Biorobotic design criteria for Innovative Limb Prosthesis

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Abstract
Research work on prostheses currently being carried out at the Robotics Laboratory (Mechanics Department, Milan Politecnico) is both innovative and stimulating, owing to the fact that not only does it involve a range of specialists but also gives rise to that interdisciplinary aspect which is absolutely essential when dealing with such complex issues.

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

Introduction
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.

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**Philosophy and design of the K3 knee system**

Correct design of a knee mechanism in lower limb prostheses requires a series of analyses 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 poses some of the most interesting problems.

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

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

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

Consequently, it is easy to understand why the design criteria of active prostheses differ totally from those of passive prostheses.

The aim of the research work carried out at our laboratory was to design and develop a prosthesis with the kind of energy store that would enable an amputee to perform almost the same type of (even complex) movements as those performed with a natural limb with, obviously, the aid of the various kinematic 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. The design of the mechanical structure will depend not only on these characteristics, but also on criteria of maximum reliability.

Therefore, during the design process, two criteria were identified: a functional criterion and a structural one. When designing this system, moreover, in order to reduce overall prosthesis weight to a minimum, downsizing is essential.

A clear, compatible and extremely simple user interface is essential to the user.
**Design method**

As far as the lower limb is concerned, the most significant issue is the one related to the degree of load needing support: excessive deformations, permanent deformations and failures should be avoided. Furthermore, it is necessary to find a physiologically appropriate alternative discharge point vis-à-vis the lower limb.

Initially, the restraints inherent in the project were analysed. This resulted in our guaranteeing, for example, two basic functions 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.

The prosthesis must therefore satisfy two different requirements relative to the ambulatory phase. The first of these is stability, requiring the assessment of constant geometries in relation to substantial loads. Owing to specific foot trajectory, the second requirement consequently requires variable geometry.

When actually designing the prosthesis, every effort needs to be made to ensure that both of these requirements are satisfied within the same system.

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 interesting phenomena have come to light:

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

Quite clearly, these two phenomena are closely connected; in fact, both are linked to the incredible progress of electronics, the consequent reduction in cost of same, the increased calculation and storage ability of chips, and the increasing convergence of mechanics and electronics.

**Design procedure**

An awareness of production processes, analysis 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 requisites, this analysis must be conducted with a view to identifying the design criteria to be followed in order 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**
It is immediately evident that the most delicate part of a lower limb prosthesis project is the joint or knee.
Since nature has created knees with ligaments for imposing the type of movement to be performed, as well as condyles for absorbing dynamic action (in short kinematics and dynamics), using a model designated by the letter “K”, we decided that it would be appropriate to draw from this situation in order to acquire data and methods applicable in the design of a mechanical knee.

**Joint Schematization**

When developing the first K3 knee design, our 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 fibia. 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 tibial inserts are aligned on the antero-posterior axis whilst their femural 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.

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 tibial 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 tibial 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 schematize the knee-joint as a quadrilateral jointed crossed system, where the femur (if considered fixed) constitutes the frame, the crossed ligaments 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
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 (monoblock 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, we maintain that it is possible to spread pressure over several different surfaces, with a function similar to that of the meniscus in a natural limb.

**Control**

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

To do it was decided to look for solutions different than the ones now in production, convinced that the actual productions shows limits of different type, such as the reliability limited by the system’s complexity, prohibitive purchase and maintenance costs.

That’s why as main element of the project has been used a bending 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’s parameters (stiffness and preload) using a simple electric motor which works on the spring by a cam.

An electromagnetic brake, coupled to a reducer, carry 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’s and so the whole joint control is obtained by an electric motor which activates the 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’s motion.

In fact the cam forms the unilateral bond on which engages the second end of the bar, this allows to preload the first bar and so translate upwards the characteristic force-rotation.

But the system’s curve is not simply translate upwards, modifying the support position cause also a reduction of the free rotation angles of the successive bars, anticipating the action.

The electric motor is controlled by a software realised as person’s pace progress. The motor action is regular. There are not hydraulic valves and servo drive.
Creation of a knee-joint model

For all prostheses 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 on the choice of construction materials. Along with the choice of material there is also a need for sturdiness (i.e. adequate material resistance to the strains which the artificial knee is subjected to). The overall cost of the device also needs to be considered.

An additional problem concerns the dragging of the tip of the foot of the artificial limb 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.

The “K3” artificial knee project envisages the creation of a new type of “knee” with an innovative mechanism aimed at solving the problems related to contact of the tip of the foot with the ground.

In fact, the design ought to be able to simulate (within technological limits) the main natural movements of the human knee, which are piloted by the crossed ligaments. The term “natural movement” merely implies the device’s being designed to cope with extension and bending of the leg - unlike the natural human limb, which is able to perform numerous other fixed movements in addition to the main elements of motion.

The crossed ligaments principle was used owing to the fact that the type of trajectory followed by the artificial limb depends on them. The ligament function was 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 tibial 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.

Diagram of sensors and effectors
As general criterion will be used to seek those sensors which will assure accuracy, repetition and reliability.

Accuracy means the distance between our and the exact measurement; repetition means the dispersion of such data respect the exact one and reliability means a certain number of working hours (or working cycles) which the device can tolerate without breaking down.

Another criterion of this study was to minimize the consumptions, since the supply available comes from some battery and therefore is limited in time; that’s why it has been decided to reduce at least the number of sensors and to apply a Fuzzy Logic control which allows to use better the potentiality of the sensor and moreover gives the chance to integrate all the information of the sensors giving in that way a complete and more detailed vision of the situation. Since the aim of sensors is to give to the control system an image of the reality in a defined moment, every part of the prosthesis must be sensorized in a functionality way, giving so to each element of the prosthesis a sensor which will gather the condition of the part connected to his function in the prosthesis economy.

In order to fulfil all the requirements and constrains of this study it has been decided to implement it with Axiomatic Design. This theory helps the designer taking the best solution among many, respecting the constrains of the project and...
accomplishing the requirements. Thus the best sensors identified to be the most suitable for this study appears to be:

1. A flexible lamina with strain-gauge to detect the knee's angle of rotation by the proportional flexion that results from the rotation. 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.
2. Two strain-gauge bridge circuits (suitably compensated), placed on the aluminium element, to measure the compression and bending in the artificial tibia.
3. A vibration sensor positioned on the stump, it permits ascertainment of the position and movement of the femur; also gives information about the frequencies of the step, thus revealing if the patient is walking, jogging or running.

Telecontrol and telediagnosis

Since the sensorisation level for the prosthesis is high, it is necessary to operate from outside onto the edge’s electronics in order to make calibration and diagnose operations.

A telecontrol system designed ad hoc, very simple but extremely versatile, permit to simplify a lot the software realization for the data transmission between leg and computer control.

As a matter of fact the programming step can be done ignoring which will be the data transmission channel, concentrating exclusively on their control; the telecontrol system will then put on their way the data transmitted on the analogical telephone line or, theoretically, ISDN or GSM (have been planned test session which will show the system’s functionality with these technology, nevertheless it is yet fully operating with analogical line).

The device by us developed try to draw the maximum advantage from the existing technology, to make up, with a simple stratagem hardware/software, for the lack found. The device is characterized by the maximum portability together with the minimum cost.

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