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Late foreign-body reaction to PLLA screws used for fixation of acetabular osteotomy

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Abstract A 31-year-old woman underwent rotational acetabular osteotomy for acetabular dysplasia. At surgery, the acetabular fragment and the grafted bone were fixed with PLLA screws. One year 7 months after surgery, the patient returned to our clinic with acute swelling and pain with sinus formation. Based on the diagnosis of an infection, local debridement was performed. Histological examination of the debrided tissue revealed inflammatory cells; however no organism was found growing on the bacterial culture. During subsequent attempts to drain the lesion, we found small PLLA particles.

Thus, we diagnosed the condition as a continued inflammatory process due to foreign-body reaction to the fragmented screw material. After a repeat debridement, the inflammation subsided. At the final follow-up two years after the last procedure, there was no recurrence and the patient had returned to regular activities. This report represents the first case of a severe local reaction to PLLA implants at and around the major joints.

Key words PLLA (poly-L-lactic acid) screws • Rotational acetabular osteotomy • Foreign-body reaction

Introduction

Biodegradable implants have been used for bony fixation on the ground of potential advantages such as gradual transfer of the load back to the bone and negation of the need for subsequent removal [1–3]. However, a troublesome complication of inflammatory foreign-body reaction provoked by the production of degraded material has also been reported [2, 4, 5].

Among the biodegradable materials, poly-L-lactic acid (PLLA) has the longest in vivo degradation time, ranging from two to six years, and is therefore expected to minimize the foreign-body reaction [2, 6–8]. However, there have been a few reports describing the occurrence of foreign-body reaction even with PLLA screws [9, 10]. In these reported cases, PLLA implants were used for small bones at superficial

regions where clearance capacity of the local tissues is limited. To date, there have been no problematic inflammatory reactions reported in the use of PLLA implants at the major joints such as the knee and the hip. In this report, we present the case of a patient who develop a significant foreign-body reaction requiring surgical debridement 19 months after acetabular osteotomy fixed with PLLA screws.

Case report

A 31-year-old woman presented with gradual onset of right hip pain. Physical examination of the right hip joint demonstrated pain on motion. Radiological findings were consistent with early stage osteoarthritis due to acetabular dyspla-

sia (Fig. 1). Despite subsequent conservative treatment, pain persisted and interfered with her daily living activities.

Two months after the initial visit, the patient underwent rotational acetabular osteotomy. At surgery, the



Fig. 1 Preoperative anteroposterior radiograph showing early stage osteoarthritis associated with acetabular dysplasia at the right hip joint

acetabular fragment and the grafted bone were fixed with two 50-mm PLLA screws (Fixorb; Johnson & Johnson Medical, Japan) with outer and core diameters of 4.5 mm and 3.4 mm, respectively (Fig. 2). The postoperative course was uneventful and the operative wound healed well. After two weeks of bed rest, gentle range of motion exercise was started. Weight bearing was allowed at 8 weeks followed by progressive weight bearing at three months. The patient could ambulate without pain at 6 months, and resumed regular daily activities at 10 months.

One year 7 months after the initial surgery, the patient returned to our department with acute swelling and pain at the lateral aspect of the right thigh. A sinus had formed around the center of the lesion, and the abundant turbid discharge was drained. Laboratory examination revealed a leukocyte count of 9 500 cells/mm³, C-reactive protein concentration was 3.5 mg/dL, and the erythrocyte sedimentation rate was 30 mm/h, suggesting an inflammatory process. Magnetic resonance imaging (MRI) showed fluid collection in the subcutaneous layer (Fig. 3). It was thought that these clinical findings and laboratory test results suggested the presence of infection at the surgical site. Based on this presumptive diagnosis, debridement and lavage were performed under spinal anesthesia. Histological examination of

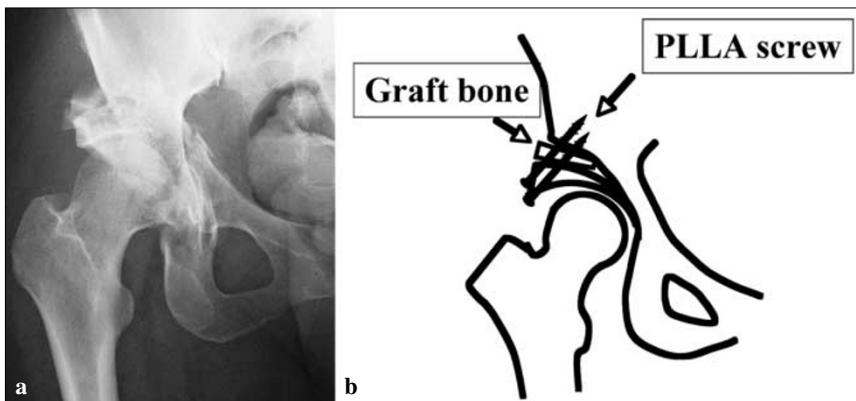


Fig. 2 Postoperative anteroposterior radiograph (a) and schematic drawing showing location of the grafted bone and the PLLA screws (b)

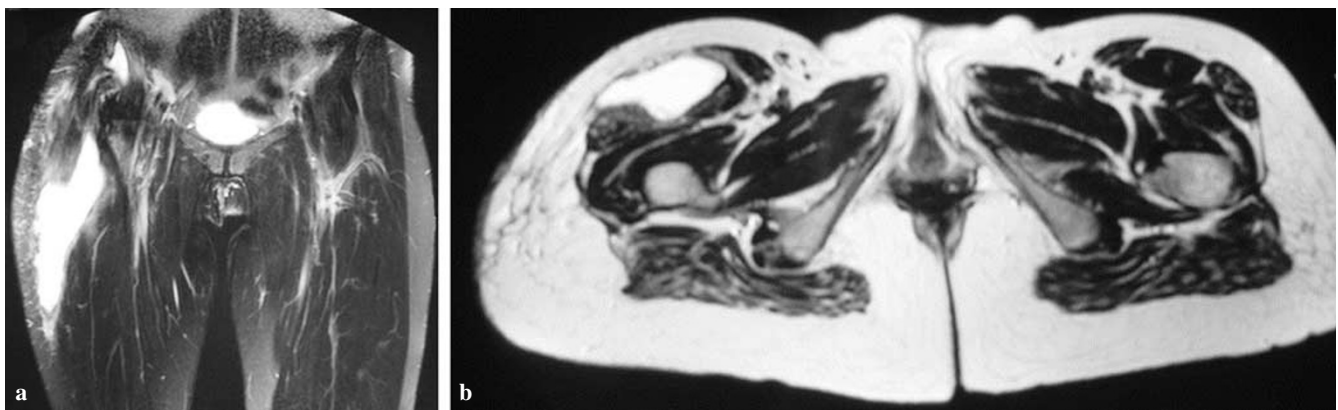


Fig. 3 T2-weighted coronal (a) and axial (b) magnetic resonance images indicating subcutaneous fluid collection

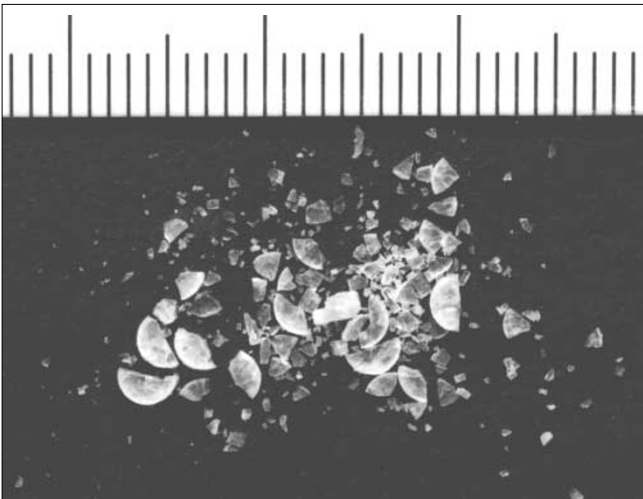


Fig. 4 Pieces of the PLLA screw retrieved 20 months after surgery

the debrided tissue revealed inflammatory cells; however no organism was found growing on the bacterial culture.

Subsequently, the swelling and pain at the femur reduced. However, three weeks after the initial debridement, a local inflammatory response recurred and continued, leading to recurrence of sinus formation. During attempts to drain the lesion under local anesthesia, we found small hard

particles in the drained exudate, which we supposed were fragments of the PLLA screw (Fig. 4). We diagnosed a continued inflammatory process due to foreign-body reaction to the fragmented screw material, requiring a thorough debridement including eradication of the foreign bodies. Thus, a repeat procedure consisting of foreign-body removal and extensive debridement of the pathological tissue was performed under general anesthesia. At surgery, milky-white muddy exudate and granulation tissue were observed to extend from the subcutaneous layer to the screw track through the vastus lateralis muscle. However, PLLA residue could not be identified in the screw socket.

Histological examination of the debrided tissue revealed abundant birefringent polymeric particles under polarized light, surrounded by infiltrated inflammatory cells (Fig. 5a). Moreover, numerous smaller polymeric particles were phagocytosed and located within histiocytes and multinucleated giant cells (Fig. 5b). The fragments were examined using infrared absorption spectrum, and the peak of absorption detected for the particles corresponded to that of PLLA (Fig. 5c).

Postoperatively, the wound healed uneventfully with no recurrence of the inflammatory response. At the final follow-up two years after the last procedure, there was no recurrence and the patient had returned to regular activi-

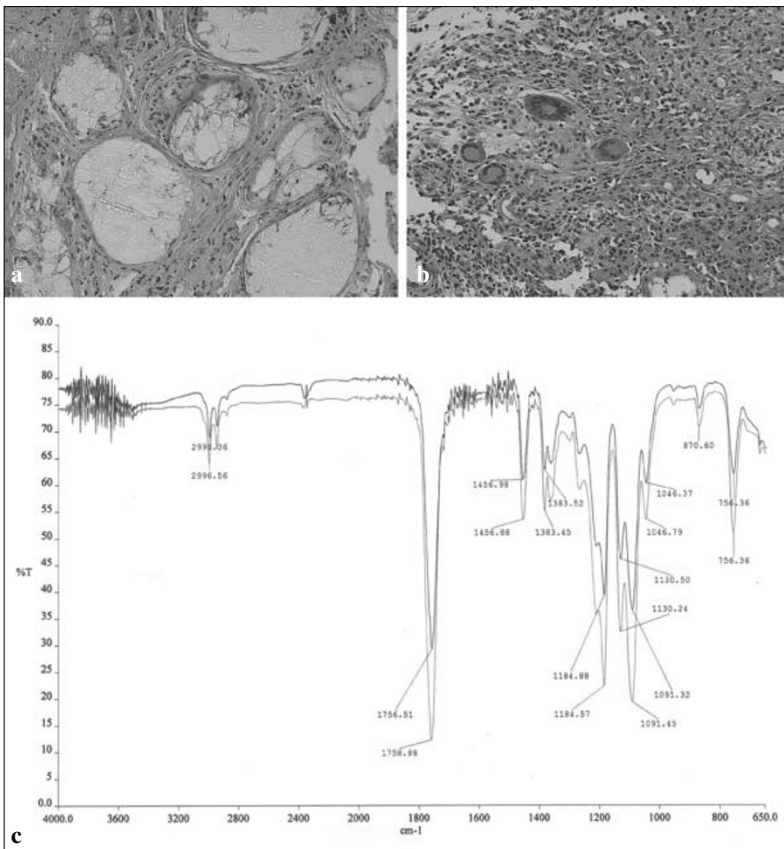




Fig. 6 Anteroposterior radiograph at the final follow-up showing complete bony healing

ties including her job. Additionally, the follow-up radiograph showed complete healing of the grafted bone with no osteolysis or osteoarthritic change (Fig. 6).

Discussion

There are several potential factors influencing the occurrence of foreign body-reaction in the use of biodegradable

implants [2, 4, 5]. First, a material with short degradation time can produce more debris leading to inflammatory reaction. Secondly, regarding the environmental factor, use of implants for small bones at superficial region can be associated with increased accumulation of degraded material causing tissue reaction. This suggests the potential for these reactions may be minimized when materials with slow degradation process such as PLLA and polylactide are used in major joints at a deeper region. Nakamura et al. [11, 12] reported satisfactory results using polylactide screws for fixation of rotational acetabular osteotomy without an associated inflammatory reaction. Although Hasegawa et al. [13] observed an increased incidence of ectopic bone formation in patients who underwent osteotomy fixed with PLLA screws, they observed no apparent reactive inflammation.

In the present case, a significant foreign-body reaction requiring surgical debridement occurred 19 months after acetabular osteotomy fixed with PLLA screws, and histological examination revealed a substantial inflammatory reaction with accumulation of abundant fragments of degrading PLLA screw. Since we initially discounted the possibility of a foreign-body reaction, establishment of diagnosis was delayed resulting in repeated surgeries and prolonged morbidity. Although this report represents only the first case of a severe local reaction to PLLA implants at and around the major joints, surgeons should keep this possible complication in mind when using degradable material regardless of the material and application mode.

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