In-vitro Wear Measurement of Artificial Knee Prostheses

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Abstract: This study describes the in-vitro measurement of wear with respect to total knee prostheses and a case study is presented. The objectives of a wear evaluation (ISO 14243) are given and test procedures for wear evaluation on joint-simulating machines are detailed. Information known about the *in vitro* conditions which a joint prosthesis faces is given, and there is a discussion of the design of a test machine. Finally an overall program for the evaluation of the wear behavior of a real artificial knee-joint prosthesis is described.

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1. Introduction

Joint replacement surgery is a well-proven method of relieving the symptoms of advanced osteoarthritis of the knee. This is a very common procedure performed in the worldwide [1-6]. While this surgery has a high success rate, implants do fail by a number of mechanisms. Wear of the ultra-high molecular weight polyethylene (UHMWPE) bearing component is a major factor in implant failure; some studies showing that up to 16% of knee fail due to wear [7]. Catastrophic wear can lead to mechanical failure. Wear debris has been associated with the most common mode of failure, which is aseptic loosening [8-10]. Measurement of wear is an important part of design assessment. There are two types of wear measurements-- in-vivo, and in-vitro simulation methods. Currently, there are no satisfactory in vivo methods for assessing knee replacement wear [1,11-12]. Although in vitro simulation studies may not be representative of in vivo wear [13-16] and have frequently resulted in false conclusions [17], from the practical point of view, the current standard method of design assessment in vitro wear simulation method follows the ISO 14243 standard [18-20]. The aim of this study was to evaluate the ISO 14243 method, and a case study was shown.

2. ISO 14243

ISO 14243 consists of the following parts, under the general title "Implants for surgery — wear of total knee joint prostheses":

Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test.

Part 2: Methods of measurement.

Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test.

ISO 14243-1 specifies the flexion/ extension relative angular movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the wear testing of total knee-joint prostheses in wear-testing machines with load control. ISO 14243-2 specifies methods of assessment of wear of the tibial component of total knee-joint prostheses using gravimetric techniques and changes in dimensional form of components tested in accordance with ISO 14243-1. ISO 14243-3 specifies relative movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the wear testing of total knee-joint prostheses in wear-testing machines having axial load control, flexion/extension angular motion control, anterior-posterior displacement control and tibial rotation control.

The kinematics of ISO 14243-3 may not be applicable to knee designs with a high degree of constraint, which could result in damage to the articulating components in the early stages of the test that would not be representative of clinical service.

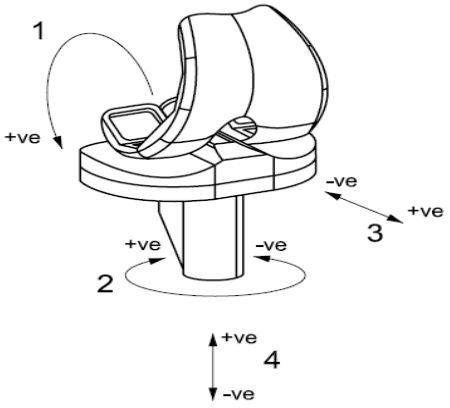
2.1 Principle

The total knee-joint prosthesis is mounted in an apparatus which applies a cyclic variation of flexion/extension angle and contact force to the interface between tibial and femoral components, simulating normal human gait [18, 21]. The tibial component is free to move relative to the femoral

component under the influence of the applied contact forces, this motion having all degrees of freedom except for the flexion/extension angle which follows a specified cyclic variation.

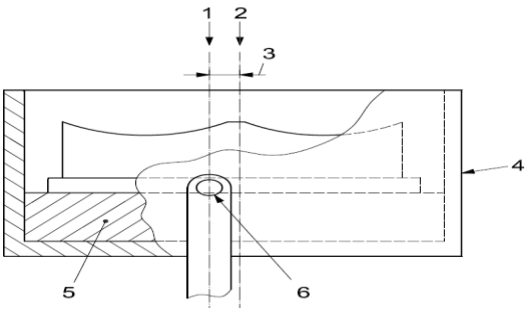
The applied contact force actions are axial force, anterior posterior (AP) force and tibial rotation torque (see Figure 1). The axial force follows a specified cyclic variation. The AP force comprises two components, one being a specified cyclic variation and the other having a magnitude which depends on, and is in the opposite direction to, AP displacement. Similarly, the tibial rotation torque comprises two components, one being a specified cyclic variation and the other a rotation torque having a magnitude that depends on, and is in the opposite direction to, tibial rotation. The load actions that depend on the AP displacement and tibial rotation correspond to the tensions transmitted by anatomical ligaments in normal knee-joint function.

The contacting surfaces of the femoral and tibial components are immersed in a fluid test medium simulating human synovial fluid. If polymers are the object of investigation, a control specimen is subjected to the fluid medium and, optionally, to the same time-varying force to determine the creep of the test specimen and/or the amount of mass change due to fluid transfer. The test takes place in a controlled environment simulating physiological conditions. The test specimen configuration is shown in Figure 2.



1 flexion (of femoral component)
2 tibial rotation, tibial rotation torque
3 AP displacement by the tibial component, AP force onthe tibial component
4 axial force

Figure 1 Sign convention for the forces, torques and motions, shown for a left total knee replacement system.



1 axial force axis
2 tibial axis
3 0.07 w offset
4 holder of tibial component
5 cement mounting for tibial component
6 axial force applied through free turning pivot(s)

Figure 2 Test specimen configuration.

2.2 Test Description

The implant is fixed in neutral position at zero degrees flexion. A cyclic variation of the flexion/extension angle as well as of the contact force during normal human gait is simulated. The variations of the axial force, AP force and tibial torque with gait cycle are shown in Figures 3-5. The tibial component is free to move relative to the femoral component under the influence of the applied contact forces, this motion having all degrees of freedom except for the flexion/extension angle, which follows a specific cyclic variation.

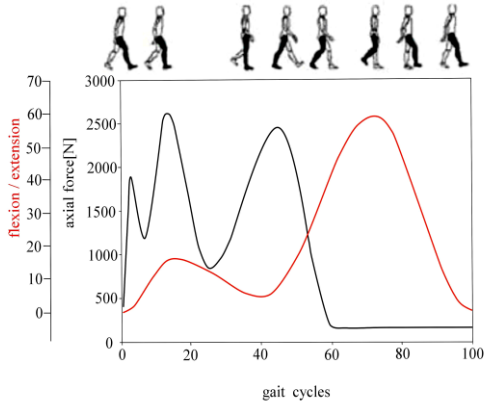


Figure 3: Variation of the axial force with gait cycle.

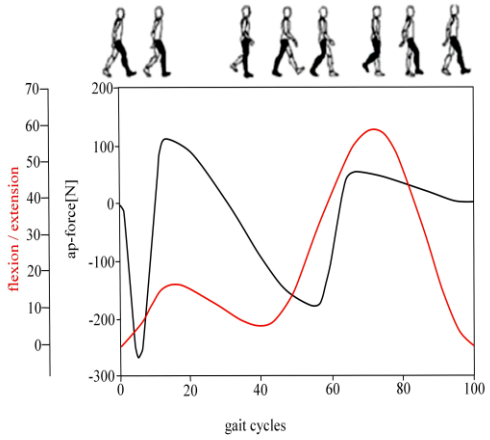


Figure 4: Variation of the AP force with gait cycle.

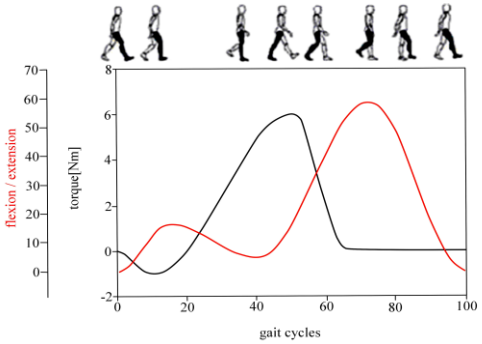


Figure 5: Variation of the tibial torque with gait cycle.

2.3 Methods of measurement

Wear can be considered as the material loss from components of the prosthetic joint due to combined movement and loading. There are two methods (Gravimetric method and Dimensional change method) in ISO 14243-2 standard.

Gravimetric method: The test specimen is soaked in a lubricant. It is repeatedly removed from the lubricant, cleaned, dried and weighed
until a steady level of fluid sorption is established. The test specimen is assessed subsequently for wear by testing for loss of mass in a knee-joint simulator. A loaded, non-articulating control specimen is intended to allow for fluid sorption and undergoes the same procedure for reference purposes.

Dimensional change method: A coordinate measuring machine is used to map the articulating surface of a total knee prosthesis relative to a reference position, direction and plane prior to the start of the wear test and at suitable intervals during the test. From these data the volumetric change between measurements is determined. Loaded non-articulating controls are intended to allow the effects of plastic flow, mainly occurring in the first 5 x10^5 cycles, to be separated from material loss.

3. Case Study

3.1 Objective:

The purpose of this test was to determine the wear behavior of tibial insert of U2 Total Knee System-PS Type.

3.2 Test standard:

ISO 14243- 1:2009 Implants for surgery - Wear of total knee joint prostheses - Part 1: Loading and displacement parameters for wear testing machines with load control and corresponding environmental conditions for tests.

ISO 14243 - 2: 2000- 10 (Implants for surgery - Wear of total knee joint prostheses - Part 2: Methods of measurement.) (Gravimetric method).

3.3 Acceptance or pass/fail criteria::

Acceptance criteria was set as the specimen completes the designated 5 x 10^6 load cycles without broken-up or delaminated of the articulating surfaces.

3.4 Specimens and test conditions:

Specimens (shown in Figure 6):
United Orthopedic Corporation (U2 Total Knee System):
U2 Posterior Stabilized Tibial Insert (UHMWPE, Fixed Bearing)
U2 Femoral Component PS (CoCrMo)
U2 Tibial Base Plate (Ti6Al4V)
Conditions:
The test specimens were soaked in the fluid test medium at 37℃±2℃. Fluid test medium: calf serum (25%±2%) diluted with the de-ionized water.

Figure 6 Specimen tested.

3.5 Test equipment:

1. Testing machine: AMTI Force 5, single station (Figure 7)
2. Balance: AND GH-252 (Figure 8)
3. Ultrasonic cleaner: DELTA D150 (Figure 9)
4. Vacuum drying system: YSC DP-40V (Figure 10)

The AMTI Force 5 is a servo-hydraulic machine with four independent actuators. It provides a vertical tension and compression axis with rotation about the same axis, and a horizontal axis with translation and rotation. With these actuators the machine can be used for many different independent or combined motions. The AMTI Force 5 is supplied with an easily adjustable load frame (24 inch clearance between the cross head and the load cell is standard) making it suitable for material, fatigue, orthopedic, product, and other single and multi-axis testing.

Figure 7 Testing machine: AMTI Force 5


Figure 8 Balance: AND GH-252

Figure 9 Ultrasonic cleaner: DELTA D150

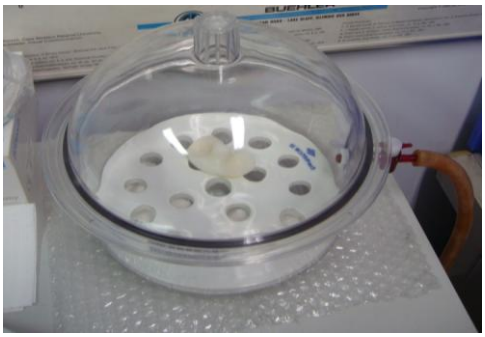


Figure 10 Vacuum drying system: YSC DP-40V

3.6 Results and analysis

1. Total number of cycles applied: 5,000,000 cycles.
2. Descriptions of all the articular surfaces of both component femoral and tibial insert after testing completed are as following:
    1. Scratching was a major wear pattern on the surface of femoral component (Figure 11).
    2. There were four major wear pattern on the articular surface of insert [22,23], (1) pitting; (2) scratching; (3) burnishing; (4) deformation (Figure 12).
    3. Burnishing was a major wear pattern on insert backside surface (Figure 13)


Figure 11(a) Femoral component: before test


Figure 11(b) Femoral component: after test of 5,000,000 cycles.

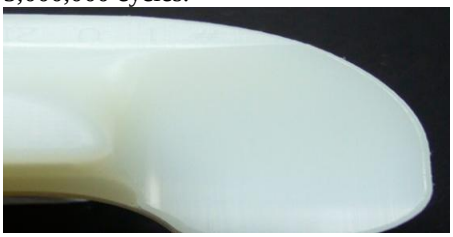


Figure 12(a) Insert: before test

Figure 12(b) Insert: after test of 5,000,000 cycles.

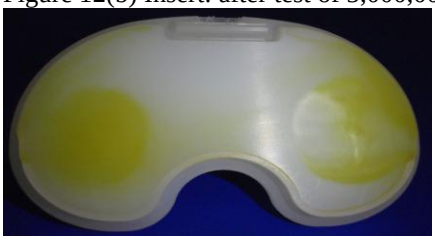


Figure 13 Insert backside surface after test of 5,000,000 cycles.

3. The curve of axial force versus 1 cycle was shown in Figure 14.

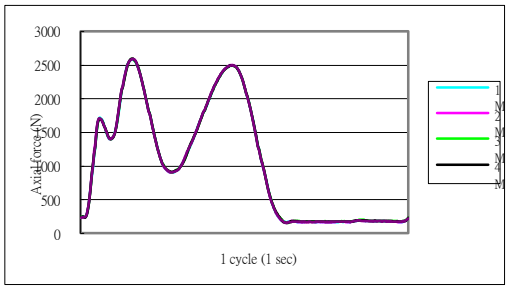


Figure 14. Axial force vs. Cycle

4. The insert was only measured first time before testing initiation and after testing completion of 5,000,000 cycles. Table 1 outlined the change in mass of tibial insert and insert plus baseplate and cement.

Wear rate: The loss of insert weight was the difference of insert weight before and after tests, which divided by 10 was the average wear rate each 500,000 cycles.

The total loss of insert: 15.34814 − 15.31051=0.03763 (g)

Wear rate: 0.03763/10=0.003763 (g/500,000 cycles)

Table 1. Wear test results

cycles	0	500,000	1,000,000	2,000,000
Insert	15.34814	- -	- -	- -
Insert+ baseplate+ cement	144.5312	144.6016	144.6005	144.6005
Cycles	3,000,000	4,000,000	5,000,000	
Insert	- -	- -	15.31051	
Insert+ baseplate+ cement	144.6221	144.6356	144.4936	

(Unit: g)

4. Conclusions

In this study, we have made an overview of the vitro wear simulation method that follows the ISO 14243 standard. The ISO 14243 standard is more practical and widely accepted in industry. The results of a real case revealed the specimen was able to withstand 5 x 10^6 cycles without break-up or delamination of the articulating surfaces. The total loss of insert was 0.003763 g; wear rate of insert was 3.763 mg every 500,000 cycles.

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