Ten-year follow-up of the non-porous Allofit cementless acetabular component

P. Zenz, J. B. Stiehl, H. Knechtel, G. Titzer-Hochmaier, W. Schwagerl

Cementless acetabular fixation has demonstrated superior long-term durability in total hip replacement, but most series have studied implants with porous metal surfaces. We retrospectively evaluated the results of 100 consecutive patients undergoing total hip replacement where a non-porous Allofit component was used for primary press-fit fixation.

This implant is pure titanium, grit-blasted, with a macro-structure of forged teeth and has a biradial shape. A total of 81 patients (82 hips) were evaluated at final follow-up at a mean of 10.1 years (8.9 to 11.9). The Harris Hip Score improved from a mean 53 points (23 to 73) pre-operatively to a mean of 96 points (78 to 100) at final review. The osseointegration of all acetabular components was radiologically evaluated with no evidence of loosening. Radiolucency was found in one DeLee-Charnley zone in four acetabular components. None of the implants required revision for aseptic loosening. Two patients were treated for infection, one requiring a two-stage revision of the implant. One femoral stem was revised for osteolysis due to the production of metal wear debris, but the acetabular shell did not require revision.

This study demonstrates that a non-porous titanium acetabular component with adjunct surface fixation offers an alternative to standard porous-coated implants.

One of the most important advances in total hip replacement (THR) has been the application of cementless fixation for acetabular components, with excellent long-term results in fixation and performance. National registry studies for THR have found the ten-year survival to range from 94% to 98%. For most recent devices, the optimal choice has been of a porous ingrowth surface designed to have an interference fit of the prosthesis, which is a dome-shaped device driven into a hemispherically prepared cavity. Experience has shown that if dense subchondral bone is preserved and the roughened surface engages with a mechanical press-fit, there is little need for additional fixation with screws, pegs or fins. Another option has been to achieve fixation with a threaded conical device that relies on thick threads cut into the bone. Although some success has been reported with these devices, the inherent movement and stress concentration of loading threaded fixation points is not as attractive.
The other important mechanical features include the roughness of the surface, which enhances bone stability, and the surface characteristics that encourage bony incorporation. Any method, such as grit-blasting or a high-porosity finish, that produces a high-friction surface will encourage bone to form directly to the surface.\textsuperscript{22,23} It has been shown that inert metals such as pure titanium and tantalum provide a favourable ionic environment which encourages bone abutment to the metal. A highly porous surface with an average pore size of 500 $\mu$m to 600 $\mu$m is optimal for substantial ingrowth into the surface.\textsuperscript{24-27}

Although porous surfaces may offer an ideal interface, their fabrication can be expensive and time-consuming. The bond of the porous material to the underlying substrate metal must be secure enough to prevent subsequent delamination. The porous surface might not provide a barrier to the ingress of wear particles that occur during typical prosthetic use. In order to address these issues, a non-porous prosthesis was created from pure titanium that had a grit-blasted roughened surface, and adjunct surface fixation consisting of macrotextured 500 $\mu$m to 600 $\mu$m teeth in the surface (Fig. 1). The prosthesis had a biradial design to create a 2 mm press-fit at the periphery on insertion. We report our results with the first 100 hips into which we used this prosthesis.

Patients and Methods
This clinical and radiological study related to the first \textit{100 consecutive THR}s performed from 1994 to 1996 using the Allofit press-fit acetabular component (Alloclassic, Zimmer, Winterthur, Switzerland). Data were collected prospectively on all patients until their death or failure of the device. All the operations were performed at the same institution by \textit{four of the authors}. The primary diagnosis in the original group was osteoarthritis in 82 hips, rheumatoid arthritis in seven, developmental dysplasia in six, and post-traumatic arthritis in five.

Of the original group, \textit{seven patients} had died, but none had required further operation related to the THR, and the most recent radiograph within \textit{two years before death} revealed a well-fixed implant. A total of \textit{11 patients} were lost to follow-up \textit{ranging from 0.9 to 8.9 years} after the initial operation. None of these patients had required known additional surgical intervention, and the most recent radiographs had revealed well-fixed implants.

The remaining 82 hips in \textit{81 patients} were available for review at a mean follow-up of 10.1 years (8.9 to 11.9). The \textit{81 patients comprised of 62 women and 19 men}. Their mean age at the time of operation was 63 years (30.6 to 79.4). Their mean weight was 71 kg (49 to 110).

The Allofit acetabular component design is modular and biradial in concept, realised by a hemispherical periphery and a flattened polar region (Fig. 1). The surface of the titanium alloy implant is prepared with a
macrostructure of grooves and ridges that create ‘teeth’ with a dimension of 400 μm to 600 μm. The entire external surface of the implant is grit-blasted with corundum. For optimal press-fitting we under-reamed the cavity by 2 mm in relation to the peripheral dimension of the device. The implant was available with five or six screw holes for additional fixation, or a solid continuous outer surface without holes, and a polar plug for the threaded polar hole used for the insertion instrument. We used the solid device without adjunct holes or screws in all patients.

The wear couples were either ceramic-on-polyethylene (16 hips) or Metasul CoCr alloy (Zimmer) metal-on-metal (84 hips). For the metal-on-metal couple, the inner bearing was a minimum of 51 mm thick and was fixed to polyethylene using a polyethylene sandwich technique. The polyethylene liner design was either neutral or asymmetrically hooded. In order to avoid rotational movements of the liner in the titanium shell, as well as to prevent abrasion between the shell and the liner, there were two metal spikes on the inside of the implant for rotational stability of the polyethylene liner. Without exception, the AlloClassic SL stem (Zimmer) was implanted as the corresponding stem. The head size was 28 mm in all cases, with different neck lengths (short in 18, medium in 44, and long in 38 hips). In 85 hips, the surgical approach was performed according to Watson-Jones, and in 15 cases using the transgluteal approach according to Bauer.

The Harris Hip Score (HHS) was determined before operation and at the most recent follow-up. Anteroposterior and lateral radiographs were taken on these occasions. Components without radiolucent lines or evidence of migration on the radiographs taken at final follow-up were considered to be well fixed. Those with a circumferential radiolucent line but without migration were considered to have a stable fibrous union. Those with progressive radiolucent lines or exhibiting migration were considered to be loose. The acetabular component was considered to have migrated if there was a change of > 3 mm horizontally or vertically over time.

The prevalence, location and extent of osteolytic lesions and progressive radiolucent lines was determined at the last follow-up. Osteolysis was defined as a lucent zone devoid of trabecular bone and usually with a sclerotic border. Per-acetabular osteolytic lesions were assessed according to the zones described by DeLee and Charnley, and the area of each lesion was measured on the last follow-up radiograph.

A Kaplan-Meier survival analysis was performed to calculate the survival of this acetabular component, the endpoint being revision or an indication for revision, such as aseptic loosening or implant migration. Survival tables were calculated using 12-month intervals. For each interval, the number of patients entering the interval, the number of failures and withdrawals for any reason, the number at risk, the annual rates of failure and success, and the cumulative success rate were calculated.
with 95% confidence intervals (CI). We determined that the endpoint of this analysis would be when fewer than a minimum of 20 patients were available for analysis.

Results
Of the 100 acetabular components, two have been revised, one for chronic infection and in the other the metal inlay was revised for severe osteolysis around the femoral component, with exchange for a polyethylene liner and a new modular stem with a ceramic head. In both cases the acetabular component was considered to be well fixed.

The clinical and radiological results were available for evaluation in 81 hips, of which 98.7% had not undergone revision of the acetabular component. The mean HHS improved from 53 (23 to 73) to 96.5 (78 to 100) points in these patients. The results were rated as excellent in 65 hips (80.2%), good in nine (11.1%), fair in seven (8.7%), and poor in none.

The radiological results showed that 81 hips had a well-fixed component with no evidence of migration or significant radiolucency. No radiolucenties were detected in 78 of 81 hips (96%). In three hips a radiolucent line of < 1 mm in width was found in DeLee-Charnley zone III. In one hip, in which a cyst in zone I had been filled with autologous bone at the time of replacement, resorption of 2 mm was observed post-operatively. No osteolysis could be observed radiologically in any hip.

The survival rate with revision of the implant as the endpoint was 97.5% (95% CI 94 to 100) after 11.9 years, according to the Kaplan-Meier method (Fig. 2). Two revisions were performed, one two-stage exchange operation after 1.1 years because of deep infection, and one exchange of a metal-on-metal inlay and replacement with polyethylene liner with a new femoral stem and head after 9.5 years, as detailed previously.

Complications included two post-operative dislocations, one acute infection within two weeks, and one late chronic infection after one year. Both dislocations were treated conservatively. The early infection was successfully treated by radical synovectomy and drainage, whereas the late infection after one year was successfully revised with a two-stage procedure.

Discussion
We found that a non-porous acetabular component could remain well fixed for a prolonged period without risk of progressive loosening or osteolysis. The radiological control after ten years showed bony osseointegration in 78 of 81 hips. However, in three cases we found radiolucency in one zone without evidence of aseptic loosening. This led us to conclude that our surface design could offer comparable results to those of other studies using implants of similar geometry and material but with a porous-coated surface.

Cementless acetabular fixation in general has several consistent features that most implant designs have followed. Importantly, the subchondral bone of the acetab-
ular interface must be maintained, particularly in the dense areas of the anterosuperior ilium and the ischium. Several reports have shown that even elderly osteoporotic patients may have satisfactory long-term implant stability if the remaining subchondral bone is preserved. Second, hemispherical geometry is a logical approach both to match the shape of the acetabulum and to load with a round structure that replicates the shape of the normal femoral head. Early biomechanical studies demonstrate that the pelvis and the cartilage interface is somewhat flexible with loading, enlarging slightly to allow for greater articulation. That concept leads to the third principle, which is a 2 mm underreamed press-fit. The press-fit then allows the implant to load on the periphery, which would be the primary contact area of the normal acetabulum. We created a biradial design for the prosthetic component in the belief that this would unload the medial wall of the acetabulum and concentrate forces to the implant periphery.

The question remains, how much biological incorporation or fixation is needed for long-term implant survival? It is known that many fully porous devices have a limited surface of bony ingrowth, with histological studies identifying up to 25% of actual porous ingrowth. The remaining surface has only fibrous incorporation or none at all. Ingrowth is the more likely to succeed, and one recent study demonstrated up to 50% incorporation of bone interface apposition with a hydroxyapatite-coated rough titanium surface. The clinical outcomes of most of these cementless devices have been exceptional, surpassing the earlier principal device which was a cemented polyethylene prosthesis. It has been proposed that wear particles will eventually overwhelm the local histological homeostasis, leading to an osteolytic inflammatory process and eventual implant loosening. How much surface apposition or ingrowth is needed to protect against this problem is currently unknown. The primary focus of current research has been to improve prosthetic tribology by limiting the particle load presented to this interface.

We are concerned by the one case of severe osteolysis resulting from the metal-on-metal couple in this study. In this patient, the acetabular shell remained stable but loss of femoral fixation occurred, which for cementless THR has been a much smaller problem than with acetabular fixation. We are concerned by further contemporary reports of osteolysis associated with metal debris occurring with longer follow-up beyond five years. This has led to a change in our clinical practice away from metal-on-metal articulations.

In conclusion, the ten-year results with the hemispherical non-porous acetabular component used in this study are satisfactory, and the device remains our preferred choice of prosthesis. We believe this option may be desirable when longevity of implant survival is balanced against the expense of producing the device. A survey of other available acetabular components for uncemented
fixation would suggest a 40% to 80% increase in cost related to surface treatments such as porous or hydroxyapatite coatings. Further evaluation will show to what extent future production of wear debris will influence these results.

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


Fig. 1 Photograph showing the allofit acetabular component with macrotextured surface.

Fig. 2 Kaplan-Meier survival curve showing revision of the implant as the endpoint.

### Table I. Survival analysis using the Kaplan-Meier method for 100 consecutive total hip replacements using the Allofit acetabular component

<table>
<thead>
<tr>
<th>Follow-up interval (yr)</th>
<th>Hips at risk</th>
<th>Hips revised</th>
<th>Survival estimate</th>
<th>95% confidence interval survival estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100</td>
<td>0</td>
<td>1.00000</td>
<td>1.000 to 1.000</td>
</tr>
<tr>
<td>2</td>
<td>96</td>
<td>1</td>
<td>0.98958</td>
<td>0.9693 to 1.000</td>
</tr>
<tr>
<td>3</td>
<td>94</td>
<td>0</td>
<td>0.98958</td>
<td>0.9693 to 1.000</td>
</tr>
<tr>
<td>4</td>
<td>94</td>
<td>0</td>
<td>0.98958</td>
<td>0.9693 to 1.000</td>
</tr>
<tr>
<td>5</td>
<td>94</td>
<td>0</td>
<td>0.98958</td>
<td>0.9693 to 1.000</td>
</tr>
<tr>
<td>6</td>
<td>92</td>
<td>0</td>
<td>0.98958</td>
<td>0.9693 to 1.000</td>
</tr>
<tr>
<td>7</td>
<td>92</td>
<td>0</td>
<td>0.98958</td>
<td>0.9693 to 1.000</td>
</tr>
<tr>
<td>8</td>
<td>90</td>
<td>0</td>
<td>0.98958</td>
<td>0.9693 to 1.000</td>
</tr>
<tr>
<td>9</td>
<td>87</td>
<td>0</td>
<td>0.98958</td>
<td>0.9693 to 1.000</td>
</tr>
<tr>
<td>10</td>
<td>78</td>
<td>1</td>
<td>0.97503</td>
<td>0.9404 to 1.000</td>
</tr>
<tr>
<td>11+</td>
<td>40</td>
<td>0</td>
<td>0.97503</td>
<td>0.9404 to 1.000</td>
</tr>
</tbody>
</table>
Author queries

Page 1  ??????: AQ - Please provide source.

Page 1  pure titanium: AQ - In the text you say it is titanium alloy. Which is correct?

Page 2  pure titanium: AQ - Pure or alloy?

Page 2  100 consecutive THR: AQ - Say in how many patients? Abstract says 100 - correct?

Page 2  four of the authors: AQ - Please give initials.

Page 2  seven patients: AQ - How many hips?

Page 2  two years before death: AQ - Is this correct?

Page 2  11 patients: AQ - How many hips?

Page 2  ranging from 0.9 to 8.9 years: AQ - Please give mean (0.9 to 8.9) with this range.

Page 2  81 patients: AQ - If 7 died and 11 were lost there was a start total of 99. Abstract says 100 - confirm.

Page 2  The 81 patients comprised of 62 women and 19 men. Their mean age at the time of operation was 63 years (30.6 to 79.4). Their mean weight was 71 kg (49 to 110): AQ - Correct 82 or 81? Please provide this info. for all 100 hips as well.

Page 3  Metasul CoCr alloy (Zimmer): AQ - Is this correct?

Page 3  Watson-Jones: AQ - Please provide reference.

Page 3  Bauer: AQ - Please provide reference.

Page 3  Harris Hip Score (HHS): AQ - Please provide reference.

Page 4  81: AQ - Should this not be 82 hips (81 patients)?

Page 4  98.7%: AQ - Please give absolute number.

Page 4  65 hips (80.2%), good in nine (11.1%), fair in seven (8.7%): AQ - Please confirm these figures 65 + 9 + 7 = 81 hips.

Page 4  81 hips: AQ - Please confirm number evaluated.

Page 4  81 hips: AQ - Please confirm number.
Page 4  results to those of other studies: AQ - Please quote references.

Page 5  The clinical outcomes of most of these cementless devices have been exceptional, surpassing the earlier principal: AQ - Please provide some references.

Page 5  which for cementless THR has been a much smaller problem than with acetabular fixation: AQ - Please provide reference.

Page 5  A survey: AQ - Is this your survey? What was your financial source?

Page 6  No benefits: AQ - Is this statement correct?

Page 7  Fig. 2: AQ - Is this ok? How should the axes be labelled?

Page 7  Table I: AQ - Please add another column. Withdrawn to list all deaths and losses to follow-up.