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ORIGINAL ARTICLE

# Long-term clinical-radiological evaluation of the CLS Spotorno stem

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**KEYWORDS**
Total hip prosthesis;
Cementless prosthesis;
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**Abstract**
*Objective:* To analyse the long-term results of the cementless, metaphyseal anchorage type, CLS Spotorno stem (Sulzer/Zimmer).
*Material y methods:* A review has been made of 166 patients in whom were implanted, primarily and consecutively, 189 CLS (CementLess Spotorno) (Sulzer/Zimmer) stems. The mean follow up was 13 years. The clinical parameters were assessed using a modified Harris scale, and the radiological ones according to the Gruen zones. The stem sinking measurements were also analysed.
*Results:* The mean follow up was 180 (156-228) months. Twelve patients (12 stems) died and 24 patients (29 stems) did not complete the follow up for different reasons. Thus the study was carried out on 130 patients (148 stems) who had the minimum follow up. The overall survival rate of the stem was 95% (confidence interval 89-98%) at the end of follow up. The Harris scale scores increased from 48 (9-76) points before surgery to 90 (63-100) points at the end of follow up.
*Conclusions:* CLS femoral stem obtains excellent long-term clinical and survival results.


**PALABRAS CLAVE**
Prótesis total
de cadera;
Prótesis no cementada;
Vástago CLS;
Anclaje metafisario

**Valoración clínico-radiológica del vástago CLS Spotorno a largo plazo**

**Resumen**
*Objetivo:* Analizar los resultados a largo plazo del vástago no cementado de anclaje metafisario tipo CLS Spotorno (Sulzer/Zimmer).
*Material y métodos:* Se han revisado 166 pacientes a los que se colocó, de forma primaria y consecutiva, 189 vástagos CLS (CementLess Spotorno) (Sulzer/Zimmer). El seguimiento mínimo ha sido de 13 años. Los parámetros clínicos se han valorado según la escala de Harris modificada, y los radiológicos según las zonas de Gruen. También se ha analizado la medición del hundimiento del vástago.

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*Resultados:* El seguimiento medio ha sido de 180 meses (156-228), 12 pacientes (12 vástagos) habían fallecido y no se ha completado el seguimiento por diferentes motivos en 24 pacientes (29 vástagos). Así, el trabajo se ha realizado sobre 130 pacientes (148 vástagos) que tienen el seguimiento mínimo. La tasa de supervivencia global del vástago ha sido del 95% al final del seguimiento (intervalo de confianza 89-98). Las mediciones de la escala de Harris han pasado de 48 (9-76) puntos antes de la cirugía a 90 (63-100) puntos al final del seguimiento.

*Conclusiones:* El vástago femoral CLS obtiene unos excelentes resultados tanto clínicos como de supervivencia a largo plazo.



## Introduction

Various implants and instruments have been used in recent years for the treatment of degenerative hip osteoarthritis. Progressive physical activity carried out by patients, together with their increasingly lower age, makes it extremely important for implants to achieve excellent clinical results and for these results to be equally good regarding the conservation of the osseous reserve, due to the high probability of replacement that patients presently have.

The non-cemented Spotorno CLS (Sulzer/Zimmer) stem is an implant made of titanium (TiAl6Nb7) with a straight rectangular structure and metaphyseal anchoring with proximal striations designed for its impaction in the proximal cancellous bone,[1] which favours primary stability.[2] The design of the metaphyseal support of the implant favours a symmetric weight distribution that transmits pressure in a decreasing way in the direction of the femoral diaphysis, lowering stiffness in the metal-bone transfer.

Our study goal is to describe the clinical and radiological results obtained in a long-term period in a group of 130 patients, who were implanted with a CLS stem.

## Material and methods

A total of 166 patients (189 implants) were treated between 1987 and 1992. They were consecutively implanted with a CLS-type stem (fig. 1). From this series, 12 patients (12 stems) died before completing follow-up and a further 24 cases (29 stems) were lost during follow-up. Although the data from these patients showed excellent clinical and radiological results, they were excluded from the study due to insufficient follow-up (2-10 years).

The final number of patients included in the study was 130, in whom 148 stems were implanted. In all cases, the minimum follow-up was 13 years (156 months). The indication criteria for this type of stem were a patient with good osseous quality and a femoral canal morphologically appropriate for the positioning of this stem. Other non-cemented stems were not used in this period in primary hip prosthesis. No patients were excluded for reasons such as age, weight or concomitant diseases.

The mean patient age was 52 (26-71) years at the time of surgery. Of these patients, 91 were male and 39 were female. The mean follow-up period was 18 months (156-228). Preoperative diagnoses were primary degenerative osteoarthritis in 108 hips (67.5%), avascular necrosis in 32 cases (20%), rheumatic process in 12 hips (7.5%), hip osteoarthritis secondary to acetabular dysplasia in 3 hips (1.87%), infantile septic degenerative osteoarthritis in 2 cases (1.25%) and 3 hips (1.87%) suffering from pigmented villonodular synovitis.

An anterolateral approach between the medium gluteus muscle and the fascia lata tensor muscle was used in all cases, with the patient in decubitus position. Five surgeons carried out all surgeries. Threaded acetabular Mecron-Rings (Mecron) were placed in 88 joints (59%) between 1987 and 1990, 46 non-cemented CLS acetabular cups (Sulzer/Zimmer) (31%) were placed during 1991 and 1992, 23 cemented acetabular cups (Sulzer/Zimmer) (15.5%) were used in osteoporotic bone cases; in one case, (0.6%) a Wagner type (Zimmer) acetabular cup was selected due to hip dysplasia.

Antibiotic prophylaxis was carried out with intravenous cefazolin during anaesthetic induction. In addition, in case another intraoperative dose was needed, 3 hours after the first administration in prolonged surgical procedures or in those with abundant blood loss (>1 litre) and every 3 hours until the end of the procedure. A last postoperative dose was supplied 8 hours after the last one.

After undergoing surgery, patients were lifted from their beds on the first postoperative day and started walking with tolerated load and the help of crutches on the second day after the operation. Antithrombotic prophylaxis was carried out with enoxaparin, one daily subcutaneous dose during 30 days.

The clinical evaluation of the patients was carried out according to the Harris evaluation scale,[3] in both the preoperative period and at the end of follow-up. In addition, a questionnaire regarding the existence or absence of pain at the level of the anterior side of the thigh or in the groin, as well as the presence of any other type of pain, was done in all cases.

The anteroposterior and axial x-rays were evaluated in the radiological study of the patients. We evaluated the presence of radiolucent lines, atrophy or cortical hypertrophy, as well as the formation of endosteal bone. All findings were classified following the Gruen zone classification.[4] The stability of the stem was assessed following Engh criteria.[5]

**Figure 1** A) Postoperative x-ray in 1987. B) Last review in 2003 with no radiological changes; the patient is currently asymptomatic.

To evaluate the alignment of the stem as neutral, varus or valgus, the position in relation to the natural axis of the femur of the most distal part of the stem was analysed. In all cases, the anteroposterior x-rays were carried out in a neutral position of the extremities.

To determine the level of stem sinking in anteroposterior x-rays, the distance in millimetres between the end of the greater trochanter and the shoulder of the prosthesis was measured. The formation of heterotrophic ossifications was evaluated following the Brooker scale.[6]

Statistical evaluation was carried out using the SPSS11.0 software package (SPSS Inc.). The level of significance was 0.05.

The survival probabilities of the implant with a 95% confidence interval were estimated using the Kaplan-Meyer curve method. For patients who did not need secondary surgery, the date of last follow-up was considered as the cut-off point. In the remaining cases, replacement due to aseptic mobilisation, replacement for any reason, the existence of x-ray signs of mobilisation and the lack of follow up were considered as cut-off points.

## Results

At the end of the follow-up period (180 months [156-228]), patients presented an average clinical evaluation of 90 points (63-100) in the Harris scale. This represents an important improvement with respect to the values presented in the preoperative evaluation, which were of 48 points (9-76).

In 7 cases, pain in the anterior side of the thigh was reported, at the level of the stem end. In 3 cases, pain was described as severe (requiring daily medication with a limitation of normal life), while in the rest of the cases it was described as mild (occasional pain, not requiring medication and not limiting daily activities, including sports).

In the radiological evaluation, we observed that the stem was in a neutral position in 123 cases (83%). In 16 (11%) cases, it was found in a position defined as varus, with a mean angle of 3.4º (3.1-3.6); and in 9 cases, its position was defined as valgus, with an angle of 1.8º (1.3-2.6).

Stem sinking was observed in 4 cases (5-10 mm or greater), produced by defects of the surgical technique during the implantation of stems that were small in relation to the medullar femoral channel. Two of these patients rejected review surgery as they presented no symptoms. Replacement surgery was performed in the other 2 cases, to place a larger stem because the initial one was clearly too small. In both cases, the final result was satisfactory.

Radiolucent lines appeared most frequently in Gruen Area 1 (fig. 3). These lines appeared during the first year after the implantation, and did not progress or have any relevance in patient development in any case. No correlation was found between the existence of radiolucency in Area 1 and pain in the thigh or limping (table 1). The remaining cases of radiolucent lines are shown in table 2. A radiolucent zone affecting the entire area surrounding the implant was observed in one case (fig. 4, table 3).

Two cases of mild cortical atrophy were found in Gruen Areas 1 and 7, and 11 cases of hypertrophy in Areas 5 and 6,

**Table 1** Correlation scale for the existence of radiolucency in Area 1 and pain in the thigh or limping

| r Correlation Coefficient | Classification |
|---|---|
| $r \leq 0.2$ | Very low |
| $0.2 < r \leq 0.5$ | Low |
| $0.5 < r \leq 0.7$ | Average |
| $0.7 < r \leq 0.9$ | High |
| $0.9 < r \leq 1$ | Very high |

**Table 2** Radiolucent lines, 148 hips. Anteroposterior x-ray

| Gruen Area | Number of Femurs (148) |
|---|---|
| None | 91 |
| Area 1 | 45 (30.5%) |
| Area 2 | — |
| Area 3 | 2 (1.3%) |
| Area 4 | — |
| Area 5 | 3 (2%) |
| Area 6 | 6 (4%) |
| Area 7 | — |
| Complete | 1 |
| More than one area | — |

in relation to the varus or valgus position of the stem. These discoveries had no correlation with the presence of pain or limping.

The formation of heterotopic ossifications was observed in 32 of the 148 stems implanted (21.6%). A total of 20 cases were evaluated as grade 1, 11 cases as grade 2 and one case as grade 3. This last case was the only one requiring surgical treatment during the resection of the ossification, due to limited mobility.

A total of 12 cases of intraoperative femoral fracture were observed (11 of them belonging to the first 50 prosthesis). According to the Johansson classification,[7] 4 of them were type 1, one of them was type 2, another one was type 3 and there were 6 fractures of the end of the main trochanter. No fracture displacement was observed in any case. One of them required a metal cerclage and 4 of them

**Table 3** Formation of the endosteal bone

| Gruen Area | Number of Femurs (148) |
|---|---|
| None | 87 (58.7%) |
| Area 3 | 28 (18.9%) |
| Area 4 | 2 (1.3%) |
| Areas 3 and 5 | 22 (14.8%) |
| Area 5 | 9 (6%) |

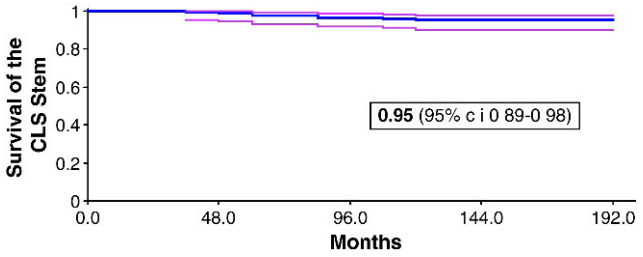


**Figure 2** Kaplan-Meyer global survival curve. Probability of survival of the Spotorno CLS cementless stem with a cut-off point of any follow-up.
**c.i.: confidence interval.**

required a screw. The fractures did not affect satisfactory patient development in any case.

In addition, we observed 4 dislocations treated in a satisfactory and conservative manner, one infection and one transitory paresis of the crural nerve.

At the end of the follow-up period, 7 (4.7%) of the stems had to be replaced. In two cases, this was due to sinking because the size of the stem used was smaller than required. In another patient, the stem was replaced in two steps by another one, which was cemented with Gentamicin, due to a deep infection of the prosthesis (this was the only infection in the series). The other 4 cases were intervened at other centres due to osteolysis of the stem secondary to polyethylene damage and acetabular mobilisation.

At the end of the study, the global survival rate of the stem was 95% (89%-98%) (fig. 2), using the Kaplan-Meyer survival curves method.

## Discussion

Obtaining primary stability of non-cemented implants is vitally important in order to obtain good clinical results.[8] This can be achieved by filling the femoral metaphyseal

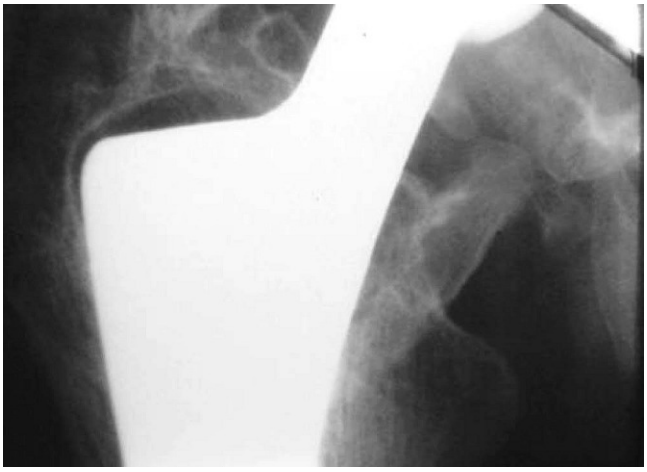

**Figure 3** The most frequent location of radiolucency was Area 1 (shoulder of the prosthesis).

**Figure 4** A) Postoperative x-ray at age 26. B) At 4 years of follow-up. C) Postoperative x-ray after the stem change. D) One year after the change.

area with a large implant, with a diaphyseal anchorage,[9,10] or by a combination of both systems.[10,11] The CLS stem has a different fixing system, achieving primary stability through the anchorage of the implant in a previously carved bed of impacted metaphyseal sponge,[2] which provides excellent attachment in the inter-trochanter area. The width of the prosthesis decreases progressively in such a way that the distal area does not occupy that whole width of the channel. The good primary stability obtained with this implant and its results have been proved in other studies with the same stem.[1,2,9,12-15] This primary stability has been demonstrated in our series by the fact that stem sinking happened in only 4 cases, despite early loads; this is relevant when we consider that in 2 cases, due to a technical error, the stem was clearly undersized.

With regard to secondary stability of the implant, titanium is known to be the metal whose stability coefficient is most similar to that of bone.[16] This fact, in addition to the excellent long term osseointegration and osteoinduction[17] also offered by titanium,[18] makes secondary stability excellent. In addition, the fact that the distal osseous reservoir remains intact makes its replacement by another diaphyseal support stem easier, in case of loosening.[16]

The excellent theoretical behaviour of the stem is supported by the excellent long-term clinical results, since an average follow-up of 15 years resulted in a score of 90 points in the Harris evaluation scale; this is equal to or above the results obtained in series with hybrid or cemented prosthesis.[17-20]

Likewise, pain in the anterior zone of the muscle, which is frequent with other cementless stems,[21,22] has been minimum in our series. Many studies relate postoperative pain in the anterior side of the thigh directly with the stem used,[21-25] but in our series this pain became a problem in only 3 cases.

The most significant complication that took place was fracture. This can be related to the learning curve with the stem, given that 11 out of 12 fractures happened in first 50 cases.

In the image study of the prosthesis, it was observed that the long-term mobility of the stem was very low. It was also observed that radiolucent lines were frequent (38%), happened mostly during the early months in Gruen Area 1, presented no further development and had no effect on the clinical development and survival of the implant.

Furthermore, the varus-valgus position of the implant did not affect the satisfactory clinical development of the patient.

Regarding the rate of secondary surgery, 2 out of 7 cases were technical errors. One of them was due to infection and the others were related with polyethylene disease due to debilitation of the acetabular crown used.

The results obtained are similar to those of other series using the same stem,[12,15,26-29] presenting 95% survival, with an average follow-up of 180 months and excellent clinical results. These factors make the femoral CLS stem an excellent option for patients of all ages with a good osseous quality.

## Level of evidence

Level of evidence IV.

## Conflict of interest

The authors declare no conflict of interest.

## References


1. Robinson RP, Deysine GR, Green TM. Uncemented total hip arthroplasty using the CLS stem: a titanium alloy implant with a corundum blast finish. Results at a mean 6 years in a prospective study. J Arthroplasty. 1996;11:286—92.
2. Spotorno L, Romagnoli S, Ivaldo N, Grappiolo G, Bibbiani E, Blaha DJ, et al. The CLS system. Theoretical concept and results. Acta Orthop Belg. 1993;1 Suppl 59:144—8.
3. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An endresult study using a new method of result evaluation. J Bone Joint Surg Am. 1969;51:737—55.
4. Gruen TA, McNeice GM, Amstutz C. Modes of failure of cemented stem-type femoral components. A radiographic analysis of loosening. Clin Orthop. 1979;141:17—27.
5. Engh CA , Bobyn JD, Glassman AH. Porous-coated hip replacement the factors ogoverning bone ingrowth, stress shielding and clinical results. J Bone Joint Surg. 1987;69-B:45—55.
6. Brooker AF, Bowerman JW, Robinson RA, Riley LH. Ectopic ossification following total hip replacement. Incidence and a method of classification. J Bone Joint Surg Am. 1973;55:1629—32.
7. Johansson JE, McBroom R, Barrington TW, Hunter GA. Fracture of the ipsilateral femur in patients with total hip replacement. J Bone Joint Surg. 1981;63A:1435—42.
8. McLaughlin JR, Lee KR. Total hip artthroplasty with an uncemented femoral component. Excellent results at ten-year follow-up. J Bone Joint Surg. 1997;79B:900—7.
9. Giacometti RC, Pace A. CLS femoral component. Orthopedics. 1989;12:1195—200.
10. Engh CA, Glassman AH, Sutners KE. The case for porous-coated hip implants: the femoral size. Clin Orthop. 1990;261:63—81.
11. Callaghan JJ, Dysart SH, Savoy CG. The uncemented porouscoated anatomic total hip prothesis: two- year results of a prospective consecutive series. J Bone Joint Surg. 1988;70A:337—46.
12. Aldinger PR, Jung AW, Breusch SJ, Ewerbeck V, Parsch D. Survival of the cementless Spotorno stem in the second decade. Clin Orthop Relat Res. 2009;467:2297—304.
13. Büllow JU, Scheller G, Arnold P, Synatschke M, Jani L. Followup (6-9 years) results of the uncemented CLS Spotorno stem. Arch Orthop Trauma Surg. 1996;115:190—4.
14. Dorr LD, Takei GK, Conaty JP. Total hip arthroplasties in patients less than forty-five years old. J Bone Joint Surg. 1983;65A: 474—9.
15. Aldinger PR, Breusch SJ, Lukosechek M, Mau H, Ewerbeck V, Thomsen M. Cementless Spotorno tapered titanium stems: excellent 10-15-year survival in 141 young patients. Acta Orthop Scand. 2003;74:253—8.
16. Dorr LD, Absatz M, Gruen TA, Saberi MT, Doerzbacher JF. Anatomic porous replacement hip arthroplasty: first 100 consecutive cases. Semin Arthroplasty. 1990;1:77—86.
17. Blasius K, Cotta H, Schneider U, Thomsen M. CLS multicenter study-8-year results. Z Orthop Ihre Grenzgeb. 1993;131:547—52.
18. Zweymuller KA, Lintner FK, Semlitsch MF. Biologic fixation of a press fit titanium hip joint endoprothesis. Clin Orthop. 1988;235:195—206.
19. Kim YH, Kim VEM. Results of Harris-Galante cementless hip prosthesis. J Bone Joint Surg. 1992;74B:83—7.
20. Oishi CS, Walker RH, Colwell CW. The femoral component in total hip arthroplasty: six to eight year follow-up on one hundred consecutive patients after use of a thirdgeneration cementing technique. J Bone Joint Surg. 1994;76A:1130—6.
21. Campbell ACL, Rorabeck CH, Bourne RB, Chess D, Nott L. Thigh pain after cementless hip arthroplasty. Annoyance or ill omen. J Bone Joint Surg. 1992;74B:63—6.
22. Büllow JU, Scheller G, Arnold P, Synatschke M, Jani L. Uncemented total hip replacement and thigh pain. Int Orthop. 1996;20:65—9.
23. Barrack RL, Jasty M, Bragdon C, Haire T, Harris WH. Thigh pain despite bone ingrowth into uncemented femoral stems. J Bone Joint Surg. 1992;74B:507—10.
24. Blaha JD, Grappiolio G, Gruen T, Spotorno L. Five to eight year follow up of a cementless, press fit, non bone ingrowth total hip stem. Orthop Trans. 1993;17:94—101.
25. Heekin RD, Callaghan JJ, Hopkinson WJ, Savory CG, Xenos JS. The porous-coated cemented anatomic total hip prosthesis, inserted without cement. Results after five to seven years an prospective study. J Bone Joint Surg. 1993;75A:77—91.
26. Schramm M, Keck F, Hohmann D, Pitto RP. Total hip arthroplasty using an Uncemented femoral component with taper design: outcome at 10 year follow-up. Arch Orthop Trauma Surg. 2000;120:407—12.
27. Schreiner U, Scheller G, Herbing J, Jani L. Mid-term results of the cementless CLS stem. A 7- to 11-year follow-up study. Arch Orthop Surg. 2001;121:321—4.
28. Siebold R, Scheller G, Schreiner U, Jani L. Long-term results with the cement-free Spotorno CLS shaft. Orthopade. 2001;30:317—22.
29. Terré RA. Estimated survival probability of the Spotorno total hip arthroplasty after a 15- to 21-year follow-up: one surgeon's results. Hip Int. 2010;20 Suppl 7:70—8.