Cementless total hip arthroplasty using a threaded cup and a rectangular tapered stem

FOLLOW-UP FOR TEN TO 17 YEARS

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We carried out a clinical and radiological review of 103 cementless primary hip arthroplasties with a tapered rectangular grit-blasted titanium press-fit femoral component and a threaded conical titanium acetabular component at a mean follow-up of 14.4 years (10.2 to 17.1).

The mean Harris hip score at the last follow-up was 89.2 (32 to 100). No early loosening and no fracture of the implant were found. One patient needed revision surgery because of a late deep infection. In 11 hips (10.7%), the reason for revision was progressive wear of the polyethylene liner. Exchange of the acetabular component because of aseptic loosening without detectable liner wear was carried out in three hips (2.9%).

After 15 years the survivorship with aseptic loosening as the definition for failure was 95.6% for the acetabular component and 100% for the femoral component.

For three decades, orthopaedic surgeons have debated the best method for fixation of the implant in total hip arthroplasty (THA). During this period many implants have undergone changes in design and/or material. Few long-term clinical and radiological studies of unchanged implants still in current usage are available. This is especially true for cementless implants.¹⁻³

The Alloclassic hip (Alloclassic SL, Zimmer/Centerpulse, Winterthur, Switzerland) was introduced in 1979,⁴ and after some early modifications, no further alterations have been undertaken since 1987. The anchoring principle has been described by various authors.^{5,6} Primary fixation of the cementless tapered titanium femoral component is achieved by diaphyseal press-fit and secondary stability by bone ongrowth onto the grit-blasted surface. The threaded conical acetabular component obtains initial fixation by conical threads, gaining long-term stability by bone ongrowth on its rough titanium surface. Although more than 250 000 implantations have been performed worldwide to date, there have been only a few long-term studies.⁷⁻¹⁰ Our aim, therefore, was to present the clinical and radiological findings including a survival analysis of a consecutive series followed for a mean period of 14.4 years (10.2 to 17.1).

Patients and Methods

Design of the implant. The femoral component is a tapered straight stem, wrought of a Prota-

sul titanium alloy TiAlNb. In its horizontal section, the shape is rectangular, allowing a secure diaphyseal press-fit in the frontal plane of the femoral canal. This provides excellent rotational stability and increases primary mechanical fixation. To achieve permanent secondary stability by osseous fixation, the stem is grit-blasted over its entire surface with corundum particles to produce a mean roughness of 4 to 6 µm.

The conical self-cutting cementless threaded acetabular component (Alloclassic; CSF, Zimmer/Centerpulse) is forged of pure titanium. The conical threads cut sharply into the acetabular bone gaining a stable primary fixation to allow osseous ongrowth onto the rough titanium surface.

The prosthesis was used in combination with an alumina-ceramic head 32 mm in diameter, fixed on a 14/16 mm taper, and with an ultrahigh-molecular-weight polyethylene (UHMWPE) inlay, sterilised under inert gas atmosphere.

Patients. From a total number of 152 primary THAs (148 patients), 103 hips (99 patients) were available for clinical and radiological evaluation with a minimum follow-up of ten years. Four patients had had bilateral procedures.

Thirty-one patients died before reaching the minimum clinical and radiological follow-up period of ten years for reasons unrelated to the hip surgery. However, they had a mean clinical and radiological follow-up of 6.9 years (0.3 to

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Fig. 1a

Fig. 1b

Fig. 1c

Radiographs showing an Alloclassic THA system a) three months after surgery, b) before exchange of the inlay and head because of polyethylene wear 15.8 years after the initial surgery and c) after revision surgery and implantation of a polyethylene-ceramic bearing.

9.3). In three the only follow-up was at three months after operation. It was not possible to obtain any further information about these patients. In 19 the exact date of death was unknown. These patients were censored in the survival analysis at their last visit. Nine patients died with the prostheses still in place. They were censored at the date of death.

Nine patients were unable or unwilling to attend for review because of distance or immobility. They underwent a telephone interview and were censored in the survival analysis by the date of this contact. One patient was revised at another clinic because of a late deep infection at 7.4 years. Eight patients were untraceable after a mean follow-up of six years.

The mean age of the patients at the initial operation was 59.2 years (28.4 to 84.0). One hundred and six prostheses were implanted in women and 46 in men.

In 86 patients (58.1%), the indication for hip surgery was idiopathic osteoarthritis, in 26 (17.6%) avascular necrosis of the femoral head, in 23 (15.5%) developmental dysplasia of the hip, in seven (4.7%) post-traumatic osteoarthritis and in six (4.1%) rheumatoid arthritis.

Evaluation. The clinical results were evaluated at a standardised follow-up visit at least ten years after implantation to assess the Harris hip score.¹¹ In the event of revision, data at the last follow-up before re-operation were included. Additionally, all patients were requested to complete SF-36 and WOMAC questionnaires.^{12,13}

Radiographs were analysed according to the method of DeLee and Charnley¹⁴ for the acetabular component. On the femoral side, the zones described by Gruen, McNeice and Amstutz¹⁵ were used. A previous report¹⁶ has shown that the lateral radiographs revealed the same findings as the anteroposterior (AP) views for this implant. Accordingly, we confined our study to the AP films.

Periprosthetic heterotopic ossification was classified according to the criteria of Brooker et al.¹⁷

Linear polyethylene wear was measured by comparing the distance from the superior margin of the acetabular component to the edge of the femoral head with that from the inferior margin of the acetabular component to the femoral head on the AP radiographs. Linear wear was defined as half the difference between these measurements, which were corrected for magnification by comparing the diameter of the femoral head on each individual radiograph with the known diameter of 32 mm.¹⁸ Osteolysis was defined as a radiolucent cystic lesion at the implant-bone interface.

Subsidence of the femoral component was defined by the distance measured between the most medial point of the lesser trochanter and the proximal tip of the stem on the pelvic radiograph. Correction for magnification was based on the femoral head diameter. All measurements were made by a single observer using a caliper.

Statistical analysis. Survivorship analysis was undertaken by calculating life tables¹⁹ and Kaplan-Meier curves²⁰

Fig. 2a

Fig. 2b

Diagrams of the typical bone remodelling process after a mean follow-up period of 14.4 years using a cementless threaded cup and a rectangular tapered stem showing the incidence of a) radiolucent lines and b) cortical hypertrophy.

including a confidence interval (CI) of 95%, as recommended by Murray, Carr and Bulstrode.²¹

Results

Revisions. Fifteen hips (14.6%) were revised, 14 of them after the minimum follow-up period of ten years. One patient needed revision surgery because of a late deep infection after 7.4 years. No early loosening and no breakage of the implant occurred in this series. All aseptic revisions were related to the acetabular side (wear or loosening).

In 11 hips (10.7%), the reason for revision was progressive UHMWPE wear. Exchange of the polyethylene inlay and the ceramic head alone was performed in eight hips. In two cases the titanium acetabular component, and in one the femoral component were also found to be loose intra-operatively because of polyethylene wear debris; these were revised. All articulating wear partners were changed to a metal-on-metal or UHMWPE-on-ceramic bearing (Fig. 1). Exchange of the acetabular component because of aseptic loosening without signs of increased polyethylene wear was performed in three hips (2.9%).

Clinical. The latest mean post-operative Harris hip score was 89.2 (32 to 100). At a mean follow-up of 14.4 years, the clinical ratings were graded as excellent and good in 83

(80.1%), fair in eight (7.7%) and poor in 12 (11.6%) of all reviewed hips. The mean pain score was 41.6 (10 to 44) and the mean functional score 47.6 (17 to 56).

A maximum pain score of 44 (i.e. no pain) was found in 89 (86.4%) of all evaluated hips. For the remainder pain was located in the gluteal region in three (2.9%), and in the region of the greater trochanter in 12 (11.6%). Three patients (2.9%) had inguinal pain and nine (8.7%) reported mild pain in changing weather conditions.

Two patients (1.9%) suffered from mild thigh pain. None showed radiological signs of increased polyethylene wear or aseptic loosening.

With respect to the SF-36 and WOMAC questionnaires 78 (75.7%) were returned fully completed and could be evaluated. The mean results of the SF-36 domains were: physical functioning 48.2; role physical 45.4; bodily pain 56.6; general health 54.2; vitality 49.5; social functioning 72.8; role emotional 66.2; mental health 66.8. The mean WOMAC scores for pain were 2.8 and 3.9 for stiffness and function.

Radiological findings

Acetabular component. Of the 103 implanted acetabular components, 100 (97.1%) were considered to be stable based on comprehensive osseointegration after a minimum period of ten years. Three (2.9%) showed a continuous

Table I. Life-table survival analysis of 152 uncemented hip arthroplasties using revision for any reason as an end-point

Annual interval (yrs)	Number of hips at start	Number withdrawn during interval	Revision for any reason	Hips at risk	Annual failure rate (%)	Annual success rate (%)	Cumulative survival rate (%)
0 to 1	152	0	0	152	0	100	100
1 to 2	152	0	0	152	0	100	100
2 to 3	152	1	0	151.5	0	100	100
3 to 4	151	2	0	150	0	100	100
4 to 5	149	1	0	148.5	0	100	100
5 to 6	148	3	0	146.5	0	100	100
6 to 7	145	6	0	142	0	100	100
7 to 8	139	7	1*	135.5	0.7	99.3	99.3
8 to 9	131	5	0	128.5	0	100	99.3
9 to 10	126	5	0	123.5	0	100	99.3
10 to 11	121	11	2 [†] + 2 [‡]	115.5	3.5	96.5	95.8
11 to 12	106	12	0	100	0	100	95.8
12 to 13	94	18	3 [‡]	85	3.5	96.5	92.4
13 to 14	73	9	2 [‡]	68.5	2.9	97.1	89.7
14 to 15	62	0	1 [‡]	62	1.6	98.4	88.3
15 to 16	61	46	1 [†] + 3 [‡]	38	10.5	89.5	79
16 to 17	11	9	0	6.5	0	100	79
17 to 18	2	2	0	1	0	100	79

* septic loosening

† aseptic loosening

‡ polyethylene wear

radiolucency with migration which led to revision as described above.

Radiolucent lines around the component were observed in DeLee and Charnley zone I in three radiographs (2.9%), in zone II in five (4.9%), and in zone III in five (4.9%). Sclerosis was seen in zone I in three hips (2.9%), in zone II in four (3.9%), and in zone III in four (3.9%). No lysis was seen around the components.

The linear rate of UHMWPE wear calculated as a simple mean of all available results after a mean follow-up of 14.4 years was 0.07 mm per year (0.00 to 0.30).

Femoral component. Subsidence occurred in two femoral components (1.9%), and was attributed to undersized stems. One component subsided continuously over the first two years with a total subsidence of 19 mm. After 24 months this component showed no further subsidence. Clinically, the patient was free from pain and had a Harris hip score of 100 at follow-up at 15 years. The second femoral component subsided 8 mm in the first year after surgery and also stabilised after 24 months. At the last follow-up, 13.6 years after operation, this patient reported no pain related to the THA.

Radiolucent lines between the stem and the bone were noted in the proximal Gruen zone 1 in 52 hips (50.5%) and zone 7 in 26 (25.2%). In zone 1, lines over 2 mm wide were seen in 16 (15.5%) and in 11 (10.6%) in zone 7. In the distal zones 3, 4 and 5, no radiolucent lines were observed. No stem demonstrated a continuous radiolucency reaching the tip of the prosthesis and, therefore, all implants were considered to be stable. Distinct osteolytic lesions were identified in the proximal zones in three radiographs (2.9%). Femoral cortical hypertrophy occurred in the distal medial zone 5 in 72 hips (69.9%) and in the lateral zone 3 in 33 (32.0%). The characteristic radiological findings are given in Figure 2.

Heterotopic ossification arose in 83 hips (80.6%) but only 16 (15.5%) were in Brooker stage III and none in stage IV. Calcar rounding with proximal bone resorption was seen in 21 hips (20.4%) and was not progressive after two years.

Thickening of the inner cortex around the tip of the stem (zone 4) was observed in 87 hips (84.5%). In most cases, the medullary sclerosis occurred on the medial cortex (55.3%) and less commonly on the lateral cortex (23.3%). Nineteen hips (18.4%) showed medial and lateral sclerosis and in five (4.9%), a complete pedestal was observed.

Survival. The ten-year cumulative survival with revision for any reason was 95.8% (Table I). The survivorship with aseptic loosening as a definition of failure was 98.3% for the acetabular component and 100% for the femoral component. After 15 years the cumulative overall survivorship decreased to 79.0% almost entirely because of polyethylene wear.

Discussion

The Alloclassic total hip system is popular in Europe. We obtained favourable results after a mean follow-up period of 14.4 years. Poor results were mostly related to old age and general health problems, or to periprosthetic disorders such as heterotopic ossification.

The results of all eight SF-36 domains compared with the SF-36 normative values for the gender-matched age group of 65 to 74 years were all within the 25th percentile.¹² The median WOMAC physical function, pain and stiffness scores (2.8, 3.9 and 3.9) for all patients were poorer than the age-matched normative values. In the age group of 65 to 74 years the mean WOMAC functional score was 1.94 (SD 4.3), the mean WOMAC stiffness score 0.34 (SD 6.7) and the mean WOMAC pain score 0.61 (SD 0.61).²² Func-

tion and stiffness of the study group were within one standard deviation of the age-matched normative values. However, the poorer SF-36 and WOMAC scores of the study group could be explained by the influence of various comorbid medical conditions on each of the studied outcomes.²³

Thigh pain is considered by some authors to be a result of aseptic loosening of the femoral component, related to the design of the implant and the difference in the stiffness between the implant and the bone.²⁴ We only observed two cases in our series, both in stable implants. The conical tapered titanium alloy stem has a lower modulus of elasticity than stainless steel or cobalt chrome. This may improve the load transfer from the cementless implant to the cortical bone, minimising micromovement. Burkart et al²⁵ have shown that a straight tapered stem can achieve a better initial stability than an anatomical stem, with a lower incidence of thigh pain.

The radiological data suggest that diaphyseal fixation may provide permanent stability if the design and material allow intimate implant-bone contact. The ten-year survival for the femoral component was 100% in our study and all stems reached the minimum follow-up of ten years without signs of deterioration or loosening. The first and only revision of the stem occurred after 13.6 years because of loosening created by increased polyethylene wear.

The Alloclassic stem is designed for a diaphyseal press-fit fixation which leads to proximal stress shielding and diaphyseal cortical hypertrophy. These bony reactions occur within the first years and continue without deterioration in the long term. In our study, radiolucent lines were present in the lateral Gruen zone 1 in 50.5% and in the medial zone 7 in 25.2% of cases. All radiolucencies appeared during the first two years after surgery and persisted without further increase in the following years.

Similar changes concerning the proximal stem-bone interface and the distal cortical thickening have been described previously by various authors^{9,26,27} and are typical for uncemented titanium alloy stems using a diaphyseal taper-anchoring concept. Proximal radiolucent lines and distal cortical thickening do not necessarily indicate instability or loosening of the femoral component if they are not progressive after the first two years.

In our study osteolytic lesions were very rare (2.9%) and were only found in the proximal zones of the stem. We attribute these findings to the use of a ceramic femoral head instead of a cobalt-chromium head. The advantage of using a ceramic head in combination with a polyethylene liner is a reduction in the wear rate compared with that of a metal head as an articulating partner.²⁸⁻³⁰ Additionally, the method of polyethylene manufacture should be considered. In 1985, Sulzer Orthopedics obtained an essentially homogenous calcium stearate-free polyethylene with substantially improved wear behaviour.³¹ In 1986, the company commenced sterilising these components using ⁶⁰Co-gamma irradiation under an inert-gas atmosphere (nitro-

gen).³² Osteolysis did not seem to be a serious problem for the survival of the implant.

Threaded acetabular components can achieve excellent clinical and radiological results after a follow-up period of more than ten years. With revision of the component for any reason as the end-point, our ten-year survival rate was 97.5%. Similar results were shown in a prospective study by Delaunay and Kapandji.³³ In our series, the main limiting factor for survival of the acetabular component after implantation for ten years was increased polyethylene wear.

Because of high rates of failure of a variety of threaded acetabular components³⁴⁻³⁶ this form of fixation is not generally considered to be satisfactory. Our data, and those of others,²⁷ suggest that screw-thread fixation of acetabular components can be satisfactorily achieved with this particular design. Our data support the continued use of the Alloclassic THA system.

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