

Fixation of an Anatomically Designed Cementless Stems in Total Hip Arthroplasty

Abstract

Purpose/Objectives: The Anatomic Fiber Metal plus stem (Zimmer) is ~~one of the~~ anatomically designed, cementless stems ~~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. Therefore, in this study, we 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 ~~e~~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 into~~ the study. **Main outcome measures:** The ~~M~~metaphyseal fit was ~~defined classified~~ as good or poor ~~in from examination of apostoperative~~ 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 ~~one~~ hip. The metaphyseal fit was good for 83 hips and poor for 54 hips. ~~There were in~~No differences ~~were observed~~ for stem fixation and bone reaction between the two ~~groups~~ classifications. **Conclusions:** ~~The f~~Fixation of ~~the the~~ Anatomic Fiber Metal plus stems ~~was stable at a mean followup of 9.7 years is~~ independently ~~from of~~ metaphyseal fit. This stem, therefore, represents a long-term option for ~~THA total hip arthroplasty~~.

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 ~~was to achieve~~ stable fixation by metaphyseal fit ~~and fill~~ [1, 2]. It has a configuration ~~that matches the~~ 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~~.

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]. However, there ~~were a~~ few reports ~~available regarding on~~ the outcomes of THA using this stem in Japanese patients. ~~The majority of the hips with osteoarthritis are d~~Dysplastic hips in Japanese patients ~~represent the majority of~~

Comment [A1]: Thanks for providing this opportunity to assist you with this manuscript. I have edited the text for language, grammar, and improved clarity. I have also checked the manuscript for conformance with the formatting guidelines provided. In the cases where additional information is required from you, I have added comments to bring them to your attention. Should you have any concerns, please feel free to get back to me. My best wishes for your success with the manuscript.

Comment [A2]: As per journal guidelines, for research papers, a subtitle with the study design (for example, "a phase III clinical trial" or "a systematic review and meta-analysis") needs to be included in the title.

Comment [A3]: On the title page, please provide for each author his or her name, affiliation (job title) at the time the paper was written, email and, for the corresponding author, the best contact address. All author...

Comment [A4]: The abstract is currently quite short and below the minimum limit of 250 words. As per journal guidelines, abstra...

Comment [A5]: I have edited the abstract headings (and added some) to conform with...

Comment [A6]: Please cite the references (provided in the Discussion) to support this statement.

Comment [A7]: This should be supported by some numerical data in the abstract.

Comment [A8]: Please also highlight in the abstract that this is the first large study in a Japanese population.

Comment [A9]: The sentence that was included here was simply a statement of the results. I have rephrased it to better convey...

Comment [A10]: As per journal guidelines, reference numbers go after commas and full stops, before semicolons and colons.

Comment [A11]: Are there any advantages of this design over the other femoral component designs? These should be discussed.

Comment [A12]: Some of these studies can be discussed so that what is known about the topic is clearly presented.

Comment [A13]: Please cite the references (provided in the Discussion) to support this statement.

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

Comment [A14]: I have added the word “worldwide” here, in order to highlight this fact as I believe this is what you were suggesting. Please confirm that this edit conveys the intended meaning.

With this in mind, 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.

Comment [A15]: It will be helpful to specify what outcomes were studied (clinical outcomes, radiological outcomes, etc.)

2. Methods

Study Population

The cementless total hip arthroplasty (THA) using the Anatomic Fiber Metal plus stem was performed for 155 hips of 139 patients between February 1994 and August 2003 at our hospital. Eighteen hips of 17 patients were excluded for the following reasons: 6 patients (7 seven hips) had died during follow-up, 8 eight patients could not be contacted, and the remaining 3 three patients were/were confirmed contacted via telephone and confirmed to have no revision and to have no hip pain, but did not visit our clinic. As a result, 137 One hundred and thirty seven hips of 122 patients were followed-monitored for more than at least five 5 years and entered into the study of/evaluated for clinical and radiographic outcomes.

Comment [A16]: Please include an additional section within the Methods to conform with the requirements of BMJ: Provide a short paragraph entitled Patient and Public Involvement detailing how they involved the patients and the public in their research. We request this to both encourage the movement and ensure that BMJ readers can easily see whether, and if so how, patients and the public were involved in the research. If they were not involved in any way this information should be formally documented in the Patient and Public Involvement section.

Comment [A17]: I would suggest subdividing this section for clarity. I have suggested subheadings, but please check that you are satisfied with these headings.

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 hips.

Comment [A18]: The data appear to be quite dated and will raise questions of why more recent and updated data were not analyzed in this study. Please clarify.

Choice of stem

The indication of the usage of the Anatomic Fiber Metal plus stem was differed 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 stem. These cases accounted for 48% % of all THA cases. Of the 155 hips inserted with this stem included in the present study, 62 hips were operated on in the non-selection period, and 93 hips were operated on in the selection period.

Comment [A19]: Please clearly describe the study design (e.g., retrospective, single-center, case-series).

Comment [A20]: This is confusing because “revision” was encountered in 12 of the cases that were included in the study. Please clarify what kind of revisions (hip/stem?) were excluded.

Comment [A21]: Although it is usually correct to write numbers under ten out in full, in cases where it would be more consistent with the rest of the sentence, it is preferable to use Arabic numerals. This is also required by the journal. I have edited as such.

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 for 76 hips.

Comment [A22]: The introduction mentions that majority of hips in the Japanese population are dysplastic. Please clarify if your data support this observation.

Analysis of Metaphyseal Fit

Comment [A23]: The hyphen has been deleted as BMJ requires that hyphens not be used where possible.

Comment [A24]: These add up to 127; what liners were used in the other 10 hips?

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 ~~in the poor metaphyseal fit cases~~ to evaluate the stem size.

INSERT FIGURE 2 HERE

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. ~~A~~The subsidence of ~~the stem~~ more than ~~four~~ 4 mm ~~was~~ ~~was defined as~~ considered significant. Loosening was defined as ~~t~~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 ~~of in~~ inclination angle of more than ~~4°~~ four degrees ~~was defined as loosening~~. The stress shielding was classified into ~~4°~~ four degrees 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] ~~in from~~ AP radiographs.

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

Statistical Analysis

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 ~~defined as~~ significant.

Ethics Statement

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

3. Results

Twelve hips ~~including one hip with late infection~~ ~~had~~ underwent revision. The mean duration between THA ~~total hip arthroplasty~~ and revision was nine ~~9~~ (1–16) years. No stem was

Comment [A25]: Formatted for consistency with the previous figure.

Comment [A26]: Please consider defining this as “acetabular loosening” to differentiate it from “loosening of the stem”

Comment [A27]: Whenever possible, state absolute rather than relative risks. Please include in the results section of your structured abstract (and in the article's results section) the following terms, as appropriate: For a clinical trial:

- Absolute event rates among experimental and control groups.
- RRR (relative risk reduction).
- NNT or NNH (number needed to treat or harm) and its 95% confidence interval (or, if the trial is of a public health intervention, number helped per 1000 or 100,000).

For a cohort study:

- Absolute event rates over time (e.g. 10 years) among exposed and non-exposed groups
- RRR (relative risk reduction)

For a case control study:

- OR (odds ratio) for strength of association between exposure and outcome

For a study of a diagnostic test:

- Sensitivity and specificity
- PPV and NPV (positive and negative predictive values)

The box stating 'what is known' and 'what this study adds' should also reflect accurately the above information. Under what this study adds, please give the one most useful summary statistic e.g. NNT.

Please do not use the term 'negative' to describe studies that have not found statistically significant differences, perhaps ...

Comment [A28]: Please include a statement indicating that patients provided informed written consent, if this was obtained. Moreover, the journal requires the following statements:

Transparency statement

Please include in your manuscript a transparency declaration: a statement that the lead author (the manuscript's guarantor) ...

Comment [A29]: It will be helpful if the Results section is structured into sub-sections and presented in the same order and sequence as the Methods. This will improve the flow of the manuscript and allow a reader to remain orientated.

Comment [A30]: When discussing definite quantities of time (i.e., not approximate time periods), Arabic numerals should be used.

revised. Six hips ~~had undergone~~ revision of acetabular components, and the remaining six hips ~~had undergone~~ revision of ~~the~~ acetabular liners. ~~Conventional polyethylene liners had been used~~ For 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~~ We 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 ~~whereof~~ 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 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~~ (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 patientis~~ described above, and ~~t~~ ~~The 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.

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~~ (range, 0.59–0.92) at the distal end

Comment [A31]: You appear to have omitted the scores here. I have inserted “x” as a place-holder; please edit these to include the JOA scores of the patients.

Comment [A32]: There is no need to specify that the radiograph was used for classification, as this is stated previously.

Comment [A33]: End-point definitions should also be provided in the appropriate location in the methods section.

Comment [A34]: The mean CFR value was missing. Please update “x” with the correct value.

of the lesser trochanter and was ~~x~~ (0.59–0.98) at the distal end of the stem. ~~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 CRFR 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%, ~~p~~). ~~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 (~~0~~). ~~We studied possible~~The relationships between metaphyseal fit and outcomes 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

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 with low he~~ rates of stem revision due to loosening ~~were reported low~~ (from 0 to 2.6%). ~~There wer~~Only 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. 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 ~~this~~ 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 comparisons ~~to~~ with our results ~~are was~~ not possible ~~proper~~, because we ~~had did~~ not use ~~d~~ the evaluation methods of Callaghan et al. [12] ~~for a number of reasons~~. In their methods, ~~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 nowould 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~~

Comment [A35]: The mean CFR value was missing. Please update “x” with the correct value

Comment [A36]: Please include results of statistical comparison between the two groups.

Comment [A37]: There appears to be some missing information here. Please check this statement and include the missing information (presumably this would have been the p value).

Comment [A38]: You have included parentheses here but no information. Did you mean to include the p value here? Please either include this information or delete the parentheses.

Comment [A39]: Please note that as per journal guidelines, the Discussion needs to be restructured according to this over all structure, although the use of subheadings is not mandatory:

- Statement of principal findings
- Strengths and weaknesses of the study
- Strengths and weaknesses in relation to other studies, discussing important differences in results
- Meaning of the study: possible explanations and implications for clinicians and policymakers
- Unanswered questions and future research

Please provide the missing information and restructure the Discussion.

Comment [A40]: Please also present the results in “%” to allow easier comparison with results of other studies in the literature, which could be similarly converted into percentages.

~~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 highlow. 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 osteoarthritics hips ~~c~~would 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 ~~causeresult ins~~ poor metaphyseal fit. However, no other stems ~~were as~~ undersized ~~like this case and or~~ showed loosening. Therefore, we ~~think~~ conclude that the usage of undersized stems was not the main reason ~~of for~~ poor metaphyseal fit.

~~The present study had several l~~imitations ~~of this study should be discussed. First, t~~The 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. ~~Second, because inee~~ 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 outeomes after longer followuptime 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, 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 independently ~~by from of~~ metaphyseal fit. This stem, therefore, represents a long-term option for THAtotal hip arthroplasty.

Comment [A41]: Please consider clarifying that the study was conducted in a Japanese population.

Comment [A42]: Please include the following:

Summary boxes

Please produce a box offering a thumbnail sketch of what your article adds to the literature. The box should be divided into two short sections, each with 1-3 short sentences.

Section 1: What is already known on this topic

In two or three single sentence bullet points, please summarize the state of scientific knowledge on this topic before you did your study, and why this study needed to be done. Be clear and specific, not vague.

Section 2: What this study adds

In one or two single sentence bullet points, give a simple answer to the question "What do we now know as a result of this study that we did not know before?"

Comment [A43]: Please be sure to include a reference list at the end of your manuscript, in Vancouver style.

Comment [A44]: Please include and acknowledgements section, transparency statement and statement of the role of the funding source, as per the requirements of the journal.

Comment [A45]: This sentence is my interpretation of the implications of your study – please check that you agree with this, and if not please add a sentence on the implications of the study findings.

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SAMPLE