Biorobotic Criteria in the Design of a New Limb Prosthesis

Alberto Rovetta
Politecnico di Milano, Dipartimento di Meccanica, Laboratorio di Robotica
Piazza Leonardo da Vinci, n. 32 - 20133 Milan (Italy)
Email alberto.rovetta@polimi.it
Internet: http://robotica.mecc.polimi.it

Marita Canina, Paolo Allara, Giovanni Campa, Sergio Della Santina

Abstract

This paper deals with a new knee, developed in the research work on prosthesis currently being carried out at Robotics Laboratory, Mechanics Department, Politecnico di Milano. A first prototype of biorobotic leg was presented at the European Biomechanics Conference, in 1984, but environmental uncertainties and low level of micro technologies were at a low level, which did not permit the production after the prototype. In 1992, a first working model was completed, with a microprocessor for the control of the artificial leg. Now techniques of concurrent and instantaneous engineering are adopted for a reengineering of the leg, with new systems. The knee prosthesis project involves a range of specialists and gives rise to interdisciplinary aspects.

The features distinguishing the K3 knee project are an increased awareness of the innovative aspects related to medical/ biological/ engineering research, and the widespread use of cutting-edge technology (electronics, information technologies, material-related technologies, etc.).

1. Introduction

A first prototype of biorobotic leg was presented at the European Biomechanics Conference, in 1984 (Ref. 1), but environmental uncertainties and low level of micro technologies were at a level which did not permit the production after the prototype. In 1992, a first working model was completed, with a microprocessor SGS (now STM) for the control of the artificial leg. Tests in an orthopaedic centre and software oriented to different applications were developed; a colour presentation is reported in Ref. 2.

Now a reengineering of the project requires new concepts, and methodology of design performed by concurrent and instantaneous engineering.

A prosthesis, fully replacing a missing body part (thereby ensuring the functioning of a specific physiological system), acts as a true spare part which the person is able to interact with. Moreover, it ought to be borne in mind that, should the man-prosthesis interface be neglected, there is the risk of the individual feeling hindered when trying to move freely (on account of there being a sense of not fulfilling "naturally" those activities which the artefact was designed for).

According to this premise, the need to analyse a knee system based on a new and different design concept, emerges. K3 knee project presents an increased awareness of aspects related to medical/ biological/ engineering research, as well as the widespread use of cutting-edge technology (electronics, IT, material-related technologies, etc.)

2. Conceptual design of the K3 knee system

Correct design of a knee mechanism in lower limb prosthesis requires a series of analysis aimed at defining shapes, materials and usage of the object itself, in order to ensure that the latter satisfies all the necessary requisites. From a bioengineering point of view, the knee system requires design capabilities.

Prosthesis may be divided up into three categories: passive prosthesis, passive prosthesis with an energy store, and active prosthesis controlled by disabled individuals.

As things presently stand in the biomechanics sector, lower limb prosthesis are passive prosthesis, i.e. they are not capable of autonomously providing energy for walking.

Fig.1 – Artificial C-LEG, by Otto Bock Inc. (courtesy)

In fact, if one wished to use traditional-type electric motors, the latter would have to be extremely powerful as well as rather large. This is due to the forces: weight of the patient, forces and torque inertia during walking, which could significantly exceed the effect of the patient's weight.

Consequently, it is easy to understand why the design criteria of active prosthesis differ totally from those of passive prosthesis. The aim of the research work carried out in Laboratory is to design and develop a prosthesis that would enable an amputee to perform almost the same type of movements as with a natural limb. It requires the aid of the various cinematic motions, inherent in a hydraulic control device or artificial muscles. The main objective of this project is to develop a device offering the requisite functional characteristics with maximum reliability. Therefore, during the design process, two criteria were identified: a functional criterion and a structural one. Also a clear and extremely simple user interface is essential to the user.

3. Design requirements

Two basic functions are necessary for a prosthesis to be worn by a thigh amputee: the transmission of inertia loads from the pelvis to the ground when standing still, and being able to move the foot through a forwards arc.

A prosthesis designed for a thigh amputee must allow for optimum walking conditions, including the option of proceeding at various rhythms.

It may be appreciated that each of these rhythms presents different dynamic characteristics. The prosthetic mechanism must be designed with a view to satisfying all of them.

Despite the theoretical simplicity of the structure, over the last few years two particularly phenomena have come to light:

- The exponential growth and development of electronics applied to prosthesis;
- The proliferation of models (often passive) differing widely from those currently available (ranging from those fitted with only a spring to oil-pressure devices).

Some positive factors for the development of new design are the progress of electronics, the consequent reduction in cost of same, the calculation and storage increased power of chips, and the increasing convergence of mechanics and electronics.

4. Design procedure

An awareness of production processes, analysis

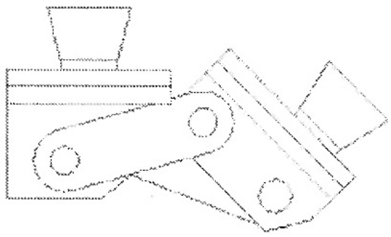

Fig.2 – CAD design of polycentric knee

methods and design procedures allows one to use not only the most suitable technology but also an approach methodology capable of solving various problems. This operation involves different stages which subsequently need to be validated.

The decision to launch a new system in the high tech devices sector involves the undertaking of a process that is generally not only long and costly in cognitive terms but which also involves various stages:

- ***Definition of an idea***

Not only is it necessary to have an awareness of discipline realities and attendant demands but also of the market niche in which the product will be positioned.

- ***Legal requirements analysis***

Based on the features of similar existing products and the technical regulations governing minimum

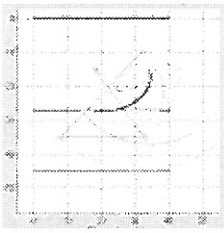

Fig. 3 – Drawing and design of profiles of polycentric knee

requisites, this analysis must identify the design criteria to be followed to ensure that the prosthesis will meet requisite demands.

- ***Formulation of a proposal and the initial technological hypotheses***

According to the above mentioned research, a first project formulation will be carried out in order to identify specific characteristics and initial cost hypotheses. Such financial hypotheses are extremely important owing to the fact that they are capable of piloting the project.

The designer's job is to identify the type of technology best suited to satisfying the requisite demands.

Design

This phase will include an initial project plan involving:

- an examination of the technologies available as well as those required;
- choice of technological tools to be used
- choice of materials and validation of same
- preparation of prototypes
- an examination of clinical data available either internally or likely to be found in literature on similar products
- assessment and reformulation of specifications.

Knee articulation

The most delicate part of a lower limb prosthesis project is the joint or knee.

Nature has created knees with ligaments for imposing the type of movement to be performed. Condyles absorb dynamic action. From this condition situation data are acquired for methods applicable in the design of a mechanical knee. The project is designated by the letter "K".

Joint Schematisation

When developing the first K3 knee design, the aim was to simulate as closely as possible the physiology and kinematics of natural joints, by employing joined profiles for the condyle function and connecting rods for that of crossed ligaments.

Two ligaments, referred to on account of their position as "crossed ligaments", may be found in the middle of the knee-joint.

In the front part of the joint, the antero-external (LCAE) crossed ligament is the most anterior on the tibia and the most external on the tibia. Behind the antero-external crossed ligament there is the postero-internal crossed ligament (LCPI), which is the most posterior on the tibia and the most internal on the femur. There is, however, a difference in inclination between the crossed ligaments. When the knee is extended, the antero-external crossed ligament is the most vertical whilst the postero-internal crossed ligament is the most horizontal.

In the frontal plane, their tibia inserts are aligned on the antero-posterior axis whilst their femoral inserts are distanced about 1.7 cm from each other. There is a constant ratio between the lengths of the two crossed ligaments. In general, the length of the antero-external crossed ligament is 5:3 *vis-à-vis* that of the postero-internal crossed ligament, i.e. LCAE:LCPI = 5:3.

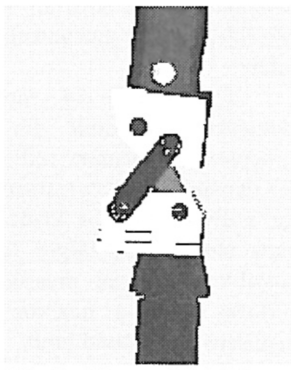

Fig.4 – The artificial knee on the prosthesis

The crossed ligaments ensure antero-posterior stability of the knee, thus allowing for hinge movements while ensuring that the joint surfaces of the condyles are always in contact. The condyle profile represents the curve that envelops the different positions of the tibia plate between bending and complete extension. This proves that the length of both crossed ligaments remains stable (or almost stable) whilst the profile of the femoral condyle remains at a tangent to the tibia plate. The shape of the condyle is geometrically determined by the length of the crossed ligaments, their proportion, and by the arrangement of their inserts.

According to the study design it is, therefore, possible to schematise the knee-joint as a quadrilateral

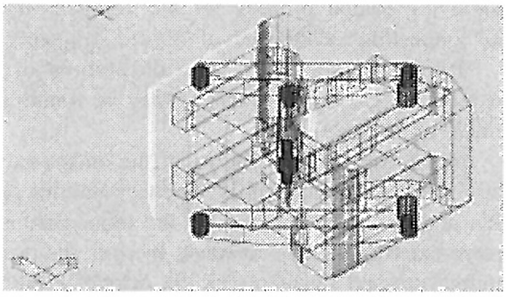

Fig. 5 – 3D drawing of the polycentric knee

jointed crossed system, where the femur (if considered fixed) constitutes the frame. The crossed ligaments represent the rods leading from the frame, with the last rod being constituted by the tibia.

One of the restraints imposed by the project are ligament lengths (average adult size with other sizes being determined for children, infants, etc.). The remainder of the structure is rendered as compact as possible, thereby guaranteeing maximum stability and safety.

The choice of separating the mechanical elements responsible for motion (single block structures, connecting rods) from those responsible for dynamic support (joined profile elements) allows for a division of the loads without jeopardizing the parts stressed by larger forces. In this way, it is possible to spread pressure over several different surfaces, with a function similar to that of the meniscus in a natural limb.

5. Polycentric knee design and construction

The crossed ligaments principle is used owing to the fact that the type of trajectory followed by the artificial limb depends on them. The ligament function is replaced by means of small bars pivoted on two mechanical structures: one connected to the femur, one to the tibia.

The pins on the two structures simulate the spatial arrangement of the tibia and femoral inserts of the ligaments themselves.

The mechanics consist of a system jointed with a crossed quadrilateral.

The measurements adopted in creation of the model and subsequent prototype simulate the average anatomical measurements obtained from x-rays both with regard to ligament length as well as positioning of inserts.

The phases for the design of the polycentric knee are:

- definition of mechanical ligaments and condyles in their position
- mathematics and equations or the shape of articulated link and shape of the envelope of condyles (Fig. 2)
- check of the dimensions and volume
- drawing of the final shape of the condyles and ligaments (Fig. 3)
- Simulation of the motion (Fig. 4)

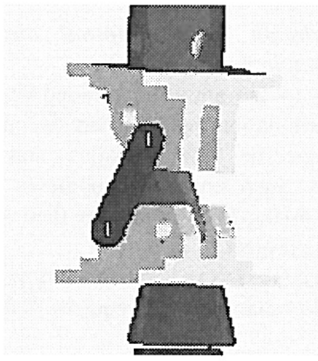

Fig. 6 – Solid model of the polycentric knee

- CAD for the design in 2D and 3D (Fig. 5)
- Analysis of mechanical stresses
- Analysis of the possible motions of the knee (Fig. 6)
- Rapid prototyping of the first model
- Manufacturing procedure: analysis of the design and choice of final materials
- Mechanical performance tests.

6. Control

The starting point of the project was to search the maximum simplicity and the maximum performances for the prosthesis.

The today productions show limits of different type, such as the reliability limited by the system complexity, quite prohibitive purchase and maintenance costs.

Main element of the project has been used a spring, which is responsible for the accumulation and successive return of the energy used during the pace by the amputated person. The particular shape allow to control and modify easily the spring parameters (stiffness and pre-load) using a simple electric motor which works on the spring by a cam.

An electromagnetic brake, coupled to a reducer, carries out the operation of pace control and works on it when the sensors placed on the limb indicate abnormal changes of the preset parameters.

The knee joint control is obtained by an electric motor which activates the speed reducer with a profiled cam so as to achieve a controlled pressure at the end of the springs of the elastic system of the accumulation and return energy of the knee motion. In fact the cam forms the unilateral bond on which engages the second end of the bar.

The electric motor is controlled by a software realised according to person's requirements. The motor action is regular. There are not hydraulic valves and servo drive.

7. Creation of a knee-joint model

For all prosthesis in general and, in particular, for those of the lower limb, one of the main problems consists in containment of the total weight of the device. For this reason, particular emphasis is placed

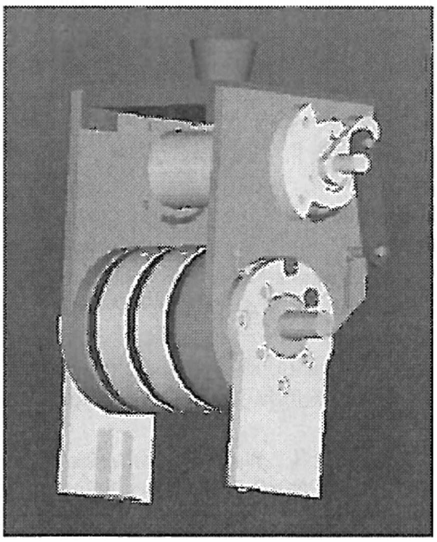

Fig. 7 – Joint in the knee on the prosthesis

on the choice of construction materials. The overall cost of the device also needs to be considered.

An additional problem concerns the dragging of the tip of the artificial limb foot on the ground. The knee with an articulated quadrilateral and parallel connecting rods is designed in such a way that when the leg moves through its arc the thigh, relatively speaking, is already considerably advanced. This therefore obviates the problem of the foot dragging on the ground; furthermore, in this way the foot need not be jointed at the ankle.

8. Scheme of sensors and actuators

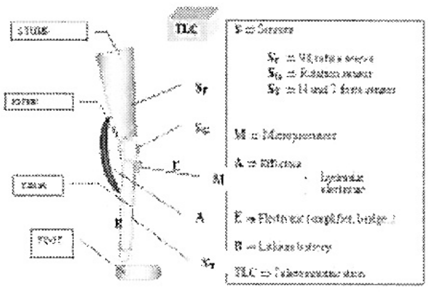

Fig. 8 – Model of the disposition of sensors and actuators in the prosthesis

The general criterion is to seek sensors which will assure accuracy, repetition and reliability.

Another criterion is to minimise the consumption, since the supply available comes from some battery and therefore is limited in time.

It has been decided to reduce the number of sensors and to apply a Fuzzy Logic control.

The knee angle of rotation is identified by the output in a potentiometer connected to the rotation of a rod.

The average speed of knee rotation over a fixed time is obtained from rotation sampling.

Since the sampling interval is constant, once the rotation value in a certain instance has been stored, an average rotation speed index is provided by the difference between the current rotation value and the previous one.

The compression and bending measurement in the artificial tibia is given by two strain-gauge bridge circuits (suitably compensated), placed on the aluminium element comprising it.

The presence of a vibration sensor positioned on the stump permits to detect the position and movement of the femur.

9. Telecontrol and telediagnosis

Since the sensors level of the prosthesis is high, it is necessary to operate from outside onto the electronics in order to make calibration and diagnosis operations. A telecontrol system designed ad hoc, very simple but extremely versatile, permits data transmission between leg and computer control. As a innovative application, programs can be done ignoring which will be the protocol of data transmission channel, concentrating exclusively on their data output. Telecontrol system will then put on their way the data transmitted on the telephone line, ISDN or GSM. Test have shown the system functionality with these technology, and it is operative. The device developed tries to draw the maximum advantage from the existing technology. The device is characterised by the maximum portability together with the minimum cost. It is proposed for a patent.

10. Conclusions

The design of a new prosthesis with the most updated technologies and with the most modern concepts of biomechanics and physiology requires integration for reducing the costs, improving the capabilities and assuring the required safety and reliability.

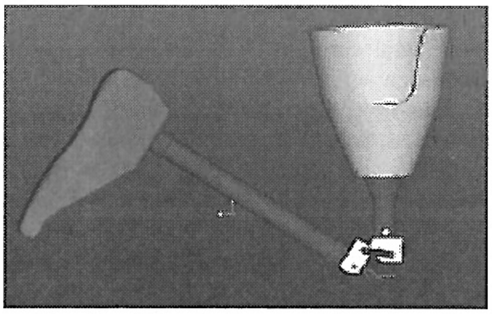

Fig. 9 - The design ought to be able to simulate the main natural movements of the human knee

The project is under development with some ideas which have been applied already in the realization of this prosthesis and which are new for the orthopaedic field.

The first results are on a new model of polycentric knee, to be inserted in high technology prosthesis, to be generated by new principles of engineering. Concurrent engineering, use of CAD and design strategies, evaluation of costs and development of prototype in short times are basic concepts for the new prosthesis which will follow the considerations here presented.

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