Fixation[A1] of ~~an~~ Anatomically Designed Cementless Stems in Total Hip Arthroplasty[A2][A3]

Abstract[A4]

~~Purpose~~Objectives[A5] **:** ~~.~~ The Anatomic Fiber Metal plus stem (Zimmer) is ~~one of the~~an anatomically ~~-~~designed, cementless stem~~s to~~ that achieves stable fixation ~~by~~ using metaphyseal fit. The press-fit and outcomes of total hip arthroplasty (THA) using this stem have been reported to be good for primary osteoarthritis in ~~-~~Caucasian patients. However, there are few reports available on the outcomes of THA using this stem in Japanese patients[A6]. Therefore, in this study, w~~W~~e evaluated ~~studied~~ the outcomes of cementless THA~~total hip arthroplasty~~ using this stem and the possible effects of the quality of metaphyseal fit on outcomes in a Japanese population. ~~-~~**~~Methods~~Participants:** ~~.~~ ~~The c~~Cementless THA~~total hip arthroplasty~~ ~~using~~ with this stem was performed ~~for~~ on 155 hips. One hundred and thirty-seven hips of 122 patients were followed up after ~~for~~ 5 ~~to 1~~ 16 (mean~~,~~ 9.7) years and ~~entered~~ enrolled in~~to~~ the study. **Main outcome measures:** ~~The~~ M~~m~~etaphyseal fit was ~~defined~~ classified as good or poor ~~in~~ from examination of ~~a~~postoperative~~n~~ anteroposterior radiographs ~~after surgery~~. We studied the fixation of the stem and bone ~~reaction~~ on an anteroposterior radiograph at the final follow~~-~~up. ~~-~~**Results** ~~.~~ : Twelve hips ~~had~~ required revision~~;~~, six for acetabular components and six for acetabular liners. No stems ~~was~~ were revised. The biological fixation of the stem was bone ingrown fixation for 136 hips and unstable for 1~~one~~ hip. The metaphyseal fit was good for 83 hips and poor for 54 hips. ~~There were n~~No differences were observed for stem fixation and bone reaction between the two ~~groups~~classifications[A7]. ~~-~~**Conclusions**[A8] ~~.~~ : ~~The f~~Fixation of ~~the~~ the Anatomic Fiber Metal plus stems ~~was stable at a mean followup of 9.7 years~~is independent~~ly from~~of metaphyseal fit~~.~~. This stem, therefore, represents a long-term option for THA~~total hip arthroplasty~~.[A9]

1. Introduction

~~For~~ A large variety of femoral component designs have been developed for cementless total hip arthroplasty (THA)~~, a large variety of femoral component designs have been developed~~. The Anatomic Fiber Metal plus stem (Zimmer, Indiana, USA) is one such design~~of the anatomically designed femoral components to be inserted without cement~~ (Figure ~~-~~1). This ~~e concept of this~~ stem ~~iwas to~~ achieves stable fixation by metaphyseal fit~~. and fill~~ [1, ~~-~~2]~~.~~ [A10]It has a configuration that matches the~~ing a~~ medullar canal of a normal femur~~,~~ and a circumferential fiber-mesh coating on the proximal ~~one~~ third. The neck of the stem has an anteversion of 12°~~twelve degrees~~.[A11]

INSERT FIGURE 1 HERE

The press-fit and outcomes of THA using this stem ~~were~~ have been reported to be good for ~~the~~ primary osteoarthritis in ~~selected~~ Caucasian patients. [1[A12]]~~.~~ However, there ~~we~~are ~~a~~ few reports available regarding ~~on~~ the outcomes of THA using this stem in Japanese patients[A13]. ~~The majority of the hips with osteoarthritis are d~~Dysplastic hips in Japanese patients represent the majority of

cases of hip osteoarthritis worldwide. [A14] [3]. Therefore, the postoperative results of this population may might be different from those in of Caucasian patients.

With this in mind, we We studied the outcomes of cementless total hip arthroplasty (THA) using the Anatomic Fiber Metal plus stem in Japanese patients and the possible effects influences of the metaphyseal fit and fill design on patient outcomes[A15].

2. Methods[A16][A17]

Study Population

The cCementless total hip arthroplastyTHA using the Anatomic Fiber Metal plus stem was performed for 155 hips of 139 patients between February 1994 and August 2003 [A18] at our hospital[A19]. Eighteen hips of 17 patients were excluded for the following reasons:. 6Six patients (7seven hips) had died during follow-up, 8eight patients could not be contacted, and the remaining 3three patients were were confirmed contacted viaby telephone and confirmed to have no revision [A20] and to have no hip pain, but did not visit our clinic. As a result, 137One hundred and thirty-seven hips of 122 patients were followed monitored for more thanat least five5 years and entered into the study ofevaluated for clinical and radiographic outcomes.

The average follow-up period of the study group was 9.7 (5–16) years, and the average age at the time of surgery was 62 (33–80) years old. The diagnosis was osteoarthritis for 117 hips, osteonecrosis of the femoral head for 18 hips, and rapidly destructive coxarthrosis for two 2[A21] hips[A22].

Choice of stem

The indication of the usage of the Anatomic Fiber Metal plus stem was differednt according to the periods of the surgery. This stem had been used principally for all hips between February 1994 and May 1999 (defined as the non-selection period). Between June 1999 and August 2003 (defined as the selection period), we had used this stem as a first choice, but selected other stems (straight-taper type or modular type) when the Anatomic Fiber Metal plus stem was did not fit to the shape of medullar canal in an anteroposterior (AP) radiograph. During this period, we used the Anatomic Fiber Metal plus stemThese cases accounted for 48% % of all THA cases. Of the 155 hips inserted with this stemincluded in the present study, 62 hips were operated on in the non-selection period, and 93 hips were operated on in the selection period.

The acetabular components were cementless spherical cups: HGP-II (Zimmer) for 22 hips and Trilogy (Zimmer) for 115 hips. The modular head was made of cobalt chromium alloy. The polyethylene of the acetabular liner was conventional for 51 hips and cross-linked[A23] for 76 hips.[A24]

Analysis of Metaphyseal Fit

We evaluated the metaphyseal fit on the postoperative AP radiograph and divided all hips into two groups (Figure 2). The metaphyseal fit was defined as good if the medial side of the stem was in contact with the endosteum of the medial femoral cortex through the area of proximal fiber-mesh coating. The metaphyseal fit was defined as poor if the medial side of the stem was not in contact with the endosteum of the medial femoral cortex at any point in the area of proximal fiber-mesh coating. In the poor metaphyseal fit cases, we calculated the canal-filling ratio (CFR) at the distal end of the lesser trochanter and at the distal end of the stem to evaluate the stem size.

INSERT FIGURE 2 HERE[A25]

Analysis of Biological Fixation

We studied the fixation of the components and bone reaction on an AP radiograph at the final follow-up. The biological fixation of the stem was classified into bone ingrown fixation, stable fibrous fixation, or unstable fixation according to the methods of Engh et al. [4]. Unstable fixation was defined as loosening of the stem. The subsidence of the stem more than four 4 mm was considered significant. Loosening[A26] was defined as the acetabular component having a clear zone of more than 1 mm in all of the three zones of DeLee and Charnley [5] around the cup or a change in inclination angle of more than 4°. The stress shielding was classified into 4° according to the method of Engh et al. [4]. Radiolucent line, spot welds, and osteolysis were evaluated in the seven zones of Gruen et al. [6] from AP radiographs.

The function of the hip was evaluated using the Japanese Orthopedic Association (JOA) hip score [7], with a total score of 100 points (pain, 40; gait, 20; range of motion, 20; and activity of daily living, 20 points).

Statistical Analysis[A27]

We studied the revision rates and survival rates of all 155 hips using the Kaplan-Meier methods. The Chi-squared test or Fisher's Exact test was used for categorical data, and the Mann-Whitney U test was used for numerical data. P-values less than 0.05 were considered significant.

Ethics Statement

This study was approved by the ethics committee of our institute and was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki[A28].

3. Results[A29]

Twelve hips—including one hip with late infection—underwent revision. The mean duration between THA and revision was 9[A30] (1–16) years. No stem was revised.

Six hips ~~had~~ underwent revision of acetabular components~~,~~ and the remaining six ~~hips had~~ underwent revision of the acetabular liners. Conventional polyethylene liners had been used f~~F~~or all 12 hips~~, conventional polyethylene liners had been used~~. Out of the six acetabular revisions, three cups were well fixed~~,~~ and the other three had no bony fixation. ~~Well~~The well~~-~~fixed ~~three~~ cups were all HGP-II cups. Cross~~-~~linked polyethylene liners were not available for HGP-II cups~~.~~; hence,~~, and so~~ w~~W~~e revised these cups to use cross~~-~~linked polyethylene liners. The reasons for liner revision were as follows: liner wear for three hips, late infection for one, dislocation for one~~,~~ and dislodge of liner for one. For one hip where~~of~~ liner revision was carried out, a bone graft was performed ~~to~~ for osteolysis at ~~the~~ zone 1 of the femur.

The average JOA score of the study group was x points before surgery and x points[A31] at the final follow~~-~~up. One hundred and three hips (75~~%~~ %) showed more than 80 points at ~~the~~ follow~~-~~up~~.~~, with ~~three~~Three hips ~~cases~~ had ~~reporting~~ thigh pain being reporting in three cases.

The biological fixation of the stem was classified as bone ingrown fixation for 136 hips (Figure ~~-~~3) and unstable for one. The ~~hip with~~ unstable stem ~~was~~ occurred in the right hip of a 45-year-old woman~~female~~ who had received bilateral THA for rapidly destructive coxarthrosis. The metaphyseal fit had been classified as poor ~~on the postoperative AP radiograph~~ [A32](Figure ~~-~~4). The stem had been undersized~~:~~; the CFR ~~had been~~was 0.63 at the distal end of the lesser trochanter and ~~was~~ 0.59 at the distal end of the stem. The follow-up radiographs showed no subsidence of the stem at ~~three~~ 3 months after surgery, but subsidence of 5 mm at ~~four~~ 4 years after surgery. The final follow-up radiographs at 6.1 years after surgery showed stem loosening with subsidence of 16 mm. ~~She~~ The patient ~~had~~ died due to unrelated pulmonary disease ~~not related to the hip~~ before revision was performed.

INSERT FIGURES 3 AND~~&~~ 4 HERE

Two hips showed subsidence. One hip ~~was in the patient~~is described above~~.~~, and t~~T~~he other ~~hip~~ had ~~had~~ sustained a ~~ffered~~ femoral neck fracture during surgery. The stem had subsided 30 mm at ~~six~~ 6 months after surgery~~,~~ but showed no ~~additional~~ further subsidence. At 7.5 years after surgery, ~~the~~ radiographs showed bone ingrown fixation. The 10~~Ten~~-year survival rate was 94 (86–97) % when any surgery or revision for any reason was defined as the end~~-~~point and ~~was~~ 99 (95–99.9) % when loosening or revision of the stem was defined as the end~~-~~point[A33].

Radiolucent lines of more than ~~one~~ 1 mm were found ~~at~~ in zones 1, 2, 5~~,~~ and 6 of one hip with stem loosening (Figure ~~-~~4~~(~~b~~)~~). Radiolucent lines of less than ~~one~~ 1 mm were found ~~at~~ in zone 2 of six~~6~~ hips,~~ at~~ zone 3 of 19 hips,~~ at~~ zone 4 of 106 hips (most frequent), ~~at~~ zone 5 of 46 hips, ~~at~~ zone 6 of 2 hips~~,~~ ~~and~~ ~~at~~ zone 7 of one hip. No hip showed radiolucent lines of less than ~~one~~ 1 mm ~~at~~ in more than four zones. Spot welds were found ~~at~~ in zone 6 of 108 hips. No spot welds were found ~~at~~ in any other zones. Osteolysis was found at the medial side of the greater trochanter in 18 hips (13 %) and ~~at~~ in zone 1 ~~in~~ of one hip. No osteolysis was found ~~at~~ in any other zone. Stress shielding was grade I for 133 hips and grade II for four hips.

~~Metaphyseal~~ The metaphyseal fit was good for 83 hips (61 %) and poor for 54 hips (39 %). In the 54 hips with poor metaphyseal fit, the mean CFR was ~~–~~x[A34] (range, 0.59–0.92) at the distal end

of the lesser trochanter and was x [A35] (0.59–0.98) at the distal end of the stem[A36]. ~~The~~ A CFR ~~of below was less than~~ 0.7 ~~at~~ for both levels ~~in~~ was only observed in one hip ~~shown in~~ (Figure ~~4(~~a). Other hips with low C~~R~~FR values at the distal end of the lesser trochanter showed good CFR at the distal stem ~~(~~for example, ~~like the hip of~~ Figure ~~2(~~b). The percentage of hips with good metaphyseal fit was significantly higher in the selection period than in the non-selection period (69% versus 47 %, [A37]). ~~In~~ With regard to ~~diagnosis~~diagnoses, the percentage of good fit was 59% for cases of osteoarthritis and 78% for cases of osteonecrosis. ~~The h~~Hips with osteoarthritis showed a tendency ~~of~~ for a lower percentage of good metaphyseal fit~~,~~; however, this trend was not found to be ~~but no significant difference was found~~ statistically significant ()[A38]. ~~We studied possible~~The relationship~~s~~ between metaphyseal fit and outcome~~s~~ of THA is presented in ~~(~~Table ~~1)~~. ~~The duration of followup showed n~~No differences were observed between the good ~~group~~ and ~~the~~ poor fit group with regards to the duration of follow-up. There were no differences ~~for~~ in JOA score ~~at the followup~~, stem fixation, ~~the~~ rate of positive radiolucent line in zone 4, spot welds in zone 6, osteolysis at the medial side of the greater trochanter~~,~~ ~~and~~ or stress shielding between the two groups at follow-up.

INSERT TABLE 1 HERE

4. Discussion[A39]

Several studies [1,2,8,9] ~~on~~ have discussed the outcomes of THA using the Anatomic stem (Zimmer, Indiana, USA) in Caucasian patients, ~~reported th at t~~with low~~he~~ rates of stem revision due to loosening ~~were~~ reported~~low~~ (from 0 to 2.6 %). ~~There wer~~Only~~e~~ two reports describe ~~on~~ the outcomes of this surgery in Japanese patients. Harada et al. [10] reported that five cups and no stems had been revised ~~in~~ out of 81 hips with a mean follow-up of 8.4 years. Nakoshi et al. [11] ~~also~~ reported that four cups and no stems had been revised in 20 hips with a mean follow-up of 12.8 years. In our study, no stems required ~~had been~~ revisioned and one stem showed loosening ~~in~~ out of 137 hips with a mean follow-up of 9.7 years[A40]. These results suggest that the biological fixation of this stem is good for 8 to 12 years after surgery ~~not only~~ in Japanese as well as Caucasian ~~but also in Japanese~~ patients.

~~There was o~~Only one previous study has~~that~~ evaluated the metaphyseal fit or press-fit of the Anatomic stem. Ragab et al. [1] evaluated the press-fit of thi~~s~~e stem in 97 hips using the methods of Callaghan et al. [12]~~,~~ and reported ~~that the press-fit was~~it to be excellent in 58 hips, good in 38 hips~~,~~ and poor in one hip. These results suggest that the press-fit of this stem is ~~good~~ appropriate for ~~the~~ hips with primary osteoarthritis in Caucasian patients. However, direct comparison~~s to~~ with our results ~~are~~ was not possible~~roper~~, because we ~~had~~ did not use~~d~~ the evaluation methods of Callaghan et al. [12] for a number of reasons. In their method~~s~~, ~~the~~ press-fit was defined as excellent if the AP radiograph showed the stem to be in contact with the cortical bone at some point on both the medial and the lateral surface. The Anatomic stem has no lateral flare to contact with the endosteum of the lateral metaphyseal cortex around the innominate tubercle. Therefore, ~~the~~ assessments of the lateral side contact ~~seem to have no~~would be meaningless for ~~in~~ this stem. Additionally, we ~~thought~~ considered that stricter assessments should be employed~~were needed~~ for the contact on the medial side. ~~These are the reasons why we had not used the methods of~~

~~Callaghan et al. There were n~~No other reports on the press-fit or metaphyseal fit of the Anatomic stem are currently available.

~~We discuss the reason for the fact that t~~Our analysis revealed that the ~~rate~~ occurrence of good metaphyseal fit was ~~not high~~low. The ~~data of the design of the~~ Anatomic stem was designed using data obtained from normal femora of cadavers. Kaneuji et al. [13] studied the three-dimensional morphology of the femur ~~on~~ in 113 hips with osteoarthritis and 36 normal hips in Japanese individuals. ~~In t~~Their study~~,~~ classified the femoral canal ~~was classified~~ into three types~~, ;and~~ the standard type accounted for 89~~%~~ % of the normal hips ~~and~~ but only 42~~%~~ % of the hips with osteoarthritis. In our study, 117 hips out of 137 hips ~~had been~~were diagnosed as having osteoarthritis. The difference ~~of~~ in femoral configuration between normal ~~hip~~ and osteoarthriti~~c~~s hip~~s~~ c~~w~~ould be one of the reasons for the high incidence of poor metaphyseal fit. The use of an undersized stem ~~like (Figure~~ Figure ~~4~~ 4) can also ~~cause~~result in~~s~~ poor metaphyseal fit. However, no other stem~~s~~ were~~as~~ undersized ~~like this case and~~or showed loosening. Therefore, we ~~think~~ conclude that the usage of undersized stem~~s~~ was not the main reason ~~of~~ for poor metaphyseal fit.

The present study had several l~~L~~imitations ~~of this study should be discussed~~. First, t~~ T~~he metaphyseal fit was evaluated from~~on~~ AP radiographs. Three-dimensional analysis using CT scan would be more precise and is supposed to show lower rates of good fit. S~~econd, because~~~~ince~~ the mean follow-up of our study was 9.7 years, ~~we cannot deny~~there may be ~~possible~~ effects of metaphyseal fit ~~on~~ that become apparent ~~outcomes~~ after longer ~~followup~~time periods that were not observed. These points ~~need~~ require further study.

5. Conclusions

~~The~~ Good metaphyseal fit was ~~good~~ only observed in about 60~~%~~ % of cases[A41], but the 10-year survival rate of the stem was 99~~%~~ %. The biological fixation of the Anatomic Fiber Metal plus stem was stable at a mean follow-up of 9.7 years independent~~ly from~~of metaphyseal fit[A42][A43][A44]. This stem, therefore, represents a long-term option for THA~~total hip arthroplasty~~.[A45]