

Cementless total hip arthroplasty with and without screw fixation: a randomized study of 78 hips

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Abstract

[Objective] This study is to evaluate the clinical and radiographic results of cementless total hip arthroplasty with and without screw fixation. [Methods] Cementless total hip arthroplasty was performed from August 2009 to August 2011. 76 patients (78 hips) were randomized screw fixation group (group A, n = 40) and non-screw fixation group (group B, n = 38). Consecutive radiographs were compared to evaluate acetabular condition at 3 months, 12 months and 24 months after surgery and the last follow-up, respectively. Harris Hip Scores (HHSs) were determined before surgery and at the most recent follow-up. The Kaplan-Meier survivorship analysis was used to estimate the survival rate of the prosthesis in the two groups. [Results] 39 hips in group A and 36 hips in group B were available for complete clinical and radiographic analysis while the lost-to-follow-up patients in group A and group B were 1 and 2, respectively. The mean follow-up period was 4.2 years (range, 2.3~5.5 years). In group A, radiolucent lines were present around the cup in 4 hips (10.3%), 3 hips (7.7%) and 1 hip (2.6%) at 3 months, 12 months and 24 months, respectively. By contrast, in group B, radiolucent lines appeared around the cup in 1 hip (2.8%), 2 hips (5.6%) and 2 hips (5.6%) at 3 months, 12 months and 24 months, respectively. Osteolysis and migration were observed in 1 hip in group A and 2 hips in group B. The Harris scores were 95 ± 2.1 points in group A and 93 ± 5.5 points in group B, respectively. The mean surgery time and operative blood loss were less in group A than those in group B. The year mean polyethylene liner wear was 0.08 mm in group A and 0.1 mm in group B, respectively. Kaplan-Meier survivorship at 4.2 years was 95% in group A and 93% in group B with radiographic loosening as the end point. [Conclusion] Additional screw fixation in principle is not necessary in press-fit cups.

Key words: screw, arthroplasty, hip, cementless

Introduction

Applications of cementless prosthesis in primary total hip arthroplasty replacement have been reported to obtain excellent results. However, it still remains controversial that whether screw fixation is needed when using cementless press-fit acetabular hip prosthesis. To address this problem, we followed up 76 patients (78 hips) who underwent total hip arthroplasty with cementless hemispheric and non-press-fit acetabular prosthesis in our department from August 2008 to December 2011, to investigate the clinical effect of the acetabular screw in the fixation of acetabular

prosthesis and to explore whether acetabular screw fixation is necessary in cementless total hip arthroplasty if the bone is under good condition.

Clinical data and methods

Patients data

From August 2008 to December 2011, 76 patients (78 hips) that need to receive total hip arthroplasty replacement but with good condition of acetabular bone were randomly divided into two groups. Group A, non-screw fixation group, is composed of 40 hips, including 21 male and 19 female with a mean age of 56 years old (range, 46-77 years) and average BMI of 21 (range, 15-32). The reasons for primary total hip arthroplasty in group A included aseptic necrosis of femoral head in 20 cases, femoral femoral neck fracture in 16 cases, ankylosing spondylitis or joint stiffness in 2 cases and osteoarthritis in 2 cases. Group B, screw fixation group, comprises of 38 patients, including 20 male and 18 female with a mean age of 54 years old (range, 21-77 years) and average BMI 21 (range, 15-32). The reasons for primary total hip arthroplasty in group B included aseptic necrosis of femoral head in 19 cases, femoral neck fracture in 19 cases and osteoarthritis in 3 cases. The age and weight of patients in group A is not significantly different from those in group B respectively ($p>0.05$).

Surgery approaches

All patients received the surgery by the same group of surgeons in our department. The operation was performed using a direct lateral transgluteal approach and with hip revealed in a conventional way. The operation materials included cementless and press-fit metal cup, polyethylene liner and metal femoral head in 28 mm diameter. The patients in group A were directly implanted with the press-fit acetabular components and the surgery took 75 min in average with 248 ml of mean intraoperative bleeding. The patients in group B were implanted with the acetabular and followed by fixation in the top with 2-3 screws. The operation took 89 min in average with 291 ml of mean intraoperative bleeding. The drainage tubes were removed after surgery and the patients was allowed to direct full weight bearing and do the functional exercises with weight-bearing ambulation. The average period of hospitalization for the patients was 18 days.

Follow-up after surgery

The patients were followed up at 1 month, 6 months, 24 months and last follow-up, respectively after operation. The Harris hip score (HHS) was assessed, the standardised anteroposterior and lateral view radiographs were taken and the radiological changes were evaluated. A vertical line against the teardrop joining line was drawn from the hip center, which would meet the teardrop joining line at an intersection. The distance between a line joining the inferior aspect of the teardrop and the acetabular component was measured as the horizontal migration of the acetabular prosthesis. The acetabular component migration greater than 4° in rotation or greater than 4 mm in width was considered to be unstable. Criteria for acetabular

loosening included continuous radiolucencies around the cup in zones 1 to 3 with respect to Delee-Charnley categories and the incidence frequency of radiolucent lines was recorded as well. The heterotopic ossification was graded according to Brooker classification and the polyethylene wear was measured according to Dorr method [Dorr and Wan (1996)] and the correction was performed based on the femoral head diameter (28 mm).

Statistical analysis

Statistical analysis was performed with the SPSS version 13.0 software. Since this was a comparative study, the results were analyzed with the paired student's t-test or chi-square test and a set point of $p < 0.05$ was considered as statistically significant. We use Kaplan-Meier survival analysis to determine the survivorship with component loosening or revision for any reason as the endpoint. The 95% confidence intervals (95% CI) were presented and the survivorship of the prosthesis from the two groups was compared.

Results

Clinical evaluation

Overall, 39 hips in group A and 36 hips in group B were available for complete clinical and radiographic analysis. The average follow-up period was 4.2 years (range, 2.3-5.5 years) after surgery. The lost-to follow-up patients in group A and group B were 1 and 2, respectively. In group A the average Harris hip score increased from 38 ± 8.1 before surgery to 95 ± 2.1 at the last follow-up 93 ± 5.5 while in group B the mean Harris hip score was improved from 36 ± 8.6 preoperatively to 95 ± 2.1 at the recently follow-up. It could be easily seen that the Harris hip scores of the both two groups were significantly increased after surgery ($p < 0.01$).

Complications associated with total hip replacement surgery were observed. In group A, one patient was found to have hip dislocation on the surgery side 20 days after surgery but the patient did not have dislocation anymore after closure. Additionally, one patient (2.6%) was reported to have osteolysis between 2 and 3 acetabular and cup aseptic loosening. But the patient only suffered from mild pain and refused revision (Figure 1). In group B, 2 patients (5.6%) had to undergo revision surgery due to loosening accompanying with moderate to severe pain. To be more specific, one of the patients suffered from septic loosening and acetabular osteolysis 2.8 years after surgery but the patient recovered well after revision and no infection occurred anymore. Overall, no patient was found to have symptomatic deep vein thrombosis or nerve damage.

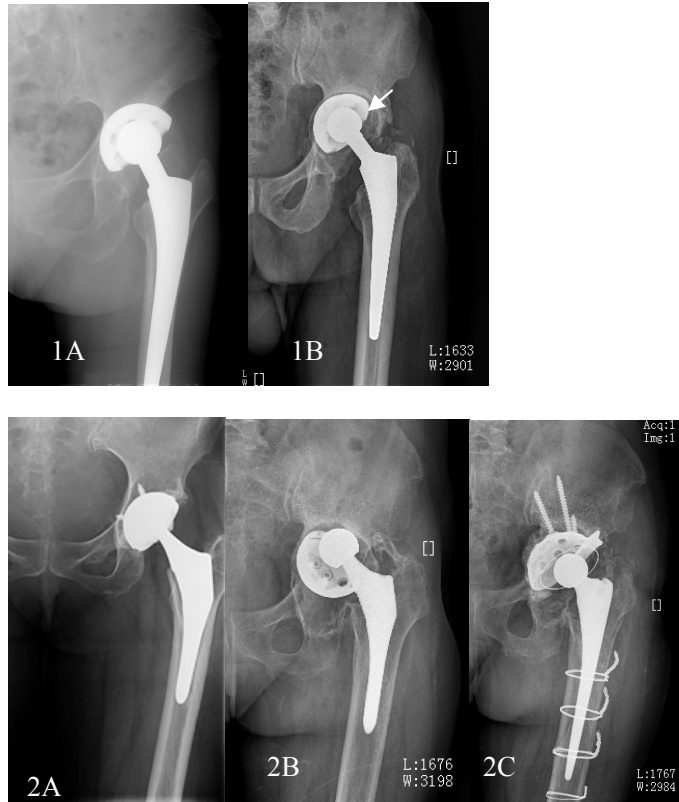


Figure 1-2 X-ray examples of hips needed revision: **1A)** A female patient with 67 years old, who suffered from fracture of the femoral neck and received cementless total hip replacement without acetabular screw fixation. **1B)** The patient was found to have acetabular osteolysis and cup migration at 4-year follow-up but she only got mild pain and refused revision. **2A)** Another female patient with 55 years old, who underwent cementless total hip replacement with screw fixation due to femoral necrosis. **2B)** The patient was found to get septic loosening and acetabular osteolysis with apparent cup migration 2.8 years after surgery. **2C)** The Harris hip score was 89 one year after revision was performed using acetabular reinforcement ring.

Radiological evaluation

In group A, radiolucent lines were present around the cup in 4 hips (10.3%), 3 hips (7.7%) and 1 hip (2.6%) at 3 months, 12 months and 24 months, respectively. At 4 years after operation, one patient had to undergo revision due to acetabular osteolysis and aseptic loosening with moderate pain. In addition, 10 hips (26%) developed heterotopic ossification and the average year polyethylene wear was 0.08 mm (range, 0-0.25 mm). By contrast, in group B, radiolucent lines appeared around the cup in 1 hip (2.8%), 2 hips (5.6%) and 2 hips (5.6%) at 3 months, 12 months and 24 months, respectively. Among them, 2 hips had to undergo revision resulting from osteolysis and migration and 11 hips shown heterotopic ossification. The average year polyethylene wear was 0.10 mm (range, 0.03-0.28 mm). The X-ray examples representative of the typical cases were shown in Figure 3.

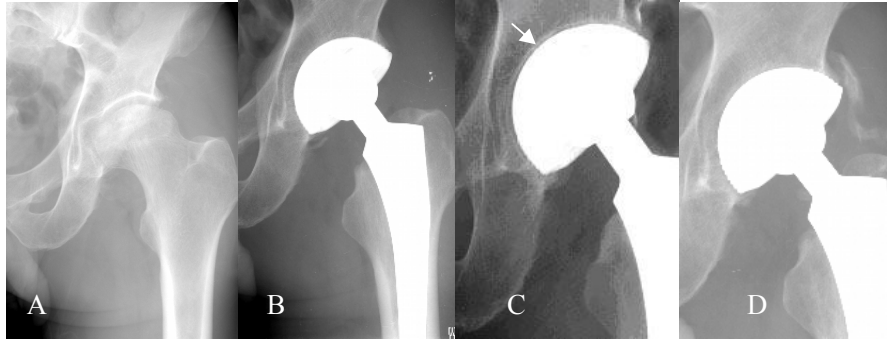


Figure 3. X-ray examples of typical cases: **A)** A female patient with 61 years old, who suffered from aseptic necrosis of femoral head; **B)** The patient underwent total hip replacement without screw fixation; **C)** Radiolucent line of 1 mm in width was present in acetabulum at 6-month follow-up; **D)** The radiolucent line disappeared and heterotopic ossification graded at level 3 appeared at 2-year follow-up

Statistical data

The clinical data of group A and B were analyzed using the Student's paired t-test or chi-square test. It could be easily seen from the table one that the operation time and blood loss during operation in non-screw fixation group were less than those in screw fixation group. Furthermore, more radiolucent lines could be observed in group A at 3-month follow-up after surgery.

Table 1. The clinical data and statistical analysis of patients in group A and B

Evaluation	Group A(n=39)	Group B(n=6)	<i>p</i>*
Harris hip scores, mean	95	93	>0.05
Operation time in min, mean	75	89	<0.05*
Bleeding in ml, mean	248	291	<0.05*
Heterotopic ossification frequency	26%	31%	>0.05
Annual polyethylene wear in mm, mean	0.08	0.10	>0.05
Occurrence of radiolucencies (3 rd .m.)	10.3%	2.8%	<0.05*
Occurrence of radiolucencies (12 rd .m.)	7.7%	5.6%	>0.05
Occurrence of radiolucencies (24 rd .m.)	2.6%	5.6%	>0.05

The Kaplan-Meier survival analysis demonstrated that the survivorship of group A and B were 0.95 (0.91-0.99) and 0.93 (0.88-0.98), respectively. Apparently, there was no significant difference between the groups in survivorship.

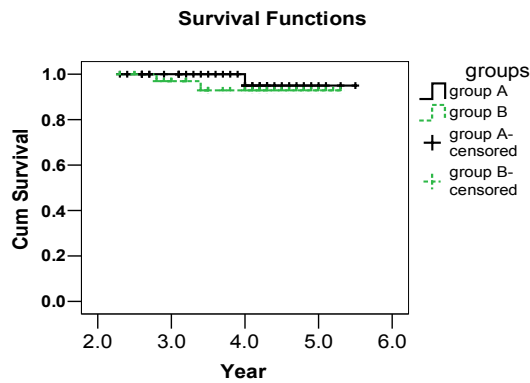


Figure 4. The Kaplan-Meier survival curve of group A and B

Discussion

Cementless acetabular prosthesis design and materials have greatly improved over the past decades. The improvement in smoothness of acetabular inner surface, the locking mechanism of polyethylene liner and the particle coating on cup surface are able to promote bone ingrowth, which significantly increase the survivorship of cementless acetabular components and enable the application of the primary total hip arthroplasty replacement to achieve excellent results. However, it still remains controversial when the use of screw fixation is essential when using a hemispherical press-fit acetabular prosthesis.

Supporters of the use of screws fixation believed that screw in the press-fit acetabular component could enhance the initial stability and osseointegration and prevent acetabular prosthesis migration in the long-term [Heller et al. (2013); Hsu and Lin (2010); Roth et al. (2006)]. In the vitro studies, researchers have found that the screw can increase the primary stability of acetabular cup by 26%. When the bone quality was not in an excellent condition, bone defect would have an impact on cup fixation. By contrast, the use of screws could significantly improve the initial cup stability, especially in bone with central defects [Heller et al. (2013)]. Hsu et al. [Hsu and Lin (2010)] demonstrated via their in vitro study that well-fitted screws would enhance the initial cup stability and the stability would enhance with the increase in the screws number. However, the screws would locally reduce the micromotion at the cup-bone interface. As a result, it was not advisable to place the screws close to one another. In addition, the screws should be placed peripherally and separately to expand the stable region, avoiding the micromotion at the cup-bond interface. Zilkens et al [Zilkens et al. (2011)] reported that 107 patients who underwent acetabular replacement combined with screw fixation were found to achieve good results at 2.6-year follow-up. They believed that screws fixation would not increase the occurrence of osteolysis and radiolucencies after acetabular replacement.

Opponents of the use of additional screws have argued that the stability of a press-fit acetabular prosthesis depends on surgical techniques and excellent press-fit technique rather than the use of screws fixation. The recent press-fit technique will provide adequate initial fixation so that adjunctive screw fixation is not indicated and

insufficient to prevent late migration. Furthermore, the in vitro results can only simulate the immediate state after surgery but do not represent the outcomes after bone ingrowth into the components. Won et al. [Won et al. (1995)] found that adding the screws to the component would reduce the micromotion at the superior cup but could increase it on the inferior side sometimes. Therefore, the author believed that screw fixation was unnecessary to improve the initial cup stability. Additionally, from the biomechanics point of view, it is not necessary to use the non-weight-bearing acetabular screws for fixation at the ischial or pubic bone. Garavaglia et al [Garavaglia et al. (2011)] reported that 335 patients underwent total hip arthroplasty without screws fixation. No hip had to be revised due to aseptic loosening or osteolysis during the follow-up up to 10 years and the ten-year survival rate of the prosthesis was about 98.8%. Udomkiat et al. [Udomkiat et al. (2002)] reported that 110 cases primary total hip replacements were performed with a porous-coated socket that was implanted using a press-fit technique. The aseptic loosening rate was only 0.9% at 10-year follow-up. The press-fit component could improve osseointegration to the coated without the loss of cup elasticity modulus. Furthermore, it could transmit the biomechanical force from the cup to the joint to reduce stress-shielding and osteolysis [Morscher et al. (2002)]. Röhrli et al [Röhrli et al. (2006)] reported that 50 patients were operated with cups using additional screw fixation. And 28 hips were observed to display osteolytic lesions with varying degrees mainly relate to screws. The author suggested that the joint pressure transmitted by the cup screws and the access of polyethylene wear debris into the cup-bound interface through the screw holes would result in component osteolysis, which would increase the risk of aseptic loosening.

In this study, we found that the cup radiolucent lines appeared more in non-screw fixation group at 3 months after surgery. But most of the radiolucent lines disappeared at 2-year follow-up. By contrast, in screw fixation group, the cup radiolucencies initially were similar to those found after the component reached to a stable stage. However, overall, there was no significant difference in the survival rate regardless screw fixation. Similar results were reported by other research groups. Pakvis et al. [Pakvis et al. (2012)] also reported that the cup radiolucent lines were present more within 2 months of healing period. But after the component was stable no significant difference could be observed from the two groups with or without the use of screw in two months after the healing period. Iorio et al. [Iorio et al. (2010)] carried out an investigation on 775 cases up to 10-year follow-up. He found that screw fixation did not have a favorable or adverse effect on the clinical outcome of the radiolucencies. However, several researches suggested that more radiological changes around the cup occurred in screw fixation group after bone healing period. Roth et al. [Roth et al. (2006)] divided 220 patients into two groups based on the use of screws or not. He found that radiolucent lines shown more in the non-screw fixation group at 5 months after surgery. But they disappeared and no cup migration occurred at 25-month follow-up. On contrary, more radiolucent lines were observed in the screw fixation group during 5-25 months after surgery. He suggested that the causes for more radiolucent lines were found in the screw fixation group could be explained by the

fact that the joint pressure transmitted by the cup screws and the access of polyethylene wear debris into the cup-bound interface through the screw holes. Therefore, he came to the conclusion that an additional screw fixation in principle was not necessary in press-fit cups. In this study, more radiolucent lines were found in the non-screw group at the early postoperative, which might be ascribed to the fact that the cup and bony acetabulum did not reach osseointegration at this stage. However, after the healing period, no significant difference in radiolucencies was found between the non-screw fixation and screw fixation group. In addition, the radiolucencies and osteolysis were inclined to increase in the screw group.

This study suggested that the acetabular screws could improve the initial stability of the cup prior to healing period. But after healing period, it made no significant difference to the component stability regardless of the use of screw fixation. However, it should be noted that the non-screw fixation procedure would reduce the operative time, blood loss and operation fees. Additionally, it could avoid injury on blood vessels and nerves caused by screws fixation and it also made it easier to perform possible revision. Therefore, the screwless fixation procedure might favor patients when the patient bone condition allowed doing it. Nevertheless, screws fixation should be carried out to improve the component stability if the following symptoms appeared, including osteomalacia after osteolysis, intraoperative acetabular fractures, acetabular dysplasia and acetabular bone defects on the edges in which good press-fit and initial stability could not be satisfied.

The authors are aware that this investigation has some limitations, such as an inadequate cases and a more subjective evaluation which would probably generate bring data bias. In recent years, some authors have advocated to use objective tests, such as using RSA (Radiostereometric Analysis) and EBBA (Einzel Bild Roentgen Analyse) to measure the component migration or use of computer-aided quantitative measurement software to analyze the radiological images [Garavaglia et al. (2011; Röhrli et al. (2006; Zilkens et al. (2011)]. However, the present study still utilizes the conventional analysis strategy. Furthermore, another limitation of this study is a short follow-up period. So a long-term follow-up should be performed.

In summary, this study suggested that when performing the total hip arthroplasty replacement, the inherent stability of the cup could be achieved via press-fit technique. In addition, the use of screw fixation did not improve the stability of the cup when the acetabular bone was in good quality condition. Thus, we arrive to the conclusion that screws are not necessary for the total hip arthroplasty replacement.

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