Wear Characterization of Hip Joint Prostheses by a Hip Simulator

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A wear characterization of commercial hip joint prostheses was conducted by means of a hip wear simulator. Bovine serum solution was used as a lubricant, and tests were conducted up to 5 × 10⁶ cycles. At first, the effect of testing conditions on wear of the hip joint prostheses was examined in order to determine the optimum conditions for hip simulator testing. As a result, it could be clarified that the serum concentration in the lubricating fluid and the intervals of time between lubricant replacements highly affect the wear of ultra-high molecular weight polyethylene (UHMWPE). Formation of a protein film on the acetabular cup and increasing wear at initial stage after lubricant replacement are likely the reasons for this phenomenon. By using standardized conditions, long-term simulator tests are conducted against six types of commercial hip joint prostheses. The results clearly reveal the difference in wear resistance of each combination. The present data can be considered to be reference data for developing new types of hip joint prosthesis.

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1. Introduction

In recent years, the attention of surgeons and bioengineers has been focused upon the long-term performance and survival of total hip replacements. Many works have been conducted on improving wear resistance of hip joint prostheses, because the osteolysis induced by excessive amount of fine polyethylene (PE) wear particles is a key factor causing loosening failure of them. The 30-years period from the early 1960s was dominated by implants with metallic femoral heads and ultra-high molecular weight polyethylene (UHMWPE) acetabular cups, while the use of ceramic femoral heads has also been favored in recent times. There has also been a growing interest in the development of hard-on-hard material combinations such as ceramic-on-ceramic or metal-on-metal joints in recent years.

For evaluating wear in these prostheses, hip joint wear simulator is very effective, and many simulator wear studies have been conducted on the latest hip joint prostheses. However, since the result of wear is very sensitive to surrounding factors such as lubricant composition, it is difficult to compare results obtained in different laboratories. Thus, it is necessary to define a wear evaluation method and to compare the data obtained under the same conditions.

In the present study, some possible factors to affect wear are examined for defining wear evaluation method. Then, by using determined testing conditions, wear characterization up to 5 × 10⁶ cycles is conducted on six types of commercial hip joint prostheses.

2. Experimental

Three types of femoral heads (ZrO₂, CoCr and Al₂O₃) and four types of acetabular cups (UHMWPE, crosslinked UHMWPE (c-UHMWPE), CoCr and Al₂O₃) are used for the simulator test. The combinations of hip joint prostheses examined in this study are summarized in Table 1. Three samples are examined in each combination.

Wear tests are performed using 12-station hip joint simulator (MTS, USA). The simulator is the orbital type, with the femoral heads oscillating ±23° about a revolving horizontal axis. The tests are conducted at a rotation frequency of 1 Hz, and the load is applied by Paul’s walking profile. Maximum load is set for 2.8 kN in the profile. All acetabular cups are mounted in the anatomical position using PE adapters to lock into the chambers.

Bovine serum solution is used as a lubricant. The bovine serum is distilled by 7 or 25%, and 20 mM ethylene diaminetetraacetic acid (EDTA) and 0.1% sodium azide are added to the lubricant. The serum solutions are supplied to 700 ml volume chambers. Wear is evaluated by measuring the weight change of cups. To compare the volumes of wear debris released into the tissues, the weight loss is converted to volumetric wear, i.e. mm³/10⁶ cycles, using densities of Al₂O₃, 3.96; CoCr, 8.3, UHMWPE, 0.936; ZrO₂, 6.08 g/cm³. The measurement is carried out every additional 250,000 or 500,000 cycles.

3. Results and discussion

At first, the effect of testing conditions on the wear of hip joint prostheses is examined in order to determine the optimum conditions on hip simulator tests. Figure 1 shows the results examining the effect of serum concentration in lubricant on ZrO₂/UHMWPE. Serum concentration in lubricant highly affects the wear of UHMWPE. In Fig. 1,
wear in 25% serum solution is higher than that in 7% one. This result is in good agreement with that reported on metal/UHMWPE. It is demonstrated that the serum concentration is also important in the combination ceramic/UHMWPE. Since the change in wear with the change in serum concentration in metal/UHMWPE is supposed to originate from the protein film formed on joints surface, it is important to focus on protein concentration. Since the protein concentration of fluid in the joint is in the range 20 to 35 mg/ml and that of serum is about 80 mg/ml, the choice of 25% serum solution seems to be reasonable. According to these arguments, the serum concentration in the lubricant has been fixed to 25%.

Figure 2 shows the results examining the effect of time intervals of lubricant replacement on ZrO$_2$/UHMWPE. Time intervals of lubricant replacement also affect the wear of UHMWPE significantly. In Fig. 2, wear decreases with increasing intervals of lubricant replacement. This result seems to correspond to the result that degraded serum solution decreases wear. However, more recent results indicate that the degree of degradation of serum solution is not so different between 3 and 6 days. An additional factor must be taken into consideration.

Figure 3 shows the comparison of relative torque change in two conditions: no replacement of lubricant (upper) and replaced twice (lower). The relative torque decreases with increasing cycles in both conditions. When the lubricant is replaced, relative torque significantly increases. Although it is difficult to explain the relationship between torque and wear quantitatively, increase of torque must cause an increase of wear in the same condition. If the amount of the change in torque is simply calculated, the change in torque in the condition replaced twice (lower) exhibits 1.5 times higher than that without replacement. This must be the origin of increasing wear under the condition of replacement in 3 days. From this result, it is clarified that frequent replacement of lubricant causes an overestimation of wear rate by increasing wear amount at the initial stage after the lubricant replacement. Then, the time intervals of lubricant replacement can be determined to be 6 days from this result. From these analyses together with additional results not reported here, wear evaluation conditions are defined.

Next, wear characterization is conducted on six types of commercial hip joint prostheses under the conditions defined in this study. The tests are conducted until $3 \times 10^6$ cycles, which would be equivalent to 5 years of use in the actual total hip replacement patient.

Figure 4 shows a comparison of wear in six types of commercial hip joint prostheses. The lower figure is drawn in enlarged scale. The wear characteristic is much different in each combination. The wear rate in each material is summarized in Table 2.

In CoCr/UHMWPE, the average net UHMWPE volume loss is 16.9 and 19.9 mm$^3$/10$^6$ in the two combinations, respectively. There is no large difference in wear between two kinds of joint prostheses provided from two different manufacturers.

The wear of UHMWPE is highly reduced by crosslinking. The average net c-UHMWPE volume loss is 3.4 mm$^3$/10$^6$ against Al$_2$O$_3$ femoral head and 2.2 mm$^3$/10$^6$ against ZrO$_2$ femoral head. These value are almost 20% of that in UHMWPE.

In CoCr/CoCr, the wear is also suppressed. The average net CoCr volume loss is 2.2 mm$^3$/10$^6$, which is almost in the same level with that in Al$_2$O$_3$ or ZrO$_2$/c-UHMWPE.

For the Al$_2$O$_3$/Al$_2$O$_3$ system, extremely low wear is observed in comparison with other combinations. The average net Al$_2$O$_3$ volume loss is less than 0.06 mm$^3$/10$^6$, which is only 2 to 3% of that in c-UHMWPE or CoCr.

From these results, a difference in wear property for each
Fig. 4. Comparisons of wear in six types of commercial hip joint prostheses.

Table 2. Comparisons of Volumetric Wear in Six Types of Hip Joint Prostheses

<table>
<thead>
<tr>
<th>Hip joint prostheses</th>
<th>Volumetric wear (mm³/10⁶)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoCr/UHMWPE (A)</td>
<td>16.9</td>
</tr>
<tr>
<td>CoCr/UHMWPE (B)</td>
<td>19.9</td>
</tr>
<tr>
<td>Al₂O₃/c-UHMWPE</td>
<td>3.4</td>
</tr>
<tr>
<td>ZrO₂/c-UHMWPE</td>
<td>2.2</td>
</tr>
<tr>
<td>CoCr/CoCr</td>
<td>2.2</td>
</tr>
<tr>
<td>Al₂O₃/Al₂O₃</td>
<td>&lt;0.06</td>
</tr>
</tbody>
</table>

combination is clearly exhibited. These data should be applied as reference data for developing new types of hip joint prostheses or selecting combination for clinical application.

4. Conclusions

Wear evaluation method by a HIP simulator has been examined and wear characterization of commercial hip joint prostheses has been conducted. The results are summarized as follows:

1. It is clarified that serum concentration in lubricant and times intervals of lubricant replacement highly affect the wear of ZrO₂/UHMWPE. Formation of protein film and increasing wear at initial stage after the lubricant replacement must be the reason for such a behavior.

2. Wear characterization up to 5 × 10⁶ cycles is conducted on six types of commercial hip joint prostheses under the conditions defined in this study. The results clearly exhibit differences in wear property for each combination.

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