Original article

Medium-term osteolysis with the Wallaby I® deep-dished total knee prosthesis

B. Marion¹,², D. Huten³, P. Boyer¹,², C. Jeanrot¹,², P. Massin¹,²,³

¹ Service de chirurgie orthopédique, hôpital Bichat-Claude-Bernard, 46, rue Henri-Huchard, 75877 Paris cedex 18, France
² EA REMES, université Paris-Diderot, Sorbonne Paris Cité, 75010 Paris, France
³ Service de chirurgie orthopédique, CHU de Rennes, 16, boulevard Bulgare, BP 90347, 35203 Rennes cedex 2, France

ABSTRACT

Background: Highly congruent total knee prostheses were introduced in the 1990s in the hope of decreasing polyethylene wear, thereby minimising loosening and particle-induced peri-prosthetic osteolysis. Despite promising long-term outcomes, substantial rates of aseptic loosening were reported with conventional gamma-irradiated polyethylene inserts, suggesting that highly reticulated polyethylene should be used instead. We assessed medium-term outcomes of the Wallaby I® total knee prosthesis with a deep-dished tibial insert made of conventional gamma-irradiated polyethylene.

Hypothesis: We hypothesised that the deep-dished Wallaby I® prosthesis was associated with similar or lower rates of aseptic loosening and peri-prosthetic osteolysis compared to posterior-stabilised prostheses.

Materials and methods: At our institution, 121 consecutive patients underwent total knee arthroplasty (TKA) with a deep-dished cemented prosthesis (Wallaby I®, Sulzer/Centerpulse, Zürich, Switzerland) between 2001 and 2005. Among them, 89 had complete follow-up data over a 4-year period and a mean follow-up of 96 months. We retrospectively analysed the clinical and radiographic IKs scores in these 89 patients.

Results: Osteolysis with aseptic loosening required revision TKA of 10 knees after a mean follow-up of 81 months. Mean 9-year prosthesis survival was 88 ± 17%. Four inserts exhibited evidence of delamination. A fracture of the postero-medial aspect of the tibial baseplate beneath a zone of insert wear was found in 1 knee and gross mobility of the insert on the baseplate in 6 knees. The other 79 patients had good clinical and radiographic outcomes with a mean range of active knee flexion of 108 ± 15°.

Discussion: The medium-term outcomes in our study were inferior to those reported with posterior-stabilised tibial components. Sporadic variations in polyethylene quality may explain the cases of osteolysis (shelf oxidation). In addition, the increased shear stresses related to the deep-dish design may increase backside wear, thereby compromising insert fixation to the baseplate. We believe the Wallaby I® prosthesis should no longer be used, and we recommend computed tomography follow-up of patients harbouring this prosthesis.

Level of evidence: Level IV (retrospective study).

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1. Introduction

Ultra-congruent prostheses for total knee arthroplasty (TKA) were introduced in the 1990s to overcome the drawbacks of posterior-stabilised implants. Absence of a posterior cam decreases the amount of bone that must be removed during preparation of the femur [1–3]. Conceivably, greater congruence might improve stability during walking and decrease long-term wear [4].

On the other hand, greater congruence is associated with stronger shear forces at the fixation interface, which might increase the long-term risk loosening [5]. The decrease in femoral rollback, in the absence of posterior stabilisation, might decrease range of motion, given the theoretical relationship between decreased femoral roll-back and range of active knee flexion [6,7].

Outcome data on ultra-congruent TKA are scarce [3,8,9]. In a study by Hofmann et al. [3], a cementless prosthesis with screw fixation of the tibial baseplate was associated with a 95% 10-year
survival rate. No cases of osteolysis were recorded in this first study, but a subsequent study of this prosthesis type reported by the same group in 2008 [9] showed aseptic loosening in 4% and radiolucent lines in 20% of cases. This second study was conducted comparatively with a prosthesis in which the insert was composed of highly reticulated polyethylene. This optimised polyethylene was associated with significantly lower rates of loosening and radiolucent lines and was consequently strongly recommended by the authors. Bourne et al. [8] found a 96% survival rate after 12 years with a cemented implant with a conventional polyethylene and reported no cases of osteolysis or loosening.

Given these conflicting data, we evaluated the medium-term outcomes of 129 ultra-congruent cemented TKAs (Wallaby I®, Sulzer/Centerpulse, Zürich, Switzerland) with a fixed-insert, implanted consecutively at our institution. We directed special attention to loosening and osteolysis. We compared these outcomes to those of historical case-series of posterior-stabilised implants [10,11]. Our working hypothesis was that the radiological and clinical medium-term outcomes with the ultra-congruent cemented Wallaby I® implant would be similar to those of posterior-stabilised implants after the same follow-up duration. We sought answers to the following two questions:

- Do the theoretical advantages of ultra-congruence translate into decreased medium-term rates of wear and osteolysis?
- How does the ultra-congruent design influence the range of active knee flexion?

2. Material and methods

Ultra-congruent TKA was performed in 121 consecutive patients (129 knees) at the Bichat-Claude-Bernard Teaching Hospital, Paris, France, between March 2001 and October 2005, by two senior orthopaedic surgeons (DH and CJ). Of the 121 patients, 13 died and 19 were lost to follow-up within 4 years after the procedure, leaving 89 patients (97 knees) with follow-ups longer than 4 years. Mean follow-up was 96 ± 18 months. The demographic characteristics were similar in the source and study populations (Table 1).

We used the Wallaby I® implant (Sulzer/Centerpulse, Zürich, Switzerland), which includes a cemented tibial baseplate (PalacosGenta®, Heraeus Medical, Wehrheim, Germany) and a fixed ultra-congruent insert sterilised by gamma irradiation (2.5 MGK). The metallic components had the posterior cruciate ligament (PCL)-retaining design whose outcomes after a mean follow-up of 7 years have been reported previously [12]. The femoral component was made of cobalt chromium and the baseplate of unpolished titanium. The back of the insert and insert fixation mode were identical to those of the PCL-retaining prosthesis: the insert was snapped into the baseplate, and a midline anterior lip was lodged under the baseplate rim to prevent anterior lifting of the insert during knee flexion. The only difference between the two models was the design of the articular aspect of the insert.

Exposure was via the medial para-patellar approach, with a pummatic tourniquet. The implantation technique involved independent bone cuts after resection of both cruciate ligaments, combined with patellar resurfacing. Mean polyethylene insert thickness was 10 ± 2 mm.

Postoperative care included conventional prophylactic antibiotic therapy for 48 hours and thromboprophylaxis with low-molecular-weight heparin for 21 days. A passive motion device (Arthromoteur®) was used for knee rehabilitation starting on the first postoperative day. Ambulation and weight bearing were allowed immediately.

The primary evaluation criterion was radiographic evidence of aseptic loosening and/or osteolysis. Aseptic loosening was defined as either a continuous line (encompassing the tibial stem) at least 2 mm in width or as partial, increasingly wide lines at the fixation interface. Osteolysis was defined as bone defects of any size. The secondary evaluation criteria were range of active knee flexion measured manually using a goniometer at last follow-up and the IKS scores [13]. Once a year, the patients underwent a clinical and radiological evaluation that included a postoperative long-leg radiograph, antero-posterior and lateral radiographs of the knee, and a patella-femoral radiograph. The radiographs were assessed by independent observers who did not participate in performing the surgical procedures (BM and PB).

We compared the demographic characteristics of the source population and study population using Student’s t-test for quantitative variables (age and body mass index) and the Chi² test for qualitative variables (sex and aetiology). Failure rates were computed as percentages of study knees. Prosthesis survival was evaluated using the Kaplan-Meier method [14] based on the 129 knees in the source population. Failure was defined as osteolysis and/or aseptic loosening (with or without revision) and as revision for any reason.

3. Results

Of the 97 knees, 10 (10.3%) exhibited marked osteolysis with mechanical pain and unequivocal loosening of one or both prosthetic components (Figs. 1 and 2). The femoral component was loose in 6 cases and both components in 4 cases (Table 2). All 10 patients underwent revision surgery with replacement of both components. Mean time to revision surgery was 81 ± 17 months (range, 60–109 months). Findings upon examination of the removed inserts consisted of marked delamination in 4 cases (Fig. 3), a notch in the posterior rim of the medial dish in 1 case (Fig. 4), and posterior wear of the medial dish in 1 case (Fig. 5). Deterioration of the snapping mechanism designed to secure the insert

Table 1

<table>
<thead>
<tr>
<th>Demographic data.</th>
<th>Source population</th>
<th>Study population</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>121</td>
<td>89</td>
<td>0.43</td>
</tr>
<tr>
<td>Number of knees</td>
<td>129</td>
<td>97</td>
<td>0.44</td>
</tr>
<tr>
<td>Age in years, mean ± SD (range)</td>
<td>66 ± 11 (36–95)</td>
<td>65 ± 11 (36–90)</td>
<td>0.85</td>
</tr>
<tr>
<td>Male/female ratio</td>
<td>0.4</td>
<td>0.36</td>
<td>0.77</td>
</tr>
<tr>
<td>BMI</td>
<td>28 ± 0.5 (17–46)</td>
<td>28 ± 0.5 (17–46)</td>
<td>1</td>
</tr>
<tr>
<td>Aetiologies, n of patients</td>
<td></td>
<td></td>
<td>0.67</td>
</tr>
<tr>
<td>Primary knee OA</td>
<td>90</td>
<td>66</td>
<td></td>
</tr>
<tr>
<td>Post-traumatic knee OA</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Avascular necrosis</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Inflammatory joint disease</td>
<td>12</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

BMI: body mass index; OA: osteoarthritis.

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Fig. 1. Postoperative radiographs in a 56-year-old male (patient #5) treated for primary knee osteoarthritis. Elevation of the anterior tibial tuberosity was performed because of knee flexion limitation to 90° (a). Radiographs after 6 years showing osteolysis with loosening of the femoral component (b). Revision of both components with implantation of a semi-constrained prosthesis including extension rods and metallic tibial and femoral wedges (c).

Fig. 2. Postoperative radiographs in a 72-year-old female (patient #1) treated for primary knee osteoarthritis with constitutional genu varum deformity. Tibial stabilisation stem to bridge the site of a tibial osteotomy performed in the distant past (a). After 7 years, bipolar osteolysis with loosening of the femoral component (b). Revision of both components with implantation of a hinged prosthesis including extension rods and femoral wedges (c).

onto the baseplate was seen in 6 cases and resulted in gross mobility between the insert and baseplate. Finally, in 1 case the postero-medial part of the metallic baseplate was fractured beneath the zone of polyethylene wear (Fig. 5). In the 79 remaining patients (87 knees), the implants seemed stable, with no radiographic evidence of loosening (partial tibial radiolucent line in 1 case). When we defined failure as aseptic loosening and/or osteolysis, we found that the 9-year survival rate in the overall population was 88 ± 17% (Table 3); one prosthesis failed later on, during the tenth year.

Among the other complications, 4 required surgical revision. A peri-prosthetic diaphyseal fracture was managed using plate fixation without removal of the prosthesis. Two deep surgical-site infections were treated by two-stage exchange arthroplasty. Finally, 1 case of laxity with knee instability was successfully managed by a secondary hinged prosthesis.

Table 2

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (years)</th>
<th>BMI (kg/m²)</th>
<th>Initial aetiology</th>
<th>Time to revision (months)</th>
<th>Location of osteolytic defects</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
<td>72</td>
<td>28.7</td>
<td>Primary knee OA</td>
<td>69</td>
<td>Femur + tibia</td>
<td>F</td>
</tr>
<tr>
<td>Patient 2</td>
<td>64</td>
<td>23</td>
<td>Primary knee OA</td>
<td>62</td>
<td>Femur + tibia</td>
<td>M</td>
</tr>
<tr>
<td>Patient 3</td>
<td>68</td>
<td>38.2</td>
<td>Primary knee OA</td>
<td>84</td>
<td>Femur + tibia</td>
<td>F</td>
</tr>
<tr>
<td>Patient 4</td>
<td>78</td>
<td>27.8</td>
<td>Primary knee OA</td>
<td>101</td>
<td>Femur</td>
<td>M</td>
</tr>
<tr>
<td>Patient 5</td>
<td>56</td>
<td>27.7</td>
<td>Primary knee OA</td>
<td>84</td>
<td>Femur + tibia</td>
<td>M</td>
</tr>
<tr>
<td>Patient 6</td>
<td>53</td>
<td>23.1</td>
<td>Rheumatoid arthritis</td>
<td>95</td>
<td>Femur</td>
<td>F</td>
</tr>
<tr>
<td>Patient 7</td>
<td>36</td>
<td>29.0</td>
<td>Rheumatoid arthritis</td>
<td>109</td>
<td>Femur + tibia</td>
<td>M</td>
</tr>
<tr>
<td>Patient 8</td>
<td>55</td>
<td>25.7</td>
<td>Primary knee OA</td>
<td>70</td>
<td>Femur + tibia</td>
<td>F</td>
</tr>
<tr>
<td>Patient 9</td>
<td>56</td>
<td>25.3</td>
<td>Primary knee OA</td>
<td>60</td>
<td>Femur + tibia</td>
<td>M</td>
</tr>
<tr>
<td>Patient 10</td>
<td>55</td>
<td>28.1</td>
<td>Rheumatoid arthritis</td>
<td>72</td>
<td>Femur + tibia</td>
<td>F</td>
</tr>
</tbody>
</table>

OA: osteoarthritis.

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managed by replacing the insert by a thicker one. When we defined failure as revision surgery for any reason, we obtained a 9-year survival rate of 83 ± 18%.

In the 79 patients (87 knees) with no evidence of osteolysis (Fig. 6), mean increase in range of knee flexion at last follow-up was 0 ± 5° (range, –40 to 65°). Mean range of active knee flexion at last follow-up was 105 ± 15° (range, 80–130°). Mean IKS knee score improved from 36 ± 17 preoperatively to 85 ± 14 at last follow-up ($P = 0.006$) and mean IKS function score from 38 ± 21 to 56 ± 31 ($P = 0.03$). The functional outcome was good or very good for 86 knees and fair for 1 knee. Moderately severe anterior knee pain was reported by 6 patients, including 2 with slightly eccentric seating of the patella. Mean tibio-femoral alignment was 179° (range, 170–187°) and malalignment by more than 3° was noted in 7 knees. Finally, lateral patellar displacement was noted in 18 cases and medial patellar displacement in 1 case.

### 4. Discussion

With a 10.3% osteolysis rate and an 88% 9-year survival rate, the outcomes in our study are inferior to those reported in two studies of cemented posterior-stabilised prostheses with inserts made of conventional gamma-irradiated polyethylene [10,11]. In these two studies, 10-year osteolysis rates were lower than 5% and 10-year survival rates were equal to or greater than 95%, with mean active knee flexion ranges of 95° to 115°. Using revision for any reason to define failure, Ranawat et al. [11] reported a 94.1% survival rate after 11 years (cemented TCK® prosthesis), with no cases of revision for osteolysis and a single case of tibial baseplate loosening that did not require revision. Radiolucent lines were visible about the tibial component in 60% of cases but were neither progressive nor symptomatic. With the same definition of failure, Meftah et al. [10] found a 10-year survival rate of 97.7% (cemented PFC Sigma® prosthesis). The reason for revision was infection or peri-prosthetic fracture, and no case of osteolysis was reported. Numerous other studies

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confirm these results of posteriorly-stabilised prostheses (Table 4), with survival rates greater than 95% after 10 years [16] and in some cases after 15 years [17] or 23 years [18]. Overall, these studies included populations similar to ours in terms of age, sex ratio, and aetologies, with a marked predominance of osteoarthritis in knees exhibiting constitutional deformities. Lachiewicz et al. reported osteolysis in 4% of knees (8/199) 7 years on average after TKA with a posteriorly-stabilised prosthesis (cemented Insall Burstein II®) [19]. None of these 8 knees showed loosening and none required revision.

Table 4

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of patients</th>
<th>Follow-up (years)</th>
<th>Flexion (°)</th>
<th>IKS knee</th>
<th>IKS function</th>
<th>Survival</th>
<th>Osteolysis or loosening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranawat et al. [11]</td>
<td>112</td>
<td>11</td>
<td>95</td>
<td>83</td>
<td></td>
<td>94.1% at 11 years (septic or aseptic loosening); 88.7% at 11 years (all-cause failure)</td>
<td>No revisions for osteolysis, 1 tibial loosening, 60% with peri-prosthetic lucent lines</td>
</tr>
<tr>
<td>Colizza et al. [15]</td>
<td>101</td>
<td>10</td>
<td>110</td>
<td>85</td>
<td>71</td>
<td>96% at 10 years (all-cause failure)</td>
<td>3% with osteolysis, 11% with lucent lines</td>
</tr>
<tr>
<td>Malkani et al. [16]</td>
<td>119</td>
<td>10</td>
<td>79</td>
<td>64</td>
<td></td>
<td>98.6% at 15 years; 98.6% at 20 years (all-cause failure)</td>
<td>0% with osteolysis</td>
</tr>
<tr>
<td>Gill et al. [17]</td>
<td>72</td>
<td>17</td>
<td>108</td>
<td>88</td>
<td>56</td>
<td>91% at 23 years (all-cause failure)</td>
<td>4% with aseptic osteolysis (revision)</td>
</tr>
<tr>
<td>Pavone et al. [18]</td>
<td>120</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lachiewicz et al. [19]</td>
<td>193</td>
<td>7</td>
<td>112</td>
<td>89</td>
<td>52</td>
<td></td>
<td>4% with aseptic loosening (no revision)</td>
</tr>
<tr>
<td>Rodricks et al. [20]</td>
<td>160</td>
<td>15</td>
<td>112</td>
<td>89</td>
<td>65</td>
<td>91.5% at 15 years; 97.2% at 15 years (aseptic loosening)</td>
<td>2.5% with aseptic osteolysis (no revision); 62% with non-progressive lucent lines</td>
</tr>
<tr>
<td>Meftah et al. [10]</td>
<td>138</td>
<td>10</td>
<td>119</td>
<td>94</td>
<td>90</td>
<td>97.7% at 10 years</td>
<td>0%</td>
</tr>
</tbody>
</table>

Fig 6. Postoperative radiographs in a 71-year-old female treated for primary knee osteoarthritis (a). Radiographs 11 years later: stable implants and optimal appearance of the fixation interface (b).

Of the 10 inserts removed in our study, 6 exhibited abnormalities suggesting that the forces applied to the insert might damage the mechanism ensuring fixation to the baseplate. The resulting mobility of the insert may have resulted in backside wear, as reported previously by Gupta et al. [21], particularly as the Wallaby I® tibial baseplate is made of unpolished titanium that can damage the backside of the insert. Another possible explanation to these few cases of massive osteolysis is sporadic low quality of the inserts, due in particular to prolonged storage before use. In 2005, the manufacturer reported having decreased packaging
permeability to ambient oxygen. This improvement occurred after inclusion of the last patient of our study. Based on insert shelf life (5 years after sterilisation) and TKA dates, we found that time on the shelf before implantation was significantly longer in the 10 knees with osteolysis than in the other knees (27 ± 15 months versus 17 ± 11 months, P=0.046). Fehring et al. [22] demonstrated that the failure rate increased by 187% per year on the shelf if the packaging did not provide an effective barrier to ambient oxygen.

Finally, paradoxical displacements seem possible even with this highly congruent prosthesis design. Thus, in a radiographic study, Louisa et al. [23] found up to 6 mm of paradoxical displacement. In vivo, using a navigation system to obtain intraoperative measurements during deep-dished TKA, Massin et al. [24] found similar paradoxical displacements. These paradoxical displacements may result in shear forces, particularly on the posterior rim of the insert during walking, similar to the forces applied to native knee menisci in the presence of chronic anterior laxity. They may explain the postero-medial wear seen on some of the removed inserts (Figs. 3 and 5).

The deep-dished design may therefore exacerbate insert wear via several mechanisms, a phenomenon not seen after implantation of the same prosthesis with PCL retention, i.e., in a less constraining configuration, and with polyethylene from the same manufacturer. Thus, Witvoet et al. [12] reported a 98.5% survival rate when defining failure as revision because of aseptic loosening. Based on these data, the cases of osteolysis in our study are probably ascribable to a combination of deleterious factors responsible for insert backside wear and delamination of the insert articular surface.

Our functional assessment showed that range of knee flexion was similar to that seen with posterior-stabilising prostheses (Table 4) [15,18,20,25]. Based on theoretical calculations, Massin et al. [6] estimated that flexion decreased by 10° for each 3-mm loss of roll-back. Yanagisawa et al. [7] demonstrated that femoral antero-posterior translation influenced postoperative range of motion. Others failed to replicate these findings, however. Thus, Kanekasu et al. found no association between prosthesis kinematics and active flexion range [26]. Although we found no adverse effect on range of active knee flexion, we cannot rule out increased impingement between the posterior border of the femur and the posterior rim of the deep-dished insert, a phenomenon suggested by the abnormalities in one of the removed inserts (Fig. 4).

Our study has several limitations. The retrospective uncon- trolled design limits the strength of the conclusions, explaining the comparison with historical case-series studies. The number of patients lost to follow-up and the absence of computed tomography evaluations can result in underestimation of the failure rate [27]. However, the failure rate was higher in our study than in the historical case-series studies.

5. Conclusion

In our hands, the ultra-congruent fixed-insert Wallaby I® prosthesis resulted in an abnormally high rate of osteolysis with aseptic loosening. The insert appears to be the vulnerable feature of this constrained configuration, suggesting a need for using optimised polyethylene secured to the baseplate by stronger mechanisms or, on the contrary, left mobile. Given the risk of osteolysis, we recommend close monitoring of apparently unaffected patients using annual computed tomography scans. We believe the configuration of this prosthesis characterised by a fixed-insert made of conventional polyethylene, as implanted in our study, should no longer be used.

Disclosure of interest

Patent royalties have been paid to Philippe Massin (Ceram-concept, Wright Medical Ortho, and Zimmer) and Denis Hunet (Centerpulse and Smith and Nephew).

B. Marion, P. Boyer and C. Jeanrot declare that they have no conflicts of interest concerning this article.

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