

EVALUATION OF THE MECHANICAL RELIABILITY OF A KNEE SPACER

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INTRODUCTION

One of the most important factors that causes the failure of a knee prosthesis is the infection that can arise in the tissues after implantation due to an incorrect surgical procedure, to a difficult repairing process or to other patient's pathological conditions. The infection can arise soon after implantation as well as in one or two years after the operation. In order to let the infection heal and to restore the knee physiological conditions, the prosthesis must be removed and antibiotic therapy must be performed. Between the removal of the prosthesis and the re-implantation of a new one, a knee spacer is implanted in the knee: the spacer has the same shape and geometry of a knee prosthesis (Figure 1) and is made of polymethylmethacrylate (PMMA) with gentamicin sulphate additive in order to obtain a locally focused therapy for infection healing.

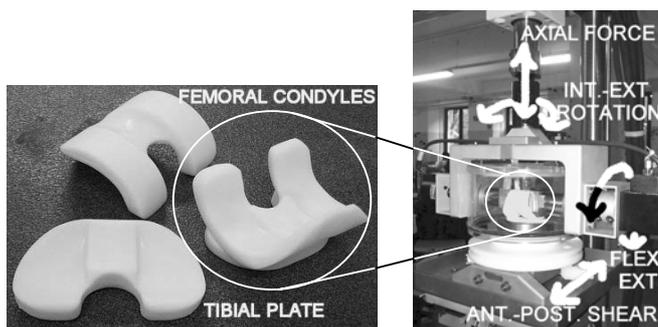


Figure 1. Knee spacer (left); MTS knee simulator (right)

Moreover the spacer allows for movements of the joint and helps the muscles remain relaxed and toned in the period before re-implantation, thus decreasing the post-operative rehabilitation period [1-4]. After assessing the validity of such device in producing infection healing, in the pre-clinical phase of evaluation, the aims of the present tests were

to assess both the mechanical reliability of this new device and its wear performances.

MATERIALS AND METHODS

Three knee spacers of three different sizes (small, medium and large) were manufactured and provided by Tecres S.p.a., Sommacampagna (VR), Italy. The mechanical performances of the spacer have been evaluated through cyclic tests performed on a four degrees of freedom MTS knee simulator (Figure 1). The knee simulator allows to impose simultaneously with the axial force three kinematic conditions, namely the flexion-extension and the internal-external rotation of the femoral condyles and the antero-posterior shear of the tibial plate. The patterns of the axial force and of the flexion-extension conditions are reported in Figure 2; the internal-external rotation was set to a fixed value because the knee spacer does not allow any rotation about the vertical axis while the lower sliding block was left free to move in order to adapt itself to the movement imposed by the condyles flexion-extension.

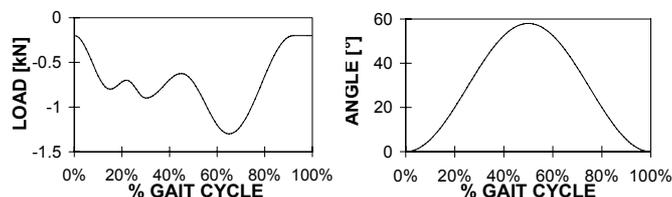


Figure 2. Load waveform (left); flexion-extension (right)

The maximum of the imposed load was set to 1300 N, half of the load that normally acts during walking: this was due to the fact that the patient, during the rehabilitation period walks with the aid of crutches. The loading cycles were repeated for 500.000 cycles, thus simulating a six month walking activity of the patient, which should be the period of implant of the spacer. In order to replicate the in vivo conditions, on

the MTS knee simulator the spacer is located into an environmental chamber and kept constantly lubricated by means of a mixing of water and bovine serum at the temperature of 37°C. At the end of the cyclic test the debris deriving from the spacer wear is collected and weighted: in order to measure the weight of the only debris a chemical procedure consisting in the acid digestion of serum proteins and in the separation from water has been set up. The experimental procedure is completed by the measurements of contact areas between the femoral condyles and the tibial plate by means of a pressure-sensitive Fuji Prescale Film before and after the cyclic test.

RESULTS

All the spacers have shown no sign of failure after the cyclic tests, thus assessing their use for at least six months of a normal walking activity. The results of the contact area measurements before and after the wear tests are summarised in Figure 3: all the spacers have increased the area due to the wear process.

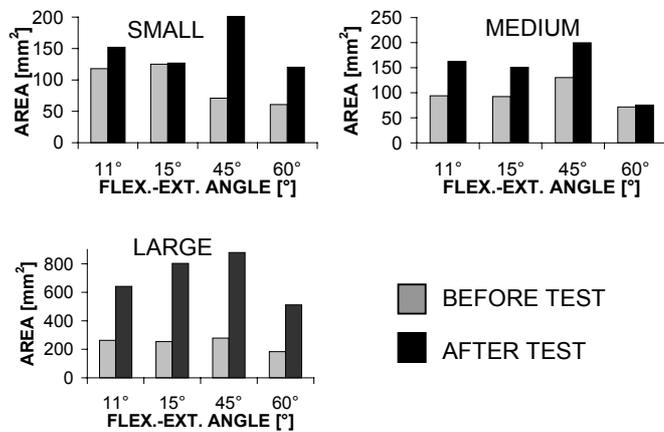


Figure 3. Contact area measurements results

The results of the wear debris measurements are reported in Table 1.

Spacer size	Debris weight [mg]	X length [mm]
Large	501.4	7.56
Medium	96.9	5.29
Small	22.6	4.78

Table 1. Wear debris measures and wear scratches lengths

DISCUSSION

As concerning the mechanical resistance, this has been assessed by the fact that no failure was recorded for any size of the spacer at the end of the loading sessions. As concerning the wear performances, the quantity of wear debris produced during the test is governed by the equation:

$$V = \int_A kx\sigma dA$$

where V is the volume of wear debris, k is the so-called wear factor, x is the sliding distance, σ is the stress related to the force acting during the wear process distributed on the A area. All the spacers, as easily

predictable, have increased their contact areas, at the end of the test, due to the fact that the components adapt their shapes as long as the test takes place. On the other hand, the influence of contact areas on the debris production is not univocally determined, as an increase of contact area involves an increase of the A factor in but, at the same time, causes a decrease of the σ value, thus producing a decrease of the wear debris. The influence of the k factor is not a key in the debris production in our tests, as k depends only on the nature of the materials of the two surfaces coming in contact. The results of the wear debris measurements indicates that the production of debris is correlated to the size of the spacer: the role of x is hence a factor that has to be examined. Starting from the wear scratches left by the wear process on the femoral condyles (Figure 4), a first-attempt estimation of x was performed: the scratched area was transferred by means of a transparent film and its digitised image was obtained through a HP ScanJet 6250C scanner. The image was then imported into a CAD software and the length x in antero-posterior direction of the trace due to the wear process was this way measured. The results of such measurements are reported in Table 1.

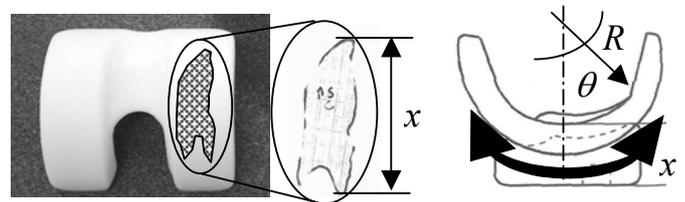


Figure 4. Wear scratches measures (left); spacer geometrical parameters (right)

Moreover, if one considers the spacer kinematic, the sliding distance x is related to the size of the spacer, being x proportional to the product $R\theta$ (Figure 4), where R is the radius of curvature of the femoral condyles and θ is flexion-extension angle. As all the tests have been conducted using the same flexion-extension angle, the x factor increases with the spacer dimension, in agreement with the measured value reported in Table 1. As a conclusion, the factor that seems to mostly influence the production of wear debris is the sliding distance, that in these tests is proportional to the size of the device: this information can be given to the surgeon that must know that a bigger spacer, that is supposed to be implanted on a bigger (and heavier) patient, probably, runs into a more severe wear debris production.

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