COMPUTER ASSISTED DESIGN AND EVALUATION OF A KNEE PROSTHESIS

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INTRODUCTION

This study deals with the design of a new knee prosthesis achieved by means of a concurrent engineering procedure through which we are able to define a virtual prototype for industrial manufacturing. The success of the industrial manufacturing depends on the ability of the prosthesis of maintaining the anatomical, functional, biological and surgical compatibility during its lifetime: these four features are strictly linked to the shape and the dimensioning of the implant, to the materials the prosthesis is made of, to the manufacturing technologies. Usually the above features can be acquired through a time and money consuming design procedure that often implies high enterprise risks, a possible early obsolescence and great marketing costs which strongly reduce the commercial competitiveness. The aim of this work is to demonstrate that part of this process can be significantly facilitated through the use of methods based on the computational codes and computer aided design (CAD) techniques. Those methods allow a feedback action in most of the steps of the whole process thus permitting an important time saving because it prevents from testing prototypes that could be rejected in advance because of non-conformities with most of the compatibility requirements. The technical core of the design procedure here adopted is based on the following steps: 1)-obtaining the digital data drawn from magnetic resonance images of a healthy knee; 2)-definining 3D CAD solid models of the knee; 3)-designing the knee prosthesis by means of CAD techniques; 4)-carrying out numerical simulations to check mechanical reliability and functional compatibility; 5)-evaluating by CAD the surgical protocol and the related surgical tools previously proposed. Furthermore the above design procedure is completed by manufacturing a stereolitographic prototype and by functional tests concerning the evaluation of contact stresses and of fatigue resistance of the tibial tray.

MATERIALS AND METHODS

1) Anatomic data acquisition from digital diagnostic

Anatomic data are obtained from nuclear magnetic resonance (NMR) axial scans a of 32 year old man's right knee; a specific acquisition protocol has been set up with a 1.5 T magnetic field, a scan interval of 1 mm obtaining 150 images at a 512x512 pixel of resolution.

2) CAD 3D reconstruction of anatomic features.

From elaboration of the NMR images, 3D CAD models of the knee are obtained (Figure 1). These models will be the anatomical-functional reference for the design of the prosthesis, for its compatibility evaluation, for the surgical instrumentation design, for the surgical operation planning.

3) CAD design of the knee prosthesis.

The prosthesis has been designed with a rotating platform and allows the retaining of the posterior cruciate ligament. CAD sketches and the 3D model of the prosthesis are here reported (Figure 1).

Figure 1. Bone volume reconstruction (left) and 3D model of the prosthesis (right)

4) Numerical simulations

The compatibility of the prosthesis has been evaluated through the use of computational codes with regard to the kinematic of the implant, to the contact pressures that rise between the components of the prosthesis, to the fatigue life of the tibial tray. The kinematic compatibility has been checked by comparing the kinematic of the normal knee with the one of the prosthetic knee (Figure 2): measurements of the length of the collateral ligaments have been performed by means of the CAD software at different flexion angles.

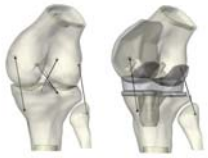

Figure 2. Kinematic model of the natural knee (left) and of the prosthetic one (right) at 60° flexion

Through the use of the commercial code Abaqus (Hibbit Karlsson & Sorenses, Inc., Pawtucket, RI, USA), the patterns of contact stresses on the proximal and distal surfaces of the Polyethylene (PE) insert have been calculated by means of Finite Element Method (FEM) at different flexion angles and the ISO 14879-1 2000 standard fatigue test on the tibial tray has been simulated (Figure 3).

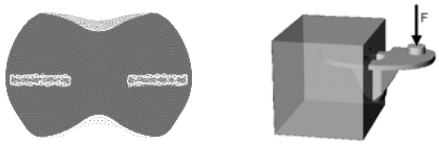

Figure 3. FEM results at 45° flexion (left) and sketch of the ISO standard fatigue test (right).

The fatigue life of the tibial tray has been predicted by matching the results of the computational simulations with the use of Sines fatigue criterion. Moreover, experimental tests have been carried out in order to validate the numerical method: contact pressures have been measured by means of Fuji pressure-sensitive film and fatigue tests according to ISO standard have been performed in order to validate FEM calculations

5) Surgical procedure simulation

Through the use of the model of the knee and the CAD software it is possible to simulate the surgical procedure (Figure 4) in order to specify the design of the surgical tools: the advantage is the possibility of previewing the results of the cutting operations and, in case of errors, the possibility of changing the procedure.

RESULTS

The results for the kinematic compatibility evaluation are reported in Figure 5 where the length variation of the ligament is reported at different flexion angles for the natural and the prosthetic knee: $\lambda=(L_0- L_\theta)/ L_0$ where L_0 is the resting length of the ligament and L_θ is the length at θ flexion angle.

As regarding the contact pressure patterns, the numerical simulations have been validated trough experimental tests whose results are reported in Table 1. On the superior surface, the first attempt design of the prosthesis caused a high concentration of stresses at 60° flexion near the tibial crest: in this case, the feedback action permitted a re-designing of the PE insert obtaining a more conforming surface thus reducing the overstresses (Figure 6).

Table 1. Comparison between FEM calculations and Fuji film measurements

FA	0		15		45		60	
	FEM	Fuji	FEM	Fuji	FEM	Fuji	FEM	Fuji
SSP	**5**	**7**	**13**	**14.5**	**24**	**25**	**22**	**22**
ISP	**2**	**2.5**	**5**	**6.5**	**10**	**11.5**	**8.5**	**9.5**

SSP= Superior surface pressure [MPa];
ISP= Inferior surface pressure [MPa]; FA=Flexion angle [°]

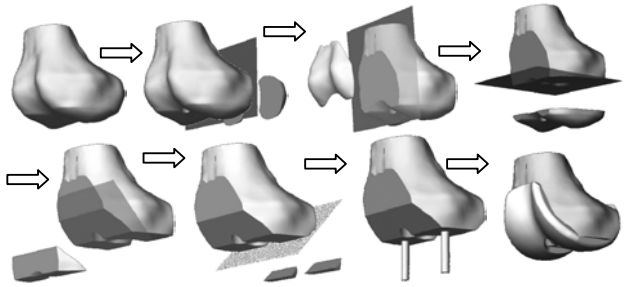

Figure 4. 3D simulation of the surgical procedure for the femur.

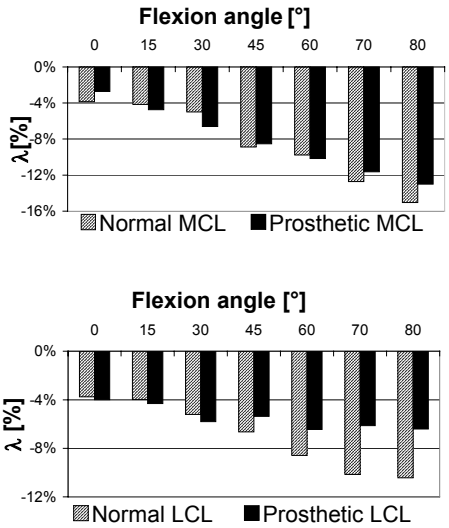

Figure 5. Results of the kinematic analysis.

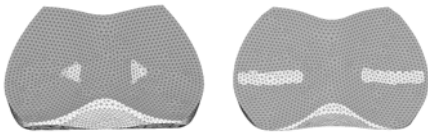

Figure 6. Contact pressures patterns at 60° flexion before the design feedback action (left) and after it (right).

As regarding the fatigue life of the tibial tray, FEM simulations predicted no failure for 500N, 2000N and 4000N loading condition: experimental tests confirmed these predictions; also for 4000N loading condition FEM simulations were confirmed by the experimental test (the prosthesis resisted less than 400.000 cycles). In order to verify the anatomical and functional compatibility of the prosthesis a stereolitographic prototype from the 3D CAD model of the bone after the surgical cuts and of the prosthesis has been manufactured (Figure 7) and mounted together.

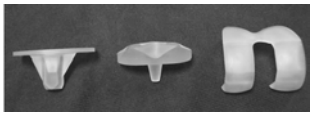

Figure 7. Stereolitographic models of the prosthesis.