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EX-IN VITRO TESTING OF TOTAL KNEE REPLACEMENTS – SECOND PART

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Abstract: The second part of the paper presents the methodology of ex-vitro testing of total knee prostheses an experimental stand. To be tested knee prosthesis was designed and constructed a number of auxiliary devices. Testing the knee prosthesis was made taking into account the provisions of international standards ASTM and ISO. To determine the degree of wear have been used a range of equipment such as a 3D coordinate measuring machine, an analytical balance and a digital microscope.

Keywords: knee prosthesis, experimental stand, analytical balance, digital microscope

1. EXPERIMENTAL STAND

To test for total hip or knee prosthesis, in the Laboratory of Biomechanics and Biomechatronics (Dep.DPMM) was designed and conducted an experimental stand in 2011. More information about the construction and operation of this stand are in the works [1],[2]. This stand allows the simulation of all the movements of the coxo-femoral joint, and in which the knee. Amplitude compression forces and movements can be varied within a fairly wide range.

Ensuring compression force required to simulate loading of hip or knee joint is achieved by means of two pneumatic pistons controlled by a distributor. Movements of synovial joints are made with an oscillating pneumatic motor and a cylinder joints driven by an electric motor. Varying the voltage of the electric motor (24V) can change the speed of rotation and oscillation frequency of knee prosthesis. According ASTM and ISO standards this frequency, where hip and knee prostheses must be less than 1 Hz.

The compression force can be varied by changing the pneumatic pressure of compressed air. Compressive forces generated by two pneumatic cylinders is measured by a force sensor (strain gauge type) mounted on the rod end cylinders. For testing we chose a total knee prosthesis made of CoCrMo alloy and UHMWPE. Knee prosthesis was extracted from the patient after 15 years of operation. Owe relatively high cost price chosen in the first phase of the project, the use of hearing excerpts from different patients. To mount the stand knee prosthesis were performed two auxiliary devices for tibial and femoral components (Figure 1). Assembly of the components of total hip prosthesis and intermediate devices is presented in Figure 2.



Figure 1: Auxiliary devices



Figure 2: Final assembly.

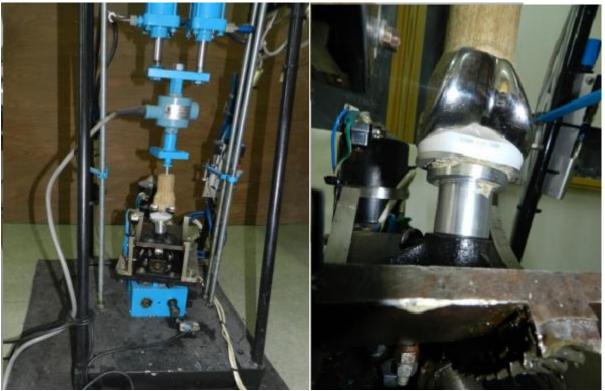


Figure 3: Total knee prosthesis fitted experimental test stand

2. METHODOLOGY FOR OBTAINING EXPERIMENTAL DATA

The methodology for obtaining reliable experimental results on wear and total knee prosthesis involves defining a working protocol. In this case, the protocol assume scroll key stages:

- preparing the stand for the experiment. This stage involves: calibration of force transducer, tune in the pneumatic circuit on the course and speed of rotation of the tibial component port assembly, start the compressor with five minutes prior to the the experiments have determined the amount of air pressure, check the pneumatic circuit to have no loss of pressure, check the motor drive mechanism functionality electric, check the level of

lubrication and gear mechanism oscillating pneumatic piston-engine rack, verification of the metering device and the number of cycles operating hours of the stand and checking the knee prosthesis fixation.

1- preparation of prosthetic components. This step is carried out before commencement and completion tests desired number of cycles includes: cleaning prosthetic components (according to ASTM F1714-96).

2 - mass determination components using an analytical balance (Santorius CP 225 type) - Figure 4,

3- determination of geometric properties femoral component, tibia and meniscus in accordance with the standards ASTM (using a coordinate measuring machine MMC DEA GLOBAL PERFORMANCE),

4 - visual inspection of surfaces using a digital microscope (KEYENCE VHX-600E type),

5- determination of surface roughness parameters articulated (using AFM NT-MDT NTEGRA microscope or roughness MarSurf XR20) – Figure 5,

6- calculation of specific parameters wear (wear linear and volumetric),

7- performance of the tests. This stage implies a total of about 3 million cycles corresponding to the activity of a person for a year. The rate of wear of the prosthesis varies greatly from one patient to another because their activities are very different. Enteritis statistical activity that a person with average distance is about 1 million/year, and the most active reach 3.2 million cycles/year. Older, less active, are between 0.2 and 0.5 million cycles / year. Men younger than 60 years go by 40% more than those over 60 years, men go to 28% more than women [3],

8 - repeating points 2, 3, 4, 5 and 6,

9- comparing the results obtained in the initial phase and final,

10- interpretation of results,

11- developing the final conclusion [4].

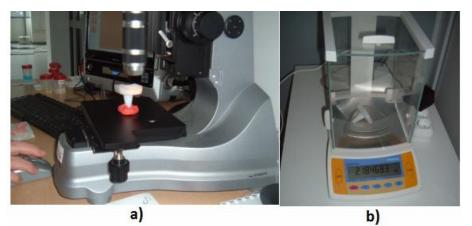


Figure 4: a)-Visual inspection of surfaces using a KEYENCE VHX-600E digital microscope and b)- mass determination components using an Santorius CP 225 analytical balance [4]

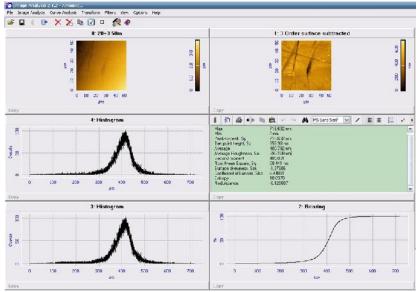


Figure 5: determination of surface roughness parameters articulated using AFM NT-MDT NTEGRA microscope (initial phase)

Comments:

- To determine the key indicators used to wear specific value of 8.20 g/cm³ density alloy Co-28Cr-6Mo,
- Generally manufacturers orthopedic components such as prosthetic hip, knee or shoulder does not provide details about the alloys used in their construction and the quality articulated,
- Given that it creates a large number of cycles necessary during the development of tests to check the
 amplitude additional compressive forces and movements of the joint.

3. CONCLUSION

Testing the knee prosthesis was performed without lubrication, so wear was quite pronounced. If you want to test the prosthesis in the presence of a lubricant can be achieved in an auxiliary device to be inserted prosthesis with a lubricating fluid (eg hyaluronic acid).

The presence of the third body in the contact zones between surface was an important factor that contributed to the acceleration of depreciation, are scientists who claim that the presence of particles (metal, ceramic, polyethylene or PMMA) may lead to duplication wear indicator value. It should be noted that the compressive force generated by pneumatic pistons was approximately constant during the progress of the tests, but in reality the resultant forces acting on the knee joint is not constant but depends on the phase of gait.

As secondary factors that contributed to increased wear and tear meniscus between the femoral component and include positioning errors.

In this case were not identified specific elements tribo-corrosion material loss is caused only by mechanical processes.

MOP (metal on polyethylene) degradation of the implant material is influenced by many factors, such as macro-geometry (diameter and the distance of insulation), deviation of spherical and alloy composition. In MoP artificial joints, sliding wear is the dominant wear mechanism. Volumetric wear rate increase is based on the decrease of the femoral component and meniscus game, this has been confirmed by other researchers. Bearing surfaces of artificial joint during a gait cycle are subject to complex multi-directional movement (sliding and rolling) and have a big impact on the wear parts. Most researchers believe that the multidirectional movements have a more pronounced effect on the wear surface than uni-directional which explains the high wear rates obtained in this case.

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