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Surface slide track mapping of implants for total disc arthroplasty

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ABSTRACT

Total disc arthroplasty has recently become a potential alternative to spinal arthrodesis. Until recently, there has been no standardized method for evaluating the wear of an artificial disc and myriad testing conditions have been used. The American Society for Testing and Materials (ASTM) and International Organization of Standardization (ISO) recently published guidance documents for the wear assessment of intervertebral spinal disc prostheses; however, various kinematic profiles are suggested, leading to different wear paths between the articulating surfaces of the implants. Since the wear between materials is influenced by the type of relative motion, it is important to select test conditions that lead to clinically realistic results. The purpose of this study was to characterize the slide tracks generated by 7 test conditions allowed for by the ISO and ASTM guidance documents and in Euler sequences consistent with 4 commercially available spine wear simulators. The analysis was performed for a ball-in-socket articulation under both lumbar and cervical motion test conditions. Results were generated analytically using a mathematical algorithm and then validated experimentally. Four tests resulted in elliptical sliding tracks of similar geometries for both the lumbar and cervical conditions. Curvilinear and ribbon-shaped wear paths were generated for 3 tests. With the data normalized for implant diameter, the sliding distance was similar between the lumbar and cervical conditions allowed for in the ASTM guidance. This distance differed compared with the results for the ISO guidance document where the lengths of cervical slide tracks were twice those for the lumbar conditions. Slide tracks were also found to be insensitive to the type of simulator under all testing conditions.

1. Introduction

Total disc arthroplasty (TDA) has recently been introduced as a potential alternative to spinal fusion for the treatment of degenerative disc disease. Artificial discs are designed to preserve the physiological range of motion, restore disc height, and provide stability to the unhealthy motion segment. Numerous artificial disc designs have been developed for the lumbar (Errico, 2005) and cervical spines (Mummaneni and Haid, 2004), most of which are comprised of one or two sites of articulation (Taksali et al., 2004). Although infrequently reported, wear particle-induced inflammatory reactions leading to osteolysis have recently been shown to occur in the spine (Fraser et al., 2004; Hallab et al., 2003; Kurtz et al., 2006, 2007; Licina and Thorpe, 2004). Therefore, similar to implants used for total joint arthroplasty, the long-term success of devices for TDA is contingent, in part, upon the ability of the artificial disc to minimize wear.

For *in vitro* biotribological evaluations of TDA implants to be clinically relevant, the testing parameters must be carefully selected. For example, the implant itself should be evaluated in a realistic, in-service state. Consequently, implants should be sterilized and polymeric components should be challenged oxidatively as both sterilization and changes due to aging have been shown to adversely affect mechanical and wear properties of polymeric total joint components (Digas et al., 2003; Edidin et al., 2000, 2002a, b; Mckellop et al., 2000). In addition, the conditions of the simulator testing technique itself should be selected carefully, as parameters such as the load, motions, type of lubrication, and frequency can affect wear mechanisms as well as the ultimate wear results of the implants being evaluated.

Until recently, there has been no consensus on the appropriate conditions under which to evaluate the wear performance of total spinal disc prostheses. Early in 2006, the American Society for Testing and Materials (ASTM) published a standard guide (F2423-05) for wear-testing artificial discs (ASTM Subcommittee F04.25, 2005). Similarly, the International Organization of Standardization (ISO) published a standard in 2007 on the same matter (18192-1:2008). Within each guidance document, a number of test conditions are allowed with each set of conditions resulting in different kinematics. The specific kinematics can be characterized by means of a slide track, defined as the path generated by a point fixed to one articular surface on its counterface during cyclic

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relative motion. Because wear is partially a function of the type of motion between articulating surfaces, it is important to understand the kinematics secondary to a specific set of test conditions. The purpose of this study was to perform a slide track analysis to determine the wear paths associated with the various test conditions allowed for in the ASTM and ISO guidance documents. A secondary objective was to determine the sensitivity of the slide track analysis to different commercially available spine wear simulators and hip wear simulators that are currently used to test spinal implants.

2. Methods

The majority of spinal motion occurs in the cervical and lumbar regions with motions occurring in the sagittal, coronal, and axial planes defined as flexion–extension (FE), lateral bending (LB), and axial rotation (AR), respectively (Fig. 1). In the normal spine, motion occurs through the deformation of the intervertebral disc that serves as a cushion between the vertebrae of the spinal column. When the intervertebral disc is replaced with an implant, the articulating surfaces of the implant necessarily experience relative motion resulting in a wear track configuration, defined here as a slide track.

The slide track analysis was performed for a ball-in-socket articulation, a commonly used configuration of mating components for lumbar and cervical TDA. For the analyses conducted in this study, a superior socket and inferior ball configuration was used. To simplify the analysis, a global coordinate system was defined with the origin located at the geometric center of the artificial disc (Fig. 2). The positive x-, y-, and z-axes were defined as the anterior, left, and superior directions, respectively. Lateral bending, φ, was defined as a rotation about x, FE, θ, was defined as a rotation about y, and AR, ψ, was defined as a rotation about z.

The slide track geometry is a function of the specific set of kinematic conditions to which the implant is subjected. As this study focused on the slide track analysis of *in vitro* wear-testing conditions, the kinematics specified in the ASTM F2423-05 standard guide and the ISO 18192-1 (2008) standard were used (ASTM Subcommittee F04.25, 2005). The ASTM standard guide allows for a broad range of kinematics, as the device can be tested under consecutive, partially combined, and fully combined motions. The ISO standard proposes both a preferred and an alternative set of loading and kinematic profiles for the evaluation of both lumbar and cervical artificial discs. Furthermore, the phase angles between the various degrees of freedom are defined in the ISO standard but remain undefined in the ASTM guide.

In this study, a slide track analysis was completed for 7 sets of kinematic conditions allowed for in the ASTM and ISO guidance (Fig. 3) (Table 1). The same 7 kinematic tests were evaluated using both cervical and lumbar ranges of motion (Table 2). In order to keep the analysis general, all calculations were normalized for a sphere of radius, R. For each test, the analysis was initially conducted for the inferior (ball) component. The motion of 33 virtual points affixed to the superior (socket) component and relative to a fixed inferior component was calculated using 3 sequential rotations. The virtual points were homogeneously distributed on the surface of the sphere from the apex to a polar angle (α) of 50°. The area analyzed corresponded to one typical articular surface in commercially available TDA devices. For increased accuracy, every motion cycle was divided into 500 discrete intervals. The motion of each point was calculated by using the Cardanian rotation matrices.

To study the sensitivity of the slide track to a specific simulator design, the kinematics generated by 4 commercially available wear simulators were evaluated in this study: the MTS Bionix® Spine Wear Simulator (Model 828.36, MTS Corporation, Eden Prairie, MN, USA), BOSE® Spinal Disc Fatigue/Wear System (Bose Corp., Eden Prairie, MN, USA), the EndoLab® Spine Simulator (EndoLab GmbH, Thansau, Germany), and the AMTI Hip Wear Tester (Model HS2-12-1000, AMTI Inc., Watertown, MA, USA).

Since the resultant motion vector is dependent on the order in which the rotations are performed, it is important to understand the mechanical design of the specific wear simulator being studied (Calonius and Saikko, 2002; Saikko and Calonius, 2002). For example, the FE actuator for the MTS Bionix® Spine Wear Simulator is fixed onto the LB motion arm. The rotation, θ, about the y-axis (FE) is then dependent on the angular position, φ, about the x-axis (LB). Finally, the AR is applied independently from the other axes. Therefore, for this particular simulator, the sequence of rotations would be $Ry(\theta) \rightarrow Rx(\varphi) \rightarrow Rz(\psi)$, as shown in Eq. (1). By substituting the directional cosine matrices into Eq. (1), the transformation matrix can be represented as Eq. (2) for the MTS Bionix® Spine Wear Simulator. The relationship between every degree of freedom and for every simulator is presented in Table 3. The analysis was repeated for the socket component using the transposed directional cosine matrices in Eq. (1).

$$S = \sum_{cycle} \left[\left(\sqrt{x_i^2 + y_i^2 + z_i^2} \right) - \left(\sqrt{x_{i-1}^2 + y_{i-1}^2 + z_{i-1}^2} \right) \right] \tag{1}$$

$$T = \begin{bmatrix} \cos(\Psi)\cos(\theta) + \sin(\Psi)\sin(\varphi)\sin(\theta) & -\sin(\Psi)\cos(\theta) + \cos(\Psi)\sin(\varphi)\sin(\theta) & \cos(\varphi)\sin(\theta) \\ \sin(\Psi)\cos(\varphi) & \cos(\Psi)\cos(\varphi) & -\sin(\varphi) \\ -\cos(\Psi)\sin(\theta) + \sin(\Psi)\sin(\varphi)\cos(\theta) & \sin(\Psi)\sin(\theta) + \cos(\Psi)\sin(\varphi)\cos(\theta) & \cos(\varphi)\cos(\theta) \end{bmatrix} \tag{2}$$

The sliding distance (S) was then calculated (Eq. (3)) by the summation of the 500 infinitesimal displacements over 1 cycle and by assuming a linear distance between every point. The sliding velocity and acceleration were calculated from the first and second derivatives of Eq. (3) using a frequency of 1 Hz.

$$\begin{bmatrix} x''' \\ y''' \\ z''' \end{bmatrix} = Rz(\Psi)\, Rx(\varphi)\, Ry(\theta) \begin{bmatrix} x \\ y \\ z \end{bmatrix} = T \begin{bmatrix} x \\ y \\ z \end{bmatrix} \tag{3}$$

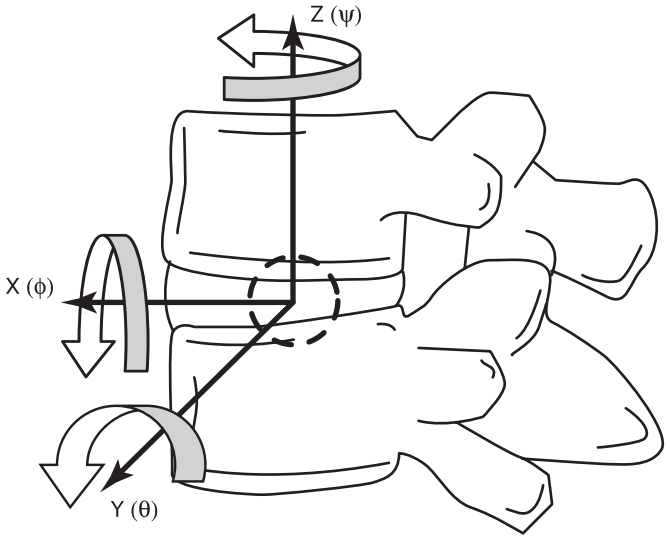

Fig. 2. Definition of the global coordinate system.

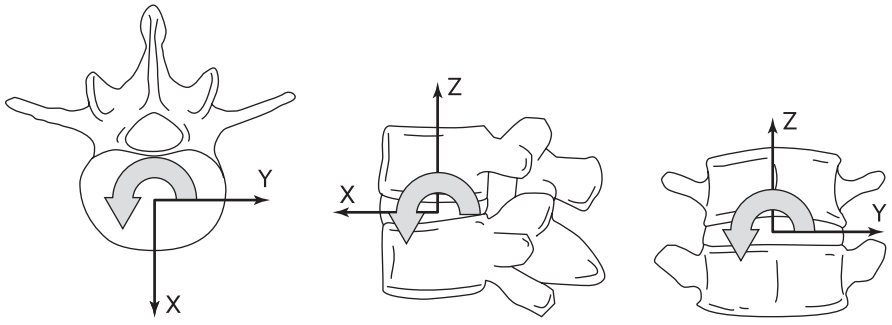

Fig. 1. Definition of the angular movements.