We reviewed 264 consecutive primary total hip replacements in 244 patients in which the Harris-Galante I porous-coated acetabular component had been used. The mean follow-up was 95 months (69 to 132). In 221 arthroplasties a 32 mm ceramic head had been used, and in the other 43 one of cobalt-chrome alloy. There were 124 women and 120 men with a mean age at operation of 56.8 years (21 to 83).

Survival analysis of the acetabular components was performed using the following definitions of failure: 1) infection; 2) removal because of aseptic loosening; 3) removal for any cause; and 4) a worst-case analysis including removal of the cup or infection or loss to follow-up.

Two well-fixed cups had been removed because of deep infection and three, similarly sound cups had been exchanged at the time of femoral revision. None of the acetabular components had required revision for aseptic loosening. After 11 years survival was 97.7% using the worst-case criterion. Radiological analysis of 187 acetabular components at a mean of 82 months (41 to 132) revealed no case of aseptic loosening. Pelvic osteolysis was seen in only one patient, but was not progressive and showed signs of regression.

The results using these acetabular components are encouraging but the need for regular follow-up remains since complications such as significant wear of the liner, massive osteolysis of the pelvis, aseptic loosening and late infection may increase in the second decade.

Received 8 September 1997; Accepted 25 November 1997
The average diameter of the cup was 54 mm in women (48 to 64) and 58 mm in men (48 to 66). The number of screws varied between three and 12. In the first year, an average of 9.7 screws was implanted, but three years later this had decreased to 5.0. We now use only two, three or four screws.

In 216 of the 264 hips (82%), an individual cementless Aldinger stem was implanted. Since we introduced this stem in our clinic it has been combined with the Harris-Galante I cup. In 48 hips, other stems were used. Metal heads were employed in 43 hips in 40 patients, 38 with Müller straight stems (cemented), two with Müller CDH stems (cemented) and three with Weller stems (cemented). The mean age of the 40 patients with metal heads was 64 years at the time of operation. In the other 221 hips a 32 mm ceramic head was used with 216 Aldinger stems (cementless), four Zweymüller stems (cementless) and one SKT stem (cementless). The mean age of the 204 patients with ceramic heads was 55 years.

Initially, we employed the Aldinger stem, together with the Harris-Galante I cup, principally in young patients, many of whom had hip dysplasia. This may account for the six patients (2.3%) with palsy of the femoral or sciatic nerve. Four out of six lesions recovered. Complications. There were no perioperative deaths, but there were 23 intra- or perioperative complications (Table II). In four patients a fracture of the greater trochanter occurred and cerclage was necessary. This complication is a specific problem with this type of individual stem since thorough curettage of the cancellous bone and hollowing-out of the greater trochanter are essential to allow correct implantation of the individual stem. The large number of dysplastic hips with high or medium dislocation (Fig. 1) may account for the six patients (2.3%) with palsy of the femoral or sciatic nerve. Four out of six lesions recovered.

In 210 of the 264 hips (80%), an individual cementless Aldinger stem was implanted. Since we introduced this stem in our clinic it has been combined with the Harris-Galante I cup. In 48 hips, other stems were used. Metal heads were employed in 43 hips in 40 patients, 38 with Müller straight stems (cemented), two with Müller CDH stems (cemented) and three with Weller stems (cemented). The mean age of the 40 patients with metal heads was 64 years at the time of operation. In the other 221 hips a 32 mm ceramic head was used with 216 Aldinger stems (cementless), four Zweymüller stems (cementless) and one SKT stem (cementless). The mean age of the 204 patients with ceramic heads was 55 years.

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Due to the lack of uniformity and objectivity of rating systems we used the three-factor hip score with separate assessment of pain, functional activity, and movement as recommended by Bryant et al. The variables of pain, walking distance, limp and range of flexion were graded as recommended. Information concerning clinical follow-up was obtained by review of the outpatient notes. Some patients were assessed by an orthopaedic surgeon near their home. Patients for whom there was insufficient clinical information were sent a questionnaire, and all who were still living were contacted by telephone. A total of 221 hips was available for assessment.

The appearance of the bone-implant interface was examined for the presence and progression of radiolucent lines in the three zones of DeLee and Charnley and the development of osteolysis around the socket. Screw breakage and radiological changes around the screws were documented. The state of bone grafts was assessed according to the criteria proposed by Lachiewicz and Hussamy. Heterotopic ossification was classified according to Brooker et al. A complete radiological assessment was available in 187 cases (71%) at a mean of 82 months (41 to 132). In the remainder some radiographs were not comparable because of different projections, some patients refused to have further films, and in others, recent radiographs were not available. None of these patients, however, reported any problems with their hip.
within a few days. In three cases (1.1%) there was postoperative dislocation, and one required an open reduction. **Clinical evaluation**

**Pain.** Before operation 93.2% of the patients had severe pain, and 6.3% moderate. Only one patient with ankylosis after tuberculosis of the hip had no pain. At the latest follow-up, 1.8% of the patients had severe, 6.8% moderate and 12.7% mild pain, while 78.7% had none. In the four patients with severe pain, aseptic loosening of the Aldinger stem was radiologically evident and revisions were planned.

Radiological follow-up in a woman with bilateral OA due to congenital dislocation of the hip. At the age of five years an acetabuloplasty had been performed on both sides. Figure 1a – Preoperative radiograph of the patient when aged 51 years. The hip on the right side was more painful. On the left side, the congenital dislocation with a false acetabulum is well seen. Figure 1b – Radiograph 26 months after THR on the right side and four months after THR on the left. On both sides, the Harris-Galante I cup was seated in the true acetabulum and autogenous shelf grafting was performed. The acetabular components were combined with an Aldinger individual stem. Figure 1c – There is a good incorporation of the autografts and no sign of aseptic loosening 77 and 55 months after THR on the right and left sides, respectively.
Walking distance. At the latest follow-up, 79.2% (175/224) hips were in patients who could walk more than 1000 m, and 15.8% were in those who could walk outdoors but for less than 1000 m. Seven patients (3.2%) could walk indoors only and four (1.8%) were unable to walk. Two of these four suffered from advanced Parkinson’s disease, one woman had had a stroke and the other had undergone stabilisation of the lumbar spine some days before the follow-up and was temporarily bedridden. No patient was immobile because of the THR.

Limp. At the latest follow-up, 57.8% (126/218) of patients walked with a normal gait, 36.7% (80/218) had a slight limp and 5.5% (12/218) a severe limp.

Range of flexion. In 46.3% (101/218) of hips flexion of more than 105° was possible, in 43.6% (95/218) the maximum flexion ranged between 75 and 105°, and in 9.6% (21/218) it ranged between 45 and 75°. In one patient the hip was ankylosed in 30° of flexion due to heterotopic ossification of Brooker class IV.

Radiological evaluation

Migration of the acetabular component. There was a mean lateral horizontal migration of 0.77 mm (–5 to +5). The mean vertical migration was 0.36 mm (–5 to +5). Within the limits of the method used in our study, there was no documented migration of the acetabular components.

Inclination. The mean postoperative inclination was 42.0°.
The inclination of the three hips which had dislocated during follow-up was 46°, 48°, and 51°. Compared with the postoperative inclination, the mean inclination at the latest radiological follow-up had increased by 0.12° (–5 to +5). Considering the limits of the method, there was no case of radiologically documented loosening.

Radiolucent lines. There was a radiolucent line in zone I in 17 cups with a maximum width of 0.5 to 1.0 mm, in zone II in five with a maximum width of 0.5 to 1.0 mm, and in zone III in 11 with a maximum width of 1.5 mm. We found a radiolucent line in all three zones in three cups. No radiolucent line had progressed rapidly and some were visible on the first postoperative radiograph. In these, removal of residual articular cartilage may have been incomplete or press-fit was not optimal. Osteolytic areas were seen in the bone adjacent to the titanium-alloy shell in only one case (Fig. 2). No radiolucency was seen around screws and none had broken.

Bone grafts. All bone grafts showed good incorporation and there was no obvious loosening of anchoring screws.

Heterotopic ossification. No heterotopic ossification was seen in 44.9% (89/187) of hips. This was of Brooker class-I in 21.4% of hips, class II in 16.6%, class III in 15.0% and class IV in four (2.1%) including the one which was ankylosed. We tested the effect of administering non-steroidal anti-inflammatory agents after operation on the suppression of heterotopic ossification using the Spearman ranking correlation. The risk was significantly reduced (p = 0.0001) by Diclofenac, the Spearman correlation coefficient being –0.394.

Survival analysis. During the period of follow-up a further operation had been required in 24 of the 264 hips. In 18 the stem was exchanged because of aseptic loosening, and in three of these, the well-fixed cup was also removed because the liner was damaged. These three revisions were all performed in other institutions and in all cases the cups were radiologically sound and good fixation of the cup was documented in the operation report. There were three deep infections, all seen within the first three years (Fig. 3). In one, the infection was cured after exchange of the stem only, but in the other two, both the stems and the well-fixed Harris-Galante acetabular components were removed. In one patient open reduction was necessary after dislocation of the hip within six months of the original operation. In two patients with limited range of movement due to heterotopic ossification, excision of this new bone was carried out in the second year after operation. In both cases, the original endoprosthesis was left in situ.

We performed survival analysis of the Harris-Galante I cup using infection, removal of the cup because of aseptic loosening, removal of the cup for any cause and worst case (removal of the cup and/or infection and/or lost to follow-up) as criteria of failure (Tables III and IV; Fig. 3). There were no removals for aseptic loosening, and therefore on this criterion survival was 100% after 11 years. Considering removal for any cause, there were two cases of deep infection and three of well-fixed cups due to damaged liners when loose stems were exchanged. Our worst-case survival, including all removals and the case of deep infection cured by exchange of the stem, was 97.7% between the fourth and the 11th years. In comparison with the excellent survival of the Harris-Galante I cup that of the Aldinger individual stem was disappointing, yielding a survival of only 84.9% (worst-case analysis) after ten years with other patients awaiting revision because of radiologically documented aseptic loosening.

Discussion

A large number of designs of THR are available, but some with excellent results in preclinical laboratory testing may not perform satisfactorily in clinical use. Results with a

<table>
<thead>
<tr>
<th>Criteria failure</th>
<th>Survival in years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>100 100</td>
</tr>
<tr>
<td>Removal of the cup because of aseptic loosening</td>
<td>100 100</td>
</tr>
<tr>
<td>Removal of the cup for any cause</td>
<td>100 100</td>
</tr>
<tr>
<td>Worst case (removal of the cup and/or infection and/or lost to follow-up)</td>
<td>99.6 (98.9 to 100)</td>
</tr>
</tbody>
</table>
Osteolysis due to aggressive granulomatosis in cemented THR is relatively common. Recently, severe osteolysis of the pelvis has also been reported in association with acetabular replacement without cement. A prospective, randomised, double-blind clinical trial comparing cemented with cementless THR yielded no difference in the prevalence of acetabular osteolysis between the two groups during a follow-up of up to six years. In another retrospective study osteolysis occurred more often in hips in which the acetabular component had been inserted with cement. The presence of particulate polyethylene wear resulting in a foreign-body reaction is thought to be the cause of these lesions. Maloney et al. regarded the holes in the shell as potential pathways for plastic debris to gain access to the implant-bone interface. Most manufacturers then produced prostheses either without holes or with only two or three holes. In our experience the metal shell with multiple holes is extremely versatile, allowing stability of fixation by screws even in dysplastic hips and at revision surgery. We could find no evidence to support the view that the presence of multiple holes increased the risk of pelvic osteolysis.

We had only one case of periacetabular osteolysis. In 84% of our hips, however, a ceramic femoral head was used. Neither Santavirta et al. nor Maloney et al. gave information about the material of the femoral head but illustrations showed metal heads. In other relevant studies with high rates of osteolysis, the femoral head was reported to be made of cobalt-chrome or titanium alloy. There is a reduced rate of polyethylene wear when a ceramic head is used. We used a metal head in only 43 out of 264 hips and the mean age of our patients with metal heads was nine years older than that of those with ceramic heads. We had no control group, and therefore we do not know definitely if there is a significant difference between metal/polyethylene and ceramic/polyethylene wear, but the reduced amount of debris could explain the low rate of osteolysis compared with that of other studies. Acetabular osteolysis may increase with time and eventually cause a significant deterioration.

In another study of Harris-Galante cups involving 42 patients aged 50 years or under, with a mean follow-up of

### Table IV. Life table with failure of THR defined as infection and/or cup removal and/or lost to follow-up (worst case)

<table>
<thead>
<tr>
<th>Years since operation</th>
<th>Number of hips at start</th>
<th>Number withdrawn</th>
<th>Number at risk</th>
<th>Number of failures</th>
<th>Annual failure rate (%)</th>
<th>Annual success rate (%)</th>
<th>Cumulative success rate (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 1</td>
<td>264</td>
<td>2</td>
<td>263</td>
<td>1</td>
<td>0.38</td>
<td>99.62</td>
<td>100</td>
<td>100 to 100</td>
</tr>
<tr>
<td>1 to 2</td>
<td>261</td>
<td>1</td>
<td>261</td>
<td>1</td>
<td>0.38</td>
<td>99.62</td>
<td>99.62</td>
<td>98.9 to 100</td>
</tr>
<tr>
<td>2 to 3</td>
<td>260</td>
<td>4</td>
<td>258</td>
<td>3</td>
<td>1.16</td>
<td>98.84</td>
<td>99.24</td>
<td>98.2 to 100</td>
</tr>
<tr>
<td>3 to 4</td>
<td>253</td>
<td>2</td>
<td>252</td>
<td>1</td>
<td>0.40</td>
<td>99.60</td>
<td>98.08</td>
<td>96.4 to 99.7</td>
</tr>
<tr>
<td>4 to 5</td>
<td>250</td>
<td>2</td>
<td>249</td>
<td>0</td>
<td>0.00</td>
<td>100.00</td>
<td>97.69</td>
<td>95.9 to 99.5</td>
</tr>
<tr>
<td>5 to 6</td>
<td>248</td>
<td>3</td>
<td>246.5</td>
<td>0</td>
<td>0.00</td>
<td>100.00</td>
<td>97.69</td>
<td>95.9 to 99.5</td>
</tr>
<tr>
<td>6 to 7</td>
<td>245</td>
<td>56</td>
<td>217</td>
<td>0</td>
<td>0.00</td>
<td>100.00</td>
<td>97.69</td>
<td>95.9 to 99.5</td>
</tr>
<tr>
<td>7 to 8</td>
<td>189</td>
<td>85</td>
<td>146.5</td>
<td>0</td>
<td>0.00</td>
<td>100.00</td>
<td>97.69</td>
<td>95.9 to 99.5</td>
</tr>
<tr>
<td>8 to 9</td>
<td>104</td>
<td>65</td>
<td>71.5</td>
<td>0</td>
<td>0.00</td>
<td>100.00</td>
<td>97.69</td>
<td>95.9 to 99.5</td>
</tr>
<tr>
<td>9 to 10</td>
<td>39</td>
<td>30</td>
<td>24</td>
<td>0</td>
<td>0.00</td>
<td>100.00</td>
<td>97.69</td>
<td>95.9 to 99.5</td>
</tr>
<tr>
<td>10 to 11</td>
<td>9</td>
<td>7</td>
<td>5.5</td>
<td>0</td>
<td>0.00</td>
<td>100.00</td>
<td>97.69</td>
<td>95.9 to 99.5</td>
</tr>
<tr>
<td>11 to 12</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0.00</td>
<td>100.00</td>
<td>97.69</td>
<td>95.9 to 99.5</td>
</tr>
</tbody>
</table>

Osteolysis due to aggressive granulomatosis in cemented minimum of ten years of follow-up are required. Unfortunately, valid data about clinical outcome are only available for a few designs. The durability of fixation of the cemented femoral component has been demonstrated even in young patients, and improved cementing techniques have produced a marked reduction in the rate of aseptic loosening. Loosening on the acetabular side, however, remains a major problem. Even advocates of cemented fixation recommend this for the cup only in carefully selected patients; those over the age of 60 years or with a life expectancy of 20 years or less. There is a recent trend towards cementless fixation of the cup, especially in young patients, but there are few data which support this. Altered method for evaluation of THR is difficult, however, to report the functional results of only one component of a THR, because it may be impossible to determine which part is responsible for poor performance. The overall state of the patients will vary so much that comparison of assessments of function with the use of different designs of prostheses may not be a suitable means of judging their quality. Considering these limitations, the functional results in the present study were within the scale of THR with cement or a hybrid THR.
7.4 years (5 to 10), six liners had to be replaced due to excessive wear, but again, there was no information about the material of the femoral head. We had no problems with excessive wear of the liners but this may become a concern, especially in young and active patients. Regular follow-up is needed because, when seen in time, replacement of the liner is a minor procedure in modular acetabular components. In small acetabular components, the use of a 28 mm liner is a minor procedure in modular acetabular components. The risk of injury to intrapelvic structures is low when anatomical studies are taken into account. Tomkins et al noted no neurovascular complication in 132 hips with at least one screw penetrating a minimum of two screw threads beyond the inner table of the pelvis.

Although radiological analysis may be useful in survival analyses of prostheses with a high incidence of aseptic loosening and a short follow-up, especially in prospective studies of new concepts of prostheses, it proved of little value in our study.

Using worst-case analysis, the survival of the Harris-Galante I cup was 97.7% after 11 years. This encouraging outcome, with no aseptic loosening of the acetabular components, suggests that cementless fixation may be equal to or even better than that using cement. Nevertheless, we have to wait another decade before a final comparison with the long-term results of the Charnley prosthesis can be made. Regular follow-up examination remains necessary.

The authors would like to thank Christoph Meisner, MA, (Department of Medical Data Processing, Eberhard-Karls-Universität, Tübingen) for statistical advice. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


