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Wear Properties of UHMWPE in CHARITE´ Artificial Inter-vertebral Disc

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ABSTRACT

Over the past three decades more than a half a million joint replacements have been performed. Several advances have been made to the design of the implants, but despite the large success of these procedures, loosening of the components and periprosthetic osteolysys often requires a revision surgery. In looking at what causes this, the wear of the UHMWPE articulation surface and the associated biological reactions to the wear debris have emerged as a major problem in total joint replacements. The main reason for wear testing is to determine the device durability, looking for potential failure modes such as fracture, or excessive wear that may lead to compromised function. The other reason is to try to predict the effect the device may have on the body. Neurotoxicity, inflammation, oncogenesis and osteolysis are all side effects that may be present when a device is implanted in the body and have been seen in cases with hip and knee replacement.

In determining the durability of an implant you first must know the types of loads that the device will be exposed to. These can be taken from research done over the past several years (see Figure1). Different loading conditions and motion controls must also be considered when testing these implants. Debates continue on the most physiologically accurate method for setting up test parameters. Current testing has shown wear debris testing of the CHARITE artificial disc to be significantly lower than the artificial hip and knee implants under similar loading conditions. When a cross-path motion loading condition is compared to curvilinear motion loading condition it can be seen that there is also significantly more wear with a cross-path motion profile. The large discrepancy in the amount of wear that can be achieved based on a different motion profile is an important consideration in the design and further development of medical devices.

For future development, there are several areas that will require research. The first is to look at the effects of sterilization methods of the UHMWPE on fatigue performance. The second is to try to gain a better understanding of loads that the body may undergo during daily activities. The third is to determine the most accurate method of testing devices concerning motion and loading parameters.

INTRODUCTION

Total disc arthroplasty has been used since the 1980's in Europe, but has only been approved for use in the US since 2004. The CHARITE artificial disc (DePuy Spine) consists of two CoCr alloy endplates on top and bottom of an Ultra High Molecular Weight Poly Ethylene (UHMWPE). This UHMWPE is similar to the material currently used in artificial hip and knee implants. The popularity of the Inter-vertebral Disc (IVD) replacement procedure is growing as a spine treatment for degenerative disc disease. The goal of the IVD replacement is to replace the painful degenerated disc with a new bearing unit to enable pain free motion. Due to the limited time of implantation of these devices, there are still many questions reguarding the wear characteristics of UHMWPE. Wear debris in hip and knee prosthesis is commonly thought to lead to prosthesis loosening as a result of osteolysis. The mechanical performance of UHMWPE is in the process of being better documented as retrievals become available, and through laboratory design evaluation and in-vitro simulation. The most clinically relevant simulation is currently being determined to establish a standard set of input parameters for future testing. The current lack of fundamental knowledge surrounding the clinical performance in the spine is particularly troubling due to the potential life threatening risks that a patient may occur in a revision surgery. The first step of testing is to determine what types of loads the implant may see, and for how long the implant needs to withstand those loads. A chart of daily loads in the spine for some typical activities can be seen in Figure 1.

ACTIVITY OF DAILY LIVING	LOAD DURATION	LOAD MAGNITUDE
Supine	8 hrs/day-constant	300 N
Walking	2,000,000 cycles/year Hedman, et al., 1991 Schmalzried, et al., 1997	850 N (10^7 cycles endurance limit 5.2kN)
Bending Forward to lift 20 kg	125,000 cycles/year Hedman, et al., 1991	1,850 N (10^7 cycles=80 years)
Lumbar Spine Fracture Strength	0 cycle/life	5,000-8,200 N

Figure 1: Typical daily loads for the spine.

There have been debates for years on how to best process and sterilize the UHMWPE for loading conditions seen in the spine. The UHMWPE has been used for several years in hip and knee implants, however studies have shown that how the material is manufactured and cleaned

can have a large affect on the wear properties, and the processes for UHMWPE in hip and knee implants may not be optimal for spinal implants. There is also much debate on how the loading pattern can affect the wear characteristics. Currently a standard set by the ASTM has been used as a benchmark for the CHARITE, however recent parameters defined by ISO have been used in studies conducted by independent labs comparing various spinal implants.

RESULTS

There are two main reasons for doing wear testing on the CHARITE artificial disc, as well as all mechanically loaded implant devices. The first is to determine the device durability, looking for potential failure modes such as fracture, or excessive wear that may lead to compromised function. The other reason is to try to predict the effect the device may have on the body. Neurotoxicity, inflammation, oncogenesis and osteolysis are all side effects that may be present when a device is implanted in the body and have been seen in cases with hip and knee replacements.

The sterilization methods of the UHMWPE have been looked at to evaluate how the processes may effect the wear properties. The initial trials of CHARITE implanted devices were sterilized using a gamma irradiation in air method. With the limited number of explanted devices, a trend can be seen showing plastic deformation and occasional fracture near the rim of the UHMWPE core (Figure 1-A). These are consistent with the types of cracks that are seen with fracture of certain total knee replacements. [Wright and Bartel, 1986]. These have been seen in some more recent implanted devices that were most likely gamma sterilized in a reduced oxygen environment. However, there have only been a few retrievals since this method has been used [David et al, 2005], and may still be too early to draw conclusions about the possibility of rim fracture in these implants. Further analysis is needed with more retrievals and better analysis of levels of oxidation, to have a better understanding of the risk of fracture in these implants.

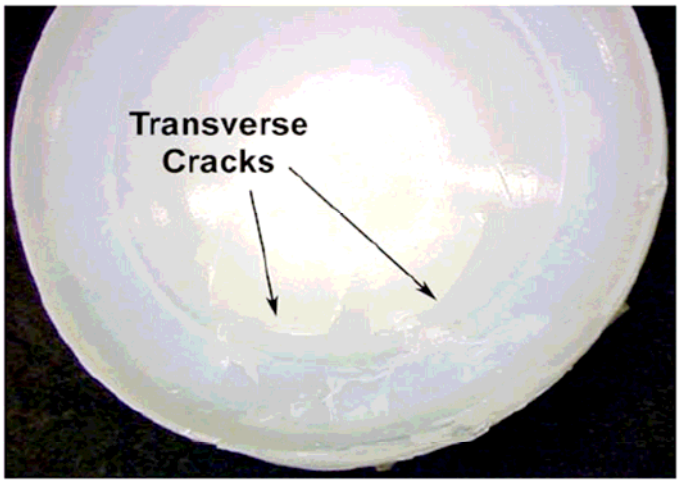

Fig. 1-A

Over the past three decades over half a million joint replacements have been performed. Several advances have been made to the design of the implants, but despite the large success of these procedures, loosening of the components and periprosthetic osteolysys often requires a revision surgery. In looking at what causes this, the wear of the UHMWPE articulation surface and the associated biological reactions to the wear debris have emerged as a major problem in total joint replacements. Even small amounts of wear debris can generate large numbers of particles which may enter the periprosthetic tissue, which can lead to periprosthetic osteolysis which necessitates and complicates revision surgery.

Some authors have dismissed the biological reactions to UHMWPE wear debris in the spine as clinically irrelevant due to the absence of a synovial joint [Link and Heller, 2003] However the findings from the recent studies [Kurtz et al, 2005] show clinical relevance of wear debris as a potential complication of total disc replacements. Despite the absence of a synovial joint, the wear debris in the periprosthetic tissues was associated with and inflammatory reaction in four patients with osteolysis in one patient.

This remains another area of the spine and total disc replacements that requires further research and detailed study.

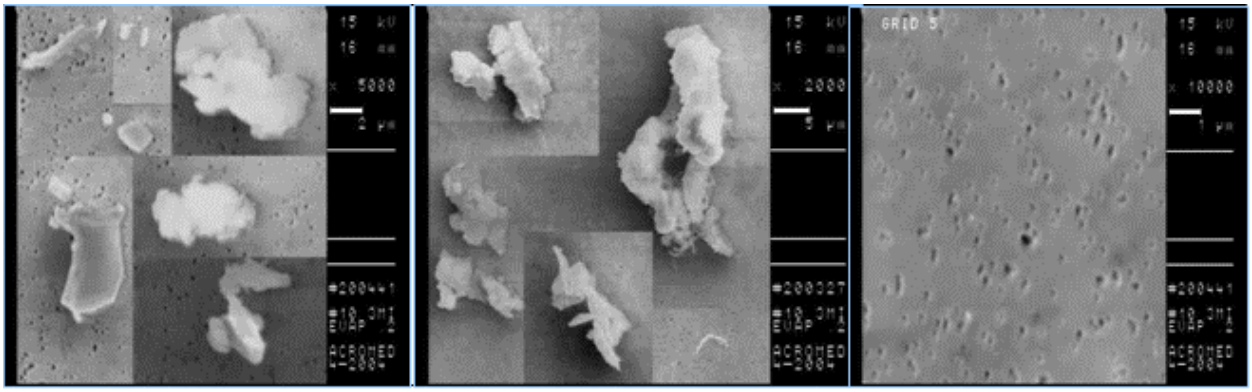

Figure 2: Typical wear debris pictured under SEM at 5000x, 2000x and 1000x magnifications

Due to the importance of minimizing wear of UHMWPE to help reduce surgical complications and revision surgeries, it is important that we develop test parameters to best simulate in-vivo, so we can design these implants to resist this loading. Figure 3 shows the test parameters set up by ASTM , the test parameters that DePuy Spine followed for FDA clearance of the CHARITE artificial disc, and the ISO test parameters (2004). There have been several debates on which parameters are “worst-case”, and which are more clinically relevant to physiologic loads.

Parameter	*in vivo** (average)	ASTM Draft[1]	DePuy Spine	ISO
ROM F/E	12-17°	15°	15°	6° / 3°
ROM Lateral	3-8°	15°	15°	4°
ROM Axial	1-3°	4°	4°	4°
Max. Frequency	1-2 Hz	2 Hz	1.35 Hz	1.0 Hz
Loading	700-1200 N	1200 N	900-1850 N	600 – 2000 N
Coupling	F/E alone; Lat bend & axial	F/E & axial; lat bend alone	F/E & axial; Lat bend & axial	All motions at once

Table 1: Test parameters for ASTM (draft 3, 2003)and ISO (2004) compared to in-vivo loads and motion [White & Panjabi, 1990]

The ASTM and ISO parameters vary significantly in the specifications for most of the parameters. The ASTM standard results in a curvilinear motion that couples flexion-extension and axial rotation, and then couples lateral bending and axial rotation, while the ISO parameters combine all loading conditions together resulting in a cross-shear motion profile. (See Figure 3).

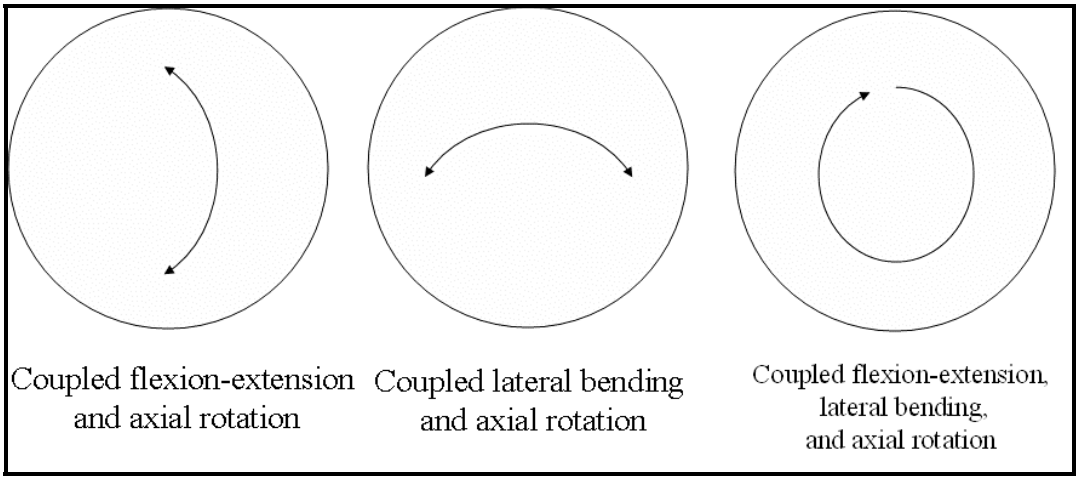

Figure 3: Motion profile for ASTM and ISO parameters

The wear rates between the two profiles differ substantially, and statistical analysis shows a significant difference in wear rates between the cross-shear and curvilinear motion patterns. (See Figure 4) [Nechtow, W, 2004] All of the contact surfaces showed highly polished areas, machine mark residuals, and light surface scratches, however there were no implant failures or plastic deformation.

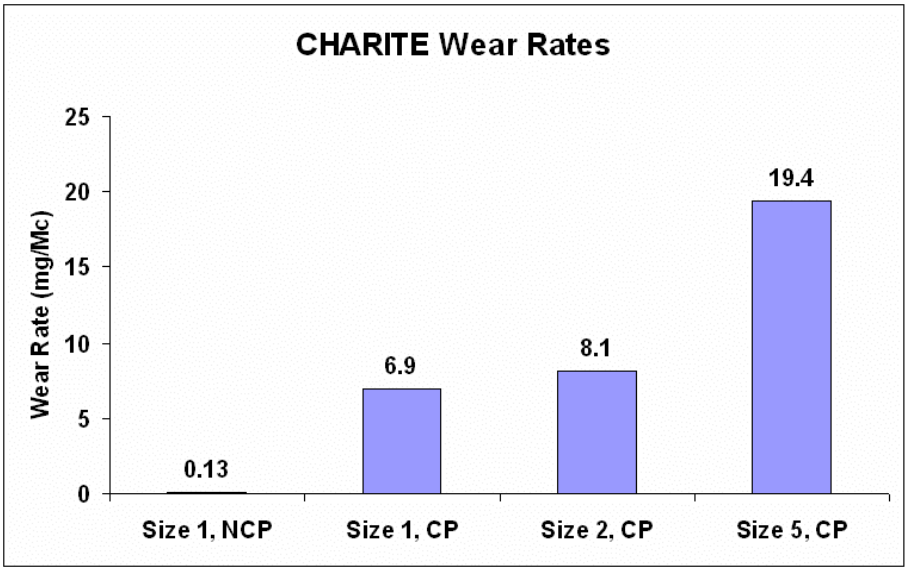

Figure 4: Shows that wear increases with cross path motion as well as implant size

The components tested in cross-shear underwent multi-directional motions that previously showed to be detrimental to UHMWPE [Wang, 2001]. The drastic wear rates between the two patterns shows the importance of using the correct input parameters for testing. These results are consistent with the hip and knee data with regards to effect of motion profile on UHMWPE wear.

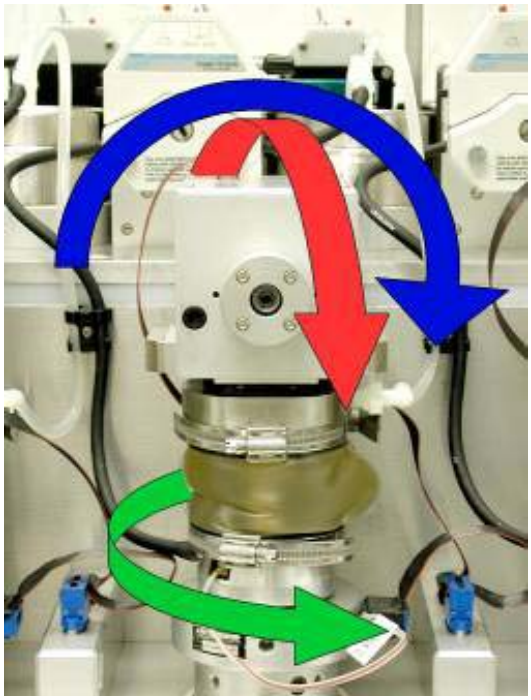

Figure 5: Test setup at Depuy Spine

The question then becomes how much cross-path motion is actually needed to best simulate the in-vivo conditions, and are the ISO parameters generating a path that is too severe. Based on retrievals, and clinical data such as clinical osteolysys (amount of wear in the body), and clinical measurements of wear (radiographs) it can be said that the cross-path wear is an accurate predictive model for hips. However in the case of the spine it is probably a mixture of cross-path and curvilinear motion patterns. [Dooris, 2005] If the same implant experiences both flexion and bending even if one is after the other, has been considered to be similar to cross-path wear. The testing conducted at DePuy, according to the ASTM protocol, includes both directions of motion, assuming that both will happen.

The question remains of how much of each direction is necessary. Figure 6 shows the setup at DePuy Spine. Figure 7 shows the motion applied to the CHARITE artificial disc.

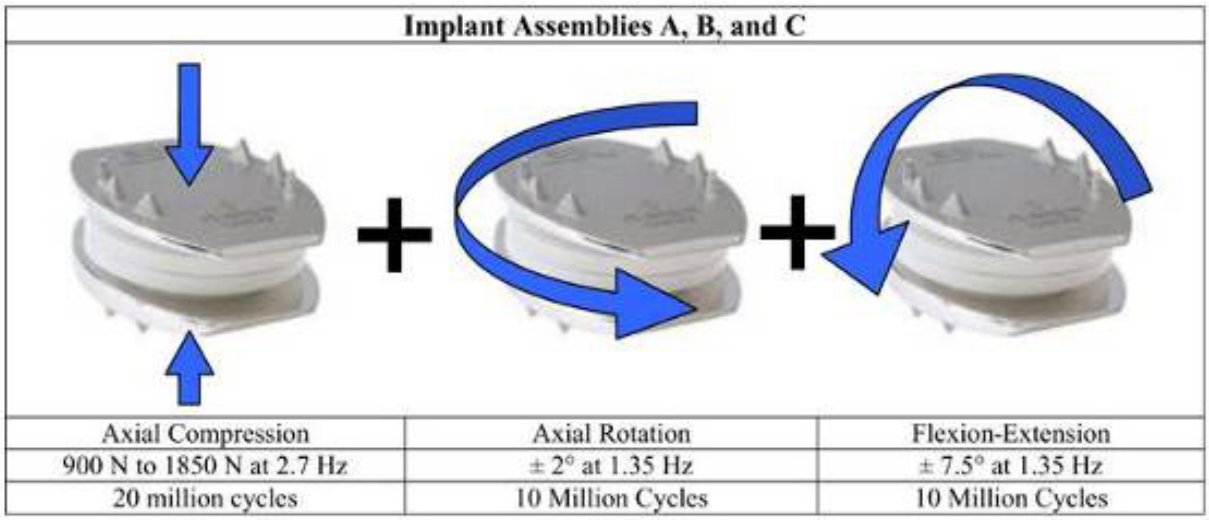

Figure 6: Compressive, rotational and flexion-extension motion on the test machine

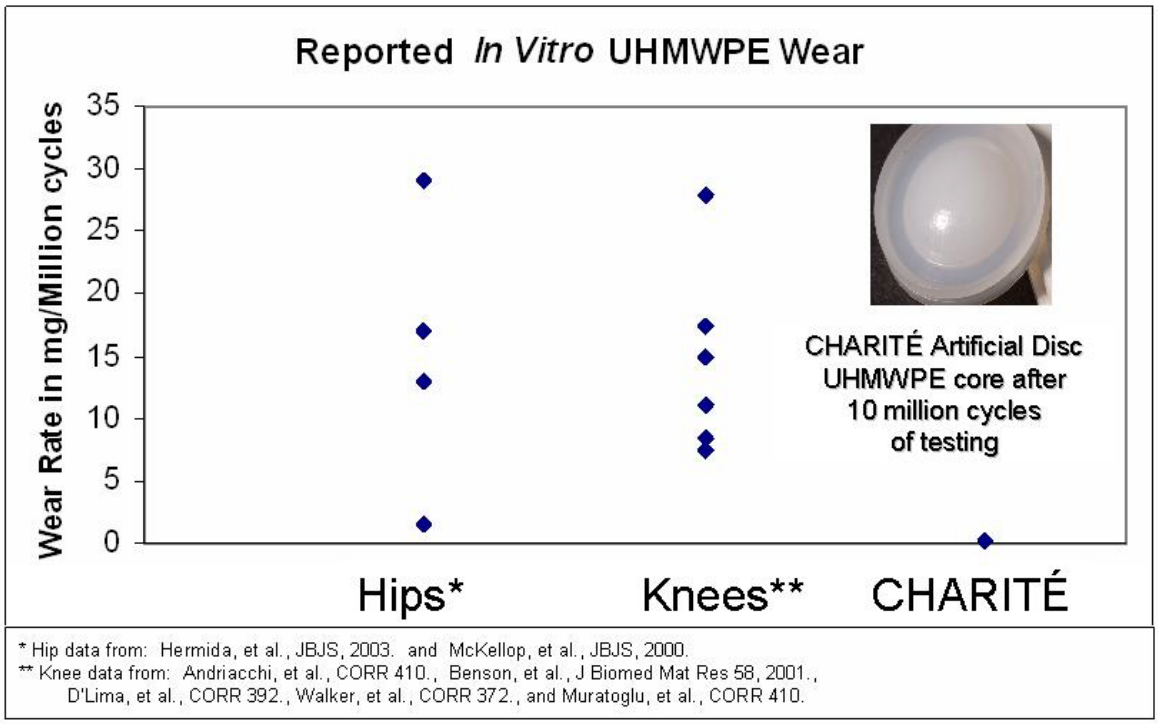

Figure 7: Wear testing results of CHARITE vs Hip and Knee implants

In the figure above, results for the CHARITE artificial disc are compared to wear data of the total hip and total knee implants. It can be seen that the CHARTE is significantly lower than both of the other implants using the same UHMWPE. IT should be noted that the CHARITE was tested in-vitro according to the ASTM test standards, while the data for the hip and knee are a combination of in-vitro testing as well as implant retrievals from in-vivo.

DISCUSSIONS

Over the past three decades more than a half a million joint replacements have been performed. Several advances have been made to the design of the implants, but despite the large success of these procedures, loosening of the components and periprosthetic osteolysys often requires a revision surgery. In looking at what causes this, the wear of the UHMWPE articulation surface and the associated biological reactions to the wear debris have emerged as a major problem in total joint replacements. Although the biological wear debris may not be seen as a large concern for spinal indications due to the absence of a synovial joint, the findings from the recent studies [Kurtz et al, 2005] show clinical relevance of wear debris as a potential complication of total disc replacements. Despite the absence of a synovial joint, the wear debris in the periprosthetic tissues can be associated with an inflammatory.

In determining the durability of an implant you first must know the types of loads that the device will be exposed to. These can be taken from research done over the past several years (see Figure1). Different loading conditions and motion controls must also be considered when testing these implants. Debates continue on the most physiologically accurate method for setting up test parameters. When a cross-path motion loading condition is compared to curvilinear motion loading condition it can be seen that there is significantly more wear with a cross-path motion profile. The large discrepancy in the amount of wear that can be achieved based on a different motion profile is an important consideration in the design and further development of medical devices.

For future development, there are several areas that will require research. The first is to look at the effects of sterilization methods of the UHMWPE on fatigue performance. The second is to try to gain a better understanding of loads that the body may undergo during daily activities. The third is to determine the most accurate method of testing devices concerning motion and loading parameters.

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*specific number values for load and wear rates at DePuy Spine have been excluded from some data for confidentiality purposes.