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**Influence of the Testing Frequency on the Wear Rates of the Prodisc-L Lumbar Disc Replacement**

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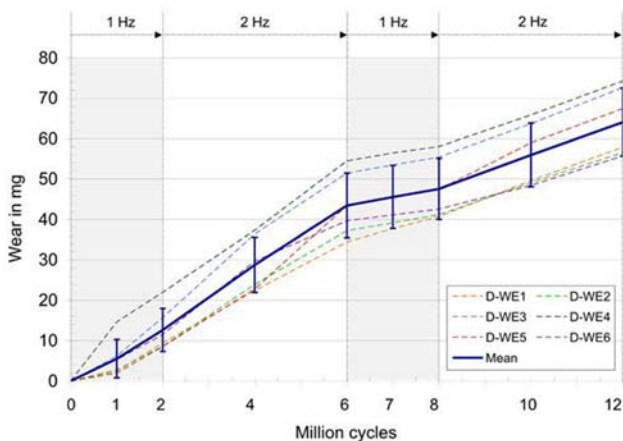
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Intervertebral disc prostheses are developed in increasing number. Clinically, some have been shown to result in an outcome comparable to or better than fusion. However, there are also complications reported. These can be associated with mechanical failure. Therefore, extensive mechanical testing is required for approval. Among various other tests, wear testing needs to be carried out. The wear behaviour is often investigated according to ISO 18192-1. Ten million multiaxial loading cycles are applied at a frequency of 1 Hz. At this frequency testing takes about four months. Testing at higher frequencies would therefore be desirable. ISO 18192-1 also offers testing at 2 Hz, however, it says the impact of test frequencies higher than 1 Hz on the implant material behaviour as well as on the accuracy of the test machine shall be investigated by the user. Data about such comparative testing is not yet available. Therefore, in this study, wear testing was carried out at 1 Hz and at 2 Hz. The aim was to investigate whether testing at 2 Hz results in the same wear rates as testing at 1 Hz.

Seven Prodisc-L (Synthes USA) lumbar intervertebral disc prostheses were tested. The polyethylene inlays were pre-soaked in calf serum at a temperature of 37°±2°C for 43 days. The implants were placed in specimen cups filled with calf serum, mounted to a Spine Wear Simulator (MTS Systems) and loaded according to ISO 18192-1:2006. Testing was carried out at a temperature of 37°±2°C. Four million loading cycles were applied at 1 Hz and eight million at 2 Hz in an alternating sequence. Each time after 12 days of testing the implants were removed to measure the weight and the height of the inlays. Then, the test serum was exchanged and the implants remounted to the testing machine.

The mean wear rate was 4.2 mg (±3.2 mg) per million cycles at 1 Hz and 5.9 mg (±2.2 mg) at 2 Hz. This difference was statistically significant (p=0.03). The mean height loss was -0.019 mm (±0.024 mm) per million cycles at 1 Hz and -0.030 mm (±0.018 mm) at 2 Hz (p=0.07). The accuracy of the test machine was within the limits described by ISO 18192-1 at both frequencies.

The results showed that testing at 2 Hz significantly increases the wear rate compared to testing at 1 Hz. At the same time the loading accuracy was within the limits for both loading frequencies. Since the loading frequency of the spine in vivo is mostly below 2 Hz, the authors suggest testing intervertebral disc prostheses such as the Prodisc-L at 1 Hz. This improves the comparability of the test results with the situation in vivo.



[Figure 1]

Figure: Cumulative wear rates of the PE-cores of the Prodisc-L. Individual values and mean with standard deviation of the six implants after correction for the loaded soak control.