Effect of Surface Conditions of Metallic Pins Simulating Cemented Femoral Stem on Subsidence in Cyclic Fatigue Testing

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The purpose of this study was to investigate whether amorphous diamond (AD) coating is effective in reducing subsidence of tapered metallic pins, which simulate cemented stems. The pins (length 70 mm, taper angle 1.27°) of titanium alloy and stainless steel were cemented in nylon blocks (height 50 mm) with bone cement. Pins were ground and polished to give Ra = 10, 50 or 100 nm. Half of the stainless steel pin set was coated with AD coating. Cyclic fatigue testing was carried out for each of the pins up to 5 million cycles. Following tendency concerning the amount of subsidence was found. With respect to material: titanium alloy < stainless steel; coating: AD coated < non-AD coated; and roughness: rough < smooth. Lower subsidence of the AD coated pins than that of the non-coated ones may be due to the surface characteristics of the AD coating providing stable bonding between the cement and the material leading to higher stability at the interface. AD coating seems to be a potential surface treatment for clinical use in cemented femoral stems.

Total hip replacement (THR) has become an efficacious and cost-effective procedure in the treatment of patients with painful end-stage arthritis. Many THR systems have been developed until now. Currently, it is considered that not only ultra high molecular weight polyethylene (UHMWPE) particles from the articular surface but also wear particles from the femoral stem and bone cement and damage of bone cement cause aseptic loosening due to osteolysis of the femoral bone in cemented total hip prostheses. At present, most of hip implants are fixed with polymethylmetacrylate (PMMA) which is also called bone cement. As a bulk material PMMA is bioinert and it can also be used as a carrier for antibiotics or chemicals. However, micromotion and heavy cyclic loading erode extensive amount of bone cement particles, which provoke strong foreign body reaction and lead to osteolysis (1). In this sense, stability of the femoral stem of total hip prosthesis is important concerning to its longevity. An extent of subsidence can be used to estimate the stability of the fixation. Excessive subsidence of a stem is indicative of clinical failure (2-4). Material, surface finish, coating and shape of the stem affect the stability at the interface between stem and cement. There exist some controversies related to them. For example, concerning to material, evidence exists that titanium may be less suitable for cemented fixation (5-7). However, good clinical results of cemented titanium alloy stems have also been reported (8-10). Regarding to surface finish, some studies recommended the polished stem or did not recommend the rough surface of the stem (11-13). However, good clinical results of stems with a rough surface have also been reported (14, 15). Furthermore, some prospective studies preferred rough surface of the stem on the basis of comparison between smooth and rough surface with identically designed geometry (16, 17). Many coatings have been developed to improve stability between stem and bone cement. Among them, amorphous diamond (AD) coating has turned out to be a promising biomaterial for artificial joint due to excellent biocompatibility, longevity and versatility (18). We hypothesize that AD coated stems would be more stable than non-AD coated ones and AD coating would lead to the stability of the stem subsequently. In this preliminary study, potential of AD coating on stem materials of THR was tested using tapered model pins simulating the taper section of a stem. In addition to AD coating, pin material and surface roughness was varied.

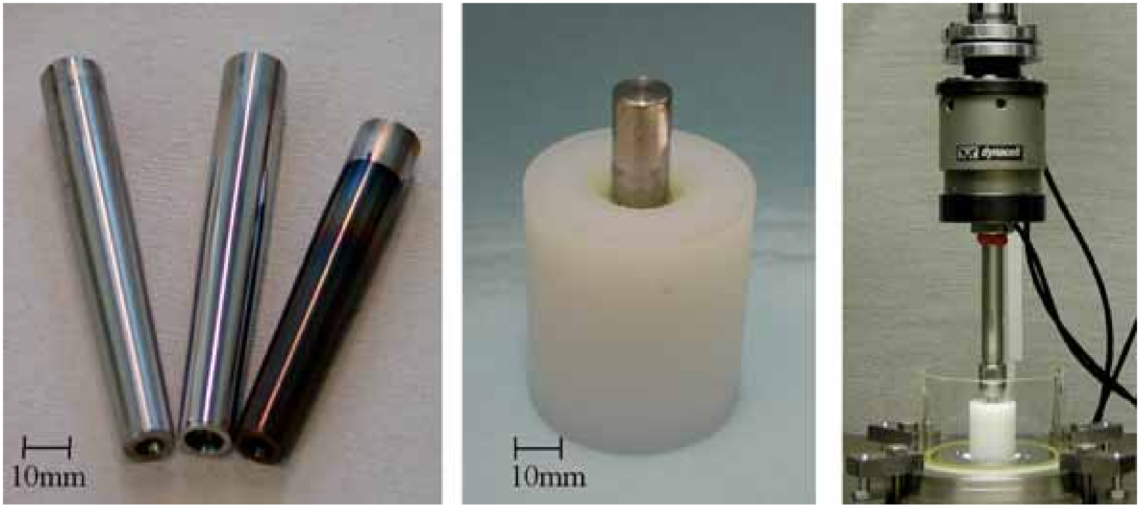

Fig. 1. (A) Cemented femoral stem-shaped metallic pins (from left to right): non-AD coated (rough), non-AD coated (smooth) and AD-coated. (B) Metallic pin specimen fixed with bone cement on a nylon block mantle. (C) A specimen mounted in the test chamber without serum lubricant.

Materials and Methods

In the tests, femoral stem-shaped pins were studied with cyclic fatigue testing. Two widely used biomaterials, titanium alloy, TiAl6V4 (N=7) and stainless steel, AISI 316L (N=12) were used. The pins (length 70 mm) had a taper angle of 1.27° corresponding proximal and distal diameters of 10 mm and 8 mm, respectively. Pins were mechanically ground and polished to give a typical surface roughness of (center line average) Ra = 50 or 100 nm for titanium alloy pins and Ra = 10 or 100 nm for stainless steel pins. The roughness was measured with a profilometer (Mitutoyo, Kawasaki, Japan). Half of the stainless steel pin set was coated with AD coating 600-800 nm thick by using filtered pulsed arc discharge method at the University of Kuopio (Kuopio, Finland) prior to tests (Fig. 1A). The pins were cemented in nylon blocks (height 50 mm) with bone cement Refobacin®-Palacos® R (Biomet Europe, Dordrecht, The Netherlands) (Fig. 1B). The cement components were pre-chilled and mixed at room temperature in a cement mixing system with vacuum. A cement gun was used to fill the hole of the nylon block in retrograde fashion. The minimum thickness of the cement mantle was 3 mm. After cementing, the specimens were stored in saline solution and/or dry condition at 37 °C with and/or without a load.

Cyclic fatigue testing (5 million cycles/pin) was carried out by using a servohydraulic testing device (Instron, Canton, MA, USA) (Fig. 1C). The vertical load profile was a scaled Paul's gait curve with a peak load of 0.850 kN at 10 Hz. The loading was scaled with respect to the sizes of the pins and the clinical stems to obtain corresponding stresses at the interface. Torsional load (◎3.750 Nm at 0.5 Hz) was applied simultaneously to simulate clinical loading. Testing was carried out in diluted bovine serum (total protein content 35 mg/ml). The vertical position, rotation angle and temperature (37 ± 1 °C) were monitored throughout the tests by the software of the testing equipment.

Results

It was found out that the storage time and conditions are important for the stability of the fixation, too. For example, it was found that longer storage time leaded to the greater cumulative subsidence of the pins up to 5,000,000 cycles. Furthermore, if the pins were stored for a long time (i.e. more than 14 days) the bonding at the interface became weak and the subsidence within the initial 10,000 cycles was high. The average storage time (9-14 days) was about the same for all the material groups which are discussed next.

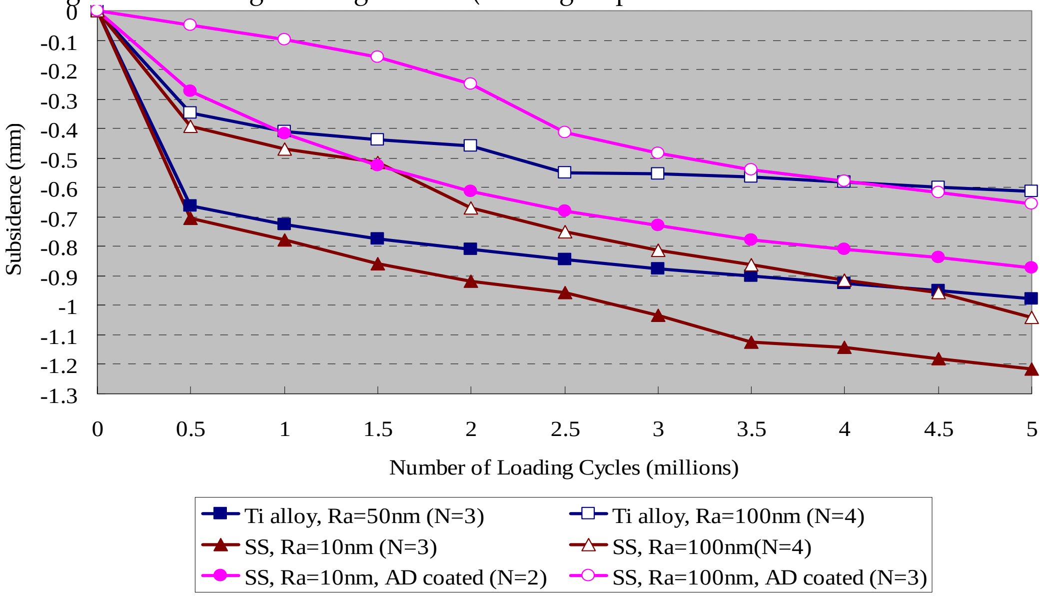

Fig. 2A. Subsidence up to 5 millions (Ti: titanium alloy, SS: stainless steel).

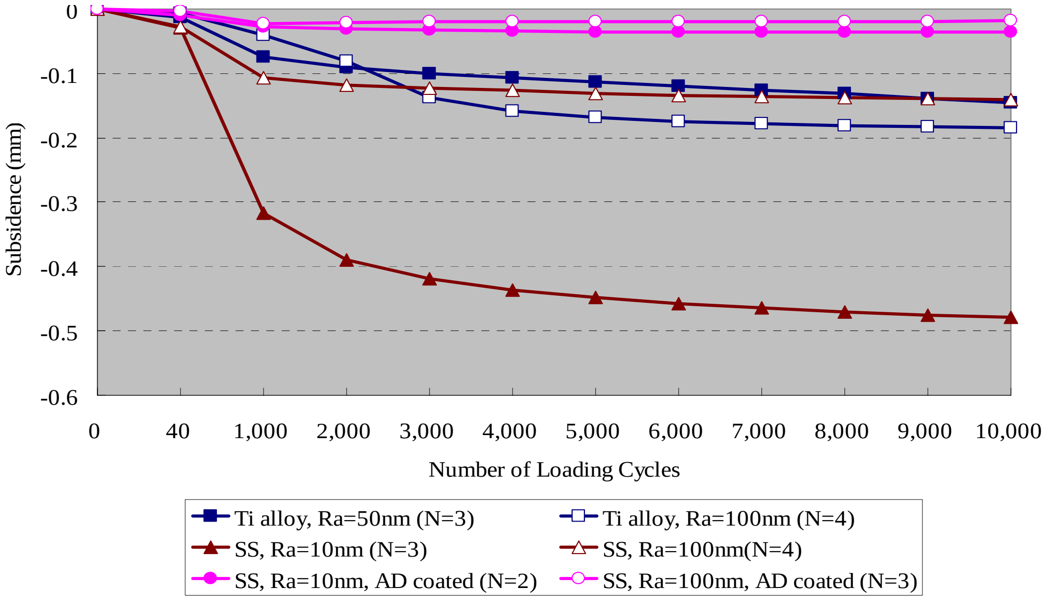

Fig. 2B. Subsidence up to 10,000 cycles (Ti: titanium alloy, SS: stainless steel).

The cumulative subsidence of the pins versus number of cycles up to 5 million cycles is shown in Fig. 2A. With respect to material, the subsidence of the titanium pins was less than that of the stainless steel pins. With respect to coating, the subsidence of the AD coated pins was less than that of the non-AD coated pins. And with respect to surface roughness, the subsidence of the rough pins was less than that of the smooth pins. Furthermore, the initial subsidence up to 10,000 cycles in the groups of non-AD coated pins occurred sharply, compared to the AD coated pins which had smooth low initial subsidence (Fig. 2B).

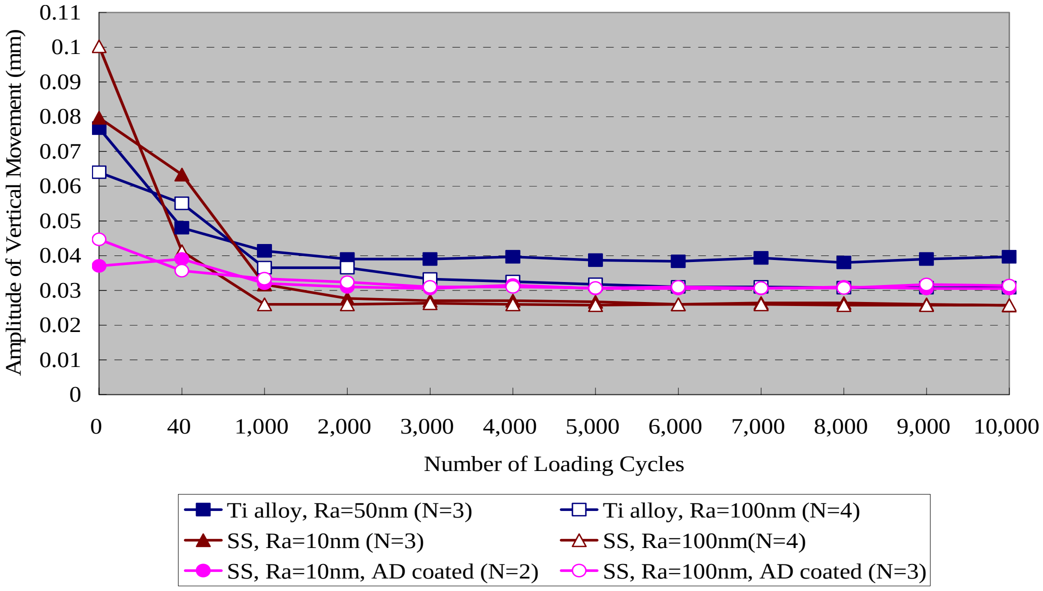

Fig. 3. Amplitude of vertical movement up to 10,000 cycles (Ti: titanium alloy, SS: stainless steel).

The amplitude of vertical movement is shown in Fig. 3. For non-AD coated pins, the amplitude of vertical movement was high within 1,000 cycles and then plateaued. On the contrary, the amplitude of AD coated pins was more stable throughout the tests.

Rotation angle varied widely depending on the state of pin loosening for all the groups.

Discussion

It is a well-known fact that wear debris from the articulating surfaces, such as UHMWPE particles, causes aseptic loosening due to periprosthetic osteolysis. Furthermore, recently, wear particles from the femoral stem and bone cement and damage of bone cement have been given attention because they may cause aseptic loosening due to osteolysis of the femoral bone on cemented total hip prostheses. These wear particles are caused by micromotion both at stem/bone cement and bone cement/bone interface. Therefore, there exists a controversy related to using bone cement on total hip replacement. Bone cement (PMMA) has good impact strength and shortens the recovery time and hospitalization by permitting the patient to load the operated limb right after the surgery. It is easy to form and its elasticity can distribute the point stresses between the flexible bone and the stiff stem over a larger area (19). PMMA is bioinert as a bulk material and can be used as a local antibiotic carrier. However, micromotion and heavy cyclic loading erode extensive amount of bone cement particles, which provoke strong foreign body reaction and lead to osteolysis (1). Therefore, excessive subsidence of cemented stem of total hip prosthesis causes wear particles and damage of bone cement and is associated with clinical failure.

Metal alloys commonly used in femoral stems are stainless steel, cobalt-chromium alloy and titanium alloy. Titanium alloy was introduced to reduce the problems of proximal stress-shielding and proximal bone resorption. Titanium alloy is strong and corrosion resistant, and has a modulus of elasticity about half of that of stainless steel and cobalt-chromium. However, evidence exists that titanium may be less suitable for cemented fixation (5-7). For such use, it should probably be at least highly polished and preferably coated with a ceramic surface (20). Furthermore, on titanium alloys, bone cement can cause severe dissolution of metal due to crevice corrosion (5, 7). Therefore, titanium alloy stems are rarely recommended for cemented total hip replacement.

Rougher surface of the material increases the shear strength at the interface. Decreased subsidence of the rough pins compared to the smooth ones may be due to this phenomenon at the cement/pin interface. The clinical results relating subsidence of the stem and clinical failure have been reported. Freeman et al. (2) and Kärrholm et al. (3) concluded that a threshold subsidence of the probability of clinical failure was 1.2 mm/yr during the first two years by analyzing Freeman femoral prosthesis (CoCrMo, Ra = 100-400 nm) using the standard radiographs and analyzing Lubinus SP I (CoCrMo, Ra not specified) using the roentgen stereophotogrammetric analysis, respectively. Kobayashi et al. (4) analysed the relationship between migration and clinical failure on basis of the result of Freeman femoral prosthesis. They recommended that new implants with migration more than 0.4 mm/year at two years should not be used because of high failure rate. Alfaro-Adrián et al. (21) investigated subsidence pattern of Exeter stem (stainless steel, Ra = 10 nm) and Charnley stem (Ortron 90, Ra = 100–1000 nm) by means of the roentgen stereophotogrammetric analysis. In that study, average subsidence of Exeter stem and Charnley stem were 1.06 mm and 0.32 mm at postoperative one year and 1.20 mm and 0.38 at two years, respectively. Nilsson and Kärrholm (22) mentioned that it is clear that there is a low risk of clinical loosening when either no subsidence is detected or it is less than 1 mm and stops after the first postoperative year. One year in the clinical case corresponds to one million in the cyclic fatigue testing. In our present study, subsidence of non-AD coated smooth stainless steel pins was greatest and second was that of non-AD coated smooth titanium alloy pins. Average values of subsidence of non-AD coated smooth stainless steel pins and smooth titanium alloy pins were 0.78 mm and 0.72 mm at one million cycles and 0.92 mm and 0.81 mm at two millions, respectively. Even these values are within the threshold of Freeman et al. (2) and Kärrholm et al. (3). Indeed these values are higher than threshold of Kobayashi et al. (4). However, because surface roughness of the pins in this study was lower than that of Freeman femoral prosthesis, we cannot make draw a conclusion that these materials should not be used. With other materials, the extent of subsidence is within the threshold. Furthermore, subsidence of non-AD coated smooth stainless steel pins bore a resemblance to that of Exeter stem by Alfaro-Adrián et al. (21). It has been reported that subsidence is fastest in the first year, then becomes slower and monotonic (23-25). Above all, Mjöberg et al. (24) mentioned that the migration was fastest during the first four months after operation. Our present study showed the same tendency. Especially, subsidence was fastest within 10,000 cycles and then became slower.

Considering the results of both subsidence and amplitude of vertical movement at the initial stage, especially within 1,000 cycles, debonding at the interface between metal and bone cement occurred at the early stage of the test in all specimens. This result gives support to the suggestion that the interface may not be bonded (3, 26). Debonding was evident in the group of non-AD coated stainless steel pins and least in the group of AD coated pins. Furthermore, considering the results of difference in storage conditions, the longer storage time leads to the severer debonding at the interface between metal and bone cement.

To date, various benefits of AD coatings have been proved experimentally. AD has the good biocompatibility and is quite inert (27). Corrosion of titanium alloy can be reduced at least by a factor of 15000 by amorphous diamond coating (18). High quality AD coatings offer superior stability (minimal wear debris release in surrounding tissues) (27). In our previous study using cobalt-chromium alloy, it was found that the AD coating can function well as a bonding surface for bone cement fixation or as a counterface against bone cement in sliding in the case of micromotion typical for pins fixed with cement (28). Lower subsidence of the AD coated pins than that of the non-coated ones in our present study is most probably due to surface characteristics of AD and stronger bonding between the cement and the pin and higher stability at the interface as discussed in our previous article (28). Extreme hardness of AD should also lead to reduced wear caused by micromotion at the interface.

Conclusions

AD coating seems to be a potential material for surface treatment of femoral stem for clinical cemented fixation. In our model system, AD coating provided stable fixation with low subsidence and protected the surface against damage due to micromotion. In the following tests it is essential to carry out tests with similar stems and cementing geometry as in clinical use.

Acknowledgements

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