



Expectations and outcome of a scientifically developed hip prosthesis in 170 hips with a follow-up of 5-12 years

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The study was performed in Medical Centre Leeuwarden, The Netherlands

Roentgen stereophotogrammetric analysis (RSA) is commonly used to assess prosthetic stability as a predictor of the long term clinical outcome of new total hip systems. Although the RSA technique is very accurate, it may not be trivial to interpret migration rates into clinical outcome, as critical migration rates depend heavily on the design of the prosthesis.

In the present study we describe the clinical results of the Scientific Hip Prosthesis® (SHP), which had unexpectedly high migration values in a clinical RSA study. We evaluated the clinical results of a single surgeon study consisting of 170 hips with a follow-up of 5-12 years (mean : 8.3 years). The survival rate was 98.8% at ten years for aseptic loosening of the stem. This study therefore indicates that a prosthetic design may function clinically rather well although relatively high migration rates have been reported. The prediction of clinical survival of new prosthetic components remains a challenging task and the interpretation of migration rates with new designs should be considered with much caution.

Keywords : total hip arthroplasty ; RSA ; survival analysis ; design techniques.

INTRODUCTION

New cemented hip systems are constantly developed to improve upon existing systems. When designing new implant systems it is highly relevant to assess the relationship between initial design rationale of existing systems and long-term clinical results. This way, one can learn how design charac-

teristics influence the ultimate clinical results.

In the late eighties a new stem (Scientific Hip Prosthesis®, SHP) for total hip replacement was developed by a Dutch engineering company (Ortech BV) and the Orthopaedic Research Laboratory of the Radboud University Medical

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Two authors were involved in the design process of the SHP, currently there is no conflict of interest as the SHP is off the marketplace.

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Centre in Nijmegen. The philosophy was that total hip prostheses commonly failed due to aseptic loosening of the cement-bone interface and that this could be prevented by smoothing of cement-bone interface stresses. The introduction of the SHP prosthesis was performed in a stepwise fashion as proposed by Huiskes (9). Firstly, it was examined whether the design rationale was achieved through design confirmation studies using finite element modelling and photo-elastic stress analysis. Secondly, the prosthesis was tested to assess the failure potential by stem fatigue testing and measuring cement strains (17). Thirdly, the implant was tested in patients to assess the clinical results. The power of this clinical trial was improved by using roentgen stereo-photogrammetric analysis (RSA) which allowed accurate quantification of the migration of the implant relative to the bone and/or cement mantle (13).

Nivbrant *et al* (16) published the RSA results of a direct prospective comparison study of the SHP and the Lubinus SPII stem. The hypothesis in this study was that migration of the SHP stem should be equal or less than that of the Lubinus SPII stem, which was one of the best performing cemented hip implants in Sweden. This was an adequate statement, because both stems were designed to be completely bonded to the cement and not to migrate. The study showed an average subsidence of 0.6 mm for the SHP stem and 0.1 mm for the Lubinus SPII stem at two years follow-up. There was also considerable difference in rotational (ante-retroversion) stability. The Lubinus SPII stem had an average retroversion-rotation of 0.3° and the SHP stem 2.6° in retroversion at two years follow-up. Their conclusion was that this was an ominous sign and that the SHP prosthesis was not the preferred stem to use, even though they found no difference in Harris hip score and pain score between the Lubinus SPII and SHP at short-term (2 years) follow-up.

The migration results in the RSA study showed that the SHP prosthesis had an inferior stability relative to the Lubinus SPII implant, which may be a negative sign. However, is it certain that this will lead to inferior clinical results on the longer term? The answer to this question can only be obtained by a longer-term clinical study.

Parallel to the study of Nivbrant *et al* (16), another clinical single surgeon study with the SHP prosthesis was started by one of the inventors and co-authors of this paper (JY). This article is the first to publish the clinical results of this series with a 5-12 years follow-up.

The question addressed in this article is whether short term high RSA migration values, obtained for a specific device, predictably lead to inferior clinical results for the longer follow-up.

Development of the Scientific Hip Prosthesis

The SHP stem was designed and developed between 1986 and 1990 using computational Numerical Shape Optimization (NSO) (8). This is a computational method in which a finite element model (FEM) is used to calculate cement-bone interface stresses. The FEM model was 2D (Fig. 1), using a side plate to account for the 3D structural integrity of the bone.

The NSO was used to vary the shape of the stem and subsequently calculate the cement-bone interface stresses, assuming a bending moment on the centre of the head. The cement-prosthesis and cement-bone interface were assumed completely bonded. The goal was to find the optimal shape with the lowest cement-bone interface stresses. The resulting shape after NSO had a wider middle part and a taper shape proximally and distally (Fig. 1). The optimal shape can be explained by the material properties; since the cement mantle is much more flexible than the cortical bone and stem material, the cement acts like a “shock absorber”. In the regions with the highest cement stresses, at the far most proximal and distal areas, the thickest cement mantle is needed to reduce the interface stresses. After NSO, the final shape model was again evaluated by calculating the stresses under axial, shear and bending forces. The stresses generated with this stem were compared to the stresses generated by the Precision Hip® (Howmedica Inc.), since this hip design generated relatively low interface stresses (8). The stresses were considerably lower when using the SHP stem (Fig. 2). This was later confirmed in an *in vivo* study of Peters *et al* (17), who showed lower cement strains in the proximal region

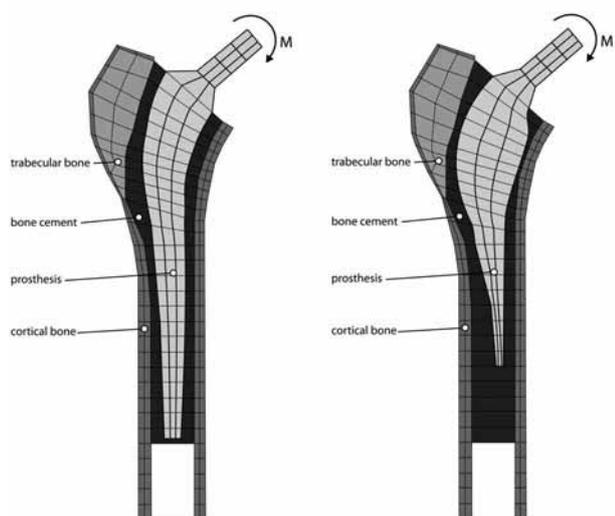


Fig. 1. — 2D FEM side-plate model used as initial shape for NSO and the resulting shape after NSO.

around the SHP stem as compared to the Centralign[®] hip prosthesis.

The final shape of the SHP stem had a belly like middle part, a slim distal stem and a narrow tip which was located centrally in the femoral canal. From a lateral view the prosthesis was curved in order to follow the postero-curvature of the femoral metaphysis. At the lateral side a flange was applied to produce maximal compressive stresses in the cement mantle (*l*) and to give extra rotational stability.

A collar was considered unnecessary since the common thought, at that time, was that the cement-prosthesis interface was completely bonded. To improve bonding strength at the locations with the highest interface stresses, the proximal and distal ends of the prosthesis were roughened.

To determine the stem material, calculations were performed for titanium (Elastic Modulus 1.1×10^5 MPa) and CoCrMo alloy (Elastic Modulus 2.0×10^5 MPa). The peak stresses were almost twice as high in the titanium model. Therefore, CoCrMo alloy was chosen for the SHP stem.

To assure central positioning of the stem in the reamed canal and reproducible cement thickness, four spacers of polymethyl methacrylate (PMMA) were placed at the widest part of the stem and distally a stem centralizer of PMMA was added. The



Fig. 2. — Cement-bone interface stresses for axial loading of the Precision Hip[®] (dark grey) and Scientific Hip Prosthesis[®] (silver).

final prosthesis is shown in Figure 3 and was named the Scientific Hip Prosthesis[®]. This prosthesis was manufactured by Pro-Motion BV, at Zwijndrecht, The Netherlands.

MATERIAL AND METHODS

Patients

Between October 1991 and April 1995, 170 total hip replacements (154 patients) were performed with the Scientific Hip Prosthesis[®] stem, combined with a cemented polyethylene cup (SHP acetabular component). Patients were excluded if one or more of the diagnoses described in Table I were met.

This is in accordance with the guidelines of the SICOT, the AAOS and the Hip Society (11,14). Ethics Committee approval was obtained. The minimal follow-up of the analyzed group was 5 years and the maximum 12 years. The clinical details and preoperative diagnosis of all patients are listed in Table II.

Surgical procedure

Surgery was performed by one of the inventors (JY) using the posterolateral approach in the lateral decubitus



Fig. 3. — The Scientific Hip Prosthesis manufactured by Pro-Motion BV.

position. The insertions of the gluteus maximus and psoas muscle were saved and the short external rotators were repaired. All patients were administered systemic antibiotic and thromboembolic prophylaxis. Diclofenac, 3×25 mg, was given to all patients during the first 2 weeks postoperatively, to prevent ectopic bone formation. Medium viscosity, radiopaque cement (Sulfix-60) was applied in all cases. The cement was mixed at room temperature using the Optivac vacuum mixing system. A cement plug was introduced and the intramedullary canal was extensively cleaned using pulsatile lavage. The cement was introduced by retrograde injection with a cement gun, followed by pressurizing during one minute. Then the prosthesis was inserted and the cement was cured under constant pressure (manual proximal sealing) with accurate positioning by the surgeon.

Clinical data collection and follow-up

The clinical results were registered on standardised forms, according to the consensus of the Commission of

Table I. — Patients exclusion criteria

General	Specific
Active infection	Revision arthroplasty
Severe obesity	Arthrodesis
Alcohol/Drug addiction	Destruction of bone femur/acetabulum
Renal insufficiency	Loss of musculature
Systemic/Metabolic disorder	Neuromuscular compromise
Severe skeletal disorder	Vascular deficiency in the affected area
	Surface replacement
	Untreated polyarthrosis
	Local osteomyelitis

Table II. — Details of the 154 patients surviving more than 5 years

	Hips	Patients
Number	170	154
Gender (%)		
<i>Male</i>		33 (21%)
<i>Female</i>		121 (79%)
Mean age at surgery		68.9 (42.1-86.3)
Diagnosis (%)		
<i>Osteoarthritis</i>	158 (92.9%)	
<i>Inflammatory arthritis</i>	6 (3.5%)	
<i>Avascular necrosis</i>	3 (1.8%)	
<i>Sec. osteoarthritis</i>	2 (1.2%)	
<i>Acute fracture</i>	1 (0.6%)	
Number lost to follow-up	13	11
Number died	33	32
Follow-up in years	8.2 (SD 2.2)	

Documentation and Evaluation of the SICOT, the Task Force of Outcome Studies of the AAOS, and the Hip Society (11,14). Clinical and radiographic evaluations were performed preoperatively, at 1 week postoperatively (only radiographic examination), at 3 months postoperatively and at 1, 2, 3, 4, 5, 7, 10 and 12 years postoperatively. A Harris Hip score (5) was recorded : a score of 90-100 points was considered to be excellent, 80-89 as good, 70-79 as fair, and less than 70 as poor.

Unfortunately, the stems were not clinically assessed anymore after a cup revision of the same hip had taken

place. We therefore had to note these cases of cup revision as 'lost to follow-up'.

All clinical examinations were performed by the surgeon (JY).

Radiographic analysis

The radiological outcome was assessed using antero-posterior radiographs of the pelvis and lateral views of the affected hips. The prosthesis-cement and the cement-bone interfaces and the presence of cysts and osteolysis of the surrounding bone were described in all Gruen zones (4). The vertical migration of the stem was measured, on plain radiographs, at the centre of the head in relation to the tip of the greater trochanter along the femoral axis. The measurement error of this method was calculated to be 9.8 mm by using a regression model analysis. Hence, this error was also high due to the fact that we could not use other features of the stem such as the shoulder, which is quite accurate for migration measurements (3,18). It was concluded that stem migration could not be measured in this way and therefore no measurements were performed anymore.

Nevertheless, radiographic loosening of the stem was defined according to Harris *et al* (6) with the following classification: A femoral component was considered *definitely* loose if there was a clear subsidence of the femoral component (with or without cement) visible on the radiograph, cement or stem fracture, or clearly visible separation between stem and cement. A stem was defined as *probably* loose if there was a continuous radiolucent line at the cement-bone interface, surrounding the entire cement mantle, on either an anteroposterior or a lateral radiograph. *Possibly* loose was defined as a radiolucent line on the cement-bone interface that was present along more than half of the circumference of the cement-bone interface.

On follow-up the ectopic bone formation was graded according to the Brooker criteria. Brooker I means islands of bone, Brooker II means spurs < 1 cm, Brooker III means spurs of > 1 cm, and Brooker IV means ankylosis.

All radiographic analyses were performed by the surgeon (JY).

Statistical Methods

Kaplan-Meier survival analysis was performed for the entire group with three different end-points: 1) revision of the femoral component for aseptic loosening; 2) revision of the femoral component for any reason (including aseptic loosening); 3) radiographic failure ("*definitely*, *probably* and *possibly* loose").

RESULTS

Clinical Results

During follow-up 32 patients (33 hips) died, 6 patients (6 hips) were revised because of cup failure and 11 patients (13 hips) stopped coming to the clinic. The latter patient group (11 patients; 13 hips), was contacted by telephone and all patients stated that travelling to the clinic had become a problem for other reasons than problems with the prosthesis. The mean follow-up was 8.2 years (5.0-12.0). The mean Harris Hip Score at 10 year follow-up was 89.2 ± 7.5 . The Harris Hip Scores during follow-up are given in Table III.

Not all patients came to the clinic according to the scheme. They sometimes did not appear at the planned check-up. This resulted in 161 patients who came to the clinic 5 years after the operation. Three of the missing nine were revised and the other six came at 6 years. Since this moment is probably not representative for 5 years of follow-up, they were not included in the calculation of the Harris Hip Score at 5 years. This explains the varying numbers at different follow-up moments.

Complications

During surgery a fracture of the greater trochanter occurred in one hip, without any consequences.

In total, dislocation occurred in 5 hips. All of them were treated with a brace for 3 months. Dislocation recurred in one, in which the cup was revised. One patient suffered a cerebrovascular accident a few days post-operatively. Two patients developed a large haematoma around the wound.

Stem revisions

Six stems (3.5%) had to be revised for any reason (Table IV). Aseptic loosening occurred in two hips which were revised at 3.8 and 4.6 years postoperatively. A fracture of the cement occurred around the prosthesis in one hip, a periprosthetic fracture in another two hips. All three fractures were caused by a fall at 3.8, 5.2, and 9.8 years postoperatively,

Table III. — Harris Hip Score preoperatively and at follow-up, divided in performance groups

Follow-up	N	Mean	SD	% poor	% fair	% good	% excellent
(Harris Hip Score)				< 70	70-79	80-89	90-100
Preoperatively	170	49.4	11.1	96.5	2.3	1.2	0.0
3 months	170	84.5	8.1	1.8	17.1	55.9	25.2
1 year	167	91.8	7.7	2.4	3.0	21.0	73.6
2 years	166	92.2	5.9	0.6	3.6	23.5	72.3
3 years	167	91.7	7.3	1.8	3.6	22.2	72.4
4 years	166	91.5	7.2	1.2	1.8	27.1	69.9
5 years	161	90.1	6.9	1.9	5.6	26.1	66.5
7 years	134	89.0	8.5	3.0	13.4	20.1	63.4
10 years	58	89.2	7.5	1.7	12.1	24.1	62.1
12 years	14	84.8	11.1	7.1	21.4	28.6	42.9

Table IV. — Summary of revised stems

Revision	Reason	Period	Operation
1	Aseptic loosening	3.8 yrs	Stem revision
2	Aseptic loosening	4.6 yrs	Stem revision
3	Fracture of cement due to a fall	3.8 yrs	Stem revision
4	Fracture of femur due to a fall	5.2 yrs	Stem revision
5	Fracture of femur due to a fall	9.8 yrs	Cerclaging of the fracture
6	Neck fatigue fracture of prosthesis	6.6 yrs	Stem revision

respectively. One stem was revised because of a fatigue fracture of the neck of the prosthesis at 6.6 years postoperatively.

Cup revisions

Four cups had to be revised, which were removed from the study and indicated as “lost to follow-up” at 6.7, 7.7, 7.9 and 9.2 years. All cups were revised for aseptic loosening and in all cases there were no signs of a stem loosening during the operation. Since this article focusses on the results of the stem, the failure of the cup is not used in the calculation of the stem survival.

Radiographic results

A total of five stems (all part of the 6 revised stems, see Table IV) showed signs of definitive loosening. Two of these stems (revisions 1 and 2)

showed signs of aseptic loosening at respectively 2.2 and 3.1 years follow up. Revision 1 showed a fracture in Gruen zones 1 and 7, at 3.1 years follow up. This stem was revised at an early stage. Revision 2 showed a fracture in Gruen zone 1, at 3.1 years follow up. Since the patient had no complaints and no other signs of loosening were present, this stem was left *in situ*. At 4.6 years of follow-up, there was also a fracture visible in Gruen zone 2 and there was also a radiolucent line visible around the whole prosthesis. Therefore, it was graded as definitively loose and was revised.

Revisions 3, 4 and 5 showed signs of definitive loosening due to fractures of the cement and/or the femur. The loosening of these stems was due to a trauma and were therefore not graded as aseptic loosening.

Revision 3 presented with a fracture of the cement mantle in Gruen zones 3 and 5 following a fall at 3.8 years of follow up. Revisions 4 and 5

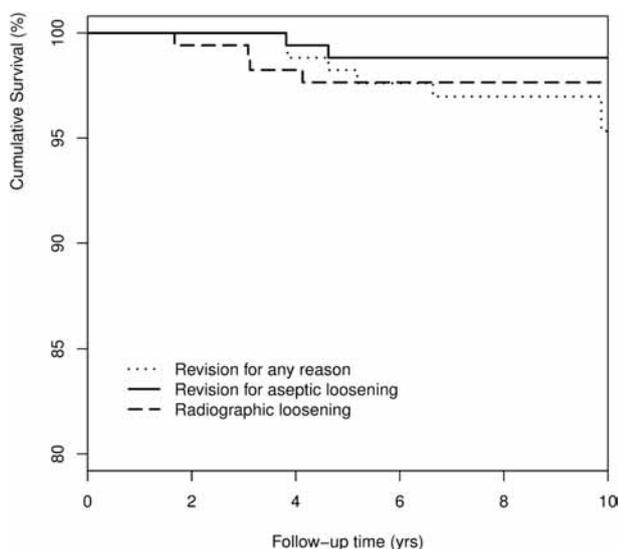


Fig. 4. — Survival curves, derived using Kaplan-Meier analysis.

presented with fractures of the femur following a fall.

None of the stems showed signs of probable loosening.

Finally, two stems showed signs of possible loosening. One of them was later revised (revision 4), because of a fracture of the femur one year after the first signs of possible loosening (radiolucent lines with a width of 1 mm in Gruen zone 1, 3, 4, 5 and 7). At the time of revision the stem showed signs of definitive loosening. The other stem showed the first signs of possible loosening at 12 years follow-up: radiolucent lines with a width of 1 mm in Gruen zone 3, 4, 5, 10, 11 and 12. At that time, the patient had no complaints and the stem was not revised.

One patient had ectopic bone formation, Brooker II, visible at 1, 2 and 3 years follow-up. At 4, 5 and 6 years follow-up it was no longer visible.

Survival analysis

The survival curves were calculated to a maximum of 10 years (58 patients), because of the limited number of patients (14) that had a follow-up of 12 years (Fig. 4). With revision of the stem for aseptic loosening as the end point, the stem survival

rate was 98.8% at ten years (95% C.I., 97.2% to 100%). In the period of 5-10 years follow-up there were no aseptic failures.

With revision of the stem for any reason as the endpoint, the survival rate was 95.3% at ten years (95% C.I., 91.3% to 99.5%). With radiographic loosening as the end point, the survival rate was 97.7% at ten years (95% C.I., 95.4% to 100%).

DISCUSSION

Until now, this is the only study reporting the mid-to-long term follow-up results for the Scientific Hip Prosthesis®. Although the stem of this prosthesis is no longer in use, it is interesting to evaluate the relation between the RSA results and the clinical results.

The high subsidence in the RSA study of Nivbrant *et al* (16) led to the hypothesis that the prosthesis would produce a lot of abrasive wear and high cement stresses, subsequently leading to early aseptic loosening of the prosthesis. The data collected in the present study does not support this hypothesis. Revision as a result of aseptic loosening was necessary in only two of the 170 prostheses implanted. The survival analysis showed results similar to other cemented hip prostheses (6,7,15).

Considering the clinical functional scores, the results show that initially, the mean Harris Hip Score improved from 49.4 preoperatively to 91.8 one year after operation. The score was rated as good or excellent in 94.6% at one year and in 86.2% at ten years follow-up. This is equal to or even better than other cemented hip prostheses (12).

The average follow-up period of this report is 8.3 years, which is relatively short. Reports have shown that there might be a tendency for a sand-blasted prosthesis, like the Spectron-EF®, to have a reasonably good survival at 8 years of follow-up, but which deteriorates quickly after this time (2). The deterioration of the HHS at 12 years of follow-up could be interpreted as an indication that this is also the case for the SHP system. However, the mean age at 12 years of follow-up is over 80 years. It is well known that the HHS deteriorates with age. So, the lower HHS is most likely caused by the high age of the patients.

Another obvious limitation of this study is that it is a single surgeon study with a relatively small number of hips, a relatively short follow-up period and no use of RSA. All the radiographic and clinical examinations were performed by the surgeon/inventor of the prosthesis. This makes the study prone to bias and it is well known that outcomes tend to be poorer in independent studies. Nevertheless, unpublished survival data of the SHP in another hospital with one surgeon only, showed a survival rate of 100% at 10 years follow-up (personal communication).

In the RSA study of Nivbrant *et al* (16), two prostheses showed fracturing of the cement mantle around the belly shaped middle part of the prosthesis (Gruen zone 1). In the present study radiolucent lines were also seen in Gruen zone 1 in revisions 1 and 2 which were performed because of aseptic loosening. Hence, this failure mechanism was apparent in both studies and can perhaps be explained by the limited strength of the thin cement mantle in this region. Third generation cementing techniques should be used to reduce the susceptibility of the cement to fracture.

The SHP was designed to be completely fixed and not to subside. However, as seen in a study of Kärrholm *et al* (12) all prostheses subside, but this does not automatically lead to poor clinical outcome as also seen in the study of Nivbrant *et al* (16). The pattern of subsidence depends on the type of prosthesis. In general, there are two types of cemented prosthesis designs: shape closed and force closed as proposed by Huiskes *et al* (10). A shape closed fixation design implies the objective of providing immediate stability by a match of shapes. An example is a prosthesis with a wide collar, like the Lubinus SPII, to be positioned on the calcar. Such a design is not supposed to subside postoperatively. A force closed fixation design is meant to obtain its stability by the action of forces. An example is the press fit cone fixation of a metal head on a femoral neck. A straight, tapered, polished stem, like the Exeter, meant to subside gradually for the accommodation of cement creep, can be seen as a force closed fixation design. The SHP has features of both shape and force closed designs. Similar to a shape closed stem, it is not

meant to subside, and the distal part has a very strong taper shape as mostly seen in force closed designs like the Exeter. This may explain why the migration values of the SHP are in between those of the Lubinus SPII and the Exeter.

In conclusion, the question proposed in the introduction whether high RSA migration values of a specific stem design on the short term predict inferior clinical results on the long term, should be answered negatively. The survival and Harris Hip Scores of the SHP hip system were good to excellent at ten years follow-up.

So, although RSA studies are a proven method for the prediction of early loosening in prosthesis with a known 'typical' migration pattern (13), it is difficult to predict early loosening when the 'typical' migration pattern is not known. Therefore, the interpretation of migration rates with new designs should be considered with much caution.

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