Expandable endoprosthesis for growing patients – constructions and researches

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1. Introduction

People in every age can be stricken by cancerous diseases. Among those diseases that afflict younger patients – kids, are bone tumors (sarcomas), which are usually localized near the knee joint [4,7]. Due to the fact that contemporary treatment can be applied cancerous disease is not a death sentence any more. In order to overwhelm the cancerous disease the sarcoma-stricken knee joint is extracted from the body and replaced with a prosthesis. Not only is such a prosthesis to restore the functionality of the limb but also it has to be possible to extend its length while growing of the patient [2,1]. High social rank, better and better treatment results and development of the techniques triggered researches on newer construction of expandable prosthesis including those which lengthening is possible without surgery.

In the paper are presented results of researches with application of computer technique in geometrical modeling, design and manufacture as well as in processing of medical images and experimental studies on initial estimation of a new expandable prosthesis construction for growing patients, that will lead to prepare it production and implantation in Poland.

2. Methods

2.1. Construction of expandable endoprosthesis

Bone sarcomas are usually localized near the knee joint. In one of treatment steps the tumor is removed and on free space en endoprosthesis is placed. The role of tumor expandable endoprosthesis is not only complete the skeletal system, but in fact that patient is still growing, complete the length of the implanted leg, that haven’t possibility to right growth [4]. Presented endoprosthesis is composed of knee module, expandable module, power and control module. It is an hybrid endoprosthesis because elongation of expandable module is realized by screw mechanism noninvasively or optional invasively. In first aim possibility the screw mechanism is connected with motoreducer powered by electromagnetic field and controlled in radio path. In the second way, realized when noninvasively procedure couldn’t be executed, the elongation is realized by a special chuck inserted to endoprosthesis through a small incision in patients leg.

Designed construction have been putted to analytical and experimental studies. Analytical studies were realized in use of FEA method, reliability estimation, new preoperative planning method. To experimental, prototype of endoprosthesis and special stands were manufactured.

2.2. FEA analysis

Finite elements methods (FEA) methods are at present basic engineering tool with allow to make estimation of designed construction in base of virtual model before it physical prototype will be made. In examinations set of endoprosthesis in tibia bone was modeled. Model of bone was created in base of CT data in Mimics program by Materialise. Two series of calculate were made – for initial and final position of expandable module. As material of endoprosthesis titanium alloy (Ti6Al4V) and ultra high molecular weight polyethylene (UHWME), and for tibia bone material with cortical bone properties were used. Assumed, isotropic properties of materials and it linear characteristics in reliable range of loading. Endoprosthesis were loaded in it axial direction by force 1500 N (threefold of 50 kg patient body weight).

2.3. Reliability estimation

Theory of reliability allow to define efficiency of object in definite time. Estimation of reliability permit to escape an mistake when construction is designed. This fact is very important in case of patients comfort and safety. Construction of endoprosthesis in aspect of it reliability allow to separate two sets depended on their localization: external (placed outside patient body) and internal (placed inside patient body) and four functional sets: knee module, expandable module, internal power and control unit and external power and control unit.

2.4. Preoperative planning

Preoperating planning is basic procedure that precede carry out a surgical operation. The part of that proceeding are anamnesis and X - ray examination, completed by CT (Computer Tomography) and MRI (Magnetic Resonance Imaging) examination, that allow better patients diagnosis[3,7]. In this way the reconstruction of patients skeletal system and choice of endoprosthesis is perform. The size of separated elements is selected in
using X-ray pictures and contour master delivered by implant producer. This procedure can be completed by using engineering technique in modelling and reconstruction diseases changed bone tissue and performed virtual simulation of surgical treatment in computer system. It allow surgeon to precisely prepare to operation[5,6]. Simulation of surgical treatment is realised in the following phases:

- creating geometrical models of bone tissue,
- model preparing to endoprosthesing fitting,
- project of endoprosthesis model and its implementation in bone model,
- endoprosthesing fitting,
- validation of simulation process.

2.5. **Experimental study of expandable module**

In normal exploitation expandable module of endoprostheses is generally subjected to a variable axial compression forces. To check changes of geometry in join thread between screw driver and out sleeve, which is the most loaded, the pneumatic stand was built. Potted in the stand expandable module was subjected to a 330 000 of cyclic load in axial force from 0 to 1508 N. After all cycles geometry of thread and axial clearance was measured and compared with condition from before load.

2.6. **Study of power system**

The goal of experiment was determine maximal axial load obtained by power system during endoprosthesing elongation, and in result if it have possibility to overcome reaction of muscles and ligaments during leg lengthening. In study power system in expandable module end special constructed stand was potted. On the stand spring with known characteristic was compressed, value of compression gave a axial force given from power system.

3. **Results**

Realized by FEA method analysis haven’t shown cross of permitted reduced stress by Huber – Misses method, both titanium alloy and polyethylene elements. Experimental study of expandable module showed that there aren’t significant change in thread join and other elements of expandable module. The spring deflection on the stand amounted to 22 mm what correspond with 260N force, so we could accept that this force is sufficient to overcome reaction of muscles and ligaments during leg lengthening about 4mm leg lengthening. Realized efficiency analysis showed to that reliability of expandable endoprostheses depend on reliability of internal power and control unit and in supposed time of use 10 years it equal 0,606.

4. **Discussion**

The role of expandable endoprostheses is not only to fill the bone loss in affected by tumor joint, but also to compensate length in patient leg during growing and in consequence restore equilibrium of whole musculoskeletal patient system. Presented construction allow to endoprostheses expandable in two ways: aim noninvasive and failure invasive what is not observed in other construction. Realized study, analytical and on manufactured prototype showed that endoprostheses was constructed properly. Application of medical system to preoperative planning allow to better prepare construction and doctor to operation in individual patients. This procedure can be wide by using bones and endoprostheses models created in one of rapid prototyping technique. The possibility of implementation are now discuss in group of constructors, doctors and manufacturer.

**References**