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Quantitative evaluation of parameters used in wear testing simulators of total hip arthroplasty components

A.L.L. Oliveira*, F.C. Trigo, F.P.R. Martins

University of Sao Paulo, Department of Mechanical Engineering, Av. Prof. Mello Moraes, 2231 Sao Paulo, Brazil

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ABSTRACT

Biomechanical simulators are extensively used in wear tests of total hip arthroplasty components. Those tests should be in accordance with ISO 14242-1, which specifies three or four abscissæ ordinates of angular displacements and six loads to be attained by the simulators. Nevertheless, the standard does not provide directions on the interpolation method; consequently, wear rates from similar specimens tested in distinct simulators present considerable dispersion which, in turn, prevents the establishment of quality patterns for those components. In this work, continuous gait curves are generated from ISO 14242-1 specified points through Piecewise Cubic Hermite Interpolation Polynomials. A subset of 100 points that best fit ISO specified tolerances, extracted from the continuous curves, is provided for using in wear simulators as a means of decreasing discrepancies in results from different machines. Moreover, a cross-correlation comparison between interpolated and actual gait curves demonstrates that maximisation of the correlation between them (time lags of -24 for flexion/extension, -71 for abduction/adduction, $+3$ for inward/outward rotation, and -10 for load data) causes loss of synchronism in the heel strike and toe-off instants. Such a result evinces an intrinsic disagreement between actual and standard-prescribed biomechanics of gait.

1. Introduction

Debris originated from wear in the contact of the rolling surfaces between prosthetic components (femoral head and acetabulum) are considered the main cause of premature failure in total hip arthroplasty (THA) [1]. During the last few decades, tests performed in biomechanical simulators have brought the major contribution for the development of prosthetics joint biotribosystems, thus increasing their longevity. Nonetheless, the lack of a strict and universally accepted protocol for performance of wear tests allowed several wear machines for THA testing to be erroneously named ‘biomechanical simulators’ [2].

In fact, a true biomechanical simulator should reproduce, as faithfully as possible, the physical and physiological conditions occurring inside the hip joint during gait, which demands a costly development process. On the other hand, unlike simulators, simplified wear testing machines aim at solely reproducing wear rates similar to those from *in vivo* replaced prosthetic components, without being concerned with the reproduction of actual gait kinematics (angular displacements, velocities and accelerations) and kinetics (load patterns) [3]. Thus, it is understandable how low cost wear testing machines have become more and more favoured.

The above statement can be corroborated by the results of a 2008 survey conducted by [4], who cataloged 16 brands of wear machines for THA testing designed between 1990 and 2007. In summary, the author showed that those machines presented distinct characteristics concerning the number of degrees of freedom, angular amplitude, loads and frequency of their application, prosthetic component fastening position, type of lubricant employed, and the number of simultaneous testing spots. However, it was concluded that neither of them could reproduce, at the same time, the complexities inherent to actual gait.

Accordingly, throughout the years, several studies sought only to depict wear rates between distinct combinations of pairs of biomaterials; as a consequence, the dispersion of wear rates is high among same pairs of components tested in different machines. This very fact has become a hindrance for the comparison of published results and, moreover, has yet prevented the definition of universal criteria to evaluate the actual performance of rolling surfaces of THA components [5].

At the beginning of the 2000s, attempts were made, through numerical techniques, to establish the relationship among the wear rates and the kinematics/kinetics features of different machines. Those computational models tried to simulate the stress

* Corresponding author. Tel.: +55 11 9 8677 5434; fax: +55 11 3091 5687.
E-mail address: and.snakes@gmail.com (A.L.L. Oliveira).

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distribution between the contact surfaces of THA components as functions of the relative displacements performed by each machine. Results suggest that the kinematic and kinetic characteristics directly affect the wear rates, even though a function relating them to the machines' testing parameters could not be established [6–10].

Considering the wide range of machines and procedures for THA wear testing, in 2002 the International Organization for Standardization (ISO) issued ISO 14242-1, which specified loads, angular displacements and environment conditions to be used in THA simulators [11]. This standard was engendered on the grounds of biomechanical evaluation of human hip joints during gait. The Technical Committee (TC-150) 'Implants for surgery', in charge of the task, adopted the borrowed the 1969 results of Johnston and Smidt [12] to stipulate angular displacements in three degrees of freedom, namely flexion/extension (F/E), abduction/adduction (A/A), and inward/outward rotation (I/O-R), and profile proposed by Paul in 1966 to specify the load pattern [13].

In 2009, the TC-150 published a second standard for the same wear test in THA components, specifically targeted at the orbital coupling machines that had been recently designed. The ISO 14242-3 prescribes the same load pattern as the ISO 14242-1, yet it must be pointed out that the prescribed amplitude for the F/E and the A/A movements, $\pm 23^{\circ}$, has no resemblance to the actual human joints biomechanics [14].

Aiming at investigating the surface phenomena on THA components tested according to ISO 14242-1 and ISO 14242-3, two similar unused prosthetic hip joint pairs were tested in a biomechanical simulator [2], being each one probed during one million cycles according to either ISO prescribed kinematic conditions. At the end of the tests, the rolling contact surfaces were compared with their initial condition, and the differences were quantified. Results state that the mean rugosity (R_a) of specimens tested according to ISO 14242-1 was around eight times higher than those of the new parts whereas, for pairs probed under ISO 14242-3 conditions, this value was more than ten times higher. This way, it was possible to conclude that ISO 14242-3 testing conditions were responsible for the severe damage impinged on the rolling surfaces of prosthetic components [15].

A straightforward manner to overcome these drawbacks would be to directly input human gait measured data to the wear simulation machines. Nevertheless, it is not possible: Raw data are acquired at high sampling rates and inherently corrupted by noise. This way, the time-amplitude curve exhibits gradients that are rather difficult to be tracked by the driving servomotors and may cause instability or undesired motions in the tribosystem [16]. The gold standard recommended by the International Society of Biomechanics (ISB) to reduce noise and limit bandwidth prior to downsampling is to process the raw data using a set of routines named GCVSPL [17]; even though, it is still necessary to downsample the processed data prior to sending them to the simulator.

When one comparatively analyses both standards, it is common sense to affirm that the testing conditions from ISO 14242-1 best reproduce the overall *in vivo* human joint gait behaviour. Nonetheless, the specification of only a few maxima and minima points of the gait cycle for which the curves representing displacements and loads exhibit alternating positive–negative gradients (see Table 1), leaves the simulator designer a wide range of possibilities to choose on how to join the gaps among those points (i.e., the machine path), so as to make the transition.

Even the specification of tolerances presented by ISO 14242-1 (the accurateness of the coordinates that define angular displacements is $\pm 3^{\circ}$, whereas the maximum load tolerance is ± 90N and ± 3% of time) for those few points are not enough to ensure a universally accepted transition curve; consequently, test results are affected.

Table 1
Points specified by ISO 14242-1 for building displacements and loads curves. Extracted and adapted from [11].

Time, % of cycle (1 Hz $\pm$0.1 Hz)	**0**	**12**	**21**	**32**	**50**	**62**	**100**
Flexion/extension (F/E)	25				−18		25
Adduction/abduction (A/A)	3		7			−4	3
Inward/outward rotation (I/O-R)	−10				2		−10
Loads	0.3	3.0		1.5	3.0	0.3	0.3

Recently, the TC-150 has published ISO series 14243 and 18192 to deal respectively with wear tests of joint prosthetic components of knee and spinal column [18,19]. Aware of the possible misleading interpretations from the contents of ISO 14242-1, these new series provide appendixes in which both parameters, loads and cyclic displacements, are accurately specified by providing a table with 100 points to define the machine path, thus reducing the discrepancy in results from specimens tested in distinct simulators.

In view of this whole scenario, the current work proposes an approach to build gait curves from the points specified by the ISO 14242-1. The main contribution of this work is, then, to set up a paradigm for calibration of wear simulators that seek to comply with ISO 14242-1 by providing a table containing 100 points extracted from the continuous curves that best fit the tolerances specified in that standard. Such information should provide a common ground for the quantitative evaluation of hip joint wear test results from distinct simulators as well as to supply a set of feasible parameters aimed at helping the design of new simulators. Furthermore, a quantitative comparison among the interpolated curves and actual gait curves presented by [12,13], from which the extrema specified by ISO 14242-1 were borrowed, is provided and discussed.

2. Methods

2.1. Curves through ISO 14242-1 specified points

As previously mentioned, the first procedure was reconstructing, for each set of hip joint movements, a sequence of coordinate points joining the extrema points specified by ISO 14242-1. This is mandatory since actual gait activity does not present sudden leaps; thus, any apparatus intended for gait simulation should perform accordingly.

Admitting that the criterion adopted for selecting the points specified by ISO was in accordance with Shannon Sampling Theorem [20], the original analog signal would be exactly reconstructed applying a sinc interpolation filter to the digital data, i.e., the few points defined by ISO.

If the above hypothesis does not hold, it entails that the information contained in the original data cannot be recovered from the available sampled points. Therefore, since it is still necessary to build a sequence of points to establish the quantitative comparison as explained in Section 2.3, any other interpolation method used will represent an *ad hoc* choice.

2.2. Features of the original curves

Instead of using a digitising table to grab the point of printed curves, a procedure that would certainly introduce bias, a computer vision method was adopted to automatically construct a vectorised representation of the actual gait curves by [12,13], Fig. 1.