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ORIGINAL STUDY

A comparative study of Osteal® stem subsidence using EBRA-FCA® method and a specific and original analysis model developed with the Imagika® software

Thierry THIRION, Pierre GEORIS

From the Chirurgie de l'Appareil Locomoteur - Traumatologie, CHU Sart-Tilman, Liège, Belgium

The radiological follow-up is an essential element of evaluation of total hip arthroplasty.
This is a retrospective study based on 71 THA using a cemented Ceraver-Osteal® stem. They were systematically associated with RM® cups in all cases with a ceramic on polyethylene bearing surface. The mean age of patients was 74.4 +/-10.2 years and the mean follow-up was 7.9 +/- 0,9 years. Aetiologies were 61 osteoarthritis, 4 osteonecrosis and 6 femoral neck fractures.
The main purpose of this work is to verify if a subsidence of femoral implants and radiological changes can be recognized in a comparable pattern using EBRA-FCA® method and Imagika® software.
The measured subsidence is 0.05 +/- 0.005 mm / year with EBRA-FCA® and 0.06 +/- 0.004 mm / year with Imagika® (p = 0.74). We did not show significant migration whatever the method used.
The precision of the Imagika® method, thanks to the automatic detection of contours and the use of a correction factor, makes it possible to objectify sub-millimeter migrations of femoral stems. The absence of a significant difference between the two methods makes it possible to validate the Imagika® method.

Keywords : THA stem subsidence ; EBRA-FCA analysis ; Imagika method.

INTRODUCTION

Total hip arthroplasty (THA) is currently an established treatment for osteoarthritis of the hip in elderly patients *(1)*.

THA is a common and successful treatment of patients suffering from severe osteoarthritis. It has been proclaimed that THA is the operation of the last century *(2)*. This surgery reduces pain and improves hip function and quality of live.

Long term success of a cemented stem depends on the longevity of the cement-bone and the cement-prothesis interface *(3)*.

THA can be degraded for numerous reasons, including deterioration of mechanical interfaces, insufficient initial stability, acetabular component wear, or product-induced osteolysis.

In the particular case of cemented prostheses, a series of factors contribute to their success or on the contrary to their failure. The most important factors are patient selection, prothesis design and intramedullary geometry, implant finish surface, type of fixation as well as primary stability (in particular the rotational stability), and surgical technique *(1,4)*.

The Ceraver-Osteal® stem prothesis, (Ceraver, Roissy CDG, France) because of its titanium alloy

■ Thierry Thirion, MD,
■ Pierre Georis
Chirurgie de l'Appareil Locomoteur - Traumatologie, CHU Sart-Tilman
Correspondence : Thierry THIRION, Chirurgie de l'Appareil Locomoteur - Traumatologie, CHU Sart-Tilman, 4000 Liège, Belgium. Fax : +3243667537.
E-mail : tthirion@chuliege.be

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composition, has a bone-like elasticity model that allows an increase in the volume of the implant without increasing its rigidity. This allows a noticeable improvement in constraints transmission *(5)*.

Regarding the analysis of THA results, clinical scores based on the assessment of the functional outcome inform only imperfectly and indirectly on the interfaces stability. The radiological study of implants migration (including stem subsidence and positioning) appears as an essential evaluation element for the follow-up of THA *(6)*. The measurement of early femoral stem subsidence is a reliable indicator of failure in short and mid-terms *(7)*. Migration of more than 2 mm in the first two years following implantation appears to be associated with early implant loosening *(1, 8)*.

However, prediction of long-term implant performance is difficult and definitive results regarding aseptic loosening are only available after lengthy follow-up *(9)*.

The interest of obtaining a great precision in the detection of stem migration is to highlight the radiological signs of implant loosening before the first symptoms appear. The demonstration of an early stem subsidence makes it possible to target the patients who will need a particularly attentive follow-up for a possible surgical revision, carried out in good conditions. The gold standard in 2D method is the Einzel-Bild-Röntgen-Analyse - Femoral-Component-Analysis (EBRA-FCA®) method developed by Russe and improved by Krismer et al *(10)*. To date, the EBRA-FCA® method refers to the detection of femoral implant migration. The sensitivity of the method decreases with time *(7)*.

EBRA-FCA® is based on an algorithm (termed the comparability limit) which selects radiographs comparable in respect of pelvic tilt in both sagittal and transverse axis. This method excludes radiographs from patient measurements series that have more than a preset level of positioning or rotational error and reduces variability secondary to patient positioning *(9)*. Migration (subsidence) is then measured exclusively between highly comparable radiographs. However, it is time consuming and requires proper training of observers *(11)*.

The purpose of this work, in addition to evaluating the results of the Ceraver-Osteal® stem, is to verify if a subsidence of femoral implants and radiological changes can be recognized in a comparable pattern using EBRA-FCA® method and Imagika® software.

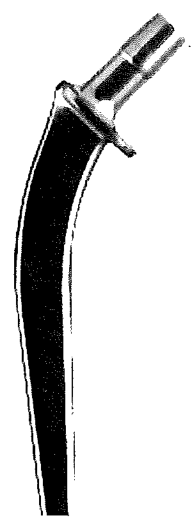

Figure 1.

MATERIALS AND METHOD

We studied 71 primary hip arthroplasties implanted between 02/2001 and 01/2006 in 65 patients using a cemented prosthetic stem of the Ceraver-Osteal® type (Fig. 1).

It is a femoral prosthesis with a Merckelian support collar made of titanium alloy.

They were all associated with RM® cups coated with titanium (Mathys, Bettlach, Switzerland). All stems were combined with prosthetic femoral heads of 28 mm diameter alumina. The average age of the patients at the time of the operation was 74.4 +/- 10.2 years (range : 36.6 to 88.4). There were 59 women and 6 men. The average follow-up is 7.9 +/- 0.9 years (range : 6.2 to 10.1).

Aetiologies were 61 osteoarthritis, 4 osteonecrosis and 6 femoral neck fractures.

All of the surgeries were performed through the posterolateral approach with the patient placed on lateral decubitus.

The clinical evaluation of the patients was performed preoperatively and at the last follow-up according a standardized examination using the Harris Hip Score *(12)*.

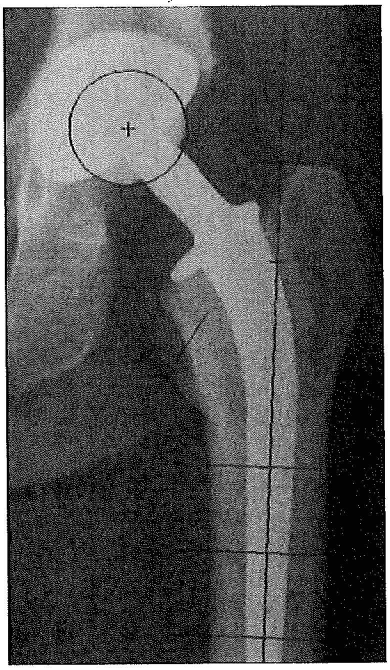

Figure 2.

In the radiographic evaluation, the femoral side was studied in the seven zones of Gruen *(13)*.

The radiographic analysis and the comparative study of the cranio-caudal migration of the stems were carried out with the software EBRA-FCA® and Imagika®.

The EBRA® method is currently the method of choice for studying the migration of hip prosthetic implants based on two-dimensional standard images.

The EBRA-FCA® software is an adaptation of the EBRA® method allowing the measurement of the migration of the femoral component from standard radiographs. Measurements are taken directly on digitized radiographs. This technique requires knowledge of the diameter of the femoral head in order to calibrate the images according to the radiological magnification. Nineteen reference points are introduced to characterize the position of the femur and the implant. From this data comes information such as the sinking and tilting of the stem. This program uses three parameters to judge the comparability of X-rays. EBRA-FCA® claims a precision of 1.5 mm or even a minimum of 1 mm for its method *(14-16)*. For the EBRA-FCA® method, a minimum of 4 comparable digitalized radiographs

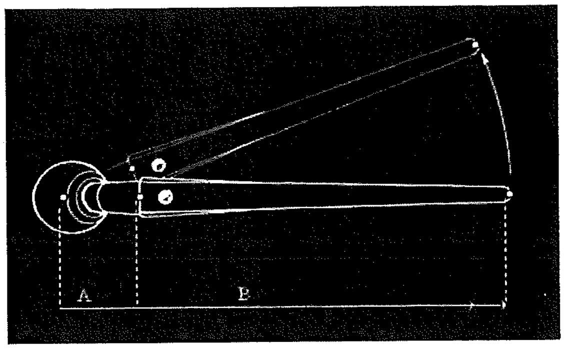

Figure 3.

are mandatory. An electronic coordinate system is placed on the x-rays to localize cup, stem and bone or prosthetic landmarks (Fig. 2).

The Imagika® method, partly developed in the orthopedic department of the University Hospital of Liège, operates on a basic principle similar to that of EBRA-FCA®. It is faster and easier to use for the hospital practitioner. Within Imagika® a specific analysis model has been developed for the Ceraver-Osteal® stem appropriate to its geometry. It uses the vertex of the greater trochanter and the lateral end of the greater trochanter as reproducible bone markers ; the prosthetic landmark was the lower part of the collar. To develop this program, three analytical models were created to determine the different bone and prosthetic landmarks to be used, and to evaluate the possibility of using a correction factor (Fig. 3) to increase comparability because successive radiographs were not taken under standardized conditions. In an orthogonal projection, the variation of distance between the center of the prosthetic head and the collar of the stem (A) and its projection (A') determines a constant value k (A/A'=k). In theory, the distance between the center of the prosthetic head and the tip of the stem (B) is equal to its measured projection (B') multiplied by the previously determined constant k value (B=kxB'). The accuracy of this method is greater than 1 mm if the vertex of the greater trochanter is used as bone marker.

RESULTS

Harris scores were respectively 62.24 and 96.53 preoperatively and at the last follow-up.

In our series, we deplored 2 hip dislocations, 1 hip algodystrophy, 1 socket loosening and 1 deep infection. Fortunately, no femoral revision due to aseptic loosening or specific complication involving the stem component were observed.

We observed radiolucent lines around the stem in two prostheses ; 1 of 1 mm in Gruen zone 1 and 1 of 1 mm in Gruen zones 1 and 7 (Fig. 4).

Seventy-one stems (100%) were studied with the Imagika® software while 65% (46 hips) were rejected by the EBRA-FCA® method because of the absence of complete radiological follow-up consisting of 4 comparable radiographs.

The cranio-caudal migration measured for the whole series is 0.05 +/- 0.005 mm / year with EBRA-FCA® and 0.06 +/- 0.004 mm / year with Imagika® respectively (p = 0.74). We could not highlight significant migration (Fig. 5).

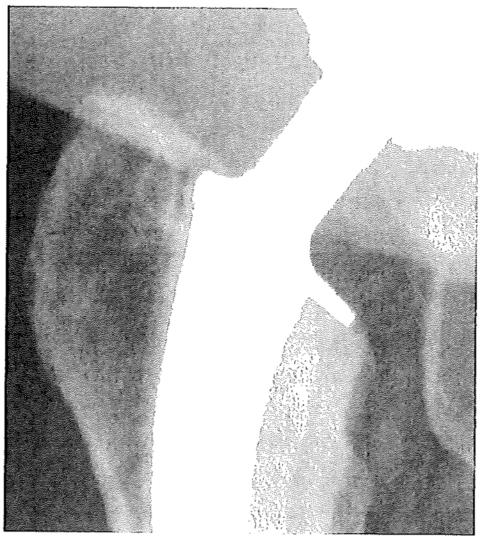

Figure 4.

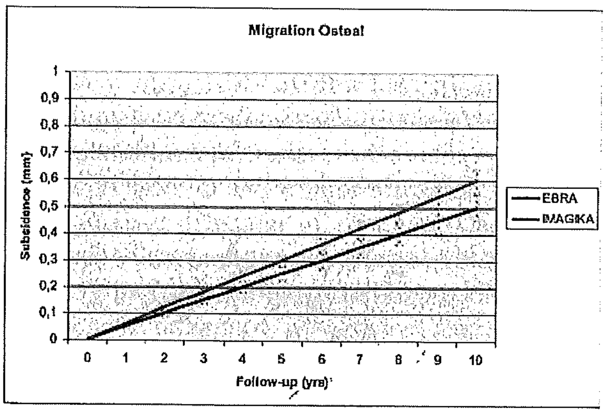

Figure 5.

DISCUSSION

We present a retrospective study with a clinical and radiological analysis of 71 cemented Ceraver Osteal® prosthetic stems using EBRA-FCA® and Imagika® analyses.

The results of our series are consistent with the literature data. As in the series of Osorovitz and Goutallier *(5)*, we did not experience a material fracture. In contrast to their series, we did not have a surgical revision directly related to loosening of the femoral implant. The relative frequency of periprosthetic edgings does not appear to be increased.

Berry *(4)*, in his study, identifies the most important factors influencing the success and survival of a cemented femoral implant. The young and male subject has an increased risk of failure with a cemented prosthesis. The geometry of the implant, in addition to its role in primary stability, determines the distribution of the cement mantle. A smooth implant minimizes the abrasion of the cement coat. It is usually the combination of geometry and surface finish that makes or breaks its success. At the moment, there is no consensus on the type of ideal surface. Extramedullary geometry (femoral neck design, neck length, and femoral offset) is important in terms of stability, biomechanics, and can be a source of neck / cup conflict. Finally, the surgical technique is essential for the preparation of the intramedullary canal, the centering of the prosthetic stem and the cementing phase.

Changes in the geometry and finish of cemented femoral implants have been proposed in the hope of improving the results obtained with the first Charnley prostheses *(17)*.

Gravius et al *(18)* in an in vitro study with 6 femoral stems of different geometry conclude that the design of the cemented femoral stem influences the cement / metal, cement / bone contact and the failure rate of the cement mantle.

Conversely, for Jewett and Collis *(17)*, the geometry of the implant does not influence the rate of loosening or radiographic failure.

Since the 1970s, cemented rods with rough surfaces have been developed in the hope of increasing cement contact with the implant *(19)*. Rods with a roughness exceeding 63.5μm have an increased failure rate *(20)*. In contrast to rough stems for which the prosthesis / cement interface is a problem, the smooth stems are more likely to show loosening at the cement / bone interface *(7,17)*.

Aseptic loosening is the main cause of recovery of total hip arthroplasty. It is therefore extremely important to be able to decide as soon as possible on the fate of the implants *(21,22)*.

The evolution of a total hip prosthesis is usually reported with reference to the clinical result. The surgeon has a series of scales to assign a clinical score. The most used are those developed by Merle d'Aubigné and Postel *(23)* in 1958, Harris *(12)* and the listing of the Hip Society *(24)*. The latter is much less employed.

All of these clinical scores consider pain, which is the most important parameter, hip mobility and walking ability. These do not always reflect the current situation at the bone-cement and cement-implant interface, nor at the level of the joint torque. In their series, Van Goethem et al *(1)* find no correlation between the Harris score and the importance of migration.

In addition, clinical monitoring does not allow evaluation of new implants or new techniques.

The radiological evaluation is unanimously approved for monitoring PTHs. The radiological changes and in particular those related to polyethylene wear and the resulting debris of particles, remain asymptomatic for a long time and only the loosening of the implants will have a clinical manifestation *(25)*. The average recovery time between the onset of the first signs of loosening and the clinical deterioration of the patient is 3.3 years in the Jewett series *(12)*. This delay is 3 years in the series of Kroell et al *(7)*.

Bone loss is a major complication of PTH. This has a detrimental role in the long-term survival of prostheses *(26)*.

Regular radiographic follow-up will make it possible to propose to the patient an operation under good conditions before major bone damage appears. It also makes it possible to discard fairly quickly the use of implants with inadequate early or midterm mechanical behavior. The study of early migration of prosthetic components can quickly provide significant information on implant fixation. Walker et al *(27)* demonstrated the predictive value for late loosening of migration at two years follow-up : 84% of the stems that subsequently loosened had migrated more than 2 mm at 2 years.

Freeman and Plante-Bordeneuve *(28)* showed that, by taking a 1.2 mm migration at 2 years as the threshold value, late loosening could also be predicted, with a specificity of 86% and a sensitivity of 78%. De Vries et al analyzed 15 different stem designs and reported 1.24 mm for polish cemented stems as the cut-off for late aseptic loosening *(29)*.

Measurements for cemented shape-closed stems on normal radiographs has a lower accuracy compared to software-based methods *(3)*.

The study of the migration of prosthetic stems appears to us as an essential element of radiological monitoring. Previously, it was only feasible on radiological films by the use of simple methods (superposition of successive radiographs). Currently, thanks to advances in computer technology and the availability of digital radiographs, the clinician prefers the use of powerful software that is much more accurate and reliable than traditional methods. However, they remain more time consuming and therefore difficult to use routinely. Among these, we favor EBRA-FCA® and Imagika® methods.

At two years of follow-up, the migration is estimated at 0.05 +/- 0.005 mm / year with EBRA-FCA for the Ceraver-Osteal® stem, which compared to the literature is excellent.

Van Goethem et al *(1)* obtained an average migration of 0.25 mm at 2 years for the Fulfix® stem (Mathys) associated with an RM® cup.

In our series, as in Van Goethem et al *(1)*, there is no learning curve ; the results of the stems implanted at the beginning are comparable to those of the last ones.

In order to be as accurate as possible, the complete radiographic record of a patient must be rigorously homogeneous in terms of comparability. EBRA-FCA® has an algorithm that rejects non-comparable X-rays, unlike Imagika®, which considers all the images.

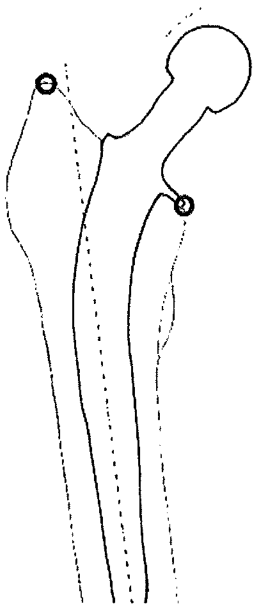

Figure 6.

To make X-rays comparable, Imagika® uses the use of a correction factor (Fig. 3). We have seen in preliminary studies carried out in the research laboratory of orthopedic surgery of the University Hospital Sart-Tilman (Liège, Belgium) that the standard deviations of prosthetic stem insertion measurements are more important for those presenting a more curvilinear silhouette, making the placement of the prosthetic reference less reproducible. Despite this difficulty, the measures taken by Imagika®, for which we can create an analysis model specific to each stem shape, did not show significant differences compared to those obtained with EBRA-FCA® (Fig. 6).

Following these observations, we consider the Imagika® software as a reliable and reproducible method of analysis for the study of femoral implant migration. It is simple to use, therefore better suited to a daily clinical activity.

The precision of the Imagika® method, thanks to the automatic detection of contours (Canny Edge Detector Filter) and the use of a correction factor (Fig. 3) to increase comparability of successive radiographs, makes it possible to objectify sub-millimeter migrations of femoral stems. The absence of a significant difference between the two methods makes it possible to validate the Imagika® method.

We believe that our study has two limitations. The first one is related to the sample size. Only 65 patients were included into the study because of the radiological follow-up available to perform EBRA-FCA measurements. The other one is that collared stems enhance implant stability and then reduce theoretically the risk of stem subsidence.

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