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Histological evaluation of bone–cement interface affected by polyethylene particles in rabbit knee

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To investigate the biological process of aseptic component loosening caused by polyethylene wear debris, nine rabbits were implanted with acrylic cement into the non-weight-bearing intercondylar notch of distal femur. Six animals were administrated the particles of polyethylene into the knee joint repeatedly for 12 weeks. At the bone-cement interface, thin connective tissue was observed, while bone sometimes existed directly next to the acrylic cement. The percentage of the length of interposed fibrous tissue against the total length of bone-cement interface was measured. The percentage was 15.8 ± 10.3 in the polyethylene-injected group and 8.3 ± 7.7 in the control group (no significance). While not significant, the amount was greater in the polyethylene-injected group. Thus it is proposed that the polyethylene particles played a role in bone resorption and fibrous tissue formation at the bone–cement interface. In some specimens, macrophages and foreign body giant cells that surrounded the particles near the articular surface were seen to cause resorption of bone. It is supposed that this phenomenon is similar to the focal osteolysis that is sometimes observed around a prosthetic component.

1. Introduction

Aseptic component loosening is the most common cause of late failure of prosthetic joints. At revision surgery, a characteristic membrane is found surrounding the loose component and this membrane is composed of fibrous tissue containing macrophages, foreign body giant cells, polyethylene debris and particulate polymethylmethacrylate. It is postulated that particulate biomaterial debris may play an important role in formation of this loosening membrane. Focusing on the polyethylene debris, the size of the polyethylene debris in failed total hip replacement was reported to be from sub-micrometre to more than 100 μm [1–3]. It is shown that components requiring revision surgery were surrounded by a loosening membrane containing polyethylene debris of very wide range of size distribution, however, the importance of particle size in the initiation of bone resorption and promotion of component loosening has not been defined.

In addition, the histological response of living tissue to polyethylene particles has been investigated [4]. Three different sizes of polyethylene particles (mean size; 15.68 μm, 26.14 μm, and 67.29 μm) were implanted in rabbit tibia without any other biomaterials. The fibrohistiocytic reaction was stimulated by the polyethylene particles, however, the reaction was very similar for the three different sizes.

The reproduction of bone resorption at the bone-cement interface has been experimentally investigated. In the presence of polyethylene wear particles in the rat knee joint after implantation of an acrylic plug into the distal part of the femur, cellular connective tissue was found at the bone–cement interface [5]. In this experiment, the connective tissue was supposed to proliferate in the pre-existing gap between the drilled bone cavity and the pre-formed acrylic plug.

The purpose of this study was to histologically investigate the interference of polyethylene particles at the interface between bone and well-fixed cement. Similar to the standard operative procedure in orthopaedic surgery, acrylic cement was injected into the drilled cavity at the non-weight-bearing part of rabbit femur. To simulate aseptic component loosening due to polyethylene wear debris, polyethylene particles were repeatedly injected into the knee joint.

2. Materials and methods

Nine male Japanese white rabbits, weighing approximately 3 kg, were used. General anesthesia was induced and was maintained by intravenous injection of

0957–4530

sodium pentobarbital (Nembutal®; 25 mg/kg body weight) and intramuscular injection of ketamine (Ketalar®; 5 mg/kg body weight). Both legs were shaved, cleaned and disinfected. Each knee joint was exposed through the medial parapatellar approach. A hole, 3.5 mm in diameter, was drilled at the intercondylar notch of the femur, parallel to the shaft. The cavity was irrigated with sterile saline solution and hematostasis was performed by packing the gauze. Orthopaedic acrylic cement (Surgical Simplex-P®, Howmedica) was injected with pressure into the cavity using a small syringe. Overflowed cement was carefully removed until the surface of the cement was slightly lower than the articular surface. The capsule and the skin were sutured with nylon.

Polyethylene powder of the same type as that used in the manufacture of joint prostheses, was used. The polyethylene particles were less than 150 micrometres in diameter and were irregularly shaped. The particles were dispersed in sodium hyaluronate (Artz®, Kaken Pharmacy Co.) (25 mg polyethylene particles/ml). Sodium hyaluronate is a very viscous solution, thus the particles could be evenly distributed.

For six of the nine animals, the polyethylene particles were injected into both knee joints, 5 mg of particles in each (Fig. 1). Intra-articular injections were performed 2, 4, 6, 8, 10 and 12 weeks after implantation of the acrylic cement. The other three animals received only sodium hyaluronate at the same time and served as the control. All animals were sacrificed 2 weeks after the last injection.

The distal part of the femur was removed, fixed in 10 % buffered formalin, and decalcified. Sagittal sections, parallel to the drilling axis, were cut at the centre of the drilled hole and stained with hematoxylin and eosin. The specimens were microscopically examined and the distribution of fibrous tissue at the bone–cement interface was investigated. To compare

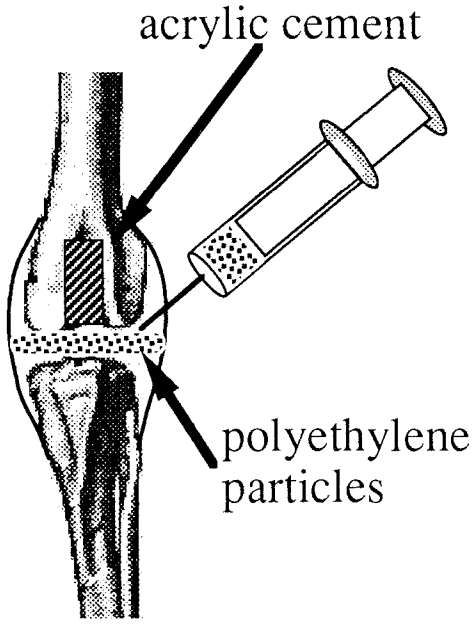
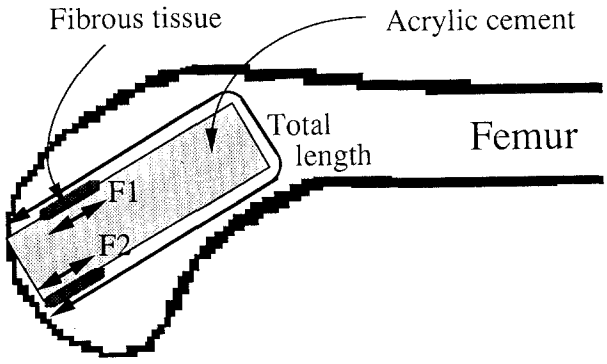


Figure 1 Polyethylene particles injected repeatedly, adjacent to a previously implanted acrylic cement.



$$\% = \frac{F1 + F2 + ...}{\text{Total length}} \times 100$$

Figure 2 Saggital section of femur. Investigating the bone–cement interface microscopically, fibrous tissue partially interposed. Total length of bone–cement interface and length of interposed fibrous tissue (F1, F2, ...) were measured. The percentage of the length of interposed fibrous tissue versus the total length of bone–cement interface was calculated.

the amount of interposed fibrous tissue, the total length of bone–cement interface and that of interposed fibrous tissue were measured using a personal computer (Centris 650, Apple) and microscope arrangement. The percentage of the length of interposed fibrous tissue versus the total length of bone–cement interface was calculated (Fig. 2.)

The statistical analyses were performed using the Mann-Whitney test.

3. Results

There was no knee joint that revealed signs of infections. At the time of sacrifice the synovial membrane was thickened and almost all the polyethylene particles were trapped in the synovial membrane and formed small nodules. Articular cartilage and two cruciate ligaments remained intact. Microscopically, the particles were surrounded by macrophages and foreign body giant cells, and further encapsulated by proliferated fibrous tissue. Synovitis was not severe.

Investigating the bone–cement interface histologically, thin fibrous tissue was observed in some cases, while bone existed directly next to the acrylic cement in other cases (Fig. 3). The percentage of the length of interposed fibrous tissue versus the total length of bone–cement interface was 15.8 ± 10.3 in the polyethylene-injected group ($n = 12$) and 8.3 ± 7.7 in the control group ($n = 6$) (no significance).

In some specimens, the bone near the articular surface was seen to have suffered some resorption, presumably caused by osteoclasts and macrophages induced by the particles (Fig. 4).

4. Discussion

This study was intended to simulate aseptic component loosening caused by polyethylene wear particles. In contrast with the previous report [5], a highly

Figure 3 Photomicrograph of the bone–cement interface. Upper vacant space was occupied by acrylic cement. The bone–cement interface is partially interposed by thin fibrous tissue. (hematoxylin and eosin, × 100).

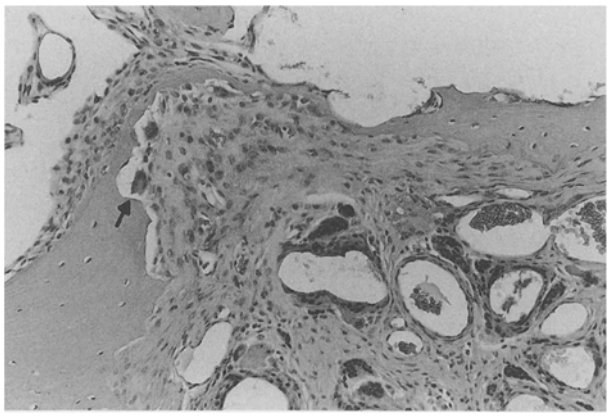


Figure 4 Photomicrograph of the bone–cement interface near the articular surface. Upper vacant space was occupied by acrylic cement. The polyethylene particles are seen in the right bottom corner. Macrophages and foreign body giant cells surround the particles, and bone (left side) suffers from resorption by osteoclasts (arrow) (hematoxylin and eosin, × 200).

cellular layer of connective tissue was not well formed at the bone–cement interface, partially due to the size of the polyethylene particles and partially due to the well implanted acrylic cement which was injected under pressure. The particle size in this study was relatively large compared with that measured in the tissue retrieved from failed implants [1–3].

Although the percentage length of interposed fibrous tissue was not significant, the amount was greater in the polyethylene-injected group. It is thus proposed that the polyethylene particles played a role in bone resorption and fibrous tissue formation. The *in vitro* experiment revealed that polyethylene particles activated bone resorption by increased release of prostaglandin E_2 [6]. In this study, polyethylene particles were observed at the synovial tissue, not at the bone–cement interface, and the particles did not cause severe synovitis. Macrophages and foreign body giant cells surrounding the particles were assumed to release chemical mediators that stimulate osteoclastic activity and cause resorption of bone focally. It is not sure that this bone resorption will extend along the interface and will bring about aseptic loosening, though it is considered that this phenomenon is similar to the focal osteolysis that is sometimes observed around prosthetic components. These results indicated that aseptic component loosening is unlikely to be caused simply by wear particles, while, in addition to the wear particles, bone resorption and fibrous tissue formation would be promoted by the synergistic effect of the pre-existing bone–cement gap or micromovement.

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