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Clinical Results of the Wear Performance of Cross-Linked Polyethylene in Total Hip Arthroplasty

Prospective Randomized Trial

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Abstract: To investigate the clinical results of cross-linked polyethylene (CLPE) and to compare the CLPE wear against zirconia and stainless steel heads, we studied the radiographic wear after a minimum 3-year follow-up in total hip arthroplasty (THA). Ninety-four hips were randomly implanted with a 22.225-mm head cemented THA—the group of non-CLPE against zirconia and CLPE against 2 different zirconias and stainless steel. The linear wear rate was significantly lower in the group of CLPE against zirconia (0.067, 0.059 mm/y) and against stainless steel (0.068 mm/y) compared with non-CLPE against zirconia (0.170 mm/y). In the short-term results, the wear performance of CLPE against zirconia was superior to that of non-CLPE; however, it did not show a better wear rate than CLPE against stainless steel. Furthermore, long-term investigations will be necessary for understanding CLPE wear in vivo. **Keywords:** wear, cross-linked polyethylene, total hip arthroplasty, clinical result, prospective randomized trial.

Long-term results of total hip arthroplasty (THA) have been improving year by year [1-3], but many problems still need to be resolved. Among them, the major problem that influences the long-term results of THA is periprosthetic osteolysis and subsequent loosening of the prosthesis [4-5].

One of the possible causes of aseptic loosening is considered to be induced by an immunologic response [6-8]. Some literature suggests that the more the acetabular polyethylene (PE) liner is worn, the more frequent the occurrence of periprosthetic osteolysis in THA [9-11].

To resolve the excessive wear of PEs, cross-linked polyethylene (CLPE) has been developed, and CLPEs are now produced by several manufacturers. The clinical use of sockets made of CLPE has become widespread in recent years. Some of the CLPEs have shown excellent wear resistance in vitro [12] and in vivo [13]. However, not all CLPEs are equal because they are produced by various methods. For such reasons, the wear performance of CLPE is still unclear.

In this study, we investigated the clinical results of CLPE and compared the wear performance of it against zirconia and stainless steel heads by analyzing radiographic wear after a minimum 3-year follow-up in THA.

Patients and Methods

From November 1999 to December 2001, 94 hips were implanted with a 22.225-mm head, primary, cemented THA in our hospital. The patients were randomly divided into 4 groups using a sealed envelope technique. All the sockets were all PE cemented acetabular components without a modular metal shell. Twenty-six hips in 23 patients (1 male and 22 females) of group A were implanted with conventional non-CLPE sockets against zirconia heads (BC socket and PHS head, Kyocera Corp, Kyoto, Japan) as control. All the other sockets were made of CLPE (Aeonian socket, Kyocera). The other femoral prostheses were divided into the following 3 groups: 25 hips in 17 patients (1 male and 16 females) of group B were implanted with Kyocera zirconia heads (PHS head, Kyocera), 23 hips in 20 patients (all females) of group C were implanted with Kobelco zirconia heads (HHZ head, Kobelco, Kobe Steel Ltd, Kobe, Japan), and 20 hips in

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17 patients (2 males and 15 females) of group D were implanted with stainless steel (Ortron-90) heads (Elite head, DePuy Inc, Warsaw, Ind). The surface finish of the heads are similar (Ra, <0.02 μm; Ry, <0. 2 μm; the data were provided by its manufacturers).

A preoperative diagnosis was as follows. In group A, 21 hips were secondary osteoarthritis as a result of developmental hip dysplasia, 3 hips were rheumatoid arthritis, and 1 hip was idiopathic avascular necrosis of femoral head (ANF) and postseptic arthritis of one hip. In group B, 24 hips were secondary osteoarthritis as a result of developmental hip dysplasia, and 1 hip was steroid-induced ANF. In group C, 22 hips were secondary osteoarthritis as a result of developmental hip dysplasia, and 1 hip was arthrodesis. In group D, 17 hips were secondary osteoarthritis as a result of developmental hip dysplasia, 2 hips were systemic lupus erythematosus, and 1 hip was steroid-induced ANF. The preoperative and postoperative activity level of the patients was classified by using the UCLA activity level index [14].

Among these groups, patients' demographics such as mean age at operation, follow-up period, the body weight before surgery, the preoperative and postoperative activity level index, and socket abduction angles were not statistically different as shown in Table 1.

The conventional BC sockets used were made of non-CLPE. They were made from GUR415, with stearic acid by ram extrusion and sterilized by ethylene oxide gas. Their average molecular weight was 7.3×10^6. The CLPE, Aeonian socket was made from GUR1050 without the use of stearic acid by compression molding. Their average molecular weight is 7.3×10^6. Cross-linking was accomplished by annealing the material at 110°C after irradiation (3.5 Mrad). These sockets were sterilized by γ irradiation (2.5 Mrad) in nitrogen.

All operations were performed by using a direct lateral approach with a trochanteric osteotomy (Dall's approach) [15]. In dysplastic hips, the femoral head was used for the graft [16]. The grafts were screwed to the superolateral aspect of the acetabular roof with poly-L-lactic acid (PLLA) screws (Fixsorb, Takiron Co Ltd, Osaka, Japan). The acetabular sockets were fixed with vacuum-mixed bone cement (Endurance, DePuy), and the femoral stems were also inserted with bone cement and a cement gun, the so-called third-generation technique [17].

Radiologic Analysis of PE Wear

Polyethylene wear was measured radiologically by determining the penetration of the center of the head relative to the center of the acetabular socket, based on the computer-aided technique described by Sychterz et al [18] and modified by Tanaka et al [19]. The analytical methods used in this study, including the digitization of radiographs and the use of software, are the same as those previously reported and verified by retrieved specimens [19].

Table 1. Patients' Demographics

Group	Acetabular Socket (Manufacturer)	Inner Head (Manufacturer)	Femoral Stem (Manufacturer)	n	Age at Operation, y (±SD)	Follow-Up years, y (±SD)	Body Weight, kg (±SD)	Activity Level Index (Preoperative/Postoperative) (Points ± SD)	Socket Abduction Angle, Degrees (±SD)
A	BC socket, non-CLPE (Kyocera Corp)	PHS head, zirconia (Kyocera Corp)	KC stem (Kyocera Corp)	26	60.0 ± 9.4	4.04 ± 0.99	52.3 ± 6.2	3.6 ± 0.9/5.2 ± 0.8	44.3 ± 4.6
B	Aeonian socket, CLPE (Kyocera Corp)	PHS head, zirconia (Kyocera Corp)	KC stem (Kyocera Corp)	25	61.6 ± 7.9	3.80 ± 0.68	50.7 ± 6.7	3.6 ± 0.7/5.2 ± 0.9	43.5 ± 4.7
C	Aeonian socket, CLPE (Kyocera Corp)	HHZ head, zirconia (Kobelco, Kobe Steel Ltd)	K-max stem (Kobelco, Kobe Steel Ltd)	23	62.7 ± 9.6	3.73 ± 0.54	51.0 ± 9.4	3.7 ± 0.6/5.3 ± 0.7	43.7 ± 3.9
D	Aeonian socket, CLPE (Kyocera Corp)	Elite head, stainless-steel (DePuy Inc)	C stem (DePuy Inc)	20	60.9 ± 7.9	4.07 ± 0.43	54.7 ± 12.6	3.7 ± 0.8/5.2 ± 0.9	44.0 ± 4.7
	P				.76	.27	.34	.86/.94	.94

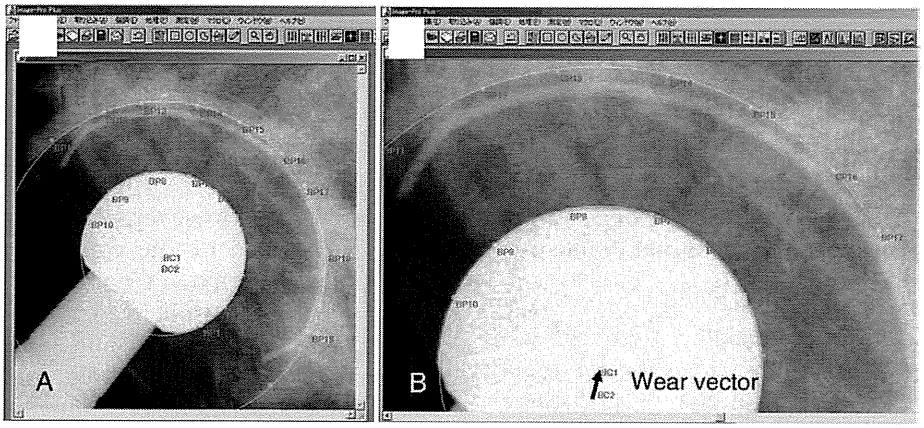

Fig. 1. Radiologic measurements of PE wear. (A) After 10 points around the periphery of the head and the cement-PE interface of the acetabular socket had been identified. (B) The image analysis software provided best-fit circles and their centers. By comparing the coordinates of the centers, the amount and the direction of penetration of the head into the acetabular PE was measured (black arrow).

For each patient, the initial postoperative and most recent radiographs of the pelvis in the weight-bearing positions were selected. First, these radiographs were digitized by using an image scanner (GT-9500, Seiko Epson Corp, Nagano, Japan). After 10 points around the periphery of the head and the cement-PE interface of the acetabular socket had been identified, the image analysis software (Image-Pro Plus version 4.0, Media Cybernetics Inc, Silver Spring, Md) provided the best-fit circles and their centers. By comparing the coordinates of the centers on the initial postoperative and the most recent radiographs, the amount and the direction of penetration of the head into the acetabular PE [20] was measured after the correction of magnification and pelvic tilting, as shown in Fig. 1. Volumetric wear was calculated by using the equation described by Hashimoto et al [21], as shown in Equation 1.

Equation 1. Hashimoto's equation of radiologic PE wear.

$$\text{Volumetric wear} = \frac{r^2 h}{2}(\pi + 2\beta + \sin 2\beta),$$

where r indicates radius of the head; h, linear wear; and β, direction of wear.

Reliability of Measurements

To validate this measurement, the author (KI) measured the PE wear in blind fashion. For 10 randomly selected cases, the measurements were repeated 3 times with 1-week intervals to assess the intraobserver repeatability.

Statistical Analysis

The differences between the groups were compared with analysis of variance, followed by Fisher post hoc test. Statistical significance was set at $P < .05$.

Results

Reliability of Measurements

The intraobserver repeatability coefficients ranged from 0.990 to 0.998 in the measurement of PE wear. The mean error in measurement of PE wear was 0.081 ± 0.062 mm.

Radiologic Analysis of PE Wear

The linear wear rate was significantly lower in the CLPE Aeonian sockets of group B (CLPE sockets against Kyocera zirconia heads, 0.067 ± 0.044 mm/y), group C (CLPE sockets against Kobelco zirconia heads, 0.059 ± 0.027 mm/y), and group D (CLPE sockets against stainless steel heads, 0.068 ± 0.039 mm/y) compared with group A (non-CLPE sockets against Kyocera zirconia heads, 0.170 ± 0.098 mm/y). The volumetric wear rate was also significantly lower in the CLPE Aeonian sockets of

Table 2. Results of Polyethylene Wear

Group	Acetabular Socket (Manufacturer)	Inner Head (Manufacturer)	n	Linear Wear Rate, mm/y (±SD)	Volumetric Wear Rate, mm^3/y (±SD)	Direction of Wear, Degrees (±SD)
A	BC socket, non-CLPE (Kyocera Corp)	PHS head, zirconia (Kyocera Corp)	26	0.170 ± 0.098	49.19 ± 29.09	−7.80 ± 34.90
B	Aeonian socket, CLPE (Kyocera Corp)	PHS head, zirconia (Kyocera Corp)	25	0.067 ± 0.044	19.82 ± 13.10	−7.61 ± 41.90
C	Aeonian socket, CLPE (Kyocera Corp)	HHZ head, zirconia (Kobelco, Kobe Steel Ltd)	23	0.059 ± 0.027	17.23 ± 7.79	−5.44 ± 35.91
D	Aeonian socket, CLPE (Kyocera Corp)	Elite head, stainless steel (DePuy Inc)	20	0.068 ± 0.039	20.00 ± 11.70	−8.26 ± 40.40
	P			<.0001	<.0001	.99

group B (19.82 ± 13.10 mm^3/y), group C (17.23 ± 7.79 mm^3/y), and group D (20.00 ± 11.70 mm^3/y) compared with group A (49.19 ± 29.09 mm^3/y), as shown in Table 1. The direction of wear was not statistically different as follows: −7.80° ± 34.90° in group A, −7.61° ± 41.90° in group B, −5.44° ± 35.91° in group C, and −8.26° ± 40.40° in group D. The material property of the head did not significantly affect wear on the CLPE socket (Table 2).

Discussion

Several CLPE sockets are available from different manufacturers. Some of the CLPEs have shown excellent wear resistance in vitro [12] and in vivo [13]. However, Digas et al [22] showed by 3-dimensional study at 0 to 3 years that the wear resistance of CLPE did not differ from conventional PE in the weight-bearing positions. The results of CLPE sockets, especially in vivo, still seem to be controversial.

The aim of the new PEs is to reduce wear, and this appears to have been achieved by minimizing free radicals. These CLPEs were produced by various methods of irradiation, sterilization, and thermal treatments [23]. The mechanical behaviors of CLPEs are influenced by the choice of PE and the methods for cross-linking. The Aeonian socket is made by compression molding GUR1050, without the use of stearic acid. Their average molecular weight is 7.3×10^6. Cross-linking is accomplished by annealing the material at 110°C after irradiation (3.5 Mrad). It is sterilized by γ irradiation (2.5 Mrad) in nitrogen. However, sterilization with 2.5 Mrad is not analogous to the highly CLPEs in the 5.0 to 10 Mrad range currently being produced by many implant companies.

Our short-term results show that the wear performance of Aeonian sockets against zirconia heads is superior to that of conventional non-CLPE sockets against zirconia heads.

Furthermore, it is unclear whether the material property of the femoral head affects the wear on CLPE sockets. According to the review article by Clarke et al [24], clinical results of zirconia heads have varied. Sakoda et al [25] reported that the wear of CLPE increased dramatically against a scratched counter surface in vitro. To clarify this problem, 2 kinds of zirconia head made by different manufacturers and 1 stainless-steel head were used in this study. The wear of these Aeonian sockets against the zirconia and stainless steel heads showed similar results. Ceramic heads were shown as excellent material for the bearing surface against PE sockets by an in vitro hip simulator wear test [26]. The reasons for such excellent results were considered to be the wettability [27] and the tribological properties [26,28]. Nevertheless, Aeonian sockets did not have a better wear rate against zirconia heads than against stainless steel heads. We speculate that the material properties of these head materials may be inconsequential for the Aeonian sockets because the surface finish of the heads is similar at the time of implantation.

These results included the so-called initial bedding-in period. Digas et al [22] reported that the penetration rate decelerated in the CLPE socket from 6 months after surgery. We therefore expect even better results in the following years. However, the wear rate of CLPE was clearly influenced by the counter surfaces [25]. Some reports have shown that regarding the phase transformation of retrieved zirconia head, the monoclinic phase was more dominantly observed, and it had a relationship with surface roughness in longer follow-up specimens [29,30]. Furthermore, the thermal conductivity of zirconia ceramics is relatively lower than that of other ceramics, especially alumina [31]. These facts suggest a possibility of accelerated phase transformation and subsequent enhanced surface roughness of zirconia head in vivo.

Moreover, Scott et al [32] reported that the size of the particulate debris of CLPE was smaller than that of conventional non-CLPE, and Green [33] reported that smaller particles induce the more active immunologic response to macrophages, which leads to osteolysis. For such reasons, it is clear that more time needs to transpire before the long-term results will be clear. These studies indicate that further long-term investigations will be necessary for understanding CLPE wear in vivo.

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Case Report

Computed Tomography-Based Navigation to Determine the Femoral Neck Osteotomy and Location of the Acetabular Socket of an Arthrodesed Hip

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Abstract: In the conversion of an arthrodesed hip to a total hip arthroplasty, the osteotomy of the femoral neck and the placement of the acetabular socket are difficult procedures as anatomical abnormalities hamper identification of the femoral neck and of the original center of the acetabulum. A 59-year-old woman who had a hip arthrodesis for dysplastic osteoarthritis at 21 years of age underwent total hip arthroplasty for relief of back pain, achievement of good gait function, and improvement of activities of daily living. In this report, we introduce a technical solution, using a computed tomography-based navigation system to determine the site and direction of the femoral neck osteotomy and the positioning of the acetabular socket. **Keywords:** computed tomography–based navigation system, total hip arthroplasty, hip arthrodesis.

Hip arthrodesis is performed in young adult patients with severe osteoarthritis, local infection, and trauma to the hip joint [1]. However, a long-term hip arthrodesis profoundly impairs patients' gait and activities of daily living. In addition, patients may have increased risk for pain in the low back, ipsilateral knee, and contralateral hip [2]. These patients then require a takedown of the arthrodesed hip and conversion to total hip arthroplasty (THA), procedures that include many difficulties, such as identification of the femoral neck and the original center of the acetabulum. To overcome these difficulties, we used a computed tomography (CT)-based navigation system to determine the site and direction of the femoral neck osteotomy and to place the acetabular socket in the correct location.

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Case Report

A 59-year-old woman with an arthrodesed left hip complained of severe low back pain and restriction of her gait and activities of daily living. She underwent arthrodesis of the left hip joint for dysplastic osteoarthritis with severe pain and gait disturbance at 21 years of age. The left hip joint was fused in the arthrodesis position of 20° of flexion, 5° of adduction, 10° of external rotation, and a leg length discrepancy of 1.7 cm (Fig. 1A). Radiographs and computed tomograms showed fusion of the acetabulum with the femoral head, the superior part of the acetabulum with the greater trochanter, and the inferior rim of the acetabulum with the lesser trochanter, and it was difficult to distinguish the border of the pelvis from the femur (Fig. 1B, C, and D). To relieve her low back pain and restore the function of the hip joint, a left THA was planned. After scanning the patient's pelvis and femur, preoperative planning and virtual implantation were performed using a CT-based navigation system software (Vector Vision Hip ver 2.5.1, Brain Lab, Munich, Germany), and the site and direction of the femoral neck osteotomy (Fig. 2A-D), the center of the original acetabulum, and the position of the acetabular socket (Fig. 2E and F) were determined. In planning, we paid attention to retaining greater trochanter as large as possible and to keeping sufficient posterosuperior bone stock in the acetabulum. During the operation, the patient

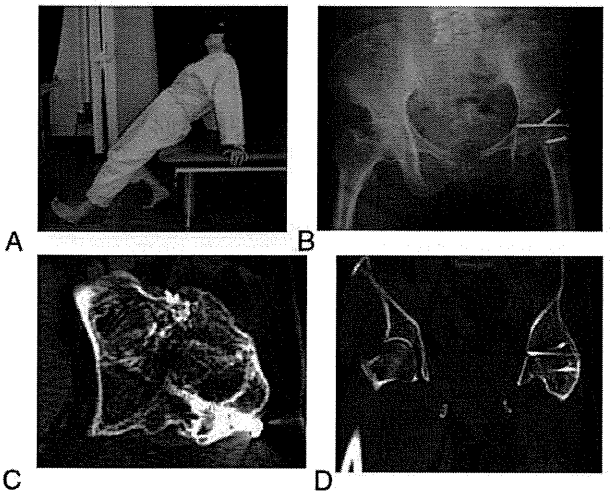

Fig. 1. (A) A preoperative picture of the 59-year-old woman. She could not sit on a chair. (B) A preoperative radiograph and computed tomograms (C, axial section, and D, coronal section) are shown.

was placed in a lateral decubitus position. The left hip joint was exposed using an anterolateral approach. Anterior part of the intertrochanteric region was exposed and then femoral neck osteotomy was performed with oscillation saw in accordance with the preoperative plan using 3 screw heads on the greater trochanter as landmarks. After the entire margin of the acetabular rim was exposed, acetabular reaming was performed in the true acetabulum in accordance with the preoperative plan with the remaining transverse acetabular ligament and the inferior margin of the acetabulum as landmarks. The acetabular socket and the femoral component (PHS type6 straight, JMM Ltd, Osaka, Japan) were implanted with bone cement. The postoperative radiographs and the computed tomograms showed that the femoral neck osteotomy and the location of the acetabular socket corresponded to those in the preoperative plan; the leg length discrepancy was also improved (Fig. 3B, C, and D). Four months after operation, the patient can sit on a chair (Fig. 3A) and walk using a crutch.

Discussion

Hip arthrodesis is a valuable technique in younger patients with an isolated severe arthritic hip condition. However, long-term hip arthrodeses cause back and

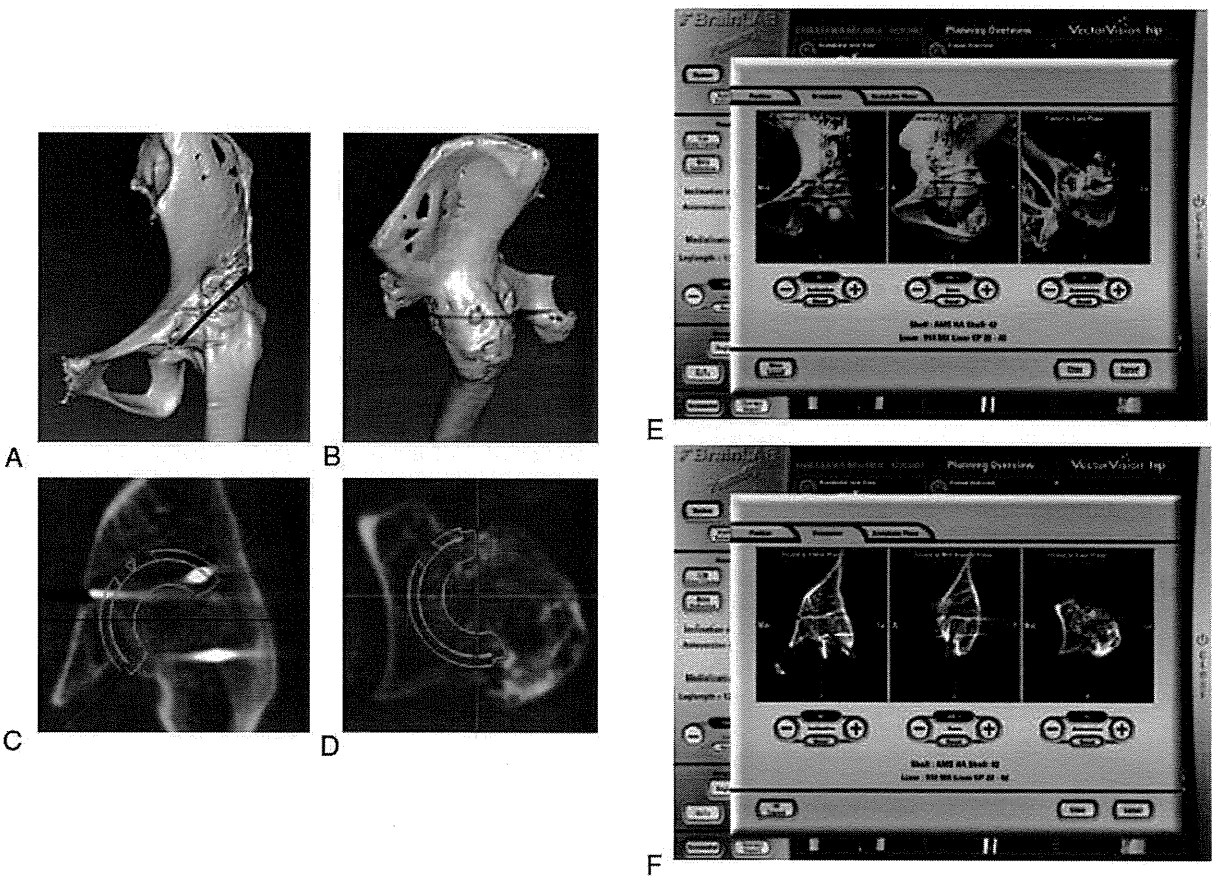

Fig. 2. (A-D) Preoperative planning for the femoral neck osteotomy and (E and F) positioning of the socket during THA using the CT-based navigation system. The putative osteotomy (black plane) is indicated on the 3-dimensional anteroposterior (A) and lateral (B) views. The osteotomy line (purple line) is also shown on the 2-dimensional coronal (C) and horizontal (D) cross-sectional views. (E) Three-dimensional views in the coronal to pelvis plane, the frontal to midsagittal plane, and the frontal to base plane with the targeted socket shaded. (F) The 2-dimensional acetabular coronal, sagittal, and inlet section views are shown with the targeted socket shaded.

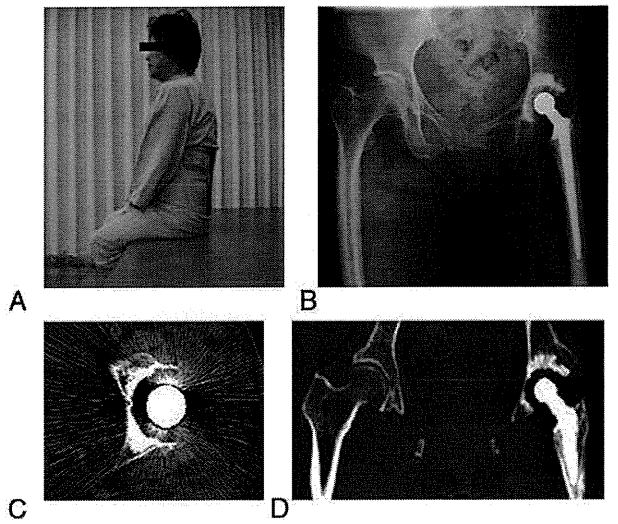

Fig. 3. (A) Postoperative picture of the patient sitting on a chair. (B) A postoperative radiograph and computed tomograms (C, axial section, and D, coronal section) are shown.

ipsilateral knee pain. In addition, activities of daily living and gait are markedly limited. Conversion of hip arthrodesis to THA can restore the functions in the arthrodesed hip joint and relieve pain in other joints. However, the procedure of conversion of hip arthrodesis to THA is technically challenging and has a high risk of postoperative complication and a high failure rate, mainly because of anatomical abnormalities of the fused hip joint [3]. Therefore, precise planning of the procedures based on preoperative evaluation of the position of the arthrodesis as well as review of radiographs is required.

In the conversion of an arthrodesed hip to THA, careful preoperative planning is required to refine operative techniques [3], in particular, precise femoral neck osteotomy, acetabular preparation, and adjustment of leg length. In addition, during the operation, intraoperative x-rays to determine the position of the femoral neck and the acetabulum are needed in most cases, as controlling the orientation of the pelvis and the femoral neck is very difficult. A CT-based navigation system for THA has recently offered a useful method for surgeons to plan and simulate an operation and to perform operative procedures accurately, and it is to be hoped to reduce the incidences of intraoperative and postoperative complications [4-7]. In our case, preoperative CT data of the patient's pelvis and femur were acquired to produce a 3-dimensional model using a CT-based navigation system, and virtual femoral neck osteotomy and implantation of the acetabular socket were done preoperatively. In planning, we focused on preservation of the greater trochanter as large as possible to allow restoration of the abductor mechanism of the hip joint. Furthermore, after the virtual femoral neck osteotomy, retention of sufficient posterosuperior bone stock for adequate containment of the acetabular socket is required. In addition, we estimated the original hip center and the placement of the acetabular socket after the virtual femoral osteotomy.

During the operation, it is quite difficult to visualize the neck-pelvis junction because of the lack of mobility of the arthrodesed hip joint and the coverage of the femoral neck by muscles. In addition, in our case, fusion of the acetabulum with the greater and lesser trochanters prevented us from distinguishing the border between the pelvis and the femur. It is also difficult to determine the original hip center and the acetabular edges with the acetabulum filled with a fused femoral head after a femoral neck osteotomy. To overcome these problems, we referred to 2-dimensional and 3-dimensional preoperative planning views of the pelvis and the femur using a CT-based computer navigation system during the femoral neck osteotomy procedures, reaming of the acetabulum, and placement of the acetabular socket. In our case, we succeeded in performing the femoral neck osteotomy and preparation of the acetabulum without CT-based computer navigation guidance during the operation. There had been 3 screws inserted from the proximal femur to achieve the arthrodesis in this patient, and these screw heads provided good landmarks for the femoral neck osteotomy, as based on the preoperative planning using the CT-based computer navigation system. Moreover, after separation of the acetabular rim from the greater and lesser trochanters, we directly visualized the entire acetabulum, in correspondence with the preoperative planning views. However, intraoperative guidance using a CT-based computer navigation system should be also helpful to monitor the position of the femoral osteotomy and the acetabular socket in most cases. Indeed, although the postoperative position of the acetabular socket is good in our case, the difference between the preoperatively determined inclination and anteversion of the socket with the postoperatively measured position was 3° and 10°, respectively, and the hip center is located 2 mm medially.

The CT-based computer navigation system used here is a powerful tool for preoperative planning and simulation of the femoral neck osteotomy and placement of the acetabular socket in conversion of an arthrodesed hip to a THA.

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Long-Term Results of Cemented Total Hip Arthroplasty for Dysplasia, With Structural Autograft Fixed With Poly-L-Lactic Acid Screws

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Abstract: This study reviewed a series of cemented total hip arthroplasty (THA) for dysplasia, with structural autograft fixed with poly-L-lactic acid screws. Grafted bone union was confirmed radiologically in every case, and there were no cases of early collapse or extravasation of grafted bone. Kaplan-Meier survivorship analysis of socket revision, radiologic loosening of the socket, and the appearance of a radiolucent line greater than 1 mm in the graft-socket interface as the end points indicated survival rates of 99%, 97.1%, and 63.5% at 10 years and 96.6%, 90.2%, and 56.1% at 15 years, respectively. The results of this study indicated that poly-L-lactic acid screws are safe and useful for the fixation of acetabular bone graft concomitant to cemented THA with a careful rehabilitation program. **Keywords:** THA, acetabular bone graft, PLLA, survivorship analysis, radiolucent line.

Poly-L-lactic acid (PLLA) is characterized by its biocompatibility and biodegradability and is used clinically [1,2]. A clinical study from our institution reported on the use of osteosynthetic screws, pins, and nails made of PLLA in the fixation of grafted bone, fractured fragments, or osteotomized bone in 143 patients who were followed up for 2 to 6 years [3]. Bone union was achieved in all but one case, and no abnormal hematologic examination, infection, or foreign body reaction occurred. In another clinical study, PLLA screws were used in the fixation of acetabular fragments in rotational acetabular osteotomies, and their clinical results were similar to those associated with fixation by Kirschner wires (K-wires), although ectopic bone formation occurred more often in patients treated with PLLA screws [4]. In our hospital, we started to use PLLA screws instead of metallic or ceramic screws in the fixation of acetabular bone grafts in total hip arthroplasty (THA) in 1990 because there were concerns about the use of rigid and non-bioabsorbable screws, which might contribute to the absorption of the grafted bone and induce metallosis or third-body wear when breakage of the screws occurs. The purpose of this study was to review a series of cemented THA with acetabular bone graft fixed with PLLA screws. We focused on the survival rate of the acetabular component and radiologic change of the grafted bone-socket interface.

Materials and Methods

Between July 1990 and December 1995, 257 consecutive cemented primary THAs were performed by several senior surgeons at our hospital, and acetabular bone grafting was performed in 167 cases (65.0%), and PLLA screws were used for graft fixation in 118 cases (94 patients, 70.7%). Of these 94 patients, 10 were lost to follow-up and 4 died. Therefore, this study included 104 cases (80 patients). All patients were followed for 10 years and reviewed retrospectively. The patients comprised 6 men and 74 women, whose average age was 55.0 years (range, 29-76 years), weight was 51.8 kg (35.0-76.5 kg), and body mass index (BMI) at the time of surgery was 22.8 kg/m^2 (16.1-36.1 kg/m^2). The original diagnosis was osteoarthritis secondary to hip dysplasia in all patients. The degree of subluxation was categorized according to the classification of Crowe et al [5], and this series included 47 hips (45.2%) in group 1, 30 hips

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(28.8%) in group 2, 13 hips (12.5%) in group 3, and 14 hips (13.5%) in group 4. Total hip arthroplasty was performed through Charnley transtrochanteric approach (24 cases) or Dall's direct lateral approach (80 cases). The applied conventional polyethylene sockets included physio-hip-system PHS (Japan Medical Materials [JMM], Osaka, Japan) in 103 cases and a Charnley Long Posterior Wall cup (DePuy, Blackpool, UK) in 1 case. The outer diameter varied from 42 to 50 mm. The applied cemented femoral prostheses were PHS type 6 (6 cases), KC (97 cases), and PHS type 7 (1 case) (JMM), all of which were made of titanium alloy. The applied modular heads (JMM) were 22-mm alumina in 95 cases and 26-mm alumina in 9 cases.

Bone grafting and acetabular component fixation were performed according to the method described by Wolfgang [6] as follows. First, the inferomedial portion of the dysplastic acetabulum (true acetabulum) was reamed according to the preoperative planning. After confirming the size and configuration of the superolateral acetabular defect formulated above the presumed socket position, a crescent-shaped graft was trimmed from the excised femoral head and fixed transiently with 2 K-wires to the defect portion. The grafted bone was then fixed rigidly with 1 or 2 PLLA screws (cancellous lag screws 6.5 mm in bore diameter and 4.1 mm in grove diameter) (Fixsorb; Takiron Co, Ltd, Osaka, Japan). The flanged socket was then fixed with polymethyl methacrylate bone cement.

Postoperative gait exercise started according to the center-edge (CE) angle as described by Sugano et al [7], which represents the angle formed by the vertical line from the inner head's center and the linear line connecting the inner head's center and the medial edge of the grafted bone. In detail, gait exercise with one-third partial weight bearing started 2 to 6 weeks after surgery if the CE angle was plus, that is, the vertical line from the inner head's center situated medially to the medial edge of the grafted bone. On the other hand, if the CE angle was minus, gait exercise with one-third partial weight bearing started 6 to 12 weeks after surgery. There was variation about the time point when the partial weight bearing gait exercise started because of the patients' conditions, and there was a tendency that weight bearing gait exercise started earlier in the late cases.

The mean follow-up period was 12.7 years (range, 10-16.3 years). Hip function was evaluated using the Japanese Orthopaedic Association (JOA) score, which is based on pain (40%), range of movement (20%), ability to walk (20%), and activities of daily living (20%) [8]. The total score is 100 for a normal hip. A paired *t* test was used to compare preoperative and final follow-up JOA scores.

Standard anterior-posterior 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 standard anterior-posterior radiographs confirmed whether the traces of the radiolucent screws were visible. The resorption of the grafted bone was defined as positive if the resorption expanded, and the lateral border of the grafted bone shifted medially beyond the vertical line from the lateral edge of the socket, because such a resorption pattern is never observed in the normal remodeling process of the grafted bone. The grafted bone was categorized into 3 groups according to the radiolucency of the grafted bone in the x-ray photograph just after the operation compared with that of the adjacent iliac bone positioned superiorly to the socket. The groups were higher radiolucency group (group H) (19 cases, 18.3%), isoradiolucency group (group I) (67 cases, 64.4%), and lower radiolucency group (group L) (18 cases, 17.3%). Cases with an obscure difference in the radiolucency were categorized into group I. The radiolucent line around the socket was evaluated in the zones described by DeLee and Charnley [9] and was defined as positive if a radiolucent line greater than 1 mm was found in a part of the zones. Radiographic loosening was assessed according to the criteria of Hodgkinson et al [10] and was confirmed as type 3 (complete demarcation) or type 4 (socket migration).

Kaplan-Meier analysis was used to evaluate the time to socket loosening and socket revision and the appearance of a radiolucent line greater than 1 mm in zone 1, which corresponded to the graft-socket interface. The log-rank test was used to test the relationships between possible risk factors and socket loosening, socket revision, or radiolucent line–free survival. The possible risk factors included sex, surgical approach, head diameter, radiolucency of the grafted bone, Crowe classification, age at surgery, BMI, body weight, socket diameter, socket inclination angle, and the CE angle [7]. In log-rank tests for the last 6 variables, the cases were divided into 2 groups based on the average value of each variable. All statistical analyses were carried out using JMP IN (version 5.1.2; SAS Institute Inc, Cary, NC) and SAS software version 9.1 (SAS Institute Inc). Two-sided *P* values of less than .05 were considered significant.

Results

The mean JOA score improved from 45.3 before the operation to 83.2 at the final follow-up. Revision surgery was performed in 4 cases. The reasons for revision were socket loosening in 2 cases and stem loosening in 2 cases. For the former 2 cases (both in group H), one socket revision was performed with the stem retained and one with the stem exchanged using the cement-in-cement technique [11] 8 and 13 years after the primary THA, respectively. For the latter 2 cases, one stem revision was performed in another hospital 12 years after the primary THA and one was performed in our hospital 17 years after the primary THA. When the stem revision was performed in our hospital, the supralateral portion of the socket

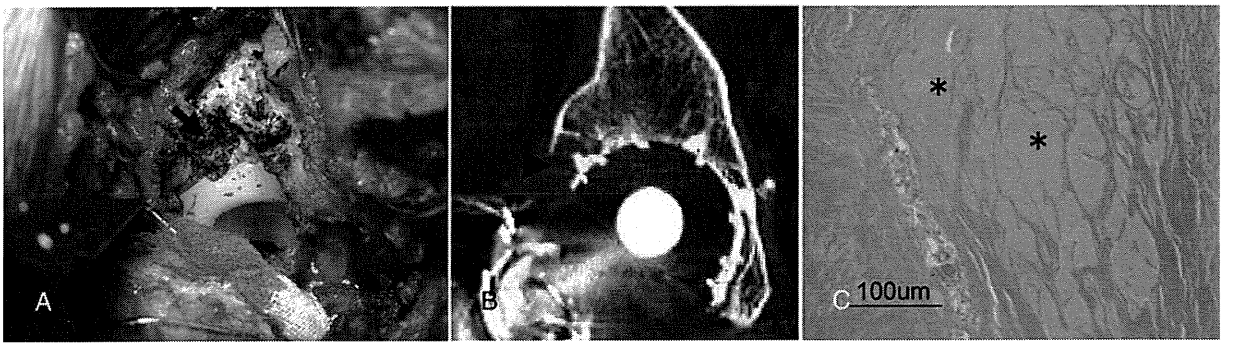

Fig. 1. (A) Photograph showing the surgical exposure of the grafted site just above the acetabular component 17 years after primary THA. (B) Preoperative computed tomography image of the coronal section. (C) Hematoxylin-eosin staining of the curetted soft tissue in the cave where the PLLA screw existed. Arrow, a cave on the grafted bone. Arrowhead, bone defect corresponding to the cave found in the revision surgery. Asterisk, amorphous eosinophilic fibrous tissue.

was exposed and the surface of the bone was inspected carefully. We found soft tissue in a hole (5 mm in depth) in the bony surface, which was curetted and examined histologically, and the inner part of the hole was found to be filled with bony tissue (Fig. 1A). This finding corresponded to that of the preoperative computed tomography examination, which showed that no remnant of the PLLA screws could be found except the hole (Fig. 1B). Histologic examination revealed that the specimen included amorphous eosinophilic fibrous tissue with bone fragments, and the infiltration of inflammatory cells could not be confirmed (Fig. 1C).

Kaplan-Meier survivorship analysis with socket revision for any reason as the end point gave survival rates of 99% (95% confidence interval [CI], 93.4%-99.9%) at 10 years and 96.6% (95% CI, 85.6%-99.2%) at 15 years (Fig. 2A).

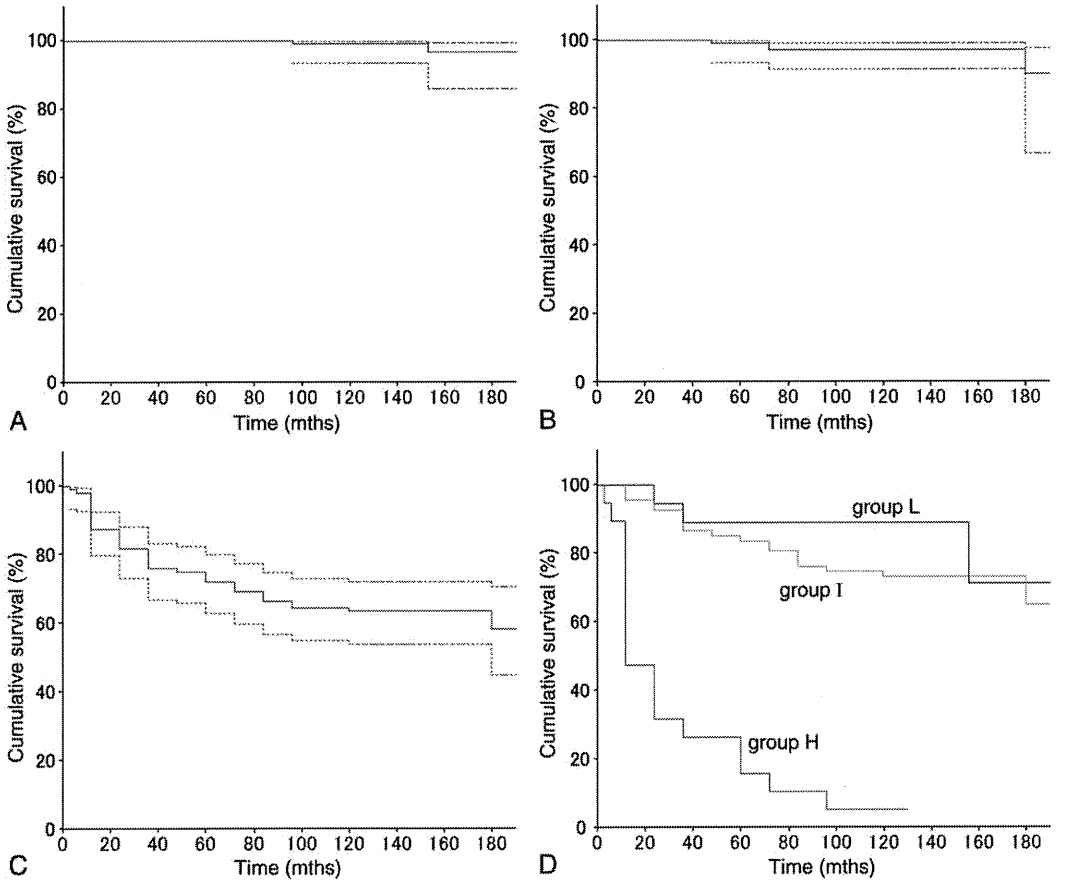

Fig. 2. Kaplan-Meier analysis with socket revision (A), radiologic loosening of the socket (B), and the appearance of a radiolucent line greater than 1 mm in zone 1 (C) as the end points. Comparison of radiologic survival without the appearance of a radiolucent line greater than 1 mm in zone 1 groups H, I, and L (D). The dotted lines indicate the 95% CIs.

Table 1. Variables Examined as Possible Factors Using Log-Rank Tests

Variable	*P*		
	Socket revision	Socket loosening	Zone 1 radiolucent line >1 mm
Sex	.71	.20	.67
Surgical approach	.30	.076 †	.13 †
Head size	.54	.19	.076 ‡
Age at surgery *	.79	.51	.56
BMI *	.23	.92	.74
Body weight *	.15	.24	.69
Socket diameter *	.21	.46	.13 §
Socket inclination angle *	.89	.22	.92
CE angle *	.13 ‖	.28	.89
RL of grafted bone	.019 ¶	.19	<.0001 #
Crowe classification	.80	.75	.84

RL, radiolucent line.

* For log-rank tests, cases were divided into 2 groups based on the average for each variable.

† Survival rates were higher using Charnley transtrochanteric approach than Dall's approach.

‡ Survival rate was higher with a 26-mm head than with a 22-mm head.

§ Survival rate was higher with larger diameter sockets than with small diameter sockets.

‖ Survival rate was higher with larger CE angles than with smaller CE angles.

¶ Group H vs group I, $P = .012$; group H vs group L, $P = .21$.

\# Group H vs groups I and L, $P < .0001$; group I vs group L, $P = .34$.

The log-rank test indicated that the socket revision–free survival rate of group H was significantly lower than that of group I ($P = .012$) or of group L ($P = .21$; Table 1). It also indicated that the socket revision-free survival rate was higher with larger CE angles than with smaller CE angles, although the difference was not significant ($P = .13$ Table 1).

Radiologic Analysis

X-ray photographs taken just after the primary operation showed an obscure but still visible radiolucent region corresponding to the inserted PLLA screws in many cases. However, x-ray photographs at the final follow-up showed an unclear radiolucent zone at the sites of the PLLA screws, and the osteosclerotic line surrounding the site where the radiolucent zone had been found was confirmed in only 4 cases (Fig. 3). Bone union was confirmed radiologically at the grafted site in every case, and there were no cases of early collapse or extravasation of the grafted bone. No positive resorption of the grafted bone was observed in any case. Ectopic bone formation was observed in 5 cases (4.8%) (grade 2 in 3 cases, grade 3 in 2 cases), but this did not affect their clinical results at the final follow-up. Socket loosening occurred in 4 cases (2 in group H and 2 in group I). Kaplan-Meier analysis with socket loosening as the end point indicated survival rates of 97.1% (95% CI, 91.3%-99.1%) at 10 years and 90.2% (95% CI, 64.6%-97.6%) at 15 years (Fig. 2B). The log-rank test indicated that the socket-loosening–free survival rates did not differ significantly between groups H, I, and L (Table 1). It also indicated that the socket-loosening–free survival rates were higher when Charnley transtrochanteric approach was used than when Dall's approach was used, but the difference was not significant ($P = .076$; Table 1).

A radiolucent line greater than 1 mm in zone 1, in which the graft bone-cement interface was situated, appeared in 40 cases during the follow-up period. These included 18 cases in group H (94.7%), 19 cases in group I (28.4%), and 3 cases in group L (16.7%). An apparent osteolysis in zone 1 was found in 5 cases in group H (26.3%), 4 cases in group I (6.0%), and none in group L. Kaplan-Meier analysis with the appearance of a radiolucent line greater than 1 mm in zone 1 as the end point indicated survival rates of 63.5% (95% CI, 53.4%-71.9%) at 10 years and 56.1% (95% CI, 41.9%-68.1%) at 15 years (Fig. 2C). A comparison of the radiolucent line–free survival in groups H, I, and L is shown in Fig. 2D. The log-rank test indicated a significant difference between groups H and L and between groups H and I ($P < .0001$) (Table 1). It also indicated that the radiolucent line–free survival rates were higher using Charnley transtrochanteric approach than Dall's approach ($P = .13$), with a 26-mm head than with a 22-mm head ($P = .076$), and with larger rather than smaller diameter sockets ($P = .13$) (Table 1).

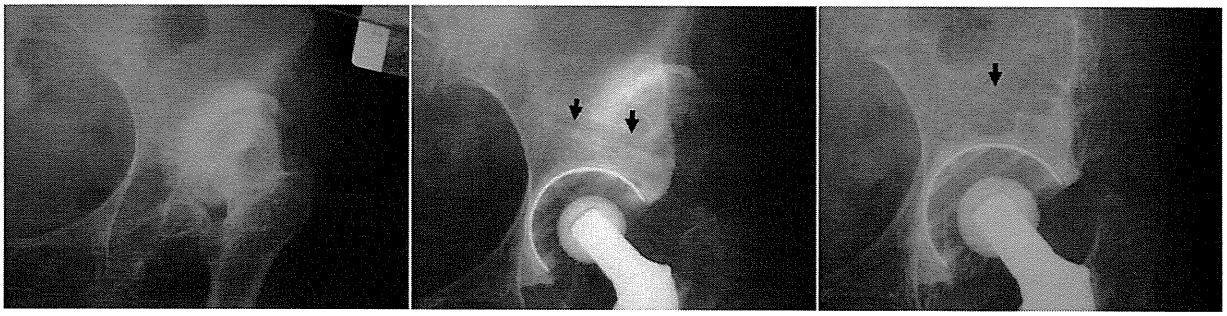

Fig. 3. Radiographs of a woman with osteoarthritis secondary to dysplasia who had primary THA at the age of 62 years. The grafted bone in this case belonged to group L. Anteroposterior radiographs just before surgery (left), just after surgery (center), and 12 years after surgery (right). Arrows indicate the sites of the PLLA screws.

Discussion

The PLLA screws used in this study were manufactured as follows. Poly-L-lactic acid with a molecular weight of 400 000 was melted, extruded, and drawn uniaxially to obtain a rod, which was then machined to the shape of a screw [12]. The initial bending strength was 240 MPa [13]. This drawn PLLA has uniform structure and is not subject to longitudinal breakage. The initial mechanical strength decreases by 10% in 8 weeks, 40% in 12 weeks, and almost 100% in 20 weeks [13]. In animal experiments, PLLA rods implanted into the medullary cavity of the rabbit femur showed no inflammatory or foreign body reaction for 52 weeks and maintained a bending strength exceeding that of human cortical bone for 8 weeks [14]. In our series, no early collapse or extravasation of grafted bone occurred, indicating that the mechanical properties of the PLLA screws were sufficient for the acetabular bone graft. However, postoperative gait exercise started slowly in these patients compared with recent rehabilitation programs for patients with THA [15]. Because of concern about the mechanical insufficiency of the PLLA screws for THA with an early weight-bearing rehabilitation program, we have used mechanically stronger and bioabsorbable screws made of forged composites of hydroxyapatite and PLLA since 2003 [16].

Although a long-term in vivo implantation study found that PLLA screws showed no signs of inflammatory foreign body reactions during the 3- to 5-year follow-up period [17], there is concern about the inflammatory reaction to biodegradable PLLA implants used especially in the joint [18]. Such tissue reactions may cause late aseptic swelling and osteolysis [19]. In our series, osteolysis occurred in zone 1 in 9 cases where PLLA screws might have been involved. However, there were no continuous abnormal findings indicating that inflammatory reactions were induced by the PLLA screws, such as pain, tenderness, local heat, redness, or swelling around the screws, and there was no radiologic evidence of progressive osteolysis proceeding along the PLLA screws. Radiologic examination indicated that the PLLA screws were replaced by bone tissue to some extent, a finding that was supported by the retrieved case in which histologic examination could be performed with stem revision.

In this series, the clinical results of the cemented THA with acetabular bone graft fixed with PLLA screws were satisfactory. The screws had no adverse effect on the long-term results because bone union was obtained at the grafted site in every case, and the survival rate of THA in this series was good compared with other studies [20-22]. However, no prospective randomized study was performed with the same operative procedure using other fixation devices, and we cannot identify the use of PLLA screws as the main reason for the good clinical results.

The radiolucency of grafted bone had a significant influence on the socket revision and zone 1 radiolucent line greater than 1 mm. Total hip arthroplasty with bone graft in the higher radiolucency group had a higher rate of socket revision and the appearance of zone 1 radiolucent line greater than 1 mm. Because the digital image processing of x-ray examination influenced the radiolucency of the grafted bone, we determined the radiolucency of the grafted bone relative to that of the adjacent iliac bone. In addition, several factors presumably affected the radiolucency, such as the anteroposterior width of grafted bone, bone mineral density, and cyst formation, which is often observed in the deformed femoral head concomitant with secondary osteoarthritis. Our results indicate that such bone grafts are desirable if they have sufficient anteroposterior width and greater mineral density and include few cysts.

Many reports have focused on the clinical results of THA with acetabular bone grafting [6,22], although there are no reports in English on the clinical and radiologic results of THA using a bioabsorbable device for bone grafting. We have reported on the long-term results of cemented THA with acetabular bone grafting in 133 hips, using mainly alumina-ceramic screws for the graft fixation [22]. The survival rate of the acetabular component with radiologic loosening as the end point was 75% at 15 years, which was inferior to that of the present study. The difference in clinical results cannot be ascribed only to the difference of the fixation device because several factors, such as the surgeons, implants, and surgical approaches, also differed. However, alumina-ceramic and metallic screws used in the previous study had some demerits. First, they are not bioabsorbable, and absorption of the grafted bone may occur because of the disturbance of stress distribution by the rigid screws. Absorption of the grafted bone or osteolysis around the ceramic screws was observed often in our previous series [13]. Second, metallic or ceramic screws may induce aggressive osteolysis via metallosis or third-body wear when the breakage of the screws occurs subsequent to socket loosening. On the other hand, the PLLA screws used in the current study were absorbed and lost their mechanical strength completely within 20 weeks after implantation [13]. These results suggest that there would be no concern about the disturbance of stress distribution and third-body wear associated with the PLLA screws and that there is no need to remove the screws when socket revision is required. Although mechanically stronger and bioabsorbable composite screws have been used recently in our institution, as mentioned above, our series demonstrates that PLLA screws are safe and useful for the fixation of grafted bone concomitant with THA. Further retrieval studies should be performed to confirm the biodegradability and biocompatibility of PLLA screws.

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ORIGINAL ARTICLE

Subaxial subluxation after atlantoaxial transarticular screw fixation in rheumatoid patients

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Abstract The most common cervical abnormality associated with rheumatoid arthritis (RA) is atlantoaxial subluxation, and atlantoaxial transarticular screw fixation has proved to be one of the most reliable, stable fixation techniques for treating atlantoaxial subluxation. Following C1–C2 fixation, however, subaxial subluxation reportedly can bring about neurological deterioration and require secondary operative interventions. Rheumatoid patients appear to have a higher risk, but there has been no systematic comparison between rheumatoid and non-rheumatoid patients. Contributing radiological factors to the subluxation have also not been evaluated. The objective of this study was to evaluate subaxial subluxation after atlantoaxial transarticular screw fixation in patients with and without RA and to find contributing factors. Forty-three patients who submitted to atlantoaxial transarticular screw fixation without any concomitant operation were followed up for more than 1 year. Subaxial subluxation and related radiological factors were evaluated by functional X-ray measurements. Statistical analyses showed that aggravations of subluxation of 2.5 mm or greater were more likely to occur in RA patients than in non-RA patients over an average of 4.2 years of follow-up, and postoperative subluxation occurred in the anterior direction in the upper cervical spine. X-ray evaluations revealed that such patients had a significantly smaller postoperative C2–C7 angle, and that the postoperative AA angle correlated negatively with this. Furthermore, anterior subluxation aggravation was significantly correlated with the perioperative atlantoaxial and C2–C7 angle changes, and these two changes were strongly correlated to each other. In conclusion, after atlantoaxial transarticular screw fixation, rheumatoid patients have a greater risk of developing subaxial subluxations. The increase of the atlantoaxial angel at the operation can lead to a decrease in the C2–C7 angle, followed by anterior subluxation of the upper cervical spine and possibly neurological deterioration.

Keywords Atlantoaxial transarticular screw fixation · Atlantoaxial subluxation · Subaxial subluxation · Rheumatoid arthritis · Operative complications

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Introduction

Rheumatoid arthritis (RA) infamously presents joint inflammation, bone and cartilage destruction and ligament laxity, all of which lead to joint instability. The cervical spine is one of the most frequently affected and the most severely damaged part in RA patients [20]. The resulting neurological impairment can lead to even a shortened life expectancy [14]. The most common cervical abnormality associated with RA is atlantoaxial subluxation, representing two-thirds of rheumatoid cervical subluxations [4], and if evidence of spinal cord compromise exists at the atlantoaxial level on MRI, neurological deterioration requiring surgical intervention is more likely to happen than with subaxial lesions [9]. Therefore, serious consideration should be paid to the treatment of such instabilities, and an operative intervention is frequently inevitable.

Atlantoaxial transarticular screw fixation, first introduced by Magerl and Seemann [13], has proved to be one of the most reliable, stable fixation techniques for treating

atlantoaxial subluxation [7, 16]. However, this operation has its own risks, notably one of which is an intraoperative injury to the vertebral artery [17, 18]. Another early complication could be non-union of either the atlantoaxial facets or the posterior bone graft, if combined, and we recently reported that this complication largely depends on the RA status of the patient and the material used for the posterior bone graft fixation [10].

On the other hand, late complications of atlantoaxial transarticular screw fixation have not been fully reported so far. Yoshimoto et al. [23] previously showed that hyperlordotic fixation of C1–C2 would eventually lead to the development of subaxial kyphosis. This was supplemented by a report that constant inclination of C1 and anterior shift of C2 are also associated with subaxial sagittal alignment changes after C1–C2 transarticular screw fixation [15]. While Kraus et al. [12] reported that subaxial subluxation requiring surgery did not develop in patients after C1–C2 fusion compared with those after occipitocervical fusion, there have been a few reports dealing with subaxial cervical spine instability following C1–C2 arthrodesis. Agarwal et al. [1] reported that 3 of 55 patients who had required C1–C2 fusion developed subaxial subluxation and had a second procedure after a mean interval of 9 years. Clarke et al. [3] also showed that 39% of their patients with atlantoaxial subluxation developed non-symptomatic or symptomatic/unstable subaxial subluxations after C1–C2 fusion. Furthermore, while the rigidity of any fixation can presumably affect biomechanical environment on the other levels that can lead to subluxations, only Mukai et al. [15] have reported subaxial subluxation after atlantoaxial transarticular screw fixation. They showed that neurological deterioration recurred in four patients because of the postoperative development of subaxial subluxation but with no details of those patients. So far, how the subaxial subluxastion progresses and what factors contribute to the development after C1–C2 fusions have not fully been analyzed, and, moreover, whether RA status affects the incidence rate remains to be proved.

In this study, we evaluated subaxial subluxation after atlantoaxial articular fixation in a consecutive series of patients who had RA as well as non-RA backgrounds, aiming to find radiological factors that might contribute to the subluxations.

Materials and methods

All of RA patients included in this study fulfilled the revised criteria of American College of Rheumatology [2]. From September 1994 to February 2006, a consecutive series of RA and non-RA patients who had atlantoaxial subluxation and intractable pain or progressive neurological involvement were evaluated medically and radiologically. Of these, 11 patients (7 RA, 4 non-RA) underwent the occipitocervical fixation and 1 (non-RA) did the atlantoaxial fixation combined with subaxial fixation because of, at least, one of the following reasons; substantial vertical and/or subaxial subluxation, irreducible atlantaxial subluxation or osseous fusion between the occiput and the altas. An RA patient received the atlantoaxial fixation only with posterior wiring and strut autograft. In the remaining patients, 56 underwent elective atlantoaxial transarticular screw fixation with a posterior strut autograft, and 12 patients (6 RA, 6 non-RA) went back to their local hospitals or were lost to follow-up within 1 year after the operation. One patient underwent concomitant cervical laminoplasty and was excluded from this study. The remaining 43 patients (33 RA, 10 non-RA) were closely followed up for more than 1 year by functional lateral X-rays and were included in this study. The mean follow-up period was 4.2 years (range 1–11 years and 8 months).

All operations were performed under fluoroscopic guidance. For transarticular screw fixation, the Reunion bone screw system (Surgical Dynamics Inc., Norwalk, CT) or the Universal cannulated screw system (SofamorDanek, Memphis, TN) was used. All types of screw had a diameter of 4 mm. In case of substantial destructive atlantoaxial instability, the Olerud cervical system with an atlas claw was used (NordOpedic AB, Uppsala, Sweden) in two cases. A unicortical iliac bone strut was fixed on C1–C2 supported with morselized bone chips, mostly according to Gallie [6] using a metal wire or cable, or a polyethylene cable (Secure Strand; Surgical Dynamics Inc.). In cases when we used an atlas claw to fix the C1–C2 arches, only bone chips were grafted. The detail of the overall surgical techniques has been described elsewhere [17, 19].

All patients were asked to wear hard or soft collars for 3 months and were closely followed up by clinical examinations and functional X-rays that were performed 3 and 6 months after the operation and every 6 months thereafter. We did not observe any intraoperative complication directly related to the initial atlantoaxial transarticular screw fixation in any of the 43 cases. However, two patients developed substantial subaxial subluxation after certain periods of time (5 years and 1 month, and 6 years and 5 months, respectively) and submitted to an operative correction because of neurological deterioration (Fig. 1). In these cases, the last X-ray dates before the reoperation were defined as the latest follow-up. Two patients developed non-fused C1–C2 with only slight motion between them and were included in this study [10]. Neutral lateral radiographs were taken with the patients standing or sitting in their natural posture before and 3 months after the operation and at the latest follow-up. Flexion-extension radiographs were taken by asking each patient to achieve his or her maximum

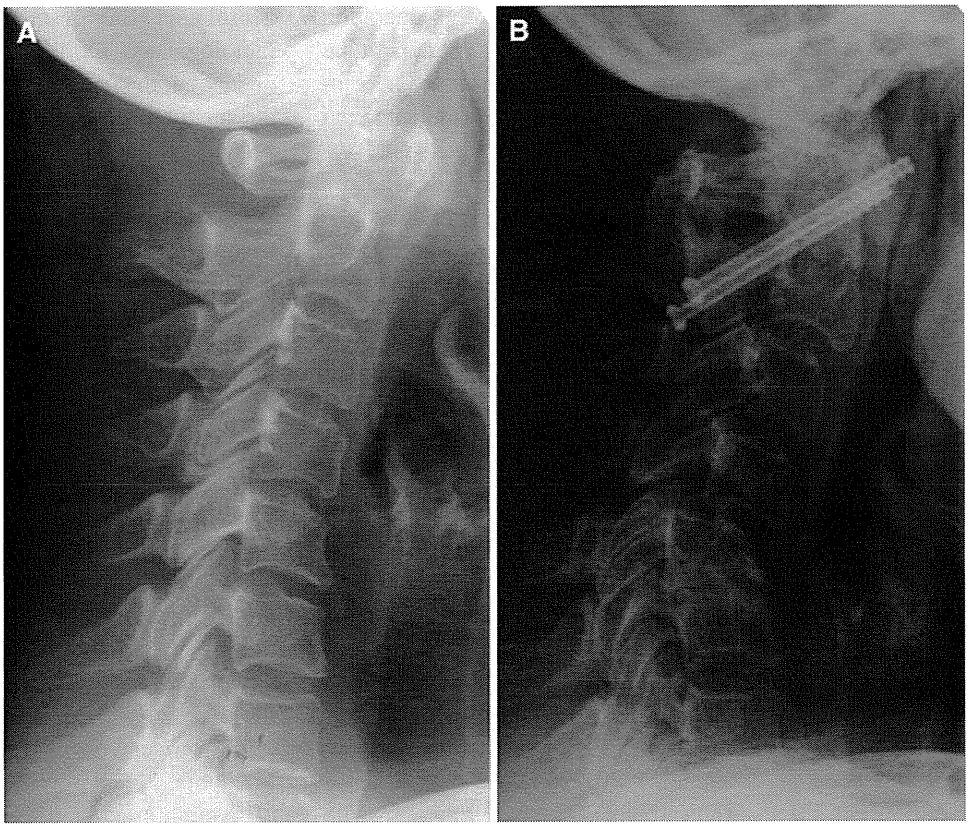

Fig. 1 **a** A 64-year-old RA woman who had severe anterior atlantoaxial subluxation underwent the atlantoaxial transarticular screw fixation. **b** She developed a substantial anterior subluxation in C4–C5 with severe neurological deterioration 6 years and 5 months after the operation

effort at flexion and extension at the same time. All of the patients' records and the radiographs were blindly evaluated and measured by the author (H. I.) who was not the responsible operator in this series of operations. The atlantoaxial angle (AA angle) was defined as the angle between an extended line connecting the centres of the anterior and the posterior arches of the atlas (C1) and an extended line connecting the inferior endplate of the axis (C2). The C2–C7 angle was defined as the angle subtended by the lines of the inferior endplate of C2 and the superior endplate of C7 [21]. A vertebral subluxation was measured on the upright lateral radiographs as the anteroposterior distance from the posteroinferior corner of the upper vertebra to the posterosuperior corner of the inferior vertebra on the superior endplate line of the inferior vertebra [21]. A distance of more than 1 mm was recorded and evaluated later. A distance of 2.5 mm or greater was defined as a subluxation, and a change of 2.5 mm or greater between the preoperative and the follow-up distances was defined as an aggravation of a subluxation. Anterior and posterior atlantodental intervals (AADI and PADI, respectively) were also measured. The intraobserver reliability was calculated from three independent measurements and was less than 0.2 mm in distance and 1° or less in angle, respectively. Two patients who had unsuccessful C1–C2 fusion were excluded in the postoperative AA angle measurement. Two patients preoperatively had substantial posterior subluxations whose levels were non-operatively fused at follow-up and were classified as no subluxation, even though it could have meant an anterior correction of the subluxation.

To examine the effect of RA status on the subaxial subluxation rate, we divided the patients into two groups: RA (33 patients) and non-RA (10 patients). We then subdivided them into groups with an anterior, posterior, anteroposterior (a combination of anterior and posterior subluxations), or no subluxation. The non-RA group consisted of four patients with os odontoideum, five with degenerative spondylosis, and one with odointoid fracture. Data are expressed as the mean ± SD. Ratios between groups were evaluated by Fisher's exact probability or by a 2×2 χ^2 test. Any difference in the means between two groups was assessed using Mann–Whitney non-parametric U test. Correlation and regression analysis was performed using Spearman's correlation approach. Significance was set at $P < 0.05$.

Results

The follow-up periods of the RA and non-RA groups were 4.2 ± 2.4 and 3.7 ± 2.1 years, respectively, which does not yield a statistical difference. First, pre- and postoperative subaxial subluxations were compared between the

RA and non-RA groups. Preoperative subluxations were more frequent in the RA group, but the difference was not significant. However, after the operation, the difference became statistically significant (Table 1). Any aggravation of the subluxation was then assessed. It was more likely to happen in RA patients than non-RA patients (Table 2). Substantial subluxation aggravation (3 mm or more) was more likely to happen in the RA (8/33 patients, 9/165 levels) than in the non-RA group (0/10, 0/45), but smaller subluxations between 2 to 2.4 mm occurred similarly in the RA (12/33 patients, 9/165 levels) and in the non-RA group (2/9, 2/45), indicating that RA patients had a greater risk of developing substantial subaxial subluxation after this operation than non-RA patients.

Next, the direction and level of the subluxation was assessed in RA patients. The preoperative subluxation was dominantly in the posterior direction (7/33 patients, 21.2%: 9/165 levels) rather than in the anterior direction (1/33 patients, 3.0%: 1/165 levels, $P = 0.023$ and 0.010, respectively, Fig. 2a). In contrast, the postoperative subluxation rates were similar between posterior and anterior subluxation directions (13 patients in the anterior vs. 11 in the posterior direction: 15 levels in the anterior vs. 13 in the posterior direction: Fig. 2a). Thus, the aggravation of the subluxation was more likely to happen in the anterior direction (11/33 patients) than in the posterior (4/33, $P = 0.040$). Evaluation of the subluxation level revealed that an increase of the anterior subluxation was more likely to happen in the upper cervical lesions ($P = 0.024$; Fig. 2b). Taken together, postoperative subluxation was more likely to occur in the anterior direction in the upper cervical spine after atlantoaxial transarticular fixation in RA patients.

To find any associated factors leading to the subluxation aggravation, preoperative AADI and PADI, and pre- and postoperative AA and C2–C7 angles were evaluated in RA patients. Table 3 shows that the incidence of anterior subluxation aggravation did not have any significant correlation with any of the preoperative AADI, PADI values or with AA, or C2–C7 angle. However, these cases did have significantly smaller postoperative C2–C7 angle and showed a tendency to have a bigger postoperative AA angle. The postoperative AA angle negatively correlated with the postoperative C2–C7 angles (Fig. 3a), although those measured preoperatively did not (data not shown). More importantly, the anterior subluxation aggravation cases had significantly bigger AA and smaller C2–C7 angle changes, respectively (Fig. 4). These two changes strongly correlated with each other (Fig. 3b), indicating that an increase in the AA angle led to a decrease in the C2–C7 angle, probably followed by subaxial subluxation. Indeed, in those patients who had an anterior subaxial subluxation aggravation, the C2–C7 angle significantly decreased in the immediate postoperative period (3 months after operation) without any aggravation of the subluxation but did not significantly change after that time even with the occurrence of the aggravation (Fig. 5). Thus, 67.9% of the total incidence of a decreased C2–C7 angle occurred during the first 3 months after the operation. On the contrary, no correlation was found between the postoperative AA and C2–C7 angles in non-RA group (data not shown).

Table 1 Comparison of the pre- and postoperative subaxial subluxation (slip) between RA and non-RA patients

	n	Preop.		Postop.	
		Slip	Rate (%)	Slip	Rate (%)
RA	33	8	24.2	19	57.6*
Non-RA	10	1	10.0	1	10.0

* $P < 0.05$

Table 2 Comparison of the slip aggravation rate in terms of patient numbers and levels, between RA and non-RA patients

	Patient			Level		
	n	Slip aggravation	Rate (%)	*n*	Slip aggravation	Rate (%)
RA	33	13	39.4*	165	15	9.1*
Non-RA	10	0	0	50	0	0

* $P < 0.05$

Discussion

Atlantoaxial transarticular screw fixation combined with posterior bone graft has established itself as a reliable surgical management for atlantoaxial subluxation [5, 7, 8] with a few serious problems, including intraoperative vascular impairments [17, 18] and non-union of bone grafts between C1 and C2 spinous processes and/or non-fused C1–C2 facets [10]. However, only a few of the late complications have been reported, one of which is subaxial sagittal alignment change [11, 15, 23]. We have encountered several patients with serious subaxial subluxations, two of whom presented with progressive neurological deterioration and required operative interventions. From this retrospective study, we found that RA patients have a greater risk of developing subaxial subluxations after atlantoaxial transarticular screw fixation. Moreover, a perioperative increase in the AA angle leads to a decrease in the C2–C7 angle, followed by new or aggravated anterior subluxations of the upper cervical spine and possibly neurological deterioration.

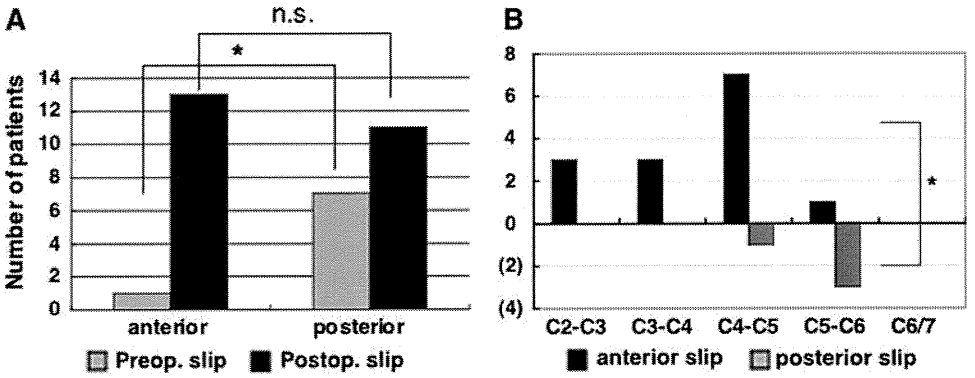

Fig. 2 **a** Pre- and post-operative subluxation (slip) in RA. **b** The level of the increased anterior and posterior slip. * $P < 0.05$

Table 3 Differences of preoperative AADI and PADI, and the pre- and postoperative AA and C2–C7 angles between patients with anterior subaxial subluxation (slip) and those with no slip

	Preop				Postop	
	AADI	PADI	AA angle	C2–C7 angle	AA angle	C2–C7 angle
Ant. slip. aggravation	10.6 ± 2.4	12.0 ± 3.5	16.3 ± 10.3	13.5 ± 3.9	24.8 ± 6.0	−3.1 ± 14.1*
No aggravation	8.7 ± 3.2	12.8 ± 3.3	18.2 ± 12.3	20.5 ± 13.5	21.2 ± 6.1	15.3 ± 13.6
Total	9.1 ± 3.0	12.6 ± 3.2	19.0 ± 12.6	18.1 ± 11.3	23.0 ± 7.5	10.6 ± 15.0

Of note, the total averages were calculated from all four groups (anterior, posterior, combination, and no slip groups)

* $P < 0.05$

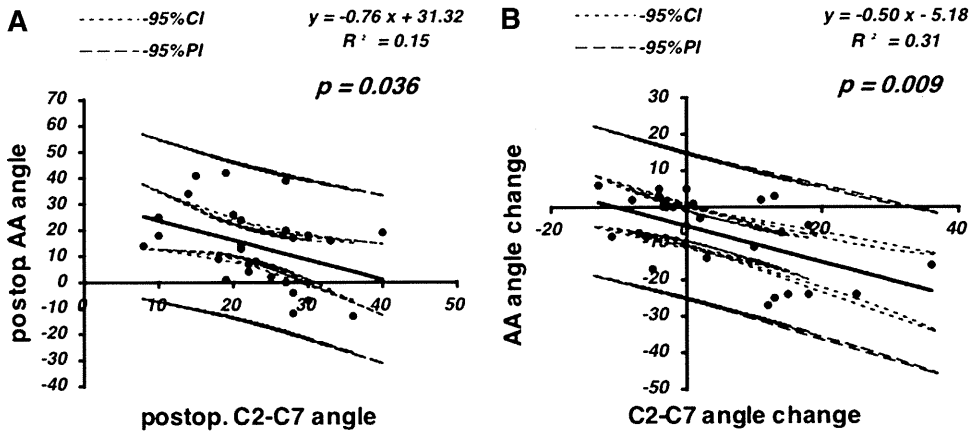

Fig. 3 **a** Correlation between the postoperative AA and C2–C7 angles. **b** Correlation between the AA and C2–C7 angle changes

One reason why such a complication has not been reported is that RA patients are not the majority of the reported cases using atlantoaxial transarticular screw fixation. RA consisted of only one-third of 191 [7] and 75 patients [8] in two of representative cohort studies, respectively. Even in one report that included 35 RA patients only, subaxial subluxation was not a major focus even though it was mentioned that the subluxation led to neurological deterioration [15], and there has been no comparative report between RA and non-RA patients. However, 13 of 33 RA cases in our series showed unmistakable, worrisome subaxial subluxation after a certain period of time (4.2 years in average) in this study. Indeed, two patients required subsequent corrective operations, and several needed further attention, while non-RA patients did not develop this instability after the operation.

The non-RA group surprisingly did not show even any correlation between the postoperative AA and C2–C7 angles, although the number in this group may be insufficient to draw a clear conclusion. One possibility is that non-RA patients would have had a similar risk but tended to have fewer biomechanical compensatory changes caused by rigidity. In contrast, the cervical spines of RA patients are susceptible to biomechanical changes caused by local instability, leading to a disruption of the cervical alignment. Mukai et al. [15] reported, indeed, an example of biomechanical compensation after C1–C2 fixation, namely an increase in C1–C2 lordosis, a progressive ventral shift of