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Expandable Non-invasive Prostheses – an Alternative to Pediatric Patients with Bone Sarcoma

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Abstract— **In the paper the problem of joint arthroplasty in children who have not reached their maturity is raised. The arthroplasty concerns replacement of a joint that does not function due to bone sarcoma that a child suffers from. Osteosarcoma and Ewing's sarcoma are the most common types of pediatric bone cancer and they afflict mainly long bones, i.e. femur and tibia. In such cases there are only two options: to amputate the affected limb or to replace the diseased bone. It goes without saying that the latter solution is most acceptable by patient and surgeon. However, a special prosthesis has to be applied as the limbs still grow. To avoid leg length discrepancy between the healthy limb and the affected one expandable prostheses are inserted. Specific designs of such prostheses allow one to lengthen the operated limb and preserve the same length of the two legs. In the paper an overview of expandable prostheses is presented. Also our own designs of expandable orthopaedic devices are shown. The devices are characterised by the fact that their length can be intelligently extended by means of a special electro-magnetic set.**

I. Introduction

T 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 development of the 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 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 (Fig. 1a) and 576 cases of Ewing's sarcoma (Fig. 1b) were reported worldwide between 1994 and 1998 for ages 0-19 [1]. 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.

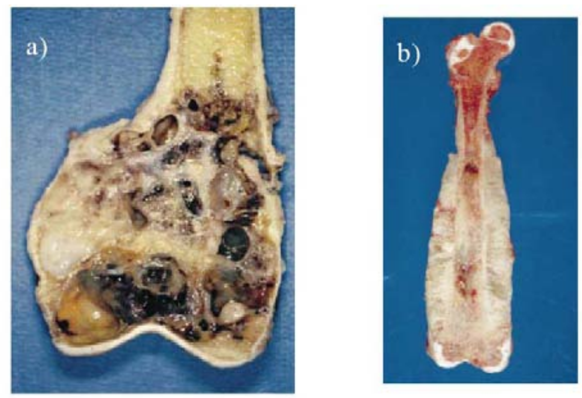

Fig. 1. Forms of bone tumors: osteosarcoma (a), Ewing's sarcoma (b).

II. Materials and Methods

The lengthening process of a prosthesis implanted into the body may be carried out either manually or by means of a special electro-magnetic tool set. The previous manner of prosthesis extension requires surgical intervention. Thus, expandable prostheses of this type are called invasive prostheses. Prosthesis lengthening performed in the latter way does not require any necessity of surgical operation. It is, thus, non-invasive manner of expandable prosthesis extension. Non-invasive prostheses are very popular nowadays as the length of the limb, into which the prosthesis was implanted, can be adjusted to that of the healthy limb in an easier for a surgeon and more comfortable for the patient manner. Moreover, the lengthening process can be performed more often, thus the prosthesis extension is more gradual and less disturbing for the muscles. The invasive way is less comfortable for a young patient and more difficult for a surgeon as it requires another operation procedure. Thus, non-invasive prostheses are more preferable both by orthopedists and patients.

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One of the first expandable prostheses was a modular prosthesis produced by Stanmore Implants [2]. The expansion of Stanmore prosthesis was achieved by replacing the short module with a longer one when the difference in length of the legs was too high. More gradual and continuous limb extension can be realised when a Lewis Expandable Adjustable Prosthesis (LEAP) is inserted. The LEAP prosthesis is extended by means of a modified Jacob's chuck key screwdriver which has to be introduced into the body. Rotation of the outer tube engages a threaded shaft that is moved forward as rotation proceeds to achieve the desired expansion. A set screw is then used to lock the Jacob's chuck to prevent accidental rotation. Currently the prosthesis is fabricated from titanium alloy. Clinical observations show Ti debris presence in the organism. In addition to this, due to application of the Jacob's chuck mechanism, which often collapsed after a relatively short time, patients lost approximately 80% of their knee flexion capability [3].

Howmedica has developed a non-invasive expandable device that consists of a telescoping mechanism where the inner cylinder is extended by a threaded spindle (Fig. 2). A ratchet mechanism (a) engages a pinion (b) that rotates the spindle (d). The tooth mechanism is activated when the flexion angle between the two components of the prosthesis is greater than 90^o. The ratchet mechanism prevents any reverse rotation. A spring (c) is connected to the pinion in order to ensure stable position of the mechanism after a revolution. Thanks to the high value of flexion angle needed to extend the prosthesis any accidental extension is rather impossible. In addition to this, the expansion increment (e) is very low – approximately 0.05 mm. Any over-extension of the prosthesis is thus avoided. An 18-fold repetition of the movement causes an elongation of 1 mm.

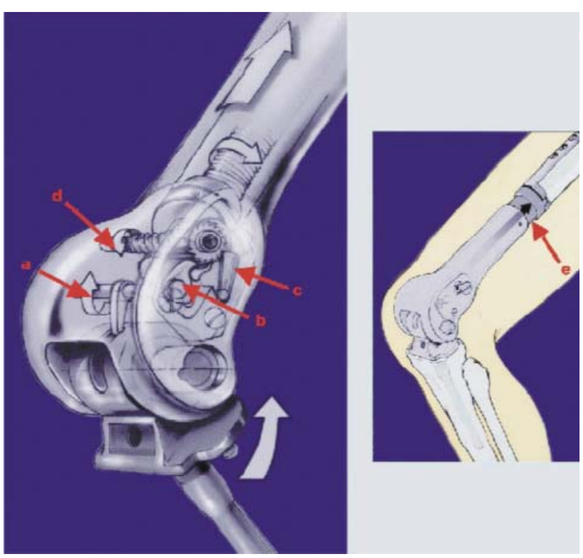

Fig. 2. Expandable prosthesis with automatic elongation mechanism.

In 1989 Verkerke and his co-workers described a device in which the motion screw was driven either electrically or magnetically [4]. In the previous case an electric motor inside the prosthesis housing drives the motion screw which, consequently, forces two telescopic tubes apart. The motor is activated by means of electromagnetic field that is converted into electric current by a coil inside the prosthesis. The electromagnetic field is produced with a coil that is placed around the leg. In the magnetically driven expansion mechanism a small permanent magnet inside the prosthesis is used. It is put into rotation by means of an external rotating electromagnet. The small magnet turns the motion screw via a gearbox. The motion screw is placed in the outer tube. When it rotates, it moves through the outer tube and forces the two tubes apart.

Phenix Medical of Paris, France have designed and created another non-invasive expandable orthopaedic device. Instead of using the threaded rod extension mechanism, they uses a compressed spring to create extension [5]. The Phenix prosthesis consists of a titanium tube with an annular protuberance inside a polyethylene tube encased in an outer housing (Fig. 3). The titanium protuberance is pushed tightly into the polyethylene tube. Between the two tubes there is an initially compressed spring. In order to achieve an elongation of the prosthesis an external coil is used to create a magnetic field and induce current in antennae located inside the prosthesis. The current heats up the device enough to soften the polyethylene. This allows the spring to decompress and the titanium protuberance moves forward through the heated portion. During the prosthesis extension the temperature in the device rises to approximately 54 ^{o}C. However, the relatively high temperature does not cause any damage to the soft tissue as the heat is easily carried off.


Fig. 3. Expandable prosthesis PHENIX produced by Wright Medical Technology.

Due to the fact that the number of patients in Poland suffering from bone cancer is much greater that the number of available on the market expandable prostheses that The Health Service can afford we launched the co-operation with surgeons in order to design and create a non-invasive expandable prosthesis for growing patients.

One of the constructions of non-invasive prosthesis invented by our group (Fig. 4) consists of a screw gear which is propelled by electrical driving unit. The prosthesis comprises three tubes connected with each other by means of thread: 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 into motion the power screw. The motoreducer located inside the prosthesis is powered from outside the body by means of a special control unit (Fig. 5). The exciter and impulse generator create an electromagnetic signal which is modulated, amplified and

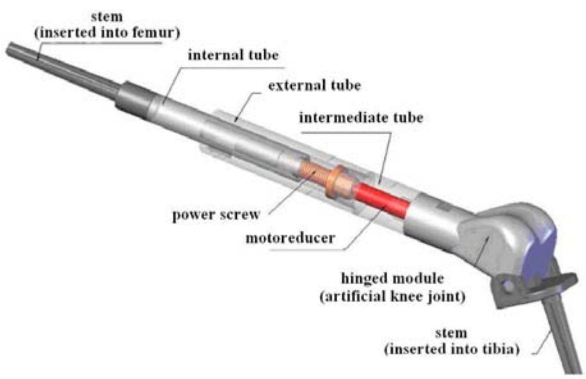

Fig. 4. Solid model of expandable non-invasive prosthesis.

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 is equalled to 100 N. Maximum possible elongation of the prosthesis is 45 mm. It was also assumed that the friction coefficient between the screw and nut is 0.08, thread efficiency equalled to 0.33 [6]. 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

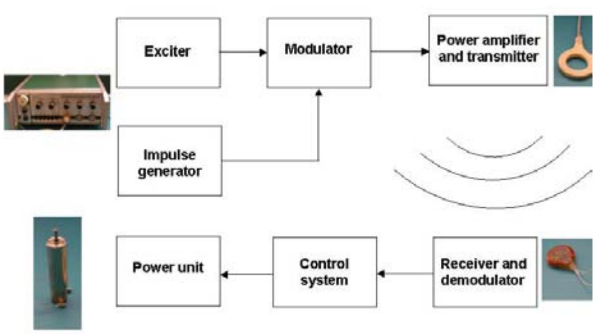

Fig. 5. The control unit utilised in prosthesis elongation process.

titanium and hydroxyapatite.

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

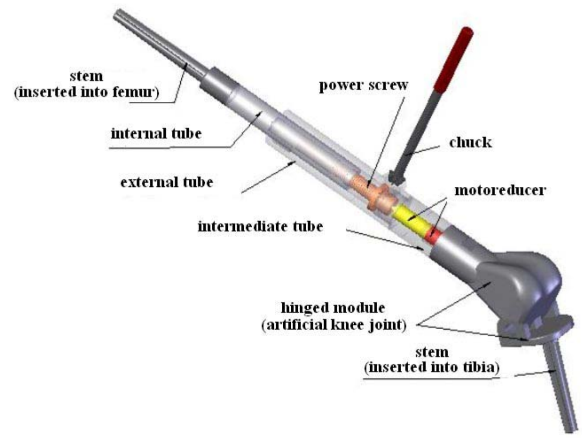

Fig. 6. Solid model of hybrid expandable non-invasive prosthesis.

Our next design of an expandable prosthesis is based on the Phenix prosthesis. It consists of: two connected sleeves (the first one is made of titanium and the other of bio-polymer), a polyethylene tube which is inserted into the titanium sleeve and a spring. A perforated flange, which is in constant contact with the polyethylene tube, is a characteristic element of the prosthesis. The sleeves are connected with each other by means of thread. Thanks to the fact that the spring is compressed it has a certain amount of energy that depends on the spring length and diameter. In order to extend non-invasively the prosthesis a segment of the polyethylene tube is heated and molten by means of electromagnet. The heated segment has to be in contact with the flange so that the molten portion of the polyethylene could flow through the wholes. This results in the spring decompression and the prosthesis extension.

In the next prosthesis the first design of expandable prosthesis was combined with the invasive solution applied in the LEAP prosthesis [7]. Thus, a hybrid expandable prosthesis was created (Fig. 6). In case of the motoreducer failure the prosthesis expansion could be attained manually by means of a special chuck which must be introduced into the body through a small incision.

III. Results and Remarks

As the power unit we utilised the motoreducer by Minimotor. The main parameters of the motoreducer are as follows: power 1.5 W, supply voltage 12 V. The planetary gear of the motoreducer has high gear ratio (4096:1), which permits slow extending of the prosthesis with the rate 1.5 mm/min. During the prosthesis elongation process the power unit has to overcome the reaction force of muscles and tendons. Therefore, a special stand for measurement of the force exerted by the motoreducer was designed and constructed (Fig. 7). The external tube with the motoreducer inside and a spring of known properties are the main elements of the stand. The motoreducer makes the spring deflects and thanks to the fact that the characteristic of the spring is known we were able to calculate the force that the power unit exerts. The spring was deflected by 18 mm, which corresponds to the force value 225 N. After

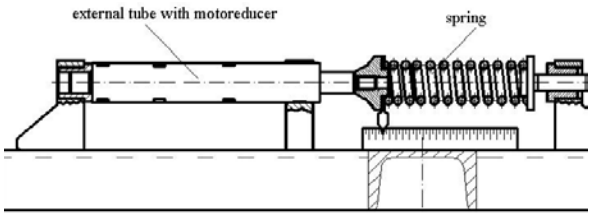

Fig. 7. Diagram of the stand for motoreducer force measurement.

consultations with the surgeon we cooperate with and literature review [8] it was decided that the power unit that we applied in the prosthesis is adequate.

The expandable prostheses available on the market are very expensive and unattainable for majority of patients in Poland. Therefore, we have decided to design such prosthesis that most or all the young patients will be able to afford. Thus, the main advantage of the prostheses of our design over the existing expandable prostheses is the fact that our designs are much cheaper.

We realise that the prosthesis constructions should be clinically tested before application. We have not perform such experiments yet. Our expandable prostheses are to be clinically tested in the future.

Operations of prosthesis implantation performed on the patients who are still growing still constitute a significant problem as the maturation process in the sick limb is disturbed. In such a case application of an oncological expandable prosthesis, in particular non-invasive one, gives the most satisfying results. The mechanism of an expandable prosthesis makes it possible to gradually extend its longitude during the organism growth. Contemporary progress of oncological arthroplasty is then focusing on expandable prostheses, particularly on non-invasive implants. Expansion of such an implant is completed without any surgery intervention which minimizes the risk of infection and other post-operative complications.

The main advantage of non-invasive prostheses is possibility of their extension without surgery intervention. This makes it easier to control the process of implant lengthening and perform it more frequently. This allows consequently to reduce the time of rehabilitation after arthroplasty. Development of the techniques has made it possible to apply not only mechanical constructions but also those that are electronically controlled.

Our constructions of non-invasive expandable prostheses allow for the possibility to electronically control the process of implant lengthening. Application of the screw gear permits precise move forward of the internal tube to the required position and enables one to better control the process of prosthesis expansion.

In the hybrid construction a planetary micro gear as well as helix gear are introduced. The gears constitute a spare mechanism that is activated in case of the non-invasive mechanism failure.

Contemporary non-invasive expandable prostheses allow a surgeon to realise the process of the implanted limb without the surgical operation and consequently, as it was already mentioned, minimise the risk of infection.

The constructions of expendable prostheses presented in the paper are the newest solutions in which the lengthening process is carried out by means of the mechanic elements (screw, spring) and electronic ones (drive, control system). The high price of the expandable prostheses offered by the worldwide producers and the high social rank of the problem are the factors that motivate both constructors and producers to create cheaper national expendable prosthesis prototypes. Those factors inspire also designers and scientific workers to continue further the studies in this area.

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