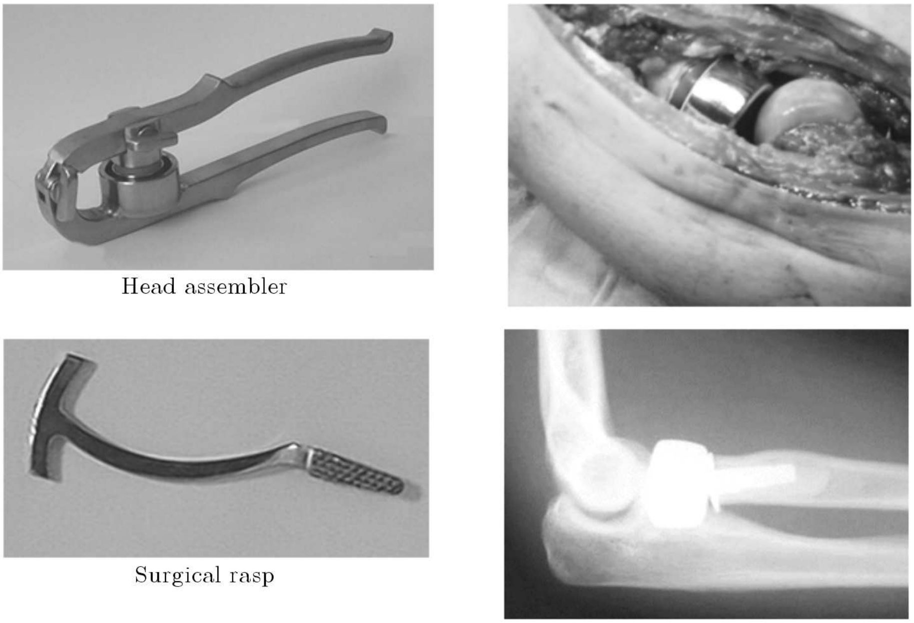

Fig. 18. Surgical instrumentation and an implanted radial head prosthesis

5. Knee joint

There are approximately 1200 cancer cases being detected yearly by children in Poland. The amount covers about 100 bone cancers, out of what about 90 are located in the region of the knee joint. Approximately 70 may be cured by surgeries and prosthesis implementation. In about 25 cases the prosthesis used should be the one of expandable capability due to the growing process of the patient's body. The best type of such expandable prostheses are those no needing systematic interventions resulting in additional surgeries. The cost of such anti-interventional expandable prostheses is considerable. The high cost causes that only few such solutions are being used yearly. This is the reason why we decided to focus on this issue.

One of the constructions of non-invasive prosthesis invented by our group consists of a screw gear which is propelled by an electrical driving unit (Fig. 19). The prosthesis comprises three tubes connected with each other by means of a thread: an external tube in which the driving unit is located, internal tube where the power screw is placed and intermediate tube. The driving unit consists of an electrical engine that is activated by means of electromagnetic coil, which during the elongation process, is placed on the skin. The electromagnetic field drives the motoreducer and the screw gear of the prosthesis is powered. During the prosthesis expansion, the internal tube is moving forward from the external one. The internal tube is driven by means of the motoreducer which puts the power screw into motion. The motoreducer located inside the prosthesis is powered from outside the body by means of a special control unit. The exciter and impulse generator create an electromagnetic signal which is modulated, amplified and then transmitted to the receiver placed inside the prosthesis. The signal is next demodulated and transmitted to the control system of the power unit (motoreducer). This way the prosthesis can be extended to a desired length. During the process of the prosthesis design it was assumed that the reactive force of the muscles during extension was equal to 100 N. The maximum possible elongation of the prosthesis is 45 mm. It was also assumed that the friction coefficient between the screw and nut was 0.08, thread efficiency equalled 0.33 (Borkowski *et al.*, 2003). The artificial knee joint is to restore functionality of the natural knee joint extracted from the body. The stems of the prosthesis are coated with pure titanium and hydroxyapatite.

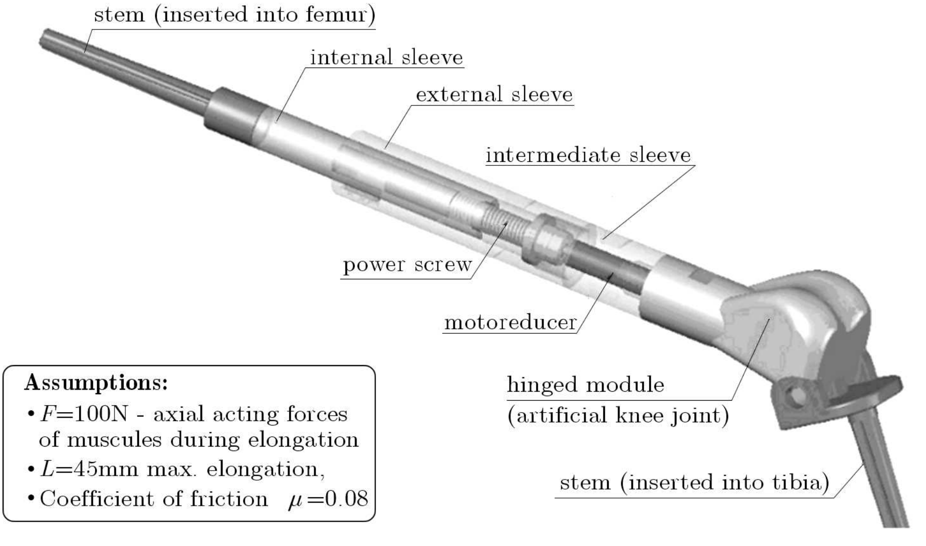

Fig. 19. Solid model of the non-invasive expandable prosthesis

The screw gear makes it possible to precisely control the elongation of the prosthesis. In addition to this, the expansion process can be frequently repeated without any discomfort to the patient.

6. Orthosis devices

As a result of accidents and various diseases, a large number of patients – including young people – suffer from parapleghia or tetrapleghia (quadripleghia). These people have spent their lives in beds or – best of all – in wheelchairs with no possibility of taking vertical position. This lack influences badly not only the quality of their life but also shortens it dramatically mainly due to disfunctions of digestive and circulatory systems.

A kind of a solution to this problem consists in special orthotic devices. The "Parapodium PW" (Fig. 20) is designed for paraplegics (Olędzki and Szymczak, 1999). This device allows the patient with still active upper extremities to take the vertical position, walk around without any additional drive, and without any assistance of other people and undertake basic everyday life actions, including visits to toilet. The same smaller device was designed for children (Fig. 20). Over 500 pieces of the device have been manufactured and sold up till now.

Fig. 20. "Parapodium PW" for paraplegics

In the much worse condition are people with four extremities paralyzed. The device for assisting them needs therefore an additional drive, e.g. electric motor. The "Tetrapodium PW" (Fig. 21) allows such people to take vertical position and undertake basic every-day life actions (Kuberacki *et al.*, 2010). It should be noted that this device, like the previous one, is perfectly safe. The stability of the device is ensured by design as if keeps the mass center of the body-devicw within the base contour.

Fig. 21. "Tetrapodium PW" for quatriplegics

7. Final remarks

Patients undergo sometimes such severe pathological changes that a customised prosthesis should be designed and implanted. As a custom-made prosthesis fits only to one particular patient its cost is greater than a standard one. However, the high cost is compensated by the fact that such a prosthesis fulfils its function for a much longer time period than a standard prosthesis does.

The number of patients who require custom design prostheses and otrhosis devices will increase due to the process of world population ageing (main factor – cancer). At present, this procedure is very expensive. However, the application of computerised techniques (CT, CAD, CAM) may considerably reduce the cost provided that the whole process (including design, manufacture and surgery) will be performed in specialised centres.

The anatomical shape of customised prosthesis stems makes the load transfer from the upper part of the body through prosthesis to the bone in which it is inserted more natural. This reduces consequently the range of undesirable bone behaviour, i.e. bone resorption.

Customised prostheses can be also applied in revision arthroplasty. In the case of a standard prosthesis failure due to, for instance, its loosening, a custom-made prosthesis can be implanted. This way the joint functionality is restored.

In order to design a customised prosthesis of extended durability it is essential to conduct the design process of the prosthesis as it was shown in the paper, i.e. to begin with CT data acquisition, then to model the joint and design a custom-made prosthesis in a CAD system and finally to verify the new-designed prosthesis numerically in a FEM system. The factor of including the bone remodelling phenomenon in the process is of significant importance. It has to be emphasised that this approach proved to be essential in the area of custom-made prosthesis design. It is obvious that during the design process consultations with a surgeon must be carried out. Thus, the modern process of customised prosthesis design is interdisciplinary and makes it possible to design and manufacture a prosthesis of higher durability and bio-compatibility.

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Indywidualne endoprotezy stawów człowieka i urządzenia ortotyczne

Streszczenie

Praca zawiera przegląd osiągnięć Międzywydziałowego Laboratorium Inżynierii Biomedycznej (LIB) Politechniki Warszawskiej, przedstawiony dla uczczenia pamięci prof. Marka Dietricha, który był jednym z pionierów badań w zakresie biomechaniki i inżynierii biomedycznej w Polsce. W szczególności zaprezentowano badania w zakresie endoprotez stawów człowieka i urządzeń ortotycznych. Przedstawiono proces produkcji endoprotez indywidualnych oraz problemy związane z ich wszczepianiem, jak również nowe konstrukcje ortoz zaprojektowanych na Politechnice Warszawskiej. W zakresie zaś endoprotez stawów człowieka przedstawiono nowe konstrukcje endoprotez: stawu biodrowego, kręgosłupa, stawu łokciowego i kolanowego.

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