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SIMPLE METHOD FOR DETERMINE THE DEGREE OF WEAR TO A TOTAL KNEE PROSTHESIS IN VITRO

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Abstract— This paper presents a simple methodology of ex in vitro testing of a Low Contact Stress (LCS) Mobile-Bearing Total Knee System, produced by DePuy Orthopaedics, Inc. USA, on an experimental stand. To be tested LCS Mobile-Bearing Total Knee System was designed and constructed two auxiliary devices. Testing the LCS System was made taking into account the provisions of international standards. The method for determining the degree of wear of the polyethylene component of the LCS System supposes several essential steps: cleaning and sterilization of the components (metallic and polymeric) of LCS System; weighing of polyethylene component; visual inspection of articulating surfaces; determining the average roughness of contact areas; determining the overall size of the system on a coordinate measuring machine (optional); performing a large number of cycles on experimental stand and determining of the specific parameters of wear and comparing them with data from the literature.

Keywords—Total Hip Arthroplasty, wear, in vitro, Low Contact Stress.

I. INTRODUCTION

TOTAL Knee Arthroplasty (TKA) is a highly successful procedure, with the percentage of patients requiring revision relatively small. However, when considering the large number of these procedures performed annually, this small percentage of failures constitutes a significant number of patients [1]. TKA fundamentally changed the prognosis of knee degenerative disease, enabling a postoperative knee close to normal functionality. Knee musculoskeletal mobile segment, is considered one of the most used joints of the human body required. In 1968, Mr. R. Merryweather used for the first time a total knee prosthesis and that was talked about total knee replacement. Since then joint replacement has become a successful treatment, so that the moment a significant number of implanted knee prosthesis [2], [3]. The knee is the intermediate joint of the lower limb; it is composed of the distal femur and proximal tibia. It is the largest and most complex joint in the body. The knee joint is composed of the tibio-femoral articulation and the patella-femoral articulation [2], [3]. Failure of total knee arthroplasty is devastating to the patient, frustrating for the surgeon, and comes at a significant cost to the healthcare system. Therefore, it is imperative to understand the mechanisms of failure in knee arthroplasty [1]. The leading causes include polyethylene wear, loosening, instability, and infection. It is important to recognize each mode of failure not only to appropriately diagnose and treat patients, but also to improve the future success of TKA.

II. TOTAL KNEE JOINT REPLACEMENT

Knee prosthesis is characterized by diversity their variability about the hinge [3]. Thus we can classify prosthetic knees after anatomical parts or joints they replace, the degree of mobility the degree of constraint, the attachment or when implanted. Prostheses, produced from biologically compatible metal and plastic materials of a high strength, are used for the total knee joint replacement. Cobalt, chromium, and molybdenum alloys are the metals used most frequently. Plastic materials are made from a Ultra-High-Molecular-Weight Polyethylene (UHMWPE). Total implants have been used for around 30 years and the body’s tolerance to them has been very good. High requirements are imposed on the components’ production, their surface must have identical properties all the time and it must be smooth and glossy [3], [4]. Only damaged areas of the joint, not the entire knee, are replaced in a total knee replacement in modern medicine. In principle, the surgery lies in the replacement of the joint surface and joint cartilage only.

Fig. 1. a)Partial knee prosthesis and b) total knee prosthesis [5].

Just a small part of the bone is removed; original ligaments, tendons and muscles are retained and re-fixed [5]. The metal femoral component is the same size and shape as the femur end. The tibial component placed on the apex of the tibia has a metal base but the upper surface is always made from UHMWPE (Ultra-High-Molecular-Weight Polyethylene) [3]. Part of the patella surface may be cut off and also be covered by UHMWPE. Several configuration of the joint replacement is shown in Fig.1. Components are frequently fixed to the bone by a special substance PMMA (polymethacrylate), a so-called "*bone cement*". Alternatively some components have a porous surface into which the bone can grow [4]. There is a wide range of models produced in different sizes for all prostheses types. The bone shape, the weight, the physical activity of the patient and the surgeon's experience and philosophy determine the selection of the prostheses [4].

In this case used the LCS (Low Contact Stress) Mobile-Bearing Total Knee System (standard 10 mm) produced by DePuy Orthopaedics, Inc. (USA) - catalog number 1178-46-025. The LCS Mobile-Bearing Total Knee System was originally implanted in 1977. Since 1977, more than 700,000 LCS mobile-bearing knees have been implanted in the USA and internationally. Long-term clinical success has been demonstrated with survivorship exceeding 96% at 20 years in some studies [6]. The system contains primary cruciate-retaining and cruciate-sacrificing components as well as a full range of revision options. Fixed all-poly as well as rotating mobile-bearing patellae are available. This system was taken to Emergency Hospital of Brasov (Orthopaedics Department) after a revision surgery (after 15 years of use).

III. METHOD USED TO OBTAIN THE DEGREE OF WEAR OF KNEE PROSTHESIS

Polyethylene wear is a primary cause for knee revision. Unlike fixed bearing designs, the self-aligning rotating-platform bearing is designed to decouple flexion-extension and rotation into two unidirectional motions and converts shear forces into compression. This allows the LCS Mobile-Bearing Total Knee System (standard 10 mm) to experience a 94 percent reduction in polyethylene wear versus a fixed bearing design (according to the literature) [6]. The LCS is designed to increase the functional Range of Motion (ROM) and reduce wear, in comparison to other fixed bearing TKA designs. For this experiment we used a range of equipment and accessories located in Biomechatronics Laboratory of the Faculty of Product Design and Environment (Transilvania University of Brasov).

A simple experimental method for determining the degree of wear of the UHMWPE component of the LCS Mobile-Bearing Total Knee System (standard 10 mm) supposes several essential steps:

1) *Specimen preparation.* Cleaning and sterilization of the components (metallic and polymeric) of total knee prosthesis was performed in accordance with the ASTM *standards (F1714-02-" Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices" and F86-00-"Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants")* [7]. The surface of the implants shall be cleaned to minimize foreign material. Sterilize the components in a manner typical of that in clinical use for such devices, including total dose and dose rate, as these may affect the wear properties of the materials. Report these processing parameters with the aging time prior to each test when known [8]. Sterilization of all test and control components within a specific test group should be done simultaneously (in a single container), when possible, to minimize variation among the specimens [9]. Prior to wear testing, careful cleaning of the polymer specimens is important to remove any contaminants that would not normally be present on the actual prosthesis. During the wear run, the components must be re-cleaned and dried before each weighing to remove any extraneous material that might affect the accuracy of the weighing. A suggested procedure for cleaning and drying of polymeric components is given in F1714-02 [7], [9].

2) *Weighing of UHMWPE Components.* Weigh the polymeric components on an analytical balance having an accuracy on the order of ±10 (μg). This degree of sensitivity is necessary to detect the slight loss in weight of polymers, such as UHMWPE, which may wear 30 (mg) or less per million cycles. Always weight specimens in the clean, dry condition [8]. Keep the components in a dust-free container and handle with clean tools to prevent contamination that might affect the weight measurement. Weigh each wear and control component three times in rotation to detect random errors in the weighing process [8]. Weighing operations component of UMHWPE tests are performed before the start and at the end (after a number of cycles). For the study was used a standard analytical balance Sartorius CP225D that have been performed a set of five measurements before and after the test (Fig.2). The difference between these values is the loss of weight. The mean value for the weight of the component of UMHWPE before the start of the test was 21.84683 (g). According with F732-00 (*Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses*) in tests where the wear rates of materials with different densities are evaluated, it may be preferable to compare these on the basis of volumetric wear, rather than weight loss. It is preferable that comparisons of the wear properties between components of polymeric materials having different densities be done on the basis of volumetric wear (is the case of UHMWPE). The volumetric wear rate may be obtained by dividing the weight-loss data by the density of the material. The accuracy of this calculation is dependent on the material being reasonably homogeneous, that is, having a constant density with wear depth. Volumetric wear was calculated using a density of 0.932 (mg/mm^3) (for UHMWPE GUR 1050). The literature data found wear rates for total knee replacements (TKR)

to be between 13.6 and 41.0 (mm^3/million cycles or Mc) and 4.4 to 13.0 (mm^3/Mc) for conventional and highly crosslinked UHMWPE (HXPE), respectively *(Stoller et al., 2010; Rawlinson et al., 2006).*

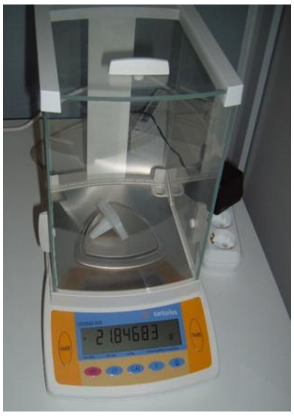

Fig. 2. Weighing of UHMWPE component.

3) *Visual inspection (according to ASTM standards) was performed using a digital microscope VHX-600E produced by KEYENCE using a magnification of x20, x200 and x300 (Fig.3).* One example of these images taken during the inspection can be seen in Fig. 4. For visual inspection were selected wear areas most pronounced, as can be seen in the figures below. The areas demarcated with a red marker (Fig.4). Visual inspection of the UHMWPE component articulated surfaces, as well as weighing, is carried out before the start of the test and at the end of them (using the same digital microscope settings).

Fig. 3. Visual inspection of the articular surfaces of the UHMWPE component using KEYENCE VHX-600E.

Fig.4. Image with area bounded on the UHMWPE component (magnification x20).

4) *Determining the average roughness of contact areas with highest wear.* Average roughness measurement was performed using an atomic force microscope AFM (Atomic Force Microscopy) model NT-MDT NTEGRA Nanolaboratory Probe with silicon peak (NSG10); the results of these measurements are shown in Fig. 5 and Table I. These measurements should be performed before starting the tests and their end to make a comparison in terms of the quality of the articular surfaces.

5) *Preparing of the stand.* This stage involves: force transducer calibration, checking the pneumatic and electric circuit, checking the device of metering the number of cycles, checking the attachment mode of components of knee prosthesis on the experimental stand (Fig.7) and setting the range of motion that to be made of the knee prosthesis.

For fixing the prosthesis on the stand was designed and built an aluminum alloy support (Fig. 6). Conducting this experiment was done under the following conditions:

a) Oscillating Frequency: about 1(Hz). (according to the standard ASTM F1714-96).

b) Pressure compressed air from the compressor output was about 4.3÷4.5 (bar);

c) Compressive force acting on the LCS Mobile-Bearing Total Knee System 200÷213 (daN);

d) Testing was carried out in the absence of lubricating fluid.

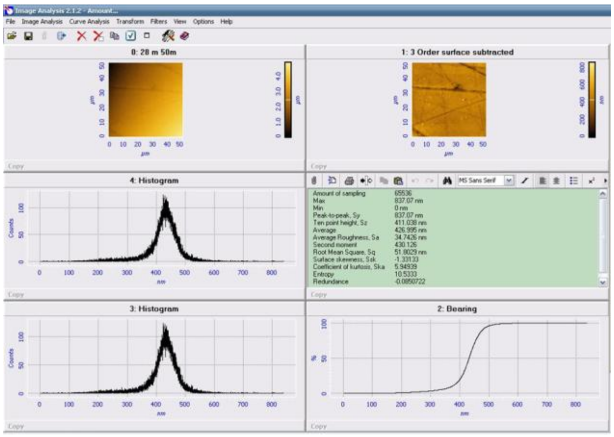

Fig. 5. Specific parameters obtained using AFM surface quality in the center bounded by the red marker (before the start).

TABLE I
SPECIFIC PARAMETERS OF SURFACE QUALITY
(BEFORE STARTING THE TESTS)

Amount of sampling	65536
Max	837.07 (nm)
Min	0 (nm)
Peak-to-peak (Sy)	837.07 (nm)
Ten point height (Sz)	411.038 (nm)
Average	426.995 (nm)
Average Roughness (Sa)	34.7426 (nm)
Second moment	430.126
Root Mean Square (Sq)	51.8029 (nm)
Surface skewness (Ssk)	-1.33133
Coefficient of kurtosis (Ska)	5.94939
Entropy	10.5333

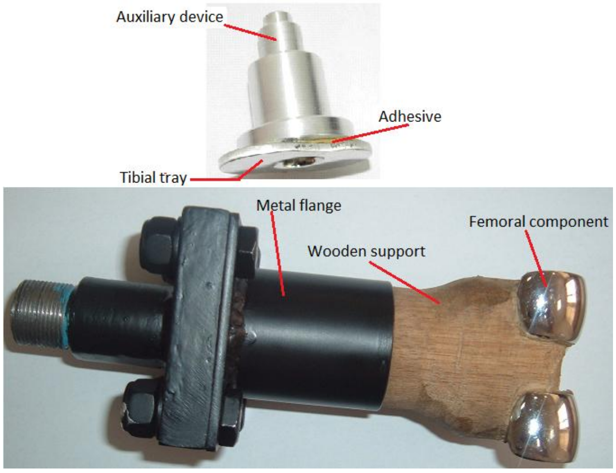

Fig. 6. Auxiliary devices used to fix the LCS Mobile-Bearing Total Knee System on the experimental stand

Fig. 7. Mounting of the LCS Mobile-Bearing Total Knee System on the stand (detail).

6) Determining of the specific parameters of the wear (linear wear, gavrimetric wear and volumetric wear).
7) Determining the overall size of the system on a coordinate measuring machine (optional).

IV. RESULTS

The testing was performed on experimental stand (found in Biomechatronics Laboratory of the Faculty of Product Design and Environment) using femoral axial loading and flexion-extension (0-58°) profiles taken from ISO 14243 (2002). The internal-external rotation was ±5°. The partial results obtained are presented in Table II. Based on partial results it was concluded that the average wear rate is approximately 21.334 ± 2.3 (mm^3/Mc). Average roughness was measured (on AFM microscope) only in the central zone which wear longer.

TABLE II
PARTIAL RESULTS

Number of cycles	Average roughness (nm)	Mass (mg)	Gavrimetric Wear (mg)	Volumetric Wear (mg)
-	34.7426	21846.83	-	-
100,000	43.8871	21844.841	1.98833	2.1334
500,000	79.5562	21836.888	7.9534	8.5337

V. CONCLUSIONS

The presence of the third body in the contact zones between surfaces was an important factor that contributed to the acceleration of depreciation, are scientists who claim that the presence of particles (metal or polyethylene) 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 MoP (Metal on Polyethylene) 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.

REFERENCES

[1] M. S. Austin, P. F. Sharkey, W. J. Hozack, R. H. Rothman, “*Knee Failure Mechanisms After Total Knee Arthroplasty* ” Lippincott Williams & Wilkins, Inc., Philadelphia, Techniques in Knee Surgery 3(1):55–59, 2004.
[2] R.D. Peterson, D.J. Bronzino , “*Biomechanics - Principles and Applications*”, CRC Press. Taylor & Francisc Group LLC, New York, 2008, pp.35-36.
[3] C.N. Druga, M Mihai, “*Ex-In Vitro testing of Total Knee Replacements – first part* ”, 5th International Conference Computational Mechanics and Virtual Engineering-COMEC 2013, Braşov, Romania.
[4] M. Horáček, O. Charvát, T. Pavelka, J. Sedlák, M. Madaj, J. Nejedlý, “*Medical implants by using RP and investment casting technologies*”, The 69th WFC Paper, 2011.
[5] http://ortopediaonline.ro/content/view ,("accessed March 2014").
[6] http://www.depuy.com/healthcare-professionals/product-details/lcs-completetrade-knee-system. ("accessed April 2014").
[7] http://www.astm.org, ("accessed February 2014")
[8] ASTM International, “*F86-00-“Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants*”, 2000, pp.1-2.
[9] ASTM International,” *F 1714 – 02 Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices*”, 2002, pp.1-4.