We followed the first 354 consecutive implantations of a cementless, double-tapered straight femoral stem in 326 patients. Follow-up was at a mean of 12 years (10 to 15). The mean age of the patients was 57 years (13 to 81). At follow-up, 56 patients (59 hips) had died, and eight (eight hips) had been lost to follow-up. Twenty-five hips underwent femoral revision, eight for infection, three for periprosthetic fracture and 14 for aseptic loosening.

The overall survival was 92% at 12 years (95% CI 88 to 95). Survival with femoral revision for aseptic loosening as an endpoint was 95% (95% CI 92 to 98). The median Harris hip score at follow-up was 84 points (23 to 100). Radiolucent lines (< 2 mm) in Gruen zones 1 and 7 were present in 38 (16%) and 34 hips (14%), respectively. Radiolucencies in zones 2 to 6 were found in five hips (2%).

The results for mid- to long-term survival with this femoral component are encouraging and compare with those achieved in primary cemented total hip arthroplasty. The high rate of loosening of the cup and the high rate of pain are, however, a source of concern.

The short-term results of cementless total hip arthroplasty (THA) are normally good and are similar to those reported after cemented THA, with respect to relief from pain and function. Long-term results with a follow-up of more than ten years are only available for a limited number of uncemented implants.1-9 Some series have to be interpreted with care as many prostheses have undergone changes of design since their first introduction or patients have been lost to follow-up. It is crucial to have access to long-term clinical data not only for the patient, but also for the surgeons and health-care providers. This allows appropriate selection of the implant and justifies their use.10

The Cementless Spotorno stem (CLS; Centerpulse, Zürich, Switzerland) has gained popularity among orthopaedic surgeons. In Europe it is one of the most commonly used cementless stems and excellent early clinical results have been reported.11-14 The anchorage concept is based on the preservation of proximal bone and fixation without an attempt to fill the canal distally. This is an entirely different 'philosophy' from that of the canal-fit concept which is popular in the USA and the distal-fit concept of the Zweymüller stem.15,16 Initial stability depends on a series of flutes or ribs on the proximal anterior and posterior aspects of the tapered, straight, grit-blasted titanium stem which, with its rectangular cross-section, provides an interference fit in the femur. It has been suggested that neither bone ingrowth nor distal fit and fill is necessary for secondary fixation of this design.12

We have evaluated the clinical and radiological outcome of the CLS femoral component in our first 326 consecutive patients.

Patients and Methods

Between January 1985 and December 1989, a consecutive series of 326 patients (166 men, 160 women) with 354 hips received a CLS stem. The median age of the men (178 hips) was 57 years (13 to 81) and of the women (176 hips) 57 years (23 to 76). The median body mass index was 27 (19 to 38) for the men and 27 (20 to 40) for the women. Informed consent was given by all patients. Fifty-six patients (59 hips) died, and eight (eight hips) were lost to follow-up (Fig. 1). For those who died, the prosthesis was in situ at the time of death and clinical parameters were gathered from relatives and general practitioners. Radiological data were taken from the last available follow-up at ten to 15 years. Follow-up data were obtained for 262 hips, for 182 directly by the first author (PRA). The remainder of the patients was seen by their local orthopaedic surgeons. Standard radiographs were taken and sent to our institution for assessment of...
these patients (64 hips). Clinical data, without radiographs, were obtained for 16 hips. A standardised questionnaire, including the Harris hip score (HHS), was used and evaluated. Details of the patients are given in Table I.

The THAs were carried out by 23 different surgeons; 49% were implanted by two surgeons with significant experience with this system and 51% by surgeons who had implanted fewer than 30 CLS stems.

**Implants.** In all patients a cementless, straight, collarless CLS stem with a neck-stem angle of 145˚ was implanted using a press-fit technique. The implant is made of Ti6Al7Nb alloy (Protasul 64; Sulzer Orthopedics) with a microporous surface treatment (Ra = 4.4 µm) according to ISO 5832-11 (CLS; Sulzer Orthopedics). It has a rectangular cross-section with proximal, anterior and posterior ribs/flutes.

Various acetabular components were used. In 63% (221) of operations a smooth cementless threaded Mecron A (Mecron Medizinische Produkte, Berlin, Germany) socket was used, in 36% (127) a smooth, threaded, cementless Weill cup (Sulzer Orthopedics) and in 1% (5) a cemented polyethylene cup (Aesculap, Tuttlingen, Germany). In all hips, 32 mm ceramic heads (Biolox; Ceramtec, Plochingen, Germany) and polyethylene liners were used.

**Operative technique.** We used either a modified Watson-Jones or a transgluteal, lateral Bauer approach with the patient in the supine position. The femoral canal was prepared using a canal finder and a series of chipped tooth broaches which increased in size. No attempt was made to achieve cortical fixation. Postoperative partial weight-bearing was encouraged for six weeks and, thereafter, weight-bearing as tolerated until three months after surgery. No prophylaxis for the prevention of heterotopic ossification was given.

**Assessment.** Clinical assessment included evaluation of the range of movement, the leg-length discrepancy, limping,
and walking distance. Patients expressed their pain in the operated hip at the time of follow-up on a visual analogue scale (0 to 10). The pain score according to Harris was used and the HHS was calculated.\textsuperscript{17}

The radiographs were examined by two independent, experienced, orthopaedic surgeons for alignment of the stem, subsidence, radiolucent lines, bone hypertrophy, osteolysis, stress shielding, pedestal formation at the tip of the stem, heterotopic ossification\textsuperscript{16} and femoral and acetabular loosening. Varus or valgus malalignment of the stem was defined as a deviation from the longitudinal femoral axis of more than 2°. Subsidence was calculated by measurements of the distance between the proximal shoulder of the prosthesis and the tip of the greater trochanter compared with the immediate postoperative films.\textsuperscript{19} Radiolucent lines were allocated to zones 1 to 7 of Gruen, McNeice and Amstutz.\textsuperscript{20} We defined bone hypertrophy as a thickening of the distal periprosthetic diaphyseal bone and osteolysis as an area of localised progressive bone resorption or endosteal erosion. According to Engh and Bobyn\textsuperscript{21} only second, third- and fourth-degree stress shielding with resorption of cortical bone medially, anteriorly or laterally was regarded as stress shielding. Rounding of the medial femoral neck was noted as calcar rounding and not considered to be a sign of stress shielding. Pedestal formation was described as a shelf or endosteal new bone at the tip of the stem, partially or completely bridging the intramedullary canal. A femoral stem was regarded as loose if radiolucent lines more than 2 mm thick were present around the entire implant or if serial radiographs showed a progressive change in the position of the femoral component with subsidence of > 5 mm or varus/valgus tilt of >5°.\textsuperscript{22} Acetabular loosening was defined as a continuous migration of more than 5 mm or tilting of more than 5° when compared with baseline radiographs. The threshold loosening of the femoral and the acetabular component was chosen to be 5 mm because of the inaccuracy of simple measurements on plain radiographs.\textsuperscript{23}

Statistical analysis. Using revision of the stem for aseptic loosening and revision of the stem for any cause as the endpoint, a Kaplan-Meier survival analysis was undertaken in order to plot the cumulative survival rate.\textsuperscript{24,25} A p value of <0.05 was regarded as significant.

Results

Patients who died before the most recent follow-up. The mean age of the patients at the time of the operation was 62 years (41 to 81) for the 56 patients (59 hips) who died less than ten years after operation. The mean length of follow-up was eight years (0 to 14) with 55 patients being followed for a minimum of one year. No femoral component had been revised before the patients died.

Outcome. The ten- to 15-year follow-up rate was 81% for the entire group and 97% for the patients who were still alive at the time of follow-up. The mean length of follow-up
was 12 years (10 to 15). In 295 patients (321 hips), the femoral prosthesis had not been revised until follow-up or death. In 25 hips, it had been revised before follow-up. Eight hips were revised because of a deep infection (two acute, six late), three for a late periprosthetic fracture at five, nine and ten years (Fig. 1) and 14 stems for other reasons. In four the femoral implant was undersized, which led to subsidence and aseptic loosening (revision at three, nine (2) and 13 years). Three stems were revised for aseptic loosening at 5, 12 and 13 years) and four at the time of revision of the acetabular cup with no radiological sign of loosening of the stem, three of them in other hospitals (revision at 6, 10 and 11 years after surgery). In one hip an intraoperative fracture of the proximal femur had occurred and stabilisation was attempted with cerclage wires. This was revised after three years for aseptic loosening. In another hip, six years after conversion of a Wagner cup arthroplasty to a CLS arthroplasty, osteolysis developed at the tip of the stem. This stem was revised for a cemented stem. In one patient, fracture of the ceramic head after five years led to massive polyethylene and metal wear, mechanical loosening and revision of the THA.

Clinical findings. The median HHS of the 246 hips (224 patients) which had been followed radiographically was 84 points (23 to 100). A low Charnley class and the presence of acetabular loosening or revision influenced the HHS (Table II). Out of a possible score of 44, 16 hips had a Harris pain score of ten or less. Eight of these had a loose acetabular component and the others suffered from other conditions such as osteoarthritis in other joints or back pain which was not related to the operated hip (Charnley class C).26 Seven patients (seven hips) in this group experienced disabling pain (Harris pain score 0). No thigh pain was reported.

Survival estimate. The Kaplan-Meier analysis (Fig. 2) showed a low annual rate of failure for the stem and a 12-year survival rate of 92% (95% confidence interval (CI) 88 to 95) for the femoral components without revision for any reason. The survival rate remained unchanged until year 15 since no more revisions had occurred in this period. Patients lost to follow-up were high in postoperative years 14 and 15 and, as a consequence, the confidence limits are wide. Survival with femoral revision for aseptic loosening as an endpoint was 95% (95% CI 92 to 98) after 13 years, with no more revisions until year 15.

Radiological findings. As regards the femoral component, radiological loosening with a continuous radiolucent line was found in one stem without clinical symptoms. In two stems (1%), subsidence was more than 5 mm, without clinical or radiological evidence of loosening. Femoral osteolysis was not observed. Rounding of the calcar was found in 73% (179) of patients. Distal cortical hypertrophy was not observed in any hip. Stress shielding with atrophy of the proximal femoral region was not detected. Pedestal formation at the tip of the prosthesis was present in 21% of hips. The radiological results are presented in Figure 3 and Table III.

As regards the acetabular component, 76 uncemented (56 Mecron and 20 Weill) and two cemented cups were revised before the most recent follow-up. Of the remaining 207 unrevised hips, 32 had migrated and are awaiting revision (23 Mecron and nine Weill). Four Mecron and five Weill cups were lost to follow-up.

Most patients with acetabular migration had only mild or moderate pain and five had severe pain. Of those with migration of the acetabular component 11 reported no pain. Of the 18 with moderate or severe pain who had a revision of the cup, 12 had migration of the cup.

Discussion

Because of the young age of the patients in this study, the diagnoses are different from those of other series. In almost 40%, developmental dysplasia of the hip, avascular necrosis or post-traumatic osteoarthritis led to THA. Taking into account the high rate of previous osteotomies, the frequency of abnormal proximal femoral anatomy and the inclusion of patients who underwent implantation during the learning curve, the survival of this cementless stem is excellent.
A high clinical follow-up rate was achieved. Only eight patients (2.0%) were lost to follow-up. Among those were six from other countries. Patients lost to follow-up have been shown to have worse results than those who are routinely reviewed, whereas those who die during a period of follow-up are comparable to the surviving population.29 With the number of patients who were lost to follow-up being lower than the number of failures, and a loss-to-follow-up quotient of 0.3 according to Murray, Britton and Bulstrode,30 the data presented in our study can be regarded as being reliable.

Several reasons for the good rate of survival have to be considered. These include the flexibility of the titanium stem with the absence of severe stress shielding and distal cortical hypertrophy on radiological assessment. This finding is in contrast to the results of more rigid cobalt-chrome implants (AML, De Puy; Warsaw, Indiana, and PCA; Howmedica, Allendale, New Jersey) which have substantial rates of aseptic loosening and revision, explained of pain and almost a quarter had moderate to severe complaints. Interestingly, half of the patients complained of pain and almost a quarter had moderate to severe pain. Other studies have shown similar outcomes, but with slightly better clinical scores. Schramm et al37 found a mean HHS of 88 points using the CLS stem in combination with threaded cups. Siebold et al9 found a mean of 94 points in combination with a Harris-Galante I cup.

Since acetabular components with a high rate of migration and failure were predominantly used with this stem, it would appear logical to attribute the pain and low HHS to acetabular problems.38 Since the association between pain and migration or loosening was not clear, it remains unknown whether the activity of the patients had been limited as a consequence of this. Most patients with migration of the cup only suffered from mild pain and presented with a short leg and a limp. Hence, it is not justified to attribute the poor clinical results solely to acetabular problems. Conversely, it could be argued that survival of the stem was excellent despite migration and wear of the cup. Besides parameters relating to the implant, a considerable number of patients in our study had other diseases, such as osteoarthritis of other joints or low back pain which may have contributed to the low HHS.20 This does not allow identification of the origin of the pain in the hip since patients’ complaints are used for the calculation of the score. As a consequence, pain may not always be related to the operated hip. If pain in the hip, regardless of its origin, was used as an endpoint for survivorship, the results are worrying. This highlights the limitations of the HHS in judging clinical success. Importantly, assessment of thigh pain was undertaken separately during clinical examination. No case of thigh pain was found, in contrast to other successful cementless stems.3,21,39 Rates of thigh pain of between 14% and 30% and rates of femoral osteolysis of up to 59%, with substantial rates of aseptic loosening and revision, have been reported at mid-term.
To date, long-term results (> 10 years) are only available for a limited number of cementless femoral implants1-3,5-9 and it is still unclear whether these results can compete with the excellent long-term results for cemented THA.27,40,41 After ten to 15 years we found a low revision rate because of aseptic loosening with the CLS stem and favourable results on radiological examination. Although the acetabular revision rate was high in this study the survival rate of the femoral component was excellent.

In our opinion the insertion of this tapered, cementless, femoral stem is less demanding than that of cemented THA because of the design of the stem. Even in a multi-surgeon series, with many trainees, the long-term results were very consistent, although the low HHS remain of concern. Further and continuous follow-up is necessary to assess the long-term outcome.

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References