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ORIGINAL RESEARCH ARTICLE

Long-term results of total hip arthroplasty with the CementLess Spotorno (CLS) system

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ABSTRACT

Background: This study presents the long-term results of the Cementless Spotorno (CLS) total hip arthroplasty system and an analysis of factors associated with clinical and radiographic outcome.

Methods: We studied a series of 120 consecutive CLS arthroplasties in a young patient group (mean age at surgery: 55.9 ± 5.9 years). The Merle d'Aubigné-Postel score, polyethylene (PE) wear, and radiographic status were recorded during follow-up. Survival analyses, repeated-measures analysis of variance, and a nested case-control study were used for statistical evaluation.

Results: After a mean follow-up of 14.6 years (range 0.1-24.2 years, including revisions and lost to follow-up), 24 revisions had been performed, 16 of which for aseptic cup loosening. Kaplan-Meier survival analysis showed a 24-year survival of 72.8% (95% CI, 63.0%-82.6%) with revision for any reason as endpoint, and 80.1% (95% CI, 70.9%-89.3%) for revision for aseptic cup loosening. Mean final Merle d'Aubigné-Postel score was 16.1 points (range 7-18). Mean PE wear at final follow-up was 2.3 mm (range 0.6-6.8 mm). A higher rate of PE wear was associated with better clinical scores but also with revision for cup loosening. Factors associated with more PE wear were: younger age at surgery; 32 - mm head; longer follow-up; and steeper inclination angle.

Conclusions: Beyond 10 years, the CLS stem is reliable, but the high revision rate for aseptic cup loosening is concerning, specifically with better performing (cementless) alternatives available.

Keywords: Follow-up study, Hip prosthesis, Osteoarthritis, Survival analysis, Treatment outcome

Introduction

Total hip arthroplasty (THA) improves the quality of life in patients with osteoarthritis and is regarded as the most efficient and cost-effective surgical procedure (1). Long-term follow-up evaluation of different designs of THA implants is important, especially since patients are increasingly undergoing surgery at a younger age, and life expectancy is increasing. By gathering this information, the optimal implant for a patient may be selected and suboptimal choices, as has been shown for e.g. metal-on-metal bearings, can be avoided (2).

In this study, we present the long-term results (>20 years) of the Cementless Spotorno (CLS) THA system, and an analysis of factors associated with clinical and radiographic outcome.

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Methods

Between 1989 and 1997 a consecutive series of 120 CLS THA procedures were performed in 96 relatively young patients at our institution (Meander Medical Centre). In a previous study, we reported the results of 102 THAs in 81 patients, with follow-up until 2007 and a 15-year survival of 78.4% (95% CI, 63.9%-92.9%) for revision for any reason (3).

In the current study, we report the results of all 120 THAs, with additional follow-up until January 2014, now including 24-year survival analyses.

Patients

Baseline inclusion criteria were: age ≤66 years at surgery; primary THA for osteoarthritis, rheumatoid arthritis, or femoral head osteonecrosis; and a femur suitable for the CLS stem (3, 4). Baseline exclusion criteria were: malignancies in the 5 years prior to index THA, no informed consent, and a neurovascularly compromised lower limb. Only patients who did not have a revision procedure were invited for additional long-term follow-up evaluation in the period between June 2012 and January 2014.

The Institutional Review Board approved all stages of the study. Informed consent was provided by all patients.

Implants and procedure

The CLS system consists of a cementless, collarless 3-D tapered wedge titanium press-fit femoral stem, and a cementless titanium-alloy expanding acetabular cup. The neck-shaft angle of 145° was the only available size at the time of implantation. A 28- or 32-mm Biolox ceramic head (CeramTec), was used in all hips. For more information on the CLS implant, we refer to our previous article (3).

2 orthopaedic surgeons (H.G.W. Vermeer and A.F.W. Barnaart) performed THA using a posterolateral surgical approach. Standard antibiotic and antithrombotic prophylaxis consisting of cefazolin (3 doses of 1g each, starting 30 minutes before surgery) and warfarin (for 6 weeks after surgery) was used. Heterotopic ossification prophylaxis (indomethacin for 5 days after surgery) was used for men and for patients who had previous hip surgery. Patients received standard postoperative care, including pain medication and physical therapy. Full weight-bearing was permitted immediately after surgery.

Clinical and radiological evaluation

Patients were invited for a preoperative visit and for postoperative follow-up visits on a regular basis. For the additional long-term follow-up visit for the current study, patient addresses were acquired using the hospital information system. If patients had moved, contact information was updated via the general practitioner. For deceased patients, the general practitioner was asked whether the patient had undergone revision surgery in another hospital.

Patients were clinically evaluated according to the Merle d'Aubigné-Postel score, as modified by Charnley (5, 6). This score consists of 3 items; hip pain, hip motion, and walking ability. The scores for each item range from 0 points (maximum symptoms) to 6 points (no symptoms). Additionally, patients were assessed with the Western Ontario and McMaster Universities Arthritis Index (WOMAC) score at the additional long-term follow-up visit between 2012 and 2014 (7).

Preoperative radiographs were used to evaluate acetabular centre-edge angle according to Wiberg (8), and mean neck shaft angle. On all postoperative radiographs, inclination angle of the acetabular component, the degree of linear wear of PE wear, and the angle of PE wear were measured according to Livermore et al (9). Measurements were performed by an independent and blinded investigator (C.S.), using the software package AGFA orthopaedic-Tools Version 2.06.

Statistical methods

Descriptive analyses were performed on baseline data and final outcomes. The results were expressed as means with standard deviations, or medians with ranges where relevant.

To assess THA survival, we used Kaplan Meier survival analyses with aseptic cup loosening, revision for any reason and aseptic stem loosening as endpoints, respectively. Cox regression analyses were performed to assess factors associated with THA survival (with regards to aseptic cup loosening).

Repeated-measures analyses of variance were conducted to study the associations of baseline data (demographics, THA characteristics, baseline clinical scores) and PE wear with Merle d'Aubigné-Postel scores during follow-up. Additional repeated measures analyses were performed to study the associations of baseline data (demographics, THA characteristics, baseline clinical scores) with PE wear in follow-up. A random effect per THA was included to account for repeated measures.

Lastly, a nested case-control study was performed to evaluate factors associated with early revision (<15 years) for aseptic cup loosening. Cases were defined as patients who had a primary revision for aseptic cup loosening within 15 years; controls where all patients who did not have a primary revision for aseptic cup loosening in this period. Unpaired t-tests were applied to compare continuous data between these groups, and chi-square tests for categorical data.

21 patients received bilateral CLS THA. We assessed each THA separately. In the case of a bilateral procedure, we assumed that this paired structure would not have a substantial influence on the assessed outcomes.

Results

Preoperative evaluation

At baseline, the total patient group comprised 96 patients (120 hips). There were 59 CLS arthroplasties in female patients (49.2%). Indications were: osteoarthritis in 105 hips; rheumatoid arthritis in 10; and osteonecrosis of the femoral head in 5. Mean age at surgery was 55.9 ± 5.9 years. Mean body mass index (BMI) was 26.4 ± 3.4 kg/m^2. Mean preoperative total Merle d'Aubigné-Postel score was 8.8 ± 2.2 points, with the following category scores: 1.6 ± 1.0 points for pain, 2.8 ± 1.2 for walking and 4.5 ± 1.0 for motion. Demographics, prosthesis and anatomical baseline characteristics are summarised in Table I.

Revisions, complications and survival analysis

Finally, after a mean follow-up of 14.6 years (range 0.1-24.2 years, including revisions and loss to follow-up), a total of 22 patients (24 THAs) underwent revision surgery (10 procedures additional to the original study). Overall, 28 patients were deceased (32 THAs) and 6 (7 THAs) were lost to follow-up for other reasons, leaving 45 (57 THAs) available for additional follow-up evaluation at our outpatient clinic. Because of poor physical condition, 2 (3 THAs) of these patients were visited at home for evaluation.

Of the total of 24 revisions, 16 were for aseptic loosening of the acetabular component. Furthermore, 2 patients had a fracture of segments of the cementless expansion cup during follow-up. There was 1 perioperative femoral fracture and 1 stem with early distal migration (subsidence), both leading to early revision (<6 months). There were 3 stems with aseptic loosening, requiring revision. And 1 patient with rheumatoid arthritis had a haematogenous infection after 186 months, leading to 2-stage revision arthroplasty.

Kaplan-Meier survival analysis showed a 24-years survival of 72.8% (95% CI, 63.0%-82.6%), with revision for any reason

TABLE I - Baseline (preoperative) patient characteristics

	All patients (n = 120)	Cases (n = 16)*	Controls (n = 69)*	Mean difference	95% CI	p value
Gender (No.)						
Male	61 (50.8%)	6 (37.5%)	36 (52.2%)			
Female	59 (49.2%)	10 (62.5%)	33 (47.8%)			0.29
Age at surgery (years)†	55.9 ± 5.9	54.0 ± 6.1	56.7 ± 5.0	2.7	-5.2-0.3	0.07
BMI (kg/M^2)†	26.4 ± 3.4	26.6 ± 4.4	26.4 ± 3.1	-0.2	-1.6-2.1	0.05
Hip†						
Neck shaft angle (deg.)	133.5 ± 8.1	136.8 ± 6.1	132.8 ± 8.3	-4	-1.8-9.9	0.17
Center-edge angle of Wiberg (deg.)	35.1 ± 8.3	39.1 ± 10.1	34.5 ± 7.8	-4.6	-2.1-10.1	0.19
Component size (mm)						
Cup	53.8 ± 2.6	52.9 ± 3.2	54.0 ± 2.4	1.1	-2.5-0.5	0.17
Stem	10.4 ± 2.0	9.8 ± 1.7	10.6 ± 2.0	0.8	-1.8-0.3	0.15
Head size (no.)						
28 mm	20	1	12			
32 mm	100	15	57			0.73
Merle d'Aubigné-Postel score (points)†						
Pain	1.6 ± 1.0	1.2 (1.0)	1.7 (0.9)	0.4	-0.1-0.9	0.11
Motion	4.5 ± 1.0	4.8 (0.7)	4.4 (1.0)	-0.4	-0.9-0.1	0.13
Walking	2.8 ± 1.2	2.6 (1.1)	3.0 (1.1)	0.3	-0.3-0.9	0.28
Total	8.8 ± 2.2	8.7 (2.4)	9.0 (2.1)	0.3	-0.9-1.5	0.57

* Cases = patients who had a revision procedure due to aseptic loosening of the acetabular component within 15 years of follow-up; Controls = all patients without a revision within 15 years postoperatively.
† Values are given as means ± standard deviations.
BMI = body mass index; CI = confidence interval.

as endpoint (Fig. 1). With revision due to aseptic cup loosening as endpoint, 24-year survival was 80.1% (95% CI, 70.9%-89.3%) (Fig. 2). Survival was 95.1% (95%CI, 90.0%-100.0%) for revision for aseptic loosening of the femoral component.

Final evaluation

Merle d'Aubigné-Postel was 16.1 points (range 7-18) after a mean follow-up of 14.6 ± 7.2 years (either evaluated in 2014, or earlier, including loss to follow-up and last evaluation before eventual revision surgery). As an additional follow-up measure to the previous study, the WOMAC score was assessed for the 57 THAs evaluated in 2013 - 2014. Mean WOMAC scores were 2.4 ± 3.4 points for pain, 1.5 ± 1.9 for stiffness and 12.4 ± 13.9 for physical function. The mean total WOMAC was 16.2 ± 18.3 points. Mean PE wear was 2.3 ± 1.0 mm at final follow-up. The mean PE wear rate was 0.15 ± 0.08 mm/year (Tab. II).

Cox regression survival analyses were used to calculate the associations of baseline patient and prosthetic characteristics with prosthesis survival, with revision for aseptic cup loosening as end point. We found associations of the following variables with an increased risk of revision arthroplasty: male sex, a higher BMI, a younger age at surgery, a smaller acetabular component size, and a larger femoral head component size (32 vs. 28 mm) (Tab. III). However, the observed hazard ratios were not statistically significant. For clinical baseline scores, a higher (better) baseline Merle d'Aubigné-Postel motion score was associated with revision for aseptic cup loosening in our data (hazard ratio = 1.80; 95% CI, 0.92-3.30; p = 0.09) (Tab. III).

In a repeated-measures analysis of variance, we assessed the associations of baseline patient and prosthesis characteristics and PE wear during follow-up (accounting for interaction between wear and follow-up), with total Merle d'Aubigné-Postel scores. Age at surgery, femoral head component size, and angle of inclination were removed from this analysis because their associated p values were >0.25, with minimal estimated effects on the clinical score. Multivariately, BMI had a statistically significant negative association with final clinical score (-0.11 per additional BMI point, p = 0.04; 95% CI, -0.22 to -0.01). There were significant positive associations of larger acetabulum component size and more PE wear, with better follow-up scores (Tab. IV).

A second repeated-measures analysis of variance was performed, to assess associations of baseline demographics and prosthesis characteristics with PE wear in follow-up. From this model, BMI, gender and acetabulum component size were removed, because their associated p values were >0.25, with minimal estimated effects on PE wear. In the final multivari-

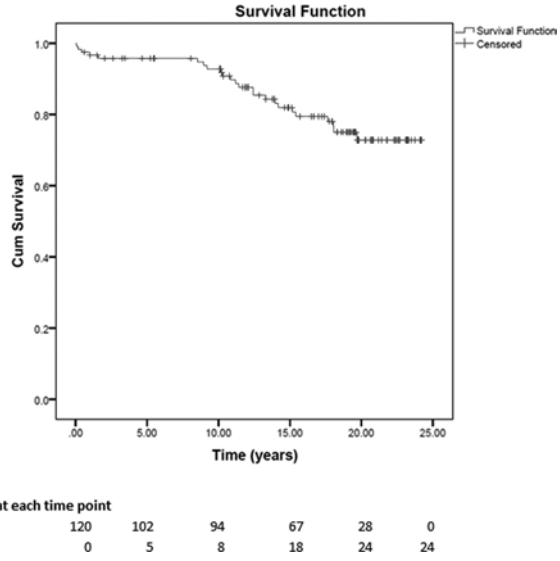

Fig. 1 - Kaplan-Meier survival analyses with revision for any reason as end-point.

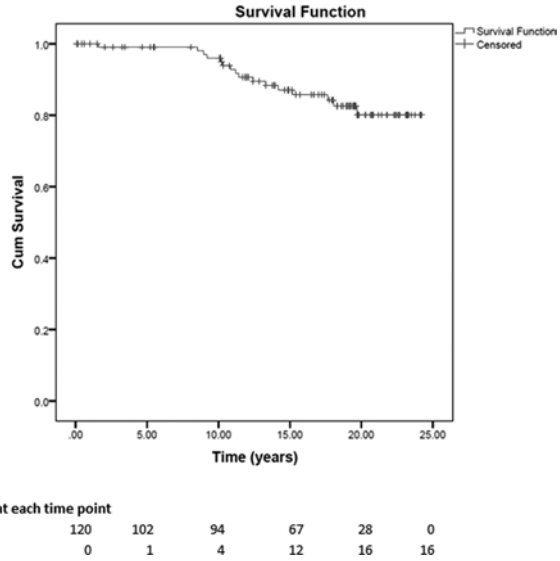

Fig. 2 - Kaplan-Meier survival analyses with revision for aseptic cup loosening as end-point.

TABLE II - Results at final follow-up, before an eventual revision procedure, for all patients, cases and controls*

	All patients (n = 120)	Cases (n = 16)*	Controls (n = 69)*	Mean difference	95% CI	p value
Duration of follow-up (months)†	762.5 ± 374.2	623.4 ± 235.0	815.4 ± 370.1			
Merle d'Aubigné-Postel score (points)†						
Pain	5.4 ± 1.0	4.9 ± 1.2	5.5 ± 1.0	0.6	-1.1-0.2	0.16
Motion	5.5 ± 0.9	5.9 ± 0.3	5.4 ± 1.0	-0.5	0.0-1.3	**0.04**
Walk	5.2 ± 1.4	4.8 ± 1.2	5.3 ± 1.4	0.5	-1.2-0.5	0.45
Total	16.1 ± 2.6	15.7 ± 2.2	16.3 ± 2.6	0.6	-1.9-1.6	0.9
Analyses of radiographs		(n = 15)	(n = 65)			
Total polyethylene wear† (mm)	2.3 ± 1.0	2.7 ± 1.1	2.3 ± 1.0	-0.4	-0.9-0.2	0.22
Polyethylene wear rate† (mm/yr)	0.15 ± 0.08	0.24 ± 0.09	0.12 ± 0.05	-0.12	-0.16-0.8	**<0.001**
Wear angle† (deg)	-17.3 ± 26.1	-17.8 ± 12.9	-19.0 ± 27.4	-1.2	-15.8-13.3	0.87
Inclination angle† (deg)	48.1 ± 8.9	48.0 ± 10.0	49.0 ± 7.0	1.0	-3.4-5.3	0.67

* Cases = patients who had a revision procedure due to aseptic loosening of the acetabular component within 15 years of follow-up; Controls = all patients without a revision within 15 years postoperatively.
† Values are given as means ± standard deviations.
CI = confidence interval.

ate model, there were significant negative associations (less PE wear) for older age at surgery and 28-mm head component size (vs. 32 mm). There were positive associations (more PE wear) with higher angle of PE wear (not significant), longer duration of follow-up, and steeper inclination angle (Tab. IV).

Nested case-control study

For the nested-case control study (cases: revisions for aseptic cup loosening within 15 years), 85 patients (69 controls and 16 cases) were available. At baseline, no statistically significant differences were found between cases and controls with respect to demographics or preoperative radiological findings (Tab. I).

At the time of final follow-up, there was a significantly higher Merle d'Aubigné-Postel score for motion in the cases (better motion) (Tab. II). There was no statistically significant difference in the total amount of PE wear between both groups, but the wear rate was significantly higher in the cases: 0.24 ± 0.09 mm/year vs. 0.12 ± 0.05 mm/year in controls, leading to a mean difference of 0.12 mm/year, p<0.001 (Tab. II).

TABLE III - Cox regression survival analyses of the effects (depicted as hazard ratios) of baseline parameters on the risk of revision for aseptic loosening of the acetabular component

	Hazard ratio	95% CI	p value
Patient charactaristics			
Gender (male vs. female)	1.53	0.55-4.21	0.41
BMI (kg/M^2)	1.04	0.88-1.24	0.64
Age at surgery (per 1-year increase)	0.94	0.88-1.01	0.11
Age at surgery (per 10-year increase)	0.56	0.28-1.13	0.11
Merle d'Aubigné-Postel score			
Pain	0.66	0.36-1.18	0.16
Motion	1.8	0.92-3.3	0.09
Walking	0.81	0.53-1.25	0.35
Total	0.96	0.77-1.20	0.7
Prosthesis component sizes			
Cup (mm)	0.89	0.74-1.08	0.22
Head size (32 vs. 28 mm)	2.84	0.37-21.63	0.31

BMI = body mass index; CI = confidence interval.

TABLE IV - Repeated-measures analysis of variance of effects of relevant parameters associated with Merle d'Aubigné-Postel score and polyethylene wear during follow-up

	Effect size	95% CI	p value
Merle d'Aubigné-Postel score			
BMI (kg/M^2)	-0.11	-0.22--0.01	**0.04**
Gender (male vs. female)	-0.69	-1.5-0.11	0.09
Cup component size (mm)	0.21	0.06-0.36	**0.01**
Time after surgery (years)	-0.003	-0.05-0.05	0.89
Amount of polyethylene wear (mm)	0.75	0.36-1.13	**<0.001**
Polyethylene wear			
Age at surgery (1-year increase)	-0.03	-0.05--0.014	**0.001**
Wear angle	0.001	-0.0004-0.004	0.108
Head size (28 vs. 32 mm)	-0.53	-0.80--0.25	**<0.001**
Inclination angle	0.013	-0.003-0.022	**0.008**
Duration of follow-up (years)	0.09	0.08-0.098	**<0.001**

BMI = body mass index; CI = confidence interval.

Discussion

In this long-term follow-up study of the Cementless Spotorno total hip system, 24 years survival was worrying, with 72.8% (95% CI, 63.0%-82.6%) for revision for any reason. Aseptic loosening of the cup was the main reason for revision, with a 24-year survival of 80.1% (95% CI, 70.9%-89.3%). We found no baseline parameters with a significant association with survival (Cox-regression analyses), but a greater age at surgery had a clinically relevant positive association with prosthesis survival in our data (not significant). A better motion score preoperatively had a clinically relevant negative association with prosthesis survival (not significant). Patients who had a revision within 15 years for aseptic cup loosening, had a higher rate of PE wear during follow-up, which was associated with a younger age at surgery, larger head component size, steeper cup inclination angle and longer duration of follow-up.

With regards to the long-term (>20 years) CLS cup survival, we found only 1 other study in the peer-reviewed English language literature, by Terré (10), reporting a cumulative survival rate of 79% at 21 years. For long-term survival (>20 years) in other cementless cups, better results have been reported: e.g. Ihle et al (11) reported a 83% probability of survival for the titanium-coated RM cup at 20 years, and Loughead et al (12) reported a 88% survival (Kaplan-Meier) at 23 years with the porous coated anatomic cup (PCA) (Howmedica). Della Valle et al (13) published reasonable results with the Zimmer Harris-Galante I cup, with 96% survival for aseptic cup loosening after a minimum of 20 years. Although long-term results for cementless cups seem somewhat better in these other studies, it has to be taken into account that in most studies,

patient age at surgery is generally higher compared to our study population. Regarding registry studies, we found no comparable durations of follow-up, with the longest reported follow-up periods of 14 years in the Australian registry and 10 years in the Swedish registry (14, 15).

For the CLS stem, we found an excellent long-term survival of 95.1% (95% CI, 90.0%-100.0%) for revision for aseptic loosening at 24 years, even with this young patient group. This is in concordance with other long-term studies of the CLS stem. For example, Biemond et al (16) report a 93.5% survival at 18.4 years of follow-up, Evola et al (17) reported 91.5% survivorship at a minimum of 21 years of follow-up, and Streit et al (18) 86% with 22 years of follow-up. Our results are also comparable with those of other reliable cementless stems in young patients. For example, for the Taperloc, 90% survival has been reported at 25 years (19), and for the Zweymuller Alloclassic 96% at 20 years (20). For cemented stems, Bedard et al (21) reported results after a minimum of 20 years of follow-up in a systematic review. In 6 studies, survivorship for aseptic loosening in patients older than 50 years of age ranged from 86% to 98% at 20 years. In 4 studies reporting 25 years of follow-up, revision rates for aseptic loosening in patients younger than 50 years were reported between 68% and 94%.

In our study, patients with an early revision for aseptic cup loosening had a higher PE wear rate during follow-up. Assessing the association of baseline parameters with PE wear, we found that younger age at surgery was associated with more PE wear, which might be due to more physical activity. This might also be an explanation for the relatively high revision rate for cup loosening in this relatively young patient group. There were also positive associations (more wear) with a higher angle of PE wear (not significant), longer duration of follow-up, steeper inclination angle of the cup, and 32-mm head component size (vs. 28-mm).

Assessing the associations of baseline parameters and PE wear with clinical scores in follow-up, we found that patients with a higher baseline BMI had worse clinical scores, corroborating our previous study (3). There were also positive associations for higher PE wear and larger cup size conferring better clinical scores in follow-up. Of course, it has to be taken into account that our results represented first generation polyethylene. The wear rate of 0.15 mm/year is unacceptably high nowadays, but it is comparable with other conventional liners (22).

The current study shows, that in a relatively young patient group, the long-term survival of CLS Spotorno stems is excellent. However, the high rate of PE wear and aseptic loosening of the CLS Spotorno cups is concerning. A 72.8% 24 years survival is undesirable and inferior compared to other cementless and cemented cups. Further evaluation is needed to assess the reasons for these failure rates, including implant design, surgical technique and our relatively young patient group, but in the intervening time, we would advise caution with the use of this particular cementless cup. Based on these experiences, we abandoned the use of the CLS cup at our institution.

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Disclosures

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Conflict of interest: None.

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