

Use of HA–PLLA Composite Screws to Fix Acetabular Bone Graft in Cemented THA: Absorption Pattern of Screws in Six Patients

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Abstract. We used a composite of uncalcined and unsintered hydroxyapatite (u-HA) particles and poly-L-lactide (PLLA) to fix the acetabular bone graft in total hip arthroplasty (THA) in a clinical trial in six patients, and followed them for over 10 years. The patients were evaluated clinically and radiologically to assess the safety and efficacy of the screws and the characteristics of their absorption. No patient in this series experienced revision or radiographic loosening during the follow-up period. The configurations of the HA–PLLA composite screws were confirmed on early post-operative radiographs in every case, whereas they appeared obscure on radiographs within 5 years after surgery, and only osteosclerotic traces remained in the screw positions at the final follow-up. Some screw heads were covered with bone within 3 months of surgery, and some screw heads migrated laterally with breakage, but were absorbed in situ within 5 years. The screws seemed to have no negative effect on the mid-term clinical results of the THAs.

Introduction

In our hospital, PLLA screws named Fixsorb (Takiron Co., Ltd.) had been used clinically to fix acetabular bone grafts in THA. However concerns had arisen regarding the mechanical insufficiency of the PLLA screws because an early rehabilitation programme after THA had become the usual practice. Therefore, mechanically stronger and bioabsorbable screws that can increase the initial stability of the grafted bone were developed. HA–PLLA composite screws, which are stiffer than PLLA screws, were produced and used for the fixation of the acetabular bone graft in THA, and underwent a clinical trial from 1996 to 1997 at our institution. The bioactivity of the composite screws could also contribute to the initial stability of the grafted bone and enhance its incorporation. The purpose of this study was to clinically and radiologically evaluate THA in patients who could be followed for over 10 years and to assess the characteristics of the absorption of the HA–PLLA screws.

Materials and Methods

Between August 1996 and November 1997, HA–PLLA composite screws or pins were used in a clinical trial involving 18 patients at our hospital. In six patients, the screws were used to fix an acetabular bone graft, and in the remainder, they were used to fix a fracture site or grafted bone at another site. Thus, this study included six consecutive cemented THAs (six patients), performed by a single surgeon between October 1996 and January 1997 at our hospital. All the patients were followed for over 10 years and reviewed retrospectively. The patients were all women, with an average age of 56.2 years (range, 49–68 years), weight of 52.8 kg (46.0–67.6 kg), and body mass index at the time of surgery of 24.8 kg/m² (21.0–31.7 kg/m²). The original diagnosis was secondary osteoarthritis in all patients. THA was performed with Dall's direct lateral approach. The

conventional polyethylene sockets were used, and all the applied femoral prostheses were cemented stems, which were made of titanium alloy. The modular heads used were 22 mm alumina in all cases. Bone grafting and acetabular component fixation were performed according to the method described by Wolfgang[1]. The grafted bone was fixed with one or two HA–PLLA composite screws (cancellous lag screws, 6.5 mm in bore diameter and 4.0 mm in groove diameter).

The mean follow-up period was 11.3 years (range, 11–11.7 years). Hip function was evaluated using the Japanese Orthopedic Association (JOA) score, which is based on pain (40%), range of movement (20%), ability to walk (20%), and activities of daily living (20%)[2]. The total score is 100 for a normal hip. Standard anterior–posterior (AP) radiographs were taken immediately after the operation, 2, 4, 6, and 8 weeks after the operation, 3, 6, 9, and 12 months after the operation, and every 6 or 12 months thereafter. The radiolucent line around the socket was evaluated in the zones described by DeLee and Charnley[3] and was defined as positive if a radiolucent line > 1 mm was found in any one of the zones.

Results

No patient in this series showed revision or radiographic loosening during the follow-up period. The average JOA score improved from 49.7 (34–60) pre-operatively to 84 (69–97) at 2 years post-operatively, and 82.5 (72–93) at the final follow-up. The configurations of the HA–PLLA composite screws were confirmed on early post-operative radiographs in every patient. However, the screws appeared obscure on radiographs 5 years after surgery, and only osteosclerotic traces remained in the screw positions at the final follow-up. The screw heads began to be covered with bone in two patients within 3 months of surgery, and were completely covered with bone within 3

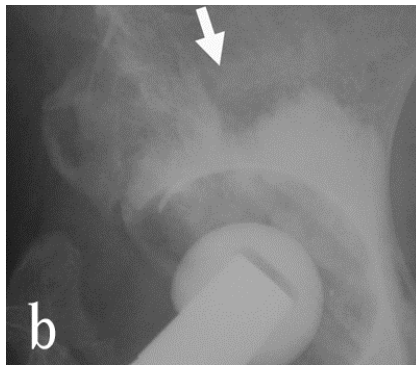
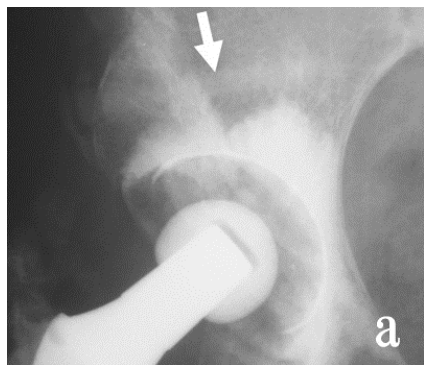


Fig. 1. 68-year-old woman. a: 6 months after surgery; b: 3 years. The screw heads began to be covered with bone within 6 months of surgery. An Arrow indicates the screw.

years of surgery in one of the patients (Figure 1). In one case, the screws had migrated laterally within 1 year and had broken within 3 years of surgery (Figure 2). However, the broken screw seemed to have been absorbed in situ within 5 years, and the remnants had not migrated at the final follow-up. A radiolucent line was detected in only one patient, in whom a line of

over 1 mm appeared 1 year after surgery in zone 1 and expanded gradually thereafter. The radiolucent line remained within zones 1 and 3 at the final follow-up (Figure 3). In this patient, a computed tomography examination was performed 11.7 years after surgery (Figure 4). The coronal image across the hip joint indicated that both of the two implanted screws had been absorbed.

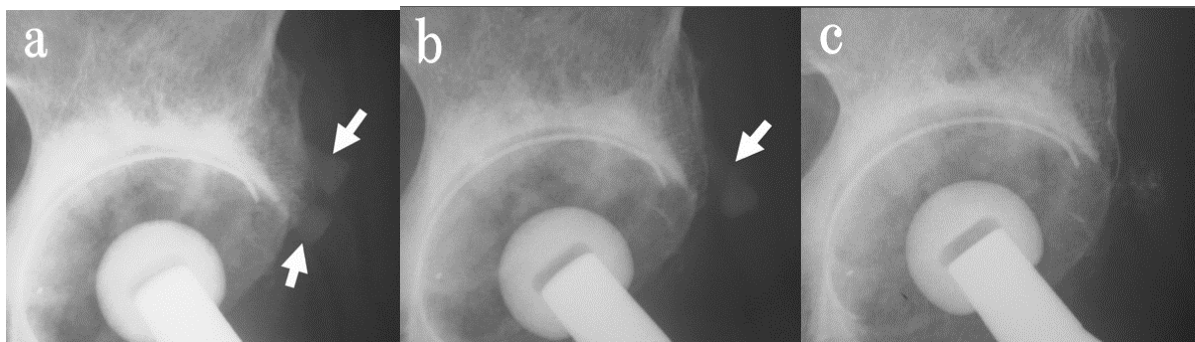


Fig. 2. 56-year-old woman. a: 1 year after surgery; b: 3 years; c: 5 years. The broken screws were absorbed in situ within 5 years of surgery. Arrows indicate the screws.

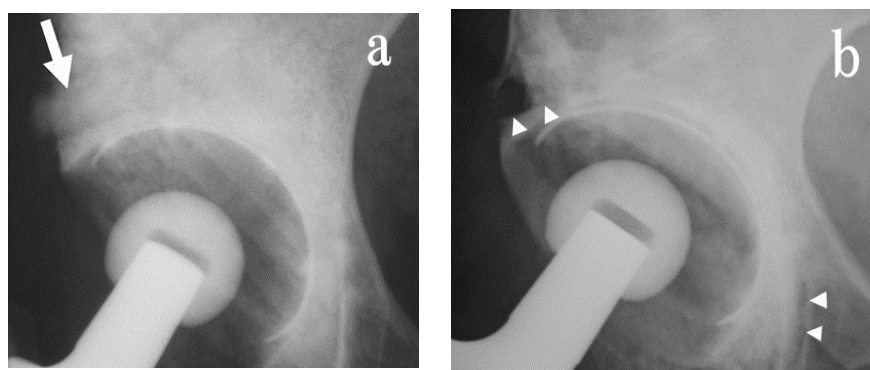


Fig. 3. 51-year-old woman. a: just after surgery; b: 10 years. A radiolucent line (arrowheads) was observed in zone 1 and 3 at 10 years after surgery. An Arrow indicates the screw.

However the screw that had been inserted at a distance from the socket had been replaced by bone, whereas the other screw, which had been inserted just above the socket, had not been replaced by bone, which was reflected in the formation of the radiolucent line in zone 1 in this patient. No other patients showed a radiolucent line during the follow-up period. No aggressive wear or osteolysis was found in any patient during the follow-up period.



Fig. 4. (a, b) 51-year-old woman. Coronal computed tomography images taken 11.7 years after surgery. The arrows indicate the traces of the absorbed screws. (a) The screw was replaced by bone. (b) The screw was not replaced by bone, which was confirmed by its original configuration. (c) 58-year-old woman who was not included in this study. A coronal image taken 3 months after surgery. The image was presented to describe the screw which was not absorbed. Arrowheads indicate the screw.

Table 2. Comparison of the mechanical properties of HA–PLLA composite screws (Superfixsorb) and PLLA screws (Fixsorb) used in a previous study. [4]

Materials	Sb (MPa)	Eb (MPa)	Ts (Nm)	Si (kJ/cm ²)
HA–PLLA composite	269.2±2.5	7.6±0.1	0.65±0.01	166.1±1.9
PLLA	258.5±2.8	6.5±0.3	0.65±0.02	76.3±5.1
Cortical bone	100–200	10–17		

Sb: bending strength; Eb: bending modulus; Ts: torsional strength; Si: impact strength.

Conclusions

We have previously reported excellent long-term results in cemented THA for dysplasia using a structural autograft fixed with PLLA screws[5]. However, these days, the rehabilitation programmes following primary THA have become shorter, and it is usual for gait exercise with full weight bearing to be commenced early. Because of concerns about the mechanical insufficiency of the PLLA screws for THA within an early weight-bearing rehabilitation programme, we started to use mechanically stronger and bioabsorbable screws made of a forged composite of unsintered HA and PLLA. The

differences in the mechanical strengths of PLLA and the HA–PLLA composite are shown in Table 2[4]. The screws used to fix acetabular bone grafts tend to be particularly exposed to bending and shear forces, as well as to impact forces in weight-bearing situations, because the direction of the force on the grafted bone under weight-bearing conditions is almost perpendicular to the axes of the screws. Moreover, the low initial stiffness of the screws could cause instability of the grafted bone, which might contribute to a delay in graft–bone union and the early migration of the socket. Therefore, the higher mechanical strength and greater stiffness of the HA–PLLA composite screw, compared with those of the PLLA screw, may favourably affect graft–bone incorporation and the clinical outcome. Furthermore, the bioactivity of the screws could enhance graft–bone union because graft–bone incorporation can be promoted by bioactive screws. In this study, although no marked change in the duration of graft–bone incorporation was observed compared with that in patients treated with non-bioactive PLLA screws[6], specific radiological changes in the screw positions were observed. Some of the screw heads, confirmed on radiographs, were covered with bony tissues within a year of surgery, which has never been observed in patients treated with non-bioactive PLLA screws[5]. Furthermore, the configurations of the screw heads became invisible within 5 years of surgery in all the patients presented in this study. The bodies of the screws also became obscure within 5 years of surgery, and there remained only osteosclerotic traces in the screw positions at the final follow-up. These results contrast with the results for patients treated with PLLA screws, in whom no osteosclerotic traces were confirmed at the screw positions[5]. These results indicate the bioactivity and bioabsorbability of the HA–PLLA composite screws.

The present study included only six patients in the clinical trial and can therefore only show a trend in the absorption process. The acetabular bone grafts fixed with HA–PLLA composite screws were well bonded to the supero-lateral wall of the acetabulum, and the screws seemed to have no negative effects on the clinical results of THA during the follow-up period. However, further follow-up studies are required to confirm the efficacy of the HA–PLLA composite screws.

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Bioceramics 23

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