The scientific problems for the creation of a knee prosthesis device

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ABSTRACT

The complexity of bone movement in the knee articulation requires a study of its anatomy to achieve a knee prosthesis device. A good prosthesis presents surface shapes allowing all physiological movements of the knee. Thus it must present a shape as close as possible to the physiological mean surfaces of the knee articulation.

The new type of prosthesis presented here, is the result of such a scientific approach.

We measure the human bone surfaces of a significant population with a triaxial measuring machine and we compute a middle surface used as a basic surface for our study.

Then, using B-splines technics, we study the parameters allowing to build again the condyle surface respecting ligament kinematics and constraint transmission. Our prosthesis device respects the position of the patella on the condyles and the trochle shows a shape close to the anatomic shape. In relation with this research it has been necessary to study new intramedullary rodes and some new technic of laying.

INTRODUCTION

The first knee prostheses had hinges like, for instance, the prosthesis of GLUCK (1890) [1] made of ivory or the one by WALLDIUS of acrylic [2]. At present the GSB 2 [3] and GUEPAR [4] prostheses, although they are not so constrained, are still based on the same principle but they are only used in particular pathological cases. This type of prostheses with hinges has very rapidly showed that it did not sufficiently respect the physiological movements of the knee articulation. So it had evolve to a type of sliding prostheses which makes it possible to follow the natural movement of the condyles and to reduce the constraints on the anchorings. This new concept is the basis of the success of prostheses such as (for example) TOTAL FREEMAN-SWANSON [5], CONDYLAR [6], ICLH FREEMAN [7], MGI [8], OSTEONICS [9], etc, prostheses.

It is difficult to compare the performances of the different prostheses on the market because they are generally implanted on old people who have reduced...
motion requirements. However all theses prostheses, even those used at present allow only an average bending of 100° to allow certain standard movements of the everyday life.

Our first aim is to design and realize the new type of prosthesis we present here in order to improve its performance and a functional device not only for old people but also for younger persons.

From a significant population of human femurs, we can define an average shape of the knee articulation: condyles TROCHLIA. This stage is carried out using a three-dimensional measuring machine which give results that are processed by a CAD-System and by softwares specially developed for this study. The smoothing techniques of B-spline functions then to perform this average shape and to associate a tibial plateau and a patella inseparable from the prosthesis. Thus the kinematics of the ligaments has been respected and the mechanically stiff points eliminated. Lastly a new type of intramedullary TIGE associated with a new technic of laying has been elaborated to complete the whole.

MEASUREMENT OF THE BONE SURFACE

Three-dimensional topography is done on a machine of the accuracy measurements 2 microns, that is represented opposite. The measures are safeguarded in a computer file which enables an easy exploitation of the data by CAD-software. Furthermore it is fitted with a device approach to normal which makes it possible to measure with a great accuracy surfaces of any shape. Different types of sensors pick ups are available to measure the most complex surfaces. Contrary to the scanner sections, it allows to take account of the thickness of the cartilage.

DATA REDUCTION

Exploitation of the data of the measuring machine
After measuring of the surfaces of femurs of different sizes data are stored in computer files of the datas.

Contrary to the large-sized femurs, the condyles of the small-sized femurs present, a more important curvature in the transverse plane and the tibial surface is flatter. A first approach could consist in defining a size of prosthesis per size of femur respecting this way the anatomic features of each size, the kinematics of the ligaments and the shape of the surfaces of the knee articulation. Nevertheless it would have the disadvantage of an important increase the number of the prototypes and of the tests and would lead to considerable overall cost.
The second approach, that we will adopt, consists in defining an average shape from all the femurs analysed. In this case we have only one shape which is extended or reduced to create the different components of the prosthesis. This shape takes most of the useful anatomic features of the shape of the condyles into account. It enables in a first time to confirm our choice of a general shape before it considers the characteristics of each size (respect of the contraints allowed by the materials, respect of the movement of bending and stretching and the stability during the functioning). We must not forget that standard simulators do not allowed to track mechanical resistance of the prosthesis during its life time. They cannot reproduce the real performances i.e. its harmonic functioning and the respect of the ligament kinematic. Therefore we have chosen to carry out some minor modifications of the average shape allowing us to determine step by step the particular features of each size.

**Determination of an average shape**

The files containing the measures are interpreted by a CAD-system in order to visualize and to compare the surface of the femurs of different dimension and orientation. These figures present a front-back scale ratio that is different from the lateral scale ratio. To compare them, it is necessary to bring them to a single dimension. We can use either the average ratio or one of the two ratios. The we choose to determine the constant front-back dimension to favour the shape in the sagittal plane, and we apply the front back scale factor in order to bring all the surfaces to a same front-back dimension.

After this change, these surfaces are reoriented to be superimposed on one of the surface used as reference. This reorientation (translation and rotation) is carried out step by step when controlling the difference between them. This technique of superposition is used as the starting point for the method which makes it possible to determine an average shape. The result of the superposition if 4 surfaces is represented on Figure 1.

After having noticed that the lateral dimensions are different, we try define an average surface. We consider two methods. The first one consist in finding the average point by point knowing that each surface is built the same way. The second method consists in determining the average surface from the normal to the surface. In this case, we choose one of the surfaces as reference and we calculate the intersection points of the other surface with the normals of reference surface. The average points located on each normal gives us the points for the definition of our average surface. These computations have been entirely carried out by ourselves.

Let us compare these two methods for our specific case. Let us consider two curves defined by circular arcs of different radius and of distinct centre; these geometric shapes are simple and are similar to the shape of the condyles in the frontal plane. We carry out a translation between these two curves to get closer
to our practical problem and determine the average curve obtained with these two methods. The results are presented on figure 2 and 3.

Figure 2: Method of the normal to the surfaces  
Figure 3: Method of the averages point by point

With the method of the normals, the average curve presents a dimension which is inferior or equal to the smallest curve and although it is built from two circular arcs. Therefore, it is no longer a circular arc but a curve with a very similar shape. If the intervals between the surfaces are important, this method as the disadvantage that it leads to a final average surface that is very limited since it is the part common they have in common.

In the case of the average curve determined point by point, we obtain an average of intermediate dimension between the two starting curves, which is bigger than the one determined by the method of the normals. Furthermore it presents the advantage that it respects the geometric characteristics of the basic curves because we obtain a circular arc as a result of the two circular arcs.

We choose this method which is really suited to our problem and which permit us to obtain an average surface which is better than the one determined with the normals. The average surface determined from the femur population is represented on figure 4.

Figure 4: Average surface of condyles

The smoothing technique by Spline functions

The spline functions constitute a particularly flexible instrument which provides unlimited possibilities to smooth curves or surfaces defined by points. The data have to be presented in the form of a square of surface (Figure 5) with a constant number of points in the direction of u and a constant number in the direction of v. The mathematical expression (1) constitutes a smoothing of the surface given by the points \( P_{i,j} \)

\[
S(u,v) = \sum_{i=0}^{m-1} \sum_{j=0}^{n-1} P_{i,j} B_{i,k}(u) B_{j,k}(v) \tag{1}
\]

Where \( B_{i,k} \) refers to the B-spline of order k defined below. \( B_{i,k} \) is a polynomial defined in giving of n real values (nodal values) and of a formula of recurrence. It depends on 2 subscripts, the first relating to the interval on which
we consider the variable $x$ and the second is the degree of the polynomial obtained. It confirms the following relation of recurrence

$$B_{i,k}(x) = \frac{x-t_i}{t_{i+k}-t_i} B_{i,k-1}(x) + \frac{t_{i+k+1}-x}{t_{i+k+1}-t_{i+1}} B_{i+1,k-1}(x)$$

where the $B_{i,0}$ are equivalent to $1$ on $[t_i,t_{i+1}]$ and to $0$ everywhere else. In the same way as for the surfaces, we can smooth the curves defined by a series of points $P_i$ with an expression such as

$$C(u) = \sum_{i=0}^{m-1} P_i B_{i,k}(u)$$

(2)

If we change the $t_i$ and the value of $k$, we can influence on request the nature of the smoothing just as well for the curves as for the surfaces. The example of figure 6 shows the influence of the values of the $t_i$ and of the doubling of the points;

![Influence of the $t_i$](image1)

![Doubling of the points](image2)

Figure 6

the example given in figure 7 shows the influence of the degree of the spline functions and of the distribution of the $t_i$ for a pyramid frustum.

![Figure 7](image3)
Improvement of the average shape

Widely used in numerous fields of industrial design, the smoothing techniques by spline functions can also be used to smooth the surface of the condyles. To make use of this technique, the surface has to be divided into squares leading to a constant number of measured points in both directions (Figure 5). Unfortunately the measurements carried out on the three-dimensional measuring machine only allow to get to the femoral surface in three distinct parts: The trochlea, the internal condyle and the external condyle. To obtain a single square, we fill in the space between the two condyles (part that is not used from a mechanical point of view) checking that this decision does not influence the surfaces of the condyles and the trochlia. So after having studied the influence of the addition of filling points by B-spline-techniques, we have established that an extension of the surfaces of the condyles in the direction of their tangent plane by points which are symmetrical to those of the condyles in relation to the edge gave complete satisfaction (Figure 8).

Our surface of the condyles appears now as a single square (composed of m.n points) that we can easily smooth to obtain an average shape. The smoothing of this surface is carried out by splines of order 3 using the expression (1) with \( k = k' = 3 \)

This leads to a mathematical expression whose graphic result is represented in figure 9.

Before elimination of the filling area

After elimination of the filling area

Figure 9: Average smoothed shapes
However this average shape presents certain imperfections (irregularities, shape of the trochlia, too small a contact surface, problem of the patellar engagement). Therefore it is necessary to modify it while keeping its anatomic characteristics (kinematics of the ligaments, unwinding of the condyles, engagement of the patella between the condyles). A study of the surfaces per contour lines of the average shape and of its rolling print shows a certain invariability of the shape (Figure 10).

![Average shape](image1)

![Rolling print](image2)

Figure 10 - Contour lines

These properties of regularity and the tools we have developed enable on the one hand to determine the "parcours" and the shape of the patella conditioning a good respect of the kinematics of the ligaments and, on the other hand, to re-create the shape of the surfaces of the condyles from only two particular curves built with the help of B-splines functions. This particularity simplifies to a large extent the possible modifications and the industrial manufacturing. The final product, a prototype made of chromium-cobalt, is represented on figure 11.

The tibial plateau and the patella

The tibial plateau is determined such as to respect the natural movement of the knee while having the greatest possible contact surface in order to reduce wear and transmitted stress. Its profile takes the required constraints of stability into account, it has been realized in polyethylene and is presented on figure 9.

The patella is a button type patella, commonly used for the other prostheses, and has been realized to be constantly all time a complementary shape with respect to the trochlia. It is also made of polyethylene and represented on figure 11.
CONCLUSION

This study has allowed to realize a set of femoral prostheses. The implantation and the test on cadaver has shown a high increase in the usual performance, especially of the bending angle. Industrial exploitation is beginning.

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